



**Information and Education Provision for Patients with
Bronchiectasis:**

**An Exploration of Unmet Needs and Development of a Novel
Resource.**

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Thesis submitted for the degree of Doctor of Philosophy

**Newcastle University
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June 2017

Thesis Abstract

Bronchiectasis is a chronic lung disease that can create significant symptom and treatment burdens for those affected, and significant costs to the National Health Service. Treatment concordance can be problematic and improvements in interventions are urgently required. There is little patient information available, yet information and education could support patients to self-manage, improve understanding and optimise engagement with treatment. This in turn could facilitate reductions in unscheduled presentations to healthcare services and improvements in longer-term health-related outcomes.

A mixed methods approach was taken to this work. Qualitative interviews were conducted with patients and carers to explore and understand their unmet information needs. Using thematic analysis, a core mediating issue emerged: what it means to learn to live your life with bronchiectasis. Embedded within this journey were issues around developing support and coping mechanisms, learning to connect with information, taking back control and developing active partnerships with the medical team.

Using the interview findings, a novel information resource was co-developed during a series of workshops with patients and carers. Potential designs, formats and content were discussed and prototypes developed, reviewed and refined. A booklet and a website featuring video content (www.bronchiectasis.me) were produced.

A feasibility study (The BRIEF Study, ISRCTN84229105) was subsequently conducted comparing use of this novel information resource to usual care. Feasibility outcomes included recruitment and retention rates and questionnaire completion rates. 62 participants were randomised; 60 completed the study. Recruitment and questionnaire completion rates were excellent. Resource evaluation conducted within the trial was positive and demands for access worldwide were high.

By understanding what it means to live with bronchiectasis, a resource that meets users' needs has been co-developed. The feasibility study indicates that a definitive trial establishing effect on understanding, self-management and health-related outcomes would be feasible and that the resource is credible and of high quality.

Dedication

This thesis is dedicated to my mother, Margaret Murphy, who was diagnosed with motor neurone disease during my PhD and sadly died just prior to its completion. Her strength, dignity and courage were inspirational.

Acknowledgements

First and foremost, I would like to thank the patients and carers who have both participated in this research, and supported its initial and ongoing development. Mr Alan Timothy was a valued member of the Trial Oversight Committee (TOC) and added both professional and personal experiences to the development of this work. Mrs Maureen Robinson was a carer representative on the TOC and also contributed significantly to the resource content. Many patients and carers shared their time, personal experiences and opinions during this research, without whom, the endpoints would not have been achievable.

I would like to thank the National Institute for Health Research (NIHR) for awarding me a Doctoral Research Fellowship to conduct this research. I am also grateful to have been allowed to take this time out of my clinical training programme to pursue this academic research. I have been privileged to have been permitted this funded, protected time to carry out research.

My supervisory team, Tony De Soyza, Tim Rapley and Julia Newton have provided me with unfailing support and expertise throughout my PhD. In addition, it was their support and advice that facilitated the applications to embark upon this work. Their diverse range of skills and knowledge have been invaluable to me and I could not have achieved this without their help.

I also want to thank Vicky Ryan for her statistical advice both in planning and reporting this work, and Holly Ainsworth for her advice on the use of statistical software. The Research Design Service at Newcastle University provided advice and support during the development of my fellowship application. Others at Newcastle University including research support teams and Library staff have been helpful aides along the way. I would also like to thank all the staff at The William Leech Centre for Lung Research. In particular, John Davison, Gareth Davies, Gerry Jones and Rebecca Johnson. Their support conducting the BRIEF study was excellent and it would not have been successful without their hard work. Their involvement, along with Dr Sophie West in the TOC was highly valued.

The British Lung Foundation (BLF) have supported this work since before the fellowship application. In particular the support of Mrs Bev Wears in trial design, oversight and resource evaluation has been incredibly helpful. Her continued

involvement in this research has led to the developed resource having potential for much wider dissemination through its connection with the BLF. I would also like to acknowledge Grow Create, for their help with developing the information resources produced during this fellowship, and Open Lab at Newcastle University for their ongoing help with making these resources publically available. To all those members of the bronchiectasis team who contributed to the resource contents, I am also very grateful.

I would like to thank my colleagues in the Institute of Health and Society, for allowing me to use a desk surrounded by others doing similar work. Being able to work alongside others and participate in data meetings has helped my development as a qualitative researcher immensely.

Finally I would like to thank my family and friends who have supported me throughout this long period of research.

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Glossary of abbreviations

BCOS	Bronchiectasis COPD Overlap Syndrome
BLF	British Lung Foundation
BKQ	Bronchiectasis Knowledge Questionnaire
BRIE	Bronchiectasis Information and Education Study
BRIEF	Bronchiectasis Information and Education Feasibility Study and evaluation of a novel resource
BSI	Bronchiectasis Severity Index
BTS	British Thoracic Society
CD	Compact Disc
CI	Chief Investigator
CONSORT	Consolidated Standards of Reporting Trials
COPD	Chronic Obstructive Pulmonary Disease
CRF	Case report form
CRN	Clinical Research Network
DMEC	Data Monitoring and Ethics Committee
DoH	Department of Health
DVD	Digital Versatile Disc
DRF	Doctoral Research Fellowship
ELF	European Lung Foundation
EPP	Expert Patient Programme
EQ-5D-5L	EuroQol 5 Dimensions 5 Level questionnaire
FAQ	Frequently asked question

FEV1	Forced expiratory volume in 1 second
FIS	Fatigue Impact Scale
GCP	Good Clinical Practice
GP	General Practitioner
HADS	Hospital Anxiety and Depression Scale
HRQOL	Health related quality of life
ID	Identification
ISRCTN	International Standard Randomised Controlled Trials Number
ITT	Intention to treat
MRC	Medical Research Council
NHS	National Health Service
NICE	National Institute of Clinical Excellence
NIHR	National Institute for Health Research
NRES	National Research Ethics Service
QOL-B	Quality of Life – Bronchiectasis
PC	Personal Computer
PhD	Doctor of philosophy
PI	Principal Investigator
PIF	Patient Information Forum
PDF	Portable Document Format
R&D	Research and Development
RCT	Randomised controlled trial

REC	Research Ethics Committee
RSQ	Resource Satisfaction Questionnaire
SAE	Serious adverse event
SD	Standard deviation
SGRQ	St George's Respiratory Questionnaire
SPACE	Self-management Programme of Activity, Coping and Education for COPD
SPSS	Statistical Package for the Social Sciences
TOC	Trial oversight committee
TSC	Trial Steering Committee
UK	United Kingdom
USA	United States of America
VAS	Visual analogue scale
WHO	World Health Organisation

Chapter 1 Introduction to thesis: Context, Overview and Structure

Bronchiectasis is a chronic lung condition that leads to a significant symptom and treatment burden for those affected, and significant costs to the National Health Service. Statistics show us that prevalence is increasing, both in the UK and worldwide (Seitz *et al.*, 2012; Ringshausen *et al.*, 2015; Quint *et al.*, 2016), yet still the evidence base for treatments and management remains poor. Historically there has been relatively little research conducted in this field and it is only in the recent past that more attention has been paid to this previously somewhat neglected disease. Improvements in interventions are urgently required.

Interventions for bronchiectasis are likely to include advancements in medical therapies, yet we also know that bronchiectasis is a 'model' chronic disease in terms of its potential for self-management. If patients and their carers know how to recognise their own symptoms of deterioration or exacerbation, and know how and when to take action, this could facilitate improvements in self-management. This in turn could potentially facilitate increases in disease stability, reductions in unscheduled presentations to acute health care services and improvements in longer-term health related outcomes.

In 2011, I carried out a pilot study during a Master of Clinical Research degree in order to begin to explore the health information and education needs within this patient group (Hester, 2012; Hester *et al.*, 2012a). I will describe this in more depth in Chapter two, yet key messages emerging from interviews were that patients felt there was a lack of credible information available to them and that they believed information could be key to them learning to live with and manage their condition. On the basis of these findings I developed a research proposal to further investigate the unmet information needs of patients with bronchiectasis and their carers, and to then use this data to develop and evaluate an intervention that would address the identified issues. In 2012, I was awarded a Doctoral Research Fellowship by the National Institute for Health Research in order to carry out this work, which comprises the contents of this thesis.

The overall aims at the outset were to explore, describe and understand the information and education needs of patients with bronchiectasis and their carers; and to produce and evaluate a novel, effective and practical educational resource. The

resource was to be patient-driven in both format and content, feasibly deliverable within the NHS setting and accessible at users' convenience. In order to effectively meet these aims, a mixed methodological approach combining a variety of qualitative and quantitative methods was required. I will discuss this in depth in Chapter 3. The approach taken for the qualitative aspects of the work falls within the realist paradigm. Specifically, a subtle realist standpoint was taken, acknowledging the fact that we can aim for an objective reality, but we can only really know reality from individuals' perspectives of it. I will further describe methodological considerations and strategies used to ensure credibility and rigour for each aspect of this work in Chapter 3.

For the purposes of study sponsor and ethics committee approvals, the work was subdivided into two stages as follows:-

Stage 1: Information and education provision for patients with bronchiectasis: a qualitative investigation of patients' needs and development of a patient-driven resource. (The BRIE study, REC Ref 12/SC/0585.)

The aim of this section of work was firstly to identify, understand and describe in detail the information and education needs within this patient group; and secondly to co-develop a high-quality, patient-driven information resource for patients with bronchiectasis in accordance with themes identified in qualitative interviews and workshops. One of the major outputs of this research is the resource itself (Appendix 1, Appendix 2). The website can also be viewed at www.bronchiectasis.me.

Stage 2: Bronchiectasis Information and Education: Feasibility Study and Evaluation of a Novel Resource. (The BRIEF Study, ISRCTN registration: ISRCTN84229105, REC Ref: 14/NE/0119.)

The aim of this stage was to conduct a feasibility study that would inform the decision process concerning whether to proceed to a definitive randomised controlled trial and whether any refinements to the design or conduct of that trial are warranted. Further aims were to evaluate and refine the patient information resources and collect information on patient preferences and resource use.

As this work was carried out in distinct yet interlinking stages, I have presented it within this thesis as the stages progressed chronologically. The background and

review of literature in Chapter 2 pertains to all aspects of this work, as do the methods and methodology in Chapter 3. Three results chapters detail the findings of the interviews, the outcomes of the resource development process and the findings of the BRIEF study respectively. There is some discussion within each results chapter, and a unifying discussion and conclusions chapter of the entire body of work is presented at the end of the thesis, drawing together outcomes, impacts and considerations for future work.

Chapter 2 Background and review of literature: Bronchiectasis, information and self-management

In the introduction, I gave a broad description of why it was important that this research was conducted, and presented an overview of the research undertaken. In this chapter I will discuss the context of this work and the literature relevant to it in more depth. Given the paucity of data available on information and education in bronchiectasis specifically, a formal systematic review was not possible. In order to ensure that a thorough review of the relevant literature was conducted, I performed detailed searches with robust search strategies using multiple databases including Medline, Ovid, Scopus and Web of Science. Searches of PubMed, Cochrane and NICE were also carried out. Searches were additionally performed in interlinking areas to include data on information and education in other chronic respiratory and medical conditions where comparisons could be drawn, and other bronchiectasis data that could have an impact upon the need for patient information.

I will begin with some background information about bronchiectasis and its management; and introduce the importance of patient information for people who have this condition. I will go on to describe information provision and self-management, both in bronchiectasis and other chronic conditions, as comparison examples. I will also discuss information seeking and the development and evaluation of information resources; concluding with a summary of the main issues and the aims and objectives for the work described within this thesis.

2.1 Bronchiectasis

2.1.1 *Bronchiectasis pathogenesis and prevalence*

Bronchiectasis is a chronic lung condition, characterised by dilated bronchi. It leads to symptoms of breathlessness, cough and a chronic infective syndrome, with inevitable additional infective exacerbations. Bronchiectasis has various potential aetiologies including immune-deficiency syndromes, chronic asthma, chronic obstructive pulmonary disease (COPD), ciliary dysfunction and post-infection. In addition, studies have found that between a quarter and half of cases are idiopathic (Pasteur *et al.*, 2000; Shoemark *et al.*, 2007). Patients often have recurrent, costly hospital admissions, a poorer quality of life (Wilson *et al.*, 1997; O'Leary *et al.*, 2002) and clinically significant fatigue (Macfarlane *et al.*, 2010; Hester *et al.*, 2012b).

Patients with bronchiectasis are at increased risk of anxiety and depression (Oliveira *et al.*, 2013; Boussoffara *et al.*, 2014; Ozgun Niksarlioglu *et al.*, 2016). New data has also shown a greater risk of coronary heart disease and stroke in patients with bronchiectasis (Navaratman *et al.*, 2017).

Recent UK statistics indicate a prevalence of between 43.4/100,000 in those aged 18-30 and 1239.7/100,000 in those aged 70-79. This equates to an estimated 300,000 in the UK with bronchiectasis, and up to 20,000 new cases being identified each year (Quint *et al.*, 2016; Navaratman *et al.*, 2017). In the North East of England there are over 1,100 patients with a diagnosis of bronchiectasis. Approximately 450 of these attend a specialist clinic at a central hospital. Overall prevalence is increasing in the UK (Quint *et al.*, 2016), and the USA (Seitz *et al.*, 2012). Higher than expected numbers were also recently reported from Europe (Ringshausen *et al.*, 2015). Importantly, studies have demonstrated that up to 50% of patients with COPD have evidence of co-existent bronchiectasis (O'Brien *et al.*, 2000; Patel *et al.*, 2004). It has been suggested more recently that COPD and bronchiectasis can co-exist as 'bronchiectasis COPD overlap syndrome' (BCOS) (Hurst *et al.*, 2015). With over 1,000,000 patients with a diagnosis of COPD in the UK (Shahab *et al.*, 2006), there is potential for a significant increase in case-finding of BCOS, and consequently a continued rise in bronchiectasis prevalence, over the coming years.

Bronchiectasis mortality rates have been reported in the UK to be twice that of the general population (Quint *et al.*, 2016) and approximately 50% higher than that of uncomplicated COPD (calculated at 3% per annum) (Office for National Statistics, 2004). Rates are increasing, with up to 1000 people dying each year from bronchiectasis (Roberts and Hubbard, 2010). The presence of BCOS also leads to increased mortality rates (Gatheral *et al.*, 2014; Goeminne *et al.*, 2014). Prognosis varies, with a study of 91 patients finding that the primary cause of death was usually respiratory, with survival rates of 91% at 4 years and 68.3% at 12.3 years (Loebinger *et al.*, 2009). The same study found factors such as chronic infection with *Pseudomonas aeruginosa* increase mortality. In addition, infective exacerbations lead to significant morbidity. The national British Thoracic Society (BTS) bronchiectasis audit reported that 38% of patients had three or more exacerbations per year (Hill *et al.*, 2013). Within a cohort of patients attending the aforementioned specialist clinic, average exacerbation rate was 4 per year (twice the rate of exacerbations in uncomplicated COPD) (McDonnell *et al.*, 2015) with an increase in

hospital bed days in recent years from 400 to 2,000 per annum. This is consistent with American data on the increasing burden of bronchiectasis (Seitz *et al.*, 2010). Previously published UK data also emphasises the burden of bronchiectasis, uncertainties in aetiology and lack of evidence for the treatments that are often used (Kelly *et al.*, 2003). Improved interventions in bronchiectasis are clearly required.

2.1.2 Management of bronchiectasis

There are national guidelines for investigation, diagnosis and management of bronchiectasis produced by the BTS (Pasteur *et al.*, 2010). There is no cure for bronchiectasis and many therapies are empiric and not evidence based. In terms of managing bronchiectasis, there are two main therapeutic streams: maintenance therapy and exacerbation management. Maintenance therapy aims to improve or maintain a patient's baseline condition, reducing both their everyday symptoms and the frequency of their exacerbations. Exacerbation management is treatment of episodic worsening with an aim of returning to baseline condition as quickly as possible.

Examples of the treatments used include mucolytics (tablets or nebulised solutions to aid sputum expectoration), physiotherapy, and antibiotics (Pasteur *et al.*, 2010). Regular use of mucolytics and physiotherapy aids sputum clearance both as maintenance therapy and as part of exacerbation management. Current modalities of antimicrobial treatment include oral, inhaled or intravenous antibiotics; both regularly and with additional courses for exacerbations. With some exceptions, treatments are broadly similar regardless of the aetiology of bronchiectasis, but specific treatment plans are tailored to the individual. These can range from no regular treatments at all, to daily use of nebulisers, physiotherapy, inhalers and tablets that can be significantly burdensome for patients and their families.

Treatments can be a cause for concern for patients which can be further complicated by any uncertainty around the specific 'type' of bronchiectasis they have. To be labelled as having 'idiopathic bronchiectasis', which has no identifiable cause, can be quite confusing for patients. It can be equally as confusing for those who, for example, have a longstanding diagnosis of COPD and then go on to develop bronchiectasis. In this situation, having a new or additional diagnosis raises questions about whether the original diagnosis was incorrect, and also whether their symptoms at any one time are attributable to bronchiectasis or COPD. Although we

have said that treatments for bronchiectasis are broadly similar regardless of aetiology, uncertainties regarding the origin of symptoms naturally leads to uncertainties for patients around what action to take and how the symptoms should be treated. For example, an exacerbation of COPD may not require antibiotics, yet an exacerbation of bronchiectasis would require a 2 week course of antimicrobial treatment (Pasteur *et al.*, 2010). Failure to commence antibiotics promptly can result in a more severe exacerbation of bronchiectasis which could require hospital admission. This would clearly lead to significant additional costs to the NHS, and a much bigger physical, psychological and social impact upon patients and their families. Conversely, inappropriately excessive antibiotic use can lead to antibiotic resistance which can also have problematic repercussions in terms of response to future treatments and longer term health outcomes. If a patient does not fully understand their diagnosis, symptom recognition and self-management are bound to be problematic.

Bronchiectasis differs from some chronic diseases in that appropriate, timely recognition of exacerbation symptoms and improved management of infections can lead to increased disease stability. Although largely not evidenced, this is the general approach towards management. Adherence to regular maintenance treatments is expected to reduce the frequency of exacerbations, yet adherence is known to be an issue. A recent trial looked at treatment adherence over a one year period and found that 41% adhered to airway clearance, and 53% inhaled antibiotics (McCullough *et al.*, 2014). When looking at adherence to all treatments, this fell to 16% of the cohort studied. Adhering to inhaled antibiotics led to a decreased exacerbation rate. Importantly, it is known that those with more frequent exacerbations suffer not only the physical effects, but also a reduction in quality of life (Wilson *et al.*, 1997). To expect patients to understand their condition, the treatments used and the implications of not taking them appropriately is quite a tall order; yet is clearly necessary. In order to facilitate such self-management, patients need to have accurate and accessible information about their condition, enabling them to recognise and respond to changes, and understand how their actions could potentially alter their prognosis. Adequate education could lead to a level of self-management that results in clinically and biologically important endpoints in bronchiectasis.

2.2 Information and self-management

2.2.1 Information provision in bronchiectasis

The BTS guidelines for management of bronchiectasis (Pasteur *et al.*, 2010) recommend education of patients; including explanations of the disease, recognition and importance of exacerbations and treatment approaches. The BTS Quality Standards for clinically significant bronchiectasis in adults also advocate a personal management plan for each patient (Bronchiectasis Quality Standards Working Group, 2012). Although patients with bronchiectasis gain information through discussion with their clinician, there is little additional information available to them in comparison to the number of resources available for other chronic conditions such as COPD or Cystic Fibrosis. Charitable organisations such as the British Lung Foundation (BLF) recognise the need for information and education for patients with chronic lung disease. They produce a range of paper and online information resources for patients with respiratory conditions. Their leaflet about bronchiectasis, however, is just one A4 page in length. The BLF recognise the need for improvements in information provision for patients with bronchiectasis and have supported this research.

If one performs an online search for information about bronchiectasis, there are resources available. However, in addition to being limited in number when compared to other conditions, many are either very brief, with little information provided, or lengthy and not patient-friendly. There are currently no widely available audio-visual information resources relevant to bronchiectasis. The BTS have a short self-management tool for bronchiectasis that is available to download (Bronchiectasis Quality Standards Working Group, 2012). This does not serve as an information resource as such, however, but a 1 page reference guide to exacerbation management. Other sources of online information include forums or 'chat rooms'. There are a limited number available that are specific to bronchiectasis (Angel, 2015). These do not necessarily serve as information resources, but can be a way for patients to gain from either looking at conversations between others, or engaging in discussion with other people who have had similar experiences. The lack of 'expert' opinion contained within these discussions however could be a deterrent to some users. Likewise, the need to share one's own story may not be something users are willing to engage with. Attendance at local support groups is another way for patients to gain information and a sense of community. An example for those with chronic

lung disease would be the Breathe Easy support groups (British Lung Foundation, 2017). These are run by the British Lung Foundation and are held nationwide. The opportunity to meet with others who also have chronic lung disease may be of interest to some, yet others may not wish to engage with something that involves them openly discussing their diagnosis. For patients with bronchiectasis, it is also less likely that others in the group would have the same diagnosis, with groups more likely to be predominated by people with more prevalent conditions such as COPD or asthma. A more detailed review of the resources currently available is detailed in chapter 5 of this thesis, where I describe the development of the novel patient information resource. This includes how knowledge of these existent resources alongside the interview data additionally influenced its design.

In a survey of 104 patients attending a specialist bronchiectasis clinic in the North East of England, 98% felt more confident with managing their condition following information and education about their treatment (Hester *et al.*, 2011). Moreover, a pilot study carried out prior to the work contained within this thesis identified the importance of patient information in the process of developing the skills and confidence to manage and live with bronchiectasis (Hester, 2012; Hester *et al.*, 2012a). I carried out this pilot study as part of a Master of Clinical Research Degree. This was an exploratory study and I recruited patients with bronchiectasis via a specialist bronchiectasis clinic. Sampling was pragmatic and essentially formed a convenience sample. The aims of the study were to begin to explore patients' views on information provision for people who have bronchiectasis and begin to identify any unmet needs. I conducted in depth, semi-structured interviews and used thematic analysis to look for emergent themes. In total, 8 patients were recruited, 6 female, 2 male with a median age of 66 years (range 33-67). The majority of participants had been living with bronchiectasis for many years. Four interlinking core themes arose from the analysis of the interview data:-

1. Information: There was a strong feeling amongst participants that there was a lack of trustworthy information (from a reliable source such as their hospital, from trusted specialists or organisations such as the BLF) available beyond that obtained in clinic. Patients felt they would benefit from a credible information resource that they could continue to access outside of a clinic setting. Timing of information was important, with users wanting information at diagnosis. Patients also indicated that a

useable resource would have to be presented in a format that met their needs and those of their carers and families.

2. Experience at diagnosis: There was often a lack of information and support at diagnosis, which patients felt impacted on their ability to cope with their condition, both at diagnosis and beyond.

3. Ongoing medical care and support: Patients felt that when they transferred to the care of a specialist bronchiectasis clinic, they had a source of help, support and information. Receiving such information empowered patients, yet they felt there was a need for accessible resources outside of this setting.

4. Living with bronchiectasis and its impact: Patients acknowledged the impacts of the condition and the support needed. They considered knowledge and information to be critical in developing the skills and confidence to live with and manage bronchiectasis.

Limitations of this study included the small sample size and the lack of within-sample variation. The majority of patients were female, in their sixth decade, and all participants were attending a specialist bronchiectasis service. The ways in which this has influenced sampling for the work contained within this thesis is described in Chapter 3, section 3.2.1. This pilot exploratory work demonstrated the importance of the lack of information provision for people with bronchiectasis to the patient group and provided further evidence that this was a worthwhile area of research.

Information is an essential commodity to facilitate better patient understanding and disease management; yet is clearly under-provided in bronchiectasis. There is an obvious requirement for further research into the unmet information needs of affected individuals and their carers, and for appropriate resource development.

2.2.2 Information provision in chronic conditions

The Department of Health and the NHS recognise the importance of information provision for patients with long-term conditions and their carers. The NHS refer to longstanding evidence that patients want to access information (Bunker, 1983) and that its provision can reduce anxiety (George *et al.*, 1983). The Audit Commission previously identified that information can improve patient outcomes (Audit Commission, 1993) and improvements in information provision have been a priority for over a decade (*The NHS Plan*, 2000). Information provision being key to

facilitating self-care is highlighted by the UK Government as fundamental to promoting patient choice and shared decision making (Department of Health, 2006). It is proposed in this document that all people with long-term conditions, and their carers, should receive information and services that will help them to manage their condition. The NHS Outcomes Framework 2012/13 (Annex A) has a domain entitled 'enhancing quality of life for people with long-term conditions' which details an area for improvement as 'ensuring people feel supported to manage their condition' (Department of Health, 2011). The Department of Health also published a policy document in 2012, entitled 'The power of information: Putting us all in control of the health and care information we need'. This described a ten year strategy framework to transform information for health and care, including both patient care information and health information resources for use by patients (Department of Health, 2012). The Patient Information Forum, an organisation that campaigns for improvements in health information, also put forward their evidence for the need to make improvements in health information for patients (Patient Information Forum, 2013). They emphasise that information is an intervention, its production is a highly skilled process and that it should be user tested, co-designed and co-produced where possible. Information provision is known to play an important role in supporting self-management and active participation in care remains a priority area of health research for all chronic conditions.

Although provision of information is clearly seen as an essential part of management of chronic conditions, it is argued that information itself does not automatically translate into behavioural change (Becker, 1990). Theoretical constructs and behavioural change techniques beyond information delivery (Michie *et al.*, 2005; Abraham and Michie, 2008) are important to consider in development of any intervention that aims to produce changes in behaviour. The use of such techniques, however, are not the only approach to optimising effectiveness of information provision. It has been proposed that information seeking is a necessary stage for action to be taken by patients and that specific information on help available may improve chances of patients taking action (Catania *et al.*, 1990). In a review of the role of education in asthma it was recognised that information about asthma should not simply be factual but allow patients to acquire skills (Partridge and Hill, 2000). Again in asthma, it is preferable to teach patients about their asthma treatments and inflammation rather than the structure and function of the lungs for example

(Takakura *et al.*, 1998). Asthma education alone does not necessarily improve outcomes but needs to be delivered in combination with medical review and written action plans (Gibson *et al.*, 2002a).

It would seem to be clear that providing patients with something as simple as a factsheet on their condition is unlikely to result in any major tangible benefits. Indeed, the currently available BLF leaflet about bronchiectasis provides no intervention details that a patient could implement as part of a self-management plan. Thinking beyond this simplistic and traditional version of an information resource and establishing what information is relevant to the patient group, and how it could be delivered in order to achieve the desired effects is therefore essential.

2.2.3 Self-management in chronic disease

Self-management and patient information provision are seemingly inextricably linked. Self-management is increasingly recognised as an important part of chronic disease management and is recommended by the World Health Organisation (WHO) (Epping-Jordan *et al.*, 2004). Information, as discussed, plays a key role in patients' ability to self-manage. The Wanless Report (Wanless, 2004) identified inadequacies in information provision as a reason for people managing their health poorly. In primary care, self-management has been referred to as patients with chronic disease making day to day decisions about their illnesses (Bodenheimer *et al.*, 2002) and the everyday tasks and activities that a person living with a chronic condition needs to carry out (Eaton *et al.*, 2015). The authors proposed self-management education rather than traditional information alone improves clinical outcomes, in keeping with the aforementioned literature. The aim in supporting self-management is to allow people to gain not only the knowledge but also the confidence and relevant skills to manage their condition; promoting patient 'activation' (Hibbard and Greene, 2013; Eaton, 2016). An important concept embedded within this is self-efficacy: the confidence that one can carry out a behaviour necessary to achieve a desired goal (Bandura, 1977). Using self-efficacy as a measurable outcome, however, is not without flaws, as was shown when trialling the expert patient programme (EPP). This was developed by Lorig, and used self-efficacy as an outcome measure (Lorig *et al.*, 1985; Lorig and Holman, 1993; Lorig *et al.*, 2001). The EPP has been used in a variety of conditions, but was initially developed for patients with arthritis. The EPP was designed to enhance disease specific information rather than replace it, as the programme is generic in nature. They found improvements in symptom control, pain

and hospitalisations as well as gains in self-efficacy. There are, however, many criticisms of the EPP. These include self-efficacy gains not leading to improvements in self-management and not necessarily reducing hospital presentations. Additionally, it has been suggested that participants in EPPs were not representative of the general population and were possibly better at self-managing than most (Gately *et al.*, 2007; Taylor and Bury, 2007; Lindsay and Vrijhoef, 2009). A UK study using a lay-led EPP (n=629) showed an increase in participant self-efficacy and energy, yet no reduction in health care utilisation (Kennedy *et al.*, 2007).

A recent systematic review and meta-analysis of self-management interventions concluded that they can be implemented without a detrimental effect on health outcomes and that they do reduce service utilisation (Panagioti *et al.*, 2014). Although the effect sizes were small overall, it is of note that respiratory conditions were amongst the two groups that had the strongest evidence. Systematic reviews of self-management education in chronic lung disease specifically, however, have been less conclusive. A review in COPD revealed inconclusive evidence of any benefits (Monninkhof *et al.*, 2003). In asthma, as discussed previously, a Cochrane review reported that self-management education could improve health outcomes only when delivered in conjunction with medical reviews and a written action plan (Gibson *et al.*, 2002b). In cystic fibrosis, an inherited multi-system disease with similar respiratory features to bronchiectasis, there was again too little data to draw firm conclusions about recommendations for self-management (Savage *et al.*, 2011). A protocol for a systematic review of self-management in non-cystic fibrosis bronchiectasis has recently been published, (Kelly *et al.*, 2017). Conclusions are likely to be limited, however, reflecting the current lack of an evidence-base for self-management in bronchiectasis.

A meta-synthesis of qualitative studies additionally highlights the importance of social networks (family, friends, communities) in the self-management of chronic illnesses (Vassilev *et al.*, 2014). A longitudinal study of patients with heart disease and diabetes also acknowledges the role of social networks in supporting self-management (Reeves *et al.*, 2014). A large international observational study explored the roles of individual support networks and community organisations within self-management of diabetes (Koetsenruijter *et al.*, 2014; Koetsenruijter *et al.*, 2015). Participation in community organisations (including online communities and health education groups) was associated with better physical and mental health. It is

apparent that when considering educational and self-management support interventions they need to be tailored to the users' approaches. Establishing users' needs and preferences and taking into account their use of social networks is therefore critical. This will enable development of suitable information and education resources and lay the groundwork for establishing their effects on numerous aspects of patients' lives and disease course.

2.2.4 Self-management in bronchiectasis

A small number of self-management resources have been produced for chronic lung diseases. The British Lung Foundation, for example, produced a document in conjunction with NHS Improvement to assist patients with the self-management of COPD (British Lung Foundation, 2012). Another self-management educational resource, SPACE for COPD, was developed by a group in Leicester (Mitchell-Wagg *et al.*, 2012). This was designed as a six week intervention. At 6 months, although there were gains in disease knowledge, anxiety and performance levels, the primary outcome measure of dyspnoea had not improved (Mitchell *et al.*, 2014). Living Well with COPD (McGill University Health Centre and Quebec Asthma and COPD Network, 2013) is a website with information and videos and requires a password obtained by patients from their physician in order to access the full material. A two year randomised controlled trial conducted in primary care did not show long term benefits over usual care when using measures of self-efficacy and quality of life. The group with access to the living well programme, however, did seem more able to manage their exacerbations (Bischoff *et al.*, 2012). It is possible that self-efficacy, as discussed, may not necessarily be the optimal outcome measure in such studies. In asthma, a study using an educational programme based on repeated short interventions (face to face sessions at 3 month intervals over 1 year, a personalised action plan and inhaler technique training) saw improvements in asthma control in the intervention group, yet they did note a degree of improvement within the control group too (Plaza *et al.*, 2015). Cost effectiveness was not examined and although the intervention was brief, it would involve staff time at considerable cost, and user information needs at other time points were not taken into account.

There still remains to be an evidence-based intervention for use in bronchiectasis. Perhaps unsurprisingly, there is very little evidence for self-management in bronchiectasis, yet there are rational arguments for its use. One study began to explore how self-management could be facilitated in bronchiectasis. Using focus

groups with patients who had bronchiectasis, they were able to explore patients' perspectives on what was required. Participants perceived lack of information and confidence as barriers to self-management and felt that disease specific information would be useful (Lavery *et al.*, 2007). The same group investigated the use of an EPP as part of a self-management programme for patients with bronchiectasis (Lavery *et al.*, 2011). The programme consisted of two sessions of disease-specific information followed by a standard, generic EPP for six weeks. Improvement was found in six of ten domains of a self-efficacy scale, including managing symptoms and depression. The intervention group, however, also reported more symptoms and reduced quality of life post intervention. The educational sessions about bronchiectasis were not patient-driven in terms of content or format of delivery, and participants commented that the sessions should be condensed and be attended by physicians. Costs, staffing, time and patient commitment involved with such a course are considerable, making it potentially unfeasible to deliver within a clinical setting. The centre that carried out this study is not using this routinely following the trial. (J.S. Elborn, December 2012, personal communication.) A successful intervention for bronchiectasis would need to meet patients' needs, be easily accessible and be feasibly deliverable within a resource constrained NHS on a long-term basis.

Another recent study has taken a different approach to aiding self-management in patients with bronchiectasis, using a novel tool, the Bronchiectasis Empowerment Tool (ISRCTN Registry, 2015). The tool consisted of a one page action plan, within a pack containing information and optional notepads. The reported aim of the study was to work alongside existing care in order to improve self-management. At the time of writing the study is closed to recruitment but no published results are available.

Self-management includes making day to day decisions about your management. In bronchiectasis, this would include making decisions surrounding adherence to treatments. As noted above, adherence to some treatments in bronchiectasis can result in fewer exacerbations (McCullough *et al.*, 2014), yet less than 20% of the cohort studied were adherent to all prescribed treatments. In a study of an inhaled antibiotic in bronchiectasis, a delay to first exacerbation was only demonstrated in patients adherent to $\geq 81\%$ of treatment (Haworth *et al.*, 2014). Factors predicting adherence to treatments could include beliefs about treatments and burden of treatment (McCullough *et al.*, 2015b). Based on these findings, further work has been done by the same group using a theoretical approach to work towards a behaviour

change intervention to promote treatment adherence (McCullough *et al.*, 2015a). Interestingly, the message about need for information came across again in this study, as interviews identified that patients felt knowledge about bronchiectasis and treatments improved adherence. Addressing the issue of treatment adherence would therefore seem to be important when delivering an educational or self-management intervention for bronchiectasis. It is not however, the only aspect of the patient experience to be considered. Common to all aspects of day to day management is the need for information. Having an in depth understanding of the information and education needs of both patients and their carers, and how these could be met is fundamental to the development and execution of novel interventions.

2.3 Information seeking

Information seeking is another important aspect to consider in developing an understanding of patients' information needs and how they might go about meeting them. Knowing how, why and when patients seek information, in addition to what information they seek, is key to the development of a successful resource.

In prior exploratory interviews with patients who have bronchiectasis (Hester, 2012; Hester *et al.*, 2012a) participants reported that they had often not persisted in information seeking beyond the clinic setting due to a lack of trust in the available online resources. Participants did state that if they had been directed to information (by their physician for example) that originated from a credible source, they would be interested in accessing it. Information from clinicians was reported to be credible information. Interestingly, there is evidence in COPD, which may well be applicable to other conditions, that gaps in knowledge of health care professionals can impact upon patients' knowledge and understanding of their condition (Edwards and Singh, 2012). Patients who have bronchiectasis may not attend a specialist bronchiectasis clinical service. Respiratory or general physicians, although they may understand the disease process, are likely to have less disease-specific experience and knowledge than a specialist delivering a bronchiectasis service. In addition, they may not have sufficient exposure to have developed a comparable practice in exchanging disease-specific information in a patient-focussed manner. With this relative lack of exposure to patients who have bronchiectasis, further development of such skills in an area outside their main expertise is likely to be problematic. Given that credibility of information received is important to patients, and that patients may not all be

receiving the same standard of information from their clinicians, there is clearly a need for high-quality resources beyond a specialist bronchiectasis clinic. Having a trustworthy and patient-driven resource that is widely available has the potential to engage patients and enable both dissemination of good practice and equity of information access amongst the patient group.

Within the aforementioned exploratory interviews, some patients indicated that their carers, partners, friends and family members played a key role in the day to day management of their condition (Hester, 2012; Hester *et al.*, 2012a). For some, this was practical assistance with treatments or other activities and for others their carers were actually the main seekers of information about their condition. Patients use information to aid their decision-making about various aspects of their management and its use can be a key coping strategy (Lambert and Loiselle, 2007). Significant others are also frequently involved in shared decision-making in a variety of different ways and that patients are rarely entirely autonomous in these processes (Ohlen *et al.*, 2006; Rapley, 2008). Previous work has also emphasised the importance of the role of family or carers in the adaptation of patients and coping with chronic illness (Anderson and Bury, 1988; Heijmans *et al.*, 1999) in keeping with the importance of social networks in self-management (Koetsenruijter *et al.*, 2014; Reeves *et al.*, 2014; Vassilev *et al.*, 2014; Koetsenruijter *et al.*, 2015). It would seem clear, therefore, that significant others are just as likely to engage with information resources as patients. As such, any newly developed resource would need to also accommodate carers and families of patients with bronchiectasis.

Another common reason identified for not seeking information in the prior pilot interviews (Hester, 2012; Hester *et al.*, 2012a) was fear of what may be found. This potential for information to worsen rather than reduce anxiety has been proposed by Lambert and Loiselle (Lambert and Loiselle, 2007), and the concept of information avoidance is recognised (Maslow, 1963; Case *et al.*, 2005). Reviews of health information seeking behaviour have concluded that a better understanding of this concept will enable the provision of better information, and that information should meet patients' individual needs (Case *et al.*, 2005; Lambert and Loiselle, 2007). Previous work looking into why patients with cancer may not want or seek information about their condition also identified that patients' attitudes and coping strategies are sometimes what limits their seeking of information (Leydon *et al.*, 2000). Leydon also demonstrates the importance of identifying the needs of the patient group in order to

tailor resources to suit them rather than assuming a 'one size fits all' approach will work.

Building on this, another theory is that information seeking behaviour is based upon personal traits rather than situational triggers (Rokeach, 1960). Again, this links with individual coping strategies and has relevance to patients with both terminal and chronic illnesses. Clear parallels can be drawn with bronchiectasis, as prognosis remains a crucial question and different patients vary in how much information they need (or want) on a personal level, as well as at different time points. A discussion of approaches to looking at information is presented by Lee (Lee *et al.*, 2016) which goes on to describe the pros and cons of a number of methods of interviewing with a view to understanding such seeking. This is all the more important when talking about how people access online information, and which sites are deemed credible, useful or easy to understand. Having an understanding of how, when and why patients seek information is clearly crucial prior to development of such an information resource. By identifying information needs using appropriate techniques and delivering an intervention that has been designed, in conjunction with patients, to complement their learning approaches, a resource can be tailored to meet needs.

2.4 Development of patient information resources: processes and formats

When suitable information resources are already felt to be in existence, patient signposting has been used for information delivery purposes. In a scheme aiming to provide patients with chronic conditions, including COPD, with patient specific information; patients were given an 'information prescription' based on their information needs identified by the patients and clinicians (McShane *et al.*, 2014). The majority of users and professionals were satisfied with the service, which facilitated access to information that was already available rather than creating novel resources. Establishing whether there is a need for novel resources prior to embarking upon development processes is essential.

Health information resources are developed in a variety of ways. A study reviewing information behaviours of carers of patients with dementia explored the differences between system-centred and user-centred approaches to developing information resources (Harland and Bath, 2008). Their conclusions were that user-centred approaches take into account individual needs which are not taken into account in system centred approaches. This further highlights the argument for co-development

of such resources, based on users' needs. Different formats and contents suit different people, and identifying the preferences and needs within the patient group must therefore be a critical part of ensuring good uptake. In addition to specific details of content, layout and information presentation, fundamentals such as whether the resource will be paper based, online, or a DVD for example, must be considered.

Paper-based information resources remain an important format. The NHS has created a toolkit for producing paper-based patient information, which provides a synopsis of the recommended processes and principles for developing basic information leaflets in line with service provision requirements (The Department of Health, 2003). It does allude to the fact that patients could be consulted and that other formats of information delivery could be considered, but it is primarily a resource to aid the production of paper leaflets written by healthcare professionals for patients. Signposting to other organisations such as the Patient Information Forum is included for those developers wanting to find out more.

Online and audio-visual formats also need to be considered when developing information resources. For some users, the use of audio-visual information is preferable to written information, whereas for others it could complement the more traditional format. Papers published in oncology, for example, have described the process of development and evaluation of audio-visual materials to prepare patients for procedures and promote self-management (Carey *et al.*, 2006; Carey *et al.*, 2007). The authors describe the principles used in development of such resources and the positive evaluations made by both patients and professionals. This group also report how their DVD led to a reduction in supportive care needs and improvements in self-efficacy (Schofield *et al.*, 2008). A group based in Newcastle described their production of an informative DVD for patients who had been newly diagnosed with Primary Biliary Cirrhosis, a chronic liver disease. They used interviews to identify what patients' needs were and consequently developed a DVD that focussed mainly on the diagnosis experience and information that would benefit patients at that time (Pearce *et al.*, 2011). This received positive feedback when shown to a group of 10 patients and carers who were asked to complete a questionnaire with free text about the DVD. The DVD has since been made available free of charge via the charity Liver North.

Although videos and now DVDs are becoming outdated, the use of the internet is now commonplace and audio-visual information can easily be accessed online. One example of information delivery using the internet is the use of 'YouTube' to access videos. This has been done to provide access to videos about pulmonary rehabilitation for example (King's College Hospital, 2007). Healthtalkonline.org provides a series of video interviews with patients and practitioners surrounding a number of health issues (Health Experience Research Group, 2013). This is based upon patients wanting to learn about other people's similar experiences when faced with health issues. This was also a sentiment expressed by patients in my prior exploratory study, yet for bronchiectasis, there are no such online resources. Not all patients, however, have the resources or ability to access information via this route, and paper resources are likely to remain in existence for some time to come.

With all potential information formats it is important to consider how accessible the resource will be to those with additional literacy or language barriers. More specifically, 'health literacy' is a term used to describe a person's ability to both read and understand information related to health. This requires a user to be able to read the information easily, understand it and be engaged with their health care. In order to optimise this, developers of resources need to ensure the absence of any potential barriers to user interaction and understanding (Raynor, 2012). These approaches should be adopted universally; producing high quality, clear information and communication for all users rather than screening for health literacy issues (Kronzer, 2016). There are online resources available to guide production of accessible information materials (Department of Health, 2010). Using plain and simple language is a key example, but there are many more ways to try to facilitate uptake. Co-developing a resource based on users' needs and reviews would facilitate production of an accessible information resource that could be readily engaged with.

2.5 Summary

People who have bronchiectasis and their carers remain poorly provided for in terms of health information and self-management guidance. This is despite clear potential for such interventions to produce tangible benefits for patients and the NHS. The prevalence of bronchiectasis is rising and makes this issue ever more pressing. Information has been identified in the literature as a requirement to enable self-management and treatment adherence. The need for improvements in information

and self-management education are widely recognised and an NHS priority for all chronic diseases. Bronchiectasis is a chronic disease in which advancements in information and self-management education could result in significant improvements in health and health service utilisation. In order to develop a resource that is well-received, engaged with and influences users' knowledge and actions, users must be involved in its production. I aimed to address this lack of provision with a patient-centred approach; incorporating what we already know about information seeking, needs and self-management in chronic disease, and exploring for the first time the specific unmet needs of those with bronchiectasis and their carers.

2.6 Aims and objectives

The specific aims and objectives of the work contained within this thesis were as follows:-

1. To identify, understand and describe the information and education needs of patients who have bronchiectasis and their carers.
2. To co-develop a high-quality, patient-driven information resource for patients with bronchiectasis in accordance with themes identified in qualitative interviews, focus groups and workshops.
3. To evaluate the resource and conduct a feasibility study to inform the decision of whether to proceed to a definitive randomised controlled trial examining the impact of the resource on users understanding, self-management, use of health care services and disease stability.

The methods used to achieve these aims and objectives are described in the following chapter.

Chapter 3 Methods and methodology: An exploration of unmet needs; development of a patient-driven information resource and the BRIEF Study protocol

This chapter provides a description of the methods used to achieve the outlined aims and objectives. I discuss the methodological approach taken to exploring and describing the information needs of patients with bronchiectasis and their carers; and to using this data to develop, trial and evaluate a novel information resource. I describe methods used for the interviews, detailing sampling, recruitment and analysis. The methods used within the resource development process are then described and lastly the design and conduct of the Bronchiectasis Information and Education: Feasibility study and evaluation of a novel resource (BRIEF) study (ISRCTN registration: ISRCTN84229105). The protocol for the BRIEF study has also been published as an open access article in *Trials* (Hester *et al.*, 2016) and is included as an appendix at the end of the thesis (Appendix 3).

3.1 Overall Methodology

A mixed methods approach has been taken for the work included in this thesis. If the interlinking stages of this research are considered as an overall research question to be answered: ‘what are the unmet information needs of patients with bronchiectasis, and can we develop and trial a resource that meets those needs and has the potential to improve understanding and self-management?’ the need for mixed methods becomes apparent. The information resource developed would be classed as a complex intervention due to its multiple components and the interactional behaviours required by those receiving the intervention in order for it to produce change (Medical Research Council, 2006). A mixed methodological approach to its development and evaluation is appropriate as outlined in the Medical Research Council (MRC) guidelines for developing and evaluating complex interventions (Campbell *et al.*, 2000; Medical Research Council, 2000; Medical Research Council, 2006). The revision of the MRC guidance in 2006 highlighted that the multiple phases of developing and evaluating a complex intervention are not necessarily sequential, and that the understanding of processes, whilst important, does not replace evaluation (Medical Research Council, 2006; Craig *et al.*, 2008). With the work described in this thesis, all phases were interlinked and an emphasis has been placed on evaluation of the intervention itself alongside the evaluation of processes

used during development and trialling of the intervention. An understanding of the evidence base is of course deemed essential by the MRC in undertaking the development and evaluation of such an intervention: the review and critique of the relevant literature has been described in chapter 2. The approach taken to this work is in keeping with these MRC guidelines, and was considered in great depth prior to the commencement of this work.

Only relatively recently has mixed methods (rather than a purist approach of either qualitative or quantitative methods alone) been considered to be a methodology in itself; the so-called 'third research paradigm' (Teddlie and Tashakkori, 2003; Johnson and Onwuegbuzie, 2004). Its development in the health sciences has since been acknowledged and described (O'Cathain and Thomas, 2006; O'Cathain, 2009). The specific mixed methods approach taken here was tailored to the research questions posed. The use of differing methods to answer a research question more completely can be regarded as triangulation in this context, a process advocated in ensuring high quality data (Sandelowski, 1995; O'Cathain *et al.*, 2010). It has been proposed that such methodological pluralism and selection of methods to suit the scenario is essential for high quality research and to obtain useful answers (Sechrest and Sidani, 1995; Johnson and Onwuegbuzie, 2004). By using a mixed methods approach for this work, my aim was to explore and answer the research questions as completely as possible.

The overall term of 'mixed methods' might be regarded as being rather vague. If looking to label the typology of mixed methods used for this work, the approach taken would probably be best described as a sequential exploratory strategy (Cresswell *et al.*, 2003). The qualitative data analysis in the first stage of work (exploration of unmet information needs) informed the development of the novel resource (which used further qualitative methods) and then this resource was used as the intervention in the randomised controlled trial (primarily quantitative methods). When looking at the RCT in separation, a further typology of mixed methods used within the feasibility study could be described as a concurrent nested approach (Cresswell *et al.*, 2003). Qualitative methods were additionally integrated into the feasibility trial design (a randomised controlled trial with end of study focus group) to allow evaluation of the resource and trial process that could not be obtained using quantitative methods alone. A relatively complex mixed methodological approach has therefore been used

overall, in order to best answer the research questions in a reliable, valid and rigorous way.

Adopting such mixed methodology in order to answer research questions seems to be an obvious example of pragmatism. Pragmatism has been described as allowing the researcher to avoid the 'forced choice dichotomy between positivism and constructivism' (Cresswell and Plano-Clark, 2007, p. 27); ending the divide between quantitative and qualitative research methods to focus on answering the research question (Hanson, 2008). As such, pragmatism seems to go hand in hand with mixed methods research (Feilzer, 2010) and is in keeping with the overall methodological approach taken to this work. It is important to note that an additional (yet complementary) philosophical approach was taken when analysing the qualitative components of this work: subtle realism. Subtle realism assumes we only know reality from our experience of it. A realist approach aims to achieve an objective reality or knowledge through rigorous methodology, based on the theory that phenomena exist independently of human knowledge of them. Subtle realism additionally acknowledges the individuality, or 'situatedness', of a person's experiences and knowledge. Although first described in the context of ethnography, this can be applied to qualitative research more widely (Hammersley, 1992; Banfield, 2004; Maxwell, 2012). By interviewing a wide variety of patients with bronchiectasis and their carers, I aimed to gain a rich dataset in order to understand the experiences of people living with bronchiectasis and how their information needs might be met. This approach provided a wealth of descriptions and viewpoints. These descriptions of experiences are individual, yet they were not simply studied in isolation. Methods were carefully considered to ensure the validity and reliability of the resultant data when looking across cases to identify similarities and differences. The methods used for sampling and data analysis take into account the requirement for methodological rigour in order to produce credible data. This included careful purposive sampling, peer and supervisor review and code checking, deviant case analysis and reflexivity.

The feasibility study in the main used quantitative methods, and as such scientific rigor in terms of randomisation, analysis and reporting of results was paramount. Although the three elements of work cannot be entirely separated given their interlinking nature, to ensure clarity, I have detailed the specific methods and results for each stage distinctly.

3.2 Methods: The Qualitative interviews

For the first stage of work, in order to fully explore the information needs of patients and carers with bronchiectasis, and obtain rich, experiential data to inform subsequent resource development, qualitative methods were the obvious choice. Using qualitative interviews allowed new and emergent ideas to develop and these ideas could then be tested and further explored over subsequent interviews. To use data collection methods such as questionnaires would not have facilitated such depth of data and transfer of views between the participants and myself, nor would it have enabled the detailed exploration of emergent ideas. Semi-structured, in-depth interviews were therefore selected as the method of choice to gain a detailed understanding of participants' experiences. This first stage of the work builds upon my prior exploratory interviews (Hester *et al.*, 2012a) which documented the need for disease-specific information for patients who have bronchiectasis, and began to explore those needs. This prior pilot study, however, had obvious limitations. To address these limitations and improve upon this groundwork, methods used for sampling and for exploring the needs within the patient group were subject to further methodological considerations.

3.2.1 Sampling

In the previously described pilot study (Hester, 2012; Hester *et al.*, 2012a) the majority of patients interviewed regarding their unmet information needs had very similar characteristics; in part due to the nature of the sampling approach used. Specifically, in the pilot study, all participants were attending a specialist bronchiectasis outpatient service in a tertiary referral centre and all had the same consultant delivering their care. All were listed on a database that indicated their interest in taking part in research and the majority were female patients in their sixth decade who had longstanding disease. Upon reflection, many of these factors had potential to influence information needs, access to information and information seeking behaviour. One would anticipate that those attending a specialist service would have access to information via their clinician that may surpass that routinely delivered in general clinics. Supporting this assumption, during pilot interviews, participants often referred to the fact that they had obtained very little information about their condition until they started attending the specialist clinic (Hester *et al.*, 2012a).

In the prior pilot study, the sample was in essence a 'convenience sample' (Patton, 1990). All potential participants were approached via a specialist bronchiectasis clinic, and all were known to be interested in being approached about research studies. Potential participants were therefore identified by the consultant as people likely to be interested in talking about their experiences. In order to address this prior lack of within-sample variation, rigorously explore emerging concepts and improve upon pilot work, purposive sampling was used to recruit participants to the interviews reported within this thesis.

Numerous different subtypes of purposive sampling have been described (Patton, 1990) and maximum variation sampling was the method used for this study. The purpose of this technique is to ensure description of themes that cut across a wide participant variation and also to specifically seek participants likely to generate the most useful data (Green and Thorogood, 2009b). Potential participants were sought with the following characteristics:-

- Attending different general respiratory clinics
- Attending a specialist bronchiectasis clinic
- Variety of ages
- Variety of social and cultural backgrounds
- Patients with a new diagnosis (within 6 months)
- Patients with a longstanding diagnosis
- Patients with additional diagnoses
- Variation in disease severity
- Patients with carers

The following inclusion and exclusion criteria were also applied:-

Inclusion Criteria: Clinical and radiological diagnosis of bronchiectasis

Age 18 years and over

Capacity to give informed consent

Exclusion Criteria: Cognitive impairment

Sampling and analysis were conducted concurrently in order to focus on particular aspects of data, emerging concepts, and potential influencing factors that were felt to

be important. For example, the first 'round' (Rapley, 2010; Rapley, 2013) of sampling aimed to concentrate on individuals who attended a general respiratory clinic rather than a specialist bronchiectasis clinic. The intention in this round was to explore how information needs may differ for those who do not attend a specialist service, hence building on the knowledge gained from the previous exploratory interviews. After analysis of this round, I focussed on sampling patients who had less severe disease, as this was an area that emerged as not having been explored. Further rounds focussed on the characteristics listed above and emerging data and ideas from ongoing interviews, which can also be referred to as theoretical sampling (Glaser, 1978).

This process obviously had to involve some flexibility, and participants wanting to take part who met criteria known to be of interest were not asked to wait until their 'round'. Sampling, as per recruitment and analysis, was an iterative process. An example of this would be sampling patients who had a more recent diagnosis of bronchiectasis. The first four participants had longstanding disease. In keeping with the findings from the pilot study, they often referred to how little information they had when first diagnosed in a non-specialist clinic. Whilst this may be an entirely correct recollection, specifically sampling patients who had received a recent diagnosis potentially allowed for more accurate descriptions of their experiences. This also enabled me to explore reactions to diagnosis when these feelings were fresh in people's minds. Ultimately I was able to recruit four patients who had received a diagnosis within the past six months, with some having a diagnosis of bronchiectasis made within just a few weeks of their interview date. Clearly this needed to be opportunistic sampling when new patients were referred to clinic and was ongoing throughout the sampling process.

In terms of sample size, an estimate was made in advance of commencement of recruitment of up to 20 patients and between 5 to 10 carers. This was flexible and the aim was to continue to interview until no new major issues relevant to the project were identified from the data. As qualitative studies aim to obtain a richness of data as opposed to simply a large number of participants, there is no definitive guidance as to how many interviews are 'enough'. The term most frequently used to guide researchers as to when they have completed an effective sample size is 'saturation' or 'data saturation' (Hennink *et al.*, 2016). Theoretical saturation was its starting point, a term used originally in grounded theory to describe the point when there is no

further emerging insight when gathering data (Glaser and Strauss, 1967; Kvale, 2007). The term data saturation is used widely in qualitative research to mean when continuing data collection does not lead to the identification of any new issues (Kerr *et al.*, 2010). There is a lack of guidance, however, on qualifying saturation and establishing the sample sizes required to achieve it (Morse, 1995; Guest *et al.*, 2006; Kerr *et al.*, 2010; Hennink *et al.*, 2016). A recent study attempted to provide guidance on numbers of interviews required to achieve saturation and found that for 'code saturation' (no new codes emerging) the number of interviews required was fairly low at 9 (Hennink *et al.*, 2016). Their findings are in keeping with previous ranges identified between 8 and 16 (Namey *et al.*, 2016) and 7 and 12 interviews (Guest *et al.*, 2006). Hennink *et al.* attempted to go further and identify when 'meaning saturation' was reached, which they defined as 'the point when we fully understand issues, and when no further dimensions, nuances, or insights of issues can be found' (Hennink *et al.*, 2016, p. 4). Although code saturation had been reached by interview 9, meaning saturation required up to 24 interviews, and was complex to predict, being affected by multiple factors including more conceptual codes needing more data to be fully understood. They proposed that a decision of whether a small, intermediate or large sample (absolute numbers not specified) would be required should be made based upon multiple factors: purpose of the study, sampling strategy, and aims such as capturing broad themes or developing new theory. Although this tells us that sample size is dependent upon the aims of the study and the sample and data obtained, it would not be possible to predict a definitive sample size for this work due to the number of influencing factors and the quality of data not being known in advance of study commencement. In practical terms, the aim in this study was to ensure that all the key questions and ideas had been as thoroughly explored as possible and further sampling rounds did not generate any significant new ideas or meaning (Rapley, 2010).

The sample size for carers (5-10) was more of a pragmatic decision, yet still facilitating the inclusion of their views as a group. As described in Chapter 2, carers can be central to patients' information needs and can in fact be the primary information seekers. It is also known that carers often play a significant role and as such are likely to have specific information needs of their own. Carers were included in this sample to explore their experiences directly, rather than solely seeking patients' accounts of their role.

More detailed characteristics of those recruited to the study, including the order in which they were interviewed are summarised in Chapter 4, the interview findings.

3.2.2 Recruitment

Patient participants were recruited from The Newcastle upon Tyne Hospitals NHS Foundation Trust. This covered multiple respiratory clinics provided by different respiratory consultants over two different hospital sites. One of the clinics is run as a specific specialist bronchiectasis service which is led by a single consultant.

First approach to potential participants was by their clinical care team. The sampling strategy outlined was applied when asking clinical care teams to identify and approach suitable potential participants. All respiratory consultants within the trust were made aware of the study and given patient information sheets by the research team which included research nurses based at the Sir William Leech Centre for Respiratory Research at the Freeman Hospital. If potential participants were interested in hearing more about the study their details were passed to the research team by their clinical care team with their consent. Patient information sheets and invitation letters were sent out in the post to them or handed to them in clinic (Appendix 4, Appendix 5). This was then followed up by a telephone call from me after a minimum time elapsing of twenty four hours. This process ensured all their questions were answered and enabled me to arrange a convenient meeting time and place if they were interested in taking part. Any patient who agreed to take part in the study was asked if they had someone who played a significant role in their lives that they would like to join them in the interview; such as a spouse, family member or close friend. These additional participants were identified as 'carers'. Written, informed consent of both patient and carer participants was obtained in advance of the interviews and was done in person, usually immediately prior to the commencement of the interview (Appendix 6).

3.2.3 Interview process

Patients and carers were invited to take part in one semi-structured interview expected to last between 30 and 90 minutes. All carer interviews were carried out as joint interviews with 'their' patient participant.

Participants were given the option of the place of interview and the majority chose their own homes. One interview took place in a participant's place of work in a private office, one took place in a patient's private room on a hospital inpatient ward, two in

private rooms at the research facility at the Freeman Hospital and one in a private room at Newcastle University. The remaining twelve interviews were conducted in the participants' homes. Different settings can impact upon the atmosphere and how a patient reacts to an interview (Green and Thorogood, 2009b) and also upon the data obtained (Green and Hart, 1999). The aim in offering choice of venue was to ensure maximum comfort and convenience for participants and to endeavour to conduct the interview with an informal conversational style allowing participants to relax and feel at ease.

All interviews were conducted by me, which raises the issue of my role as an interviewer and how this may have influenced the narratives and responses from the interview participants. All of the participants were aware that I am a respiratory doctor. I carefully considered whether I would attempt to avoid declaring my 'medical identity' and ultimately decided against it. It has been described in the literature that interviewees' perceptions of the interviewer affect interview interactions, and that professional role can influence this (Hoddinott and Pill, 1997; Hoddinott and Pill, 1999; Richards and Emslie, 2000). I felt that to be consistent I would need to declare my role as a doctor to all participants, prior to commencement of the interviews. When considering what influence this may or may not have upon the interviews, and on people's decisions about taking part, I felt that I needed to be open about this. For example, I could have introduced myself to potential participants as a 'researcher'. I wondered what I would then say if people asked me what I knew about bronchiectasis, or if I worked with their healthcare team, or knew their consultant. I also knew that there was a definite probability that some participants would have already have come into contact with me in a clinical capacity. In order to maintain consistency between participants, and to avoid being conservative with the truth, I felt that the best approach would be to simply present my actual identity: a trainee respiratory doctor, who has expertise in bronchiectasis, and is currently a researcher.

There may well be assumptions or beliefs that I bring as a doctor that others wouldn't. Obviously, how the interview data would have differed with a different researcher is unknown. This, however, would be the case regardless of my role as solely a researcher or as a doctor in addition. It was possible that my profession would influence what accounts participants were willing to give to a 'doctor' rather than a 'researcher'. Arguably there may also have been answers that would only be given because I was a doctor. In order to maximise consistency and transparency,

another important aspect of methodological rigour, I opted to make my role as a doctor who knew about bronchiectasis clear. I did this during introductions in telephone calls prior to the interviews being arranged. I will go on to reflect upon my role as interviewer in the discussion of the interview findings in Chapter 4.

Much consideration was given to the interview schedule. The original interview topic guide is provided as an appendix (Appendix 7). Note that this was developmental and interviews were tailored to the answers of each interviewee and adapted over the course of the project as new research questions emerged from the analysis of prior interviews. The content of the topic guide at the outset was developed by building upon areas of interest arising from the pilot study (Hester, 2012; Hester *et al.*, 2012a) and by drawing on past literature surrounding information seeking (Leydon *et al.*, 2000; Cotten and Gupta, 2004; Case *et al.*, 2005; Lambert and Loiselle, 2007; Lee *et al.*, 2016). Also influencing the topic guide was what is already known about self-management (as detailed in Chapter 2) as well as interview methods and practicalities (Kvale, 2007; Green and Thorogood, 2009b; Lee *et al.*, 2016). Discussion with supervisors regarding both content of the guide and style of questioning also shaped the interviews, by integrating both clinical and sociological content.

The interviews aimed to cover 4 main topic areas:-

‘Learning about bronchiectasis’

This was the opening topic for each interview, and was introduced very broadly by asking participants to talk about when they first found out that they (or the person they cared for) had bronchiectasis. Although this generally invited a response that detailed the patient’s ‘story’ I then led this towards an exploration of the information they had been given at the time of diagnosis, as this had been a subject that had arisen as an area of need in the pilot interviews. This then allowed conversation about whether or not they had gone in search of more information since diagnosis: why, where and when this may or may not have occurred. ‘Learning about bronchiectasis’ also covered what people wanted to know about their condition, or what they already knew. By allowing discussion very generally around these subjects, I was able to explore both factual knowledge about their condition and approaches or barriers to information seeking. It was important to be able to establish from the interview data what factual aspects were felt to be important or areas they

were lacking information about (i.e. more clinical details) and also how, why, where or when people may or may not need or want information (i.e. more sociological or behavioural details). Both these aspects of data were critical to being able to effectively inform the design of the information package.

‘Managing bronchiectasis’

Discussions in this area aimed to explore knowledge and practices surrounding self-management to elicit details regarding perceived abilities, roles, confidence and support required. This too was important for the planned information resource.

‘Future information formats’

This section aimed to further explore participants’ views of different modes of information delivery. To facilitate discussions around this and prompt opinions on styles of information resource, examples were shown to participants within the interviews. They were shown different styles of written information leaflets, an information DVD and several information websites. In order not to cloud judgement with details of actual content, the examples used were relevant to conditions other than bronchiectasis. The approach of ‘talking whilst looking’ at the information resources was taken to try to best understand their online information seeking, likes and dislikes (Lee *et al.*, 2016).

‘About you’

This was a section included to ensure that relevant details such as length of time since diagnosis, age and nature of bronchiectasis were recorded in case they had not already been discussed earlier in the interview.

The topics as set out in the interview schedule were not covered in order, yet served as a guide for the interview to ensure inclusion of important points. As the interviews progressed and other topics of importance arose, these were included within subsequent interviews in order to cross-check and further explore them. For example, prognosis was a topic often raised by participants, along with wanting to relate to other people in similar situations. These then became topics that would be raised in subsequent interviews for discussion if not already raised spontaneously by the participants.

The interviews were recorded using a digital audio recorder so as to ensure accurate data and allow conversational flow. Additional field notes were made both during and immediately following the interviews. These were notes to myself taken during the interviews concerning points that I felt to be significant, or wanted to explore further.

3.2.4 *Handling of interview data*

The interviews were audio recorded and audio files were transcribed verbatim. All data was stripped of strong identifiers and only identifiable by a unique study number. Only authorised members of the research team, operating to written codes of confidentiality, had access to the link between anonymised data and patient or professional identifiable details. Patients and professionals were not identifiable in any publications emanating from the work described in this thesis. Data was handled, computerised and stored in accordance with the Data Protection Act 1998. No participant identifiable data left the study site.

3.2.5 *Analysis of data*

Thematic analysis was used for the analysis of interview data and field notes were reviewed in conjunction with the transcripts to inform analysis. The process of thematic analysis begins when the researcher begins to notice and look for patterns of meaning and issues of potential interest within the data. Analysis therefore started during the collection of the data, i.e. at the interviews. The end point was when the themes and their content and meaning were reported. There are several stages of thematic analysis (Grbich, 1999; Braun and Clarke, 2006; Gibbs, 2007):-

1. Becoming familiar with the data by reading repeatedly to search for meanings
2. Develop a list of ideas about the data, applying codes and organising into meaningful groups
3. Looking for themes
4. Reviewing the themes
5. Defining and naming themes and a written detailed analysis of each theme
6. Written report including all themes

To give a little more detail on how the above process was applied to analysis of my data I will give some more specific examples. Firstly, as discussed in the sampling section, I carried out data analysis and sampling concurrently in 'rounds' (Rapley, 2010). This approach involved carrying out the first few interviews, and then reflecting upon analysis of the data generated in order to aid further sampling and

highlight areas to focus on in future interviews. In order to do this, interviews were transcribed as soon as possible. Whilst this was taking place, interview audio recordings were listened to repeatedly to review the content of the interview and initial ideas. By reading and re-reading the interview transcripts and field notes, and re-listening to the audio-recordings, I became familiar with the data. A great deal of time was spent becoming familiar with the data so as to ensure accurate detail when conducting the analysis. When familiar with the data within the first few interviews, I began to develop a list of ideas about the key issues at that stage. Having used different codes to describe small sections of data within these initial transcripts, (e.g. impact of bronchiectasis) I then began to assimilate a list of codes (Appendix 8) and applied these codes to the data within the subsequent transcripts. I revised this list throughout the analysis process as ideas developed and evolved throughout further rounds of sampling and analysis. This was used for ease of updating and application of the generated codes and sub-codes (used to establish grouping of similar ideas, e.g. sub-codes of the code 'impact of bronchiectasis' include physical, emotional, role) to subsequent transcripts as the analysis progressed. This enabled me to document clearly when new codes were generated and to ensure no potentially confusing repetitions were made.

When the first round of interviews had been coded in this way, I began to develop ideas about the themes within the data. Themes developed, changed and became more conceptual over time. Themes described the broader meanings within the data rather than coding specific small sections of data. As themes developed I wrote written analyses of individual themes (memos) which also changed over time. By dedicating large amounts of time to analysis during the time of the interviews and beyond, I was able to pay very careful attention to detail within the data.

I referred previously to the consideration of methods to ensure the validity and reliability of the resultant data. There are differing views with regards to attaining rigour and validity in qualitative research and approaches obviously differ from that of quantitative research. Key components in qualitative work include peer and supervisor review and code checking, deviant case analysis and reflexivity. Ensuring such validity, reliability and generalisability started at the outset of this work. A basic yet important aspect of reliability is ensuring accuracy of transcripts and using audio-recording to allow this (Green and Thorogood, 2009b). As described, careful checking of the transcripts was carried out and verbatim transcription was used.

Throughout the interviews, I used careful purposive sampling and concurrent data analysis. This iterative process, including writing memos alongside analysis throughout, allowed for the development, exploration and 'testing' of new ideas emerging from the data and adds to methodological rigour (Gibbs, 2007; Kvale, 2007; Rapley, 2010; Rapley, 2013). Using this approach ensured optimisation of the validity and generalisability of the data. To add further to this validity, ensuring descriptions and emerging themes were genuinely representative of the data and participants' experiences, I used both peer and supervisor review. Coding of randomly selected transcripts was checked by my PhD supervisor. Some data has also been analysed collectively in 'data clinics'. Within these data clinics, members of the research team, including supervisors, postdoctoral researchers and doctoral students share and exchange interpretations of key issues emerging from the data. This is done by taking along sections of anonymised interview transcripts. This review and discussion with my peers and supervisory team has formed a vital part of ensuring methodological rigour and a more complete understanding of the data. This has added to both the validity and reliability of the data, with confirmation of reproducibility of findings with different investigators as well as different participants (Gibbs, 2007).

Another method employed to maximise validity and hence rigour was searching for and the analysis of 'deviant cases' or 'negative cases' (Green and Thorogood, 2009a; Rapley, 2010). Interestingly, the very first participant interviewed stood out as a 'deviant case' when describing his disinterest in hearing about other people's similar health experiences. As I will describe in Chapter 4, this was an aspect of information that other participants found to be very helpful. Further analysis of such contradictory instances in fact added strength to the theme rather than disproving it, with this one participant highlighted as a marked exception to the norm.

Finally, the use of reflexivity also played an important role within this analytical process (Gibbs, 2007; Green and Thorogood, 2009c). This involved both continuous reflection upon the data and the interviews themselves, and also reflection upon my role as interviewer and how my medical or social milieu potentially impacted upon the data and its analysis. As I referred to earlier, one specific example would be the impact of my role as a doctor (Hoddinott and Pill, 1997; Hoddinott and Pill, 1999; Richards and Emslie, 2000; McNair *et al.*, 2008). I will discuss my reflections on the

potential influence of my day to day work role upon the interviews in Chapter 4, along with detailed results of the analysis of the interview data.

3.3 Methods: The resource development process

Once interview analysis was complete, the process of developing the novel patient information resource based on the interview findings was commenced. How the findings of the interviews specifically influenced the resource will be described in Chapter 5. The methods used to develop the resource and ensure that it met users' needs will be described here. By co-developing the resource with users, I aimed to ensure that interpretation of the interview findings and subsequent translation into a novel resource was an accurate representation of users' requirements, and that it was developed in a way that would maximise potential uptake. The literature pertaining to the development of patient information has been discussed in the previous chapter.

3.3.1 *Sampling and recruitment*

The focus group style workshops used during the co-development process were detailed within the patient information leaflets given to potential interview participants (Appendix 4). It was stated that interview participants may be invited to attend a focus group to discuss the findings of the interviews and how these might inform the design of the new resource. Whilst all interviewees were invited to attend the focus groups, not all wished to or were able to attend and additional patients with bronchiectasis were also invited to join the groups. A purposive yet pragmatic approach was taken to this further sampling, and a mix of female, male, newly diagnosed and longstanding patients who had not taken part in the interviews were invited to attend, with or without their carers. For these additional participants, the same inclusion and exclusion criteria and recruitment processes were used as described previously for the interviews. A separate patient information leaflet and consent form was provided for those patients and carers taking part who had not been interviewed (Appendix 9, Appendix 10).

3.3.2 *The workshop sequence: Ideas, concepts, prototypes and refinements*

Once the main emergent themes had been identified and described, I developed some initial ideas about the resource based on those themes, and other important elements of the interview data relevant to the resource. In basic terms, this involved creating lists of themes and their descriptions to further explore and check, and also options as to what information may be included, what formats may be used and how it may be presented. Potential concepts for the new resource were drafted to get

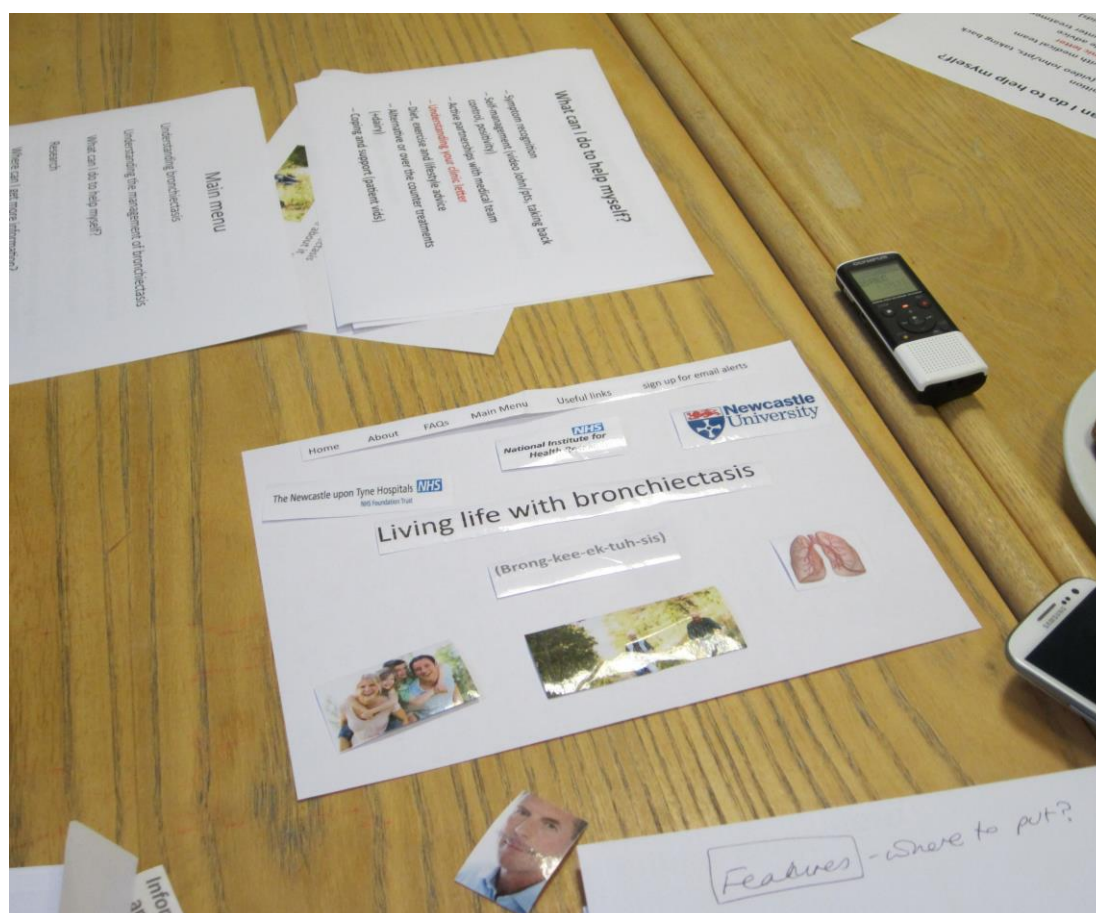
further views and opinions. This enabled me to check the validity of the findings of the interviews and confirm how this could translate into a user-friendly resource.

Workshop 1: ideas and concepts

The aims for Workshop 1 were to establish agreement (or disagreement) with the main themes and ideas for contents and by doing so further refine the ideas for the resource. I additionally aimed to confirm what format the resource would be developed in, i.e. a booklet, website or DVD. The workshop was facilitated by me and a specialist bronchiectasis nurse. An extensive topic guide (Appendix 11) was used as a basis for discussion given the large volume of contents to be addressed, albeit at a preliminary level.

Details of the main themes and their key components were printed out and placed on a central table to aid discussion (Appendix 12). Also printed out for discussion were ideas for the main contents and sections to be included within the information resource. Additionally, basic mock up booklet cover pages and website homepages were created with removable elements to establish priorities for these, ranging from what to include on a front page to what the title of the resource should be (Figure 1). The workshop sessions were audio recorded and still photographic images were taken with permission of participants.

Figure 1. Workshop 1 materials.



Prototype development

Once the ideas for the concept and design of the resource and its overall content were affirmed and refined, work began on the development of the resource. I did this with additional help from both the Freeman Hospital Adult Bronchiectasis Service team and a recommended media company specialising in website design. I held a series of discussions with potential contributors, including a specialist bronchiectasis nurse, bronchiectasis consultant, physiotherapists, dietitian, incontinence nurse, lung function technicians, patients and carers in order to establish who would have an input into which sections of content. I met with the media design company to establish what we envisaged for the end product – the information resource. In order to achieve this I needed to describe to them the purpose of the resource, the required content and format and the characteristics of a typical potential user.

The vast majority of actual content was written by me and verified by my clinical supervisor, a bronchiectasis consultant. Specialist sections were written by their provider and then edited by me. For example, the bronchiectasis specialist

physiotherapist wrote the pages covering physiotherapy techniques and exercise advice, and the dietician wrote the content relevant to her expertise. By using the whole bronchiectasis multidisciplinary team's expert knowledge and experience, I was able to create a resource offering credible, up to date and accurate advice and information from clinical experts. By inviting patients and carers to contribute to certain sections, elements identified as important to the final resource were also incorporated. The ways in which the contributions to and review of the prototype by users and the expert health care providers shaped the final product is described further in the results chapters.

All written contents were edited by me and checked by other members of the contributing team. The Easy Read principles were taken into consideration when reviewing written content, to try to maximise accessibility (Department of Health, 2010). I had extensively reviewed relevant literature and guidelines pertaining to this, and also attended a training workshop to further develop my skills in this area. Although this was not a resource specifically aimed at those with low literacy levels or learning disabilities, as highlighted in Chapter 2, it is important to adopt an aim of producing accessible information during the production of any new materials (Kronzer, 2016).

All video content was filmed and edited by me, and permissions for any images included were obtained by me. Once the prototype content was finalised, this was sent on to the media company to build into the prototype website, the final version of which was hosted by Fasthosts, on a virtual server, at an annual cost. The contributory team, a respiratory consultant not involved with the project, and invited user reviewers (including a BLF user representative) commented on content in addition to initial styles and layouts developed as examples by the media team. Views were fed back in order to agree a final style and images for the website homepage and to refine content. As content was developed further following this, I undertook training to access to the content management system for the website and thus was able to add or amend any content, plus create user access logins and passwords. Once the content was completed for this first prototype version, the second and third workshops were held to review and refine this further, and to decide on the contents of a booklet version of the resource.

Workshops 2 and 3: Refinements

The second workshop again had patient and carer participants and was facilitated by myself and the specialist bronchiectasis nurse. For this workshop the topic guide was much more concise (Appendix 13) as the aim of the session was to show the participants the current version of the website at that time to obtain feedback. I particularly wanted to get feedback about the appeal and credibility of the homepage, and navigation through the website. We also discussed the contents of relevant sections, including text, images and video, and the overall impression of the resource in comparison to others they may have seen. Additionally, this session was used as a forum to discuss thoughts about which sections should or should not be included within the short booklet version of the website.

The third and final workshop followed the same guide as workshop 2, yet was a more focussed and detailed review of the website content with a much smaller group.

3.3.3 Data handling

The workshops were audio recorded and audio files were transcribed verbatim. All data was stripped of strong identifiers and only identifiable by a unique study number. Only authorised members of the research team, operating to written codes of confidentiality, had access to the link between anonymised data and patient/professional identifiable details. Patients and professionals were not identifiable in any publications emanating from the work described in this thesis. Data was handled, computerised and stored in accordance with the Data Protection Act 1998. No participant identifiable data left the study site.

3.3.4 Analysis of workshop data

A pragmatic approach was taken to analysis of the data obtained through the workshops. A thematic analysis approach was used, yet the majority of the useful data was 'real-time' feedback. Notes were taken during the sessions, and discussions reviewed through subsequent reading and re-reading of the transcripts to ensure familiarity with the data. Discussions within and between the workshops tended to concur and as such 'themes' identified within the data were collective opinions. Any disagreements or deviations were usually discussed within the session and a common ground found. I used the transcripts to confirm workshop discussions and identify any further themes to aid resource refinement. Conclusions about alterations and refinements, sections that were liked or not, and how things should be

amended were directly applied to the resource development process. By using this iterative approach, a final working version of the resource, in website and booklet form, was produced to be used within the Bronchiectasis Information and Education Feasibility study. Results of the resource development are described in Chapter 5.

3.4 Methods: Bronchiectasis Information and Education: Feasibility study and evaluation of a novel resource (The BRIEF Study)

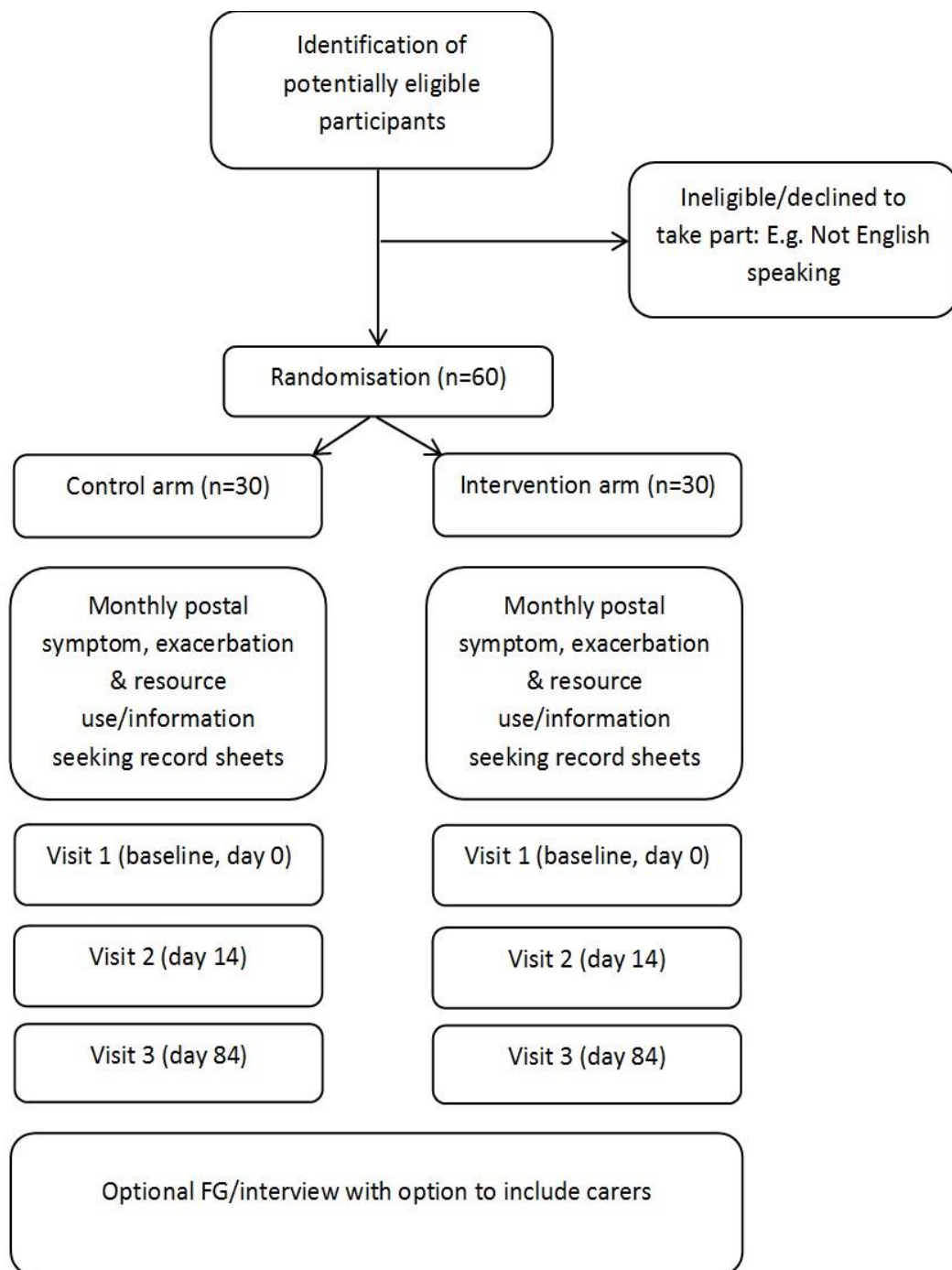
Once the resource had been developed, its use as an intervention needed to be assessed. In order to go beyond a simple evaluation process, a feasibility study was conducted in order to both review the intervention itself, and to determine the feasibility of being able to conduct a future full randomised controlled trial (RCT). A definitive, multi-centre trial would address the research question: can the provision of patient-focussed information and education improve health outcomes in bronchiectasis? The rationale for the BRIEF study was, in advance of the definitive trial, it is necessary to assess whether the proposed design for the trial is practicable and will allow the proposed outcomes to be assessed. In addition the intervention was evaluated and further refined for use within the definitive trial. The full protocol is available as an appendix (Appendix 3) and has been published in Trials journal. (Hester *et al.*, 2016).

3.4.1 Study design and setting

The BRIEF study was an unblinded single centre randomised controlled trial with two parallel groups, comparing a novel patient information resource to usual care in bronchiectasis. The BRIEF study took place in The Newcastle upon Tyne Hospitals NHS Foundation Trust. This consists of two teaching hospital sites: The Freeman Hospital and The Royal Victoria Infirmary. Study visits all took place within the Freeman Hospital. The running of the trial was based within the Freeman Hospital at the Sir William Leech Centre for Respiratory Research. Patients were recruited from either hospital site.

Study duration for each participant was 3 months from study entry date. Due to variations in month length, this was calculated at 12 weeks (84 days). Study completion date was the date of the last assessment visit of the last entrant and completion of the end of study focus group. Study flow can also be seen in the flow chart (Figure 2).

Figure 2. BRIEF study flow chart.



3.4.2 Study objectives

Primary objective: To conduct a feasibility study that will inform the decision of whether to proceed to the definitive RCT and whether any refinements to the design or conduct of that trial are warranted.

Secondary objectives: To evaluate and further refine the patient information resources and collect information on patient preferences.

Definitive future trial objectives: To assess whether provision of a patient-focussed information and education resource can improve patient understanding, self-management and health outcomes in bronchiectasis.

3.4.3 Study Intervention details

The BRIEF study compared the newly developed patient information resource (detailed in Chapter 5) with usual care. Those in the usual care arm did not receive any additional information but were able to obtain any information routinely acquired during their usual contacts with their healthcare team or their own information seeking. At the baseline visit, participants randomised to the intervention received the patient information resource: an overview booklet and website (password required for website access). Verbal and written instructions were given by appropriate members of the research team (as per delegation log) about how to access the website. The participants then had access to the intervention for the duration of the study. Their use or not of the information resource was down to individual choice, yet, through discussion with the research team member conducting each study visit, participants were encouraged to utilise the resource and to allow their families or carers to also utilise them should they so wish. Some participants may not have had direct access to a computer or internet use. This did not preclude them from entry as long as they could access the internet via their family, friends or local institutions such as libraries. For those who did not wish to or did not have the skills to access the website, participation using a PDF version of the information contained within the website was offered. This enabled them to view all the information content other than the video clips. At study completion, those randomised to the intervention group were allowed continued access to the resource. Those in the control group were offered access to the resource following completion of their study period so as to minimise potential disappointment due to their allocation to the control arm. This decision was made following discussions with the Trial Oversight Committee (TOC) and ethics committee

members. We felt this was a more acceptable way to conduct the trial as most potential participants had an interest in learning more about their condition. Any uptake of the resource following study completion did not form part of data collection.

The intervention used in the BRIEF study was a non-clinical intervention and I did not expect any reasons for discontinuing the intervention other than participant preference. Any participant could choose to leave the study at any point with no effect on usual care. Potential participants currently participating in another trial were not approached for entry into the study.

3.4.4 Study outcome measures

The primary outcome measures for the BRIEF study were those measuring feasibility. These included:-

- Participants' willingness to enter the trial (consented participant to potentially eligible participants approached ratio).
- Participant recruitment rate (as measured by the number of patients randomised divided by the length of the recruitment period).
- Participants' acceptability of study design (as measured by the completion rate of participants in each randomised group, 'study completers').
- Participant completion of required study forms and visits as per protocol.

Secondary outcome measures included the measures used to evaluate the information resource and the measures that would be used within a definitive trial to assess impact of the intervention upon health-related outcomes. For the purposes of this feasibility study, these measures contributed to the assessment of completion of study forms by participants and also to the resource evaluation process. Measures included:-

Resource evaluation outcomes (unvalidated questionnaires):-

- Resource Satisfaction Questionnaire (RSQ)
- Monthly postal symptom questionnaire
- Bronchiectasis Knowledge Questionnaire (BKQ)

Health-related and quality of life outcomes:-

- Quality of Life-Bronchiectasis (QOL-B) (Quittner *et al.*, 2014)
- St George's Respiratory Questionnaire (SGRQ) (Wilson *et al.*, 1997)
- Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983)
- Fatigue Impact Scale (FIS) (Fisk *et al.*, 1994)
- EuroQol 5 Dimensions 5 levels questionnaire (EQ-5D-5L) (Herdman *et al.*, 2011)
- Number of unscheduled visits to primary or secondary care
- Exacerbation frequency
- Forced Expiratory Volume in 1 second (FEV1)

All outcome measures were used in assessing feasibility of a future definitive trial, including recruitment, retention and study questionnaire completion rates. Participant evaluation of acceptability of the newly developed package was established through questionnaires and open questioning to include their satisfaction with the information provided, knowledge about their condition and management, and additional features that they felt may strengthen the intervention. Use of the resources provided and preferred formats identified within these questionnaires also informed feasibility of a future trial and allowed for refinement of intervention formats. A single focus group was held at study completion to strengthen data on the patient experience.

Outcome measures were recorded at baseline (day 0) and then at 2 weeks (day 14) (i.e. shortly after initial viewing of information in order to facilitate obtaining first opinions), and 3 months (day 84) post recruitment. This was done during patient visits that were anticipated to take less than 1 hour each. Visit 2 could be conducted via telephone interview if participants preferred. Information was retrieved from the patient visits and patients' symptom and information sheets (patients were asked to complete a monthly postal record sheet, (week 4, 8 and 12) enabling identification of episodes of change in symptoms and actions taken, in addition to any information resource use, without the burden of a daily diary record) and also through GP and hospital recorded attendances if patients were unable to report or recollect.

EQ-5D-5L was used to allow some estimate of health economic evaluation for a future RCT. It was anticipated that there could be potential health economic benefits if patients were empowered to self-manage thereby reducing service use. The

number of unscheduled presentations, exacerbation rate and FEV1 could potentially be used in a future full trial as a representation of the patients' ability to self-manage their condition and disease stability. Health related quality of life (HRQOL) measures were also felt to be important to include in a future definitive trial and were therefore recorded within this study. A recent review of their use in bronchiectasis has shown that they have good validity and repeatability. Specifically QOL-B and SGRQ were identified as having good psychometric properties, and QOL-B is the only disease-specific HRQOL questionnaire available for bronchiectasis (Spinou *et al.*, 2016). Of note, self-efficacy was not used as an outcome measure in the BRIEF study. As discussed in Chapter 2, self-efficacy is not always useful as an outcome measure *per se*, but is more a predictor of outcomes. There is no pre-defined minimal important clinical difference for example. In previous studies of self-management interventions, changes in self-efficacy do not necessarily produce measurable clinical differences. Having reviewed this at length, including discussion with Professor Lorig, who used this as a measure in the EPP studies (Lorig *et al.*, 1985; Lorig and Holman, 1993; Lorig *et al.*, 2001), it was concluded that it would not be appropriate to use this as an outcome measure for this study of an information provision intervention.

3.4.5 Eligibility criteria

Inclusion criteria

1. Participant has capacity to provide written informed consent
2. Aged 18 years or over
3. Clinical and radiological diagnosis of bronchiectasis
4. English speaking

Exclusion criteria

1. Cognitive impairment
2. Non-English speaking
3. Aged <18 years
4. Participation in the preceding Bronchiectasis Information and Education (BRIE) study

Due to the nature of the study, English language was a necessary inclusion criterion to ensure usability of the information provided. As this was a small feasibility study, resources were not available to produce the information in other languages, nor to

provide a funded means of internet access. For those participants who did not have internet access, yet wished to take part in the study, the information within the website (excluding video clips) was provided in Portable Document Format (PDF). If a participant elected to enter the study as a 'PDF participant', this was recorded and the participants proceeded with the same visits and outcomes. Numbers requesting this mode of study entry were recorded to enable evaluation of resource format preferences.

3.4.6 *Participants*

Potential participants were identified by case-note review and attendance at outpatient clinics and were given or sent a letter of invitation to the study and a patient information sheet (Appendix 14, Appendix 15). Written informed consent was obtained from willing participants (Appendix 16). Patients could withdraw consent at any point with no effect on usual care. At the end of the study, some participants were invited to attend a focus group about their experience. Participants invited to attend the focus group were sampled purposively. The aim was to form a group that included participants of differing backgrounds and time since diagnosis, some from the control and some from the intervention group, and those that had differing preferences in terms of format used. Involvement in the focus group, however, was an optional extra and as such a pragmatic approach had to be taken. Anyone agreeing to take part in the focus group was invited to bring along their 'carer', who was then sent the appropriate information sheet to consider whether they would like to take part. Additional information sheets (Appendix 17) and consent forms (Appendix 18) were produced for those participants.

3.4.7 *Participant recruitment, identification and screening*

Patients were identified as described above. This was done on a sequential basis aiming to recruit 1 patient per weekly clinic. Eligible participants were invited to participate by their consultant, the Principal Investigator (PI) or the Chief Investigator (CI) who were part of the medical team. The study was explained to them further by the research team. A study participant information sheet was provided at this time and the patient could take this away for consideration. For those identified by case note review, a letter of invitation (Appendix 14) was sent in the post along with the patient information sheet and details of how to get in touch if interested. They were offered opportunity to discuss this further with the research team.

The details of the study were also discussed as part of a bronchiectasis open day held at the Freeman Hospital run by the Adult Bronchiectasis Service. This open day was advertised in the local press and on the trust intranet and was attended by both patients and staff. Patients who were interested in hearing more about the study could register interest using a form at the open day. A patient information sheet was then sent to their given address. In this setting there were a number of interested patients who were not attending clinics within the trust and therefore were not eligible for recruitment. This was explained to them and they were given general information about the study so that they could enquire about study results if they wished.

A screening log was kept to document details of subjects invited to participate in the study. For subjects who declined participation, this documented any reasons available for non-participation. The log also ensured potential participants were only approached once.

3.4.8 Sample size

Sample size was up to 70, with a minimum of 30 being randomised to both the control and intervention groups. This was based on previous recommendations for good practice in feasibility studies (Lancaster *et al.*, 2004). Due to this being a feasibility study, no formal power calculations were carried out. Up to 10 additional 'carer' participants were anticipated to be recruited for the end of study focus group, as described above.

I anticipated that 24 months would be adequate time to recruit 70 patients to this study, based on a clinic attendance of approximately 60 per month with an estimate of 50% of patients approached who were willing and able to enter. 70 patients recruited from approximately 140 patients approached would correspond to a 95% confidence interval for the recruitment rate of 41%-59% (an acceptable width of $\pm 9\%$). I expected low attrition rates based on previous work and prior experience in this field. There was a 3 month additional period planned for follow up of the last recruited participants and time beyond for the focus group and analysis.

3.4.9 Randomisation

Participants were randomised to intervention or control groups in a 1:1 ratio, using random permuted blocks within strata. Because I knew there to be a disproportionate number of females within the potential study population and was uncertain of the

effect of gender on outcomes, randomisation was stratified by gender. The randomisation allocation schedule was generated by a statistician with no other involvement in the study. Randomisation was performed by the CI at site, or individual with delegated authority, using a secure password-protected web-based system administered by Newcastle Clinical Trials Unit. Randomisation generated a unique 3-digit Study identification (ID) number for each participant. Participants were informed of their allocated treatment group following randomisation. Blinding was not feasible for this study for patients or the research team conducting the study visits due to the nature of the intervention. Given that I, as the data analyst, was also involved directly with the study processes and data collection, blinding of the analyst was not possible.

3.4.10 Data collection and handling

Main study data

Data was collected at study visits by the research team as per the delegation log and a summary is tabulated (Table 1). Visits 1 and 3 were done in person and visit 2 could be either in person or on the telephone. Other than the spirometry performed at visits 1 and 3, all outcome measures were questionnaires and were either self-completed by the participants or with the help of the research team member conducting the study visit. All answers were recorded in paper copies of each questionnaire within the participants' files. The study team member conducting the visit checked for omissions after completion with the participant. All members of the delegation log were trained in the use of the questionnaires and lung function tests. The questionnaires completed are tabulated (Table 2) and also supplied as appendices (Appendix 19, Appendix 20, Appendix 21, Appendix 22, Appendix 23, Appendix 24, Appendix 25, Appendix 26).

There was additional data collection through the use of monthly (week 4, 8, 12) postal symptom and resource use record sheets sent to participants (Appendix 19). This aimed to enable more accurate recollection of symptoms and information use than at the study visits alone, yet is a reduction in burden compared to completing a daily diary. Phone calls were made to encourage completion if the forms were not returned.

Data on the use and attempted access to the online information resource was collected using Google Analytics. Basic data was collected to detail factors including

number of page views, most popular pages and navigation through the site. This was based on site access and use by individual participants was not monitored.

Data collected on paper forms were entered by the CI or appropriately trained study research team members (as per delegation log) on a secure password protected study computer. Participants were identifiable on records only by a unique study identifier on all recorded data. Only authorised members of the research team, operating to written codes of confidentiality, had access to the link between anonymised data and patient identifiable details.

Personal data was regarded as strictly confidential. To preserve anonymity, any data leaving the site identified participants by a unique study identification code only. The study complied with the Data Protection Act, 1998. All study records and Investigator Site Files were kept on site in a locked filing cabinet with restricted access. Only members of the research team had access to the final dataset, and that required for necessary audit and monitoring.

Focus group data

A single focus group was conducted after completion of the study. A brief topic guide (Appendix 27), in conjunction with the resource itself, was used to prompt discussion and the group was facilitated by me. The focus group was audio recorded and audio files were transcribed verbatim. All data was stripped of strong identifiers and only identifiable by a unique study number. Only authorised members of the research team, operating to written codes of confidentiality, had access to the link between anonymised data and patient/professional identifiable details. Patients and professionals were not identifiable in any publications emanating from the work described in this application. Data was handled, computerised and stored in accordance with the Data Protection Act 1998. No participant identifiable data left the study site.

Table 1. BRIEF Study data collection schedule.

	Visit 1	Visit 2	Visit 3: final visit
	Day 0	Week 2 (Day 14)	Week 12(Day 84)
Written informed consent and randomisation(if not done prior to V1) and collection of baseline demographics	x		
Resource use (not baseline visit) and information seeking	(x)	x	x
Resource satisfaction questionnaire		x	x
Bronchiectasis Knowledge questionnaire	x	x	x
QOL-B	x	x	x
SGRQ	x		x
HADS	x	x	x
FIS	x		x
EQ-5D-5L	x	x	x
Number of unscheduled visits	x	x	x
Exacerbation frequency	x	x	x
FEV1	X(If not done in past 3 months)		x

Table 2. BRIEF Study data.

Study instrument	Description
Resource use and information seeking	Unvalidated questionnaire developed for use within the BRIEF study
Resource satisfaction questionnaire	Unvalidated questionnaire developed for use within the BRIEF study
Bronchiectasis Knowledge questionnaire	Unvalidated questionnaire developed for use within the BRIEF study
QOL-B	Validated quality of life in bronchiectasis questionnaire
SGRQ	Validated quality of life/respiratory health questionnaire
HADS	Validated anxiety and depression score
FIS	Validated fatigue impact score
EQ-5D-5L	Validated quality of life questionnaire
Number of unscheduled visits	Patients report of healthcare visits
Exacerbation frequency	Patients report of number of exacerbations
FEV1 (Absolute value and % predicted)	Lung function test using calibrated equipment

3.4.11 Compliance and withdrawal

Compliance

Where feasible, study visits were arranged to coincide with routine clinical follow-up, to enhance the likelihood of good compliance. Visit windows of +/- 1 week were allowed to aid visit attendance; non-attendance for study visits prompted follow-up by telephone. Participants were given the option of completing visit 2 by telephone interview to reduce the burden of travel for study visits. Non-return of monthly postal record sheets also prompted follow-up by telephone.

Withdrawal of participants

Participants had the right to withdraw from the study at any time without having to reveal a reason. The investigators also had the right to withdraw patients from the study intervention if judged to be in the patient's best interests. As an excessive rate of withdrawals can render the study uninterpretable, unnecessary withdrawal of patients was avoided. If a patient decided to withdraw from the study, all efforts were made to report the reason for withdrawal (if given) as thoroughly as possible.

There were two withdrawal options:

1. Withdrawing completely (withdrawal from both the study intervention and provision of follow-up data)
2. Withdrawing partially (withdrawal from study intervention but continuing to provide follow-up data by attending clinic and completing questionnaires).

Consent was sought from participants choosing option 1 to retain data collected up to the point of withdrawal. Participants were asked if they would be happy for any given reason for the decision to withdraw to be recorded.

3.4.12 Statistical analysis

Statistical analysis was performed using SPSS 22.0. All analysis was carried out in keeping with a pre-written statistical analysis plan (Appendix 28). As this was a feasibility study, the analyses of the data collected were mainly descriptive. As the BRIEF study had a randomised controlled trial design, primary analysis was based on the intention to treat principle with analysis groups based on the groups allocated at randomisation and all randomised patients being included in the analysis. The extent of missing data was assessed and reported and analysis of outcomes carried

out on a complete-case basis. Rates were calculated as defined. At baseline and by intervention group the distribution of all numerical variables was examined graphically and summarised by measures of location and spread. Similarly, baseline categorical variables were tabulated and percentages reported. Change in the questionnaire outcomes from baseline to 2 weeks and 3 months was summarised. The difference in the mean change between the intervention groups from baseline to each of the two time points was explored for all validated outcome measures. Data was examined graphically and reported as appropriate for the distribution. The mean (SD) of the change data has also been presented given change data is most often symmetrical and this data could be used if calculating a sample size for a future definitive study based on this feasibility study design. No interpretation has been made of this basic change data nor of any apparent change within allocation groups given the fact that this cannot be meaningfully interpreted without further analysis and can be misleading (Vickers and Altman, 2001; Bland and Altman, 2011).

All results were interpreted cautiously because of the size of the study and the possible imbalance in pre-randomisation baseline covariates. Data were examined graphically and analysed descriptively. No formal statistical testing was performed as this was a feasibility study, not powered to detect significant change within variables, and as such the reportable outcomes relate to feasibility.

3.4.13 Analysis of focus group data

The focus group conducted at the end of the study explored the experiences of participants and their carers. Topics covered both their views on the resource and their views on the trial itself. In a similar way to the analysis of the workshop data during the resource development process, a thematic analysis approach was taken. The group was audio-recorded and transcribed verbatim and transcripts were used to read and re-read and confirm issues identified during the focus group. Feedback themes were identified, summarised and reported.

3.4.14 Monitoring

This was a low risk trial and major safety issues were not anticipated. As agreed by Newcastle upon Tyne Hospitals NHS Foundation Trust, the Trial Oversight Committee (TOC) adopted the joint roles of Trial Steering Committee (TSC) and Data Monitoring & Ethics Committee (DMEC), with independent members meeting in closed session to fulfil the DMEC role. The TOC comprised an independent chair, an

independent consumer representative, a patient representative, a carer representative, CI, PI, data manager and statistician. The TOC met bi-annually. Their role was to monitor progress and supervise the trial to ensure it was conducted to high standards in accordance with the protocol, the principles of Good Clinical Practice (GCP), relevant regulations & guidelines and with regard to participant safety. Monitoring of study conduct and data collected was performed by site review to ensure the study was conducted in accordance with GCP. The main areas of focus included consent, serious adverse events and essential documents.

The study was liable to be subject to inspection and audit by Newcastle upon Tyne Hospitals NHS Foundation Trust under their remit as sponsor, and other regulatory bodies to ensure adherence to GCP. The investigator(s) / institutions would have permitted trial-related monitoring, audits, Research Ethics Committee (REC) review and regulatory inspection(s), and provided direct access to source data/documents.

There was no interim analysis for this study.

3.4.15 Ethics and regulatory issues

The conduct of this study was in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

Favourable ethical opinion from NRES Committee North East - Sunderland (ref 14/NE/0119) was granted and R&D approval (ref 7005) from the Newcastle upon Tyne Hospitals NHS Foundation Trust was granted prior to commencement of the study. Any protocol amendments were approved by R&D and the Sunderland REC and were communicated to all relevant parties: investigators, registries, participants.

The study was registered with ISCTRN (ISRCTN84229105) on the 25/7/2014. The study was also accepted onto the CRN portfolio (UKCRN ID 16655).

Information sheets were provided to all eligible subjects and written informed consent obtained prior to any study procedures.

3.4.16 Informed consent procedures

Informed consent discussions were undertaken by appropriately trained site staff (as per delegation log) involved in the study, including medical staff and research nurses, with opportunity for participants to ask any questions. Following receipt of information

about the study, participants were given reasonable time (with an aim of a minimum of 24 hours) to decide whether or not they would like to participate. Those wishing to take part provided written informed consent by signing and dating the study consent form, which was witnessed and dated by a member of the research team with documented, delegated responsibility to do so. Written informed consent was always obtained prior to randomisation and prior to study specific procedures and investigations.

The original signed consent form was retained in the Investigator Site File, with a copy in the clinical notes and a copy provided to the participant. The participants specifically consented to their GP being informed of their participation in the study.

The right to refuse to participate without giving reasons was respected.

Due to the small subject population and the inclusion criteria, the information sheet and consent form for the study was available only in English.

3.4.17 Insurance and finance

The sponsor, Newcastle upon Tyne Hospitals NHS Foundation Trust, had liability for any clinical negligence that harmed individuals toward whom they have a duty of care. NHS Indemnity covered NHS staff and medical academic staff with honorary contracts conducting the trial for potential liability in respect of negligent harm arising from the conduct of the study. The Newcastle upon Tyne Hospitals NHS Trust was Sponsor and through the Sponsor, NHS indemnity was provided in respect of potential liability and negligent harm arising from study management. Indemnity in respect of potential liability arising from negligent harm related to study design was provided by NHS schemes for those protocol authors who have their substantive contracts of employment with the NHS and by Newcastle University Insurance schemes for those protocol authors who have their substantive contract of employment with the university. This was a non-commercial study and there were no arrangements for non-negligent compensation. Newcastle University provided insurance cover for the trial design. NIHR funded the study through a doctoral research fellowship awarded to the CI.

Results of the BRIEF study are detailed in Chapter 6.

3.5 Summary

As described within this chapter, this body of work has been conducted in three interlinking stages, using a mixed methods approach. The review of literature in Chapter 2 explained the need for improvements in information and education provision for patients with bronchiectasis and their carers and described how the nature of the resource and means of development are critical. By using qualitative methods to establish needs and involving patients and carers throughout the development process, I aimed to create a resource that met users' requirements. By conducting the described feasibility study, I aimed to evaluate the resource and also establish the feasibility of conducting a future definitive trial to establish the impact of such an intervention and the refinements needed to both the intervention and protocol to facilitate such a trial.

The results of the three stages of this work will be reported separately in the three subsequent results chapters. The results of the interviews are presented first, followed by the resource co-development process and subsequently the results of the BRIEF study.

Chapter 4 Results 1: Findings of the qualitative interviews

In this chapter I begin with a summary of participant characteristics and recruitment and then describe the findings of the qualitative interviews with patients and carers. Within the interview data, four interlinking themes were identified, with the core emergent theme being 'living your life with bronchiectasis'. This overarching theme describes the physical and non-physical impacts of living with bronchiectasis, and how these relate to the patient journey. The second theme, 'developing support and coping mechanisms' covers how both patients and carers learn to cope with this condition, and how they are supported in doing so. Thirdly, how patients 'take back control and develop active partnerships with the medical team' will be explored, describing how and when this process is facilitated. Lastly, this is linked with how patients and carers 'connect with information', the important features an information resource would require, and how this data could be used to inform the development of such a resource.

4.1 Participant summary

4.1.1 *Participant characteristics*

Interviews with seventeen patients who have bronchiectasis took place, and nine of these interviews were conducted as joint interviews with the patient and their carer. Thus, there were twenty six participants in total. Of the nine carers that took part in the joint interviews, seven were spouses of the patient participant and two were siblings that co-habited with the patient they were interviewed with.

The age range of participants was 33 to 78 years with a median age of 65 years. Ten patient participants were male and seven female. Of the carer participants, seven were female and 2 male. Time since diagnosis ranged from a few weeks to 65 years. Six of the patient participants attended a general respiratory outpatient clinic and 11 were recruited from a 'specialist' bronchiectasis clinic. Of these eleven, four were newly diagnosed patients and as such had not received extensive information at the specialist clinic by the time of the interview.

Whilst bronchiectasis has varying aetiologies, most participants had idiopathic disease. Of those who did not have idiopathic bronchiectasis, two had associated immune-deficiency syndromes and the remainder were thought to have been caused

by previous pneumonias. The majority of patients had additional medical diagnoses or comorbidities which varied in nature and severity.

I recorded selected details on patients' social circumstances, including who they lived with, current or previous occupations and age at which they left education. This was intended as a crude measure of socio-economic status, as factors including literacy levels could potentially influence the subject of interest: information needs. The majority of patients were retired, and jobs ranged from manual to professional with a wide variety of educational levels attained.

The participants were sampled purposively as described in chapter two, in order to obtain a maximum variation sample and achieve a rich dataset. The participant characteristics relevant to the sampling strategy have been summarised (Table 3). Sampling was based upon patient characteristics rather than their carers hence the relative lack of detail about the carers. Carers' details appear directly beneath 'their' patient in the table.

Table 3. Interview participant characteristics.

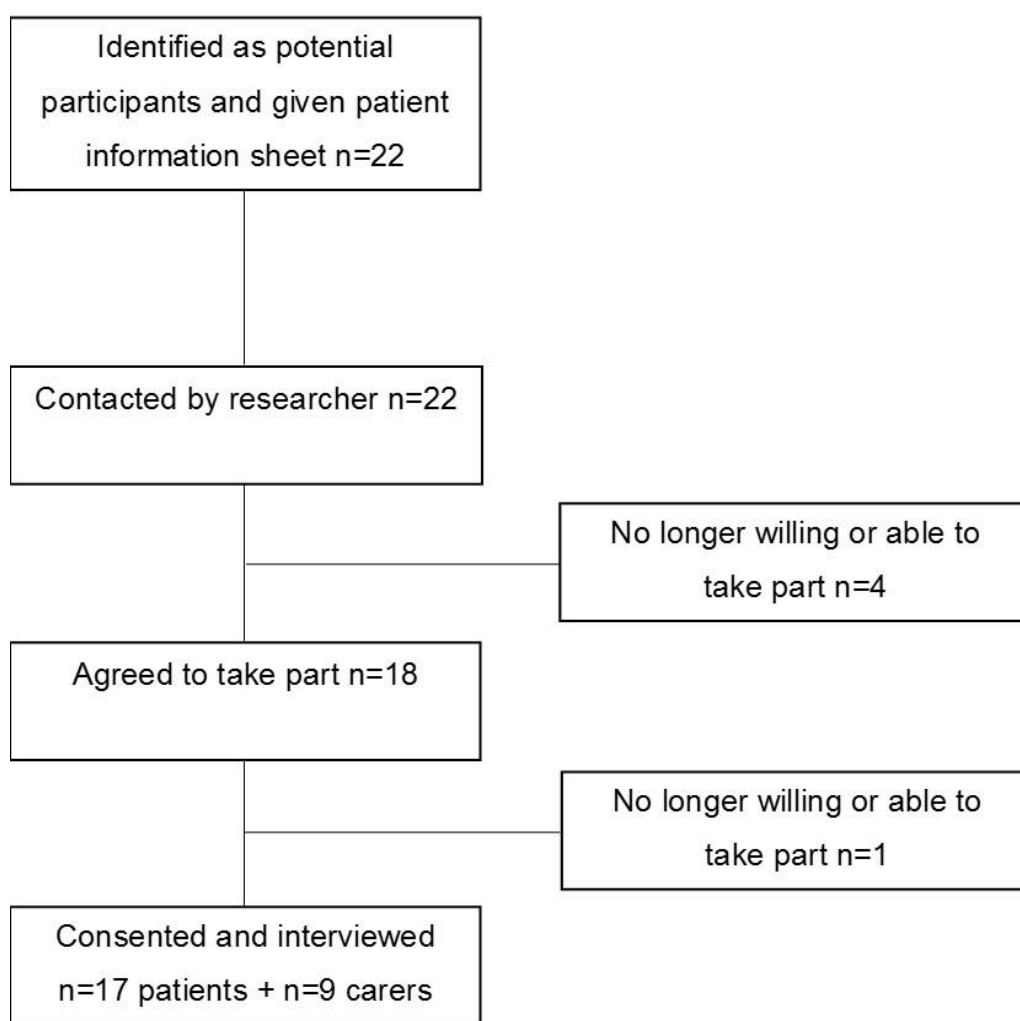
Gender	Age	Time since diagnosis	Bronchiectasis Type	Additional Diagnoses	Disease Severity	Clinic Attending	Social Circumstances	Internet Access
M	78	2 years	Idiopathic	Yes	Severe	General	Retired butcher, lives with sister (carer)	No
F (carer)	68							
M	63	2 years	Idiopathic	Yes	Moderate	General	Retired construction worker, lives alone	No
F	67	19 years	Immunodeficiency associated	Yes	Severe	General	Retired nurse, lives with husband - she is carer	Yes
F	67	5 years	Idiopathic	Yes	Mild	Specialist	Left school at 14, husband works offshore	Yes
F	67	6 weeks	Idiopathic	Yes	Mild	Specialist (new)	Retired head teacher, lives with husband	Yes
M (carer)	68						Retired environment protection officer	Yes
M	70	65 years	Post childhood pneumonia	Yes	Moderate/severe	Specialist	Retired electrician/singer, lives with wife	Yes
F (carer)	65						Retired factory worker	
M	65	6 months	Idiopathic	Yes	Mild	General	Taxi driver, lives with wife	Yes
M	61		Idiopathic	No	Severe	Specialist	Retired heating engineer, lives with wife	Yes
F (carer)	57							
F	60	few years	Idiopathic	Yes	Mild	Specialist	Vietnamese, lives with extended family	Yes
M	33	3 years	Idiopathic/post childhood pneumonia	No	Mild	Specialist	Manager for council, lives with wife and young children	Yes
M	64	6 years	Idiopathic	Yes	Mild/moderate	General	Business coach, lives with wife	Yes
F (carer)								
F	64	20 years	Immunodeficiency associated	Yes	Mild/moderate	Specialist	Retired office/sales work, lives with husband	Yes
M (carer)								Yes
F	75	few weeks	Idiopathic	Yes	Mild	Specialist (new)	Retired teacher, lives with husband	Yes
M	43	18 months	Idiopathic	Yes	Mild	Specialist	Analyst for large company, married	Yes
M	75	12 years	Idiopathic/post childhood pneumonia	Yes	Moderate	General	Retired joiner, lives with wife	No
F (carer)								
F	76	few weeks	Idiopathic/post pneumonia/Asthma	Yes	Severe	Specialist (new)	Retired teacher, lives with sister	Yes
F (carer)							Retired teacher	
M	59	few weeks	Idiopathic/post previous pneumonia	Yes	Severe	Specialist (new)	Retired family sports company, lives with wife	Yes
F (carer)								

4.1.2 Participant recruitment rates

There was a high rate of recruitment to the study amongst those identified as being interested in taking part. Four patients identified as potentially interested in taking part declined entry to the study when contacted by the researcher, stating poor health as their reason. One further patient cancelled their interview due to family commitments and was unable to rearrange. Recruitment and interviews took place over an eight month period of time.

The recruitment flow chart summarises recruitment details (Figure 3).

Figure 3. Interview recruitment flow chart



4.2 Main emergent theme: Living your life with bronchiectasis

Living your life with bronchiectasis is the central issue emerging from the data. Note that the primary focus of the interviews at the outset was to establish unmet information needs. Interestingly, however, the overriding discussion within the interview data revolved around the impact that bronchiectasis has: what it means to live your life with this condition. Living your life with bronchiectasis encompasses experiences of diagnosis and the ongoing patient journey, and experiences of both the physical and emotional impacts of the condition.

4.2.1 Diagnosis and prognosis: the patient journey

Stories of diagnosis and concerns about prognosis were common throughout the interviews. Some recounted these tales from distant memory, whereas for others this was a very recent experience. The impact of the diagnosis itself varied between individuals, with multiple factors potentially influencing people's reactions. One of these factors was timing of diagnosis. Some participants had received a diagnosis at a young age, others more advanced in years. Importantly, the way in which this influenced impact was not uniform. People's experiences of living with the symptoms of bronchiectasis prior to diagnosis played an important role whatever their age. For example, several of those who were diagnosed later in life describe having not known any difference. Although they had recently received an official, clinical, diagnosis, they had had symptoms for as long as they could remember:

'I don't feel any different than I have done for the last goodness knows how many years, it's something that's always been there and I guess I've just got used to it, but yeah, instead of me thinking it was asthma, which I thought it had been for years, now it has a name.' (P17 26-32)

'I've had respiratory problems since 1967...and "bronchiectasis"...I just thought it was another word for 'bronchitis' really, I didn't give it much more thought.' (P15 9-16)

These patients essentially describe their reaction as a 'non-reaction'. The impact of their diagnosis, or the attribution of a name to their symptoms, was minimal. They now have a label, or a new label, for their symptoms, but nothing else has changed. Their symptoms are so much a part of their life that to be told they will continue is of little surprise to them. This continuance of their norm was exactly as expected.

There were also patients who had been living with the symptoms of undiagnosed bronchiectasis for many years, yet had a slightly different reaction. This patient described how he felt on receiving a diagnosis of bronchiectasis:

‘I was shocked but sort of glad in a way, because it explained why I hadn’t been well for so long and, I mean, the littlest of coughs and colds I would be in bed for like a week because I couldn’t fight it basically, and now that explains why.’ (P10 16-19)

Although this patient describes the element of shock at first that he actually did have a ‘condition’, he simultaneously experienced a positive reaction to the news. Within my data, this subgroup with undiagnosed symptoms tended to have a response of relief rather than despair when initially faced with the fact that they had a named chronic disease. Although their life would continue as they already knew it, they were not indifferent to the receipt of this diagnosis. Having this diagnosis enabled them to make sense of their experiences, and as such was well received.

For some, however, receiving a diagnosis of bronchiectasis was a huge blow. Having ‘more to lose’ seemed to magnify the impact of a diagnosis, as this patient and her husband described:

‘I was pretty low. Wasn’t I? [C02: yes, totally] We were both pretty low because I thought well, you know, that’s it. Because I’d been such a busy, active person in the community I just feel that... I’m sorry..., I just feel as if my life, you know, has taken a bit of a downward spiral to be honest. It was quite emotional.’ (P05 C02 10-14)

This lady’s reaction to receiving the diagnosis of bronchiectasis was one of finality: ‘that’s it’. Being so active before the diagnosis, she felt she had a lot to lose, that this diagnosis would change her life as she knew it. Her previous experiences of illnesses had been conditions with surgical solutions, whereas this would be ongoing, an incurable illness. For this patient, amongst others, the point of receipt of diagnosis was a very negative experience; the end of their hopes that their symptoms could be explained away by ‘normal ageing’ and the start of their journey as a patient with a chronic disease.

A patient’s ‘journey’ seemed to be directly linked with the presumed prognosis. Bronchiectasis differs from some other diagnoses in that there is often uncertainty surrounding prognosis. Patients are usually told that bronchiectasis is a chronic condition that can be managed, yet it cannot be cured. There is much variation in

terms of severity of symptoms. This uncertainty regarding prognosis was reflected in the interviews and clearly extends to the patients as well as the medical profession. One patient, with a very recent diagnosis, repeatedly led the conversation back to prognosis throughout the interview. Her primary concern was lack of information about the prognosis of bronchiectasis:

‘I am interested in knowing about how progressive it is once you’ve got it, whether it’s got a grip on you and you’re never going to be released from this grip, so it’s a matter of containing what you’ve got?’ (P13 100-103)

This lady wanted to be clear about the progressive nature of the condition and what this meant practically, which was a common feature of many interviews. How can someone plan for this patient journey without knowing what lies ahead? Having such a diagnosis without knowing a definite prognosis can be very hard to process, as another patient describes:

‘Well I wasn’t aware what to expect. I knew I would deteriorate as time went on obviously, people get older, but not what path it would take, I know it’s not the same for every patient.’ (P03 163-165)

As this patient demonstrated, knowing what to expect is important. Not knowing is a problem. It is a problem that continues beyond people’s initial reactions to their diagnosis.

Centrally, time since diagnosis did not seem to influence desire for knowledge about prognosis. The continued focus upon prognosis of this incurable disease suggests that although patients may have had the initial diagnosis or ‘disruption’ many years ago, this biographical shift or change in trajectory is still laden with uncertainty. The shift is not a permanent and fixed new trajectory, but a move to an almost continuously or repeatedly disrupted one. A change from a presumed smooth life trajectory to the threat or reality of a constantly or periodically changing one. For those who had symptoms of bronchiectasis all their lives, their version of disruption could be likened to that of children with cystic fibrosis (an inherited multisystem disease with cystic bronchiectasis of the lungs): ‘non-difference’ (Williams *et al.*, 2009). For most, however, the diagnosis of a chronic illness such as bronchiectasis does not simply alter one’s biography but opens the door to an uncertain future. Therefore one would imagine the process of acceptance, adjustment, or ‘learning to

live with' the condition cannot be 'completed' at some point post diagnosis, as the symptoms or limitations that need to be accepted will be subject to change. This seems to lead to a lifelong adjustment process, requiring further work dependent on disease progression and changes in circumstance.

How patients and their carers progressed on their 'journey' from diagnosis and dealt with the uncertainty of their prognosis varied, and those interviewed were at different stages of this journey. It was clear, however, that both the physical and psychological impacts of bronchiectasis directly influence the patient journey. Both are subject to change over time and both again are subject to much uncertainty.

4.2.2 Living with the physical impacts of bronchiectasis

Physically, symptoms of breathlessness, fatigue, cough and recurrent infections impose limitations on patients' preferred lifestyles; affecting their ability to do things as they previously would have done. Adaptations needed to be made to allow for these new symptoms. These adaptations were not simply to physical activities, but also to people's lifestyle, such as not going on aeroplanes, avoiding people with colds and changing drinking habits. This was all in an effort to reduce the impact of the physical symptoms, or reduce their chances of getting another infection and thereby not worsen their physical symptoms.

Changes required to lessen the physical impacts of bronchiectasis were also affected by patient's individual circumstances. For example, family commitments may dictate what changes to lifestyle are possible; lifestyle prior to symptom onset may influence the degree of change required; and factors such as a person's level of social support or personal character traits also influenced impact and change. For some participants, changes also needed to be made to daily routines to allow for regular treatments. Patients often require more than simple oral medications. Nebulised antibiotics and physiotherapy regimes are often used which can be time consuming and socially restricting. Having bronchiectasis imposes change on one's life. Due to the impacts it has, life is no longer 'normal'.

One might presume that any physical, or resultant practical, impacts (and indeed psychological impacts) may be directly proportional to the extent of disease. The degree to which symptoms impacted upon patients, however, did not consistently correlate with clinical severity. A medical diagnosis of 'mild' bronchiectasis was not

necessarily in keeping with the patients' experience of their condition as this lady described:

'A mild case ... I would hate to think anybody was worse than me, I think mine's bad enough.' (P04 63-163)

Perception of severity is obviously subjective, highlighting the differences between a clinical label and a lived experience. Despite the classification of this patient's condition as 'mild', this has had such an impact on her life that she can barely imagine how it could be worse. For her, this alleged 'mildness' provides little comfort or reassurance.

Even when the clinical label does fit with the patients' experience of their symptoms, there are still uncertainties. Another patient described how she felt about being told that her condition was classified as 'mild':

'mine fortunately is mild...it's so mild that generally I'm feeling so well that it hasn't made any impact on me, but I think it has had an emotional impact on me, to find that there is something wrong, but I need to discuss about the mildness of it, whether it could be milder.' (P13 68-77)

Although medical classification of this patient's disease as physically 'mild' makes sense to her in terms of her symptoms, it is still important for her to make sense of whether it is modifiable. Having a label of 'mild bronchiectasis' is not necessarily reassuring, without putting it into context. This quote reinforces the uncertainties that patients are faced with when receiving such a diagnosis; not only is the absolute prognosis uncertain, but the symptoms one should expect are also uncertain.

Part of the issue concerning uncertainty is the fact that the symptoms experienced are likely to change, both on a long and short term basis. Bronchiectasis is a condition that can deteriorate over time, and by its nature, there will be periods of exacerbation of symptoms. For example, one gentleman described how for many years he was not limited by his condition but that as his disease has progressed it has had a much greater impact on his lifestyle as a consequence of increasing physical symptoms:

'I (could) manage the bronchiectasis, cos I was working full-time, in fact sometimes I was working 50 hours a week when I was managing.

...

I'm leading a boring life at the moment, you know, not getting out much unless it's in the car somewhere. I can't go out for walks because...I'm struggling just to get to the end of the path.' (P08 25-27; 614-617)

This gentleman had bronchiectasis diagnosed as a young adult, and had spent the majority of his working life being able to cope with the physical impacts that bronchiectasis presented. The adaptations he needed to make to his life were minimal. However, as things have deteriorated more recently, his lifestyle bears little resemblance to the life he once had, despite the fact that he was also 'living with bronchiectasis' at that time too. Having bronchiectasis does not simply impose a single, permanent change to one's life.

As noted above, aside from the potential for progressive change over time, bronchiectasis also presents additional intermittent changes to the level of physical symptoms. This temporary worsening of symptoms during periods of exacerbation leads to extra changes having to be made to patients' daily lives as this lady explained:

'The breathing gets a lot more difficult, I get a lot of pain, I've constantly got pain but it gets a lot worse if I'm having a flare-up, I get a lot more dependent on people...Some days I can't even be bothered to get dressed, but I push myself to get dressed cos I want some normality in my life.' (P03 228-230, 383-384)

These periods of worsening of symptoms clearly result in physical limitations that make usual everyday activities become laborious and difficult, potentially changing a person's ability to carry out their roles both in their work and personal life. Making it seem as though they no longer have a 'normal' life. For this patient, just carrying out these daily rituals in order to maintain a sense of normality took all of her efforts and required additional support.

In order to present a comprehensive picture of the descriptions of change over time, it is important to include the fact that there were periods of time for some patients that were much easier to manage. As well as deteriorations and intermittent exacerbations, participants also described improvements in their condition as a result of changes to their treatment regimes:

‘I probably haven’t been as fit as I’ve ever been now (sic), since I’ve been diagnosed, which is a bit weird, I mean I haven’t had a...one (exacerbation) for about two years...which is great for me, so it’s something that I don’t think about, to be fair.’
(P10 26-31)

This sentiment echoed the feelings of several participants. Patients talked about how they forgot about things when they were relatively well between exacerbations, when their physical symptoms were not enough to impact upon their lives to a significant degree. Without the physical symptoms to remind them of their diagnosis, little time was given over to thought or worry about it. Without the physical symptoms to impact upon their lifestyle, little effort was required to maintain their usual lifestyle. Whilst able to live their ‘normal’ life therefore, the psychological and psychosocial impact of bronchiectasis was also at a minimum. The link between the physical and psychological impacts of bronchiectasis was clear.

4.2.3 *Beyond the physical*

As noted above, the effects of bronchiectasis go beyond the physical impacts, and like the physical symptoms, the emotional impacts of having bronchiectasis can also be subject to change over time. Psychological effects are clearly linked with these physical symptoms, but are also influenced by other factors, such as passage of time and personal circumstances. Patients talked about the emotional impacts of the condition, and the conscious effort required to try to manage these impacts. This patient described the challenges of managing the emotional effects of bronchiectasis:

‘Certain times if I’m busy, I sort of half forget about it...There’s some mind over matter going on in my head at the moment...but you can’t keep busy all day long, you know, you just can’t do it, you can’t focus your mind on something else all day long.’ (P05 161-165)

Trying to deal with these psychological impacts took considerable effort. Like the physical symptoms, these effects are seemingly an ever-present issue, yet she does refer to ‘half-forgetting’ about things when busy. Having to sustain this effort to eliminate the psychological impact however seems a burdensome task, almost unachievable. In addition, this constant ‘presence’ of bronchiectasis leads to psychological and social impacts that not only affect the patients but extend to others in their life as this patient and his wife explain:

'C04: Your life is just..., well it's just, I wouldn't say it's a routine but there's just no end to it.

P08: You can't plan anything.

C04: You can't go away for two weeks and sort of like just unwind, it's just there constantly isn't it? It's something that you've just got to live with.' (C04 P08 294-297)

It seems having bronchiectasis is at times all-consuming, it can rarely be forgotten about and impacts on lives to such an extent that patients and their carers can rarely plan ahead with any certainty. Those whose lives and lifestyles are interlinked also experience the effects of bronchiectasis first hand. There is no choice offered than to 'live with' bronchiectasis for both patients and their carers.

For the patients, the emotional impact of their condition not only included low mood, but went so far as to re-define the person's sense of self or role in life. As one patient explained:

'It has made me unhappy, definitely. It's made me depressed, it's made me unhappy, and sometimes I feel as if I'm not the person I used to be.'

...

'Bronchiectasis...it takes it out of you, you know, you're not exactly the same person at all.' (P04 146-147; 605-626)

The disease has transformed this patient's sense of self. As Charmaz described, in chronic illness the unity between the body and self is disrupted and so peoples' identities are reconfigured (Charmaz, 1983; Charmaz, 1995). As this lady described, with the onset of the disease, 'you're not exactly the same person'. Linked with this change in sense of self or identity were changes in how people felt they were viewed by others. Participants described many situations in which they had encountered stigma. This included both perceived stigma from strangers and enacted stigma from interactions with friends (Goffman, 1963). Firstly, a frequent reference to the stigma attached to having an audible cough, and as such a socially visible condition, was the belief that others assumed they must be a smoker and have COPD. This is mentioned both in terms of what others would think of them and the general public's lack of understanding about bronchiectasis. This carer describes the experience of having a lung disease which is assumed to be something it isn't:

'I think there's a stigma though, when you're diagnosed, not just with bronchiectasis, they'll say you've got COPD and the first thing they say is "Have you stopped smoking now?" He's never smoked in his life.' (C04 258-260)

It was difficult for patients to manage this perception that others may assume they had a smoking related illness; that it was self-inflicted and they were therefore culpable. It has been described that conditions such as COPD that are liable to have been self-induced do not receive much understanding or sympathy (Williams, 1989; Williams and Bury, 1989). 'Chronic lung disease' has also been described as 'anti-social' and 'isolating' (Toms and Harrison, 2002). Toms and Harrison's small focus group study (n=7) included 2 patients with bronchiectasis and 5 with COPD. Within my interview data, having COPD is clearly viewed in a different 'category'. Moreover, some patients made reference to the fact that their doctors had also assumed that they were smokers. Some had possibly misinterpreted the taking of a smoking history as an accusatory line of enquiry rather than a process of diagnostic elimination. This aside, however, the fact that patients were so frustrated with their doctors for seemingly not believing them demonstrates how significant the impact of this presumption of smoking status and culpability is for patients. One participant also described how this lack of culpability and often unidentifiable cause of bronchiectasis led to further uncertainty for her:

'I mean I've never smoked so it's obviously not caused by, you know, self-inflicted, I mean...you had this sense of "What have I done?" Not "to deserve this", because life isn't fair I know that, but getting it round in my mind "What's caused it?"' (P05 592-598)

Having no certain cause for her condition seemed to lead to more emotional work. Knowing that she was not 'to blame' for her diagnosis did not alleviate her concern regarding causation, just eliminated one potential culprit.

The sometimes public nature of symptoms led friends to offer lay diagnoses such as 'you sound as if you've got TB!' (P13 145-146). Interactions with friends and family often led to patients encountering such enacted stigma. The same patient described another such encounter:

'A friend of mine, I visited her in the summer, and she said to me when I coughed – her husband was a doctor – she said "Your cough sounds like a death's cough".' (P13 114-116)

Note how, the description of 'a death's cough' is situated in a context where the speaker is marked as having some medical credibility, albeit indirectly. The association of the cough of bronchiectasis with the negative description of a 'death's cough' or 'TB' demonstrates both the social stigma associated with such a cough, and the accessibility of the symptoms to those around you. It is almost impossible not to disclose such a diagnosis: the cough will do it for you. In order to ensure you are not considered to have a self-inflicted smoking related condition, a contagious illness, or a fatal disease, it is imperative to openly discuss the fact that you have bronchiectasis, both with those you may wish to, and others that you may not. The impact that this has on people psychologically and socially is significant.

Additionally, one patient described self-stigma when relating to her experiences in childhood of elderly men coughing and spitting in the street, saying:

'To me bringing up phlegm makes me feel dirty...it's not womanly is it?' (P04 156-162)

This led to her avoiding coughing or taking inhalers in public as she was always taught that coughing up phlegm was a disgusting thing to do and it was something she associated with 'dirty old men' (P04 155). For her, she now has the embarrassment of having an audibly productive cough and therefore a socially visible illness. Having bronchiectasis had impacted upon her identity as a woman, and as someone who takes pride in their appearance and cleanliness. This embarrassment is something that has lessened with time since diagnosis, however, as she has begun to learn to live her life with bronchiectasis. This process of acceptance, or adaptation (Charmaz, 1995) has lessened the impact of bronchiectasis on her life, in particular in relation to social situations that used to lead to much embarrassment for her:

'It's like part of my life now, part of my day. Go out with an inhaler, plenty hankies and your medication in your little bag and that's it.' (P04 378-379)

This quote illustrates her adaptation in terms of learning to manage bronchiectasis and also how this adaptation along with passage of time has led to the normalisation of living with the condition. Being able to confidently manage her condition and cope with the changes it dictates has been fundamental to her learning to live with bronchiectasis. The potential for the various impacts of bronchiectasis to fluctuate

over time throughout the patient journey is inevitable. It was evident however that all of the participants had developed, or were beginning to develop, their own ways of dealing with their diagnosis and its implications.

4.3 Developing support and coping mechanisms

Patients and carers explained how they had developed their own support and coping mechanisms over time. It was through the use of these mechanisms that patients and their families managed 'having the condition'. Central to this managing process are mechanisms of practical and emotional support, varying modes of reassurance, and the understanding of 'normality' for people with bronchiectasis. By developing good support or coping mechanisms, patients and their carers were able to lessen the impact or disruption that bronchiectasis presents.

One of the key ways in which participants are supported is by other people around them. The main characters in these storylines were usually families, friends and the medical team. One patient, for example, found that her family's support and reassurance have helped her significantly:

'My husband is good, my daughter's good, my grandson, they are all pretty good with "come on, howay," you know "don't worry about anything, we are here for you. If you need anything, we'll help you".' (P04 206-210)

This practical and emotional support from her extended family had lessened the impact of bronchiectasis on her life, helping her to manage life with bronchiectasis and to develop an acceptance of her new condition. This support of family was a mechanism often used, and is in keeping with Bury's descriptions of 'mobilisation of resources' (Bury, 1982). Resources often used alongside the support of family were the patients' medical teams and other patients who had experienced similar issues.

Bronchiectasis is a relatively rare condition when compared to asthma and COPD, for example. Often people had never heard of it before their diagnosis and hadn't met anyone else with the disease. As noted above, making sense of what was 'normal' for bronchiectasis was central to being able to develop coping mechanisms. Being able to relate to others in a similar situation was therefore reassuring and facilitated an exploration of 'normal' experiences of bronchiectasis. This patient echoes the feelings of many participants when she describes how important it is to be able to understand one's 'new normal' with bronchiectasis:

‘That’s a big part when you are chronically ill, having something to reassure you that that’s normal for your condition, or you need to get looked at. ... It’s easy, say with my problems, for it to creep up on you, because it’s every day, you’re just sort of accepting that debilitation, and you don’t realise how small your world’s got until it’s more or less disappeared.’ (P12 370-376)

This patient felt as though she had no idea what she should expect to happen, and as such had no sense of what should trigger her asking for help and what she should just accept as ‘normal for bronchiectasis’. By learning about themselves from other people’s experiences, participants were able to get a sense of what they should expect: which symptoms are normal for bronchiectasis, and which are not. Another patient echoed these thoughts about relating to others’ similar experiences:

‘It is some normality to what you are feeling, cos even though it’s an illness and it’s a symptom ... it’s normal for what you’ve got.’ (P03 394-396)

The understanding of what is ‘normal’ for bronchiectasis, as this patient described, was key to several aspects of ‘coping’. Not only does it allow patients to learn when to worry about their symptoms and when to just ‘manage’, i.e. if their experiences are ‘normal’, it also allows them to feel ‘normal’ in themselves. Knowing that others are experiencing the same symptoms and feelings assigns normality and validity to their own experiences.

Additionally, being able to relate to others who had similar experiences generated a sense of solidarity when coming across stories of others who have the same condition, as this patient described:

‘Because then you can recognise yourself. ... So then you know you are not alone, some people have got the same problems.’ (P09 274-275)

Being able to identify with others who have bronchiectasis was important to most of those interviewed. As we have established, such information about bronchiectasis is currently scarce, yet the importance of having such resources as a support mechanism was clear. Specifically, in terms of the use of information from others as a support mechanism, we have already shown the importance of prognosis to patients. It was often prognosis that people had sought reassurance about from others with bronchiectasis. This lady described her use of an internet forum for this purpose:

'I had to think to myself "Right, it's not going to get to that stage, I'm going to do the best that I can with it" you know, "if these people can live with it, I can live with it" you know, and there was loads and loads of suggestions and things what other people did and how they have coped, you know, and that really helped me to come to terms with it.' (P04 260-64)

This patient demonstrated the need for reassurance as a mechanism of support, and the importance of the experiential expertise of those offering that reassurance. For such a support mechanism to be effective, the user needs to know they can relate to the provider, that their experiences, and thus their methods of coping, could mirror their own. This clear use of information seeking as a form of reassurance, further confirms that a sound information resource could act as a support mechanism for patients and carers.

Finally, in addition to normalising bronchiectasis, patients also wanted to maintain some sense of what they previously knew as 'normal' in their lives. Patients and carers described the efforts they made to combat the physical and emotional impacts of the disease in order to try to feel 'normal'. As described earlier, this lady described how she tried to keep a sense of normal routines in her life:

'Some days I can't be bothered to get dressed but I push myself to get dressed cos I want some normality in my life.' (P03 383-385)

Even though she barely had the energy to complete a simple task of daily living, she attached much significance to doing so. By making such an effort to get dressed she could feel as if she was 'normal'. Despite the obvious impacts of bronchiectasis, people want to try to live as 'normal' a lifestyle as possible, whilst still acknowledging and understanding the 'new normal' of living with bronchiectasis. Establishing their own support and coping strategies empowered patients to move towards regaining control over the aspects of their lives that bronchiectasis impacts upon and start to play an active role in managing their condition.

4.4 Taking back control and developing active partnerships

Patients and their carers wanted to become a member of the team that has responsibility for their future - to be able to play an active role in the management of their condition. Being able to take back some control over the condition in this way, rather than bronchiectasis controlling their lives, was of great importance. Arriving at

this point of the patient journey took a variable amount of time, and acceptance of the diagnosis seemed to be an integral part of the process.

One patient with longstanding disease explained that it had taken her a long time to accept her diagnosis. This initial lack of acceptance seemed to have impacted upon her ability to take control of her condition. She talked about this almost conscious decision not to accept things as 'stubbornness':

'It was probably a few years after the diagnosis that I sort of woke up and smelt the coffee type thing.

IV: So it took a few years to kind of learn how to manage things?

Yes, purely because I was stubborn, I think that's got a lot to do with it with me.' (P03 256-263)

Patients felt that once they were more accepting of their diagnosis, they were able to play a more active role in its management. This process of acceptance and adaptation helped patients to learn to live with and manage their condition, which in turn allowed them to maintain an element of control over their situation.

Acceptance also seemed to influence participants' development of a sense of responsibility for their own health. This was referred to by most as if it was a conscious decision or even an obligation; often in the later stages of their journey since symptom onset. Wanting to have such responsibility, or be part of an active partnership with the medical team, included wanting to do additional things beyond medical treatments to try to improve their condition and thereby lessen the impact of bronchiectasis on their lives. Learning about what they could possibly do to help themselves was of real importance to participants. The examples of diet or lifestyle were often given as factors participants would hope to be able to change in order to live with their condition in the optimal way. This patient was one of many who described why this was so important:

'How to help it ... so you can sort of say "Right well I will do my bit".' (P02 75-94)

Feeling as though they were playing an active role in keeping themselves well was a way of both being an active member of the team and exerting some control over their lives. They already knew that bronchiectasis is an incurable condition, so they began to focus more on making the most of their situation. It seemed diet and exercise were

things patients and carers felt they could realistically influence, and by doing so they could again take some responsibility for their health. Perhaps focussing on diet and exercise allows control over something that is actually controllable, unlike their diagnosis. One patient specifically stated that there should be advice given to new patients about taking control yourself:

‘There should be one part where it is saying that it cannot be cured, so you’ve got to help yourself, making you aware of pulling yourself together ... like it’s not the end of the world.’ (P04 586-599)

This lady thought having that advice early on would help people to acknowledge the active role that they need to play in taking control of their condition and learning to accept their diagnosis. This patient’s description highlights both the practical and psychological elements of this process, with reference to the requirement for you to ‘help yourself’ and ‘pull yourself together’. Although both require active participation, they describe very different aspects of self-help.

Questions about how to self-help also extended to carers, who wanted to know what role they could play within the team. Clearly being able to have this active input is important to both patients and carers alike. One carer explained why she wanted to know about what she could do:

‘I do know that it’s a progressive complaint and that it won’t get any better, but on the side of like, caring, it’s hard to see him struggling and if there was anything that we could do to, to help...’ (C01 134-136)

As per the feelings of patients themselves, this carer acknowledged the incurable nature of the condition, yet still wanted to know more about how she could help, what other avenues she could pursue to cushion the impacts of bronchiectasis on their lives. Another carer echoed this lady’s sentiment of knowing there is maybe little they can do to influence the disease process, but wanting to know what (if anything) it was possible to have an influence on:

‘I think the main crux of it is you want to make sure there’s nothing you do that is making it any worse, and you want to know if there is anything that can make it better, that you have that information, and you can do it.’ (C09, 571-574)

Again, this fits with both patients and carers wanting to exert any potential control they could have over the disease course; to be aware of and make any feasible changes that they can.

To reiterate the sense of responsibility amongst patients and carers, in some cases the query about what 'could' be done, despite the fact that bronchiectasis is an incurable condition, was also described as what 'had' to be done. These descriptions were almost of an obligation or duty, rather than just a personal sense of wanting to take responsibility. One patient described her duty to:

'Just try and keep well really.' (P03 25-27)

This was a specific effort that she, amongst other patients, felt she needed to make to ensure that she remained as healthy as possible, rather than just describing 'wellness' as something beyond her control. This sense of duty to be well and need for control again extended to carers. In addition to having to keep up with the daily treatment regime and monitoring for signs of infection there were other responsibilities, such as:

'We have to keep you fit' (C04 533)

This carer felt duty bound to keep her husband 'fit'. This was again meant as exercise and diet related fitness rather than 'wellness' or health. An aspect of care that it was possible for her to try to influence.

An area of perhaps more clarity or certainty than this concept of self-help, was self-management of bronchiectasis. Many patients had started to self-manage, having developed skills of symptom recognition through experience rather than precise medical instructions. Although the medical team will give advice about how to recognise changes, the predictors of impending exacerbation are personal and individual, so beginning to recognise one's own warning signs is a crucial step in beginning to self-manage. Patients talked of how they had learned over time to recognise symptom changes and their early indicators of exacerbations. One lady described this process as:

'Trial and error I think!' (P03 214)

Although she had learnt about action to take from the medical team, understanding triggers for taking action had to be gained through experience. Most patients had learned when to take action in terms of treatment adjustments over time. Rather than simply being a 'passive' patient, awaiting direction from the medical team, this reinforced their role within an active partnership. One participant described in a slightly different way how she had learnt this art of self-management - 'studying herself':

'I studied myself as well. Every time it was hot weather I got a really bad lung infection...I had to learn myself because I can't every minute go to see the doctor ... so I have to study how to balance my life.' (P09 21-37)

By monitoring her own bodily responses to environmental triggers she had learnt how to adapt to manage her condition better. Again this demonstrates patients' sense of wanting to play an active role in their own management, the sense of some degree of responsibility for their own health and the desire (or indeed practical requirement) for a degree of independence.

A potential factor influencing this need for independence is ease of access to trusted healthcare services. To be an active partner within the healthcare team, one has to have some sort of relationship with the rest of the team. Although most described a positive relationship with their secondary care team and easily accessible advice or appointments, the degree of interaction with their primary care service was not always the same. Several interviewees described a lack of faith in their GP, and a sense that bronchiectasis was not something that their GP knew a great deal about. It seemed that GPs maybe have a diminishing role with time since diagnosis. This could be due to a stronger relationship being formed with the secondary care team, and perhaps the changing nature of patients' needs over time.

The feeling of not being listened to when explaining their symptoms prior to diagnosis was described by several patients. This again may contribute to a less positive relationship with their GP once a diagnosis has been made, with people preferring to deal only with the doctor or hospital that succeeded in diagnosing their condition having listened to their stories. The trust now embedded within that relationship is key to their working within this active partnership, and directly influences their views on credibility of information given. Being their trusted healthcare professional automatically lends credence to any information you impart. Having this connection

with credible information is the final and fundamental part of the process of learning to live with and manage bronchiectasis that I will describe.

4.5 Connecting with information

The crux of the interview schedule was to explore and understand the unmet information needs of patients and their carers. As such, discussion within the interviews covered information needs and how these were, or might be, addressed. This theme describes patients' and carers' experiences of information and the different ways in which they 'connect' with information. Connecting with information describes triggers, approaches and barriers to information seeking, in addition to preferred contents and format. Centrally, it is how people connect with information that will govern whether it is of any use, or has any influence upon them.

4.5.1 Triggers and reasons for seeking information

It was clear that patients and carers needed to have a trigger or reason to be seeking information, to have an unanswered question for example, or an ongoing concern. In this sense, timing was everything, with the need to access information being directly related to the individual's current circumstance. One key time-point that was discussed by patients and carers was the time of diagnosis. The more longstanding patients often commented that they would have liked to have had more information at their time of diagnosis. As we have established above, an issue often at the forefront of people's minds when receiving such a diagnosis, and indeed throughout their experience of living with bronchiectasis, is that of prognosis. One patient described how this was really the only thing that she had a pressing need to find out more about:

'I didn't really look up a lot, only enough to satisfy my mind that I'm not going to die, I can live with it, get on with it.' (P04 288-289)

Once she had established her likely prognosis her main concerns were answered and she therefore didn't feel she was lacking information. The trigger to seek information - an unanswered question - was no longer there. Prognosis specifically, however, was a topic of interest to patients at all stages of the journey since diagnosis. Although initially broad concerns about prognosis may be addressed, as things change over time more reassurance may be needed. Participants often reported development of a new symptom as a likely reason to seek information about

their condition again. At its outset, a new symptom will not necessarily have a clear cause and thus is not always immediately aligned to a specific condition. A patient may either have a number of diagnoses, or just simply not know if a particular symptom should be attributed to bronchiectasis or not. Seeking information about this new symptom enabled patients and carers not only to understand the symptom, but also to attempt to attribute it to one particular condition. Is this a symptom that is normal for bronchiectasis, or is this a new problem? Making sense of symptoms through this use of information seeking enabled patients and their carers to assess the 'normality' of their symptom dependent on its likely cause. As has been established, this understanding of normality is essential to the process of learning to live with bronchiectasis. When a patient's experience of their known illness breached expectations in terms of symptoms, new treatments or change in personal circumstance, this generation of new, or revised, information needs prompted further seeking.

A further time point that was felt to be important was during an exacerbation. Again, this was a change in the norm triggering new enquiries. Some mentioned they felt it would be useful to be able to access information if in hospital with an exacerbation, or upon discharge:

'If something comes through saying "You've had 10 days in hospital, however, you're still not well and you should really be doing this, or not doing this just yet" and I think then, it might sink home to them ... "change your diet" or "try a little exercise", you know, remind them about their breathing exercises. Because I think once they're out of hospital, it's like they forget everything, they think "That didn't happen, I'm back home now", I think maybe a little prompt.' (C04 568-581)

This was felt to be both a time when questions are likely be raised and also a time when people may be receptive to new information. Having an admission to hospital is likely to be a situation that could generate new information needs and be a trigger to seek answers. It may also be a time during which having the right information could make a difference in terms of taking actions and responsibility for one's own health.

4.5.2 Barriers and reasons not to seek information

Acceptance of the diagnosis of bronchiectasis seemed to have the potential to play opposing roles in information seeking. As discussed within the review of the literature in Chapter 2, information is not always actively sought, and at times, is actively

avoided (Maslow, 1963; Case *et al.*, 2005). As I have also established within this cohort, some patients found that they didn't want to look up anything about bronchiectasis at first, until they had developed an acceptance of their condition. In this scenario, a lack of acceptance could be considered to be a barrier to information seeking. For others, however, information seeking played a significant role in coming to terms with having bronchiectasis, and it is known that information seeking can be a key coping strategy (Lambert and Loiselle, 2007). Either way, it is apparent that the seeking of information plays a significant part in the development of these coping mechanisms, so any barriers or reasons to not seek information will directly impact upon this process.

Barriers to information seeking can be quite simple and obvious. One very practical barrier brought to light was poor eyesight. Some found smaller text very difficult to read, which needs to be taken into consideration with the development of any information resource. Poor hearing was raised as another sensory barrier to receiving information. Participants described how listening to information was often more useful than reading something as you could make decisions about whether something was of importance or not based upon tone of voice and time spent discussing different matters. Seeing someone speaking was very important. Having information in unsuitable formats would clearly impose additional barriers, and optimising accessibility is vital.

Some interviewees considered their lack of use of a computer or the internet as a barrier to information seeking. Some liked the idea of a web-based resource and reacted very positively to the example websites shown to them in the interviews, yet didn't feel that this was a format of information that they would realistically be able to access. Age was indirectly implicated as a barrier to information access with interviewees often being of the opinion that a website would not be used by more elderly patients. People described this both with respect to themselves, and also in general terms, as if speaking for 'imagined others'; older patients that would not use the internet. This conclusion, however, is not in keeping with previous work I carried out in a bronchiectasis clinic which established that over 90% of a sample surveyed had internet access, with ages ranging up to 90 years (unpublished data). Additionally, within the data described here, age of participant was not seemingly linked with internet access. Interestingly, one of the interviewees who had actually gleaned most of her information from the internet felt that this would not be the best

format for her, as she didn't feel she was a confident user. Whatever one's preferred style or format of resource, not having access to a suitable resource that you feel confident using is clearly a potential barrier to obtaining information.

Suitability of resources is key to their uptake. As reported by Harland and Bath, (2008) having user-centred rather than system-centred resources allows for individuals' needs to be taken into account. Leydon also described how information needs differ amongst patients with cancer and explored their reasons for not seeking information (Leydon *et al.*, 2000). Not being able to find information set at the right level, or finding contradictory resources was an issue for my participants. Some felt that searching online for information could be confusing, with conflicting advice found. Patients described how there were some very basic information resources available and then some very clinical resources, but that there was very little middle ground. This highlighted a need to ensure that the developed resource was accurate, yet also accessible to patients with differing levels of health literacy and information requirements.

Information requirements are bound to differ between individuals, and also to vary for an individual at different time points. Having a resource that is presented in such a way that users can look at specific information they do want, and not at things they would rather not know about, is important. Whilst some people want to learn as much as they can about their condition, fear of what one may read or a feeling of 'ignorance is bliss' was also described by both patients and carers:

'If he read about it he would dwell on the bad bit, you know what I mean, whereas I would get my frame of mind in, if it gets to the bad bit I'd be able to cope cos I know what's coming. But he's the opposite way round, he doesn't want to know the bad bit.'
(C03 628-631)

This carer demonstrates how this is a very personal stance, with some wanting to know what the future held, and others preferring to just deal with things as they come along. The differing opinions here will always remain. Having the information available is clearly necessary, yet it is also necessary to avoid the creation of additional barriers for those only seeking specific information within their boundaries of comfort. To be able to choose or filter which sections of information one looks at is clearly important.

Another aspect to consider when assessing 'suitability' of a resource is that in order for a user to connect with information, they need to consider it credible. Apparent untrustworthiness of a resource, therefore, is an obvious barrier to its use. A variety of issues with the use of internet resources have been discussed by Henwood (2003), with trustworthiness being one of them. Zulman presented trust as an issue for older users of the internet when accessing health information resources (Zulman *et al.*, 2011). For my interviewees, trust emerged as an issue for many people when accessing information, regardless of their age. In the main, this related to online information seeking. Having a credible information resource was of great importance to people; yet finding such a thing through your own self-directed seeking was problematic:

'I'll be honest it's mostly the NHS sites I go onto, because I think "well at least I know they are genuine sites" type of thing, where some of them you go on and you think "well, no I don't think that's right".' (P03 140-142)

As this patient described, participants were often unsure of how to judge credibility of the available information and wanted to be advised about which websites to use or avoid. Being directed to a trustworthy resource by one's medical team for example, or the website having recognised markers of credibility, would make people more comfortable using the information within it. As we have learnt, developing a partnership with trusted professionals is of great importance. If an information source is created, endorsed, or recommended by your trusted professional, it automatically becomes one to trust.

4.5.3 Approaches and sources

Participants varied in their approaches to information seeking. One thing that stood out, however, was the need for convenience, or ease of access. Several of the interviewees described how they would not go 'out of their way' to seek information. Many had only seen the BLF leaflet which was often handed to patients in person when attending clinic, requiring no self-directed seeking. Patients and carers valued convenience and information resources that fit in with their lifestyle. This may be due to a lack of inclination to put in any effort to seek information or may simply be people being realistic about what they would get round to doing. Again, triggers to seek information play a role here, as without such triggers or questions, why would effort be made to search for answers?

The convenience or effort factor also influenced the sources used. Again, this naturally differed for different people, depending on their specific circumstances. Within this cohort, the vast majority felt that an online approach to information seeking was the most straightforward. There were participants, however, who described alternative approaches and sources that were more convenient for them. One patient, who was a retired nurse, described looking in the medical textbooks that she still had at home and when she started coming into the ward regularly she looked at the information leaflets available there. These were convenient ways to access information that was already there for the taking. She did however, as with many participants, have a hierarchy and method in her information seeking. Any queries not answered by these sources she would save and either look up online when she was using the internet for other reasons, or write down and ask when attending her appointments. This process of upgrading the approach or source of information was commonly deployed, with participants' own doctor usually at the top of the chain.

Another participant described opportunistic information seeking. He stated that he would ask his doctor, but only if he was there anyway, or if he saw someone in the street using an inhaler he might ask them about how they find it and see if they have anything in common. He only described picking up information by chance and stated that he had never really actively sought any information beyond these personal interactions:

'I haven't thought about it at all, like looking into it.' (P02 141-153)

He did not consider that he had made an active decision to seek information in this way, but had chanced upon various bits of information opportunistically. In keeping with this, he also thought that television was a good source of information, as he tended to spend most of his day watching it. Again this confirms that for a resource to have maximum uptake, it needs to be accessible in a variety of ways, to try to accommodate the 'easiest' route for the majority without excluding the minority. For different people, this pathway of least resistance will vary.

Importantly, patients mentioned that their families had a role in information seeking. In some cases, it was only really family members who sought additional information, with the patient themselves not doing so. Having the input of both patients and their families is clearly critical in developing a resource that meets the needs of those who

will be accessing it, whether they be patients, carers, family or friends. Convenience and suitability is key.

4.5.4 Content, style and format

To enhance discussion around preferences of content, format and style of information, interviewees were shown examples of information resources about other medical conditions. They were shown websites, leaflets and a patient information DVD. This was to prompt views on presentation and layout of information, rather than the content itself. In terms of format, participants often expressed an interest in the DVD, commenting that information delivered audio-visually was better than written information alone. Watching or listening to information seemed to be universally preferred to reading text, or at least seen as an enhancement, as these participants described:

‘It’s people talking; it seems to sink in a bit better ... it makes you listen ... more than just reading it in a booklet.’ (P01/C01 670-685)

Their description suggests that reception and even retention of information could be improved by such a mode of delivery. Several suggested however that a DVD is not something that they would really refer back to as they would a booklet, yet obviously one could re-watch a DVD as many times as desired. Perhaps the effort or time thought to be involved in ‘watching a DVD’ is greater than simply getting out the booklet for a quick look at the section that you have a current query about. So, although the DVD as a mode of delivery was highly praised, most added that a booklet would be useful to have in addition. The participants’ preference for the DVD was really the format and presentation, rather than the device itself. In fact, many acknowledged that the DVD was fast becoming outdated and little used. It was the use of ‘video’ within the DVD to deliver information that was liked. Clearly this is something which can easily be incorporated into a website for example, and is not exclusive to the use of a DVD.

The video content that was praised specifically was that of other patients telling their stories. Talking was an important feature, particularly when considering the experiences of other patients, with this type of information seeming to be much more accessible when delivered as a video:

‘I don’t know much so if I see a video like that, of people talking and learn about myself through that video, so I know which one is similar to my symptoms...when you see that, when they talk like that, then you know.’ (P09 326-31)

This lady reflects the views of many of the participants, who valued being able to relate to other people’s experiences in the process of learning to live with bronchiectasis. Drawing on how other patients came to terms with their condition may aid this process in others, and having this in a format based upon a personal interaction, i.e. a video, may optimise its usefulness. In essence, presenting information in a way which people can really relate to is a priority, as this patient described:

‘that’s a good example, I think, of where you are just looking at the facts, any clinical facts about it, versus “what does it actually mean to a person who’s had it?” and that can be quite different.’ (P14 240-242)

This patient concurred with the many participants who explained that having pathophysiological descriptions of the disease process as per a clinical textbook was of limited use. What they would like to see is information that is of use to them, that they can identify with. In particular, the youngest patient made reference to wanting to hear people his own age talking about their experiences so that he could relate to them, rather than more elderly people. A few expressed a fear of seeing people worse off than them, and explained that they would want to be reassured, not worried, when hearing other peoples’ stories. Providing accurate yet positive content was important to the majority of participants.

Volume of information emerged as an issue when patients compared two different written information sources. One was a thicker booklet which they often referred to as ‘the book’ and the other a leaflet, which was a single page of A4 paper folded over. When comparing the two, there were lots of differences including use of images and smaller sections with headings in the larger booklet, for example, but the unanimously stated fact was that ‘the book’ had more information. One patient compared the shorter leaflet to one she had previously read about bronchiectasis, stating that it had left her with unanswered questions. More information seemed to be better and the concise leaflet was thought to be inadequate. Despite the general preference for a greater volume of information, a few participants wondered if too much information could lead to unnecessary worrying. They thought that looking at

very detailed information could lead to people looking at things that were not relevant to them, and that a less detailed initial leaflet may be a better starting point. Several of this group wondered if a shorter information guide with access to a more detailed version, if and when desired, may be preferable. Allowing for such selectivity seemed to be an important feature within a resource.

Clarity of both content and presentation was a major issue and was demonstrated in ways other than direct opinions of the example resources. Misunderstanding of 'jargon', for example, was often raised in interviews and frequently related to copy letters from clinic. Several participants talked about the content of their letters and how they couldn't understand the terminology used. In some cases, having this additional source of information, yet misinterpreting it, led to more anxiety rather than being a source of reassurance. A lack of jargon and clarity of explanations were key to information being usable. Even the pronunciation of the word bronchiectasis was raised as an issue, with patients often being embarrassed about their uncertainties surrounding this. Having the phonetic spelling clearly presented within the resource seemed to be a simple step to eliminate this problem.

Clarity was important for the presentation of information. Layouts with headings and diagrams seemed to be preferred for ease of reading, and the presence of extra links or advertisements on web pages were often a deterrent as this carer described:

'Not too many bits and bobs on the side' (C04, line 946)

She was not alone in considering that online information resources with lots of distracting features at the edges of the page were unhelpful. This seemed to stem both from a sense of them detracting from the main content, but also generated an element of distrust in the site. If they were advertising products for example, what were their motives? Was this information trustworthy, or was its provision simply a money-making exercise? Nettleton discusses how users account their trusting of online resources using a 'rhetoric of reliability' (Nettleton *et al.*, 2005). This similarly includes the assessment of whether a resource seems to be 'commercial'. In an American survey of trust and sources of health information, physicians emerged as the most trusted source, yet the internet was the most frequently first accessed source (Hesse *et al.*, 2005). As credibility of information is so important, recognising any markers of unreliability is crucial to optimise usage.

For the resource to be effective the data described by 'connecting with information' needed to be central to design, content and development: incorporating features that would optimise users' connection with the resource and thereby its benefit.

Participants felt that being able to access more information, about what they want to know, would further enable them to take an active role in their own management. Participants wanted more information, and they wanted this to be information that would be of use to them. They needed information that could help to lessen the impact of bronchiectasis on their lives, allowing them to regain the all-important normality and control.

4.6 Deviant case analysis

During analysis of the data, as well as looking for common themes, I explored any potential deviant cases in order to improve validity and rigour and to explore these areas in more depth in future interviews. There are in fact only two points to raise.

The first is a deviation from the commonly expressed desire to hear of other peoples' experiences. There was only one participant who felt this would not be a useful exercise. He had been diagnosed with bronchiectasis 2 years ago, had an additional diagnosis of lung cancer, and had never attended the specialist bronchiectasis clinic. He lived with his sister who was his main carer, and interestingly shared his disinterest in hearing about other peoples' experiences. Neither had actively sought any information about bronchiectasis, despite having unanswered queries. Both wanted information about what they could do to help themselves or things that may be of benefit to them, very much in keeping with other participants. When asked about hearing of other people's experiences of bronchiectasis they were not keen:

P01: In hospital all the patients around you are all similarly affected.

C01: Really poorly, some of them yeah.

P01: And I dunno err I can't say I would want to know all of their stories.

IV: Right, so how does that make you feel when you are in hospital with all the other patients?

C01: Depressed!

C01: He does get one or two bits of information, you know.

P01: Oh yeah

C01: Because I mean they do talk about their complaints, I mean because people do sort of say, 'oh he is here for that' and 'for this' and he does pick up bits of information about his own complaints.

P01: But it's not something I would want to talk about.' (P01 C01 404-435)

They described both a reluctance to hear of others' experiences and a reluctance to interact with others by talking about these shared experiences. It is possible his additional diagnosis of lung cancer may have influenced his perception of whether he would benefit from listening to others' stories. This patient did have severe bronchiectasis and additional complications. Given that his symptoms were possibly more severe than most others, his ability to relate to their experiences may have been diminished if he could not draw comparisons between their symptom level and his own. Making these comparisons could also have reinforced the severity of his own condition. This patient did unfortunately die a few months after the interview took place. There were participants with similarly severe bronchiectasis, however, who did want to hear about other peoples' experiences and still felt they had something to gain by doing so. It is likely that there is an element of the patients' character or nature influencing whether this would be a useful resource for them. The final line of the quoted interaction above: 'it's not something I would want to talk about' is notable. It suggests that the reluctance to interact with such a style of information resource may be his own natural reticence to take part in a conversation that may involve talking about himself as well. It is possible that his own objections to sharing such information would influence his lack of desire to listen to someone else discussing their experiences. He went on to additionally suggest that patients' views were inferior to that of a doctor:

'Well if you are gathering information you want to listen to the experts not the patients because patients can be, well funny, can't they at times' (P01 803-804)

This stance again was in opposition to the other participants, who felt that hearing what others have been through was a valuable way to learn more about their condition and provided reassurance. This patient, however, seemed to think that this would not provide any credible information, yet burden him with other peoples' problems rather than help him to put his symptoms into perspective. Although I pursued this in subsequent interviews, his remained an atypical view. It is also at odds with the literature describing this method of drawing on others experiences (Williams, 1984; Bury, 1991). When showing examples of patients discussing their

symptoms and disease journeys to those that had not yet heard other's experiences, they stated that a patient's perspective would be extremely beneficial to them in learning to live with their condition.

The second deviance was regarding the optimal volume of information to receive. Volume was important, and the example information 'booklet' shown to participants within the interviews was preferred to the single page 'leaflet'. One patient, however, stood out as having quite specific views on information format. This was based mainly on his personal experiences of providing information to executives. He seemed quite focussed on reducing information to an absolute minimum and keeping everything extremely simple. He also liked the idea of audio-visual information in keeping with other participants. Not quite in keeping with his views, however, he did like the example from the NHS website that has extensive text only content. The reason given for this was that it had plenty of 'white space' on the page. He felt that this meant it was clear, even though it didn't seem to fit with his 'keep it simple' motto and had no audio or visual enhancements. His opinions regarding the more extensive booklet were based on his own principles of delivery of key points to aid retention, rather than a disagreement with the actual content. As such, the basis of his objection was in fact in keeping with others' views, yet could be viewed as a deviance from the group's preferences. The exploration of this matter of presentation and volume of information (and reasons behind opinions) in subsequent interviews proved to be very useful in terms of teasing out exactly what features of different examples people were drawn to.

Both these described cases of deviance from the collective view have ensured rigor and thoroughness in my lines of enquiry within interviews. This has informed the development of the resource in terms of content and features, and also in understanding what it is that makes people 'connect' with information.

4.7 Reflections on my role as interviewer

It is possible, as discussed in Chapter 3, that my profession did influence what accounts participants were willing to give to a 'doctor' rather than a 'researcher'. For the vast majority of the participants however I was not 'their' doctor and they did not withhold accounts of medical care they had been dissatisfied with for example. It is possible that participants felt more obliged to present to a 'doctor' as being someone who was seeking information about their condition and trying to help themselves.

There were interviewees, however, who did describe their lack of seeking. In reality, this willingness to be seen as a 'good patient' could be the case with any 'researcher' who is interviewing them. There may have been answers that were modified due to the fact that I was a doctor but arguably there may also have been answers that were only given because I was a doctor. Talking with a doctor, who has clinical knowledge about the condition you have, removed the need for certain explanations and created an instant understanding. To have this shared knowledge and understanding, albeit it from a different perspective, I believe played a role in enabling me to establish a good rapport with all the interviewees.

There are many aspects of the interview data that I believe I have been able to engage with more productively due to my 'insider knowledge' both of the disease and the medical system. There have been comments made by participants that a non-medical interviewer may not have picked up on, or not pursued, that could be critical to the understanding of the data. By having this added insight I have been able to explore and extend lines of questioning or conversation further than someone who does not have such an understanding. I have also been able to interrogate the data in more ways, picking up on certain areas of knowledge for example that were obvious to me as a doctor to be lacking in accuracy.

Additionally, the majority of participants have asked medical questions which I have discussed further post-interview. Some misunderstandings for example had actually arisen from typographical errors in clinic letters and had led to much worry. In these instances getting a copy of the letter had done more harm than good in terms of understanding and reassurance. This led to my spending significant amounts of time going through and explaining the contents of these letters, which were often shown to me during the interviews. At the end of the majority of interviews I spent a significant length of time talking to the patients and carers and addressing any misunderstandings or concerns they had. This both made me feel I had done something useful for the participants in return for their time and participation, and it also seemed that patients and carers felt they had actually gained something more by taking part. They had been involved in the research, yet also had access to a bronchiectasis doctor during a less time pressured period than a routine clinic appointment.

I think overall that it was important for me to acknowledge and reflect upon my role and its potential influence on the data in order to have complete transparency of methodology. Although it implicitly will have affected the process, the impact upon the data, the analysis and the participants has many positives.

4.8 Summary of interview findings

In this chapter I have described the main themes emerging from the analysis of interviews with seventeen patients and nine of their carers. The core theme, 'living your life with bronchiectasis', is central to the understanding of the three further interlinking themes. A key finding within this core theme was that living with bronchiectasis means living with uncertainty. Having this diagnosis is not a single time-point disruption of one's biography, but generates the potential for an ever-changing one. Although variations of biographical disruption have been extensively described (Dingwall, 1976; Bury, 1982; Corbin and Strauss, 1985; Corbin and Strauss, 1987; Sanders *et al.*, 2002; Williams *et al.*, 2009), the concept that to have a diagnosis of bronchiectasis is to embark upon an uncertain future direction represents a novel finding. Being able to manage living with bronchiectasis does not simply involve learning what medical treatments are required and making once only adjustments to one's life, but learning to live with the changing 'new normal' presenting itself throughout the patient journey. This ability to cope with having a condition with an uncertain prognosis is a complex process as I have explored, and involved deployment of numerous coping and support mechanisms. I will discuss the concept of biographical disruption and associated literature with respect to a diagnosis of bronchiectasis in more depth in the final discussion chapter of the thesis.

Part of learning to live with bronchiectasis was the desire to regain control over the condition. Incorporated within this process was a sense of duty to self-help. This has links with both Parsons work in relation to the sick role, and the concept of the duty of a patient, or the duty to be well (Greco, 1993). What my data has shown, is that this duty extends to carers, with family members also describing a sense of responsibility for 'their' patient's health and wellbeing. Both patients and carers wanted to take any helpful action they could and become part of the team working towards optimising their health and prognosis. It is important to note that the vast majority were keen to play an active role in their own care, wanting to find out what they could do to help their situation. It is possible that this represents a more motivated group, as having

volunteered for research about patient information, they may naturally be people who are interested in information. Although some were more motivated or proactive than others, there were none within this cohort that were against taking an active role.

Patients and carers want more information about bronchiectasis, and this information needs to have a format, content and style that users will connect with. Some information needs were fairly explicit, yet some have been gently teased from the data within more general discussions about experiences of living with bronchiectasis. Information seeking has been shown to provide reassurance; to be a fundamental support mechanism for patients and carers. Incorporating the multiplicity of factors required for a 'useful' and credible resource identified within this data provided an opportunity to produce a universally accessible and functional resource. This unique insight into the experiences and needs of those who are actually living with bronchiectasis was key to the co-development of the novel user-driven information resource that is described in the following chapter.

Chapter 5 Results 2: Co-development of a novel patient information resource

Drawing on the findings of the interviews described in the previous chapter the co-development process of a novel user-driven information resource began. Building on the understanding achieved through the exploration of patients' and carers' needs and preferences, a resource designed to inform, engage and reassure was produced. This information resource was then used as an intervention within the subsequent study, Bronchiectasis Information and Education: Feasibility study and evaluation of a novel resource (The BRIEF Study, Chapter 6). In this chapter I describe how the interview findings informed the resource design, the co-development process and the resultant information resource.

5.1 Exploring available resources: searches and interviews

During preparation for the interviews with patients and carers, I carried out background research into the bronchiectasis patient information resources that were readily available in the public domain. A tabulated summary (Table 4) shows some of the resources easily found by searching online in the UK for 'bronchiectasis information' and 'patient information bronchiectasis'. When searching I used the search engines Google and Bing and the search terms stated were searched for separately. Searching for 'bronchiectasis information' using Google revealed 1,330,000 results and 'patient information bronchiectasis' revealed 938,000 results. Searching using Bing revealed 600,000 and 500,000 respectively. This includes all languages and all types of resources. The tabulated summary simply provides an overview of a selection of those resources available in English that were within the first few pages of search results. This was not therefore a systematic review, but was intended to reflect what patients may be able to readily access. There are additional resources (in English) that I was aware of, yet did not readily appear on UK searching without more specific search terms. Some of these have been reviewed by a patient team for the European Lung Foundation (ELF) (Table 5).

Notably, since this search was first carried out at the time of the interviews and resource development process, a few years have passed and the figures I have provided here are for the more recent search in February 2017. As time has gone on more resources about bronchiectasis have become available. To my knowledge,

however, there remain no resources currently available that have been as rigorously researched, developed, tested and evaluated in the way that the resource detailed in this chapter has.

Table 4. Available information resources (English language).

Resource	Provider	Description
https://www.blf.org.uk/support-for-you/bronchiectasis	British Lung Foundation	Online and booklet version available. Quite brief information about bronchiectasis (900 words). Participants felt was too little information.
http://www.nhs.uk/Conditions/Bronchiectasis/Pages/Diagnosis.aspx	National Health Service	Quite lengthy online information (3,600 words). Lots of text on the page to scroll through plus extra items alongside which put some participants off.
http://patient.info/health/bronchiectasis-leaflet	Patient (patient and professional information provider)	Online text. Lots of adverts alongside. Includes discussion forum.
http://www.bronchiectasishelp.org.uk/	Written by a patient with bronchiectasis	Patient's perspective with input from professionals. Basic information. Not text-heavy. No Adverts
https://www.nhlbi.nih.gov/health/health-topics/topics/brn	National Heart Lung and Blood Institute (USA)	Well organised sections. Quite a bit of information and text (4,500 words). No Adverts.
http://www.bronchiectasis.info/	Run by patients with bronchiectasis	Discussion forum and online community rather than an information resource.
https://en.wikipedia.org/wiki/Bronchiectasis	Wikipedia	Text and images. Not always considered credible.
https://medlineplus.gov/ency/article/000144.htm	US National Library of Medicine	Small amount of basic information (570 words).
http://bestpractice.bmj.com/best-practice/pdf/patient-summaries/531907.pdf	British Medical Journal	Concise information (1200 words) no adverts.

Table 5. Other available information resources.

Resource	Provider	Description
https://www.chss.org.uk/documents/2013/08/c4_bronchiectasis-pdf.pdf	Chest Heart and Stroke Scotland	In depth information as a downloadable PDF. Some contribution from patients. (Not in existence at the start of this work.) This was considered the best open access resource in an unpublished patient survey. (Conducted by ELF, personal communication.)
https://www.youtube.com/watch?v=7OOvfsTtTYM	BLF online presentation and question and answers with consultant and physiotherapist.	YouTube video of presentation slides and audio. Patient questions and answers.
http://www.webmd.boots.com/a-to-z-guides/bronchiectasis	Boots	Online text information (1300 words). Lots of adverts on the page and unrelated images which some find off-putting.
http://www.bronchiectasis.scot.nhs.uk/	NHS Lothian and input from patients with bronchiectasis	Online information with input from patients (Approximately 3,000 words plus written patient stories). (Not in existence at start of this work)

As confirmed by these searches, when looking online for 'bronchiectasis information' there would seem at first glance to be numerous resources available to patients. Their usefulness or appeal to patients, however, was still unclear. As described in the previous chapter, patients were often confused about which sites they should look at when presented with such search results. Determining credibility was a necessary step in the selection process. Being affiliated with a well-known lung charity or the NHS were factors that frequently influenced a resource being used or trusted. The actual content of the resource was obviously also a factor once that initial criterion had been met. The interview data confirmed that having long documents of text containing medical jargon, for example, was off-putting, as was having advertisements on a website. Despite this apparent wealth of available information online, patients and carers still felt that there was a lack of credible and user-friendly information. To create an accessible, trustworthy resource containing information that users wanted, rather than just information that providers have decided they should have, were key objectives of the development process described in this chapter.

During the interviews, examples of styles and formats of information resources about conditions other than bronchiectasis were shown to participants to prompt discussions. These included websites, a DVD, a booklet and a short leaflet. Participants' views about various features of information resources were considered within the analysis of the interviews. This incorporated both specific views on the example resources and general discussion around information needs. As described in Chapter 4, analysis of the qualitative data highlighted many aspects of patients' and carers' experiences of living with bronchiectasis that needed to be woven into the novel resource design. This was not simply a list of facts to be included, but use of the new found insight into their experiences of bronchiectasis and approaches to information use. This approach enabled design of the information resource in a format that aimed to engage users and facilitate their understanding. In Chapter 2, the literature supporting such an understanding of the needs of the patient group and developing information to meet those needs was discussed (Leydon *et al.*, 2000; Case *et al.*, 2005; Lambert and Loiselle, 2007). The benefit of user-centred approaches and co-development were also discussed (Harland and Bath, 2008; Patient Information Forum, 2013). As described in the methods in Chapter 3, the first step in this process was to discuss an overview of the interview findings and initial concepts for the novel resource with a group of patients and carers.

5.2 Workshop 1: Confirmation of themes and refinement of ideas and concepts

The first workshop was attended by 5 patients with bronchiectasis and 2 carers. As described in the methods (Chapter 3) some participants had taken part in an interview and others had not. I facilitated the session along with a specialist bronchiectasis nurse. A topic guide was used as I aimed to cover quite a lot of material in the session (Appendix 11). I described the interview findings to the workshop attendees and showed them a list of the four main emergent themes and their relevant subthemes as detailed in the topic guide. Participants discussed these themes and how they could be incorporated into patient information within a website or booklet. Their views overall confirmed the interview findings, yet this further and more focussed consideration helped to refine my initial ideas about how these findings would influence the resource design. Interestingly, in keeping with the main emergent theme of the interviews, participants spent a lot of time discussing their own experiences of living with bronchiectasis and their own needs in terms of information and resource provision. This interaction between the participants was also concordant with the desire to relate to others' experiences identified within the interviews. Being given such a space in which to discuss their shared experiences was clearly welcome (Figure 4 (used with permission)).

Figure 4. Workshop 1.



5.2.1 Resource format

One key area arising from the interview analysis was the format of the resource. The group concurred with the interviewees: a website and a substantial booklet (rather than a single page leaflet) would be the preferable ways to present the information. The use of video clips with professionals, patients and carers was also confirmed to be a relevant and important way of delivering additional information. The consensus was that the use of video clips should be incorporated into a website rather than a DVD. DVDs were felt to be outdated and little used. Although there was the risk of exclusion of those without internet access, it was felt that such video content could be additionally supplied on request, should there be demand for it. This approach was agreed to be the most consistent with our findings on preferences and the most economical use of funding. Cost is clearly an important consideration when developing information resources for use within a budget constrained NHS.

5.2.2 Resource homepage, front cover and title

The next step in this co-development process was to try to reach an agreement on what the front page of a booklet or website should look like. This was important to ensure early engagement with an information resource, as patients reported a significant rejection rate based upon website homepages. For this purpose I had

created a very basic template with removable sections using features from the interviews that had been identified as important to patients and carers (Figure 5). These included components such as the title choice and a choice of images that users could potentially relate to. Affiliations that may inspire trust and engagement were also found to be important in the interviews and were included as options.

Figure 5. Workshop 1 template use.



Participants then discussed which elements they felt should remain or be removed: which added to the resource, and which were superfluous to requirements. For example, one feature I had included on the front page template was the phonetic spelling of bronchiectasis (brong-kee-**ek**-tuh-sis). In keeping with the interview findings, several workshop participants were, or had been, unsure of how to pronounce bronchiectasis:

P21: The way that you put, the way that you pronounce it. Because I can never say that word. I've always said "bronchiexi-whatsit". But that's helpful actually.

F: And then do you think that's something you would put, like, on a front page of the website, or would you have that somewhere else?

P21: No, put it on the front page.

P20: Yeah.

P19: 'If it's on the front you know exactly what it is.' (FG1, 1854-1873)

Even those that didn't specifically mention the importance of pronunciation did sometimes mis-pronounce it. One participant had wondered whether it was the same as bronchitis, as it sounded the same. Although this may seem like a minor point, this was considered an important element of the website homepage. Simply putting the phonetic spelling to aid with pronunciation could help a lot of patients feel more confident about this and save them the embarrassment and confusion that some participants had experienced.

As an example of a feature that was not chosen to be included, I had suggested as potential options for the front page some images of a pair of lungs and a doctor. On discussion, participants felt that overall these added little to the homepage in terms of giving information or fitting with the overall design theme and purpose. The decision was therefore made that these would not be included on a final version, as they may be considered to be 'cluttering' the page rather than improving it.

I also began discussions about the title choice included within the template by asking what people thought of the proposed title 'Living your life with bronchiectasis', and whether it should be changed or simply be entitled 'Bronchiectasis information' for example. Participants felt that the choice of title was good:

'C11: No, I think living with is good. Personally, I think that's what you want.

P22: Yes, because that's what we are doing, we are living with it. So I think that's very appropriate.

P18: And it's positive isn't it?' (FG1 2107-2112)

This is exactly why the proposed title had been created: to portray a positive message, how one can still live life with bronchiectasis. Patients and carers were very clear that they wanted positivity within any information received so to ensure this was embodied within the title of the resource was crucial. By using the interview data I had created this title to portray the purpose and nature of the information and to capture the essence of the interview findings. The agreement of the workshop participants that this met requirements confirmed that my translation of these findings into an engaging title had been effective.

Another key outcome was to design the resource to ensure credibility; to encourage potential users to look at and trust the resource. A range of logos were included in the template: those for Newcastle University, Newcastle upon Tyne Hospitals NHS Foundation Trust, NIHR and the BLF. Participants felt these were essential to include on a front page, and that the NHS logo itself was the most likely to inspire trust. It was agreed that all logos used would remain at the bottom of the front page to optimise initial engagement. This decision reflected both the interview and workshop findings that users are more likely to engage with and trust 'authentic' information resources from trusted organisations.

5.2.3 Resource contents: sections and headings

Moving on to the content of the resource, I then shared with the group draft content headings based upon the interview findings (Appendix 12). We initially discussed which elements required a prominent position within an information resource, and which could possibly be omitted or repositioned. The content headings had been based on the findings of the interviews, to try to ensure that sections of information were organised and titled in a way that users could relate to. By reviewing these provisional section headings and the concepts for their content within the workshop we were able to refine this further as a group. For example, I had included a section about the 'medical team' which I proposed would include a description of each member of the team that someone with bronchiectasis was likely to see. The aim was to explain the role of the multidisciplinary team, and the ways in which they can help, so that people would know what to expect, and who to turn to. I suggested that this would be a combination of both text and video clips, with each team member making a short video clip describing their role. Participants felt that this was useful, but maybe could be presented slightly differently:

'C11: It's also useful to know that there is a whole team to deal with this. If you are going in and see five, "Oh crikey there's five or six things wrong with me...It's not just the one"

Co-F: Can I ask you a question? So P21, when you see the term there, 'The medical team' what does that make you think of?

P21: Well as an ex-nurse, I would automatically think doctors, nurses, physios....

P19: ...So instead of putting it as 'medical team', could you not put, 'People who you are likely to see'? Because medical, you think, surgical...Or it's going to be invasive...

F: Yes, that's a good idea.' (FG1 2471-2507)

By understanding users' reactions to the proposed presentation of this section, I was able to change it to be entitled 'People you may need to see'. I then described who the potential people involved would be alongside a video clip of each individual explaining their role (respiratory consultant, respiratory physiotherapist, specialist nurse, continence nurse, lung function technician, dietitian). By using these templates of initial ideas within the workshop, it was possible to tease out more subtle requirements for acceptability to users.

Similar subject areas were identified as important to the workshop participants as had been with the interviewees. Workshop participants also wanted to receive 'useful' information: information about things that would help them, or things they could do to help themselves. Again, nearly all used diet and lifestyle advice as examples. Prognosis also came up again as an important subject area to be included. This is something that was clearly required to feature within the resource as accurately as possible, yet in a way that would offer hope and positivity. In terms of format, it was felt that explanations about a complex subject such as prognosis may be better achieved through the use of video to complement written information. Having video clips of professionals and also patients, both new and old, talking about their experiences and how their lives have or have not changed was also thought likely to add credibility and be more engaging than written descriptions alone.

By discussing the proposed sections and contents we were able to review which elements were agreed to be important components of the resource. By discussing proposed ways of sectioning different aspects of information, and how each section should be titled and organised, we began to build a much clearer picture of how the contents would look. The views of participants in this first workshop built upon and reaffirmed the findings of the interviews. This new knowledge made it possible to begin to develop a first prototype of the novel user-driven resource.

5.3 Prototype development

Once the findings of both the interviews and the first workshop had been assimilated, I had an initial meeting with a media production company and my supervisory team to discuss content and design of the agreed resources: a website and a booklet. We discussed concepts and ideas behind the resource, and the key requirements. Although I was responsible for production of the content of the booklet and website, the actual website construction and design was developed in conjunction with the media company based on my explanations of what we were aiming to achieve. I gave details of the title, sections required, what needed to be on the homepage, navigation features that had been highlighted as important, images and login requirements, to name but a few. I briefed them on the opinions of users of some of the available resources tabulated above to aid with the design and conceptualisation of our planned resource. I also explained to them the findings of the interviews, and some of the typical experiences of people living with bronchiectasis, so that they understood the potential resource users. The media designer then spent time creating a few options in terms of design and layout and a variety of images to potentially be used on the homepage.

Whilst this was being done, I began to develop the written, video and image content of the website in a structure that was in keeping with my qualitative findings and the workshop discussions. Transcripts and written analyses were used to facilitate this as described in the methods in Chapter 3. Additionally, members of the multidisciplinary bronchiectasis care team each contributed to their own expert sections. I held discussions with the members of the bronchiectasis MDT about the findings of the interviews and workshops and how they might present information relevant to their expertise in keeping with these findings. Each then provided their version of information, which was usually the information they would give to a typical patient when seeing them on a clinical basis. This ensured that the information provided would meet the needs identified, yet also be presented by an expert in that field in a way which would reflect information received when attending a specialist clinic. By using the whole team, as would be done in a clinical setting, the resource was further shaped and developed around the users' identified needs and ensured that any additional content thought fundamental to their specialist area was included. Content was written or edited by me and my clinical supervisor and also reviewed by contributors, potential users and independent reviewers. This rigorous process of

peer review was important to ensure that the information provided was accurate, unbiased and of high quality.

Video clips were recorded by me using a camcorder. Videos of healthcare professionals were recorded within clinic rooms, and patients and carers were given the option of recording theirs either at home or at the hospital or university sites. Only 1 participant opted to film at the hospital as this was more convenient for her, others were recorded in participants' homes. I gave all contributors a briefing about what was required (topic matter and duration) in advance, but all content was decided by the person being recorded. The clips were not edited and patients, staff and carers gave their stories in their words. I did not know in advance what they had planned to say and they were not scripted. I felt this was the most honest and realistic way to record the video clips so that users could potentially more easily relate to them.

Written and video content was then uploaded to the website by both the design company initially, and then by me once I had completed training in the content management system. This meant that I was able to make amendments as required throughout the development process and create logins for new reviewers and users. This training was essential to ensure that I could have ownership of the resource and promptly fix any issues as they arose.

5.3.1 Prototype content and organisation

Rather than setting the resource out in a traditional textbook layout: causes, investigations, symptoms and so on, (which I had learnt to be contrary to users' desires for a resource) I focussed on addressing the main issues within the data. I grouped the information into 5 main sections, each of which had a relevant group of subsections (Table 6).

Table 6. Website section and subsection headings.

Main Heading	Learn	Treatment	Help and Advice	Carers and Families	Research
Subheadings	Getting a diagnosis Why have I got bronchiectasis? What is wrong with my lungs? What symptoms might I get? What is the prognosis? What does this mean for my life now?	People you may need to see Treatments Treating chest infections Managing breathlessness Treating coughing blood New drugs and research	Recognising symptoms Self-management Active partnerships with your team Understanding your clinic letter Diet, exercise and lifestyle advice Coping and support Patient experiences Useful links	How you can help How you may feel	What research is being done? What is being done in my local area? How can I get involved?

The groupings were based upon discussions within the interviews and workshop and also which subsections ‘naturally’ went together. One feature that was clearly in demand was for users to be able to look at the information they wanted to look at, and not have to look at other information that may not be relevant or of interest to them. For this resource to be a quick and simple way for users to access information specific to their needs at a given time was clearly important. In order to enable this, many of these listed subsections were also subdivided again, to facilitate ease of searching for (and possibly avoidance of) specific information. Detailed contents and menu tabs, inter-section links and straightforward navigation systems were incorporated into the resource for this purpose also.

As an example of information content, prognosis and disease trajectory was a topic raised by many. This was included in the ‘Learn’ section (Table 6). I wanted to cover this topic in a way that would address the prognosis concerns that people have described, rather than just giving medical evidence and figures. This needed to serve as reassurance to patients rather than create more confusion and concern.

Specifically, it was clear from the data that participants were comfortable with the term 'prognosis' but that this should also be addressed by quoting things patients have actually said in interviews: 'How will I live with this?' and 'What does this mean for my life from now on?', in addition to facts about prognosis and symptoms. This written information was complemented by videos from patients explaining how they have coped after a diagnosis, and a video from a consultant explaining more about prognosis. Wording this in ways that linked directly with discussions had within interviews and workshops ensured that users would be able to relate to the information and experiences described.

Another section 'Help and Advice' facilitated incorporation of general diet and lifestyle advice, a topic of concern to many, in a similarly positive way. This section additionally enabled promotion of the importance of doing physiotherapy regularly by emphasising the benefits they should feel. Also included was advice about changes in symptoms to facilitate self-management, emphasising how this could help their condition remain stable. All advice was given in such a way that related back to the findings of the qualitative interviews, with a view to making this resource relevant and 'useful' to users.

The actual content of information and the way in which it was presented has been influenced by all of the interview and workshop data and the relevant literature described in Chapter 2. As described in Chapter 4, one of the primary purposes of information seeking seemed to be to somehow lessen the impact of bronchiectasis. It was therefore crucial that the resource was developed in a style that would enable users to easily see that this resource could help them to understand their concerns and consequently may lessen the impact that bronchiectasis is having on their life. The fact that potential users would have differing levels of clinical support emphasises the importance of universal accessibility to user-friendly information beyond the clinic experience.

5.3.2 Key points for resource development

Alongside the development of the actual content, format and presentation of the resource, there were other important points that arose during discussions and analysis of data. Many of these have been described already, yet for clarity, I have tabulated a summary of some of the general points that were important to take into account in order to optimise information delivery, uptake and benefit (Table 7).

Table 7. Resource general principles

General Principles
The resource should be positive yet realistic
Clarity: black on white, no jargon, Easy Read principles.
Detailed contents and navigation: what you view is up to you.
Booklet to accommodate those who do not want 'too much information'.
Placement is key to maximising value: most are 'opportunistic seekers'.
Trust: needs to be endorsed or recommended. 'NHS' logo essential.
Multi-format: website, video content, booklet.
Accessibility: incorporates all above points

I have also presented some examples of specific points that clearly needed to be included (Table 8). These summaries were used to confirm the important features and principles with the co-development group, including the media team. For them to be clear about exactly what we were aiming to achieve was vital to being able to move forwards with developing a high quality resource in keeping with our findings. These points, along with the section headings given above began to give a better picture of how we envisaged the prototype. By using these as a framework, the prototype information resource could be constructed. Once the prototype had been completed, further workshops were held to review and refine the resource.

Table 8. Specific examples of resource content and features

Specific examples of content and features to be included
Phonetic spelling to aid pronunciation on front page (brong-kee-ek-tuh-sis)
'Understanding your clinic letter' picture of example letter and links to key words and sentences e.g. terminology, imaging and lung function. This was commonly misunderstood as learned from interview data.
Clearly distinguish from COPD and asthma and lack of connection with smoking and explain what and why doctors will ask (not accusatory). This was clearly an issue for patients who had never smoked yet were repeatedly asked if they had.
Explaining common misconceptions – is bronchiectasis contagious or smoking-related?
Explain conditions it may be linked with
Drugs and side effects and other management: physiotherapy, pulmonary rehabilitation, transplant (emphasise rarity so as not to cause unnecessary worry).
Research and the future: links to what is happening locally if want to get involved.
FAQs and expert advice – participants would appreciate an 'email and answer' section but wouldn't be practical at this stage. Initially just FAQs as determined by interview data.
Have a variety of patients and carers giving their experiences in terms of reactions to diagnosis, and how they manage on a daily basis to give hope and positivity. Incorporate people's reactions and management strategies relating to interview findings of biographical disruption and flow.
Prognosis: include videos of participants recalling thoughts at diagnosis and now, how changed over time.
Self-management tips, as with above, to aid readers to feel empowered to 'take back control' or form an 'active partnership' including others' experiences and symptom recognition – incorporate 'normality' and put into context 'Put it into their daily lives so that you really understand' (C09 434).
Advice about playing an active role. This seems to particularly relate to diet and lifestyle advice.
Practical advice e.g. holiday insurance.
Links with other trusted online resources.

5.4 Workshops 2 and 3: Refining the resource

Workshops 2 and 3 focussed on patients and carers reviewing the resource prototype and finalising ideas on content of the overview booklet to accompany the website. A concise topic guide was used for these sessions (Appendix 13).

Workshop 2 was attended by 5 patients and 1 carer, and was facilitated by me and a specialist bronchiectasis nurse. Workshop 3 was attended by 1 patient and 1 carer and facilitated by me.

Prior to workshops 2 and 3, all contributors to the website had the opportunity to give feedback and suggest changes to the prototype, and the prototype site had also been reviewed by a patient representative from the British Lung Foundation and a number of 'expert' patients. During the workshops, participants were shown the prototype website. It was made clear to them that this was a starting point and the purpose of the session was to get their views and feedback and make any necessary alterations. They were shown example sections chosen by me, and the participants also selected sections they particularly wanted to look at. I gave demonstrations of how to navigate through the site and participants could try this for themselves. The extensive review of the prototype began with discussion of the website home page and their reactions to it.

5.4.1 Homepage

The appearance of the home page was our starting point. At that stage in the development process, there were 2 potential options for how the homepage could be set out (Figure 6, Figure 7). The images show the website when viewing on a PC (main image) or mobile device (image the the left of main image).

Figure 6. Website homepage option 1.

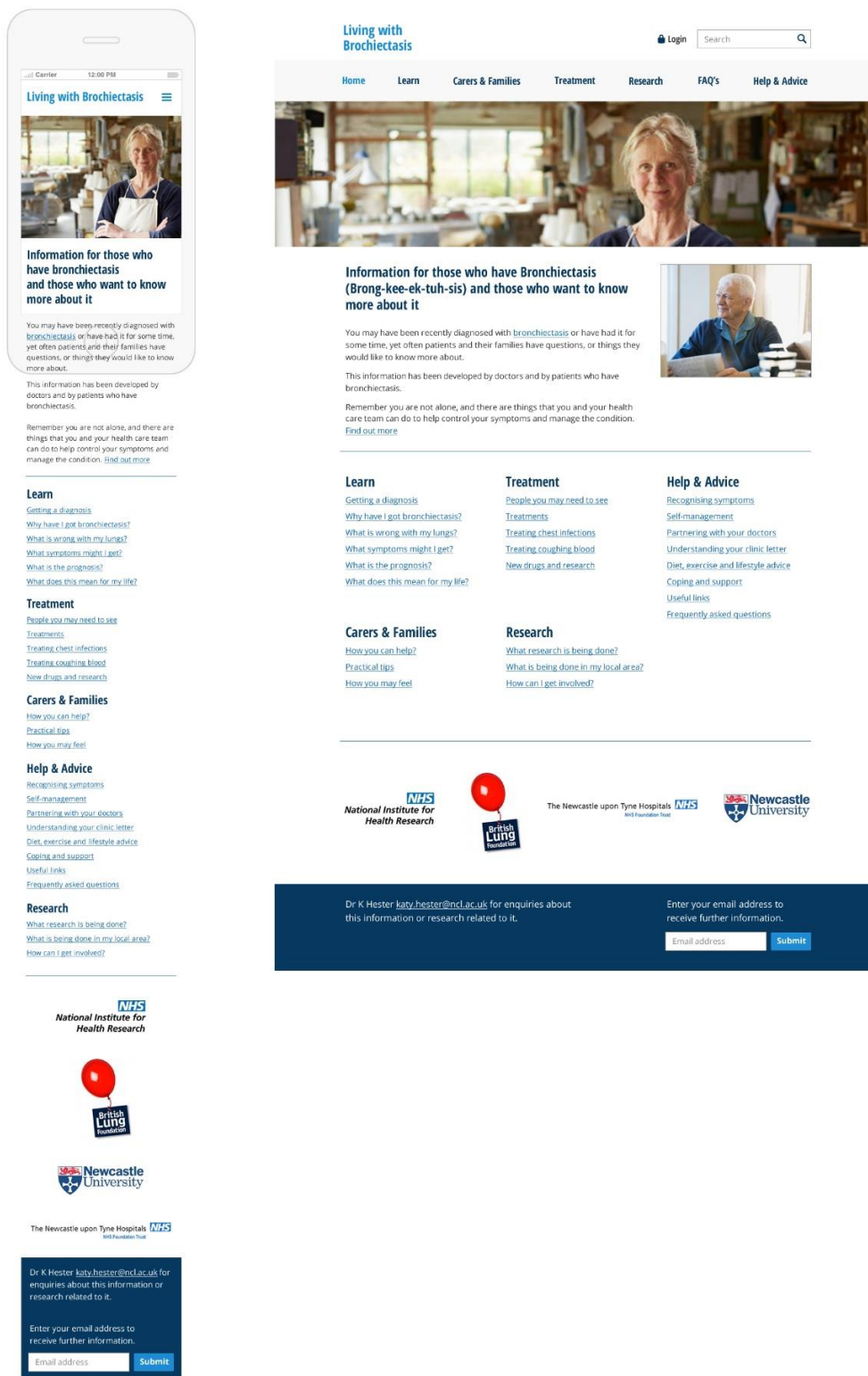
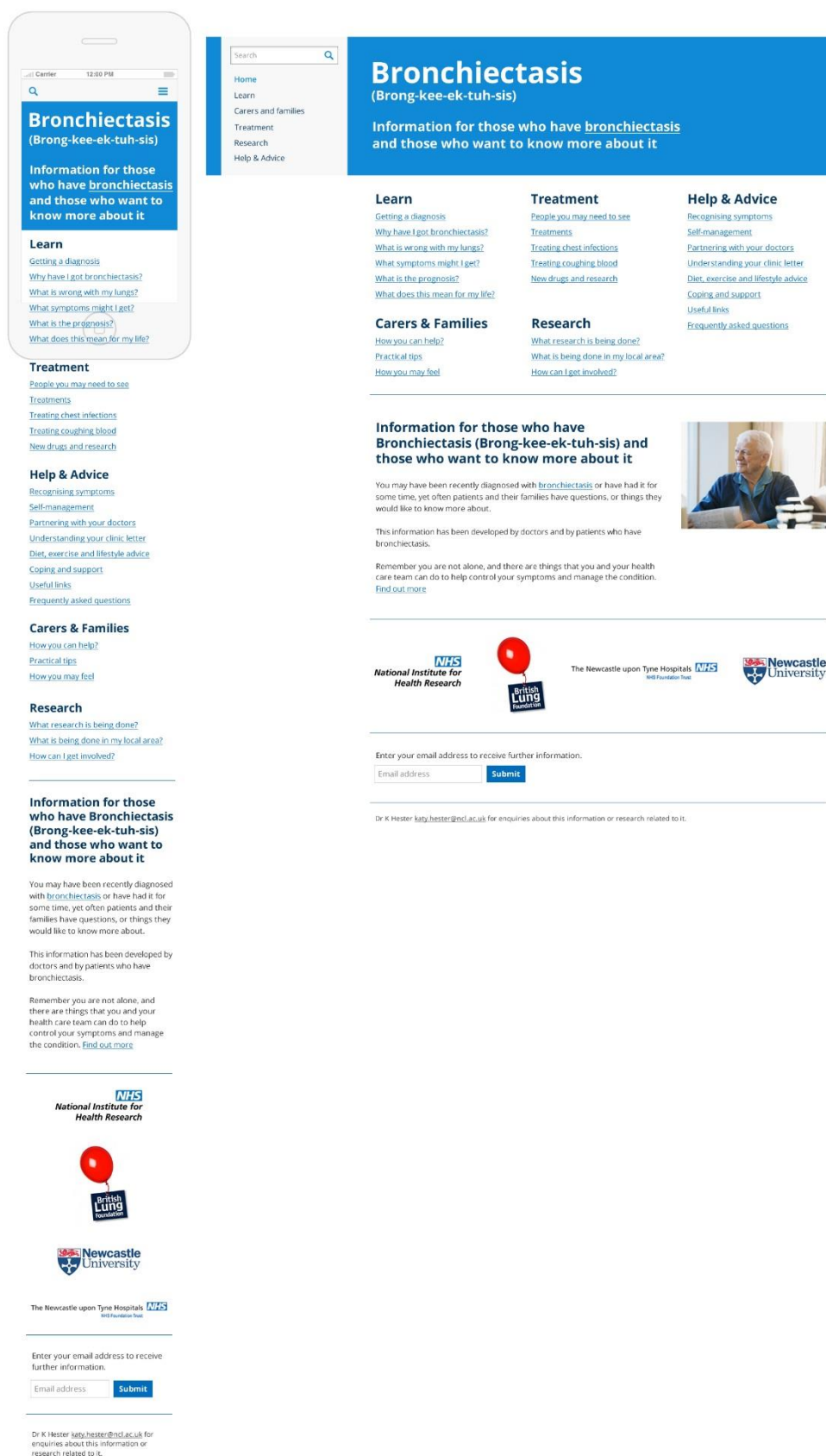


Figure 7. Website homepage option 2.



A lot of importance was attached to the images that would be on the homepage as they were felt to be representing bronchiectasis and people who may have it. The participants wanted to portray a positive image, as per the interview findings. There was one participant who initially felt that the images were not representative of someone with bronchiectasis. He wondered if someone wearing an oxygen mask should be portrayed. A discussion ensued and the consensus was that the majority of people with bronchiectasis will be well most of the time, and that this is what should be represented. All agreed (including the participant who raised the original suggestion of including an oxygen mask) this was preferable to presenting the 'worst case scenario' which does not fit the need for a positive approach that users had expressed, nor does it represent the majority of people with the condition:

'P27: When I'm well, I'm well, and I look well.

...

P24: I mean that's one of the reasons why I stopped reading stuff from the internet about bronchiectasis... 'cause there's a lot of doom and gloom. And you, you read it, and you come off and you think, "My God!" You think that y- your life's over, but I suppose them pictures show that you don't have to be – it doesn't have to be a life debilitating illness... You can still have a quality of life at the same time.

...

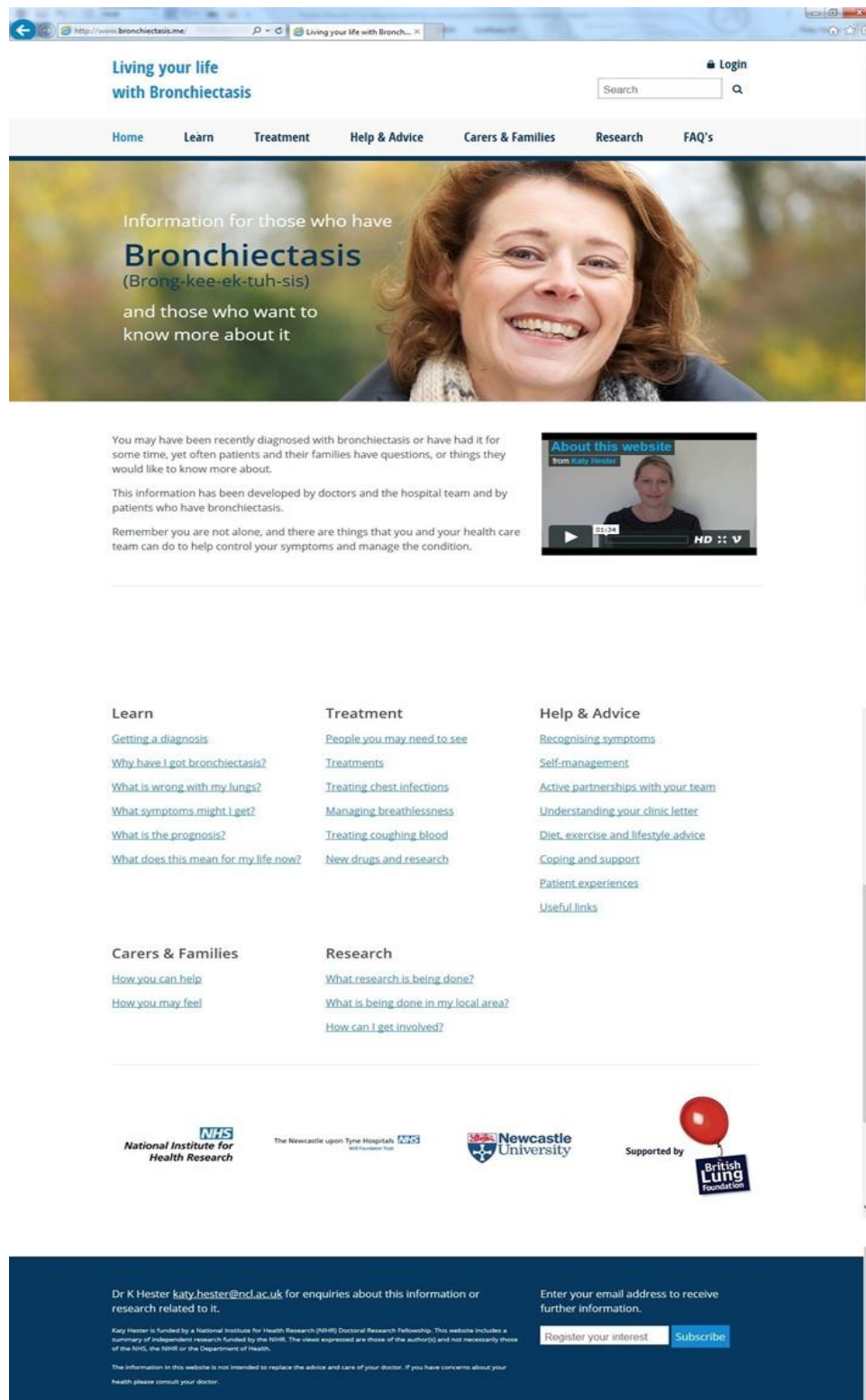
P26: I think you need to start with where the mean is, so they will be the majority of people looking...I think on the first screen you want to capture the presence of the main group of people.' (FG2 336-429)

Building on this point, some participants had concerns that the man shown in option 2 (Figure 7) looked like he might be wearing a dressing gown and that this was not an ideal image to portray. On the basis of these discussions we were able to make changes to the homepage and alter it to include an image which fitted with an 'average' patient with bronchiectasis: a middle-aged woman who looks well.

Also agreed to be important features of the homepage were the phonetic spelling of bronchiectasis, logos and contact details that confirm credibility, easy menu options to allow swift access to the area of information required, and a video clip explaining the purpose of the website and how it had been developed. The final website

homepage incorporating these features was created with all these points taken into consideration (Figure 8).

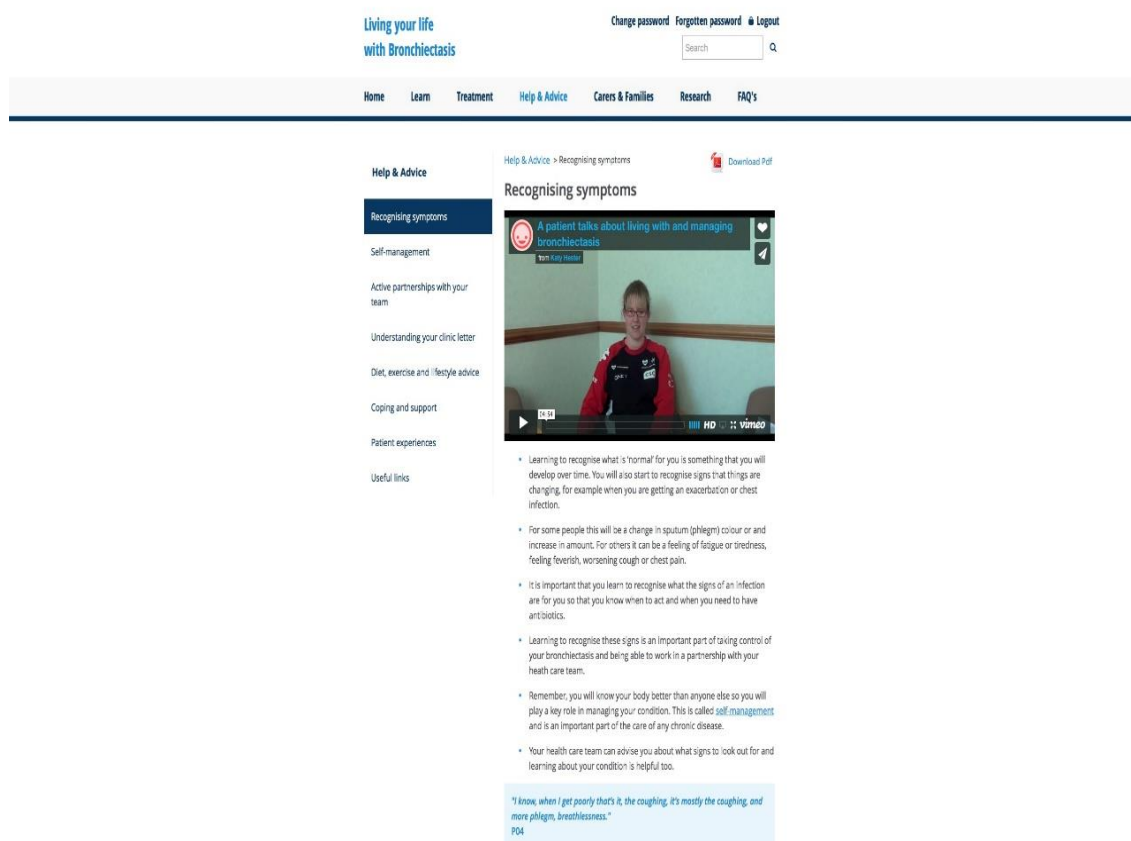
Figure 8. Final version website homepage.



5.4.2 Section contents and navigation

When talking generally about the site content, participants agreed again that the title of the site was positive, as was the web address: www.bronchiectasis.me. This domain name was considered carefully before purchasing for the site. They also felt the positive message of coping with bronchiectasis came across throughout the site. Discussion about sections of the website ensued and useful changes were able to be made to make navigation and searching more straightforward. Participants gave their views on the way that sections were ordered, and the organisation of menus to the side of the screen that intended to make looking at specific subsections of a page much easier. For example, the Help and Advice section (Figure 9).

Figure 9. Help and Advice section.



To make it easier to narrow down exactly which aspect users wanted to look at, we had a side menu including recognising symptoms, self-management, diet and lifestyle advice and so on. Not all sections of the website can be discussed in depth here, but all were reviewed and revised as per discussions within the workshop.

For a more in depth look at the website content, a PDF version of the site is included as an appendix (Appendix 2). The website can also be viewed at www.bronchiectasis.me. People opting to enter the feasibility study without internet access were given the PDF as an alternative to viewing the website. Unfortunately this did mean they were not able to access the video content, nor the interactive content such as the example clinic letter. Although this was an incomplete and less than ideal way of accessing the information contained within the resource, it did serve as a next best option for those wanting to engage with the information and enter the feasibility study.

5.4.3 Final revisions

In workshop 3, participants were shown the further revised version of the website with the final homepage (Figure 8) and asked to look through the site and give their feedback. Participants felt that the revised images were positive and likely to appeal to users. They also concurred that having the explanatory video on the homepage was a good way to both get across a message in a different format, and introduce what could be expected within the site, as many more video clips are used throughout.

During workshop 3, minor errors such as typing errors and non-functioning links were also identified and final revisions were facilitated. The overall view was extremely positive:

‘I think it looks really professional...and I think you should be very proud of yourself...I think that would have answered everything I wanted to know and...I think a lot of it would have reassured me. And I think you’ve done a good job in sort of saying, ‘This isn’t necessarily going to happen’.’ (P28, FG3 1438-1454)

This participant had a relatively new diagnosis, and had found that previous online searching for information had been very frightening when not knowing what information was reliable, and what she should believe. It was very reassuring to hear that the resource I had co-developed with patients and carers based upon the

interview findings and workshops would have met the needs of a new patient such as her. This was further confirmation that the development methods had allowed me to meet the aims I had set.

5.4.4 *The overview booklet*

Following this third workshop, the website in its final version was again reviewed by patients, an independent respiratory physician and all contributors. We then further discussed and finalised the contents of the booklet. This was to be a 14 page glossy booklet with a similar front page to the website homepage. The 'essential' contents to be included within this booklet were determined by both discussions within the interviews and workshops, and feedback from patient reviewers and healthcare professional that contributed to the information resource. The booklet was presented in a similar style, and quotes from participants aimed to replace the videos used on the website. Only a limited amount of information could be included within the booklet, so focussing on what was important was crucial. Again the contents were added by me based upon the website content, and the design company organised the layout options which I reviewed. The prototype was then reviewed by contributors, patients, carers and an independent respiratory consultant as per the website. Amendments were made and a final version agreed. A PDF of the final booklet is included as an appendix (Appendix 1).

5.5 Summary

The process of resource co-development took approximately 8 months. This included development time, filming, content writing and revision and re-design in between workshops and reviews. This process was informed by concurrent analysis of workshop discussions and transcripts and by referring back to the interview data analysis. Being able to co-develop the resource with patients and carers in this way meant that potential users influenced the development process and end products directly, in addition to the resource being designed around the qualitative interview findings. All reviewers felt that a useful, positive, credible and informative resource had been developed. The resource seemed to both meet users' requirements and incorporate insights into their experiences gleaned from analysis of interviews. The next step was for the resource to be used as the intervention within the BRIEF Study. The findings of the BRIEF study, including further resource evaluation, are described in the following chapter.

Chapter 6 Results 3: Bronchiectasis Information and Education: Feasibility and evaluation of a novel resource (The BRIEF Study) findings

In this chapter I describe the findings of the Bronchiectasis Information and Education: Feasibility and evaluation of a novel resource (BRIEF Study, ISRCTN84229105). This reporting of results is in keeping with the newly published extension of the 2010 CONSORT statement for randomised pilot and feasibility studies (Eldridge et al., 2016). The methods and design of the study have been described in detail in Chapter 3, where the study protocol was presented. The findings of the qualitative interviews and the results of the resource co-development, which formed the intervention for this feasibility study, were described in Chapters 4 and 5. The BRIEF study was a feasibility study, and therefore its primary purpose was to determine the feasibility of conducting a future definitive RCT based on this study design and protocol. In addition, I aimed to further evaluate the information resource that formed the intervention within the study. In this chapter I will present the results of the feasibility outcomes (detailing recruitment, retention and study visit completion) in addition to the baseline demographic data and descriptive analysis of the data collected at study visits. As this was a feasibility study, no formal statistical testing has been performed in keeping with the protocol and pre-written statistical analysis plan described in Chapter 3. (See also (Hester *et al.*, 2016).) Participants' views on the resource and the trial process were explored both in study questionnaires and a focus group at the end of the study. The outcomes of these are presented along with analytical data on the use of the website. Findings are discussed at the end of the chapter and then further in the overall discussion (Chapter 7) which concludes the thesis.

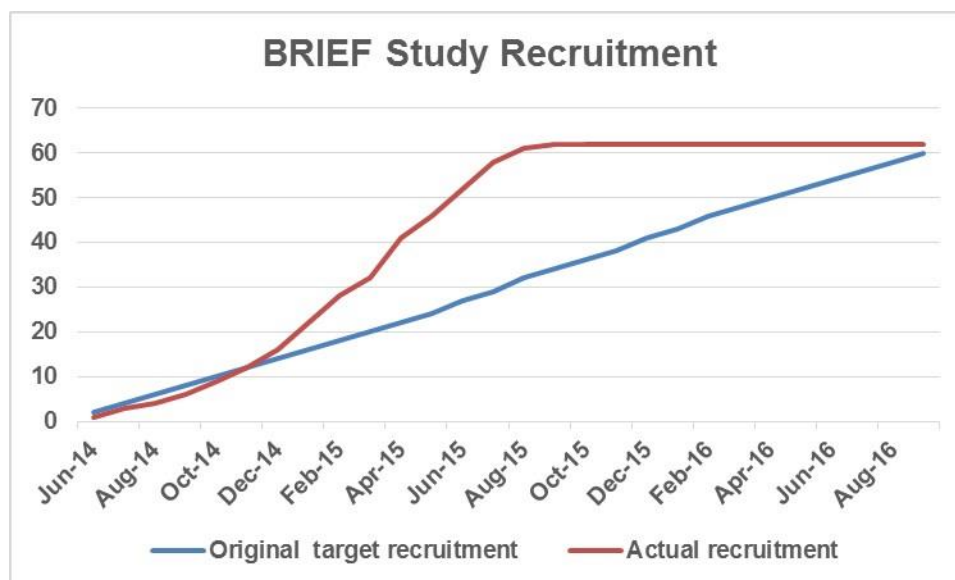
6.1 Participants and recruitment

As described in the methods (Chapter 3), potential participants were approached by their usual care team following review of case notes, usually at a clinic appointment. A participant information leaflet (Appendix 15) was given to them in person or agreement established to their being contacted for further information about the study by the research team. If participants had agreed to being contacted but the team were unable to contact them despite repeat attempts at postal and telephone contact, they were deemed 'uncontactable'.

At study commencement, the aim was to recruit and randomise a minimum of 60 patients, in keeping with recommendations for feasibility studies (Browne, 1995; Lancaster *et al.*, 2004). Study recruitment was expected to take place over a period of just over 2 years, with projected patient accrual of 2-3 patients per month.

Overall, 62 patients were randomised. As the aim was for 30 per arm, given the availability of potential participants, 62 were randomised to ensure follow up data was achieved for 30 participants per arm to facilitate estimation of sample size for a full study (Browne, 1995; Lancaster *et al.*, 2004). Recruitment took place over a 16 month period (the first patient was randomised on 10th June 2014, and the last on 23rd September 2015), with a participant recruitment rate of 3.9/month (Figure 10). Recruitment target numbers were therefore achieved ahead of time.

Figure 10. BRIEF Study cumulative number of participants randomised: original target compared to actual recruitment.



6.1.1 Distribution of participants by randomisation strata

Participants were randomised using random permuted blocks within strata by means of the Newcastle University online randomisation system. Randomisation was stratified according to gender. Overall more women were recruited than men, which had been anticipated in keeping with the patient demographic. There were equivalent male to female ratios in each group. The distribution of patients by randomisation strata is included in the table of baseline characteristics (Table 12).

6.1.2 Adverse events

Within the control group there were two serious adverse events (SAE) unrelated to the study, one of which resulted in the death of the participant (Table 9). The latter event clearly resulted in the complete withdrawal of the participant. The participant with fractured ribs was able to continue with study visits, but was unable to perform the lung function tests at visit 3.

Table 9. SAE summary table.

group allocation	Allocation date	Date of initial report	SAE Description	Onset Date	SAE reason	Outcome of SAE
Control	16/09/14	27/11/14	Pulmonary embolus	26/11/14	Hospital admission	Death
Control	10/04/15	10/06/15	Fractured ribs	10/06/15	Hospital admission	Resolution with treatment

6.1.3 Withdrawals and loss to follow up

There was 1 withdrawal from the intervention group at day 15 due to personal circumstances (Table 10). The participant had an unexpected change in circumstances that they felt prevented them from continuing with study visits. Only visit 1 of 3 was completed. This was a complete withdrawal and as defined in the protocol (Chapter 3) consent was obtained to retain and use data up to the point of withdrawal but the participant was not followed up further within the study. Other than the death (detailed in 6.1.2) and this withdrawal, there were no further patients lost to follow-up.

Table 10. BRIEF study withdrawals.

group allocation	Allocation date	Date of withdrawal	Withdrawal type	Withdrawal reason
Intervention	30/09/14	14/10/14	Complete	Change in personal circumstances

6.1.4 Data collection, validation and analysis

The trial protocol in Chapter 3 (Hester *et al.*, 2016) describes the methods of data collection and the main features of the analysis. The statistical analysis plan (Appendix 28) describes, in more detail, the predetermined strategy that was used for the statistical analysis and presentation of data collected for The BRIEF Study.

The CONSORT Statement for Reporting Randomised Trials recommends that all analyses should be planned and outlined in a statistical analysis plan prior to the unblinding of the data so as to avoid any *post hoc* decisions which may affect the interpretation of the statistical analyses (Moher *et al.*, 2010; Eldridge *et al.*, 2016). The CONSORT statement also recommends that when writing research papers authors should specify whether analyses were planned or suggested by the data – planned analyses have greater credibility and are in line with Good Clinical Practice. A statistical analysis plan was therefore written (with advice from a statistician) for the BRIEF study prior to embarking upon any data analysis. Participants recruited to The BRIEF study were not blinded due to the nature of the intervention making this impractical. The research staff conducting study visits were also unable to be blinded to the allocation groups. The same principles have been applied for the purposes of analysis however, and those initially entering data into the database and cross checking with study files were not directly involved in the trial.

Trial data was entered manually into the BRIEF study database by data managers at the study site. All data was originally hand written into each study record folder and entered into an excel database subsequently.

The following checks were carried out before any analysis:

- Treatment arm allocation as recorded in the randomisation log checked against that recorded in the CRF
- Randomisation stratification variable as recorded in the randomisation log, checked against Visit 1 CRF
- Age at randomisation ≥ 18 years (from randomisation log and CRF visit 1)
- All dates examined to check timings and compliance with the protocol.

Data analysis was performed as per the pre-written plan by me, the chief investigator. Due to the nature of both the intervention and the study (receipt of the intervention resource in a feasibility study with no additional funding for an independent data analyst), I was not blinded to the allocation groups either. Analysis was, however, performed on the fully anonymised data set using the pre-determined plan.

6.1.5 Definition of analysis sets

Statistical analyses were based on the intention to treat principle with analysis sets based on the groups allocated at randomisation and all randomised participants being included in the analysis.

No data were available at week 12 for participants lost to follow-up (n=2). Given this was a feasibility study, analyses of change data were based on the 'Completers' analysis set (Table 11).

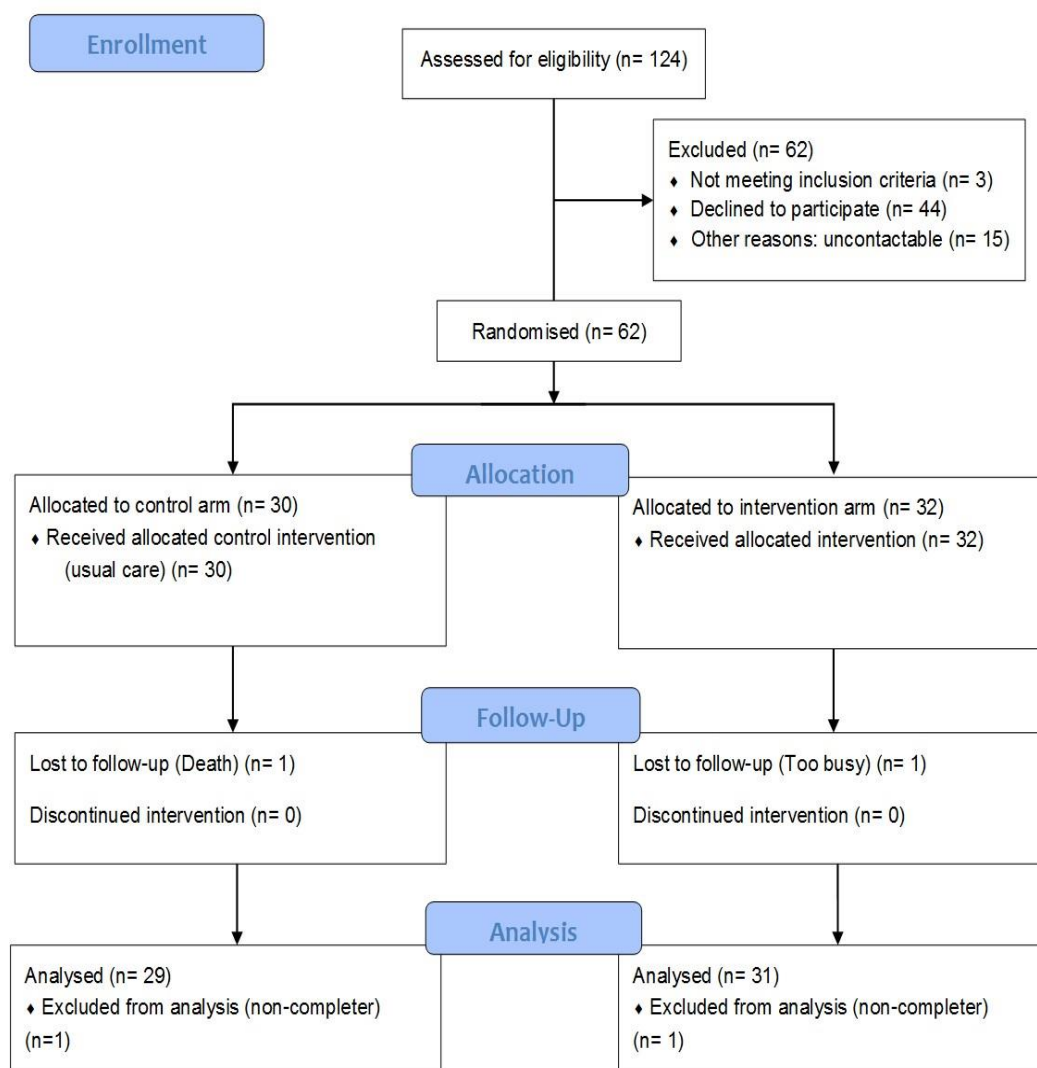
Table 11. Definition of analysis sets.

Analysis set	n	Definition:
Intention-to-treat (ITT)	62	All randomised participants, retaining participants in their randomised allocation groups.
Completers	60	All randomised participants, retaining participants in their randomised allocation groups, who attended their final study visit at 12 weeks post randomisation.

6.1.6 Patient flow

Section 6.1 described recruitment, which was completed at a faster rate than expected. It had been anticipated that approximately 50% of those approached would ultimately be eligible or willing to enter. It is difficult to predict with certainty the number of patients screened who will be deemed ineligible or decline study entry. A recent review of influential RCTs found that only around half of trials report with sufficient detail to calculate a non-recruitment rate (Humphreys *et al.*, 2013). A mean of 40.1% (SD 23.7%) non-recruitment was found amongst those studies reporting adequately. A conservative estimate of 50% non-recruitment was made ahead of this study. Of the 124 potentially eligible participants approached, 44 declined participation (35%), 15 were deemed uncontactable after repeated attempts to re-contact following receipt of the patient information sheet (12%), and 3 deemed ineligible (2%). Overall therefore, exactly 50% of those approached were willing and eligible to enter the study, which was in keeping with what we had anticipated. The following CONSORT diagram further details patient flow through the study (Figure 11).

Figure 11. BRIEF study CONSORT flow diagram.



6.2 Participant characteristics

Demographic and clinical baseline characteristics and trial stratification factors at randomisation were compared across treatment groups descriptively. For these baseline study entry characteristics, data for all participants has been included (ITT analysis set n=62). For data analysis beyond this point, only the data from 'study completers' (n=60, as defined in section 6.1.5) has been considered. Descriptive statistics were tabulated by treatment group and overall (Table 12).

The majority of characteristics are reported as absolute numbers and percentages. Continuous data were examined graphically and described appropriately dependent on distribution. Consequently, age was reported as median and range, as were FEV1% predicted and time since diagnosis. To describe the population at baseline, features characterising individuals (e.g. age, gender); the nature of their disease (e.g. lung function, severity scores (BSI (Chalmers *et al.*, 2014)), time since diagnosis, microbiology) and information seeking were recorded. It is anticipated in a randomised trial that baseline characteristics of the intervention and control groups would be very similar. For example, as shown in the table, median age is comparable between groups here. Gender is equal between groups, as randomisation was stratified by gender. However, with the small numbers involved and unequal splitting within some categories, some imbalance between groups in this study would be unsurprising. For example, it can be seen in the table that FEV1% predicted seems to be higher (75%) in the control group than the intervention group (67%). The clinical significance of this is hard to determine from one variable alone. The number of participants in the intervention group who have had bronchiectasis for more than 10 years (17/32 (53%)) was greater than that of the control group (9/30 (30%)). Again, the clinical significance of this and its relevance to information use is hard to determine. It is possible that this could reflect a greater number with more severe disease in the intervention group, yet length of time since diagnosis and severity of disease do not necessarily go hand in hand. The majority of participants had idiopathic bronchiectasis in both groups.

Notably, 28/30(93%) and 30/32 (94%) of the control and intervention groups respectively were recruited from the specialist bronchiectasis clinic. Only a minority were recruited from general respiratory clinics, which I will refer to again in the discussion. 9/30 (30%) of the control group, and 5/32 (16%) of the intervention group

had not actively sought information in the past, and a variety of methods of information seeking and access were described (Table 12). Overall, groups seem as balanced as expected given the small numbers. These characteristics allow a description of the groups at baseline. Variables described could potentially influence interaction with the intervention or health outcomes in a future definitive trial. No significance testing was carried out due to the randomised nature of the study (Altman, 1985; Roberts and Torgerson, 1999; Moher *et al.*, 2010).

Table 12. Baseline participant characteristics by allocation group (ITT analysis set).

	Control group <i>n</i> =30	Intervention group <i>N</i> =32	Total <i>n</i> =62
Gender			
Female	18 (60%)	20 (62.5%)	38 (61%)
Male	12 (40%)	12 (37.5%)	24 (39%)
Age (years)			
Median (range)	65 (34-81)	65 (18-81)	65 (18-81)
FEV1 (% predicted)			
Median (range)	75(21-120)	67(10-110)	68(10-120)
BSI score¹			
Median (range)	6(2-15)	7(2-14)	6(2-15)
BSI Severity group			
Mild (score 0-4)	9(30%)	13(41%)	22(35%)
Moderate (score 5-8)	14(47%)	13(41%)	27(44%)
Severe (score >8)	7(23%)	6(19%)	13(21%)
Time since diagnosis (years)			
Median (range)	6(0.5-70)	15(0.25-70)	10(0.25-70)
> 10	9(30%)	17(53%)	26(42%)
> 5 ≤ 10	5(17%)	2(6%)	7(11%)
>1 ≤ 5	10(33%)	6(19%)	16(26%)
>6 months ≤1 year	5(17%)	3(9%)	8(13%)
≤6 months	1(3%)	3(9%)	4(6%)
Bronchiectasis aetiology			
Idiopathic			
Post-infection	12(40%)	10(31%)	22(35%)
Secondary to chronic asthma/COPD	6(20%)	11(34%)	17(27%)
	7(23%)	5(16%)	12(19%)
Immune deficiency associated			
Other ²	2(7%)	1(3%)	3(5%)
	3(10%)	5(16%)	8(13%)
Exacerbations per year			
<3	13(43%)	10(31%)	23(37%)
≥3	17(67%)	22(69%)	39(63%)

¹ Newcastle Bronchiectasis Severity Index, CT scoring not included

² Pink's Disease, Rheumatoid Arthritis, Marfan's Syndrome, Connective Tissue Disease, Wegener's Granulomatosis.

	Control group <i>n</i> =30	Intervention group <i>N</i> =32	Total <i>n</i> =62
Use of home intravenous antibiotics			
Y	8(27%)	15(47%)	23(37%)
N	22(73%)	17(53%)	39(63%)
Clinic attended			
Specialist	28(93%)	30(94%)	58(94%)
General	2(7%)	2(6%)	4(6%)
Prior bronchiectasis hospital admissions			
Y	16(53%)	25(78%)	41(66%)
N	14(47%)	7(22%)	21(34%)
Sputum microbiology			
<i>Pseudomonas aeruginosa</i>	8(27%)	9(28%)	17(27%)
Other ³	8(27%)	11(34%)	19(31%)
Not colonised	13(43%)	11(34%)	24(39%)
No samples	1(3%)	1(3%)	2(3%)
Drug treatments			
Azithromycin	10(33%)	18(56%)	28(45%)
Nebulised antibiotics	6(20%)	3(9%)	9(15%)
Devices used to access internet/resource			
Mobile	2(7%)	8(25%)	10(16%)
Tablet	13(43%)	10(31%)	23(37%)
PC/laptop	28(93%)	28(88%)	56(90%)
No access	0	1(3%)	1(2%)
Previous bronchiectasis information seeking			
None	9(30%)	5(16%)	14(23%)
Paper	9(30%)	14(44%)	23(37%)
Online	14(47%)	16(50%)	30(48%)
In person	4(13%)	3(9%)	7(11%)

³ *Haemophilus influenzae*, *Klebsiella* spp, *Staphylococcus aureus*, *Serratia marcescens*, *Moraxella catarrhalis*, *Escherichia coli*.

6.3 Analysis of feasibility outcome measures

The primary outcome measures for the BRIEF study were those measuring feasibility. These criteria included:-

- Participants' willingness to enter the trial (consented participant to potentially eligible participants approached ratio).
- Participant recruitment rate (as measured by the number of patients randomised divided by the length of the recruitment period). The recruitment period runs from the date that recruitment opened to the date of the last randomisation.
- Participants' acceptability of study design (as measured by the completion rate of participants in each randomised group, 'study completers').
- Participant completion of required study forms and visits as per protocol.

For the primary outcome measures all proportions/rates were calculated as defined (Table 13, Table 14).

6.3.1 Willingness to enter and recruitment rate

As described in section 6.1.6, willingness to enter the trial was as originally predicted. 62/124 (50%) of potentially eligible participants approached entered the study. When removing the 3 ineligible participants, 62/121 (51%) of potential participants were consented and entered the study. Recruitment rate exceeded expectations, with recruitment to target numbers achieved ahead of time. A projected participant recruitment rate of 2-3 per month was surpassed, with an actual recruitment rate of 3.9/month.

Table 13. Participant recruitment.

Outcome measure	Result
Willingness to enter trial (consented participants/ potentially eligible approached)	62/121 (51%)
Participant recruitment rate	3.9/month

6.3.2 Study completion rate

Study completion rates were recorded as a measure of acceptability of the trial design to participants, which formed part of the assessment of feasibility. If the design of the study was acceptable to participants, a higher study completion rate would be anticipated. As described in sections 6.1.2, 6.1.3 and 6.1.5, there were just 2 participants who did not complete the study (1 death and 1 lost to follow-up). There were therefore 60/62 (97%) participants in the 'completers' analysis set. One participant was lost from each of the randomisation groups, leaving a 97% study completion rate in both arms as shown (Table 14). In the study completers group, all participants completed the 3 required study visits as per protocol.

Table 14. Study completion rates.

Outcome measure	(n=62)	
	Control group n=30	Intervention group n=32
Study completers	29/30 (97%)	31/32 (97%)

6.3.3 Completion of study forms

At each visit (as described in Chapter 3), a series of questionnaires were completed. Validated questionnaires were used, plus 3 unvalidated questionnaires, produced for use within this study. The unvalidated questionnaires consisted of the Bronchiectasis Knowledge Questionnaire (BKQ), the Resource Satisfaction Questionnaire (RSQ) and a postal questionnaire concerning symptoms and information use. The analyses of data within all study forms are described individually subsequently. For the purposes of determining feasibility, the completion rates of all questionnaires and lung function tests were examined.

Completion of validated questionnaires and lung function tests

Completion rates of validated questionnaires and lung function tests were excellent (Table 15). The Fatigue Impact Scale (Appendix 25), EQ-5D-5L (Appendix 26) and HADS (Appendix 24) were all fully completed by all study completers at each study visit. Lung function was omitted in one case in both the control and intervention groups, for clinical reasons. The SGRQ (Appendix 23) was well completed in both the control and intervention groups, with the omission of a few individual questions leading to an inability to calculate a total score for just 2/29 cases in the control group

(7%) and 1/31 in the intervention group (2%). When looking at the QOL-B questionnaire (Appendix 22), the figures for 'Treatment burden' seem at first glance to demonstrate a lesser completion rate for this section of the questionnaire (72% in the control group and 71% in the intervention group) compared to the very high completion rates for other sections. This in fact does not represent an issue with form completion. If patients are not taking any treatment, they do not score in this section. This is a feature of the questionnaire scoring system rather than an error or omission in completion. When looking back to the raw data and the paper questionnaires, all had been completed accurately. A summary of complete cases for the validated questionnaires and lung function is tabulated (Table 15).

Table 15. Summary of number of complete questionnaires and lung function at each study visit by randomisation group.

Outcome measure	Control group complete cases (n=29) Number (% rounded)				Intervention group complete cases (n=31) Number (% rounded)			
	V1	V2	V3	Total complete at all visits	V1	V2	V3	Total complete at all visits
FEV1 % predicted	29(100)		28 (97)	28 (97)	31(100)		30 (98)	30 (98)
FIS:-								
Cognitive	29(100)		29(100)	29(100)	31(100)		31(100)	31(100)
Physical	29(100)		29(100)	29(100)	31(100)		31(100)	31(100)
Social	29(100)		29(100)	29(100)	31(100)		31(100)	31(100)
Total	29(100)		29(100)	29(100)	31(100)		31(100)	31(100)
EQ-5D-5L	29(100)	29(100)	29(100)	29(100)	31(100)	31(100)	31(100)	31(100)
HADS	29(100)	29(100)	29(100)	29(100)	31(100)	31(100)	31(100)	31(100)
SGRQ:-								
Symptoms	29(100)		29(100)	29(100)	31(100)		30(98)	30(98)
Activity	28(97)		28(97)	27(93)	31(100)		31(100)	31(100)
Impacts	29(100)		29(100)	29(100)	31(100)		31(100)	31(100)
Total	28(97)		28(97)	27(93)	31(100)		30(98)	30(98)
QOL-B:-								
Physical	29(100)	29(100)	29(100)	29(100)	31(100)	31(100)	31(100)	31(100)
Role	29(100)	29(100)	29(100)	29(100)	31(100)	31(100)	31(100)	31(100)
Vitality	29(100)	29(100)	29(100)	29(100)	31(100)	31(100)	31(100)	31(100)
Emotion	29(100)	29(100)	29(100)	29(100)	31(100)	31(100)	31(100)	31(100)
Social	29(100)	29(100)	29(100)	29(100)	31(100)	31(100)	31(100)	31(100)
Treatment Burden	23(79)	25(86)	26(90)	21(72)	27(87)	26(84)	27(87)	22(71)
Health	29(100)	29(100)	29(100)	29(100)	31(100)	31(100)	31(100)	31(100)
Respiration	29(100)	29(100)	28(97)	28(97)	31(100)	31(100)	31(100)	31(100)

Completion of unvalidated questionnaires

As described, 3 unvalidated questionnaires were also used within the study. Details of the data within these questionnaires is described in more detail in section 6.4.2. Completion rates of these questionnaires were used as measures of feasibility and are described here.

The Resource Satisfaction Questionnaire (RSQ) (Appendix 20) was completed only by the intervention group, and only at visits 2 and 3, as it detailed views and usage of the resource provided. This questionnaire had many individual questions. When looking at overall completion, 31/31 (100%) of those in the intervention group completed the form (Table 16). The breakdown of completion of individual questions is included as an appendix due to the volume of data (Appendix 29). 20/31 (65%) at visit 2 and 19/31 (61%) at visit 3 were completed without any omissions. It must be noted that the form was completed by all participants, but with omissions. Most of these consisted of a few unanswered questions, and it may be that these were felt not to apply rather than just having been missed. This was the first time that this questionnaire had been used, and as stated it is not a validated questionnaire. The main purpose of this questionnaire was to gain feedback on the resource, which is described further in section 6.5.

The Bronchiectasis Knowledge Questionnaire (BKQ) (Appendix 21) was very well completed. Total completion rates at all 3 visits were 28/29 (97%) in the control group and 30/31 (97%) in the intervention group (Table 16). Omissions were minimal. The breakdown of completion of individual questions is supplied as an appendix (Appendix 30).

The third unvalidated questionnaire was a postal symptom and information use questionnaire, completed monthly and returned in the post. Despite the additional effort required to complete and return this form, it was still well completed (Table 16). In the control group, 24/29 (83%) returned form 1, 27/29 (93%) returned form 2, and 29/29 (100%) completed and returned form 3. In the intervention group, 30/31 (97%) returned form 1, 28/31 (90%) returned form 2 and 31/31 (100%) returned form 3. Due to the fact it was not the same participants who failed to return forms 1 and 2 each time, the total completing all 3 of their forms was slightly lower at 21/29 (72%) in the control group, and 27/31 (87%) in the intervention group. This is detailed again on a

per question basis as an appendix (Appendix 31). A summary of total form completion rates is tabulated (Table 16), with individual details appended as detailed. Individual completion rates of forms are all above 90%. Even when looking at those completing all forms at all visits, the lowest rate is 72%. These rates are very reassuring in terms of assessing feasibility for a future trial.

Table 16. Summary of completion and return of unvalidated questionnaires.

Outcome measure	Control group complete cases (n=29) Number (% rounded)				Intervention group complete cases (n=31) Number (% rounded)			
	V1	V2	V3	Total completing at all visits	V1	V2	V3	Total completing at all visits
RSQ						31(100)	31(100)	31(100)
BKQ	29(100)	28(97)	29(100)	28(97)	31(100)	30(97)	31(100)	30(97)
Postal	24(83)	27(93)	29(100)	21(72)	30(97)	28(90)	31(100)	27(87)

6.4 Analysis of secondary outcome measures

The secondary outcome measures recorded were as listed:-

- Forced Expiratory Volume in 1 second (FEV1)
- Number of unscheduled visits to primary or secondary care
- Exacerbation frequency
- Quality of life – Bronchiectasis (QOL-B) (Quittner *et al.*, 2014)
- St George's Respiratory Questionnaire (SGRQ) (Wilson *et al.*, 1997)
- Hospital Anxiety and Depression score (HADS) (Zigmond and Snaith, 1983)
- Fatigue Impact Score (FIS) (Fisk *et al.*, 1994)
- EQ-5D-5L (Herdman *et al.*, 2011)
- Bronchiectasis Knowledge Questionnaire
- Resource Satisfaction Questionnaire
- Postal symptom questionnaire

Secondary outcome measures were recorded at study visits as per the study protocol (Chapter 3). The actual completion rates of the questionnaires listed and lung function tests were used as measures of feasibility and acceptability of the study design as described. The outcome measures themselves were chosen as measures that would be used in a definitive trial of the information resource, to measure impact of the intervention. FEV1, number of unscheduled visits and exacerbation frequency would be used as measures of disease stability. QOL-B and SGRQ are quality of life scores specific to bronchiectasis and respiratory conditions respectively. HADS is used to measure anxiety and depression, known to be prevalent in bronchiectasis, as is fatigue, measured by the FIS. EQ-5D-5L was recorded as a quality of life score that could be used in a definitive trial to estimate any health economic benefit. Recording use of and satisfaction with the information resource would enable assessment of the intervention and any refinements needing to be made to this. This is of use both within this feasibility study as an evaluation of the resource and in a future definitive trial. Knowledge of bronchiectasis was also assessed, using a questionnaire developed for this purpose. It had not been validated, yet there are no other validated knowledge questionnaires for use in bronchiectasis. In a future trial, some assessment of knowledge would be important when measuring impact of the intervention.

In accordance with recommendations for the analysis of feasibility studies (where a formal power calculation is not carried out) the data analysis of these measures was descriptive and statistical comparisons between the randomisation groups were not

undertaken (Lancaster *et al.*, 2004; Thabane *et al.*, 2010). All summaries were interpreted cautiously because of the size of the study and the possible imbalance in pre-randomisation baseline covariates. Due to the nature of the intervention adherence to protocol was not assessed.

6.4.1 Analysis of validated outcome measures

Lung function tests and validated secondary outcome measures for study completers were described at baseline. Baseline data were examined graphically and due to distribution, median and range are presented for complete cases at baseline (Table 17).

Table 17. Baseline data for validated outcome measures.

	Control group (n=29)		Intervention group (n=31)	
	N (complete cases at all time-points)	baseline Median (range)	N (complete cases at all time-points)	baseline Median (range)
EQ-5D-5L⁴				
Index Value	29	0.8 (0-1)	31	0.7 (0.1-1)
Vas	29	70 (30-100)	31	65 (20-95)
SGRQ⁵				
Symptoms	29	61 (21-93)	30	74 (12-91)
Activity	27	59 (12-100)	31	60 (0-100)
Impacts	29	29 (0-83)	31	36 (5-65)
Total	27	49 (17-86)	30	48 (10-88)
QOL-B⁶				
Physical	29	53 (0-100)	30	53 (0-100)
Role	29	73 (7-100)	30	73 (7-100)
Vitality	29	44 (0-100)	30	44 (0-77)
Emotion	29	92 (44-100)	30	92 (25-100)
Social	29	67 (0-100)	30	63 (8-100)
Treatment Burden ⁷	21	78 (22-100)	22	78 (22-100)
Health	29	50 (0-83)	30	42 (0-92)
Respiration	28	62 (11-100)	30	52 (19-100)
HADS⁸				
A	29	5 (1-13)	31	6 (0-14)
D	29	3 (0-12)	31	4 (0-8)
FIS⁹				
Cognitive	29	5 (0-34)	31	6 (0-21)
Physical	29	12 (0-38)	31	12 (0-32)
Social	29	11 (0-71)	31	11 (0-47)
Total	29	30 (0-143)	31	31 (0-93)
FEV1 (%predicted)	28	77 (21-120)	30	67 (10-110)

⁴ EuroQol 5D 5L: self-reported health status (Index Value range: VAS range: 0-100%)

⁵ St George's Respiratory Questionnaire: Scores are expressed as a percentage of overall impairment where 100 represents worst possible health status and 0 indicates best possible health status.

⁶ Quality of Life – Bronchiectasis: Scaled score 0-100, higher scores= better quality of life

⁷ Treatment burden is not scored if participant is on no treatment hence apparent lower n.

⁸ Hospital Anxiety and Depression Score: Anxiety 0-21, depression 0-21. 11+ significant

⁹ Fatigue Impact Scale: Cognitive: 0-40, Physical: 0-40, Social, 0-80, Total 0-160. Higher score=bigger impact of fatigue.

For validated questionnaires scored using provided calculators, pre-determined rules for missing data were followed. For those questionnaires that were either unvalidated or had no pre-defined rules for dealing with missing data; missing data points were treated as such. Missing data due to participant non-completion of study questionnaires were not imputed and therefore the analyses of change data were for complete cases (i.e. those participants completing the particular outcome/questionnaire at each of the specified time-points) on an outcome by outcome basis. Numbers of complete cases and descriptive analysis of baseline and change data is tabulated (Table 17, Table 18) and each measure described individually.

EQ-5D-5L

This is a brief questionnaire consisting of 5 dimensions (mobility, usual activities, self-care, pain/discomfort and anxiety/depression) (Appendix 26) (Herdman *et al.*, 2011). Participants rate these each on a scale of 1-5. An index value is calculated from these scores and in addition a self-scored measure of health on a visual analogue scale (VAS) labelled from 'worst health you can imagine' to 'best health you can imagine'. All questions are answered as the participants health is 'today'. In addition to assessing quality of life, this scale allows estimation of health economic evaluation for a future trial. If patients' understanding and self-management are improved by an intervention (the information resource) then this could facilitate a reduction in service use and consequent reduction in costs to the NHS. For the purposes of this study, feasibility outcomes were looked at, and data described to aid in planning a future trial, rather than attempting to assess any benefit at this stage. The EQ-5D-5L had a 100% completion rate, completed by all participants at all visits in each of the randomisation groups (Table 15). Median score at baseline for the VAS was 70 (30-100) in the control group, and 65 (20-95) in the intervention group, with an index score of 0.8 (0-1) in the control and 0.7 (0.1-1) in the intervention group (Table 17). Change data is also presented (Table 18).

SGRQ

The St George's Respiratory Questionnaire is a quality of life and respiratory health questionnaire (Wilson *et al.*, 1997) (Appendix 23). Scales differ for different questions in part 1, and in part 2 responses are mainly true or false. Scores are calculated using an official calculator tool. Scores are obtained for Symptoms, Activity, Impacts, and a Total score. Each score is expressed as a percentage of overall impairment

where 0 is the worst and 100 the best. Median (range) baseline scores (Table 17) and change data were recorded (Table 18). Completion rates were good for SGRQ, with 27/29 (93%) obtaining data complete enough to calculate a total score at all visits in the control group, and 30/31 (97%) in the intervention group (Table 15). Median total score at baseline in the control group was 49 (17-86) and 48 (10-88) in the intervention group.

QOL-B

QOL-B is a quality of life questionnaire specific to bronchiectasis (Quittner *et al.*, 2014) (Appendix 22). A score is calculated in 8 domains (physical, role, vitality, emotion, social, treatment burden, health and respiration) with no total score calculation. Scores are scaled 0-100, with higher scores indicating better health. As can be seen (Table 15), completion rates at all visits were 29/29 (100%) in the control group, and 30/31 (97%) in the intervention group, for all bar the treatment burden domain. This is a feature of the QOL-B scoring system, in that a treatment burden score is simply not generated if patients take no treatment. The lower 'complete case numbers' of 21/29 (72%) and 22/31 (71%) reflect the number of generated scores for this domain. This does not therefore represent a problem with form completion, but the number of patients within each group who do not take regular treatment for bronchiectasis. Median (range) baseline scores (Table 17) and change data (Table 18) are summarised.

HADS

The Hospital anxiety and depression scale is a short questionnaire completed by the participants (Zigmond and Snaith, 1983) (Appendix 24). Completion of this form was 100% at all visits in each randomisation group (Table 15). There are 7 questions relating to anxiety, each scaled response from 0-3, and the same for depression. Total scores for each domain range from 0-21. Higher scores represent worse anxiety or depression, with scores of 11 or more being clinically significant. As can be seen in the table (Table 17), median baseline scores for anxiety were 5 (1-13) in the control group and 6 (0-14) in the intervention group. Depression median baseline scores were 3 (0-12) and 4 (0-8) in the control and intervention groups respectively. All median baseline scores are below significance level.

FIS

The fatigue impact scale is subdivided into cognitive, physical and social domains and then a total score is calculated (Fisk *et al.*, 1994) (Appendix 25). The questionnaire consists of 40 questions with scaled responses indicating how much of a problem fatigue presents in different areas of one's life. It is answered with the past 4 weeks in mind. Total score can be from 0-160, with higher scores indicating a greater impact of fatigue. A score of 40 or more is considered to be significant. This questionnaire had 100% completion at all visits in both groups (Table 15). Baseline data show a median total score of 30 (0-143) in the control group and 31 (0-93) in the intervention group (Table 17). Change data are also tabulated (Table 18).

FEV1 % predicted

Spirometry was performed at baseline and visit 3. There was only 1 omission per group due to participants not being able to perform the test (Table 15). The Forced expiratory volume in 1 second (litres) and the percentage this volume was of the participants predicted ideal FEV1 were recorded (Table 17, Table 18). At baseline the median FEV1 % predicted was 77 (21-120) in the control group, and 67 (10-110) in the intervention group. There is possibly a slightly lower overall FEV1 % predicted in the intervention group at baseline, but no statistical significance can be attached to this. Change data is also presented (Table 18).

Overall the quality of the data for the validated questionnaires is excellent: the number of complete cases is high, with over 97% of complete cases for each of the outcome measures. The majority of measures at baseline seem comparable between groups. The data demonstrates that for a large number of outcome measures there is enormous variation between and within participants. The change from baseline to 12 weeks (and 2 weeks where applicable) was also summarised (Table 18). Data were again examined graphically and the majority of change data were approximately normally distributed, although for some variables the change data were slightly skewed. It was decided most appropriate to report the change data consistently as mean (SD) given the normal (or near-normal) distribution of data. Change data is most often symmetrical and presenting the data in this way allows it to be used if calculating a sample size for a future definitive study based on this feasibility study design. Although the validated outcome measure data at baseline have been described using medians and ranges in Table 9, they are summarised again using means (SD) so that the change summary measures can be interpreted in context. No further statistical

interpretation has been made of this basic change data nor of any apparent change within allocation groups given the fact that this cannot be meaningfully interpreted without further analysis and can be misleading (Vickers and Altman, 2001; Bland and Altman, 2011).

Table 18. Summary of baseline and change data for lung function and validated questionnaires.

	n	Control group n=29			N	Intervention group n=31		
		Baseline mean (sd)	mean change ¹⁰ baseline to 2 weeks (sd)	mean change baseline to 12 weeks (sd)		Baseline mean (sd)	mean change baseline to 2 weeks (sd)	mean change baseline to 12 weeks (sd)
EQ-5D-5L¹¹								
Index Value	29	0.75(0.24)	0.01(0.17)	-0.50(0.19)	31	0.70(0.23)	0.06(0.13)	2.11(11.7)
VAS	29	68.6(18.5)	-1.55(13.0)	0.48(16.2)	31	65.4(18.0)	5.97(12.0)	-3.0(16.7)
SGRQ¹²								
Symptoms	29	57.6(23.4)		0.25(15.0)	30	65.9(21.3)		-7.89(25.7)
Activity	27	56.3(23.5)		-4.85(13.4)	31	56.1(28.3)		-4.79(14.8)
Impacts	29	33.6(21.5)		0.02(11.3)	31	32.9(17.2)		-3.06(13.0)
Total	27	46.1(19.9)		-1.53(8.3)	30	44.9(19.1)		-2.62(9.46)
QOL-B¹³								
Physical	29	48.1(32.3)	2.30(17.8)	-3.85(16.7)	30	51.6(35.1)	3.11(16.2)	-4.94(25.2)
Role	29	63.5(29.3)	0.23(13.6)	1.32(17.6)	30	64.9(25.8)	5.33(18.7)	2.22(17.8)
Vitality	29	44.1(24.0)	-1.53(18.5)	0.38(16.9)	30	43.7(22.4)	4.44(18.4)	-0.74(21.0)
Emotion	29	84.0(17.0)	1.05(14.9)	-2.1(13.0)	30	85.0(18.6)	4.44(15.3)	2.22(10.2)
QOL-B								
Social	29	59.7(31.2)	-0.77(22.1)	2.97(14.7)	30	58.1(22.8)	5.37(17.2)	3.14(19.0)
Treatment burden ¹⁴	21	71.2(22.7)	-1.06(16.8)	0.53(14.7)	22	71.7(21.6)	2.02(14.8)	1.01(14.1)
Health	29	45.0(25.3)	1.25(18.2)	-0.10(13.0)	30	44.0(24.3)	7.04(15.8)	3.06(18.4)
Respiration	28	60.6(23.7)	3.97(17.3)	3.6(16.3)	30	54.3(22.8)	9.7(14.6)	6.3(16.8)
HADS¹⁵								
A	29	5.69(3.87)	-0.14(2.86)	-0.31(3.11)	31	5.87(4.01)	-1.32(2.4)	0.44(6.6)
D	29	4.52(3.61)	0.00(2.38)	0.14(1.76)	31	3.81(2.33)	-0.10(1.7)	2.12(13.2)

¹⁰ A negative change indicates a numerical fall on average from baseline to 12 weeks.

¹¹ EuroQol 5D 5L: self-reported health status (VAS range: 0-100%)

¹² St George's Respiratory Questionnaire: Scores a percentage of overall impairment .100 represents worst possible health status and 0 indicates best possible health status.

¹³ Quality of Life – Bronchiectasis: Scaled score 0-100, higher scores= better quality of life

¹⁴ Treatment burden is not scored if participant is on no treatment hence apparent lower n.

¹⁵ Hospital Anxiety and Depression Score: Anxiety 0-21, depression 0-21. 11+ significant

	n	Control group <i>n</i> =29			N	Intervention group <i>n</i> =31		
		Baseline mean (sd)	mean change ¹⁰ baseline to 2 weeks (sd)	mean change baseline to 12 weeks (sd)		Baseline mean (sd)	mean change baseline to 2 weeks (sd)	mean change baseline to 12 weeks (sd)
FIS¹⁶								
Cognitive	29	8.52(9.44)		2.07(7.2)	31	7.55(5.84)		1.26(5.7)
Physical	29	15.52(12.3)		-1.69(5.6)	31	12.9(8.18)		0.39(6.9)
Social	29	21.79(21.95)		-0.59(8.8)	31	15.7(13.4)		2.72(12.9)
Total	29	45.8(42.5)		-0.21(18.3)	31	36.2(26.0)		2.70(19.7)
FEV1 (%predicted)	28	72.6(26.7)		3.78(8.61)	30	63.7(23.8)		-0.78(10.1)
FEV1 (Litres)	28	1.82(0.73)		0.08(0.23)	30	1.64(0.75)		0.23(1.15)

¹⁶ Fatigue Impact Scale: Cognitive: 0-40, Physical: 0-40, Social, 0-80, Total 0-160. Higher score=bigger impact of fatigue.

6.4.2 Analysis of unvalidated questionnaires

The BRIEF study used several unvalidated questionnaires as described. These were primarily used to assess participants' engagement with such questionnaires for any future studies and to evaluate the resource. A secondary aim of the questionnaires was to develop some data on the participants' knowledge about bronchiectasis, their current symptoms and use of healthcare services. Three questionnaires were produced and will be reported individually. Change data has not been formally calculated for these measures, but the results are described and tabulated below.

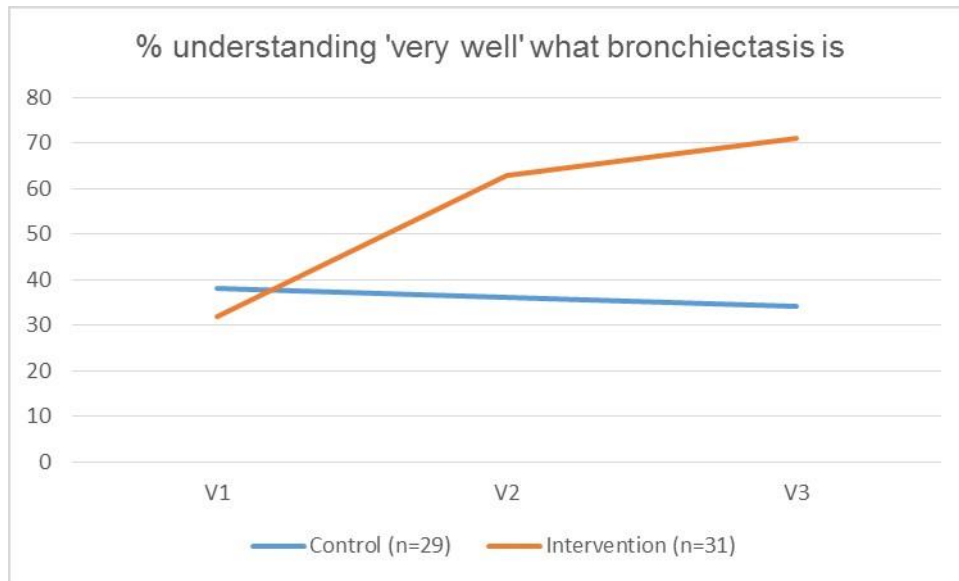
The Bronchiectasis Knowledge Questionnaire

The Bronchiectasis Knowledge Questionnaire (BKQ) is an unvalidated questionnaire created for use within this study (Appendix 21). There are no validated questionnaires assessing knowledge of bronchiectasis currently available. Given the lack of available materials, and the need to measure participants' understanding of their condition, I opted to produce a questionnaire aiming to assess knowledge and understanding specific to bronchiectasis. The BKQ was additionally used to assess engagement with a knowledge questionnaire in the absence of an existing validated questionnaire. Although a formal questionnaire development process was not used (the BKQ was not piloted and validated prior to its use within this study), a rigorous and methodical approach was taken. Other validated respiratory knowledge questionnaires were used for reference. An example is the Bristol COPD Knowledge Questionnaire, which consists of 13 questions to be answered 'true', 'false' or 'don't know' (White *et al.*, 2006). However, this specific questionnaire was not suitable for direct use within our study with patients who have bronchiectasis. The questions within the BKQ were designed to reflect aspects of understanding about bronchiectasis that the specialist team and patients and carers had already identified as being important throughout the qualitative phases of this work. I began the development by creating a list of subject areas that were identified within interviews as areas that people wanted more information about, or had a lack of understanding of. I then formulated questions and had the questionnaire reviewed by members of the bronchiectasis service specialist team, including a bronchiectasis consultant and specialist nurse. Revisions were made based upon these discussions to both the question content and format. The questionnaire was then further reviewed by user representatives. The questions in the final version of the BKQ aimed to establish knowledge about areas considered (by users and professionals) to be relevant to

patients being able to understand and manage their condition appropriately. The aim was to assess knowledge and re-assess after use of the information resource. The BKQ is in 2 parts. The first part consists of 15 statements about bronchiectasis to which the respondent can select from 4 responses to grade their understanding of that issue. The second part comprises 11 questions to be answered true, false or don't know. As the primary role of this questionnaire was to assess engagement, responses were summarised as numbers and percentages of participants giving each response at each study visit. Participants who did not complete each question at each visit were not excluded from this analysis as absolute numbers and percentages giving each response were recorded at each visit. Individual change data were therefore not calculated for this unvalidated questionnaire. The main findings are presented here and a summary of all question responses is tabulated and presented as an appendix due to the volume of data (Appendix 32).

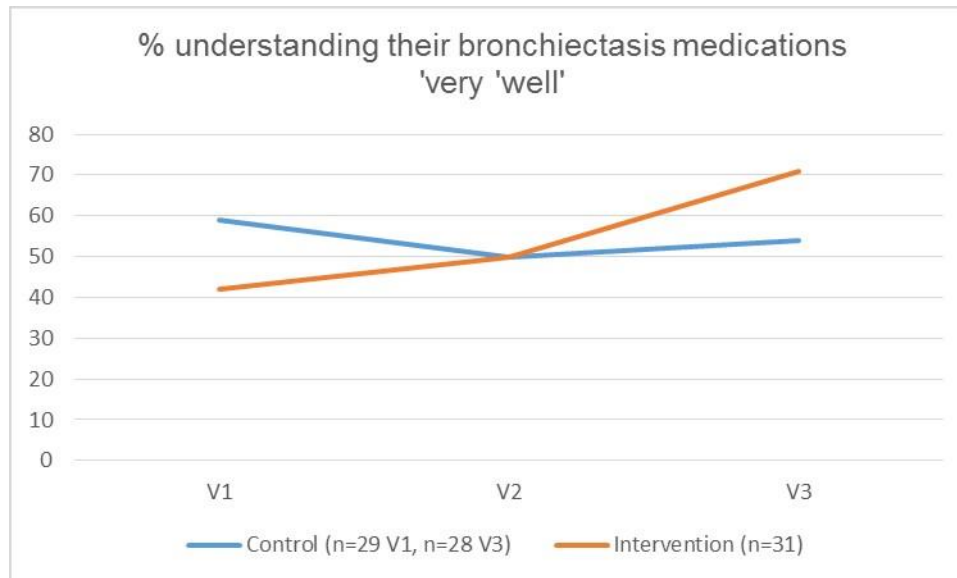
Completion rates and data quality for the BKQ were excellent. As the BKQ is an unvalidated questionnaire being used within a feasibility study, it is not possible to establish whether or not there are significant improvements in knowledge as a result of the intervention. However, increases in participants reporting understanding aspects of their condition 'very well' seem to be more obvious across study visits in the intervention group than the control group (Appendix 32). For example, 'I understand what bronchiectasis is' was graded 'very well' by 10/31 (32%) at visit 1 rising to 22/31 (71%) at visit 3 in the intervention group. In the control group percentage understanding this 'very well' remained roughly the same: visit 1, 11/29 (38%) and visit 3 10/29 (34%) (Figure 12).

Figure 12. Percentage understanding 'very well' what bronchiectasis is.



The percentage understanding 'very well' what their treatments were for increased from 13/31 (42%) to 22/31 (71%) in the intervention group, yet again remained the same in the control group: visit 1 17/29 (59%), visit 3 15/28 (54%) (Figure 13).

Figure 13. Percentage understanding 'very well' what their treatments are for.



The percentage understanding 'very well' what to do when having a bronchiectasis flare up rose from 17/31 (55%) to 25/31 (81%) in the intervention group, whereas the control group again remained the same (Figure 14). Importantly for this study, understanding 'very well' where to get more information rose from 9/31 (29%) to 22/31 (71%) in the intervention group, and remained the same in the control group (Figure 15).

This pattern can be seen for several questions, yet no statistical significance can be attached to this due to the nature of the study (feasibility study, not powered to detect such change) and the questionnaire (unvalidated). It also should be noted that there are other questions for which such patterns were not seen (Appendix 32).

Figure 14. Percentage understanding very 'well' how to manage a flare up.

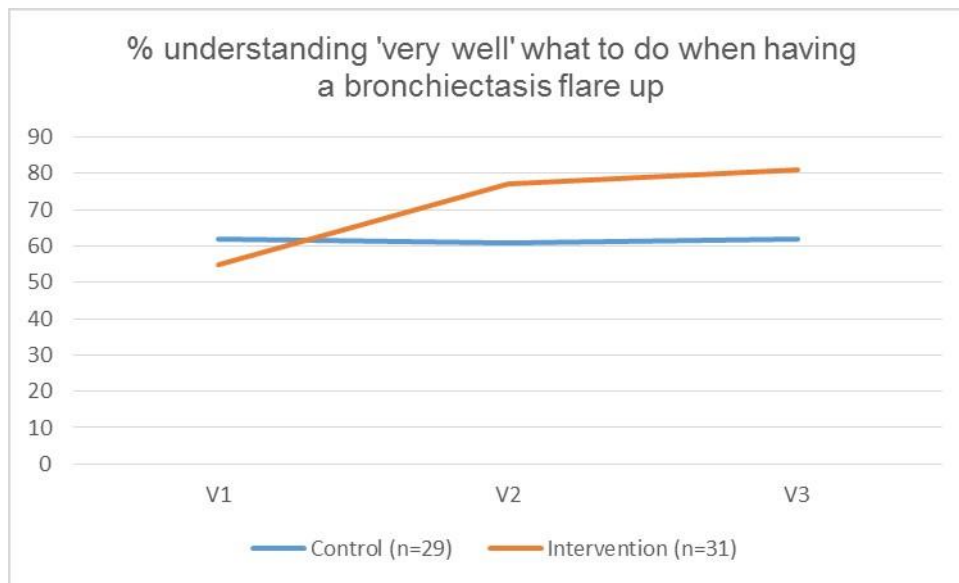
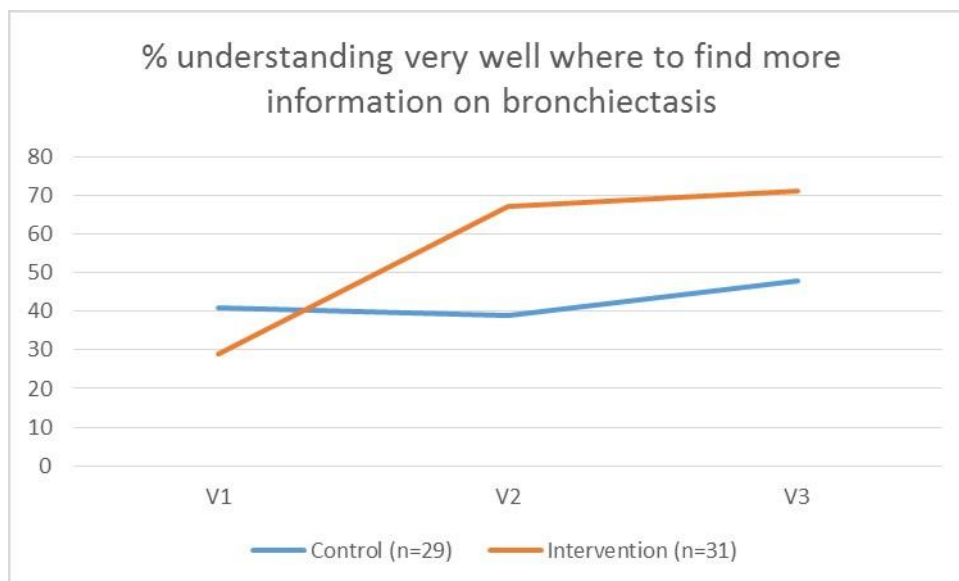


Figure 15. Percentage understanding very 'well' where to find more information.



The postal questionnaire

A postal questionnaire was sent out each month to study participants (Appendix 19). For postal questionnaire 1 (week 4) and 2 (week 8), they were asked to complete and return the 1 page document in a prepaid envelope. The third and final questionnaire was actually completed at the final study visit (week 12) rather than by post, which is reflected in the 100% completion rate for this third form. Overall the completion rates were excellent and above expected (Table 19), with a systematic review of postal questionnaires in studies reporting an average rate of 65% (Nakash *et al.*, 2006). The same review reported that telephone follow up reminders and shorter forms improved completion and return rates, both of which were strategies used within this study.

Table 19. Postal questionnaire completion rates.

Return of postal questionnaires	Control group(n=29) n (%)	Intervention group (n=31) n (%)
1	24(83%)	29(94%)
2	26(90%)	30(97%)
3	29(100%)	31(100%)

The questionnaire had 3 sections, covering current level of symptoms compared to their usual, any additional treatments or medical advice required and use of information since their last visit. This was an unvalidated questionnaire developed for the purposes of this study and specific change data has not been calculated. Results are presented as numbers answering and rounded percentages. All responses are included. Main findings are presented here and again full summaries of responses are tabulated and presented as an appendix due to volume of data (Appendix 33).

In the intervention group, at month 1, 25/29 (86%) reported having used the information, at month 2, 19/28 (68%), and at month 3, 24/31 (77%). This demonstrates that, overall, those who received the resource report using it, with the majority stating they used the resource weekly or monthly rather than daily. Interestingly, some participants in the control group appeared to answer in error to the questions about the information resource, claiming to have used the resource daily or weekly, despite being in the control group with no access to the resource.

This suggests in future studies the questionnaire needs to be further developed and piloted. Providing some explanation about which questions to answer, or indeed a questionnaire specific to each randomisation arm are possible considerations.

The remainder of the postal questionnaire posed questions about health and service use specific to bronchiectasis. In a definitive trial over a longer follow up period, responses to questions about current level of symptoms could be used to identify the potential impact of the intervention on exacerbation rate and unscheduled use of healthcare services. In this feasibility study they were well completed, yet are not validated questionnaires. It is noteworthy that the reports are consistent with a high morbidity population with considerable numbers reporting seeking GP or specialist help.

6.5 Resource evaluation

Further aims of the study were to evaluate the resource that had been developed, and assess its acceptability for use. For this to be done, we asked for feedback from participants about the information package provided. The resource was in 3 main formats: website, overview booklet and PDF version of website for those without internet access. A questionnaire: The Resource Satisfaction Questionnaire (RSQ) (Appendix 20) was created for use within the study in order to ask questions about the resource and participants' preferences. In addition, at the end of the study, participants (and their carers) were invited to a focus group to discuss both the resource itself and the trial process. Whilst the trial was running, the website use was also monitored using basic level analytics to determine page views, navigation through the site and attempts at access from those outside of the study.

6.5.1 The Resource Satisfaction Questionnaire

The RSQ was produced to enable feedback on the use of the resource from the participants within the intervention group only. As this relied upon their experiences of using (or not using) the resource it was not completed at the first study visit. A series of questions were asked about the use of the information provided and their opinions of it. Both scaled responses and free text were used within the questionnaire. For scaled response questions, options were: 'strongly disagree', 'disagree', 'neither', 'agree' or 'strongly agree'. For the purposes of summarising responses here, these have been further grouped into 'disagree' ('strongly disagree' and 'disagree' combined), 'neutral' or 'agree' ('strongly agree' and 'agree' combined).

This is an unvalidated questionnaire designed to provide feedback about the resource. All completed participant responses have been included for each visit within the summaries presented. Participants who did not complete each question at each visit were not excluded from this analysis, but absolute numbers and percentages giving each response were recorded at each visit. Individual change data were therefore not calculated for this unvalidated questionnaire. The main findings are presented here and summaries of all question responses are tabulated yet presented as an appendix due to the amount of data (Appendix 34, Appendix 35).

About the information overall

The completion rates were again excellent (100% of study completers, n=31), and 87% reported that they had used the information provided (Table 20).

Table 20. RSQ: overall use of information.

	Numbers in intervention group completing questionnaire (n=31)	Yes n (%)	No n (%)
Did you use the information provided?			
Visit 2	31	27(87)	4 (13)
Visit 3	31	27(87)	4(13)

Of those that used the information, 25/27 (93%) reported that they found it useful (Table 21). More than 80% thought that the information was easy to use, covered the topics they wanted and that the right amount was given. By visit 3, 18/28 (64%) felt that they were more able to manage their bronchiectasis. Over 50% had shared the information with their family. Interestingly, knowledge was reported to have improved in 22/27 (81%) at visit 2, but only 18/28 (64%) at visit 3 (Table 21). This could potentially reflect a reduction in use of the resource as time went on, or an interpretation of the question to mean an increase in knowledge since the last study visit rather than since the start of the study. It is also important to note that this is not looking at individual change on a case by case basis, but an overall number and percentage of the group who gave each response at each visit. Due to the small numbers involved and the unvalidated nature of the questionnaire it is therefore not possible to draw absolute conclusions from this.

Table 21. RSQ: Review of information resource overall.

	Numbers completing questionnaire (n=31)	Agree n (%)	Neutral n (%)	Disagree n (%)
1. I found the information useful.				
V2	27	25(93)	1(4)	1(4)
V3	28	26(93)	1(4)	1(4)
2. My knowledge about my condition has improved.				
V2	27	22(81)	4(15)	1(4)
V3	28	18(64)	8(29)	2(7)
3. I feel more able to manage my condition.				
V2	27	13(48)	12(44)	2(7)
V3	28	18(64)	8(29)	2(7)
4. The information provided was easy to understand.				
V2	27	26(96)	0	1(4)
V3	28	25(89)	1(4)	2(7)
5. The right amount of information was given.				
V2	27	24(89)	2(7)	1(4)
V3	28	23(82)	4(14)	1(4)
6. The things I wanted to know about were covered.				
V2	27	25(93)	2(7)	0
V3	28	24(86)	2(7)	2(7)
7. My partner/family member/friend used the information.				
V2	27	11(41)	3(11)	13(48)
V3	27	15(56)	4(15)	8(30)

About the website

At study entry, those in the intervention group received a login and password to access the online version of the information resource (www.bronchiectasis.me) in addition to the overview booklet. More than 60% reported to have used the website (Table 22).

Table 22. RSQ: Website use.

	Numbers in intervention group completing questionnaire (n=31)	Yes n (%)	No n (%)
I used the website.			
V2	30	19(63)	11(37)
V3	28	18(64)	10(36)

The full summary of responses has been tabulated as an appendix due to the volume of data (Appendix 34). Of note, 19/20 (95%) at visit 2 and 20/21 at visit 3 (95%) agreed that it was easy to find the sections they wanted to look at within the website. At visit 2, 90% of participants completing the questionnaire thought the video clips and diagrams were helpful. In addition 90% (18/20) stated that they found the login procedure easy to use. At visit 3, approximately 50% (11/21) reported that the website was their preferred version of the provided information. Response rates to individual questions can be seen in the appended table. Again, these are overall numbers and percentages for each question answered and do not look at change between visits for individual participants.

About the overview booklet

Those in the intervention group also received a 15 page A5 sized information booklet about bronchiectasis to accompany the online information resource. At visit 2, 28/31 (93%) reported to have used the overview booklet, and 24/31 (77%) at visit 3 (Table 23). As discussed, this may reflect answering the question as 'since last visit' rather than since the start of the study.

Table 23. RSQ: Booklet use.

	Numbers in intervention group completing questionnaire (n=31)	Yes n (%)	No n (%)
I used the overview booklet.			
V2	31	28(93)	3(7)
V3	31	24(77)	7(23)

Half of participants that completed the questionnaire reported that the overview booklet was their preferred version of the information resource, which is in keeping with the preferences reported for the website. The vast majority reported that the text was easy to read and it was easy to find the sections they wanted. The majority also reported having looked at the whole booklet rather than just certain sections. The detailed summary of these findings are tabulated as an appendix due to volume of data (Appendix 35).

About the PDF

Within the website it was possible to download the text and images for each section as a PDF (Portable Document Format). This was offered as an option at entry to the study for those who did not have internet access. In the PDF version however, the video clips were obviously not able to be viewed and interactive features could not be used. Two participants chose this option of study entry.

This section of the questionnaire sought feedback about the PDF version from those who had the PDF at entry to the study and to establish if participants used this function within the website. From the summary table (Table 24) it can be seen that the vast majority of participants did not use this facility.

Table 24. RSQ: PDF use.

	Responders n	Yes n (%)	No n (%)
I downloaded the PDF.			
V2	30	4(13)	26(87)
V3	28	6(21)	22(79)
I printed out the PDF.			
V2	25	2(8)	23(92)
V3	24	2(8)	22(92)
I received the PDF in place of the website at study entry.			
V2	24	2(8)	22(92)
V3	20	1(5)	19(95)

RSQ free text feedback

At the end of each section of the RSQ, there was a space for participants to add free text comments or suggestions. This was not always completed but there was some very useful feedback. Positive feedback in free text is tabulated (Table 25).

Table 25. RSQ free text positive feedback.

	Positive Comments
Regarding the use of video	Enjoyed watching the video of patients
	Video clips helpful.
	Liked patient video clips.
	Found videos comforting
	Found videos of patients doing nebulisers useful
	The videos were good
	Confirmation of own self-management technique helpful also seeing other patients -same problems helpful.
Regarding the website	I will use the website in future especially as I will be out of the country for 2 months
	Website excellent
General overall views	Quite happy with resources provided
	Everything was clear and easy to understand
	Thought good and clear, language good, easy to understand.
	Well balanced
	Well done
	I can never have enough information
Regarding use by family	My youngest son has a better understanding of bronchiectasis

The videos were commented on frequently and these were positive comments, the only negative comments concerning the video clips were that people would have liked to have seen more of them. In the main, negative comments seem to be about the access to the website (Table 26). These could reflect a lack of clarity with the access procedure, however 90% reported in the RSQ that the login process was easy to use. It is possible that they may reflect personal technical issues.

Any problems or suggestions for improvement were also recorded and tabulated (Table 26). This feedback was assimilated and reviewed in advance of the end of study focus group, to ensure any issues that had been raised were further explored.

Table 26. Free text suggestions for improvement.

	Problems or suggestions
Regarding the use of video	Would like more case studies
	A patient sharing how to use the nebuliser would be more helpful than a technician showing how it works.
	More patient stories
Regarding the website	Problems getting on to internet site
	Unable to access website.
	When scrolling down things disappeared but did come back.
	Login email + password could be clearer
	Patient unable to access website due to invalid password. Advice sought from Research staff
	Could not access web on my computer
	Could not get on website : - password
General overall views	I have not used the information provided due to hospital stay and work commitments
	I find that now the information has stopped for me. I.e. there is nothing new to read about.
Regarding use by family	Family members not interested – just want me well, quite embarrassed about emotion and keep quiet about my condition

6.5.2 The end of study focus group

Following the last participant's last study visit, participants (and their carers) were invited to a focus group to strengthen data obtained from the RSQ, and to discuss the trial process. A pragmatic approach was taken to the purposive sampling for participant selection with a view to inviting a range of participants. In total, 11 people attended the focus group which was facilitated by me. There were 8 patient participants and 3 carers. There were a mix of male and female participants and carers from both the control and intervention group. One participant had no internet access and had elected to enter the study with the PDF version of the site. Participants had a range of ages and times since diagnosis.

The focus group aimed to explore participants' experiences of taking part in the BRIEF study and their views on the information resource. As with the interviews (Chapter 4), and to some extent the co-development workshops (Chapter 5), the main content of the discussion was in fact people's experiences of living with bronchiectasis. I did have pre-defined questions that I wanted to address in the form of a topic guide (Appendix 27) and although I made repeated attempts to concentrate on these areas, the need of the participants to discuss amongst each other their shared experiences was clear, and tended to dominate the conversation. The focus group lasted for approximately one hour, and I used the booklet and the website to prompt discussion.

Areas of discussion common to the interviews included delay to diagnosis, a lack of understanding of bronchiectasis amongst GPs and wanting guidance on management. There was relatively little discussion about the trial process itself, with participants reporting not having found it burdensome. Regarding the content of the information resource, participants commented that they had learnt new things, such as fatigue being a symptom linked with bronchiectasis, for example.

Participants made positive comments about the booklet, including it being easier to have a quick look at, particularly if you didn't have internet access. One participant talked about how he had given the overview booklet to his friend who had been diagnosed with bronchiectasis and that the friend had found it very helpful. They also thought it was a good resource for learning about how to find more information on bronchiectasis.

The website also received favourable reviews, in particular in comparison to other available resources as this carer stated:

‘To answer your question about the website, because I’ve looked at other things, I think it’s clear, concise...it’s easier to understand...the thing that’s good about it you’ve got a carer’s perspective, you’ve got patient perspective, consultant and so on.’ FGC1 770-778.

He qualifies his opinion by explaining that he has seen other resources and explains that he liked the fact that this information resource is both patient and carer-orientated. Another participant echoed this saying that it would be useful for your family, particularly if you are too unwell to want to look at the information. Further positive features of the website that were identified were the videos; that you can’t mislay it like you could a leaflet; and that it is easier to update.

There were some negative comments, including issues with passwords. Forgetting passwords or not being able to log on easily was clearly a barrier to use. These reflect the negative comments within the RSQ. Ease of access to the site was possibly an aspect that could be improved upon.

6.5.3 Website analytics

Google Analytics was used to perform basic web analytics for the website www.bronchiectasis.me. Each individual’s activity was not monitored, but this did allow an overall view of how and when the site was accessed, how long people stayed on the site, which pages had the most views and how users navigated the site.

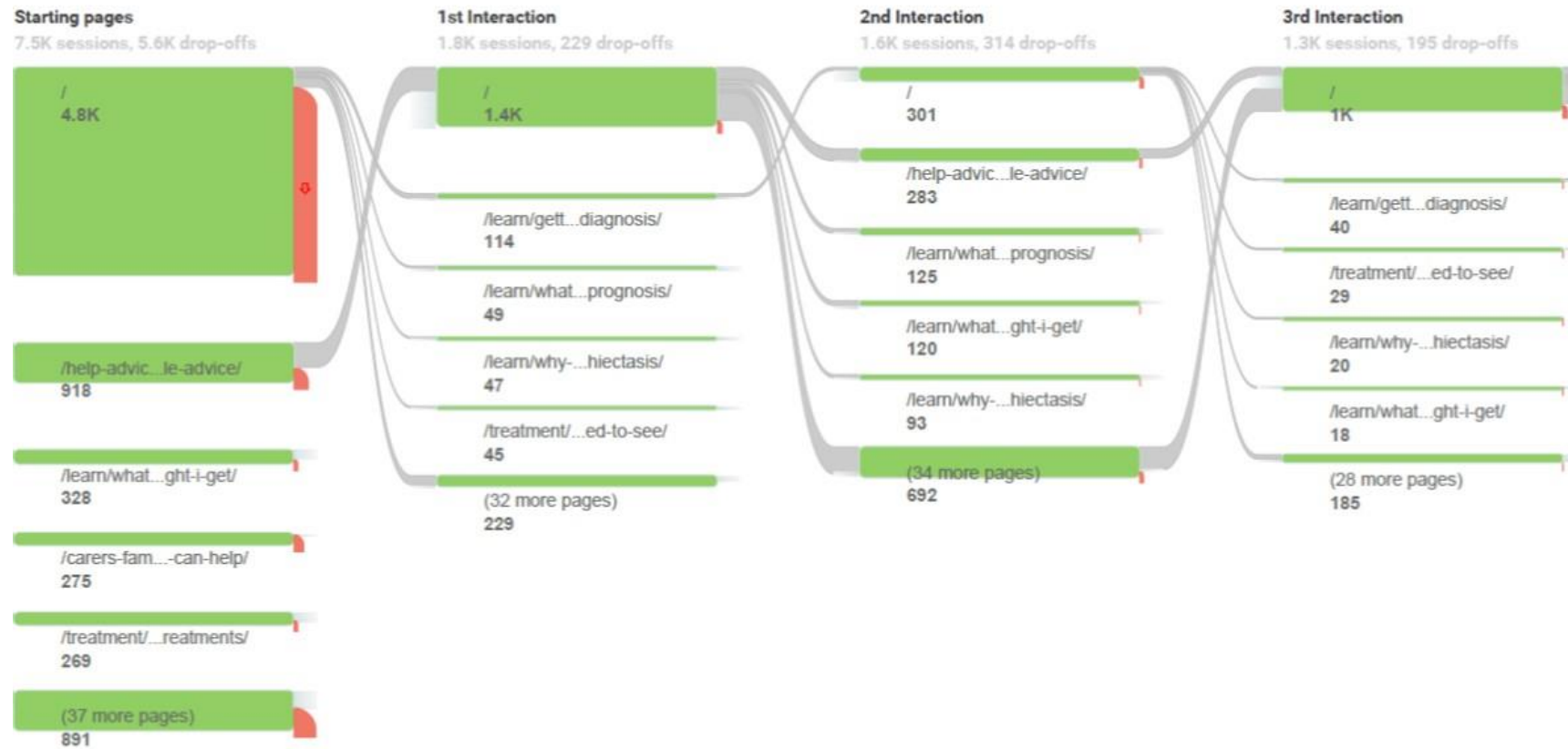
The website could be found using internet search engines, yet a password was required to access it beyond the homepage. The home page explained that the site was for use within a study and that access to the site for those not in the study was not possible. An email address was on this home page and I received multiple emails from people who had bronchiectasis both locally and from all over the world who wanted advice about their condition. I replied to emails detailing the study and advising people to see their own doctor.

Looking at the web analytics, the countries of origin of those attempting access to the site included the USA, UK, Japan, Canada, Russia, Japan, Brazil, China, India, Australia, and many more. The ‘bounce rate’, i.e. those who exited the site on the

same page they entered it without looking around (presumed in the main to be due to inability to gain further access to the site due to a lack of password) was 68%. Over the duration of the study, there were 7553 sessions by 6456 users, with over 20,000 page views. The average numbers of pages per session was 2.71, yet this will be skewed hugely by the number of those only viewing the home page. During this time period 13% of page views were from returning visitors to the site. We noted part way through the study that some page content could be read behind the pop up box when accessing a page other than the homepage via internet search engines. This was addressed by making the background page darker so that it was unreadable.

When looking at the most popular pages within the site, it is possible to look at 'user flow'. This shows how users navigate through the site, which pages they go to first and what they go to next, and how many drop offs there are at each step. An example snapshot of this is shown below (Figure 16).

Figure 16. User flow for first 3 interactions with the site.



When looking over the flow analysis, it is clear that the pages about diet and lifestyle advice are the most popular, with ‘learning about prognosis’; ‘getting a diagnosis’; ‘why have I got bronchiectasis?’; ‘what symptoms I might get?’ and ‘who might I need to see?’ also being very popular. Total numbers of page views for these pages are tabulated below (Table 27). This would include those that were ‘bounced’ from these pages. It is likely that people who attempted to look at the page after searching for example for ‘diet and lifestyle advice in bronchiectasis’ using a search engine form the majority of these. If one used a search engine to search for the above, one would be directed to the page, but a pop up asking for log in details would cover the screen. For this reason the bounce rate is also tabulated. Although this data does not accurately describe the use of the site for individual participants, to be able to capture the overall use, and worldwide searching for, or interest in, identifiable topics is of great value.

Table 27. Website page views.

Webpage	Number of views	Bounce rate
Diet exercise and lifestyle advice	2061	32%
What symptoms might I get?	835	32%
Getting a diagnosis	764	45%
Carers and families – how you can help	723	63%
Treatments	628	30%
What is the prognosis?	546	33%
What does this mean for my life now?	536	35%
People you may need to see	525	84%
Why have I got bronchiectasis?	483	33%

6.6 Summary of the BRIEF Study findings and implications for future studies

In this chapter I have presented the findings of the BRIEF study, including feasibility outcomes and evaluation of the resource. The successful recruitment process, high retention rate and excellent study form completion rates, indicate that it was feasible to conduct this pilot study, and that it could be feasible to conduct a full trial based on this study design. There are however always points to consider when assessing feasibility and moving from a pilot trial to planning a definitive trial (Thabane *et al.*, 2010; Bugge *et al.*, 2013).

The BRIEF study was a single centre trial, although participants could be recruited from two sites within the same trust. Recruitment was mainly from a specialist bronchiectasis clinic, with 94% of participants recruited from that clinic. Refusal rates of those approached did not differ according to clinic attended. Recruiting relatively small numbers of participants from the site where the research staff were working from a cohort of patients under specialist care went smoothly. For a larger, multicentre, definitive trial, recruitment may be more difficult.

Research staff found the study straightforward to carry out, and found study visits easy to conduct. This is consistent with participants' reports also. The excellent data quality shows that staff were able to follow protocol and complete study measures as required. The BRIEF study was feasible to conduct over a 3 month period and the data obtained could be used in the future to calculate a sample size and predicted recruitment time period for a definitive study. Planning a future study with an adaptive design may be useful, as the follow up period for the BRIEF study was only 3 months, and change data over a longer period of time may need to be studied to establish if any change is maintained or ongoing. By using an adaptive design, data could be collected part way through, for example at 6 months and sample size requirements re-assessed.

Given the short time duration of the BRIEF study, some outcome measures such as lung function and antibiotic use could be affected by the specific months during which participants entered the trial. For example, if a participant tends to exacerbate more in the winter than summer, and also if they were exacerbating at the time of study entry. Randomisation, however, used random permuted blocks within strata, and

therefore study entry time would be expected to be balanced between the control and intervention groups. Should a full trial be performed, however, the follow up period would need to be much longer. This would allow for measurement of change in outcomes such as exacerbation frequency for example, which would need to be recorded over a longer time period. For the purposes of this feasibility study, a 3 month duration was a pragmatic and acceptable design.

When considering the baseline data in the BRIEF study, the two groups are approximately comparable. There were more participants in the intervention group though who had had bronchiectasis for more than 10 years (17/32 (53%) compared to 9/30 (30%)). The number who had bronchiectasis for more than 5 years were more comparable between groups however with 14/30(47%) in the control group and 18/32 (60%) in the intervention group. Time since diagnosis could potentially influence the type of information needs a person may have. During the interview process however, it was apparent that although some information needs do change over time, many unanswered questions were common to those who had both new and longstanding diagnoses. The numbers of those who had a relatively new diagnosis (<1year) were more even, 6/30 (20%) in the control group and 6/32 (18%) in the intervention group. If time since diagnosis was thought to be a potential confounder, stratification by time since diagnosis could be considered when planning a full trial. With larger numbers in a definitive trial however, it would be anticipated that the balance between arms for potential confounders would even out.

In the Bronchiectasis Knowledge Questionnaire, there were some areas of understanding that seemed to improve over the visits for the intervention group. For the True/False questions, that seemed less apparent. It could be the design of the questions, or their content, influencing this. It is also possible that there are some areas that are amenable to knowledge gain through such resources, and others that may need face to face interaction. The questionnaires were not designed using a formal questionnaire development process and the fact that there were no validated questionnaires to be used is a limitation of the study. The BKQ was, however, well completed and as such seemed acceptable to users. It was reassuring to see that there seemed to be a trend towards an increase in participants' understanding of their condition in the intervention group and a raised understanding of how to find more information. It is important to keep in mind however that these are not statistically significant changes and the questionnaires are not validated.

The findings of the BKQ are in keeping with the responses given in the RSQ. Feedback from the RSQ demonstrated a perceived increase in knowledge amongst those using the resource. This seemed to rise by visit 2 (2 weeks after receiving the resource) but then fall slightly by visit 3 (12 weeks after receiving the resource). This could represent a perceived plateau in knowledge gain if the question was interpreted as meaning an increase in knowledge since the last visit rather than the start of the study. This could strengthen the argument for a formal questionnaire development process, improving question wording and layout. It may simply represent a lack of knowledge retention if participants used the resource at the outset and then didn't engage further with it. Exploring this further within focus groups could also facilitate a better understanding of question interpretation and improvements in questionnaire design. This point was not specifically discussed in the end of study focus group.

In addition, with hindsight, to follow up on the question regarding understanding about treatments (which participants perceived to improve in the intervention group) a useful question could have been: 'are you now more likely to take your medications regularly' as a marker of influence on adherence. Moving on to assessing the impact of a reported improvement of understanding in practical terms would be beneficial in a future study.

The RSQ gave some very useful feedback about the resource. Interestingly, approximately half preferred the website and half the booklet. When looking at which was used the most however, the split was approximately 60/40 in favour of the booklet. There are clearly different features that were advantageous to different people with each format. It would seem that although the majority have internet access, this does not necessarily mean that it is their preferred version of the information resource. The PDF version however was little used, and only 2 participants chose PDF entry to the study. In order to remain inclusive, having this option, however little used, was important with this being a feasibility study. Acceptability of different formats of the resource was a key finding.

From the free text feedback about the resource, negative comments mainly highlighted technical access problems with the website. These may be specific to the user, but it could be that the login process was not as intuitive as we had hoped. For the purposes of the trial, in order not to compromise the trial integrity, the access had

to be password controlled. It is possible though that if the website was accessible without a password, uptake within the trial could have been improved upon. Certainly in terms of wider access, looking at the web analytics we can see that the majority of attempts at site access were bounced, and that the demand for access to the information world-wide was high.

Further evidence of the demand for such a resource is that the British Lung Foundation have requested to use the booklet as the basis of their new and improved bronchiectasis patient information and encouraged me to openly publish the website for them to reference. Perceived by patients and carers as a highly credible resource provider, their use of this developed resource is a commendable outcome of this research. I will discuss this further in chapter 7 in terms of the potential impact of this work.

Chapter 7 Overall Discussion and Conclusions

This thesis has highlighted the importance of healthcare information and described how bronchiectasis was, until quite recently, viewed as a relatively rare condition. Bronchiectasis has previously been somewhat neglected in terms of provision of information and education materials for patients and their carers. I have described the potential impact that an accessible, credible resource could have for those living with bronchiectasis, and how the needs of potential users had to be identified and understood in order to develop an effective and user-friendly intervention. Related issues surrounding information seeking, provision and development, and links with self-management have also been explored, both in the current literature, and in the interviews with patients and carers described in this thesis. The findings of these qualitative interviews provided new insight into the experiences and information needs of people living with bronchiectasis, and enabled the co-development of a novel information resource. During evaluation of this resource within the BRIEF study users reported it to be trustworthy and to meet their requirements; and the trial comparing its use to usual care was feasible to conduct. In this discussion, I will reflect upon the key findings and strengths and limitations of this work and also present its potential impact, recommendations for future research and my overall conclusions.

7.1 The qualitative interviews: key findings

At the outset of the interviews, the main focus was to establish the unmet information needs of patients with bronchiectasis and their carers. In total interviews with 17 patients and 9 carers took place. A key finding was that during the interviews, information needs were almost invariably discussed in the context of their own experiences of living with bronchiectasis; the main emergent theme. I have therefore been able to understand and describe the physical and psychological impacts of the condition, and the biographical disruption and impact upon sense of self that bronchiectasis can present. I have also identified and described the ways in which people mobilise resources; develop their own support and coping mechanisms and develop active partnerships with the healthcare team. Not only have the interviews established the unmet information needs of this group, and how users 'connect' with information, but also their lived experiences of the disease. Developing an understanding of the participants lives and how they been affected by bronchiectasis,

laid the groundwork for understanding their interactions with information and how their needs could be met. To my knowledge, this is the first time that the experiences of those living with bronchiectasis have been explored and described in such depth; and the first time that requirements for information and education in the context of these experiences has been understood.

7.1.1 *Bronchiectasis as a biographical disruption*

The core theme within the interview data, 'Living life with bronchiectasis', described the lived experiences of patients with bronchiectasis and their carers and the physical and psychological impacts bronchiectasis had upon their lives during their journey since diagnosis. The 'disruption' that a diagnosis of bronchiectasis presents was particularly prominent within the data. As discussed in Chapter 4, to further understand the disruption that a diagnosis of bronchiectasis brings, I reviewed the key literature conceptualising the impacts of chronic illness. Of particular relevance to this thesis was Bury's conceptualisation of chronic illness as a biographical disruption (Bury, 1982). Bury's work built upon prior descriptions of chronic illness as a 'critical situation' (Giddens, 1979) and a 'disruption' (Dingwall, 1976) and descriptions of how it affects quality of life (Strauss and Glaser, 1975). Bury described chronic illness as an event that has three aspects of disruption: taken for granted assumptions and behaviours; the individual's self-concept and biography, and their response in mobilisation of resources in an altered situation. He described how in patients with rheumatoid arthritis the insidious onset of symptoms often leads to patients dismissing them initially, yet as these progress their 'common-sense assumptions' fail to explain their experiences. Within my interviews, participants often reported having symptoms for a long time prior to diagnosis. This seemed in the case of bronchiectasis, however, to be a misinterpretation of symptoms by both patients and clinicians alike rather than a one-sided dismissal of their significance.

Some of my participants, who had bronchiectasis symptom onset later in life, wondered if the symptoms were just a natural process at first, with some expectation of becoming breathless on exertion at a certain age. Studies in osteoarthritis and stroke have found that age does influence the presumption of symptoms being due to 'normal ageing' (Sanders *et al.*, 2002). Age can also mediate the impact of the diagnosis, with previous hardship and experiences of ill health seemingly modifying individuals' responses (Pound *et al.*, 1998). Studies of stroke and recovery have highlighted that age, co-morbidities and knowledge of their condition additionally

influence impact of the diagnosis (Faircloth *et al.*, 2004). Many of the participants in my study had co-morbidities, and it is possible that dependent on the nature or relative severity of the co-morbidities, they could lessen the impact of bronchiectasis upon their lives. With bronchiectasis however, that relationship is often a changeable one. Bronchiectasis by its nature is a chronic condition that has periods of exacerbation and worsening: there will be times when a co-morbidity seems to be the most impactful, interspersed with times when bronchiectasis causes the predominant 'disruption'.

In contrast to Bury's group of newly diagnosed patients with rheumatoid arthritis, my interview participants ranged from those with new to very longstanding diagnoses. Interestingly, their ongoing need for information (particularly about prognosis) further suggested that a diagnosis of bronchiectasis does not involve a simple, one step biographical disruption, but that the change in trajectory remained laden with uncertainty. Whilst arguably this may be the case for many long term conditions with variable disease course (including rheumatoid arthritis) my description specific to bronchiectasis with the emphasis on ongoing need for information represents a new finding. The disruption associated with a diagnosis of bronchiectasis is subject to repeated superimposition of further 'shifts', both temporarily and permanently. The diagnosis of a chronic condition such as bronchiectasis does not simply alter a patient's biography, but opens the door to an uncertain future. This state of not knowing what the future may hold impacted upon patient's journeys to acceptance and adaptation, with no assurance of what was around the next corner. Although patients and carers tried to accept a 'new normal', this 'work' often had to be done repeatedly.

Early descriptions of the 'work' of managing chronic illness (Corbin and Strauss, 1985) identified the three main types of work carried out by both patients and their partners as 'illness work', 'everyday work' and 'biographical work'. Corbin and Strauss further described 'biographical work' as what people do to manage the new situation that they face when diagnosed with a chronic illness (Corbin and Strauss, 1987). They proposed 3 dimensions to a person's biography ('conception of self', 'biographical time' and 'conception of body') as the components of the 'biographical body conception chain' which need to be reconstructed following a biographical disruption. Bury has referred to the process following the initial disruption at diagnosis or onset of disease as 'explanation and legitimation' (Bury, 1991). Patients

want explanations for their symptoms both medically, and in context, perhaps with narratives from others or their own prior experiences (Williams, 1984). Within my interview data also, participants commonly sought such explanations from these sources, with a great emphasis on the importance of hearing stories of others' experiences. These actions concur with Bury's definition of the term legitimization: 'the process of attempting to repair disruption, and establish an acceptable and legitimate place for the condition within the person's life' (Bury, 1991). This access to prior experiences (both their own and others') is clearly an important part of attempting to repair this disruption. As described, in my participants with bronchiectasis this 'work' is more of an ongoing, developing and changing process due to the nature of the condition, with variations in levels of symptoms both on a long and short-term basis.

In summary, there are many similarities to Bury's work and further concepts of biographical disruption in my data. My concept of a diagnosis of bronchiectasis as a biographical disruption with further superimpositions of change seems to describe the experiences of patients living with bronchiectasis, and indeed their carers.

7.1.2 *Strengths and limitations of the interviews*

The analysis of the interview data has provided new insights into the experiences of those who are living with bronchiectasis and their carers. The inclusion of carers strengthened the data by ensuring that their views, experiences and specific information needs were also explored and incorporated into the resource development. By describing the experiences of carers this study has added to our understanding of the lives of those who are affected by bronchiectasis. By using the methods outlined in Chapter 3, including the consideration of the approach to the interviews when exploring information needs and seeking: 'talking whilst looking' (Lee *et al.*, 2016), and the use of maximum variation purposive sampling, the depth of understanding of the needs of participants was optimised. By exploring deviant cases, further rigour was added. My role as a bronchiectasis doctor and interviewer additionally added strength to the qualitative interviews and the analysis of data arising from them as described in both the methods and interview results chapters. Critically, having an understanding and knowledge of bronchiectasis enriched my interaction with participants and added insight to my interrogation and understanding of the data.

As with all studies, there are limitations to consider. The limitations I would like to discuss pertaining to these interviews relate to sampling. All patients were recruited from one hospital trust, as this was a single centre study. Had time and resources allowed, I would have aimed to have recruited participants from different centres to enable an exploration of any potential differences in experiences and information needs relating to the clinical contact they had. Because this was a single centre study, and as such the group of potential participants had already been reduced, purposive sampling was used in order to obtain a maximum variation sample. Participants were recruited from a specialist bronchiectasis clinic and several general respiratory clinics, each run by a different consultant. The aim of this approach was to recruit patients with different experiences of healthcare services and information provision. Although the sample was varied, it could (as always) have been more so. When looking at the overall group of participants, 11 patients were recruited from the specialist bronchiectasis clinic, and 6 from general respiratory clinics (Table 3). This was a good mix, yet still the majority had already been attending a specialist service and receiving bronchiectasis specific information from a consultant with an interest in patient education within this setting. As discussed in the methods (Chapter 3) the aim had been to ensure that participants had different experiences of provision of information by their clinical teams, as this might influence their needs. In order to improve upon this in the future, recruitment would be from different hospital trusts, ideally in different geographical locations.

Another focus with further sampling would be to aim to recruit some much younger patients. Although the ages ranged from 33 to 78, and the median age of 65 was representative of the wider patient group in general, having the views of those under 25 for example would be interesting. Given the saturation of data within this sample, it may be that views would not differ, but bronchiectasis is a condition that can be diagnosed in childhood. There are patients of all ages living with bronchiectasis. To have the views of young adults or even children (and their parent carers) would enrich the data further, both by understanding the lived experiences of younger people with bronchiectasis, and exploring their information needs. It may be that information needs do not differ, but preferences in terms of format and delivery may vary. In particular moving forwards, for such a resource to be developed or expanded upon with younger adults or children in mind, it is bound to take on a different form.

Having the input of children and their parents would be vital in ensuring that this could be extended to meet their needs.

The social circumstances of participants could also be considered in more depth. Although I recorded occupation or education as a basic indicator, as well as home circumstances, this was done at the interview stage rather than as part of the sampling process at first. I was mindful, however, from the pilot exploratory interviews I had previously conducted, that I needed to try to sample a group with differing social backgrounds, aware of the influence this could have upon information needs and access. Within the sampling strategy for the interviews described in this thesis I aimed to broaden the variation within the group and achieved this. In further work, having a multi-centre study recruiting from different geographical areas would enable a much broader variation in social backgrounds within the cohort.

In summary, analysis of these interviews has enabled the first in-depth description of the experiences of both patients and carers who are living with bronchiectasis and the biographical disruption that this presents. The information needs of patients and carers, and how these could be met have been explored and described. The relationship between the need for information and their lived experiences has been understood. My role as interviewer and data analyst, the rigorous methods used and the maximum variation sample achieved has added depth to this understanding. The consequent confidence in this new found understanding has enabled the effective co-development of the novel information resource.

7.2 The co-development of a novel information resource: key findings

The data obtained from the interviews both enhanced understanding of the experiences of those living with bronchiectasis, and informed co-development of the patient-driven information resource. By having a user-driven development process, built upon a careful and analytical assessment of experiences, preferences and needs, a resource that met potential users' requirements was created.

The methods described in Chapter 3 were carefully considered when planning the approach to developing a novel information resource. The aim was that this resource would meet users' needs, facilitate an improvement in their knowledge and understanding, and ultimately have the potential to improve self-management and health outcomes. Having such a solid framework: the interview data, to build the co-

development process upon, significantly enhanced the end product. The subsequent co-development itself was an iterative process, with the series of 3 user workshops influencing ideas and concepts. Affirmations, adaptations and revisions allowed the generation of a resource that had genuinely been driven and developed with the user group.

As had been identified within the interview data, users wanted to have information that would be 'useful' and would help them, or allow them to help themselves. They wanted to be able to access the specific information that they needed at that time. They did not want to trawl through pages of information about bronchiectasis in order to find the one piece of information they were interested in. They did not want to look at websites that they did not trust, that were advertising products or that were not presented with clarity. By having an understanding of these key participant preferences, and an understanding of how people did or did not 'connect' with different information resources, the creation of an 'ideal' resource was facilitated. In Chapter 2, I described the literature supporting the use of development processes that involve and are centred on potential users (Harland and Bath, 2008; Patient Information Forum, 2013). The literature also supports understanding users' needs and developing information to meet those needs (Leydon *et al.*, 2000; Case *et al.*, 2005; Lambert and Loiselle, 2007). By planning this series of workshops with patients and carers, and working with a multidisciplinary team of expert and lay contributors, the development process was a smooth and logical one. Allowing time in between workshops to read and then re-read transcripts and confirm views and discussions enabled changes and revisions to be made. By having users' views on all aspects of the resource I was able to optimise achievement of the desired aims. As described, the final version of the information resource consisted of a website www.bronchiectasis.me and a 14 page booklet entitled 'Living your life with bronchiectasis'.

7.2.1 Strengths and limitations of the resource co-development

The patient-driven, user co-development approach to the production of this resource has been key to its success. The strengths of this resource are due to its development process. Establishing users' needs using qualitative interviews prior to the commencement of development is a major strength. Not only has this resource been co-developed with patients and carers but its content, format and presentation is entirely based upon an understanding of users' experiences and needs.

Furthermore, through an understanding of patients' needs, patient information provision on a routine clinical basis can also be improved. For example, one issue that I identified is the misinterpretation of copy clinic letters sent to patients in the post. The provision of a 'plain English summary' to patients following clinic appointments could aid understanding and consequently any required action. This is unlikely to be possible for every letter written given the volume of work it would generate, but it could be feasible to put this at the end of letters to new patients for example. Links to the relevant sections of the information resource could be included within letters so that patients can review this if they need further clarification.

There are some potential limitations with the design of this development process and consequently the resource itself. By recruiting patients and their carers to a study concerning information provision it is possible that the group self-selected as a group who have an interest in patient information. The sampling process aimed to recruit a maximum variation sample, yet it is possible that those who did not have an interest in information would naturally decline entry to the study. This may well limit the inclusion of the views of those who are not interested in engaging with information, and thus limit the ability to develop a resource that would appeal to this 'hard to reach' group. Against this theory however, there was a very high uptake rate amongst those invited to enter the study (17/22, 77%), and amongst those interviewed were several who had not actively sought information before. By gaining an understanding of the views of this purposively sampled group, the needs of the wider patient group have in theory been accommodated. The review and co-development process further refined the resource to ensure that this was the case, as did the evaluation process within the feasibility study. Despite the possible lack of inclusion of the views of harder to reach users, all efforts have been made to make this resource as widely accessible and user-friendly as possible.

Another point to consider is that the resource was not developed based on a specific theory of behaviour change from the outset. The theory behind this resource was that basing it upon the experiences and needs of potential users and developing it with users, would be an effective way to optimise engagement and effect. The information resource is not simply a factsheet. It has been designed to facilitate understanding, address identified issues, and reinforce potential impacts of actions on health. Clearly, one way to develop such a resource would be to base it upon specific behaviour change techniques (Michie *et al.*, 2005; Abraham and Michie, 2008), and

interestingly it can be seen that many elements of the resource are actually aligned with such theory. For example, there are several video demonstrations within the resource, and instructions on how to perform certain tasks such as chest clearance. This provision of instruction and demonstration of behaviours is in keeping with social-cognitive theory (Bandura, 1977). In addition there is information on behaviour-health links and consequences of actions or inactions, in keeping with an information-motivation-behavioural skills model (Fisher and Fisher, 1992). Although the resource is primarily an information resource rather than a self-management 'programme', it contains information about self-management and self-help. The aim was that by having information about self-management (which was amongst the identified needs), along with all the other needs-driven information within the resource, patients and carers would be able to improve their knowledge and understanding of their condition, their treatments and what they could do to help themselves. The methodological approach taken to the production of this user-driven and co-developed information resource has ensured that each element of the resource has been influenced by the theories, literature, and interview data relevant to it.

The understanding of patients and carers' experiences of living with bronchiectasis, and their requirements for information has enabled the co-development of a novel resource that meets users' needs. By developing, designing and formatting the information in such a heavily researched and considered way, a resource that aims to optimise engagement and impact has been created.

7.3 The BRIEF Study: key findings

The BRIEF study aimed to determine feasibility of conducting a future definitive trial of the described novel information resource. A definitive trial would aim to assess the impact of the information resource on users' understanding, ability to self-manage and health outcomes. Any potential health economic benefits could also be assessed in a future study. Due to the expense and numbers involved in such definitive trials, feasibility studies are considered an essential requirement for the planning of future trials (Thabane *et al.*, 2010). Safety of interventions, and feasibility of recruitment and trial conduct can be established. For the BRIEF study, establishing such feasibility and evaluating the novel intervention were key outcomes. The CONSORT extension to randomised pilot and feasibility studies guideline was followed (Moher *et al.*, 2010; Eldridge *et al.*, 2016) to ensure adequate reporting of the trial.

The BRIEF study was feasible to recruit to and was conducted to time and target. Recruitment took place over a period of 16 months, at a rate of 3.9 participants/month. 62 participants were recruited to the trial, with only 1 death and 1 loss to follow-up. Study form completion rates were excellent as detailed in Chapter 6. Many of the questionnaires used achieved 100% completion rates. The postal questionnaires had slightly lower completion rates, but were still in excess of published average postal questionnaire return rates of 65% (Nakash *et al.*, 2006). Data quality was exemplary with very few missing data or errors. It is important to note however, that such data integrity could drop in a multicentre design.

Pre-defined feasibility outcomes (Chapter 3, Chapter 6) were therefore met. Willingness to enter the trial was within predicted numbers and the recruitment rate was above expected. Study design was acceptable as judged by study completion rates, qualitative feedback in the end of study focus group, and the completion of study forms as per protocol. On the basis of these findings it can be concluded that this study was feasible to conduct. This is key when designing a definitive, larger, multicentre trial based upon this study design, yet there are additional points to consider when moving from pilot to definitive studies (Thabane *et al.*, 2010; Bugge *et al.*, 2013). Specifically for the BRIEF study, points to consider for further planning would include the ability to recruit from different centres, planning required follow-up time, retention rates with a longer study follow-up time and changes to study design to improve chances of recruiting adequate numbers. Planning a definitive trial with an adaptive design would allow for re-assessment of required sample size part way through data collection, for example at 6 months. It is likely that for some outcomes such as frequency of exacerbations, a much longer follow up period, of at least a year would be required, given the likely number of exacerbations per year, and the seasonal variation that can occur (Bibby *et al.*, 2015). Based on the findings of the BRIEF study, this study design is acceptable and feasible to conduct, and could be easily adapted to plan a future definitive trial.

7.3.1 Evaluation of the novel resource within the BRIEF study: key findings

Evaluation of the intervention itself took place as part of the BRIEF study. A questionnaire created for use within the study assessed users satisfaction with the resources provided. A focus group at the end of the study also explored participants' (and carers') views on the resources. Further analysis was possible through the use

of Google Analytics, to establish use of the website www.bronchiectasis.me beyond users' reports.

Feedback in the questionnaire identified that participants used the resource (87%), and found it useful (93% of users). In addition there was a suggestion of an improvement in perceived understanding of bronchiectasis, its treatments and where to find more information amongst the intervention group. Users highlighted their like of the video clips within the website, particularly those depicting other patients' stories. Interestingly, the website and the overview booklet had equal numbers preferring one or the other. When reporting which format they had used the most, however, 60% said the booklet. There were different reasons to explain this, some of which concurred with the prior interview data. The ability to use the booklet as a quick reference was reported as useful, and the website, although preferred by half, had some problems reported. When looking through the problems highlighted in the free text questionnaire data, it seemed access or 'logins' had been problematic for some. It was unclear whether this was an issue with the website or the users' devices, yet is clearly an area for improvement. If there were issues with access to the website, rectifying these could potentially lead to an increase in the proportion of users preferring the online version.

By using the data obtained via website analysis, numbers accessing the site and most popular pages to view were confirmed. This proved to be a further method of data triangulation, as the pages viewed most frequently were in keeping with those that had been identified within the interviews and co-development process to be most important to users. They were also consistent with the identified key information selected to be included within the overview booklet. This evaluation proved to be very useful both in obtaining feedback about the resource and re-confirming prior qualitative findings. The fact that the demand for access to the site was shown to be high worldwide has also confirmed findings that patients want to be able to access credible bronchiectasis information resources. Further positive evaluation of the resource has been made by the British Lung Foundation. To have this request for use of the information resource by an internationally recognised provider of lung disease information adds confirmation that a high quality resource has been successfully developed.

7.3.2 Strengths and limitations of the BRIEF study

As highlighted within Chapter 6, this is the first trial of a bronchiectasis information resource that has been based upon qualitative exploration and understanding of users' needs and experiences. Patients and carers were involved in the study and intervention design from the outset, in addition to an independent user representative. A study protocol was produced in keeping with the MRC guidelines for evaluating complex interventions (Medical Research Council, 2000) and this was published and made openly accessible (Hester *et al.*, 2016). Findings have been reported in keeping with the CONSORT guidelines (Moher *et al.*, 2010; Eldridge *et al.*, 2016) and a pre-defined statistical analysis plan was used when analysing data. As with any study, however, there are some limitations to consider.

The first concerns blinding. This was a feasibility study, with limited funding and a sample size of 62. Due to the nature of the intervention, patients could not be blinded to whether or not they were receiving the resource to use whilst in the study. As the research staff conducting study visits needed to provide access details and support to those within the intervention group, they too were unblinded. It should be considered whether blinding of the data analyst is possible, and some argue that this should be possible in almost all cases (Polit, 2011). The BRIEF study however was being conducted during my doctoral research fellowship, and although some initial data entry was done by a data manager within the research team, all data checking and analysis was my responsibility. In order to check data accurately and effectively, it was not possible to be blinded to allocation groups. For example, some questionnaires were only completed by the intervention group, and I was directly involved in all study processes, and solely responsible for data analysis. In order to ensure data was analysed without bias, and was not influenced during analysis, a pre-defined analysis plan was written with advice from a statistician prior to data analysis. This analysis plan is attached as an appendix, and was strictly adhered to (Appendix 28). The analysis plan was included in the published study protocol (Hester *et al.*, 2016). It should also be noted that outcomes for the feasibility study were in the main concerning response rate and recruitment rather than looking for an effect in the intervention group. For a future definitive trial, blinding of the data analyst should be aimed for. The lack of blinding in the BRIEF study, however, should not be considered to have influenced data analysis and outcomes.

The second limitation concerns both the definition and monitoring of exacerbations. There is no current gold standard for objectively measuring what constitutes an exacerbation in bronchiectasis. The BRIEF study did not have a protocol definition of exacerbations. At the first study visit, the number of exacerbations participants had in the preceding 12 months was recorded. This was done by patient recollection and case note review. During completion of study questionnaires, patients were also asked to recall numbers of exacerbations or courses of antibiotics since their last visit. This was done over a short time period. During a trial with a longer time period between study visits, GP and hospital notes may need to be relied upon more for accurate recording of events. Due to the potential burden of a daily symptom diary (as identified by patient reviewers of the study design), we opted to ask patients to record such details on a monthly basis. As this study did not aim to impact upon participants symptoms, this was felt to be adequate recording, and could be used to consider any potential ascertainment bias when planning a future study. In a definitive trial of this intervention however, improvements in self-management and consequently disease stability would be assessed. When adapting this study design for a future trial, a protocol definition of an exacerbation, and more rigorous reporting of events would be preferable. This could include, for example, electronic symptom diaries.

Although numbers of courses of antibiotics would be important information to collect within a definitive trial, it would be difficult to use as a primary outcome measure. As the intervention would aim to improve participants' recognition and management of exacerbations, this could lead to an increase in number of antibiotic courses taken (if a participant had previously been under-recognising treatment requirements), yet for others it may lead to a reduction (if they had previously been reacting to 'normal' variations in symptoms unnecessarily). Measuring change in number of courses of antibiotics therefore would be difficult to interpret with meaning. It is likely that exacerbation rate, along with a primary outcome measure of unscheduled healthcare visits (representing unpredicted and unmanaged exacerbations), would be the most accurate measure of improvements in self-management and health outcomes. This would be in conjunction with assessing knowledge and understanding of bronchiectasis. In order to more accurately report this, further work would need to be done to improve upon and validate the knowledge questionnaires used within the BRIEF study.

The third limitation relates to sample diversity. Although patients were recruited from all respiratory clinics within the trust, at 2 sites, the vast majority 58/62 (94%) were recruited from the specialist bronchiectasis clinic. This may be in part due to the fact that research staff familiar with all ongoing studies have a presence within the bronchiectasis clinic, reminding the clinical care team about recruitment, and being available to speak to potential participants if required. Recruitment from the general respiratory clinics relied upon the consultants delivering those clinics remembering to ask patients if they might be interested in hearing more about the study. Although consultants were reminded throughout the study by email, it may not have been at the forefront of their minds. As with all studies, ensuring adequate 'advertising' would have to be incorporated into future trial designs. By recruiting from all types of clinic, the aim was to have a patient group who had different clinical experiences and differing information provision. Although the majority had been to the specialist clinic, given the differing times since diagnosis, access to information from the clinic still varied.

Also regarding sample diversity, patients' backgrounds in terms of socio-economic status were not recorded in detail within the BRIEF study. This is something that could be considered in more depth if planning a definitive trial. Users' backgrounds and educational level certainly have the potential to influence interaction with the resource. How users 'connect' with information was highlighted as important within the interview data, so establishing any additional social factors which may have an effect on this within a future trial would be useful. During the BRIEF study, although sampling included a range of patients (e.g. age, time since diagnosis, severity of disease), there are other factors such as this which were not heavily focussed upon.

Another aspect of recruitment to discuss is that when approaching potentially eligible patients, a 50% consent rate was achieved. Although this was consistent with our predicted numbers, it is possibly slightly lower than could be anticipated. There are no definitive figures as to what to expect in this scenario, as there are many factors that vary between potential participant populations and different study requirements. A review of influential randomised trials reported a mean non-recruitment rate of 40.1% (SD23.7%) (Humphreys *et al.*, 2013). Rates vary hugely between studies however as described. The recruitment rate in the BRIEF study was lower than this reported mean, yet it is a small single centre study, not an influential RCT. There were no new treatments to potentially receive and it was not a heavily marketed

study. When compared to the recruitment rate for my qualitative interviews (17/22 approached (77%)) the uptake rate of 50% is still much lower. It may be the nature of the BRIEF study compared to the interviews (12 week time period with 3 visits compared to a single, hour long interview) that seemed less appealing. For a definitive trial, follow-up time period would need to be longer still, so this is something that would need to be considered if it was a factor influencing refusal rates. It is also possible that recruitment was taking place within a group saturated with research study requests. There were several studies recruiting patients with bronchiectasis at the same time at the study centre and there are a finite number of patients with bronchiectasis. It may be that those approached had already been approached for entry into (or had entered) other studies and felt unable to enter another. Recruitment also took place at other general respiratory clinics within the single centre, yet few were recruited from outside of the specialist clinic. Although basic data was collected on reason for refusal and reported in Chapter 6, factors that may have encouraged participation were not explored, as this had not been written into the study design. In future studies, exploring this in more depth would be useful to influence future trial design. Importantly, however, recruitment was achieved to target numbers within the target timescale, and retention rates were excellent. Qualitative data collected within the end of study focus group also highlighted that participation was not considered to be burdensome, with no obvious areas for improvement. Those conducting study visits also found them straightforward.

The final limitation I will discuss is the standardisation of 'usual care' for those randomised to the control arm. For the BRIEF study, it was decided that 'usual care' would be simply receiving no additional information resource, but making no restrictions on the information that could be otherwise used or sought. This is quite difficult to standardise, as each individual will have different clinical contact and information given, and different approaches to seeking or not seeking information by themselves. During design of the trial, one option considered was to provide those in the control arm with the current BLF bronchiectasis leaflet as a form of 'usual care'. Ultimately this was decided against, as 'usual care' would not necessarily involve even the provision of this leaflet in some clinics. It was also assumed that all participants would already have different experiences of information provision prior to study entry. A simple example would be which clinic they attended, with the assumption that those attending a specialist clinic would potentially have access to a

level of information beyond that expected in a general respiratory clinic. This is not necessarily the case. Arguably, however, clinic attended, or prior information provision could be considered as a stratification variable during randomisation for a definitive trial if thought to be a potential confounding factor. Other related factors that could potentially influence outcomes or impact of an educational intervention could also be considered as stratification variables for a full trial. Examples could include prior access to information from a specialist clinician (as described above); time since diagnosis (which could influence the nature of information required); access to the internet (which could affect formats of resource able to fully engage with) and educational history or health literacy levels (which could influence both types of resources required and ability to engage with and understand them). Any factors felt to be relevant could be identified and used as stratification variables when planning recruitment and randomisation in a definitive trial.

Accessing additional information resources during the BRIEF study was not restricted as this was felt to be difficult to do accurately. For those in the intervention group, looking at the resources provided could trigger seeking of further information elsewhere. For those in the control group, knowing they were not receiving the information resource could have triggered information seeking. The significant difference in information provision for the two groups within the trial however was the novel information resource. The ability to monitor additional seeking or provision of information is limited, and really has to be accepted as a variable which is not practicably controllable and reflects 'usual' patient practices. At study conclusion, all those who had taken part in the study (including those in the control group) were given access to the resource indefinitely.

Despite the limitations of the BRIEF study, the design had a number of strengths and it was conducted successfully. The trial protocol underwent extensive peer review through NIHR during the doctoral research fellowship application process, and also during publication in *Trials* (Hester *et al.*, 2016). The majority of the highlighted limitations are factors to consider for a definitive trial based upon this feasibility study. Resource evaluation and qualitative data added to the usefulness of this study by informing refinements to both the resource and trial design. For this feasibility study design to be adapted for a future definitive trial, changes would need to be made as discussed, and sample sizes calculated using the data presented. The indication is that a future multicentre study evaluating the impact of this resource on patient

understanding, self-management, health outcomes and health service use would be feasible to conduct.

7.4 Overall impact and contributions to knowledge

The mixed methodological approach used within this overall body of work has enabled the use of a combination of rigorous methods to achieve the aims and objectives set out at the start of this thesis:-

1. To identify, understand and describe the information and education needs of patients who have bronchiectasis and their carers.
2. To co-develop a high-quality, patient-driven information resource for patients with bronchiectasis in accordance with themes identified in qualitative interviews, focus groups and workshops.
3. To evaluate the resource and conduct a feasibility study to inform the decision of whether to proceed to a definitive randomised controlled trial examining the impact of the resource on users understanding, self-management, use of health care services and disease stability.

Firstly, a deeper understanding of the experiences of those living with bronchiectasis has been achieved. The nature of the biographical disruption that bronchiectasis presents, and the ways in which people manage this and develop active partnerships with their healthcare providers has been described for the first time. The ways in which those living with bronchiectasis 'connect' with information has also been explored and described. This new level of understanding could facilitate improvements in partnerships between healthcare providers and those living with bronchiectasis. This new knowledge therefore stands to benefit patients, carers and healthcare professionals and has facilitated the co-development of a user-driven information resource.

Secondly, the co-development of a novel information resource that meets users' needs has resulted in a website and booklet based upon this new understanding of the experiences of those living with bronchiectasis. By understanding unmet needs, preferences and required purpose of information resources, high-quality, useful resources have been developed. By using the particular iterative processes and methods described, and evaluating along the way, it has been possible to produce resources that are engaging, credible and well-received. This is the first step towards

using such a resource to positively influence patients' understanding, ability to self-manage and healthcare service use. In addition to the impact for those with bronchiectasis, this methodological approach could be extrapolated for use within other chronic conditions, contributing to further research in the future.

Thirdly, the feasibility of using a randomised controlled trial to assess the impact of the novel resources has been established in the BRIEF study. In order to conduct a definitive trial, more work would need to be done to adapt the BRIEF study protocol and estimate sample sizes required. The success of the BRIEF study is a strong indicator that with appropriate adaptation, this protocol and study design could be used in future work. Qualitative methods incorporated into the trial design have additionally yielded data that could further influence such adaptations. The protocol for the BRIEF study was published openly, so could also be used by researchers in other related fields to plan similar feasibility studies, or to adapt for use for a full trial. The questionnaires produced and used for the first time in this study, particularly the Bronchiectasis Knowledge Questionnaire, are another useful output. With further development and validation, these could be used as outcome measures in future work.

The BRIEF study also provided detailed evaluation and qualitative data on the resources provided. This has both enabled confirmation of the effective use of the interview findings and co-development process, and facilitated further refinements to the resources. The website www.bronchiectasis.me and the accompanying booklet 'Living your life with bronchiectasis' are tangible outputs of this research. The booklet is currently being used by the British Lung Foundation as the basis for their revised information resource (paper and online versions), which I have reviewed and amended for publication. Within their booklet, Newcastle University, Newcastle Hospitals Trust, NIHR and I will be acknowledged. The website developed for use within the BRIEF study is also currently under further development and has now been made openly available with the support of the Open Lab at Newcastle University. The BLF include the link to this website within their new information which will hugely increase anticipated traffic through the site. Having the resource used and endorsed by a charity with international recognition for provision of information on lung disease will hugely increase the potential impact it could have for users, and the number of people that will be signposted to the resource. This collaboration could also be a means of facilitating and disseminating future research.

As information seeking is often opportunistic, this raises the importance of placement and how best to make this available to patients. Aside from being available openly to any seekers of information online, to maximise value and uptake of the new resource it would make sense for it to be available in a clinical environment. Information received from patients' own clinician's tends to be trusted information. For details of this resource to be shared in clinic, on the ward and details given to patients within clinic letters of how to access the information would be a good step towards making the information accessible. The NHS trust in which this resource was developed are currently approving the booklet for use.

There have been several contributions to knowledge and tangible outputs from this body of work, all in keeping with the aims and objectives at the outset. In order to maximise impact, all findings have been disseminated widely.

7.5 Dissemination

I have presented each stage of this work throughout my fellowship period. The work has been presented in a variety of settings, including Research Discussion Forums both within my host institute, the Institute of Cellular Medicine, and the Institute of Health and Society where I have formed strong connections on the basis of the nature of work undertaken. I have presented findings within the Newcastle upon Tyne Hospitals NHS Trust, both at medical meetings and also at an open educational day about bronchiectasis, attended by patients, carers and healthcare providers. This day was advertised within the local press and had over 50 attendees. Also locally, I have presented findings at the North East Bronchiectasis Research Interest Group meeting, attended by healthcare providers from around the region and a BLF representative.

I have presented findings from all stages of this work at international conferences including the British Sociological Association Medical Sociology Conference, British Thoracic Society Winter Meetings and the first World Bronchiectasis Conference.

I have published the BRIEF study protocol in *Trials* (Hester *et al.*, 2016), and have three further papers in preparation:-

- Bronchiectasis education: a review of patient information and education provision.

- Living life with bronchiectasis: A qualitative exploration of what it means to live with bronchiectasis for patients and carers.
- The BRIEF study: Development of a novel educational intervention for patients with bronchiectasis based on a qualitative exploration of the unmet information needs of patients and their carers, and the outcome of a feasibility study comparing the intervention to usual care in bronchiectasis.

In addition, the booklet produced during the research is currently being approved for use within the Newcastle Hospitals Trust and also being used by the BLF as described. By making the website openly available, and linking with the BLF, dissemination amongst the user group will be maximised. Both the booklet and website include details of the research involved in their production. All participants have also received summaries of findings.

7.6 Recommendations for future research

Potential future research building upon this work would include delivering a full trial to determine the impact of the developed resources. In order to carry out a definitive trial, adaptations would need to be made to the BRIEF study protocol in keeping with the discussion in this chapter and in Chapter 6. Sample size calculations would need to be made, and consideration of potential sites for a multi-centre study. Outcome measures would also need to be re-considered. Identifying an impactful primary outcome measure could be challenging. Whilst patient knowledge and understanding are important, measures of health stability and service use would be critical to assessing whether the intervention had an effect on health outcomes and any economic benefits. The feasibility of such a study in terms of recruitment on a much larger scale, costs involved and therefore funding required are important considerations. Securing funding for such a study is by no means guaranteed. Given these factors, in combination with the opportunity to make this information resource openly available to the user group through collaboration with the BLF, I opted to disseminate the resource for more immediate patient benefit rather than to proceed with a full trial at this stage.

Even without delivering a full trial, however, future developments can still be made. The questionnaires used within the study could be re-assessed and further developed and validated. If proven to be useful measures, these could then be used within future trials to assess impact of information resources on patient knowledge

and understanding of bronchiectasis. The information resources themselves are also primed for further development. By extending the exploration of information needs and the co-development process to younger patients and even children, for example, an understanding of the experiences of younger people with bronchiectasis could be gained. This could facilitate the development of resources specific to their needs, or the adaptation of the current resource to incorporate age-specific sections. To take this a step further, the information needs of healthcare professionals managing patients with bronchiectasis, such as GPs, could also be explored and provided for.

The website, which is currently under development to be made openly available, has great potential to be developed further. Although at first this will be set up as a 'static' site, further work could be done to make this much more interactive, facilitating research into users' engagement with digital resources in bronchiectasis. One feature that was highlighted as being of use within the interviews, was the ability to 'ask a question' through a website. For the resource developed within this body of work, this was not a feasible option in terms of technical features of the site and monitoring and upkeep. In future work, this could be incorporated into the site, for example by asking users to register questions, which could be rated by the user group in polls. Other users can answer the questions, and professional answers could be added to the most popular questions on a weekly basis. This not only promotes ongoing interaction with the resource, but also offers an opportunity to gain further insight into users' needs. This could inform its ongoing development, for example moving towards a patient self-management programme within the site if users identified this as an unmet need. It could also help to identify other potential research projects favoured by those living with bronchiectasis. By not having to 'login' to the site when it becomes openly available, access is bound to increase, and we already know that demand for access has been high. By asking those using the site to complete a registration process, informing users about future research and promoting best practice in management could be facilitated. The options for development are numerous, and potential for future, further impact is significant.

7.7 Conclusions

This thesis presents a first in-depth description of the experiences of those living with bronchiectasis, and the biographical disruption they face. This understanding of patients' and carers' experiences and unmet information needs has informed the co-

development of a novel information resource. A pilot study comparing use of the resource to usual care has proven feasible to conduct and shown it meets users' requirements. All aims outlined at the start of this body of work have been achieved. In addition, a highly rated booklet and website are being made openly available to patients and carers. Having these resources available for public use, and maximising promotion and accessibility through their adoption by the British Lung Foundation have enabled an immediate improvement in the provision of credible information resources for those living with bronchiectasis, and created a wealth of future options for development.

Living your life with Bronchiectasis



The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust

Newcastle
University



About this information

You may have been recently diagnosed with bronchiectasis or have had it for some time, yet often patients and their families have questions, or things they would like to know more about.

This information has been developed by doctors, the hospital team and by patients who have bronchiectasis.

This booklet is designed to provide a small amount of information for quick reference and accompanies the full information which can be found on the website: **www.bronchiectasis.me**

Remember you are not alone, and there are things that you and your health care team can do to help control your symptoms and manage the condition.

For enquiries about this information or research related to it contact Dr K Hester.
Email: katy.hester@ncl.ac.uk



Katy Hester is funded by a National Institute for Health Research (NIHR) Doctoral Research Fellowship. This booklet includes a summary of independent research funded by the NIHR. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

'The information in this booklet is not intended to replace the advice and care of your doctor. If you have concerns about your health please consult your doctor.'

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Learning about bronchiectasis

Why have I got bronchiectasis?

- Up to half of people who are diagnosed with bronchiectasis have 'idiopathic bronchiectasis'. This means that they have bronchiectasis, but do not have any other underlying cause. There are also certain illnesses that can be linked with bronchiectasis, including:
- Inflammatory bowel disease (ulcerative colitis and Crohn's disease)
- Rheumatoid arthritis and Sjogren's syndrome.
- Immune system deficiencies.
- Previous whooping cough, pneumonia or TB.
- A problem with the normal structure or function of the lungs including conditions such as primary ciliary dyskinesia, where the tiny hairs that work to protect the lungs do not work properly.
- Sometimes, people who have had chronic obstructive pulmonary disease or asthma for many years can go on to develop bronchiectasis also.

Bronchiectasis is NOT caused by smoking, is NOT asthma and is NOT COPD.

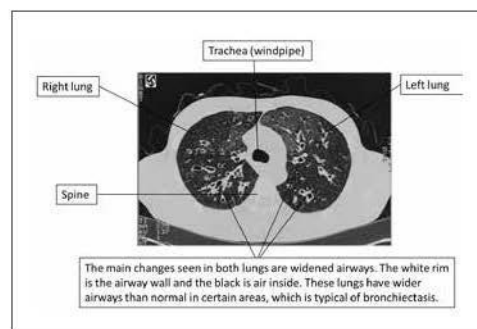
However, there can be some confusion caused by the fact that some of the breathing test results we see with bronchiectasis can show the same sort of pattern as those seen in COPD or asthma. Also, some people may have asthma or COPD, and then develop bronchiectasis as well. If you have had smoking-related COPD for many years and then go on to have bronchiectasis you could say that smoking had been an underlying cause in this specific scenario.

"I thought a cough and a spit sort of thing was like when old people had been smoking and things like that, and they've brought it on themselves, not something that just happened to you, I mean I don't smoke." P04

"Have I still got emphysema? Is bronchiectasis worse than emphysema, or different?" P16

What is wrong with my lungs?

- Bronchiectasis is a long term condition affecting the airway tubes (bronchi and bronchioles). The airway tubes have become narrower due to inflammation, in certain small areas the breathing tubes have developed pockets probably due to both scarring and weakness around the airway. These pockets in the airways mean that mucus gets trapped. The trapped mucus doesn't get removed as quickly as usual and this allows bugs that land in the lung to stay down in the lungs. Once the bugs grow to a certain level a chest infection or flare up occurs.
- So in summary the airways are both scarred and inflamed leaving thick mucus that gets trapped in the lung making you prone to infection. As there is a bit of scarring round the airways the condition cannot be cured, but it is very treatable.



What symptoms might I get?

Symptoms vary between individuals, and you may have only 1 or 2, or all of the listed symptoms. Symptoms that can be experienced by people who have bronchiectasis include:-

- Chronic cough and sputum (phlegm) production
- Frequent chest infections
- Breathlessness
- Fatigue (extreme tiredness)
- Cough incontinence (bladder leakage)
- Coughing blood
- Anxiety or depression
- Pains in the chest

Getting a diagnosis

"I was shocked but sort of glad in a way, because it explained why I hadn't been well for so long" P10

Your doctor will ask lots of questions about you and your symptoms in order to make a correct diagnosis. You will also have some tests which are likely to include:

- Chest xray and chest CT scan
- Breathing tests to test the function of your lungs
- Sputum (phlegm) tests
- Blood tests
- Occasionally genetic blood tests, bronchoscopy (camera test of the lungs) or different types of scans are also needed.

What is the prognosis?

- Previous work has shown bronchiectasis causes repeated infections. Newer treatments seem to reduce these infections but patients will still get infections from time to time. Some patients do seem at risk of either more severe infections or more frequent infections.
- In general we think that bronchiectasis is a long term condition and that most people do pretty well with it. Researchers are developing scoring systems to work out who is at greatest risk of being poorly to help us target more intensive treatments to these patients.
- Some adults with bronchiectasis developed symptoms in childhood, so living with bronchiectasis for more than 40-50 years after diagnosis is well recognised.

"I suppose you want to know if it could get worse, what could cause that. Or, is this the level that's it going to be if I you know do what I'm told, as I don't know how things might progress as I'm older and less active." IB08

"I always had it in my head I was going to die with it you know, and that's what used to worry me." P04

Treatment of bronchiectasis

Your specific treatment will be tailored to you and depend on your symptoms, which bugs are found in your phlegm and other factors such as how often you have infections. Overall, the most commonly used treatments include:

Antibiotics

- Antibiotics are needed for 14 days when you have an exacerbation (chest infection or flare-up) of bronchiectasis. The antibiotics used will vary depending on which bugs there are in your sputum. This is why **it is important to give a phlegm sample** when you notice things changing, so that your doctor knows which antibiotics would be best for you to have. You can then start a course of antibiotics without having to wait for the results.
- Often antibiotic choice will be guided by what bugs you have had in the past or which antibiotics have worked best for you in the past. If the results show a new bug or a bug that will not be treated by the antibiotics you have started, your doctor may prescribe a different antibiotic.
- Standard antibiotics for flare-ups or chest infections in bronchiectasis tend to be Amoxicillin 500mg three times a day for 14 days or Clarithromycin 500mg twice a day for 14 days if you are allergic to penicillin. Other tablet antibiotics frequently used for flare-ups include doxycycline and ciprofloxacin. Ciprofloxacin tends to be used if you have the bug *Pseudomonas aeruginosa* in your phlegm.
- Antibiotics may also sometimes need to be given into the vein. This may be done in hospital or you can learn to do this at home.
- Sometimes, antibiotics are also used long-term, not just for a 2 week course. These include a tablet called azithromycin, and nebulised antibiotics such as gentamicin and colomycin.

Sputum (phlegm) clearance

- Clearing phlegm from your lungs is very important in bronchiectasis and can reduce the number of infections that you have.
- A tablet called carbocisteine or Mucodyne is sometimes used to help make sputum (phlegm or mucus) easier to clear from your lungs. This is something that your doctor may suggest if you have difficulty clearing your chest.
- Your respiratory physiotherapist will teach you airway clearance techniques to do daily at home.
- This is to help keep your chest clear of phlegm so that your condition impacts as little as possible on your everyday life. It will also help with the irritating or embarrassing cough that many people have.

Nebulised treatments

The 2 most commonly used treatments that are delivered via a nebuliser in a mist that is breathed in through a mouthpiece are:

Antibiotics: which may be used long term in some people

Hypertonic saline: This is a strong salt solution which is used in a nebuliser. It is something your doctor may suggest trying if you are having frequent infections or have difficulty clearing sputum from your lungs when doing physiotherapy. Using this treatment can help to break the phlegm up and make it easier to cough.

Other Treatments

Surgery and embolization

In the past, surgery was more often performed. We now know that this is not often helpful, and so surgery is very rarely performed in bronchiectasis any more. Sometimes people can have a problem with coughing blood. If there are vessels that can be seen to be the cause of the bleeding then this can be helped by a procedure called embolisation where the blood vessels causing the trouble are blocked off, and occasionally by surgery to remove the area of lung with abnormal vessels and bleeding.

Lung Transplantation

Lung transplantation is again rarely needed in bronchiectasis. In certain circumstances, this may be thought to be a suitable treatment. This is reserved for people who have very severe lung disease and no other treatment options. They would also have to be otherwise healthy and meet certain other criteria such as fitness to pull through a major operation, good health in other body systems and having completed pulmonary rehabilitation. These circumstances are rare and often only apply to those 60 years or less.

Help and advice

Self-management and active partnerships

- Learning to recognise what is 'normal' for you is something that you will develop over time. You will also start to recognise signs that things are changing, for example when you are getting an exacerbation or chest infection.
- For some people this will be a change in sputum (phlegm) colour and/or increase in amount. For others it can be a feeling of fatigue or tiredness, feeling feverish, worsening cough or chest pain.
- Learning to recognise these signs is an important part of taking control of your bronchiectasis and being able to work in a partnership with your health care team. Developing an 'active partnership' with your health care team, means working with them and having some control over your own health and your medical care. This may include having an 'emergency' pack of antibiotics at home that you are able to take when you recognise the signs that you are having an exacerbation or chest infection. This is often very useful, particularly if you have difficulty getting a GP appointment quickly, or for example, if you are unwell when you are on holiday.
- Your health care team can advise you about what signs to look out for and learning about your condition is helpful too.
- Remember, you will know your body better than anyone else so you will play a key role in managing your condition. This is called self-management and is an important part of the care of any chronic disease.

'I know, when I get poorly that's it, the coughing, it's mostly the coughing, and more phlegm, breathlessness.' P04

'It depends, I suppose, but I would say that I judge the severity of the infection with the colour of the phlegm, and then I would take a sample to the doctors and ... I start taking...what they call a sort of rescue pack (of antibiotics).' P16

What you can do

Routine care

- Submit a sputum sample twice a year.
- Get a flu vaccine every year (unless advised not to)
- Know your sputum –amount –colour
- Take your medication.
- Make sure you have rescue antibiotics.
- When you have antibiotics these should be for 2 weeks.
- Clear your chest as advised by your physiotherapist.
- Keep a symptom diary.

What about flare ups?

A flare up is usually when, for more than 48 hours you:

- Feel unwell
- Cough more sputum
- Have a change in sputum colour
- Are more breathless / wheezy

What should I do?

- Send a sputum sample to GP or hospital.
- Start emergency pack of antibiotics for 14 days.
- Let your GP know you're unwell if you haven't already.

Bronchiectasis is not catching or contagious. If you have bronchiectasis, you may find that if you are around people who have chest infections or colds that you are more prone to becoming unwell yourself. The day to day coughing of a person who has bronchiectasis however is not 'catching'.

Diet exercise and lifestyle advice

Nutrition and Bronchiectasis

- Your diet and nutritional intake are very important if you have bronchiectasis. A balanced and varied diet can help you to maintain strength and fitness. If your body is well nourished then you are more able to fight infections.
- You may be surprised to learn that food affects your breathing. Food is the fuel used by your body for all of its activities and functions including breathing. The right mix of nutrients in your diet can help with your breathing.
- If you become overweight your heart and lungs have to work harder to supply oxygen to your body.
- If you are underweight or lose too much weight then you may be more at risk of infections.
- If you don't drink enough fluids, your secretions may become thick and sticky and will increase your risk of an infection. You should have at least 7-8 cups of fluid per day.
- Your dietitian can help you with a specific plan that meets your individual needs, as not everyone with bronchiectasis will have the same needs.

Exercise

- Any form of exercise that makes you a little breathless, such as walking and swimming is extremely beneficial for people with bronchiectasis.
- It may help you to clear your chest and will improve your overall fitness. Staying or getting fit will help you build resistance to infections.
- Your physiotherapist will advise you on the appropriate exercise to suit you and, where appropriate refer you to a specialist exercise group called Pulmonary Rehabilitation which is usually run at your local hospital.
- If you are affected by breathlessness then a physiotherapist will give you advice on how best to manage it. This may include advice about breathing techniques to help you control your breathing, positions to help relieve your breathlessness, how to pace yourself and techniques to help you conserve your energy.

Coping and support

- The impact of having bronchiectasis can vary from person to person. It can also vary at different time points, as you may have times where you have very few symptoms, and times when they are more troublesome.
- We know from previous work with patients and their families that bronchiectasis can affect more than just your physical health. It is not surprising that bronchiectasis can have a huge emotional impact and that it can also affect people's families and friends, their work and their day to day life and social activities.
- It is important to remember that you are not alone. There are lots of others who have similar feelings and you may find it helpful to see some of the videos on our website of patients talking about their experiences. It is also important to have a support network, which could include family, friends and your health care team, such as your GP, or specialist nurse in clinic. The British Lung Foundation can also offer support through a helpline and also an online community where you can talk to others in similar situations.

'Even though it's an illness and it's a symptom... it's normal for what you've got' P03

'My experience has been greatly helped over the last two or three years, or two years, since 've met the bronchiectasis nurse...He personally has helped me a lot, both psychologically and obviously as a patient...And he showed me, he, he showed me a lot of things that, erm, I was unaware of, really...I feel as though I could always contact him if I have a problem...and he will advise me accordingly.' P20

It is difficult to say exactly how many people have bronchiectasis, but estimates are between 26 and 50 thousand patients in the UK. This is much less common than conditions such as COPD, yet much more common than conditions such as cystic fibrosis.

In the North East we have approximately 1200 patients with a diagnosis of bronchiectasis, with over 300 attending the bronchiectasis clinic at the Freeman Hospital.

Carers and families

- Often family members and friends are acting as 'carers' without realising. If you provide support to someone who could not manage without this help, then you may be classed as a 'carer'.
- Caring for someone with bronchiectasis will vary depending on their specific needs, but at times this can be physically and emotionally difficult. Often people with bronchiectasis may not have any care needs at all.
- Things you may be able to help with include medications such as nebulisers which require washing after every use, or sometimes home IV antibiotics. You may also provide practical support with things that are now difficult to do alone, or simply emotional support. You may find that you can help with self-management, as you may be the first one to recognise signs of a chest infection for example.
- If you are a carer, having support from family members, friends and also the healthcare team is essential.
- You may be entitled to support or benefits and you can ask your GP about this.
- The British Lung Foundation and Carers UK can also offer advice.

'I try to reassure her to say, "You know, it's not as bad as that, try and be a bit more positive".' C02

'I think the hard thing is not just the emotional side of things for the patient, it's also for the family.' P11

'I just worry when he's ill, that's when I worry and I know when he's not right, I can tell.' C07

Further information

If you would like to find out more about bronchiectasis then you can go to the website that accompanies this booklet:

www.bronchiectasis.me

Other useful sources of information include:

The Newcastle Hospitals Bronchiectasis Service:

www.newcastle-hospitals.org.uk/services/cardiothoracic_services_bronchiectasis.aspx

The British Lung Foundation:

www.blf.org.uk/Home

Chest heart and stroke Scotland (CHSS)

www.chss.org.uk/chest/chest_conditions/bronchiectasis/index.php

CHSS bronchiectasis information booklet:

www.chss.org.uk/publications/documents/Chest/C4_bronchiectasis.pdf

Patient.co.uk information about bronchiectasis:

www.patient.co.uk/health/bronchiectasis-leaflet

Bronchiectasis information developed by a patient:

www.bronchiectasishelp.org.uk/#features/25

Bronchiectasis R Us: a forum and information site run by a patient:

www.bronchiectasis.info/

Information for carers:

www.carersuk.org/

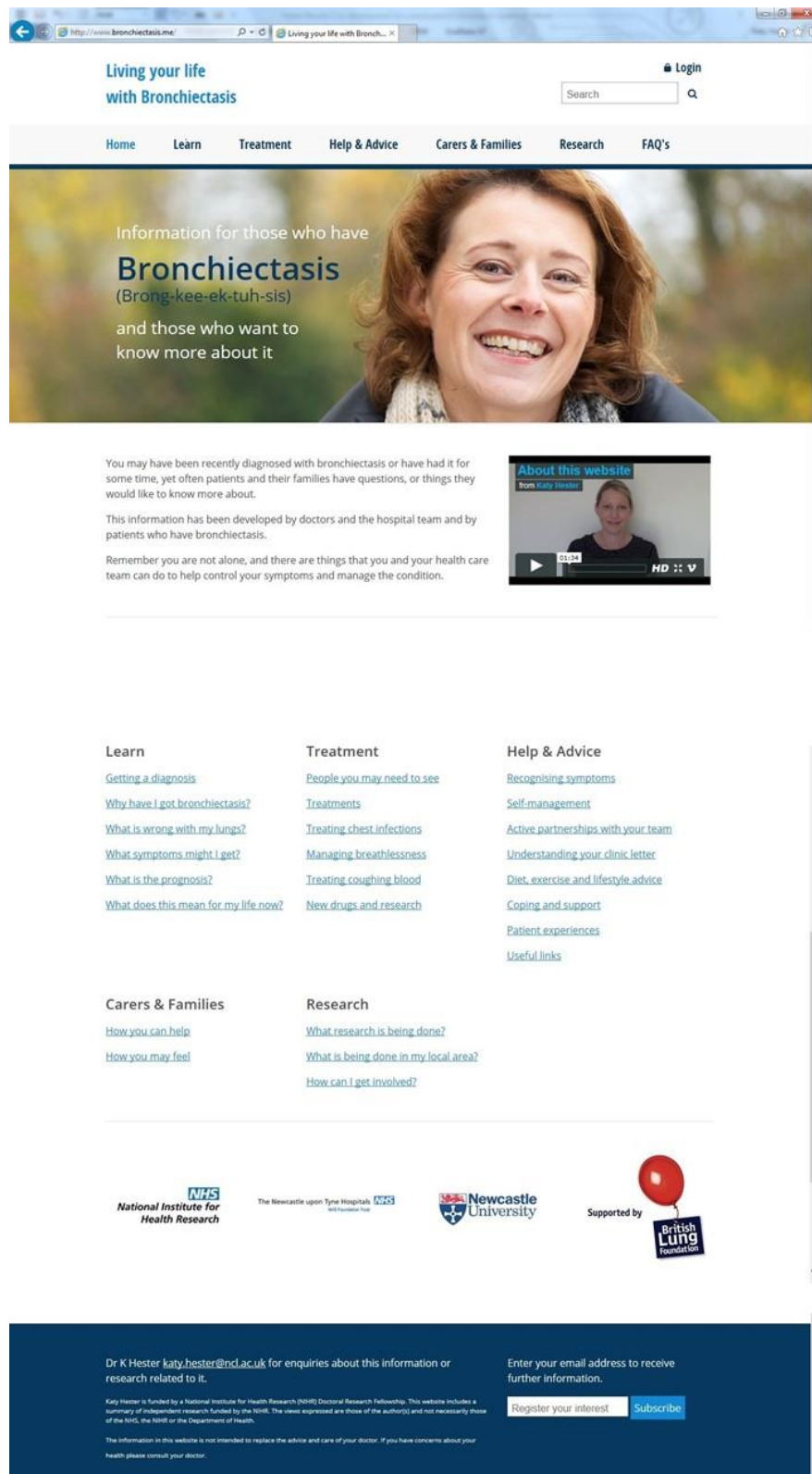
British Thoracic Society guidelines for management of bronchiectasis (*this is intended for medical professionals*):

www.brit-thoracic.org.uk/Portals/0/Guidelines/Bronchiectasis/BronchiectasisQFG_web.pdf

Current research studies in bronchiectasis and other lung conditions:

public.ukcrn.org.uk/Search/Portfolio.aspx?Level1=27&Level2=119&Level3=129&Status=34

Appendix 2 PDF of website www.bronchiectasis.me



The screenshot shows the homepage of the website www.bronchiectasis.me. The browser address bar shows the URL. The page has a navigation menu with links: Home, Learn, Treatment, Help & Advice, Carers & Families, Research, and FAQ's. A search bar is located in the top right corner. The main header features a large image of a smiling woman with the text: "Information for those who have **Bronchiectasis** (Brong-kee-ek-tuh-sis) and those who want to know more about it". Below this, there is a paragraph of text and a video player titled "About this website" featuring Katy Hester. The page is divided into several sections: "Learn" with links like "Getting a diagnosis" and "Why have I got bronchiectasis?"; "Treatment" with links like "People you may need to see" and "Treatments"; "Help & Advice" with links like "Recognising symptoms" and "Self-management"; "Carers & Families" with links like "How you can help" and "How you may feel"; and "Research" with links like "What research is being done?". The footer includes logos for the National Institute for Health Research, Newcastle University, and the British Lung Foundation, along with contact information for Dr K Hester and a sign-up form for email updates.

Living your life with Bronchiectasis

Search

Home Learn Treatment Help & Advice Carers & Families Research FAQ's

Information for those who have **Bronchiectasis** (Brong-kee-ek-tuh-sis) and those who want to know more about it

You may have been recently diagnosed with bronchiectasis or have had it for some time, yet often patients and their families have questions, or things they would like to know more about.

This information has been developed by doctors and the hospital team and by patients who have bronchiectasis.

Remember you are not alone, and there are things that you and your health care team can do to help control your symptoms and manage the condition.

About this website from Katy Hester

Learn

- [Getting a diagnosis](#)
- [Why have I got bronchiectasis?](#)
- [What is wrong with my lungs?](#)
- [What symptoms might I get?](#)
- [What is the prognosis?](#)
- [What does this mean for my life now?](#)

Treatment

- [People you may need to see](#)
- [Treatments](#)
- [Treating chest infections](#)
- [Managing breathlessness](#)
- [Treating coughing blood](#)
- [New drugs and research](#)

Help & Advice

- [Recognising symptoms](#)
- [Self-management](#)
- [Active partnerships with your team](#)
- [Understanding your clinic letter](#)
- [Diet, exercise and lifestyle advice](#)
- [Coping and support](#)
- [Patient experiences](#)
- [Useful links](#)

Carers & Families

- [How you can help](#)
- [How you may feel](#)

Research

- [What research is being done?](#)
- [What is being done in my local area?](#)
- [How can I get involved?](#)

National Institute for Health Research

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Newcastle University

Supported by British Lung Foundation

Dr K Hester katy.hester@ncl.ac.uk for enquiries about this information or research related to it.

Katy Hester is funded by a National Institute for Health Research (NIHR) Doctoral Research Fellowship. This website includes a summary of independent research funded by the NIHR. The views expressed are those of the author(s) and not necessarily those of the NIHR, the NIHR or the Department of Health.

The information in this website is not intended to replace the advice and care of your doctor. If you have concerns about your health please consult your doctor.

Enter your email address to receive further information.

Register your interest [Subscribe](#)

Getting a diagnosis

What the doctor may ask and why

If you see a doctor about the symptoms you have been having, they will ask you questions about:

- The symptoms you have e.g. cough, phlegm, breathlessness, number of infections and antibiotic courses.
- How long you have had these symptoms- sometimes people with bronchiectasis have symptoms for quite a while before a diagnosis.
- Any other medical problems you may have or medication you may take.
- Any family history of health problems.
- Your doctor will also need to ask you about smoking or contact with anything that can potentially affect people's lungs. People with bronchiectasis have often never smoked, whereas some lung conditions are caused by smoking, so to make sure a correct diagnosis is made, it is important to ask.
- If a diagnosis of bronchiectasis is suspected, you will be referred to see a hospital doctor who specialises in this condition.

How you may feel

- Getting a diagnosis of bronchiectasis affects people differently and reactions can include disbelief, worry or even relief to have an explanation for your symptoms. Some people can feel frustrated if they have had symptoms for a long time.
- We interviewed patients to find out about their experiences of diagnosis and these are some of their thoughts:

"I was shocked but sort of glad in a way, because it explained why I hadn't been well for so long" Tom, 33

"What first went through my mind...what caused it? Can it be cured? What does it mean for me?" Mike, 43

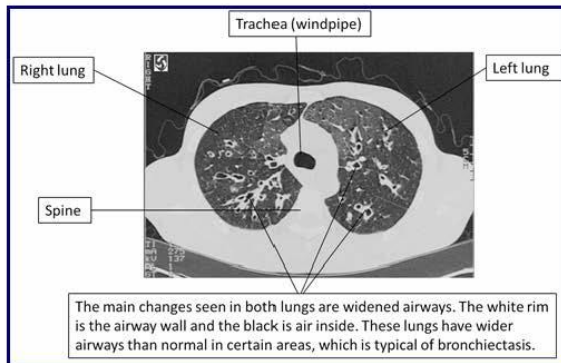
"Bronchiectasis... I just thought it was another word for 'bronchitis' really, I didn't give it much more thought." Paul, 75

"I often wonder 'Did I have it when I was a child?' when I think back to different symptoms I had." Shirley, 67

Tests that may be done

X rays and CT scans

- You are likely to have a chest X Ray performed first and then go on to have a CT scan of your lungs if bronchiectasis is suspected. This may be requested either by your GP, or when you attend your hospital clinic appointment.
- A chest X Ray may not necessarily show any changes in patients with bronchiectasis, and a CT scan is needed to confirm a diagnosis.



This is an image that you would get from having a CT scan of your lungs. These images are taken as 'slices' through the lungs and looked at as if looking up from your feet as you are lying down. Your doctor will be able to see any changes that are typically seen in bronchiectasis.

Breathing tests

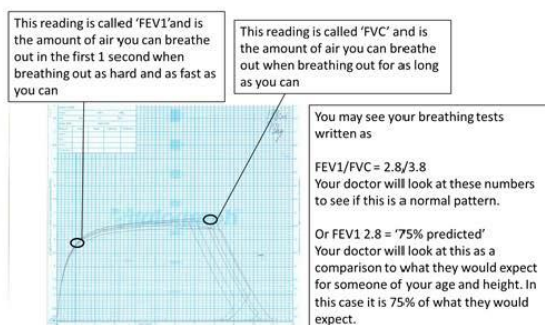
Breathing tests

- These may also be called lung function tests, pulmonary function tests, or spirometry.
- Sometimes these can be done by your GP, but more often they are done at a hospital clinic by the [lung function technician or lung physiologist](#) or by the doctor.
- This test shows how well your lungs are functioning and can guide your treatment.
- Your results may be normal even if you do have bronchiectasis, or they may show some changes.
- You will probably repeat these tests each time you attend a clinic appointment so that your lung function and progress can be monitored.

Breathing tests are done using the machine pictured.



When you blow into the attached tube, the machine records how much air you can breathe out in 1 second (FEV1 or Forced Expiratory Volume) and also when you breathe all the way out (FVC or Forced Vital Capacity). The machine produces a graph like the one below.



The results are then compared to what we would expect them to be for someone of your age and height. That way we can see if your lungs are working as well as they should be.

Sputum (phlegm) tests

- It is very important to be able to clear any phlegm from your chest, and also for samples to be regularly sent to the laboratory to be analysed.
- That way we can see which bugs may be present in the lungs, which can help to guide your treatment.
- You will be asked to give a phlegm sample in a sterile pot when you attend clinic.
- It is helpful if you can try to give a sample when you have an infection or flare up before you start a course of antibiotics to ensure you are on the correct treatment. You may start antibiotics before results are available, as these can take several days.

Blood tests

- When making a diagnosis of bronchiectasis, there are certain blood tests that need to be done. These are often done at your first hospital appointment, but may be done by your GP.
- After these initial blood tests, you will probably not need regular blood tests, just if there is a specific need. Some medications may require you have regular blood tests.

Your blood will be sent to:

Immunology

Checking your immune system and your body's response to certain bacteria, vaccines and things you may be allergic to.

Haematology

Checking your blood cells.

Biochemistry

Checking your kidneys, liver and vitamin D levels.

Genetics

In certain situations more detailed genetic tests may be done.



More detailed tests

- Occasionally more detailed tests need to be done.
- This may include genetic tests or tests of how the cilia (tiny hairs within the lungs and airways) are working, depending on your age and family history, or special types of imaging, for example if you have been coughing blood (haemoptysis), or a camera test of the lungs called bronchoscopy. These are extra tests and are not done routinely. Your doctor will explain to you about these tests if you need to have them.
- The British Thoracic Society have [guidelines for bronchiectasis](#) that give details of what tests should be done and why. These guidelines are written for health care professionals rather than patients.

Why have I got bronchiectasis?

It is difficult to say exactly how many people have bronchiectasis. Estimates used to be between 26 and 50 thousand patients in the UK. A more recent study suggested that there are over 300,000 living with bronchiectasis in the UK. This is much less common than conditions such as COPD, yet much more common than conditions such as cystic fibrosis. In the North East of England, for example, there are approximately 1200 patients with a diagnosis of bronchiectasis.

Causes

- Up to half of people who are diagnosed with bronchiectasis have 'idiopathic bronchiectasis'. This means that they have bronchiectasis, but do not have any other underlying cause. There are also certain illnesses that are linked with bronchiectasis:
- Some other medical conditions are associated with bronchiectasis such as inflammatory bowel disease (ulcerative colitis and Crohn's disease), rheumatoid arthritis and sjogren's syndrome.
- Having an immune system deficiency can also be linked with developing bronchiectasis.
- Certain lung infections often seen in childhood such as whooping cough, pneumonia or TB can be linked with developing bronchiectasis later in life.
- A problem with the normal structure or function of the lungs can also lead to bronchiectasis. This includes conditions such as primary ciliary dyskinesia, where the tiny hairs that work to protect the lungs do not work properly.
- Sometimes, people who have had chronic obstructive pulmonary disease or asthma for many years can go on to develop bronchiectasis also.
- If your doctor suspects a diagnosis of bronchiectasis, they will also test for any of these related causes to ensure that you have the right treatment.

Common misunderstandings

"I thought a cough and a spit sort of thing was like when old people had been smoking and things like that, and they've brought it on themselves, not something that just happened to you, I mean I don't smoke." Celia, 67

"Have I still got emphysema? Is bronchiectasis worse than emphysema, or different?" Jean, 76

People often ask if bronchiectasis is the same as the smoking related lung disease COPD, and people who have bronchiectasis are often upset and frustrated that others assume smoking has caused the problems with their lungs.

Bronchiectasis is not the same as COPD or asthma.

Bronchiectasis is caused by many different conditions.

Many patients with bronchiectasis have never smoked, whilst COPD is caused by smoking fairly heavily.

It is important to note that some patients develop bronchiectasis as a complication of COPD. As both conditions can cause, cough, breathlessness, repeated chest infections and abnormal breathing tests, it is not surprising that they can also sometimes be mixed up.

In the UK, most GPs will look after 150-200 patients with COPD, whereas most practices will have less than 10 patients with bronchiectasis.

One thing that clearly links the two conditions is the need to stop smoking if you are a smoker to reduce your chances of further lung damage and also reduce the risks of developing lung cancer and other smoking-related diseases.

“Is it catching?”

Bronchiectasis is not catching or contagious. If you have bronchiectasis, you may find that if you are around people who have chest infections or colds that you are more prone to becoming unwell yourself. The day to day coughing of a person who has bronchiectasis however is not 'catching'.

There are strict cross infection guidelines for cystic fibrosis (a rarer cause of bronchiectasis). This is because in that setting there is clear evidence of bacteria being spread between patients. There are very limited studies in bronchiectasis and current practice is therefore based on opinion. As new research becomes available the advice may change. It is practical to suggest avoiding mixing with other patients who have bronchiectasis when they have an active infection. You should ask your Doctor or Nurse if you have concerns.

What is wrong with my lungs?

- Bronchiectasis is a long term condition affecting the airway tubes (bronchi and bronchioles). The airway tubes have become damaged and widened due to inflammation, and can develop 'pockets' probably due to both scarring and weakness around the airway. These 'pockets' in the airways mean that mucus gets trapped. The trapped mucus doesn't get removed as quickly as usual and this allows bugs that land in the lung to stay down in the lungs. Once the bugs grow to a certain level a chest infection or flare up occurs.
- In summary the airways are widened and inflamed leaving thick mucus that gets trapped in the lung making you prone to infection. As there is a bit of scarring round the airways the condition cannot be cured, but it is very treatable.

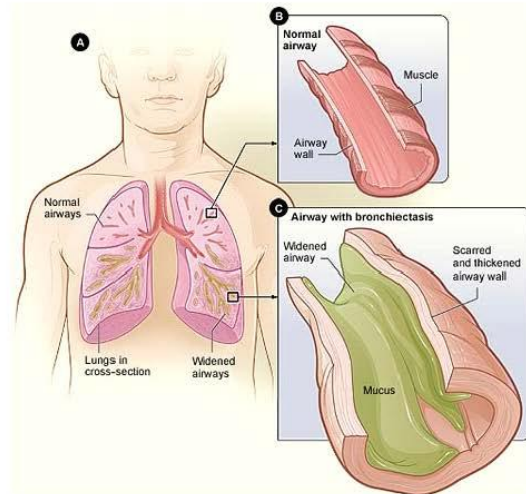


Image courtesy of National Heart Lung and Blood Institute

What symptoms might I get?

Cough

- It is usual for people who have bronchiectasis to have a chronic, productive cough. This means that you are likely to cough, and produce phlegm, on most days.
- This is not the case for everyone, and with the correct treatment, including good physiotherapy to clear your chest regularly, your cough should become less of a problem.
- Your cough is likely to change, for example if you have a chest infection. You may notice that you are coughing more often, producing more phlegm, or a change in colour of your phlegm, becoming more yellow or green. Over time you will become more aware of your 'normal' cough and phlegm and what changes signal that you need antibiotics.

Cough incontinence

- Urinary incontinence (bladder leakage) is common in patients with bronchiectasis. Although incontinence is not life-threatening, the impact on patients, families and carers may be profound and it is vital that people are given every opportunity to regain their continence.
- People who are referred into the continence service will be seen as an outpatient where a continence assessment and a personalised treatment plan will be made based on treatments relating to:-

1. general bladder health
2. training in pelvic floor strengthening
3. urge suppression techniques
4. voiding techniques
5. bladder re-training

The treatment you have will depend on the identified type of incontinence.

- A common identified bladder symptom is stress urinary incontinence and this is when urine leaks from the bladder due to a sudden extra pressure, for example when you cough. This occurs because the pelvic floor muscles and urethra cannot withstand the extra pressure and the pelvic floor muscles are weak. The amount of urine leaked can vary.
- Evidence suggests that pelvic floor muscle exercises are an effective treatment for stress urinary incontinence. These exercises are appropriate for all women except those who have had recent pelvic floor surgery.
- If you are experiencing any problems with your bladder then please discuss this with your Specialist Consultant who is used to helping people with this kind of problem and who can refer you for assessment and treatment to the appropriate specialist service.

[Click here to see the role of the continence nurse](#)

For other advice about Bladder care visit:
<http://www.bladderandbowelfoundation.org/>

Coughing blood (haemoptysis)

- Sometimes, coughing blood can be a symptom that people with bronchiectasis experience. Coughing blood can be frightening, and your doctor is likely to do some tests to find out why this has happened. This can occasionally be a sign of other lung conditions and should always be reported to your doctor.
- Coughing blood could be small amounts of fresh (red) or old (brown or rusty) blood mixed in with phlegm. For some people with bronchiectasis, this can happen when they have a chest infection and settles when they are given antibiotics.

- Occasionally coughing larger amounts of blood can be a problem. This can happen if some of the blood vessels in certain areas of the lungs become more likely to bleed. If you have coughed up blood, it is important to tell your doctor, and if it is larger amounts this needs to be treated quickly.
- If this is a problem for you then you may have a specific type of scan called pulmonary angiography to look at the blood vessels in the lungs. If there are vessels that can be seen to be the cause of the bleeding then this can be helped by a procedure called embolisation where the blood vessel(s) causing the trouble are blocked off. Occasionally surgery is used to remove the area of lung with abnormal vessels and bleeding.

Sputum (phlegm)

- Having a chronic cough and phlegm are symptoms of bronchiectasis. This could be described as 'normal' for people who have the condition. Some people however, have very little phlegm unless they have an infection, or may only produce phlegm first thing in the morning. Others produce large amounts of phlegm on a daily basis.
- Amount and colour of phlegm varies between individuals, and can also vary at different times of the day, or if you have a chest infection. Over time you will begin to learn what is 'normal' for you, and what changes in your phlegm signal that you have a chest infection.
- Changes can include an increase in amount of phlegm or a change in its colour, for example a darker green than usual, or a change from white to yellow. It all depends on the individual, and learning to recognise these signs is an important step in [self-management](#).
- Clearing the phlegm from your chest is vital to keep your lungs as healthy as possible.

Clearing your chest

Physiotherapy

Why do I need physiotherapy?

- Bronchiectasis can cause mucus to collect in the lungs and become infected.
- As a result of this you will be more susceptible to chest infections than other people. You may also have a persistent cough.
- Each time you get a chest infection it can cause a little more damage and scarring to the lungs.
- You may find that with these problems you get more breathless and can lose fitness.

How can physiotherapy help me?

- Your respiratory physiotherapist will teach you airway clearance techniques to do daily at home.
- This is to help keep your chest clear of sputum so that your condition impacts you as little as possible on your everyday life.
- It will also help with the persistent cough that many people have.
- It is very important to keep fit so that you remain as well as possible. See 'diet exercise and lifestyle advice'. There are also techniques to help with managing breathlessness.

What will this physiotherapy be?

- Your physiotherapist will need to fully assess you. He or she will ask you questions about your symptoms and your sputum, and will examine your chest.
- You will then discuss options of different methods to help you remove the sputum from your lungs.
- Your physiotherapist will help you choose the airway clearance technique that is most suited to you and your particular needs, and recommend how often you should perform them.

How will I know if my regular chest physiotherapy is not enough or if I should change my treatment?

- If the method you use to clear your chest is not working for you, if you have difficulty in clearing your sputum, or you are not comfortable with the technique, contact your physiotherapist about trying a different one.
- At times when you have a chest infection you may also need to change or add to your treatment.

Microbiology (bugs)

The common bugs seen in Bronchiectasis are bugs generally known to be found in the upper airway of healthy people.

These include:

Haemophilus influenzae
Moraxella catarrhalis
Streptococcus pneumonia
Staphylococcus aureus

- We think these bugs land in everyone's lungs all the time but in bronchiectasis instead of being swept out of the lungs by the tiny hairs they get trapped and start to cause infections. Rarer bugs are found from time to time and you should ask your doctor what these mean.
- One key point is that the above bugs often respond to common tablet antibiotics such as Amoxicillin or Doxycycline.
- As the mucus and the airway walls in bronchiectasis are thicker, the current national guidelines are that people with bronchiectasis should have 14 days (a fortnight) worth of antibiotics.
- One of the reasons we ask patients to give a sample when you are stable at clinic AND when you are having a flare up is to keep an eye on which bugs are in the lung. Most patients do "keep" the same bugs. The resistance against antibiotics can however change in the "same" bug from time to time, which may mean an antibiotic that has worked for you in the past may not work so well.
- From time to time a new "visitor" bug can appear in the sputum. This might also mean you need different antibiotics to your usual. If we don't keep an eye on your bugs through sputum samples the risk is that we use the wrong antibiotic and you remain poorly for longer.
- Pseudomonas is a bug often seen in patients needing specialist care in hospital clinics. Pseudomonas almost never responds to standard antibiotics and the only tablet antibiotic known to work against it is ciprofloxacin. If you have Pseudomonas long term then ciprofloxacin is the first choice treatment for flare ups. If you have Pseudomonas and don't improve with ciprofloxacin tablets this may mean you need to have a course of intravenous antibiotics through a "drip".
- In patients with repeated infections we can try nebulised (mist delivered) antibiotics. Colistin (often called colomycin) and Gentamicin are two very different antibiotics that might reduce flare ups by keeping the bug numbers low. These treatments won't make you feel suddenly better. When used in this way they are not treatments for a flare up but are long term treatment aiming to drop the number of infections you get in a year. One challenge is that these treatments do take time and effort as the nebuliser can take over 10 minutes twice a day. Some patients struggle to keep taking them regularly.
- At present there are no licenced antibiotic inhalers for use in bronchiectasis. These are currently being tested in research trials so may be an option in the future.

Exacerbations (chest infections)

- Exacerbations or chest infections are common in bronchiectasis. Having repeated chest infections is often what leads people to seek their doctor's advice before a diagnosis is made.
- Although people who have bronchiectasis may usually have a cough and phlegm that is 'normal' for them, from time to time these symptoms will change and could indicate the start of a chest infection.

Common signs of a chest infection include

Coughing more than usual
Change in colour or amount of phlegm
Feeling more breathless than usual
Having a high temperature
Feeling generally unwell
Occasionally, having pain in the chest

- Not all people will have all of these symptoms with a chest infection. Over time, you may start to recognise a pattern that tells you that you have a chest infection.
- Managing infections correctly and quickly is very important in bronchiectasis. You can find out more about what you should do if you think you have an infection [here](#).

Breathlessness

- Breathlessness can be described in many ways. Some people call it feeling out of breath, feeling short of breath or having trouble catching their breath. Doctors often call breathlessness 'dyspnoea'.
- Breathlessness can be a symptom of bronchiectasis, but not for everyone. Some people find they do not get breathless, whereas others may have some breathlessness even when they are well.
- Knowing what level of breathlessness is 'normal' for you will help you to recognise if this symptom gets worse.
- Some people find that feeling more breathless than usual can be a sign that they are developing a chest infection. Often this is as well as a change in amount or colour of phlegm.
- Breathlessness can also be a symptom of other illnesses, so it is important to discuss any changes in breathlessness with your doctor.

You can find out more about how to [manage breathlessness here](#).

Fatigue

"But bronchiectasis does make you feel tired as well, it takes it out of you, you know." Celia, 67

- If you have bronchiectasis and experience fatigue or extreme tiredness, you are not alone. We know that many people with bronchiectasis have fatigue. Unfortunately, we do not know the exact reasons why this happens.
- Fatigue can be a problem in many chronic diseases, including other diseases of the lungs, such as chronic obstructive pulmonary disease (often called COPD) and diseases involving other parts of the body, such as the liver.
- When we carried out some research into fatigue in bronchiectasis we found that people with more symptoms of breathlessness tended to have more problems with fatigue. People with low levels of lung function measured by breathing tests were also more likely to experience fatigue. Having fatigue doesn't mean you have very severe bronchiectasis - it can be a symptom across all stages.
- People who have bronchiectasis often say that fatigue can be worse when they feel an exacerbation or infection coming on. If you have recognised this, you may have found that this is an early warning sign for you. If you think you may need antibiotics it is important to follow your self-management plan if you have one, or speak to your doctor or nurse.
- People who have periods of feeling extremely tired say they have to rest on those days if possible, and look forward to the days when they are not feeling so fatigued. Pacing yourself is very important. Looking after your body, managing your bronchiectasis and treating flare ups quickly is important. Doing this could help you to feel less tired.
- Pulmonary rehabilitation (a series of gentle exercises to improve body strength often supervised by a physiotherapist) is something you may wish to discuss with your doctors. It is recommended in the UK

national guidelines for patients who have breathlessness when walking 100 yards or less on the flat. It can help people have a better quality of life.

- Remember, you are not alone in feeling like this, but you should always discuss any symptoms with your doctor, particularly any sudden change in fatigue. They will do any necessary tests and may be able to offer you help and advice.

Anxiety and Depression

"I try not to let it get me down, but obviously sometimes it does." Shirley, 67

"Some days it gets on top of me, and others I just say ... pull yourself together, you are stronger than that, it's just a bit of phlegm... and there are people that are worse off than me, so you just get on with it and accept it." Celia, 67

- Anxiety and depression can be a problem for anyone who is living with a chronic illness, and may vary depending on how the illness is affecting you at any one time.
- We know that people with bronchiectasis can experience anxiety and depression. You may be asked to fill in a questionnaire about this when you attend clinic. This way we can see if this is a problem for you, and help you to find ways to manage it.
- One trigger for anxiety can be the feeling of breathlessness. This can sometimes be quite frightening, and along with treating any medical cause such as a chest infection, you may find it helpful to develop ways to manage this feeling. You can find out more about [managing breathlessness here](#).
- Sometimes, you may be asked if you would like to see a specialist nurse who may be able to help you with these feelings.
- The British Lung Foundation can also offer advice about coping with anxiety and depression. For more information visit www.blf.org

What does this mean for my life now?

"Even though it's an illness and it's a symptom... it's normal for what you've got." Shirley, 67

Impact and coping

- We know from previous work with patients that having bronchiectasis can have a huge impact on many aspects of your life. This includes not only the physical impact that bronchiectasis can have, but the emotional impact, and how it affects things such as work, daily activities, families, relationships and social activities.
- Having a support network can be very helpful. This may include your family, friends and your health care team such as your GP or specialist nurse.
- Some people find it helpful to speak to or hear about others who can relate to the problems they are having. You may find some of the videos and quotes on this website from other patients helpful. There are also other websites that you may find useful.
- [You can see patients talking about their experiences here.](#)
- [The British Lung Foundation have a support line](#) and an [online community](#) where you can chat to others in similar situations.
- There are also some bronchiectasis websites set up by patients. Follow the links below to look at these.

<http://www.bronchiectasishelp.org.uk/#features/>
<http://www.bronchiectasis.info/>

Remember you are not alone in feeling like this. Please speak to your doctor or nurse if you are having difficulty coping.

Practical tips

Holidays, flying, insurance

- Many patients with bronchiectasis and other chronic diseases requiring long term treatment have queries about holidays. Often people worry about whether they should fly, and how much their insurance will cost.
- Unless your doctor has advised you not to fly for a specific reason (sometimes you may need to have a 'flight test' to see if your oxygen levels would be ok on-board a flight) then you should be fine to fly. If you are worried, ask your doctor. You will need to take your usual medication and a copy of your prescription or clinic letter with you. These should be carried in hand luggage. If you use a nebuliser there may be quite a bit of equipment, including needles to take on the flight. This will be allowed as long as you have evidence that it is your prescribed treatment.
- Holiday insurance can be expensive for anyone who has health problems. Shopping around is the best way to try to find a good deal. The British Lung Foundation have recommendations on their website:

<http://www.blf.org.uk/Page/Travel>

Devices

- There are a number of devices that are used in bronchiectasis. These include simple things such as chest clearance aids including flutter and acapella devices and also nebulisers, oxygen cylinders or concentrators and rarely machines and masks that help with breathing (usually at night) called non-invasive ventilation or CPAP.
- Again, when travelling you will need to take this equipment with you. All these devices can be taken on an aircraft, but you should make it clear that you have them in advance.

- We know from other research that some people choose not to take their nebuliser when on holiday. This is probably ok for short periods, but you should always take your treatment as directed by your doctor and taking to your treatments regularly is extremely important. If you want to have a 'treatment holiday' from any of your treatments you should discuss this with your doctor.

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People you may need to see

Hospital consultant and team

If your GP suspects you may have bronchiectasis, you will be referred to a hospital doctor who specialises in this condition. You will attend an outpatient clinic appointment where you will see either the consultant or one of their team.

GP

- Some people see their GP quite frequently and others have little contact with them.
- Once you have a diagnosis of bronchiectasis you may find that you see the hospital team more than your GP.
- You will still need to see your GP at times and also to ensure that you get the medication that you need.
- It is important that you communicate with your GP. It is particularly important that they know about the type of [antibiotics](#) that you need and how long you need them for. If you play an active role then you can make sure that everyone knows what you need.

Physiotherapist

- Physiotherapy is extremely important to make sure that you can [clear the sputum or phlegm from your lungs](#).
- You will see a physiotherapist who specialises in how to do this.
- Physiotherapists can also help you with maintaining fitness, [managing breathlessness](#), pulmonary rehabilitation and [cough incontinence](#).

Specialist nurse

- Often the hospital will have a nurse who specialises in lung diseases and bronchiectasis.
- You may see them when you go to clinic or if you are ever admitted to the hospital ward.
- In some hospitals the specialist nurse may be able to offer advice over the phone about your treatment or any problems you are having. They may also offer a service for people who need to take [antibiotics into the vein](#) but prefer to do this at home rather than in hospital.

Lung function technician

- When you are referred to the hospital you will have some breathing tests done.
- These are often done by a lung function technician or physiologist.
- These tests may be done in the clinic or you may go to a separate department to have them done.

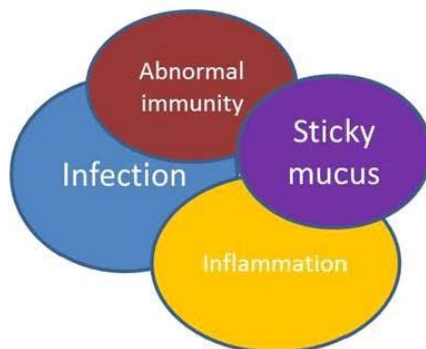
Dietician

- Often people with bronchiectasis can be helped by having advice from a dietician.
- This may be general healthy [diet and lifestyle](#) advice or specific advice tailored to your needs.
- Sometimes people with bronchiectasis struggle to keep their weight up and a dietician can advise you.

Continence nurse

- Having a chronic cough can cause some people to experience [bladder leakage or cough incontinence](#).
- This is something that is important to tell your doctor about so that they can refer you to a nurse who specialises in helping with this.

Treatments



This diagram shows the problems that contribute to the symptoms of bronchiectasis. They are all linked together: Having sticky mucus that is difficult to clear from your chest will lead to more infections and inflammation in the lungs. If your immune system is not working properly you will also be prone to infections.

- To treat bronchiectasis, different treatments are needed to work on each of these factors.
- Treatments will differ between people depending on which aspects cause most of a problem for them.
- For example, to help with [mucus clearance](#), tablets that make the mucus thinner and easier to cough up can be used, and physiotherapy is very important to help to clear the mucus from your lungs.

Frequently used treatments

Antibiotics

Antibiotics are needed for 14 days when you have a [chest infection](#), [flare-up](#) or [exacerbation](#) of bronchiectasis.

The antibiotics used will vary depending on which bugs there are in your sputum. This is why it is important to give a phlegm sample when you notice things changing, so that your doctor knows which antibiotics would be best for you to have. You can then start a course of antibiotics without having to wait for the results. Often antibiotic choice will be guided by what bugs you have had in the past or which antibiotics have worked best for you in the past. If the results show a new bug or a bug that will not be treated by the antibiotics you have started, your doctor may prescribe a different antibiotic.

It is important that you play an active role in putting in a sputum sample early, and telling your doctor which treatments work best for you.

Sometimes, antibiotics are also used long-term, not just for a 2 week course. These include a tablet called [azithromycin](#), and nebulised antibiotics such as [gentamicin](#) and [colomycin](#).

More details can be found below

Antibiotic tablets

- Standard antibiotics for flare-ups or chest infections in bronchiectasis tend to be:
- Amoxicillin 500mg three times a day for 14 days or Clarithromycin 500mg twice a day for 14 days if you

are allergic to penicillin.

- Other tablet antibiotics frequently used for flare-ups include doxycycline and ciprofloxacin. Ciprofloxacin tends to be used if you have the bug *Pseudomonas aeruginosa* in your phlegm. There are other tablets that are used depending on the bugs in your sputum.
- If you are having more than 3 courses of antibiotics in a year, your doctor may recommend trying a tablet called azithromycin. This is an antibiotic that also reduces inflammation in the lungs. It is usually taken 3 times a week (mon/weds/fri) and you may stay on this long-term. If you are on this tablet you will need to have regular liver blood tests and mention any hearing problems to your doctor.

[Click here to see more information about azithromycin](#)

- Another way of taking long-term antibiotics is by nebuliser.

Nebulised antibiotics

- If you have more than 3 infections per year requiring antibiotics, have lots of troublesome sputum or if the bug *pseudomonas aeruginosa* is repeatedly grown from your sputum samples, having long term antibiotics via a nebuliser may be an option.
- Antibiotics that are given through a nebuliser commonly include gentamicin and colomycin.
- More details can be found in the [nebulised treatments](#) and [microbiology](#) sections.

Antibiotics into veins (intravenous/IV)

Sometimes you might need IV antibiotics if you are very unwell or if you have an infection that does not respond to tablet antibiotics.

Having IVs in hospital

- Some people come into hospital for their IV antibiotics and stay there while they have the course of treatment (usually 2 weeks). This may be because you're unwell or don't have the support to continue your treatment at home. In this case, hospital is the safest place to be. Often being in a place of safety and having the opportunity to rest and recover will enhance your recovery from a flare up of bronchiectasis.
- In addition to your IV antibiotics treatment, you will also meet a range of health professionals who can help you with your disease. These will include doctors, nurses, physiotherapists, dieticians and other members of staff.

Having IVs at home

- You may be able to have IV antibiotics at home. You or your family member can be trained to prepare and give IV antibiotics. This will depend on whether your medical team are able to offer this service. If they are, they will make sure that you have the right training, education and support in order to be able to do this. They will also offer a point of contact at the hospital in case you have any problems when you are at home. Usually you will be in hospital for a short time and then continue the course at home.
- If you don't feel confident doing this yourself at home, some community teams have nurses who have the skills to help. Unfortunately, not all areas currently offer this service. Please speak to hospital staff to see if this is an option.

"I'm quite confident now. At first it's nerve-wracking trying to remember what to do but when I had finished this fortnight I was quite confident...the nurse is very helpful, and I've got a sheet of paper telling me exactly what to do, so I was quite confident really when I started them." Elaine, 68

IV antibiotics can be given by:

1. **Cannula:** a small plastic tube inserted into a vein in your arm. The IV antibiotics are given directly into

this. A cannula usually needs to be changed every 3 days for infection control reasons.

2. **Midline catheter:** a very thin tube, longer than a cannula, which is also inserted into a vein in your arm. This is done on the ward by a very experienced nurse or doctor and is a much safer way of giving your IV antibiotics. A midline is more comfortable and can also stay in the arm for the duration of the treatment and does not need to be changed.
3. **Portacath:** a small device which is inserted under the skin in your chest. This is performed by a radiology doctor in the x-ray department. A tube connects the portacath to your veins. When you need IV antibiotics an experienced nurse will insert a special needle into this portacath and secure it with a dressing. This special needle then stays in for the course of the treatment. When the treatment is finished the needle is removed. We generally reserve portacaths for people with difficult veins or those who require frequent courses of IV antibiotics. Portacaths can stay in place for many years and complications are rare.

[Click here to see how to give IV Ceftazadime](#)

[Click here to see a Home IV Instruction Manual](#)

ALWAYS GIVE A SPUTUM SAMPLE BEFORE STARTING A COURSE OF ANTIBIOTICS

Nebulised treatments

- Nebulised treatments involve converting a liquid into a mist which you can then breathe in. By aiming the treatment directly at your lungs we can minimise any side effects.
- Nebulised treatments can cause you to have some wheezing or cough either on commencement of the treatment or after a period of a few weeks.
- Patients go into hospital to commence the treatment and staff will measure your breathing tests and monitor you to make sure that the treatment is right for you.
- A number of different nebulisers are available. The hospital are likely to give you a standard nebuliser, but smaller, faster versions are available that you may find easier to travel with for example.
- Nebulisers take up a certain amount of your time – both to prepare and inhale the treatment, and to clean the nebuliser afterwards.

[Click here to see a nebuliser information leaflet.](#)

A number of different treatments can be given via a nebuliser. In bronchiectasis the most commonly used are:

Nebulised Antibiotics

- Colomycin and gentamicin are the most commonly used nebulised antibiotics in bronchiectasis. This involves inhaling a fine mist of liquid antibiotics which can be breathed in through a mouthpiece.
- Your doctor may suggest that you try these if for example you are having lots of chest infections or flare ups, have lots of troublesome sputum or if you have particular bugs such as *pseudomonas aeruginosa*. The aim of the treatment is to reduce the number of flare ups you have been having and to improve your symptoms. Some people feel that the volume of sputum is reduced whilst on inhaled antibiotics. You may have a trial for a few months at first, and then continue long-term if you have had improvements in your symptoms.
- If you are starting a new nebulised treatment, you will have a test dose at the hospital first. This is to make sure that you know how to do the treatment and that you do not have any reactions to it. Occasionally inhaling treatments can make some people wheezy. If this is a particular problem for you, you may have to try alternative treatments.

[Click here for more information about nebulised gentamicin.](#)

[Click here for more information and nebulised colomycin.](#)

Nebulised hypertonic saline (salty water)

- This is a strong salt solution which is used in a nebuliser. This is something your doctor may suggest trying if you are having frequent infections or have difficulty clearing sputum from your lungs when doing physiotherapy. Using this treatment can help to break the phlegm up and make it easier to cough. We normally prescribe it twice a day.
- Some patients use it twice a day when their phlegm is sticky or if they are unwell. When they are feeling better, or their sputum is less sticky, they may reduce the frequency.
- When you first start you will have a test dose in hospital and have your breathing tests checked before and afterwards. This is because it can make some people breathless and we need to check that this is not a problem for you.
- Click on these links to get more information about hypertonic saline.

[Information about nebulised hypertonic saline](http://www.youtube.com/watch?v=LIdaiSe3Pn8)
<http://www.youtube.com/watch?v=LIdaiSe3Pn8>

Inhalers

- Sometimes inhalers are used in bronchiectasis.
- Although bronchiectasis is NOT the same as asthma or COPD (smoking related lung damage), some of the ways the lungs are affected are similar.
- This means that for some people, inhalers can be useful.
- These may include 'relievers' (salbutamol), which act to open up the airways, relieving breathlessness on exertion.
- Some inhalers contain a small dose of steroid, which acts to reduce inflammation in the airways (beclometasone) and are usually used in asthma. Evidence from studies in bronchiectasis only supports the use of these inhalers in bronchiectasis if there are some asthma symptoms too.
- Other inhalers contain a combination of a steroid and an airway opener, such as symbicort or seretide. Although these are not routinely used in all patients with bronchiectasis, they are sometimes used.
- The decision to use inhalers will be based upon your symptoms, your medical history and your breathing test results.
- If you do take inhalers it is very important that you follow the correct procedure for taking them.

Here are some links to see videos about how to use your inhalers

[How to use an accuhaler \(seretide\)](#)

[How to use a turbohaler \(symbicort\)](#)

[How to use a metered dose inhaler](#)

[How to use a metered dose inhaler with a spacer](#)

[How to use an easi-breathe inhaler](#)

[How to use a handihaler \(Spiriva/tiotropium\)](#)

[How to use a respimat inhaler](#)

Mucus (phlegm) thinning tablets

- A tablet called carbocisteine or Mucodyne is sometimes used to help make sputum (phlegm or mucus) easier to clear from your lungs.
- This is something that your doctor may suggest if you have difficulty clearing your chest.
- Clearing phlegm from your lungs is very important in bronchiectasis and can reduce the number of infections that you have.

Mucus (phlegm) clearance

- This is extremely important for people who have bronchiectasis.
- Performing chest physiotherapy is essential to clear your chest.

Please see the additional sections relating to this for more information and videos:

[Physiotherapist](#)

[Clearing your chest](#)

[Symptoms you might get](#)

Treatments less frequently used

Surgery and embolisation

- In the past, surgery was more often performed for people who had bronchiectasis in a particular lung segment. This would involve that section of the lung being removed. We now know that this is not often helpful, and so surgery is very rarely performed in bronchiectasis any more.
- Sometimes people can have a problem with [coughing blood](#). If this is a problem for you then you may have a specific type of scan called pulmonary angiography to look at the blood vessels in the lungs. If there are vessels that can be seen to be the cause of the bleeding then this can be helped by a procedure called embolisation where the blood vessel(s) causing the trouble are blocked off, and occasionally by surgery to remove the area of lung with abnormal vessels and bleeding.

Lung Transplantation

- Lung transplantation is again rarely needed in bronchiectasis.
- In certain circumstances, this may be thought to be a suitable treatment. This is reserved for people who have very severe lung disease and no other treatment options. They would also have to be otherwise healthy and meet certain other criteria.
- This is a very complex process, but if your doctor thinks it may be the best treatment for you then they will discuss this with you.

[The British Lung Foundation](#) can provide more information about lung transplantation.

Oxygen

- Occasionally, people who have severe lung disease of any kind, require oxygen to be used at home.
- When you attend clinic and have breathing tests done, your oxygen saturation levels are also checked. If your oxygen falls below a certain level, then you may need to be assessed for home oxygen use.

[The British Lung Foundation](#) can provide more information about oxygen.

Treating chest infections

- Recognising the signs of a flare-up and knowing what to do is very important.
- Give a sputum sample at the first sign of an infection, before starting antibiotics.
- Make sure you take your antibiotic course for 14 days – remind your GP if necessary.

For treatments see the relevant sections

Managing breathlessness

- [Breathlessness](#) can sometimes be a problem for people who have bronchiectasis. Some people may not really experience breathlessness at all, and some may find this is their main symptom.
- Over time you will begin to learn what level of breathlessness is 'normal' for you. For some people, becoming more breathless can be a sign of a chest infection. Breathlessness can be frightening and you should seek medical help if you have a change in your level of breathlessness that concerns you.
- Your doctor can assess the reasons for your breathlessness as it can have different causes. One of the ways in which your breathing can be assessed is by doing [simple breathing tests](#). This way your doctor can see how well your lungs are functioning.
- Your doctor may also use a scale called the Medical Research Council Dyspnoea Scale, to record your level of breathlessness:
 1. Not troubled by breathlessness except on strenuous exercise
 2. Short of breath when hurrying or walking up a slight hill
 3. Walks slower than contemporaries on the level because of breathlessness, or has to stop for breath when walking at own pace
 4. Stops for breath after about 100 m or after a few minutes on the level
 5. Too breathless to leave the house, or breathless when dressing or undressing
- You may be offered pulmonary rehabilitation sessions. This is a supervised group exercise programme in your area specifically for individuals with lung conditions. It is a mixture of exercise and education sessions over a number of weeks. Pulmonary rehabilitation has been shown to be beneficial for some people with bronchiectasis. If you are interested, please discuss with your physiotherapist, consultant or GP.
- Maintaining some level of exercise can also help with breathlessness, you can find more information in our [diet, exercise and lifestyle advice section](#).
- If you do get breathless, pacing your activities can be very helpful. Your [physiotherapist](#) will be able to offer you more advice tailored to your specific needs.
- The British Lung Foundation also offer advice about [breathlessness](#).

Treating coughing blood

- Sometimes people can have a problem with [coughing blood](#). This can be frightening and it is important to report it to your doctor.
- This may be very small amounts and happen when you have a chest infection, or occasionally it can be larger amounts. This may need to be treated urgently and you should seek help if this happens to you.
- A tablet called tranexamic acid is sometimes used when people are [coughing blood](#).
- You may have a specific type of scan called pulmonary angiography to look at the blood vessels in the lungs. If there are vessels that can be seen to be the cause of the bleeding then this can be helped by a procedure called embolisation where the blood vessel(s) causing the trouble are blocked off, and occasionally by surgery to remove the area of lung with abnormal vessels and bleeding.

New drugs and research

There is a huge amount we still need to learn about bronchiectasis. It has previously been a poorly funded research area within lung diseases but we are making progress.

If you are interested in learning more about research then ask your doctors and nurses. A great deal has happened in the last 5 years and many research studies are underway.

There are 2 main areas that researchers are working on:

1) Can we understand more about the condition?

This includes learning more about the bugs that cause infections, and factors that are linked with increased infections or getting sick quicker.

2) Can we apply this knowledge to develop new treatments?

Some of the drugs currently being used to treat bronchiectasis are not based on big research studies specifically looking at their effect in patients with bronchiectasis. They are used in hope that the benefits proven in other lung conditions such as Asthma or COPD (smoking-related lung disease) where they have been rigorously tested, might apply in bronchiectasis.

Some trials test whether such treatments also work in bronchiectasis. The other type of trials are those with medications specially designed for bronchiectasis such as new nebulised or inhaled antibiotics. It often takes several years for newly developed drugs to be tested and become available for patients to use. You can ask your doctor about any new treatments that may become available soon.

[For more information please see the research section.](#)

Details of national respiratory studies can be found on the [UK Clinical Research Network Study Portfolio](#).

Recognising symptoms

- Learning to recognise what is 'normal' for you is something that you will develop over time. You will also start to recognise signs that things are changing, for example when you are getting an exacerbation or chest infection.
- For some people this will be a change in sputum (phlegm) colour or and increase in amount. For others it can be a feeling of fatigue or tiredness, feeling feverish, worsening cough or chest pain.
- It is important that you learn to recognise what the signs of an infection are for you so that you know when to act and when you need to have antibiotics.
- Learning to recognise these signs is an important part of taking control of your bronchiectasis and being able to work in a partnership with your health care team.
- Remember, you will know your body better than anyone else so you will play a key role in managing your condition. This is called [self-management](#) and is an important part of the care of any chronic disease.
- Your health care team can advise you about what signs to look out for and learning about your condition is helpful too.

"I know, when I get poorly that's it, the coughing, it's mostly the coughing, and more phlegm, breathlessness." Celia, 67

Self-management

- Self-management is an important part of the care of any chronic condition, including bronchiectasis.
- Patients have told us that having information about bronchiectasis is important in learning how to manage your condition.
- Developing the skills needed to recognise changes and act on them is something that you will become more confident with over time as you begin to see patterns in how your symptoms change.
- This does not mean that you will have to manage bronchiectasis by yourself, but that you can take back some control over your body and your health and can play a role in managing your condition in partnership with your medical team. This may include having an 'emergency' pack of antibiotics at home that you are able to take when you recognise the signs that you are having an exacerbation or chest infection. This is often very useful, particularly if you have difficulty getting a GP appointment quickly, or for example, if you are unwell when you are on holiday.

[This PDF shows some of the signs to look out for and how to act.](#)

The British Thoracic Society also have a simple '[self-management tool](#)' for bronchiectasis.

"It depends, I suppose, but I would say that I judge the severity of the infection with the colour of the phlegm, and then I would take a sample to the doctors and...I start taking...what they call a sort of rescue pack (of antibiotics)." Jean, 76

Active partnerships with your team

- Developing an 'active partnership' with your health care team, means working with them and having some control over your own health and your medical care.
- Learning to [recognise changes in your symptoms](#) and developing [self-management skills](#) is part of the process of becoming able to work with the team and take back some control. Knowing about bronchiectasis and how to manage it can help you with this, and your health care team will advise you.
- Patients have told us that that they feel this is very important when you are living with a chronic condition such as bronchiectasis.

[The British Lung Foundation can offer advice about getting the best from your doctor.](#)

Diet, exercise and lifestyle advice

Nutrition and Bronchiectasis

- Your diet and nutritional intake are very important if you have a disease like bronchiectasis. A balanced and varied diet can help you to maintain strength and fitness. If your body is well nourished then you are more able to fight infections.
- You may be surprised to learn that food affects your breathing. Food is the fuel used by your body for all of its activities and functions including breathing. The right mix of nutrients in your diet can help with your breathing.
- Protein, carbohydrate and fat all provide energy.
- Protein foods are needed for healthy strong muscles. You should try to have a good source of protein at least twice a day. Protein foods include meat, fish, eggs, cheese, milk, nuts, beans and lentils
- Carbohydrates are the major source of energy for the body. These include starchy and sugary foods.
- Starchy foods should always be included at each meal, e.g. bread, potatoes, rice, pasta and cereals.
- Sugary foods include cakes, biscuits, sweets and fizzy drinks. These can provide excess energy and may need to be limited if you are overweight.
- Fat is a concentrated source of energy. Sources include butter, margarine, vegetable oils, and cream.

Weight

- It is important to know about your weight. You should get into the habit of checking your weight and observing any changes.
- If you become overweight your heart and lungs have to work harder to supply oxygen to your body.
- If you are underweight or lose too much weight then you may be more at risk of infections.
- Loss of muscle mass will affect your general muscle strength, however it will also weaken the muscles that help with your breathing.

Overweight

- Losing excess weight through a healthy diet and exercise will make your breathing easier. You should reduce your intake of foods high in sugar and fat content, and reduce portion sizes and snacking.

Underweight

- You may find that you are losing weight without trying and are feeling weaker. You should try to increase your energy and protein intake to help you gain weight and feel stronger.
- Your breathing may be using more energy compared to a healthy person. Infections can also increase the energy your body needs.
- You may also find that you lose your appetite. If you are more breathless, this in turn can make eating more difficult and therefore you may eat less. You should try to eat 3 smaller nutrient dense meals a day with additional snacks or milky drinks between meals. You may find it easier to eat softer foods that require less chewing.
- If you are trying to gain weight, you should include more high fat foods in your diet.

Nutritional Supplements

- You may find it difficult to meet your energy needs from the food you are eating.
- Your Doctor or Dietitian may recommend special nutritional products that provide extra energy and nutrients. These should be taken in addition to your diet.

Fluids

- It is important to keep secretions in your lungs thin and easy to cough up.
- If you don't drink enough fluids, your secretions may become thick and sticky and will increase your risk of an infection.
- You should have at least 7-8 cups of fluid per day.
- If drinking fluids with meals makes you too full to eat, then limit fluids at mealtimes and drink an hour after eating.

Exercise

- Any form of exercise that makes you a little breathless, such as walking and swimming is extremely beneficial for people with bronchiectasis.
- It may help you to clear your chest and will improve your overall fitness. Staying or getting fit will help you build resistance to infections.
- Your physiotherapist will advise you on the appropriate exercise to suit you and, where appropriate refer you to a specialist exercise group called Pulmonary Rehabilitation (see below) which is usually run at your local hospital.

The British Lung Foundation also offer advice about [exercise](#).

Pulmonary Rehabilitation (PR)

- This is a supervised group exercise programme in your area specifically for individuals with lung conditions.
- It is a mixture of exercise and education sessions over a number of weeks.
- PR has been shown to be beneficial for some people with bronchiectasis.
- If you are interested, please discuss with your physiotherapist, consultant or GP

Pelvic Floor Exercises

- Some individuals with a persistent cough are troubled by [incontinence](#) (leaking) of urine.
- It is a common problem and can be very embarrassing or difficult to cope with in everyday life.
- It may also make you less inclined to do your airway clearance, which is not helpful to your condition.
- If you do suffer from this, please ask for help, as it is very likely to be improved by treatment from a physiotherapist or continence nurse who specialises in these problems.

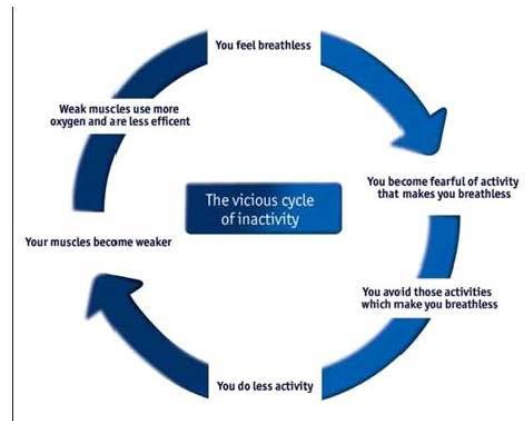
Exercise makes me breathless, how can physiotherapy help?

Breathlessness management

If you are affected by breathlessness then a physiotherapist will give you advice on how best to manage it. This may include advice on:

- Breathing techniques to help you control your breathing.
- Positions to help relieve your breathlessness.
- How to pace yourself.
- Techniques to help you conserve your energy.

What can happen if I don't exercise as much as I should?



You may fall into the vicious cycle of inactivity (see below) which can exacerbate your symptoms.

Smoking

- We know that bronchiectasis is not a condition that is caused directly by smoking. You can find out more about the [causes of bronchiectasis](#) in the relevant section of this site.
- However, if you have bronchiectasis and you do smoke, it is very important that you stop smoking. If you have a lung condition such as bronchiectasis, stopping smoking will improve your prognosis and reduce your chance of developing other lung damage caused by smoking such as Chronic Obstructive Pulmonary Disease (COPD) and lung cancer.
- You can speak to your doctor or nurse about stopping smoking and they can advise you and support you in giving up.
- The British lung Foundation also offer advice about [stopping smoking](#).

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Coping and support

"My experience has been greatly helped over the last two or three years, or two years, since I've met the bronchiectasis nurse...He personally has helped me a lot, both psychologically and obviously as a patient...And he showed me a lot of things that I was unaware of, really...I feel as though I could always contact him, if I have a problem...and he will advise me accordingly." Chris, patient

- The impact of having bronchiectasis can vary from person to person. It can also vary at different time points, as you may have times where you have very few symptoms, and times when they are more troublesome.
- We know from previous work with patients and their families that bronchiectasis can affect more than just your physical health. It is not surprising that bronchiectasis can have a huge emotional impact and that it can also affect people's families and friends, their work and their day to day life and social activities.
- It is important to remember that you are not alone. There are lots of others who have similar feelings and you may find it helpful to see some of the videos on this website of patients talking about their experiences. It is also important to have a support network, which could include family, friends and your health care team, such as your GP, or specialist nurse in clinic. The British Lung Foundation can also offer support through a [helpline](#) and also an [online community](#) where you can talk to others in similar situations.

The following websites have been developed by patients who have bronchiectasis and also have other patient and carer experiences or an online community:

<http://www.bronchiectasishelp.org.uk/#features/>
<http://www.bronchiectasis.info/>

The British Lung Foundation can also offer some general advice on [living with a lung condition](#).

Patient experiences

- In a research study, people who are living with bronchiectasis have said that they find it useful and reassuring to hear that others have gone through what they are going through
- Remember you are not alone, and there ways that bronchiectasis can be managed.

You may find it helpful to watch these videos about other people's experiences.

Useful links

There are lots of links to other websites and information documents throughout this website in the relevant sections.

Below you will find a list of some of these links, and others that we think you may find useful.

[The Newcastle Hospitals Bronchiectasis Service](#)

[The British Lung Foundation](#)

[Chest heart and stroke Scotland \(CHSS\)](#)

[CHSS bronchiectasis information booklet](#)

[Patient.co.uk information about bronchiectasis](#)

[Bronchiectasis information developed by a patient](#)

[Bronchiectasis R Us: a forum and information site run by a patient](#)

[Information for carers](#)

[British Thoracic Society guidelines for management of bronchiectasis](#)
(this is intended for medical professionals).

[Current research studies in bronchiectasis and other lung conditions](#)

How you can help

- Often family members and friends are acting as 'carers' without realising. If you provide support to someone who could not manage without this help, then you may be classed as a 'carer'.
- Caring for someone with bronchiectasis will vary depending on their specific needs, but at times this can be physically and emotionally difficult. Often people with bronchiectasis may not have any care needs at all.
- Things you may be able to help with include medications such as nebulisers which require washing after every use, or sometimes home IV antibiotics. You may also provide practical support with things that are now difficult to do alone, or simply emotional support. You may find that you can help with self-management, as you may be the first one to recognise signs of a chest infection for example.
- If you are a carer, having support from family members, friends and also the healthcare team is essential.

You may be entitled to support or benefits and you can ask your GP about this.

[The British Lung Foundation offer advice for carers and families.](#)
[Carers UK can also offer advice to carers](#)

How you may feel

- If you are caring for someone who has bronchiectasis it may at times be physically and emotionally demanding. Having support yourself is important. This may be from other family members or friends, or from the healthcare team. Your GP can also offer advice and support.
- [The British Lung Foundation](#) and [Carers UK](#) can also offer advice.
- You are not alone, and there are other people who have similar experiences. Sometimes hearing about how they have coped can be useful.

Some quotes from carers involved in our research:

"I try to reassure her to say, "You know, it's not as bad as that, try and be a bit more positive." David, 63, carer

"I think the hard thing is not just the emotional side of things for the patient, it's also for the family." William, 64, patient

"I just worry when he's ill, that's when I worry and I know when he's not right, I can tell." Vera, carer

What research is being done?

There is a huge amount we still need to learn about bronchiectasis. It has previously been a poorly funded research area within lung diseases but we are making progress.

If you are interested in learning more about research then ask your doctors and nurses. A great deal has happened in the last 5 years and many research studies are underway.

There are 2 main areas that researchers are working on:

1) Can we understand more about the condition?

This includes learning more about the bugs that cause infections, and factors that are linked with increased infections or getting sick quicker.

2) Can we apply this knowledge to develop new treatments?

Some of the drugs currently being used to treat bronchiectasis are not based on big research studies specifically looking at their effect in patients with bronchiectasis. They are used in hope that the benefits proven in other lung conditions such as Asthma or COPD (smoking-related lung disease) where they have been rigorously tested, might apply in bronchiectasis.

Some trials test whether such treatments also work in bronchiectasis. The other type of trials are those with medications specially designed for bronchiectasis such as new nebulised or inhaled antibiotics. It often takes several years for newly developed drugs to be tested and become available for patients to use. You can ask your doctor about any new treatments that may become available soon.

What is being done in my local area?

- You can find out which trials or research projects are ongoing in your local area by talking to your doctor or health care team.
- Some hospitals are involved in more research than others, and the trials change on a regular basis as studies close and new trials begin.
- Your health care team can advise you about what research studies you may be eligible for, as they can have quite specific criteria for entry.
- In the Newcastle area, for example, several bronchiectasis studies are being carried out at the Sir William Leech Centre for Lung Research, in the Freeman Hospital.
- Patient participation in research projects helps increase our knowledge, so if you have bronchiectasis and can spare some time to help with research, please get in touch. Projects range from single visits to a number of visits over a few months.

For more details if you live in the Newcastle area contact the research department at the Sir William Leech Centre for Lung Research at the Freeman Hospital:

Tel: 0191 223 1148.

To find out about research in your local area, ask your health care team.

How can I get involved?

Patient participation in research projects helps increase our knowledge, so if you have bronchiectasis and can spare some time to help with research, please get in touch. Projects range from single visits to a number of visits over a few months.

If you live in the Newcastle area, for more details, contact the research department at the Sir William Leech Centre for Lung research at the Freeman Hospital:

Tel: 0191 223 1148.

There are several areas of active research in bronchiectasis.

Further information may be found on the following sites:

[The British Lung Foundation](#) also have information about research.

The NHS also offers [advice about being involved in research](#)

FAQ's

How do you pronounce bronchiectasis?

(Brong-kee-ek-tuh-sis)

"One of the things that did frustrate me a lot was that I never knew how to pronounce it – bronchiectasis, and it probably wasn't until after about 6-9 months that I actually found out how to pronounce it properly, and it sounds such a silly little thing but if you mention it to somebody and you don't know how to pronounce it, it's a little bit embarrassing." Mike, 43

Why have I got bronchiectasis?

[See relevant section](#)

What is actually wrong with my lungs?

[See relevant section](#)

Does bronchiectasis run in families?

- Yes, Bronchiectasis can run in families but this appears to be very rare.
- In our clinic of over 400 patients we have only found 6 people with a possible family history.
- Researchers are very interested in such families as researching them might help us find out what genes might increase the risk of bronchiectasis in any patient.
- It is important to note that most people with bronchiectasis do not have any family members affected and the chances of "passing it on" seem very small. This does vary dependent on the cause of bronchiectasis, so if you are unsure ask your clinical team of nurses and Doctors.

Is bronchiectasis caused by smoking?

People often ask if bronchiectasis is the same as the smoking related lung disease COPD, and people who have bronchiectasis are often upset and frustrated that others assume smoking has caused the problems with their lungs.

Bronchiectasis is NOT caused by smoking, is NOT asthma and is NOT COPD.

However, there can be some confusion caused by the fact that some of the breathing test results we see with bronchiectasis can show the same sort of pattern as those seen in COPD or asthma. Also, some people may have asthma or COPD, and then develop bronchiectasis as well. If you have had smoking-related COPD for many years and then go on to have bronchiectasis you could say that smoking had been an underlying cause in this specific scenario.

If you have bronchiectasis and you do smoke, trying to give up is very important. You can find out more about this in our [diet, exercise and lifestyle section](#).

Is bronchiectasis the same as COPD?

People often ask if bronchiectasis is the same as the smoking related lung disease COPD, and people who have bronchiectasis are often upset and frustrated that others assume smoking has caused the problems with their lungs.

Bronchiectasis is not the same as COPD or asthma.

Bronchiectasis is caused by many different conditions.

Many patients with bronchiectasis have never smoked, whilst COPD is caused by smoking fairly heavily.

It is important to note that some patients develop bronchiectasis as a complication of COPD. As both conditions can cause, cough, breathlessness, repeated chest infections and abnormal breathing tests, it is not surprising that they can also sometimes be mixed up.

In the UK, most GPs will look after 150-200 patients with COPD, whereas most practices will have less than 10 patients with bronchiectasis.

One thing that clearly links the two conditions is the need to stop smoking if you are a smoker to reduce your chances of further lung damage and also reduce the risks of developing lung cancer and other smoking-related diseases.

What symptoms might I get?

[See relevant section](#)

What tests will I need?

[See relevant section](#)

How is bronchiectasis treated?

[See relevant section](#)

Who will treat my bronchiectasis?

[See relevant section](#)

What is the prognosis for bronchiectasis?

[See relevant section](#)

What can I do to help myself?

[See relevant section](#)

Can I fly or go on holiday?

[See relevant section](#)

Understanding your clinic letter?

[See relevant section](#)

I feel like I am the only one

[See relevant section](#)

Tips for carers and families

[See relevant section](#)

What research is being done?

[See relevant section](#)

Where can I find out more?

[See relevant section](#)

Appendix 3 The BRIEF Study published protocol.

Hester et al. *Trials* (2016) 17:210
DOI 10.1186/s13063-016-1330-4

Trials

STUDY PROTOCOL

Open Access

Evaluation of a novel information resource for patients with bronchiectasis: study protocol for a randomised controlled trial



Katy L. M. Hester^{1*}, Julia Newton², Tim Rapley³ and Anthony De Souza^{1,4}

Abstract

Background: There is currently little patient information on bronchiectasis, a chronic lung disease with rising prevalence. Previous work shows that patients and their families want more information, which could potentially improve their understanding and self-management. Using interviews and focus groups, we have co-developed a novel patient and carer information resource, aiming to meet their identified needs.

The aims and objectives are:

1. To assess the potential impact of the information resource
2. To evaluate and refine the intervention
3. To establish the feasibility of carrying out a multi-centre randomised controlled trial to determine its effect on understanding, self-management and health outcomes

Methods/design: This is a feasibility study, with a single-centre, randomised controlled trial design, comparing use of a novel patient information resource to usual care in bronchiectasis. Additionally, patients and carers will be invited to focus groups to discuss their views on both the intervention itself and the trial process.

The study duration for each participant will be 3 months from the study entry date. A total of 70 patients will be recruited to the study, and a minimum of 30 will be randomised to each arm. Ten participants (and their carers if applicable) will be invited to attend focus groups on completion of the study visits. Participants will be adults with bronchiectasis diagnosed as per national bronchiectasis guidelines.

Once consented, participants will be randomised to the intervention or control arm using random permuted blocks to ensure treatment group numbers are evenly balanced. Randomisation will be web-based. Those randomised to the intervention will receive the information resource (website and booklet) and instructions on its use. Outcome measures (resource satisfaction, resource use and alternative information seeking, quality of life questionnaires, unscheduled healthcare visits, exacerbation frequency, bronchiectasis knowledge questionnaire and lung function tests) will be recorded at baseline, 2 weeks and 3 months.

Discussion: All outcome measures will be used in assessing feasibility and acceptability of a future definitive trial. Feasibility outcomes include recruitment, retention and study scale from completion rates. Focus groups will strengthen qualitative data for resource refinement and to identify participant views on the trial process, which will also inform feasibility assessments. Questionnaires will also be used to evaluate and refine the resource.

Trial registration: ISRCTN84229105

Keywords: Bronchiectasis, Exacerbation, Self-management, Education, Information, Randomised controlled trial, Feasibility study, Qualitative research

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Background

Bronchiectasis is a chronic lung condition, characterised by dilated bronchi, leading to symptoms of breathlessness and chronic productive cough, with intermittent infective exacerbations. Bronchiectasis has various potential aetiologies including immune deficiency syndromes, chronic asthma, chronic obstructive pulmonary disease, ciliary dysfunction and post-infectious causes, yet studies have found that between a quarter and half of cases are idiopathic [1, 2]. Patients often have recurrent, costly hospital admissions, a poorer quality of life [3, 4] and clinically significant fatigue [5, 6].

Current estimates suggest a rise in prevalence in the UK and indicate a prevalence of between 43.4/100,000 in those aged 18–30 and 1239.7/100,000 in those aged 70–79 [7]. Importantly, studies demonstrate that up to 50 % of patients with chronic obstructive pulmonary disease (COPD) have co-existent bronchiectasis [8]. There are approximately 1,000,000 patients with COPD in the UK [9]; thus there is potential for a significant increase in case finding of COPD-associated bronchiectasis over the coming years.

Bronchiectasis mortality rates are approximately 50 % higher than that of uncomplicated COPD (calculated at 3 % per annum) and are increasing [10]. The prognosis varies, with a recent study of 91 patients [11] finding that the primary cause of death was usually respiratory, with survival rates of 91 % at 4 years and 68.3 % at 12.3 years. Infective exacerbations lead to significant morbidity. Previously published UK data also emphasise the burden of bronchiectasis, uncertainties in aetiology and lack of evidence for the treatments that are often used [12]. This is consistent with recently published American data on the increasing burden of bronchiectasis [13].

There is no cure for bronchiectasis. Current modalities of treatment include oral, inhaled or intravenously administered antibiotics, used both regularly and with additional courses for exacerbations. Mucolytics and regular physiotherapy are used to aid sputum clearance, and additional guidelines for investigation, diagnosis and management of bronchiectasis have been provided by the British Thoracic Society (BTS) [14]. Inappropriate antibiotic use can lead to antibiotic resistance. Conversely, not commencing antibiotics promptly can result in a severe exacerbation requiring costly hospital admission. Bronchiectasis differs from many chronic diseases in that appropriate, timely recognition of symptoms and improved management of infections could lead to increased disease stability. This could potentially lead to longer term improvement in respiratory outcomes. For example, carrying out regular chest physiotherapy and responding appropriately to symptoms of exacerbation may prevent deterioration and reduce admissions. Patient self-care therefore could make a significant difference to management.

In order to facilitate self-care, patients need to have accurate information about their condition, empowering them to recognise changes, respond to them and understand how their self-management could potentially alter their prognosis. The BTS guidelines for the management of bronchiectasis [14] recommend education of patients within their management plan. There is relatively little information produced for patients with bronchiectasis. Sources include a one-page leaflet produced by the British Lung Foundation (BLF) and limited online resources. The BTS has a brief self-management tool for bronchiectasis that is available to download. It does not serve as an information resource but is a one-page reference guide to exacerbation management.

In addition to the need for information and education being recognised by organisations such as the BTS and the BLF, a survey of 104 patients attending a specialist bronchiectasis clinic in the North East of England found 98 % felt more confident about managing their condition after receiving information and education about their treatment [15]. A study using focus groups involving patients who have bronchiectasis has highlighted lack of information as one of the perceived obstacles to self-management [16]. In addition, a pilot study of qualitative interviews with patients identified the importance of patient information in the process of developing the skills and confidence to manage and live with bronchiectasis [17, 18]. There was a strong feeling amongst participants that there was a lack of trustworthy information (from a reliable source such as their hospital, trusted specialists or organisations such as the BLF) available to them beyond that obtained in clinic. Patients felt they would benefit from a credible information source that they could continue to access outside of a specialist clinic setting. Despite this there remains a lack of development in this area to date, and many chronic conditions that are less prevalent than bronchiectasis have many more accessible resources.

Our yet unpublished qualitative study used in-depth interviews with a cohort of 26 patients and carers to identify their unmet information needs and priorities for an information resource. We have used the themes and needs identified during analysis of these interviews to develop a novel patient information resource. The content and format of the resource are based on the findings of the interviews and subsequent focus groups with patients and carers to refine the intervention.

A definitive, multi-centre trial would address the research question: Can the provision of patient-focussed information and education improve health outcomes in bronchiectasis? The rationale for the Bronchiectasis Information and Education Feasibility (BRIEF) study is that, in advance of the definitive trial, it is necessary to assess whether the proposed design for the trial is practicable

and will allow the proposed outcomes to be assessed. In addition, the intervention will be evaluated and further refined for use within the definitive trial.

The trial will be conducted as an unblinded, randomised controlled trial comparing the use of the information resource as an intervention to usual care.

Objectives

Primary objective

The primary objective is to conduct a feasibility study that will inform the decision of whether to proceed to the definitive randomised controlled trial (RCT) and whether any refinements to the design or conduct of that trial are warranted.

Secondary objective

The secondary objective is to evaluate and further refine the patient information resource and collect information on patient preferences.

Definitive trial objectives

The definitive trial objectives are to assess whether provision of a patient-focussed information and education resource can improve patient understanding, self-management and health outcomes in bronchiectasis.

Methods/design

Participants, interventions and outcomes

Study setting

This is a single-centre study taking place in the UK in the Newcastle upon Tyne Hospitals NHS Foundation Trust. This consists of two teaching hospital sites: the Freeman Hospital and the Royal Victoria Infirmary. Study visits will all take place within the Freeman Hospital. The running of the trial will be based within the Freeman Hospital at the William Leech Clinical Trials Centre. Patients will be recruited from either hospital site.

Eligibility criteria

Inclusion criteria To fulfil the inclusion criteria, the participant must:

1. Have the capacity to provide written informed consent
2. Be aged 18 years or older
3. Have received a clinical and radiological diagnosis of bronchiectasis
4. Be English speaking

Exclusion criteria The exclusion criteria include:

1. Cognitive impairment
2. Non-English speaking
3. Age <18 years

4. Participation in the preceding Bronchiectasis Information and Education (BRIE) study

Due to the nature of the study, knowledge of the English language is a necessary inclusion criterion to ensure usability of the information provided. As this is a small feasibility study, resources are not currently available to produce the information in other languages or to provide funded Internet access. For those potential participants who do not have Internet access yet wish to take part in the study, the information within the website (excluding video clips) can be provided in PDF format. This will be recorded on the Case Report Form (CRF), and the participant will proceed with the same visits and outcomes.

Study intervention details

The BRIEF study will compare the patient information resource (developed within the previously conducted qualitative study) with usual care. At the baseline visit, participants randomised to the intervention will receive the patient information resource: an overview booklet and website. Verbal and written instructions will be given by appropriate members of the research team (as per the delegation log) about how to access the website. The participants will then have access to the intervention for the duration of the study. Their use or not of the information resource will be down to individual choice, yet through discussion with the research team member conducting each study visit participants will be encouraged to utilise the resource and to allow their families or carers to utilise it also should they so wish. Some participants may not have direct access to a computer or Internet use. This does not preclude them from entry as long as they can access the Internet via their family, friends or local institutions such as libraries. For those who do not wish or do not have the skills to access the website, participation using a PDF version of the information contained within the website will be offered. This will enable them to view all information except the video clips. At study completion, those randomised to the intervention group will be allowed continued access to the resource. Those in the control group will be offered access to the resource following completion of their study period so as to minimise disappointment due to their allocation to the control arm. Any uptake of the resource following study completion does not form part of data collection.

This is a non-clinical intervention, and we do not expect any reasons for discontinuing the intervention other than participant preference. Any participant may choose to leave the study at any point with no effect on usual care. Potential participants currently participating

in another trial would not be approached for entry into the study.

Study design and outcome measures

See Fig. 1 and Table 1.

Design This feasibility study is an unblinded, single-centre randomised controlled trial with two parallel groups that compares a novel patient information resource to usual care in bronchiectasis.

Duration The study duration for each participant will be 3 months from the study entry date. Due to variations in month length, this will be calculated at 12 weeks

(84 days). The study completion date will be after the date of the last assessment visit of the last entrant and completion of the final focus group.

Outcome measures The outcome measures are as follows:

1. Ability to recruit adequate numbers of participants (ratio of consented participants to potentially eligible participants approached)
2. Numbers completing study
3. Numbers completing study scale forms, questionnaires and visits
4. Resource satisfaction questionnaire

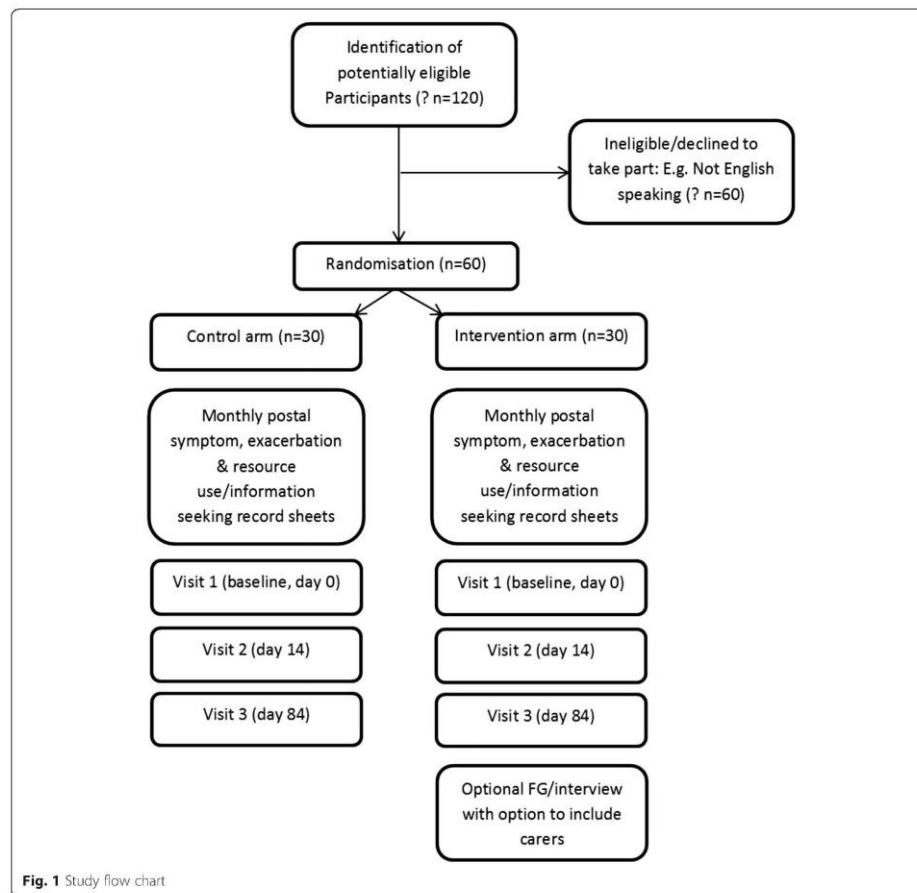


Fig. 1 Study flow chart

Table 1 Study visits and data collection

	Visit 1 Day 0	Visit 2 Week 2 (Day 14)	Visit 3: final visit Week 12 (Day 84)
Written informed consent and randomisation (if not done prior to visit 1) and collection of baseline demographics	x		
Resource use (not baseline visit) and information seeking	(x)	x	x
Resource satisfaction questionnaire		x	x
Bronchiectasis knowledge questionnaire	x	x	x
QOL-B	x	x	x
SGRQ	x		x
HADS	x	x	x
FIS	x		x
EQ-5D	x	x	x
Number of unscheduled visits	x	x	x
Exacerbation frequency	x	x	x
FEV1	x (if not done in past 3 months)		x

QOL-B Quality of Life Questionnaire-Bronchiectasis, SGRQ St. George's Respiratory Questionnaire, HADS Hospital Anxiety and Depression Scale, FIS Fatigue Impact Scale, EQ-5D Euroqol 5-dimension (quality of life scale), FEV1 forced expiratory volume in 1 second

5. Recorded use of resource and alternative information seeking
6. Quality of Life Questionnaire-Bronchiectasis (QOL-B)
7. St George's Respiratory Questionnaire (SGRQ)
8. Hospital Anxiety and Depression Scale (HADS)
9. Fatigue Impact Scale (FIS)
10. Euroqol 5-dimension (quality of life scale), EQ-5D
11. Number of unscheduled visits to primary or secondary care
12. Exacerbation frequency
13. Forced expiratory volume in 1 second (FEV1)
14. Knowledge of condition and management questionnaire

All outcome measures will be used in assessing the feasibility of a future definitive trial, including recruitment, retention and study scale form completion rates. Participant evaluation of acceptability of the newly developed package will be established through a questionnaire and open questioning to include their satisfaction with the information provided, knowledge about their condition and management, and additional features that they feel may strengthen the intervention. Use of the resources provided and preferred formats identified within these questionnaires will also inform feasibility of a future trial and allow refinement of intervention formats. Focus groups will also be held to strengthen data on the patient experience.

Outcome measures will be recorded at baseline (day 0) and then at 2 weeks (day 14) (that is, shortly after initial viewing of information in order to facilitate obtaining first opinions) and 3 months (day 84) post recruitment. This will be done during patient visits that are anticipated to take less than 1 hour each.

Visit 2 can be done via telephone interview if participants prefer.

The time taken to complete the scales and estimates of variability in outcome measures for the population at the various time points, with associated confidence intervals, will help to inform a future sample size calculation for a definitive RCT. We will describe these data as a reference for this patient group and as baseline measures to inform a future RCT. We will examine the relationship between outcomes and baseline covariates in order to identify any efficacy gains through the use of stratification in a future full RCT.

EQ-5D will be used to allow some estimate of health economic evaluation for a future RCT. We anticipate potential health economic benefits with patients empowered to self-manage, thereby reducing service use. The number of unscheduled presentations, exacerbation rate and FEV1 could potentially be used in a future full trial as a representation of the patients' ability to self-manage their condition. This information will be retrieved from the patient visits and patients' symptom and information sheets (patients will be asked to complete a monthly postal record sheet [at weeks 4, 8 and 12] enabling identification of episodes of change in symptoms and actions taken, in addition to any information resource use, without the burden of a daily diary record) and also through general practitioner (GP) and hospital recorded attendances if patients are unable to report or recollect.

Participants

Potential participants will be identified by case note review and attendance at outpatient clinics and will be given or sent a letter of invitation to the study and a patient information sheet. Written informed consent will be obtained

from willing participants (see Additional file 1). Patients can withdraw consent at any point with no effect on usual care. At the end of the study, some participants will be invited to attend a focus group and a possible in-depth interview about their experience. For this section of the study only, if participants in the intervention group indicate that their partner/family member or friend has also used the resource, then they may be invited to attend discussion groups also. Up to a maximum of 10 additional participants will be recruited for this purpose. Additional information sheets and consent forms have been produced for these participants (see Additional file 2). Participants invited to attend the focus group will be sampled purposively. The intent is to form a group that includes participants of differing backgrounds and time since diagnosis, some from the control and some from the intervention group, and those who had differing preferences in terms of format used. Involvement in the focus group, however, is an optional extra, and as such a pragmatic approach will have to be taken. Anyone agreeing to take part in the focus group will be invited to bring along their 'carer', who will then be sent the appropriate information sheet to consider whether they would like to take part.

Participant identification and screening

Patients will be identified through case note review and clinic attendance. Eligible participants will be invited to participate by their consultant, the principal investigator (PI) or the chief investigator (CI), who is part of the medical team. The study will be explained to them further by the research team. A study Participant Information Sheet will be provided at this time, which the patient can take away for consideration. For those identified by case note review, a letter of invitation will be sent in the post along with the Participant Information Sheet and details of how to get in touch if interested. They will be offered the opportunity to discuss this further with the research team.

A screening log will be kept to document details of subjects invited to participate in the study. For subjects who decline participation, this will document any reasons available for non-participation. The log will also ensure potential participants are only approached once.

Sample size

The sample size will be 70, with a minimum of 30 being randomised to each arm. This is based on previous recommendations for good practice in feasibility studies [19]. Because this is a feasibility study, no formal power calculations have been carried out. Up to 10 non-patient (carer) participants will be recruited for the qualitative section of the study, as discussed in the section 'Focus group data'.

We anticipate that 24 months will be adequate time to recruit 70 patients to this study, based on a clinic

attendance of approximately 60 per month with an estimate of 50 % of patients approached who are willing and able to enter. Seventy patients recruited from approximately 140 patients approached would correspond to a 95 % confidence interval for the recruitment rate of 41–59 % (an acceptable width of ± 9 %). We expect low attrition rates based on previous work and our prior experience in this field. There will be a 3-month additional period for follow-up of the last recruited participants and time beyond for the interviews, focus groups and analysis.

Assignment of intervention

Randomisation

Participants will be randomised to intervention or control in a 1:1 ratio, using random permuted blocks within strata. Randomisation will be stratified by gender. The randomisation allocation schedule will be generated by a statistician with no other involvement in the study. Randomisation will be performed by the CI at site, or an individual with delegated authority, using a secure password-protected web-based system administered by Newcastle Clinical Trials Unit. Randomisation will generate a unique 3-digit study identification number for each participant. Participants will be informed of their allocated treatment group following randomisation. Blinding is not feasible for this study for patients or the research team conducting the study visits due to the nature of the intervention. The data analyst is also involved directly with the study processes and data collection, and thus blinding of the analyst is not possible.

Data collection, management and analysis

Data collection

Data will be collected at study visits by the research team as per the delegation log. Visits 1 and 3 will be done in person; visit 2 can be either in person or on the telephone. Other than breathing tests at visits 1 and 3, all outcome measures are questionnaires and will be either self-completed by the participants or completed with the help of the research team member conducting the study visit. All answers will be recorded in paper copies of each questionnaire within the CRF. The study team member conducting the visit will check for omissions after completion with the participant. All members of the delegate log will be trained in the use of the questionnaires and lung function tests. The questionnaires to be completed are summarised in Table 2. Additional data collection will be obtained via monthly (weeks 4, 8, 12) postal symptom and resource use record sheets sent to participants. This will enable more accurate recollection of symptoms and information use than at the study visits alone, yet is a reduction in burden as compared to completing a daily diary. Phone calls will be made to encourage completion if the forms are not returned.

Table 2 Outcome measures

Study instrument	Description
Resource use and information seeking	Unvalidated questionnaire
Resource satisfaction questionnaire	Unvalidated questionnaire
Bronchiectasis knowledge questionnaire	Unvalidated questionnaire
QOL-B	Validated Quality of Life Questionnaire-Bronchiectasis [26]
SGRQ	Validated St George's Respiratory Questionnaire [3]
HADS	Validated Hospital Anxiety and Depression Scale [27]
FIS	Validated Fatigue Impact Scale [28]
EQ-5D	Validated Euroqol 5-dimension quality of life questionnaire [29]
Number of unscheduled visits	Patient's report of healthcare visits
Exacerbation frequency	Patient's report of number of exacerbations
FEV1 (absolute value and % predicted)	Lung function test (forced expiratory volume) using calibrated equipment

Focus group data

A number of participants will be invited to a focus group to discuss participation in the trial and views on further refinements to the intervention and the study protocol. Should specific issues arise within the focus groups that need further exploration, then a number of in-depth interviews may also be held. These would be entirely optional. If participants indicate that their partner, family member or friend has used the resource, then they may be invited to this section of the study also. A maximum of 10 carers will be recruited and given the appropriate Participant Information Sheet, and written informed consent will be obtained. Thematic analysis will be used to look for patterns of meaning and 'themes' in the data content. Data will be organised into meaningful groups to identify and describe themes and issues raised in the interviews.

Data handling and record keeping

Data collected on paper CRFs will be entered by the CI or appropriately trained study delivery staff and data manager (as per the delegation log) on a secure password-protected study computer. Participants will be identifiable only by a unique study identifier on all recorded data.

Focus group audio files will be transcribed verbatim. All data will be stripped of strong identifiers and will only be identified by a unique study number, and only authorised members of the research team, operating to written codes of confidentiality, will have access to the link between anonymised data and patient/professional

identifiable details. Patients and professionals will not be identifiable in any publications emanating from the work described in this application. Data will be handled, computerised and stored in accordance with the Data Protection Act 1998. No participant identifiable data will leave the study site.

Compliance and withdrawal

Compliance Where feasible, study visits will coincide with routine clinical follow-up to enhance the likelihood of good compliance. Visit windows of 2 weeks should ensure visit attendance; non-attendance for study visits will prompt follow-up by telephone. Participants will be given the option of completing visit 2 by telephone interview to reduce the burden of travel for study visits. Non-return of monthly postal record sheets will also prompt follow-up by telephone.

Withdrawal of participants Participants have the right to withdraw from the study at any time for any reason and without giving a reason. The investigator also has the right to withdraw patients from the study intervention if she/he judges this to be in the patient's best interests. It is understood by all concerned that an excessive rate of withdrawals can render the study uninterpretable; therefore, unnecessary withdrawal of patients should be avoided. Should a patient decide to withdraw from the study, all efforts will be made to report the reason for withdrawal as thoroughly as possible.

There are two withdrawal options:

1. Withdrawing completely (withdrawal from both the study intervention and provision of follow-up data)
2. Withdrawing partially (withdrawal from the study intervention but continuing to provide follow-up data by attending clinic and completing questionnaires)

Consent will be sought from participants choosing option 1 to retain data collected up to the point of withdrawal. Participants will be asked if they would allow the reason for the decision to withdraw to be recorded.

Statistical analysis

A statistical analysis will be performed using SPSS 17.0. As this is a feasibility study, the analyses of the data collected will be mainly descriptive, with 95 % confidence intervals reported where appropriate. As a randomised controlled trial, the primary analysis will be based on the intention-to-treat principle with analysis groups based on the groups allocated at randomisation and all randomised patients being included in the analysis. As a feasibility study, the extent of missing data will be assessed

and reported, and analysis of outcomes may also be carried out on a complete-case basis. Rates will be calculated as defined and reported with 95 % confidence intervals. At baseline and by intervention group the distribution of all numerical variables will be examined and summarised using measures of location and spread. Similarly, baseline categorical variables will be tabulated and percentages reported. Change in the questionnaire outcomes from baseline to 2 weeks and 3 months will be summarised. The difference in the mean change between the intervention groups from baseline to each of the two time points will be explored for all outcome measures and reported with accompanying 95 % confidence intervals. Such results will be interpreted cautiously because of the size of the study and the possible imbalance in pre-randomisation baseline covariates. The relationship between baseline covariates and outcome measures will be examined graphically and quantified appropriately depending on their distribution. No formal statistical testing will be performed. Confidence limits for the estimated standard deviations of key study parameters will be calculated and used in sensitivity analyses for sample size calculations for a future definitive RCT.

Monitoring

This is a low risk trial, and major safety data are not anticipated. As agreed upon by Newcastle upon Tyne Hospitals, the Trial Oversight Committee (TOC) will adopt the joint roles of Trial Steering Committee (TSC) and Data Monitoring and Ethics Committee (DMEC) with independent members meeting in closed session to fulfil the DMEC role. The TOC comprises an independent chair, an independent consumer representative, a patient representative, a carer representative, CI, PI, data manager and statistician. The TOC will meet bi-annually. Their role is to monitor progress and supervise the trial to ensure it is conducted to high standards in accordance with the protocol, the principles of good clinical practice (GCP) and relevant regulations and guidelines and with regard to participant safety. The purpose of this committee will be to monitor study progress and patient safety. Monitoring of study conduct and data collected will be performed by site review to ensure the study is conducted in accordance with GCP. The main areas of focus will include consent, serious adverse events and essential documents in study.

The study may be subject to inspection and audit by Newcastle upon Tyne Hospitals under their remit as sponsor and by other regulatory bodies to ensure adherence to GCP. The investigator(s)/institutions will permit trial-related monitoring, audits, Research Ethics Committee (REC) review and regulatory inspection(s), providing direct access to source data/documents.

There is no interim analysis planned for this study.

Adverse event monitoring and reporting

Definitions

Adverse event (AE) An AE is an untoward medical occurrence in a subject to whom a study intervention or procedure has been administered, including occurrences which are not necessarily caused by or related to that intervention. An AE, therefore, does not necessarily have a causal relationship with the treatment. In this context, 'treatment' includes all interventions (including comparative agents) administered during the course of the study. Medical conditions/diseases present before starting study treatment are only considered AEs if they worsen after starting study treatment.

Related adverse event A related AE is one that results from administration of any of the research study procedures. All AEs judged by either the reporting investigator or the sponsor as having reasonable causal relationship to a study procedure qualify as 'related adverse events'. The expression 'reasonable causal relationship' means to convey in general that there is evidence or argument to suggest a causal relationship.

Causality The assignment of the causality should be made by the investigator responsible for the care of the participant using the definitions in Table 3. All AEs judged as having a reasonable suspected causal relationship to a study procedure (that is, definitely, probably or possibly related) are considered to be related AEs. If any doubt about the causality exists, the local investigator (PI) should inform the CI. In the case of discrepant

Table 3 Definitions of causality

Relationship	Description
Unrelated	There is no evidence of any causal relationship
Unlikely	There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the study procedure). There is another reasonable explanation for the event (e.g. the participant's clinical condition or other concomitant treatment)
Possible	There is some evidence to suggest a causal relationship (e.g. because the event occurs within a reasonable time after administration of the study procedure). However, the influence of other factors may have contributed to the event (e.g. the participant's clinical condition or other concomitant treatments)
Probable	There is evidence to suggest a causal relationship and the influence of other factors is unlikely
Definitely	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out
Not assessable	There is insufficient or incomplete evidence to make a clinical judgement of the causal relationship

views on causality between the investigator and others, all parties will discuss the case. In the event that no agreement is made, the main REC and other bodies will be informed of both points of view.

Unexpected adverse event

An unexpected AE is one that is not listed in the study protocol as an expected occurrence in the circumstances of this trial.

Serious adverse event (SAE)

An SAE is an untoward occurrence (whether expected or not) that:

- Results in death
- Is life-threatening (refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe)
- Requires hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability or incapacity
- Consists of a congenital anomaly or birth defect
- Is otherwise considered medically significant by the investigator

Medical judgement should be exercised in deciding whether an AE is serious in other situations. Important medical events that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the patient or may require intervention to prevent one of the other outcomes listed in the definition above should also be considered serious.

Severity (intensity) of adverse events and adverse reactions

The severity of all AEs will be graded on a three-point scale of intensity (mild, moderate and severe):

- Mild: Discomfort is noticed, but there is no disruption of normal daily activities.
- Moderate: Discomfort is sufficient to reduce or affect normal daily activities.
- Severe: Discomfort is incapacitating, resulting in inability to work or to perform normal daily activities.

An AE may be severe but not serious.

Expected adverse reactions

This is a low risk study, and there are no expected adverse reactions (ARs) from the intervention as it is an information resource rather than a treatment. Study procedures in the main are completing forms. Very occasionally when people perform spirometry (which will

be measured at study visits) they may feel light headed for a short while afterwards. Spirometry tests will be performed seated, and if participants have a known tendency, this test will be omitted. As this is a rare but expected AR, it would not be reported. Only suspected unexpected serious adverse reactions (SUSARs) will be reported.

Recording and reporting adverse events or reactions

All AEs should be reported as per protocol specifications. Depending on the nature of the event, the reporting procedures in the succeeding paragraphs should be followed. Any questions concerning AE reporting should be directed to the CI or PI in the first instance.

Adverse events

All non-serious AEs during study participation will be reported on the study CRF and sent to the CI within 2 weeks of the form being due. Severity of AEs will be graded on a three-point scale (mild, moderate and severe). Relation (causality) and seriousness of the AE to the treatment should be assessed by the investigator at site in the first instance. The individual investigator will be responsible for managing all AEs according to local policy.

Serious adverse events

All SAEs during study participation shall be reported to the CI within 24 hours of the site learning of its occurrence. The initial report can be made by telephone or email. Use of the SOHO66 fax system ensures that the NCTU, sponsor and CI are all informed by email simultaneously.

In the case of incomplete information at the time of initial reporting, all appropriate information should be provided as follow-up as soon as it becomes available. The relationship of the SAE to study procedures should be assessed by the investigator at site, as should the expected or unexpected nature of the SAE.

Ethics and dissemination

Ethics and regulatory issues

The conduct of this study will be in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki, 1964 and later revisions.

Favourable ethical opinion from NRES Committee North East - Sunderland (reference 14/NE/0119) has been granted, and R&D approval (reference 7005) from the Newcastle upon Tyne Hospitals NHS Foundation Trust was granted prior to commencement of the study. Any protocol amendments will be approved by R&D and the Sunderland REC and will be communicated to all relevant parties: investigators, registries, participants.

Information sheets will be provided to all eligible subjects and written informed consent obtained prior to any study procedures.

Informed consent procedures

Informed consent discussions will be undertaken by appropriately trained site staff (as per the delegation log) involved in the study, including medical staff and research nurses, with the opportunity for participants to ask any questions. Following receipt of information about the study, participants will be given reasonable time (aiming for a minimum of 24 hours) to decide whether or not they would like to participate. Those wishing to take part will provide written informed consent by signing and dating the study consent form, which will be witnessed and dated by a member of the research team with documented, delegated responsibility to do so. Written informed consent will always be obtained prior to randomisation and prior to study-specific procedures/investigations.

The original signed consent form will be retained in the Investigator Site File, with a copy in the clinical notes and a copy provided to the participant. The participant will specifically consent to his/her GP being informed of their participation in the study.

The right to refuse to participate without giving reasons will be respected.

Due to the small subject population and the inclusion criteria, the information sheet and consent form for the study will be available only in English.

Confidentiality

Personal data will be regarded as strictly confidential. To preserve anonymity, any data leaving the site will identify participants by their initials and a unique study identification code only. The study will comply with the Data Protection Act 1998. All study records and Investigator Site Files will be kept at site in a locked filing cabinet with restricted access. Only members of the research team will have access to the final dataset and access as required for necessary audit and monitoring.

Insurance and finance

The sponsor, the Newcastle upon Tyne Hospitals NHS Foundation Trust, has liability for clinical negligence that harms individuals toward whom they have a duty of care. NHS indemnity covers NHS staff and medical academic staff with honorary contracts conducting the trial for potential liability in respect of negligent harm arising from the conduct of the study. The Newcastle upon Tyne Hospitals NHS Trust is sponsor and, through the sponsor, NHS indemnity is provided in respect of potential liability and negligent harm arising from study management. Indemnity in respect of potential liability arising from negligent harm related to study design is

provided by NHS schemes for those protocol authors who have their substantive contracts of employment with the NHS and by Newcastle University insurance schemes for those protocol authors who have their substantive contract of employment with the university. This is a non-commercial study, and there are no arrangements for non-negligent compensation. Newcastle University provides insurance coverage for the trial design.

The National Institute for Health Research (NIHR) is funding the study through a doctoral research fellowship awarded to the CI.

Study reporting and publications

It is planned to publish this study in peer-reviewed articles and to present data at national and international meetings. Results of the study will also be reported to the sponsor (Newcastle upon Tyne Hospitals) and funder (NIHR) and will be available on their websites. All manuscripts, abstracts or other modes of presentation will be reviewed by the Trial Overview Committee and funder prior to submission. This will also form part of the PhD thesis of the CI. Individuals will not be identified from any study report. Participants will be informed about their contribution to the study, including a lay summary of the results, at the end of the study.

Discussion

This study is a low risk study. As the study and intervention have been co-developed with potential users, we hope this will make the trial process and use of the resource straightforward and beneficial. The study will both inform a future multi-centre trial and allow for evaluation and refinement of the patient information resource to maximise potential future uptake and impact. Analysis of outcome measures will begin to determine impact of this novel information resource on patient knowledge and confidence to self-manage and inform development of a definitive trial to determine the effect on disease stability.

The relatively short duration of the feasibility study may limit the usefulness of exacerbation frequency data in terms of defining this rate for a definitive trial. We are collecting these data to determine the feasibility of their use as an outcome measure, yet for a definitive trial with a longer follow-up period, it is likely that we would need to refer to previously published rates of exacerbation frequency in bronchiectasis. Within a recent analysis of 155 patients at our centre this was found to be roughly 4 per annum [20], although this does differ between publications as outlined in the BTS guidelines for the treatment of bronchiectasis [14]. It has also been demonstrated that exacerbation rates vary seasonally [21], and with a shorter feasibility study frequency is therefore harder to extrapolate accurately. Additionally,

in terms of reporting of exacerbations, within this study design we have relied upon patient reporting of numbers of exacerbations for which they have required treatment with a course of antibiotics. We have not included a strict definition of an exacerbation within the protocol as we have not asked patients to report changes in symptoms in real time nor made decisions about diagnosis of exacerbations or treatment for them. We do not anticipate a significant problem with ascertainment bias, yet consideration of this will also help to inform the definitive trial. Due to the short amount of time between visits in this study, we do not anticipate issues with recall, although patient notes can be used as an alternative mechanism.

One of the potential impacts of the intervention will be to improve symptom recognition and management. This will not, however, be a uniform change. Some participants were likely to have under-recognised exacerbations prior to study participation, and others were possibly taking courses of antibiotics for symptoms they felt were indicative of an exacerbation that were in fact just 'normal' variations in their chronic symptoms. Thus, using number of courses of antibiotics or change in number is not necessarily a useful measure; hence the additional recording of unscheduled healthcare usage.

The addition of qualitative data through the use of focus groups will allow for a richer exploration of the experience of both the trial process and use of the information package for participants. Although we know that patients want more information about bronchiectasis [17], it is argued that health information alone does not necessarily produce changes in behaviour [22]. However, asthma studies have shown that delivering education about the key aspects of the condition, allowing patients to acquire skills, and education in combination with clinical review and action plans can lead to demonstrable improvements [23–25]. By providing improved educational interventions that meet the needs of patients with bronchiectasis and their carers, we aim to facilitate improvements in self-management. Our aim is that in addition to providing a resource that is a reassuring source of support for patients and carers, improvements in understanding and management will lead to improvements in health outcomes and healthcare service use longer term. By evaluating and refining this patient-driven intervention and assessing the feasibility of conducting a future definitive RCT, we are making important progress in the provision of much needed interventions in bronchiectasis.

Trial status

The study is still recruiting at time of submission. The first recruit was on 10/6/2014.

Additional files

Additional file 1: Patient consent form. (DOC 103 kb)
Additional file 2: Carer consent form. (DOC 102 kb)

Abbreviations

AE: adverse event; AR: adverse reaction; CI: Chief Investigator; CRF: Case Report Form; DMEC: Data Monitoring and Ethics Committee; EQ-5D: Euroqol 5-dimension (quality of life scale); FEV1: forced expiratory volume in 1 second; FIS: Fatigue Impact Scale; GCP: Good Clinical Practice; HADS: Hospital Anxiety and Depression Scale; MREC: Main Research Ethics Committee; NCTU: Newcastle Clinical Trials Unit; NIHR: National Institute for Health Research; NUTH: Newcastle upon Tyne Hospitals; PI: Principal Investigator (at each site); QOL-B: Quality of Life Questionnaire-Bronchiectasis; R&D: research and development; RCT: randomised controlled trial; SAE: serious adverse event; SGRQ: St George's Respiratory Questionnaire; SUSAR: suspected unexpected serious adverse reaction; TOC: Trial Oversight Committee; UP: unscheduled presentation to primary or secondary care.

Competing interests

There are no known competing interests for any of the authors. KH is funded by a National Institute for Health Research Doctoral Research Fellowship. This article presents independent research funded by the National Institute for Health Research (NIHR). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health. ADS acknowledges funding to the BronchUK network from the UK Medical Research Council (grant MR/L011263/1) and a prior Higher Education Funding Council (HFCE senior lectureship).

Authors' contributions

KH conceived of the study and its design and coordination and developed the intervention used. KH drafted the manuscript and is primary author of this work, which forms part of her current PhD thesis. ADS supervised and contributed to concept, design and coordination of the study and the intervention used. ADS participated in and contributed to the manuscript preparation. TR contributed to the concept and design of the study and the intervention and manuscript preparation. JN contributed to the concept and design of the study and the intervention and manuscript preparation. All authors read and approved the final manuscript.

Acknowledgements

We would like to acknowledge Dr Vicky Ryan for advice about the statistical analysis plan. We would like to acknowledge research nurses Gareth Davies and Geraldine Jones for their contribution to recruitment and study visits. We are grateful to the National Institute for Health Research for funding this work through a National Institute for Health Research Doctoral Research Fellowship Award (DRF-2012-05-149) awarded to Dr Katy Hester. The sponsor of this work is the Newcastle upon Tyne Hospitals NHS Foundation Trust R&D (reference 7005).

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Received: 3 February 2016 Accepted: 7 April 2016

Published online: 23 April 2016

References

1. Pasteur MC et al. An investigation into causative factors in patients with bronchiectasis. *Am J Respir Crit Care Med*. 2000;162(4 Pt 1):1277–84.
2. Shoemark A, Ozerovitch L, Wilson R. Aetiology in adult patients with bronchiectasis. *Respir Med*. 2007;101(6):1163–70.
3. Wilson CB et al. Validation of the St. George's Respiratory Questionnaire in bronchiectasis. *Am J Respir Crit Care Med*. 1997;156(2 Pt 1):536–41.
4. O'Leary CJ et al. Relationship between psychological well-being and lung health status in patients with bronchiectasis. *Respir Med*. 2002;96(9):686–92.
5. Hester KLM et al. Fatigue in bronchiectasis. *Q J Med*. 2012;105(3):235–40.

6. Macfarlane JG et al. Fatigue in bronchiectasis: its relationship to pseudomonas colonisation, dyspnoea and airflow obstruction. *Thorax*. 2010;65:A60.
7. Quint JK et al. Changes in the incidence, prevalence and mortality of bronchiectasis in the UK from 2004 to 2013: a population-based cohort study. *Eur Respir J*. 2016;47(1):186–93.
8. Patel IS et al. Bronchiectasis, exacerbation indices, and inflammation in chronic obstructive pulmonary disease. *Am J Respir Crit Care Med*. 2004;170(4):400–7.
9. Shahab L et al. Prevalence, diagnosis and relation to tobacco dependence of chronic obstructive pulmonary disease in a nationally representative population sample. *Thorax*. 2006;61(12):1043–7.
10. Roberts HJ, Hubbard R. Trends in bronchiectasis mortality in England and Wales. *Respir Med*. 2010;104(7):981–5.
11. Loebinger MR et al. Mortality in bronchiectasis: a long-term study assessing the factors influencing survival. *Eur Respir J*. 2009;34(4):843–9.
12. Kelly MG, Murphy S, Elborn JS. Bronchiectasis in secondary care: a comprehensive profile of a neglected disease. *Eur J Intern Med*. 2003;14(8):488–92.
13. Seitz AE et al. Trends and burden of bronchiectasis-associated hospitalizations in the United States, 1993–2006. *Chest*. 2010;138(4):944–9.
14. Pasteur MC, Bilton D, Hill AT. British Thoracic Society guideline for non-CF bronchiectasis. *Thorax*. 2010;65 Suppl 1:11–58.
15. Hester KLM, McAlinden P, De Soya A. Education and information for patients with bronchiectasis: what do patients want? *Eur Respir J*. 2011;38(supplement 35):P3622.
16. Lavery K et al. Self-management in bronchiectasis: the patients' perspective. *Eur Respir J*. 2007;29(3):541–7.
17. Hester KLM, De Soya A, Rapley T. Information and education needs of patients with bronchiectasis: a qualitative investigation. *Thorax*. 2012;67(supplement 2):A141.
18. Hester KLM. Information and education provision for patients with bronchiectasis: a qualitative study. Newcastle upon Tyne: Newcastle University; 2012.
19. Lancaster G, Dodd S, Williamson P. Design and analysis of pilot studies: recommendations for good practice. *J Evaluation Clinical Practice*. 2004;10(2):307–12.
20. McDonnell MJ et al. Non cystic fibrosis bronchiectasis: a longitudinal retrospective observational cohort study of Pseudomonas persistence and resistance. *Respiratory Medicine*. 2015;109(6):716–26.
21. Bibby S, Milne R, Beasley R. Hospital admissions for non-cystic fibrosis bronchiectasis in New Zealand. *New Zealand Med J*. 2015;128(1421):30–8.
22. Becker MH, Becker MH. Theoretical models of adherence and strategies for improving adherence. In: Shumaker SA, editor. *The handbook of health behaviour change*. New York: Springer Publishing Company; 1990. p. 5–43.
23. Gibson PG et al. Limited (information only) patient education programs for adults with asthma. *Cochrane Database Syst Rev*. 2002;2:CD001005.
24. Partridge MR, Hill SR. Enhancing care for people with asthma: the role of communication, education, training and self-management. *Eur Respir J*. 2000;16(2):333–48.
25. Takakura S, Hasegawa T, Ishihara K. Assessment of patients' understanding of their asthmatic condition established in an outpatient clinic. *Eur Respir J*. 1998;12(supplement 29):245.
26. Quittner AL, et al. Quality of Life Questionnaire-Bronchiectasis: final psychometric analyses and determination of minimal important difference scores. *Thorax*. 2014;0:1–9.
27. Zigmond AS, Snaith RP. The Hospital Anxiety and Depression Scale. *Acta Psychiatrica Scandinavica*. 1983;67(6):361–70.
28. Fisk JD et al. Measuring the functional impact of fatigue: initial validation of the fatigue impact scale. *Clinical Infectious Dis*. 1994;18(Supplement 1):S79–83.
29. Herdman M et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5 L). *Qual Life Res*. 2011;20(10):1727–36.

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Appendix 4 Qualitative interviews participant information sheet

PARTICIPANT INFORMATION SHEET

Study Title: Information and education provision for patients with bronchiectasis: a qualitative investigation of patients' needs and development of a patient-driven resource.

Short Title: Bronchiectasis information and education.

Study Code: **Version number:** 2.0 (9th October 2012)

We would like to invite you to take part in a research study. Before you decide whether you would like to take part, you need to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you may have. This will take about 30 minutes. Please take time to read the following information carefully. Talk to others about the study if you wish.

Part 1 of the information sheet tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study.

Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

PART 1

What is the purpose of the study?

Bronchiectasis is a chronic lung condition that causes problems with breathlessness, cough and frequent chest infections. There is currently limited information available to patients with bronchiectasis and their carers, including a 1 page leaflet from the British Lung Foundation and a few websites. Patients at our bronchiectasis clinic completed a questionnaire which revealed that they learned more about their condition and felt more confident with their treatment having attended clinic. We think that patients may benefit from more information and education about their condition, but first we need to know what patients think. We have carried out a small study to begin to understand what information people whose lives are affected by bronchiectasis need and found that overall more information was needed. In this study we would like to find out what information patients with bronchiectasis and their carers would like and in what way they would like to get this information. We will then use this to develop a new information package that is driven by your views.

The research is also being undertaken for educational purposes and will form part of a PhD for the researcher, Dr Katy Hester, from Newcastle University.

Why have I been invited?

You have been invited to take part because you have bronchiectasis, or care for someone with bronchiectasis. We are hoping to involve up to 20-30 patients in the study and up to 10 carers or partners of patients with bronchiectasis.

Do I have to take part?

It is up to you to decide. We have sent you this information sheet, and you can contact the respiratory research doctor (Dr Katy Hester) if you would like to receive further information regarding this study. If you decide to take part, we will ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of any care you are receiving, nor your involvement in any other study.

What will happen to me if I take part?

If you decide you would like to take part in the study, the researcher will discuss the study further and if you agree to take part we will ask you to sign the consent form.

After this we will have a discussion or 'interview' to ask questions about your experiences and feelings about bronchiectasis information and education. We expect the interview to take approximately an hour. All interviews will be recorded using an audio-digital recorder. There will not be video imaging. For your confidentiality, the interview data will be transcribed with personal details (e.g. names) removed and codes used instead. The audio recordings will be kept until 6 months after the study closes. They will then be destroyed.

If you have been given a diagnosis of bronchiectasis recently (under 1 year), then we will also invite you to take part in a second follow-up interview a few months later. This is so that we can see if your information needs have changed along your patient journey.

We will be developing an information package following the interviews. In order to involve you in the development of this information package we will then invite you to attend 1 focus group. This

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2

is a group meeting where the researcher would meet with a few of the patients and carers taking part in the study. During the focus group we will show you the resource we have developed and get your views on how to improve and change it. This will allow us to produce new information that meets your needs.

We expect these group meetings to last up to an hour. We may invite some additional people who have not taken part in an interview but they will still be patients with bronchiectasis or carers of a person with bronchiectasis.

Expenses and payments

Reasonable expenses (e.g. travel for the interview) will be refunded.

What will I have to do?

If you decide to take part then you will be required to meet with the researcher and take part in the interview as described in the previous section. You will also be invited to a group meeting that you can attend if you wish.

There will be no changes made to your usual treatment or medical care.

What are the possible disadvantages and risks of taking part?

The interview and focus groups will take up approximately 1 hour of your time each, which you may not find convenient.

What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get from this study may help improve the understanding of patients' needs, and help us develop better information resources for patients with bronchiectasis.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

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Part 2

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any point. This would not affect any ongoing care. If you do withdraw from the study, all information relating to you will be destroyed if you wish.

What if there is a problem?

If you have a concern about any aspect of this study, you can speak to the researchers who will do their best to answer your questions. You can contact the team on 0191 223 1148. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital Patient Advice and Liaison Service (PALS) on 0800 032 0202 or 0191233 6161.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against The Newcastle upon Tyne Hospitals NHS Foundation Trust. You may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part in this study be kept confidential?

All information collected about you during the course of the research will be kept strictly confidential, and any information about you that leaves the hospital will have your name and address removed so that you cannot be identified.

All personal identifiable information and data (e.g. name and address) collected will be subject to the Data Protection Act and Caldicott Principles.

Audio recordings will be made during this study and kept until 6 months after the study closes and destroyed following this. Any electronic data will be stored on an NHS or University password protected computer. This will be within a locked office in the research office within the trust or university and can only be accessed by authorised people. Authorised people may include members of the research team, auditors and regulatory authorities. Once the recordings are transcribed your personal details will be removed and they will be identified only by an anonymous code. These anonymised transcripts will be kept for 10 years after the study ends in a locked cabinet within the research facility and then destroyed.

Please note, the results of the study may be published in medical literature, but you will not be identified.

You have the right to request information about your data held by the researcher. You also have the right to request that any inaccuracies in such data be corrected. If you wish to make a request, then please contact the researcher.

If you withdraw your consent, the researcher will no longer use your data.

If we wished to use your information for further studies, your further consent would be sought.

Involvement of the General Practitioner/Family doctor (GP)

We would like to inform your GP that you are taking part in this study, if you are happy for us to do so. We will ask you about this and seek your consent.

What will happen to the results of the research study?

When the research is completed you will be offered a summary of the findings. The research will form part of a thesis towards a PhD for the researcher, Katy Hester, from Newcastle University. We would also expect to present our work at local, national and international conferences, and publish our findings in peer reviewed journals. All information is anonymised and you will not be identified in any of these.

Who is organising and funding the research?

This research is being done as part of the researcher's completion of a PhD Fellowship. This is being sponsored by the Newcastle upon Tyne Hospitals NHS Trust and funded by the The National Institute for Health Research. There will be no payments to the trust or researcher for including you in this study.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your interests. This study has been reviewed by the NRES Committee South Central - Berkshire B Proportionate Review Sub-Committee.

You will be given a copy of this information sheet and a signed consent form to keep.

Further information and contact details

If you would like further information about this study, or research in general, please contact the researcher, Dr Katy Hester, on 0191 223 1148. If you need further advice as to whether you should participate, you can also speak to the research team on the above number, or you may wish to speak to your own GP. If you are unhappy with the study you can approach the research team, or get advice from PALS as outlined in the complaints section.

Appendix 5 Qualitative interviews invitation letter

The Newcastle upon Tyne Hospitals 



DEPARTMENT OF RESPIRATORY MEDICINE
Sir William Leech Centre for Lung Research

Freeman Hospital
High Heaton
Newcastle upon Tyne
NE7 7DN

Letter of invitation

Study Title: Information and education provision for patients with bronchiectasis: a qualitative investigation of patients' needs and development of a patient-driven resource. (Bronchiectasis information and education.)

Name of Researchers: Dr Katy Hester
Dr Anthony De Soyza, Dr Tim Rapley, Professor Julia Newton

Dear.....

We are writing to tell you about a new research study at the Freeman hospital which we think you may be interested in participating in. We are investigating what information and education patients with bronchiectasis and their carers feel they need. We are aware that there is limited information available and want to find out what patients would like to have, and if they feel they would benefit from more information. We will then develop a new information package that will be driven by your views as a group.

You have been invited as you have a diagnosis of bronchiectasis, or care for someone who has bronchiectasis, and we believe that you may be a suitable candidate for the study.

We have enclosed a copy of the participant information sheet for this study to give you more details of what would be involved.

If you are interested in finding out more then please contact us, and we will arrange to discuss this in more detail.

Thank you for your time.

Yours sincerely,

Dr Katy Hester

For further information about the study please contact:
Dr Katy Hester: 0191 223 1148 or address above

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Appendix 6 Qualitative interviews consent form

The Newcastle upon Tyne Hospitals 

DEPARTMENT OF RESPIRATORY MEDICINE
Sir William Leech Centre for Lung Research

Freeman Hospital
High Heaton
Newcastle upon Tyne
NE7 7DN



PARTICIPANT INFORMED CONSENT FORM

Study Title: Information and education provision for patients with bronchiectasis: a qualitative investigation of patients' needs and development of a patient-driven resource.

Short Title: Bronchiectasis information and education

Researchers: Dr Katy Hester
Dr Anthony De Soyza, Dr Tim Rapley, Professor Julia Newton

Participant initials:

Participant code number:

**Please
initial
boxes**

1. I confirm that I have read and understand the information provided in the participant information sheet, dated 20th September 2012, version 1.0. The information has been explained to me, I have been given the opportunity to ask questions and I am satisfied with the explanations provided.

☐

2. I am aware that my participation in this study is entirely voluntary. I understand that I may withdraw at any time, without giving a reason, without this affecting my future care or legal rights.

☐

3. I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from the research team, The Newcastle upon Tyne NHS Hospitals Foundation Trust, or from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

☐

4. I understand that an audio recording will be made of my interview that will only be used for the purposes of this research and agree to this being done.

☐

5. I agree to my GP being informed of my participation in the study.

☐

6. I understand that I will receive a signed copy of this consent form.

☐

7. I agree to take part in this study

☐

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- 1 of 2 -*

Signatures

Name of participant:

Date:

Signature:

Name of person taking consent:

Date:

Signature:

Appendix 7 Interview topic guide

Semi-structured interview discussion topics

The interview schedule is developmental. The questions will need to be tailored to the specific answers of each interviewee. The interview schedule given here is therefore a *general topic guide* for the one-to-one qualitative interviews.

1. Learning about bronchiectasis

Can you tell me when you (or person you care for) first found out that you (they) had bronchiectasis?

- Explore what information they were given
- If they were given information, has this helped them?

Since the diagnosis, have you been given or gone in search of more information about bronchiectasis?

- Explore where they got this information
- Explore what the content of the information is
- Explore what motivated them to get this information
- Explore role of family and friends (e.g. helping them, motivating them)/carers perceptions of role
- Did they find it difficult to get information
- If they have information has this helped them?

Would you like to know more about bronchiectasis?

- Explore what sort of things they would like to know more about
- If answer is no, explore why
- If they do want more, explore why & what benefits they perceive will arise from better information/ knowledge

Are you aware of where you can access information?

- Explore information sources they are aware of
- Explore how they discovered this/who gave the lead
- Explore whether they have accessed information they are aware of and why/why not
- Explore which sources of information they preferred if looked at different ones
- Explore what makes them trust the information
- If search online – how do you do this and what affects what they choose to look at?

Are you satisfied with the service and level of information provided?

- Explore their experiences of the bronchiectasis clinic/inpatient stays
- Explore their opinion of the information gained from these sources.
- What aspects would they like to be able to revisit if any?

2. Managing bronchiectasis

Can you tell me what you know about how to manage bronchiectasis?

- Explore their knowledge of bronchiectasis treatment options and in particular what they (or the person they care for) are being treated with

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Are you confident in how to recognise an exacerbation?

- Explore what constitutes an exacerbation for them
- Explore how they usually deal with this and how it makes them feel (the person they care for feel)
- For carers – what role do you play in this

Are you confident in how to self-manage an exacerbation, and when to seek help?

- Explore their current practices, whether they are confident to manage their own symptoms
- Explore whether they prefer to be able to manage their own symptoms when reasonable or not
- Explore what triggers them to seek medical help
- For carers – what role do you play?

3. Future Information Formats

What format(s) do you feel would be best to receive information?

- Discuss various forms of information (e. g. DVD/ written/ email/ website/ short course similar to pulmonary rehabilitation) explore which they find easiest to understand/retain.
- Demonstrate using examples of different formats of patient information and explore what aspects of each they like/dislike
- Explore what format they would find most user-friendly.
- Explore what format they would like as a refresher for such information and if they would wish this to be self directed (e.g. patient manual) or other.

Do you have any suggestions or comments about developing and evaluating a new informative educational package for patients with bronchiectasis?

4. About you

If not already covered during interview:-

Age

Length of time since diagnosis

Nature of bronchiectasis

Attend specialist or general clinic

Current or previous employment

Educational level

Appendix 8 Interview list of codes

BRIE summary of codes: coding manual and lists

List of basic codes

1. Preferred information format
2. Preferred information content
3. Information needs
4. Information seeking
5. Reasons/triggers for information seeking
6. Barriers
7. Trusting information
8. Information provision
9. Retaining information
10. Onset of symptoms
11. Health beliefs/ lay reasoning
12. Diagnosis
13. Prognosis/death
14. Other diagnoses
15. Impact
16. Family support
17. Medical team
18. GP role
19. Relating to others' experiences
20. Support groups forums
21. Other professionals
22. Treatment
23. Self-management
24. Confidence
25. Normality
26. Reassurance
27. Acceptance
28. Wanting to help
29. Research
30. Patient duty/role
31. Advice to others

Description of codes and their sub-codes

BRIE code 1: Preferred information format

This is about what information formats people prefer and the reasons behind that. Includes general formats and also more specific details such as layout of booklets.

- Preferred information format – booklet
- Preferred information format – website
- Preferred information format – DVD
- Preferred information format – other
- Preferred information format – style details (text, images, video, layout, size)
- Preferred information format – consultation
- Preferred information format – to refer back to
- Preferred information format – accessible to all/lack of jargon (added 141113 P05)

BRIE code 2: Preferred information content

This is about what patients and carers feel they would like to know or like to be in an information resource. This includes general and more specific details on content. The universally mentioned subject was wanting to know more about what they could do for themselves beyond medical treatment so that they were 'doing their bit'. They all used diet and lifestyle factors as an example. Patients particularly seemed to think that they would benefit from hearing about other people's stories and information about prognosis and treatment. They also seemed to place emphasis on volume of information and preferred 'more' information.

- Preferred information content – other people's stories
- Preferred information content – medication and treatments and side effects
- Preferred information content – volume of information
- Preferred information content – question and answers
- Preferred information content – self-help (diet and lifestyle)
- Preferred information content – prognosis
- Preferred information content – causes of bronchiectasis
- Preferred information content – self-management/symptom recognition
- Preferred information content – information for carers
- Preferred information content – practical help (aids, driving, insurance, travel)
- Preferred information content – research/new drugs
- Preferred information content – level of depth/jargon (added P07 240413)
- Preferred information content – up to date
- Preferred information content – physiotherapy
- Preferred information content – microbiology
- Preferred information content – imaging (own)/lung function
- Preferred information content – impact (physical/emotional)
- Preferred information content – acceptance/coping
- Preferred information content – symptoms (haemoptysis)
- Preferred information content – Positivity

- Preferred information content – transplantation

BRIE Code 3: Information needs

This covers all data in which participants are discussing their information requirements. This closely links in with information content and format but also covers sections where patients are talking about what they haven't had answered in the past, for example patients frequently mentioned they would have liked to have had more information at an earlier stage or more than the basic information. Carers also wanted more information on what they could do.

- Information needs – self-help (what they can do themselves beyond medical treatment)
- Information needs – timing
- Information needs – treatments (tablets/inhalers/NIV/oxygen/physio)
- Information needs – exercise
- Information needs – caring for someone with bronchiectasis
- Information needs – beyond basic information resource
- Information needs – prognosis
- Information needs – benefit from information
- Information needs – level of understanding of bronchiectasis
- Information needs – symptoms, new symptoms ? bronchiectasis related (030413 BRIE P09)
- Information needs – microbiology
- Information needs – imaging (own)
- Information needs – restrictions
- Information needs – accessibility to all

BRIE code 4: Information seeking

This is patients' accounts of looking for or not looking for information. It includes how, where and when they have sought information and what resources they have used. Patients discuss their reasons for this and whether their efforts were successful. This closely links with triggers for information seeking, information needs and information format and content.

- Information seeking – reasons for seeking
- Information seeking – reasons for not seeking (never thought to, scared, no time)
- Information seeking – mode (opportunistic, effortful)
- Information seeking – role of family/friends
- Information seeking – internet
- Information seeking – needs met?
- Information seeking – source - doctor
- Information seeking – impact (added 131113 BRIE P05)

BRIE Code 5: reasons/triggers for seeking information

This code is about people's accounts of why they look for information. Triggers to seeking information seem to be a change in their condition or development of a new symptom. Patients talk about this both for bronchiectasis and other diagnoses. Patients also refer to looking up things that

have not been explained to them adequately or they have not remembered. This links in with information needs, seeking and retaining information.

- Information seeking triggers – new symptom/ change in condition
- Information seeking triggers – lack of explanation from doctor/not remembering
- Information seeking triggers – problems with medication

BRIE code 6: barriers

This code is about patients accounts of barriers to information seeking. The commonest foreseen barrier was lack of internet use. Some patients described their families looking up information on the internet for them but others did not want to ask their families. Even a lady who did use the internet to seek information stated that she didn't think she was skilled enough at it for it to be her preferred source. Lack of access to or ability to use the particular format was a common reason and this applies to DVD players and also booklets. This could be the case for both those who are unable to read and also those with poor eyesight. Another factor was trustworthy and user-friendly information. People described concerns about credibility both in terms of source and also conflicting advice between sources, and lack of information pitched at the right level. Personality could also be a factor as one lady describes not wanting to use forums due to not being 'a mixer'.

- Barriers – lack of ability to access/use resource format
- Barriers – personal factors
- Barriers – credibility
- Barriers – lack of availability/advertising/ease of access

BRIE Code 7: Trusting information

Trusting information is important and people have different ways of measuring this. Most comments relate to lack of trust of internet sites and not knowing what to believe with people preferring to have something recommended to them by their doctor or a specialist in bronchiectasis. Having a sense of a website being legitimate e.g. NHS made it more trustworthy. Others made comparisons and trusted information if it seemed to concur with other sources. Patients also talked about trusting information from the doctor rather than other patients.

- Trusting information – websites legitimate/endorsed/recommended
- Not trusting information
- Trusting information – source – own doctor
- Trusting information – no concerns

BRIE code 8: Information provision

This is accounts of what information patients have had provided to them, or not as the case may be. They describe information provision from both clinic and wards and from doctors and nurses. Adequacy of available information was also discussed.

- Information provision – clinic
- Information provision – hospital

- Information provision – doctor
- Information provision – nurse
- Information provision – GP
- Information provision – inadequacy/suitability
- Information provision – physiotherapy
- Information provision – no cure
- Information provision – lack of consistency

BRIE Code 9: retaining information

This could be all merged into a main information code with current codes as sub-codes. This is about not being able to retain all information given in clinic.

- Not retaining information
- Able to retain

BRIE Code 10: Onset of symptoms

This is patients' accounts of how and when their symptoms first started. There are links with lay reasoning and patients having to try to come up with explanations or causes of bronchiectasis.

- Time since onset
- Account of onset of symptoms

BRIE Code 11: Health beliefs/ lay reasoning

Patient's account of what they feel could have been implicated in the cause/onset of bronchiectasis. Not actually correct in some cases and patient alludes to this but still feels must be a factor. This also includes patients descriptions of what they know/understand about the disease whether these be factually correct or not.

- Causative factors - their fault
- Causative factors – smoking
- Factors patients feel contributed to onset of bronchiectasis
- Knowledge about condition

BRIE Code 12: Diagnosis

This is anything relating to the patient's diagnosis experience. Some describe this as a traumatic event and often felt they have little information at diagnosis. Some describe the difficulties leading up to a diagnosis including the feeling that nobody was listening to them, or thought there was nothing wrong with them. People's emotional responses and reactions to diagnosis are also described.

- Diagnosis – impact
- Diagnosis – difficulties
- Diagnosis – relief

BRIE Code 13: Prognosis/death

This is about patients concern about prognosis or disease trajectory. This seems to be a priority at diagnosis and patients seek reassurance about this from both their practitioner and from hearing other people's experiences. Disappointment about the lack of cure for bronchiectasis and some fear of knowing potential prognosis at the outset.

- Wanting to know prognosis/disease trajectory
- Lack of cure
- Duty to keep well?
- Wanting reassurance from medical team
- Wanting reassurance from information about other people's experiences
- Uncertainty (added 250413 BRIE P08/C04)

BRIE Code 14: other diagnoses

This is anything about diagnoses that patients have in addition to bronchiectasis. This may relate to how they position this in relation to bronchiectasis in terms of impact or information seeking.

- Other diagnoses – impact
- Other diagnoses – information
- Other diagnoses – link with bronchiectasis

BRIE code 15: Impact

This is any data that includes patients' accounts of how bronchiectasis has impacted upon their lives. This is both initial and on-going impact. Patients discuss how the disease impacts upon them and their families both physically and emotionally; on their role in life and their coping strategies to deal with these effects. They describe a conscious effort to come to terms with things. The realisation that there is no cure seemed to have a big psychological impact and the impact of treatments were also discussed.

- Impact – physical (fatigue, cough, breathlessness)
- Impact – emotional (upset, depressed, anxiety, fear)
- Impact - on carers/family
- Impact – coping strategies (concerted effort)
- Impact – role (sense of self, work)
- Impact – treatments
- Impact – insurance
- Impact – investigations
- Impact –neglected?
- Impact – change over time (added 11/11/13 P08)
- Impact – stigma (added 121113 P08)
- Impact – social/lifestyle (added 121113 P08)
- Impact – lack of (added 131113 P10)

BRIE code 16: Family/friend support

This is about how patients are supported by their families and friends, or lack of support. This is done both on a practical carer level and also emotional support and helping with information seeking.

- Family support – emotional
- Family support – practical/self-management help/carers
- Family support – lack of
- Family support – information

BRIE code 17: Medical team

This is any data referring to the medical team involved in their care. This may relate to a doctor, nurse or hospital in general and includes discussion about self-management education, answering questions and support.

- Medical team – bronchiectasis nurse
- Medical team – doctor
- Medical team – specialist clinic
- Medical team – hospital
- Medical team – grateful/happy with care
- Medical team – disappointed with care
- Medical team – lost to follow-up
- Medical team – private care
- Medical team – wanting help
- Medical team – not wanting/embarrassed to be a burden
- Medical team – speed of response
- Medical team – accessibility
- Medical team – lack of expertise
- Medical team – physio (added 121113 P08)

BRIE Code 18: GP Role

The role of the GP differs between patients. There is a suggestion that their role diminishes over time as patients become more established. Although some GPs play an active role in day to day care there is also a significant lack of faith in their ability to deal with bronchiectasis and also patients feeling they were not listened to at initial presentation.

- GP role
- Lack of faith in GP/not listening

BRIE code 19: relating to others' experiences

This is about how patients relate to hearing about other people's experiences of bronchiectasis and can be either directly through talking to people they meet or indirectly e.g. reading people's stories online. People seem to gain reassurance from hearing about how others have coped, realising that others are worse off than they are and feeling that they are not alone. They also describe learning

about the condition and managing it from others. This seems to be a much liked way of learning about bronchiectasis in all but one patient who preferred to hear from doctors not patients.

- Relating to others – learning
- Relating to others – coping/acceptance
- Relating to others – worse off than me
- Relating to others – directly/indirectly
- Relating to others – not alone
- Relating to others – not keen

BRIE code 20: support groups/forums

This is really about support groups and online patient forums or blogs. So far just about not wanting to use support groups but some use of forums-not necessarily actively participating but useful to look at.

- Not using forums or support groups
- Using

BRIE Code 21: other professionals involved

Only one extract so far. This seems to be both about getting support from a pharmacist as another professional and also about the patient feeling that she has to make extra effort to recruit help due to her GP not listening to her so links in with lack of role of GP.

- Support from pharmacist

BRIE Code 22: Treatment

This is about what drugs patients take both for bronchiectasis and for any other conditions they may have. Patients discuss their knowledge about drugs or want for information about them. They also talk about the side effects and the positive effects of the medication they are taking. Some patients talk about how they manage their medication which links with self-management.

- Treatment – positive effects
- Treatment – side effects
- Treatment – information
- Treatment – self management
- Treatment – lack of effect
- Treatment – future
- Treatment – burden
- Treatment – surgery
- Treatment – preventing further damage

BRIE code 23: Self-management

This is any data where patients are discussing self-management of their condition. This includes whether they are able to self-manage or not and how they have developed the skills to do this. It also covers their knowledge about treatments which links in with treatment.

- Self- management – symptom recognition
- Self-management – developing skills
- Self-management – lack of experience/confidence/fear
- Self-management – understanding treatments
- Self-management – physiotherapy
- Self-management – taking control/active partnership
- Self-management – lifestyle changes
- Self- management - Self-help/alternative therapies/supplements
- Self-management – studying self/self-monitoring (added 030413 BRIE 09)
- Self-management – home IVs (added 121113 P08)

BRIE Code 24: Confidence

This is related to confidence in self-management due to information and instruction and practice.

- With self-management
- From information
- From clinic

BRIE Code 25: normality

This seems to be about patients wanting their life to be 'normal' or wanting to feel normal themselves. There are also areas about whether their experiences are 'normal for bronchiectasis' and learning to live with their new normal.

- Wanting normality
- Normal for bronchiectasis/new normal

BRIE Code 26: reassurance

This is about different ways in which patients need or get reassurance. Firstly wanting reassurance regarding prognosis, and getting reassurance from other people's experiences and seeking information that would reassure them both independently and from their doctor.

- Information seeking to reassure
- Reassurance from others' experiences
- Reassurance from medical team

BRIE Code 27: Acceptance

This is patients' accounts of how they have come to terms with their diagnosis and what has helped them to reach this point; how long it took to accept. Patients mention the fact that there is no cure for this which seems to impact upon the process of acceptance. They describe finding relating to other people's experiences helpful in coming to terms with their condition. Their descriptions can

seem to suggest a conscious effort or decision to accept the condition or make the most of what they have and get on with life.

- Acceptance – time taken
- Acceptance – what helped

BRIE Code 28: Wanting to help

This is patients' accounts of wanting to help either due to gratitude to the hospital, with research etc or wanting to help others who have the condition either now or in the future.

- Wanting to help – giving something back/research
- Wanting to help – others with the condition

BRIE code 29: Research

This has been added due to discussion about not being interested in research hence doesn't fit with previous category

- Not keen
- Lack of in bronchiectasis (added 121113 P08)

BRIE code 30: Patient duty/role

Added from BRIE P08/C04. Patient talking about what he 'had ' to do when increasing symptoms, and being contacted that he 'had' to get some different antibiotics. Seems not to really fit with treatment or self-management directly – is this a new code of the enforced duty/role of patients or carers?

- Patient duty
- Carer duty

BRIE code 31: Advice to others

Added from P10. I asked this question directly. What advice they would give to someone with a new diagnosis of bronchiectasis.

Simplified coding lists

Codes
1. Preferred information format
1.1 Booklet 1.2 Website 1.3 DVD 1.4 Other 1.5 Style details (text, images, video, layout, size) 1.6 Consultation 1.7 To refer back to 1.8 Accessible to all/lack of jargon 1.9 Other
2. Preferred information content
2.1 Other people's stories 2.2 Medication and treatments and side effects 2.3 Volume of information 2.4 Question and answers 2.5 Self-help (diet and lifestyle)/alternative treatments/supplements 2.6 Prognosis 2.7 Causes of bronchiectasis 2.8 Self-management/symptom recognition 2.9 Information for carers 2.10 Practical help (aids, driving, insurance) 2.11 Research 2.12 Level of depth/jargon 2.13 Up to date 2.14 Physiotherapy 2.15 Microbiology 2.16 Imaging/lung function 2.17 Impact 2.18 Acceptance/coping 2.19 Symptoms (haemoptysis) 2.20 Positivity/hope 2.21 Transplantation 2.22 Other
3. Information needs
3.1 Self-help (what they can do themselves beyond medical treatment) 3.2 Timing 3.3 Treatments (tablets/inhalers/NIV/oxygen) 3.4 Exercise 3.5 Caring for someone with bronchiectasis 3.6 Beyond basic information resource 3.7 Prognosis 3.8 Benefit from information 3.9 Level of understanding of bronchiectasis 3.10 Symptoms (incl new symptoms ? Bx related) 3.11 Microbiology 3.12 Restrictions/limitations 3.13 Accessibility to all 3.14 Other
4. Information seeking
4.1 Reasons for seeking 4.2 Reasons for not seeking (never thought to, scared) 4.3 Mode (opportunistic, effortful) 4.4 Role of family/friends 4.5 Internet 4.6 Needs met? 4.7 Source – doctor 4.8 Impact

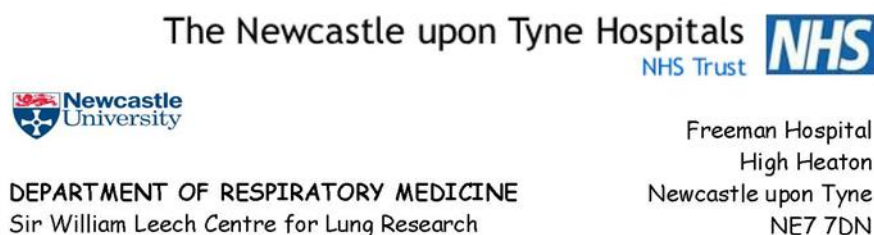
4.9 Other
5. Reasons/triggers for seeking information
5.1 New symptom/ change in condition 5.2 Lack of explanation from doctor/not remembering 5.3 Problems with medication 5.4 Other
6. Barriers
6.1 Lack of ability to access/use resource format 6.2 Personal factors 6.3 Credibility 6.4 Lack of availability 6.5 Other
7. Trusting information
7.1 Websites legitimate/endorsed/recommended 7.2 Not trusting information 7.3 Source – own doctor 7.4 No concerns 7.5 Other
8. Information provision
8.1 Clinic 8.2 Hospital 8.3 Doctor 8.4 Nurse 8.5 GP 8.6 Inadequacy/suitability 8.7 Physiotherapy 8.8 No cure 8.9 Lack of consistency 8.10 Other
9. Retaining Information
9.1 Not retaining information 9.2 Able to retain 9.3 Other
10. Onset of symptoms
10.1 Time since onset 10.2 Account of onset of symptoms 10.3 Other
11. Health beliefs/lay reasoning
11.1 Causative factors - their fault 11.2 Causative factors – smoking 11.3 Factors patients feel contributed to onset of bronchiectasis 11.4 Knowledge about condition 11.5 Other
12. Diagnosis
12.1 Impact 12.2 Difficulties 12.3 Relief 12.4 Other
13. Prognosis/death
13.1 Wanting to know prognosis/disease trajectory 13.2 Lack of cure 13.3 Duty to keep well? 13.4 Wanting reassurance from medical team 13.5 Wanting reassurance from information about other people's experiences

13.6 Uncertainty
13.7 Other
14. Other diagnoses
14.1 Impact
14.2 Information
14.3 Link with bronchiectasis
14.4 Other
15. Impact
15.1 Physical (fatigue, cough, breathlessness)
15.2 Emotional (upset, depressed, anxiety, loss of hope)
15.3 On carers/family
15.4 Coping strategies (concerted effort, denial)
15.5 Role (sense of self, work)
15.6 Treatments
15.7 Insurance
15.8 Investigations
15.9 Neglected?
15.10 Change over time
15.11 Stigma
15.12 Social/lifestyle
15.13 Lack of
15.14 Other
16. Family/friend support
16.1 Emotional
16.2 Practical/self-management help/carer
16.3 Lack of
16.4 Information
16.5 Other
17. Medical team
17.1 Bronchiectasis nurse
17.2 Doctor
17.3 Specialist clinic
17.4 Hospital
17.5 Grateful/happy with care
17.6 Disappointed with care
17.7 Lost to follow-up
17.8 Private care
17.9 Wanting help
17.10 Not wanting to be a burden
17.11 Speed of response
17.12 Accessibility
17.13 Lack of expertise
17.14 Physio
17.14 Other
18. GP role
18.1 GP role
18.2 Lack of faith in GP/not listening
18.3 other
19. Relating to others' experiences
19.1 Learning
19.2 Coping/acceptance
19.3 Worse off than me
19.4 Directly/indirectly
19.5 Not alone
19.6 Not keen
19.7 Other
20. Support groups/forums

20.1 Not using forums or support groups
20.2 Using
20.3 Other
21. Other professionals
21.1 Support from pharmacist
21.2 Other
22. Treatment
22.1 Positive effects
22.2 Side effects
22.3 Information
22.4 Self-management
22.5 Lack of effect
22.6 Future
22.7 Burden
22.8 Surgery
22.9 Preventing further damage
22.10 Other
23. Self-management
23.1 Symptom recognition
23.2 Developing skills
23.3 Lack of experience/confidence
23.4 Understanding treatments
23.5 Physiotherapy
23.6 Taking control/active partnership
23.7 Lifestyle changes
23.8 Self-help/alternative therapies/supplements
23.9 Studying self
23.10 Home IVs
23.11 Other
24. Confidence
24.1 With self-management
24.2 From information
24.3 From clinic
24.4 Other
25. Normality
25.1 Wanting normality
25.2 Normal for bronchiectasis/new normal
25.3 Other
26. Reassurance
26.1 Information seeking to reassure
26.2 Reassurance from others' experiences
26.3 Reassurance from medical team
26.4 Other
27. Acceptance
27.1 Time taken
27.2 What helped
27.3 Other
28. Wanting to help
28.1 Giving back/research
28.2 Helping others with bronchiectasis
28.3 Other
29. Research
29.1 Not keen
29.2 Lack of in bronchiectasis

30. Patient duty/role
30.1 Patient duty 30.2 Carer duty
31. Advice to others

Appendix 9 Focus group participant information sheet



PARTICIPANT INFORMATION SHEET **(Focus groups only)**

Study Title: Information and education provision for patients with bronchiectasis: a qualitative investigation of patients' needs and development of a patient-driven resource.

Short Title: Bronchiectasis information and education.

Study Code: **Version number:** 2.0 (9th October 2012)

We would like to invite you to take part in a research study. Before you decide whether you would like to take part, you need to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you may have. This will take about 30 minutes. Please take time to read the following information carefully. Talk to others about the study if you wish.

Part 1 of the information sheet tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study.

Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

PART 1

What is the purpose of the study?

Bronchiectasis is a chronic lung condition that causes problems with breathlessness, cough and frequent chest infections. There is currently limited information available to patients with bronchiectasis and their carers, including a 1 page leaflet from the British Lung Foundation and a few websites. Patients at our bronchiectasis clinic completed a questionnaire which revealed that they learned more about their condition and felt more confident with their treatment having attended clinic. We think that patients may benefit from more information and education about their condition, but first we need to know what patients think. We have carried out a small study to begin to understand what information people whose lives are affected by bronchiectasis need and found that overall more information was needed. In this study we would like to find out what information patients with bronchiectasis and their carers would like and in what way they would like to get this information. We will then use this to develop a new information package that is driven by your views.

The research is also being undertaken for educational purposes and will form part of a PhD for the researcher, Dr Katy Hester, from Newcastle University.

Why have I been invited?

You have been invited to take part because you have bronchiectasis, or care for someone with bronchiectasis. We are hoping to involve up to 20-30 patients in the study and up to 10 carers or partners of patients with bronchiectasis.

Do I have to take part?

It is up to you to decide. We have sent you this information sheet, and you can contact the respiratory research doctor (Dr Katy Hester) if you would like to receive further information regarding this study. If you decide to take part, we will ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of any care you are receiving, nor your involvement in any other study.

What will happen to me if I take part?

If you decide you would like to take part in the study, the researcher will arrange a convenient time to discuss the study further and if you agree to take part we will ask you to sign the consent form.

We will invite you to attend a 'focus group' at the Newcastle Hospitals Trust or Newcastle University. This is a group meeting where the researcher would meet with a few of the patients and carers taking part in the study. In a separate part of this study we have carried out interviews with patients and carers of patients with bronchiectasis. We have used the information we have gained from these interviews to develop a new patient information resource. We have tried to design this to meet patients' and carers' needs. We would like to show you this new information during the focus groups. By doing this we can get your views on how to improve and change it. This will allow us to produce new information that meets your needs.

We expect these group meetings to last up to an hour. Some members of the group will have taken part in an interview earlier in the study.

All focus groups will be recorded using an audio-digital recorder. There will not be video imaging. For your confidentiality, the data will be transcribed with personal details (e.g. names) ²

Bronchiectasis information and education V2.0 9th October 2012 REC Ref: 12/SC/0585

removed and codes used instead. The audio recordings will be kept until 6 months after the study closes. They will then be destroyed. Anonymised transcripts will be kept within a locked cabinet in the research facility for 10 years after the study closes and then destroyed.

Expenses and payments

Reasonable expenses (e.g. travel for the interview) will be refunded.

What will I have to do?

If you decide to take part then you will be invited to attend 1 focus group that will last for about 1 hour.

There will be no changes made to your usual treatment or medical care.

What are the possible disadvantages and risks of taking part?

The focus groups will take up approximately 1 hour of your time each, which you may not find convenient.

What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get from this study may help improve the understanding of patients' needs, and help us develop better information resources for patients with bronchiectasis.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any point. This would not affect any ongoing care. If you do withdraw from the study, all information relating to you will be destroyed if you wish.

What if there is a problem?

If you have a concern about any aspect of this study, you can speak to the researchers who will do their best to answer your questions. You can contact the team on 0191 223 1148. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital Patient Advice and Liaison Service (PALS) on 0800 032 0202 or 0191233 6161.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against The Newcastle upon Tyne Hospitals NHS Foundation Trust. You may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part in this study be kept confidential?

All information collected about you during the course of the research will be kept strictly confidential, and any information about you that leaves the hospital will have your name and address removed so that you cannot be identified.

All personal identifiable information and data (e.g. name and address) collected will be subject to the Data Protection Act and Caldicott Principles.

Audio recordings will be made during this study and kept until 6 months after the study closes and destroyed following this. Any electronic data will be stored on an NHS or University password protected computer. This will be within a locked office in the research office within the trust or university and can only be accessed by authorised people. Authorised people may include members of the research team, auditors and regulatory authorities. Once the recordings are transcribed your personal details will be removed and they will be identified only by an anonymous code. These anonymised transcripts will be kept for 10 years after the study ends in a locked cabinet within the research facility and then destroyed.

Please note, the results of the study may be published in medical literature, but you will not be identified.

You have the right to request information about your data held by the researcher. You also have the right to request that any inaccuracies in such data be corrected. If you wish to make a request, then please contact the researcher.

If you withdraw your consent, the researcher will no longer use your data.

If we wished to use your information for further studies, your further consent would be sought.

Involvement of the General Practitioner/Family doctor (GP)

We would like to inform your GP that you are taking part in this study, if you are happy for us to do so. We will ask you about this and seek your consent.

What will happen to the results of the research study?

When the research is completed you will be offered a summary of the findings. The research will form part of a thesis towards a PhD for the researcher, Katy Hester, from Newcastle University. We would also expect to present our work at local, national and international conferences, and publish our findings in peer reviewed journals. All information is anonymised and you will not be identified in any of these.

Who is organising and funding the research?

This research is being done as part of the researcher's completion of a PhD Fellowship. This is being sponsored by the Newcastle upon Tyne Hospitals NHS Trust and funded by the The National Institute for Health Research. There will be no payments to the trust or researcher for including you in this study.

Who has reviewed the study?


All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your interests. This study has been reviewed by the NRES Committee South Central - Berkshire B Proportionate Review Sub-Committee.

You will be given a copy of this information sheet and a signed consent form to keep.

Further information and contact details

If you would like further information about this study, or research in general, please contact the researcher, Dr Katy Hester, on 0191 223 1148. If you need further advice as to whether you should participate, you can also speak to the research team on the above number, or you may wish to speak to your own GP. If you are unhappy with the study you can approach the research team, or get advice from PALS as outlined in the complaints section.

Appendix 10 Focus group consent form

The Newcastle upon Tyne Hospitals 

DEPARTMENT OF RESPIRATORY MEDICINE
Sir William Leech Centre for Lung Research

Freeman Hospital
High Heaton
Newcastle upon Tyne
NE7 7DN



PARTICIPANT INFORMED CONSENT FORM **(Focus group only)**

Study Title: Information and education provision for patients with
bronchiectasis: a qualitative investigation of patients' needs
and development of a patient-driven resource.

Short Title: Bronchiectasis information and education

Researchers: Dr Katy Hester
Dr Anthony De Soyza, Dr Tim Rapley, Professor Julia Newton

Participant initials:

Participant code number:

Please
initial
boxes

1. I confirm that I have read and understand the information provided in the participant information sheet, dated 20th September 2012, version 1.0. The information has been explained to me, I have been given the opportunity to ask questions and I am satisfied with the explanations provided.

☐

2. I am aware that my participation in this study is entirely voluntary. I understand that I may withdraw at any time, without giving a reason, without this affecting my future care or legal rights.

☐

3. I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from the research team, The Newcastle upon Tyne NHS Hospitals Foundation Trust, or from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

☐

4. I understand that an audio recording will be made of my interview that will only be used for the purposes of this research and agree to this being done.

☐

5. I agree to my GP being informed of my participation in the study.

☐

6. I understand that I will receive a signed copy of this consent form.

☐

7. I agree to take part in this study.

☐

Bronchiectasis information and education V1.0 20th September 2012 REC Ref: 12/SC/0585
- 1 of 2 -

Signatures

Name of participant:

Date:

Signature:

Name of person taking consent:

Date:

Signature:

Appendix 11 Workshop 1 topic guide

BRIE FG1

Thank you all for coming, really appreciate you all taking the time to come along and I hope you enjoy it.

Explain a bit about study:

We know that there is a limited amount of information available on bronchiectasis, and that people would like more information about it. The aim of the study is to find out what you want in terms of information about bronchiectasis so that we can design a new information resource that will meet your needs and then test whether it can help people to manage and cope with the condition better.

So to start to find out about this I have done interviews with patients and their families, some of you here have taken part in an interview already – thank you for that.

Looked at all the interview transcripts in great depth and found the common themes and things that are important to both patients and their 'carers' this is just partner/family member/friend, anyone else who would have an interest in bronchiectasis information.

The other thing we are interested in is both the overall format of delivery i.e. booklet/DVD/website and more specific points such as how the content is organised and what you think would be important to have for example on the front page.

So what I would like to do today is show you what the main themes arising from analysing the interviews are, get your opinions on those and also get your views on which sections you feel are most important or how they should be presented, and I have got a few little props for that. It is all very informal, just say what you think and talk amongst yourselves, there are not any right or wrong answers and your views are really important to making this a success.

So, just to start off if we go around the room and just introduce ourselves. This is partly for the recorder so that the typist can identify people's voices. Maybe just say your name and whether you have already taken part in an interview and how long you have been coming to the Freeman.

I will start off:

I'm Katy Hester, I am a respiratory registrar and I am currently researching information in bronchiectasis.

John: Co-facilitating

Participants in turn...

Main Themes arising from data:

1. Living life with bronchiectasis
2. Developing support and coping mechanisms
3. Connecting with information
4. Taking back control and developing active partnerships

So if we maybe take each one in turn and I will just show you a bit about what kind of things fit into each category.

Living life with bronchiectasis

This ended up being the main focus of all the interviews as we discussed how it affects people's lives and how they manage and cope, how it impacts on things they want to do, their family, jobs etc.

I will just show you a sheet that outlines some of the things that fell into this category and see if you have any comments about these...

Developing support and coping mechanisms

This is about how people sort of manage actually having the condition rather than managing bronchiectasis in terms of treatment for example, so how they get support from families or friends and also their medical team and how they access help.

So again I will show you a sheet with a few more details about this and see what you think...

Connecting with information

As you know the aim of the interviews was to find out about information needs. And beyond a list of what things people want to know, this sort of explains how people look for or use information, what prevents them using information or how they think it could help them.

So here is the sheet about this, any thoughts or comments....

Taking back control and developing active partnerships

This seems to be something that happens along the way after people have had a diagnosis and got to grips with things a bit. So it seemed to include things such as acceptance and developing the confidence to start to manage the condition yourself. Working with the medical team rather than just waiting to be told what to do. People talked about what they do when they know they need antibiotics for example, and how they have got to the point where they know what to do and what to look out for, yet even very new patients seemed to be thinking already about this and wanting to have some control and take charge themselves.

And I have another sheet about this if anyone has any comments or questions....

LIVING LIFE WITH BRONCHIECTASIS

Onset of symptoms

Health beliefs

Diagnosis

Prognosis

Other conditions

Impact: Physical, emotional, family, work, stigma

Family support

Medical team

Reassurance

Treatment

Self-management and self-help

Developing support and coping mechanisms

Reassurance

Family/friend support

Medical team

Other professionals – pharmacist

GP role

Relating to others' experiences

Information seeking

CONNECTING WITH INFORMATION

Information needs

Preferred content (Positive! Lifestyle)

Preferred format

Information seeking

Reasons/triggers to seek information

Barriers

Trusting information

Information provision

Retaining information

Relating to others experiences

TAKING BACK CONTROL & DEVELOPING ACTIVE PARTNERSHIPS

Self-management

Confidence

Acceptance

Normality

Wanting to help

Research

Medical team

Patient duty/role

Advice to others

So now we have discussed the findings a bit I would just like to show you the sort of contents overview for the information resource and see what you think about that.

I would be particularly interested in anything you think that has been missed off that would be important, and also which things you think are the priorities to be put for example on a front page or grouped together.

We need to remember that this information will be made into a booklet and a website and a DVD as these things were all wanted by interviewees, so it may be that they are presented slightly differently in each format.

I have also got some examples of other things that may complement any written or text info such as pictures, diagrams, video interviews and different backgrounds to see which you think would fit with which sections, so we can play around with these a bit and see what we come up with.

Contents overview

1. Understanding bronchiectasis

1.1. Diagnosis

- 1.1.1. Questions asked and why (smoking) (Dr Vid)
- 1.1.2. Symptoms
- 1.1.3. How you may feel (Pt Vid)
- 1.1.4. Tests (BTS guidelines)
 - 1.1.4.1. Imaging (Images)
 - 1.1.4.2. Lung function (Vid)
 - 1.1.4.3. Microbiology (Images/vid)
 - 1.1.4.4. Blood tests
 - 1.1.4.5. More detailed tests

1.2. Why have I got bronchiectasis?

- 1.2.1. Causes (+non-causes eg smoking)
 - 1.2.1.1. Idiopathic
 - 1.2.1.2. Hereditary
 - 1.2.1.3. Post infection etc etc

1.3. What is actually wrong with my lungs?

- 1.3.1. Dr explaining – video
- 1.3.2. Distinguish from bronchitis/COPD/Asthma
- 1.3.3. Simple text explanation and diagrams/CT

1.4. What symptoms might I get and how can I manage them?

- 1.4.1. Cough (stigma, patient videos)
 - 1.4.1.1. Cough incontinence (bladder leakage)
 - 1.4.1.2. Haemoptysis (coughing blood)
- 1.4.2. Sputum/phlegm
 - 1.4.2.1. Physiotherapy (videos)
 - 1.4.2.2. Microbiology (bugs)
- 1.4.3. Exacerbations/flare-ups/chest infections (link to section+treatments)
- 1.4.4. Shortness of breath
- 1.4.5. Fatigue
- 1.4.6. Pain
- 1.4.7. Anxiety and depression

- 1.5. Prognosis (outline and vids – dr/pt)**
- 1.6. What does this mean for my life now?**
 - 1.6.1. Impact (all) + coping (patient videos)
 - 1.6.2. Self-management (link to section)
 - 1.6.3. Practical tips
 - 1.6.3.1. Holidays + insurance
 - 1.6.3.2. Driving
 - 1.6.3.3. Flying
 - 1.6.3.4. Devices (nebs, oxygen etc)
 - 1.6.3.5. Advice for carers and families
 - 1.6.3.6. Links to useful sites/support
- 1.7. Some common misunderstandings**
 - 1.7.1. Smoking
 - 1.7.2. COPD/Bronchitis
 - 1.7.3. Contagious/infection
- 1.8. FAQs**
- 2. Understanding the management of bronchiectasis**
 - 2.1. The medical team (description and vid of each)**
 - 2.1.1. Hospital consultant and their team
 - 2.1.2. GP (will they look after me still?)
 - 2.1.3. Physiotherapist
 - 2.1.4. Dietician
 - 2.1.5. Respiratory nurse
 - 2.1.6. Lung function technician
 - 2.1.7. Radiologist
 - 2.2. Treatments (overview and circles diagram)**
 - 2.2.1. Antibiotics
 - 2.2.1.1. Oral (by mouth)
 - 2.2.1.2. Intravenous (by injection/drip, mention ports)
 - 2.2.1.3. Nebulised (pt experiences)
 - 2.2.1.4. Prophylactic
 - 2.2.1.5. Self-admin (pt videos)
 - 2.2.2. Nebulisers
 - 2.2.2.1. Antibiotics

- 2.2.2.2. Hypertonic saline
- 2.2.2.3. Bronchodilators
- 2.2.3. Inhalers
- 2.2.4. Mucolytics
- 2.2.5. Physio/chest clearance/devices (videos)
- 2.2.6. Surgery
- 2.2.7. Transplant
- 2.2.8. Oxygen
- 2.3. Managing exacerbations
- 2.4. Managing haemoptysis
- 2.5. New drugs and research
- 3. What can I do to help myself?
 - 3.1. Symptom recognition
 - 3.2. Self-management (video John and pts, taking back control, positivity)
 - 3.3. Active partnerships with medical team
 - 3.4. Understanding your clinic letter
 - 3.5. Diet, exercise and lifestyle advice
 - 3.6. Alternative or over the counter treatments (+dairy)
 - 3.7. Coping and support (patient vids)
 - 3.7.1. Feeling alone
 - 3.7.2. Coping with uncertainty
 - 3.7.3. Support groups
 - 3.7.4. Medical team
 - 3.7.5. BLF etc
 - 3.7.6. All impact aspects
 - 3.7.7. Family and friends (+tips for link)
- 4. Research
 - 4.1. National/international
 - 4.2. New drugs being trialled
 - 4.3. Local

- 4.4. Contacts to get involved/option to sign up to be contacted**
- 5. Where can I get more information?**
 - 5.1. Links to trusted sites/sources**
 - 5.2. Option to sign up for emails**

Important features to rate:

I have got some examples of front pages – based on a website but adaptable to a booklet or DVD, and some bits to stick on and give ideas about the relative importance of each point. If you could either stick them on the pages or rank them in order of importance or discard them if you don't think they are useful.

Positivity

Clarity

Optional what you look at – detailed search/navigation/contents

NHS logo

University logo

NIHR logo (National Institute of Health Research)

Video interviews with patients

Video advice from health care professionals

Diagrams

Pictures

How to pronounce medical terms

Explanation of clinic letters/jargon – where to put

Reminders/email links for information sent e.g. monthly

Thank you all for coming, if anyone has any ideas or thoughts that we haven't discussed and you think are relevant then please say...

LIVING LIFE WITH BRONCHIECTASIS

Onset of symptoms	Family support
Health beliefs	Medical team
Diagnosis	Reassurance
Prognosis	Treatment
Other conditions	Self-management and self-help
Impact: Physical, emotional, family, work, stigma	

Developing support and coping mechanisms

Reassurance	GP role
Family/friend support	Relating to others' experiences
Medical team	
Other professionals – pharmacist	Information seeking

CONNECTING WITH INFORMATION

Information needs	Barriers
Preferred content (Positive! Lifestyle)	Trusting information
Preferred format	Information provision
Information seeking	Retaining information
Reasons/triggers to seek information	Relating to others experiences

TAKING BACK CONTROL & DEVELOPING ACTIVE PARTNERSHIPS

Self-management	Wanting to help
Confidence	Research
Acceptance	Medical team
Normality	Patient duty/role
	Advice to others



Living life with bronchiectasis

(Brong-kee-ek-tuh-sis)

Information for those who have bronchiectasis
and those who want to know more about it



About

- You may have been recently diagnosed with bronchiectasis or have had it for some time, yet often patients and their families have questions, or things they would like to know more about
- This information has been developed by doctors and by patients who have bronchiectasis
- By clicking on any of the boxes that interest you, we hope to answer your queries
- Remember you are not alone, and there are things that you and your health care team can do to help control your symptoms and manage the condition

Main menu

Understanding bronchiectasis

Understanding the management of bronchiectasis

What can I do to help myself?

Research

Where can I get more information?

Understanding bronchiectasis

- **Diagnosis**
- **Why have I got bronchiectasis?**
- **What is actually wrong with my lungs?**
- **What symptoms might I get and how can I manage them?**
- **Prognosis (outline and vids – dr/pt)**
- **What does this mean for my life now?**
- **Some common misunderstandings**
- **FAQs**

Understanding the management of bronchiectasis

- The medical team (description/vid of each)
- Treatments (overview and circles diagram)
- Managing exacerbations
- Managing haemoptysis
- New drugs and research

What can I do to help myself?

- Symptom recognition
- Self-management (video John/pts, taking back control, positivity)
- Active partnerships with medical team
- **Understanding your clinic letter**
- Diet, exercise and lifestyle advice
- Alternative or over the counter treatments (+dairy)
- Coping and support (patient vids)

Research

- National/international**
- New drugs being trialled**
- Local**
- Contacts to get involved/option to sign up to be contacted**

Where can I get more information?

- Links to trusted sites/sources**
- Option to sign up for emails**

- Video Patients
- Pictures
- Video doctor/nurse/physio
- Diagram
- Video
- Diagram
- Video
- Video

Appendix 13 Workshop 2 and 3 topic guide

BRIE Workshop 2 and 3 Topic Guide

1. Introductions
2. Overview of study so far
3. Aims of the website
4. Aims of the focus group
5. How many use the internet in the group?
6. How many have looked up information about bronchiectasis?
7. Show example sections of the site to include:-

Front page – views on layout/images/whether they would read on/trustworthy/clarity/ease of finding what want/anything missing/more in about or own section/intro video

What you would be drawn to look at next? Look at that section (if populated)

Getting a diagnosis

What is wrong with my lungs?

What symptoms might I get? Sputum – clearing your chest video

What is the prognosis?

People you may need to see – john/dietitian/physio videos

Carers and families

Overall views:

Is it useful?

Is it reassuring or worrying?

How does it compare to other things you have looked up?


Does it look professional/official enough?


What would you change to improve it?

Change sections around etc?

Ease of finding what want?

Appendix 14 BRIEF study invitation letter

The Newcastle upon Tyne Hospitals 
NHS Trust

 Newcastle University

DEPARTMENT OF RESPIRATORY MEDICINE
Sir William Leech Centre for Lung Research

Freeman Hospital
High Heaton
Newcastle upon Tyne
NE7 7DN

Letter of invitation

Study Title: **Bronchiectasis Information and Education: Feasibility Study and Evaluation of a Novel Resource**

Short Title: **Bronchiectasis Information and Education Feasibility (BRIEF)**

Researchers: **Dr Katy Hester
Dr Tim Rapley, Professor Julia Newton, Dr Anthony De Soyza**

Dear.....

We are writing to tell you about a new research study at the Freeman hospital which we think you may be interested in participating in. We have developed a new patient information package based on what information and education patients with bronchiectasis and their carers feel they need.

We now need to find out if it would be feasible for us to carry out a study to assess if the information package can help patients. We also want to get patients' views on the information package.

You have been invited as you have a diagnosis of bronchiectasis, and we believe that you may be a suitable candidate for the study.

We have enclosed a copy of the participant information sheet for this study to give you more details of what would be involved.

If you are interested in finding out more then please contact us, and we will arrange to discuss this in more detail.

Thank you for your time.

Yours sincerely,

Dr Katy Hester

For further information about the study please contact:
Dr Katy Hester: katy.hester@ncl.ac.uk (0191 223 1148 or address above)

*BRIEF letter of invitation V1.0 23rd January 2014
1 of 1*

Appendix 15 BRIEF study participant information sheet



DEPARTMENT OF RESPIRATORY MEDICINE
Sir William Leech Centre for Lung Research

The Newcastle upon Tyne Hospitals 

Freeman Hospital
High Heaton
Newcastle upon Tyne
NE7 7DN

PARTICIPANT INFORMATION SHEET

Study Title: Bronchiectasis Information and Education: Feasibility Study and Evaluation of a Novel Resource

Short Title: Bronchiectasis Information and Education Feasibility (BRIEF)

Researchers: Dr Katy Hester
Dr Tim Rapley, Professor Julia Newton, Dr Anthony De Soyza

Study Code: Version number: 1.2 (11th June 2014)

We would like to invite you to take part in a research study. Before you decide whether you would like to take part, you need to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you may have. This will take about 30 minutes. Please take time to read the following information carefully. Talk to others about the study if you wish.

Part 1 of the information sheet tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study.

Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

PART 1

What is the purpose of the study?

Bronchiectasis is a chronic lung condition that causes problems with breathlessness, cough and frequent chest infections. There is currently limited information available to patients with bronchiectasis and their carers, including a 1 page leaflet from the British Lung Foundation and a few websites. Patients at our bronchiectasis clinic completed a questionnaire which revealed that they learned more about their condition and felt more confident with their treatment having attended clinic.

We have now completed a study during which we interviewed and had group discussions with patients and their families about what information and education they wanted, and how they preferred this to be presented. We used this work to develop a new information package in a booklet and a website for patients and their families based on what they told us. We would now like to establish if it would be possible to carry out a study to check if this is useful in helping people to understand and manage bronchiectasis. We also want to know people's views on the information package.

The research is also being undertaken for educational purposes and will form part of a PhD for the researcher, Dr Katy Hester, from Newcastle University.

Why have I been invited?

You have been invited to take part because you have bronchiectasis. We are hoping to involve up to 70 people in the study.

Do I have to take part?

It is up to you to decide. We have sent you this information sheet, and you can contact the respiratory research doctor (Dr Katy Hester) if you would like to receive further information regarding this study. If you decide to take part, we will ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of any care you are receiving, nor your involvement in any other study.

What will happen to me if I take part?

If you decide you would like to take part in the study, the researcher will discuss the study further and if you agree to take part we will ask you to sign the consent form.

On starting the study you will either be assigned to receive the information package (booklet and website if you use the internet) or to continue with your usual bronchiectasis care, and not receive the information package. This will be randomly selected by a computer. We need to do this so that we can see if having the information has any different effects to having usual care.

If you are in the group who do not receive the information package during the study, we will offer the information pack to you for you to use after you have finished the study.

At the first visit you will be asked to complete several questionnaires about your symptoms and about your condition and have some breathing tests done. The whole visit should take less than 1 hour.

About 2 weeks after joining the study, you will be asked to complete the questionnaires again. This can either be done at the hospital or over the telephone if this is more convenient for you.

The third and final study visit will be approximately 3 months (12 weeks) after joining. Again you will be asked to complete the questionnaires and have breathing tests and the visit should be less than 1 hour.

During the 3 months that you are in the study, we will also ask you to complete a record sheet of your symptoms and about what information you may have looked at. This will happen once a month and forms can be either posted, emailed or returned at your next visit.

At the end of the study, we may also invite you to attend a group discussion about your experience of being involved in the study, and if you received the information package, what you thought about it. If you have a family member who has used the information package provided during the study then they will have the option of coming along to join the discussion also, should they wish.

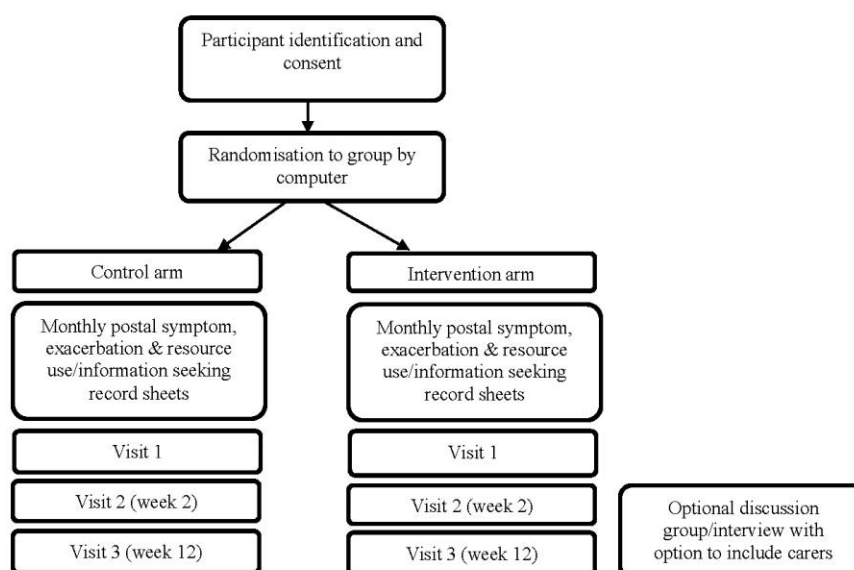
We expect the group discussion to take approximately an hour. All groups will be recorded using an audio-digital recorder. There will not be video imaging. For your confidentiality, the interview data will be transcribed with personal details (e.g. names) removed and codes used instead. The audio recordings will be kept until 6 months after the study closes. They will then be destroyed.

Expenses and payments

Reasonable expenses (e.g. travel for the study visits) will be refunded.

What will I have to do?

If you decide to take part then you will be required to meet with the researcher and take part in the study as described in the previous section. The following chart shows this in a simple format. There will be no changes made to your usual treatment or medical care.



What are the possible disadvantages and risks of taking part?

There are no real risks with the study. The study visits will take up approximately 3 hours of your time over 3 months. You may find that this is too inconvenient for you. If you choose to take part in the focus group this would be an additional hour, yet this is entirely optional. If you are assigned to receive the information package, the amount of time you spend looking at this over the course of the study is entirely up to you. You may feel disappointed if you are randomly selected not to receive the information package. This needs to be done randomly to make sure the study is not biased and will not affect your usual care. This group is just as important to the study as the group who do receive the information package. If you do not receive the information package during the study, you will be offered access to it after you complete the study.

What are the possible benefits of taking part?

We cannot promise the study will help you but you. The information we get from this study may help improve the understanding of patients' needs, and help us develop better information resources for patients with bronchiectasis.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any point. This would not affect any ongoing care. If you do withdraw from the study, all information relating to you will be destroyed if you wish.

What if there is a problem?

If you have a concern about any aspect of this study, you can speak to the researchers who will do their best to answer your questions. You can contact the team on 0191 223 1148. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital Patient Advice and Liaison Service (PALS) on 0800 032 0202 or 0191233 6161.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against The Newcastle upon Tyne Hospitals NHS Foundation Trust. You may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part in this study be kept confidential?

All information collected about you during the course of the research will be kept strictly confidential, and any information about you that leaves the hospital will have your name and address removed so that you cannot be identified.

All personal identifiable information and data (e.g. name and address) collected will be subject to the Data Protection Act and Caldicott Principles.

Audio recordings will be made during this study and kept until 6 months after the study closes and destroyed following this. Any electronic data will be stored on an NHS or University password protected computer. This will be within a locked office in the research office within the trust or university and can only be accessed by authorised people. Authorised people may include members of the research team, auditors and regulatory authorities. Once the recordings are transcribed your personal details will be removed and they will be identified only by an anonymous code. These anonymised transcripts will be kept for 15 years after the study ends in a locked cabinet within the research facility and then destroyed.

Please note, the results of the study may be published in medical literature, but you will not be identified.

You have the right to request information about your data held by the researcher. You also have the right to request that any inaccuracies in such data be corrected. If you wish to make a request, then please contact the researcher.

If you withdraw your consent, the researcher will no longer use your data.

If we wished to use your information for further studies, your further consent would be sought.

Involvement of the General Practitioner/Family doctor (GP)

We would like to inform your GP that you are taking part in this study, if you are happy for us to do so. We will ask you about this and seek your consent.

What will happen to the results of the research study?

When the research is completed you will be offered a summary of the findings. The research will form part of a thesis towards a PhD for the researcher, Katy Hester, from Newcastle University. We would also expect to present our work at local, national and international conferences, and publish our findings in peer reviewed journals. All information is anonymised and you will not be identified in any of these.

Who is organising and funding the research?

This research is being done as part of the researcher's completion of a PhD Fellowship. This is being sponsored by the Newcastle upon Tyne Hospitals NHS Trust and funded by the The National Institute for Health Research. There will be no payments to the trust or researcher for including you in this study.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your interests. This study has been reviewed by the Sunderland NRES Committee (ref: 14/NE/0119).

You will be given a copy of this information sheet and a signed consent form to keep.

Further information and contact details

If you would like further information about this study, or research in general, please contact the researcher, Dr Katy Hester, on katy.hester@ncl.ac.uk or 0191 223 1148.

If you need further advice as to whether you should participate, you can also speak to the research team on the above number, or you may wish to speak to your own GP. If you are unhappy with the study you can approach the research team, or get advice from PALS as outlined in the complaints section.

Appendix 16 BRIEF study consent form

The Newcastle upon Tyne Hospitals 

DEPARTMENT OF RESPIRATORY MEDICINE
Sir William Leech Centre for Lung Research

Freeman Hospital
High Heaton
Newcastle upon Tyne
NE7 7DN



PARTICIPANT INFORMED CONSENT FORM

Short Title: Bronchiectasis Information and Education Feasibility (BRIEF)

Researchers: Dr Katy Hester, Dr Tim Rapley, Prof Julia Newton, Dr Anthony De Soyza

Participant initials:

Participant code number:

**Please
initial
boxes**

1. I confirm that I have read and understand the information provided in the participant information sheet, dated 11th June 2014, version 1.2. The information has been explained to me, I have been given the opportunity to ask questions and I am satisfied with the explanations provided.

☐

2. I am aware that my participation in this study is entirely voluntary. I understand that I may withdraw at any time, without giving a reason, without this affecting my future care or legal rights.

☐

3. I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from the research team, The Newcastle upon Tyne NHS Hospitals Foundation Trust, or from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

☐

4. I understand that an audio recording will be made if I participate in a focus group that will only be used for the purposes of this research and agree to this being done.

☐

5. I agree to my GP being informed of my participation in the study.

☐

6. I understand that I will receive a signed copy of this consent form.

☐

7. I agree to take part in this study.

☐

Signatures

Name of participant:

Date:

Signature:

Name of person taking consent:

Date:

Signature:

*BRIEF consent V1.2 11th June 2014
-1 of 1 -*

Appendix 17 BRIEF carer focus group information sheet

PARTICIPANT INFORMATION SHEET **(Focus groups only)**

Study Title: Bronchiectasis Information and Education: Feasibility Study and Evaluation of a Novel Resource

Short Title: Bronchiectasis Information and Education Feasibility (BRIEF)

Researchers: Dr Katy Hester
Dr Tim Rapley, Professor Julia Newton, Dr Anthony De Soyza

Study Code: **Version number:** 1.0 (23rd January 2014)

We would like to invite you to take part in a research study. Before you decide whether you would like to take part, you need to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you may have. This will take about 30 minutes. Please take time to read the following information carefully. Talk to others about the study if you wish.

Part 1 of the information sheet tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study.

Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

PART 1

What is the purpose of the study?

Bronchiectasis is a chronic lung condition that causes problems with breathlessness, cough and frequent chest infections. There is currently limited information available to patients with bronchiectasis and their carers, including a 1 page leaflet from the British Lung Foundation and a few websites. Patients at our bronchiectasis clinic completed a questionnaire which revealed that they learned more about their condition and felt more confident with their treatment having attended clinic.

We have now completed a study during which we interviewed and had group discussions with patients and their families about what information and education they wanted, and how they preferred this to be presented. We used this work to develop a new information package in a booklet and a website for patients and their families based on what they told us. We would now like to establish if it would be possible to carry out a study to check if this is useful in helping people to understand and manage bronchiectasis. We also want to know people's views on the information package.

The research is also being undertaken for educational purposes and will form part of a PhD for the researcher, Dr Katy Hester, from Newcastle University.

Why have I been invited?

You have been invited to take part because you care for someone with bronchiectasis who has taken part in this study. As you have also used the information package provided we would like to hear your views about it. We are hoping to involve up to 70 people in this study in total, including 10 family members, friends or 'carers'.

Do I have to take part?

It is up to you to decide. We have sent you this information sheet, and you can contact the respiratory research doctor (Dr Katy Hester) if you would like to receive further information regarding this study. If you decide to take part, we will ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of any care you are receiving, nor your involvement in any other study.

What will happen to me if I take part?

If you decide you would like to take part in the study, the researcher will arrange a convenient time to discuss the study further and if you agree to take part we will ask you to sign the consent form.

We will invite you to attend a 'focus group' at the Newcastle Hospitals Trust or Newcastle University. This is a group meeting of 6-8 people where the researcher would meet with patients who have taken part in the study and their families. By doing this we can get your views on the information package and your experience of being involved in the study. This will allow us to produce new information that meets your needs.

We expect these group meetings to last up to an hour. All focus groups will be recorded using an audio-digital recorder. There will not be video imaging. For your confidentiality, the data will be transcribed with personal details (e.g. names) removed and codes used instead. The audio recordings will be kept until 6 months after the study closes. They will then be destroyed.

Anonymised transcripts will be kept within a locked cabinet in the research facility for 15 years after the study closes and then destroyed.

Expenses and payments

Reasonable expenses (e.g. travel for the interview) will be refunded.

What will I have to do?

If you decide to take part then you will be invited to attend 1 focus group that will last for about 1 hour.

There will be no changes made to your usual treatment or medical care.

What are the possible disadvantages and risks of taking part?

The focus group will take up approximately 1 hour of your time, which you may not find convenient.

What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get from this study may help improve the understanding of patients' needs, and help us develop better information resources for patients with bronchiectasis.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any point. This would not affect any ongoing care. If you do withdraw from the study, all information relating to you will be destroyed if you wish.

What if there is a problem?

If you have a concern about any aspect of this study, you can speak to the researchers who will do their best to answer your questions. You can contact the team on 0191 223 1148. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital Patient Advice and Liaison Service (PALS) on 0800 032 0202 or 0191233 6161.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against The Newcastle upon Tyne Hospitals NHS Foundation Trust. You may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part in this study be kept confidential?

All information collected about you during the course of the research will be kept strictly confidential, and any information about you that leaves the hospital will have your name and address removed so that you cannot be identified.

All personal identifiable information and data (e.g. name and address) collected will be subject to the Data Protection Act and Caldicott Principles.

Audio recordings will be made during this study and kept until 6 months after the study closes and destroyed following this. Any electronic data will be stored on an NHS or University password protected computer. This will be within a locked office in the research office within the trust or university and can only be accessed by authorised people. Authorised people may include members of the research team, auditors and regulatory authorities. Once the recordings are transcribed your personal details will be removed and they will be identified only by an anonymous code. These anonymised transcripts will be kept for 15 years after the study ends in a locked cabinet within the research facility and then destroyed.

Please note, the results of the study may be published in medical literature, but you will not be identified.

You have the right to request information about your data held by the researcher. You also have the right to request that any inaccuracies in such data be corrected. If you wish to make a request, then please contact the researcher.

If you withdraw your consent, the researcher will no longer use your data.

If we wished to use your information for further studies, your further consent would be sought.

Involvement of the General Practitioner/Family doctor (GP)

As you are not a patient yourself and your involvement in this study is discussion only then we do not intend to inform your GP.

What will happen to the results of the research study?

When the research is completed you will be offered a summary of the findings. The research will form part of a thesis towards a PhD for the researcher, Katy Hester, from Newcastle University. We would also expect to present our work at local, national and international conferences, and publish our findings in peer reviewed journals. All information is anonymised and you will not be identified in any of these.

Who is organising and funding the research?

This research is being done as part of the researcher's completion of a PhD Fellowship. This is being sponsored by the Newcastle upon Tyne Hospitals NHS Trust and funded by the The National Institute for Health Research. There will be no payments to the trust or researcher for including you in this study.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your interests. This study has been reviewed by the Sunderland NRES Committee (ref 14/NE/0119).

You will be given a copy of this information sheet and a signed consent form to keep.

Further information and contact details

If you would like further information about this study, or research in general, please contact the researcher, Dr Katy Hester, on katy.hester@ncl.ac.uk or 0191 223 1148.

If you need further advice as to whether you should participate, you can also speak to the research team on the above number, or you may wish to speak to your own GP. If you are unhappy with the study you can approach the research team, or get advice from PALS as outlined in the complaints section.

Appendix 18 BRIEF carer consent form

The Newcastle upon Tyne Hospitals 

DEPARTMENT OF RESPIRATORY MEDICINE
Sir William Leech Centre for Lung Research

Freeman Hospital
High Heaton
Newcastle upon Tyne
NE7 7DN



PARTICIPANT INFORMED CONSENT FORM **(Focus group only)**

Short Title: Bronchiectasis information and Education Feasibility (BRIEF)

Researchers: Dr Katy Hester, Dr Tim Rapley, Prof Julia Newton, Dr Anthony De Soyza

Participant initials:

Participant code number:

Please
initial
boxes

1. I confirm that I have read and understand the information provided in the participant information sheet, dated 23rd January 2014, version 1.0. The information has been explained to me, I have been given the opportunity to ask questions and I am satisfied with the explanations provided.

☐

2. I am aware that my participation in this study is entirely voluntary. I understand that I may withdraw at any time, without giving a reason, without this affecting my future care or legal rights.

☐

3. I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from the research team, The Newcastle upon Tyne NHS Hospitals Foundation Trust, or from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

☐

4. I understand that an audio recording will be made of my interview that will only be used for the purposes of this research and agree to this being done.

☐

6. I understand that I will receive a signed copy of this consent form.

☐

7. I agree to take part in this study.

☐

Signatures

Name of participant:

Date:

Signature:

Name of person taking consent:

Date:

Signature:

Appendix 19 BRIEF study postal questionnaire

Participant ID:

Month: 1 2 3 4

Date:

BRIEF Study Monthly Symptom and Information use Record

Please complete the following table about your treatment over the past month:

	Number
Number of courses of extra antibiotics (or emergency packs used) for an exacerbation or infection	
Number of times I have visited my GP about my bronchiectasis	
Number of times I have had to go to hospital because of bronchiectasis (emergency visit or admission, not a routine or planned clinic appointment)	
Number of times I have contacted a member of the hospital team about my bronchiectasis	

Please complete the following table about your symptoms over the past month:

	Same as usual	Better than usual	Worse than usual	I don't have this symptom
Cough				
Sputum (phlegm)				
Fatigue				
Breathlessness				
Sleep disturbance				
Chest pain				

Please complete the following table about any information about bronchiectasis you have used over the past month:

	Once a day	Once a week	Once a month	Not at all	I am not in the information group
I have used the provided information					
I have shared the information with others close to me					
I have looked up other information myself					

Appendix 20 Resource satisfaction questionnaire

Participant ID:

Study visit: 1 2 3

Date:

BRIEF Resource satisfaction questionnaire

Please answer the questions below about your use of the provided information. There are no right or wrong answers and your responses are confidential. Thank you for taking the time to complete this questionnaire.

I used the information provided: YES/NO

(Please circle. If yes answer questions below, if no go to next page)

	Strongly disagree	Disagree	Neither disagree nor agree	Agree	Strongly agree
I found the information useful					
My knowledge about my condition has improved					
I feel more able to manage my condition					
The information provided was easy to understand					
The right amount of information was given					
The things I wanted to know about were covered					
My partner/family member/friend used the information					

Please use this space to add any other comments and suggestions for improvement

Participant ID:

Study visit: 1 2 3

Date:

About the website

I used the website: YES/NO (Please circle. If yes answer questions below, if no go to next page)

	Strongly disagree	Disagree	Neither disagree nor agree	Agree	Strongly agree
I used the website more than the overview booklet					
The website was my preferred version of the information					
It was easy to find the sections I wanted to look at					
I only looked at certain sections					
I looked at all of the website					
The login procedure was easy to use					
I found the video clips helpful					
I found the diagrams helpful					
My partner/family member/friend used the website					

Please use this space to add any other comments and suggestions for improvement

Participant ID:

Study visit: 1 2 3

Date:

About the overview booklet provided

I used the overview booklet: YES/NO (Please circle. If yes answer questions below, if no go to next page)

	Strongly disagree	Disagree	Neither disagree nor agree	Agree	Strongly agree
I used the overview booklet more than the website					
The overview booklet was my preferred version of the information					
It was easy to find the sections I wanted to look at					
I only looked at certain sections					
I looked at the whole overview booklet					
I found the diagrams helpful					
The text was easy to read					
My partner/family member/friend used the overview booklet					

<p>Please use this space to add any other comments and suggestions for improvement</p>
--

Participant ID:

Study visit: 1 2 3

Date:

About the downloaded full booklet available on the website (or those who have the PDF in place of internet access at study start)

I downloaded the full booklet: YES/NO (Please circle. If yes answer questions below, if no go to next page)

I printed out the booklet: YES / NO

I received the full booklet in place of the website as I do not use the internet: YES/NO (circle)

	Strongly disagree	Disagree	Neither disagree nor agree	Agree	Strongly agree
I used the full booklet more than the website or overview booklet					
The full booklet was my preferred version of the information					
It was easy to find the sections I wanted to look at					
I only looked at certain sections					
I looked at the whole full booklet					
I found the diagrams helpful					
The text was easy to read					
My partner/family member/friend used the full booklet					

Please use this space to add any other comments and suggestions for improvement

Appendix 21 Bronchiectasis Knowledge Questionnaire

Participant ID:

Study Visit: 1 2 3

Date:

BRIEF Study Bronchiectasis Knowledge Questionnaire

Please indicate how well you feel you understand the following:

	Very well	Quite well	Not very well	Not at all well
I understand what bronchiectasis is				
I understand why bronchiectasis gives me the symptoms that I have				
I understand the prognosis or long term effects bronchiectasis might have				
I understand what can cause bronchiectasis				
I understand what the bronchiectasis medications I take are for				
I know what signs might tell me I am having a bronchiectasis flare up and need antibiotics				
I know what to do when I have a bronchiectasis flare up				
I understand what extra things I can do to help myself look after my bronchiectasis				
I know who to go to when I need help or advice about bronchiectasis				
I understand my bronchiectasis clinic letter from the doctor				
I know where to find more information on bronchiectasis				
I know who I might see at the hospital and why				
I know how to pronounce bronchiectasis				
I can explain about my bronchiectasis to others				
I feel I can cope and live with my bronchiectasis				

Participant ID:

Study Visit: 1 2 3

Date:

Please indicate what you think about the following statements:

	True	False	Don't know
Bronchiectasis is always caused by smoking			
Bronchiectasis is the same as Chronic Obstructive Pulmonary Disease (COPD)			
Bronchiectasis cannot be cured in most cases but can be managed or controlled			
Bronchiectasis can be cured in most cases			
Fatigue or extreme tiredness can be a symptom of bronchiectasis			
Antibiotics for bronchiectasis chest infections should be taken for 5 days and then stopped			
Antibiotics are always needed if I am coughing phlegm			
Chest clearance, breathing exercises or physio are only required during an infection			
It is recommended I should have a flu jab every year			
I should not exercise if I have bronchiectasis			
Patients with bronchiectasis sometimes cough up blood when they have a chest infection			

Appendix 22 Quality of Life Bronchiectasis (QOL-B)



QUALITY OF LIFE QUESTIONNAIRE – BRONCHIECTASIS

Understanding the impact of your illness and treatments on your everyday life can help your doctor monitor your health and adjust your treatments. For this reason, we have developed a quality of life questionnaire specifically for people who have bronchiectasis. Thank you for your willingness to fill in this questionnaire.

Instructions: The following questions are about the current state of your health, as you perceive it. This information will allow us to better understand how you feel in your everyday life.

Please answer all the questions. There are **no** right or wrong answers! If you are not sure how to answer, choose the response that seems closest to your situation.

Demographics

Please fill in the information or tick the box to indicate your answer.

- A. What is your date of birth?
Date

Day	Month					Year	
- B. What is your gender?
☐ Male ☐ Female
- C. During the **past week**, have you been on holiday or not studying or working for reasons **NOT** related to your health?
☐ Yes ☐ No
- D. What is your current marital status?
☐ Single/never married
☐ Married
☐ Widowed
☐ Divorced
☐ Separated
☐ Remarried
☐ Living with a partner
- E. Which of the following best describes your ethnic group?
☐ White
☐ Mixed/multiple ethnic groups
☐ Asian/Asian British
☐ Black/African/Caribbean/Black British
☐ Other (please describe) _____
☐ Prefer not to answer this question
- F. What is the highest level of education you have completed?
☐ Some secondary school or less
☐ GCSEs/Standard Grades or equivalent
☐ A Level/Higher/Advanced Higher or equivalent
☐ Some college or university
☐ College qualification (e.g. HNC, HND, Foundation Degree)
☐ Undergraduate degree (e.g. BA, BSc)
☐ Postgraduate degree (e.g. MA, MSc, PhD)
- G. Which of the following best describes your current work or educational status?
☐ Studying outside the home
☐ Studying at home/distance learning
☐ Seeking work
☐ Working full-time or part-time (either outside the home or at a home-based business)
☐ Full-time housewife/househusband
☐ Not studying or working due to my health
☐ Not working for other reasons/Retired

Continue to Next Page

**Section I. Quality of Life***Please tick a box to indicate your answer.*

<i>During the past week, to what extent have you had difficulty:</i>	A lot of difficulty	Moderate difficulty	A little difficulty	No difficulty
1. Performing vigorous activities, such as gardening or exercising	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Walking as fast as other people (family, friends, etc.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Carrying heavy things, such as books or shopping bags	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Climbing one flight of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

<i>During the past week, indicate how often:</i>	Always	Often	Sometimes	Never
5. You felt well	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. You felt tired	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. You felt anxious	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. You felt energetic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. You felt exhausted	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. You felt sad	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. You felt depressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Are you currently on any treatments (such as: oral or inhaled medications; a PEP, Acapella® or Flutter® device; chest physiotherapy; or Vest) for bronchiectasis?

☐ Yes ☐ No (Go to Question 15 on the next page)

Please circle a number to indicate your answer. Please choose only one answer for each question.

12. To what extent do your treatments for bronchiectasis make your daily life more difficult?
1. Not at all
 2. A little
 3. Moderately
 4. A lot
13. How much time do you currently spend each day on your treatments for bronchiectasis?
1. A lot
 2. A moderate amount
 3. A little
 4. Almost none
14. How difficult is it for you to fit in your treatments for bronchiectasis each day?
1. Not at all
 2. A little
 3. Moderately
 4. Very

Continue to Next Page



QUALITY OF LIFE QUESTIONNAIRE – BRONCHIECTASIS

Please circle a number to indicate your answer. Please choose only one answer for each question.

15. How do you think your health is now?

1. Excellent
2. Good
3. Fair
4. Poor

Please tick a box to indicate your answer.

Thinking about your health during the past week, indicate the extent to which each sentence is true for you.

	Completely true	Mostly true	A little true	Not at all true	
16. I have to limit vigorous activities, such as walking or exercising	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
17. I have to stay at home more than I want to	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
18. I am worried about being exposed to other people who are ill	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Doesn't apply
19. It is difficult to be intimate with a partner (kissing, hugging, sexual activity).....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. I lead a normal life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
21. I am concerned that my health will get worse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
22. I think my coughing bothers other people	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
23. I often feel lonely.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
24. I feel healthy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
25. It is difficult to make plans for the future (holidays, attending family events, etc.).....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
26. I feel embarrassed when I am coughing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Please circle a number or tick a box to indicate your answer.

During the past week:

27. To what extent did you have trouble keeping up with your job, housework, or other daily activities?

1. You have had no trouble keeping up
2. You have managed to keep up but it has been difficult
3. You have been behind
4. You have not been able to do these activities at all

	Always	Often	Sometimes	Never
28. How often does having bronchiectasis get in the way of meeting your work, household, family, or personal goals?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Continue to Next Page

**Section II. Respiratory Symptoms***Please tick a box to indicate your answer.*

<i>Indicate how you have been feeling during the past week:</i>	A lot	A moderate amount	A little	Not at all
29. Have you felt congestion (fullness) in your chest?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. Have you been coughing during the day?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31. Have you had to cough up sputum?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

32. Has your sputum been mostly:
- | | | |
|--|---|--|
| <input type="checkbox"/> Clear | <input type="checkbox"/> Clear to yellow | <input type="checkbox"/> Yellowish-green |
| <input type="checkbox"/> Brownish-dark | <input type="checkbox"/> Green with traces of blood | <input type="checkbox"/> Don't know |

<i>How often during the past week:</i>	Always	Often	Sometimes	Never
33. Have you had shortness of breath when being more active, such as when doing housework or gardening?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
34. Have you had wheezing?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
35. Have you had chest pain?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
36. Have you had shortness of breath when talking?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
37. Have you woken up during the night because you were coughing?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

*Please make sure you have answered all the questions.***THANK YOU FOR YOUR COOPERATION!**

Appendix 23 St George's Respiratory Questionnaire (SGRQ)

ST. GEORGE'S RESPIRATORY QUESTIONNAIRE ORIGINAL ENGLISH VERSION

ST. GEORGE'S RESPIRATORY QUESTIONNAIRE (SGRQ)

This questionnaire is designed to help us learn much more about how your breathing is troubling you and how it affects your life. We are using it to find out which aspects of your illness cause you most problems, rather than what the doctors and nurses think your problems are.

Please read the instructions carefully and ask if you do not understand anything. Do not spend too long deciding about your answers.

Before completing the rest of the questionnaire:

Please tick in one box to show how you describe your current health:

Very good	Good	Fair	Poor	Very poor
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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UK/ English (original) version

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continued...

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St. George's Respiratory Questionnaire PART 1

Questions about how much chest trouble you have had over the past 3 months.					
Please tick (✓) one box for each question:					
	most days a week	several days a week	a few days a month	only with chest infections	not at all
1. Over the past 3 months, I have coughed:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Over the past 3 months, I have brought up phlegm (sputum):	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Over the past 3 months, I have had shortness of breath:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Over the past 3 months, I have had attacks of wheezing:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. During the past 3 months how many severe or very unpleasant attacks of chest trouble have you had?	Please tick (✓) one:				
	more than 3 attacks <input type="checkbox"/>				
	3 attacks <input type="checkbox"/>				
	2 attacks <input type="checkbox"/>				
	1 attack <input type="checkbox"/>				
	no attacks <input type="checkbox"/>				
6. How long did the worst attack of chest trouble last? (Go to question 7 if you had no severe attacks)	Please tick (✓) one:				
	a week or more <input type="checkbox"/>				
	3 or more days <input type="checkbox"/>				
	1 or 2 days <input type="checkbox"/>				
	less than a day <input type="checkbox"/>				
7. Over the past 3 months, in an average week, how many good days (with little chest trouble) have you had?	Please tick (✓) one:				
	No good days <input type="checkbox"/>				
	1 or 2 good days <input type="checkbox"/>				
	3 or 4 good days <input type="checkbox"/>				
	nearly every day is good <input type="checkbox"/>				
	every day is good <input type="checkbox"/>				
8. If you have a wheeze, is it worse in the morning?	Please tick (✓) one:				
	No <input type="checkbox"/>				
	Yes <input type="checkbox"/>				

St. George's Respiratory Questionnaire PART 2

Section 1

How would you describe your chest condition?

Please tick (✓) *one*:

- The most important problem I have ☐
- Causes me quite a lot of problems ☐
- Causes me a few problems ☐
- Causes no problem ☐

If you have ever had paid employment.

Please tick (✓) *one*:

- My chest trouble made me stop work altogether ☐
- My chest trouble interferes with my work or made me change my work ☐
- My chest trouble does not affect my work ☐

Section 2

Questions about what activities usually make you feel breathless these days.

Please tick (✓) in **each box** that applies to you ***these days***:

	True	False
Sitting or lying still	<input type="checkbox"/>	<input type="checkbox"/>
Getting washed or dressed	<input type="checkbox"/>	<input type="checkbox"/>
Walking around the home	<input type="checkbox"/>	<input type="checkbox"/>
Walking outside on the level	<input type="checkbox"/>	<input type="checkbox"/>
Walking up a flight of stairs	<input type="checkbox"/>	<input type="checkbox"/>
Walking up hills	<input type="checkbox"/>	<input type="checkbox"/>
Playing sports or games	<input type="checkbox"/>	<input type="checkbox"/>

St. George's Respiratory Questionnaire PART 2

Section 3

Some more questions about your cough and breathlessness these days.

Please tick (✓) in **each box** that applies to you **these days**:

	True	False
My cough hurts	<input type="checkbox"/>	<input type="checkbox"/>
My cough makes me tired	<input type="checkbox"/>	<input type="checkbox"/>
I am breathless when I talk	<input type="checkbox"/>	<input type="checkbox"/>
I am breathless when I bend over	<input type="checkbox"/>	<input type="checkbox"/>
My cough or breathing disturbs my sleep	<input type="checkbox"/>	<input type="checkbox"/>
I get exhausted easily	<input type="checkbox"/>	<input type="checkbox"/>

Section 4

Questions about other effects that your chest trouble may have on you these days.

Please tick (✓) in **each box** that applies to you **these days**:

	True	False
My cough or breathing is embarrassing in public	<input type="checkbox"/>	<input type="checkbox"/>
My chest trouble is a nuisance to my family, friends or neighbours	<input type="checkbox"/>	<input type="checkbox"/>
I get afraid or panic when I cannot get my breath	<input type="checkbox"/>	<input type="checkbox"/>
I feel that I am not in control of my chest problem	<input type="checkbox"/>	<input type="checkbox"/>
I do not expect my chest to get any better	<input type="checkbox"/>	<input type="checkbox"/>
I have become frail or an invalid because of my chest	<input type="checkbox"/>	<input type="checkbox"/>
Exercise is not safe for me	<input type="checkbox"/>	<input type="checkbox"/>
Everything seems too much of an effort	<input type="checkbox"/>	<input type="checkbox"/>

Section 5

Questions about your medication, if you are receiving no medication go straight to section 6.

Please tick (✓) in **each box** that applies to you **these days**:

	True	False
My medication does not help me very much	<input type="checkbox"/>	<input type="checkbox"/>
I get embarrassed using my medication in public	<input type="checkbox"/>	<input type="checkbox"/>
I have unpleasant side effects from my medication	<input type="checkbox"/>	<input type="checkbox"/>
My medication interferes with my life a lot	<input type="checkbox"/>	<input type="checkbox"/>

St. George's Respiratory Questionnaire PART 2

Section 6

These are questions about how your activities might be affected by your breathing.

Please tick (✓) in **each box** that applies to you **because of your breathing**:

	True	False
I take a long time to get washed or dressed	<input type="checkbox"/>	<input type="checkbox"/>
I cannot take a bath or shower, or I take a long time	<input type="checkbox"/>	<input type="checkbox"/>
I walk slower than other people, or I stop for rests	<input type="checkbox"/>	<input type="checkbox"/>
Jobs such as housework take a long time, or I have to stop for rests	<input type="checkbox"/>	<input type="checkbox"/>
If I walk up one flight of stairs, I have to go slowly or stop	<input type="checkbox"/>	<input type="checkbox"/>
If I hurry or walk fast, I have to stop or slow down	<input type="checkbox"/>	<input type="checkbox"/>
My breathing makes it difficult to do things such as walk up hills, carrying things up stairs, light gardening such as weeding, dance, play bowls or play golf	<input type="checkbox"/>	<input type="checkbox"/>
My breathing makes it difficult to do things such as carry heavy loads, dig the garden or shovel snow, jog or walk at 5 miles per hour, play tennis or swim	<input type="checkbox"/>	<input type="checkbox"/>
My breathing makes it difficult to do things such as very heavy manual work, run, cycle, swim fast or play competitive sports	<input type="checkbox"/>	<input type="checkbox"/>

Section 7

We would like to know how your chest usually affects your daily life.

Please tick (✓) in **each box** that applies to you **because of your chest trouble**:

	True	False
I cannot play sports or games	<input type="checkbox"/>	<input type="checkbox"/>
I cannot go out for entertainment or recreation	<input type="checkbox"/>	<input type="checkbox"/>
I cannot go out of the house to do the shopping	<input type="checkbox"/>	<input type="checkbox"/>
I cannot do housework	<input type="checkbox"/>	<input type="checkbox"/>
I cannot move far from my bed or chair	<input type="checkbox"/>	<input type="checkbox"/>

St. George's Respiratory Questionnaire

Here is a list of other activities that your chest trouble may prevent you doing. (You do not have to tick these, they are just to remind you of ways in which your breathlessness may affect you):

Going for walks or walking the dog
Doing things at home or in the garden
Sexual intercourse
Going out to church, pub, club or place of entertainment
Going out in bad weather or into smoky rooms
Visiting family or friends or playing with children

Please write in any other important activities that your chest trouble may stop you doing:

.....
.....
.....
.....

Now would you tick in the box (one only) which you think best describes how your chest affects you:

- It does not stop me doing anything I would like to do ☐
It stops me doing one or two things I would like to do ☐
It stops me doing most of the things I would like to do ☐
It stops me doing everything I would like to do ☐

Thank you for filling in this questionnaire. Before you finish would you please check to see that you have answered all the questions.

Appendix 24 Hospital Anxiety and Depression Scale (HADS)

HADS Questionnaire:HADS Questionnaire 26/6/13 13:12 Page 1

Hospital Anxiety and Depression Scale (HADS)



Name: _____ Date: _____

Clinicians are aware that emotions play an important part in most illnesses. If your clinician knows about these feelings he or she will be able to help you more.

This questionnaire is designed to help your clinician to know how you feel. Read each item below and **underline the reply** which comes closest to how you have been feeling in the past week. Ignore the numbers printed at the edge of the questionnaire.

Don't take too long over your replies, your immediate reaction to each item will probably be more accurate than a long, thought-out response.

FOLD HERE				FOLD HERE	
A	D			A	D
3		I feel tense or 'wound up'	I feel as if I am slowed down	3	
2		Most of the time	Nearly all the time	2	
1		A lot of the time	Very often	1	
0		From time to time, occasionally	Sometimes	0	
		Not at all	Not at all		
	0	I still enjoy the things I used to enjoy	I get a sort of frightened feeling like 'butterflies' in the stomach	0	
	1	Definitely as much	Not at all	1	
	2	Not quite so much	Occasionally	2	
	3	Only a little	Quite often	3	
		Hardly at all	Very often		
3		I get a sort of frightened feeling as if something awful is about to happen	I have lost interest in my appearance	3	
2		Very definitely and quite badly	Definitely	2	
1		Yes, but not too badly	I don't take as much care as I should	1	
0		A little, but it doesn't worry me	I may not take quite as much care	0	
		Not at all	I take just as much care as ever		
	0	I can laugh and see the funny side of things	I feel restless as if I have to be on the move	3	
	1	As much as I always could	Very much indeed	2	
	2	Not quite so much now	Quite a lot	1	
	3	Definitely not so much now	Not very much	0	
		Not at all	Not at all		
3		Worrying thoughts go through my mind	I look forward with enjoyment to things	0	
2		A great deal of the time	As much as I ever did	1	
1		A lot of the time	Rather less than I used to	2	
0		Not too often	Definitely less than I used to	3	
		Very little	Hardly at all		
	3	I feel cheerful	I get sudden feelings of panic	3	
	2	Never	Very often indeed	2	
	1	Not often	Quite often	1	
	0	Sometimes	Not very often	0	
		Most of the time	Not at all		
0		I can sit at ease and feel relaxed	I can enjoy a good book or radio or television programme	0	
1		Definitely	Often	1	
2		Usually	Sometimes	2	
3		Not often	Not often	3	
		Not at all	Very seldom		

Now check that you have answered all the questions

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First published in 1994 by nferNelson Publishing Company Ltd.

Published by GL Assessment Limited, 389 Chiswick High Road, 9th Floor East, London W4 4AL

GL Assessment is part of the GL Education Group

Printed in Great Britain

Code 0090002511 13(7.13)

Appendix 25 Fatigue Impact Scale (FIS)

Fatigue Impact Scale

Patient Number: _____

Date: _____

Below is a list of statements that describe how fatigue may cause problems in people's lives. Please read each statement carefully. Circle one number that best indicates how much of a problem fatigue has been for you these past four (4) weeks, including today. Please circle one number for each statement and do not skip any statements.

<i>Circle one number on each line</i>	No Problem	Small Problem	Moderate Problem	Big Problem	Extreme Problem
1. <i>Because of my fatigue, I feel less alert.</i>	0	1	2	3	4
2. <i>Because of my fatigue, I feel that I am more isolated from social contact.</i>	0	1	2	3	4
3. <i>Because of my fatigue, I have had to reduce my workload or responsibilities.</i>	0	1	2	3	4
4. <i>Because of my fatigue, I am more moody.</i>	0	1	2	3	4
5. <i>Because of my fatigue, I have difficulty in paying attention for a long period of time.</i>	0	1	2	3	4
6. <i>Because of my fatigue, I feel as if I cannot think clearly.</i>	0	1	2	3	4
7. <i>Because of my fatigue, I work less effectively (this applies to work inside or outside the home).</i>	0	1	2	3	4
8. <i>Because of my fatigue, I have to rely more on others to help me or do things for me.</i>	0	1	2	3	4
9. <i>Because of my fatigue, I have difficulty in planning activities in advance because my fatigue may interfere with them.</i>	0	1	2	3	4
10. <i>Because of my fatigue, I am more clumsy and uncoordinated.</i>	0	1	2	3	4
11. <i>Because of my fatigue, I find that I am more forgetful.</i>	0	1	2	3	4
12. <i>Because of my fatigue, I am more irritable and get angry more easily.</i>	0	1	2	3	4
13. <i>Because of my fatigue, I have to be careful about pacing my physical activities.</i>	0	1	2	3	4
14. <i>Because of my fatigue, I am less motivated to do anything that requires physical effort.</i>	0	1	2	3	4
15. <i>Because of my fatigue, I am less motivated to engage in social activities.</i>	0	1	2	3	4
16. <i>Because of my fatigue, my ability to travel outside my home is limited.</i>	0	1	2	3	4
17. <i>Because of my fatigue, I have trouble maintaining physical effort for long periods.</i>	0	1	2	3	4
18. <i>Because of my fatigue, I find it difficult to make decisions.</i>	0	1	2	3	4
19. <i>Because of my fatigue, I have few social contacts outside my own home.</i>	0	1	2	3	4
20. <i>Because of my fatigue, normal day-to-day events are stressful for me.</i>	0	1	2	3	4

UK English version of the Fatigue Impact Scale - Copyright 1991 J.D. Fisk, P.G. Ritvo & C.J. Archibald

FIS - United Kingdom/English - Version of 01 Oct 12 - MAPI Institute.
ID7079 / FIS_AU2.0_eng-GB.doc

<i>Circle one number on each line</i>	No Problem	Small Problem	Moderate Problem	Big Problem	Extreme Problem
21. <i>Because of my fatigue, I am less motivated to do anything that requires thinking.</i>	0	1	2	3	4
22. <i>Because of my fatigue, I avoid situations that are stressful for me.</i>	0	1	2	3	4
23. <i>Because of my fatigue, my muscles feel much weaker than they should.</i>	0	1	2	3	4
24. <i>Because of my fatigue, my physical discomfort is increased.</i>	0	1	2	3	4
25. <i>Because of my fatigue, I have difficulty dealing with anything new.</i>	0	1	2	3	4
26. <i>Because of my fatigue, I am less able to finish tasks that require thinking.</i>	0	1	2	3	4
27. <i>Because of my fatigue, I feel unable to meet the demands that people place on me.</i>	0	1	2	3	4
28. <i>Because of my fatigue, I feel less able to provide financial support for myself and my family.</i>	0	1	2	3	4
29. <i>Because of my fatigue, I engage in less sexual activity.</i>	0	1	2	3	4
30. <i>Because of my fatigue, I find it difficult to organise my thoughts when I am doing things at home or at work.</i>	0	1	2	3	4
31. <i>Because of my fatigue, I am less able to complete tasks that require physical effort.</i>	0	1	2	3	4
32. <i>Because of my fatigue, I worry about how I look to other people.</i>	0	1	2	3	4
33. <i>Because of my fatigue, I am less able to deal with emotional issues.</i>	0	1	2	3	4
34. <i>Because of my fatigue, I feel slowed down in my thinking.</i>	0	1	2	3	4
35. <i>Because of my fatigue, I find it hard to concentrate.</i>	0	1	2	3	4
36. <i>Because of my fatigue, I have difficulty in participating fully in family activities.</i>	0	1	2	3	4
37. <i>Because of my fatigue, I have to limit my physical activities.</i>	0	1	2	3	4
38. <i>Because of my fatigue, I require more frequent or longer periods of rest.</i>	0	1	2	3	4
39. <i>Because of my fatigue, I am not able to provide as much emotional support to my family as I should.</i>	0	1	2	3	4
40. <i>Because of my fatigue, minor difficulties seem like major difficulties.</i>	0	1	2	3	4

UK English version of the Fatigue Impact Scale - Copyright 1991 J.D. Fisk, P.G. Ritvo & C.J. Archibald

FIS - United Kingdom/English - Version of 01 Oct 12 - MAPI Institute.
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Appendix 26 EQ-5D-5L



Health Questionnaire

English version for the UK

UK (English) v.2 © 2009 EuroQol Group. EQ-5D™ is a trade mark of the EuroQol Group

Under each heading, please tick the ONE box that best describes your health TODAY

MOBILITY

- I have no problems in walking about ☐
- I have slight problems in walking about ☐
- I have moderate problems in walking about ☐
- I have severe problems in walking about ☐
- I am unable to walk about ☐

SELF-CARE

- I have no problems washing or dressing myself ☐
- I have slight problems washing or dressing myself ☐
- I have moderate problems washing or dressing myself ☐
- I have severe problems washing or dressing myself ☐
- I am unable to wash or dress myself ☐

USUAL ACTIVITIES (*e.g. work, study, housework, family or leisure activities*)

- I have no problems doing my usual activities ☐
- I have slight problems doing my usual activities ☐
- I have moderate problems doing my usual activities ☐
- I have severe problems doing my usual activities ☐
- I am unable to do my usual activities ☐

PAIN / DISCOMFORT

- I have no pain or discomfort ☐
- I have slight pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have severe pain or discomfort ☐
- I have extreme pain or discomfort ☐

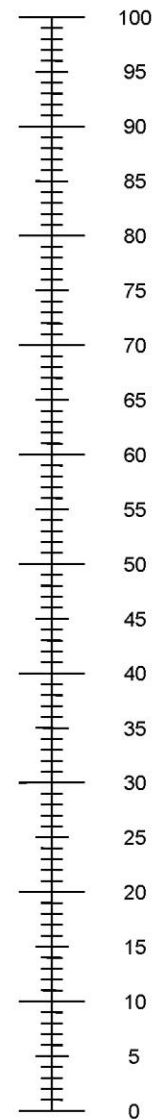
ANXIETY / DEPRESSION

- I am not anxious or depressed ☐
- I am slightly anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am severely anxious or depressed ☐
- I am extremely anxious or depressed ☐

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =

The best health
you can imagine



The worst health
you can imagine

Appendix 27 BRIEF study focus group topic guide

Introductions

Discuss intervention and control groups and experiences

PDF entrants

Feedback and experiences of the resource

Preferences

Feedback and experiences of the trial itself

Look at sections of the resource for discussion

Comparisons to other resources used

Any problems or comments

Suggestions for the future

Appendix 28 BRIEF study statistical analysis plan

Bronchiectasis Information and Education Feasibility Study (BRIEF Study)
A randomised controlled trial

STATISTICAL ANALYSIS PLAN

Author: Katy Hester

Trial details:

Chief Investigator: Dr Katy Hester

Principal Investigator: Dr Anthony de Soyza

Statistician: Ms Vicky Ryan

Trial Manager: Mr Chris Speed (No longer in post) (NCTU)

ISRCTN Number: ISRCTN84229105

REC Reference: 14/NE/0119

Sponsor: Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor Protocol Number: 7005

Funder: NIHR DRF (DRF-2012-05-149)

Study design: A feasibility study for the proposed future BRIE RCT

Study intervention: Arm 1: Novel patient information resource
Arm 2: Usual care

Primary objective: To inform the decision of whether to proceed to the BRIE RCT and whether any refinements to the design or conduct of that trial are warranted.

Secondary objective: To evaluate and further refine the patient information resource and collect information on patient preferences.

Specific Objectives:

- To assess participants' willingness to enter the trial
- To gauge participants' acceptability of study design
- To study length of time required to complete recruitment
- To study retention rate and completion of required study forms
- To evaluate the intervention and experience of trial involvement

Primary outcome: The confirmation or otherwise that the study site will be able to identify, recruit and retain the required number of eligible participants. The acceptability of the intervention (as manifested through recruitment and retention levels), the feasibility and acceptability of the data collection tools (completion rates and quality of

data) and clinical data to calculate the sample size for the BRIE RCT. Production of protocols for the full trial.

Secondary outcome: To modify and refine the patient information resource and its delivery based on quantitative and qualitative data.

Specific outcome measures:

- Participants' willingness to enter the trial (consented participant to eligible participants approached ratio).
- Participants' acceptability of study design (as measured by the completion rate of participants in each randomised group).
- Participant recruitment rate (as measured by the number of patients randomised divided by the length of the recruitment period). The recruitment period runs from the date that recruitment opened to the date of the last randomisation.
- Completion of forms.
- Evaluation of resource and trial experience to include 'compliance with' (use of) intervention.

Study site: Newcastle upon Tyne Hospitals NHS Trust – Freeman and RVI sites for recruitment, Freeman only for study visits.

Sample size required: 60 (30 in each arm) plus up to 10 for focus groups to discuss resource and trial.

Study duration: 28 months. A patient is within the main study for 3 months (calculated at 12 weeks or 84 days).

Protocol approval and amendment dates:

Protocol version	Amendment	Details	Approved Date
V1.0, dated 23/04/2014	Original submission	14/NE/0119	02/05/2014
V1.1, dated 27/05/2014	As per ethical approval committee meeting	To include those without internet access	29/05/2014
V1.2, dated 11/06/2015	Minor protocol changes	Continued access to resource after study completion and access for control group after study completion	16/06/2015
V1.3 Dated 13/08/2015	Minor protocol Changes	No FEV1 required at V1 if recorded in past 3 months	26/08/2015

Introduction

The trial protocol describes the method of data collection and the main features of the analysis. This document describes, in more detail, the proposed strategy for the statistical analysis and presentation of data collected for this trial, guiding the final analyses.

Both the ICH Guidance on Statistical Principles for Clinical Trials (ICH E9) and the Revised CONSORT Statement for Reporting Randomized Trials recommend that all analyses should be planned and outlined in a statistical analysis plan prior to the unblinding of the data so as to avoid any post hoc decisions which may affect the interpretation of the statistical analyses. The CONSORT statement also recommends that when writing research papers authors should specify whether analyses were planned or suggested by the data – planned analyses have greater credibility and are in line with Good Clinical Practice. The BRIEF study was not blinded due to the nature of the intervention making this impractical. The same principles have been applied for the purposes of analysis however.

1. Data validation

Trial data has been entered manually into the BRIEF study database by the data managers at the William Leech Centre for Lung Research from where the study was conducted. All data is originally hand written into each study record folder and then entered into an excel database subsequently.

The following checks will be carried out before any analysis:

- treatment arm allocation as recorded in the randomisation log checked against that recorded in the CRF
- randomisation stratification variable as recorded in the randomisation log, checked against Visit 1 CRF
- Age at randomisation ≥ 18 years (from randomisation log and CRF visit 1)
- examine all dates to check timings and compliance with the protocol.

2. Recruitment

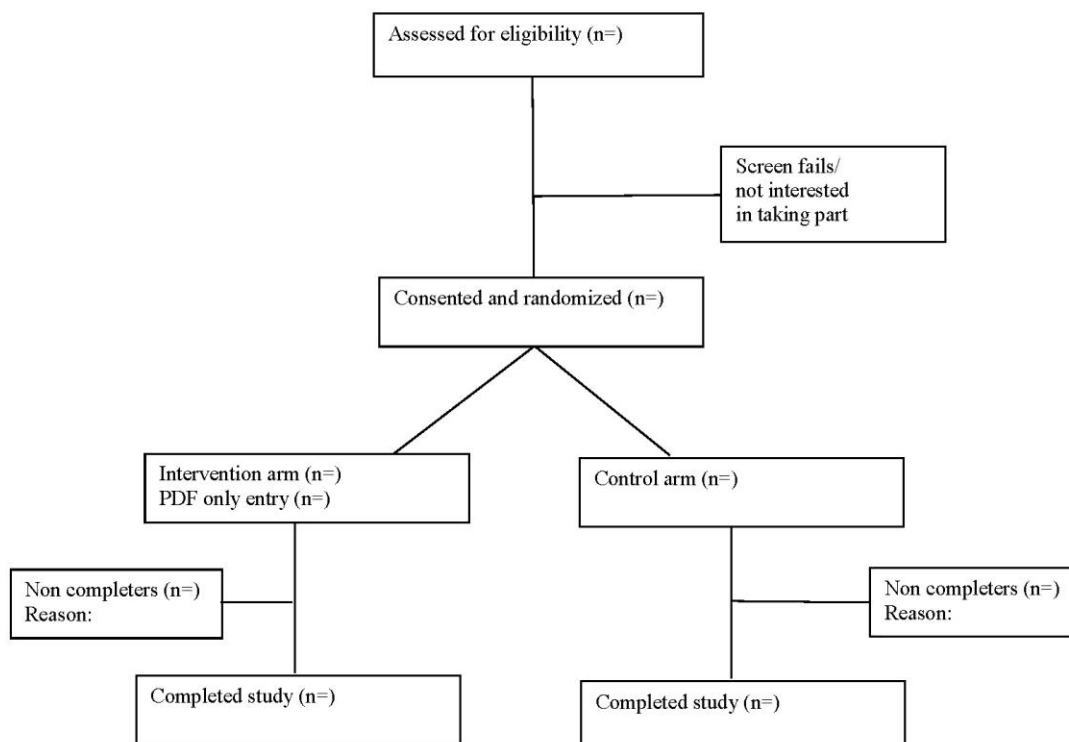
The BRIEF study aimed to randomise 60 patients.

Study open dates run from June 2014 until Sep 2016.

Recruitment is expected to be over 28 months and projected patient accrual 2-3 patients/month.

A subsequent maximum of 10 patients and carers will be recruited (but not randomised) to a focus group that aims to discuss the resource and the trial process. This data will be purely qualitative in nature and is not included within this analysis plan.

2.1 Recruitment summary:



2.2 Plot of cumulative number of patients randomised: actual and predicted

Plot will be inserted here

3. Distribution of patients by randomisation strata

Patients will be randomised using random permuted blocks within strata.

Randomisation is stratified according to gender.

Randomisation is to be performed by the research staff using the Newcastle University online randomisation system.

3.1 Table of the distribution of patients by randomisation strata

Strata	Control Group <i>n</i>=	Intervention Group <i>n</i>=	Total <i>n</i> =
Male			
Female			

4. Ineligible participants

The number of ineligible patients and reasons for ineligibility will be reported.

5. Baseline patient characteristics

Demographic and clinical baseline characteristics and trial stratification factors at randomisation will be compared across treatment groups descriptively. Descriptive statistics will be tabulated by treatment group and overall.

No significance testing will be carried out due to the randomised nature of the study^{1,2,3}.

Formal tests will not be carried out but any imbalances will be explored further (see analyses of outcome measures below).

Baseline characteristics, by allocation group (n=).

	Control group n=	Intervention group n=	Total n =
Gender			
Female	x (%)	x (%)	x (%)
Male	x (%)	x (%)	x (%)
Age (years)			
Median (range)	m (range)	m (range)	m (range)
FEV1 (% predicted)			
Median (range)			
BSI score*			
Median (range)			
BSI Severity group			
Mild (score 0-4)			
Moderate (score 5-8)			
Severe (score >8)			
Time since diagnosis (years)			
Median (range)			
> 10			
> 5 ≤ 10			
>1 ≤ 5			
>6 months ≤1 year			
≤6 months			
Bronchiectasis aetiology			
Idiopathic			
Post-infection			
Secondary to chronic asthma/COPD			
Immune deficiency associated			
Other**			
Exacerbations per year			
<3			
≥3			

	Control group <i>n</i> =	Intervention group <i>n</i> =	Total <i>n</i> =
Use of home IVs Y N			
Clinic attended Specialist General			
Prior bronchiectasis hospital admissions Y N			
Sputum microbiology Pseudomonas aeruginosa Other*** Not colonised No samples			
Drug treatments Azithromycin Nebulised antibiotics			
Devices used to access internet/resource Mobile Tablet PC/laptop No access			
Previous bronchiectasis information seeking None Paper Online In person			

1

¹ * Newcastle Bronchiectasis Severity Index, CT scoring not included

** Pink's Disease, Rheumatoid arthritis, Marfan's Syndrome, Connective Tissue Disease, Wegener's Granulomatosis

*** Haemophilus Influenzae, Klebsiella, Staphylococcus aureus, Serratia marcescens, Moraxella catarrhalis, Escherichia Coli.

6. Summary of AEs, SAEs, withdrawals and loss to follow-up

6.1 Chronological listing of SAEs:

group allocation	Date of initial report	SAE Description	Onset Date	SAE reason	Outcome of SAE

6.2 Chronological listing of withdrawals:

group allocation	Randomisation date	Withdrawal date	Days in the study	Type of withdrawal	Reason/comment

6.3 Chronological listing of patients lost to follow up:

If x withdrawals listed in Section 6.2 agreed for their data up to the point of withdrawal to be used for study purposes, there data will be used up until point of withdrawal, but these patients will not be followed up further within the study.

7. Definition of analysis group

Statistical analyses will be based on the intention to treat principle with analysis groups based on the groups allocated at randomisation and all randomised patients being included in the analysis. Missing data due to participant loss to follow-up or non-completion of study visits or questionnaires will not be imputed and therefore the analyses of change data will be for complete cases.

Due to the nature of the intervention adherence to protocol was not assessed.

8. Analysis of outcome measures

Primary outcome measures:

- Participants' willingness to enter the trial (consented participant to potentially eligible participants approached ratio).
- Participants' acceptability of study design (as measured by the completion rate of participants in each randomised group).
- Participant recruitment rate (as measured by the number of patients randomised divided by the length of the recruitment period). The recruitment period runs from the date that recruitment opened to the date of the last randomisation.
- Participant completion of required study forms and visits

Secondary outcome measures:

- Resource satisfaction questionnaire
- Recorded use of resource and alternative information seeking
- QOL-B
- SGRQ
- HADS
- FIS
- EQ-5D
- Number of unscheduled visits to primary or secondary care
- Exacerbation frequency
- FEV1
- Knowledge of condition and management questionnaire

In accordance with recommendations for the analysis of feasibility studies^{4,5} (where a formal power calculation is not carried out) the data analysis will be

descriptive and statistical comparisons between the randomisation groups will not be undertaken.

For the primary outcome measures all proportions/rates will be calculated as defined.

Example table:

Outcome measure	(n=)	
	Control group n=	Intervention group n=
Percent remaining in the trial up to week 12	x/n (%)	x/n (%)

All summaries will be interpreted cautiously because of the size of the study and the possible imbalance in pre-randomisation baseline covariates.

Secondary outcome measures will be described at baseline and the change from baseline to 12 weeks will be summarised (and reported as mean (sd) or median (IQR) depending on the distribution of the data).

For missing data, published guidelines will be followed for validated questionnaires and otherwise generic rules (such as 'rule of halves') which are recommended in the literature will be described and employed. The details of individual questionnaires will be described individually.

Variable	n*	Control group n=			n*	Intervention group n=		
		Baseline mean (sd)	mean change** baseline to 2 weeks (sd)	mean change** baseline to 12 weeks (sd)		Baseline mean (sd)	mean change** baseline to 2 weeks (sd)	mean change** baseline to 12 weeks (sd)
RSQ								
BKQ								
EQ-5D								
SGRQ								
QOL-B								
HADS								
FIS								
FEV1								
Recorded use of resource								
Recorded information seeking								
Exacerbation frequency								
Number of unscheduled presentations								

*n=number of participants with all three measures

**A negative change indicates a fall on average from baseline to 12 weeks

8.1 Treatment comparisons

The study has not been designed to make treatment comparisons or draw inferences and as such no formal statistical testing will be performed.

8.2 Informing future studies

References:

1. Moher D, Hopewell S, Shultz KF, et al, CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials. *BMJ* 2010;340:c869 doi: 10.1136/bmj.c869
2. Altman DG, Comparability of randomised groups. *Statistician* 1985;34:125-36.
3. Roberts C and Torgerson DJ, Baseline imbalance in randomised controlled trials. *BMJ* 1999;319:185
4. Lancaster GA, Dodd S, Williamson PR, et al. Design and analysis of pilot studies: recommendations for good practice. *J Eval Clin Pract* 2004;10:307–12.
5. Thabane L, Ma J, Chu R, et al. A tutorial on pilot studies: the what, why and how. *BMC Med Res Methodol* 2010;10:1.

Appendix 29 RSQ completion data

Resource Satisfaction Questionnaire :-	Intervention group (n=31) numbers completing questions (%rounded)		
	V2	V3	Total complete both visits
Form completed but had omissions	31(100)	31(100)	31(100)
Form completed without omissions	20(65)	19(61)	15(48)
P 1 'I used the information provided' answering YES (no moves to P2)	27(87)	27(87)	24(77)
I found the information useful	27(87)	27(87)	24(77)
My knowledge about the condition has improved	27(87)	27(87)	24(77)
I feel more able to manage my condition	27(87)	27(87)	24(77)
The information provided was easy to understand	27(87)	27(87)	24(77)
The right amount of information was given	27(87)	27(87)	24(77)
The things I wanted to know about were covered	27(87)	27(87)	24(77)
My partner/family/friend used the information	27(87)	26(84)	23(74)
Free text comment made	9(29)	8(26)	
P 2 'I used the website' answering YES (no moves to P3)	19(61)	18(58)	17(55)
I used the website more than the overview booklet	19(61)	21(68)	20(65)
The website was my preferred version of the information	19(61)	21(68)	20(65)
It was easy to find the sections I wanted to look at	19(61)	21(68)	20(65)
I only looked at certain sections	19(61)	21(68)	20(65)
I looked at all of the website	19(61)	21(68)	20(65)
The login procedure was easy to use	19(61)	21(68)	20(65)
I found the video clips helpful	19(61)	21(68)	20(65)
I found the diagrams helpful	19(61)	21(68)	20(65)
My partner/family/friend used the website	19(61)	20(65)	19(61)
Free text comment made	5(16)	6(19)	
P 3 'I used the overview booklet' answering YES (no moves to P4)	28(90)	24(77)	21(68)
I used the overview booklet more than the website	28(90)	24(77)	21(68)
The overview booklet was my preferred version of the information	28(90)	24(77)	21(68)
It was easy to find the sections I wanted to look at	28(90)	24(77)	21(68)
I only looked at certain sections	28(90)	23(74)	20(65)
I looked at the whole overview booklet	28(90)	23(74)	20(65)
I found the diagrams helpful	28(90)	23(74)	20(65)
The text was easy to read	28(90)	23(74)	20(65)
My partner/family/friend used the overview booklet	28(90)	22(71)	19(61)
Free text comment made	5(16)	2(6)	
P 4 'I downloaded the full booklet' answering YES (no completes questionnaire)	4(13)	6(19)	2(6)
I used the full booklet more than the website or overview booklet	4(13)	6(19)	2(6)
The full booklet was my preferred version of the information	4(13)	6(19)	2(6)
It was easy to find the sections I wanted to look at	4(13)	6(19)	2(6)
I only looked at certain sections	4(13)	6(19)	2(6)
I looked at the whole full booklet	4(13)	5(16)	1(3)
I found the diagrams helpful	4(13)	6(19)	2(6)
The text was easy to read	4(13)	6(19)	2(6)
My partner/family/friend used the full booklet	4(13)	6(19)	2(6)
Free text comment made	1(3)	0(0)	

Appendix 30 BKQ completion data

	Control group number of complete cases (n=29) number (% rounded)				Intervention group number of complete cases (n=31) number (% rounded)			
	V1	V2	V3	Total overall complete cases	V1	V2	V3	Total overall complete cases
Bronchiectasis Knowledge Questionnaire:-								
form completed but had omissions	29(100)	28(97)	29(100)	28(97)	31(100)	30(97)	31(100)	30(97)
form completed without omissions	28(97)	27(93)	28(97)	27(93)	30(97)	29(94)	30(97)	29(94)
scaled questions:-								
1. I understand what bronchiectasis is	29(100)	28(97)	29(100)	28(97)	31(100)	30(97)	31(100)	30(97)
2. I understand why bronchiectasis gives me the symptoms that I have	29(100)	28(97)	29(100)	28(97)	31(100)	30(97)	31(100)	30(97)
3. I understand the prognosis or long term effects bronchiectasis might have	29(100)	28(97)	29(100)	28(97)	31(100)	30(97)	31(100)	30(97)
4. I understand what can cause bronchiectasis	29(100)	28(97)	29(100)	28(97)	30(97)	30(97)	31(100)	29(94)
5. I understand what the bronchiectasis medications I take are for	29(100)	28(97)	28(97)	27(93)	31(100)	30(97)	31(100)	30(97)
6. I know what signs might tell me I am having a bronchiectasis flare up and need antibiotics	29(100)	27(93)	29(100)	27(93)	31(100)	30(97)	31(100)	30(97)
7. I know what to do when I have a bronchiectasis flare up	29(100)	28(97)	29(100)	28(97)	31(100)	30(97)	31(100)	30(97)
8. I understand what extra things I can do to help myself look after my bronchiectasis	29(100)	28(97)	29(100)	28(97)	31(100)	30(97)	31(100)	30(97)
9. I know who to go to when I need help or advice about bronchiectasis	29(100)	28(97)	29(100)	28(97)	31(100)	30(97)	31(100)	30(97)
10. I understand my clinic letter from the doctor	29(100)	28(97)	29(100)	28(97)	31(100)	29(94)	31(100)	29(94)
11. I know where to find more information on bronchiectasis	29(100)	28(97)	29(100)	28(97)	31(100)	30(97)	31(100)	30(97)
12. I know who I might see at the hospital and why	29(100)	28(97)	29(100)	28(97)	31(100)	30(97)	31(100)	30(97)
13. I know how to pronounce bronchiectasis	28(97)	28(97)	29(100)	27(93)	31(100)	30(97)	31(100)	30(97)
14. I can explain about my bronchiectasis to others	29(100)	28(97)	29(100)	28(97)	31(100)	30(97)	31(100)	30(97)
15. I feel I can cope and live with my bronchiectasis	29(100)	28(97)	29(100)	28(97)	31(100)	30(97)	31(100)	30(97)
True/False questions:-								
1. Bronchiectasis is always caused by smoking	29(100)	28(97)	29(100)	28(97)	31(100)	30(97)	30(97)	30(97)
2. Bronchiectasis is the same as COPD	29(100)	28(97)	29(100)	28(97)	31(100)	30(97)	30(97)	30(97)
3. Bronchiectasis cannot be cured in most cases but can be managed or controlled	29(100)	28(97)	29(100)	28(97)	31(100)	30(97)	30(97)	30(97)
4. Bronchiectasis can be cured in most cases	29(100)	28(97)	29(100)	28(97)	31(100)	30(97)	30(97)	30(97)
5. Fatigue or extreme tiredness can be a symptom of bronchiectasis	29(100)	28(97)	29(100)	28(97)	31(100)	30(97)	30(97)	30(97)
6. Antibiotics for bronchiectasis chest infections should be taken for 5 days then stopped	29(100)	28(97)	29(100)	28(97)	31(100)	30(97)	30(97)	30(97)
7. Antibiotics are always needed if I am coughing phlegm	29(100)	28(97)	29(100)	28(97)	31(100)	30(97)	30(97)	30(97)
8. Chest clearance, breathing exercises or physio are only required during an infection	29(100)	28(97)	29(100)	28(97)	31(100)	30(97)	30(97)	30(97)
It is recommended I should have a flu jab every year	29(100)	28(97)	29(100)	28(97)	31(100)	30(97)	30(97)	30(97)
10. I should not exercise if I have bronchiectasis	29(100)	28(97)	29(100)	28(97)	31(100)	30(97)	30(97)	30(97)
11. Patients with bronchiectasis sometimes cough up blood when they have a chest infection	29(100)	28(97)	29(100)	28(97)	31(100)	30(97)	30(97)	30(97)

Appendix 31 Postal questionnaire completion data

From postal questionnaires:-	Control group complete cases (n=29) Number (% rounded)				Intervention group complete cases (n=31) Number (% rounded)			
	P1	P2	P3	Total cases completing all	P1	P2	P3	Total cases completing all
Form returned	24(83)	27(93)	29(100)	21(72)	30(97)	28(90)	31(100)	27(87)
unscheduled visits	24(83)	25(86)	29(100)	19(66)	29(94)	27(87)	31(100)	25(81)
use of resource (also recorded in RSQ)					30(97)	28(90)	31(100)	27(87)
exacerbation frequency	24(83)	27(93)	29(100)	21(72)	29(94)	28(90)	31(100)	26(84)
Symptoms	24(83)	25(86)	29(100)	19(66)	30(97)	28(90)	31(100)	27(87)

Appendix 32 BKQ question responses

	n	Control group n and (%)				n	Intervention group n and (%)			
Question/Visit		Not at all well	Not very well	Quite well	Very well		Not at all well	Not very well	Quite well	Very well
1. I understand what bronchiectasis is.	29	0	3(10)	15(52)	11(38)	31	1(3)	3(10)	17(55)	10(32)
V1	28	0	3(11)	15(54)	10(36)	30	0	0	11(37)	19(63)
V2	29	0	2(7)	17(59)	10(34)	31	0	0	9(29)	22(71)
V3										
2. I understand why bronchiectasis gives me the symptoms that I have.	29	0	6(21)	15(52)	8(28)	31	0	6(19)	13(42)	12(39)
V1	28	0	4(14)	13(46)	11(39)	30	0	0	12(40)	18(60)
V2	29	0	2(7)	16(55)	11(38)	31	0	2(6)	7(23)	22(71)
V3										
3. I understand the prognosis or long term effects bronchiectasis might have.	29	2(7)	12(41)	9(31)	6(21)	31	2(6)	8(26)	11(35)	10(32)
V1	28	2(7)	8(29)	8(29)	10(36)	30	0	4(13)	14(47)	12(40)
V2	29	1(3)	8(29)	10(34)	9(31)	31	0	2(6)	13(42)	16(52)
V3			9(31)							
4. I understand what can cause bronchiectasis.	29	1(3)	9(31)	14(48)	5(17)	31	6(19)	10(32)	8(26)	7(23)
V1	28	3(11)	10(36)	8(29)	7(25)	30	1(3)	2	11(37)	12(40)
V2	29	0	6	13(45)	8(28)	31	3(10)	6(20)	8(26)	16(52)
V3			8(28)					4(13)		
5. I understand what the bronchiectasis medications I take are for.	29	0	0	12(41)	17(59)	31	0	6(19)	12(39)	13(42)
V1	28	0	3(11)	11(39)	14(50)	30	0	2(7)	13(43)	15(50)
V2	28	0	0	13(46)	15(54)	31	0	1(3)	8(26)	22(71)
V3										

	n	Control group n and (%)				n	Intervention group n and (%)			
Question/Visit		Not at all well	Not very well	Quite well	Very well		Not at all well	Not very well	Quite well	Very well
6. I know what signs might tell me I am having a bronchiectasis flare up and need antibiotics.										
V1	29	0	4(14)	9(31)	16(55)	31	1(3)	3(10)	12(42)	15(48)
V2	27	0	4(15)	11(41)	12(43)	30	0	2(7)	8(27)	20(67)
V3	29	0	1(3)	11(38)	17(59)	31	0	0	8(26)	23(74)
7. I know what to do when I have a bronchiectasis flare up.										
V1	29	1(3)	1(3)	9(31)	18(62)	31	1(3)	2(6)	11(35)	17(55)
V2	28	0	1(4)	10(36)	17(61)	30	0	0	7(23)	23(77)
V3	29	0	2(7)	9(31)	18(62)	31	0	0	6(19)	25(81)
8. I understand what extra things I can do to help myself look after my bronchiectasis.										
V1	29	0	6(21)	16(55)	7(24)	31	1(3)	6(19)	11(35)	13(42)
V2	28	0	3(11)	8(29)	20(71)	30	0	2(7)	12(40)	16(53)
V3	29	0	5(17)	10(34)	14(48)	31	0	2(6)	11(35)	18(58)
9. I know who to go to when I need help or advice about my bronchiectasis.										
V1	29	0	1(3)	8(28)	20(69)	31	0	4(13)	6(19)	21(68)
V2	28	0	0	12(43)	16(57)	30	0	1(3)	7(23)	22(73)
V3	29	0	2(7)	6(21)	21(72)	31	0	0	8(26)	23(74)
10. I understand my bronchiectasis clinic letter from the doctor.										
V1	29	0	2(7)	10(34)	17(59)	31	0	3(10)	10(32)	18(58)
V2	28	0	0	12(43)	16(57)	29	0	4(14)	7(24)	18(62)
V3	29	0	1(3)	11(38)	17(59)	31	0	0	10(32)	21(68)

	n	Control group n and (%)				n	Intervention group n and (%)			
Question/Visit		Not at all well	Not very well	Quite well	Very well		Not at all well	Not very well	Quite well	Very well
11. I know where to find more information on bronchiectasis.	29	1(3)	7(24)	9(31)	12(41)	31	1(3)	11(35)	10(32)	9(29)
V1	28	0	3(11)	14(50)	11(39)	30	0	0	10(33)	20(67)
V2	29	0	5(17)	10(34)	14(48)	31	0	1(3)	8(26)	22(71)
V3										
12. I know who I might see at the hospital and why.	29	0	1(3)	6(21)	22(76)	31	0	1(3)	11(35)	19(61)
V1	28	0	0	7(25)	21(75)	30	0	1(3)	4(13)	25(83)
V2	29	0	1(3)	7(23)	21(70)	31	0	0	6(19)	25(81)
V3										
13. I know how to pronounce bronchiectasis.	28	0	3(11)	4(14)	21(75)	31	0	0	7(23)	24(77)
V1	28	0	1(4)	4(14)	23(82)	30	0	0	4(13)	26(87)
V2	29	0	1(3)	5(17)	23(79)	31	0	0	4(13)	27(87)
V3										
14. I can explain about my bronchiectasis to others.	29	1(3)	3(10)	11(38)	14(48)	31	1(3)	5(16)	12(39)	13(42)
V1	28	2(7)	3(11)	17(61)	6(21)	30	0	3(10)	8(27)	19(63)
V2	29	0	5(17)	10(34)	14(48)	31	0	1(3)	10(32)	20(65)
V3										
15. I feel I can cope with and live with my bronchiectasis.	29	0	2(7)	16(55)	11(38)	31	0	2(6)	19(61)	10(32)
V1	28	0	5(18)	17(61)	6(21)	30	0	1(3)	12(40)	17(57)
V2	29	0	2(7)	18(62)	9(30)	31	0	2(6)	12(39)	17(55)
V3										

	n	Control group n and (%)				Intervention group n and (%)		
Question/Visit		Answered correctly	Answered incorrectly	Didn't know		Answered correctly	Answered Incorrectly	Didn't know
1. Bronchiectasis is always caused by smoking. (F)								
V1	29	22(76)	0	7(24)	31	28(90)	0	3(10)
V2	28	27(96)	0	1(4)	30	29(97)	0	1(3)
V3	29	24(83)	1(3)	4(14)	30	30(100)	0	0
2. Bronchiectasis is the same as chronic obstructive pulmonary disease (COPD) (F)								
V1	29	17(59)	2(7)	9(31)	31	18(58)	4(13)	9(29)
V2	28	18(64)	3(11)	7(25)	30	23(77)	0	7(23)
V3	29	20(69)	2(7)	7(24)	30	24(80)	2(7)	4(13)
3. Bronchiectasis cannot be cured in most cases but can be managed or controlled. (T)								
V1	29	28(97)	0	1(3)	31	30(97)	1(3)	0
V2	28	28(100)	0	0	30	30(100)	0	0
V3	29	25(86)	2(7)	2(7)	30	30(100)	0	0
4. Bronchiectasis can be cured in most cases. (F)								
V1	29	25(86)	0	4(14)	31	29(94)	0	2(6)
V2	28	27(96)	0	1(4)	30	29(97)	0	1(3)
V3	29	24(83)	1(3)	4(14)	30	30(100)	0	0
5. Fatigue or extreme tiredness can be a symptom of bronchiectasis. (T)								
V1	29	20(69)	0	9(31)	31	23(74)	1(3)	7(23)
V2	28	23(82)	0	5(17)	30	30(100)	0	0
V3	29	24(83)	1(3)	4(14)	30	29(97)	1(3)	0
6. Antibiotics for bronchiectasis chest infections should be taken for 5 days and then stopped. (F)								
V1	29	25(86)	1(3)	3(10)	31	29(94)	0	2(6)
V2	28	24(86)	1(4)	3(11)	30	24(80)	2(7)	4(13)
V3	29	25(86)	2(7)	2(7)	30	27(90)	2(7)	1(3)

	n	Control group n and (%)				Intervention group n and (%)		
Question/Visit		Answered correctly	Answered incorrectly	Didn't know		Answered correctly	Answered incorrectly	Didn't know
7. Antibiotics are <i>always</i> needed if I am coughing phlegm. (F)								
V1	29	20(69)	6(21)	3(10)	31	26(84)	4(13)	1(3)
V2	28	20(71)	5(18)	3(11)	30	23(77)	2(7)	5(17)
V3	29	22(76)	4(14)	3(10)	30	23(77)	2(7)	5(17)
8. Chest clearance, breathing exercises or physio are only required during an infection. (F)								
V1	29	27(93)	0	2(7)	31	29(94)	0	2(6)
V2	28	25(89)	1(4)	2(7)	30	29(97)	1(3)	0
V3	29	25(86)	2(7)	2(7)	30	29(97)	1(3)	0
9. It is recommended that I should have a flu jab every year. (T)								
V1	29	28(97)	0	1(3)	31	31(100)	0	0
V2	28	28(100)	0	0	30	30(100)	0	0
V3	29	28(97)	0	1(3)	30	30(100)	0	0
10. I should not exercise if I have bronchiectasis. (F)								
V1	29	24(83)	0	5(17)	31	27(87)	1(3)	3(10)
V2	28	23(82)	2(7)	3(11)	30	29(97)	0	1(3)
V3	29	27(93)	2(7)	0	30	29(97)	0	1(3)
11. Patients with bronchiectasis sometimes cough up blood when they have a chest infection. (T)								
V1	29	14(48)	5(17)	10(34)	31	18(58)	2(6)	11(35)
V2	28	14(50)	4(14)	10(36)	30	30(100)	0	0
V3	29	16(55)	4(14)	9(31)	30	25(83)	0	5(17)

Appendix 33 Postal questionnaire question responses

	n	Control group n and (%)				n	Intervention group n and (%)			
Question		Once a day	Once a week	Once a month	Not at all		Once a day	Once a week	Once a month	Not at all
I have used the information provided										
P1	22	0	3(14)	5(23)	14(64)	29	3(10)	13(45)	9(31)	4(14)
P2	26	1(4)	2(8)	4(15)	19(73)	28	0	6(21)	13(46)	9(32)
P3	29	0	2(7)	0	27(93)	31	2(6)	7(23)	15(48)	7(23)
I have shared the information with others close to me										
P1	23	0	3(13)	2(9)	18(78)	30	0	9(30)	11(37)	10(33)
P2	26	0	4(15)	4(15)	18(69)	28	0	5(18)	12(43)	11(39)
P3	28	0	3(11)	0	25(89)	31	1(3)	5(16)	12(39)	13(42)
I have looked up other information myself										
P1	17	0	3(18)	3(18)	11(65)	30	0	6(20)	12(40)	12(40)
P2	21	0	4(19)	4(19)	13(62)	28	0	3(11)	6(21)	19(68)
P3	23	0	0	11(48)	12(52)	31	0	5(16)	5(16)	21(68)

Symptom	n	Control group n and (%)			n	Intervention group n and (%)		
		Same	Better	Worse		Same	Better	Worse
								N/A
Cough	23		5(22)					
	P1	13(57)	4(15)	4(17)	30	18(60)	4(13)	4(13)
	P2	13(50)	4(14)	8(31)	28	14(50)	5(18)	6(21)
	P3	17(59)		7(24)	31	13(42)	5(16)	10(32)
Sputum	23	13(57)	5(22)	2(9)	30	14(47)	6(20)	8(27)
	P1	9(35)	2(8)	12(46)	28	8(29)	8(29)	11(39)
	P2	13(45)	4(14)	7(24)	31	12(39)	4(13)	14(45)
	P3							
Fatigue	22	15(68)	2(9)	4(18)	30	17(57)	1(3)	8(27)
	P1	9(36)	3(12)	12(48)	28	14(50)	5(18)	8(29)
	P2	18(62)	1(3)	7(24)	31	14(45)	2(6)	13(42)
	P3							
Breathlessness	23	17(74)	2(9)	2(9)	30	13(43)	4(13)	9(30)
	P1	13(50)	2(8)	9(35)	28	13(46)	7(25)	7(25)
	P2	19(66)	2(7)	5(17)	31	15(48)	1(3)	13(42)
	P3							
Sleep disturbance	23	10(43)	3(13)	6(26)	30	17(57)	2(7)	6(20)
	P1	11(44)	0	11(44)	28	16(57)	2(7)	5(18)
	P2	15(52)	1(3)	6(21)	31	14(45)	3(10)	7(23)
	P3							
Chest pain	23	3(13)	2(9)	2(9)	30	10(33)	5(17)	1(3)
	P1	5(20)	2(8)	3(12)	28	7(25)	7(25)	2(7)
	P2	6(21)	1(4)	4(14)	31	10(32)	3(10)	2(6)
	P3							

	n	Control group n and (%)					n	Intervention group n and (%)				
Question		0	1	2	3	4		0	1	2	3	4
Number of courses of extra antibiotics (or emergency packs used) for an exacerbation or infection												
P1	23	14(61)	6(26)	3(13)	0	0	28	19(68)	7(25)	1(4)	1(4)	0
P2	26	15(58)	6(23)	5(19)	0	0	27	21(78)	3(11)	2(7)	0	1(4)
P3	29	16(55)	9(31)	4(14)	0	0	31	19(61)	8(26)	4(13)	0	0
Number of times I have visited my GP about my bronchiectasis												
P1	23	20(87)	1(4)	1(4)	0	1(4)	29	27(93)	2(7)	0	0	0
P2	26	16(62)	8(31)	2(8)	0	0	27	25(93)	1(4)	1(4)	0	0
P3	29	20(69)	9(31)	4(14)	0	0	31	28(90)	2(7)	1(3)	0	0
Number of times I have had to go to hospital because of bronchiectasis (emergency visit or admission)												
P1	23	22(96)	0	1(4)	0	0	29	27(93)	2(7)	0	0	0
P2	24	23(96)	1(4)	0	0	0	27	27(100)	0	0	0	0
P3	29	27(93)	2(7)	0	0	0	31	30(97)	0	1(3)	0	0
Number of times I have contacted a member of the hospital team about my bronchiectasis												
P1	23	20(87)	0	2(9)	1(4)	0	29	23(79)	3(10)	2(7)	0	1(3)
P2	26	22(85)	2(8)	2(8)	0	0	27	26(96)	1(4)	0	0	0
P3	29	24(83)	1(3)	3(10)	1(3)	0	30	25(83)	4(13)	1(3)	0	0

Appendix 34 RSQ website question responses

	Numbers in intervention group completing question (n=31)	Agree n (%)	Neutral n (%)	Disagree n (%)
1. I used the website more than the overview booklet.				
V2	20	9(45)	5(25)	6(30)
V3	21	9(43)	7(33)	5(24)
2. The website was my preferred version of the information.				
V2	20	8(40)	5(25)	9(45)
V3	21	11(52)	4(19)	6(29)
3. It was easy to find the sections I wanted to look at.				
V2	20	19(95)	1(5)	0
V3	21	20(95)	0	1(5)
4. I only looked at certain sections.				
V2	20	14(70)	2(10)	4(20)
V3	21	5(24)	5(24)	11(52)
5. I looked at all of the website.				
V2	20	7(35)	7(35)	6(30)
V3	21	11(52)	5(24)	5(24)
6. The login procedure was easy to use.				
V2	20	18(90)	1(5)	1(5)
V3	21	18(86)	0	3(14)
7. I found the video clips helpful.				
V2	20	18(90)	1(5)	1(5)
V3	21	16(76)	2(10)	3(14)
8. I found the diagrams helpful.				
V2	20	18(90)	1(5)	1(5)
V3	21	18(86)	1(5)	2(10)
9. My partner/family/friend used the website				
V2	20	9(45)	2(10)	9(45)
V3	20	13(65)	1(5)	6(30)

Appendix 35 RSQ booklet question responses

	Numbers in intervention group completing the questionnaire (n=31)	Agree n (%)	Neutral n (%)	Disagree n (%)
1. I used the overview booklet more than the website.				
V2	28	17(61)	4(14)	7(25)
V3	24	13(54)	7(29)	4(17)
2. The overview booklet was my preferred version of the information.				
V2	28	14(50)	8(29)	6(21)
V3	24	12(50)	6(25)	6(25)
3. It was easy to find the sections I wanted to look at.				
V2	28	26(93)	1(4)	1(4)
V3	24	20(83)	2(8)	2(8)
4. I only looked at certain sections.				
V2	28	11(39)	5(18)	12(43)
V3	24	7(29)	6(25)	11(46)
5. I looked at the whole overview booklet.				
V2	28	22(79)	1(4)	5(18)
V3	23	18(78)	2(9)	3(13)
6. I found the diagrams helpful.				
V2	28	25(89)	3(11)	0
V3	22	17(77)	3(14)	2(9)
7. The text was easy to read.				
V2	28	27(96)	1(4)	0
V3	23	20(87)	1(4)	2(9)
8. My partner/family/friend used the overview booklet.				
V2	28	12(43)	5(18)	11(39)
V3	22	13(59)	1(5)	8(36)

References

- Abraham, C. and Michie, S. (2008) 'A taxonomy of behaviour change techniques used in interventions', *Health Psychology*, 27(3), pp. 379-387.
- Altman, D.G. (1985) 'Comparability of randomised groups', *The Statistician*, 34(1), pp. 125-136.
- Anderson, R. and Bury, M. (1988) *Living the chronic illness: the experiences of patients and their families*. London: Unwin Hyman.
- Angel (2015) *Bronchiectasis R Us*. Available at: <http://www.bronchiectasis.info/>.
- Audit Commission (1993) *What seems to be the matter: communication between hospital and patients*. London.
- Bandura, A. (1977) 'Self-efficacy: toward a unifying theory of behavioural change', *Psychological Review*, 84(2), pp. 191-215.
- Banfield, G. (2004) 'What's really wrong with ethnography?', *International Education Journal*, 4(4), pp. 53-63.
- Becker, M.H. (1990) 'Theoretical models of adherence and strategies for improving adherence', in Shumaker, S.A. (ed.) *The handbook of health behaviour change*. New York: Springer Publishing Company, pp. 5-43.
- Bibby, S., Milne, R. and Beasley, R. (2015) 'Hospital admissions for non-cystic fibrosis bronchiectasis in New Zealand.', *New Zealand Medical Journal*, 128(1421), pp. 30-8.
- Bischoff, E., Akkermans, R., Bourbeau, J., van Weel, C., Vercoulen, J. and Schermer, T. (2012) 'Comprehensive self-management and routine monitoring in chronic obstructive pulmonary disease patients in general practice: randomised controlled trial', *BMJ*, 345, p. 14.
- Bland, J.M. and Altman, D.G. (2011) 'Comparisons within randomised groups can be very misleading.', *BMJ*, 342, p. d561.
- Bodenheimer, T., Lorig, K., Holman, H. and Grumbach, K. (2002) 'Patient self-management of disease in primary care', *JAMA*, 288(19), pp. 2469-75.
- Boussoffara, L., Boudawara, N., Gharsallaoui, Z., Sakka, M. and Knani, J. (2014) 'Anxiety-depressive disorders and bronchiectasis.', *Rev Mal Respir*, 31(3), pp. 230-236.
- Braun, V. and Clarke, V. (2006) 'Using thematic analysis in psychology', *Qualitative Research in Psychology*, 3(2), pp. 77-101.
- British Lung Foundation (2012) 'What should I expect from managing flare-ups of my COPD? A guide for people with breathing problems in England.'
- British Lung Foundation (2017) *Breathe Easy Support Groups*. Available at: <https://www.blf.org.uk/support-for-you/breathe-easy>.
- Bronchiectasis Quality Standards Working Group (2012) 'Quality standards for clinically significant bronchiectasis in adults', *British Thoracic Society Reports*, 4(1).
- Browne, R.H. (1995) 'On the use of a pilot sample for sample size determination.', *Statistics in Medicine*, 14, pp. 1933-1940.
- Bugge, C., Williams, B., Hagen, S., Logan, J., Glazener, C., Pringle, S. and Sinclair, L. (2013) 'A process for Decision-making after Pilot and feasibility Trials (ADePT): development following a feasibility study of a complex intervention for pelvic organ prolapse.', *Trials*, 14, p. 353.
- Bunker, T.D. (1983) 'An information leaflet for surgical patients', *Annals of the Royal College of Surgeons of England*, 65(4), pp. 242-3.
- Bury, M. (1982) 'Chronic illness as a biographical disruption.', *Sociology of Health and Illness*, 4(2), pp. 167-182.

Bury, M. (1991) 'The sociology of chronic illness: a review of research and prospects.', *Sociology of Health and Illness*, 13(4), pp. 451-468.

Campbell, M.J., Fitzpatrick, R., Haines, A., Kinmonth, A.L., Sandercock, P., Spiegelhalter, D. and Tyrer, P. (2000) 'Framework for the design and evaluation of complex interventions to improve health. ', *British Medical Journal*, 321, pp. 694-696.

Carey, M., Jefford, M., Schofield, P., Kelly, S., Krishnasamy, M. and Aranda, S. (2006) 'Development and evaluation of an audiovisual information resource to promote self-management of chemotherapy side-effects.', *Support Care Cancer* 14, pp. 361-368.

Carey, M., Schofield, P., Jefford, M., Krishnasamy, M. and Aranda, S. (2007) 'The development of audio-visual materials to prepare patients for medical procedures: an oncology application.', *European Journal of Cancer Care*, 16, pp. 417-423.

Case, D.O., Andrews, J.E., Johnson, J.D. and Allard, S.L. (2005) 'Avoiding versus seeking: the relationship of information seeking to avoidance, blunting, coping, dissonance and related concepts.', *Journal of the Medical Library Association.*, 93(3), pp. 353-62.

Catania, J.A., Kegeles, S.M. and Coates, T.J. (1990) 'Towards an understanding of risk behaviour: an AIDS risk reduction model (ARRM).', *Health Education Quarterly*, 17(1), pp. 53-72.

Chalmers, J.D., Goeminne, P., Alberti, S., McDonnell, M.J., Lonni, S., Davidson, J., Poppelwell, L., Salih, W., Pesci, A., Dupont, L.J., Fardon, T., De Soyza, A. and Hill, A.T. (2014) 'The bronchiectasis severity index. An international derivation and validation study.', *American Journal of Respiratory and Critical Care Medicine*, 189(5), pp. 576-585.

Charmaz, K. (1983) 'Loss of self: a fundamental form of suffering in the chronically ill.', *Sociology of Health and Illness*, 5(168-195).

Charmaz, K. (1995) 'The body, identity and self: adapting to impairment.', *The Sociological Quarterly*, 34(4), pp. 657-680.

Corbin, J. and Strauss, A. (1985) 'Managing chronic illness at home: three lines of work.', *Qualitative Sociology*, 8(3), pp. 224-247.

Corbin, J. and Strauss, A. (1987) 'Accompaniments of chronic illness changes in body, self, biography and biographical time.', *Research in the Sociology of Health Care*, 6, pp. 249-281.

Cotten, S.R. and Gupta, S.S. (2004) 'Characteristics of online and offline health information seekers and factors that discriminate between them.', *Social Science and Medicine*, 59, pp. 1795-1806.

Craig, P., Dieppe, P., Macintyre, S., Michie, S. and Nazareth, I. (2008) 'Developing and evaluating complex interventions: the new Medical Research Council guidance.', *British Medical Journal*, 337, p. a1655.

Cresswell, J.W. and Plano-Clark, V. (2007) *Designing and conducting mixed methods research*. Thousand Oaks, CA.: Sage.

Cresswell, J.W., Plano-Clark, V., Gutmann, M.L. and Hanson, W.E. (2003) 'Advanced mixed methods research designs.', in Tashakkori, A. and Teddlie, C. (eds.) *Handbook of Mixed methods in Social and Behavioural Research*. Thousand Oaks, CA.: Sage, pp. 209-240.

Department of Health (2006) *Our health, our care, our say: a new direction for community services*.

Department of Health (2010) *Guidance for people who commission or produce Easy Read information - Revised edition 2010*. Department of Health.

Department of Health (2011) *The NHS Outcomes Framework 2012/13*.

Department of Health (2012) 'The power of information: putting all of us in control of the health and care information we need. '.

- Dingwall, R. (1976) *Aspects of Illness*. London: Martin Robertson.
- Eaton, S. (2016) 'Delivering person-centred care in long-term conditions.', *Future Hospital Journal*, 3(2), pp. 128-131.
- Eaton, S., Roberts, S. and Turner, B. (2015) 'Delivering person centred care in long term conditions.', *BMJ*, 350, p. h181.
- Edwards, K. and Singh, S. (2012) 'The Bristol COPD knowledge questionnaire (BCKQ): assessing the knowledge of healthcare professionals involved in the delivery of COPD services.', *Thorax*, 67(Suppl 2), p. P235.
- Eldridge, S.M., Chan, C.L., Campbell, M.J., Bond, C.M., Hopewell, S., Thabane, L., Lancaster, G. and On behalf of the PAFS consensus group (2016) 'CONSORT 2010 statement: extension to randomised pilot and feasibility trials.', *BMJ*, 355, p. i5239.
- Epping-Jordan, J.E., Pruitt, S.D., Bengoa, R. and Wagner, E.H. (2004) 'Improving the quality of health care for chronic conditions', *Qual Saf Health Care*, 13, pp. 299-305.
- Faircloth, C.A., Boylstein, C., Rittman, M., Young, M.E. and Gubrium, J. (2004) 'Sudden illness and biographical flow in narratives of stroke discovery', *Sociology of Health and Illness*, 26(2), pp. 242-261.
- Feilzer, M.Y. (2010) 'Doing Mixed Methods Research Pragmatically: Implications for the Rediscovery of Pragmatism as a Research Paradigm', *Journal of Mixed Methods Research*, 4(1), pp. 6-16.
- Fisher, J.D. and Fisher, W.A. (1992) 'Changing AIDS risk behavior.', *Psychological Bulletin*, 111, pp. 455-474.
- Fisk, J.D., Ritvo, P.G., Ross, L., Haase, D.A., Marrie, T.J. and Schlech, W.F. (1994) 'Measuring the functional impact of fatigue: initial validation of the fatigue impact scale.', *Clinical infectious diseases*, 18(Supplement 1), pp. S79-83.
- Gately, C., Rogers, A. and Sanders, C. (2007) 'Re-thinking the relationship between long-term condition self-management education and the utilisation of health services.', *Social Science and Medicine*, 65(5), pp. 934-945.
- Gatheral, T., Kumar, N., Sansom, B., Lai, D., Nair, A., Vlahos, I. and Baker, E.H. (2014) 'COPD-related bronchiectasis; independent impact on disease course and outcomes.', *COPD*, 11, pp. 605-614.
- George, C.F., Waters, W.E. and Nicholas, J.A. (1983) 'Prescription information leaflets: a pilot study in general practice', *British Medical Journal (Clinical Research Ed.)*, 287(6400), pp. 1193-6.
- Gibbs, G. (2007) *Analyzing qualitative data*. London: Sage.
- Gibson, P.G., Powell, H., Coughlan, J., Wilson, A.J., Hensley, M.J., Abramson, M., Bauman, A. and Walters, E.H. (2002a) 'Limited (information only) patient education programmes for adults with asthma.', *Cochrane database Sytematic Review*, (2), p. CD001005.
- Gibson, P.G., Powell, H., Wilson, A., Abramson, M.J., Haywood, P., Bauman, A., Hensley, M.J., Walters, E.H. and Roberts, J.L. (2002b) 'Self-management education and regular practitioner review for adults with asthma.', *Cochrane database of Sytematic Reviews*, (3).
- Giddens, A. (1979) *Central problems in social theory*. London: Macmillan.
- Glaser, B. (1978) *Theoretical sensitivity: Advances in grounded theory*. Mill Valley, CA.: The Sociology Press.
- Glaser, B. and Strauss, A. (1967) *The discovery of grounded theory: startegies for qualitative research*. Chicago: Aldine.
- Goeminne, P.C., Nawrot, T.S., Ruttens, D., Seys, S. and Dupont, L.I. (2014) 'Mortality in non-cystic fibrosis bronchiectasis: a prospective cohort anlaysis.', *Respiratory Medicine*, 108, pp. 287-296.
- Goffman, E. (1963) *Stigma: notes on the management of a spoiled identity*. New Jersey: Prentice-Hall Inc.

Grbich, C. (1999) *Qualitative research in health: an introduction*. London: Sage.

Greco, M. (1993) 'Psychosomatic subjects and the duty to be well - personal agency within medical rationality.', *Economy and Society*, 22(3), pp. 357-372.

Green, J. and Hart, L. (1999) 'The impact of context on data', in Barbour, R. and Kitzinger, J. (eds.) *Developing focus group research: politics, theory and practice*. London: Sage, pp. 21-35.

Green, J. and Thorogood, N. (2009a) 'Analysing Qualitative Data.', in Silverman, D. (ed.) *Qualitative Methods for Health Research*. London: Sage, pp. 195-228.

Green, J. and Thorogood, N. (2009b) 'In-depth interviews', in *Qualitative methods for health research*

2nd edn. London: Sage.

Green, J. and Thorogood, N. (2009c) 'Qualitative methodology and Health Research.', in Silverman, D. (ed.) *Qualitative Methods for Health Research*. London: Sage, pp. 3-34.

Guest, G., Bunce, A. and Johnson, L. (2006) 'How many interviews are enough? An experiment with data saturation and variability.', *Field Methods*, 18, pp. 59-82.

Hammersley, M. (1992) *What's wrong with ethnography? - Methodological Explorations*. London: Routledge.

Hanson, B. (2008) 'Wither qualitative/quantitative? Grounds for methodological convergence.', *Quality and Quantity*, 42, pp. 97-111.

Harland, J. and Bath, P. (2008) 'Understanding the information behaviours of carers of people with dementia: A critical review of models from information science.', *Aging and Mental Health*, 12(4), pp. 467-477.

Haworth, C.S., Foweraker, J.E., Wilkinson, P., Kenyon, R.F. and Bilton, D. (2014) 'Inhaled colistin in patients with bronchiectasis and chronic pseudomonas infection.', *American Journal of Respiratory and Critical Care Medicine*, 189(8), pp. 975-982.

Health Experience Research Group (2013) 'healthtalkonline.org'. Available at: www.healthtalkonline.org.

Heijmans, M., de Ridder, D. and Bensing, J. (1999) 'Dissimilarity in patients' and spouses' representations of chronic illness: exploration of relations to patient adaptation.', *Psychology and Health*, 14(3), pp. 451-466.

Hennink, M., Kaiser, B. and Marconi, V. (2016) 'Code saturation versus meaning saturation: How many interviews are enough?', *Qualitative Health Research*, pp. 1-18.

Henwood, F., Wyatt, S., Hart, A. and Smith, J. (2003) 'Ignorance is bliss sometimes': constraints on the emergence of the 'informed patient' in the changing landscapes of health information.', *Sociology of Health and Illness*, 25(6), pp. 589-607.

Herdman, M., Gudex, C., Lloyd, A., Janssen, M., Kind, P., Parkin, D., Bonser, G. and Badia, X. (2011) 'Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L)', *Quality of Life Research*, 20(10), pp. 1727-36.

Hesse, B.W., Nelson, D.E., Kreps, G.L., Croyle, R.T., Arora, N.K., Rimer, B.K. and Viswanath, K. (2005) 'Trust and sources of health information the impact and findings of the internet and its implications for health care providers: findings from the first health information national trends survey.', *Arch Intern Med*, 165(22), pp. 2618-2624.

Hester, K.L.M. (2012) *Information and education provision for patients with bronchiectasis: a qualitative study*. MClinRes thesis. Newcastle University.

Hester, K.L.M., De Soyza, A. and Rapley, T. (2012a) 'Information and education needs of patients with bronchiectasis: a qualitative investigation. ', *Thorax*, 67(supplement 2), p. A141.

- Hester, K.L.M., Macfarlane, J.G., Tedd, H., Jary, H., McAlinden, P., Rostron, L., Small, T., Newton, J. and De Soyza, A. (2012b) 'Fatigue in bronchiectasis', *Quarterly Journal of Medicine*, 105(3), pp. 235-40.
- Hester, K.L.M., McAlinden, P. and De Soyza, A. (2011) 'Education and information for patients with bronchiectasis: what do patients want?', *European Respiratory Journal*, 38(supplement 35), p. P3622.
- Hester, K.L.M., Newton, J., Rapley, T. and De Soyza, A. (2016) 'Evaluation of a novel information resource for patients with bronchiectasis: study protocol for a randomised controlled trial.', *Trials*, 17, p. 210.
- Hibbard, J.H. and Greene, J. (2013) 'What the evidence shows about patient activation: better health outcomes and care experiences; fewer data on costs.', *Health Aff*, 32, pp. 207-14.
- Hill, A.T., Routh, C. and Welham, S. (2013) 'National BTS bronchiectasis audit 2012: is the quality standard being adhered to in adult secondary care?', *Thorax*, 0, pp. 1-3.
- Hoddinott, P. and Pill, R. (1997) 'Qualitative research interviewing by general practitioners. A personal view of the opportunities and pitfalls', *Family Practice*, 14(4), pp. 307-312.
- Hoddinott, P. and Pill, R. (1999) 'Qualitative study of decisions about infant feeding among women in east end of London', *British Medical Journal*, 318, pp. 30-34.
- Humphreys, K., Maisel, N.C., Blodgett, J.C., Fuh, I.L. and Finney, J.W. (2013) 'Extent and reporting of patient non-enrollment in influential randomized clinical trials, 2002-2010.', *JAMA Intern Med*, 173(11), pp. 1029-1031.
- Hurst, J.R., Elborn, J.S. and De Soyza, A. (2015) 'COPD-bronchiectasis overlap syndrome', *European Respiratory Journal*, 45, pp. 310-313.
- ISRCTN Registry (2015) *Evaluation of Bronchiectasis Empowerment Tool (BET)*. Available at: <http://www.isrctn.com/ISRCTN18400127?q=&filters=conditionCategory:Respiratory,trialStatus:Completed&sort=&offset=26&totalResults=574&page=1&pageSize=100&searchType=basic-search>.
- Johnson, R.B. and Onwuegbuzie, A.J. (2004) 'Mixed Methods Research: A Research Paradigm Whose Time Has Come', *Educational Researcher*, 33(7), pp. 14-26.
- Kelly, C., Spencer, S., Grundy, S., Lynes, D. and Evans, D.J.W. (2017) 'Self-management for non-cystic fibrosis bronchiectasis.', *Cochrane Database of Systematic Reviews*, (1).
- Kelly, M.G., Murphy, S. and Elborn, J.S. (2003) 'Bronchiectasis in secondary care: a comprehensive profile of a neglected disease', *European Journal of Internal Medicine*, 14(8), pp. 488-492.
- Kennedy, A., Reeves, D., Lee, V., Middleton, E., Richardson, G., Gardner, C., Gately, C., Bower, P. and Rogers, A. (2007) 'The effectiveness and cost effectiveness of a national lay led self care support programme for patients with long-term conditions: a pragmatic randomised controlled trial.', *Journal of Epidemiology and Community Health*, 61(3), pp. 254-261.
- Kerr, C., Nixon, A. and Wild, D. (2010) 'Assessing and demonstrating data saturation in qualitative inquiry supporting patient-reported outcomes research.', *Expert Review of Pharmacoeconomics & Outcomes Research*, 10, pp. 269-281.
- King's College Hospital (2007) 'Understanding pulmonary rehabilitation' realtamedia. Youtube. Available at: <http://www.youtube.com/watch?v=3goKI9Vr8iw>.
- Koetsenruijter, J., van Lieshout, J., Lionis, C., Portillo, M.C., Vassilev, I., Todorova, E., Foss, C., Serrano Gil, M., Knutsen, I., Angelaki, A., Mujika, A., Roukova, P., Kennedy, A., Rogers, A. and Wensing, M. (2015) 'Social Support and Health in Diabetes Patients: An Observational Study in Six European Countries in an Era of Austerity', *PLoS ONE*, 10(8), p. e0135079.

- Koetsenruijter, J., van Lieshout, J., Vassilev, I., Portillo, M.C., Serrano, M., Knutsen, I., Roukova, P., Lionis, C., Todorova, E., Foss, C., Rogers, A. and Wensing, M. (2014) 'Social support systems as determinants of self-management and quality of life of people with diabetes across Europe: study protocol for an observational study.', *Health and Quality of Life Outcomes*, 12(29).
- Kronzer, V.L. (2016) 'Screening for health literacy is not the answer.', *BMJ*, 354, p. i3699.
- Kvale, S. (2007) *Doing interviews*. London: Sage.
- Lambert, S.D. and Loiselle, C.G. (2007) 'Health information--seeking behaviour', *Qual Health Res*, 17, pp. 1006-1019.
- Lancaster, G., Dodd, S. and Williamson, P. (2004) 'Design and analysis of pilot studies: recommendations for good practice.', *Journal of Evaluation in Clinical Practice*, 10(2), pp. 307-312.
- Lavery, K., O'Neill, B., Elborn, J.S., Reilly, J. and Bradley, J.M. (2007) 'Self-management in bronchiectasis: the patients' perspective', *European Respiratory Journal*, 29(3), pp. 541-7.
- Lavery, K., O'Neill, B., Parker, M., Elborn, J.S. and Bradley, J.M. (2011) 'Expert patient self-management program versus usual care in bronchiectasis: a randomized controlled trial.', *Arch Phys Med Rehabil*, 92, pp. 1194-1201.
- Lee, R.P., Thompson, B., Whybrow, P. and Rapley, T. (2016) 'Talking about looking: three approaches to interviewing carers of people with rheumatoid arthritis about information seeking.', *Qualitative Health Research*, 26(9), pp. 1229-1239.
- Leydon, G.M., Boulton, M., Moynihan, C., Jones, A., Boudioni, M. and McPherson, K. (2000) 'Cancer patients' information needs and information seeking behaviour: in depth interview study.', *BMJ*, 320(7239), pp. 909-13.
- Lindsay, S. and Vrijhoef, H.J.M. (2009) 'A sociological focus on 'expert patients'', *Health Sociology Review*, 18(2), pp. 139-144.
- Loebinger, M.R., Wells, A.U., Hansell, D.M., Chinyanganya, N., Dveraj, A., Meister, M. and Wilson, R. (2009) 'Mortality in bronchiectasis: a long-term study assessing the factors influencing survival', *European Respiratory Journal*, 34(4), pp. 843-9.
- Lorig, K. and Holman, H. (1993) 'Arthritis self-management studies: a twelve-year review', *Health Educ Q*, 20(1), pp. 17-28.
- Lorig, K., Lubeck, D., Kraines, R.G., Seleznick, M. and Holman, H.R. (1985) 'Outcomes of self-help education for patients with arthritis', *Arthritis and Rheumatism*, 28(6), pp. 680-5.
- Lorig, K.R., Ritter, P., Stewart, A.L., Sobel, D.S., Brown, B.W.J., Bandura, A., Gonzalez, V.M., Laurent, D.D. and Holman, H.R. (2001) 'Chronic disease self-management program: 2-year health status and health care utilization outcomes.', *Medical Care*, 39(11), pp. 1217-23.
- Macfarlane, J.G., Tedd, H., McAlinden, P., Small, T., Rostron, L., Newton, J. and De Soya, A. (2010) 'Fatigue in bronchiectasis: its relationship to pseudomonas colonisation, dyspnoea and airflow obstruction', *Thorax*, 65, p. A60.
- Maslow, A.H. (1963) 'The need to know and the fear of knowing.', *J Gen Psychol*, 68, pp. 111-25.
- Maxwell, J.A. (2012) *A Realist Approach for Qualitative Research*. Sage.
- McCullough, A.R., Ryan, C., O'Neill, B., Bradley, J.M., Elborn, J.S. and Hughes, C.M. (2015a) 'Defining the content and delivery of an intervention to change adherence to treatment in bronchiectasis (CAN-BE): a qualitative approach incorporating the Theoretical Domains Framework, behavioural change techniques and stakeholder expert panels.', *BMC Health Services Research*, 15(1), p. 342.

- McCullough, A.R., Tunney, M.M., Elborn, J.S., Bradley, J.M. and Hughes, C.M. (2015b) 'Predictors of adherence to treatment in bronchiectasis.', *Respiratory Medicine*, 109(7), pp. 838-845.
- McCullough, A.R., Tunney, M.M., Quittner, A.L., Elborn, J.S., Bradley, J.M. and Hughes, C.M. (2014) 'Treatment adherence and health outcomes in patients with bronchiectasis.', *BMC Pulmonary Medicine*, 14(107).
- McDonnell, M.J., Jary, H., Perry, A., MacFarlane, J.G., Hester, K.L.M., Small, T., Molyneux, C., Perry, J.D., Walton, K.E. and De Soyza, A. (2015) 'Non cystic fibrosis bronchiectasis: A longitudinal retrospective observational cohort study of Pseudomonas persistence and resistance', *Respiratory Medicine*, 109(6), pp. 716-726.
- McGill University Health Centre and Quebec Asthma and COPD Network (2013) *Living well with COPD a plan of action for life*. Available at: <http://www.livingwellwithcopd.com/> (Accessed: 09/04/2013).
- McNair, R., Taft, A. and Hegarty, K. (2008) 'Using reflexivity to enhance in-depth interviewing skills for the clinician researcher', *BMC Medical Research Methodology*, 8, p. 73.
- McShane, L., Greenwell, K., Corbett, S. and Walker, R. (2014) 'Developing a long term condition's information service in collaboration with third sector organisations.', *Health Info Libr J*, 31(2), pp. 106-15.
- Medical Research Council (2000) *A framework for the development and evaluation of RCTs for complex interventions to improve health*. London: Medical Research Council.
- Medical Research Council (2006) *Developing and evaluating complex interventions: new guidance*. London.
- Michie, S., Johnston, M., Abraham, C., Lawton, R., Parker, D. and Walker, A. (2005) 'Making psychological theory useful for implementing evidence based practice: a consensus approach on behalf on the "Psychological Theory" Group.', *Qual Saf Health Care*, 14, pp. 26-33.
- Mitchell-Wagg, K., Warrington, V., Apps, L., Sewell, L., Bankart, J., Steiner, M., Morgan, M. and Singh, S. (2012) 'A self-management program of activity coping and exercise (SPACE) for COPD: results from a randomised controlled trial.', *Thorax*, 67 supplement II, p. A25.
- Mitchell, K.E., Johnson-Warrington, V., Apps, L.D., Bankart, J., Sewell, L., Williams, J.E., Rees, K., Jolly, K., Steiner, M., Morgan, M. and Singh, S. (2014) 'A self-management programme for COPD: a randomised controlled trial.', *European Respiratory Journal*, 44(6), pp. 1538-1547.
- Moher, D., Hopewell, S., Schulz, K.F., Montori, V., Gotzsche, P.C., Devereaux, P.J., Elbourne, D., Egger, M. and Altman, D.G. (2010) 'CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials', *BMJ*, 340, p. c869.
- Monninkhof, E.E.M., Van der Valk, P., Van der Palen, J., Van Herwaarden, C., Partridge, M.R. and Zielhuis, G. (2003) 'Self-management education for patients with chronic obstructive pulmonary disease: a systematic review', *Thorax*, 58, pp. 394-398.
- Morse, J. (1995) 'The significance of saturation.', *Qualitative Health Research*, 5, pp. 147-149.
- Nakash, R.A., Hutton, J.L., Jorstad-Stein, E.C., Gates, S. and Lamb, S.E. (2006) 'Maximising response to postal questionnaires - A systematic review of randomised trials in health research.', *BMC Medical Research Methodology*, 6(5).
- Namey, E., Guest, G., McKenna, K. and Chen, M. (2016) 'Evaluating bang for the buck: A cost-effectiveness comparison between individual interviews and focus

groups based on thematic saturation levels.', *American Journal of Evaluation*, 37, pp. 425-440.

Navaratman, V., Millet, E.R.C., Hurst, J.R., Thomas, S.L., Smeeth, L., Hubbard, R., Brown, J. and Quint, J.K. (2017) 'Bronchiectasis and the risk of cardiovascular disease: a population-based study.', *Thorax*, 72, pp. 161-166.

Nettleton, S., Burrows, R. and O'Malley, L. (2005) 'The mundane realities of the everyday lay use of the internet for health and their consequences for media convergence.', *Sociology of Health and Illness*, 27(7), pp. 972-992.

The NHS Plan (2000).

O'Brien, C., Guest, P.J. and Hill, S.L. (2000) 'Physiological and radiological characterisation of patients diagnosed with chronic obstructive pulmonary disease in primary care.', *Thorax*, 55, pp. 635-642.

O'Cathain, A. (2009) 'Mixed methods research in the health sciences: A quiet revolution.', *Journal of Mixed Methods Research*, 3(1), pp. 3-6.

O'Cathain, A., Murphy, E. and Nicholl, J. (2010) 'Three techniques for integrating data in mixed methods studies.', *BMJ*, 341, p. c4587.

O'Cathain, A. and Thomas, K. (2006) 'Combining qualitative and quantitative methods.', in Pope, C. and Mays, N. (eds.) *Qualitative research in health care*. 3rd edn. Oxford, UK: Blackwell, pp. 102-111.

O'Leary, C.J., Wilson, C.B., Hansell, D.M., Cole, P.J., Wilson, R. and Jones, P.W. (2002) 'Relationship between psychological well-being and lung health status in patients with bronchiectasis.', *Respiratory Medicine*, 96(9), pp. 686-92.

Office for National Statistics (2004) *Mortality Statistics by cause*. London: The Stationary Office.

Ohlen, J., Balneaves, L.G., Bottorff, J.L. and Brazier, A.S. (2006) 'The influence of significant others in complementary and alternative medicine decisions by cancer patients.', *Social Science and Medicine*, 63(6), pp. 1625-36.

Olveira, C., Olveira, G., Gaspar, I., Dorado, A., Soriguer, F., Quittner, A.L. and Espildora, F. (2013) 'Depression and anxiety symptoms in bronchiectasis: associations with health-related quality of life.', *Qual Life Res*, 22(3), pp. 597-605.

Ozgun Niksarlioglu, E.Y., Ozkan, G., Gunluoglu, G., Atilla Uysal, M., Gul, S., Kilic, L., Yeter, A. and Camsarij, G. (2016) 'Factors related to depression and anxiety in adults with bronchiectasis.', *Neuropsychiatric Disease and Treatment*, 12, pp. 3005-3010.

Panagioti, M., Richardson, G., Small, N., Murray, E., Rogers, A., Kennedy, A., Newman, S. and Bower, P. (2014) 'Self-management support interventions to reduce health care utilisation without compromising outcomes: a systematic review and meta-analysis.', *BMC Health Services Research*, 14(356).

Partridge, M.R. and Hill, S.R. (2000) 'Enhancing care for people with asthma: the role of communication, education, training and self-management. ', *European Respiratory Journal*, 16(2), pp. 333-48.

Pasteur, M.C., Bilton, D. and Hill, A.T. (2010) 'British Thoracic Society guideline for non-CF bronchiectasis', *Thorax*, 65 (Suppl 1), pp. i1-58.

Pasteur, M.C., Helliwell, S.M., Houghton, S.J., Webb, S.C., Foweraker, J.E., Coulden, R.A., Flower, C.D., Bilton, D. and Keogan, M.T. (2000) 'An investigation into causative factors in patients with bronchiectasis', *American Journal of Respiratory and Critical Care Medicine*, 162(4 Pt 1), pp. 1277-84.

Patel, I.S., Vlahos, I., Wilkinson, T.M., Lloyd-Owen, S.J., Donaldson, G.C., Wilks, M., Reznick, R.H. and Wedzicha, J.A. (2004) 'Bronchiectasis, exacerbation indices, and inflammation in chronic obstructive pulmonary disease.', *American Journal of Respiratory and Critical Care Medicine*, 170(4), pp. 400-7.

Patient Information Forum (2013) 'Making the case for information'.

- Patton, M.Q. (1990) *Qualitative evaluation and research methods (2nd Ed.)*. Newbury Park, CA.: Sage Publications Inc.
- Pearce, R.M., Jones, D.E. and Newton, J.L. (2011) 'Development of an evidence-based patient information medium:empowering newly diagnosed patients with primary biliary cirrhosis.', *J Vis Commun Med.*, 34(1), pp. 4-13.
- Plaza, V., Peiro, M., Torrejon, M., Fletcher, M., Lopez-Vina, A., Ignacio, J.M., Quintano, J.A., Bardagi, S., Gich, I. and Group., P.S. (2015) 'A repeated short educational intervention improves asthma control and quality of life.', *European Respiratory Journal*, 46(5), pp. 1298-307.
- Polit, D.F. (2011) 'Blinding during the analysis of research data.', *International Journal of Nursing Studies*, 48(5), pp. 636-41.
- Pound, P., Gompertz, P. and Ebrahim, S. (1998) 'Illness in the context of older age: the case of stroke.', *Sociology of Health and Illness*, 20(4), pp. 489-506.
- Quint, J.K., Millet, E.R.C., Joshi, M., Navaratman, V., Thomas, S.L., Hurst, J.R., Smeeth, L. and Brown, J.S. (2016) 'Changes in the incidence, prevalence and mortality of bronchiectasis in the UK from 2004-2013: a population based cohort study.', *European Respiratory Journal*, 47(1), pp. 186-93.
- Quittner, A.L., O'Donnell, A.E., Salathe, M.A., Lewis, S.A., Li, X., Montgomery, A.B., O'Riordan, T.G. and Barker, A.F. (2014) 'Quality of Life Questionnaire- Bronchiectasis: final psychometric analyses and determination of minimal important difference scores.', *Thorax*, 0, pp. 1-9.
- Rapley, T. (2008) 'Distributed decision making: the anatomy of decisions-in-action.', *Sociology of Health and Illness*, 30(3), pp. 429-444.
- Rapley, T. (2010) 'Some Pragmatics of Data Analysis', in Silverman, D. (ed.) *Qualitative Reaserch: Theory, Method and Practice*. . London: Sage.
- Rapley, T. (2013) 'Sampling Strategies in Qualitative Research.', in Flick, U. (ed.) *The SAGE Handbook of Qualitative Data Analysis*. London: Sage.
- Raynor, K.T. (2012) 'Health literacy: is it time to shift our focus from patient to provider?', *BMJ*, 344, p. e2188.
- Reeves, D., Blickem, C., Vassilev, I., Brooks, H., Kennedy, A., Richardson, G. and Rogers, A. (2014) 'The contribution of social networks to the health and management of patients with long-term conditions: a longitudinal study.', *PLoS ONE*, 9(6), p. e98340.
- Richards, H. and Emslie, C. (2000) 'The 'doctor' or the 'girl from the university'? Considering the influence of professional roles on qualitative interviewing', *Family Practice*, 17(1), pp. 71-75.
- Ringshausen, F.C., de Roux, A., Diel, R., Hohmann, D., Welte, T. and Wademacher, J. (2015) 'Bronchiectasis in Germany: a population-based estimation of disease prevalence.', *European Respiratory Journal*, 46, pp. 1805-1807.
- Roberts, C. and Torgerson, D.J. (1999) 'Baseline imbalance in randomised controlled trials.', *BMJ*, 319, p. 185.
- Roberts, H.J. and Hubbard, R. (2010) 'Trends in bronchiectasis mortality in England and Wales', *Respiratory Medicine*, 104(7), pp. 981-5.
- Rokeach, M. (1960) *The open and closed mind*. New York, NY: Basic Books.
- Sandelowski, M. (1995) 'Triangles and crystals: on the geometry of qualitative research.', *Res Nurs Health*, 18, pp. 569-74.
- Sanders, C., Donovan, J. and Dieppe, P. (2002) 'The significance and consequences of having painful and disabled joints in older age: co-existing accounts of normal and disrupted biographies.', *Sociology of Health and Illness*, 24(2), pp. 227-253.
- Savage, E., Beirne, P.V., Ni Chroinin, M., Duff, A., Fitzgerald, T. and Farrell, D. (2011) 'Self-management education for cystic fibrosis (Review)', *The Cochrane Library*, (7).

- Schofield, P., Jefford, M., Carey, M., Thomson, K., Evans, M., Baravelli, C. and Aranda, S. (2008) 'Preparing patients for threatening medical treatments: effects of a chemotherapy educational DVD on anxiety, unmet needs, and self-efficacy.', *Support Care Cancer* 16, pp. 37-45.
- Sechrest, L. and Sidani, S. (1995) 'Quantitative and qualitative methods: Is there an alternative?', *Evaluation and Programme Planning*, 18(1), pp. 77-87.
- Seitz, A.E., Olivier, K.N., Adjemian, J., Holland, S.M. and Prevots, R. (2012) 'Trends in bronchiectasis among medicare beneficiaries in the United States, 2000 to 2007.', *Chest*, 142, pp. 432-439.
- Seitz, A.E., Olivier, K.N., Steiner, C.A., Montes de Oca, R., Holland, S.M. and Prevots, D.R. (2010) 'Trends and burden of bronchiectasis-associated hospitalizations in the United States, 1993-2006.', *Chest*, 138(4), pp. 944-9.
- Shahab, L., Jarvis, M.J., Britton, J. and West, R. (2006) 'Prevalence, diagnosis and relation to tobacco dependence of chronic obstructive pulmonary disease in a nationally representative population sample', *Thorax*, 61(12), pp. 1043-7.
- Shoemark, A., Ozerovitch, L. and Wilson, R. (2007) 'Aetiology in adult patients with bronchiectasis', *Respiratory Medicine*, 101(6), pp. 1163-70.
- Spinou, A., Fragkos, K.C., Lee, K.K., Elston, C., Siegert, R.J., Loebinger, M.R., Wilson, R., Garrod, R. and Birring, S.S. (2016) 'The validity of health-related quality of life questionnaires in bronchiectasis: a systematic review and meta-analysis.', *BMJ*, 71, pp. 683-694.
- Strauss, A. and Glaser, B. (1975) *Chronic illness and the quality of life*. St Louis, Toronto: Mosby.
- Takakura, S., Hasegawa, T. and Ishihara, K. (1998) 'Assessment of patients' understanding of their asthmatic condition established in an outpatient clinic.', *European Respiratory Journal*, 12(supplement 29), p. 24S.
- Taylor, D. and Bury, M. (2007) 'Chronic illness, expert patients and care transition.', *Sociology of Health and Illness*, 29(1), pp. 27-45.
- Teddlie, C. and Tashakkori, A. (2003) 'Major issues and controversies in the use of mixed methods in the social and behavioural sciences.', in Tashakkori, A. and Teddlie, C. (eds.) *Handbook of mixed methods in social and behavioural research*. Thousand Oaks, CA.: Sage, pp. 3-50.
- Thabane, L., Ma, J., Chu, R., Cheng, J., Ismaila, A., Rios, L.P., Robson, R., Thabane, M., Giangregorio, L. and Goldsmith, C.H. (2010) 'A tutorial on pilot studies: the what, why and how.', *BMC Medical Research Methodology*, 10, p. 1.
- The Department of Health (2003) *Toolkit for producing patient information*.
- Toms, J. and Harrison, K. (2002) 'Living with chronic lung disease and the effect of pulmonary rehabilitation.', *Physiotherapy*, 88(10), pp. 605-619.
- Vassilev, I., Rogers, A., Kennedy, A. and Koetsenruijter, J. (2014) 'The influence of social networks on self-management support: a metasynthesis.', *BMC Public Health*, 14(719).
- Vickers, A.J. and Altman, D.G. (2001) 'Analysing controlled trials with baseline and follow up measurements.', *BMJ*, 323.
- Wanless, D. (2004) *Securing good health for the whole population*. HMSO.
- White, R., Walker, P., Roberts, S., Kalisky, S. and White, P. (2006) 'Bristol COPD Knowledge Questionnaire (BCKQ): testing what we teach patients about COPD.', *Chronic Respiratory Disease*, 3, pp. 123-131.
- Williams, B., Corlett, J., Dowell, J.S., Coyle, J. and Mukhopadhyay, S. (2009) '"I've never not had it so I don't really know what it's like not to": Nondifference and biographical disruption among children and young people with cystic fibrosis.', *Qual Health Res*, 19(10), pp. 1443-1455.

- Williams, G. (1984) 'The genesis of chronic illness: narrative re-construction.', *Sociology of Health and Illness*, 6(2), pp. 175-200.
- Williams, S.J. (1989) 'Chronic respiratory illness and disability: a critical review of the psychosocial literature.', *Social Science and Medicine*, 28, pp. 791-803.
- Williams, S.J. and Bury, M.R. (1989) 'Impairment disability and handicap in chronic respiratory disease.', *Social Science and Medicine*, 29, pp. 609-616.
- Wilson, C.B., Jones, P.W., O'Leary, C.J., Cole, P.J. and Wilson, R. (1997) 'Validation of the St George's Respiratory Questionnaire in Bronchiectasis.', *American Journal of Respiratory and Critical Care Medicine*, 156(2), pp. 536-541.
- Zigmond, A.S. and Snaith, R.P. (1983) 'The Hospital Anxiety and Depression Scale', *Acta Psychiatrica Scandinavica*, 67(6), pp. 361-370.
- Zulman, D., Kirch, M., Zheng, K. and An, L.C. (2011) 'Trust in the internet as a health resource among older adults: analysis of data from a nationally representative survey.', *Journal of Medical Internet Research*, 13(1), p. e19.