Development and feasibility evaluation of a repetitive functional task practice (RFTP) programme for upper limb recovery early after stroke.

A thesis submitted for the degree of Doctor of Philosophy

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Abstract

Introduction:

Loss of arm function is common after stroke. Systematic reviews suggest upper limb recovery following stroke may be improved by repetitive functional task practice (RFTP), but results fell short of statistical significance.

Methods:

Development and evaluation of an intervention to improve upper limb function post-stroke following the MRC Framework:

1. Development of an upper limb RFTP programme for patients with acute stroke based on published RCTs, motor learning theory, clinical expertise and stakeholder feedback.

2. Delivery of the RFTP programme to seven stroke patients by a research physiotherapist. Adaptations following feedback from patients and therapists.

3. A multicentre feasibility randomised controlled trial.

Results:

An evidence-based upper limb RFTP programme was developed, tested and refined. It commenced within 14 days of acute stroke and consisted of functional goal setting followed by independent activity practice (total 80 daily repetitions), for up to four weeks with twice weekly therapist reviews.

In the multicentre feasibility RCT, 55 eligible patients were identified from three study sites representing 4-6% of patients screened. Twenty four participants were randomised to receive the RFTP programme delivered by NHS therapists + usual care (intervention group) or usual care (control group). Two sites met the recruitment target of 1-2 per month. The programme was delivered as intended at 2/3 sites. The median number of therapist sessions delivered was 6 [IQR 3-8]. Participants recorded a median 80 daily repetitions [IQR 39-80]. Outcome assessments were undertaken for 22/24 (92%) participants at 1 month and 20/24 (83%) at 3 months.

Conclusion:

A structured approach has been followed to develop and evaluate an upper limb RFTP programme which is acceptable to patients and NHS therapists. A multicentre

RCT to evaluate an upper limb RFTP programme is feasible, but this project identified issues which need to be addressed when designing a Phase III study.

Dedication

This thesis is dedicated to my brother Adam Vlatko Brkić who always believed in me and was the most courageous man I've ever met. I'll always look up to you and hope I've made you proud.

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I would like to thank the following people:

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Project participants: Thank you for taking part in this project during a difficult time in your lives.

Local NHS study site staff: Thank you to the study site Principal Investigators, NIHR Stroke Research Network staff, local study therapists and outcome assessors at all study sites.

The Stroke Association: Thank you for funding the project and allowing me to undertake the project as a PhD.

Dr Helen Bosomworth: Thank you for being a fantastic friend and for helping me wrestle the EndNote beast – we won in the end!

My parents: Thank you both for your limitless support and love. I could not have done this without you. Dad – thank you for being the project poster boy and 'model father', posing for endless pictures for study documents.

My friends: Thank you for supporting me, listening to endless 'thesis talk' and making me laugh, even during the hard times.

Thesis author responsibilities / contribution

This project was developed by Professor Helen Rodgers and co-investigators (Dr Lisa Shaw, Professor Frederike van Wijck, Dr Christopher Price, Professor Caroline Watkins, Professor Anne Forster and Professor Peter Langhorne) who secured a project grant from the Stroke Association to conduct this work.

I joined the team at the start of the project (September 2011), when I was seconded from my NHS position as a senior neurological physiotherapist to work on design and development of the RFTP programme. After commencing work on the project, I was offered the opportunity to undertake the project as a PhD and remain working on the project until its completion. The study stages were outlined by the study investigators. Some aspects of the RFTP programme were pre-specified in the project funding application and details are provided in Chapter 3. My contribution during each stage is explained further below.

Development of an upper limb RFTP programme

I was responsible for developing the RFTP programme with assistance from my supervisory team.

Delivery of the RFTP programme to stroke patients by a research physiotherapist and subsequent modification following feedback from patients and therapists

I prepared study documents and applications for Research Ethics Committee (REC) approval and local R&D approvals under the supervision of Professor Helen Rodgers and with assistance from Dr Lisa Shaw. I attended the REC meeting with Professor Rodgers. I was the local Principal Investigator for one of the study sites and the research physiotherapist who delivered the RFTP programme to seven patients with stroke. I performed the data analysis and modified the programme for use in the multicentre feasibility RCT.

Multicentre feasibility randomised controlled trial (known as the RAFTAS study)

Under the supervision of Professor Rodgers and Dr Lisa Shaw, I co-ordinated study set up which included preparation of study documents (e.g. Participant Information Sheet, consent forms) and applications for REC approval and local R&D approvals. I attended the REC meeting alone.

During the RAFTAS feasibility study, under the supervision of Professor Helen Rodgers and Dr Lisa Shaw I:

- Identified appropriate local NHS therapists at each study site who were suitable to work as local study therapists and negotiated with relevant local therapy managers.
- Acted in the role of local Principal Investigator for one of the study sites.
- Trained local study site staff including 8 local NIHR Stroke Research Network staff members (study screening and baseline assessment procedures), 7 local therapists (delivery of the RFTP programme and outcome assessments) and 6 usual post stroke rehabilitation staff (completion of usual post stroke rehabilitation data collection forms).
- Supported all local site staff and assisted with procedures at site when necessary.
- Conducted semi-structured interviews with participants who received the RFTP programme and local study therapists who delivered the RFTP programme.
- Completed and submitted annual reports to the study funder (the Stroke Association)
- Completed analysis of quantitative data (with guidance from Dr Richard Francis who has expertise in quantitative data analysis).
- Completed analysis of qualitative data (with advice from Professor Catherine Exley, Professor of Qualitative Health Research).
- Interpreted RAFTAS feasibility study results.

Mr Michael Adams (research support staff) transcribed the local study therapist and participant interviews and entered data onto the study database.

Publications and presentations

Conference oral presentations:

Title: A pilot randomised controlled trial of a repetitive functional task practice programme for patients with reduced upper limb function early after stroke

Organisation: The Society for Rehabilitation in Research

Venue: St. James' Park, Newcastle

Presentation Date: 09/06/2015

Conference poster presentations:

1. **Title:** Development of a repetitive functional task practice (RFTP) programme for upper limb recovery early after stroke (WIP)
   Organisation: The Society for Rehabilitation in Research
   Venue: East Midlands Conference Centre
   Presentation Date: 05/02/2013

2. **Title:** Repetitive arm functional tasks after stroke (RAFTAS) study
   Organisation: NIHR North East Stroke Research Network Conference
   Venue: The Civic Centre, Newcastle
   Presentation Date: 19/09/2013

3. **Title:** Repetitive arm functional tasks after stroke (RAFTAS) study
   Organisation: The UK Stroke Forum
   Venue: Harrogate International Centre, Harrogate
   Presentation Date: 04/12/2013

4. **Title:** Repetitive arm functional tasks after stroke (RAFTAS) study: Phase B
   Organisation: Joint NICR/IAH post-graduate research day
   Venue: Newcastle University
   Presentation Date: 07/03/2014

5. **Title:** Development of a Repetitive functional task practice (RFTP) programme for patients with upper limb impairment early after stroke

Organisation: Scottish Stroke Allied Health Professions Forum
Venue: Dewar's Conference Centre, Perth
Presentation Date: 12/06/2014

6. **Title:** Development of a repetitive functional task practice (RFTP) programme for patients with upper limb impairment early after stroke
Organisation: The Society for Rehabilitation in Research
Venue: Glasgow Caledonian University
Presentation Date: 10/06/2014

7. **Title:** A pilot randomised controlled trial of a repetitive functional task practice programme for patients with reduced upper limb function early after stroke
Organisation: European Congress of Neurorehabilitation
Venue: Hofburg Congress Center, Vienna, Austria
Presentation Date: 03/12/2015

Journal publications and submissions:

1. **L Brkic,** L Shaw, F van Wijck, C Price, C Watkins, A Forster, P Langhorne, H Rodgers. 2015. Development of a repetitive functional task practice (RFTP) programme for patients with upper limb impairment early after stroke. Proceedings of SRR, Clinical Rehabilitation, vol 29 (4) 394-412

2. **L Brkic,** L Shaw, F van Wijck, C Price, C Watkins, A Forster, P Langhorne, H Rodgers. 2015. A pilot randomised controlled trial of a repetitive functional task programme for patients with reduced upper limb function early after stroke. Proceedings of European Congress of Neurorehabilitation, Neurologie & Rehabilitation, Special issue 7.

3. **L Brkic,** L Shaw, F van Wijck, C Price, C Watkins, A Forster, P Langhorne, H Rodgers. 2016. Repetitive arm functional tasks after stroke (RAFTAS): a pilot randomised controlled trial. Pilot and Feasibility Studies, 2:50.

Invited oral presentation:

Title: Development and feasibility evaluation of a repetitive functional task practice (RFTP) programme for upper limb recovery early after stroke

Organisation: NIHR Clinical Research Network, North East Regional Rehabilitation Showcase

Venue: Research Beehive, Newcastle University

Presentation Date: 04/11/2014

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Chapter 1. Introduction

1.1 Overview of stroke

The World Health Organisation (WHO) defines stroke as “rapidly developing clinical signs of focal (or global) disturbance of cerebral function lasting more than 24 hours or leading to death, with no apparent cause other than of vascular origin”[1]. This definition includes neurological deficits caused by cerebral infarction, cerebral haemorrhage and subarachnoid haemorrhage [1].

Stroke is a worldwide major cause of death and disability with almost 17 million [2] people diagnosed with first ever stroke per year and 6.7 million deaths per year [3]. In the UK, stroke is the fourth most common cause of death in adults [4-6]; 152,000 people per year are diagnosed with stroke [7] and approximately 25% of strokes result in death within the first year [8-10]. There are 1.2 million stroke survivors in the UK [11, 12] and over half of all stroke survivors are disabled [11, 13], making stroke one of the largest causes of disability [11, 13].

Incidence of and mortality due to stroke are reducing [2], but owing to the ageing population, the burden of stroke (premature death, illness and disability) has been estimated to double worldwide by 2030 [2].

1.2 Consequences of stroke

Stroke can result in numerous and often complex impairments including; reduced motor control (reduced movement, muscle weakness and incoordination); sensory loss; impairments in vision, cognition, bladder and bowel control, swallowing and speech and language ability; depression; dementia; and emotionalism [14, 15]. Impairments can affect a person’s engagement in functional activities and participation in society [15] resulting in stroke being associated with a greater disability impact compared to other chronic conditions [13].

1.3 Upper limb problems after stroke

Upper limb impairments after stroke include loss of active movement, reduced sensation, coordination and dexterity. Impairments may lead to difficulties in completing everyday functional activities (loss of function) such as washing, dressing and eating / drinking, [15] as activities often require fine finger dexterity and / or

coordination of both upper limbs. Loss of arm function is common after stroke, affecting up to 69% of patients [16]. Twenty one percent of stroke survivors have reduced arm function on hospital discharge [16]. Less than half of patients with reduced upper limb function following stroke regain normal upper limb function by six months [17].

Loss of arm function directly impacts on quality of life and wellbeing after stroke [18]. Stroke patients who are unable to use their arm may require long term support from their families or social services. Patients describe loss of arm function as one of the most distressing long term consequences of stroke [19]. Research into optimising arm function has been identified by stroke survivors, carers and health care professionals as a research priority [20].

1.4 Upper limb rehabilitation after stroke

Rehabilitation after stroke aims to minimise impairments, prevent secondary complications and increase functional independence with activities of daily living [21]. Upper limb rehabilitation is usually provided by physiotherapists and occupational therapists, but can also be provided by other clinicians (e.g. nurses) or carers / family members [22].

1.4.1 Neuroplasticity and early upper limb rehabilitation after stroke

Neuroplasticity is the ability of the cerebral cortex to undertake functional reorganisation in response to experience, which may result in the acquisition of new skills [23]. Neuroplasticity occurs throughout life and evidence suggests that injury to the central nervous system (such as stroke) evokes increased neuroplasticity. Surviving areas of the brain undertake alteration in structure and functional activity allowing restoration of skills, so providing the foundation for recovery [23]. Neurophysiological research evidence suggests the period of maximum reorganisation / plasticity induced by injury occurs within one month of stroke, making this the optimal time for rehabilitation [24]. Early upper limb therapeutic intervention is also supported by evidence that most significant recovery of upper limb ADL function occurs within the first two months after stroke [16]. However, it has been recognised that evidence relating to the influence of time post stroke on the effectiveness of therapeutic interventions on upper limb recovery is low quality and further investigation is required [25].

1.4.2 Therapeutic interventions for improving upper limb functional recovery

There are many interventions that have been developed which aim to improve upper limb function early after stroke. Interventions may be targeted towards functional movements (e.g. grasp and release) or at specific impairments (e.g. muscle weakness) [25]. Interventions can be used individually, or combined in order to address the complex nature of problems following stroke [25].

Treatments delivered by healthcare professionals are generally selected considering a patient's goals and following an assessment of upper limb activity, impairment and effects of impairments on participation (disability) [26]. Interventions or treatment approaches in current use that aim to increase upper limb functional ability after stroke include; bilateral arm training; biofeedback; Bobath approach; constraint induced movement therapy (CIMT); electrical stimulation; manual therapy techniques; mental practice; motor learning approach; robotics; sensory interventions and repetitive functional task practice (RFTP) [25].

A Cochrane overview of systematic reviews examining interventions for improving upper limb function after stroke (2014) [25] found no high GRADE (Grades of Recommendation, Assessment, Development and Evaluation) quality evidence for any routine upper limb intervention. Moderate quality GRADE evidence was found for repetitive task training and authors called for further research [25]. This overview of systematic reviews [25] was published in 2014 – after the current project had commenced (2010). Prior to the start of the current project, a Cochrane review examining the effectiveness of repetitive task practice for improving functional ability after stroke was published (2007) [27] which found the intervention promising, but also called for further research. Current evidence for repetitive functional task practice (RFTP) for improving upper limb function after stoke is appraised and discussed in section 1.7.

1.5 Repetitive functional task practice (RFTP) definition and theoretical basis

Repetitive functional task practice (RFTP) is repeated practice of functional tasks within a single training session. RFTP includes practice of whole functional activities, movements aimed towards a functional activity or components of a functional activity [27]. Systematic reviews have indicated that patients benefit most from therapy interventions involving direct practice of functional tasks, rather than impairment based exercise programmes such as muscle strengthening [28-30]. An example of a functional task in the context of early stroke rehabilitation is reaching towards and

picking up a cup - with the goal of regaining independence with drinking. Practice of components of functional activities (part task practice) involves dividing the functional activity into components ('segmentation') and practising each section separately. Progression of the task is achieved by adding sections of the task together ('chaining') with the aim of mastering the whole task [31].

Repetitive functional task practice (RFTP) is underpinned by theories related to stroke rehabilitation [32] and motor learning [31]. Motor learning has been described as alteration of the spatial and temporal organisation of muscle synergies, resulting in movement sequences which are accurate, smooth and consistent [33]. Repetitive functional task practice (RFTP) seeks to enhance motor learning by undertaking practice of functionally relevant tasks [27, 34]. Selection of relevant functional activities promotes active cognitive engagement in rehabilitation and is considered a key factor to enhance motivation. Intrinsic motivation relates to achieving internal satisfaction (e.g. possessing a sense of autonomy). Functional activities that are meaningful and relevant to patients nurture intrinsic motivation and so encourage patients to participate in rehabilitation [35]. It has been theorised that direct practice of a functional task improves quality and relevance of the motor experience and so enhances learning of the task [34] (specificity of learning hypothesis).

Other components of RFTP supported by motor learning theory include feedback on performance [32] and practice type and intensity. Feedback on performance can be either intrinsic or extrinsic. Intrinsic feedback is information provided by the sensory systems of the individual who is moving, e.g. how the movement feels. Extrinsic feedback is additional sensory information e.g. a therapist providing commentary about a patient's movement [35].

RFTP can be delivered through a variety of practice schedules including constant or variable practice, random or blocked practice, part or whole task practice and massed or distributed practice. Selection of practice type is dependent on the patient's stage of learning. Key stages of motor learning have been described as; verbal-cognitive stage (getting an 'idea' of the activity to be learned), motor stage ('fine tuning' of performance) and autonomous stage (mastering the activity) [34].

Intensity of practice as well as type of practice is fundamental to upper limb recovery. After injury, the brain can form either adaptive or maladaptive pathways depending on not only the quality but the quantity of motor experiences encountered [24]. The

optimal intensity of therapy post stroke remains unclear, but there is increasing evidence that greater frequency and intensity of therapy enhances recovery post stroke [26, 28, 36] and high intensity practice is an important component of effective rehabilitation [36]. High intensity training, delivered through RFTP is supported by several high quality neurophysiological studies which have demonstrated that skilled motor learning requires not only context dependent practice (achieved through direct practice of functional activities) but also repetition of practice [24]. Animal studies of neuroplasticity have suggested that hundreds of repetitions are likely to be required to drive neuroplastic changes and improve recovery post stroke [37].

Guidelines concerning the optimal number of repetitions to include in a clinical rehabilitation practice session have not been developed [26] and there is currently no consensus in defining how many task repetitions within a RFTP session constitute 'repetitive practice'. In the Cochrane review examining the effectiveness of repetitive task practice (2007) [27], authors did not state a minimum number of repetitions required per session in their description of the intervention nor in criteria for considering studies for the review. Studies were included if repetition of an active motor sequence occurred and the time duration or number of repetitions within a practice session (and the number of sessions provided) could be identified [27].

Physiologically, the use of RFTP early after stroke is supported by neuroplasticity (discussed earlier). Cortical reorganisation as a neuroplastic mechanism for upper limb recovery has been shown by positron emission tomography (PET), functional magnetic response imaging (fMRI), transcranial magnetic stimulation (TMS) and magnetoencephalography (MEG) [38-41]. The central nervous system can be described as a functionally organised, distributed hierarchical circuit where information is processed in a parallel-distributed manner. Dedicated neural networks in the brain represent specific skills or behavioural functions [42]. The implication for rehabilitation is that that if a particular function is to be improved, training needs to focus on that specific neural network, so supporting use of functional activities (i.e. task specific training).

Neurophysiological studies using animal models have provided evidence that such task specific training can produce changes in neural architecture, such as synaptogenesis, dentritic branching and neural sprouting [43-47]. Data from animal models further support this and demonstrate that task specific training in post stroke rehabilitation can activate molecular pathways, e.g. the up-regulation of brain-derived

neurotrophic factors that are important for learning and neurogenesis [48]. RFTP also reflects Hebbian ideas of neuroplasticity where connections between neurons are strengthened when neurons are simultaneously active (neurons which 'fire' together 'wire' together) [49].

Functional neuroimaging studies investigating changes in brain activity after stroke have demonstrated evidence of training related neuroplastic changes in humans [50-52].

In conclusion, theories related to stroke rehabilitation and motor learning, studies evaluating intensity of practice and neurophysiological and neuroimaging research provide rational for key components of RFTP; context dependency, use of functionally relevant tasks, active cognitive engagement, feedback on performance and high intensity practice.

1.6 Current UK recommendations for use of RFTP

The National Institute for Clinical Excellence (NICE) guideline for Stroke Rehabilitation advises stroke services offer "*repetitive task training after stroke on a range of tasks for upper limb weakness*" [53]. The National Clinical Guideline for Stroke also advises "*repetitive task training for the upper limb, such as reaching, grasping and other functionally meaningful tasks*" [14], but recommendations in both guidelines were supported by consensus based on the authors' collective views.

1.7 Evidence for repetitive functional task practice (RFTP) for improving upper limb function after stoke

Randomised controlled trials evaluating the use of RFTP to date have been appraised. The Cochrane review examining the effectiveness of repetitive task practice for improving functional ability after stroke (2007) [27] was also appraised.

1.7.1 Randomised controlled trials evaluating the use of RFTP for the upper limb after stroke

1.7.1.1 Literature review methods

The Cochrane review examining the effectiveness of repetitive task practice for improving functional ability after stroke (2007) [27] offered a basis for the literature review and search strategy. Methodology used by the Cochrane Collaboration is regarded as robust, using explicit methods to minimise bias and produce reliable results. The literature search included in the Cochrane review [27] was up to date on the 09.04.2007, so subsequent searches were limited from 2007 onwards. An initial

search was undertaken and alerts for each data base checked each month until 01.01.2016.

Three electronic databases were searched; Medline, EMBASE and Scopus. Due to the nature of each individual electronic database, different search terms were used for each database (see appendix 1).

The National Institute for Health Research Clinical Research Network (NIHR CRN) register, the *meta*Register of Controlled Trials (*m*RCT) and the ClinicalTrials.gov Register (international register) were also examined for relevant completed or on-going studies (last checked 01.01.2016).

The search criteria concerning types of studies and interventions were based on the approach taken in the Cochrane review (2007) [27], but criteria were modified as explained below: The Cochrane review (2007) [27] refers to RFTP as 'repetitive task training (RTT)'.

1.7.1.1.1 Types of studies

In considering the types of studies to be included in the Cochrane review (2007) [27], the authors stated;

'We included randomised and quasi-randomised trials (such as those allocating by date or alternation) in the review. One arm of the trial had to include RTT, compared against usual practice (including 'no treatment'), or an attention control group. Examples of attention-control treatment are comparable time spent receiving therapy on a different limb, or participating in an activity with no potential motor benefits. We accepted usual-practice comparison groups when the intervention received by the control group was considered a normal or usual component of stroke rehabilitation practices, including neurophysiological or orthopaedic approaches. We assumed that, early after stroke, usual practice would mean that people would receive some therapy', (p. 3) [27].

The criteria were still appropriate, so applied to the current literature review search.

1.7.1.1.2 Types of interventions

In considering the types of study interventions to be included in the Cochrane review (2007) [27], the authors stated:

'One arm of the trial had to include an intervention where an active motor sequence was performed repetitively within a single training session, and where the practice was aimed towards a clear functional goal. Functional goals could involve complex whole tasks, or pre-task movements for a whole limb or limb segment such as grasp, grip, or movement in a trajectory to facilitate an ADL-type activity. To be included, trials of repetitive activity were required to involve complex multi-joint movement with functional measurement of outcome, rather than the exercise of a single joint or muscle group orientated to motor performance outcomes. We included any intensity and duration of task training schedule However, we only included trials if the time duration or number of repetitions within a session of practice and the number of sessions delivered could be identified' (p. 3) [27].

The criteria were applied when screening titles / abstracts for the current literature review. If the content of the intervention was unclear, the full text paper was used.

The authors of the Cochrane review (2007) [27] included studies that;

'clearly used motor relearning as a whole therapy approach if we could identify the amount of task-specific training received' (p.3) [27].

Studies evaluating motor learning were included in the current review and details specifying intervention intensity / repetition were sought. If insufficient information was available in the study paper to allow the intervention to be determined as RFTP, then the study was excluded.

The Cochrane review [27] included studies that combined;

' RTT with person-delivered, mechanical or robotic movement assistance if the purpose of the assistance was to facilitate a task-related repetition. We excluded studies if assisted movement was predominant, or could not easily be related to a functional goal' (p. 3) [27].

The criteria in the current review differed from the Cochrane review (2007) [27] as studies on robotics were excluded. The use of robotics was considered a different intervention to RFTP as use of robotics does not include the direct practice of functional tasks. It is possible that studies into robotics may have been considered for the Cochrane review as they were limited in number prior to 2007. Studies incorporating robotics were not presented in the Cochrane review [27].

The Cochrane review [27] omitted studies that;

'combined RTT with another intervention where the influence of task repetition could not be isolated, for example electrical stimulation, virtual environments, performance or biofeedback, forced use, bilateral movement, or mental rehearsal. We also excluded trials if the intervention used mechanical means simply to increase endurance' (p. 4) [27].

This criterion was applied to the search strategy of the current review. Common adjuncts such as mirrors, electro-stimulation and constraint induced movement therapy (CIMT) are likely to impact on the nature of the repetitive task practice study interventions / results and so were specifically excluded in the search terms for the current literature review.

1.7.1.2 Literature review results

The Cochrane review [27] included fourteen studies, seven of which addressed the upper limb [54-60] and have been included in the current review. The initial search for the thesis review was completed in October 2013 where a total of 2,376 bibliographic references were identified from database searches (1,993 Scopus, 289 Medline and 94 Embase).

Unsuitable studies were filtered out by title and further detail was collected from abstracts and full papers if required. Four suitable studies [61-64] were identified in the initial search and included in the review. After the initial search (October 2013), another three studies were identified for possible inclusion in the literature review. Monthly database alerts yielded two appropriate studies [65-67] (last alert 01.01.2016). One study has been appraised [65, 66] and one was ongoing, so has not been appraised [67].

After removing duplications, one further study was identified [68] after searching the National Institute for Health Research Clinical Research Network (NIHR CRN) register, the *meta*Register of Controlled Trials (*m*RCT) and the ClinicalTrials.gov Register for completed and on-going studies. The study [68] had been completed, but unfortunately, there were no publications.

1.7.1.3 Appraisal of randomised controlled trials evaluating the use of repetitive functional task practice for the upper limb after stroke

A total of 12 studies have been appraised and are presented in date order. The Scottish Intercollegiate Guidelines Network (SIGN) randomised controlled trials (RCT) appraisal tool [69] was used to inform the appraisal. Further information about the studies is presented in tables; study design (table 1); study eligibility criteria (table 2); RFTP based therapy input (table 3); appraisal of study methodology (table 4). Available information about the ongoing study [67] and the unpublished completed study [68] is presented in table 5.

Turton and Fraser, 1990 [58]

This was a single centre RCT to evaluate the effectiveness of delivering therapy using home therapy programmes for recovery of reaching movements in patients with stroke. Stroke patients discharged from inpatient care with impaired upper limb function on the ten hole peg test were included. Patients were considered to have impaired upper limb function if they scored less than 95% of 'normal performance', but a 'normal performance' score was unspecified (full eligibility criteria available in table 2).

Twenty two participants were assigned to study groups (intervention =12, control = 10) in alternate runs of five (quasi-randomisation). As group allocation was not truly random, this may have resulted in selection bias during randomisation. The intervention group received a therapy programme based on the motor learning approach. Therapy content and intensity were not standardised between participants, but individualised to the participant in relation to presenting problems and stage of recovery. Length of the intervention period was a minimum of eight weeks (no maximum length specified). This may have led to large variations in the intervention delivered. Content or intensity of home programmes delivered were not reported and lack of information would make reproduction of the intervention challenging. Available information on RFTP based input is presented in table 3. Participants in the control group were visited at home for outcome assessments only. All study participants continued with usual post stroke rehabilitation (out-patient therapy or no therapy follow up) but usual post stroke rehabilitation content or intensity was not recorded.

Outcome measures were the Southern Motor Group's motor assessment (section for the upper limb performed in sitting), an uncommon measure which evaluates a

patient's ability to achieve different arm and hand positions. Use of measures not commonly used makes results less comparable with other studies. The 10 hole peg test (measure of finger dexterity) was also included for participants considered to possess sufficient motor activity. Timing of outcomes were poorly standardised, occurring at approximate time points - around every four weeks. Timing of the last assessment (primary end point) may have varied between participants, influencing the amount of therapy input and time since stroke onset. Such confounding variables may have impacted on study results. Outcome measures were conducted by the same therapist who delivered the study intervention, which may have led to assessor bias. Neither patients nor the outcome assessor were blinded to treatment group allocation.

The Mann Whitney U test was applied. A formal power calculation was not reported. Results were presented for 12 intervention group participants and 10 control group participants (0% attrition). The two study groups did not appear similar at baseline, differing in the mean time post – stroke (intervention = 24 weeks, control = 16 weeks), 10 hole peg test scores (intervention = 47.6 seconds, control = 40 seconds) and ability to complete the test (intervention = 7/12, control = 4/10). This may indicate that the intervention group were more severely affected at baseline.

Change between initial assessment and final assessment were reported for the Southern Motor Group's motor assessment and the ten hole peg test. The intervention group demonstrated improvement on the Motor Assessment Scale compared to the control group and but this was not statistically significant (intervention mean change = +2, control change = 0, p= >0.05). The intervention group also showed greater improvement on the ten hole peg test than the control group and this result was statistically significant (p = <0.05). Outcome data from other assessment time points were not presented.

Compliance with the therapy intervention was reported. Participants were requested to record each self-practiced therapy session. The mean rate of self-reported compliance with the home exercise programme was 68%. The reasons for not completing the programme (e.g. due to fatigue) were not reported. Such data could assist in future study and therapy programme development.

Authors concluded there was an improvement in arm and hand movement when repeated exercises were practiced at home. Authors conclusions may be challenged

as interpretation of the results may be not meaningful due to potential insufficient sample size (power calculation not undertaken). In addition, the ten hole peg test result should be interpreted with caution as scores were recorded only for participants able to undertake the test. There are some methodological limitations to the appraised study, but studies testing self-practiced programmes are rare and valuable insight can be gained from the study.

Kwakkel et al., 1999 [56]

This multicentre RCT explored the effects of different intensities of upper limb and lower limb rehabilitation on walking ability, activities of daily living (ADL) and paretic upper limb dexterity. Participants aged 30 – 80 years with first ever stroke in the middle-cerebral artery (MCA) and impaired motor function were included. The age limiting criterion was not justified and motor function assessment was unspecified (full eligibility criteria are available in table 2).

One hundred and one participants were randomised into three groups; arm-training (n=33), leg training (n=31) and control (n=37) using sealed envelopes. Use of sealed envelopes for randomisation is considered inferior to computer software. Groups were similar at baseline.

Arm training sessions consisted of functional exercises to facilitate forced upper limb activity (e.g. leaning, reaching, and dressing). Strengthening exercises were used if treatment at a disability level was not possible. Leg training sessions focussed on improving gait velocity and stability through weight bearing, standing and sitting exercises and use of treadmills. Limited information detailing study intervention content was provided, making study interventions difficult to replicate. The control group received immobilisation of their affected upper and lower limbs via inflatable pressure splints during treatment sessions. Inflatable splints could be considered an attention control treatment or alternative intervention. The comparison of study interventions against a usual post stroke rehabilitation group may have been more appropriate. Treatments in all three study groups lasted for 30 minutes, 5 days per week for 20 weeks post stroke (see table 3 for therapy programme details). In addition, all three study groups were provided a set amount and content of usual post stroke rehabilitation determined by the study.

Outcome measures were performed by a blinded assessor (assessor unblinded to10% of patients) once per week for the first 10 weeks then once every fortnight until

week 20. Measurements were repeated at 26 weeks post stroke. Primary outcome measures were the Barthel Index (measure of disability or dependence in activities of daily living), Functional Ambulation Classification (categorises walking ability) and the Action Research Arm Test (ARAT - used to measure arm function at a disability level, scores range from 0-57, 0 = no ability). There was a wider range of outcome measures used to detect changes in mobility compared to arm function.

A description of the power calculation was not presented and 12 participants withdrew prior to 20 weeks (4 arm training, 5 leg training and 3 control). It was unclear whether an intention to treat analysis was undertaken.

There were significant differences between the three groups at 6, 12 and 20 weeks after stroke for the three primary outcome measures listed. The arm training group showed greater improvements in the ARAT compared to the control group in weeks 12 ($p = <0.05$), 20 ($p = <0.01$), and 26 ($p = <0.05$). There were no differences in Barthel Index scores between the arm training group and the control group at any time point. The leg training group showed greater improvements than the arm training group and the control group in the Barthel Index at week 6 ($p = <0.05$ and $p = <0.01$ respectively). It is worth noting that from weeks 20 - 26 weeks, decisions about treatment interventions and intensity were made by the participant's usual post stroke rehabilitation team.

Adherence to therapy was monitored through coding of activities and time spent in therapy. Planned difference in time spent between study groups and content of interventions were achieved.

Authors concluded increased arm rehabilitation intensity resulted in small improvements in dexterity and that this result provided further evidence for specificity of training. There were some methodological limitations to this study and further details about interventions would have been useful.

Langhammer and Stanghelle, 2000 [57]

The aim of this single centre RCT was to compare the impact of two therapeutic approaches on patient outcome early after stroke. Sixty one patients with acute first-ever stroke were randomised to receive therapy following the Bobath approach (Bobath group = 28) or the Motor Relearning Programme approach (MRP = 33). The study used blocked randomisation and the sample was stratified according to

hemisphere site and gender. Level of initial functional ability was not considered (full eligibility criteria available in table 2).

The intervention group received treatments based on the Motor Relearning Programme which included functional task training using repetition. The control group received a Bobath based intervention. Programmes were standardised by the use of therapy manuals outlining the philosophy of each approach. Further details about study interventions or adherence to the programmes were not reported.

Participants in both groups received physiotherapy five days per week (minimum 40 minutes per session). Study physiotherapy continued as long as participants were hospitalised, so the length of the intervention period was not standardised. Participants continued with the same treatment approaches in follow up physiotherapy services on hospital discharge, which may have varied in intensity and duration (not reported).

Participants considered independent in activities of daily living on hospital discharge did not receive any follow up physiotherapy. Few of the participants discharged to nursing homes continued with physiotherapy (number of participants not provided) - stopping rehabilitation for such patients may have influenced study results.

Study physiotherapy interventions were in place of usual physiotherapy care. All participants continued with usual occupational therapy, medical care, and speech and language therapy during the intervention period. The content and intensity of occupational therapy provided was not included in the study paper. Occupational therapists provide training in activities of daily living (and so in accordance to the motor relearning approach), and input could have varied between participants causing contamination of study treatments.

Outcome measurements were taken by a blinded assessor at three days post admission, two weeks later and at three months post stroke. Success of blinding was not reported. The Motor Assessment Scale (MAS- everyday motor function) and the Sødring motor evaluation scale (SMES) were recorded on each occasion. The SMES is a measure of arm, leg and gross motor function in stroke, but is not commonly used making results less comparable with other studies. The Barthel ADL index was used on the first and third data collection points and the Nottingham Health Profile (NHP – quality of life) was used on the third test period only. Length of hospital stay, discharge destination and use of assistive devices for mobility were also recorded.

Authors reported that the study was double blinded (outcome assessors and participants), but success was not reported.

A sample size of a minimum of 55 was calculated (details not provided). Student's *t*-test was used to evaluate group differences. Eight participants were lost to follow up (MRP = 4 Bobath = 4), it was unclear if an intention to treat analysis was performed.

It is not possible to distinguish whether the two groups were comparable at baseline due to lack of data. A statistically significant difference was seen between groups in the MAS at two weeks in favour of the MRP programme ($p = 0.05$), but there was no difference at three months ($p = 0.31$). The SMES score was analysed under the three subscales. A significant difference in improvement in favour of the MRP programme was seen in the SMES part 2 sum score (only when comparing between two weeks after admission minus three days after admission differences ($p = 0.018$)). There was no difference when comparing the other 2 subscales or comparing the Barthel Index or the NHP results at three months post stroke.

The MRP group had a much shorter length of stay compared to the Bobath group (21 and 34 days respectively, $p = 0.008$). Forty six percent of the Bobath group were discharged to their own homes compared to 52% of the MRP patients (p value unavailable). Although adherence to the therapy protocols was encouraged, monitoring of adherence to the designated interventions delivered once patients were discharged home was not mentioned.

The main conclusion was that patients treated with MRP had a shorter hospital stay and greater improvement in motor function compared to patients receiving the Bobath approach. However, results were not sustained as there no difference between groups at three months. Authors recognised differences in treatment approaches delivered by therapists may not have been maintained post hospital discharge and participants were likely to be practising more activities of daily living. A further explanation offered was that the MRP approach worked more rapidly but did not affect the overall longer term outcome of the patients.

Although the paper does support the use of RFTP, it would not be possible to reproduce programmes from the limited information available and there were several methodological issues that indicate the need for further research.

The study was followed up in 2003 [70] when authors aimed to establish the longer term effects of two treatment approaches.

Patients who had participated in the previous study were re-assessed at 1 year post stroke (48 participants, MRP n=27, Bobath n=21) and four years post stroke (37 participants MRP n=21, Bobath n=16). An assessment of the data collected by authors revealed that all living participants agreed to participate in the follow up study and none were lost to follow up. Mortality rate was recorded and outcome measures (used in the initial study [57]) were repeated. Semi-structured interviews with participants (details not provided) were also undertaken. It was unclear whether outcome assessors or the physiotherapist conducting study interviews were blinded to participant treatment allocation.

The same method of statistical analysis as previous study [57] (Student's t-test) was undertaken. Data presented for both groups indicated a deterioration in MAS, SMES (all three sub scales), and the NHP. A statistical analysis comparing between group differences was not presented in the paper; authors stated there were 'no significant differences between groups in any of the tests'. The authors concluded that the initial therapeutic approach did not have a meaningful impact on longer term outcome of patients. It is unclear why authors undertook the follow up study as initial improvements observed in the first study were not sustained after three months.

Blennerhassett and Dite, 2004 [54]

The aim of this single centred study was to determine whether additional task practice directed towards mobility or the upper limb improves functional outcome in patients early after stroke (full eligibility criteria are available in table 2).

Thirty participants with stroke (up to three months post stroke) with the ability to walk ten metres were recruited and randomised into two groups (n=15, n=15). Upper limb ability / function was not considered in the inclusion criteria. Randomisation was performed by drawing pre-sealed envelopes (no further information reported), a randomisation procedure which may be open to selection bias.

One group received additional upper limb task related practice and the other group received additional mobility task practice. Interventions were delivered through separate group classes that lasted one hour, five days per week for four weeks. Both classes involved circuit training through 10 work stations (five minutes per station)

and were supervised by a physiotherapist who customised and progressed exercises as appropriate. Although programmes were customised, overall treatment goals were managed separately to the study (in usual post stroke rehabilitation), questioning how well the content was individualised. The upper limb class comprised of functional tasks (working on reach and grasp), stretching (as required), hand-eye co-ordination activities and strengthening using gym equipment. The mobility class practiced functional tasks such as sit to stand, endurance tasks (treadmill and static bike) and strengthening exercises.

Usual physiotherapy care included one hour five days per week and was based mainly on the movement science approach. Researchers recorded time spent in interdisciplinary usual post stroke rehabilitation and time practising upper limb tasks and mobility in physiotherapy. Usual post stroke rehabilitation physiotherapists may have been un-blinded to participant group allocation but the success of blinding was not recorded. Time spent on upper limb or mobility tasks in occupational therapy was not reported.

Outcome measures were recorded at baseline, post-intervention (four weeks) and six months post - intervention by blinded assessors (success of blinding not described). Locomotor performance was measured by the six minute walk test (6MWT), the step test and the timed up and go test (TUGT). Measurement of upper limb ability was measured using the upper limb and hand items of the Motor Assessment Scale (MAS) and the combined time for the three sub-tests from the Jebsen Taylor hand function test (JTHFT, an uncommonly used measure).

The study was powered in relation to mobility performance (steps per second), possibly making the study more sensitive to detecting changes in the mobility group rather than the upper limb group. Data were analysed by intention to treat. A variety of statistical tests were used to examine between – group differences including split-plot ANOVAs, independent sample *t*-tests and chi-square tests.

Participant groups were reported as similar at baseline, but the range of demographic data collected and compared was limited. Follow-up was 97% at six months.

No significant difference was found when comparing individual outcome measures between groups across three time-points, with the exception of two results in favour of the mobility group (6MWT $p = 0.01$ and TUGT $p = 0.02$) at four weeks. Individual outcome measures were compared within groups for changes over time. The upper

limb group significantly improved in the 6MWT ($p < 0.001$), TUGH ($p = 0.006$), the step test ($p = 0.001$) and the JTHFT ($p = 0.005$). In addition, the upper limb group improved on the MAS upper arm item (change between initial - four weeks $p < 0.001$ and change between initial - six month testing $p = 0.004$). Data concerning therapy provision between post-intervention testing and six months was not collected and therapy input may have varied between groups during this time, affecting results.

It was concluded that study results indicated the provision of supplementary task related practice improves functional outcomes during in-patient stroke rehabilitation. It is difficult to understand how authors established their conclusion as significant differences were only seen within groups, not across groups. Improvements within groups could have been spontaneous recovery only and not influenced by the interventions. Addition of a control group that only received usual post stroke rehabilitation would have allowed for a more appropriate comparison and conclusions about supplementary therapy to be made. Authors recognised the results should be interpreted with caution due to limitations in the sample (participants were mobile with close supervision and relatively young). A further point for caution (but not recognised by authors) was that the study was powered to detect changes in mobility rather than upper limb function.

Winstein et al. 2004 [60]

This was a single centre RCT pilot study designed to provide feasibility data to inform a larger study. The primary objective was to evaluate immediate and long term outcomes of two different upper limb rehabilitation approaches. Objectives relating to the feasibility of undertaking a Phase III study were not included (e.g. testing the study protocol or establishing the likely recruitment rate for a future study) [71].

Patients aged 29 – 76 (age specification not justified) within 2 - 35 days after anterior circulation infarction were included (full eligibility criteria available in table 2). The post stroke recruitment time period could be considered too wide, allowing large variations in time, so capacity for neuroplasticity, post stroke between participants.

Sixty four participants were randomised into three groups; task specific functional training with standard care (FT = 22), strength training with standard care (ST = 21) and standard care only (SC = 21) within severity strata (determined by baseline Orpington Prognostic Scale (OPS) score, allocation ranges unspecified), using sealed envelopes.

Standard care (usual post stroke rehabilitation) was based on the neurodevelopmental approach and mainly delivered by occupational therapists. It is unclear whether the amount or content of standard care received by participants in all three study groups was monitored. A comparison of standard care received between 3 groups would have been appropriate to detect possible competitive therapy bias or contamination of usual post stroke rehabilitation treatments. Competitive therapy bias is when patients in the control group receive more usual therapy if staff feel they are 'missing out' [72]. This would decrease potential differences between the study groups.

FT training group participants undertook individualised repetitive and systematic practice of tasks performed within the level of their available voluntary movement (see table 3 for all available details). The ST group's programme used resistance training within active movement present in the upper limb.

Study interventions were provided for one hour per day, five days per week for four to six weeks (total of 20 hours additional therapy time). The range in number of exercise repetitions provided was not detailed in the study paper, making programmes difficult to replicate. Interventions were provided by physiotherapists who were 'broad-certified neurological clinical specialists'. Details of study specific training were not provided.

Outcome measures were taken by an un-blinded assessor at post intervention period and at six and nine months post-stroke. Use of an un-blinded assessor may have led to observer bias.

The authors used several outcome measures including the upper limb portion of the Fugl-Meyer assessment scale (measure of impairment), grip and pinch force (hand held dynamometer), the Functional Test for Hemi paretic Upper Extremity (FTHUE, measure of self-care) and isometric torque at the shoulder, elbow and wrist (dynamometer).

It was not appropriate to undertake a power calculation as this was a pilot study. The planned sample size was 60. Authors analysed results three ways using a significance level of 0.05. The first analysis was a comparison of differences in change in scores at post-intervention and follow up across the 3 groups using analyses of covariance (ANCOVAs) procedures. Multiple comparisons were used employing the Tukey adjustment procedure if significant differences were found

across groups. The second analysis compared SC against combined treatments (FT+ST) data at the same time interval (aim was to contrast SC with focussed upper limb rehabilitation and does not relate to the study objective). The third analysis repeated both analyses for ‘less severely’ and ‘more severely’ affected participants (determined by OPS score, allocation ranges unspecified).

Participants were similar at baseline. At nine months follow up, data from only 15, 13 and 16 (SC, FT and ST groups respectively) participants’ data were available for analysis, but it was unclear if an intention to treat analysis was performed.

When comparing post treatment scores to baseline across treatment groups, a significant difference was seen in isometric torque only ($p = 0.05$), but no significant differences were seen between treatment groups when using the Tukey procedure. Significantly greater improvements in upper extremity Fugl-Meyer (motor function) ($p = 0.04$) and isometric torque ($p = 0.02$) were found when comparing combined FT and ST group data against SC. All other post treatment results were not significantly different.

When assessing long term changes (nine months), no differences were seen across treatment groups or when comparing FT and ST groups against standard care.

Results for ‘less severely’ affected participants are as follows; when comparing post treatment scores to baseline across treatment groups, significant differences were only seen in Fugl-Meyer (motor function) ($p = 0.02$). When employing multiple comparisons, the FT and ST groups Fugl-Meyer scores improved more than the SC group (Tukey $p< 0.05$). Participants in the FT and ST groups combined showed significantly greater improvements in Fugl-Meyer (motor function) ($p = 0.005$), isometric torque ($p = 0.03$) and FTHUE ($p = 0.05$) compared to the SC group. No differences were seen when comparing ‘more severely’ affected participants.

Long term, significant differences were seen in ‘less severe’ participants across treatment groups in isometric torque ($p = 0.02$), and palmar pinch (0.03). Differences were seen during when performing multiple comparisons in favour of the FT group (FT improved more than the SC group palmer pinch and FT improved more than the ST group in isometric torque – Tukey values both $p < 0.05$). FT + ST groups combined demonstrated a greater improvement in palmer pinch than SC group ($p = 0.05$).

A substantial amount of study data were not presented in the paper. Data comparing FT and ST, in “more severe” participants and data for post-intervention secondary outcome measures were both omitted from the paper due to lack of observed differences between groups.

It was concluded that similar benefits were seen from functional training and strength training approaches compared to standard care in the short term but benefits of functional training were greater in the longer term. It was noted that more treatment benefit was seen in the less severely affected participants in the short term providing evidence for severity of impairment and response to treatment.

There were several methodological concerns such as use of a wide recruitment window after stroke and non-blinded assessors. In addition, the authors’ conclusions need to be interpreted with caution. Differences observed were only in a small number the outcome measures and as this was a feasibility study, formal statistical comparisons (and conclusions about effectiveness) were not appropriate.

van Vliet et al., 2005 [59]

This single centred RCT aimed to evaluate whether the movement science based (MSB) approach or the Bobath (BB) approach is more effective in improving functional independence and movement ability in patients with stroke.

One hundred and twenty patients with acute stroke and who were referred to physiotherapy were randomised (blocked randomisation using computer software) to receive therapy based on either the Bobath approach (BB = 60) or the movement science based approach (MSB = 60). Full eligibility criteria are available in table 2.

The therapeutic approaches delivered in the study (MSB and BB) were provided in place of usual physiotherapy care. Authors stated the usual physiotherapy care approach was the BB approach, indicating the approach would be more familiar to study therapists. Recruitment was dependent on the treating physiotherapists’ caseloads which may have caused selection bias (9% of excluded patients were due to physiotherapy caseload).

Physiotherapists were provided with guidelines containing the main clinical objectives and theoretical concepts for each approach. The length of intervention period was individualised per participant and could have differed considerably between participants and study groups. Further intervention details were absent from the

paper, including information on repeated practice, making reproduction of study treatments not possible. The authors accepted study interventions were influenced by physiotherapists' own experience, knowledge and interpretation of the literature. Allowing this level of subjectivity and interpretation could have reduced standardisation of interventions further. Monitoring for adherence to the treatment protocol was not reported.

Usual post stroke rehabilitation occupational therapists also used the allocated therapy approach. Training of occupational therapists in relevant approaches was not reported.

Some treatments were provided by physiotherapy assistants working alone, but assistant training in delivering study interventions was also not described. This is important as the amount of treatments provided by lone assistants was greater in the MSB group than in the BB group ($p = 0.0001$).

Study outcome assessments were undertaken at one, three and six months post-randomisation by a successfully blinded assessor. Success of blinding was analysed using the κ statistic which indicated poor agreement between assessors' guesses and actual group allocation ($\kappa = 0.22$). Assessment of effects on motor impairment were measured using the Rivermead Motor Assessment (RMA) Scale (gross function) and the Motor Assessment Scale (MAS). The former was developed by therapists using the BB approach and the latter the MSB approach. Several secondary outcome measures were recorded (see table 1).

The study was powered based on the RMA scale which may have produced a bias in detecting changes in participants receiving the BB approach (due to its orientation). An intention to treat analysis was performed. Data analysis to compare participant outcomes involved using serial measurements utilising the area under the curve (AUC) and Mann-Whitney U tests.

At baseline, study group characteristics were similar. At six months, loss to follow up was similar between groups and totalled 28%. Authors found no statistically significant difference between groups for any of the outcome measures at any of the outcome testing time–points when comparing the AUC. A small number of differences were identified between groups when using the Mann-Whitney U tests. There was a significant difference in MAS scores (supine to sitting) at six months ($p = 0.0067$) in favour of the BB group. At one month outcome testing there were

statistically significant differences between groups in favour of the MSB in small sections of two of the secondary outcome measures.

It was concluded there was no difference in patient outcome was found between the approaches studied, although some study limitations were recognised. Authors acknowledged the risk of treatment contamination and difficulty in altering a single environment to suit both approaches. It was also recognised that treatment intensity may have been too low to produce a different outcome between groups.

It was interesting that no difference in participant outcome was detected between groups and a greater proportion of MSB treatments being delivered by assistants working alone. This result may have advantageous cost implications.

The methodological quality and validity of this study is limited mainly due to concerns with standardisation of the study approaches.

An observational study by van Vliet et al. (2001) [73] was undertaken in parallel to the randomised controlled trial published by the same authors in 2005 [59]. The aim of the study was to compare the content of movement science based (MSB) approach with Bobath (BB) approach treatments. Therapists followed the same protocols for each approach used in the RCT [59] and the content of the therapy sessions was analysed and compared between groups. The authors concluded there were differences in treatment content between the two approaches.

Interestingly, the authors explained the Bobath approach used in the study 'incorporated other ideas as well' but further explanation was not provided. It is not possible to establish how close the treatment protocol was compared to the Bobath theoretical approach. Considering this, the results of not only this study but the effectiveness study published in 2005 [59] must be considered with caution.

Higgins et al., 2006 [55]

This multicentre RCT evaluated the efficacy of a task-orientated intervention to improve walking ability within one year of stroke (minimum time post stroke unspecified). A parallel objective of the study was to evaluate the efficacy of task-orientated training to improve upper limb function.

Ninety one participants (arm training = 47, mobility training = 44) were randomised via use of envelopes and stratified according to walking ability (upper limb ability not

considered). Eligibility criteria were extensive (see table 2) which may have led to selection bias and reduced external validity of the study. The majority of inclusion criteria were based on general functional ability and walking ability rather than upper limb ability.

Participants received either upper limb or mobility training delivered on a one to one basis, three times per week, for six weeks. Each therapy session lasted approximately 90 minutes.

Each upper limb therapy session commenced with identifying what the participant wished to improve on, then subsequent practice of the functional task identified (if sufficient upper limb movement was available). The paper did not indicate whether formal goal setting procedures were followed. If insufficient movement was available the therapist facilitated the limb to perform the tasks and applied passive range of movement and vibration with the aim to facilitate mobility and reduce spasticity. Exercises were progressed as appropriate and at the discretion of the therapist. It is unclear whether progression was guided / standardised / monitored and this may have led to inconsistency of treatments. Lack of further details makes the intervention impossible to replicate.

The mobility training intervention consisted of 10 functional tasks and was more standardised and reproducible than the upper limb intervention. Participants had to be discharged from usual post stroke rehabilitation to meet study eligibility criteria.

Blinded outcome assessments were undertaken post intervention (six weeks) by trained assessors. Success of blinding was not reported. Further testing at later time intervals to observe longer term treatment effects would have been interesting to establish if any treatment effects persisted.

The Box and Block Test (gross manual dexterity), the nine-hole peg test (fine manual dexterity) and the Test d'Evaluation des Members supérieurs des Personnes Agées (TEMPA) were employed as measures of upper limb activity limitation. The TEMPA is measure of upper limb activity performance and is not widely used, meaning results are less comparable with other studies. Some of the selected outcome measures for upper limb activity (the Box and Block Test, the Nine Hole Peg Test), may be considered insensitive to changes in participants with lower ability levels because of a floor effect. Impairment measures used for the upper limb included grip strength (dynamometer) and the upper extremity subscale of the Stroke Rehabilitation

Assessment of Movement (STREAM). Other global outcome measures used were used included the Barthel Index.

The study was powered considering both mobility and upper limb ability (using the Box and Block Test and the Six Minute Walk Test). The primary analysis was the chi-squared test and compared the number of participants between groups who had deteriorated, remained the same, improved between one and six blocks and improved between more than six blocks on the Box and Block Test. Several other statistical analyses were employed to analyse secondary outcomes. An intention to treat analysis was undertaken.

Groups were similar at baseline. Seven participants (5% attrition) were lost to follow up (arm training = 4 participants, mobility training = 3 participants) and missing values were imputed. Participant compliance was reported by the number of sessions attended (72% of the participants attended 17-18/18 sessions). At post intervention testing, the proportion of participants in each classification of Box and Block Test was the same in the arm training group compared to the mobility group, showing no significant difference between groups ($p = 0.818$). The result was mirrored in all other study outcome measures which were not clinically meaningful or statistically significant.

The results indicate that task specific arm training did not improve manual dexterity or voluntary movement. Several limitations were recognised including not stratifying participants according to level of upper limb ability and lack of sensitivity of some of the outcome measures to the study population.

Further limitations not recognised were lack of standardisation of the upper limb rehabilitation programme, apparent bias in study methodology towards the mobility group and lack of follow up assessments to detect possible longer term treatment effects.

Harris et al., 2009 [63]

The aim of this single-blind, multicentre RCT was to establish the effectiveness of a self-administered graded repetitive arm supplementary programme (GRASP) on upper limb recovery in stroke. Acute stroke patients with scapular elevation (against gravity) and palpable wrist extension (grade 1 Oxford scale - as a minimum upper limb activity requirement) scoring between 10 and 57 on the Fugl-Meyer Assessment

were included (see table 2 for full eligibility criteria). It was unclear whether patients with recurrent stroke were included.

One hundred and three participants were randomised (using computer software) into two groups (GRASP protocol = 53 and education protocol = 50). The four week long GRASP protocol was a self-administered homework based programme consisting of three ability levels; for mild, moderate and severe upper limb impairment (details of appropriate level selection unspecified). The protocol was designed in reference to the Fugl-Meyer Motor Impairment Scale. The Fugl-Meyer Assessment was used in eligibility criteria and development of the GRASP protocol but not used as an outcome measure.

The GRASP protocol included strengthening, range of motion and repetitive goal and task orientated activities (e.g. lifting, pouring). Programmes were tailored to participant's requirements by grading the number of repetitions performed but not by altering the types of exercises to target participant goals / needs. The protocols offered a degree of standardisation of the intervention between participants at the expense of limited individualisation to participants. The programme (lasting 60 minutes per day) was completed independently six days per week. Participants were tutored and monitored by a site co-ordinator once per week. A log sheet was provided to allow participants to record the amount of time and number of days spent on the programme – mean hours per week and days per week were reported (3 hours/week and 4.8 days/week). Participants were also asked to record any pain (Visual Analogue Scale) and fatigue (Fatigue Severity Scale) experienced on the log sheets.

Control group participants were supplied with an education book containing information and homework assignments on stroke recovery and general health. Control group participants also met individually with the site co-ordinator weekly for four weeks. The aim of the study was to compare the GRASP protocol to usual post stroke rehabilitation but it could be argued that this was not achieved. Considering the input provided to the control group (educational booklet and time spent with the site co-ordinator) the study should be considered as either an attention control study or a study comparing two interventions. It is not possible to make the distinction as insufficient detail concerning educational booklet content was provided (unable to establish possible effects on upper limb recovery).

Intervention participants were asked to continue the programme between the post-intervention period and three months after post-intervention testing, but adherence to the programme during this time was not monitored. It is also unclear whether control group participants received specific instructions during this time.

Both groups continued with usual post stroke rehabilitation throughout the study and time spent in usual post stroke rehabilitation was recorded. Content of usual post stroke rehabilitation was not recorded and may have been useful to enable group comparisons.

Blinding of clinicians on the rehabilitation unit and outcome assessors to participant group allocation was attempted but success of blinding not reported.

Participants were assessed at baseline, post-intervention (four weeks) and three months. Measures included; the Chedoke Arm and Hand Activity Inventory (CAHAI, primary outcome measure, upper limb functional assessment). The CAHAI measures bilateral upper limb function, so does not account for the unaffected side assisting the affected side (compensations). Other measures included the ARAT, the Motor Activity Log (MAL, structured questionnaire measuring motor activity), dynamometer and the Medical Outcomes Study Short Form-12 (SF-12, health survey).

Authors assessed participant satisfaction by requesting completion of a questionnaire based on an ordinal scale. It is unclear how the ordinal scale was designed or whether it had been tested for reliability and validity.

A power calculation was undertaken indicating a sample size of 96 participants was required. The primary outcome measure was analysed using analysis of covariance (ANCOVA), secondary outcome measures were analysed using multivariate analysis of covariance (MANCOVA) to control for type I error and an intention to treat analysis was undertaken. It was noted that the study was not powered or designed for comparisons at three months post-intervention (analysis performed to inform future studies only).

Participants were similar at baseline. Nine participants withdrew from the study prior to post-intervention testing (GRASP protocol = 3 and control group = 6) but were included in the analysis by use of extrapolated data. On post-intervention testing, the GRASP group scored significantly higher on the CAHAI compared to the control group ($p<0.001$). Significant effects were also found in favour of the GRASP protocol

in all secondary variables excluding SF-12. At four months post randomisation, the GRASP group sustained a significantly higher CAHAI score compared to the control group ($p = 0.037$). The result had to be interpreted with caution due to attrition of data at four months potentially causing a distortion bias. Data was not presented in the paper for the secondary outcome measurements at four months post randomisation which may have provided an interesting comparison.

Authors stated that intervention participants reported high levels of satisfaction with the GRASP protocol, but failed to comment that similar satisfaction rates (with the education booklet) were reported in the control group (4.1/5 and 4.4/5 respectively).

Upper limb pain was initially reported by 28% of the intervention group and pain levels dissipated to mild or non-existent by week three. Pain levels in the control group were not mentioned. Comparison of pain and fatigue between groups may have been beneficial to clarify influence of the supplementary GRASP protocol. The paper states no serious adverse events were reported, however a standardised reporting system for serious adverse events was not outlined.

It was concluded that the GRASP protocol provided an effective treatment delivery model for upper limb rehabilitation, and results indicated enhanced improvement in the GRASP group compared to the control group. The GRASP protocol was described as cost and time effective (cost or time effectiveness analysis not reported), so it is unclear whether this was an assumption made by authors due to the nature of the intervention (self-practiced programme).

It was not possible to distinguish whether it was additional rehabilitation or the method of delivery (homework based treatment method) that led to positive results. Authors addressed this by suggesting a replication of the study but with a third group provided with an equivalent increase in therapy time (one on one therapy sessions). An additional suggestion is for the control group to be provided with usual post stroke rehabilitation only (and not an educational book in addition) or all groups provided with the educational booklet.

There are some methodological limitations to this study, and it is unclear whether assumptions over perceived benefits were made (such as it being cost effective), but studies testing supplemental inpatient exercise programmes, especially homework based, are rare and provide valuable data.

Donaldson et al., 2009 [62]

This pilot RCT aimed to assess the feasibility of a phase II randomised controlled trial to compare functional strength training (FST) with conventional physiotherapy (CPT) for upper limb recovery post stroke. The study objectives were appropriate for a feasibility study (e.g. estimating recruitment rates, collecting data to inform a future power calculation).

Patients diagnosed with anterior circulation infarct and within one week to three months post stroke were included (see table 2 for full eligibility criteria). The post stroke recruitment time period could be considered too wide, allowing large variations in time post stroke between participants. It was also unclear whether participants with recurrent stroke were included.

Thirty participants were randomised (using computer software and sealed envelopes) into three groups; conventional physiotherapy (CPT = 10), CPT plus additional CPT (CPT+CPT = 10) and CPT plus functional strength training (CPT+FST = 10). The sample was stratified considering participant baseline ARAT scores.

All study participants received conventional physiotherapy (CPT) which replaced usual upper limb rehabilitative care. CPT treatments were guided by a standardised treatment schedule. The CPT+CPT group received CPT with additional CPT (recorded using the treatment schedule). The CPT + FST were provided with CPT plus functional strength training which involved goal focussed functional activities, repetition and verbal feedback (see table 3 for all available information). Study interventions additional to CPT (that replaced usual post stroke rehabilitation) lasted for ‘up to an hour’ and were provided four days per week for six weeks. Study participants continued with occupational therapy (OT), but the amount and content were not measured nor described. OT often includes direct practice of activities of daily living, similar to the FPT intervention, which may have caused treatment contamination.

An attempt was made to blind usual post stroke rehabilitation therapists to participant group allocation, but success was not reported.

Study outcome measurements were the ARAT (primary outcome measure), the Nine Hole Peg Test, hand grip force, pinch grip force, isometric elbow flexion force and isometric extension force. Participants were re-assessed by blinded assessors on

completion of the study intervention (six weeks) and at twelve weeks (success of blinding not reported).

Change in scores between groups from baseline to post intervention and baseline to last outcome assessment were compared. It is unclear whether an intention to treat analysis was performed. Data were analysed and interpreted relating to clinically important differences in outcome measures selected (ARAT = 5.7 points, 9HPT = 1 peg in 50 seconds, 10 N in muscle force) and the Kruskal-Wallis test to detect across group differences.

The CPT+FST group scored lower than the other two groups in all baseline assessment measures but the difference was not statistically significant.

Two participants were absent from the CPT group at post intervention testing and a total of 11 participants (over one third) were lost to follow up at 12 weeks (CPT = 5, CPT + CPT = 4 and CPT + FST = 2). The greatest difference in score seen in the primary outcome measure (ARAT) was observed in the CPT+FST group (median change from baseline to outcome = 19.5); a far greater change than seen in the CPT+CPT group (median change from baseline to outcome = 8.0) and the CPT group (median change from baseline to outcome = 11.5). However, the difference in scores between groups was not statistically significant ($p = 0.232$).

The CPT + FST group also showed greater improvements than the other two groups in all other measures except hand grip force, but results did not always reach a clinically important or statistically significant difference. CPT showed greater improvements than the other groups in hand grip force but this was not clinically or statistically significantly different.

Authors reported the results may indicate a trend towards functional strength training improving upper limb recovery but no statistically significant differences were seen across treatment groups. This result needs to be interpreted with caution as pilot studies lack adequate statistical power to compare groups. Authors also concluded further work towards a Phase III trial was justified.

This study was of better methodological quality than the others previously discussed, but still had some methodological limitations outlined above.

Pandian et al., 2012 [64]

The aim of this study was to compare the effectiveness of hand therapy protocols based on the Brunnstrom movement therapy approach ('Brunnstrom hand manipulation – BHM') and the motor relearning programme (MRP) in chronic stroke patients.

Study eligibility criteria were extensive (see table 2). In particular, patients were required to be aged between 35 – 60 years (reason for age restriction not provided) and classed as stage 3 of Brunnstrom recovery stage of the hand (BRS-H). Selecting patients scoring Brunnstrom recovery stage 3 (some finger activity allowing for grasp of objects) made the study results only relevant to patients at that specific stage of recovery.

Thirty participants were randomised into two study groups (BHM = 15 and MRP = 15, further randomisation details unavailable). Both study groups were male dominant (n=10 in the BHM group and n=14 in the MRP group).

Study interventions were delivered by two occupational therapists, but details of training in study interventions was unspecified. The interventions were delivered for one hour, three days per week for four weeks (approximately 12 sessions, variation in the number of sessions not provided). Therapy provided to the (MRP) group involved direct practice of functional tasks and followed a set protocol with the aim of improving functional skills (see table 3 for further details). The BHM group's treatments also followed a set protocol, but with the aim of regaining mass grip and release of objects. It was recognised that the MRP protocol worked on the entire upper limb compared to the hand and wrist specific BHM protocol. A therapy protocol based on the Brunnstrom approach encompassing the entire upper limb may have been a more appropriate comparison within this study. High levels of protocol standardisation may have made study treatments less appropriate or meaningful to participants.

Both protocols were provided in addition to usual occupational therapy (OT) for the upper (excluding the hand) and lower limbs. Usual occupational therapy included direct practice of activities of daily living and could be considered similar to the MRP approach. This may have led to treatment contamination within the BHM group. Duration and content of usual OT sessions were not recorded and usual physiotherapy care was not acknowledged.

Participants were assessed at baseline and post-intervention (four weeks) by an independent examiner. Success of assessor blinding was not reported. Follow up assessments to determine long term treatment effects were not included and would have been interesting.

Two objective measures were used; the Brunnstrom recovery stage of the hand (BRS-H) and the Fugl-Meyer Assessment – wrist and hand subtest (FMA-WH). The BRS-H determines level of motor recovery post-stroke and comprises of six stages of recovery. The FMA-WH is divided into sub-groups; VII (wrist control), VIII (hand motor recovery – mass finger flexion, extension and grasp) and IX (movement co-ordination).

The selected outcome measures may be considered more sensitive to detecting changes in the BHM group rather than the MRP group (recognised by the authors) as protocols had different aims – the BHM protocol focussed on mass grip and release and MRP protocol focussed on improving functional skills. The selected outcome measures used in the study detect changes in recovery of movement / grasp and release / impairment level rather than changes in functional ability, making them more likely to detect changes in the BHM study group rather than the MRP group. The inclusion of a measure of functional ability such as the Action Research Arm Test would have provided a wider and more generic comparison.

A formal sample size calculation was not reported (acknowledged as a study limitation). Despite no formal sample size calculation, formal statistical comparisons were still undertaken between groups (at baseline and post-intervention) and within groups over time, and comparisons may not have been appropriate.

All participants were reported as receiving allocated interventions (not formally monitored or assessed) and attended for outcome assessments (0% attrition). There were no statistically significant differences in baseline characteristics between groups (limited range of demographics available). Both groups showed an improvement in BRS-H between baseline and post intervention and there was no statistically significant difference between groups ($p = 0.346$). When comparing between groups, changes in individual FMA sub scores (FMA - VII, FMA - VIII and IX) and the FMA-WH as a whole were analysed. There were no statistically significant differences between groups when comparing the sub-tests FMA-VII and FMA-IX ($p= 0.180$ and $p = 0.118$), however there was a statistically significant difference when comparing the

FMA-IX (p = 0.033) in favour of the BHM group. When the authors compared overall FMA – WH scores (all the individual sub-tests together), there was a statistically significant difference between the groups in favour of the BHM protocol (p = 0.004).

The authors concluded that both approaches were beneficial for hand recovery but greater motor recovery was seen following the Brunnstrom approach. However, the only statistically significant difference identified between groups was in one sub group of the FMA-WH (FMA-IX) which influenced the overall result of the FMA-WH.

Results should be interpreted with caution due to small sample size, few numbers of therapy sessions and limited outcome measures (limitations recognised by the authors).

Arya et al., 2012 [61]

This single centre RCT aimed to evaluate the effectiveness of Meaningful Task-Specific Training (MTST) on upper limb recovery, activity limitation and the amount and quality of upper limb use during activities of daily living in sub-acute stroke.

One hundred and three patients were randomised (using sequentially numbered envelopes containing group allocation, generated via a computer programme) to receive either the MTST programme (n = 51) or the study control (Brunnstrom and Bobath combined intervention, n = 52).

Eligibility criteria were extensive (see table 2) making results relevant to specific patients with stroke. Patients between 4 – 24 weeks post stoke were selected which may be regarded a wide recruitment window considering changes in capacity for neuroplasticity early and later after stroke. Authors used a functional ambulation classification in the inclusion criteria (level I and above) and it was unclear why a level of walking ability was used in an upper limb study.

The study intervention period lasted four weeks. The MTST programme consisted of repetitive practice of a specific number of meaningful tasks that were common to all participants. In addition, participant specific tasks were selected from a set ‘task bank’. Therapists further individualised treatments by altering the number of repetitions, speed, time or (see table 3 for further information). Interventions lasted one hour and each task varied from 1 to 5 sets or 2 sets of 5 minutes of 10 – 20 repetitions.

The study control treatment was dose matched to the intervention group (details unspecified) and based on a combination of the Brunnstrom movement therapy approach and the Bobath neurodevelopmental technique. Further details were not provided, but considering the approaches involved it is likely that the control treatment was less standardised / structured and subsequently less repeatable than the MTST programme. Consideration of usual post stroke rehabilitation input was absent from the paper and may have varied considerably.

The study was described as ‘double blinded’ (outcome assessors and participants) but success of blinding was unreported. Participants were assessed at baseline, post-intervention (4 weeks) and followed up at eight weeks. The upper extremity section of the Fugl-Meyer (FMA-UE) and the wrist and hand (FMA-WH) and the Action Research Arm Test were all considered the primary measures.

Secondary outcome measures included the upper limb specific Graded Wolf Motor Function Test (GWMFT), which assesses time taken to complete specific tasks and the quality of the movement when completing the tasks. At the time of study publication, reliability and validity of the GWMFT was not available in literature. A further secondary outcome used was the participant self-reported Motor Activity Log.

A power calculation for the study was performed (47 participants required per group) using the Fugl-Meyer Assessment and ARAT (unclear if combined or separate). Data were analysed using repeated measures two-way ANOVA (significance level set at < 0.05) using a Bonferroni correction (to reduce the probability of type I errors) and an intension to treat analysis with the last observation carried forward was incorporated.

Participants were similar at baseline across a variety of patient characteristics and demographics. The MTST group demonstrated a greater improvement in scores in most outcome measures between baseline, post-intervention and follow-up compared to the control group. Post-intervention p values were not provided. Both treatment groups showed an improvement in overall FMA-UE and also within each sub-section (FMA-UA and FMA-WH), between baseline, post-intervention and at follow-up. The MTST group had significantly greater improvements than the control group in the FMA-UE and also within each sub-section (FMA-UA and FMA-WH) ($p = < 0.001$).

A similar result was seen when comparing ARAT scores between groups (p = <0.01 in favour of the MTST group at follow-up). Results for the secondary measures (GWMFT and MAL) also showed a statistically significant difference in improvement in favour of the MTST group compared to the control group (p = < 0.001).

The authors concluded that MTST improved motor recovery, reduced activity limitation and improved time and quality of movement and the amount the affected upper limb was involved in activities of daily living. However, the study was potentially underpowered, and problems with study methodology mean the authors' conclusions need to be interpreted with caution. It may not be possible to generalise the results to all sub-acute stroke patients as the eligibility criteria were extensive. Lack of details about the study control intervention means that the study could not be replicated.

Mares et al. 2014 [65, 66]

This single centre study evaluated the feasibility of a future phase III trial to determine if functional strength training (FST) improves motor function and ability to perform everyday tasks in patients from six months to five years post stroke. The study objectives were appropriate for a feasibility study, and included estimating recruitment rate, collecting data to inform the future sample size calculation and exploring participant experiences of FST.

Inclusion criteria were extensive (see table 2 for full criteria); patients were required to have anterior or middle cerebral artery infarct or haemorrhage and be discharged from usual post stroke rehabilitation.

Fifty two participants were randomised into two groups via an independent automated system. The sample was stratified considering both upper and lower limb function scores (Functional Ambulation Category (FAC) and ARAT).

Both groups received a study intervention; one group was allocated to FST for the upper limb (FST UL); the other group to FST for the lower limb (FST LL). Authors explained that this design allowed each group to act as a control for the other and reduce the potential confounder of comparing interventions to a lower dose of conventional treatment / no treatment. This design was also to increase value for money compared to a three group design (additional group receives no treatment or a placebo). The clinical expectation of a cross training effect between upper and lower limbs was recognised, but authors reviewed recent evidence and concluded

results were unclear. They decided if a cross training effect was evident then the future study design would be amended. The study sample size was estimated, so it was unclear if the sample size was sufficient to determine if a cross training effect occurred.

Study treatments were delivered by research therapists in participants' homes for one hour/day, 4 days/week for 6 weeks. The FST UL treatment consisted of repetitive and progressive resistance exercises during functional task practice training. The FST LL treatment included variations of lower limb functional tasks e.g. ascending and descending stairs. Available information on therapy programme content is presented in table 3.

Outcome measures were the ARAT and Functional Ambulation Categories (see table 1 for full list of outcome measures). Interestingly, measures of upper limb or lower limb strength were not included. Participants were assessed at baseline, six weeks (post intervention) and twelve weeks. Assessments were undertaken by blinded outcome assessors. Methods to promote blinding / success of blinding were not reported. Participant interviews were conducted by a qualitative researcher and occurred at baseline (prior to group allocation) and six weeks (post intervention).

Adverse events data were limited - only the number of participants discharged from the programme due to pain was reported (nil discharged). Testing methods of collecting more detailed adverse events data would have would been useful in this feasibility study.

Authors reported a change in recruitment strategy during the study due to poor recruitment rate. Early Supportive Discharge team therapists and therapists from other community teams highlighted potential participants, which led to inclusion of participants with posterior circulation infarcts (such patients should have been excluded). Referral of patients who were provided rehabilitation may have led to patients receiving ongoing rehabilitation whilst participating in the study, although this is unclear.

Authors followed an intention to treat principle and performed a variety of statistical tests including the Mann-Whitney test for the ARAT and the proportional odds model for the FAC. The main aim of the analyses was to estimate parameters needed to perform a future sample size calculation (by calculation of the clinical efficacy, and its variance, of FST-UL and FST-LL).

Participants appeared well matched at baseline but statistical comparisons were not reported. The effect sizes between groups for the ARAT were -5.06 (95% CI – 9.93 to -0.18) post intervention and -5.91 (95% CI -10.85 to -0.97) at twelve weeks. The proportional odds assumption for the FAC was tested and authors reported no reasons to reject the fit of the model (post intervention: p=0.964, twelve weeks: p=0.821). Authors reported participants were entirely positive about the programmes at interview. It is interesting to note that there were more FST LL participants (4/6) interviewed than FST UL (2/6).

Adherence to the FST interventions was reported by presenting the proportion of hours received/number of hours intended (FST UL 71.3% and FST LL 64.6%) and authors described content was consistent with the study protocol.

Authors concluded it was feasible to undertake a fully powered randomised controlled trial, with some modifications to the protocol (in particular, recruitment strategy). It is important to note that this was a single centre study and additional feasibility findings may have been identified if undertaken at more than one study site. The study useful data including successful delivery of interventions at home and issues concerning recording of adverse events.

Table 1: Previous studies including RFTP for the upper limb after stroke – study design overview

Author	Title of study paper	Study aim	Design and setting	Sample size and study groups	Stroke details and timing post stroke	Outcome measures	Follow up outcome assessments
Turton and Fraser, 1990 [58]	The use of home therapy programmes for improving recovery of the upper limb following stroke.	To evaluate the effectiveness of delivering therapy using home therapy programmes to facilitate to recovery of reaching movements in patients with stroke.	Single centre RCT. Neuro-rehabilitation unit. UK.	22 (home therapy programme =12, control = 10).	Diagnosis of stroke. Patients discharged from in-patient care.	Southern Motor Group's motor assessment, 10 hole peg test, questionnaire developed by the study researchers.	Approximately every four weeks whilst receiving treatment and at the end of the intervention period – no further details provided.
Kwakkel et al. 1999 [56]	Intensity of leg and arm training after primary middle-cerebral-artery stroke: a randomised trial.	To explore the effects of different intensities of upper limb and lower limb rehabilitation on walking ability, activities of daily living and paretic upper limb dexterity.	Multicentre RCT. Seven hospitals. Netherlands.	101 (UL training = 33, LL training = 31, control = 37).	MCA strokes only. First ever stroke. Within fourteen days post stroke.	ARAT, BI, FAC, NHP, 10 Metre timed walk test, and a short geriatric version of the Sickness Impact Profile.	Weekly between weeks 1-10 and every two weeks until week 20. Final measurements at 26 weeks.
Langhammer and Stanghelle, 2000 [57]	Bobath or Motor Relearning Programme? A comparison of two different approaches of physiotherapy in stroke rehabilitation: a randomized controlled study.	To compare patient outcome between two therapeutic approaches early after stroke (Bobath and motor relearning programme).	Single centre RCT. Hospital. Norway.	61 (motor relearning = 33, Bobath = 28).	First ever stroke. Unspecified time after stroke - recruited within 3 days of admission.	MAS, SMES, BI, NHP, length of hospital stay, discharge destination and use of assistive devices for mobility.	Two weeks and three months post stroke.

Table 1: Previous studies including RFTP for the upper limb after stroke – study design overview (continued)

Author	Title of study paper	Study aim	Design and setting	Sample size and study groups	Stroke details and timing post stroke	Outcome measures	Follow up outcome assessments
Langhammer and Stanghelle, 2003 [70]	Bobath or Motor Relearning Programme? A follow-up one and four years post stroke.	To establish the longer term effects of two treatment approaches (Bobath and motor relearning programme).	Follow up study of a, single centre RCT. Norway.	48 (MRP = 27, Bobath = 21). Four years post stroke 37 (MRP = 21, Bobath = 16).	First ever stroke One year and four years post stroke.	MAS, SMES, BI,, NHP and the Berg Balance Scale.	One year and four years post stroke.
Blennerhassett and Dite, 2004 [54]	Additional task related practice improves mobility and upper limb function early after stroke: A randomised controlled trial.	To establish whether additional task practice directed towards mobility or the upper limb improves function outcome in patients early after stroke.	Single centre RCT. Rehabilitation centre. Australia.	30 (upper limb therapy = 15, mobility training =15).	Diagnosis of stroke – unclear whether recurrent stroke was included. Time after stroke unspecified.	6MWT, step test, TUGT, upper limb and hand items of the MAS and the combined time for the three sub-tests from the JTHFT.	Post-intervention (four weeks) and six months after completing the intervention.
Winstein et al., 2004 [60]	A randomized Controlled Comparison of Upper-Extremity Rehabilitation Strategies in Acute Stroke: A Pilot Study of Immediate and Long-Term Outcomes.	To evaluate immediate and long term outcomes of two different upper limb rehabilitation approaches.	Single centre pilot RCT. Rehabilitation centre. USA.	64 (functional task practice = 22, strength training = 21, usual post stroke rehabilitation = 21).	First ever stroke. Two - 35 days post stroke.	Primary: upper extremity portion of the FMA, dynamometer, FTHUE and isometric torque at the shoulder, elbow and wrist (dynamometer). Secondary: self-care and mobility portions of the FIM.	Post- intervention (four weeks) and at six and nine months post-stroke.

Table 1: Previous studies including RFTP for the upper limb after stroke – study design overview (continued)

Author	Title of study paper	Study aim	Design and setting	Sample size and study groups	Stroke details and timing post stroke	Outcome measures	Follow up outcome assessments
van Vliet et al., 2005 [59]	Comparison of Bobath based and movement science based treatment for stroke: a randomised controlled trial.	To evaluate whether the movement science based (MSB) approach or the Bobath (BB) approach is more effective in improving functional independence and movement ability in patients with stroke.	Single centre RCT. Stroke rehabilitation ward. England.	120 (Bobath based approach = 60, movement science based treatment = 60).	Diagnosis of stroke – unclear whether recurrent stroke was included. Within fourteen days post stroke.	Primary outcomes – Rivermead Motor Assessment (gross function) and the MAS. Secondary outcomes – ten hole peg test, Modified Ashworth Scale, 6MWT, BI, Nottingham sensory assessment.	One, three and six months post-randomisation.
Higgins et al. 2006 [55]	The effect of a task orientated intervention on arm function in people with stroke: a randomized controlled trial.	To evaluate the efficacy of a task-orientated intervention to improve walking ability within one year of stroke.	Multi centre RCT. Nine hospitals and two rehabilitation centres. Canada.	91 (arm exercise group = 47, walking group = 44).	First ever or recurrent stroke. Within one year post stroke.	Box and Plot test (upper limb function), NHPT, TEMPA (upper limb activity limitation), grip strength (dynamometer), STREAM (arm sub-scale only- an assessment of movement), BI, OASS-IADL, SF-36 (health survey), and the Geriatric Depression Scale.	Post intervention (six weeks).

Table 1: Previous studies including RFTP for the upper limb after stroke – study design overview (continued)

Author	Title of study paper	Study aim	Design and setting	Sample size and study groups	Stroke details and timing post stroke	Outcome measures	Follow up outcome assessments
Harris et al. 2009 [63]	A Self-Administered Graded Repetitive Arm Supplementary Program (GRASP) Improves Arm Function During Inpatient Stroke Rehabilitation A multi-site randomized controlled trial.	To establish the effectiveness of a self-administered graded repetitive arm supplementary programme (GRASP) on upper limb recovery in stroke.	Single blind, multicentre RCT. Four rehabilitation centres. Canada.	103 (GRASP = 53, control = 50).	Diagnosis of stroke – unclear whether recurrent stroke was included. Unclear time after stroke - patients screened in acute facility then recruited approx. 14 days later in rehabilitation centres.	CAHAI, ARAT, MAL, SF-12 (health survey), VAS (pain), Fatigue Severity Scale, dynamometer (grip strength).	Post intervention (four weeks) and follow up (four months post intervention).
Donaldson et al., 2009 [62]	Effects of conventional physical therapy and functional strength training on upper limb motor recovery after stroke: a randomised phase II study.	To assess the feasibility of a phase III randomised controlled trial to compare functional strength training (FST) with conventional physiotherapy (CPT) for upper limb recovery post stroke.	Randomised pilot RCT. Single centre implied. Setting unspecified. England.	30 (conventional physical therapy [CPT] = 10, higher intensity CPT [CPT + CPT] = 10 and CPT + functional strength training [CPT + FST] = 10).	Diagnosis of stroke - unclear whether recurrent stroke was included. One week to three months post stroke.	ARAT, NHPT, myometer (upper limb strength), questionnaire (participants' blinding status).	Post intervention (six weeks) and twelve weeks.

Table 1: Previous studies including RFTP for the upper limb after stroke – study design overview (continued)

Author	Title of study paper	Study aim	Design and setting	Sample size and study groups	Stroke details and timing post stroke	Outcome measures	Follow up outcome assessments
Pandian et al., 2012 [64]	Comparison of Brunnstrom movement therapy and motor relearning program in rehabilitation of post-stroke hemi paretic hand: A randomized trial.	To compare the effectiveness of hand therapy protocols based on Brunnstrom hand manipulation (BHM) and the motor relearning programme (MRP) of the hand in chronic stroke patients.	Single centre RCT. Outpatients department. India.	30 (BHM = 15, MRP = 15).	Diagnosis of stroke. Unclear whether recurrent stroke was included. 'Chronic' patients – no further details provided.	BRS-H and the FMA-WH.	Post-intervention period (four weeks).
Arya et al., 2012 [61]	Meaningful Task-Specific Training (MTST) for Stroke Rehabilitation: A Randomized Controlled Trial.	To evaluate the effectiveness of MTST on upper limb recovery in sub-acute stroke patients	Multi centre RCT. One inpatient neurology ward and one OT unit of a rehabilitation institute. India.	103 (MTST = 51, Brunnstrom and Bobath combined intervention = 52).	First ever stroke. Recruited 4-24 weeks post stroke.	FMA, ARAT, GWMFT, and MAL.	Post-intervention (four weeks) and follow up (eight weeks).
Mares et al. 2014 [65, 66]	Feasibility of a randomised controlled trial of functional strength training for people between six months and five years: FeSTivaLS trial	To evaluate the feasibility of a subsequent fully powered, randomised controlled trial.	Single centre, two group, randomised, observer blind feasibility study. One NHS health trust (3 sources – database, 6 month review clinic, therapy referral team). UK.	52 (Functional strength training (FST) upper limb = 27, FST lower limb = 25).	Anterior or middle cerebral artery infarct or haemorrhage. Unclear whether recurrent stroke was included. Between 6 months and 5 years post stroke.	FAC, ARAT, Modified Rivermead Mobility Index, TUGT and NHPT.	Post intervention (six weeks) and follow up (12 weeks).

MAS = Motor Assessment Scale (motor function); **SMES** = Sødring Motor Evaluation Scale (motor function in stroke); **NHP** = Nottingham Health Profile; **6MWT** = Six Minute Walk Test; **TUGT** = Timed Up and Go Test; **JTHFT** = Jebsen Taylor Hand Function Test; **FTHUE** = Functional Test for Hemi paretic Upper Extremity; **FIM** = Functional Independence Measure; Fatigue Severity Scale, **TEMPA =** Test d'Evaluation des Members supérieurs des Personnes Agées (upper limb activity limitation); **STREAM** = Stroke Rehabilitation Assessment of Movement (arm sub-scale only- an assessment of movement); **OASS-IADL** = Older Americans Resource Scale for Instrumental Activities of Daily Living; **CAHAI** = Chedoke Arm and Hand Activity Inventory (upper limb functional assessment); **MAL**= Motor Activity Log-14 (structured questionnaire measuring motor activity); **VAS** = Visual Analogue Scale; **FMA** = Fugl-Meyer Assessment (upper limb impairment); **FMA-WH** = Fugl-Meyer Assessment (wrist and hand impairment sub-test); **BRS-H** = Brunnstrom recovery stage of the hand (motor recovery level); **GWMFT** = Graded Wolf Motor Function Test; **FAC** = Functional Ambulation Category; **ARAT** = Action Research Arm Test; **NHPT =** Nine Hole Peg Test (dexterity), **BI** = Barthel Index (activities of daily living).

Table 2: Previous studies including RFTP for the upper limb after stroke – eligibility criteria

Author	Inclusion criteria	Exclusion criteria
Turton and Fraser, 1990 [58]	Diagnosis of stroke. Impaired function (< 95% of normal performance on the 10 hole peg test). Patients who had apraxia and perceptual or cognitive impairments were considered for study inclusion provided they could understand instructions.	Unspecified.
Kwakkel et al. 1999 [56]	Primary first-ever stroke in the territory of the middle cerebral artery confirmed by CT / MRI. Aged 30 - 80 yrs. Impaired function of the upper and lower limbs. No Significant comorbidity. No Severe communication, memory or understanding deficits.	Unspecified.
Langhammer and Stanghelle, 2000 [57]	First-ever stroke and hemi-paresis as identified clinically and by CT scan.	More than one incidence of stroke, presence of brain tumours, subarachnoid bleeding, other severe medical conditions and a score of >5 on the Motor Assessment Scale.
Blennerhassett and Dite, 2004 [54]	Primary diagnosis of stroke and the ability to walk ten metres.	Deteriorating medical condition or 'independent community ambulators' (definition provided in the paper).
Winstein et al., 2004 [60]	First time infarction confirmed by CT or MRI in the anterior circulation, 2 -, 35 days post-stroke, FIM instrument total score of between 40 and 80 on admission. Criteria were expanded early in the recruitment phase to incorporate haemorrhagic or pontine strokes and a wider range of FIM scores on admission.	Reduced upper limb movement due to orthopaedic or peripheral nerve conditions, angina and cardiac disease that limited function due to dyspnoea, severe fatigue, progressive hydrocephalus, previous history of brain injury, severe aphasia, neglect and agitation or depression that would limit participation.
van Vliet et al., 2005 [59]	Diagnosis of stroke and referral to physiotherapy.	>2 weeks post stroke, unable to toilet themselves independently prior to stroke, unconscious on hospital admission, unable to tolerate the initial assessment (30 minutes including physical tasks) if they lived more than 25 km from the hospital.

Table 2: Previous studies including RFTP for the upper limb after stroke – eligibility criteria (continued)

Author	Inclusion criteria	Exclusion criteria
Higgins et al. 2006 [55]	Clinical diagnosis of first or recurrent stroke, residual walking deficit, Minimum score of 14/22 MMSE, able to walk 10m independently, sufficient language ability to follow testing procedures, live in the community, discharged from physical rehabilitation, less than 1 year post stroke at time of recruitment.	Neurological deficit related to metastatic disease, recovery of functional walking ability defined by age-gender norms, discharge to a long term care facility, comorbid conditions that precluded participation in arm or walking training.
Harris et al. 2009 [63]	Confirmation of a haemorrhage or infarct on computerised axial tomography (CT) or magnetic resonance (MRI) scan, scapular elevation (against gravity) and palpable wrist extension (grade 1 Oxford scale), score between 10 - 57 on the Fugl-Meyer Assessment (impairment orientated measure).	Unstable cardiovascular status, significant musculoskeletal or neurological condition (other than stroke) affecting the upper limb, receptive dysphasia and Mini-Mental Status examination <20.
Donaldson et al., 2009 [62]	Diagnosis anterior circulation infarct on CT or MRI, one week - three months post stroke, ARAT score 4+/57, Nine Hole Peg Test 50 seconds or less. Able to use the effected limb to pick up a cup and drink from it prior to their stroke, no obvious unilateral visuospacial neglect on clinical observation, follow a one-stage command and be able to participate in routine therapy.	Unspecified.
Pandian et al., 2012 [64]	Diagnosis of stroke confirmed by CT or MRI scan, aged 35 – 60 years, stage 3 BRS-H, cognitively and perceptually intact.	Cerebellar lesions, painful or subluxed shoulder, upper limb contractures or deformities and lack of siting balance.
Arya et al., 2012 [61]	Diagnosis of unilateral first ever stroke confirmed by CT or MRI scan, 4 – 24 weeks post stroke, functional ambulation classification level 1 and above, ability to understand instructions - Hindi Mental State Examination (score of > 240), National Institute of Health Stroke Scale (NIHSS) score of <14, classed as Brunnstrom Stages of Arm Recovery 2 – 5 and able to cope with an intensive programme.	Perceptual or cognitive deficits, dementia, depression, shoulder subluxation, aphasia, sensory loss, impaired vision, reduced conscious level, concomitant medical illness and cardiovascular instability.

Table 2: Previous studies including RFTP for the upper limb after stroke – eligibility criteria (continued)

Author	Inclusion criteria	Exclusion criteria
Mares et al., 2014 [65, 66]	Aged 18 and over, 6 months to five years post stroke (infarct or haemorrhage) in the anterior circulation (anterior or middle cerebral artery), able to walk four steps with support from one person and/or an assistive device, but in 15 seconds unable to step on and off a 7.5com block, with either leg, more than 14 times, able to move the paretic hand from lap to table surface, but unable to pick up £1 coins individually and stack four in an even pile, able to follow a one stage command with the non-paretic upper limb, no known pathology contraindicating participation in FST and not participating in formal upper or lower limb physical therapy.	Unspecified.

Table 3: Previous studies including RFTP for the upper limb after stroke – RFTP based input

Therapy intervention details	Author		
	Turton and Fraser, 1990 [58]	**Kwakkel et al., 1999** [56]	**Langhammer and Stanghelle** [57, 70]
Activity type	Progressive exercises based on a normal reaching action.	Functional exercises facilitating forced arm and hand activity, e.g. leaning, grasping, reaching, dressing, hair combing, moving objects. If treatment at disability level not possible, strengthening exercises.	Motor relearning programme (MRP), nil else identified.
Programme delivery	Self-administered.	One on one therapy time.	One on one therapy time.
Intensity of programme	Two to three times per day, Intensity reviewed and altered as appropriate. Number of sessions per week or length of sessions unspecified. Minimum length of intervention specified as 8 weeks.	Average 30 minutes, 5 days per week for 20 weeks.	40 minutes, 5 days per week, number of weeks varied.
Programme content	Based on the motor-relearning approach.	Therapist selected exercises from a treatment protocol.	Principles of motor relearning, no other detail provided.
Use of goals	Unspecified.	Used in recording programme content but not programme generation.	Unspecified.
Equipment	Unspecified.	Unspecified.	Unspecified.
Number of repetitions	Unspecified.	Unspecified.	Unspecified.
Recording of programme (who recorded and how)	Content recorded by participants in a ‘record book’	Content recorded by therapists using 25 different codes representing task specific goals for the upper limb.	Unspecified.
Individualised versus standardised between participants	Appears highly individualised but unstandardised.	Good balance between components likely.	Difficult to establish, appears highly individualised.
Intervention in comparison group(s)	Usual post stroke rehabilitation.	Other study intervention group = leg training. Study control group = use of pressurised splinting.	Bobath programme.

Table 3: Previous studies including RFTP for the upper limb after stroke – RFTP based input (continued)

Therapy intervention details	Author		
	Blennerhassett and Dite, 2004 [54]	**Winstein et al., 2004 [60]**	**van Vliet et al., 2005 [59]**
Activity type	Functional tasks (working on reach and grasp), stretching (as required), hand-eye co-ordination activities and strengthening using gym equipment. The therapists facilitated upper limb tasks manually as appropriate.	Systematic and repetitive task practice. Task specific functional training within the level of available voluntary motion. Standard, repeatable and have a functional goal (e.g. stirring, grasping, pointing).	Physiotherapists followed guidelines for the movement science based approach. No further details provided.
Programme delivery	Circuit training classes (4 participants per class).	One on one therapy time.	One on one therapy time.
Intensity of programme	1hour per day, 5 days per week for 4 weeks.	1hour per day, 5 days per week for 4 weeks.	Matched to usual post stroke rehabilitation but not specified.
Programme content	Task related practice, circuit training using ten work stations. Exercises customised and progressed as appropriate.	Principles of motor learning, no other detail provided.	Movement science based treatment.
Use of goals	Not used – made independently to the conduct of the study.	Unspecified.	Unspecified.
Equipment	Gym equipment, nil else identified.	Unspecified.	Unspecified.
Number of repetitions	Unspecified number but 5 minutes per station.	Unspecified.	Unspecified.
Recording of programme (who recorded and how)	Unspecified.	Unspecified.	Unspecified.
Individualised versus standardised between participants	Some attempt to individualise.	Difficult to establish, appears highly individualised.	Very unstructured but highly individualised.
Intervention in comparison group(s)	Mobility group (task related practice).	Strength training and standard care groups.	Bobath approach.

Table 3: Previous studies including RFTP for the upper limb after stroke – RFTP based input (continued)

Therapy intervention details	Author		
	Higgins et al. 2006 [55]	**Harris et al., 2009 [63]**	**Donaldson et al., 2009 [62]**
Activity type	Functional exercises guided by participant preference. Facilitation of activity, passive range of movement and vibration given if insufficient movement available.	Strengthening, range of motion and repetitive goal and task orientated activities (e.g. lifting, pouring).	Specific functional tasks or specific movements, in preparation for functional tasks. Hand grip activities, hand manipulation activities pick and place activities, upper limb gross patterns of functional movements.
Programme delivery	One on one therapy time.	Self-administered (3 ability levels) monitored twice weekly.	One on one therapy time.
Intensity of programme	Ninety minutes, 3 times per week for 6 weeks. Home programme, 15 minutes daily.	6 days per week, 60 minutes per day, 4 weeks.	'Up to an hour' four days per week for six weeks.
Programme content	Functional activities selected by the participant.	Three exercise protocols ;(mild, moderate and severe).	Unspecified.
Use of goals	Apparent use of goals but no obvious formal goal setting.	Unspecified.	Unspecified.
Equipment	Household objects.	Equipment kit containing abstract objects (e.g. bean bag) and functional objects (e.g. towel).	Everyday objects such as food items, pegs, pens, shopping bags, reaching to a shelf.
Number of repetitions	Unspecified.	Graded to participant requirement.	Up to 5 sets of 10 repetitions.
Recording of programme (who recorded and how)	Recorded by therapist, no further details provided.	Recorded by participants on log sheets.	Unspecified.
Individualised versus standardised between participants	Very unstructured but highly individualised.	Highly structured, poorly individualised.	Appears highly individualised and poorly standardised.
Intervention in comparison group(s)	Mobility training group.	Education book.	Conventional physical therapy (CPT) and CPT+CPT.

Table 3: Previous studies including RFTP for the upper limb after stroke – RFTP based input (continued)

Therapy intervention details	Author	
	Pandian et al., 2012 [64]	**Arya et al., 2012 [61]**
Activity type	Motor relearning programme - direct practice of context specific motor skills (e.g. reaching and grasping) following a set protocol using a four step sequence; 'analysis of the task, practice of the missing component of the task and practice of the entire task'. Verbal instruction, manual guidance, visual demonstration, feedback and practice of the task were provided in addition. Specific protocol provided in study paper.	Repetitive practice of a specific number of meaningful tasks common to all participants. Additional, participant specific tasks were selected from a set 'task bank'. If required the participant was passively supported, guided, actively assisted or directed by the therapist. Therapists altered the number of repetitions, speed, time or distance to make the intervention more challenging for the participant. Variables such as distance, speed, time or repetitions were altered to make treatments more challenging. Auditory, visual and proprioceptive feedback also given.
Programme delivery	One on one therapy time.	One on one therapy time.
Intensity of programme	One hour, three days per week for four weeks (approximately 12 sessions).	Four weeks.
Programme content	Followed a set protocol.	Mix of set activities and activities and other activities selected by setting goals.
Use of goals	Unspecified.	Yes.
Equipment	Use of cylindrical objects, everyday objects (e.g. bowl, cup) and unspecified objects.	Everyday functional objects (e.g. water bottle, glass, folded towel).
Number of repetitions	Unspecified.	10 -20 repetitions or 1 – 5 sets of 2 – 5 minutes.
Recording of programme (who recorded and how)	Unspecified but therapists followed a set protocol.	Unspecified but therapists followed a set protocol.
Individualised versus standardised between participants	Very standardised, some possible individualisation (use of relevant objects) but unclear.	Interventions standardised but some individualisation of programme content by use of goals.
Intervention in comparison group(s)	Brunnstrom movement therapy	Based on the Brunnstrom movement therapy and the Bobath techniques.

Table 3: Previous studies including RFTP for the upper limb after stroke – RFTP based input (continued)

Therapy intervention details	Author
	Mares et al., 2014 [65, 66]
Activity type	Repetitive progressive resistive exercise during functional task-specific training. Examples provided included variations of; reaching, picking up a jug containing water and pouring contents into a container; picking up a container and removing the screw lid; reaching down to a foot and then using both hands to lace up a shoe; and picking up and then moving everyday objects of various weights and sizes to position them in a different locations of diverse heights. Activities were systematically progressed by increasing resistance and number of repetitions. Functional items (such as bottles) were used to increase loading during tasks.
Programme delivery	One on one therapy time. Delivered in participants' homes.
Intensity of programme	One hour/day, 4 days/week for 6 weeks
Programme content	Identification of activities affected by muscle weakness during the first therapy session.
Use of goals	Unspecified.
Equipment	Everyday objects implied.
Number of repetitions	Number of activities selected and number of repetitions practiced both unspecified. Activities practised for a maximum of one hour, but included rest periods if required. Activities progressed systematically by increasing resistance and number of repetitions. Therapy session could be <1 hour if the participant was unable to continue due to fatigue.
Recording of programme (who recorded and how)	Recorded by therapists on a standardised treatment schedule (amount and type of intervention provided).
Individualised versus standardised between participants	Content individualised to participants following initial physical assessment and response to treatment (systematic progression or reduction of resistance and repetitions).
Intervention in comparison group(s)	Repetitive progressive resistive exercise during functional task-specific training. Examples provided included variations of; standing up and sitting down and going up and down stairs.

Table 4: Previous studies including RFTP for the upper limb after stroke – study methodology

	Turton and Fraser, 1990 [58]	Kwakkel et al., 1999 [56]	Langhammer and Stanghelle [57, 70]
Appropriate and clearly focussed question	Yes	Yes	Yes
Assignment to groups is randomised	Yes	Yes	Yes
Adequate concealment method used	Can't say	Can't say	Can't say
Blinded subjects and investigators	No	Yes	Can't say
Participant groups similar at baseline	No	Yes	Can't say
Only difference between groups is the intervention	Can't say	Yes	Can't say
Outcomes measured in a standard, valid and reliable way	Yes	Can't say	Can't say
Intension to treat analysis	Yes	Yes	Can't say
Results comparable across all sites	Does not apply	Yes	Does not apply
How well was the study done to minimise bias?	Low quality	High quality	Low quality
Intervention investigated	Home therapy programme (based on motor-relearning).	Different intensities of arm and leg rehabilitation training.	Motor relearning programme.
Study funding	East Anglian Regional Health Authority.	Netherlands Heart Foundation.	Unspecified.

Table 4: Previous studies including RFTP for the upper limb after stroke – study methodology (continued)

	Blennerhassett and Dite, 2004 [54]	Winstein et al., 2004 [60]	van Vliet et al., 2005 [59]	Higgins et al. 2006 [55]
Appropriate and clearly focussed question	Yes	Yes	Yes	Yes
Assignment to groups is randomised	Yes	Yes	Yes	Yes
Adequate concealment method used	Can't say	Can't say	Can't say	Can't say
Blinded subjects and investigators	Can't say	No	Yes	Can't say
Participant groups similar at baseline	Can't say	Yes	Yes	Yes
Only difference between groups is the intervention	Yes	Can't say	Can't say	Yes
Outcomes measured in a standard, valid and reliable way	Yes	Yes	Yes	Yes
Intension to treat analysis	Yes	Can't say	Yes	Yes
Results comparable across all sites	Does not apply	Does not apply	Does not apply	Can't say
How well was the study done to minimise bias?	Acceptable	Low quality	Acceptable	Acceptable
Intervention investigated	Supplementary upper limb programme (circuit training class).	Functional task practice training.	Movement science based physiotherapy.	Practice of functional unilateral and bilateral tasks in the upper limb.
Study funding	Royal Talbot Rehabilitation Centre, Australia.	National Institute of Child Health and Human Development and the Foundation for Physical Therapy, USA.	Stroke Association, UK.	Québec *Réseau provincial de recherché en adaption-réadaptation*, The Heart and Stroke Foundation of Canada, Canadian Stroke Network.

Table 4: Previous studies including RFTP for the upper limb after stroke – study methodology (continued)

	Harris et al. 2009 [63]	Donaldson et al., 2009 [62]	Pandian et al., 2012 [64]	Arya et al., 2012 [61]
Appropriate and clearly focussed question	Yes	Yes	Yes	Yes
Assignment to groups is randomised	Yes .	Yes	Yes	Yes
Adequate concealment method used	Yes	Yes	Can't say	Can't say
Blinded subjects and investigators	Can't say	Can't say	Can't say	Can't say
Participant groups similar at baseline	Yes	Yes	Yes	Yes
Only difference between groups is the intervention	Can't say	Yes	Can't say	Can't say
Outcomes measured in a standard, valid and reliable way	Can't say	Can't say	Can't say	Yes
Intension to treat analysis	Yes	Can't say	Can't say	Yes
Results comparable across all sites	Yes	Does not apply	Does not apply	Does not apply
How well was the study done to minimise bias?	Acceptable	Acceptable	Low quality	Acceptable
Intervention investigated	Self-administered graded supplementary programme to impaired upper limb.	Functional strength training.	Motor relearning programme.	Meaningful Task-Specific Training.
Study funding	Heart and Stroke Foundation of British Columbia, Canadian Institute of Health Research.	The Wellcome Trust, UK.	Unspecified, India.	Unspecified, India.

Table 4: Previous studies including RFTP for the upper limb after stroke – study methodology (continued)

	Mares et al. [65, 66]
Appropriate and clearly focussed question	Yes
Assignment to groups is randomised	Yes
Adequate concealment method used	Yes
Blinded subjects and investigators	Can't say
Participant groups similar at baseline	Can't say
Only difference between groups is the intervention	Yes
Outcomes measured in a standard, valid and reliable way	Can't say
Intension to treat analysis	Yes
Results comparable across all sites	Does not apply
How well was the study done to minimise bias?	Acceptable
Intervention investigated	Functional strength training
Study funding	The Stroke Association, UK

Table 5: Ongoing study and unpublished completed study

	Turton et al., 2013 [67]	Galea et al. [68]
Title of study	Home based reach-to-grasp training for people after stroke: study protocol for a feasibility randomized controlled trial	Task-Related Training of Arm Use After Stroke: a Randomised Controlled Trial.
Study aim	To assess the acceptability of home-based task-specific reach-to-grasp (RTG) training for people with stroke, and to gather data to inform sample size, recruitment and retention for a future definitive RCT.	To determine if task-specific training of the affected upper limb early after stroke results in significantly better functional outcome than standard intervention.
Design and setting	Two arm, multicentre, assessor-blinded feasibility RCT.	Single blind RCT
Sample size	50 participants.	30 participants.
Inclusion criteria	Diagnosis of stroke (recurrent stroke included); discharged home from hospital; residual deficit in upper limb movement (defined as inability to pick up a 6mm ball bearing from a table top, between index finger and thumb and place it on a shelf 370com above the table). Disability judged to be due to recent stroke.	Within 6 weeks of first stroke; unilateral stroke; impaired arm function; able to cope with intensive training program; medically stable; able to understand instructions.
Exclusion criteria	Pre stroke pathology of the stroke-affected upper limb preventing RTG; unable to lift their hand off their lap when asked to place their hand behind their head; severe fixed contractures of the elbow or wrist; more than 12 months post stroke.	Uncontrolled systemic disease; significant musculotendinous or bony restrictions of the affected upper limb; any serious chronic disease independently causing significant disability of the affected limb.
Stroke details	Diagnosis of stroke (recurrent stroke included).	Diagnosis of stroke - unclear whether recurrent stroke is included
Outcome measures	Action Research Arm Test (ARAT); Wolf Motor Function Test (WMFT); Stroke Impact Scale (SIS); health and social care questionnaire; Motor Activity Log (MAL); Caregiver Strain Index (CSI).	Motor Assessment Scale (arm and hand function); Chedoke Arm and Hand Activity Inventory (arm and hand function); dynamometer (grip and pinch strength); NK Dexterity Board (dexterity); Stroke-adapted Sickness Impact Profile (quality of life); validated assessment of tactile spatial resolution (sensation).
Follow – up outcome assessments	Seven weeks post randomisation, 3 months and six months.	Post intervention (intervention length unspecified) and 3 months.

Table 5: Ongoing study and unpublished completed study (continued)

	Turton et al., 2013 [67]	Galea et al. [68]
Blinding	Blinded outcome assessors.	Blinded outcome assessors.
Therapy intervention details	A progressive training programme comprising practice of whole reach-to-grasp tasks and, where required, practice of the component parts that can be systematically reassembled into the whole task, with the aim of improving reach-to-grasp ability in daily activities. The intervention is based on biomechanical analysis of functional reach-to-grasp movements and principles of motor learning.	Behavioural task training. Task-specific training programme focussing on performance of functional tasks and intensity of practice. Participants practice tasks during and outside of therapy sessions.
Comparison group details	Usual post stroke rehabilitation plus an information booklet containing information about the frequency of study assessment visits.	Intervention that does not involve upper limb training (further details unavailable).
Location	UK	Australia

1.7.2 Appraisal of the Cochrane systematic review (2007) [27] of repetitive task practice for improving functional ability after stroke.

This systematic review offered a basis for the thesis literature review and search strategy, so has been appraised to assess the methodological rigour, appropriateness of included studies (in relation to upper limb rehabilitation) and authors' conclusions. The Critical Appraisal Skills Programme (CASP) systematic review checklist was used to inform the appraisal [74]. The authors included studies that evaluated the effectiveness of RFTP in the upper and lower limbs.

The authors asked a clearly focussed question in relation to the population and intervention studied. The Cochrane review aimed to consider if repetitive task practice *'can lead to sustainable functional gains'* (p. 3) [27].

A thorough search was undertaken by the authors to identify all relevant studies in bibliographic databases (Cochrane stroke trials register [October 2006]), the Cochrane Library, EMBASE, MEDLINE and an additional eight electronic databases). The team contacted study authors for additional information to allow for improved assessment of methodological quality. The authors also searched unpublished studies, non- English language studies, followed-up reference lists, checked conference proceedings and requested information on bulletin boards. Detailed inclusion criteria of studies were listed clearly under the following headings; types of studies, participants, interventions and outcome measures (including primary and secondary outcomes).

Randomised and quasi-randomised trials were included in the review. The authors explained that one randomisation group had to contain repetitive task practice and be compared to a control group, an attention control group or usual post stroke rehabilitation. Trials including participants with acute, sub-acute and chronic stroke were considered for inclusion. Study interventions had to include *'repetitive activity involving complex multi-joint movement with functional measurement of outcome, rather than an exercise of a single joint or muscle group or practice of a functional motor sequence which was repetitive in nature' (p. 3) [27].*

Studies that combined repetitive task practice with other interventions were excluded if the influence of the repetitive practice could not be isolated. Primary outcome measures of included studies assessed upper limb function / reach, mobility / balance and global motor function. Secondary outcomes included measures of

activities of daily living, task performance or impairment, quality of life, health status, user satisfaction, carer burden, motivation or perceived improvement and adverse outcomes.

Each review author was allocated eight studies from which they extracted data and completed critical appraisals. Inter-rater reliability of authors' assessments was evaluated using seven criteria for quality assessment. A clear, pre-determined strategy was undertaken to assess the quality of the included studies. Studies were evaluated for methodological quality and considered to be inadequate, adequate or unclear for selection bias, performance bias, attrition bias, detection bias and reporting bias. Authors assessed treatment effect and heterogeneity, performed subgroup analysis and sensitivity analysis.

A meta-analysis was completed and the combined results of the studies presented. The reviewers reported outcomes relating to upper limb function, hand function, sitting balance/reach, combined outcome measurements, dosage of task practice, time since stroke and type of intervention. Completing a meta –analysis may not have been appropriate due to the diversity of therapy intervention treatments and outcome measures between studies. Authors combined results of outcome measures which assess different elements of ability in the meta-analysis. An example of this was when authors compared post-treatment upper limb function. The study by Kwakkel et al. [56] used the Action Research Arm Test (ARAT) and results data were combined with Motor Assessment Scale data from the study by Langhammer and Stanghelle [57]. The ARAT [75] measures upper limb function whereas the Motor Assessment Scale [76] measures activities of daily living and functional mobility. However, it is recognised that this is a methodological issue for many meta-analyses publications.

The results were presented as standardised mean differences. When the reviewers compared upper limb function data, the results favoured the treatment intervention. However, the confidence interval crossed the line of no effect in each instance. The authors concluded that there was insufficient evidence in favour of use of RFTP in the treatment of the upper limb and insufficient evidence to use RFTP in the upper limb routinely in clinical practice. However, authors recognised the conclusion should be considered with caution due to the lack of sufficient evidence / quality of studies reviewed.

The authors recognised that studies recruited participants at different lengths of time post stroke and participants possessed different levels of ability at the point of study entry. There were a variety of study settings (hospital wards, out-patient and community) and methods of delivery (one on one, group settings, homework based). There was also limited information about the content of the interventions provided by the included study authors.

Studies used a range of outcomes including measures specific to upper limb function (e.g. the Action Research Arm Test), hand function (e.g. Nine Hole Peg Test) and sitting balance and reach (e.g. the Motor Assessment Scale – balanced sitting). Global motor function, impairment measures, quality of life / health status and adverse events were also recorded. Such outcome measure data are valuable to health professionals and policy makers, although the cost effectiveness of the intervention was not formally considered by any of the included study authors. The reviewers acknowledged that although few adverse events were reported in the trials evaluated, there was a lack of formal reporting.

In conclusion, upper limb recovery may be improved by RFTP, but results fell short of statistical significance. It was recognised that insufficient appropriate evidence was available to initiate changes in policy and / or practice. The methodology of the review was rigorous and conclusions appear appropriate.

1.7.3 Discussion of the evidence for repetitive functional task practice (RFTP) for improving upper limb function after stoke

A review of the published studies illustrated that the quality of research evidence into RFTP for improving upper limb function after stroke is variable. Many studies were small and underpowered but presented as effectiveness studies, which was inappropriate. Eight out of twelve studies [54, 55, 57, 58, 60, 62, 64-66] recruited <100 participants. Three out of the eight small studies were presented as feasibility / pilot studies [60, 62, 65, 66], but two [60, 62] made conclusions that were not appropriate for their size.

Published studies were heterogeneous in relation to study population, interventions, comparison groups and outcome measures. There were several other methodological and reporting issues identified when appraising the studies.

Population of stroke survivors included in previous studies

Some studies had very restrictive eligibility criteria; 2/12 studies [61, 64-66] had extensive criteria and 3/12 studies [61, 62, 64] excluded patients with common post stroke symptoms (e.g. painful or subluxed shoulder). Other studies used age limiting criteria [56, 60, 64] selecting relatively younger participants. Restricting study eligibility could have limited the range of participants included in the studies and potentially excluded patients who may have benefited from interventions. Using extensive eligibility criteria in studies may be useful if targeting interventions to a specific group of patients. It was unclear if was the authors' intention to target interventions and this was not reflected in many authors' conclusions.

Conversely, some studies did not indicate specific and / or measured levels of upper limb function or impairment in the inclusion criteria [54, 56, 57]. Selection of participants with a determined level of ability allows appropriate design of the study intervention, and accurate conclusions to be made about the intervention (in relation to the types of patients that may / may not benefit).

The window of recruitment period could be considered too wide in 5/12 studies [54, 61, 62, 64-66], allowing large variations in time post stroke between participants. Variations in time post stroke may make future conclusions about appropriate timing of study interventions post stroke difficult.

RFTP based interventions

The RFTP based interventions investigated in previous studies were poorly reported. It is well recognised that the quality of descriptions of interventions in research publications are often limited [77]. Lack of details makes replication of the studies, or use of study interventions in clinical practice not possible and it was disappointing that key components of RFTP were badly reported (intensity and content). Nine out of twelve studies [54-57, 60, 62-66] provided details about length of therapy sessions, but only 2/12 [61, 62] detailed the number of repetitions practiced per session. There were insufficient details concerning intervention content in 9/12 studies [54-60, 62, 65, 66]. When intervention details were available, programmes were not standardised between participants but highly relevant to the individual (making interventions difficult to replicate) [55, 57-60, 62, 65, 66], or highly standardised at the cost of individualisation [54, 63, 64] (so less relevant to participants). 3/12 of the studies [54, 56, 61] managed to achieve a more acceptable balance. In addition, the length of the intervention period was not pre-determined in 3/12 studies [57-59], further reducing standardisation of interventions.

Comparison treatments

Comparison treatment groups varied between studies. 10/12 of the previous studies included comparisons of RFTP based programmes to attention control interventions [54-57, 59-61, 63-66] (e.g. lower limb training programmes) or other therapy approaches. 9/12 continued with usual post stroke rehabilitation [54, 56-60, 62-64], but only 4/9 attempted to measure usual post stroke rehabilitation received [54, 56, 62, 63]. Recording usual post stroke rehabilitation is challenging as compliance with usual post stroke rehabilitation data collection can be low as participants in rehabilitation studies are often treated by several rehabilitation teams (making data collection logistically difficult).

Outcomes and study blinding

A wide range of outcome measures were used in the reviewed studies. Some studies (2/12) selected outcome measures more sensitive to detecting changes in the comparison group [56, 64], which may have influenced study results. 6/12 studies [54, 55, 57, 58, 60, 61] included outcomes that are not commonly used, making comparison of results across studies / meta-analysis difficult. Reviewing studies emphasises the

need for appropriate selection of outcome measures to ensure sensitivity to change and comparability with other studies.

Many studies did not adequately address blinding of outcome assessors to participant group allocation which may have led to observer bias. Two studies used un-blinded assessors [58, 60] and many of the studies reported blinding of assessors was attempted but did not describe success [54, 55, 57, 61, 63, 64, 66]. Only 2/12 studies [62, 63] discussed blinding of usual post stroke rehabilitation staff to participant group allocation, but success of blinding was not reported. An awareness of group allocation by therapists providing usual post stroke rehabilitation may have produced a competitive therapy bias. 2/12 studies [56, 61] aimed to blind participants to group allocation. Blinding of participants in rehabilitation trials is challenging due to the nature of interventions and informed consent procedures.

Reviewing published studies into RFTP allowed valuable insight into current evidence to support use of RFTP for improving upper limb function after stroke. Overall, as most studies were underpowered, no conclusions can be made about effectiveness. Instead, feasibility questions should have been addressed which could then be followed by large scale, fully powered, methodologically robust effectiveness studies.

As described, there was insufficient evidence to make any recommendations following the Cochrane systematic review examining the effectiveness of repetitive task practice for improving functional ability after stroke (2007) [27]. In 2014, (after this project commenced) the Cochrane collaboration published an overview of systematic reviews examining interventions for improving upper limb function after stroke [25]. The review found moderate GRADE quality evidence demonstrating RFTP involving at least 20 hours of supplementary therapy may be beneficial [25]. The authors also recognised further investigation is required, and recommended large scale randomised controlled trials [25] be undertaken so the Cochrane systematic review examining repetitive task practice for improving functional ability after stroke could be updated [25].

In conclusion, RFTP for the upper limb after stroke is a promising intervention but further research is needed to strengthen evidence. A well described and reproducible RFTP programme needed developing and study feasibility issues investigating prior to a future Phase III study.

1.8 Developing and evaluating complex interventions

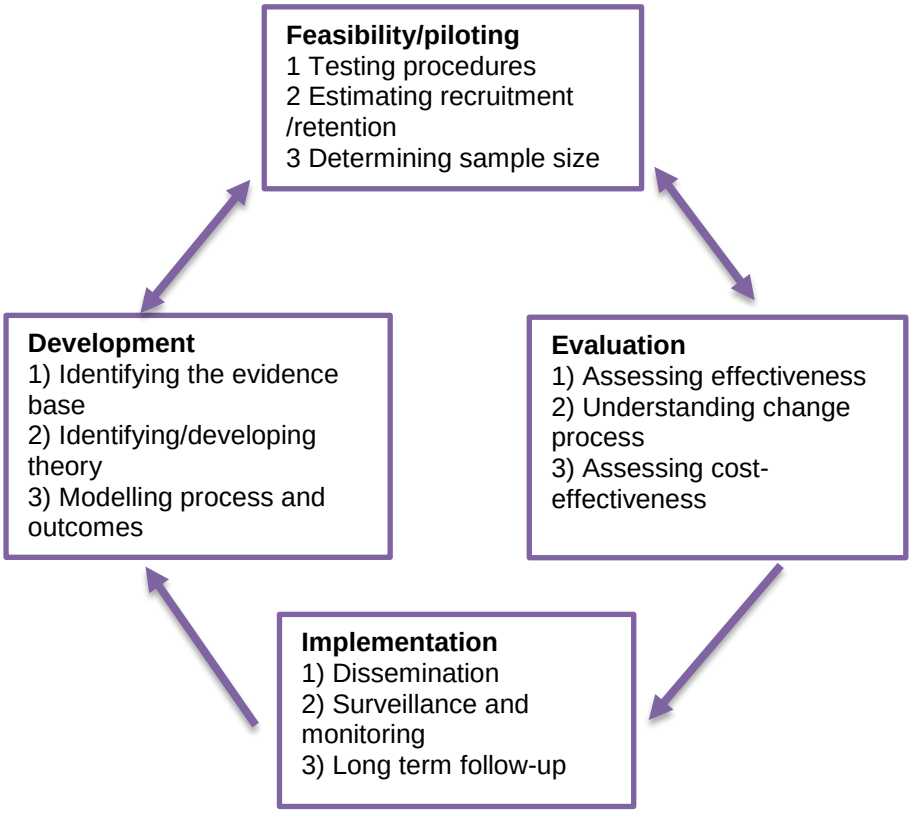
This thesis project was undertaken to develop a RFTP programme and evaluate the feasibility of a Phase III study. The project was guided by the Medical Research Council (MRC) framework for developing and evaluating complex interventions to improve health [78].

The aim of the MRC framework [78] is to assist researchers and research funders to identify and follow appropriate research methods. Complex interventions are categorised by several interacting components within experimental and control interventions, they rely on behaviours required by therapists (delivering the intervention) and patients (practicing the intervention) and there may be a number of organisational / environmental levels targeted by the programme (acute ward setting or community based programmes [78]). Considering this, RFTP may be described as a complex intervention.

Evaluating complex interventions such as RFTP present challenges for researchers including methodological and practical difficulties, which were apparent when appraising previous studies into RFTP. The updated guidance explained that developing and evaluating complex interventions includes several phases; 'Development', 'Feasibility / piloting', 'Evaluation' and 'Implementation' [78], which may not follow a linear process (see figure 1).

The guidance highlights the importance of all stages and warns that inadequate development and piloting work or appropriate exploration into practical implementation results in poorer interventions that are more difficult to evaluate and less likely to be implemented. The thesis project is focussed on 'Development' and 'Feasibility / piloting' stages.

Figure 1: Phases of designing and developing complex interventions in the Medical Research Council (MRC) framework [78]



1.9 Summary of introduction

The theory of neuroplasticity underpins stroke rehabilitation. Neuroplasticity occurs throughout life and is heightened early after stroke. Neurorehabilitation aims to capitalise on neuroplasticity, which in turn drives recovery. Several interventions or treatment approaches are currently being delivered by healthcare professionals to improve upper limb recovery after stroke - including RFTP. The use of RFTP for enhancing upper limb recovery early after stroke is supported by neuroplasticity, the movement science approach to rehabilitation and the theory of motor learning. RFTP is currently recommended by UK guidelines, which acknowledge recommendations are based on consensus of guideline authors.

Further research into RFTP for improving upper limb function after stroke is needed. Previous studies were underpowered, included interventions which were poorly described and there were several methodological concerns. Systematic reviews have indicated the potential value of RFTP programmes, but results did not achieve statistical significance or evidence was of moderate GRADE quality.

A well-defined and described RFTP programme required developing and study feasibility issues investigated prior to undertaking a Phase III study. The MRC framework for developing and evaluating complex interventions [78] was used to guide this project.

Chapter 2. Project Aim and Objectives

2.1 Project aim

To establish the feasibility of a multicentre randomised controlled trial to determine the clinical effectiveness of a repetitive upper limb functional task practise programme for upper limb recovery early after stroke.

2.2 Project objectives

The objectives of the project were:

1. To develop and describe an upper limb repetitive functional task practice (RFTP) programme for patients early after stroke which can be delivered by UK NHS stroke services.
2. To seek the views and experiences of patients, carers, physiotherapists, occupational therapists, and other healthcare professionals about the upper limb RFTP programme.
3. To undertake a feasibility study to demonstrate the feasibility and methodological rigor of a future multicentre RCT.

The literature review informed the development of the project aim and objectives. The literature review highlighted the need for a high quality large scale study. As RFTP based programmes from previous studies did not describe interventions in detail and few were UK based, preliminary work was required develop a RFTP programme that could be delivered within the NHS (and was acceptable to patients and healthcare professionals) and issues of feasibility investigated.

The project was conducted in three sections following the MRC framework [78] guidance about developing and evaluating complex interventions to improve health:

1. Development of an upper limb RFTP programme for patients with acute stroke based on published RCTs, motor learning theory, clinical expertise and stakeholder feedback.
2. Delivery of the RFTP programme to stroke patients by a research physiotherapist and subsequent modification following feedback from patients and therapists (known as ‘Non-randomised feasibility study’).
3. A multicentre feasibility randomised controlled trial (known as ‘RAFTAS feasibility study’).

Aim and objectives specific to each project section are described in Chapters 3, 4 and 5.

Details explaining how the literature review informed content of the RFTP programme are described in Chapter 3.

Chapter 3. Development of the initial RFTP programme

This chapter describes initial development of the RFTP programme. Some aspects of the RFTP programme were pre-specified in the funding application for the project (prior to the thesis author's involvement in the project, submitted in 2010). Some pre-specified aspects of the RFTP programme were incorporated into its design and others were amended after consideration. Pre-specified and amended aspects of the RFTP programme are discussed when describing its development.

3.1 Aim and objectives

3.1.1 Aim

To develop and describe an upper limb repetitive functional task practise (RFTP) programme which can be delivered by UK NHS stroke services to patients early after stroke.

3.1.2 Objectives

1. To develop an upper limb RFTP programme that is:
    - Evidence based
    - Well described and reproducible / standardised (to allow replication of the programme)
    - Individualised and meaningful to patients (person centred)
    - Deliverable in acute and community settings
    - Possible for participants to practise independently
    - Safe

2. To seek stakeholder feedback to inform development of the RFTP programme

3.2 Sources of information used to model the RFTP programme

Several sources of information were used to model the RFTP programme including:

- Current literature
- Clinical guidelines
- Pragmatic considerations of current NHS settings
- Clinical experience (of the thesis author and local physiotherapists and occupational therapists)
- Stroke survivors' and their carers' experience

RFTP based interventions delivered in studies published prior to development of the RFTP programme (before 2011) were reviewed [54-57, 59, 60, 62, 63, 67]. As discussed in chapter one, details concerning interventions were lacking in many of the studies, but available information regarding programme content, dose and delivery were collected from each paper and used to inform the initial modelling process. The initial programme was developed then modified following stakeholder feedback.

3.3 Modelling the initial RFTP programme: Setting, content, delivery and dose

3.3.1 RFTP programme setting

The setting of the RFTP programme was considered in its design. The project grant application specified participants would commence the RFTP programme within one week of acute stroke, which influenced where the RFTP could potentially be undertaken.

There is strong evidence that patients who receive specialist inpatient stroke services are more likely to regain independence with activities of daily living [22, 79]. The National Clinical Guideline for Stroke [14] recommends that patients with suspected stroke should be admitted directly to specialist stroke services, and patients diagnosed with stroke who have inpatient rehabilitation needs should be treated in specialist rehabilitation stroke units [14]. The RFTP programme needed to be deliverable in such acute specialist inpatient settings.

Current NHS policy aims to transfer some of the provision of healthcare from hospital to the community, and as a result the median length of stay in UK stroke units is just 7.1 days [IQR 2.7-22.1] [80]. As length of stay is short, it was likely that the main setting for the RFTP programme would be in the community. The National Clinical Guideline for Stroke [14] recommends patients should continue to be supported by specialist stroke teams after hospital discharge. The recommendation, coupled with reduced length of inpatient stay has resulted in a shift towards community rehabilitation. Within the NHS, the amount and type of community support is dependent on local service configuration. Therapy can be provided by specialist early supported discharge teams, community stroke teams or generic rehabilitation services. Some patients do not receive any therapy post hospital discharge. Discharge destination is determined by patient factors (ability, medical status and social circumstances) and local rehabilitation and support services. Patients with stroke may be discharged to a range of destinations including their own homes,

residential rehabilitation units, residential care (short or long term) and nursing care. The range of possible discharge destinations meant there were many potential RFTP programme community settings and the programme needed to be deliverable in all (in addition to the acute stroke unit).

There is ongoing research into effectiveness of hospital based upper limb rehabilitation interventions [25], but there is currently insufficient evidence for the effectiveness of home-based therapy for improving upper limb function after stroke [22]. However, two previous studies evaluating RFTP based interventions for the upper limb after stroke successfully delivered home based rehabilitation programmes [58, 63].

The different settings of the RFTP programme influenced potential available resources for RFTP programme practice (e.g. equipment and space) and practicalities/logistics of delivering the RFTP programme. Potential physical resources (e.g. equipment) available across a variety of settings was also considered when modelling the RFTP programme.

3.3.2 RFTP programme content

The project grant application specified the content of the RFTP programme was to be relevant to individual patients and comprise of a number of functional tasks requiring multi-joint movements in a style orientated towards a relevant activity of daily living.

RFTP involves task specific training and can include whole or part task practice [30] of functional activities. Given the specificity of training principle, in order to improve performance of a specific task, optimal practice comprises practising that specific task where possible [34].

As the RFTP programme was to be used in a pragmatic study, it needed to be appropriate for patients with a wide range of upper limb abilities. Patients would need sufficient retained function to complete functional tasks from the programme, so the RFTP programme included exercises that were whole or part of a functional task. Whole task practice, for example picking up a cup to have a drink, could be too challenging for some participants early after stroke (e.g. due to paresis or task complexity). Practising part of the task may be more achievable and appropriate for such patients. Part task practice [81] involves dividing the functional activity into components (‘segmentation’) and practising each section separately. For the example of having a drink, part task practice could be practising reaching towards a

cup. For more able patients, in the context of RFTP, part task practice could also offer an opportunity to target practice on the most challenging part of the functional task.

3.3.2.1 Generation of the standardised RFTP exercise list

As discussed in chapter one, the majority of previous studies evaluating RFTP interventions failed to achieve a balance between standardising programmes (to enable replication), and individualising programmes (to ensure programmes were appropriate and meaningful to participants [54, 55, 57, 59, 60, 62-64, 67]). An attempt was made to balance programme standardisation and individualisation when developing the RFTP programme. In order to achieve a balance, a standard list of RFTP exercises was developed. Therapists and participants could select appropriate exercises from the standardised list, following upper limb assessment and discussion with each participant to establish what would be suitable and meaningful to practice (see 'RFTP programme delivery'). The list provided standardisation, and selection of appropriate exercises for each participant ensured individualisation.

For the RFTP programme to be pragmatic, the standardised RFTP exercise list needed to include a wide variety of upper limb functional exercises - covering a range of perceptuo-motor skills involving the upper limb.

In order to develop the standardised exercise list, available upper limb exercise programme content was collected from previous studies evaluating RFTP [54-57, 59, 60, 62, 63, 67]. Impairment based exercises (e.g. using theraputty) were excluded, leaving only exercises functional in nature. As previous programmes were poorly described, this process generated a limited number of exercises and did not sufficiently cover the range of tasks required.

Exercises were also developed from a functional upper limb rehabilitation programme [82] used in an effectiveness trial (Botulinum Toxin for the upper limb after stroke [83], BoTULS). In the BoTULS [83] trial, participants selected upper limb rehabilitation goals. Selected goals were used to generate more RFTP exercises and ensure they were meaningful and appropriate to patients with stroke. The majority of goals in the BoTULS [83] trial were categorised as; 'Washing', 'Dressing' and 'Eating / Drinking', while a minority of varied goals were categorised as "Optional" - these goal categories formed a basis for developing further exercises [82].

To inform the RFTP exercise list further, equipment that may be available to participants in hospital and community settings was considered. A list of everyday objects involved in completion of common upper limb functional tasks during activities of daily living (e.g. during washing) was created. Everyday objects chosen were considered readily available on stroke units or in the community. Examples of such objects were a tooth brush, a jumper and cutlery. Using objects that were familiar to participants aimed to make the programme more relevant and was supported by research that showed using familiar objects within a functional context improves coordinated movement [84] and promotes occupational embedding of tasks practised (carry over of practice into real life situations). Once created, the list of everyday objects was used in combination with clinical experience of the thesis author to generate ideas for further whole task and part task practice exercises.

Specific exercises that required minimal activity in the affected upper limb were also included to ensure an adequate range of exercises were available. These involved using the affected upper limb for stability whilst actively completing the exercise with the unaffected upper limb. This ensured exercises were included for participants with more severe upper limb function (e.g. shoulder movement only). An example is 'Hold / support wash bag with you affected hand and take objects out / put them back in with your unaffected hand.'

The resulting standardised RFTP exercise list included a total of 183 exercises. Once the initial list had been created it was necessary to arrange it in a logical order for use by therapists. The goal categories used in the BoTULS trial [82] became the exercise categories of the RFTP exercise list ('Washing', 'Dressing', 'Eating/Drinking' and 'Optional').

The 'Optional' category was to allow scope for therapists to provide exercises that had been omitted from the list, (e.g. using a mobile phone) and for participants to identify their own exercises to practise. Optional exercises aimed to offer further choice to participants and enhance participant motivation. Rather than detailing specific exercises under the optional category (the list would have been too extensive), themes to explore with participants were suggested (e.g. gardening).

Once the RFTP exercises had been divided into categories, it became apparent that the exercises could then be sub-categorised, to further assist use of the list by

therapists. Categories were sub-categorised as appropriate, for example ‘Exercises using cutlery’ under the category ‘Eating/Drinking’.

As the exercises covered a wide range of upper limb abilities, it was logical to then arrange the exercises in order of patient ability. The exercises were subsequently ordered into three levels of ability by considering sensorimotor problems (e.g. the amount of upper limb movement and coordination required) and the level of cognitive processing needed to complete the exercise. For example, a level three exercise (appropriate for a participant with mild upper limb functional impairment) was ‘Hold the shampoo bottle with the unaffected hand and take the lid off / replace the lid using the affected hand = 1 repetition’. Further details of exercise levels are shown in table 6.

Table 6: Details of Exercise Levels

Exercise level	Description
Level 1	Gross upper limb movement only required. No hand dexterity / grip available. Exercises often involve simple gross movements or ‘propping’ / weight bearing through the affected side and completing the exercise with the unaffected side.
Level 2	Return of some activity in shoulder / elbow / wrist. Minimal hand dexterity / grip required for some of the exercises. The affected side is more actively involved in the exercise / may complete a simple exercise independently. Some exercises are more complex and require more complex cognitive processing.
Level 3	Good return of shoulder / elbow / wrist activity and dexterity / grip. The **affected** side undertakes the exercise independently or leads the exercise if the activity is bimanual. Some exercises are complex and require greater cognitive processing.

The RFTP exercise list is available in appendix 3 (finalised version). For safety, it was stipulated that all exercises should be practised in a seated position unless otherwise advised by the treating therapist. The stipulation was included as participants were to be practising the programme early after stroke and may not have sufficient balance to practise the programme safely in independent standing. Although the focus of the programme was completion of functional exercises, therapists were to encourage normal movement patterns through guiding participants in appropriate completion of exercises.

3.3.3 RFTP programme delivery

In the project grant application, it was specified that each participant's RFTP programme would be individualised and determined by the therapist after undertaking a structured patient assessment. Participants were to practise the programme independently. The therapist would re-assess the participant twice per week to review recovery and modify the content according to progress. The patients were to be reviewed once per week after hospital discharge.

Stroke rehabilitation follows a cyclical process involving patient assessment (to determine needs), goal setting (to establish realistic and achievable rehabilitation goals), intervention (to work towards goal achievement) and reassessment (to establish progress towards agreed goals) [85]. The same cyclical process was followed in the RFTP programme. The intention was to provide a standardised reproducible procedure that was familiar to therapists that could be easily incorporated into patient care within the project and ultimately clinical practice (if shown to be effective).

3.3.3.1 Therapist profession

Either physiotherapists or occupational therapists could deliver the RFTP programme as they have an overlap of knowledge and skills, so reflecting clinical practice. Programmes were delivered by either physiotherapists or occupational therapists in previous studies into RFTP [54-57, 59, 60, 63, 86] .

3.3.3.2 Selecting exercises for participants to practise

3.3.3.2.1 Upper limb assessment (patient assessment)

To individualise the RFTP programme to each participant, it was necessary to include an assessment of each participant's upper limb to establish motor impairment / ability and other neurological deficits that may impact on upper limb function. A standardised clinical RFTP programme upper limb assessment was developed that mirrored a standard neurological therapy assessment performed by therapists in usual post stroke rehabilitation and included assessment of; passive range of motion available at each upper limb joint, selective muscle activity, muscle tone, sensation, proprioception, presence of compensatory movement patterns, presence of associated reactions, pain and upper limb coordination. In addition, any upper limb impairment on the contralateral side to the side affected by stroke was to be noted as this could impact on rehabilitation.

A thorough upper limb assessment in the RFTP programme for use in the project was also required as the programme could be delivered by therapists unfamiliar with participants (i.e. did not provide the participant's usual post stroke rehabilitation).

3.3.3.2.2 Goal setting

Goal setting is *'the identification of and agreement on a behavioural target which the patient, therapist or team will work towards over a specified period of time'* [14] (p. 31). Establishing goals and monitoring goal achievement is considered crucial for rehabilitation and can increase patient motivation and engagement in therapy [87].

The National clinical Guideline for Stroke [14] recommendations for goal setting are shown in figure 2.

Figure 2: The National Clinical Guideline for Stroke recommendations for goal setting [14]

Every patient involved in the rehabilitation process should have goals that:

- are meaningful and relevant to the patient
- are challenging but achievable
- include both short-term (days/weeks) and long-term (weeks/months) targets
- include both single clinicians and also the whole team
- are documented, with specified, time-bound measurable outcomes
- have achievement evaluated using goal attainment
- include carers where appropriate
- are used to guide and inform therapy and treatment.

It is important that the patient feels what they are practising is meaningful to them and what they wish to achieve during therapy. Goal setting also ensures that the patient and clinicians are working towards the same goal, allows monitoring of change (so ineffective interventions can be altered) and ensures important issues are not overlooked [87]. Goals can be considered as either an intended future state / ability (a change from the current ability or maintenance of current ability) or an intended consequence of actions undertaken by a patient or rehabilitative team [87].

Including upper limb rehabilitation goal setting in the RFTP programme enabled it to be individualised and relevant to each participant. Goal setting was used with the upper limb assessment findings to select appropriate exercises from the RFTP

exercise list. This process aimed to ensure that the content of each participant's RFTP programme was linked to their specific upper limb goals. The aim was to make the programme relevant and meaningful to each participant and encourage participant adherence to the programme. Goals were to be realistic and achievable within the four week study period. Goal setting was used in previous studies into RFTP to ensure functional relevance of activities [55, 61].

3.3.3.3 Independent practice

Possible options for provision of RFTP practice sessions were considered. Previous studies that evaluated RFTP for the upper limb used group based therapy, one to one therapy and homework based therapy [58, 63] (independent practice). Ten out of twelve studies delivered therapy under the direct supervision of a trained therapist (one to one and group based therapy) [54-57, 59-62, 64-66]. Delivery of an RFTP programme under the direct supervision of a therapist would require significant resource provision from the NHS. This amount of therapy would be a challenge for most UK stroke services who are not achieving intensity of therapy recommended by clinical guidelines [14, 53] for the majority of patients [88].

Two previous studies evaluating RFTP successfully delivered homework based therapy, indicating it may have been possible for the RFTP programme to be undertaken independently (or with the help of friends / family / carers) without the direct supervision of a therapist. An independently practised programme could provide enhanced rehabilitation within current NHS climate. Independent practice is supported by UK guidelines which specify rehabilitation should be a combination of time spent with therapists and with the patient practising with other professionals, with carers or alone [14].

Additional possible benefits of independent practice were that the RFTP programme could be practised when convenient to participants (rather than at set therapy appointments) which could offer flexibility and make the programme more deliverable across the wide variety of settings. As independent practice offers choice about when to practise, it could promote a sense of empowerment and control over one's own rehabilitation and increase confidence.

There were several areas of concern relating to the choice of independent practice. Although two previous studies evaluating RFTP successfully delivered homework based therapy [58, 63], both were practised by participants with sub-acute stroke, so it

was not possible to establish whether an upper limb RFTP could be adhered to and independently practiced early after stroke. The decision was made that the RFTP programme would include independent practice, but the implications for this would be monitored when testing the programme, including the numbers of patients suitable to take part in the planned evaluations of the programme, adverse events reported and adherence to the programme.

3.3.3.3.1 Prompting independent practice (cues)

When considering the use of independent practice for the RFTP programme, it was anticipated that some participants may find it challenging to remember to practice. This might be due to issues such as being in an unfamiliar environment and / or cognitive or memory problems. To attempt to assist with this potential issue, a cueing technique was included in the programme.

Participants were advised to use cues from their daily routine to prompt programme practice. An example of a cue is using the activity of washing one's face in the morning to initiate a RFTP washing exercise. Another potential benefit from using cues was that exercises would be practiced in context, so promote 'carry over' of ability into everyday life (occupational embedding).

The cueing technique had additional potential benefits. It would ensure relevant everyday objects required were easily available at an appropriate time as practice would directly follow / precede the activity of daily living. Incorporating the RFTP exercises into daily routine could ensure the different exercises were spaced throughout the day allowing for adequate rest periods between practise sessions. Resting between sessions could potentially assist fatigue management and allow improved movement quality during practice.

3.3.3.4 Warm up

As often undertaken in clinical practice, a brief warm up was included to promote focus of attention onto the upper limb and provide stimulation to the nervous system prior to programme practice. The warm up consisted of a simple upper limb stretch (see appendix 4).

3.3.3.5 Reviewing and progressing participants during the RFTP programme (reassessment)

As the RFTP programme was to be undertaken early after stroke, it was likely that participant abilities would alter during the duration of the intervention period. Reviewing progress and altering individual programmes accordingly would be necessary to keep programmes relevant, appropriate and interesting for participants. Regular reviews would also provide support to participants who may be experiencing difficulties undertaking the programme. Therapy reviews included reassessment of the participant's affected upper limb and review of progress towards their chosen goals. The goals and / or exercises were to be adjusted according to progress and goals and / or exercises altered as required.

Dynamic changes in upper limb ability seen early after stroke could mean twice weekly reviews were required to keep the programme relevant. Twice weekly therapy reviews (for participants in hospital and after hospital discharge) were considered manageable for therapists whilst still supporting participants and progressing their rehabilitation. Due to a short average length of stay, participants were likely to have little experience of the RFTP programme on hospital discharge and therefore it was thought that twice weekly support would need to be continued after hospital discharge (not once per week, as stated in the project grant application).

The purpose of the final therapy review was to summarise the participant's progress and included a formal review of overall achievement towards selected goals and provide advice about maintaining and improving upper limb function after the conclusion of the programme.

Therapy reviews also offered an opportunity to collect feedback from participants about undertaking the RFTP programme to inform further programme development. Therapists were asked to gather feedback from participants about how they were managing with independent practice and their views and opinions about the RFTP programme.

3.3.4 RFTP programme dose

In the project grant application, the RFTP programme dose was specified as twice daily 30 minute practice sessions completed seven days per week for four weeks. Each session was to include at least 20 repetitions (total: potential 28 hours over 4 weeks, at least 1120 repetitions).

The RFTP programme dose required careful consideration. Individual trials of increased therapy intensity have showed mixed results, but meta-analysis suggested a small but significant benefit for speed of upper limb recovery when increased therapy time was provided [28]. The RFTP programme was to be supplementary to usual post stroke rehabilitation, to increase intensity of therapy and maximise rehabilitation potential Therapy programmes were successfully delivered in addition to usual rehabilitative care were provided in previous studies evaluating RFTP [54, 56, 60-64].

The dose of the RFTP programme was dependent on the duration of the programme (length of intervention period) and intensity at which the programme would be practised. It was anticipated that the majority of participants would continue to receive usual post stroke rehabilitation whilst being provided with the supplementary RFTP programme. The dose of the programme needed to be great enough to have a possible effect on upper limb recovery, but also needed to avoid detrimental effects on participants' health [89] (e.g. excessive fatigue), have a negative impact on patients participating in usual post stroke rehabilitation or encroach on participants' daily lives.

3.3.4.1 RFTP programme duration

The duration of RFTP based upper limb interventions provided in previous studies ranged from 4-20 weeks. The most frequent duration of study intervention was 4 weeks [54, 60, 63]. The RFTP programme for the current study was to last for four weeks to facilitate future comparisons with other studies.

3.3.4.2 RFTP programme intensity

Several factors were considered when modelling RFTP programme intensity: current literature, what was feasible for a self-practised programme undertaken early after stroke and clinical experience.

Practising repetitions for a set length of time (in minutes) or counting numbers of repetitions were both considered as options for establishing intensity of RFTP programme practice. Use of a set length of time could have been challenging for participants as they may not have access to a wrist watch or clock, could have been interrupted during programme practice (so lose track of the amount of practise undertaken) and some participants may have taken longer to complete repetitions (so complete fewer repetitions per session). Counting the number of repetitions

appeared to be a more flexible option and could promote standardisation of programme intensity.

As discussed in chapter one, there is no agreement in the literature which specifies the number of repetitions required to classify a practice session as ‘repetitive practice’ and animal studies of neuroplasticity have suggested that hundreds of repetitions are likely to be required to drive neuroplastic changes and improve recovery post stroke [37]. In current clinical practice, the average number of repetitions per treatment session has been reported as 32 [90]. In a previous feasibility study of high-repetition, upper limb task specific training for patients with stroke, participants managed to practice a mean of 322 repetitions per session (lasting 60 minutes [91]). However, sessions were delivered face to face by therapists (not self-practised) and participants were a mean of 40 months post stroke (min=6 months, max=120 months) rather than early after stroke.

Two previous studies that evaluated RFTP for the upper limb after stroke provided self-practised programmes, but neither reported the number of repetitions practised per session during the study [58, 63], so could not inform repetition intensity.

Considering current evidence, it was not possible to determine the number of repetitions that would be practical, acceptable and safe for participants to independently practice early after stroke. The feasibility and acceptability of intensity of practice to participants was an area to explore and monitor in the project.

Prior to setting the number of repetitions, the number of exercises provided to participants needed to be considered. Repeated practice of the same exercise for large numbers of repetitions could be unstimulating and potentially affect adherence to the RFTP programme. Considering this, the decision was made to provide participants with several different exercises per day. As four categories had been established on the RFTP exercise list, it was logical to select one exercise from each category - providing participants a total of four different exercises to practice per day. Using clinical experience, the decision was made to request participants to practice as many repetitions of each exercise as possible, up to a maximum of 20 repetitions (80 repetitions per RFTP practice session). To increase the daily number of repetitions the programme was to be practised twice per day. This would result in a maximum of 160 daily repetitions, which was greater than numbers of repetitions

practiced in usual post stroke rehabilitation, potentially high enough to promote neuroplastic changes yet still possibly feasible to practice independently and safely.

Incorporation of twice daily practise aimed to increase the overall number of daily repetitions whilst promoting rest periods between practise sessions and encouraging good quality practise. A maximum number of repetitions per exercise were set to prevent enthusiastic participants developing excessive fatigue. The programme was to be practised by participants seven days per week in order to maximise rehabilitation potential.

Overall, the resulting dose of the initial RFTP programme was 80 repetitions, twice per day (160 daily repetitions), 7 days per week for a duration of four weeks.

3.4 Designing the RFTP programme documentation

The project grant application included development of a manual for therapists and log sheets for participant use to enable participants to record content and duration of sessions and provide feedback about feasibility of practising the programme.

Documentation for therapist and participant use was produced in addition to the 'RFTP exercise list' described earlier.

3.4.1 Documentation for participant use

3.4.1.1 Exercise log sheets

Recording RFTP practice sessions independently undertaken by participants was required to report participant adherence and explore feasibility and acceptability of the programme. Collecting the number of repetitions practised would indicate whether programme intensity was achievable and also enable participants to monitor their progress. A data collection tool suitable for participants early after stroke and compatible with a variety of settings (hospital and community) was needed.

Participants could have found it challenging to count then record the number of repetitions practised, in particular if their dominant hand was affected by stroke. This led to the development of log sheets that included a grid design with 20 cells (see appendix 5 for example finalised version). Participants could log a single repetition of an exercise by marking a cell. It was anticipated that cells could be easily marked during exercise practice, even if the dominant hand was affected. An additional cell was added to the log sheets to allow participants to indicate if they had not practised

any exercises that day. The additional cell aimed to differentiate between exercises not being logged and exercises not being practiced.

Exercise specific instructions were included on the log sheet by using photographs and text. The use of pictorial and written instructions aimed to support independent practice and make log sheets more user friendly. Inclusion of exercise specific instructions lead to the development of numerous exercise specific log sheets to cover all exercises included on the RFTP exercise list. To tailor the log sheets to specific participant needs, a supplementary section was included to allow therapists to provide participant specific instructions (e.g. 'be careful not to hunch your shoulder during the exercise'). A generic log sheet was also produced for recording activates practiced under the 'optional' category (see appendix 6 for finalised version).

The log sheets presented an opportunity to collect participant feedback at the time of exercise practice to inform feasibility of the programme and future development. Additional sections were included covering views and opinions about the number of repetitions, the length of time it took to complete the session and any other comments about the programme or exercise.

Printed copies of the exercise log sheets were carried by therapists in folders, ready for use with participants. The therapist demonstrated how to complete the log sheets when providing participants with their chosen exercises.

3.4.1.2 Participant handbooks

Participants required somewhere accessible to store their exercise log sheets - it was logical to keep the log sheets in a folder held by participants (known as the participant handbook (see appendix 4 for finalised version). Using participant held documentation also aimed to allow participants' programmes to travel with them across hospital and community settings. Information about completing the RFTP programme and log sheets was included in the participant handbook to support participants with independent practice of the programme. In addition, information about stroke, rehabilitation and advice about correct positioning of the upper limb after stroke was included.

The decision was made to produce two versions of the participant handbook for use later in the project; one version for intervention group participants and the other for control group participants. The control group handbook only contained information about stroke, rehabilitation and advice about correct positioning of the upper limb

after stroke. Both handbooks were identical in external appearance. The aim was to promote blinding of usual post stroke rehabilitation staff and reduce feelings of 'resentful demoralisation' in control group participants. Resentful demoralisation is when participants in the control group feel disappointed about not receiving the study intervention [92] (the RFTP programme).

The handbooks aimed to be suitable for participants with mild to moderate dysphasia. The handbooks were shown to a senior speech and language therapist who felt the language and style of the handbooks was acceptable for patients with mild to moderate aphasia.

3.4.2 Documentation for therapist use

Documentation for therapists to use when delivering the initial therapy session, therapy reviews and the final review session was produced (see appendix 7 for finalised versions). The initial assessment form contained prompts to guide therapists through the assessment and record assessment findings, participant's goals and exercises selected. Therapy review documentation was similar to the initial assessment form, but included open ended questions to collect participant feedback about the RFTP programme and specific feedback about log sheet completion. In the Non-randomised feasibility study, additional sections were added to record adverse events (open ended questions). The final review form collected data on adverse events, overall progress towards goals and specific semi-structured questions about programme feasibility.

3.4.2.1 Therapy manual

A therapy manual was produced to be used as a training tool and guide for therapists. The manual contained information about the project, how to deliver the RFTP programme and copies of therapy documentation (see appendix 8 for finalised version).

3.5 Stakeholder involvement and modifications to the RFTP programme following feedback

3.5.1 Collection of stakeholder feedback

Feedback about the initial RFTP programme was sought from stakeholders. The RFTP programme and study materials were presented by the thesis author to the North East Stroke Research Network (SRN) patient and carer panel. A total of twelve panel members participated in the discussion. Further feedback was gathered via

post for three additional panel members who were unable to attend. The National Institute for Health Research (NIHR) recommends the public should be actively involved in research [93]. Gathering views and opinions from stroke survivors and their carers was particularly valued as the RFTP programme was to be self-practiced.

The initial programme was also presented to two groups of NHS therapists over two events (totally thirteen therapists) to gather expert clinical opinions. The therapists worked in a local North East NHS trust, which participated as a Study Site later in the project (see Chapters 4 and 5). The therapist groups were a mix of physiotherapists (n=7), occupational therapists (n=4) and therapy assistants (n=2). Some therapists worked on acute stroke units and some worked in stroke specialist community based teams.

Topics covered with the North East SRN patient and carer panel and local therapists were:

- Practicing the RFTP programme early after stroke
- RFTP programme design (i.e. using cues, independent practice of the programme)
- Programme terminology ‘tasks’ versus ‘exercises’ versus ’activities’
- The RFTP exercise list
- Exercise log sheets
- Participant handbooks

The North East SRN patient and carer panel and local therapists were also asked which they would prioritise in RFTP programme design:

- Relevance to patients and their wishes
- Easy to follow / well set out
- Quick to complete

Additional topics discussed with the local therapist groups were:

- Feasibility of the proposed the RFTP programme for patients early after stroke
- Therapy reviews (duration and intensity)

The thesis author led face to face discussions with each group. Feedback was documented by another member of the study team according to the relevant topic headings and any additional comments were also recorded.

3.5.2 Stakeholder feedback

Stakeholder feedback collected from face to face discussions was analysed using content analysis due to the nature of data collected (multiple short comments collected under distinct headings). Feedback was coded according to discussion topic headings and categorised into three themes; ‘positive feedback about the initial RFTP programme design and materials’ (table 7), ‘suggested alterations to the initial RFTP programme design and materials’ (table 8) and ‘potential feasibility and acceptability issues’ (table 9).

Table 7: Stakeholder comments – positive feedback about the initial RFTP programme design and materials

Code	Stakeholder group	Feedback example(s)
Undertaking the programme early after stroke	P and T	Liked early involvement as that was maximising time to make improvement (P) Many therapists thought it was a good idea as patients report they want to do something to help their recovery between therapy sessions (T)
Range of exercises	T	Thought everything was covered - nil they could think of (T) Agreed that some sequential tasks should be split down focusing on problem areas (T)
Use of cues	P and T	Using cues felt to be good as doing it anyway so a good reminder (P) Like the use of daily routine cues to initiate practice of the activities – they felt this would assist people with memory problems and help them to relate what they are doing (exercises) to their 'normal' activities which they wish to regain (T)
Exercise log sheet design	P and T	Pictures are a good idea, colour is better than black and white (P) Liked the 'tick boxes' – useful for participants with their dominant hand affected (T) Felt that the use of the picture was very helpful (T)
Use of ring binder folders for the participant handbook	P and T	People like the ring binder idea as it stays open at the right page easily (P) Felt that participants would manage to open / use the folder fine (T)
Carer involvement (as required) during exercise practice	T	Good to involve the family early after stroke to make them feel like they are helping towards their loved one's rehab. This also promotes long term support in their loved one's rehabilitation (T)
Twice weekly therapy reviews	T	Two per week feasible, but may be the maximum possible (T)

P = North East SRN patient and carer panel
T = Local therapists

Each group reached a consensus and agreed the priority for the RFTP programme design was for it to be 'relevant to you and what you wish to be able to do'.

Table 8: Stakeholder comments - suggested alterations to the initial RFTP programme design and materials

Code	Stakeholder group	Example(s) of feedback
Programme intensity	T	Felt four activities / log sheets may be too many to practise – liked the idea of two instead as more feasible and likely to get compliance with completing paperwork. (T)
Programme terminology	P and T	Preferred the term 'recovery activities' rather than 'tasks' or 'exercises' – 'tasks' sounds too difficult. Wording is important to patients so they don't feel de-motivated (P) The term 'exercise' may put people off if they have never regularly exercised. The term 'activities' sounds more related to what they (patients) normally do. Encourages the idea that they aren't just practising things as 'therapy', but doing things for a functional reason i.e. regaining the ability to do something (T)
Twice weekly therapy reviews	T	There may be some benefit from grading reviews e.g. 3 times per week for the first week, 2 times for the next 2 weeks followed by follow up phone call in the last week (T)

P = North East SRN patient and carer panel
T = Local therapists

Table 9: Stakeholder feedback - potential feasibility and acceptability issues

Code	Stakeholder group	Example(s) of feedback
Undertaking the programme early after stroke	P and T	People may be too 'shell shocked' to do the exercises (P) Some therapists thought it was too early post stroke – may be too much for some patients to 'take in' at this time (T)
Independent practice – participant motivation	P and T	It could be frustrating if they can't do the exercises, so just 'give up'(P) Some therapists felt there would be a range in compliance with the exercise programme – some patients would be unmotivated and not practice at all whilst others may practice almost too much and tire themselves out (T)
Independent practice – cognition	T	Cognitive / memory impairment may hinder ability to comply with the programme (T)
Independent practice – other	T	Any exercise routine would be difficult in the ward situation due to constant interruptions from the MDT (T)
Participant fatigue	P and T	Some felt patients might be too tired at specific times (P) Fatigue in general due to an increase in activity may be a problem (T)
Cues	T	Some thought participants may be too tired to practise the programme straight after their 'real life' activity (T)
Exercise log sheet – design and logistics of delivery	T	Worried the number of cells on the log sheets (to mark repetitions) would either put patients off doing the exercises (intimidating) or put them under pressure to keep going despite presence of fatigue / pain (T) Some concerns about the feasibility of delivering the exercise log sheets in the community setting (T)
Setting	T	Some concerns over how feasible it would be in the community setting (T)

P = North East SRN patient and carer panel
T = Local therapists

3.5.3 Further modelling of the RFTP programme following stakeholder feedback

Positive stakeholder feedback supported several components of the initial RFTP programme and study materials – early intervention, range of exercises, use of cues, exercise log sheet design, use of ring binder folders for participant handbooks, carer involvement and twice weekly therapy reviews.

Feedback from stakeholders resulted in changes to study terminology and modifications to the RFTP programme intensity.

The North East SRN patient and carer panel and local NHS therapists both preferred the term ‘activity’ rather than ‘exercise’ and the North East SRN patient and carer panel suggested use of the term ‘recovery activity’ to make the programme more user friendly. The title of the ‘RFTP exercise list’ was altered to ‘recovery activity list’ and the ‘exercise log sheets’ changed to ‘recovery activity log sheets’.

The RFTP programme intensity was also altered following stakeholder feedback. Local NHS therapists advised selection of two rehabilitation goals and subsequent practise of two appropriate recovery activities twice per day (80 daily repetitions) rather than selection of four rehabilitation goals (160 daily repetitions). Local therapists felt strongly that fewer exercise types and lower daily intensity was more manageable for independent practice early after stroke and would assist participant adherence.

Some local therapists felt it would be beneficial to grade the number of weekly therapy reviews – starting at three per week. However, therapists also felt NHS services would be unable to deliver three sessions per week. The intensity of therapy reviews remained at twice per week.

Stakeholders highlighted several feasibility and acceptability issues to be explored in later in the project.

3.6 Summary of the developed RFTP programme

The RFTP therapy programme was a four week programme of twice daily repetitive functional task practise for patients with upper limb impairment. The programme comprised of functional tasks embedded in routine everyday activities undertaken on the ward or at home. This made the programme highly relevant to the participant, promoted ‘carry over’ into real life situations and encouraged motivation to practise the programme.

Participants were invited to select and practise activities of daily living which involved use of the upper limb. Each activity was practised independently by the participant for up to 20 times, twice a day, for four weeks (maximum 80 repetitions per day). The activities related to washing, dressing and eating/drinking. There was also an ‘optional’ category which was included to allow participants to select an activity not

listed under the other categories, for example using a mobile phone. Optional activities offered further choice and aimed to enhance participant motivation.

The treating therapist could be a physiotherapist or an occupational therapist. At the start of the programme, the therapist performed an assessment of the upper limb to determine motor impairment and assessed other neurological deficits (e.g. sensory loss or inattention) that may have impacted on upper limb function. The therapist and participant then discussed rehabilitation concerning washing, dressing, eating/drinking and/or other activities involving the upper limb. The participant identified their two most important upper limb rehabilitation needs and these were used to set two functional rehabilitation goals. An example of a functional rehabilitation goal is 'I would like to use my affected hand when washing my face'. Goals were to be realistic and potentially achievable within the four week RFTP programme.

The selected functional rehabilitation goals were used to choose activities to practise to achieve the goals. Activities (named 'recovery activities' in the RFTP programme) were selected from a list (named 'recovery activity list') which had been created for each functional category (Washing, Dressing Eating / Drinking, Optional). A wide range of activities were available in each category which were ordered into three levels of ability. Ability levels were generated by considering sensorimotor parameters (e.g. amount of upper limb movement and coordination required) and the level of cognitive processing needed to complete the activity. The levels were used to guide the therapist in appropriate activity selection. For example, a level one activity was appropriate for a participant with severe upper limb functional impairment.

The therapist demonstrated the chosen activities and ensured the participant was confident to practise independently. To assist the participant to remember to perform the activities twice daily, the therapist advised participants to use cues from their daily routine. Cueing also ensured the relevant everyday objects required for the activity were readily available to participants. The cueing technique aimed to incorporate the RFTP activities into the participant's daily routine, causing minimal disruption to them, the ward staff and their family / friends. Using daily routine cues aimed to ensure the different activities were spaced throughout the day and allowed for adequate rest periods between activities, promoting 'good quality' practise.

Participants were given recovery activity specific log sheets (named ‘recovery activity log sheets’) that contained written guidance about undertaking their chosen activities and sections to log their twice daily practice. In addition, they were asked to provide feedback about performing the activities. The study therapist demonstrated how to complete the log sheets and placed them into a participant held handbook (named ‘participant handbook’). For participants who were unable to complete the log sheet, the therapist asked a family member / friend / member of staff to complete the log on their behalf. The participant handbook also included general information about the RFTP programme, advice and information concerning stroke recovery and positioning of their affected upper limb.

Prior to practising their RFTP recovery activities, participants were asked undertake a brief warm up session. This consisted of gently stretching the upper limb in a reaching motion. The aim was to focus their attention on the affected upper limb and prepare for recovery activity practice.

Participants were reviewed by the therapist twice per week. These sessions consisted of a brief upper limb re-assessment, and review of progress towards their chosen goals. The goals and / or recovery activities were adjusted according to progress and new log sheets issued. If the participant achieved a goal, a new goal was set and a new activity selected. If the participant found a goal or activity too challenging or if they were experiencing other problems, an alternative was selected. Participants could be discharged from the programme early if they regained normal upper limb function and achieved all upper limb goals. The therapy reviews also included gathering feedback from the participant concerning their experiences of participating in the programme.

At the final therapy session, the therapist and participant discussed the participant’s progress and advice was given about maintaining and improving upper limb function. Further feedback from participants about their involvement with the RFTP programme was also sought. After the final therapy session, the therapist liaised with the participant’s usual post stroke rehabilitation therapist(s) or other clinical teams (as appropriate) about progress made.

3.7 Potential strengths and weaknesses of the RFTP programme

3.7.1 Potential strengths of the RFTP programme

- The RFTP programme:
    - Is evidence based.
    - Commences early after stroke when capacity for neuroplasticity is greatest.
    - Is supplementary to usual post stroke rehabilitation so could maximise rehabilitative potential.
    - Is structured but can be tailored to meet individual requirements of participants, achieving a balance between standardisation and individualisation (unlike many previous RFTP programmes used in published research).
    - Involves participants in selection of recovery activities for their individualised programme and is independently practiced, so promotes self-management.
    - Is designed to follow participants from acute to community settings (unlike previous studies evaluating RFTP that were restricted to one setting) and remain relevant across the trajectory.
- The 'recovery activity list' covers a wide variety of activities of daily living and participant ability levels, making the programme suitable for a range of participants, unlike programmes described in previous studies evaluating RFTP.
- The 'optional' recovery activities allow further individualisation to participants.
- Delivery of the programme by therapists mirrors usual clinical practise and aims to be easily incorporated into patient care within the project and (if found to be affective) clinical practice.
- The cueing technique is a novel approach that could assist initiation of programme practice, make activities relevant / meaningful and embed the recovery activities into the participants' daily routine. Using the cueing technique could promote carry over of activities practiced into automatic use of the affected upper limb in everyday activities of daily living.
- Regular reassessment of participants allows the programme to be graded in relation to the participant ability, keeping the programme appropriate and relevant.

- Components of the RFTP programme can be adequately described to enable replication of the programme in research and clinical settings – unlike programmes described in previous studies evaluating RFTP.

3.7.2 Potential weaknesses of the RFTP programme:

- The large number of recovery activities on the 'recovery activity list' (n=183) and additional selection of 'optional' activities could be seen as reducing standardisation of the RFTP programme.
- The RFTP programme is independently practiced, which may limit the number of patients able to undertake the programme compared to programmes provided under the direct supervision of therapists. Independent practice requires sufficient cognition, memory and motivation although some less able participants could undertake the programme if adequate support from family members or carers is available.
- RFTP programme practice without direct supervision of a therapist could lead to participants developing compensatory patterns of movement. However, the inclusion of regular therapy reviews and advice provided by therapists could prevent / address development of compensatory movement patterns.
- It is widely appreciated that self-reporting of therapy programmes can be problematic and adherence with self-recording low, so determining the amount of RFTP undertaken by participants may not be possible.

3.8 Conclusion

Development of the RFTP programme was informed by a number of difference sources, i.e.; current literature, clinical guidelines, pragmatic considerations of current NHS settings and the thesis author's clinical experience. Modification of the RFTP programme was undertaken following feedback from stakeholders. The resulting programme was used in the next stage of the project (Non-randomised feasibility study).

Chapter 4. Non-randomised feasibility study

This chapter describes delivery of the newly developed RFTP programme by the research physiotherapist (thesis author). In addition to testing feasibility and acceptability of the RFTP programme, the Non-randomised feasibility study enabled eligibility criteria and usual post stroke rehabilitation data collection to be investigated for the next project stage (RAFTAS feasibility study).

4.1 Non-randomised feasibility study: Aim and objectives

4.1.1 Non-randomised feasibility study aim

The aim was to test the feasibility and acceptability of the upper limb RFTP programme for patients early after stroke and to test usual post stroke rehabilitation data collection for use in the RAFTAS feasibility study.

4.1.2 Non-randomised feasibility study objectives

The study objectives were:

Objective 1: To test proposed eligibility criteria

Objective 2: To test the feasibility and acceptability of the RFTP programme

Objective 3: To test usual post stroke rehabilitation data collection

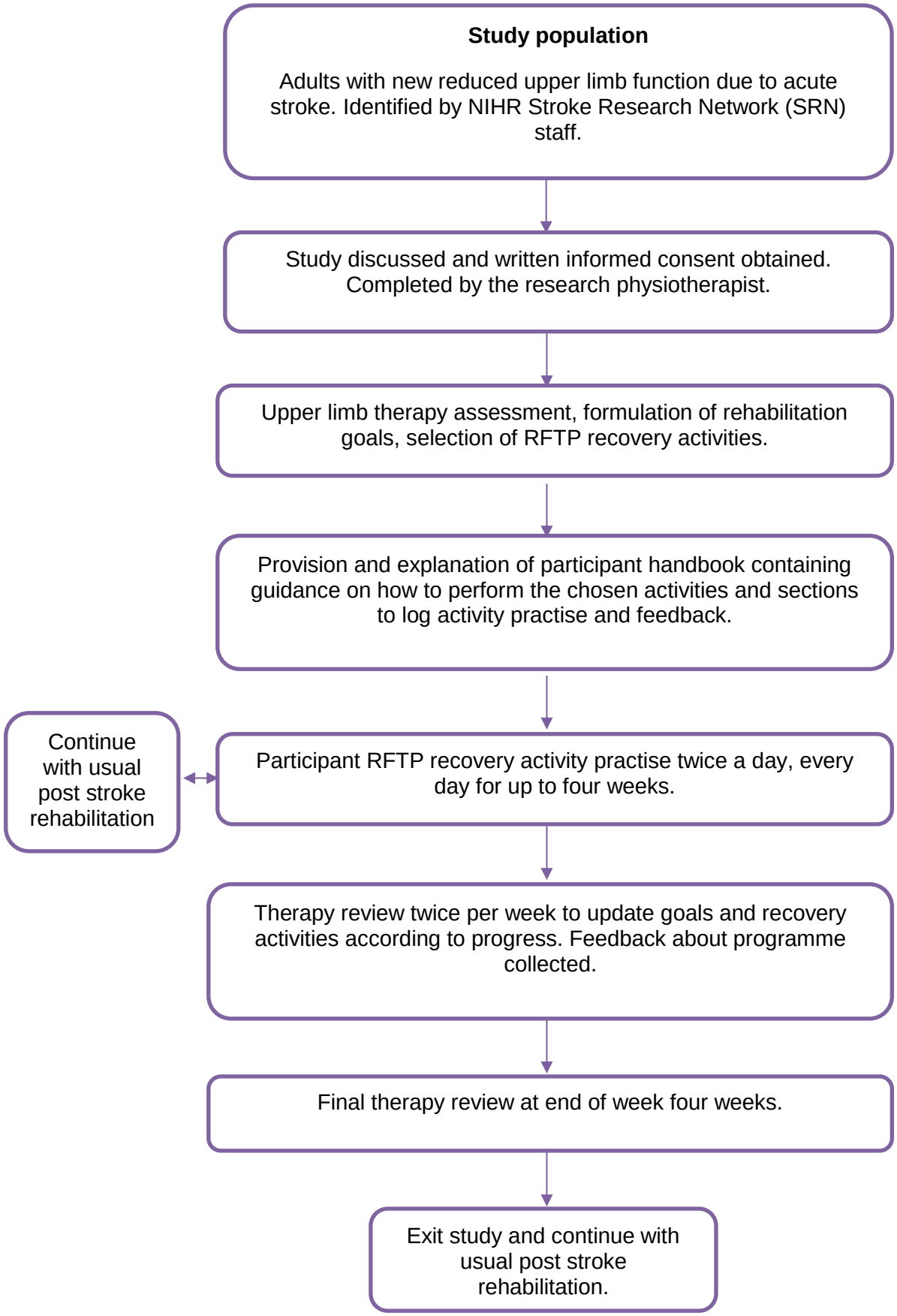
Objective 4: To report preliminary safety data about the RFTP programme

4.2 Non-randomised feasibility study: Methods

4.2.1 Study design

A flowchart of the study design is shown in figure 3.

Figure 3: Flowchart of the study design



4.2.2 Setting

The study took place in two NHS stroke services in North East England. Both services had an acute stroke unit which provided care and rehabilitation for up to 30 patients. At Site A, patients were admitted directly to the stroke unit. At Site B, patients were admitted via the Accident and Emergency Department.

Patients at Site A stroke unit were discharged directly to their own homes, residential rehabilitation facilities, residential care homes or nursing homes. Site A had a ward based therapy team and a separate community based specialist stroke rehabilitation team who provided therapy following hospital discharge.

Patients at site B stroke unit were discharged directly to their own homes, residential homes or nursing homes. Therapy was provided by the same team across hospital and community settings.

The RFTP programme was delivered by the research physiotherapist (thesis author) on the stroke units to those who were in-patients. Participants who were discharged before the end of the RFTP programme were reviewed by the research physiotherapist in the community.

4.2.3 Population

Patients who fulfilled the following criteria were eligible:

4.2.3.1 Inclusion criteria

- Age ≥ 18 years.
- Within 10 days of stroke onset.
- New reduced upper limb function due to acute stroke.
- Able to comply with the requirements of the RFTP therapy programme.

4.2.3.2 Exclusion criteria

- Severe reduced upper limb function which resulted in inability to lift the affected hand off the lap when sitting.
- Unable to follow the RFTP programme due to significant cognitive impairment, significant memory impairment or receptive dysphasia.

- Other significant upper limb impairment e.g. fixed contracture, frozen shoulder, severe arthritis, upper limb pain that inhibited participation in the RFTP programme.
- Diagnosis likely to interfere with rehabilitation e.g. registered blind, palliative care.

4.2.4 Screening and recruitment

Patients admitted to the acute stroke units were regularly screened by local NIHR SRN staff for potential inclusion up to 10 days post stroke. Potentially eligible participants were approached by a local NIHR SRN staff member who discussed the study and provided them with a patient information sheet. After allowing sufficient time for this information to be considered (>24 hours), the local NIHR SRN staff member established whether the patient wished to take part in the study. If they did, their details were provided to the research physiotherapist. The research physiotherapist arranged an appointment to provide a more detailed explanation of the RFTP programme and subsequently sought written informed consent. Patients with mild to moderate aphasia were included if they were able to provide informed consent.

Local NIHR SRN staff completed a screening log for all patients considered for the study and subsequently included or excluded. Information was collected about:

- If a patient was eligible
- If a patient was eligible but did not participate
- The reason why a patient was ineligible
- The number of patients who entered the study

4.2.5 The RFTP programme

The RFTP programme developed in Chapter 3 was provided by the research physiotherapist (thesis author). The RFTP programme was in addition to usual post stroke rehabilitation.

4.2.6 Data collection

4.2.6.1 Participant demographics

The initial therapy assessment was performed by the research physiotherapist following patient consent to the study. The following data were collected: name, address, telephone number (used for arranging community visits), age, date of

stroke, stroke type (e.g. infarct, haemorrhage) and stroke sub-type (TACS, PACS, LACS, POCS) [94], upper limb motor impairment, and other neurological deficits that may have impacted on upper limb function (e.g. sensory loss or inattention). Standardised measures of arm movement or function were not included; the research physiotherapist used clinical observations to assess study participants' upper limbs.

4.2.6.2 RFTP programme feasibility and acceptability

The initial therapy assessment recorded participants' upper limb rehabilitation goals and the RFTP recovery activities selected to meet their chosen goals. The therapy review appointments recorded changes to upper limb impairment, rehabilitation goals, recovery activities, and feedback from the participants regarding experiences of the programme (free text responses). Participants were asked to record feedback onto their recovery activity log sheets during recovery activity practice (free text responses). Topic headings on activity log sheets were; 'Reason for stopping session if less than 20 repetitions', 'Comments regarding the task/programme', 'Approximate time spent doing repetitions' and 'Help given from another person'. Log sheets also recorded the number of repetitions of each recovery activity performed.

The research physiotherapist documented general observations about delivering the RFTP programme in a research journal.

4.2.6.3 Local NHS staff feedback

Local NIHR SRN staff experiences in identifying and recruiting patients using the eligibility criteria were collected. The research physiotherapist (thesis author) liaised regularly with local NIHR SRN staff to discuss patients' suitability for study inclusion and which patients had been approached about study inclusion. Informal feedback from local NIHR SRN staff was documented by the research physiotherapist in a research journal throughout the study intervention period.

Usual post stroke rehabilitation staff comments about the RFTP programme (e.g. influence on delivery of usual post stroke rehabilitation) were informally collected by the research physiotherapist whilst delivering the RFTP programme to establish if any concerns were identified. The research physiotherapist also collected feedback from usual post stroke rehabilitation staff about their experiences of recording usual post stroke rehabilitation data (see below 4.2.6.4). Feedback from usual post stroke rehabilitation staff was also logged in the research physiotherapist's research journal.

4.2.6.4 Usual post stroke rehabilitation

Participants continued with usual post stroke rehabilitation during the study. A form which had been developed to record usual post stroke rehabilitation for use later in the project was tested (appendix 9). The form captured therapy provided by usual post stroke rehabilitation physiotherapists, occupational therapists and (where appropriate) nursing staff. Development of the form was informed by published literature and materials designed by other academics (kindly provided for review).

The research physiotherapist trained usual post stroke rehabilitation staff to complete the data collection form. On patient recruitment, the research physiotherapist identified participants to hospital based staff, who then proceeded with data collection. At hospital discharge, the hospital based staff were asked to liaise with community teams so data collection could be continued. The research physiotherapist recorded observations about the logistics of collecting data across settings in the research journal.

4.2.7 Study withdrawal

No specific study withdrawal criteria were set. Participants could withdraw from the study at any time for any reason. If a participant decided to withdraw from the study, a reason was sought but patients could chose to withdraw without providing an explanation. If a participant decided to withdraw it did not affect the normal care they received. Data collected prior to withdrawal were used in the study analysis unless consent for this was specifically withdrawn.

Clinical teams, the research physiotherapist or investigators could also withdraw participants from the study at any time if they felt it was no longer in their interest to continue, for example, because of intercurrent illness.

4.2.8 Safety of the RFTP programme

The safety of the RFTP programme was evaluated by examining the occurrence of all adverse events (AEs). All AEs were recorded for the duration of a participant's involvement in the study. Recording took place at the twice weekly therapy review appointment by inclusion of the following question: "are there any new medical problems since the last therapy appointment?" The research physiotherapist specifically enquired about fatigue, pain and change in muscle tone (on the affected side) which could be anticipated with a therapy programme. Adverse event data were also collected from comments documented on recovery activity log sheets completed

by participants during each recovery activity practise session. A separate study form was available to be used to record serious adverse events (SAEs).

4.2.9 Training of NHS staff

Local NIHR SRN staff were provided with a study specific induction delivered by the research physiotherapist. The study was introduced to local study site multidisciplinary team members via short presentations and informal meetings.

4.2.10 Sample size

The study aimed to recruit ten participants in three months.

4.2.11 Study data analysis

Numerical data were presented descriptively. Informal feedback collected in the research physiotherapist's research journal was summarised under topic area (e.g. 'experiences of RFTP programme delivery', 'Local NIHR SRN staff feedback'). Feedback was coded under topic area (e.g. logistical problems of RFTP programme delivery', 'Eligibility criteria observations').

Participant feedback and adverse events data collected during therapy reviews and from activity log sheets were coded and categorised using content analysis due to the nature of data collected (multiple short comments collected under distinct headings). Other data were presented descriptively.

4.2.12 Ethics and governance

Research Ethics Committee approval was granted on 04.05.2012 (REC reference number 12/NE/0118). Local Research and Development approvals for the feasibility study were obtained Site A on 18.06.2012 and Site B on 01.06.2012. The study complied with the Data Protection Act 1998 and Caldicott Principles. The study sponsor was Northumbria NHS Foundation Trust and was adopted by the NIHR SRN.

4.3 Non-randomised feasibility study: Results

4.3.1 Study recruitment

Study sites were open to recruitment as soon as local Research and Development approvals were obtained. Recruitment ran from 01.06.2012 to 04.11.2012 (five months). The recruitment period was longer than planned (planned for three months) as unfortunately, the research physiotherapist (thesis author) who was delivering the RFTP programme had a period of absence due to ill health from 04.07.2012 to 06.08.2012. Ill health and a phased return to work resulted in recruitment to the study being suspended between 04.07.2012 and 03.09.2012 (2 months). Recruitment recommenced on 03.09.2012 and ended on 04.11.2012.

Due to differing Research and Development approval dates, screening occurred at Site A from 01.06.2012 – 04.11.2012 (22 weeks) and Site B from 16.06.2012 – 03.11.2012 (20 weeks). Screening for potential participants continued during the research physiotherapist's period of absence to help provide data about potential study recruitment based on the eligibility criteria set.

Figure 4 shows a summary of the screening data. Figures 5 and 6 show summary screening data for the individual study sites.

Study recruitment rate at Site A was 1.4 / month and Site B was 0.7 / month. Two hundred and fifty eight patients were screened for possible study inclusion. Thirty three patients (12%) were considered eligible. The proportion of eligible patients were: Site A 16/59 (27%) and Site B 17/199 (9%). The main reason for ineligibility was that patients did not have new reduced arm function: 111/224 (50%). Forty one (18%) were considered unable to comply with the programme because of speech or cognitive problems and 32/224 (14%) had a diagnosis likely to interfere with rehabilitation (e.g. palliative care).

Seven of the thirty three (21%) eligible participants were enrolled in the study: Site A 5/16 (31%) and Site B 2/17 (12%). Of the 26/33 (79%) eligible patients who were not enrolled in the study 19/26 (73%) were not approached due to the research physiotherapist's unavailability and 4/26 (15%) lived outside the community services catchment area covered by Site B. If patients lived outside the community services catchment area then it was not possible for the research physiotherapist to deliver the RFTP programme in the community due to R&D governance approvals. Only one person declined to take part in the study, but the reason was not provided.

Figure 4: All sites: Summary of study screening data

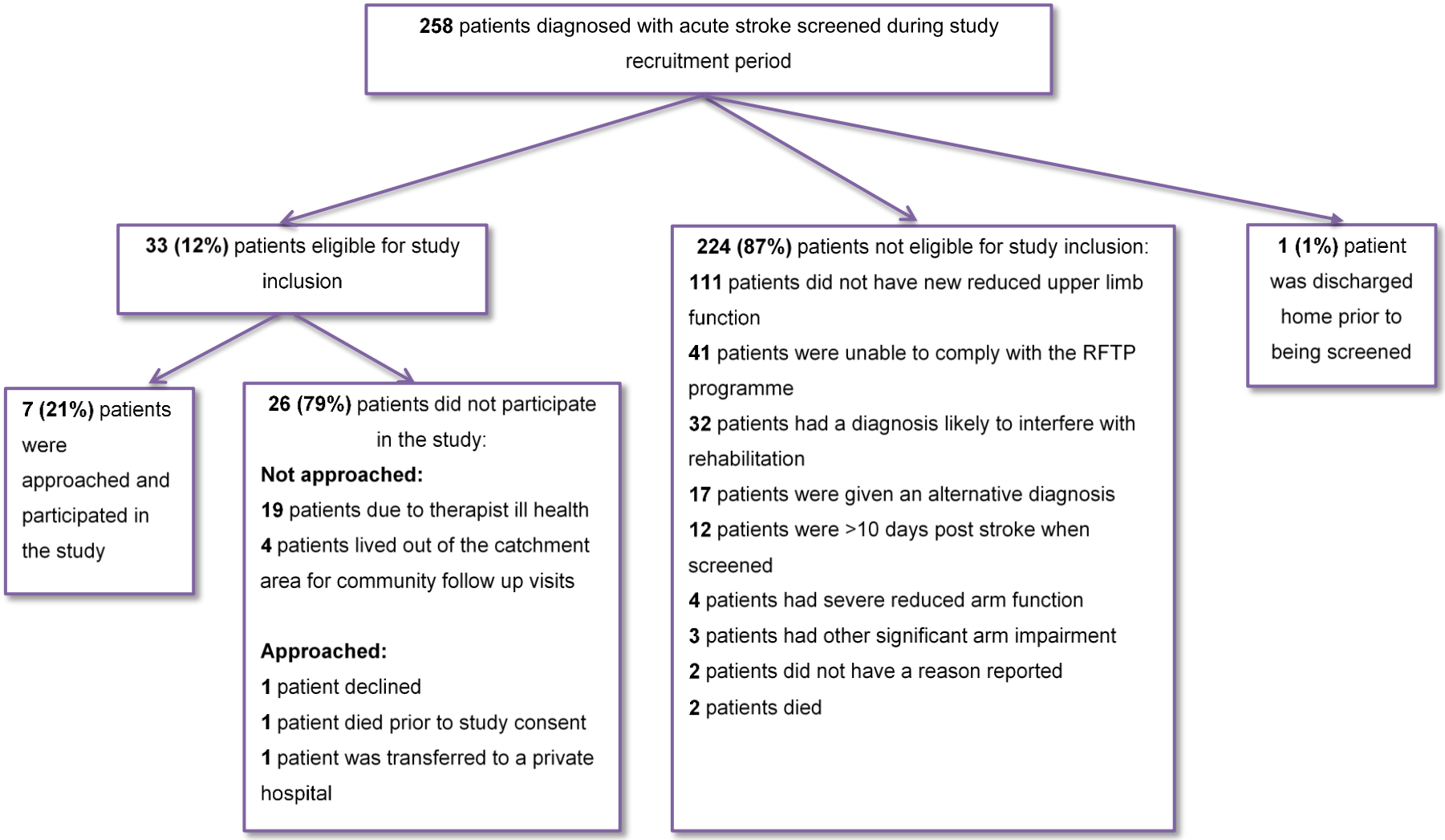


Figure 5: Study Site A: summary of study screening data

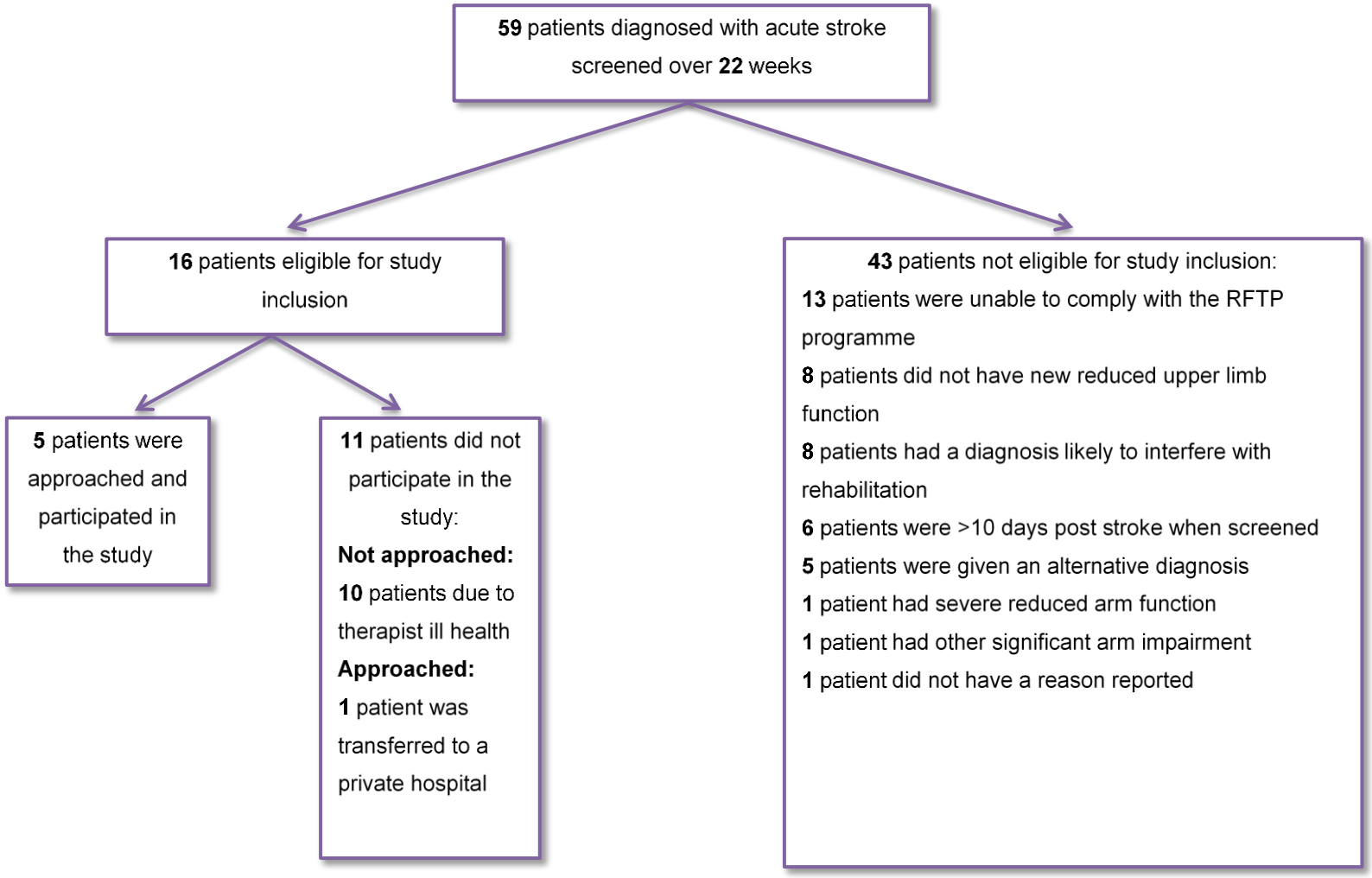
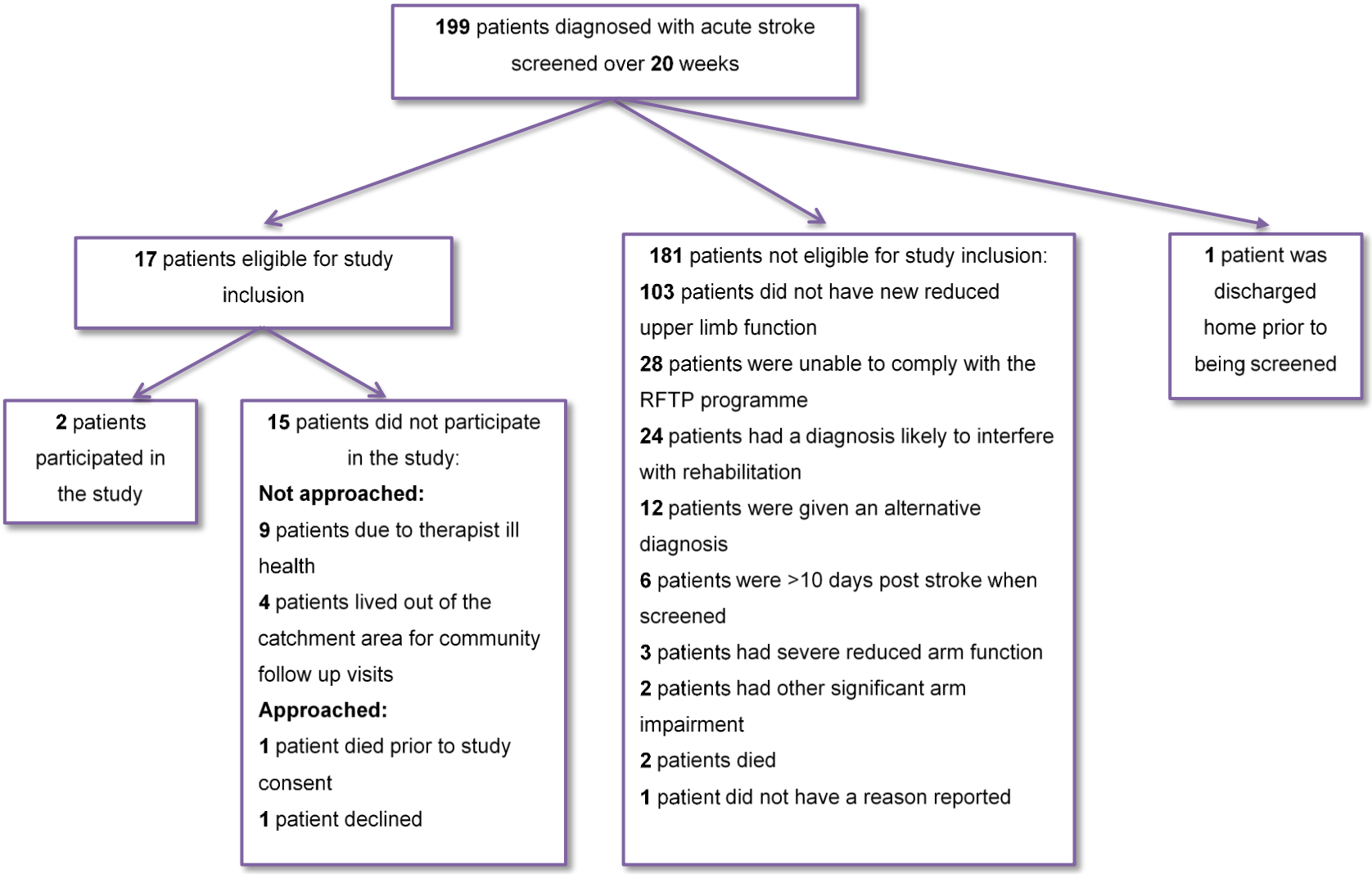


Figure 6: Study Site B: summary of study screening data



4.3.2 Participant baseline characteristics

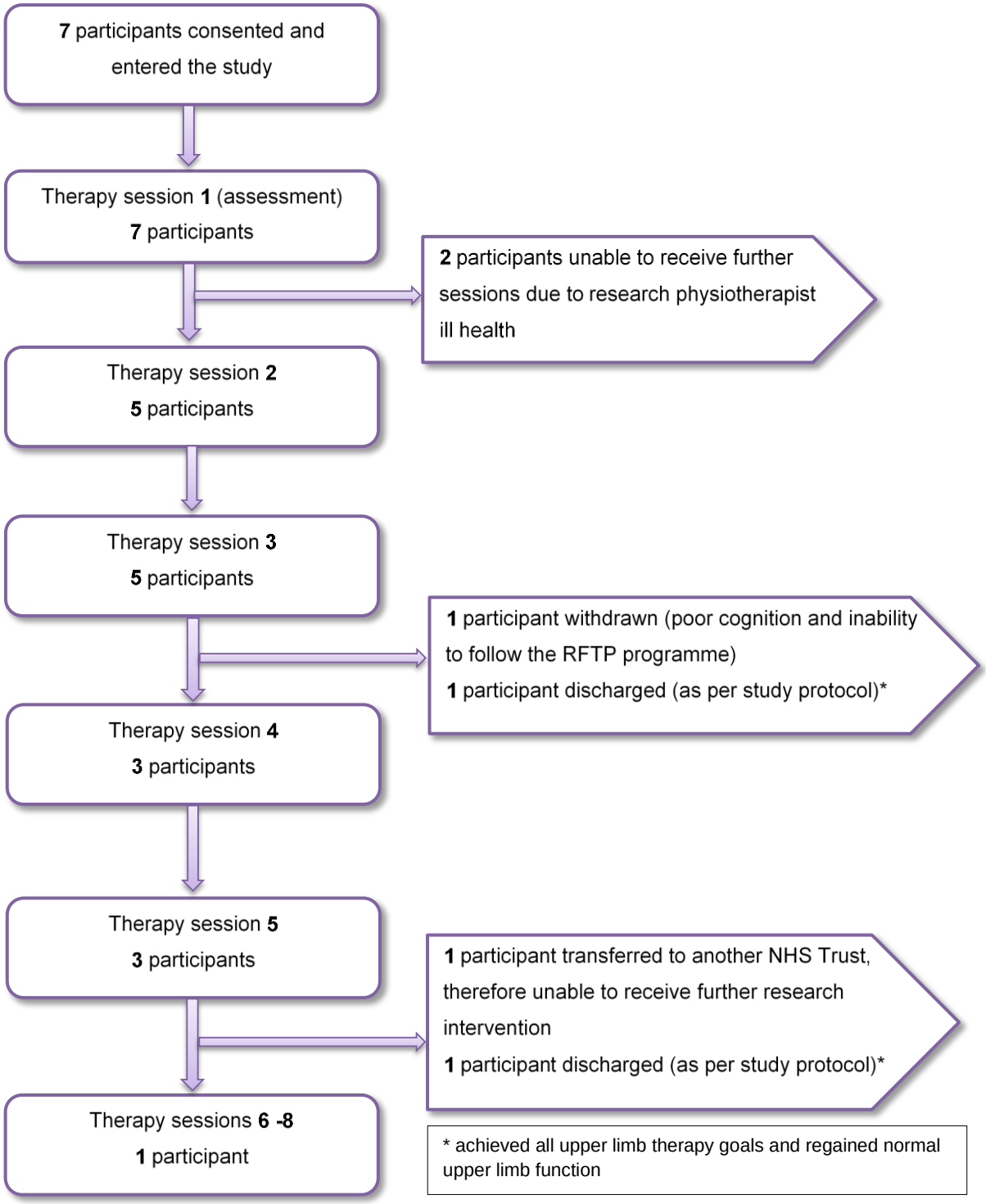
The median age of participants was 71 years (IQR 59-79, min 54, max 88). Three of the seven participants (43%) were male and 4/7 (57%) were female. Six of the seven participants (86%) had a stroke due to cerebral infarction and 1/7 (14%) had an intracerebral haemorrhage. In relation to stroke sub-type, 3/7 (43%) participants had a lacunar stroke, 2/7 (29%) a partial anterior circulation syndrome, 1/7 (14%) a total anterior circulation syndrome and sub-type was missing for 1/7 (14%) participant. The median number of days post stroke at study entry was 5 (IQR 3-7, min=1, max=8).

At study entry, all participants had some retained active shoulder movement; clinically, three participants were considered to have minimal shoulder movement and four had good shoulder movement. All participants had some active elbow movement; two participants had minimal movement, two had good movement and three had full elbow movement. All participants had some active wrist movement; five participants had minimal wrist movement and two had good wrist movement. Two participants had no hand / finger movement and five had minimal hand / finger movement.

4.3.3 Therapy sessions delivered

Eight therapy sessions were available within the four week RFTP programme. Participants received a mean of 4 therapy sessions (SD 2.5, min = 1, max = 8) during their participation in the study. The number of therapy sessions delivered is shown in Figure 7.

Figure 7: Number of therapy sessions delivered



4.3.3.1 Upper limb goals and recovery activities selected

During the study a total of 33 upper limb rehabilitation goals were selected by the 7 participants. Twelve out of the thirty three goals (36%) related to washing activities, 8/33 (24%) to dressing, 9/33 (27%) to eating and drinking and 4/33 (12%) were in the optional category. Three optional goals involved regaining the ability to write using the affected hand, and one optional goal was to be able to lock / unlock a door using keys in the affected hand.

Appropriate recovery activities were selected for practise in relation to the participants' goals and ability levels. Thirty nine activities were selected in total. More activities were selected (39 activities) than goals set (33 goals) because more than one recovery activity could be practised per goal as participant ability altered. Eleven of the 39 (28%) selected activities related to washing, 6/39 (15%) to dressing, 10/39 (26%) to eating / drinking and 12/39 (31%) were selected using the optional recovery activity alternative.

To review the content of the recovery activity list for future use, the range of recovery activities selected was examined. A total of 21 different activities were selected using the set activities provided on the recovery activity list under the categories of 'washing', 'dressing' and 'eating / drinking'. The remaining 8 different recovery activities were provided using blank optional recovery activity log sheets. Recovery activities provided using blank optional recovery activity log sheets were categorised and are shown in table 10.

Table 10: Recovery activities provided using blank optional activity log sheets

Category	Recovery activity provided	Number of times recovery activity provided
Washing	Rest the affected elbow on the table. Turn the toothbrush over clockwise then anti-clockwise. 1 turn = 1 repetition	3
	pick up toothbrush out of holder and then replace it	1
Dressing	Practice fastening and unfastening bra (whole task)	1
	Place bra onto table and practice hooking and unhooking (1 'hook and eye' = 1 repetition)	1
Eating/drinking Writing	Pick up a knife/fork and put it back onto the table	2
	Pick up a cup and put it back onto the table	
	Practice writing signature, one signature = one repetition	3
Using keys	Place key in lock then remove	1

Progress towards functional goals was re-assessed during therapy review sessions through discussion with participants and clinical re-assessment. Two out of the seven (29%) participants did not have their goals re-assessed (4 goals) as they did not receive further sessions due to research physiotherapist ill health. The participant withdrawn from the study due to poor cognition achieved 1/3 (33%) goals set. The participant who transferred to another NHS Trust (therefore discharged from the RFTP programme) achieved 4/6 goals and was ongoing with two further goals on discharge. The remaining three participants set a total of 20 goals; 15/20 (75%) were achieved, 3/20 (15%) were changed due to participant preference and 2/20 (10%) were changed due to participants feeling frustrated with the recovery activity.

4.3.3.2 Participant independent practice and logging of recovery activities

The number of daily repetitions of recovery activities practised were recorded by participants on recovery activity log sheets. The maximum number of repetitions possible to be recorded on recovery activity log sheets per day was 80, if the programme was delivered and practised as intended (20 repetitions of two activities, twice per day).

All study participants who practised the RFTP programme and had returned recovery activity log sheets were able to indicate the number of repetitions practised by marking cells on the log sheets. The median number of daily repetitions recorded by participants was 41 (IQR 0.25-80, min=0, max=83).

The number of daily repetitions of recovery activities logged per participant is shown in Table 11.

Table 11: The number of daily repetitions of recovery activities logged by participants

Participant number	Median [IQR] daily recorded repetitions	Minimum number of recorded daily repetitions	Maximum number of recorded daily repetitions	Comments
A1	80 [80-80]	80	80	Completed all repetitions
A2	N/A	N/A	N/A	Data not collected as participant not reviewed after initial assessment (due to research physiotherapist ill health)
A3	N/A	N/A	N/A	Data not collected as participant not reviewed after initial assessment (due to research physiotherapist ill health)
A4	80 [80-80]	80	83	Completed all repetitions
A5	40 [40-60]	0	80	Participant reported practising the programme but not logging practise on several occasions
B1	0 [0-0]	*Missing*	*Missing*	Participant withdrawn from the study due to poor cognition. Recovery activities not practiced or logged.
B2	40.5 [22-55.5]	0	80	Participant unsure of the programme initially, so not practising / recording repetitions. Recovery activity practise and logging improved as participant became more familiar with the programme. Participant transferred to another NHS trust after therapy session 5, therefore unable to continue with the RFTP programme.

4.3.4 Participant feedback about the RFTP programme

4.3.4.1 Logging recovery activity practice

During each therapy review, the research physiotherapist collected recovery activity log sheets from participants and checked for completion. The research physiotherapist documented participant feedback on therapy review documentation about completing the recovery activities and logging recovery activity practice.

Eighteen therapy reviews were undertaken during the study. Two reviews were undertaken by telephone (at the participants' request), so it was not possible to collect the final sets of recovery activity log sheets provided to two participants.

At 7/16 (44%) therapy reviews, participants had logged all daily repetitions possible (80 per day) on all recovery activity log sheets returned. At 4/16 (25%) therapy reviews, participants had logged less than 80 daily repetitions on returned recovery activity log sheets and at 5/16 (31%) reviews no recovery activities were logged on returned recovery activity log sheets.

Examples of feedback provided by participants who logged all daily recovery activity repetitions possible (n=4 participants) were:

"Just 2 activities is better. Twenty repetitions were hard at first, I feel I could handle more now. I would be happy doing 3 activities now" (A1)

"Having 20 boxes made me want to complete 20 (repetitions), but I didn't feel put under pressure" (A4)

Feedback from participants who logged less than 80 daily recovery activity repetitions (recorded by the research physiotherapist) was coded and categorised into three themes (see table 12).

Table 12: Feedback from participants who logged less than 80 daily recovery activity repetitions

Code	Category	Number of times a themed comment provided	Number of participants	Example comment
Less than 80 recovery activity repetitions logged	Participant forgot to log practice	3	2	*'States she has been practising 'on and off' during the day but has not always recorded it'* (A5)
No recovery activity repetitions logged	Recovery activity practise completed but forgot to log practice	2	1	*'Has been practising but not filling in - going to fill it in later but didn't get round to it'* (B2)
	Participant unsure what to do	2	1	*'participant unsure about what he needed to do'* (B1)
	Not formally practising the recovery activities	1	1	*'none completed but has been trying to use left* (affected) *hand in all activities'*(A5)

4.3.4.2 Time spent practising recovery activities

Participants were asked to record time spent practising recovery activity repetitions on their recovery activity log sheets. Data were available for 4/7 participants. The median time spent practising recovery activities was 7 minutes (IQR 5-14, min=1 minute 30 seconds, max=30).

4.3.4.3 Help provided from another person

Participants were asked to record on recovery activity log sheets if they required assistance completing recovery activities. Data were provided by 4/7 (57%) participants and all participants indicated they did not require any assistance and managed to complete the programme independently.

4.3.4.4 Participant comments about the RFTP programme

Feedback from participants was collected at therapy reviews, final therapy reviews and from the recovery activity log sheets by inclusion of open ended questions. Free text responses were documented by the research physiotherapist.

Comments were provided by 5/7 (71%) participants. A total of 71 comments were coded and then categorised under three headings: positive experiences; negative experiences; and other comments (see table 13).

Table 13: Participant comments about the RFTP programme

Category	Code	Number of times a coded comment made	Number of participants to make a coded comment	Example (participant number)
Positive experiences	The programme was helpful / beneficial	17	4	*"….so helpful, I'm grateful to the therapist and happy I was involved"* (A4)
	The programme was good/excellent	9	5	*"The programme is excellent, I don't think I would have come on as good without it"* (A5)
	Participants liked having something to do	7	4	*"I would be just sat otherwise…I would rather be doing something"* (A5)
	Participants felt they benefited from practising the programme early after stroke	5	4	*"…better that it was earlier, to get going and have things to do"* (B2)
	Participants liked practising the programme independently	4	2	*"I liked having things to practise on my own, I didn't feel self-conscious in front of anyone"* (A1)
	The programme was enjoyable	3	2	*"I'm enjoying the programme and practising it more"* (B2)
	The programme helped motivate participation in rehabilitation	3	3	*"being reviewed and progressed on has really helped motivate me"* (A5)
	The programme improved confidence	2	2	*"I feel more confident moving my arm in general"* (A1)
	The programme gave people hope	2	2	*"It gave me something to look forward to - like hope or something"* (A5)
	Participants liked having focussed activities	1	1	*"fantastic having focussed activities"* (carer of A5)
TOTAL positive experiences	-	53	5	-
Negative experiences	The programme was hard work	4	3	*"hard work"* (B2)
	Participants were frustrated during recovery activity practice	3	3	*"it was really frustrating initially"* (A1)
	Participants were unsure about programme practice	1	1	*"unsure about the dressing activity*" (A5)

Table 13: Participant comments about the RFTP programme (continued)

Category	Code	Number of times a coded comment made	Number of participants to make a coded comment	Example (participant number)
TOTAL negative experiences	-	8	4	-
Other comments	Participants did not practice recovery activities	5	2	*"Too much distraction on the ward"* (A5)
	Suggestions made for improvement	2	2	*"days of the week should be on the recovery activity logs"*(A4)
	Participants felt there was nothing bad about the programme	2		*"nothing bad"* (A4)
	Use of cueing technique	1		*"I didn't need to use the cues"* (A1)
TOTAL other comments	-	10	5	-
TOTAL all comments	-	71	5	-

In addition, at the final therapy review, participants were asked to comment specifically about the programme content and set up. Participants were happy with programme content / delivery and no negative comments were made. The use of goals to select activities was well liked by participants *"using goals was useful, it gives you a target or incentive"*(B2), *"I chose what was best for me"* (A4) and they also like the repetitive nature of the activities *"repetition is something to aim for, get things to practise on, concentrates on two things"* (A1).

Participants felt there was a good range of activities and the recovery activity log sheets were easy to use. Participants thought that being reviewed twice per week by the therapist was appropriate *"just right"* (A1), *"definitely twice per week, I had something to look forward to, I knew I was going to start moving"* (A5). No participants reported that the number of recovery activity repetitions requested was too great.

Participants felt the programme had a positive impact on their recovery *"excellent, if you hadn't come or I had refused you I wouldn't have achieved what I have with your knowledge, literature provided and the programme" (A5)*. Participants liked the participant handbooks they *"found the information useful, especially in the beginning" (A1).*

4.3.5 Research physiotherapist's observations about delivering the RFTP programme

The research physiotherapist documented general observations in a research journal when delivering the RFTP programme. Participant adherence with practising and logging activities improved as participants became more familiar with the programme and participants were using their affected hand more automatically:

'the participant is using the left (affected) arm more automatically - gesturing and moving objects around the bed space. Putting glasses on using both hands and looking / leafing through the handbook using both hands' (documented about participant A5).

When reviewing and setting new rehabilitation goals with participants, it became apparent that some participants had already tried additional functional activities at home. Participants felt this was a result of being more aware of how their affected upper limb could be involved in functional activities:

‘(participant name) feels like the programme has made her think about how she can use her arm, so she is trying things she may not have done otherwise’ (documented about participant A4).

The research physiotherapist noted that external events impacted on recovery activity practise - one participant noticed she felt more fatigued once back in her home environment, so did not complete as much of the programme.

It was logistically difficult for the research physiotherapist to maintain and transport several large folders containing the printed recovery activity log sheets (due to the many different recovery activities on offer). Other areas of the RFTP programme that could be improved included minor modifications to documentation (including the therapy session number on the therapy session forms and days of the week on recovery activity log sheets).

4.3.6 Local NHS staff feedback

Local NHS staff reported they thought the programme was a good idea and was well designed. They did not feel the programme interfered with the participants’ usual post stroke rehabilitation and no concerns were identified.

Informal feedback was sought from NIHR SRN staff who recruited patients regarding aspects of the study that could be improved. The staff considered the recruitment window after stroke (up to 10 days post stroke) too short. Some patients who were initially medically unwell and unable to participate recovered and met all other recruitment criteria shortly after 10 days post stroke.

Local NIHR SRN staff also reported that some eligible participants did not live within the catchment area for the services covered by the NHS organisations taking part. This meant that these patients could not be invited to take part as the research physiotherapist was unable to review them after discharge due to research governance permissions.

Further feedback indicated patients considered waiting 24 hours between providing the ‘Participant Information Sheet’ and completing consent / starting the RFTP programme was too long, as they wished to commence the programme as soon as possible.

4.3.7 Safety of the RFTP programme

RFTP programme safety data were collected by the research physiotherapist during twice weekly therapy review appointments and by participants on recovery activity log sheets at the time of recovery activity practice.

No serious adverse events were reported during the study. The maximum number of opportunities adverse events could be recorded per participant if all recovery activity log sheets and therapy sessions were completed (as the RFTP programme intended, over 4 weeks) was 84. The number of opportunities for reporting adverse events varied between participants due to different lengths of time participants remained in the study. The total number of opportunities to report an adverse event for each study participant and the total number of times an adverse event was reported is displayed in Table 14.

Table 14: Opportunities to report an adverse event and number of adverse events reported

Participant	Number of opportunities to report an AE	Number of AEs reported
B1	20	1
B2	28	4
A1	22	3
A2	N/A	N/A
A3	N/A	N/A
A4	38	5
A5	84	18
TOTAL	192	31

There were a total of 192 opportunities for participants to report an adverse event. Thirty one adverse events were reported; 18/31 (58%) related to fatigue, 9/31 (29%) related to pain or discomfort in the affected arm, 1/31 (3%) related to an increase in muscle tone in the affected arm and 3/31 (10%) were other adverse events (feeling unwell, arm *"feels heavy"* (A5) and an allergic reaction to medication).

The number of participants who reported each adverse event type (per study week) is shown in table 15. The most commonly reported adverse events were fatigue and pain or discomfort in the affected arm.

Table 15: The number of participants who reported each adverse event type (per study week)

	Adverse event										
	Fatigue		Pain or discomfort (affected arm)		Increased muscle tone (affected arm)		Other				
Study week	Number of AE reported	Number of participants	Number of AE reported	Number of participants	Number of AE reported	Number of participants	Number of AE reported	Number of participants	Total number of AEs reported	Total number of participants	Total number of opportunities possible for reporting an AE
Study week 1	10	4	4	2	0	0	1	1	15	4	104
Study week 2	3	2	0	0	1	1	1	1	5	2	40
Study week 3	2	1	2	1	0	0	1	1	5	1	26
Study week 4	3	1	3	1	0	0	0	0	6	1	22
TOTAL	18	4	9	3	1	1	3	1	31	4	192

4.3.8 Usual post stroke rehabilitation

Both study sites provided physiotherapy and occupational therapy on acute stroke units and patients could be referred for rehabilitation provided by specialist community stroke teams on hospital discharge. Stroke services offered a five day service across hospital and community settings at Site A. At Site B, stroke services covered seven days per week in hospital and five days per week if patients were referred to community teams.

The maximum number of days usual post stroke rehabilitation could potentially be recorded per participant varied due to study sites providing seven day or five days per week therapy services and differing lengths of time participants followed the RFTP programme. The potential number of days usual post stroke rehabilitation was provided and the total number of days usual post stroke rehabilitation data were collected (per participant) is shown in table 16.

Table 16: The potential number of days usual post stroke rehabilitation was provided and the total number of days usual post stroke rehabilitation data was collected (per participant)

Participant number	Potential number of days usual post stroke rehabilitation provided	Number of days usual post stroke rehabilitation data collected
B1	7	3
B2	8	5
A1	4	0
A2	N/A	N/A
A3	N/A	N/A
A4	12	4
A5	20	2
TOTAL	51	14

There was a total of 51 days when usual post stroke rehabilitation data collection were potentially possible. Usual post stroke rehabilitation data was collected for fourteen days only. Content of usual post stroke rehabilitation recorded is not shown due to lack of available data.

The research physiotherapist collected informal feedback from occupational therapists, physiotherapists and therapy assistants across both study sites about the usual post stroke rehabilitation form. All therapists and therapy assistants who provided feedback liked the design of the data collection forms, found them quick and easy to complete and could not suggest any improvements.

During the study, the research physiotherapist noted few usual post stroke rehabilitation data collection forms being completed and sought feedback from usual post stroke rehabilitation staff. Reasons why data collection forms were not completed were that hospital based therapists forgot to complete forms whilst participants were in-patients and also forgot to liaise with community teams so data collection could be continued after hospital discharge. Practical solutions were discussed (including relocating the study usual post stroke rehabilitation folder on the stroke unit or filing the usual post stroke rehabilitation forms in the participants' usual post stroke rehabilitation therapy notes rather than in the study folder provided).

The research physiotherapist also liaised with and prompted usual post stroke rehabilitation staff to complete data collection forms and contacted therapists in community teams when participants were discharged form hospital. When contacting community teams, the research physiotherapist needed to train the relevant therapist(s) to complete the usual post stroke rehabilitation data collection forms.

4.4 Non-randomised feasibility study: Discussion

Study recruitment

The study did not achieve the recruitment target of ten participants. Although 33 participants were eligible, only 7/33 (21%) of eligible patients were recruited. This was mainly due to the unforeseen ill health of the research physiotherapist (19/26 (73%) eligible patients who did not participate). An unanticipated reason why eligible patients were not recruited was due to patients living outwith the catchment area for community follow up visits by the research physiotherapist (at one site). During the study, this was perceived to be an issue due to R&D governance approvals, however further information was sought later in the project (during the RAFTAS feasibility study set up) which revealed this was a misconception. Discussions around the community service catchment area for study sites also led to identifying the issue of potential travelling distances for therapists later in the project (maximum distance logistically possible). The eligibility criteria was modified to ensure participants lived within the community services catchment area of a participating study site and travelling distances for therapists were agreed in the RAFTAS feasibility study. The proportion of eligible participants differed between sites (Site A 27% and Site B 8.5%), but the reason for differences between sites was unclear.

The main reason for ineligibility was that patients did not have new reduced arm function, which could be expected. Other major reasons for exclusion were perceived inability to comply with the RFTP programme and patients having a diagnosis likely to interfere with rehabilitation. Local NIHR SRN staff feedback indicated study recruitment may be improved by extending the recruitment window post stroke to allow patients who were initially medically unwell time to recover and become eligible to participate. The recruitment window was extended to up to 14 days post stroke for use in the RAFTAS feasibility study.

Only one patient who was approached declined to take part indicating that eligible patients were willing to participate in the RFTP programme.

Participant baseline characteristics

Although the sample size was small (n=7), the median age of participants (71 years) was similar to UK average age of onset (74 years) [95], and the proportion of participants with cerebral infarcts (86%) and intracerebral haemorrhage (14%) were similar to usual incidence (85% and 15% respectively) [2].

The range of time post stroke was 1-8 days and participants had differing amounts of selective upper limb movement, which offered the opportunity to test suitability of the RFTP programme across a range of participants.

Therapy sessions delivered

Three out of the seven (43%) participants received the number of face to face therapy sessions as intended, indicating that it was possible to review participants twice weekly over four weeks or until discharged as per study protocol. It was disappointing that 4/7 (57%) participants didn't receive therapy sessions as intended. However, 3/4 (75%) participants left the RFTP programme due to unforeseen issues not associated with the RFTP programme design (2/3 unable to receive further sessions due to the research physiotherapist's ill health and 1/4 transferred to another NHS trust, therefore unable to continue due to research governance approvals). The remaining patient was withdrawn due to poor cognition and inability to follow the RFTP programme, which indicated an error in recruitment rather than an issue with the RFTP programme. Withdrawal of the participant highlighted the need for effective collaboration with local usual post stroke rehabilitation staff during patient screening.

RFTP programme undertaken by participants

Selected upper limb rehabilitation goals were predominantly in accordance with the three main categories of the RFTP programme ('Washing', 'Dressing' and 'Eating / Drinking'), indicating categories were appropriate and important to participants. Some participants set goals under the 'optional' category, suggesting inclusion of 'Optional' goals was a useful design feature.

The majority of recovery activities selected were pre-specified on the recovery activity list, indicating there was an adequate range of activities available. Including optional recovery activities allowed scope for identifying missing activities from the recovery activity list and also enabled some participants to select alternative recovery activities that were not in accordance with the three main categories ('Washing', 'Dressing' and 'Eating / Drinking').

Although not many participants selected 'optional' goals and recovery activities, the decision was made to keep the 'optional' category as use of the 'optional' category may not have been fully explored due to the small sample size.

The maximum number of daily recovery activity repetitions possible in the RFTP programme was 80. It was not possible to report the number of daily repetitions logged by 2/7 participants as recovery activity log sheets were not returned to the co-ordinating centre (due to research physiotherapist ill health). The median number of daily repetitions logged was 41 [IQR 0.25-80], but median daily repetitions differed greatly between participants (min=0, max=83). Four out of the seven (57%) participants logged 80 daily repetitions on at least one occasion, suggesting 80 daily repetitions was an appropriate dose to test further in the RAFTAS feasibility study.

Participant feedback about the RFTP programme

Feedback collected when participants logged 80 daily repetitions (4/7 participants) indicated the number of recovery activity repetitions per session (20 repetitions per recovery activity per session) was acceptable. Feedback collected when participants logged less than 80 daily repetitions (3/7 participants) indicated participants either did not practice recovery activities or forgot to log recovery activity practice – which may have led to a recording bias. Participant adherence to the RFTP programme was further explored in the RAFTAS feasibility study.

Participant feedback from 4/5 (80%) participants with returned recovery activity log sheets indicated they managed to complete the programme independently. The median time taken for participants to complete recovery activity repetitions was 7 minutes, which may be considered an acceptable amount of time.

The majority of participant feedback about the programme was positive in nature (53/71, 75%) and few negative comments were made (8/71, 11%). Positive participant experiences supported the RFTP programme content including goal setting / individualising the programme, repetitive activities, and the range of recovery activities available. Positive experiences specific to RFTP programme delivery also supported independent practice, twice weekly therapy reviews and participant handbook content. Participants described other positive experiences relating to undertaking the RFTP programme (e.g. increased motivation to participate in usual post stroke rehabilitation). Negative participant experiences related to undertaking recovery activity practice. Some participants described the recovery activities as 'hard work' or 'frustrating' and one participant was unsure how to complete a recovery activity.

Research physiotherapist's observations about delivering the RFTP programme

Observations made by the research physiotherapist highlighted need for minor modifications to documentation. Modifications were streamlining the number of recovery activity log sheets, producing recovery activity 'continuation sheets' (containing grids for marking repetitions and participant feedback sections only) and adding days of the week to recovery activity log sheets (to increase ease of use for participants).

Other observations documented by the research physiotherapist (e.g. increased automatic use of the affected upper limb), coupled with other experiences described by participants (on recovery activity log sheets and during therapy reviews) indicated participants' views and experiences should be further explored later in the project.

Feedback from local NHS staff and NIHR SRN staff

Local NHS stroke staff felt the RFTP programme did not interfere with participants' care, suggesting the programme was compatible with usual post stroke rehabilitation.

Local NIHR SRN staff feedback was used to help inform eligibility criteria used in the RAFTAS feasibility study. The recruitment window post stroke was increased to 14

days and the unforeseen impact of local community services catchment area considered (discussed above). Local NIHR SRN staff experiences of consenting patients to the study indicated participants wished to choose how much time they needed to decide about study participation (rather than waiting >24 hours).

Safety of the RFTP programme

No SAEs were reported and the number of AEs recorded was minimal when compared to the number of opportunities AEs could be reported. Adverse events reported by participants were mainly common post stroke issues (e.g. fatigue or pain). Preliminary safety data suggested there did not appear to be any concerns, so it was considered safe to proceed to the next project stage (RAFTAS feasibility study).

Usual post stroke rehabilitation

Adherence with usual post stroke rehabilitation data collection was poor. Transfer of participant care from hospital to community teams made data collection logistically difficult. Contacting the correct usual post stroke rehabilitation team and specific therapist was challenging for the research physiotherapist due to the large number of community teams available. After contacting usual post stroke rehabilitation teams, it was time consuming for the research physiotherapist to train each relevant therapist(s) to complete the usual post stroke rehabilitation forms. It was not feasible to train all usual post stroke rehabilitation therapists at the start of the study due to the large numbers of therapists involved (compared to relatively few participants to be recruited). It was also challenging for the research physiotherapist to engage some usual post stroke rehabilitation staff in usual post stroke rehabilitation data collection as some therapists did not appear to have an interest in research.

Efforts made by the research physiotherapist to improve data collection would not be feasible in a larger study. As experience of usual post stroke rehabilitation data collection was limited (due to the small sample size), the decision was made to continue with usual post stroke rehabilitation data collection later in the project but with modification to co-ordination of collection. In the RAFTAS feasibility study (next project stage) a designated usual post stroke rehabilitation staff member from each clinical team (ward based teams and community based teams) at each study site was trained and responsible for usual post stroke rehabilitation data collection.

4.5 Summary of implications for later in the project (RAFTAS feasibility study)

Feedback and experiences collected from the non-randomised feasibility study resulted in modifications to the RFTP programme, eligibility criteria, consent process and usual post stroke rehabilitation data collection for use later in the project (RAFTAS feasibility study).

Modifications to the RFTP programme were:

- The recovery activity list was modified to include the additional recovery activities identified by participants.
- The number of recovery activity log sheets was streamlined and a recovery activity log 'continuation sheet' (see appendix 10) was produced making it easier for the therapist to maintain and transport folders containing the printed recovery activity log sheets.
- Recovery activity log sheets were modified to include days of the week to increase ease of use for participants.

Eligibility criteria were revised by increasing the recruitment window after stroke to 14 days and by ensuring potential participants lived within the agreed community services catchment area of a participating study site. Unforeseen ill health of the research physiotherapist highlighted the need to train more than one therapist per study site to deliver the RFTP programme later in the project (RAFTAS feasibility study).

The consent procedure was altered to enable participants to choose how long they wished to consider the information in the 'Participant Information Sheet' prior to deciding whether they wished to participate in the study. Research physiotherapist observations and participant feedback led to the inclusion of semi-structured interviews (with a sample of participants) in the RAFTAS feasibility study to allow more detailed exploration of comments made.

Experiences of usual post stroke rehabilitation data collection led to a change in logistics of data collection in the RAFTAS feasibility study where a designated local rehabilitation staff member from each clinical team (ward based teams and community based teams) was identified, trained and responsible for data collection.

4.6 Future reporting of the RFTP programme

As mentioned in chapter one, RFTP based interventions in previous studies were often inadequately described to allow replication by researchers or clinicians. The Template for Intervention Description and Replication (TIDieR) checklist and guide [77] were published in 2014 with the aim of ensuring completeness of reporting in publications by improving the quality of descriptions. Although the guide was published after development of the RFTP programme (so could not be used to assist development), the completed TIDieR checklist for the RFTP programme is shown in table 17 to demonstrate the programme could be reported using the TIDieR [77] checklist.

Table 17: Completed Template for Intervention Description and Replication (TIDieR) checklist for the RFTP programme

1	**Name- Intervention title**	Repetitive Functional Task Practice (RFTP) programme for upper limb recovery early after stroke
2	**Why - Rationale, theory and essential elements of the intervention**	**Rationale** • Evidence from rehabilitation research, skill acquisition research and neuroscience suggests that, in order to promote recovery of functional skills after stroke, intensive task-specific practice is required. • Additionally, task-specific practice should commence early after stroke as the level of neuroplasticity, and hence the potential for recovery, is greatest in the first few weeks after the acute event. • In order to engage people with stroke in skill acquisition, the intervention needs to focus on activities that are meaningful to the individual. • Evidence supporting intensive task-specific practice to improve arm function in the acute stage after stroke required strengthening. • RFTP based programmes from previous studies did not describe interventions in detail. • A RFTP programme was developed but elements of the intervention needed to be tested for their feasibility early after stroke. **Essential elements**: • Repetitive practice • Focus on functional activities considered meaningful by each participant, selected after goal setting. • Association between daily routines and practice of specific activities through “cueing” (i.e. prompts) • Progression through re-assessment and progress towards participant selected upper limb rehabilitation goals.

Table 17: Completed Template for Intervention Description and Replication (TIDieR) checklist for the RFTP programme (continued)

3	**What – materials**	• Therapy manual with a total of 183 pre-defined recovery activities, focused on person-centred goals, i.e. washing, dressing, eating and drinking (mainly based on the previous BoTULS study [82, 83]. Optional recovery activities could also be selected to enhance participant engagement with the programme. • Written recovery activity log sheets with pictures (i.e. sheets of individual recovery activities from the manual, selected by the therapist and participant based on each participant's goals and baseline level of ability), aimed at enabling each participant to undertake self-practice. Ability levels were generated by considering sensorimotor parameters (e.g. amount of upper limb movement and coordination required) and the level of cognitive processing required to complete the activity. The aim was to progress the participant to more challenging levels of ability.
4	**What – procedures**	• Initial assessment of participant's arm function, to establish baseline ability level for the intervention. • Discussion with participant on upper limb goals, to establish type of recovery activity for the intervention. • Selection, together with participant, of recovery activities for self-practice. • Demonstration and education to ensure participant was safe and confident undertaking self-practice of selected recovery activities. • Review (2x per week), for 4 weeks (totally a maximum of 8 face to face sessions). • Re-assessment. • Tailoring content and progression according to participant response to the intervention. • Participants could be discharged from the programme prior to 4 weeks if participants achieved all upper limb therapy goals and regained normal upper limb function.
5	**Who provided**	Band 6 NHS Physiotherapists and Occupational Therapists were trained at three study sites and delivered the intervention.
6	**How- Method of delivery**	• Independent practise by participants with twice weekly therapist reviews. • Cueing (i.e. prompting) was used to associate practice of specific activities with daily routines with the aim to encourage self-practice.

Table 17: Completed Template for Intervention Description and Replication (TIDieR) checklist for the RFTP programme (continued)

7	**Where- Location**	The intervention was delivered in the participant's current environment, which could include the acute stroke unit, outpatient department, home environment (including residential or nursing homes).
8	**When and How much**	**When:** • As soon as possible after stroke onset with an upper time limit of 14 days. **Dose:** • Two activities, practised up to 20 repetitions each on two separate occasions per day (i.e. up to 80 repetitions per day), 7 days per week, for a total of 4 weeks
9	**Tailoring**	The intervention was tailored to individuals by: • Selecting the type of activities on the basis of each participant's prioritised goals • Selecting an appropriate ability level, based on the initial assessment of each participant • Using cues related to each participant's individual daily routine • Progressing the level of difficulty according to each participant's response to the intervention.
10	**How well**	**Planned:** Participants were asked to complete 'recovery activity log sheets'. For those needing support, the therapist asks a family member / friend / member of staff to complete the log on their behalf. **Adherence reported using:** • Number of face to face therapy sessions • Goals and recovery activities selected • Number and completion of recovery activity log sheets returned from participants • Number of daily repetitions practiced by participants

4.7 Non-randomised feasibility study: conclusion

In conclusion, a non-randomised feasibility study of the RFTP programme and study data collection tools was undertaken. The proposed eligibility criteria, feasibility and acceptability of the RFTP programme and post stroke rehabilitation data collection were tested and preliminary safety data about the RFTP programme reported.

The study demonstrated that the RFTP programme was acceptable to patients diagnosed with stroke. Preliminary safety data suggested there were no apparent safety concerns. Modifications were made to the eligibility criteria, the RFTP programme and study procedures for use in the next stage of the project (RAFTAS feasibility study).

Chapter 5. Repetitive arm functional tasks after stroke (RAFTAS) feasibility study: Aim, objectives and methods

5.1 RAFTAS feasibility study: Introduction

The National Institute for Health Research (NIHR) defines a feasibility study as *'a piece of research done before the main study in order to answer the question 'Can this study be done?'* [96]

Feasibility studies can be undertaken in order investigate all or some of the following parameters [71, 96]:

- Test the study protocol, intervention and training materials
- Establish the likely recruitment rate of a future study
- Ensure that eligibility criteria are appropriate
- Test the randomisation procedure
- Record adherence to intervention and control treatments
- Explore the acceptability of the intervention to participants and clinicians
- Test data collection methods, forms and questionnaires
- Determine the success of blinding procedures
- Record attrition, data quality and completeness
- Report patient safety data
- Select the most appropriate outcome measure for a future trial
- Ascertain the standard deviation of the primary outcome measure to inform the sample size of a future trial
- Establish the strengths and limitations of the study database
- Determine the time needed to collect, enter and analyse data.

The results of a feasibility study should provide evidence to potential funders and referees that a larger trial can be undertaken and successfully delivered.

5.2 RAFTAS feasibility study: Aim and objectives

5.2.1 RAFTAS feasibility study aim

The aim was to assess the feasibility of a multicentre, observer blind parallel group randomised controlled trial of a RFTP programme for upper limb recovery early after stroke.

5.2.2 RAFTAS feasibility study objectives

Objective 1: To report the study recruitment rate and the main reasons why patients were not enrolled in the study.

Objective 2: To report data completeness and summary statistics at baseline.

Objective 3: To report local study therapist and participant adherence to the RFTP programme.

Objective 4: To report the usual post stroke rehabilitation received by control and intervention groups within the study intervention period.

Objective 5: To report attrition, data completeness and summary statistics of clinical outcomes at 1 and 3 months.

Objective 6: To report the success of outcome assessor blinding to participant group allocation.

Objective 7: To report adverse events in control and intervention groups during the study.

Objective 8: To seek and report the views and experiences of study participants and therapists about the RFTP programme.

5.3 RAFTAS feasibility study: Methods

A flowchart of the RAFTAS feasibility study design is shown in figure 8.

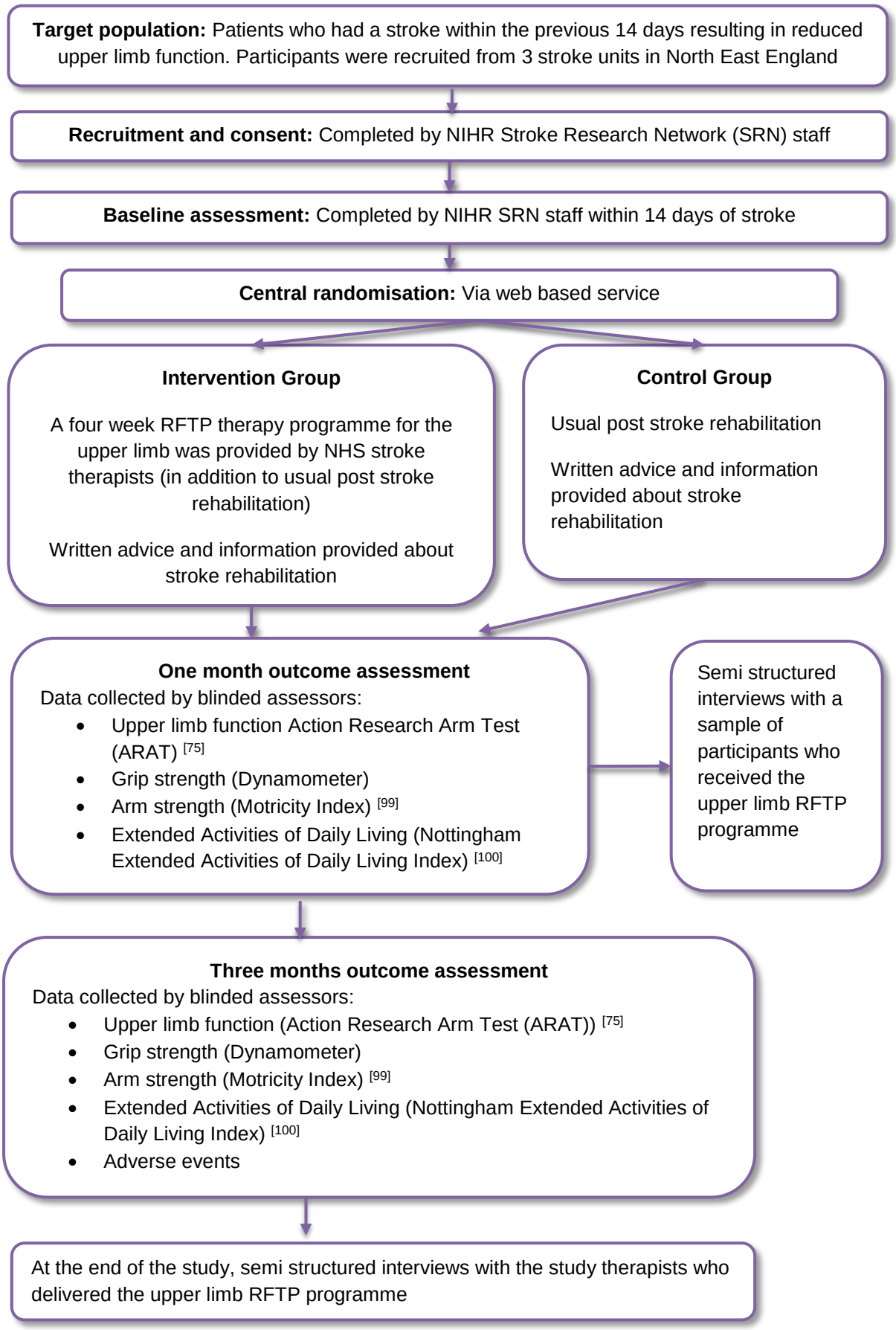
5.3.1 Study design

The RAFTAS feasibility study was a pragmatic observer blind parallel group RCT. Participants were randomised to either:

i. Intervention group: RFTP programme (provided in addition to usual post stroke rehabilitation)
ii. Control group: continue with usual post stroke rehabilitation.

In addition, both study groups received written advice and information about stroke, rehabilitation and positioning of the arm and hand after stroke, prepared by the thesis author.

Figure 8: Flowchart of the RAFTAS feasibility study design



5.3.2 Study setting and study site selection

The RAFTAS feasibility study took place in three NHS stroke services in North East England (known as study Sites 1, 2 and 3). All study sites had acute stroke units providing care and rehabilitation for up to 30 patients. Two study sites had been involved earlier in the project (Non-randomised feasibility study; Study Site A became Site 1 and Study Site B became Site 2). Contextual information about services at Sites 1 and 2 has been described previously (see Chapter 4, section 4.2.2). Study site 3 was included after local staff expressed an interest to participate.

At Study Site 3, patients were admitted directly to the stroke unit at a large regional hospital. Patients were repatriated to smaller community hospitals or discharged directly to their own homes, residential homes or nursing homes. Inpatient therapy was delivered in the community hospitals, but there was very limited community therapy available from a generic therapy team. Delivery of community based input for the RAFTAS feasibility study was negotiated during the study set up phase.

Stroke services were typical of sites which would be invited to participate in a Phase III study. The results of each study site are anonymised.

Recruitment to the RAFTAS feasibility study was planned to commence at all three sites on 01.04.2013 and last for 12 months. Potential participants were identified and recruited from the stroke units by local NIHR Stroke Research Network (SRN) staff. The study intervention (RFTP programme) was delivered by NHS therapists on the stroke unit or community hospitals to those patients who were in-patients. Participants who were discharged before the end of the RFTP programme were reviewed by NHS therapists at their own home, residential care or the stroke unit according to participant preference.

5.3.3 Local study site staff

Local site staff at Sites 1 and 3 had minimal experience of stroke rehabilitation research compared to Site 2 where rehabilitation research was well established within the stroke service.

Local NIHR SRN staff undertook participant recruitment, consent, study baseline assessments and randomisation. Local NIHR SRN staff were trained at site by the thesis author.

Physiotherapists or occupational therapists working in stroke rehabilitation services at each study site were approached by the thesis author about participating as either a local study therapist (delivering the RFTP programme) or as a study outcome assessor. Recruited therapists were trained by the thesis author about 'Good Clinical Practice', delivery of the RFTP programme and completion of outcome assessments according to their role. The thesis author supported local site staff throughout the feasibility study and provided further training sessions as appropriate.

5.3.4 Study population

Patients who fulfilled the following criteria were eligible:

5.3.4.1 Inclusion Criteria

- Age ≥ 18 years.
- Within 14 days of stroke onset.
- New reduced upper limb function due to acute stroke but with retained ability to lift the affected hand off their lap.
- Capable of undertaking the RFTP therapy programme and adhering to the study protocol.
- Able to provide informed consent to participate in the study.
- Lived within the community services catchment area of a participating study Site.

5.3.4.2 Exclusion criteria

- Unable to follow the RFTP programme for example due to cognitive impairment or receptive aphasia.
- Other significant upper limb impairment e.g. fixed contracture, frozen shoulder, severe arthritis, and upper limb pain that inhibits participation in the RFTP programme.
- Diagnosis likely to interfere with rehabilitation e.g. registered blind, palliative care.

5.3.5 Study screening and recruitment data

Patients admitted to the acute stroke units were regularly screened by local NIHR SRN staff for potential inclusion up to 14 days post stroke. Local NIHR SRN staff were requested to complete a screening log to provide information about:

- If a patient was eligible
- If a patient was eligible but did not participate
- The primary reason why a patient was ineligible
- The number of patients who entered the study

5.3.6 Case ascertainment, recruitment and consent

Potentially eligible participants were identified by both local NIHR SRN staff and local stroke unit staff who discussed the study with them and provided a study information sheet. After allowing sufficient time for this information to be considered (as agreed with each patient), and an opportunity to ask questions, local NIHR SRN staff obtained written consent. Patients with mild to moderate aphasia were included if they were able to provide informed consent. Local NIHR SRN staff liaised with local staff and speech and language therapists if assistance was required.

5.3.7 Baseline assessment

A baseline assessment was performed by local NIHR SRN staff following patient consent to study participation. Prior to baseline assessment and participant randomisation, local NIHR SRN staff checked that the local study therapist was available to provide the initial therapy session within 24 hours, should the participant have been allocated to the intervention group.

The following data were collected: date of stroke, first ever or recurrent stroke, stroke type (e.g. infarct, haemorrhage), stroke sub-type (TACS, PACS, LACS, POCS) [94], stroke severity (National Institutes of Health Stroke Scale (NIHSS)) [97], pre-stroke OHS (Oxford Handicap Scale) [98], hand dominance, arm function (Action Research Arm Test (ARAT) [75], grip strength (dynamometer) and arm strength (Motricity Index) [99].

5.3.8 Randomisation

Participants were randomised using a central independent web based service hosted by Newcastle University Clinical Trials Unit. Participants were stratified according to study site and randomised to intervention and control in a 1:1 ratio using variable sized permuted block sequences. Participants were stratified according to study site to ensure that intervention and control group participants were evenly distributed across study sites. Randomisation was performed by local NIHR SRN staff after the baseline assessment.

5.3.9 Study intervention treatment (RFTP programme)

The study intervention treatment was the developed RFTP programme (see chapters 3 and 4). This was provided by local study therapists. The intervention treatment was in addition to usual post stroke rehabilitation. Participants in the intervention group

received a participant handbook which contained generic advice and information about stroke, rehabilitation and positioning of the arm and hand after stroke as well as their personalised RFTP programme (see appendix 4).

5.3.10 Study control treatment

The study control treatment was usual post stroke rehabilitation. Participants randomised to the control group also received the generic component of the participant handbook. Handbooks provided to intervention and control participants were externally identical to promote blinding to study group allocation.

5.3.11 Usual post stroke rehabilitation

The content and duration of usual post stroke rehabilitation sessions were collected using the case report form (CRF) developed for the feasibility study (see appendix 9). A data collection field to capture RFTP delivered in usual care was included on the CRF. RFTP is not a novel intervention and can be delivered by therapists in usual care, so it will be necessary to collect the amount of RFTP delivered in a future phase III study. Collecting the amount of RFTP delivered in usual rehabilitative care will also be required to determine if usual care treatments have been contaminated in a future phase III study (analysis over time).

A designated local rehabilitation staff member from each clinical team (ward based teams and community based teams) at each study site was identified and trained by the thesis author to complete the usual post stroke rehabilitation data collection forms. The designated local rehabilitation staff member was offered a letter of acknowledgement from the thesis author which could be used as evidence in their 'Knowledge and Skills Framework' portfolio as an incentive to complete usual post stroke rehabilitation data collection forms.

5.3.12 Outcome assessments

Outcomes were assessed at one month (+/- three days) and three months (+/- five days) following randomisation. The following data were collected: arm function (Action Research Arm Test (ARAT) [75], grip strength (dynamometer), arm strength (Motricity Index), [99] extended activities of daily living (Nottingham Extended Activities of Daily Living Index) [100].

5.3.13 Blinding of outcome assessments

Due to the nature of the intervention, it was not possible to blind participants to treatment allocation. Outcome assessments were performed by researchers intended

to be blinded to treatment allocation. After each assessment, the outcome assessor was asked to record whether they had unintentionally become aware of treatment allocation.

5.3.14 Study withdrawal

No specific study withdrawal criteria were set. Participants could withdraw from the study at any time for any reason. If a participant decided to withdraw from the study, a reason was sought. However, participants could have withdrawn without providing an explanation. Data collected prior to withdrawal were included in the study analysis. Clinical teams, local study therapists or investigators were able to withdraw participants from the study at any time if they felt it was no longer in the participant's interest to continue, for example, because of intercurrent illness.

5.3.15 Safety

The safety of the RFTP programme was evaluated by examining adverse events as defined by the Medicines for Human Use (Clinical Trials) Regulations [101].
All adverse events were recorded for the duration of each participant's involvement in the study. An adverse event is any untoward medical occurrence in a participant to whom a study intervention or procedure has been administered, including occurrences which are not necessarily caused by or related to that intervention. A Serious Adverse Events (SAE) is an untoward occurrence that:

- Results in death
- Is life-threatening
- 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 [96].

Participants were asked at each outcome assessment if they had any new medical problems or had been admitted to hospital. Additional assessment of anticipated adverse events was also incorporated by inclusion of specific questions concerning presence and severity of pain in the affected upper limb (measured by a Visual Analogue Scale [102]), fatigue severity (measured by a Visual Analogue Scale) and presence of increased upper limb muscle tone (measured by the Modified Ashworth Scale) [103]. Events considered to be SAEs were documented onto a separate study SAE form, and a causality and expectedness assessment was performed.

5.3.16 Sample size

A formal sample size calculation is not required for a feasibility study. The sample size was designed be large enough to provide information about key components e.g. recruitment and gaining experience of undertaking the intervention in the NHS [104]. The study aimed to recruit 60 patients in one year from three study sites at a rate of 1-2 patients per study site, per month (30 intervention and 30 control). The recruitment rate was considered realistic and was informed by previous trials [72, 105] undertaken by the study team. Data to inform the sample size calculation for a Phase III study was not sought as data are available from larger studies of upper limb interventions post stroke, which recruited participants from a similar patient population and used the same validated outcome measures [56, 63].

5.3.17 Data analysis

Analysis of feasibility studies should be mainly descriptive [71, 104]. Numbers and percentages were used for categorical variables. Mean and standard deviation (SD), or median and interquartile range [IQR] were reported. SPPS version 22 was used to perform data analysis. It was not appropriate to undertake statistical comparisons of clinical outcomes between randomisation groups in this small feasibility study. Analysis of qualitative data is included below (section 5.3.18).

5.3.18 The views and experiences of study participants and local study therapists about the RFTP programme

Feedback was collected from participants about undertaking the RFTP programme and local study therapists about delivering the programme.

During the programme, participants were asked to record data on recovery activity log sheets. Participants recorded free text responses under the following headings; ‘Reason for stopping session if less than 20 repetitions’, ‘Comments regarding the task/programme’, ‘Approximate time spent doing repetitions’ and ‘Help given from another person’. Local study therapists recorded participants’ comments about undertaking the RFTP programme (free text responses) during therapy review sessions.

Semi-structured interviews were undertaken with a sample of participants at the end of the participant’s programme (within two months of last therapist visit). Sampling of participants for interviews was intended to consider variables of study site, gender,

stroke severity (NIHSS [97]), length of hospital stay, positive and negative feedback about the programme and completion/non-completion of the RFTP programme (purposive sampling). Convenience sampling was necessary due to study recruitment and logistical issues.

During the study intervention period, local study therapists recorded feedback about delivering the programme on participants' final therapy session forms (free text responses). Semi-structured interviews were undertaken with local study therapists at the end of the study intervention period. Local study therapists and participants selected for interview received a letter of invitation and a written information sheet. The letter was followed by a telephone call and consent obtained by the thesis author prior to the start of the interview. Interviews were conducted by the thesis author on a 1:1 basis.

The participant interview topic guide covered areas directly relating to the RFTP programme (e.g. ability to use the affected upper limb in activities of daily living) and study materials (see appendix 11). The local study therapist interview guide covered RFTP programme design and content, ease of use of the study materials and delivery of the RFTP programme in hospital and community settings (see appendix 12).

Participant and local study therapist feedback were analysed separately.

Feedback collected from study pro forma was analysed using content analysis due to the nature of data collected (multiple short comments collected under specific headings). Responses were coded and categorised and results presented numerically.

Participant and therapist interviews were digitally recorded and then transcribed by study co-ordinating centre staff. Transcribed interviews were checked against the audio recordings and corrected for errors by the interviewer (thesis author). A thematic analysis of the interview data was undertaken which entailed familiarisation with the material, coding and category development in reference to the interview schedules. Common feedback and outlier views by respondent were identified. It was intended that a sub-sample of interview data would be independently analysed by a study co-investigator and compared to the analysis undertaken by the interviewer, but insufficient resources were available.

5.3.19 Ethics and Governance

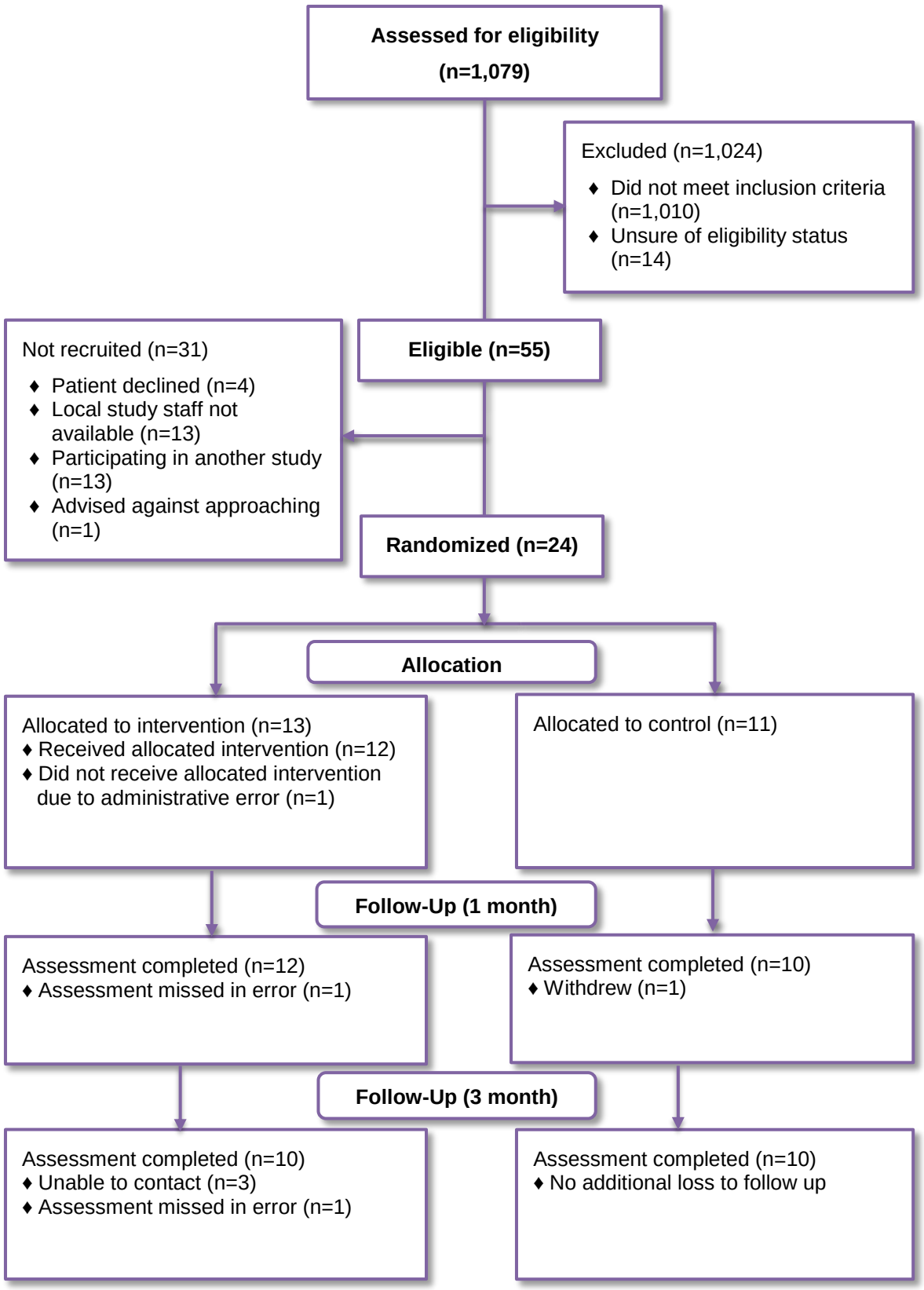
Research Ethics Committee approval was granted on 30.4.2013 (REC reference number 13/NE/0074). Local Research and Development approvals for the RAFTAS feasibility study were obtained Site 2 on 28.05.2013, Site 1 on 1.06.2013 and Site 3 on 11.06.2013. The study complied with the Data Protection Act 1998 and Caldicott Principles. The study sponsor was Northumbria NHS Foundation Trust and the study was adopted by the NIHR SRN.

Chapter 6. Repetitive arm functional tasks after stroke (RAFTAS) feasibility study: Consolidated Standards of Reporting (CONSORT) flow diagram

The Consolidated Standards of Reporting (CONSORT) statement [106] is widely used to improve how randomised trials are reported. This helps facilitate completeness and transparency of reporting and assists with interpretation and appraisal. The CONSORT statement consists of a 25 item checklist used in article writing and a flow diagram detailing progress through phases of a parallel randomised trial of two groups (enrolment, intervention allocation, follow-up, and data analysis).

The CONSORT Flow Diagram of the RAFTAS Feasibility study is shown in figure 9.

Figure 9: CONSORT Flow Diagram of the RAFTAS Feasibility Study



Chapter 7. Repetitive arm functional tasks after stroke (RAFTAS) feasibility study: Recruitment rate and the main reasons why patients were not enrolled in the study.

Objective 1: To report the study recruitment rate and the main reasons why patients were not enrolled in the study.

7.1 Results

7.1.1 Recruitment period

The study opened two months later than originally planned as preparing study documents and obtaining ethical and local Research and Development applications took longer than anticipated. The REC application was submitted 19.2.2013 and approval was granted 30.04.2013.

Study sites were open to recruitment as soon as local Research and Development approvals were obtained, but again these took longer than anticipated. The feasibility study was open for recruitment at Site 1 from 12.06.2013 – 28.02.2014 (37 weeks), Site 2 from 03.06.2013 – 28.02.2014 (38 weeks) and Site 3 from 16.07.2013 – 14.02.2014 (30 weeks). Recruitment was less than the planned 52 weeks to adhere to the study timeline and Site 3 closed early due to lack of local study therapist engagement.

7.1.2 Screening and enrolment

Figure 10 shows a summary of the RAFTAS feasibility study screening data. Figures 11, 12 and 13 show summary screening data for the individual study sites.

One thousand and seventy nine patients with acute stroke were screened for eligibility. Fifty five (5%) were considered eligible. At each study site, the proportion of patients eligible was: Site 1: 23/411 (6%); Site 2: 11/311 (4%); and Site 3: 21/358 (6%).

The main reason for ineligibility was not recorded for 337 (33%) patients. The most frequent recorded reason for ineligibility was no new reduced upper limb function: 206/673 (31%). One hundred and eighty one patients (27%) were considered unable to comply with the upper limb RFTP programme because of speech or cognitive problems and 147 (22%) lived outside the catchment area for community follow up visits.

Twenty four of the 55 (44%) eligible patients were enrolled in the feasibility study: Site 1: 9/32 (28%); Site 2: 11/11 (100%); and Site 3: 4/21(19%).

Of the 31/55 (56%) eligible patients who were not enrolled in the study, 27/31 (87%) were not approached. The reasons were: already enrolled in another clinical trial (n=13) which did not allow co-enrolment (common at Site 3), and lack of availability of local NIHR SRN staff (n=6) or local study therapists (n=7) (common at Sites 1 and 3).

Four patients (all from Site 1) declined to take part in the study: one felt that the RFTP programme would be too difficult; one felt that there was insufficient content; and two did not give a reason.

Figure 10: All Sites: Summary of the RAFTAS feasibility study screening data

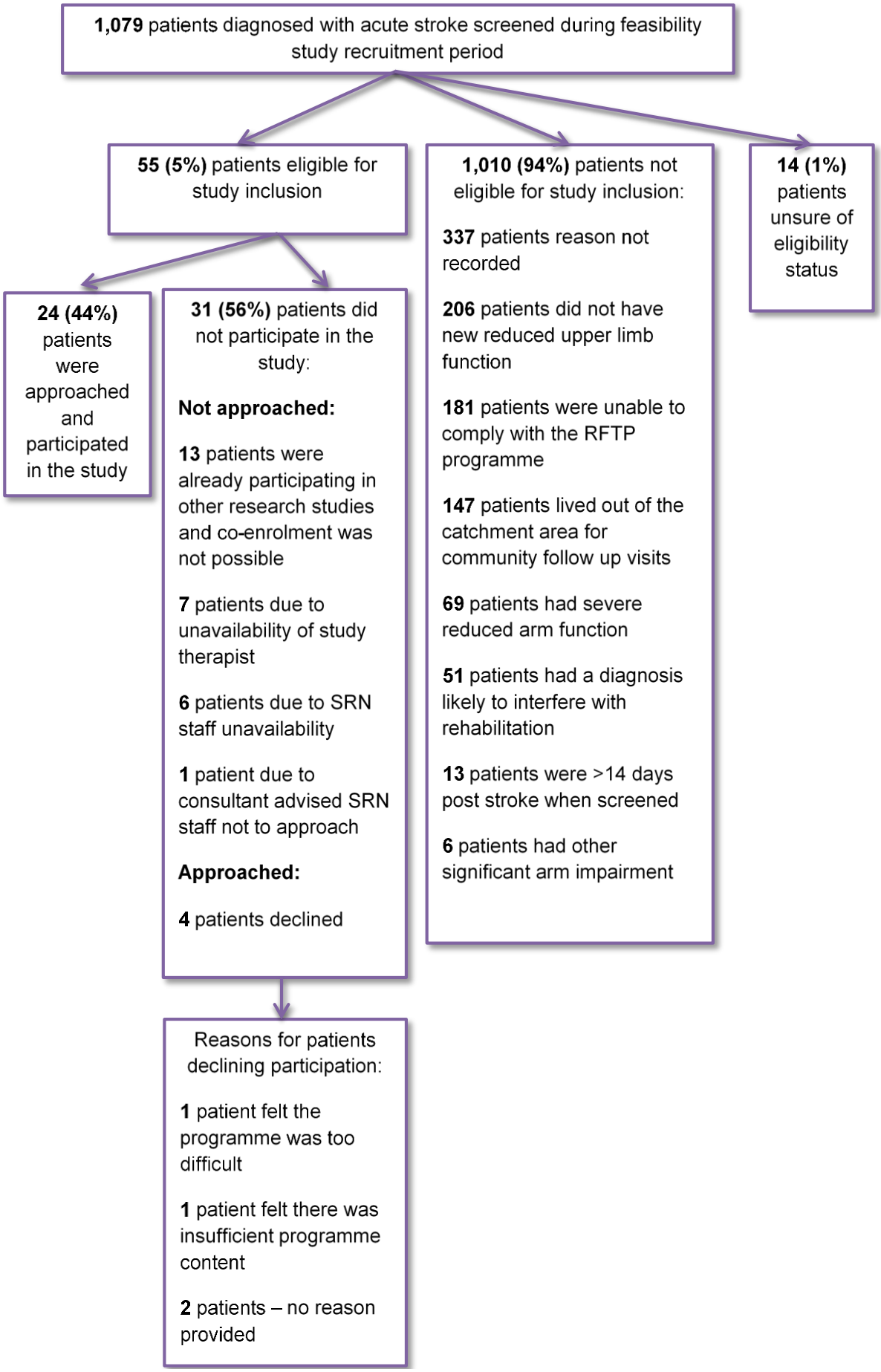


Figure 11: Study Site 1: Summary of the RAFTAS feasibility study screening data

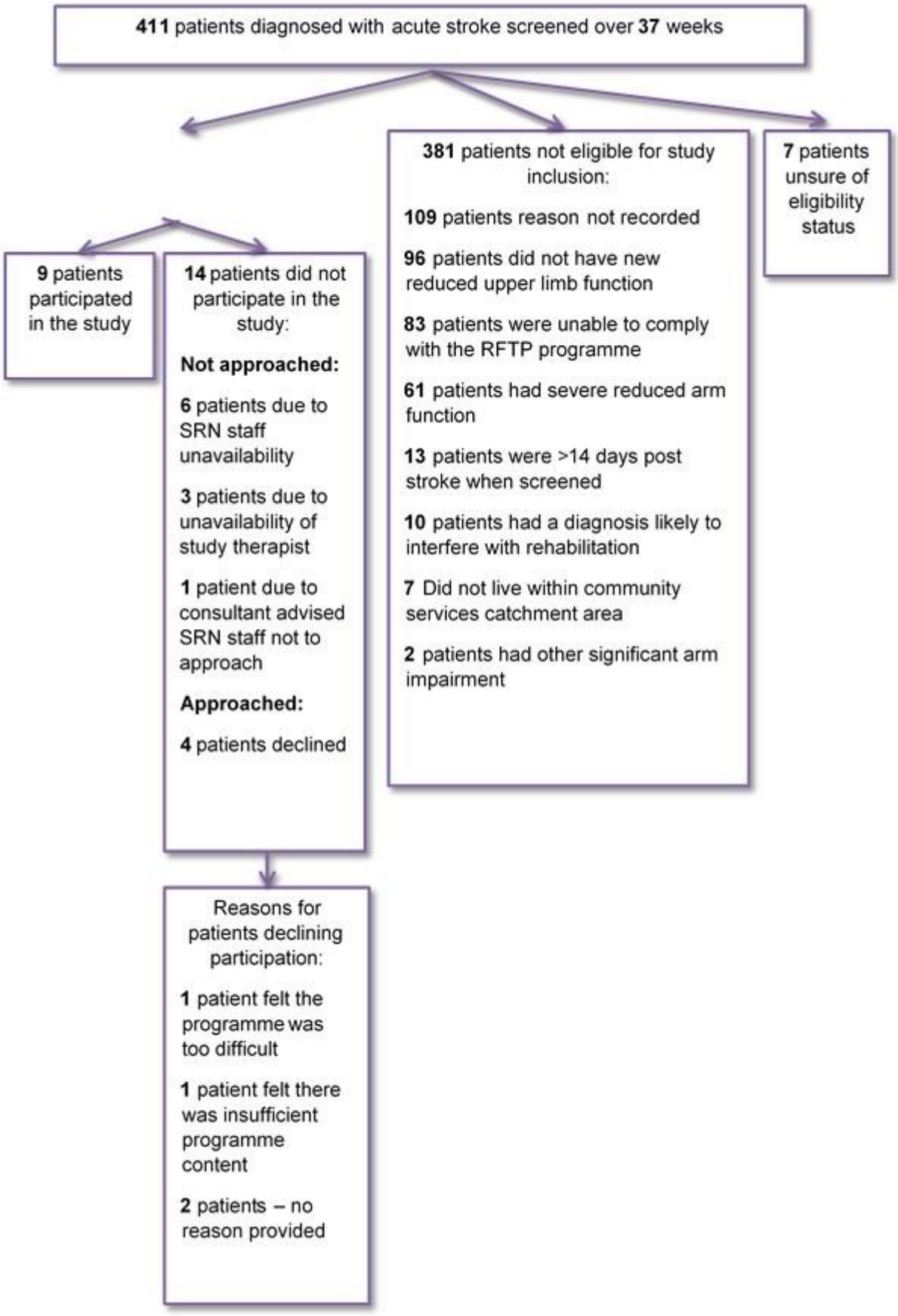


Figure 12: Study Site 2: Summary of the RAFTAS feasibility study screening data

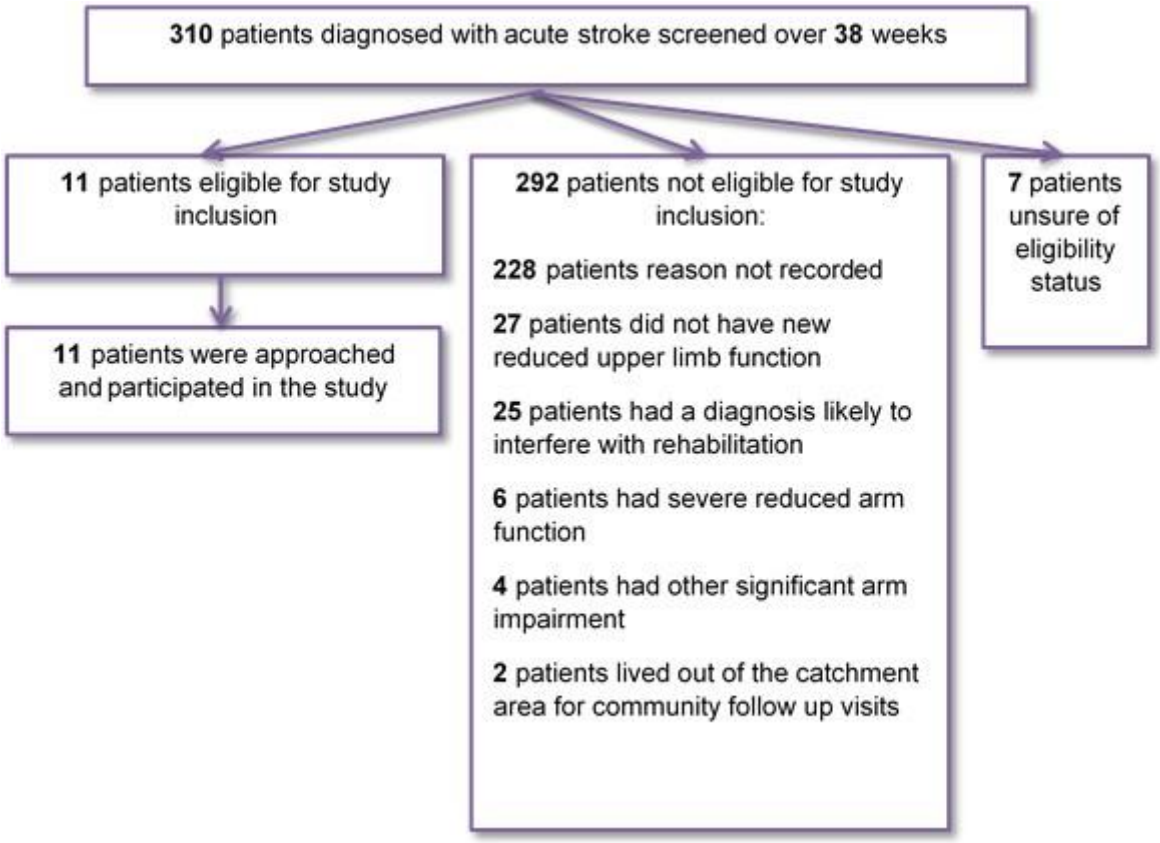
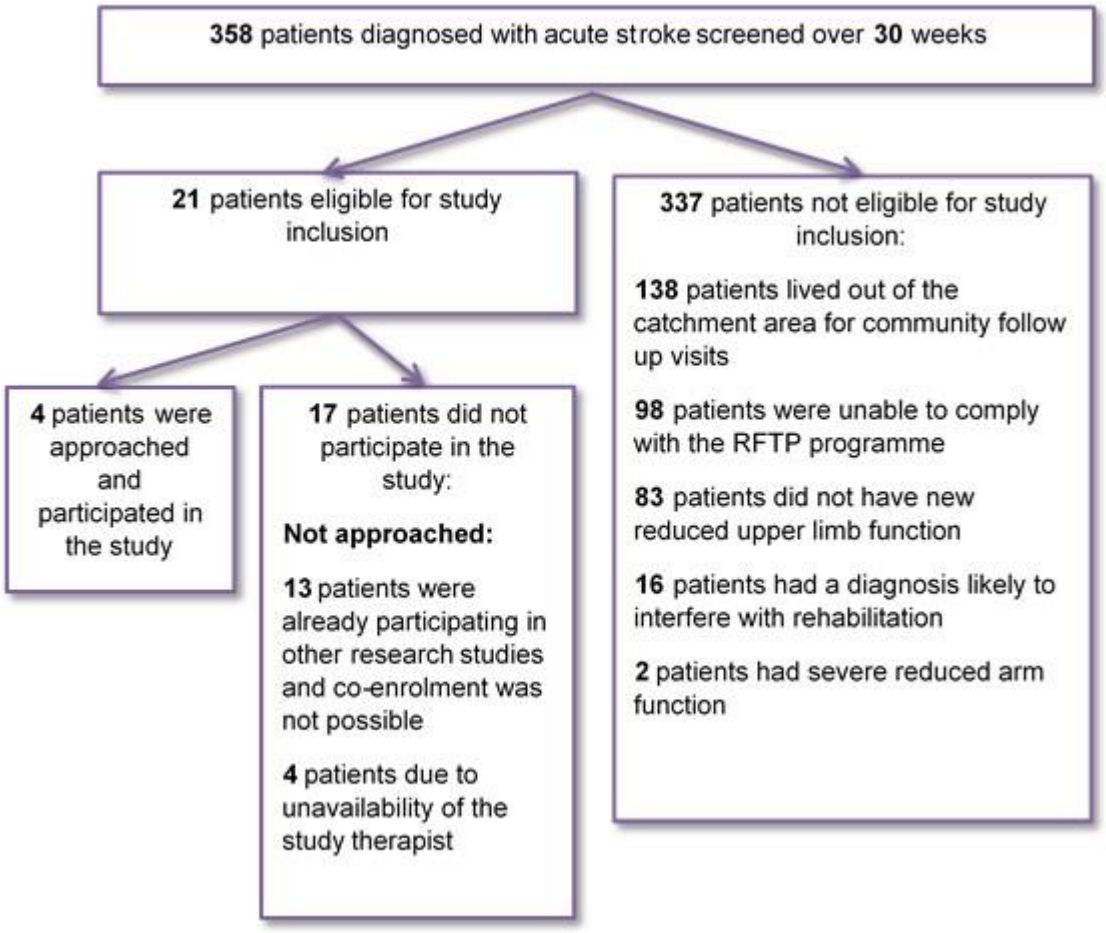


Figure 13: Study Site 3: Summary of the RAFTAS feasibility study screening data



7.1.3 RAFTAS feasibility study recruitment rate

Twenty four patients were recruited to the study: Site 1 nine participants; Site 2 11 participants; and Site 3 four participants. The mean recruitment rate was: Site 1: 1 / month; Site 2: 1.2 / month; and Site 3: 0.5 / month.

RAFTAS feasibility study recruitment rate is shown in Table 18.

Table 18: RAFTAS feasibility study recruitment rate

Study site	2013							2014		Study site TOTAL
	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	
Site 1	1	3	2	0	0	1	1	1	0	9
Site 2	2	2	1	4	0	1	0	1	0	11
Site 3	- (site not open)	1	0	0	1	1	0	1	0 (site closed early)	4
Month TOTAL	3	6	3	4	1	3	1	3	0	TOTAL = 24

7.2 Discussion

The initial recruitment target of 60 participants was not achieved, in part due to a shortened recruitment period at all sites. Study sites were open to recruitment between 7 and 9 months rather than 12 months as planned. The shortened recruitment period had a revised predicted sample size of 25–50 participants (1-2 participants/site/month). This was not achieved: 24 participants were recruited.

Sites 1 and 2 achieved the recruitment target of 1-2 participants per month. Both of these sites had participated in early phases and were enthusiastic about the study. During the recruitment period, Sites 1 and 2 had a change of local NIHR SRN staff which may have reduced recruitment. Site 3 did not meet the recruitment target despite identifying sufficient eligible participants. Site 3 staff were initially enthusiastic about the study but did not fully engage in delivery. The reluctance of local study therapists to deliver the RFTP programme across the whole catchment area of the study site affected recruitment at Site 3 which covered a large geographical area. Patients living out of the catchment area for community follow up visits was the main reason why patients were ineligible, but was not thought to be an issue when Site 3 joined the study.

The proportion of patients admitted to the three acute stroke units eligible to take part in the study was 5%. All sites reported a similar eligibility rate. In previous studies evaluating RFTP for the upper limb after stroke, the eligibility proportion was between 3% - 82% (table 19). The large variation is because different populations were

screened. Some studies took place in an acute setting and screened all admissions while others recruited from rehabilitation hospitals or community services and only screened patients who were likely to be eligible.

Three studies [56, 59, 60] aimed to recruit participants within a similar time post stroke to the RAFTAS feasibility study. Kwakkel et al. [56] recruited participants from seven acute hospitals and 3% of stroke admissions were eligible. The recruitment rate was 3.2 per month across all sites. Individual site eligibility and recruitment is not published, but assuming that all sites were open to recruitment during the study period the recruitment rate was 0.5 participants per centre per month. Van Vliet et al. [59] recruited participants from a stroke rehabilitation ward. Twenty nine percent of patients were eligible and the recruitment rate was 5.7 participants per month. Winstein et al. [60] recruited participants from a neuro-rehabilitation centre and 12% of patients were eligible to be invited to take part in the study but the recruitment window (2-35 days) was much wider than the RAFTAS feasibility study.

Fifty five eligible patients were identified in the RAFTAS feasibility study, so it is disappointing that only 24 (44%) were enrolled. Availability of staff to recruit patients and/or provide the RFTP programme was an issue for enrolment of eligible patients. Only three previous studies gave specific reasons why patients were excluded [59, 62, 63]. In the early intervention study undertaken by van Vliet et al. [59] staff availability was also a problem – 38/569 (7%) were not recruited as the physiotherapist had a full case load. Unfortunately detailed reasons for exclusion were not given by early intervention studies published by Kwakkel et al. [56] and Winstein et al. [60]. Comparative data would have been helpful. Harris et al. [63] reported no new upper limb deficit as a primary reason for exclusion - 186/542 (34%) compared to the RAFTAS feasibility study 206/1079 (19%). This study recruited participants a mean of 21 days after stroke from four acute rehabilitation facilities rather than acute stroke units and case mix may explain this difference. Two previous studies reported living ‘out of area’ as a reason for exclusion – 5/371 (1%) [62] and 12/569 (2%) [59] compared to 147/1079 (14%) in the RAFTAS feasibility study.

Patient inability to comply with the RFTP programme was a frequent reason for exclusion: 181/1079 (17%) of patients screened for the RAFTAS feasibility study were excluded because they would not be able to follow the RFTP programme. Further data about ‘inability to comply’ would have been helpful but were not collected because of the additional data collection burden. The protocol did not give

assessment criteria for inability to comply with the RFTP programme but left this to clinical judgement. Although vague, this eligibility criterion allows for the consideration of multiple factors which could affect a patient's ability to undertake the RFTP programme. The GRASP programme developed by Harris et al., [63] also involved self-practice and 88/542 (16%) were excluded because of cognitive or speech problems. Patients with no upper limb movement were excluded from both GRASP [63] and the RAFTAS feasibility study as participants needed to have some retained upper limb movement to undertake repetitive activities. In the RAFTAS feasibility study 69/1079 (6%) were excluded because they had severe upper limb impairment compared to 66/542 (12%) in the study by Harris et al., [63] but the definition of severe upper limb impairment differed between studies.

Comparisons between screening data for different studies is challenging because of the different populations screened, completeness of the log, differing definitions and although a patient has more than one reason for exclusion, usually a single factor is recorded.

When approached to participate in the RAFTAS feasibility study, most patients agreed (24/28 (86%)).The refusal rate for previous studies was between 0-64%. However, in 8/10 published studies where the data are available, refusal rates were 15% or lower [56-62, 64] (table 19).

In previous studies including RFTP for the upper limb after stroke recruitment rates were between 1.6 and 6.4 participants per month (table 19). Assuming that all centres were open throughout the study recruitment period this is 0.3-5.7 per centre per month. Recruitment rates were higher in studies which recruited chronic patients. In the RAFTAS feasibility study average recruitment was 1 per centre per month across three sites. This is the level of recruitment expected per site for most rehabilitation trials adopted by the NIHR Stroke Research Network [107].

Table 19: Previous studies including RFTP for the upper limb after stroke – screening and recruitment

		Time from stroke		Recruitment					
Author	**Setting**	**Specified in eligibility criteria**	**Result**	**Recruitment period (months)**	**Number of patients screened**	**Total eligible n%**	**Total of eligible recruited n%**	**Study recruitment rate per month**	**Recruitment rate per centre per month**
Turnton and Fraser, 1990[58]	Single centre neurorehabilitation unit	Unspecified - recruited on discharge from unit	Median weeks = 15 Missing not reported	14	28	23(82%)	22 (96%)	1.6	1.6
Kwakkel et al., 1999[56]	Multi centre 7 hospitals	Within 14 days	Mean days = 7.2 Missing not reported	32	3,420	110 (3%)	101 (92%)	3.2	0.5
Langhammer and Stanghelle, 2000[57]	Single centre hospital	Unspecified – recruited within 3 days of admission	Not reported	11	185	61 (33%)	61 (100%)	5.5	5.5
Blennerhassett, 2004[54]	Single centre rehabilitation centre	Unspecified	Not reported	18	Not reported	Not reported	30	1.7	1.7
Winstein et al., 2004[60]	Single centre rehabilitation centre	2-35 days	Mean days = 16 Missing not reported	Not reported	593	68 (11%)	64 (94%)	Not reported	Not reported
Van Vliet, 2005[59]	Single centre stroke rehab ward	Within 14 days	Not reported	21	569	165 (29%)	120 (73%)	5.7	5.7
Higgins et al., 2006[55]	Multi centre 9 hospitals 2 rehabilitation centres	Within 1 year	Mean days = 228 Missing not reported	33	1,056	344 (33%)	91 (26%)	2.8	0.3

Table 19: Previous studies including RFTP for the upper limb after stroke – screening and recruitment (continued)

		Time from stroke		Recruitment					
Author	**Setting**	**Specified in eligibility criteria**	**Result**	**Recruitment period (months)**	**Number of patients screened**	**Total eligible n%**	**Total of eligible recruited n%**	**Study recruitment rate per month**	**Recruitment rate per centre per month**
Harris et al., 2009[63]	Multi centre 4 rehabilitation centres	Unspecified – patients screened in acute facility then recruited in rehabilitation centres	Mean days = 20.7 Missing not reported	16	542	144 (27%)	103 (72%)	6.4	1.6
Donaldson et al., 2009[62]	Single centre implied – unspecified	1 week - 3 months	Mean days = 20.2 Missing = 0	Not reported	371	35 (9%)	30 (86%)	Not reported	Not reported
Pandian et al., 2012[64]	Single centre outpatients department	Unspecified – ‘chronic’	Mean months = 35 Missing not reported	18	54	30 (56%)	30 (100%)	1.7	1.7
Arya et al., 2012[61]	Multi centre 1 inpatient neurology ward; 1 OT unit of a rehabilitation institute	4-24 weeks	Mean weeks = 12.1 Missing not reported	14	319	120 (38%)	103 (86%)	7.4	3.7

Table 19: Previous studies including RFTP for the upper limb after stroke – screening and recruitment (continued)

		Time from stroke		Recruitment					
Author	**Setting**	**Specified in eligibility criteria**	**Result**	**Recruitment period (months)**	**Number of patients screened**	**Total eligible n%**	**Total of eligible recruited n%**	**Study recruitment rate per month**	**Recruitment rate per centre per month**
Mares et al., 2014[66]	Single centre 3 sources – database, 6 month review clinic, therapy referral team	6 months – 5 years	Mean months = 24.4 Missing not reported	24	1,127	52 (4.6%)	52 (100%)	2.2	2.2

Chapter 8. Repetitive arm functional tasks after stroke (RAFTAS) feasibility study: Data completeness and summary statistics at baseline

Objective 2: To report data completeness and summary statistics at baseline.

8.1 Results

Baseline data are shown in tables 20 – 22.

Data were 100% complete for: gender; first ever stroke; side of body affected; hand dominance; time from stroke to randomisation; pre-stroke OHS (Oxford Handicap Scale) [98]; and arm function (Action Research Arm Test (ARAT) [75].

Data were complete for 23/24 (96%) participants for: stroke severity (National Institutes of Health Stroke Scale) [97] and arm strength (Motricity Index) [99].

Data were complete for 22/24 (92%) participants: stroke sub-type and grip strength (dynamometer). Data were complete for 21/24 (88%) for age and 20/24 (83%) stroke type (infarct, haemorrhage) participants. Participants were recruited a median of 5 [IQR 2-11] days from stroke. All participants were randomised within 14 days of stroke as per protocol.

The median age of participants was 68 years [IQR 61-78 years]. Seventeen were male and seven were female. Nineteen had a stroke due to cerebral infarction and one had an intracerebral haemorrhage. In terms of stroke sub-type, 12 patients had a lacunar stroke, seven a partial anterior circulation stroke, two a total anterior circulation stroke, and one a posterior circulation stroke. All participants had reduced upper limb function with a median ARAT of 20 [IQR 3-35].

One participant had an ARAT score of zero indicating that they had no retained movement and so were ineligible to participate in the study.

Table 20: Baseline demography and stroke characteristics

	Intervention group n = 13	**Control group n = 11**
Gender	n = 13	n = 11
Male n (%)	8 (61.5%)	9 (82%)
Female n (%)	5 (38.5%)	2 (18%)
Missing	*0*	*0*
Age (years)	n = 11	n = 10
Median [IQR]	71 [67 – 78]	65 [57 – 72]
Missing	*2*	*1*
Stroke type	n = 11	n = 9
Assumed infarct (no clinically relevant infarct on CT)	0 (0%)	3 (27%)
Clinically relevant infarct on CT/MRI	11 (85%)	5 (46%)
Intracerebral haemorrhage	0 (0%)	1 (9%)
Missing	*2 (15%)*	*2 (18%)*
Stroke sub-type (n %)	n =12	n =11
Total anterior circulation syndrome (TACS)	1 (8%)	1 (9%)
Partial anterior circulation syndrome (PACS)	2 (15%)	5 (46%)
Lacunar stroke (LACS)	8 (62%)	4 (36%)
Posterior Circulation Stroke (POCS)	0 (0%)	1 (9%)
Uncertain	0 (0%)	0 (0%)
Missing	*2 (15%)*	*0 (0%)*
First ever stroke	n = 13	n = 11
Yes n (%)	8 (61.5%)	8 (73%)
No n (%)	5 (38.5%)	3 (27%)
Missing	*0*	*0*
If no, residual deficit	n = 5	n = 3
Yes n (%)	0 (0%)	1 (9%)
No n (%)	5 (38%)	2 (18%)
Missing	*0*	*0*
Description of residual deficit (code):	n = 0	n = 1
Right arm and leg weakness	-	1 (9%)
Missing	*0*	*0*
Side of body affected by current stroke	n = 13	n = 11
Right	5 (39%)	7 (64%)
Left	8 (62%)	4 (36%)
Missing	*0*	*0*
Hand dominance (prior to stroke)	n = 13	n = 11
Right handed	11 (84%)	11 (100%)
Left handed	2 (15%)	0 (0%)
Dominant hand affected by stroke	5 (39%)	7 (64%)
Missing	*0*	*0*
Time from stroke to randomisation	n = 13	n = 11
Median [IQR] days	6 [3 – 12]	4 [2 – 9]
Min, Max	1, 13	2, 12
Missing	*0*	*0*
Time from stroke to randomisation n (%) days		
0 – 3	4 (31%)	5 (46%)
4 – 7	4 (31%)	2 (18%)
8 – 10	1 (8%)	2 (18%)
11 - 14	4 (31%)	2 (18%)

Pre stroke Oxford Handicap scale results are shown in table 21.

Table 21: Pre stroke Oxford Handicap scale

Pre stroke Oxford Handicap scale	Intervention group n = 13	Control group n = 11
Score*	n = 13	n = 11
0	12 (92%)	5 (45%)
1	0 (0%)	3 (27%)
2	1 (8%)	2 (18%)
3	0 (0%)	1 (9%)
4	0 (0%)	0 (0%)
5	0 (0%)	0 (0%)
Missing	*0*	*0*

* 0 = no symptoms and coped well with life, 5 = severe handicap

Table 22: Baseline functional ability and activity limitation

	Intervention group n = 13	**Control group n = 11**
Action Research Arm Test – for affected side only (total scores, 0 – 57, higher score = greater functional ability)	n = 13	n = 11
Total score Median [IQR]	32 [10 – 37]	8 [1 – 22]
Min, Max	2, 57	0, 53
Sub scores:		
Grasp Median [IQR]	12 [2 – 17]	3 [0 – 6]
Min, Max	0, 18	0, 18
Grip Median [IQR]	7 [2 – 8]	0 [0 – 5]
Min, Max	0, 12	0, 10
Pinch Median [IQR]	4 [0 – 10]	0 [0 – 6]
Min, Max	0, 18	0, 17
Gross Median [IQR]	7 [5 – 9]	3 [1 – 8]
Min, Max	2, 9	0, 9
Missing	*0*	*0*
Baseline National Institutes of Health Stroke Scale (NIHSS) (0 = no symptoms, 42 = severe stroke)	n = 12	n = 11
Median [IQR]	3 [2 – 5]	6 [3 – 7]
Min, Max	1, 7	2, 11
Missing	*1*	*0*
Mean dynamometer (kg) (grip strength)	n = 11	n = 11
Affected upper limb Median [IQR]	12 [4 – 21]	7 [2 – 18]
Min, Max	2, 37	0, 19
Missing	*2*	*0*
Motricity Index (0 = no movement,100 = normal strength)	n = 13	n = 11
Total affected side Median [IQR]	74 [56 – 76]	47 [31 – 67]
Min, Max	28, 84	19, 84
Arm Median [IQR]	73 [48 – 77]	40 [29 -52]
Min, Max	28, 83	18, 76
Leg Median [IQR]	75 [64 – 79]	58 [23 – 74]
Min, Max	28, 99	9, 99
Missing	*2*	*0*

8.2 Discussion

Overall completeness of key data items was over 90%. The reason why age was not available for 100% of participants is unclear. The data item with most missing data was stroke type which required information to be obtained from a CT or MRI head scan report. This should have been recorded in the clinical notes, and would also have been available electronically or from a member of the clinical team.

The RFTP programme was designed for patients with some retained upper limb movement and to be eligible patients needed to be able to lift their hand off their lap.

This equates with an ARAT score of one. It was surprising that one participant had an ARAT score of zero as this patient did not fulfil the eligibility criteria and therefore represents a protocol violation.

Study participants were the type of patients anticipated to take part in the study. The baseline characteristics of participants in each randomisation group were not formally compared as this was a feasibility study. Groups were not well matched on key baseline variables and this relates to the small sample size.

The amount of missing data were not clearly reported in previous studies especially when means and medians are reported rather than percentages (tables 23 and 24).

Table 23: Previous studies including RFTP for the upper limb after stroke – baseline demography and stroke characteristics

Author	Gender	Age (years)	Stroke type	Stroke sub-type	First ever stroke	Side of body affected by stroke	Dominant hand affected by stroke	Time from stroke
Turnton and Fraser, 1990[58]	Male = 55% Female = 45% Missing = 0	Mean = 55 Missing not reported	Not reported	Not reported	Not reported	Right = 60% Left = 40% Missing = 0	Not reported	Median weeks = 15 Missing not reported
Kwakkel et al., 1999[56]	Male = 43% Female = 57% Missing = 0	Mean = 66 Missing not reported	Not reported	TACS = 60% PACS = 31% LACS = 7% POCS = 0% (excluded) Missing = 3%	Set as inclusion criterion	Right = 58% Left = 42% Missing = 0	Not reported	Mean days = 7.2 Missing not reported
Langhammer and Stanghelle, 2000[57]	Male = 59% Female = 41% Missing = 0	Not reported	Not reported	Not reported	Set as inclusion criterion	Right = 44% Left = 56% Missing = 0	Not reported	Not reported
Blennerhassett, 2004[54]	Male = 57% Female = 43% Missing = 0	Mean = 55 Missing not reported.	Ischaemic = 73% Haemorrhagic = 27% Missing = 0	Not reported	97% Missing = 0	Right = 47% Left = 53% Missing = 0	Not reported	Not reported
Winstein et al., 2004[60]	Male = 52% Female = 42% Missing = 4	Mean not reported Stated participants mainly 35-75 years Missing not reported.	Ischaemic = 80% Haemorrhagic = 9% Missing = 11%	Not reported	Set as inclusion criterion	Right = 30% Left = 64% Missing = 6%	Not reported	Mean days = 16 Missing not reported

Table 23: Previous studies including RFTP for the upper limb after stroke – baseline demography and stroke characteristics (continued)

Author	Gender	Age (years)	Stroke type	Stroke sub-type	First ever stroke	Side of body affected by stroke	Dominant hand affected by stroke	Time from stroke
Van Vliet, 2005[59]	Male = 50% Female = 50% Missing = 0	Mean = 74 Missing = 0	Not reported	TACS = 14% LACS = 21% PACS = 51% POCS = 8% Unsure = 6% Missing = 0	Not reported	Right = 51% Left = 47% Bilateral = 2% Missing = 0	Not reported	Not reported
Higgins et al., 2006[55]	Male = 62% Female = 38% Missing not reported	Mean = 74 Missing = 0	Ischaemic = 83% Haemorrhagic = 17% Missing = 0	Not reported	88% Missing = 0	Not reported	60% Missing not reported	Mean days = 228 Missing not reported
Harris et al., 2009[63]	Male = 57% Female = 43% Missing = 0	Mean = 71 Missing not reported	Ischaemic = 67% Haemorrhagic = 22% Lacunar = 11% Missing = 0	Not reported	Not reported	Right = 37% Left = 63% Missing = 0	33% Missing not reported	Mean days = 20.7 Missing not reported
Donaldson et al., 2009[62]	Male = 43% Female = 57% Missing = 0	Mean = 72.8 Missing = 0	Not reported	Not reported	Not reported	Right = 47% Left = 53% Missing = 0	Not reported	Mean days = 20.2 Missing = 0

Table 23: Previous studies including RFTP for the upper limb after stroke – baseline demography and stroke characteristics (continued)

Author	Gender	Age (years)	Stroke type	Stroke sub-type	First ever stroke	Side of body affected by stroke	Dominant hand affected by stroke	Time from stroke
Pandian et al., 2012[64]	Male = 80% Female = 20% Missing = 0	Mean = 49.6 Missing not reported	Ischaemic = 70% Haemorrhagic = 30% Missing = 0	Not reported	Not reported	Right = 47% Left = 53% Missing = 0	Not reported	Mean months = 35 Missing not reported
Arya et al., 2012[61]	Male = 60% Female = 40% Missing = 0	Mean = 51 Missing = 4.6%	Ischaemic = 67% Haemorrhagic = 33% Missing = 0	Not reported	Set as inclusion criterion	Right = 66% Left = 34% Missing = 0	Not reported	Mean weeks = 12.1 Missing not reported
Mares et al., 2014[66]	Male = 67% Female = 33% Missing = 0	Mean = 68.3 Missing =	Ischaemic = 94% Haemorrhagic = 6% Missing = 0	TACS = 17% PACS = 40% LACS = 29% POCS = 8% Haemorrhagic = 6% Missing = 0	Not reported	Right = 48% Left = 52% Missing = 0	Not reported	Mean months = 24.4 Missing not reported

Table 24: Previous studies including RFTP for the upper limb after stroke – pre-stroke function and baseline functional ability and activity limitation

Author	Pre-stroke Oxford Handicap Scale	Action Research Arm Test (ARAT)	National Institute of Health Stroke Scale (NIHSS)	Dynamometer (grip strength) kg	Motricity (arm strength)	Other measures
Turnton and Fraser, 1990[58]	Not reported	Not reported	Not reported	Not reported	Not reported	Southern Motor Group's motor assessment (performance achieving hand and arm positions), ten hole peg test.
Kwakkel et al., 1999[56]	Not reported	Median = 0 Missing = not reported	Not reported	Not reported	Not reported	ARAT, Thumb finding test, Frenchay Activities Index (ADL scale), BI, FAC, walking velocity m/sec, a short geriatric version of Sickness Impact Profile, NHP, Glasgow Coma Scale, Mini Mental State Exam and Orpington Prognosis Scale.
Langhammer and Stanghelle, 2000[57]	Not reported	Not reported	Not reported	Not reported	Not reported	MAS, SMES, BI and NHP.
Blennerhassett, 2004[54]	Not reported	Not reported	Not reported	Not reported	Not reported	Upper limb and hand items of the MAS, JTHFT, 6MWT, step test and TUGT.
Winstein et al., 2004[60]	Not reported	Not reported	Not reported	Mean = 1.7 Missing = not reported	Not reported	Upper extremity portion of FMA, grip and pinch force (dynamometer), FTHUE, isometric torque at the shoulder, elbow and wrist (dynamometer), self-care and mobility portions of the FIM and Orpington Prognostic Scale.

Table 24: Previous studies including RFTP for the upper limb after stroke – pre-stroke function and baseline functional ability and activity limitation (continued)

Author	Pre-stroke Oxford Handicap Scale	Action Research Arm Test (ARAT)	National Institute of Health Stroke Scale (NIHSS)	Dynamometer (grip strength) kg	Motricity (arm strength)	Other measures
Van Vliet, 2005[59]	Not reported	Not reported	Not reported	Not reported	Not reported	Rivermead Motor Assessment (gross function), MAS, ten hole peg test, Modified Ashworth Scale, 6MWT, BI, Nottingham sensory assessment, extended ADL scale, Sheffield Screening Test, story recall, Star Cancellation Test and Rey figure copy test.
Higgins et al., 2006[55]	Not reported	Not reported	Not reported	Mean = 16.5 Missing = not reported	Not reported	Box and Plot test (upper limb function), NHPT, TEMPA, grip strength (dynamometer), STREAM (arm sub-scale only), BI, OASS-IADL, SF-36 (health survey), and the Geriatric Depression Scale.
Harris et al., 2009[63]	Not reported	Mean = 31 Missing = not reported	Not reported	Mean = 8.9 Missing = not reported	Not reported	CAHAI, ARAT, dynamometer, SF-12 (health survey), Star Cancellation Test, FMA and MAL.
Donaldson et al., 2009[62]	Not reported	Mean = 31 Missing = 0	Not reported	Not reported	Not reported	ARAT, NHPT and myometer (upper limb strength).
Pandian et al., 2012[64]	Not reported	Not reported	Not reported	Not reported	Not reported	BRS-H and the FMA.
Arya et al., 2012[61]	Not reported	Mean = 6.1 Missing = 1	Mean = 5.5 Missing = not reported	Not reported	Not reported	FMA, ARAT, GWMFT, Hindi Mental State Examination and MAL.

Table 24: Previous studies including RFTP for the upper limb after stroke – pre-stroke function and baseline functional ability and activity limitation (continued)

Author	Pre-stroke Oxford Handicap Scale	Action Research Arm Test (ARAT)	National Institute of Health Stroke Scale (NIHSS)	Dynamometer (grip strength) kg	Motricity (arm strength)	Other measures
Mares et al., 2014[66]	Not reported	Median total = 15.7 Missing = not reported	Not reported	Not reported	Not reported	FAC (FAC), ARAT, ability to complete NHPT, Modified Rivermead Mobility Index, TUGT.

MAS = Motor Assessment Scale (motor function); **SMES** = Sødring Motor Evaluation Scale (motor function in stroke); **NHP** = Nottingham Health Profile; **6MWT** = Six Minute Walk Test; **TUGT** = Timed Up and Go Test; **JTHFT** = Jebsen Taylor Hand Function Test; **FTHUE** = Functional Test for Hemi paretic Upper Extremity; **FIM** = Functional Independence Measure; Fatigue Severity Scale, **TEMPA =** Test d'Evaluation des Members supérieurs des Personnes Agées (upper limb activity limitation); **STREAM** = Stroke Rehabilitation Assessment of Movement (arm sub-scale only- an assessment of movement); **OASS-IADL** = Older Americans Resource Scale for Instrumental Activities of Daily Living; **CAHAI** = Chedoke Arm and Hand Activity Inventory (upper limb functional assessment); **MAL**= Motor Activity Log-14 (structured questionnaire measuring motor activity); **VAS** = Visual Analogue Scale; **FMA** = Fugl-Meyer Assessment (upper limb impairment); **FMA-WH** = Fugl-Meyer Assessment (wrist and hand impairment sub-test); **BRS-H** = Brunnstrom recovery stage of the hand (motor recovery level); **GWMFT** = Graded Wolf Motor Function Test; **FAC** = Functional Ambulation Category; **ARAT** = Action Research Arm Test; **NHPT =** Nine Hole Peg Test (dexterity), **BI** = Barthel Index (activities of daily living).

In previous studies data were 100% complete for gender. Completeness of data for age was unclear in 6/12 (50%) studies [54, 56, 58, 60, 63, 64]. Stroke type was reported in 7/12 studies [54, 55, 60, 61, 63, 64, 66] and data were complete for six studies: 11% were missing for one study [60]. Stroke sub-type was reported by three studies [56, 59, 66] and 2% data were missing for one study [56]. Four studies [56, 57, 60, 61] only recruited patients with first ever stroke, two [54, 55] reported complete data for patients with first ever and recurrent stroke and six [58, 59, 62-64, 66] did not report this variable. Surprisingly only two studies [55, 63] reported whether or not the dominant hand was affected by stroke and missing data were not reported in these studies.

Two studies [57, 59] did not report time from stroke as a baseline variable. Both recruited within a short time window; 3 days from admission and 2 weeks post stroke. Missing data was zero in the one study which reported these data [62].

None of the previous studies used the Oxford Handicap Scale or any other scale to report pre-stroke handicap, but one study [55] reported the number of comorbid conditions. Five used the ARAT to measure upper limb function [56, 61-63, 66]. Missing data were only reported by one study [61] where the baseline ARAT score was not available for one participant. Although widely used in acute stroke research, the NIHSS stroke scale was used to describe stroke severity in only one previous study [61]. The dynamometer was used to measure grip strength in three previous studies [55, 60, 63] and levels of missing data were not reported. The Motricity Index was not used to measure strength in any previous study of RFTP.

Other measures used by more than one study were; the Nine or Ten Hole Peg Test to measure dexterity (n=5) [55, 58, 59, 62, 66]; the Fugl-Meyer Assessment [108] to measure upper limb impairment (n=4) [60, 61, 63, 64]; the Barthel Index to measure Activities of Daily Living [109] (n=4) [55-57, 59]; the Motor Assessment Scale [76] to measure motor function (n=3) [54, 57, 59] and the Motor Activity Log [110] to measure arm function (n=2) [61, 63].

Only one previous study [66] reported protocol violations where 4/52 patients with stroke affecting the posterior circulation were recruited who should have been excluded.

The majority of participants in the RAFTAS feasibility study were male 17/24 71%). In 4/12 previous studies 60% or more of participants were male. As the risk of stroke is similar for both men and women the reason for the disproportionate number of men

is unclear. The median age of stroke is 74 years in the UK [95]. Participants in the RAFTAS feasibility study were younger than this and this is commonly found in clinical trials. Six [54, 56, 58, 61, 64, 66] of the eleven [54-56, 58-64, 66] studies which reported age had a mean age of less than 70 years.

Eighty per cent of stroke is due to cerebral infarction and 20% due to intracerebral haemorrhage [94]. 17/20 (85%) of participants in the RAFTAS feasibility study had a cerebral infarction and in other previous studies this figure was between 67 and 83%.

Incidence of stroke sub-types as described by Bamford [94] are; TACS (17%); LACS (25%); PACS (34%) and POCS (24%). In the RAFTAS feasibility study, the most common stroke sub-type was LACS (12/24, 50%) followed by PACS (7/24, 29%) and stroke sub-type was missing for 2/24 (8%) participants. Stroke sub-type was reported in only 3/12 previous studies [56, 59, 66] into RFTP. In 2/3 studies [59, 66], the majority of participants were classified as either PACS or LACS. This figure was between 21 and 41% and there were no missing data. In 1/3 previous studies [56], the majority of participants were classified as TACS (60%) or PACS (31%) and there were 3% missing data.

Chapter 9. Repetitive arm functional tasks after stroke (RAFTAS) feasibility study: Local study therapist and participant adherence to the RFTP programme

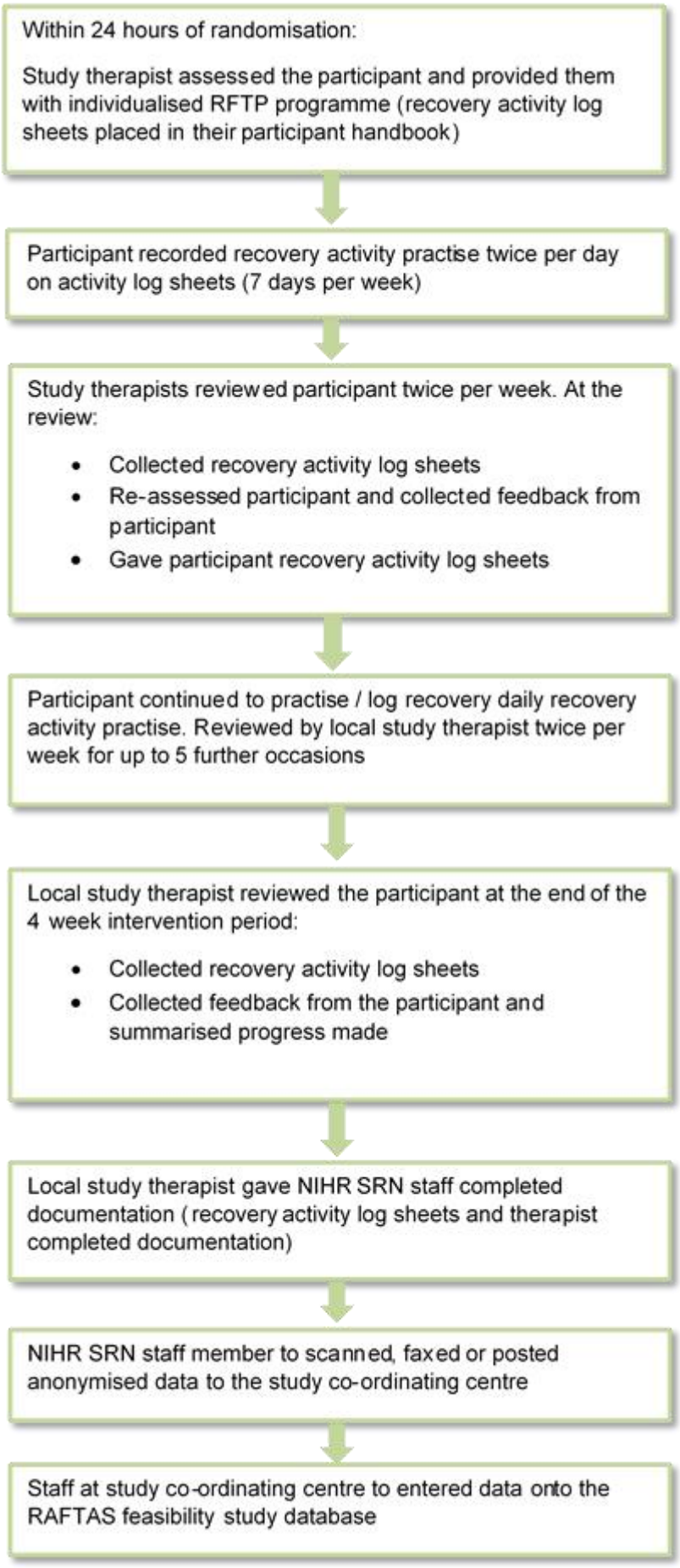
Objective 3: To report local study therapist and participant adherence to the RFTP programme.

9.1 Results

The following data were recorded to describe the adherence of local study therapists and participants to the RFTP programme: time from randomisation to the initial therapy assessment; the number and content of RAFTAS therapy sessions delivered; recovery activities, selected goals and action taken by local study therapists; and the amount of participant independent practice of recovery activities.

Figure 14 describes delivery of the RFTP programme.

Figure 14: Delivery of the RFTP programme



9.1.1 Time from randomisation to the initial therapy assessment

Local study therapists were asked to complete the initial therapy assessment within 24 hours of randomisation. Table 25 shows the time from randomisation to the initial therapy assessment.

Table 25: Time from randomisation to the initial therapy assessment

Completed within 24 hours?	n (%)
Site 1 (n = 5)	
Yes	3 (60%)
No	1 (20%)
Missing (reason)	*1 (20%)*
Assessment form missing	1 (100% of missing)
Site 2 (n = 5)	
Yes	2 (40%)
No	2 (40%)
Missing (reason)	*1 (20%)*
Completed but not dated	1 (100% of missing)
Site 3 (n = 3)	
Yes	0 (0%)
No	0 (0%)
Missing (reason)	*3 (100%)*
Completed but not dated	1 (33% of missing)
Assessment form missing	2 (67% of missing)
TOTAL (n = 13)	
Yes	5 (38.5%)
No	3 (23%)
Missing (reason)	*5 (38.5%)*
Completed but not dated	2 (40% of missing)
Assessment form missing	3 (60% of missing)

For all study sites (combined), 38.5% of participants' initial assessments were known to have been completed on time. This information was missing for 5/13 (38.5%). Again there was a particular problem at Site 3 where none of these data were available. When dated initial assessments were considered, only 5/8 (62%) were completed within 24 hours of randomisation. Reasons for the delay were not formally recorded but local study therapists reported that on occasion there were difficulties incorporating an initial RAFTAS therapy assessment into their clinical activities.

9.1.2 Number of RAFTAS therapy sessions delivered

Eight RAFTAS therapy sessions were available for each participant within the four week RFTP programme. However, a participant could be discharged prior to four weeks if all their upper limb therapy goals had been achieved and they had regained normal upper limb function. The number of therapy sessions delivered is presented in table 26. Delivery of RAFTAS study sessions is shown in figure 15.

Table 26: Number of therapy sessions delivered

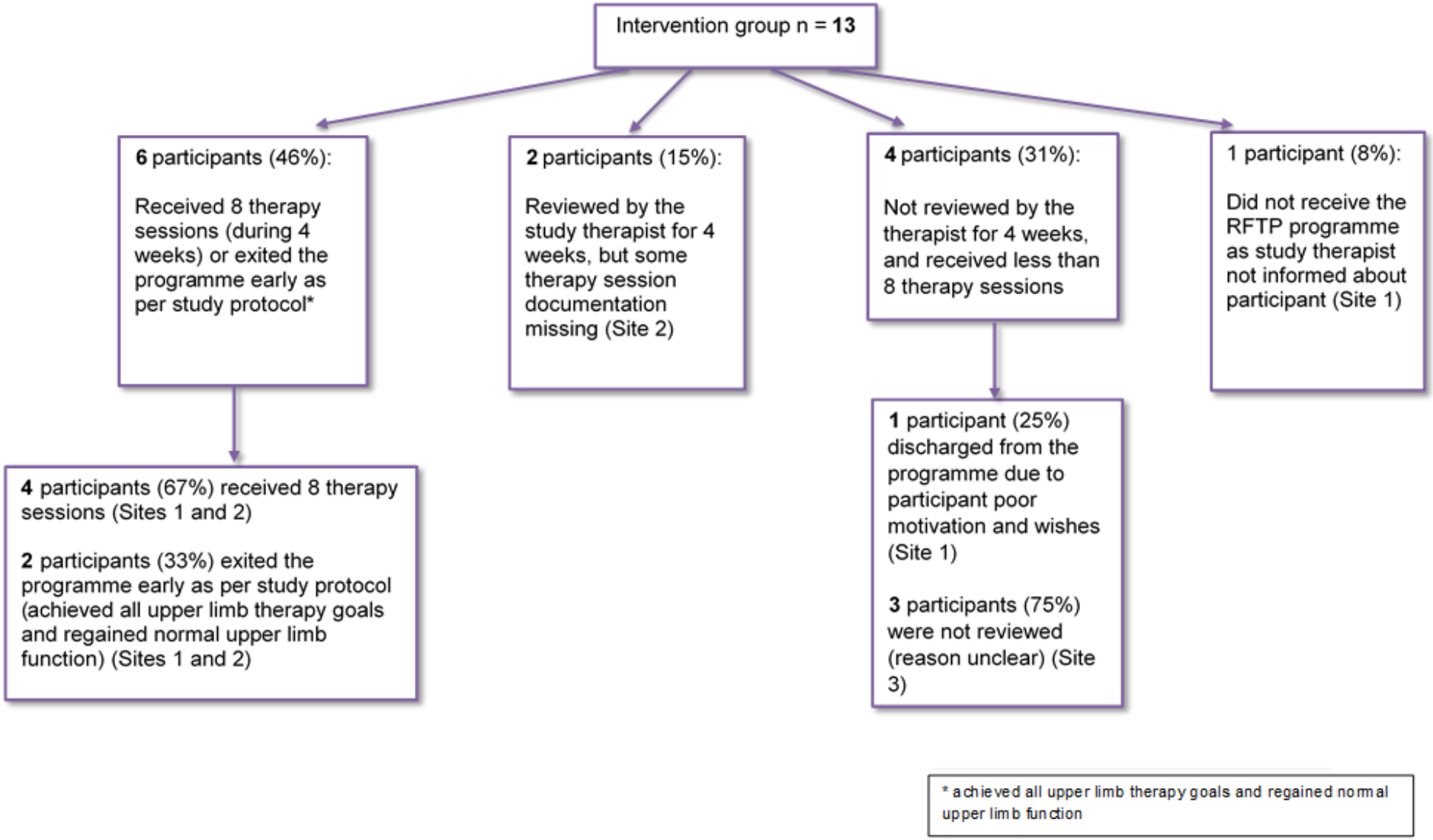
Intervention group n = 13	
Number of sessions n (%): 0	1 (7.7)
1	0 (0%)
2	1 (7.7%)
3	1 (7.7%)
4	1 (7.7%)
5	1 (7.7%)
6	1 (7.7%)
7	1 (7.7%)
8	4 (31%)
Missing	*2 (15.4%)*
Median [IQR]	6 [3 – 8]

The median number of recorded RAFTAS therapy sessions was 6 [IQR 3-8]. Data were missing for two participants. 7/13 (54%) remained in the RFTP programme for four weeks and two participants were discharged from the RFTP programme prior to four weeks as per protocol.

The total available sessions was 96. The reported number of sessions provided was 59/96 (61%). No information about the number therapy sessions was available for two participants as forms were not returned by the local study therapists. If these participants are excluded from the analysis, the number of available sessions was 80 and 59/80 (74%).

Again there was a problem at Site 3 where documentation about the number of RAFTAS therapy sessions provided was not available for 2/3 participants in the intervention group. One participant at Site 1 received zero RAFTAS therapy sessions as the local study therapist was not informed about the participant.

Figure 15: Delivery of RAFTAS study sessions

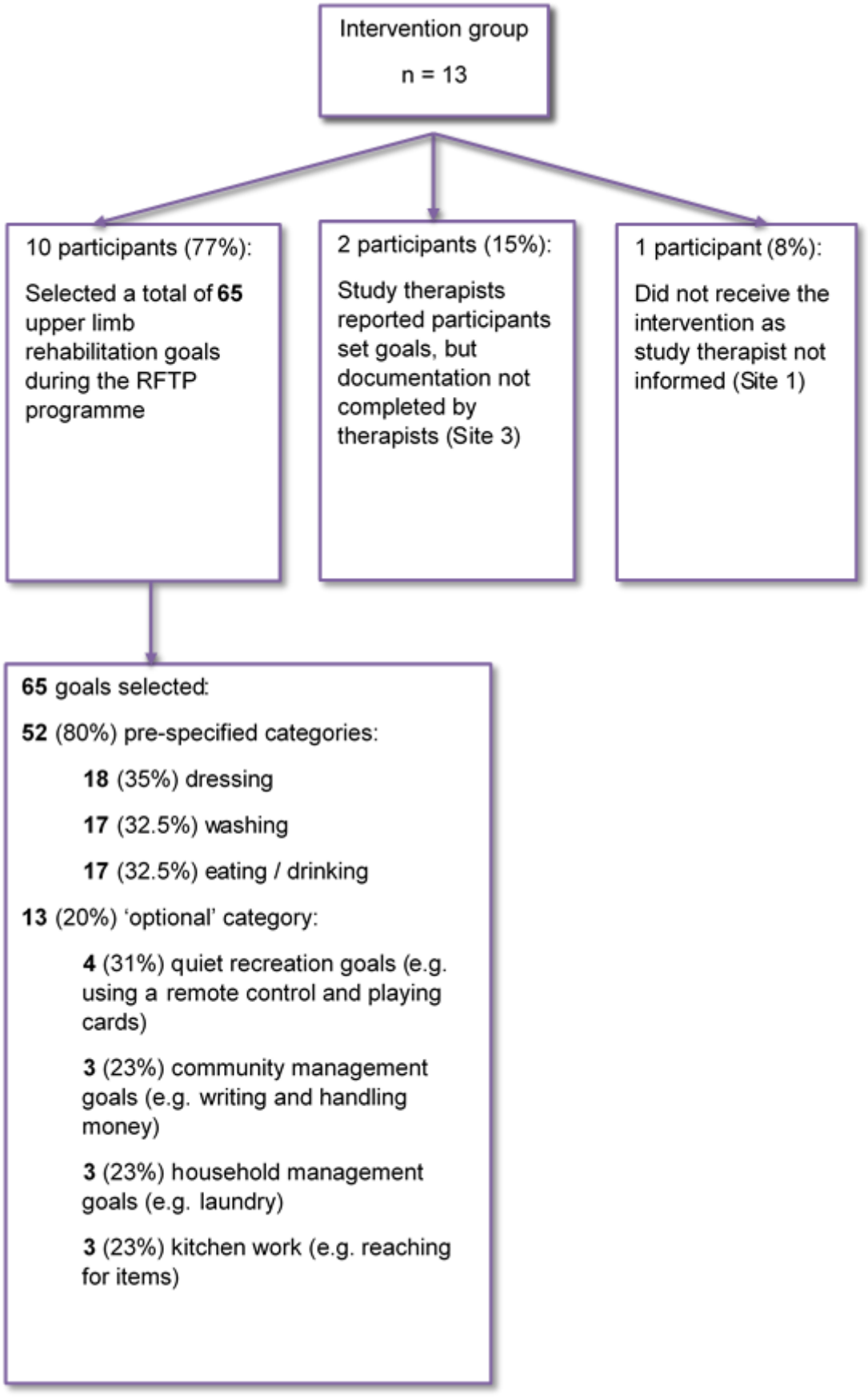


9.1.3 Patient selected upper limb rehabilitation goals

Data about the goals selected were available for 10/13 (77%) participants. Missing data were from Site 3 (n=2) and Site 1 (n=1, the participant did not receive the RFTP programme).

A total of sixty five goals were selected (figure 16). Fifty two out of sixty five goals (80%) related to RAFTAS pre-specified categories: 18/52 (35%) dressing, 17/52 (32.5%) washing and 17/52 (32.5%) eating/drinking. Thirteen out of sixty five goals (20%) were in the optional category.

Figure 16: Upper limb rehabilitation goals selected by participants



9.1.4 Recovery activities selected

Data about the recovery activities selected were available for 10/13 (77%) participants. Missing data were from Site 3 (n=2) and Site 1 (n=1, the participant did not receive the RFTP programme).

Fifty different recovery activities were selected to be practised by participants during the RAFTAS feasibility study. Thirty four out of fifty (68%) different recovery activities were selected from the 'recovery activity list'; washing (n=15), eating / drinking (n=10) and dressing (n=9).

There were 16 different 'optional' recovery activities. These activities were categorised and are displayed in Table 27.

Table 27: 'Optional' recovery activities provided to participants

Category	Recovery activity provided
Washing	Pick up razor with guard on and mimic shaving movement across face.
	Peel potato to help understand pressure in preparation for shaving.
Dressing	Tie shoelaces.
Kitchen work	Pick and place items in high cupboard.
	Reach up and touch top shelf of kitchen unit.
	Reach into cupboard.
Quiet recreation	Turning playing cards over one by one.
	Pick up TV remote control.
Community management	Remove and replace three coins from purse.
	Draw straight lines and circles.
	Write a sentence 20 times taking care to keep size of letters even.
Household management / laundry	Iron with x20 strokes of *(cold)* iron.
	Pick up and replace iron.
	Hold a piece of card in unaffected hand and use the affected hand to clip10 pegs onto card.
Other	Reach edge of table with the affected hand.
	Bring thumb across hand to touch little finger.

9.1.5 Action taken by local study therapists at each RAFTAS therapy session

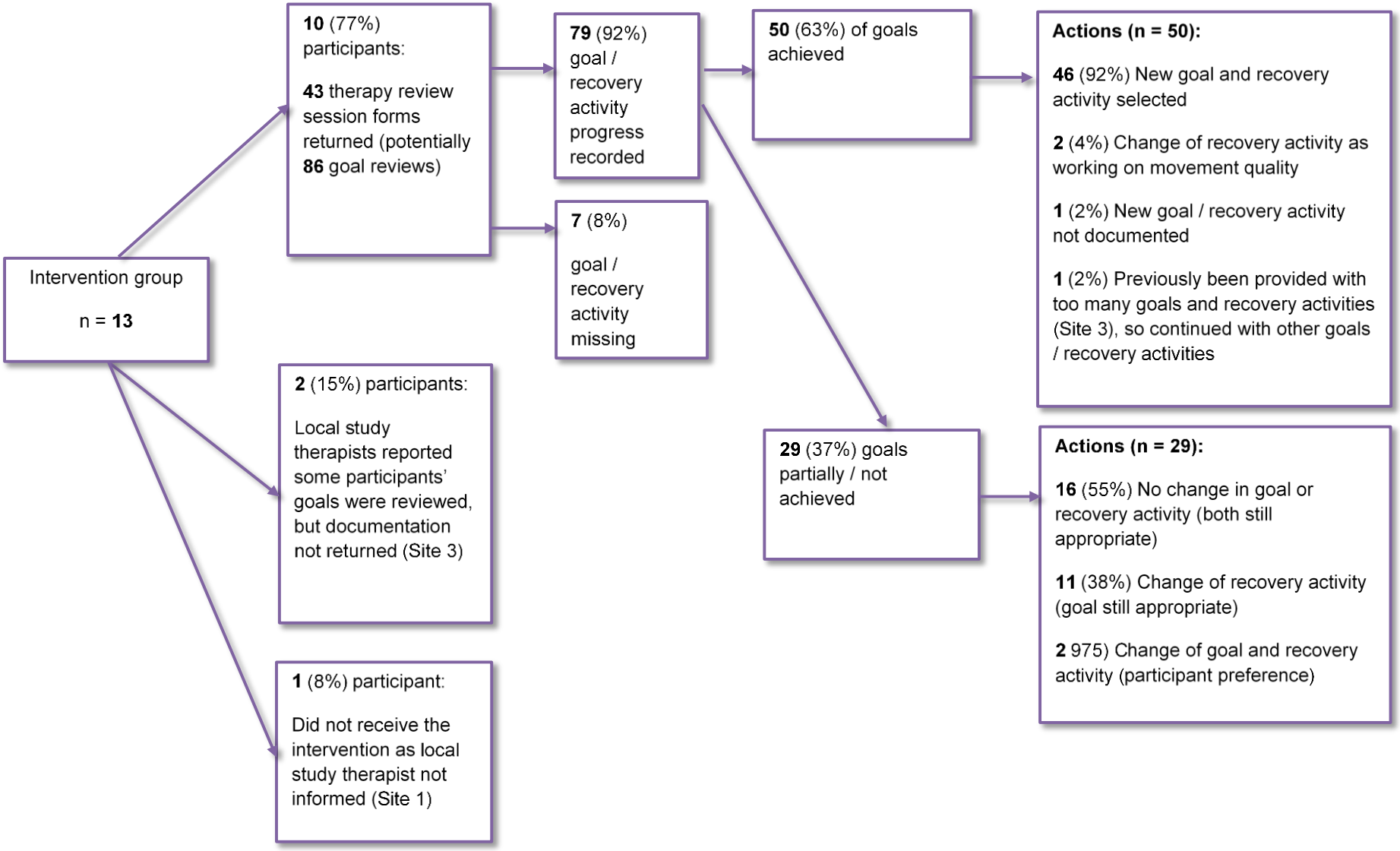
At each RAFTAS therapy session, local study therapists were requested to review the participant's two goals and recovery activities set at the previous session. Goals / recovery activities were amended if appropriate and progress recorded.

Action taken at RAFTAS therapy sessions are shown in figure 17.

Data about actions taken by local study therapists at each RAFTAS therapy review were available for 10/13 (77%) participants. Missing data were from Site 3 (n=2) and Site 1 (n=1, the participant did not receive the RFTP programme).

49/84 (58%) therapy review forms were returned to the study coordinating centre and gave information about progress against 79/86 (92%) goals. Therapists took appropriate action, as per protocol, when reviewing goals and recovery activities.

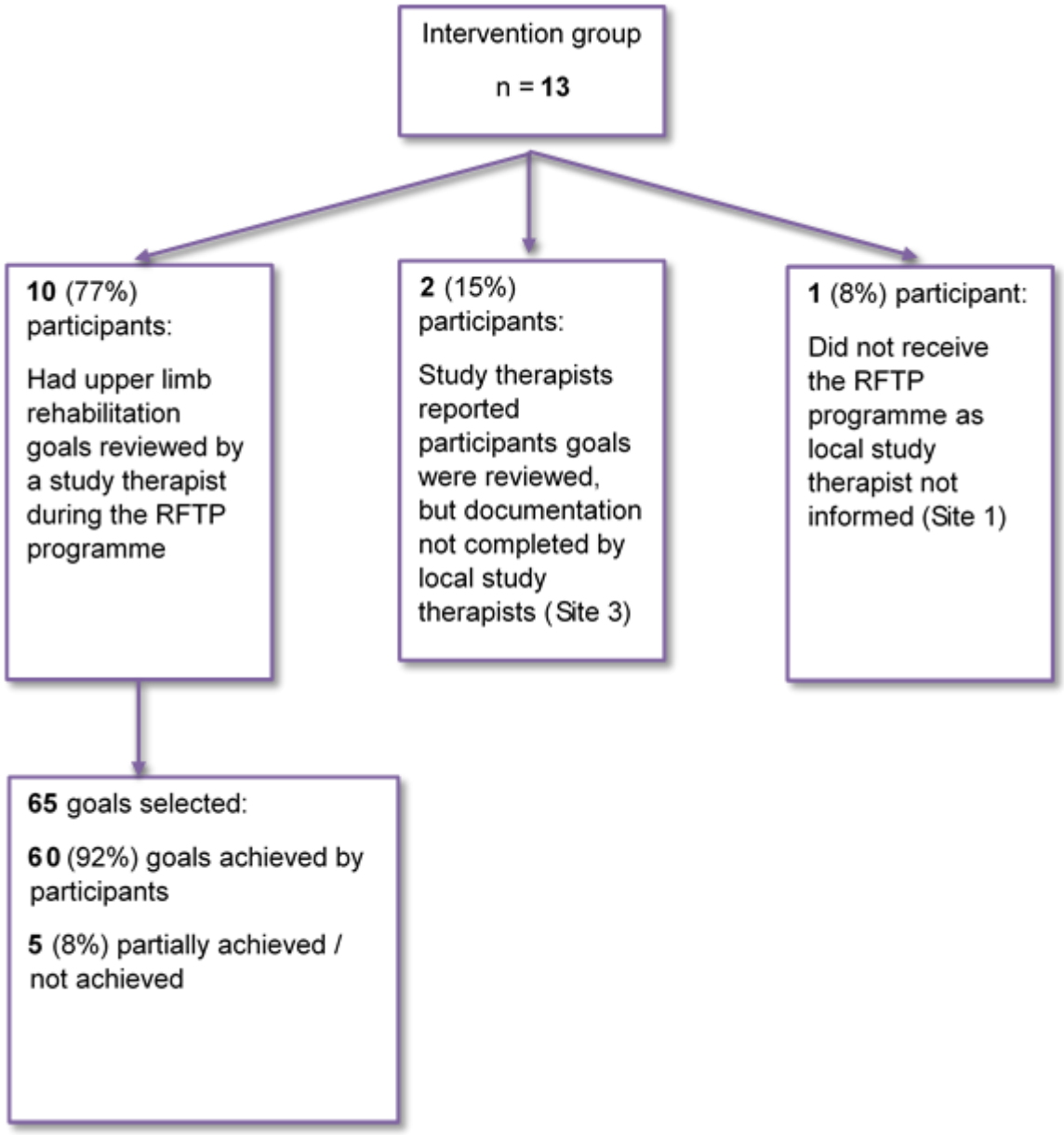
Figure 17: Action taken at RAFTAS therapy sessions



Progress against selected goals by the last RFTP programme review is shown in Figure 18. Data relate to 65 goals which were set throughout the intervention period.

Participants (with data available) achieved the 60/65 (92%) goals selected during the RFTP therapy programme by their last assessment.

Figure 18: Progress against selected goals by the last RFTP programme review



9.1.6 Participant independent practice and logging of recovery activities

9.1.6.1 Returned activity log sheets

Returned activity log sheets and activity log sheet completion data are displayed in table 28.

The number of days activity practice could be logged differed between participants. The RFTP programme was continued until the final review by the local study therapist at 28 days. Patients who achieved all upper limb therapy goals and regained upper limb function could be discharged prior to this time.

A least four participants who received eight therapy sessions had final reviews undertaken prior to 28 days, so these patients did not have the opportunity to practice for the full intervention period.

Activity log sheets were returned for 11 participants with a median of 20 days [2.5-24] per participant. Activities were recorded as being practiced for a median of 15 days [4.25-21.5 days]. The median percentage adherence to logging daily practice by patients who were provided with activity log sheets was 96% [IQR 67% - 100%], indicating a high level of adherence to logging activity practice. However as recovery activity log sheets were not always provided for 28 days by local study therapists, activity log sheets were only available for 28 days for one participant.

Table 28: Returned recovery activity log sheets and activity log sheet completion

Study site	Participant number	Number of days in programme*	Number of days from initial therapy assessment until last therapy review	Actual number of days with activity log sheets	Actual/expected activity logs returned (%)	No of days RFTP programme attempted (by marking a repetition box on the 'activity log sheet')	Number of days activity practice recorded / number of days activity log returned (%)
1	101	13	13*	0	0	N/A	N/A
	103	28	22	21	95%	14	67%
	106	28	24	23	96%	22	96%
	110	28	12*	3	25%	1	33%
	111	28	0	0	0	0	N/A
2	201	28	22	23	105%	23	100%
	203	28	23	26	113%	13	50%
	204	28	29	28	97%	28	100%
	207	28	33	16	48%	16	100%
	210	11	*Missing**	11	N/A	11	100%
3	302	28	*Missing*	25	N/A	20	80%
	303	28	*Missing*	2	N/A	2	100%
	304	28	*Missing*	20	N/A	18	90%
All participants Median [IQR] *Missing*		28 [28-28] *0*	22 [12.5-26.5] *4*	20 [2.5-24] *0*	95 [12.5-101] *4*	15 [4.25-21.5] *1*	96 [67-100] *2*

* Less than 28 days if discharged early as per protocol (achieved all upper limb therapy goals and regained normal upper limb function).

9.1.6.2 Daily repetitions logged by participants on recovery activity log sheets

The number of daily repetitions of recovery activities practised were recorded by participants on recovery activity log sheets. The maximum number of repetitions possible to be recorded on activity log sheets was 80 per day, if the programme was delivered and practised as intended (20 repetitions of two activities, twice per day).

The number of daily repetitions of recovery activities from returned activity log sheets is shown in Table 29. When considering all participants with returned activity log sheets, the median number of daily repetitions was 80 [IQR 39 – 80].

Table 29: Daily repetitions of recovery activities from returned recovery activity log sheets

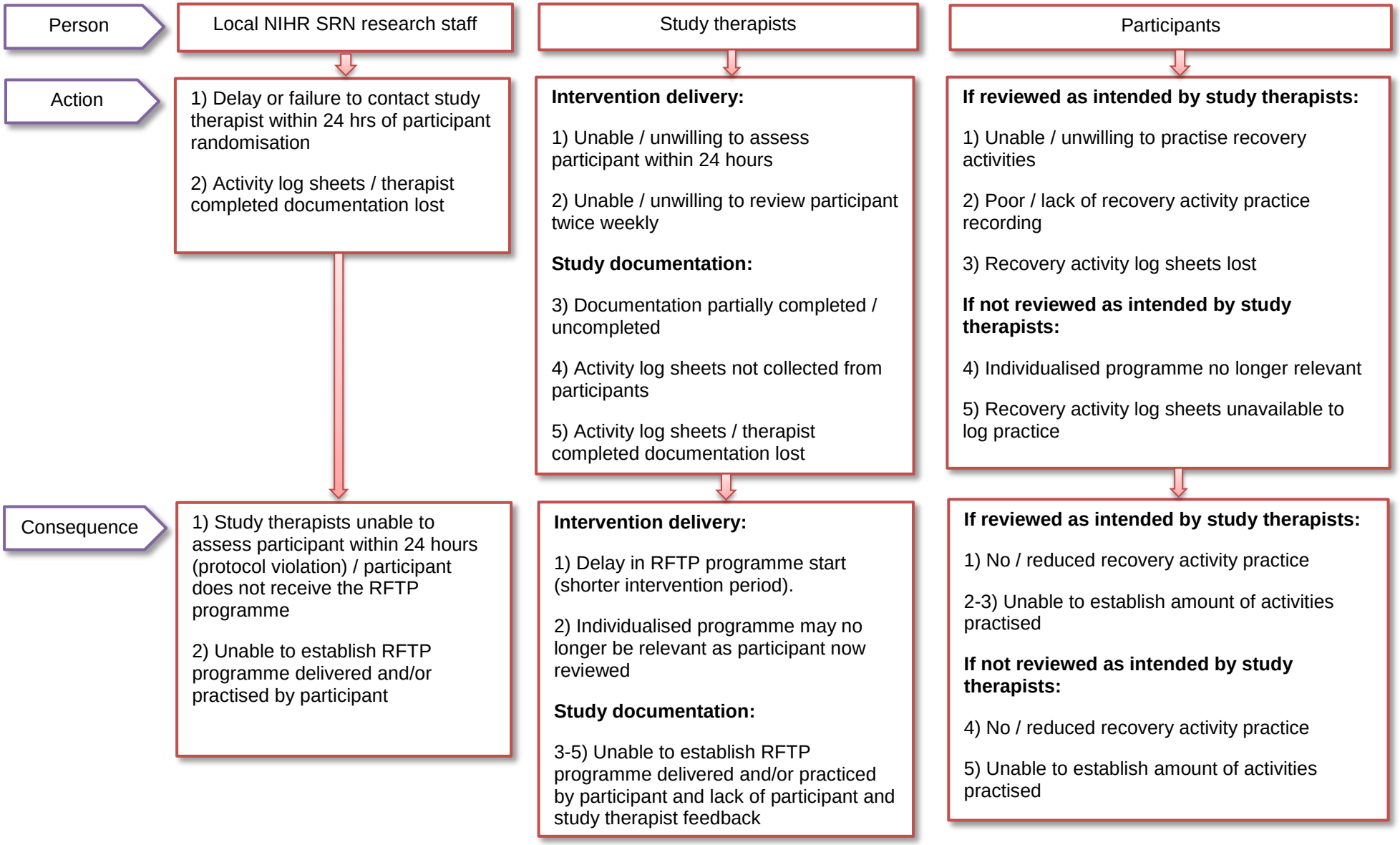
Study site	Participant number	Number of days with activity log sheets returned	Median [IQR] daily recorded repetitions (of returned activity log sheets)	Minimum number of recorded daily repetitions	Maximum number of recorded daily repetitions	Comments (as appropriate)
1	101	0	Missing	Missing	Missing	Activity log sheets were not returned by local study therapist
	103	21	33 [0 - 55.5]	0	80	-
	106	23	60 [54 – 80]	0	80	-
	110	3	0 [0 – 0]	0	22	Participant was discharged early from the programme due to poor motivation / participant's wishes
	111	0	Missing	Missing	Missing	Participant did not receive the RFTP programme
2	201	23	80 [80 – 80]	36	80	-
	203	26	2.5 [0 – 47]	0	92	-
	204	28	80 [79 – 80]	40	120	Max > 80 as participant completed double the amount of morning sessions specified
	207	16	80 [65 – 80]	7	120	Max > 80 as participant completed double the amount of morning sessions specified
	210	11	80 [80 – 80]	80	100	Max > 80 as participant completed double the amount of morning sessions specified
3	302	25	80 [23 – 117]	0	150	Max >80 as participant was given 4 daily activities (therapist error)
	303	2	60	40	80	-
	304	20	70 [40 – 80]	0	80	-
TOTAL – all participants		Median =20 [2.5-24]	80 [39 – 80]	0	150	-

9.2 Discussion

The RAFTAS feasibility study used a number of parameters to describe and measure adherence to the intervention by local study therapists and participants: time from randomisation to the initial therapy assessment; the number and content of therapy sessions delivered; recovery activities selected, goals selected and action taken by local study therapists; and the amount of participant independent practise of recovery activities.

The RAFTAS feasibility study had a training programme for local study therapists, a therapy manual and study specific documentation. In addition, the thesis author was in regular contact by telephone and email and undertook regular study site visits. Funding was available for the additional therapy. Despite this there were issues for a number of these parameters especially at Site 3 as shown in Figure 19.

Figure 19: Adherence to the intervention: Areas to be addressed



Early closure of Site 3 was necessary due to major problems with intervention delivery. This emphasises the importance of site selection and ensuring that local study therapists are willing to participate in the study and understand and agree to follow study procedures. Monitoring was not undertaken as part of the RAFTAS feasibility study but in retrospect should have been undertaken.

Only 40% of participants were recorded as receiving their initial therapy assessment within 24 hours of randomisation. On occasion this was because the date was not recorded but usually was because of the reported lack of availability of the local study therapist. This is surprising as NIHR SRN staff were asked to ensure that a local study therapist was available prior to randomising a participant.

Two of the three sites delivered the number of sessions as per protocol and returned the majority of study documents. Goal setting and subsequent recovery activity selection was undertaken as per protocol in two sites. Appropriate actions were undertaken by local study therapists at therapy reviews at these sites.

The RAFTAS feasibility study did not specify a time window for the final therapy review and some of these were completed early so that participants were unable to complete 28 days of therapy practice. In retrospect there should have been a time window for completion of the RAFTAS upper limb therapy programme within the protocol and training programme.

There was a low rate of return for activity log sheets, making it difficult to be clear whether or not activities had been practiced. It is not possible to determine whether this was due to participant, therapist or local NIHR SRN research staff. Returned recovery activity log sheets indicated high adherence to daily practice, although this is self-reported. It was not possible to use an objective measure to determine the number of repetitions undertaken.

Table 30 describes the adherence to the intervention of participants in 12 previous studies of RFTP. Nine studies [54-56, 58, 60-63, 66] reported adherence but it was usually adherence to intended dose of therapy completed. Two studies monitored content of therapy provided [56, 66]. Only one study reported results compared to protocol [66] whilst the other compared content delivered between study groups [56].

Table 30: Previous studies including RFTP for the upper limb after stroke - adherence to the study intervention

Author	Method of reporting adherence	Success of adherence (as reported)
Turnton and Fraser, 1990[58]	Percentage adherence = number of participant recorded sessions / number of prescribed sessions.	Reported 68% adherence (SD 25%). Number of sessions estimated retrospectively by 14% of participants.
Kwakkel et al., 1999[56]	Amount of therapy (time), Intended dose was 30 minutes, 5 days per week and 1.5 hours ADL training/week for 20 weeks (total 57.5 hours). Content of therapy coded. All recorded by therapists.	Upper limb group: mean minutes per working day = 38.6 (SD 10.7). Planned difference in time spent between study groups achieved. Content of arm training compared across study groups and no significant difference reported.
Langhammer and Stanghelle, 2000[57]	Not reported.	Not reported.
Blennerhassett, 2004[54]	Number of sessions attended. Intended dose was 1 hour/day, 5 days/week for 4 weeks (total 20 hours).	Upper limb group: mean = 15.9 (SD = 2.4) sessions. Reported as similar between study groups (p=0.52-0.87).
Winstein et al., 2004[60]	Number of hours completed. Intended dose was 1 hour/day, 5 days/week for 4-6 weeks (total 20 hours).	Limited data available. Narrative account states compliance near perfect except one participant who completed 15/20 hours.
Van Vliet, 2005[59]	Not reported.	Not reported.
Higgins et al., 2006[55]	Number of treatment sessions (maximum 18 sessions of approximately 90 minutes).	Upper limb group; 34/44 (77%) attended 17-18 sessions.
Harris et al., 2009[63]	Participant self-reported. Time spent practicing programme and number of daily sessions completed. Intended dose was 60 minutes per day, 6 days per week for 4 weeks.	Hours /week: mean = 3 hours (range= 1-7) Days per week: mean = 4.8 (range 1.3 -7).
Donaldson et al., 2009[62]	Number of hours completed. Intended dose was up to an hour' four days per week for six weeks (24 hours).	Total hours (functional strength training group): mean 17.7 (SD = 7.5).
Pandian et al., 2012[64]	Not reported.	Not reported.
Arya et al., 2012[61]	Amount of therapy (time). Intended dose per session was one hour. Intervention was 4-5 days/week for 4 weeks.	Narrative account states all completed 4 week treatment protocol. Mean duration of intervention per session (task specific programme group) = 54.67 minutes (SD 10.9 minutes).
Mares et al., 2014[66]	Percentage adherence = number of hours delivered / number of hours intended. Intended dose was one hour/day, 4 days/week for 6 weeks (total 24 hours). Content of therapy delivered compared to protocol.	Upper limb functional strength training group. Total hours: mean 17.1 (71% adherence). Content of programme consistent with study protocol.

Chapter 10. Repetitive arm functional tasks after stroke (RAFTAS) feasibility study: Usual post stroke rehabilitation

Objective 4: To report the usual post stroke rehabilitation received by control and intervention groups within the study intervention period.

10.1 Results

Data concerning the content and duration of the usual physiotherapy and occupational therapy provided to study participants for four weeks post randomisation were recorded.

The number of participants with usual post stroke rehabilitation documentation collected is shown in table 31. The usual post stroke rehabilitation received by study participants was recorded each day by NHS therapists.

Table 31: Number of participants with usual post stroke rehabilitation documentation collected

Study site	Intervention group n = 13	Control group n = 11	All participants n = 24
1 (n = 9)			
n (%)	4 (80%)	2 (50%)	6 (67%)
Missing (%)	*1 (20%)*	*2 (50%)*	*3 (33%)*
2 (n = 11)			
n (%)	4 (80%)	6 (100%)	10 (91%)
Discharged from usual post stroke rehabilitation (%)	1 (20%)	0 (0%)	1 (9%)
Missing (%)	*0 (0%)*	*0 (0%)*	*0 (0%)*
3 (n = 4)			
n (%)	0 (0%)	1 (100%)	1 (25%)
Missing (%)	*3 (100%)*	*0 (0%)*	*3 (75%)*
All study sites (n = 24)			
n (%)	8 (62%)	9 (83%)	17 (71%)
Discharged from usual post stroke rehabilitation (%)	1 (7%)	0 (0%)	1 (4%)
Missing (%)	*4 (31%)*	*2 (17%)*	*6 (25%)*

Usual post stroke rehabilitation forms were returned for 17/24 (71%) participants and return rates varied between sites. Site 2 returned data for all study participants who received usual post stroke rehabilitation.

The thesis author gathered informal feedback from study sites concerning why documentation had not been collected. Reported reasons are shown in Table 32.

Table 32: Reasons why participants did not have usual post stroke rehabilitation data collected/returned

Reasons why usual post stroke rehabilitation data not collected/returned	Intervention group n = 13	Control group n = 11
Forms completed but lost at study site	-	2 (Site 1)
Forms not completed due to usual post stroke rehabilitation staff not being informed that patient was participating in the study	1 (Site 1)	-
Forms not completed by therapist	3 (Site 3)	-

The number of days usual post stroke rehabilitation data were collected and sessions provided are shown in table 33. Data were available for 17 participants and one participant had been discharged from usual post stroke rehabilitation prior to study recruitment.

Table 33: Number of days usual post stroke rehabilitation data were collected and therapy sessions provided

	Intervention group n=9	Control group n=9
Number of days data collected:		
Median [IQR]	8 [6–19.5]	5 [3.5–11.5]
Min, max	0, 43	3, 18
Sessions per recorded day :		
Median [IQR]	1 [1–2]	1 [1–1]
Min, max	1, 3	1, 3
Profession involved in therapy sessions n (%):	n* = 179	n* = 83
OT only	33 (18%)	34 (41%)
Physiotherapist only	50 (28%)	34 (41%)
Therapy assistant only	37 (21%)	5 (6%)
Nurse only	1 (1%)	1 (1%)
Mix of professions	58 (32%)	9 (11%)
Total face to face therapy time per recorded session:	n* = 132	n* = 77
Minutes		
Mean (SD)	34 (17)	41 (14)
Median [IQR]	30 [20–45]	45 [30-45]
Min, max	10, 120	10, 85

n* = number of usual post stroke rehabilitation forms returned (1 form per day)

The majority of both intervention and control group participants were recorded as receiving a median of one therapy session per day.

Table 34 shows the content of recorded usual post stroke rehabilitation received by participants. Recorded therapy sessions may have been a mix of more than one type of therapy (i.e. a mix of ‘mobility’ and ‘upper limb (RFTP)’).

Table 34: Content of recorded usual post stroke rehabilitation received by participants

	Intervention group n=9	Control group n=9
Therapy session content (n = number of times content recorded)	n = 238	n = 94
Mobility:	n = 100 (42%)	n = 43 (45%)
Time spent (mins)		
Median [IQR]	15 [10 – 20]	30 [25 – 45]
Min, max	5, 40	10, 50
Upper limb (RFTP):	n = 21 (9%)	n = 8 (9%)
Time spent (mins)		
Median [IQR]	15 [10 – 30]	30 [12.5 – 40]
Min, max	5, 45	5, 45
Upper limb (other):	n = 53 (23%)	n = 21 (22%)
Time spent (mins)		
Median [IQR]	15 [10 – 20]	25 [20 – 43]
Min, max	2, 40	10, 60
ADL (personal):	n = 27 (11%)	n = 9 (10%)
Time spent (mins)		
Median [IQR]	20 [10 – 45]	40 [28 – 45]
Min, max	5, 45	20, 45
ADL (domestic):	n = 10 (4%)	n = 4 (4%)
Time spent (mins)		
Median [IQR]	10 [10 – 33]	37.5 [26 – 49]
Min, max	5, 40	25, 50
'Other':	n = 27 (11%)	n = 9 (10%)
Time spent (mins)		
Median [IQR]	20 [15 – 25]	25 [10 – 45]
Min, max	10, 45	10, 60
Not described	7	1
'Other' content codes:	n = 39	n = 12
n (%)		
Assessment	7 (18%)	2 (17%)
Chair based exercises	3 (8%)	-
Standing / sit to stand	2 (5%)	1 (8%)
Balance work	4 (10%)	1 (8%)
Lower limb exercises	6 (15%)	-
Exercises (other)	3 (8%)	-
Group exercise session	4 (10%)	-
Social integration	2 (5%)	-
Swallow/communication	-	1 (8%)
Not described	8 (21%)	7 (59%)

The most common type of usual post stroke rehabilitation delivered to intervention and control groups was mobility practice. Nine per cent of therapy sessions included upper limb RFTP. There was limited focus on ADL (both personal and domestic) in both treatment groups and few 'other' treatment modalities were provided. The

majority of ‘other’ treatment modalities listed by usual post stroke rehabilitation therapists related to lower limb / mobility work.

10.2 Discussion

It was possible to record the time and content of the usual physiotherapy and occupational therapy received by study participants, but data were missing for 5/24 (21%), with the majority of missing data at Site 3. Co-ordination of usual post stroke rehabilitation data recording / collection was challenging as several teams were involved in delivery of usual post stroke rehabilitation across a variety of clinical settings (acute and community).

Usual post stroke rehabilitation CRFs did not include a section for therapists to indicate if the participant had been discharged from therapy, so it was not possible to know what proportion of documentation was returned. In retrospect, this information should have been collected.

Approximately twice as much data about the content of therapy sessions were available for analysis in intervention group than in control group participants. This could be a reporting bias or represent a change of practice for therapists who provided usual post stroke rehabilitation to intervention group participants. This issue will need addressing in the design of a multicentre study.

It is important to be able to describe the usual post stroke rehabilitation received by participants in both intervention and control groups in a clinical trial. In clinical practice stroke rehabilitation is not standardised and the content, intensity, and duration of therapy varies considerably between therapists and services [111].

Most stroke rehabilitation studies do not adequately describe usual post stroke rehabilitation [112]. Table 35 show the information provided about the therapy received by study comparison group(s) and the usual post stroke rehabilitation received by all groups in the 12 previous trials which included RFTP for upper limb recovery after stroke.

Table 35: Previous studies including RFTP for the upper limb after stroke - therapy received by study comparison group(s) and usual post stroke rehabilitation received by all groups

Author	Comparison group(s)		Usual post stroke rehabilitation	
	Description	Method of measurement	Description	Method of measurement
Turnton and Fraser, 1990[58]	Usual care	Not reported	Continued with usual post stroke rehabilitation	Not reported
Kwakkel et al., 1999[56]	Two groups; immobilisation by splinting paretic upper and lower limbs and lower limb training. Provided at same intensity as upper limb group.	Time spent receiving intervention (minutes per working day). Content of lower limb training coded.	Specified by the study; all groups received 15 minutes/day lower limb, 15 minutes/day upper limb physiotherapy and 1.5 hours/week occupational therapy ADL training.	Number of hours delivered and content of interventions coded by 2 therapists.
Langhammer and Stanghelle, 2000[57]	Bobath approach	Not reported	Study intervention replaced physiotherapy. Continued with usual occupational therapy and other MDT care.	Not reported
Blennerhassett, 2004[54]	Mobility training (endurance training, strengthening and functional tasks).	Number of sessions received.	Continued with usual interdisciplinary care. Physiotherapy provided for 1 hour/day, 5 days/week and based on the movement science approach.	Time spent in interdisciplinary therapy recorded during the intervention period (4 weeks).
Winstein et al., 2004[60]	Two groups; usual care and upper limb strength training.	Number of hours completed. Intended dose was 1 hour/day, 5 days/week for 4-6 weeks (total 20 hours).	'Standard dose of physiotherapy and occupational therapy' – no further details provided.	Not reported

Table 35: Previous studies including RFTP for the upper limb after stroke: therapy received by study comparison group(s) and usual post stroke rehabilitation received by all groups (continued)

Author	Comparison group(s)		Usual post stroke rehabilitation	
	Description	Method of measurement	Description	Method of measurement
Van Vliet, 2005[59]	Bobath approach	Mean minutes per day and total minutes during the intervention period.	Study intervention replaced physiotherapy. Usual post stroke rehabilitation occupational therapy followed study allocated approach.	Not reported (occupational therapy).
Higgins et al., 2006[55]	Walking tasks (functional strengthening).	Number of sessions delivered.	N/A – only patients "discharged from physical rehabilitation" included.	N/A
Harris et al., 2009[63]	Received an education book with homework assignments. Education book homework reviewed by site co-ordinator. Face to face time matched with intervention group.	Hours per week spent with site co-ordinator.	Continued with usual MDT care.	Hours per week.
Donaldson et al., 2009[62]	Two groups; usual care and usual care plus additional usual care.	Total hours received	Physiotherapy usual post stroke rehabilitation received as part of study intervention (all groups), provided using a standardised schedule. Occupational therapy not reported.	Total physiotherapy hours received.
Pandian et al., 2012[64]	Brunnstrom movement therapy protocol.	Not reported.	Functional activities (non-paretic upper limb), lower limb activities and ADL practice.	Not reported.
Arya et al., 2012[61]	'Standard training group' based on Brunnstrom stage and the Bobath approach.	Mean minutes per session.	Not reported.	Not reported.
Mares et al., 2014[66]	Lower limb functional strength training.	Total hours of training received.	N/A – only patients "not receiving formal therapy for their upper or lower limb" included.	N/A

Usual post stroke rehabilitation approach or interventions were specified within study protocol by 4/12 previous studies [56, 57, 59, 62], but only two studies [56, 59] considered both occupational therapy and physiotherapy input. This approach would not be acceptable or achievable within the NHS. Participants continued with normal usual post stroke rehabilitation in 5/12 studies [54, 58, 60, 63, 64] and discharge from usual post stroke rehabilitation was part of eligibility criteria in two studies [55, 66]. Only 4/12 previous studies [54, 56, 62, 63] measured usual post stroke rehabilitation received by participants.

Chapter 11. Repetitive arm functional tasks after stroke (RAFTAS) feasibility study: Attrition, data completeness and summary statistics of clinical outcomes at 1 and 3 months

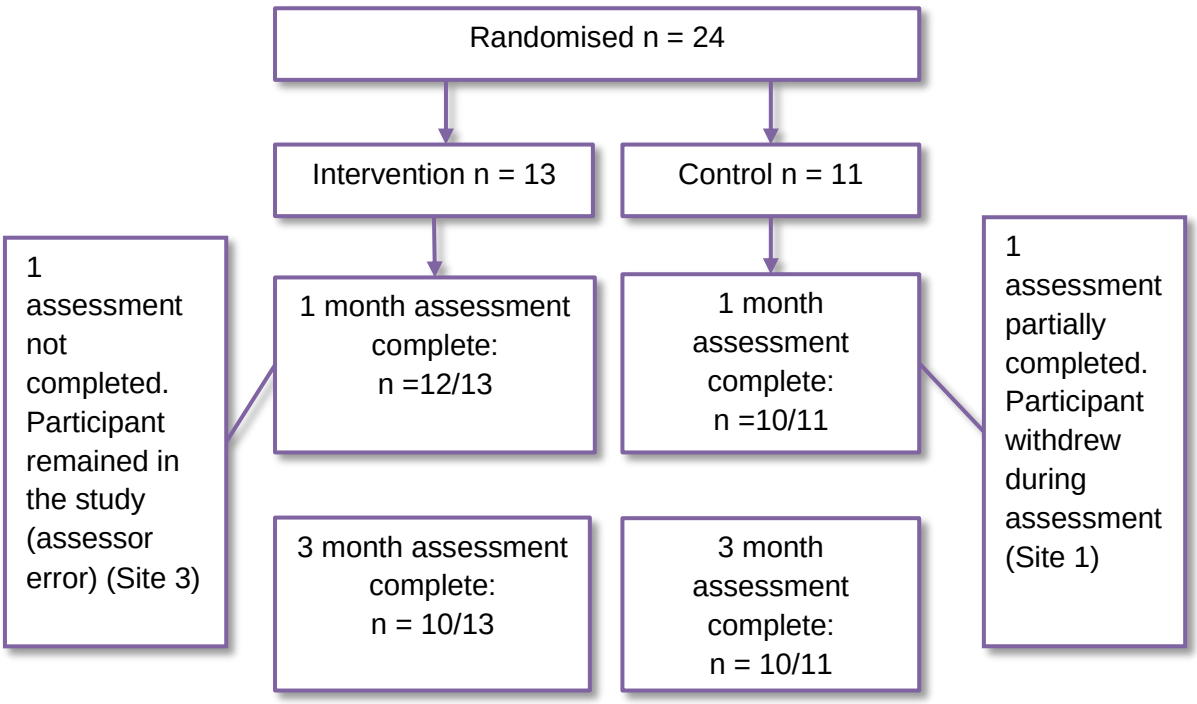
Objective 5: To report attrition, data completeness and summary statistics of clinical outcomes at 1 and 3 months.

11.1 Results

11.1.1 Attrition

Figure 20 shows study follow up.

Figure 20: Study follow up



Follow up at one month was 22/24 (92%) - 8% attrition rate and at three months 20/24 (83%) – 17% attrition rate. Reasons for study attrition are shown in table 36.

Table 36: Reasons for study attrition

	Intervention group (n = 13)	Control group (n = 11)
Withdrawn n and reason(s) (Site number)		
0 – 1 month	0	1,self-withdrawal (emotional about health condition) (participant 105, Site 1)
>1 – 3 months	0	1,self-withdrawal (emotional about health condition) (participant 105, Site 1)
Assessment not completed n and reason(s) (Site number)		
0 – 1 month	1, outcome assessor error (Site 3)	0
>1 – 3 months	1, outcome assessor error (Site 3)	0
	2, unable to contact participant (Sites 1 and 2)	0

11.1.2 Timing of study outcome assessments

In the RAFTAS feasibility study protocol, the one month outcome assessment was considered on time if completed +/- 3 days of the randomisation date (calendar month). The three month outcome assessment was considered on time if completed +/- 5 days of the randomisation date (calendar month). Timing of outcome assessments are shown in table 37.

Table 37: Timing of outcome assessments (per study site and total for all sites)

Completed on time?	One month assessment (+/- >3 days)	Three month assessment (+/- >5 days
Site 1 (n = 9) Yes, n (%) No, n (%) + <7 days (n) + 15 – 28 days (n) Missing (n)	 7 (78%) 2 (22%) 2 0 0 (0%)	 6 (67%) 1 (11%) 0 1 2 (22%)
Site 2 (n = 11) Yes, n (%) No, n (%) + <7 days (n) + 7 – 14 days (n) Missing (n)	 9 (82%) 2 (18%) 2 0 0 (0%)	 7(64%) 4 (36%) 2 2 0 (0%)
Site 3 (n = 4) Yes, n (%) No, n (%) + <7 days (n) + 29 - 43 days (n) +166 days (n) Missing (n)	 1 (25%) 2 (50%) 0 1 1 1 (50%)	 1 (25%) 2 (50%) 1 1 0 1 (50%)
TOTAL (n = 24) Yes, n (%) No, n (%) + < 7 days (n) + 7 - 14 days (n) + 15 – 28 days (n) + 29 - 43 days (n) + 166 days (n) Missing (n %)	 17 (71%) 6 (25%) 4 0 0 1 1 1 (4%)	 14 (58%) 7 (29%) 3 2 1 1 0 3 (13 %)

If only participants who had outcome assessments within the time windows specified in the protocol then this would have meant that follow up at one month was 17/24 (71%) – 29% attrition rate and at three months 14/24 (58%) – 42% attrition rate.

There was a notable difference in performance between Sites 1 and 2, compared to study Site 3. In Sites 1 and 2, the majority of outcome assessments were on time at both one and three months. If Site 3 were to be excluded, then 16/20 (80%) one month assessments and 13/18 (72%) three months assessments would have been completed on time.

At Site 3, 50% of outcome assessments were undertaken outside the time window for each assessment. Three assessments at Site 3 were over 28 days late and in retrospect should not have been included in the analysis. This would meant that follow up at one month was 20/24 (83%) – 17% attrition rate and at three months 19/24 (79%) – 21% attrition rate.

11.1.3 Clinical outcomes

11.1.3.1 Arm function: Action Research Arm Test (ARAT)

The Action Research Arm Test (ARAT) is likely to be the primary outcome measure for a Phase III study. ARAT scores are shown in table 38. The maximum score achievable on the ARAT is 57. The ARAT score was not available for 3/24 (13%) participants at one month and 4/24 (17%) at three months. For the 22 participants who had a 1 month assessment, the ARAT was available for 21/22 (95%) and all 20 patients who had a 3 month assessment completed the ARAT (100%).

The median ARAT at one month was 55 [IQR 38-57] for the intervention group and 46 [IQR 29-57] for the control group. At three months the median ARAT score for the intervention group was 57 [IQR 50-57] and 48 [IQR 35 – 57] for the control group.

Table 38: Action Research Arm Test (ARAT) results

	One month		Three months	
	Intervention group n=13	Control group n=11	Intervention group n=13	Control group n=11
Total* Median [IQR] Min, max *Missing*	55 [38 – 57] 12, 57 *1*	46 [29 – 57] 13, 57 *2*	57 [50 – 57] 2, 57 *3*	48 [35 – 57] 23, 57 *1*
Sub scores:				
Grasp Median [IQR] Min, max *Missing*	18 [15 – 18] 5, 18 *1*	15 [9 – 18] 0, 18 *1*	18 [16 – 18] 0, 18 *3*	18 [14 – 18] 8, 18 *1*
Grip Median [IQR] Min, max *Missing*	12 [9 – 12] 4, 12 *1*	12 [7 – 18] 4, 12 *2*	12 [12 – 12] 0, 12 *3*	12 [8 – 12] 8, 12 *1*
Pinch Median [IQR] Min, max *Missing*	16 [9 – 18] 0, 18 *1*	7 [2 – 18] 0, 18 *1*	18 [15 – 18] 0, 18 *3*	11 [6 – 18] 0, 18 *1*
Gross Median [IQR] Min, max *Missing*	9 [7 – 9] 3, 9 *1*	8 [7 – 9] 5, 9 *2*	9 [8 – 9] 2, 9 *3*	9 [7 – 9] 5, 9 *1*

* For affected side only (total scores, 0 – 57, higher score = greater functional ability)

11.1.3.2 Secondary outcomes

Secondary outcomes which may be used in a Phase III study are Dynamometer (grip strength), Motricity Index [99] (arm strength) and Nottingham Extended Activities of Daily Living Index (extended activities of daily living) [100].Secondary outcome results are shown in table 39.

Table 39: Secondary outcome results

	One month		Three months	
	Intervention group n=12	Control group n=10	Intervention group n=9	Control group n=10
Dynamometer (kg) Median [IQR] Min, max *Missing*	 15 [8 – 20] 1, 26 *3*	 11 [5 – 26] 2, 59 *1*	 13 [5-21] 1, 24 *4*	 14 [4-28] 3, 39 *1*
Motricity Index* Median [IQR] Min, max *Missing* Arm Median [IQR] Min, max *Missing* Leg Median [IQR] Min, max *Missing*	 87 [67 – 99] 52, 99 *1* 91 [76 – 99] 50, 99 *1* 79 [56 – 99] 42, 99 *1*	 77 [67 – 86] 57, 91 *1* 79 [55 – 91] 50, 91 *1* 75 [63 – 91] 47, 99 *1*	 88 [67 – 99] 60, 99 *3* 88 [65 – 99] 45, 99 *3* 87 [71 – 99] 57, 99 *3*	 91 [74 – 95] 46, 95 *(1)* 88 [72 – 94] 50, 99 *1* 95 [77 – 99] 42, 99 *1*
Nottingham Extended Activities of Daily Living Scale** Median [IQR] Min, Max *Missing*	 36 [10-54] 4, 63 *3*	 34 [25 – 46] 4, 55 *2*	 43 [9-60] 8, 66 *3*	 52 [32-58] 29, 64 *2*

*Motricity Index, 0 = no movement, 100 = normal strength
**Nottingham Extended Activities of Daily Living Scale, 0- 66 (66 = normal functional ability)

Data were complete at one and three months for: dynamometer 20/22 (92%) and 19/19 (100%); Motricity Index 22/22 (100%) and 19/20 (95%); Nottingham EADL 19/22 (86%) and 19/20 (95%).

11.2 Discussion

The participant attrition rate at one and three months was acceptable, but not all assessments were completed within the time window specified in the protocol. Outcome assessments were missing at Site 3 for two out of four study participants and a further three outcome assessments were undertaken very late. This reflects site engagement in the study and were some of the reasons (along with failure to deliver the intervention as per protocol) why Site 3 was closed early.

Attrition in previous studies including RFTP for the upper limb is shown in table 40.

Table 40: Previous studies including RFTP for the upper limb after stroke - attrition

Author	Attrition time points and % attrition	Reported reason(s) for attrition (data presented as available)
Turnton and Fraser, 1990[58]	'Last visit' (variable time) = 0%	N/A
Kwakkel et al., 1999[56]	4 weeks = 1% 12 weeks = 11% 20 weeks = 12%	Total; recurrent stroke (n=6), cancer (n=2), carotid endarterectomy (n=1), refused control treatment (n=2), died (n=1).
Langhammer and Stanghelle, 2000[57]	2 weeks = 7% 3 months = 12%	Total; lost to follow up (n=8).
Blennerhassett, 2004[54]	4 weeks = 0% 6 months = 3%	Total; hip fracture (n=1).
Winstein et al., 2004[60]	6 months = 6% 9 months = 31%	Total; moved away, lost contact (n=16).
Van Vliet, 2005[59]	1 month = 18% 3 months = 29% 6 months = 28%	Total; ill, died (n=16), unable to contact, refused, administrative error, lost to follow up, moved away.
Higgins et al., 2006[55]	6 weeks = 5%	Total; ill (n=3), unwilling to travel (n=1), groin pain (n=1).
Harris et al., 2009[63]	4 weeks = 9% 3 months = 42%	Four weeks; in acute care (n=4), complex regional pain syndrome (n=1), declined as control group (n=3), arthritis pain (n=1). Reasons for attrition at 3 months not provided.

Table 40: Previous studies including RFTP for the upper limb after stroke - attrition (continued)

Author	Attrition time points and % attrition	Reported reason(s) for attrition (data presented as available)
Donaldson et al., 2009[62]	6 weeks = 7% 12 weeks = 37%	Six weeks; new stroke (n=1), bail (n=1) Twelve weeks; unwell (n=5), died (n=2), abroad (n=2) bail (n=1), moved house (n=1).
Pandian et al., 2012[64]	4 weeks = 0%	N/A.
Arya et al., 2012[61]	4 weeks = (unclear) 8 weeks = 7%	Total; personal (n=1), other reasons for attrition not provided.
Mares et al., 2014[66]	6 weeks = 15% 12 weeks = 15%	Six weeks; unable to complete measures to protocol (n=1), unwell (n=4), unable to contact (n=1), did not take part in intervention (n=2). Twelve weeks; unable to complete measures (n=1), unwell (n=3), unable to contact (n=1), did not take part in intervention (n=2), away when measures due (n=1).

Attrition at the final outcome assessment was reported for all previous studies and ranged between 0-37% (table 40). The mean attrition rate of the 12 studies was 16%. The attrition rate for the four previous multicentre studies [55, 56, 63, 66] was 5-42%. For studies which recruited participants in a similar time window after stroke attrition was 12% [56], 28% [59] and 31% [60]. No study reported the proportion of outcome assessments undertaken within a specified time window.

The quality of reporting reasons for loss to follow up was variable. All of the attrition in the study by Kwakkel et al., [56] was because of withdrawal of participants (n=12). Some studies reported loss to follow up as an intention to treat loss and others reported loss to follow up as a per protocol analysis. The reported reasons for loss to follow up across all studies were: acute illness; unable to contact; administrative error; withdrawal (did not wish to take part in study). In the studies undertaken by Higgins et al., [55] and Harris et al., [63] a small number of participants withdrew (n=2 and n=3) because they were unhappy that they had been allocated to the comparator group.

Completeness of data at outcome(s) reported in previous studies including RFTP are shown in table 41.

Table 41: Previous studies including RFTP for the upper limb after stroke - completeness of data at outcome(s)

Author	Outcome time point	ARAT (% missing)	Dynamometer (% missing)	Other measure(s) (% missing)
Turnton and Fraser, 1990[58]	Every four weeks; data for final visit compared to baseline. Mean = 9 weeks.	Not used	Not used	Final visit; Southern Motor Group's motor assessment (0%), ten hole peg test (0%).
Kwakkel et al., 1999[56]	6 weeks 12 weeks 20 weeks 26 weeks	Not reported	Not used	BI, FAC, 10 Metre Timed Walk Test, Missing data not reported for all measures.
Langhammer and Stanghelle, 2000[57]	2 weeks 3 months	Not used	Not used	MAS, SMES, BI, NHP, length of hospital stay, discharge destination and use of assistive devices for mobility. Missing data not reported for all measures.
Blennerhassett, 2004[54]	4 weeks 6 months	Not used	Not used	Four weeks; 6MWT, TUGT, step test and MAS (0%), JTHFT (10%). Six months; 6MWT, TUGT, step test and MAS (3%). JTHFT (10%).
Winstein et al., 2004[60]	4 weeks 6 months post stroke 9 months post stroke	Not used	Not reported	Primary: arm portion of the FMA, dynamometer, FTHUE and isometric torque at the shoulder, elbow and wrist (dynamometer). Secondary: self-care and mobility portions of FIM. Missing data not reported for all measures.

Table 41: Previous studies including RFTP for the upper limb after stroke - completeness of data at outcome(s) (continued)

Author	Outcome time point	ARAT (% missing)	Dynamometer (% missing)	Motricity Index (% missing)	Other measure(s) (% missing)
Van Vliet, 2005[59]	1 month 3 months 6 months	Not used	Not used	Not used	Primary outcomes – Rivermead Motor Assessment (gross function) and the MAS. Secondary outcomes – ten hole peg test, Modified Ashworth scale, 6MWT, BI, Nottingham sensory assessment. Missing data not reported for all measures.
Higgins et al., 2006[55]	6 weeks	Not used	Six weeks; 7 (%)	Not used	Box and Plot test, NHPT, TEMPA, grip strength, STREAM, BI, OASS-IADL and the Geriatric Depression Scale (5%). SF-36 (7%).
Harris et al., 2009[63]	4 weeks 4 months	Not reported	Not reported	Not used	CAHAI, MAL, SF-12, VAS (pain), Fatigue Severity Scale, dynamometer. Missing data not reported for all measures.
Donaldson et al., 2009[62]	6 weeks 12 weeks	Six weeks (7%) Twelve weeks; not reported.	Not used	Not used	Six weeks; NHPT, myometer (7%). Twelve weeks; not reported.
Pandian et al., 2012[64]	4 weeks	Not used	Not used	Not used	BRS-H and FMA-WH. Missing data not reported for all measures.
Arya et al., 2012[61]	4 weeks 8 weeks	Missing not reported	Not used	Not used	FMA, GWMFT, and MAL. Missing data not reported for all measures.

Table 41: Previous studies including RFTP for the upper limb after stroke - completeness of data at outcome(s) (continued)

Author	Outcome time point	ARAT (% missing)	Dynamometer (% missing)	Motricity Index (% missing)	Other measure(s) (% missing)
Mares et al., 2014[66]	6 weeks 12 weeks	Six weeks (17%) Twelve weeks (17%)	Not used	Not used	Six weeks; FAC and ability to complete TUG (8%), ability to complete NHPT (21%), Modified Rivermead Mobility Index (25%). Twelve weeks; FAC (8%), ability to complete TUG (17%), ability to complete NHPT (56%), Modified Rivermead Mobility Index (27%).

MAS = Motor Assessment Scale (motor function); **SMES** = Sødring Motor Evaluation Scale (motor function in stroke); **NHP** = Nottingham Health Profile; **6MWT** = Six Minute Walk Test; **TUGT** = Timed Up and Go Test; **JTHFT** = Jebsen Taylor Hand Function Test; **FTHUE** = Functional Test for Hemi paretic Upper Extremity; **FIM** = Functional Independence Measure; Fatigue Severity Scale, **TEMPA =** Test d'Evaluation des Members supérieurs des Personnes Agées (upper limb activity limitation); **STREAM** = Stroke Rehabilitation Assessment of Movement (arm sub-scale only- an assessment of movement); **OASS-IADL** = Older Americans Resource Scale for Instrumental Activities of Daily Living; **CAHAI** = Chedoke Arm and Hand Activity Inventory (upper limb functional assessment); **MAL**= Motor Activity Log-14 (structured questionnaire measuring motor activity); **VAS** = Visual Analogue Scale; **FMA** = Fugl-Meyer Assessment (upper limb impairment); **FMA-WH** = Fugl-Meyer Assessment (wrist and hand impairment sub-test); **BRS-H** = Brunnstrom recovery stage of the hand (motor recovery level); **GWMFT** = Graded Wolf Motor Function Test; **FAC** = Functional Ambulation Category; **ARAT** = Action Research Arm Test; **NHPT =** Nine Hole Peg Test (dexterity), **BI** = Barthel Index (activities of daily living).

Completion of the ARAT and secondary outcome measures was very good in the RAFTAS feasibility study. Seven of the 12 previous studies did not report completeness of outcome data and it was only well reported in four studies [54, 55, 58, 66]. One study which reported missing data used ARAT at the primary end point and 9/52 (17%) of data were missing [66]. Another study reported 6/91 (7%) missing Dynamometer data [55]. Completeness of secondary outcome measures was between 0% and 56% for all studies that reported completeness of outcome data [54, 55, 58, 66]. All of the secondary outcome measures used in this study were different from those used in the RAFTAS feasibility study.

Chapter 12. Repetitive arm functional tasks after stroke (RAFTAS) feasibility study: Outcome assessor blinding

Objective 6: To report the success of outcome assessor blinding to participant group allocation.

12.1 Results

Outcome assessors were asked if they were certain about a participant's treatment group allocation at the one month and three month outcome assessments. Outcome assessors were asked to select which treatment group they thought the participant had been allocated to (see tables 42 and 43).

Table 42: Assessor certainty of randomisation group at 1 month

	Intervention group n = 13	Control group n = 11	Total n = 24
Assessor certain of study group	n = 12	n = 10	n = 22
Yes (%)	9 (75%)	3 (30%)	12 (55%)
No (%)	3 (25%)	7 (70%)	10 (45%)
Missing	*1*	*1*	*2*
Correct study group selected for those certain	n = 9	n = 3	n = 12
Yes (%)	8 (89%)	3 (100%)	11 (92%)
No (%)	1 (11%)	0 (0%)	1 (8%)
Missing	*0*	*0*	*0*

Table 43: Assessor certainty of randomisation group at 3 months

	Intervention group n = 13	Control group n = 11	Total n = 24
Assessor certain of study group	n = 10	n = 9	n = 19
Yes (%)	6 (60%)	3 (33%)	9 (47%)
No (%)	4 (40%)	6 (67%)	10 (53%)
Missing	*3*	*2*	*5*
Correct study group selected for those certain	n = 4	n = 3	n = 7
Yes (%)	3 (75%)	3 (100%)	6 (86%)
No (%)	1 (25%)	0 (0%)	1 (14%)
Missing	*2*	*0*	*2*

Outcome assessors reported that they were certain of the randomisation group for 12/22 (55%) patients at one month and they were correct for 11/12 92%. Outcome assessors were unblinded to participant group allocation for 11/22 (50%) at one month.

At three months 9/20 (45%) reported that they were aware of the randomisation group were correct for 6/9 (67%). Outcome assessors were unblinded to participant group allocation for 6/20 (30%).

The one and three month assessments were carried out by the same assessor for 20/21(95%) participants who undertook both assessments.

12.2 Discussion

Results indicate that blinding of outcome assessors to participant group allocation was poor. Outcome assessors were not asked how and when they became unblinded to the participants group allocation and in retrospect it would have been helpful to have sought this information.

During the RAFTAS feasibility study, the majority of assessors were either based in the same office as the local study therapists who provided the RFTP programme or were involved in the participants' usual post stroke rehabilitation. Outcome assessors may have been unblinded during their normal working day (by being aware of study treatments or treatment allocation disclosed by participants), or by participants during outcome assessments.

It is difficult to compare the success of outcome assessor blinding to previous studies into RFTP as it is poorly reported.

Blinding of the primary outcome assessments was attempted in 9/12 previous studies [54-57, 59, 61, 63, 64, 66] into RFTP. Only 2/9 studies reported success of outcome assessor blinding [55, 56, 59]. Kwakkel et al., [56] reported treatment allocation was disclosed for 10/101 (10%) participants during the study, but did not indicate how many primary outcome assessments were affected. Van Vliet et al., [59] used a κ statistic to assess agreement between participants' group allocation and outcome assessors' guesses - result was 0.22, which indicated poor agreement. The authors also did not indicate if this result was for all assessments or the primary outcome assessment.

Chapter 13. Repetitive arm functional tasks after stroke (RAFTAS) feasibility study: Adverse events

Objective 7: To report adverse events in control and intervention groups during the study.

13.1 Results

Outcome assessments included specific questions to collect potential adverse event data. These covered:

- New medical problems.
- Pain in the upper limb affected by stroke.
- Fatigue.
- Increased tone (spasticity) in the upper limb affected by stroke.

13.1.1 New medical problems

Participant responses to the question 'have you suffered any new medical problems in the last month (question included at the one month assessment) and last two months (question included at the three month assessment)?' are shown in table 44.

Table 44: Response to occurrence of any new medical problems

Adverse event?	One month		Three months	
	Intervention group n = 13	Control group n = 11	Intervention group n = 13	Control group n = 11
Yes n (%) No n (%) *Missing*	3 (23%) 9 (69%) *1 (8%)*	1 (9%) 10 (91%) *0 (0%)*	4 (31%) 6 (46%) *3 (23%)*	2 (18%) 8 (73%) *1 (9%)*

Details about the new medical problems are shown in table 45 (one month) and table 46 (three months).

Table 45: New medical problems at one month

Adverse event	Intervention group n=3	Control group n=1
Hospital admission due to abdominal cramps, diarrhoea and chest pain	1	-
Lower limb problem (unspecified)	1	-
Leg pain and swelling	1	-
Kidney function investigation (out-patient)	1*	-
Mild leg swelling	-	1
Sleeping difficulty due to unspecified discomfort	-	1*
TOTAL	4	2
Missing	*0*	*0*

*Response recorded as 'no' to the question "has the participant suffered from any new medical problems" but details of a problem provided as free text.

Table 46: New medical problems at the three months

Adverse event	Intervention group n=4	Control group n=2
AEs affecting the upper limb		
Dry skin (hands)	1∞*	-
Intermittent ache (left hand)	1	-
Pain in arm, leg and head	-	1
Neurogenic pain (affected arm)	-	1
Falls		
Fall	1∞*	-
Fall (resulting in hospital admission)	1	-
Fall (due to loss of balance)	-	1*
Other		
Now taking blood pressure medication	1	
Leg pain (resulting in alteration of medication)	-	1 *
Postural hypotension (blackouts)	1	-
High blood pressure (visited GP)	-	1 *
TOTAL	6	5
Missing	*0*	*0*

∞ Events reported by the same participant. *Response recorded as 'no' to the question "has the participant suffered from any new medical problems?" but details of a problem provided as free text.

In summary, there were 10 new medical problems reported from intervention group participants and 7 from control group participants during their involvement in the study.

13.1.2 Pain in the upper limb affected by stroke

Participants were asked if they had any pain in their upper limb affected by stroke in the last month (question included at the one month assessment) and last two months

(question included at the three month assessment). They were also asked to provide details about the pain and provide a score for severity on a 10 point linear (horizontal) Visual Analogue Scale. Results are shown in tables 47 – 50.

Table 47: Presence of pain in the upper limb pain affected by stroke

Pain (in affected upper limb)	One month assessment		Three month assessment	
	Intervention group n = 13	Control group n = 11	Intervention group n = 13	Control group n = 11
No n (%) Yes n (%) *Missing*	9 (69%) 3 (23%) *1 (8%)*	6 (54.5 %) 5 (45.5%) *0 (0%)*	5 (38.5%) 5 (38.5%) *3 (23%)*	6 (55%) 4 (36%) *1 (9%)*

Table 48: Details about upper limb pain provided at one month

Affected upper limb pain details	Intervention group n=3	Control group n=5
Arthritic pain thumb and finger	1*	-
At rest, no pain, on moving arm out and in certain positions, get a pulling pain in shoulder and down deltoid	1	-
A niggling pain a couple of times when stretching himself a bit far	1	-
Muscular pain when doing activity involving extending the shoulder	1	-
Soreness in fingers	-	1
Right shoulder / scapular / thorax	-	1
Couple of times in the evening – aching, getting less	-	1
Numbness / aching	-	1
Numbness in finger but no pain	-	1*
TOTAL	4	5
Missing	*0*	*1*

*Response recorded as 'no' to the question "has the participant had any pain in their upper limb affected by stroke?" but details of a problem provided as free text.

Table 49: Details about upper limb pain provided at three months

Affected upper limb pain details	Intervention group n=5	Control group n=4
Aching in left hand	1	-
When lying on arm and hip in bed	1	-
On lifting arm past 90 degrees	1	-
Shoulder pain on active movement.	1∞	-
Hand and wrist pain due to contractures	1∞	
Aching pain from neck, down whole arm into chest. Inhibits movement	-	1
Gets pain every couple of hours then eases. Has medication	-	1
Aches, sharp pain in hands	-	1
TOTAL	5	3
Missing	*1*	*1*

∞ Events reported by the same participant

Table 50: Upper limb pain severity

Pain (in affected upper limb)	One month assessment		Three month assessment	
	Intervention group n = 13	Control group n = 11	Intervention group n = 13	Control group n = 11
VAS score n (%)				
0	6 (46%)	5 (46%)	4 (31%)	4 (36%)
1	-	1 (9%)	-	1 (9%)
2	1 (8%)	-	1 (8%)	-
3	-	-	-	-
4	1 (8%)	1 (9%)	-	-
5	1 (8%)	1 (9%)	2 (15%)	1 (9%)
6	1 (8%)	2 (18%)	-	-
7	-	-	-	1 (9%)
8	-	-	2 (1%)	1 (9%)
9	-	-	-	1 (9%)
10	-	-	-	-
Total with scores >0	4 (31%)	5 (45%)	5 (38%)	5 (45%)
Median [IQR]	0 [0 – 4]	0.5 [0 – 5]	2 [0 – 6.5]	1 [0 – 7.5]
Min, Max	0, 6	0, 6	0, 8	0, 9
Mean (SD)	2 (2.4)	2 (2.7)	3 (3)	3 (4)
Missing	*3 (23%)*	*1 (9%)*	*4 (31%)*	*2 (18%)*

There were inconsistencies in pain data recorded; for example one intervention group participant reported they had upper limb pain, provided details about their upper limb pain, but scored zero on the VAS; another participant reported no pain,

did not provide details about pain but scored 2 on the VAS. In total, inconsistencies were recorded for 7/42 (17%) assessments as shown in table 51.

Table 51: Inconsistencies in reporting of adverse events

	One month				Three months		
	Intervention		Control		Intervention		Control
	n=1	n=1	n=1	n=1	n=1	n=1	n=1
Pain in affected upper limb yes/no	No	Yes	No	Yes	Yes	No	Yes
Pain details provided yes/no	Missing	Yes	Yes (but stated no pain)	Missing	Missing	Missing	Missing
Pain score >0	Yes	No	No	Yes	Yes	Yes	Yes

Combining all the data (presence of pain 'yes', detail about pain provided and/or a VAS score of greater than 0), at one month, 5/13 (38%) participants in the intervention group and 6/11 (55%) participants in the control group reported pain in the upper limb affected by stroke. At three months these corresponding data were: 5/13 (38%) in the intervention group and 5/11 (45%) in the control group.

13.1.3 Fatigue

Fatigue experienced by participants was determined by inclusion of a horizontal linear visual analogue scale (score of 0 = 'not tired at all' to score of 10 = 'extremely tired') at each outcome assessment. Participants were asked to consider fatigue in relation to the last month (question included at 1 month assessment) and last 2 months (question included at 3 month assessment) to cover the duration of the study. Data are shown in table 52.

Table 52: Fatigue severity

Fatigue VAS score	One month assessment		Three month assessment	
	Intervention group n = 13	Control group n = 11	Intervention group n = 13	Control group n = 11
(%)				
	1 (8%)	1 (9%)	-	-
1	-	-	-	-
2	1 (8%)	-	-	1 (9%)
3	-	-	2 (15%)	2 (18%)
4	1 (8%)	1 (9%)	-	
5	2 (15%)	5 (46%)	3 (23%)	2 (18%)
6	2 (15%)	-	1 (8%)	2 (18%)
7	4 (31%)	3 (27%)	3 (23%)	3 (27%)
8	-	1 (9%)	-	-
9	-	-	-	-
10	1 (8%)	-	1 (8%)	-
Total with scores >0	10 (77%)	10 (91%)	10 (77%)	10 (91%)
Median [IQR]	6 [4 – 7]	5 [5 – 7]	5.5 [4.5 – 7]	5.5 [3 – 7]
Min, Max	0, 10	0, 8	3, 10	2, 7
Missing	*1* (8%)	*0* (*0%*)	*3 (23%)*	*1 (9%)*

These data indicate that the majority of participants in both groups experienced fatigue throughout the duration of the study.

13.1.4 Increased muscle tone (spasticity) in the upper limb affected by stroke

To determine increased tone, data were sought from both participants and therapists. Participants were asked if they had noted any tightness in the arm affected by stroke and if so to give details. Therapists were asked to perform an assessment of the arm affected by stroke to determine the presence of increased tone and then to give a score for increased tone at the elbow using the Modified Ashworth Scale [103]. Results are shown in tables 53 - 56.

Table 53: Participant reported upper limb muscle tightness at one and three months

Upper limb tightness	One month assessment		Three month assessment	
	Intervention group n = 13	Control group n = 11	Intervention group n = 13	Control group n = 11
No n (%) Yes n (%) *Missing*	10 (77%) 2 (15%) *1 (8%)*	9 (82%) 2 (18%) *0 (0%)*	8 (62%) 2 (15%) *3 (23%)*	7 (64%) 2 (18%) *2 (18%)*

Table 54: Participant reported details about upper limb muscle tightness at one month

Muscle tightness details	Intervention group n=2	Control group n=2
Feel upper arm muscles (triceps) pulling on activity	1	-
Heaviness	1	-
After doing exercise feels tightness in right upper body	-	1
Shoulder	-	1
TOTAL	2	2
Missing	*0*	*0*

Table 55: Participant reported details about upper limb muscle tightness at three months

Muscle tightness details	Intervention group n = 2	Control group n = 2
Sometimes gets spasms in arms	1*	-
Upper arm, during the afternoon when medication starts to wear off	1	-
Contractures in left wrist and hand	1	-
Two falls in house didn't see GP or go to hospital. Reports no injury	-	1**
At odd times in shoulder	-	1*
Top of arm	-	1
TOTAL	3	3
Missing	*0*	*1*

* participant documented as responding 'no' to the question concerning presence of muscle tightness but details provided as free text.

** 'Yes / no' response to whether the participant had noticed arm tightness was missing and details do not relate to the upper limb / muscle tightness.

Table 56: Therapist determined location and severity (MAS at elbow) of increased muscle tone at one month and three months

Increased muscle tone (affected arm)	One month assessment		Three month assessment	
	Intervention group n = 13	Control group n = 11	Intervention group n = 13	Control group n = 11
Location of increased muscle tone n (%):				
Shoulder only	1 (8%)	2 (18%)	2 (15%)	5 (46%)
Elbow only	-	-	-	-
Wrist only	-	-	-	-
Hand only	3 (23%)	-	-	1 (9%)
Shoulder and elbow	1 (8%)	3 (27%)	-	1 (9%)
Wrist and hand	-	-	1 (8%)	-
Shoulder, elbow, wrist and hand	1 (8%)	-	-	-
Other combinations	-	-	-	-
TOTAL	6 (46%)	5 (45%)	3 (23%)	7 (64%)
Missing	*7 (54%)*	*6 (55%)*	*10 (77%)*	*4 (36%)*
Modified Ashworth Scale for elbow flexors n (%):				
0 (no increase in muscle tone)	8 (62%)	5 (46%)	8 (62%)	5 (46%)
Tone increasing: 1	4 (31%)	3 (27%)	1 (8%)	3 (27%)
1+	-	-	-	-
2	-	2 (18%)	1 (8%)	1 (9%)
3	-	-	-	1 (9%)
4	-	-	-	-
Total with scores >0	4 (31%)	5 (45%)	2 (15%)	5 (46%)
Missing	*1 (8%)*	*1 (9%)*	*3 (23%)*	*1 (9%)*

Data provided by participant response and therapist assessment were compared. Several discrepancies were noted:

- There were instances where the participant response was ‘no’ to the presence of muscle tightness but therapists documented increased tone (one month: intervention group = 5 participants, control group = 4 participants and at three months: intervention group = 1 participant, control group = 4 participants)
- There were also instances where the participant response was ‘no’ to the presence of muscle tightness but therapists recorded a score of greater than 0 on the MAS (one month: intervention = 4, control = 4 and three months: intervention = 0, control = 3) which indicted the presence of increased tone.
- In contrast, there was one control group participant who was recorded as responding ‘yes’ to the presence of muscle tightness but then recorded as scoring ‘0’ (no increase in muscle tone) on the MAS.

Data provided by therapists was compared and further discrepancies were noted. The number of participants with increased tone recorded as located around the elbow was smaller than the number of participants with MAS scores >0 (indicating increased tone at the elbow). The discrepancy at one month was intervention = 2 and control = 2 and the discrepancy at three months was intervention = 2 and control = 4.

If all responses that suggested any increased tone are combined (participant 'yes' to tightness, detail about tightness provided or therapist locates tone in one or more muscle groups and/or MAS >0), at one month 5/13 (38%) participants in the intervention group and 5/11 (45%) participants in the control group had increased tone. At three months these corresponding data were: 3/13 (23%) in the intervention group and 5/11 (45%) in the control group.

13.1.5 Serious adverse events (SAEs)

During the course of the study, four events were considered to fulfil the criteria for a SAE. There were two SAEs for two intervention group participants.

The first participant (from study site one) had two hospital admissions; one reported due to 'falls secondary to postural hypotension' and the second 'gastritis'. The second participant (from study site 3) also had two hospital admissions; one due to 'dizzy spells / falls' and one due to 'postural hypotension'. None of these SAEs were believed to be related to the RFTP programme.

13.2 Discussion

In the RAFTAS feasibility study, adverse events were recorded to check the suitability of recording processes for a Phase III study and also attempt to ensure there were no safety issues with the RFTP programme. In terms of safety assessment, it would not be appropriate to perform statistical comparisons between the groups but observation of the data does not appear to suggest any concerns as there were no obvious differences between groups.

There were a similar number of new medical problems reported from participants in both groups. As new medical problems were collected at blinded outcome assessments, a process to assess if an event was believed related to the RFTP programme was not included. However, considering the events recorded, it does not appear that any were likely be related to the RFTP programme.

Interpretation of pain and presence of increased muscle in the affected upper limb data were limited by the inconsistencies in data recording. However, overall, it appears that similar numbers of participants in both groups had pain and increased muscle tone during the study. Unfortunately, pain and increased muscle tone were not measured at baseline which may have been useful. It also appears that similar numbers of participants in both groups experienced fatigue during the study. The only SAEs reported were from intervention group participants, but these events were not considered related to the RFTP programme. Considering this, adverse events data collected during the RAFTAS feasibility study suggests the RFTP programme is safe.

Adverse events reported in previous studies evaluation RFTP in the upper limb are shown in table 57.

Table 57: Previous studies including RFTP for the upper limb after stroke: Adverse events

Author	Specific adverse events data collected	If no, data available in CONSORT diagram / narrative text	Adverse event(s) detail(s) as available
Turnton and Fraser, 1990[58]	No	No	Not reported
Kwakkel et al., 1999[56]	No	Yes	Time of AE/SAE unavailable. Reported reasons for study withdrawal; recurrent stroke (n=6), cancer (n=2), carotid endarterectomy (n=1), died (n=1).
Langhammer and Stanghelle, 2000[57]	No	No	Not reported
Blennerhassett, 2004[54]	No	Yes	Six months; Reported reason for withdrawal; fractured hip secondary to a fall (n=1).
Winstein et al., 2004[60]	No	Yes	Time of AE/SAE unavailable. Medical complications, admitted to hospital (n=2).
Van Vliet, 2005[59]	Yes	N/A	One month; ill (n=9), died (n=5). Three months; ill (n=12), died (n=12). Six months; ill (n=7), died (n=16).
Higgins et al., 2006[55]	No	Yes	Six weeks; myocardial infarction (n=1), fall and rib fracture (n=1), cancer metastases (n=1), groin pain (n=1).
Harris et al., 2009[63]	Yes	N/A	No SAEs. For intervention participants during the intervention period only (4 weeks); upper limb pain (n=15), fatigue (n = unavailable, mean 3/7 Fatigue Severity Scale).
Donaldson et al., 2009[62]	No	Yes	Six weeks; new stroke (n=1). Twelve weeks; unwell (n=5), died (n=12).
Pandian et al., 2012[64]	No	No	Not reported
Arya et al., 2012[61]	No	No	Not reported
Mares et al., 2014[66]	Yes	N/A	At randomisation; too unwell to receive intervention (n=1). During the intervention; 'overuse syndrome' recorded only (n=0).

Adverse events were poorly reported in previous studies into RFTP. In 10/12 [54-62, 64] (83%) studies specific adverse events were not collected. However, for 6/10 [54-56, 59, 60, 62] (60%) it was possible to determine some adverse events from the CONSORT chart [106]. Adverse event details determined for more than one study were; death [56, 59, 62], recurrent stroke [56, 62], unwell (non-specific) [59, 62], fracture secondary to fall [54, 55], and cancer [55, 56].

Two studies collected anticipated adverse events data [63, 66]. It is not possible to compare adverse events data as methods of collection were dissimilar to the

RAFTAS feasibility study. In the two previous studies [63, 66], data were only collected during the intervention period and at the time of programme practise. The GRASP study [63] evaluated a self-practiced programme and collected pain and fatigue severity using the pain VAS [102] and the Fatigue Severity Scale [113]. Authors stated that 28% of participants reported pain during the study (scoring 2-8 VAS) and pain levels were reduced to 'mild/non-existent' by week three (specific data unavailable). Fatigue levels were low (mean score = 3 out of a seven point Likert scale) over the intervention period.

The study by Mares et al., [66] discharged participants from the study programme if pain was reported to the study therapist on four consecutive visits [66]. A participant discharge due to pain was classed as an adverse event and data were collected for both study groups. Authors reported that no adverse events occurred.

In addition, the GRASP study [63] collected SAE data and reported no SAEs occurred.

Chapter 14. Repetitive arm functional tasks after stroke (RAFTAS) feasibility study: Views and experiences of study participants and therapists about the RFTP programme

Objective 8: To seek and report the views and experiences of study participants and therapists about the RFTP programme.

14.1 Results

14.1.1 Study participants

Participants' views of the RTFP therapy programme were sought during and at the end of the programme.

14.1.1.1 Participant self-reported comments collected at the time of recovery activity practice sessions

Participants were asked to record data on their recovery activity log sheets about: the time spent practicing recovery activities; whether help was provided by another person; comments about the recovery activity or RFTP programme; and reasons for stopping recovery activity practice sessions (before completing 20 repetitions).

Completed recovery activity log sheets were returned for 11/13 (85%) participants.

14.1.1.1.1 Time spent practising recovery activities

Four hundred and eighty four recovery activity log sheets were returned from 11 participants and data concerning time spent practising repetitions was recorded on 328 activity log sheets (68%). The median time spent practising the recovery activities was 9 minutes. The IQR was 3-12 and the range was 0.25 – 55 minutes.

14.1.1.1.2 Help provided from another person

A total of 200 comments were provided by 11 participants (table 58). On 165/200 (83%) of occasions participants were able to practice recovery activities independently. When help was provided this was verbal encouragement rather than practical support. On three occasions, participants needed help to complete the activity log sheets from a relative/carer.

Table 58: Help provided from another person

Theme	Number of times a themed comment made	Number of participants to make a themed comment	Example (participant number)
No help	165	11	*'No help with exercise' (103)*
Encouragement	21	2	*'Encouragement'* (106)
Assistance of therapist	5	2	*'To complete form and re-instruct on movements'* (303)
Help provided but unspecified	3	2	'(Name) *helps*' (106)
Help with completing activity log sheets	3	1	*'Scribe'* (203)
Verbal help	2	1	*'Verbal instructions'* (304)
Timing	1	1	*'Timing'* (201)
TOTAL comments	200	11	-

14.1.1.1.3 Participants' comments about the recovery activity / RFTP programme

Comments were provided by 10/13 (77%) participants. A total of 229 comments were coded and then categorised under four headings; positive experiences; negative experiences; fatigue / upper limb symptom; and additional information. Participants' comments about the recovery activity / RFTP programme are shown in table 59.

Table 59: Comments regarding the recovery activity / RFTP programme

Category	Code	Number of times a coded comment made	Number of participants to make a coded comment	Example (participant number)
Positive experiences	Upper limb improving (function and / or symptoms) or activities easier	101	10	*'Hand movement almost back to normal.'(304)*
	Positive feedback specific to activity / programme	6	2	*'Good to do'(103)*
TOTAL - Positive	-	107	7	-
Negative / mixed experiences	Difficulty completing the recovery activity / found it challenging	37	7	*'Finding hard to grip pen after a while'(204)*
	Frustrating	2	2	*'Frustrating but worth persevering with'(207)*
TOTAL - Negative	-	39	7	-
Fatigue / upper limb symptoms	Fatigue	25	3	*'Feeling tired as repetitions progressed'(302)*
	Arm feels heavy / cramp / stiffness	7	2	*'Cramp for a while. Smooth 2nd half'(201)*
	Pain (unaffected upper limb specified / implied)	4	1	*'Pain right (unaffected) shoulder' (303)*
	Pain (affected / unaffected upper limb not specified / implied)	6	4	*'Wrist still sore after slip'(210)*
	Pain (other body part)	3	1	*'Back ache problems' (302)*
TOTAL - Fatigue / upper limb symptoms	-	45	4	-
OVERALL TOTAL	-	191	10	-

The majority of comments were positive experiences of the programme (107/191, 56%) and most positive experiences related to the participant's upper limb improving / activities becoming easier to complete (101/191, 53%). Thirty nine negative / mixed experience comments were made (20%), which mainly referred to activities being difficult / challenging. Fatigue was reported by three participants on 25/191 (12%) occasions.

14.1.1.1.4 Reasons for stopping recovery activity practice sessions

Eleven participants reported that they stopped at least one recovery activity session before completing 20 repetitions (see table 60). There could be more than one reason for stopping each recovery activity session. A total of 63 comments were provided. Fatigue was the main reason for not completing recovery activities: 3

participants stopped recovery activity practice due to fatigue for a total of 16 occasions.

Table 60: Reason for stopping recovery activity practice session

Category	Code	Number of times a coded comment made	Number of participants to make a coded comment	Example comment (participant number)
Fatigue / medical issue	Fatigue	16	3	*'Difficult to continue, tired' (302)*
	Medical (general)	5	1	*'Nose Bleeds' (304)*
	Upper limb swelling	5	1	*'Left hand fingers swollen' (302)*
	Non specific	4	1	*'Not feeling well' (203)*
	Pain	2	2	*'Left hand hurting' (302)*
TOTAL – Fatigue / medical issue	-	32	4	-
Recovery activity related	Recovery activity difficult	7	4	*'Couldn't hold peeler for 20 reps' (106)*
	Participant choice	1	1	*'Didn't want to do anymore' (302)*
	Did all could manage	1	1	*'Done most I could' (103)*
TOTAL - Activity related	-	9	4	-
Medical appointment	Medical appointment / usual post stroke rehabilitation	5	2	*'Hospital appointments and tiredness' (302)*
	Hospital discharge	1	1	*'Did not do as being discharged from hospital' (106)*
	Late start following study therapist session	1	1	*'Late start after (therapist name) went' (103)*
TOTAL - Medical appointment	-	7	4	-
Everyday living activity	Participated in more ADLs	2	2	*'Tried an outing shopping. Very, very tired, forgot' (302)*
	Hospital visitors	2	1	*'Went out, visitor' (103)*
	Other appointment (personal)	1	1	*'Had my hair done' (103)*
TOTAL- Everyday living activity	-	5	2	-
Forgot	-	2	1	*'Forgot' (302)*
Other	-	8	4	*'Starting morning session on Tuesday' (207)*
OVERALL TOTAL	-	63	11	-

14.1.1.2 Participant feedback collected during therapy review sessions and during the final therapy review

At each therapy review session, therapists were asked to record participants' comments about the RFTP programme (table 61). Results were available for 10/13 (77%) participants. Six participants reported that they had benefited from the programme. Five reported the programme was difficult / tiring. A total of 54 specific comments were recorded. 37/54 (69%) were 'good points' and 9/54 (17%) were 'bad points' about the RFTP programme.

Table 61: Participant comments about the programme

Category	Code	Number of times a coded comment made	Number of participants to make a coded comment	Example comment (participant number)
'Good points'	Improving / benefiting from the programme	7	6	*Feels hand has got better (210)*
	Participant self-progressing own rehabilitation	6	3	*Programme is giving more confidence for patient to use hand for other activities outside the programme (204)*
	General positive comments	6	4	*It is really good (106)*
	Participant managing to complete the programme	6	5	*Managing well (210)*
	Activities enjoyable	5	3	*Enjoying the exercises as its making her use her affected hand (103)*
	Programme helps focus on rehabilitation	4	2	*Finding it mentally helping to keep going and motivated (207)*
	Extra therapy	2	1	*Good - extra therapy (207)*
	Activities easy	1	1	*Finding activities easy this week. Ready to move on (201)*
TOTAL - 'Good points'		37	9	
'Bad points'	Programme difficult / tiring	5	5	*Finding it a bit difficult but rewarding (201)*
	Participant unwell/ activities aggravating symptoms	2	1	*W3.17 - Aggravated back problems (302)*
	Difficult to find time to practice	1	1	*Sometimes difficult to fit in but managing (101)*
	Programme not enjoyable	1	1	*Patient knows he has to do them but not particularly enjoying them (110)*
TOTAL – 'Bad points'		9	8	
Other	Has not completed the programme	2	2	*Hasn't completed the programme - the participant was discharged… handbook was lost during the move so he was unable to complete any activities (110)*
	Participant struggling to feedback	2	1	*Difficult to express opinions due to dysphasia (203)*
	"No comment" response	4	3	N/A
TOTAL- All comments	-	54	10	-

During therapy review sessions and at the final therapy review, local study therapists were asked to review the participant's recovery activity log sheets, specifically to check completion and ask participants for feedback. Therapists recorded their own

comments about recovery activity log completion and also responses from participants (see table 62). Comments were collected from 10/13 intervention group participants.

A total of 38 responses were collected. Responses were coded and categorised under two main categories; ‘completing activity log sheets well’ and ‘activity log sheets incomplete’. The majority of comments (22/38, 60%) related to ‘completing activity log sheets well.’

Table 62: Comments about activity log sheet completion

Response category	Code	Number of times a themed comment made	Number of participants with recorded themed comment	Example (participant number)
Completing activity log sheets well	Participant completing activity log sheets	15	7	*'All completed with comments'* (201)
	Feedback about completion – no problems completing	5	3	*'Easy to fill in'* (210)
	Positive feedback about activity log sheet design	2	2	*'Feels a really good idea along with log sheets'* (106)
TOTAL Completing activity log sheets	-	22	7	-
Activity log sheets incomplete	Not completing programme and / or activity log sheets	6	3	*'Not completed. Patient reports he is doing them as and when'* (110)
	Feedback about completion - some difficulties with self-completion	3	1	*'Found sheets ok but difficult to fill in due to dominant hand being affected'* (103)
	Feedback about completion –needed support	2	2	*'Husband supporting work to complete log sheets'* (302)
	Reason for non-completion – Practical	3	3	*'He couldn't reach his file and also did not have a pen'* (101)
	Feedback about the recovery activities – some difficulties in completing activities	2	2	*'Found extra tasks hard. Glasses poor fit, made tasks harder.'* (103)
TOTAL Activity log sheets incomplete		16	7	-
TOTAL Comments	-	38	10	-

Further participant feedback about the RFTP programme and study materials was collected by therapists during the final therapy session by the inclusion of specific questions (table 63). Recorded free text responses were coded. Seven participants had final therapy session documentation completed (54% of intervention group participants), and no final therapy session forms were completed at Site 3.

Table 63: Participant feedback recorded at final therapy sessions

	Number of participants (n = 7)	Example comment (if appropriate)
Participating in the study early after stroke Coded comments:		
Good to start the programme early after stroke	7	*'It was important for that to happen straight away to get my brain trained to start working again' (participant 207)*
Benefited from starting programme early after stroke	5	*'Found it good to move straight from having stroke into programme in order to keep rehab motivation going' (participant 201)*
Goal setting Useful?		
Yes	7	-
No	0	-
Missing	0	-
Coded comments:		
Gave focus / incentive	2	*'It gave something to focus on and practise. I was able to practise by myself' (103)*
Encouraged thinking about other things they could do (outside of the programme)	2	*'…it encouraged me to think of other things for myself e.g. Washing dishes…' (201)*
Benefited from using goals	1	*'…. helped get back to normal' (207)*
Hard but good	1	*'Hard but good' (203)*
No comments provided	1	-
Cueing technique Used?		
Yes	1	-
No	6	-
Missing	0	-
Coded comments:		
If yes,		
Memory aid	1	*'They helped memory' (106)*
If no,		
Felt it was unnecessary	4	*'Did not need cueing technique, were able to remember to practise' (103)*
Not encouraged by therapist	1	*'Not encouraged by therapist as very motivated to carry out tasks independently' (207)*
Unclear why not	1	*'Unclear why not but compliance was variable depending on other issues going on with rehab' (203)*

Table 63: Feedback recorded at final therapy sessions (continued)

	Number of participants (n = 7)	Example comment
Independent practice		
Coded comments:		
Managed independently		
Fine / easy	6	*'OK, just used sheets to remind the picture helped. It was good, I has something to do in my own time' (103)*
Clear what to do	3	*'Found it fine. Was always clear about what to do and had a try with therapist first' (204)*
Required assistance	2	-
Needed help from family	1	*'Family encouraged which is important. ….. Son helped throughout assisting to count and point out when errors were made' (106)*
Difficult as needed help	1	*'Hard because needs somebody to help' (203)*
Twice weekly therapy reviews		
Too often	0	-
Not often enough	1	-
About right	6	-
Missing	0	-
Coded comments:		*'Benefitted from regular reviews to keep motivated and move forward' (207)*
Twice per week appropriate	3	
Twice per week not enough	1	*'Preferred if come every day' (203)*
No comments provided	3	-
Recovery activity log sheets		
Coded comments:		
Positive comments (total):	6	-
Pictures helpful	2	*'Found pictures helpful' (103)*
A/L sheets useful / easy to use	5	*'Easy to understand' (204)*
Difficulties with completion (total):	3	-
Problems with recording	2	*'Good but found it difficult to fill out. Can't spell and struggled to read' (203)*
Areas for improvement	2	*'Monotonous having to tick all 20' boxes' (210)*

Table 63: Feedback recorded at final therapy sessions (continued)

	Number of participants (n = 7)	Example comment
Opinions about the participant handbook Coded comments:		
Useful / good	6	*'All at hand, useful to refer back to' (106)*
Did not read information provided	2	*'Didn't really use the additional information in handbook, just concentrated on activities' (201)*
No comments provided	0	-

All participants who provided feedback felt that it was good / beneficial to commence the programme early after stroke and that goal setting with the local study therapist was useful. Most participants did not use the cueing technique (6/7, 86%) as they felt it was unnecessary. The majority of participants managed to practise the programme independently of the local study therapist (6/7, 86%) and felt that twice weekly reviews by the local study therapist was 'about right' (6/7, 86%). Although the majority of participants provided positive feedback about the activity log sheets (6/7, 86%), three participants (43%) experienced difficulties in completing log sheets. The majority of participants found the participant handbook useful / good (6/7, 86%).

14.1.1.3 Participant feedback collected at the end of participants' programme intervention period (semi-structured interviews)

Recruitment of participants to take part in semi-structured interviews did not go as well as planned. There was a delay in inviting participants to take part in the interviews during the RAFTAS feasibility study due to the thesis author awaiting appropriate training to undertake and analyse the interviews. Once relevant training had been completed, participant recruitment to the study had slowed down. After liaising with local site staff, it was determined that some of the recruited participants were not appropriate to be invited to interview (e.g. due to ill health / hospital admission). Participants who had been recruited earlier in the study were considered to be too long after receiving the intervention to be approached to recall their experiences. A total of three participants were approached and all agreed to be interviewed.

Two participants were interviewed from Site 2 (participants A and B) and participants indicated the RFTP programme had been delivered as intended by one (and the same) local study therapist.

One participant (participant C), was interviewed from Site 3, and the RFTP programme had been delivered by two different local study therapists. During the interview of participant C it became apparent that the RFTP programme had not been delivered as intended (the participant had not been regularly reviewed). .

Participant interviews lasted from 15 minutes to 30 minutes and transcriptions ranged from 6,746 – 9,632 words in length. An example of initial coding of a participant interview is shown in Appendix 13. Interview data were analysed using thematic analysis (see section 5.3.18). Participant feedback was coded and categorised into two themes; what participants felt worked well (table 64) and what participants felt didn't work so well (table 65). An example of Results of interview data are presented in table format, following a pragmatic approach due to low numbers of interviewees.

Table 64: What participants felt worked well

Participants	Code	Sub codes	Example comment (participant)
A, B and C	Programme design	Number of repetitions of activities acceptable	*"I found that I had the time to do the twenty in the morning and twenty and hour later on different other stuff"* (Participant A)
		Happy to independently practice the activities	*"It's quite easy on your own, it's easier. It's better on your own because you'll do it"* (Participant B)
	Programme delivery	Managed to log activity practice on 'activity log sheets'	*"They can see you focussing, and every single day you're doing it, you know you're getting better and then you can look back on that week and think, God, I fastened my shoelaces…"* (Participant A)
		Acceptable to follow the programme early after stroke	"…*the sooner the better"* (Participant A)
		Liked having a programme to practise in between formal therapy sessions	*"… it was good because it passes the time and gives you something to focus on; otherwise you'd just be sat in the chair" (Participant C)*
A and B	Programme design	Goal setting valuable / liked being involved	*"(therapist name) asked us what I needed – what the best was for me….. you know - to pick mobile phones up and stuff like that so it was both of us really - you know - deciding together"* (Participant A)
		Sufficient range of recovery activities	*…. there was certain things for your hands and your arms, everything that she give us was for that purpose*…(anything missing?),.. *Not that I can think of, no"* (Participant B)
		Benefited from functional nature of activities	*"….I found out, I couldn't lift the fork to hold it you know? Then after a couple of goes I got used to it and got pretty handy"* (Participant B)
	Programme delivery	Number of therapy reviews per week appropriate	"…*you've got to show it when she comes back that you can do it"* (Participant B)
		Therapy reviews helped motivation to practice programme	*"…. the things that were given to me (were) everyday tasks to do. I mean, when you go out, you've got to fasten your shoelaces, you've got to fasten your zip" (Participant A)*
	Additional positive benefits	Programme helped confidence in ability to complete ADLs	*"It definitely gives you the confidence to go and do other things"* (Participant A)

Table 65: What participants felt did not work so well

Participant(s)	Code	Sub codes	Example comment (participant)
A and B	Programme delivery	Recovery activity log sheet design	*"Well, I thought that was a bit silly (marking the repetition grids)… By the end of the week you're like ahhhh... I'm doing it but I just tick them off (at the end)"* (B)
B	Programme design	Problems with clarification of a recovery activity repetition	*"I did count to twenty, you know, one….two… but sometimes I couldn't remember if she'd said 20 was lifting it up and taking it down"*
C	Programme design	Programme not challenging enough	*"Well it was very easy for me, and actually, boring, I found it boring"*
		Standard exercises would be better than an individualised programme	*"I think maybe a standard set of exercises would have been better than just two exercises. I know (therapists name) threw in a couple more at the end but we didn't have any sheets so I just used to look at them to do them"*

14.1.2 Local study therapists

Local study therapists' views of the RTFP therapy programme were sought during participants' final therapy sessions and at the end of the study intervention period.

14.1.2.1 Local study therapist feedback collected at participants' final therapy sessions

Local study therapists were requested to record feedback about the RFTP programme and study materials when completing the final therapy session for each participant.

Local study therapists' feedback collected from the final assessment form was very limited. A total of 7/13 (54%) final therapy session forms were completed by local study therapists. Local study therapists at Site 3 did not complete any final therapy session forms. Free text comments provided by local study therapists were coded and categorised (table 66). The majority of feedback collected was positive, and related to the programme design.

Table 66: Local study therapist feedback collected at the participants' final therapy sessions

Theme	Code		Local study therapist(s)	Number of themed comments made	Example comment
Positive	Programme design	Recovery activities	A	3	*'I feel the recovery list is a great way to negotiate goals giving concrete examples. It also allows for manipulation of activities to meet other goals than intended as the movements cross over.'*
		Patients achieving goals / responding well to the programme	B	3	*'Programme is being well received by patients and helping them reach their goals quickly which aids motivation.'*
	Programme empowered participants		A and B	3	*'The programme has really benefitted patient, gave her some ownership of goals and encouraged her to try things for herself.' (study therapist B)*
	Other positive		A	1	*'The whole process feels very positive, organised and purposeful.'*
TOTAL Positive	-	-	-	10	-
Suggested improvement	Improvement to study materials	Activity log sheets	B	1	*'…could it be condensed in any way? Perhaps a sheet to cover the whole four weeks and more upper limb assessment? Separate weekly sheets rather than x2 days to a sheet of activities?'*
TOTAL Suggested improvement	-	-	-	1	-
Other observations	Ability to practise the programme independently	Difficulty in practising / recording activities	A and B	3	*'Study subject did have support every time from family member so did not complete alone.' (study therapist A)*
	Programme delivery		B	1	*'Pushed therapist to write increasingly more difficult tasks.'*
TOTAL Other observations	-	-	-	4	-

14.1.2.2 Local study therapist feedback collected at the end of the study intervention period (semi structured interviews)

At the end of the study intervention period, three local study therapists were invited and participated in semi-structured interviews (one per study site) conducted by the thesis author.

Local study therapist interviews lasted from 45 minutes to 55 minutes and transcriptions ranged from 3,118-4,057 words in length. Interview data were analysed using thematic analysis (see section 5.3.18). Local study therapist feedback was coded and categorised under three themes; ‘what local study therapists felt worked well’ (table 67), ‘what local study therapists felt did not work so well’ (table 68), and ‘suggested RFTP programme improvements / considerations for a Phase III study’ (table 69). Results of interview data are presented are presented in table format, following a pragmatic approach due to low numbers of interviewees.

Table 67: What local study therapists felt worked well

Codes	Sub codes	Local study therapist(s)	Example comment (local study therapist)
Programme design	Patients benefited from joint goal setting / recovery activity selection	A, B and C	*"….they quite quickly started to identify things for themselves, I think they felt involved with setting their own goals and so then you'd go back and they'd already tried things"* (B).
	Sufficient range of activities		*(Wide enough range of activities?) "Definitely. I think, that got easier to use, the more you used it.*
	Direct practice of functional tasks beneficial		*"I also feel that it gives them a feel of what they can do and a feel of . . . that they're not helpless.. by practising it they get better at the activity (in everyday life)."* (C)
	Part task practice beneficial		*"it was actually looking at much smaller movements like, just touch the cup, so it was really achievable for the patients…. I thought that worked well."* (B)
	Independent practice was beneficial for participants		*"I think giving them, from day one, things to do themselves, and maybe seeing the outcomes…I think that'll kind of set them up for when they go home"* (A)
	Seven day / week activity practice acceptable		*(Is it acceptable?) "Yeah. Practice every day, yeah."* (B)
	Number of therapy reviews per week appropriate		*"It was enough that they were ticking things over, but it was frequent enough that it was keeping them interested"* (B)
	'Optional' category useful	A and B	*""I think that kind of leaves that open for, you know, anything the patient wants to do" (*B)
	Length of programme (4 weeks) appropriate		*"I think that was about right."* (A)
	2 goals / activities appropriate	A and C	*"… I think two is maybe better because if they have more I think they'd lose their focus, yeah."* (C)
	Cueing technique beneficial for some participants		*"Yeah, one particular person, it reminded her"* (C)
	Twice daily practice manageable	B and C	*"Twice a day is more than manageable…."* (B)
Programme delivery	Therapist documentation clear and easy to complete	A, B and C	*"They were quite self-explanatory."* (A)

Table 67: What local study therapists felt worked well (continued)

Codes	Sub codes	Local study therapist(s)	Example comment (local study therapist)
Other positive feedback	Reported positive participant feedback		*"They've (participants) all been really positive, yeah. I've not had anyone I don't think who's not been positive about it." (*B)
	Programme considered beneficial to participants		*"We've seen really good results; it's been a really nice way of breaking tasks down into really sort of, very achievable goals"* (B)
	Programme did not interfere with usual post stroke rehabilitation, but enhanced usual post stroke rehabilitation		*"It didn't interfere with it (usual care), it was an extra….. I think it could be very easily slotted in, yeah, yeah."* (B)

Table 68: What local study therapists felt did not work so well

Codes	Local study therapists	Sub codes	Example comment (local study therapist)
Programme design	A, B and C	Independent practice (some participants)	*"… well a few of them weren't doing the exercises at all, and then a couple were saying that it was a bit patchy when they did them."* (A)
		Poor participant logging of recovery activity practice (some participants)	*"….I knew that she'd been practising because she could remember everything, however the (activity log) sheet wasn't really filled out a lot of the time"* (A)
	B and C	Cueing technique not required by most participants	*"I tried to use it with people and I would suggest things but I didn't feel it was all that necessary…. but it didn't matter; the patients were really on board"* (B)
		Warm up stretch not used	*"I will say though, that people didn't tend to do the warm up activity."* (C)
Local study therapist staffing	A, B and C	Challenges in staffing delivery of the programme	*"For me it was just, more the logistics of doing it….fitting them into your diary, yeah, yeah, especially with the extra staffing pressures that we had (staff sickness)…."* (A)
Programme delivery	B and C	Large volume of paperwork required – sometimes logistically difficult	*"I think the only disadvantage, I think this just goes back to the amount of paperwork"* (B)

Table 69: Suggested RFTP programme improvements / considerations for a Phase III study

Codes	Local study therapist(s)	Sub codes	Example comment (local study therapist)
Programme design improvement	A, B and C	Individualise intensity of recovery activity practice	*"I think you could encourage people to do more (than 20 repetitions). I think maybe it would need to be depending on the patient."* (B)
Programme delivery improvement	B and C	Simplify recovery activity log sheets	*"…. maybe recording the repetitions rather than having the tickies (repetition grids), I would maybe just get them to write it at the end because a lot of them didn't fill in the ticks."* (B)
Future local study therapists selection		Use of 2 local study therapists per site (one ward based and one community based)	*"…I'm sure how much it would matter if it did have a change of therapist in the community because every time you see them you're moving the goals on anyway"* (B)
Future local study therapists selection	C	Importance of careful selection of local study therapists	*"…..being selective about who you've chosen (local study therapist) , somebody that's going to be organised"* (C)

Local study therapists A and B both indicated possible usual post stroke rehabilitation therapy contamination:

"I think, the therapists that were maybe supporting them in the usual care, you know, therapy, seeing what other things that they were doing, kind of gave them, a realisation that they can do a bit more for themselves and how to progress that" (local study therapist A).

The majority of feedback from local study therapists concerned elements of the RFTP programme design and delivery that worked well.

14.2 Discussion

Overall, participants were positive about the RFTP programme and felt that the timing of the intervention in relation to stroke and twice weekly review by a therapist were appropriate. Participants were able to undertake self-practice and found goal setting helpful. They felt that cueing of activity practice into their daily routine was not needed. Not all participants felt that they had received the RFTP programme as intended and felt disappointed as a result. Fatigue was reported by several patients and is a common problem after stroke [21].

The median reported time taken to complete recovery activity repetitions was 9 minutes, suggesting that activity practice took an acceptable length of time. Participants appreciated the handbook but some found the activity log sheets difficult to complete because of their neurological deficit.

Several approaches were used to report the views and experiences of participants randomised to receive the RFTP programme. Information was collected prospectively and retrospectively. Response rates were lower than expected, especially from Site 3, so there may be a response bias in these results.

Feedback indicated that the RFTP programme was well received by local study therapists. The majority of feedback was positive. Therapists were supportive of the content, timing, and method of delivery of the intervention. Local study therapists highlighted some areas for consideration for a Phase III study. These included further tailoring of the intervention for individual patients and reducing/simplifying paperwork.

For the semi-structured interviews, it is important to note that local study therapists were aware that the interviewer (thesis author) had designed the RFTP programme. The thesis author encouraged local study therapists to be candid about their views

and experiences, but it is not possible to establish if knowledge of the thesis author's involvement in the study impacted on local study therapists' feedback.

Chapter 15. Repetitive arm functional tasks after stroke (RAFTAS) feasibility study: Study outcome and lessons learnt to inform the design and conduct of a Phase III study

15.1 RAFTAS feasibility study outcome

Thebane et al., [104] described the potential outcomes of feasibility studies as:

'(i) *stop, main study not feasible; (ii) continue, but modify protocol (feasible with modifications); (iii) continue without modifications but monitor closely (feasible with close monitoring) and (iv); continue without modifications (feasible as it is)'* (p. 5) [104]

The RAFTAS feasibility study has demonstrated that a multicentre randomised controlled trial to determine the clinical effectiveness of the upper limb RFTP therapy programme is feasible with modifications to the protocol. Lessons learnt to inform the design and conduct of a Phase III study are described below.

15.2 Lessons learnt to inform the design` and conduct of a Phase III study

15.2.1 Selection of study sites

NHS site selection will be an important issue for successful completion of a multicentre Phase III study. One of the strengths of the RAFTAS feasibility study was that it was a multicentre study undertaken in sites which are typical of sites likely to participate in a Phase III study. Pilot / feasibility studies are often undertaken in a single centre where the chief investigator is based, with strong local ownership and engagement of clinical and research teams. This can lead to over-optimism about the feasibility of a multicentre study.

15.2.1.1 Support of study sites

Valuable insight about issues likely to be encountered in a Phase III study has been obtained, with an understanding about the type and amount of support sites are likely to need from the study co-ordinating centre. Multicentre stroke rehabilitation studies are relatively rare and 2/3 sites had limited experience of stroke rehabilitation research. Study sites would need considerable training, support and advice about: recruitment; provision of the intervention; undertaking outcome assessments; ensuring blinding; reporting adverse events; and timely completion of study documents. The amount of regular support required should not be underestimated. It

may be helpful to have several linked sites within a region supported by a local study co-ordinator who visits sites regularly.

15.2.1.2 Study site selection process

No formal criteria were set for selecting sites for the RAFTAS feasibility study - the three sites were invited to participate by the study team. A Phase III study would be open to sites around the UK and criteria and a process for site selection could be developed. An expression of interest form would be required to seek information about service configuration, patient flow and repatriation, to ensure the RFTP programme is compatible with local service provision. The quality of the local stroke service could be assessed by reviewing a site's Sentinel Stroke National Audit Programme (SSNAP) performance which will shortly be expanded to include community services.

In selecting sites and throughout a Phase III study, the commitment of a stroke service to the trial as well as their ability to deliver the study as per protocol is key. Prior to final site selection, sites could be visited by the study co-ordinator to ensure that the organisation and key individuals are willing and able to deliver the study. The importance of teamwork between local NHS research support staff and therapists who provide the study intervention is crucial to study success. Evidence of successful recruitment to stroke rehabilitation studies and the research experience of stroke unit and community staff should also be considered. Where possible sites should have a track record of recruiting participants to NIHR CRN: Stroke portfolio studies to time and target.

15.2.1.3 Study site research portfolio and impact of funding models

A number of eligible patients were not approached as they were participating in studies which did not allow co-enrolment. These were hyper acute and acute drug studies. Provided that there are no potential interactions between interventions, and assessments are not too burdensome, patients should be offered the opportunity to participate in a second study. The compatibility of a future Phase III study with the site's portfolio of research studies would need determining and discussions about co-enrolment held with the chief investigators of ongoing studies.

In the RAFTAS feasibility study, funding for the upper limb RFTP programme was a NHS excess treatment cost [114]. In the UK, there is wide variation between NHS organisations in their approach to NHS excess treatment costs. Some NHS

organisations provide additional funding to individual therapists or rehabilitation services to deliver study treatments, whilst others agree for study treatments to be undertaken within the current service budget. In the RAFTAS feasibility study, the programme was delivered by local NHS therapists in addition to their usual work load and therapists did not always have dedicated time to provide the intervention and to complete study documents. The local approach to excess treatment costs and the views of local therapists about delivering the upper limb RFTP programme within the local excess treatment costs policy would need considering in future study site selection. The approach of a NHS organisation to excess treatment costs may impact upon delivery of the intervention and whether or not a site agrees to participate in the study.

15.2.2 Recruitment

15.2.2.1 Recruitment rate

It is important that a Phase III study sets a realistic recruitment target for study sites. A recruitment target of 1-2 participants per month per site is achievable. NIHR CRN: Stroke has recently recommended a recruitment target of 1.8 participants per site per month for stroke rehabilitation trials [107]. It is unlikely that sites in a Phase III trial would be able to treat more than two intervention participants at any one time because of the additional work load for local NHS therapists, so there is likely to be a recruitment ceiling at study sites.

In the RAFTAS feasibility study, NIHR SRN staff recruited study participants but this organisation has now been superseded by NIHR CRN: Stroke. Recruitment to stroke rehabilitation studies has not fallen since this transition [107] but research support staff are now more likely to recruit participants to studies across a number of clinical areas, not just stroke. For a Phase III study, it would be important that training and data required for screening logs are appropriate for generic research staff.

15.2.2.2 RFTP programme utility for clinical practice

The proportion of patients eligible for the study was low at (5%), questioning the RFTP programme's utility in clinical practice. However, the number of patients who would be able to undertake the programme in clinical practice may be greater than 5%. In the RAFTAS feasibility study, eligibility status was missing for some patients and the reason for ineligibility was not recorded for 337/1,079 (31%) of patients. A proportion of these patients may have been excluded due to other study eligibility criteria rather than an inability to undertake the RFTP programme.

There were logistical issues relevant to the study and research practices, which meant a high proportion of eligible patients (27/55, 49%) were not approached about the study, and these patients may have been able to undertake the RFTP programme itself. Some eligible patients were not approached due to inability to co-enrol with other studies or unavailability of local study site staff; issues that would not affect participation in the RFTP programme in clinical practice.

15.2.2.3 Local study site staffing

As experienced in the RAFTAS feasibility study, potentially eligible patients may not be recruited due to either lack of availability of NHS research support staff to recruit participants or local NHS therapists to deliver the upper limb RFTP therapy programme. Unless ring fenced resource is available to provide study treatments, a Phase III study would need to allow for the impact of holidays, sick leave, change of staff etc. upon recruitment and delivery of the intervention.

In addition, the study timetable and recruitment strategy would need to have a contingency plan for potential delays to the intended recruitment start date (e.g. in obtaining research governance approvals) for changes in local site staff during the study period, and early site closure.

15.2.3 Eligibility criteria

The RFTP programme has been designed to be appropriate for patients with a wide range of upper limb impairments. Participants were willing to take part in the study within 14 days of acute stroke and felt that this was a reasonable time to be approached. The eligibility criteria were pragmatic and based upon clinical judgement, as would be used to decide whether or not to provide the treatment in clinical practice. Eligibility criteria were easy to apply and can be used in a Phase III study.

However, a measure of arm function (the ARAT [75]) may be required as an eligibility criterion for a Phase III study. The maximum ARAT score is 57 and the minimum clinically important difference is 5.7 points [115]. Because of a ceiling effect, patients who score 51 or above at baseline may need to be excluded so that a clinically important difference can be detected at one and three months.

15.2.4 Consent and randomisation / stratification

The consent and randomisation procedures worked well and could be used in a future study. A centralised electronic randomisation procedure is the gold standard

randomisation procedure. In a Phase III study, randomisation will be stratified by site to ensure that each site is allocated a similar proportion of intervention and control patients. Participants would be stratified by ARAT score at randomisation, as it is important that groups are balanced at baseline in terms of severity of upper limb function.

15.2.5 The RFTP programme (intervention)

The RFTP programme allows for individualisation of therapy within a standardised structured framework. The intervention has been carefully developed based upon available research evidence and with patient, carer and therapist involvement at all stages. The intervention has been described using TIDieR (Template for Intervention Description and Replication [77]) which provides a standardised structure for describing the RFTP programme. The therapy manual and participant documents could be used in a Phase III study and will need only minor modification.

15.2.5.1 Adherence to the RFTP programme

It is important to report both the intended intervention and the actual intervention delivered. However, these data are often lacking in rehabilitation trials. The RAFTAS feasibility study has collected data about the amount and content of RFTP programme received, although data completeness could be improved. Therapist adherence to the intervention was good at 2/3 sites. It will be important to monitor therapist adherence to the intervention through regular oversight by the co-ordinating centre in a Phase III study. The RAFTAS feasibility study collected data about self-reported practice, a Phase III study may also wish to consider using an objective measure e.g. accelerometer to measure arm activity during recovery activity practice sessions.

Ideally interventions should not be evaluated while sites are at the start of a learning curve for delivering a new treatment. A run in period prior to commencing randomisation would be valuable as this would enable each site to become familiar in delivering the intervention prior to joining the study. Pre-specified parameters could be set about intervention provision to ensure that they are delivered as per protocol. However, a run in period may not be possible because of the additional costs involved.

15.2.5.2 Process evaluation

Problems encountered with delivering the RAFTAS feasibility study (predominantly at one site), indicated the importance of including a process evaluation in a Phase III study. Process evaluation is a method of assessing how the intervention is being delivered and is considered essential when evaluating complex interventions [78, 116] such as RFTP. It is important to understand the contextual factors that contribute to successful or unsuccessful intervention delivery, as lack of intervention impact may be due to problems with delivery rather than ineffectiveness of the intervention [78]. The design of a Phase III study could incorporate staff surveys, qualitative interviews with site staff and participants and extraction and analysis of therapy notes.

15.2.5.3 RFTP programme delivery and dose

Participants were able to undertake and record self-practice sessions with twice weekly review by therapists in both hospital and community settings. Eighty repetitions per day could be achieved by many patients. Some participants recorded >80 daily repetitions. A Phase III study could consider tailoring the number of repetitions and time spent undertaking repetitions to a participant's abilities and wishes, as more able participants may be able to achieve ≥200 repetitions per session [91, 117]. It will be important to monitor participant adherence to the intervention in a Phase III study.

A Cochrane overview of systematic reviews examining interventions for improving upper limb function after stroke (2014) [25] found moderate quality evidence to support that more than 20 hours additional task specific training had a beneficial effect. In the RAFTAS feasibility study, it was not possible to report the number of hours of RFTP undertaken by participants due to poor data quality. The time spent practicing the RFTP programme is a key data item and data quality would need to be improved and carefully monitored during a Phase III study. A Phase III study should consider providing an additional 20 hours of RFTP compared with the control treatment.

15.2.5.4 Goal attainment and cueing technique

A Phase III study may wish to consider using formal goal attainment scaling rather than the goal achieved 'yes / no / partially' used in the RAFTAS feasibility study. Due to poor compliance, the use of the cueing technique to initiate recovery activity practice needs to be reviewed.

15.2.6 Control treatment and usual post stroke rehabilitation

In the RAFTAS feasibility study, usual post stroke rehabilitation was selected as the control treatment in order to assess the effectiveness of the intervention in addition to current clinical practice. Control group participants also received a Participant Handbook containing advice and information. In a Phase III study, usual post stroke rehabilitation should continue to be the control treatment. To minimise contamination of usual care in a Phase III study, local study therapists could provide either intervention or control therapy, although the logistics would be challenging.

As the RFTP programme is in addition to usual post stroke rehabilitation, possible effects of the RFTP programme observed in a Phase III study may be due to an increase in therapy intensity. Including an additional randomisation group that would receive either a different intensity of RFTP or an attention control could be considered in a future study, but additional group(s) would significantly increase the sample size, study complexity and costs.

Data concerning usual post stroke rehabilitation received by all participants was collected in the RAFTAS feasibility study. In a Phase III study, it would be important to record and monitor the care received by participants to report and compare the treatment received by different randomisation groups. During the RAFTAS feasibility study, the number of returned usual post stroke rehabilitation data collection forms was low and data quality was poor. Methods to improve data collection and data quality would need further development prior to a Phase III study (see data quality and monitoring).

15.2.7 Study attrition and timing of outcome assessments

The participant attrition rate was acceptable for a stroke rehabilitation study and there was no differential attrition between randomisation groups. The main cause of loss to follow up was failure of staff to conduct assessments, especially at one site. Outcome assessors were part time NHS stroke therapists who agreed to undertake this work for a pro-rata payment. This emphasises the need for careful site selection, recruitment and training of assessors, and monitoring of timing of outcome assessments.

Methods to prevent participants being lost to follow up in a Phase III study could include use of electronic prompts and reminder letters for outcome assessors and participants. In addition, the co-ordinating centre could include timely completion of

assessments (as recorded in the online database) in regular site reports. Plans to support poor performing sites could be developed.

In a Phase III study, consideration should be given to a pre-specified time cut off point after which data will not be included in the analysis. In retrospect, this should have been used in the RAFTAS feasibility study.

Unlike some previous studies, no participants withdrew from the RAFTAS feasibility study because they were allocated to the control group. It is important to ensure that patients understand and agree to be randomised to either intervention or control when consent is obtained. Differential attrition between intervention and control groups can lead to bias and would need to be closely monitored.

15.2.8 Outcome measures

15.2.8.1 Primary and secondary outcome measures

A Phase III study will seek to investigate the clinical effectiveness of the RFTP programme upon upper limb function. The ARAT will be the primary outcome measure as it is a widely used and well validated measure of upper limb function after stroke. In the RAFTAS feasibility study, the ARAT data completeness was good indicating that it could be used in a future study.

Further thought needs to be given to the selection of secondary outcome measures based upon the clinical importance of the measure and comparability with other studies. A commonly used measure of upper limb impairment is the Fugl-Meyer Assessment [108], which is also validated and widely used (4/12 previous studies evaluating RFTP [60, 61, 63, 64]). The Fugl-Meyer could be considered as a secondary outcome measure in a Phase III study as an alternative to other measures of impairment used in the RAFTAS feasibility study e.g. Motricity Index [99], dynamometer.

Participant feedback from those who received the RFTP programme indicated an increase in confidence and it may be helpful to consider including a scale which measures confidence as a secondary outcome measure. The inclusion of each outcome measure in a Phase III study needs careful thought and justification to avoid overburdening participants.

15.2.8.2 Inter-rater reliability

It would have been helpful to have assessed the inter-rater reliability of the ARAT and other key scales within the RAFTAS feasibility study. Previous studies have shown high inter-rater reliability for the ARAT (Intra Class Correlation co-efficient and Spearman's rho >0.95) [118]. This work will need to be undertaken during a Phase III study.

15.2.9 Data quality, completeness and monitoring

15.2.9.1 Data quality and completeness

In the RAFTAS feasibility study, the completeness of key measures at baseline and outcome assessments was acceptable but could be improved. In a Phase III study, data management systems could be introduced to enable data entry to be undertaken electronically at site rather than onto paper pro forma. Systems would need to be in place for regular checks of data quality and completeness with timely prompts for research staff to seek missing data. Electronic data entry should also prevent some ineligible patients being randomised.

Participants were able to undertake self-practice, but a reliable method of ensuring that recovery activity log sheets are returned to the co-ordinating centre needs to be developed. Alternatively, methods to facilitate self-completion as opposed to pen and paper could be explored, e.g. using an electronic data application. There were a number of non-returned or poorly completed therapist pro formas in the RAFTAS feasibility study. Methods of minimising this will also need to be included in a Phase III study.

15.2.9.2 Usual rehabilitative care data collection

The forms used to record the amount and content of usual post stroke rehabilitation would require further development by the study team and NHS therapists to see if forms can be simplified and / or reduced. A more robust system of ensuring their return to the study co-ordinating centre needs establishing, with regular checks for data completeness and quality. Alternatively an electronic system could be developed to collect data with reminders and prompts, but additional resource would be needed to support local data entry. Formal sessions to train local staff in usual post stroke rehabilitation data collection could be undertaken in a Phase III study, although this may be challenging to deliver across a range of teams within a study site's stroke service.

15.2.9.3 Data monitoring

Systems would need to be developed to inform sites about their data quality e.g. traffic light system. It may also be helpful to have email discussion groups between the coordinating centre and study sites and regular teleconferences of study teams to look at ways of optimising recruitment, retention and data quality.

15.2.10 Study blinding

Ideally study participants, treating therapists, outcome assessors and those involved in usual post stroke rehabilitation should be blinded to participant group allocation. However, because of the nature of the intervention in the RAFTAS feasibility study (and many other rehabilitation trials) it was only possible to attempt blinding of outcome assessors.

It was disappointing that a large number of outcome assessments were unblinded at the one and three months in the RAFTAS feasibility study. Unfortunately, the RAFTAS feasibility study did not record when and how outcome assessors became unblinded. Outcome assessors could have been unblinded if the participant mentioned the treatment they received or if the outcome assessor had seen the participant undertaking RFTP. All outcome assessors worked within the stroke unit and community stroke services at the site where they undertook assessments. For a Phase III study outcome assessors who work outwith the stroke service could be employed, but this would involve additional travel costs. Alternatively, a cluster randomised controlled design could be used, but this would entail a more complex design and analysis and require more participants. Success of study blinding would be carefully recorded in a Phase III study. Reasons for unblinding would be recorded and actions taken to minimise these events.

Lack of blinding can result in numerous sources of bias. Particular risks for stroke rehabilitation trials are resentful demoralisation of participants randomised to the control group [119] and competitive therapy bias, where therapy staff may feel that patients in the control group are disadvantaged and subsequently provide them with increased rehabilitation [72]. Inclusion of an attention control treatment could be considered for a Phase III study, but this will add to the complexity and cost of the study.

15.2.11 Adverse events / safety

In the RAFTAS feasibility study, upper limb pain, fatigue and increased muscle tone were recorded in addition to a more standard capture of new medical problems - presenting a more thorough approach compared to previous studies evaluating RFTP [54-62, 64]. There did not appear to be any safety concerns that should preclude a Phase III study. The safety reporting system could be used in a future study, but tools for collection would need to be improved to reduce inconsistencies and subsequent difficulties with interpretation.

A number of patients in both intervention and control groups experienced fatigue. This is likely to be stroke related rather than specific to the intervention as there is a high prevalence of fatigue following stroke [21]. Fatigue needs to be taken into account when considering rehabilitation goals and recovery activities. During a Phase III study an Independent Data Monitoring and Ethics Committee (IDMEC) could monitor differences between intervention and control groups in fatigue levels.

15.3 Conclusion

A Phase III study to evaluate the developed RFTP programme for upper limb recovery early after stroke is feasible, but there are issues that need to be addressed when designing a future study. Due to the issues found in the RAFTAS feasibility study, a Phase III study may benefit from an internal pilot study.

There is often confusion surrounding definitions of feasibility and pilot studies [120]. A review of current practice and editorial policy found no clear distinction in the use of terminology for ‘feasibility’ and ‘pilot’ studies in literature [120]. The NIHR defines feasibility studies and pilot studies separately. Feasibility studies determine if a future study can be undertaken and do not evaluate the outcome of interest [121]. Pilot studies are defined as a smaller version of a large scale study undertaken to test if all components of the main study can work together and include assessment of the primary outcome [122]. It was therefore appropriate to undertake the RAFTAS feasibility study rather than an external pilot study.

An internal pilot study can be undertaken in the first phase of a substantive phase III study. Inclusion of an internal pilot in a future phase III study would determine if the actions taken to address the issues raised in the RAFTAS feasibility study have been successful. An internal pilot study would include clear pre-specified progression rules (or ‘stop / go’ rules) to establish if the study should continue or be terminated at the

end of the internal pilot [123]. Stop / go rules would have clearly defined targets based upon recruitment rate, adherence to the intervention, attrition and completeness of outcome assessments to ensure the Phase III study is deliverable. Data collected during the internal pilot would contribute to the final study analysis [122].

Evaluation the RFTP programme in a Phase III study would form the next stage in development and evaluation of this promising complex intervention.

Appendix 1: Database search strategies

Ovid MEDLINE search strategy

1 exp Stroke/

2 Exercise Therapy/

3 "Recovery of Function"/

4 Physical Therapy Modalities/

5 task related prac$.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

6 2 or 3 or 4 or 5

7 exp Upper Extremity/

8 1 and 6 and 7

9 limit 8 to (english language and humans and yr="2007 - Current")

10 ("robot*" or "constraint" or "electrical" or "mirror*" or "CIMT").mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

11 9 not 10

Embase search strategy

1 exp cerebrovascular accident/

2 exp kinesiotherapy/

3 convalescence/

4 exp physiotherapy/

5 task related practi$.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]

6 exp arm/

7 2 or 3 or 4 or 5

8 1 and 6 and 7

9 limit 8 to (human and english language and yr="2007 - Current")

10 ("robot*" or "constraint" or "electrical" or "mirror*" or "CIMT").mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]

11 9 not 10

Scopus search strategy

((((TITLE-ABS-KEY("cerebrovascular dis*") OR TITLE-ABS-KEY("basal ganglia cerebrovascular dis*,") OR TITLE-ABS-KEY("stroke") OR TITLE-ABS-KEY("brain ischemia") OR TITLE-ABS-KEY("carotid artery diseases") OR TITLE-ABS-KEY("cerebrovascular acciden*") OR TITLE-ABS-KEY("brain infarction") OR TITLE-ABS-KEY("cerebrovascular trauma") OR TITLE-ABS-KEY("hypoxia-ischemia") OR TITLE-ABS-KEY("intracranial arterial diseases") OR TITLE-ABS-KEY("intracranial embolism") OR TITLE-ABS-KEY("intracranial thrombosis") OR TITLE-ABS-KEY("intracranial hemorrhag*") OR TITLE-ABS-KEY("poststroke") OR TITLE-ABS-KEY("post stroke") OR TITLE-ABS-KEY("cerebrovasc*") OR TITLE-ABS-KEY("brain vasc*") OR TITLE-ABS-KEY("cva") OR TITLE-ABS-KEY("cerebral vasc*") OR TITLE-ABS-KEY("hemiplegia"))) OR (TITLE-ABS-KEY(subarachnoid))) AND (((TITLE-ABS-KEY("arm") OR TITLE-ABS-KEY("upper limb") OR TITLE-ABS-KEY("upper extremity") OR TITLE-ABS-KEY("shoulder") OR TITLE-ABS-KEY("elbow") OR TITLE-ABS-KEY("hand") OR TITLE-ABS-KEY("wrist"))) OR (TITLE-ABS-KEY("upper extremit*"))) AND (((TITLE-ABS-KEY("practice") OR TITLE-ABS-KEY("repetitive") OR TITLE-ABS-KEY("repetitio*") OR TITLE-ABS-KEY("task") OR TITLE-ABS-KEY("tasks") OR TITLE-ABS-KEY("functional") OR TITLE-ABS-KEY("task practice") OR TITLE-ABS-KEY("task practise") OR TITLE-ABS-KEY("task related practice") OR TITLE-ABS-KEY("task related practise") OR TITLE-ABS-KEY("function") OR TITLE-ABS-KEY("intensity") OR TITLE-ABS-KEY("intense") OR TITLE-ABS-KEY("intensive") OR TITLE-ABS-KEY("task orientated") OR TITLE-ABS-KEY("goal orientated"))) OR (TITLE-ABS-KEY(repetit*)))) AND NOT ((TITLE-ABS-KEY(mirror*) OR TITLE-ABS-KEY(robot*) OR TITLE-ABS-KEY(constraint*) OR TITLE-ABS-KEY(cimt) OR TITLE-ABS-KEY(electr*))) AND (LIMIT-TO(PUBYEAR, 2013) OR LIMIT-TO(PUBYEAR, 2012) OR LIMIT-TO(PUBYEAR, 2011) OR LIMIT-TO(PUBYEAR, 2010) OR LIMIT-TO(PUBYEAR, 2009) OR LIMIT-TO(PUBYEAR, 2008) OR LIMIT-TO(PUBYEAR, 2007)) AND (EXCLUDE(SUBJAREA, "BIOC") OR EXCLUDE(SUBJAREA, "PSYC") OR EXCLUDE(SUBJAREA, "ENGI") OR EXCLUDE(SUBJAREA, "COMP") OR EXCLUDE(SUBJAREA, "PHAR") OR EXCLUDE(SUBJAREA, "SOCI") OR EXCLUDE(SUBJAREA, "ARTS") OR EXCLUDE(SUBJAREA, "AGRI") OR EXCLUDE(SUBJAREA, "CENG") OR EXCLUDE(SUBJAREA, "IMMU") OR EXCLUDE(SUBJAREA, "ENVI") OR EXCLUDE(SUBJAREA, "MATH") OR EXCLUDE(SUBJAREA, "PHYS") OR EXCLUDE(SUBJAREA, "CHEM") OR EXCLUDE(SUBJAREA, "DECI") OR

EXCLUDE(SUBJAREA, "MATE") OR EXCLUDE(SUBJAREA, "EART") OR EXCLUDE(SUBJAREA, "ENER") OR EXCLUDE(SUBJAREA, "DENT") OR EXCLUDE(SUBJAREA, "BUSI") OR EXCLUDE(SUBJAREA, "VETE") OR EXCLUDE(SUBJAREA, "ECON")) AND (LIMIT-TO(LANGUAGE, "English"))

Appendix 2. Scottish Intercollegiate Guidelines Network (SIGN) Checklist

SIGN

Methodology Checklist 2: Controlled Trials

Study identification (*Include author, title, year of publication, journal title, pages*)

Guideline topic:	Key Question No:	Reviewer:

Before completing this checklist, consider:

1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+
2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question ☐ 2. Other reason ☐ (please specify):

SECTION 1: INTERNAL VALIDITY

	In a well conducted RCT study…	***Does this study do it?***
1.1	The study addresses an appropriate and clearly focused question.	Yes ☐ No ☐ Can't say ☐
1.2	The assignment of subjects to treatment groups is randomised.	Yes ☐ No ☐ Can't say ☐
1.3	An adequate concealment method is used.	Yes ☐ No ☐ Can't say ☐
1.4	The design keeps subjects and investigators 'blind' about treatment allocation.	Yes ☐ No ☐ Can't say ☐
1.5	The treatment and control groups are similar at the start of the trial.	Yes ☐ No ☐ Can't say ☐
1.6	The only difference between groups is the treatment under investigation.	Yes ☐ No ☐ Can't say ☐
1.7	All relevant outcomes are measured in a standard, valid and reliable way.	Yes ☐ No ☐ Can't say ☐
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	
1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).	Yes ☐ No ☐ Can't say ☐ Does not apply ☐
1.10	Where the study is carried out at more than one site, results are comparable for all sites.	Yes ☐ No ☐ Can't say ☐ Does not apply ☐

SECTION 2: OVERALL ASSESSMENT OF THE STUDY		
2.1	How well was the study done to minimise bias? *Code as follows:*	High quality (++)☐ Acceptable (+)☐ Low quality (-)☐ Unacceptable – reject 0 ☐
2.2	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	
2.3	Are the results of this study directly applicable to the patient group targeted by this guideline?	
2.4	**Notes.** Summarise the authors' conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.	

Appendix 3: Recovery activity List

Recovery activity list

A list of recovery activities have been created for each functional category of daily living (washing, dressing, eating/drinking and optional).

There are a wide range of activities available in each category which are ordered into three levels of ability. Ability levels were generated by considering biomechanical parameters (for example amount of upper limb movement and coordination required) and the level of mental processing needed to complete the activity.

The levels are used as a guide to select an appropriate activity for the study participant. For example, a level 1 activity is appropriate for a participant with severe upper limb functional impairment.

Level 1	Gross upper limb movement only required. No hand dexterity / grip available. Activities often involve simple gross movements or 'propping'/weight bearing through the **affected** side and completing the activity with the **unaffected** side.
Level 2	Return of some activity in shoulder / elbow / wrist. Minimal hand dexterity / grip required for some of the activities. The **affected** side is more actively involved in the activity / may complete a simple activity independently. Some activities are more complex and require more complex mental processing.
Level 3	Good return of shoulder / elbow / wrist activity and dexterity / grip. The **affected** side undertakes the activity independently or leads the activity if the activity is bimanual. Some activities are complex and require greater mental processing.

Activities are listed on a 'sliding scale' for each category. Participants may be provided with activities listed under different ability levels within the same review session.

The participant should practice the activities in a seated position unless stated or specifically advised by the treating study therapist.

Category 1 - Washing Activities

Touch the following using the affected hand (either side of the body as appropriate):

Level 1:

- W1.01 Wrist
- W1.02 Hand
- W1.03 Knee (right or left)
- W1.04 Chest (midline)
- W1.05 Chin
- W1.06 Mouth
- W1.07 Nose
- W1.08 Eye (right or left)
- W1.09 Face (right or left cheek)
- W1.10 Ear (right or left)
- W1.11 Shoulder (right or left)
- W1.12 Under arm

Level 2:

- W2.01 Back of waistband
- W2.02 Forehead
- W2.03 Head (top of)
- W2.04 Head (back of)
- W2.05 Ankle
- W2.06 Open **affected** hand (to allow for cleaning) touch with the **unaffected** hand.

Level 3:

Touch or rub the body part with your **affected** hand using a sponge, flannel, tissue or towel.

- W3.01 Wrist
- W3.02 Hand
- W3.03 Knee (right or left)
- W3.04 Chest (midline)
- W3.05 Chin
- W3.06 Mouth
- W3.07 Nose
- W3.08 Eye (right or left)
- W3.09 Face (right or left cheek)
- W3.10 Ear (right or left)
- W3.11 Shoulder (right or left)
- W3.12 Under arm
- W3.13 Back of waistband
- W3.14 Forehead
- W3.15 Head (top of)
- W3.16 Head (back of)
- W3.17 Ankle
- W3.18 Open **affected** hand (to allow for cleaning) touch with the **unaffected** hand).

'Pick and place' objects

Level 1

- W1.13 Sit in front of a table to complete this task. Prop / weight bear through the **affected** side and complete the activity with the **unaffected** side. Move objects from one side of the table to the other. Please select the appropriate object from the following list to practice the activity:
  - ❖ Tooth brush
  - ❖ Tooth paste
  - ❖ Hair brush / comb
  - ❖ Deodorant
  - ❖ Wash bag

Level 2

- W2.07 Sit in front of a table to complete this task. Move objects from one side of the table to the other **using both hands together**. Please select the appropriate object from the following list to practice the activity:
  - ❖ Tooth brush
  - ❖ Tooth paste
  - ❖ Hair brush / comb
  - ❖ Deodorant
  - ❖ Wash bag

Level 3:

- W3.19 Sit in front of a table to complete this task. Move an object from one side of the table to the other using the **affected** hand. Please select the appropriate object from the following list to practice the activity:
  - ❖ Tooth paste
  - ❖ Hair brush / comb
  - ❖ Deodorant
  - ❖ Wash bag

- W3.20 Sit next to two surfaces of different heights (for example a table and a bed side cabinet). Move an object from one surface to another using the **affected** hand (remain seated). Please select the appropriate object from the following list to practice the activity:
  - ❖ Tooth brush
  - ❖ Tooth paste
  - ❖ Hair brush / comb
  - ❖ Deodorant
  - ❖ Wash bag

Wash bag activities

Level 1:

The **affected** hand is in a supportive role and the main part of the activity is completed by the **unaffected** side.

- W1.14 Pick up the deodorant with the **unaffected** hand and position under the **affected** arm. Return the deodorant back to the table = 1 repetition.
- W1.15 Hold / support the wash bag with the **affected** hand and take objects out / put them back inside using the **unaffected** hand. Lifting one object out of the wash bag and placing it on to the table = 1 repetition. Picking one object up off the table and placing one object back into the wash bag = 1 repetition.
- W1.16 Hold / support the wash bag with the **affected** hand – fasten then unfasten the wash bag = 1 repetition.
- W1.17 Ring out wash cloth / flannel **using both hands**, and then place back on the table = 1 repetition.

Level 2:

- W2.08 Hold / support the wash bag with the **unaffected** hand and take objects out / put them back inside using the **affected** hand. . Lifting one object out of the wash bag and placing it on to the table = 1 repetition. Picking one object up off the table and placing one object back into the wash bag = 1 repetition.
- W2.09 Hold the deodorant with **affected** hand and take the lid off / replace with the **unaffected** hand. Taking the lid off the deodorant then replacing the lid = 1 repetition.
- W2.10 Pick up the deodorant with the **affected** hand and position it under the **unaffected** arm. Return the deodorant back to the table = 1 repetition.
- W2.11 Hold the shampoo bottle with the **affected** hand and take the lid off / put it back on with the **unaffected** hand = 1 repetition.
- W2.12 Hold a tube of toothpaste with the **affected** hand and take the lid off / put it back on with **unaffected** hand = 1 repetition.

Level 3

The **unaffected** hand is in a supportive role and the main part of the activity is completed by the **affected** side.

- W3.21 Hold a tube of toothpaste with the **unaffected** hand and take the lid off / replace the lid using the **affected** hand = 1 repetition.
- W3.22 Hold / support the wash bag with the **unaffected** hand. Fasten then unfasten the wash bag using the **affected** hand = 1 repetition.
- W3.23 Hold the deodorant with the **unaffected** hand and take the lid off / replace the lid using the **affected** hand = 1 repetition.
- W3.24 Hold the shampoo bottle with the **unaffected** hand and take the lid off / replace the lid using the **affected** hand = 1 repetition.

Category 2 - Dressing / Grooming Activities

Manipulate item:

Level 1:
Adjust item of clothing (whilst wearing it). Prop / weight bear through the **affected** side and complete the activity with the **unaffected** side:

- D1.01 Slippers
- D1.02 Waistband

Level 2:
Adjust item of clothing (whilst wearing it) **using both hands**. Please select the appropriate object from the following list to practice the activity:

- D2.01 Adjust top
- D2.02 Adjust glasses
- D2.03 Adjust hearing aid
- D2.04 Adjust collar
- D2.05 Adjust slipper
- D2.06 Adjust waistband

Touch the following with the objects listed (use the **affected** hand to complete the activity):

- D2.07 Ear (hearing aid)
- D2.08 Face (glasses)
- D2.09 Top of Head (hair brush / comb)
- D2.10 Back of head (hair brush / comb)
- D2.11 Brush hair (using both hands)

Put on the following item then take it off (practise part of this activity which is most appropriate to the participant).

- D2.12 Top
- D2.13 Glasses
- D2.14 Hearing aid
- D2.15 Slippers
- D2.16 Trousers
- D2.17 Skirt

Level 3

- D3.01 Fasten then unfasten zip using the both hands = 2 repetitions.
- D3.02 Fasten then unfasten shirt buttons using both hands. Fastening then unfastening a button = 2 repetitions.
- D3.03 Fasten then unfasten shoe lases using both hands = 2 repetitions.
- D3.04 Place bra on knee or on a table. Fasten then unfasten bra using both hands. Fastening of 1 hook and eye = 1 repetition. Unfastening of 1 hook and eye = 1 repetition.
- D3.05 Pull sleeve of **unaffected** side down using **affected** hand, then push the sleeve up again = 2 repetitions.
- D3.06 Brush hair using the **affected** hand.

'Pick and place'

Level 1

- D1.03 Sit in front of a table to complete this task. Prop / weight bear through the **affected** side and complete the activity with the **unaffected** side. Move objects from one side of the table to the other. Please select the appropriate object from the following list to practice the activity:
  the appropriate object from the following list to practice the activity:
  - ❖ Item of clothing (e.g. socks, top, trousers etc)
  - ❖ Glasses
  - ❖ Hearing aid

- D1.04 Sit in a chair to complete the task. Prop / weight bear through the **affected** side and complete the activity with the **unaffected** side. Pick up slippers from the floor and move to the opposite side of your feet.

Level 2

- D2.18 Sit in front of a table to complete this task. Move object from one side of the table to the other **using both hands together**. Please select the appropriate object from the following list to practice the activity:
  - ❖ Item of clothing (e.g. socks, top, trousers etc)
  - ❖ Glasses
  - ❖ Hearing aid

- D2.19 Sit in a chair to complete the task. Use both hands together (to support your **affected** hand). Pick up slippers from the floor and move to the opposite side of your feet.

Level 3

- D3.07 Sit in front of a table to complete this task. Move object from one side of the table to the other using the **affected** hand. Please select an object from the following list to practice the activity:
  - ❖ Item of clothing (e.g. socks, top, trousers etc)
  - ❖ Glasses
  - ❖ Hearing aid

- D3.08 Activity to be performed in sitting. Complete the activity using your **affected** hand. Pick up your slippers up off the floor and move them to the other side of your feet.

Category 3 – Eating and Drinking Activities

'Pick and place' the following objects

Level 1:

- F1.01 Sit in front of a table to complete this task. Prop / weight bear through the **affected** side and complete the activity with the **unaffected** side. Move objects from one side of the table to the other. Please select the appropriate object from the following list to practice theactivity:
  - ❖ Coffee / tea cup (empty)
  - ❖ Water glass or beaker (empty)
  - ❖ Drinks bottle (empty)
  - ❖ Bowl (empty)
  - ❖ Plate (empty)
  - ❖ Knife or fork
  - ❖ Coffee / tea cup (half full)
  - ❖ Water glass or beaker (half full)
  - ❖ Drinks bottle (half full)
  - ❖ Bowl (with food)
  - ❖ Plate (with food)
  - ❖ Knife or fork
  - ❖ Plate (empty, lift and reach)
  - ❖ Plate (with food, lift and reach)

- F1.02 Sit in front of a table to complete this task. Start with your hand resting on the table. Reach towards an object using the **affected** hand. Touch the object, then return to the start position. Please select the appropriate object from the following list to practice the activity:
  - ❖ Coffee / tea cup (empty)
  - ❖ Water glass or beaker (empty)
  - ❖ Drinks bottle (empty)
  - ❖ Bowl (empty)
  - ❖ Plate (empty)
  - ❖ Knife or fork
  - ❖ Coffee / tea cup (half full)
  - ❖ Water glass or beaker (half full)
  - ❖ Drinks bottle (half full)
  - ❖ Bowl (with food)
  - ❖ Plate (with food)
  - ❖ Knife or fork
  - ❖ Plate (empty, lift and reach)
  - ❖ Plate (with food, lift and reach)

Level 2:

- F2.01 Sit in front of a table to complete this task. Move objects from one side of the table to the other **using both hands together**. Please select the appropriate object from the following list to practice the activity:
  - ❖ Coffee / tea cup (empty)
  - ❖ Water glass or beaker (empty)
  - ❖ Drinks bottle (empty)
  - ❖ Bowl (empty)
  - ❖ Plate (empty)
  - ❖ Knife or fork
  - ❖ Coffee / tea cup (half full)
  - ❖ Water glass or beaker (half full)
  - ❖ Drinks bottle (half full)
  - ❖ Bowl (with food)
  - ❖ Plate (with food)
  - ❖ Knife or fork
  - ❖ Plate (empty, lift and reach)
  - ❖ Plate (with food, lift and reach)

Level 3:

- F3.01 Sit in front of a table to complete this task. Move an object from one side of the table to the other using the **affected** hand. Please select the appropriate object from the following list to practice the activity:
  - ❖ Coffee / tea cup (empty)
  - ❖ Water glass or beaker (empty)
  - ❖ Drinks bottle (empty)
  - ❖ Bowl (empty)
  - ❖ Plate (empty)
  - ❖ Knife or fork
  - ❖ Coffee / tea cup (half full)
  - ❖ Water glass or beaker (half full)
  - ❖ Drinks bottle (half full)
  - ❖ Bowl (with food)
  - ❖ Plate (with food)
  - ❖ Knife or fork
  - ❖ Plate (empty, lift and reach)
  - ❖ Plate (with food, lift and reach)

- F3.02 Sit in front of a table to complete this task. Pick up a plate/bowl with the affected hand. Reach forwards/to the side as if trying to pass it to somebody. Place the plate or bowl back onto the table.

Bimanual activities:

Level 1

- F1.03 Sit in front of a table to complete this task. Prop / weight bear through the **affected** side and complete the activity with the **unaffected** side. Perform stirring motion with **unaffected** side (no fluid inside cup).
- F1.04 Sit in front of a table to complete this task. Support an empty tea / coffee cup with **affected** side and stir with **unaffected** side.

Level 2

- F2.02 Pour liquid from one cup to another (support cup with **affected** side and pour with **unaffected**)
- F2.03 Support beaker with **affected** hand and pour water into it from a jug.

Level 3

- F3.03 Support drink of coffee / tea with the **unaffected** hand and stir with **affected** hand.
- F3.04 Pour liquid from one cup to another (support cup with **unaffected** side and pour with **affected**)
- F3.05 Stabilise beaker with **unaffected** hand and pour water into it from a jug using **affected** hand.

'Hand to mouth' activities:

Level 2 (use both hands)

- F2.04 Touch mouth with cup (empty)
- F2.05 Touch mouth with fork (empty)
- F2.06 Touch mouth with spoon (empty)

Level 3 (using **affected** hand)

- F3.06 Touch mouth with cup (with liquid)
- F3.07 Touch mouth with fork (with food)
- F3.08 Touch mouth with spoon (with food)
- F3.09 Touch mouth with cup or beaker (half full and drink)

Activities using cutlery

Level 3

- F3.10 Pick up a piece of food using a fork and put it back down = 1 repetition.
- F3.11 Pick up a piece of food using a knife and fork and put it back down = 1 repetition.
- F3.12 Pick up a piece of food using a spoon and put it back down = 1 repetition.
- F3.13 Cut up food (1 slice = 1 repetition)
- F3.14 Pick up a knife and fork, hold in position and place back down on the table = 1 repetition

Category 4 - Other/Optional Activity List

The following activities are suggestions to assist with selection of an 'optional' activity to work towards the 'optional goal' selected.

If desired, a goal can be set and activities used relating to the previous categories if the participant wishes.

An activity can be chosen from this list or a different activity can be practised to work towards the 'optional activity' goal.

Activities for each sub category are ordered from easiest to most challenging.

Some activities may be appropriate only in the home environment.

Self care

1. Personal care
- Open **affected** hand / position to enable nail cutting
- Stand using the **affected** arm to stabilise (e.g. at the sink)
- Shave- bimanual
- Brush teeth using toothbrush (bimanual / **affected** hand as able)
- Apply cream to face / body
- Use both hands to scoop up water from the sink to wash face
- Apply make-up
- Apply / remove resting splint
- Apply / remove wrist watch
- Handle medication
-

2. Functional mobility
- Arrange bed clothes
- Open doors with **affected** hand
- Turn a key in the door using the **affected** hand

3. Community management
- Hold / manipulate money
- Practise sitting to standing then standing to sitting with a hand on each arm of the chair, pushing through both hands.

Productivity

- Stabilise paper with **affected** side and write with **unaffected**
- 'Pick and place' pen
- 'Pick and place' book
- Stabilise paper with **unaffected** side and write with **affected** side.

Leisure

1. Quiet recreation

- Stabilise book with **affected** side and turn pages with **unaffected** side
- Stabilise magazine / newspaper with **affected** side and turn pages with **unaffected** side
- 'Pick and place' magazine
- Stabilise magazine / newspaper with **unaffected** side and turn pages with **affected** side
- Stabilise book with **unaffected** side and turn pages with **affected** side
- Art and craft activities

2. Active recreation

- Use of an MP3 player / iPod / laptop
- Holding / manipulating playing cards
- Use of TV control

3. Socialising

- 'Pick and place' mobile phone
- Pick up and hold mobile phone in dialling position then place back on the table
- Telephone use (land line)
- Using an mobile phone (lifting phone up to the ear)
- Using a key pad / key board

Appendix 4: Participant handbook

Repetitive arm functional tasks after stroke (RAFTAS II) study

Participant Handbook

Participant study number: _____

Stroke association

Newcastle University

Welcome to the repetitive arm functional tasks after stroke (RAFTAS) study II and thank you for agreeing to take part.

About the RAFTAS study II

- Up to 85% of patients early after stroke have difficulty using their arm.
- At the moment it is unclear how to best provide therapy to improve arm recovery.
- Recent research has suggested that recovery may be improved by practising activities a lot of times, especially if the activity is for a specific functional purpose.
- An example of an activity for a functional purpose is 'use your affected hand to touch your cheek with a flannel'.
- In order to test whether RFTP therapy will improve arm recovery, we need to conduct a large research study called a randomised controlled trial (RCT).
- However, before we do a large clinical trial it's important to do a small version of the trial (a pilot trial) to check that the design and logistics of the trial are acceptable.
- In a RCT, a new treatment is compared with the 'standard' treatment available. We put people into two groups at random and give one group the new treatment (RFTP therapy in this study) and the other group the standard treatment (usual post stroke rehabilitation in this study).
- The RAFTAS II study is a small pilot RCT which will enable us to design the large clinical trial to determine if RFTP therapy will improve arm recovery after stroke.
- You have been allocated to receive RFTP therapy.

About this handbook

This study handbook is written by the RAFTAS study team and is for your information and interest. It contains advice and information about stroke, rehabilitation and positioning of your affected arm and hand after stroke.

What is a stroke?

- The brain needs a constant supply of blood in order for it to function.
- A stroke occurs when the blood supply to the brain is interrupted because of a clot or bleed. When this happens, the brain cells are damaged or can die.
- Control of movement, speech, bodily functions (such as going to the toilet) and thinking are co-ordinated by the brain. These functions may be lost or disrupted when a stroke takes place.
- A stroke affects people in different ways. This depends on which area of the brain is affected and how much damage has occurred.
- Common symptoms of stroke are loss of movement and numbness down one side of the body.
- This is due to the stroke affecting parts of the brain that control arm and leg movement and/or sensation, rather than a problem in the muscles themselves.
- If the stroke happens in the right side of the brain it affects the left side of the body and vice versa.

Rehabilitation after stroke

- Rehabilitation is about relearning skills and the ability to do things again. The aim is to be as independent as possible
- This means taking an active, positive approach focusing on what you can do rather than what you can't do.
- As stroke affects people so differently it is difficult to work out exactly how much recovery is possible in each person.
- It may take a long time for some people to recover after stroke.
- It is possible to still see some improvements a year or more after stroke, but some people who have problems at this stage will have long term symptoms.
- Research has found that the more you do the better you get. However, it is important to rest regularly as tiredness can be a problem.
- Therefore, it is important that you find a balance between rest and activity that is right for you.

Suggestions to aid recovery

- Concentrate on what you would like to achieve and take the support that is on offer to reach your potential.
- Staying positive will help with your rehabilitation – focus on what you are able to do rather than what you can no longer do.
- Be persistent – remember that recovery may be slow.
- Remember to balance being active with resting when you need to.
- Try and be realistic about what you would like to achieve in the short term and in the long term – your physiotherapist / occupational therapist can help guide you with this.
- Use your affected arm – try to do as much as you can for yourself but ask for help when you need it.

Arm and hand recovery after stroke

- A lot of people with stroke often use their non-affected arm to do activities as this is easier than using their affected arm.
- The problem with this is that you get used to not using your affected arm. This can impact on arm recovery.
- Recovering the use of your arm is different to recovering the use of your leg. People who have had a stroke automatically use their affected leg, such as when they want to get up from a chair.
- It is important to spend as much time working on your arm as on your leg recovery.

Positioning of the arm and hand after stroke

- After a stroke some people may develop some pain and tightness in your arm and hand.
- It is important to handle and position your arm and hand carefully as described in the next few pages.
- This will help to minimise problems, help prevent future problems from occurring and increase your awareness of your arm.

Recommendations for positioning the arm and hand

- The following recommendations (on pages 7 - 12) are to be used as a guide. Please consult the local study therapist if you are unsure whether something applies to you.

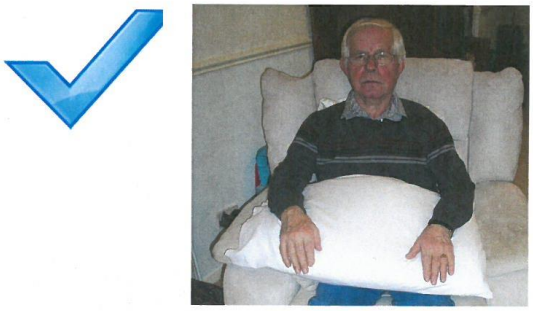
When sitting in a chair

PLEASE TRY TO

✓ Sit upright in a supportive chair, preferably with arm rest support.
✓ Be aware of where your arm is.

If you have **minimal movement** in your arm:

✓ Place both of your arms onto a pillow, on your lap or on the table in front. Make sure the palm of your hand is facing downwards.



PLEASE DON'T

✗ Let your arm hang over the side of the chair as this can cause problems and pain in your shoulder.
✗ Cradle your arm across your body as this may cause muscle tightness and pain.

When sitting up in bed

PLEASE TRY TO

- ✓ Sit as upright as possible, with good pillow support around your back and sides.

If you have **minimal movement** in your arm:

- ✓ Arms should be placed on either side of your body, resting on pillows.

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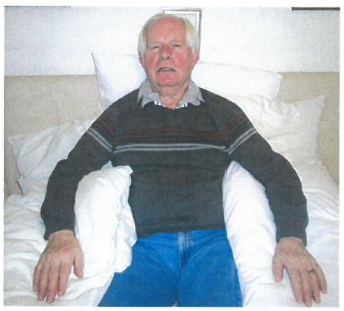


PLEASE DON'T

- ✗ Cradle your arm across your body as this may cause tightness in the muscles and pain.
- ✗ Allow your arm to 'hang' by your side as this may cause pain and injury to your shoulder.

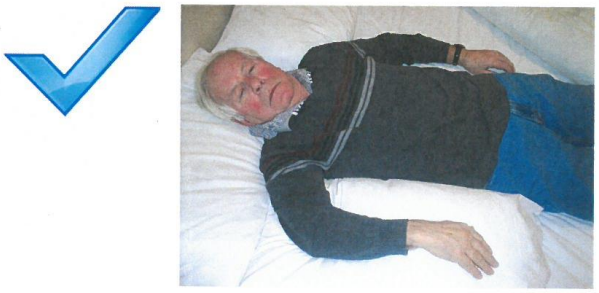
When lying on your back in bed

PLEASE TRY TO

- ✓ Position your arm by your side rather than across your body.

<u>If you have **minimal movement** in your arm:</u>

- ✓ Place pillows under your head, affected arm and shoulder.
- ✓ Make sure your arm is positioned slightly away from our body and that your hand is well supported by the pillow.
- ✓ You may need to ask somebody to help you do this.



PLEASE DON'T

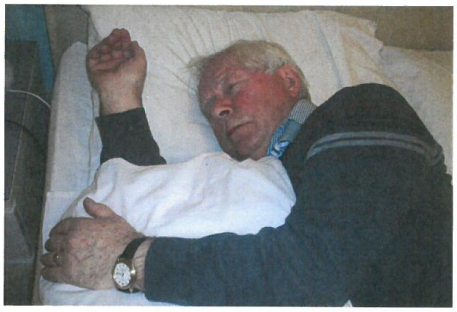
- ✗ 'Tuck' your hand under your body as this may cause injury.
- ✗ Cradle your arm across your body as this may cause tightness in the muscles and pain.

When lying on your unaffected side in bed

If you have **minimal movement** in your arm:

PLEASE TRY TO

- ✓ Place your affected arm out in front of you on a pillow.
- ✓ Position your affected leg forwards on to a pillow and slightly bend your knee – this will stop you from rolling onto your back.



PLEASE DON'T

- ✗ Allow your arm to fall behind your back.
- ✗ 'Tuck' your hand under your body as this may cause injury.

When lying on your affected side in bed

If you have **minimal movement** in your arm:

PLEASE TRY TO

- ✓ Make sure that your affected shoulder is positioned well forward so that your body weight is taken through the flat of your shoulder blade (flat on the bed) rather than the side of your shoulder.
- ✓ Bring your unaffected leg forward and place it onto a pillow with the knee bent. This will stop you rolling onto your back.

PLEASE DON'T

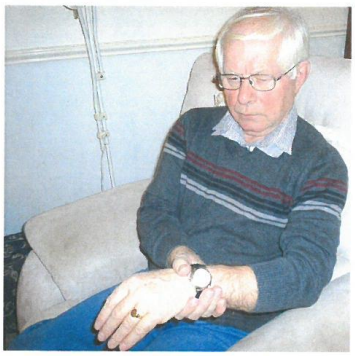
- ✗ Bend your affected elbow and tuck it into your waist so you are lying on your arm – this may cause injury.

When moving your arm

If you have **minimal movement** in your arm:

PLEASE TRY TO

- ✓ If possible, move your own arm rather than asking somebody to move it for you.
- ✓ Support your arm at the wrist when you move it.
- ✓ If someone is helping you, ask them to support your arm with one hand under your elbow and one hand under your wrist.



PLEASE DON'T

- ✗ Allow anyone to move or lift your arm by placing their hands under your armpit.
- ✗ Lift your arm by the hand only as this will strain your joints.
- ✗ Allow anyone to pull on your arm by holding your hand.

RFTP programme

The following pages explain the RFTP therapy programme and how to practise your recovery activities.

- The recovery activities you will practise in this research study are extra to the therapy that you are having in hospital or at home.
- We would like you to practise the recovery programme on your own or with help from your family / friends.
- To make the activities relevant to you we would like you to use everyday objects, most of which you will already have with you in hospital or at home.
- The local study therapist will help you choose what to practise.
- Please try and do as many repetitions of each individual recovery activity as you can when practising that particular activity (up to a maximum of 20).

What is in the RFTP programme?

- The activities in the programme are about different things that you do in daily life. These include washing, dressing and eating / drinking (if appropriate).
- There is also an 'optional category' so you can choose something important to you which may or may not be included under the other categories.
- We hope that this will make the programme interesting and applicable to you.
- We would like you (with the help of the local study therapist) to decide which of the recovery activities you wish to practise.
- Your choice of activity will be guided by what you want to be able to achieve in that category.
- If you have very little movement to start with the local study therapist may suggest an activity from the list that works towards your chosen everyday activity, rather than the activity itself.
- The local study therapist will show you how to complete the programme and fill the sheets in.

How to complete the programme

- It is important for your recovery that you get used to practising activities on your own, rather than just during therapy.
- Considering this, we would like you to practice the activities on your own or with your family / friends every day, if possible.
- We would like you to start with a quick 'warm up' as described in the next section.
- We would like you to repeat each recovery activity as many times as possible in one go (max 20 times).
- We would like you to do this in the morning and then again in the afternoon or evening every day.

- You may wish to use your daily routine to remind you to practise a specific recovery activity, for example:

    1. Washing activity - after getting washed in the morning.

    2. Dressing activity - whilst / after getting dressed / undressed.

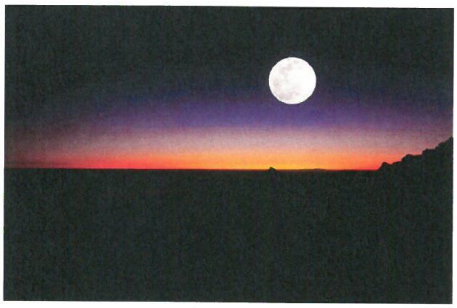
    3. Eating or drinking activity - during meal times or tea / coffee times (if appropriate).

    4. Any activity during visiting times.

- You can of course practise the activities whenever it is convenient to you.

Activity Log Sheets

- The local study therapist will provide you with sheets with information on about your chosen recovery activities. The local study therapist will practise the activities with you and show you how to fill the sheets in.
- Please ensure that you record the number of times you do the activities on the 'recovery activity log' sheets.
- Please mark one box on your 'recovery activity log' sheet for each time you practise the activity. This is so we can count up how many times you do it at once.
- You will need to mark the number of times you do each activity in your morning session and then in your afternoon / evening session.



- If you are unable to complete the activities, please tell us why on your 'recovery activity log' sheet. An example of this could be that you are feeling too tired / unwell.
- Any feedback given to us (good or bad) will help us to improve the programme.
- You can provide feedback by talking to the local study therapist or ideally by filling in the 'activity log sheets'. You may need to ask for assistance from a member of staff or a family member / friend.
- The local will review you twice a week to check on your progress and alter the programme with you to keep things interesting.

General advice / tips

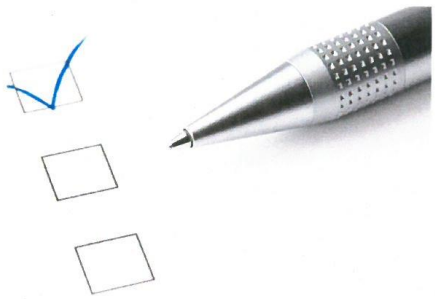
1. Remember, you can use your daily routine to remind you to practise your chosen activities.

    - For example: after getting washed in the morning you can ask staff / a relative / friend to leave your wash bag close by. This means the things you need are close by so you can practise your chosen washing activity.

    - Getting into this routine will remind you to practise the recovery activity programme and you will have the things you need close by.

2. You can involve your family members / friends if you wish.

    - You can do this by asking them to help set out the objects you are using or by asking them to keep a record of your achievements in your handbook.



Safety Advice

1. Please inform the local study therapist or a member of staff as soon as possible if pain stops you from doing the exercises or if you cannot participate in your normal therapy on the ward as the study exercises are making you feel too tired.

2. If you feel that your arm is stiffening up or getting tired during the exercises:

   - Try repeating the 'warm up' between exercises.
   - You will find the 'warm up' in the next section of the handbook.
   - Take a short rest after each repetition of the exercise.

Please remember to fill out your 'recovery activity log sheets' so you can keep track of your progress.

We hope that you will enjoy the programme and find it worthwhile.

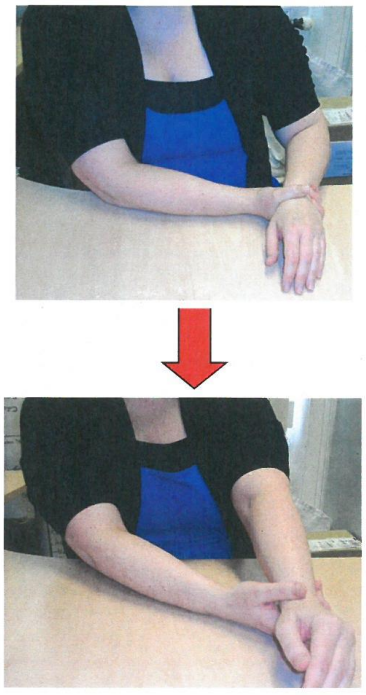
Warm up

- It is important to maintain the flexibility in your arm to stop your joints and muscles from stiffening up.
- A couple of simple movements and touching your arm and hand can act as a 'warm up' for your arm.
- This helps to stimulate your arm before practising the rehabilitation activity.
- The warm up is described at the start of each recovery activity section in this workbook.
- Please do each warm up once before each activity.

Warm up

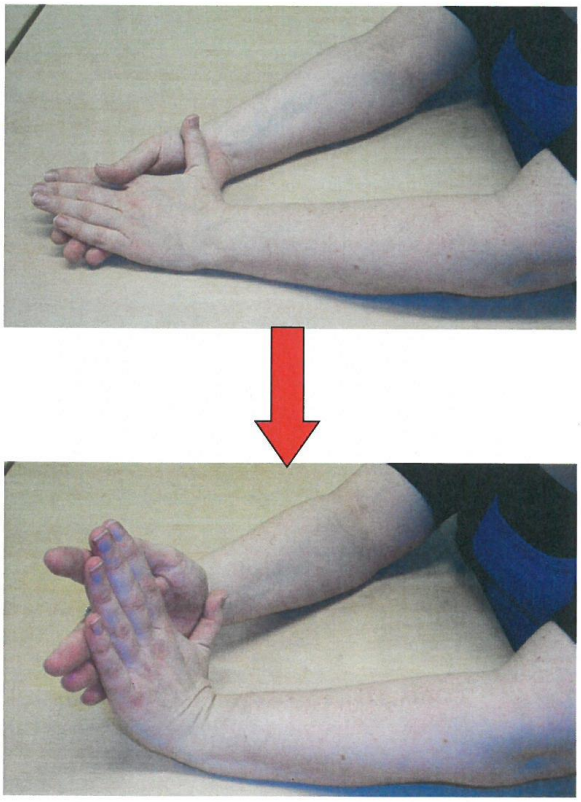
Stretch 1 – this stretches down the full length of your arm.

- Please do each warm up once before each activity.
- You can rest your hand on your knee or on a table in front of you.
- Place your affected hand flat on the table (palm down)
- Take hold of the wrist of your affected arm.
- Slowly slide your affected hand forwards on the table so that your elbow straightens out. You should not feel any pain.
- Make sure your body remains still and you don't lean forward. Then relax.
- Hold for approximately 20 – 30 seconds.

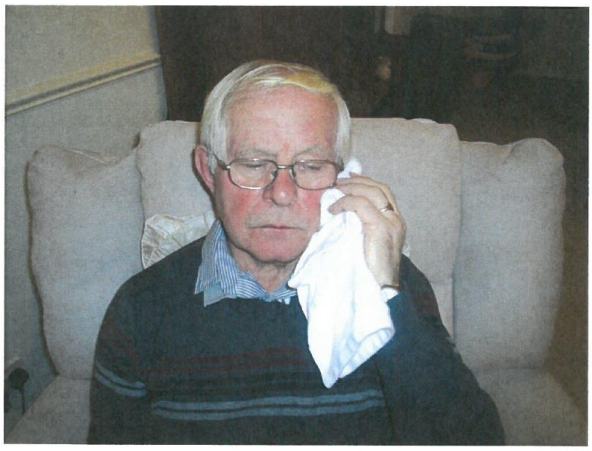


Stretch 2 - focuses on your wrist and fingers

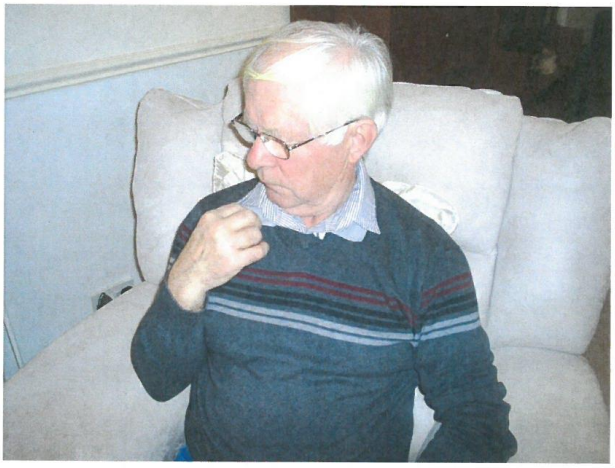
- Place your hand flat on the table in front.
- Slide the fingers of your unaffected hand under the fingers of your affected hand.
- Make sure your wrist stays on the table.
- Slowly lift your fingers up (keeping them straight). You are aiming to bend your wrist backwards.
- You should feel a gentle stretch down your fingers, palm and wrist. You should not feel any pain.
- Hold for approximately 20 – 30 seconds. Then relax.



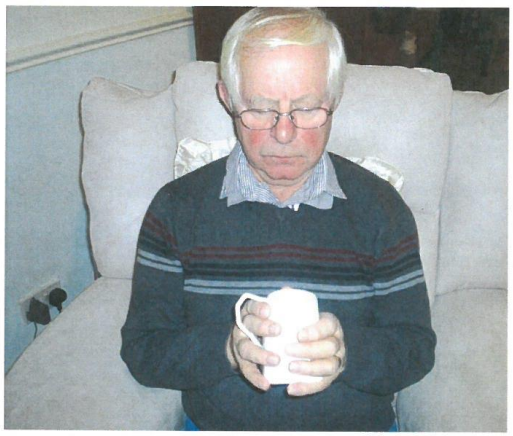
Washing Activity



Dressing Activity



Eating and Drinking Activity



Optional Activity

RAFTAS study team contact details

If you have any queries about the RAFTAS study II, please do not hesitate to contact either:

Miss Lianne Brkic (study research physiotherapist) at the Newcastle University Stroke Research Group on: 0191 2228209 or 07964 328778.

OR

Professor Helen Rodgers (Chief Investigator) at the Newcastle University Stroke Research Group on: 0191 222 6779.

Appendix 5: Recovery activity Log Sheet example

Eating & Drinking Activity

F2.02: Pour liquid from one cup to another

Participant Number: ☐☐☐ Date: _____

1. **Using both hands** to complete the activity.
2. Start with your hands on your lap.
3. Support an empty cup/beaker using your **affected** side.
4. Hold a beaker with liquid inside with your **unaffected** side.
5. Pour the liquid into the empty cup.
6. Place your hands back onto your lap.

Special reminders:	

Please mark a box for each attempt of the activity.

MORNING

AFTERNOON/EVENING

Reason for stopping session if less than 20 repetitions:	
Comments regarding the task/programme:	
Approximate time spent doing repetitions:	
Help given from another person:	

No activity today ☐

Appendix 6: Recovery activity Log Sheet – Optional Activity

Optional Activity

Activity: _____

Participant Number: _____ Date: _____

Special reminders:	

Please mark a box for each attempt of the activity.

MORNING

AFTERNOON/EVENING

Reason for stopping session if less than 20 repetitions:	
Comments regarding the task/programme:	
Approximate time spent doing repetitions:	
Help given from another person:	

No activity today ☐

Appendix 7: Therapy session documents

RAFTAS Study II	Participant Number ☐ ☐ ☐	Initial Therapy Session

Initial therapy session

Participant number ☐ ☐ ☐

Please provide the participant with an overview of the RFTP programme including:

- The initial therapy session.
- Therapy review sessions.
- The final therapy session.

Write the participant's study number in the space provided on the participant handbook front cover.

RAFTAS Study II	Participant Number ☐ ☐ ☐	Initial Therapy Session

Upper limb assessment

Side of body affected by current stroke: _____

Prompts:

- Selective movement
- Passive range of movement
- Muscle tone
- Compensations
- Associated reactions
- Sensation
- Proprioception
- Coordination
- Pain

Shoulder	
Elbow	
Wrist	
Hand	

Inattention / other comments: _____

_____

Upper limb impairment on the non-stroke side: _____

_____

RAFTAS Study II	Participant Number ☐ ☐ ☐	Initial Therapy Session

Upper limb rehabilitation needs identified following discussion:

Washing _____

_____

_____

Dressing _____

_____

_____

Eating/drinking (if appropriate)_____

_____

_____

Other _____

_____

_____

Goals and recovery activities selected:

Goal 1. (W, D, E/D, O – please circle)_____

_____

Recovery activity: (please detail the activity and document the number from the 'Recovery activity list)'.

_____

_____

Goal 2(W, D, E/D, O – please circle)_____

_____

Recovery activity: (please detail the activity and document the number from the 'Recovery activity list)'.

_____

_____

RAFTAS Study II	Participant Number ☐ ☐ ☐	Initial Therapy Session

Please:

1. Demonstrate and practice the activities with the participant and ensure they are confident to undertake their RFTP programme without therapist supervision.
2. Place the appropriate 'recovery activity log sheets' into the relevant sections of the participant's handbook.
3. Ensure the participant has sufficient recovery activity continuation sheets for each activity.
4. Demonstrate how to complete the activity log sheets.
5. Remind the participant to practice each activity up to 20 times, twice per day.
6. Explain / demonstrate the 'warm up' to be completed prior to recovery activity practice.
7. Discuss and decide upon possible recovery activity cues the participant can use to initiate RFTP programme practice.
8. Set date of next therapy session = _____
9. Please document the date and time of the next therapy session in the participant's handbook.

Therapist Name (print) _____

Signature _____ **Date** _____

The initial therapy assessment is now complete.

RAFTAS Study II	Participant Number ☐☐☐	Therapy Review Session

Therapy review session ( )

Participant Number ☐☐☐

Participant's comments about the programme (good and bad points):

_____

_____

_____

_____

Any other comments:

_____

_____

_____

_____

Review of participant's 'activity log sheets' (check for completion and ask for feedback)

_____

_____

_____

Please collect the participant's activity log sheets from the participant's handbook.

RAFTAS Study II	Participant Number ☐ ☐ ☐	Therapy Review Session

Upper limb reassessment

- Selective movement
- Passive range of movement
- Muscle tone
- Compensations
- Associated reactions
- Sensation
- Proprioception
- Coordination
- Pain

Shoulder	
Elbow	
Wrist	
Hand	

Inattention / other comments: _____

_____

_____

RAFTAS Study II	Participant Number ☐ ☐ ☐	Therapy Review Session

Rehabilitation goals achieved / progress made?

Goal 1: _____

_____

Goal achieved? Yes ☐ No ☐ Partially ☐

Change of goal / activity? If Yes, please document reason why:

_____

_____

_____

New goal set (if appropriate):

New goal 1 (W, D, E/D, O – please circle)_____

_____

_____

New activity set: (please detail the activity and document the number from the 'Recovery activity list)'.

_____

_____

_____

RAFTAS Study II	Participant Number ☐ ☐ ☐	Therapy Review Session

Goal 2: _____

_____

Goal achieved? Yes ☐ No ☐ Partially ☐

Change of goal / activity? If Yes, please document reason why:

_____

_____

_____

New goal set (if appropriate):

New goal 2 (W, D, E/D, O – please circle)_____

_____

_____

New activity set: (please detail the activity and document the number from the 'Recovery activity list)'.

_____

_____

_____

RAFTAS Study II	Participant Number ☐ ☐ ☐	Therapy Review Session

Please:

1. Demonstrate and practice the activities with the participant and ensure they are confident to undertake their RFTP programme without therapist supervision.
2. Place the appropriate 'recovery activity log sheets' into the relevant sections of the participant's handbook.
3. Ensure the participant has sufficient recovery activity continuation sheets for each activity.
4. Demonstrate how to complete the activity log sheets.
5. Remind the participant to practice each activity up to 20 times, twice per day.
6. Explain / demonstrate the 'warm up' to be completed prior to recovery activity practice.
7. Discuss and decide upon possible recovery activity cues the participant can use to initiate RFTP programme practice.
8. Set date of next therapy session = _____
9. Please document the date and time of the next therapy session in the participant's handbook.

Therapist Name (print) _____

Signature _____ **Date** _____

RAFTAS Study II	Participant Number ☐ ☐ ☐	Final Therapy Session

Final therapy session

Participant Number ☐ ☐ ☐

Review of participant's 'activity log sheets' (check for completion and ask for feedback)

_____

_____

_____

Any other comments:

_____

_____

_____

Please collect the participant's activity log sheets from the participant's handbook.

RAFTAS Study II	Participant Number ☐ ☐ ☐	Final Therapy Session

Rehabilitation goals achieved / progress made?

Goal1: _____

_____

Goal achieved? Yes ☐ No ☐ Partially ☐

Any comments: _____

_____

Goal 2: _____

_____

Goal achieved? Yes ☐ No ☐ Partially ☐

Any comments: _____

_____

RAFTAS Study II	Participant Number ☐ ☐ ☐	Final Therapy Session

Participant feedback

Please ask the participant:

1. In this study, we are including people who have recently had a stroke (up to 14 days after). How do you feel about being included in this study early after your stroke had occurred?

_____

_____

2. Do you think it was useful to use setting goals with the study therapist to help select what to include in the study programme?

Yes ☐ No ☐

Any comments: _____

_____

3. Did you use the cueing technique? Yes ☐ No ☐

If yes, was it useful?_____

_____

_____

If no, why not?

_____

_____

4. How did you find practicing your study therapy programme without the direct supervision of the study therapist?

_____

_____

RAFTAS Study II	Participant Number ☐ ☐ ☐	Final Therapy Session

5. You were reviewed twice per week by the study therapist during the study programme. Do you think this was often enough?

Too often ☐ Not often enough ☐ About right ☐

Any comments: _____

_____

6. What do you think about the activity log sheets (lay out, ease of use, pictures)?

_____

_____

7. What do you think about the participant handbook (use of ring binder folders, quality of general information, ease of use)

_____

_____

8. Any general comments:_____

_____

The final therapy session is now complete.

RAFTAS Study II	Participant Number ☐ ☐ ☐	Final Therapy Session

Please summarise goals and recovery activities selected during the RFTP programme:

Rehabilitation goals set during participant in programme (please list)

1. (W, D, E/D, O – please circle)_____

_____

Goal achieved? Yes ☐ No ☐ Partially ☐

2. (W, D, E/D, O – please circle)_____

_____

Goal achieved? Yes ☐ No ☐ Partially ☐

3. (W, D, E/D, O – please circle)_____

_____

Goal achieved? Yes ☐ No ☐ Partially ☐

4. (W, D, E/D, O – please circle)_____

_____

Goal achieved? Yes ☐ No ☐ Partially ☐

RAFTAS Study II	Participant Number ☐ ☐ ☐	Final Therapy Session

5. (W, D, E/D, O – please circle)_____

_____

Goal achieved? Yes ☐ No ☐ Partially ☐

6. (W, D, E/D, O – please circle)_____

_____

Goal achieved? Yes ☐ No ☐ Partially ☐

7. (W, D, E/D, O – please circle)_____

_____

Goal achieved? Yes ☐ No ☐ Partially ☐

8. (W, D, E/D, O – please circle)_____

_____

Goal achieved? Yes ☐ No ☐ Partially ☐

9. (W, D, E/D, O – please circle)_____

_____

Goal achieved? Yes ☐ No ☐ Partially ☐

RAFTAS Study II	Participant Number ☐ ☐ ☐	Final Therapy Session

10. (W, D, E/D, O – please circle)_____

_____

Goal achieved? Yes ☐ No ☐ Partially ☐

11. (W, D, E/D, O – please circle)_____

_____

Goal achieved? Yes ☐ No ☐ Partially ☐

12. (W, D, E/D, O – please circle)_____

_____

Goal achieved? Yes ☐ No ☐ Partially ☐

Recovery activities selected during the RFTP programme:

_____ _____
_____ _____
_____ _____
_____ _____
_____ _____
_____ _____
_____ _____
_____ _____
_____ _____

RAFTAS Study II	Participant Number ☐ ☐ ☐	Final Therapy Session

Study therapists:

Please provide any comments about the RFTP programme and study materials below:

_____

_____

_____

_____

Therapist Name (print) _____

Signature _____ **Date** _____

Study therapists:

Please give all therapy documentation and collected activity log sheets to the SRN staff member.

SRN staff:

Please photocopy all therapy documentation.

The original must be kept in the Investigator site file. Please send the copy to Lianne Brkic or Debbie Jones at Newcastle University.

Thank you for your contribution to the RAFTAS study II.

Appendix 8: Therapy manual

Repetitive arm functional tasks after stroke

(RAFTAS) study II

Therapy Manual

Please do not hesitate to contact Lianne Brkic at the Newcastle University Stroke Research Group if you have any queries on:

Tel: 0191 2228209 or 07964 328778.

Email: lianne.brkic@newcastle.ac.uk

Stroke association

Newcastle University

Contents

Background to the research project

Loss of upper limb function affects up to 69% of patients with acute stroke (1). Patients report that it is one of the most distressing long term consequences and that rehabilitation pays insufficient attention to recovery of their upper limb. Only 5%-20% of stroke patients with initial upper limb impairment fully regain function, and 30-66% have no upper limb function at six months. In contrast, 80% of patients are eventually able to walk again (2). Stroke patients who are unable to use their upper limb, even if ambulant, may require a prolonged inpatient stay and long term support from their families, friends or social services.

It is unclear how to optimize upper limb recovery after stroke. Individual trials of increased therapy intensity have shown mixed results, but meta-analysis suggests a small but significant benefit for speed of upper limb recovery when increased therapy time is provided (3). A study providing supplementary upper limb therapy suggested that 20 extra hours of upper limb training, starting at 2 -3 weeks post stroke (lasting 4 – 6 weeks) yielded better outcomes than usual upper limb rehabilitation (4), suggesting that benefit is more likely if additional treatment is given early following acute stroke. The potential value of early intervention is also supported by research indicating that most significant recovery of upper limb function occurs within the first four weeks after stroke (1).

Theories of neuroplasticity and motor learning support an approach based on repetition of functional tasks (5). Systematic reviews of therapy interventions suggest that patients benefit most from exercise programmes in which functional tasks are directly practised, rather than interventions which are impairment focused, such as muscle strengthening (3, 6, 7). A Cochrane systematic review of available evidence showed that occupational therapy specifically aimed at improving functional Activities of Daily Living (ADL) improved outcomes after stroke (8).

A further Cochrane systematic review suggested that upper limb recovery following stroke may be improved by repetitive functional task practice (RFTP), but this fell short of statistical significance (9). Included studies were small, did not describe interventions in detail and were often of poor quality. In most studies, RFTP interventions were delivered under the direct supervision of a therapist and provision of this amount of therapy would be a challenge for most stroke services in the UK. A study from Canada found that a self-administered graded repetitive upper limb supplementary programme improved upper limb recovery in the sub-acute phase (3 weeks post stroke) (10).

RFTP could be an intervention which selected patients undertake themselves after an initial therapy assessment, with on-going supervision from a therapist. It could be carried out by patients in both the hospital and home setting providing enhanced rehabilitation within current NHS funding constraints. A RFTP programme which is individualised to patient ability and context specific involving practicing tasks that are relevant to the participant both in hospital and at home is likely to promote ability to perform activities in everyday life.

We have been awarded funding from The Stroke Association to develop and pilot a RFTP programme for stroke patients with reduced upper limb function. This work will inform the design of a multicentre randomised controlled trial to determine the clinical and cost effectiveness of the RFTP programme. Our work to date includes theory based development of an initial RFTP programme and testing this on a small number of patients. Development of the RFTP programme was based on a review of patient-selected goals and activities in previous randomised controlled trials (RCT) of RFTP, while considering the context of programme delivery (i.e. hospital and home settings) and upper limb activities of daily living. Consultations with a local patient/carer panel and local stroke therapists occurred throughout programme development.

The initial RFTP programme was delivered to seven participants in two study centres by the study research physiotherapist who developed the programme. Feedback collected from study participants and the experience gained by the study research physiotherapist allowed further modification and revision of the programme. This updated RFTP programme is the study intervention in this pilot RCT.

Overview of the RAFTAS study II

Study aim

The aim of the study is to assess the feasibility of a multi-centre, observer blind parallel group randomised controlled trial of a RFTP programme for the upper limb early after stroke.

Study inclusion/exclusion criteria

Adults with acute stroke who fulfil the following criteria will be eligible:

Inclusion criteria:

- Age > 18 years.
- Within 14 days of stroke onset.
- New reduced upper limb function due to acute stroke but with retained ability to lift the affected hand off their lap.
- Capable of undertaking the RFTP therapy programme and adhering to the study protocol.
- Able to provide informed consent to participate in the study.
- Lives within the community services catchment area of a participating study centre.

Exclusion criteria:

- Severe reduced upper limb function which results in inability to lift the affected hand off their lap.
- Unable to follow the RFTP programme for example due to cognitive impairment or receptive aphasia.
- Other significant upper limb impairment e.g. fixed contracture, frozen shoulder, severe arthritis, and upper limb pain that inhibits participation in the RFTP programme.
- Diagnosis likely to interfere with rehabilitation e.g. registered blind, palliative care.

Case ascertainment, recruitment and consent

Potentially eligible participants will be identified by the local Stroke Research Network (SRN) staff or local stroke unit staff. Potentially eligible patients will be approached by the local SRN staff member who will discuss the study and complete the consent process if the patient is agreeable.

Baseline assessment

A baseline assessment will be performed by the local SRN staff member following patient consent to study participation. Prior to baseline assessment and participant randomisation, the local SRN staff member will check that the local study therapist is available to provide the initial therapy session within 24 hours for participants allocated to the intervention group.

The following data will be collected: name, address, telephone number, date of stroke, first ever or recurrent stroke, stroke type (e.g. infarct, haemorrhage), stroke subtype (TACS, PACS, LACS, POCS), National Institutes of Health Stroke Scale (NIHSS), pre-stroke OHS (Oxford Handicap Scale) and hand dominance.

The following data will also be collected; arm function (Action Research Arm Test (ARAT) (11)), grip strength (dynamometer) and arm strength (Motricity Index (12)).

Randomisation

Participants will be randomised via a central independent web based service hosted by Newcastle University Clinical Trials Unit. Participants will be stratified according to research centre and randomised to intervention and control in a 1:1 ratio using permuted block sequences. Randomisation will be performed by the local SRN staff member after the baseline assessment.

Outcome assessments

Outcomes will be assessed at one month (+/- 3 days) and three months (+/- 5 days) following randomisation, and undertaken by research staff blinded to participant allocation.

The following data will be collected: arm function (Action Research Arm Test (ARAT) (11), grip strength (dynamometer), arm strength (Motricity Index (12)), extended activities of daily living (Nottingham Extended Activities of Daily Living Index (13)).

Blinding

Due to the nature of the intervention, it is not possible to blind stroke patients to treatment allocation. Outcome assessments will be performed by researchers (local study centre therapist or researcher from Newcastle University) blinded to treatment allocation and the success of this monitored.

In addition, we will attempt blinding of local stroke service staff providing usual rehabilitation care during the study intervention period. This is to minimise competitive therapy bias i.e. to minimise patients in the control group receiving more usual therapy if staff feel they are 'missing out'. This would decrease potential differences between the study groups. Stroke service staff blinding is being attempted by means of the participant handbook which is being given to both control and intervention groups and is identical in external appearance.

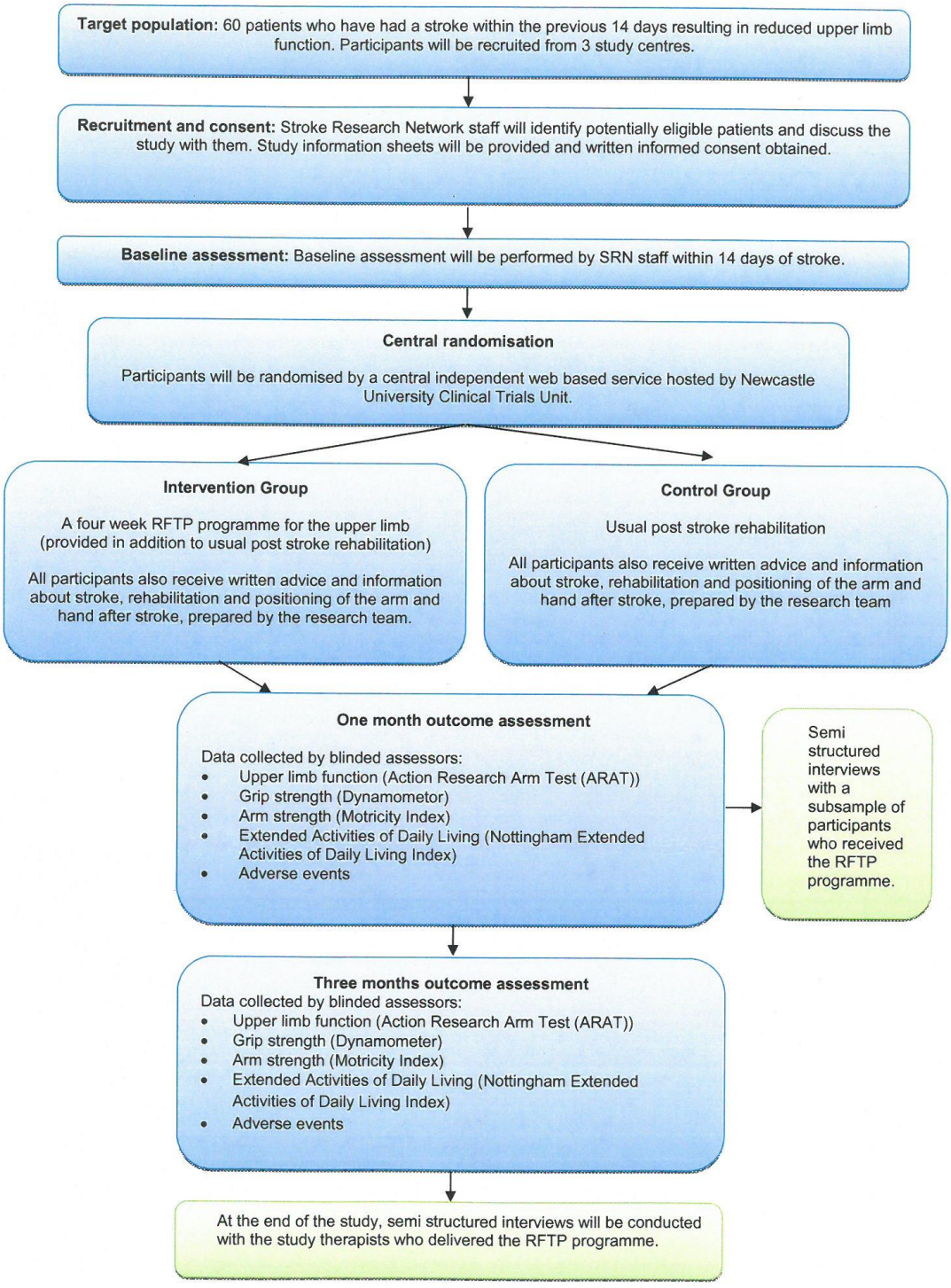
Study withdrawal

No specific study withdrawal criteria have been set. Participants may withdraw from the study at any time for any reason. Should a patient decide to withdraw from the study, a reason for withdrawal will be sought but patients can chose to withdraw without providing an explanation. If a participant decides to withdraw it will not affect the normal care they receive.

If a participant does not wish to continue to complete the RFTP programme, they will be asked if they are willing to continue to attend outcome assessments.

Clinical teams, local study therapists or investigators may also withdraw participants from the study at any time if they feel it is no longer in the participant's interest to continue, for example, because of intercurrent illness.

Study summary



RFTP programme

The study intervention treatment developed in earlier phases of this research project is a four week programme of twice daily repetitive functional task practice for patients with upper limb impairment which is undertaken early after stroke. The programme comprises of functional tasks embedded in routine everyday activities which are undertaken on the ward or at home. This makes the programme highly relevant to the participant, promotes 'carry over' into real life situations and encourages motivation to practise the programme.

Participants select and practise activities of daily living which involve use of the upper limb. Each activity is practised independently by the participant for up to 20 times, twice a day, for four weeks (maximum 80 repetitions per day). The activities relate to washing, dressing and eating/drinking. There is also an 'optional' category which is included to allow participants to select an activity that is not listed under the other categories, for example using a mobile phone. Optional tasks offer choice and should enhance participant motivation.

At the start of the programme, the designated local study therapist will perform an assessment to determine upper limb motor impairment and assess other neurological deficits (e.g. sensory loss or inattention) that may impact on upper limb function. The local study therapist and participant will then discuss rehabilitation concerning washing, dressing, eating/drinking and/or other activities involving the upper limb.

The participant will identify their two most important upper limb activities of daily living they would like to be able to perform again, and these will be used to set two functional rehabilitation goals. An example of a functional rehabilitation goal is 'I would like to use my affected hand when washing my face'. Goals will be realistic and potentially achievable within the four week programme.

The functional rehabilitation goals will be used to choose activities to practise to achieve the goals. Activities (named 'recovery activities' in the RFTP programme) will be selected from a list which has been created for each functional category (washing, dressing eating/drinking, optional). A wide range of activities are available in each category which are ordered into three levels of ability. Ability levels were generated by considering biomechanical parameters (for example amount of upper limb movement and coordination required) and the level of mental processing needed to complete the activity. The levels will be used to guide the local study therapist in appropriate activity selection. For example, a level 1 activity is appropriate for a participant with severe upper limb functional impairment.

The local study therapist will demonstrate the chosen activities and ensure the participant is confident to practise independently. To assist the participant to remember that activities are twice daily, the therapist will advise participants to use cues from their daily routine. An example of cueing is using getting washed in the morning to prompt a RFTP washing recovery activity. Cueing will also ensure the relevant everyday objects required for the activity are readily available to participants. The cueing technique will incorporate the RFTP activities into the participant's daily routine, causing minimal disruption to them, the ward staff and their family / friends. Using daily routine cues should ensure the different activities are spaced throughout the day and allow for adequate rest periods between activities.

All participants will be given written guidance about undertaking their chosen activities along and asked to log their twice daily practice. In addition, they will be asked to provide feedback about performing the activities. The local study therapist will demonstrate how to complete the log sheets. For participants who are unable to complete the log sheet, the local study therapist will ask a family member / friend / member of staff to complete the log on their behalf.

Prior to practising their RFTP recovery activities, participants will undertake a brief warm up session. This consists of gently stretching the upper limb in a reaching motion. The aim of this is to focus their attention on the affected upper limb and prepare for recovery activity practice.

Participants will be reviewed by the local study therapist twice per week. These sessions will consist of a brief re-assessment of the participant's upper limb function, and review of progress towards their chosen goals. The goals and/or recovery activities will be adjusted according to progress and new log sheets issued as required. If the participant has achieved a goal, a new goal will be set and a new activity selected. If the participant is finding a goal or activity too challenging, alternatives will be selected. Should a participant regain normal upper limb function before the end of the four week study, they will be discharged from the programme. The therapy reviews will also include gathering feedback from the participant concerning their experiences of participating in the programme.

At the final therapy session, there will be a discussion about the participant's progress and advice will be given about maintaining and improving upper limb function. Further feedback from participants about their involvement with the RFTP programme will also be sought. After the final therapy session, the local study therapist will liaise with the participant's usual NHS therapist(s) or other clinical teams (as appropriate) about progress made. After the final therapy session, the local study therapist will liaise with the participant's usual NHS therapist(s) or other clinical teams (as appropriate) about progress made. The RFTP programme is in addition to usual post stroke rehabilitation, which the participants will continue to receive throughout their involvement in the study and once the study ends.

We aim for the RFTP programme to commence as soon as possible after stroke onset with an upper time limit of 14 days. SRN staff and local study therapists will work together to ensure recruitment/randomisation and commencement of therapy are closely co-ordinated to ensure this is possible. If a participant who is discharged home wishes to have their RFTP therapy review sessions in hospital, this will be arranged.

Delivery of the RFTP programme

1. Participant initial assessment and generation of an individualised RFTP programme

The first RFTP therapy session will take approximately 60 minutes and comprise of the following:

a. Overview of the RFTP programme

The local study therapist will explain further about the RFTP programme and answer any questions the participant has about the study or RFTP programme.

b. Upper limb assessment and goal setting

- The local study therapist will complete an upper limb assessment to establish motor impairment and other neurological deficits that may impact on the participant's upper limb function.
- A discussion will then take place regarding upper limb rehabilitation needs under the four categories (i.e. washing, dressing, eating/drinking and optional)..
- The local study therapist will assist the participant to select two needs that are most important to them and set a realistic functional goal for each which can be potentially achieved within the four week therapy programme. NB 'eating and drinking' goals may not be appropriate in participants who are 'nil by mouth' or may require advice from the local speech and language therapist.

c. Selection and demonstration of RFTP recovery activities

- The local study therapist will use the 'recovery activity' list to select an appropriate 'recovery activity' for each functional goal.
- Recovery activities are ordered into three ability levels and the local study therapist will use their clinical judgement to select activities which are most appropriate to the current upper limb functional level of the participant. For example, participants with minimal selective movement may require a recovery activity that is a component of / works towards a functional task. For the participant goal 'to wash under my arm', recovery activity (touch your chest – midline- with your affected hand) may be a good initial choice.
- The local study therapist will explain and demonstrate the selected activities to ensure they are a suitable choice and that the participant will be able to practise independently.

d. Advice on how to carry out RFTP recovery activity practice

- The local study therapist will advise on:
  i. Twice daily activity practice for seven days each week for four weeks.
  ii. Up to 20 repetitions of each activity at each session.
  iiii. A suitable cue which the participant may use to trigger the activity practice.
  iv. Recovery activity practice in a seated position unless otherwise specifically stated (for safety)
- The local study therapist will also demonstrate the simple arm warm up exercises to be performed prior to recovery activity practice.

e. Provision and explanation of the participant handbook

- The local study therapist will provide the participant with a study intervention participant handbook.

- The local study therapist will demonstrate how to use the participant handbook.
- The appropriate activity log sheets (matching the participant recovery activity choice) will be placed into the handbook.
- The local study therapist will demonstrate how to complete each log sheet.

2. Twice weekly therapy reviews

RFTP therapy review sessions will be undertaken twice per week, will take from 30 – 40 minutes and comprise of the following:

a. Discussion about participating in the RFTP programme since the last therapy face to face session

- The local study therapist will enquire about:
  i. How the participant has been finding the activity practice and gather any feedback about positive points or difficulties / concerns.
  ii. Anticipated RFTP therapy related adverse events.
- The local study therapist will also review the activity log sheets to determine if there have been any difficulties with completion.

b. Re-assessment of the upper limb

- The local study therapist will complete a further upper limb assessment to review motor impairment and other neurological deficits impacting on upper limb function.

c. Review of functional goals and recovery activities

- The local study therapist will review progress towards the goals previously set.
- A new goal will be set if the goal has been achieved and a new recovery activity chosen.
- A modified goal or activity will be set if the goal has been too challenging.
- A modified/new goal or activity will be also chosen if a participant wishes.

d. Demonstration of any new recovery activities and provision of additional log sheets

- The local study therapist will explain and demonstrate any new activities to ensure they are a suitable choice and that the participant will be able to practise independently.
- The appropriate new activity log sheets (matching the participant recovery activity choice) will be placed into the handbook.
- The local study therapist will demonstrate how to complete each log sheet.
- Old activity log sheets will be collected and stored with the participant's study therapy notes.

e. Advice on how to carry out RFTP recovery activity practice

- The local study therapist will remind the participant about:
  i. Twice daily activity practice for seven days each week for four weeks.
  ii. Practice up to 20 repetitions of each activity at each session.
  iii. Use a suitable cue which the participant may use to trigger the activity practice.
  iv. Warm up exercises prior to recovery activity practice

3. Final therapy review

A final RFTP therapy review will take place at the end of week four (or earlier if the participant regains normal upper limb function) and will comprise of the following:

a. Review of functional goals

- The local study therapist will review progress towards the goals set each week during the RFTP programme.
- Advice will be given about maintaining upper limb function achieved.

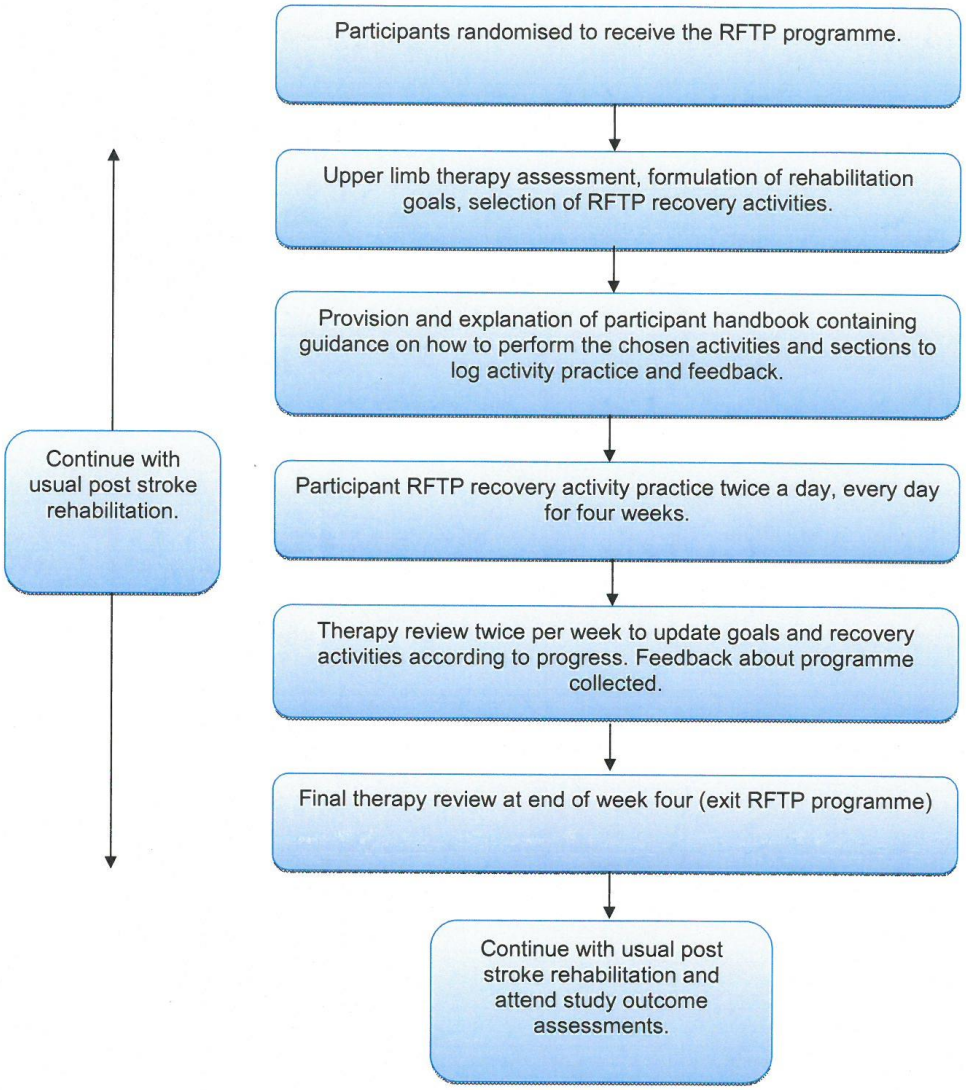
b. Discussion about participating in the RFTP programme

- The local study therapist will collect further feedback about participating in the RFTP therapy programme.
- The local study therapist will review the activity log sheets to determine if there have been any difficulties with completion.
- A final enquiry about anticipated RFTP therapy related adverse events will be made.
- The local study therapist will remind the participant that they will be contacted by the study team to arrange their outcome assessments.

c. Liaison with routine NHS therapy team

- The local study therapist will speak to the participant's usual NHS stroke therapist(s), (if still participating in routine therapy) to provide an update on upper limb progress during the study.

RFTP programme summary



Study control treatment

Participants in the control group will receive usual upper limb rehabilitation.

Participants in the control group will also receive a participant handbook which explains the study and contains advice and information about stroke, rehabilitation and positioning of the arm and hand after stroke ('control group handbook'). The control group handbook appears the same as the handbook provided to intervention participants and will be given to control group participants by the local SRN staff member.

The information in the control group handbook is the same as that provided to the intervention group but the control group handbook does not contain the individualised RFTP programme. The purpose of this handbook is to attempt blinding of stroke unit staff who provide usual rehabilitation care and help to minimise competitive therapy bias. In addition, we believe the handbook will reduce feelings of 'resentful demoralisation' in some control group participants. Resentful demoralisation is when participants in the control group feel disappointed about not receiving the study intervention (the RFTP programme).

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Study roles

Role of the local Stroke Research Network staff member(s)

1. To identify potential participants in collaboration with local stroke unit staff.
2. To initially approach potential participants to discuss the research study, provide an information sheet and subsequently obtain written informed consent.
3. To contact the local study therapist to ensure the initial therapy assessment can be completed within 24 hours of baseline assessment and randomisation.
4. To complete the baseline assessment.
5. To perform study randomisation
6. To inform the participant about group allocation
7. To contact the local study therapist to inform them of the participant's group allocation.
8. To send the GP letter
9. To maintain the study screening log
10. To report serious adverse events

Role of the local study therapist

1. To assist local SRN staff to identify potentially eligible participants for the research project. Be aware that some patients may not be suitable immediately following hospital admission but may become potentially eligible within the study recruitment period (0 - 14 days post stroke).
2. To inform the local SRN staff about potentially eligible patients. The initial discussion of the research study with a participant should be performed by the local SRN staff.
3. To provide the RFTP programme as outlined in 'Delivery of the RFTP programme' (see page10).
4. To prompt participants to practise their RFTP 'recovery activities' where possible.
5. To identify and report potential serious adverse events to the local SRN staff member who will complete an SAE form and forward this to the study research physiotherapist/ chief investigator.
6. To feedback to the participant's usual NHS stroke therapist(s) about participant progress at the end of their involvement in the study.

Role of the participants

All participants will be asked to:

1. Undergo a baseline assessment with a local SRN staff member.
2. Participate in two research outcome assessments at one month and three months post-randomisation.

Participants randomised to the intervention group will be asked to participate in the RFT programme:

1. Undergo an initial arm assessment, select two rehabilitation goals and select two recovery activities.
2. Practise the recovery activities for up to 20 times, twice per day for four weeks.
3. Log recovery activity practise and feedback in their participant handbook.
4. Undergo twice weekly therapy reviews with the local study therapist to allow modification of rehabilitation goals and recovery activities according to progress, and provide feedback on the therapy.
5. Undergo a final therapy review at the end of the study to review participant goals (to document progress) and provide further feedback.

Role of the usual NHS stroke care therapists in supporting the study

1. To assist local SRN staff members to identify potentially eligible participants for the research project. Be aware that some patients may not be suitable immediately following hospital admission but may become potentially eligible within the study recruitment period (0 - 14 days post stroke). The initial discussion of the research study with a participant should be performed by a local SRN staff member.

Role of the study research physiotherapist (based at Newcastle University)

1. To set up and day to day management of the RAFTAS II study.
2. To provide training to deliver the RFTP programme for the local study therapist(s).
3. To provide information about the RFTP programme to other local stroke staff.
4. To provide support to the local study therapist(s) delivering the RFTP programme
5. To conduct 1:1 interviews with a purposive sample of intervention group participants and the local study therapists.

Role of the outcome assessor

1. To arrange outcome assessments with all study participants.
2. To regularly liaise with SRN staff.
3. To perform outcome assessments.

Further reading: theoretical basis and development of the RFTP programme

Earlier work in this study included theory based development of an initial RFTP programme which was tested on a small number of patients with stroke. Consultations with a local patient/carer panel and local stroke therapists occurred throughout programme development.

RFTP programme requirements:

In designing the RFTP programme we considered that it needed to be:

- ✓ Easily adhered to by participants and staff.
- ✓ Compatible with other aspects of the patient's care and rehabilitation programme.
- ✓ Easy for the participant to understand.
- ✓ Standardised but involving individual participant goal setting and activity choice.

In designing the specific 'recovery activities' we considered that they needed to be:

- ✓ Relevant to the participant.
- ✓ Individual to each participant.
- ✓ Challenging yet achievable.
- ✓ Engaging.
- ✓ Promote long term retention of acquired skills as opposed to short term performance benefits.
- ✓ Suitable to cover a range of arm functional ability.

These RFTP programme requirements can be used as a guide when considering feedback about the programme.

Summary of the RFTP programme development

Creating the recovery activity list

- The use of a list of recovery activities for this RFTP programme is to provide standardisation, to ensure activities to be practised are functional or towards a functional purpose, and to facilitate ease of delivery of the programme by therapists.
- Research papers included in the Cochrane systematic review of repetitive task training and other studies published since the review were examined. The exercise programme and content described were collected from each applicable paper. Exercises involving abstract equipment such as small weights / theraputty were excluded, leaving only exercises functional in nature.
- A list everyday objects used in tasks involving the upper limb was created. Everyday objects chosen should be readily available on a stroke unit and in the participant's home (i.e. participant's possessions, cutlery etc).
- This list was used to generate ideas for further everyday functional tasks in the context of the acute ward / home environment.
- Recovery activities were divided up into different categories relating to activities of daily living involving the upper limb (washing, dressing eating/drinking, optional).

- Recovery activities were then ordered into three levels of ability. Ability levels were generated by considering biomechanical parameters (for example selective activity present and coordination required) and the level of mental processing needed to complete the activity.

Use of goal setting to assist with recovery activity selection

- It is familiar to therapists and common in everyday therapy practice to use goal setting to focus rehabilitation and tailor treatment towards what the patient wishes to achieve. It was logical to use the same familiar process in this research study.
- Goal setting will enable participants to choose recovery activities that are most relevant and appropriate to them. The aim is to make the RFTP programme as individualised and relevant as possible.

Number of recovery activity repetitions

- A component of this study is to establish the number of repetitions which are both feasible and acceptable to patients.
- There must be a sufficient number of repetitions of activities for the programme to be classed as 'repetitive practice' but the number must also be feasible in everyday life.
- A variety of considerations need to be addressed including:
  i. Time taken to complete the repetitions.
  ii. Establishing a realistic number of repetitions to perform during the day(finding the time to do them).
  iii. Determining the number of repetitions that do not cause unreasonable fatigue in patients.
- Taking the above into consideration, it was decided that participants will be asked to perform as many repetitions as possible up to a maximum of 20. A maximum number of repetitions has been set to prevent enthusiastic participants from experiencing excessive fatigue.

Number of recovery activities

- After dividing recovery activities into four categories it was initially suggested that participants should select one goal from each category i.e. four activities in total. However, feedback received from local stroke therapists and a SRN lay panel was that practising high numbers of repetitions of four activities would be too intensive / demanding for participants.
- The focus of this study concerns repetitive practice, so the number of recovery activities selected was reduced to two, rather than reducing the number of repetitions. Practise of two recovery activities rather than four should make the RFTP programme more manageable for participants whilst preserving the variety of activities and interest of participants.

Twice daily practice

- Twice daily practice aims to increase the overall number of daily repetitions whilst promoting rest periods between practice sessions. This should allow a high number of recovery activity repetitions without compromising good quality practice.

Individual practice

- Delivery of an RFTP programme under the direct supervision of a therapist would require significant resource provision from the NHS. This amount of therapy would be a challenge for most UK stroke services.
- We believe that RFTP is an intervention which selected patients could undertake themselves after an initial therapy assessment, with on-going supervision from a therapist. This could be carried out by the participant in both the hospital and home setting providing enhanced rehabilitation within current NHS funding constraints.
- Individual practice should also promote a sense of empowerment and control over participants' own rehabilitation.

Cueing technique

- Stroke is a life changing event. An unfamiliar environment and/or cognitive/memory problems can make initiating independent therapy practice challenging. To address this issue participants are advised to use cues from their daily routine to prompt them to practise the recovery activities.
- Using the cueing technique should assist them to remember to perform the activities and help incorporate recovery activity practice into their daily routine. This should put the recovery activities into context for the participants and hopefully promote 'carry over' into everyday life.
- Using the cueing technique should space out activities during the day and allow adequate rest periods between activity practice. Resting between recovery activity practice sessions could also promote good quality practice.

Twice weekly reviews

- Part of the feasibility study is to establish how many review sessions per week is manageable for therapists and how many is most suitable for participants.
- When deciding upon the optimal number of therapy reviews the challenge was to balance supporting and progressing rehabilitation in participants whilst not demanding too much face to face therapy time.
- Twice weekly therapy reviews with appropriate alteration of the RFTP programme should ensure participants are kept stimulated and should maximise their rehabilitation potential without demanding too much of the therapist's time.

The initial RFTP programme produced was delivered to seven participants across two study centres by the research physiotherapist who developed the programme. Feedback collected from study participants and the experience gained by the research physiotherapist allowed further modification and revision of the programme. The resulting RFTP programme is the study intervention in this pilot RCT.

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Appendix 9: Usual post stroke rehabilitation data collection form

RAFTAS Study II	Participant number ☐☐☐☐	Date .....

Repetitive Arm Functional Tasks after Stroke (RAFTAS) Study II.

Usual care form: mobility, upper limb and ADL rehabilitation.

Please record face to face contact therapy sessions each day (one sheet per day) for the time the participant is enrolled in the study.

	Therapy session provided by (tick more than one if joint session:	**Total face to face therapy time (minutes)**	**Time spent in therapy session focussed on:**
Session 1 Hospital / community session (please circle)	OT ☐ Physio ☐ Therapy assistant ☐ Nurse ☐	.....	Mobility .....mins Upper limb (RFTP) *.....mins Upper limb (other) .....mins ADL (personal) .....mins ADL (domestic) ..... Other .....
Session 2 Hospital / community session (please circle)	OT ☐ Physio ☐ Therapy assistant ☐ Nurse ☐	.....	Mobility .....mins Upper limb (RFTP) .....mins Upper limb (other) .....mins ADL (personal) .....mins ADL (domestic) .....mins Other .....mins
Session 3 Hospital / community session (please circle)	OT ☐ Physio ☐ Therapy assistant ☐ Nurse ☐	.....	Mobility .....mins Upper limb (RFTP) .....mins Upper limb (other) .....mins ADL (personal) .....mins ADL (domestic) .....mins Other .....mins

*RFTP = repetitive functional task practice (functional tasks involving the upper limb are directly practised a number of times during the session).

Usual care form, V1, May 2013

Appendix 10: Recovery activity Log continuation sheet

Participant Number: _____

Day: _____ Date: _____

Please mark a box for each attempt of the activity.

MORNING

AFTERNOON/EVENING

Reason for stopping session if less than 20 repetitions:	
Comments regarding the task/programme:	
Approximate time spent doing repetitions:	
Help given from another person:	

No activity today ☐

Day: _____ Date: _____

Please mark a box for each attempt of the activity.

MORNING

AFTERNOON/EVENING

Reason for stopping session if less than 20 repetitions:	
Comments regarding the task/programme:	
Approximate time spent doing repetitions:	
Help given from another person:	

No activity today ☐

Activity Continuation Sheet (RAFTAS II) Version 2: April 2013

Appendix 11: Participant interview Topic Guide

Participant number ☐☐☐

Repetitive arm functional tasks after stroke (RAFTAS) study II

Qualitative Interview Topic Guide

We are interested in hearing about your views and experiences on the RFTP therapy programme which you practiced for the RAFTAS II study. Reminder that they can stop the interview at any time.
Start by:

1. Talking generally about experiences undertaking the programme and what you practiced.
2. Move on to how the programme was organised and delivered.

Section 1: Overall, what do you think about the study programme?

Area covered	Additional notes
Goals (preferred standard?) ☐	
Involved in deciding ☐	
Recovery activities • Range ☐ • Relevance ☐	
Practicing helped with everyday life (carry over)? ☐	
Number of repetitions ☐	
Help ☐	
Independent practice ☐	
Cueing technique Help ☐	
Handbooks ☐	
Activity log sheets ☐	

Participant number ☐☐☐

I'd like to ask you more about what you think about practicing the exercises on your own.

Area covered	Additional notes
How feel about it ☐	
Effect on your confidence ☐	
Altered view about practicing alone ☐	
Effect on confidence in trying everyday activities on discharge home ☐	

I'd like to talk about the activities and what effects you think they had on your motivation to practice.

Area covered	Additional notes
Do you think that practicing everyday activities that you wished to be able to perform again help motivate you to practice the programme? ☐	
Do you think undertaking the RFTP programme had an effect on your motivation to participate in your usual NHS rehabilitation? ☐	

Participant number ☐☐☐

Section 2: Move on to how the programme was organised and delivered.

Area covered	Notes
Timing of recruitment ☐	
Length of programme ☐	
Time taken to complete practice ☐	
Therapist supervision ☐	
How well the programme fits in with usual therapy ☐	

All in all

Area covered	Notes
Good ☐	
Could have been better ☐	
Positive impacts ☐	
Negative impacts ☐	
Ways of improving the programme ☐	

Name..... Signed.....

Date.....

Appendix 12: Local study therapist interview topic guide

Repetitive arm functional tasks after stroke (RAFTAS) study II
Therapist interview: interview topic guide for therapists who delivered the RFTP programme

Note: remind the therapist that they can stop the interview at any time.

The interview will be in 3 sections:

1. RFTP programme design and content
2. Ease of use of the study materials
3. Delivery of the RFTP programme in hospital and community settings.

Start with the general question: 'What is your opinion about the RFTP programme?'

Section 1: RFTP programme design and content

Note: first focus on the design then the content.

Design

What do you think about the design of the RFTP programme?

Prompts:

- Individualised assessment and goal setting
- Joint decision making with participants
- Participant independent practice of the RFTP programme
- Cueing technique
- Length of the study programme
- Number of therapy reviews per week

Content

What do you think about the content of the RFTP programme?

Prompts:

- Direct practice of functional activities
- Recovery activities included in the programme
  - range (ability levels)
  - relevance
- Intensity:
  - Numbers of repetitions
  - Number of daily practice sessions
  - Practice 7 days per week
  - Number of goals / activities
- Cueing technique

What advantages/disadvantages might be considered for **patients** participating in the RFTP programme.

- What do you feel works 'well' (and why) for patients?
- What do you feel could be improved for patients (why and how)?
- What's your impression about what patients think about it/will think about it?
- Do you think some patients will be better suited to it than others (if so, which ones/why?)

Section 2: Ease of use of the study materials

What do you think about the study materials?

Prompts:

- Therapy materials
  - assessment and review forms
  - Use of folders
- Activity log sheets
  - Logistics for delivery
  - Use by participants
- Participant handbooks

Section 3: Delivery of the RFTP programme in hospital and community settings

First can we discuss how the programme was delivered within your NHS trust?

Prompts:

- Please can you describe the post stroke therapy service available to patients in your trust?
- What is your role within the stroke service/background?
- Do you work full time / part time?
- Where were the majority of the therapy sessions based?
- Do you think these factors had an influence on how the programme was delivered?
- What are your views on the ideal type of therapists to deliver the programme?
  - Do you think community therapists or ward based therapists are more suitable for delivering the programme and why?
  - Part time or full time workers?

Next can we focus on your experiences in delivery of the programme.

Prompts:

What were your experiences in delivery of the programme?

- Different settings (ward and community)
- How well the RFTP programme fits in with usual care
- Barriers to delivery
- Enablers to delivery
- Responses from participants:
    - Help with practising the programme
    - Ability to complete documentation

What advantages/disadvantages might be considered for **therapy staff** who would be providing this therapy?

Can you see the RFTP programme becoming part of normal service provision for stroke patients (if shown to be effective)? (why/why not)

Summary

Overall:

- What worked well?
- What didn't work so well?
- Can you make any suggestions for improvement?

Summary/closing:

Is there anything else that we haven't covered, that you would like to comment on?

Interviewer: Thank you for your time and for contributing to the RAFTAS study.

Appendix 13: Example of initial coding of a participant interview

** NB Each participant interview was coded. The coding framework followed an iterative process and was progressively developed during participant interview analysis. Coded interview transcripts were colour coded (per participant) and combined. Codes were then categorised into themes.*

Participant interview analysis – initial coding Participant A

A priori codes - reflected closely to the questions used in the interview

Code: Importance of individualisation of the programme / relevance of activities

L: Do you think it helped that you had specific things that you were working towards then? Using the goals?

P: Yeah.

P: Eye, eye, every single day I was focused on the stuff that you never ever dreamed you couldn't do, that you have to do again. Everything, it was important to us.

L: Aw, that's really nice to hear. So do you feel that the tasks were – well, it sounds like they were very relevant to what you wanted to work on?

P: Yeah they were, definitely.

P: Yeah, they're relevant for everybody, because you've got to be able to clothe yourself and hold a knife and fork. So you've got to, there's no way around it, you've got to those things, so every task that I done, was relevant.

P: Yeah, you know, it's the kind of things you do every day and you've got to train your brain to start doing them again.

Code: Joint goal setting / participant self-efficacy?

L: Did you like being involved in deciding what you were going to practise, and what you were going to work towards?

P: Erm, [therapist name] asked us what I needed – what the best was for me – but also [therapist name] was basically saying well, you know, I need to learn this to get myself dressed, I need to learn (you know) to pick mobile phones up and stuff like that so it was both of us really (you know) deciding together.

L: Yeah, both deciding together. So, did you like being more involved in that.

P: Yes, nobody was telling us what to do, because this left arm was weak and I also spoke to me occupational therapist to say, I need that arm strengthening up. They sent me to the gym, referred me to the gym, stuff like that. [therapist name] asked me what I was struggling with; my fine finger movement. I couldn't use my mobile phone on my left hand side, bear in mind, I'm right handed anyways, so it was twice as hard but the zips and the buttons were something you have to do, and [therapist name] put that forward in the tasks, so we both discussed the tasks.

L: **That's good. So, you liked working together, to discuss what you were going to work on?**

P: Yeah.

Code: Adequate range of recovery activities

L: **You know once you'd decided what you were going to work on, [therapist name] then went to a list of different activities to choose to work towards. Did you think there was a wide enough range to choose from, for what you needed? Do you think there were things missing or do you think it was good enough; the list?**

P: No.

L: **So, was everything there, that you needed?**

P: Yeah, everything that I needed. Everything that she give us that we'd discussed was everything that I needed and as I said, I wouldn't be like this if it wasn't for the tasks.

Code: Programme intensity achievable

L: **Good stuff. So, you said about the number of repetitions you did during the day. Do you think, that was about the right number of repetitions to do?**

P: Yeah, definitely, definitely.

L: **Or do you think you could have managed more?**

P: I think it depends on the person.

L: **What about for you?**

P: Well, I'm quite impatient. Erm, twenty…at first I was tending to hurry the twenty because (believe it or not) I didn't think I had enough time in the day to do it but I did.

P: I found that I had the time to do the twenty in the morning and twenty and hour later on different other stuff, one on my hand and one on my legs, mainly all the fine movements.

L: **So the stuff you were marking, the RAFTAS stuff, the repetitions. You thought that was about right?**

P: I think so.

Code: Did not read information in handbooks

L: **What did you think about the general layout of that handbook? Was that information useful?**

P: No, I've never been one for books and things. I think when you're doing it physically, that's the only result. You can sit and read books and pictures, but it's not the same

as actually doing it. So when you're doing the tasks and doing the stuff she's asking you to, it's different from reading a book.

L: **So were you just, more using the sheets that she'd left you?**

P: Yeah the sheets, just to monitor my times and how long it me to do every repetition.

Code: Activity log sheets - monitoring own progress

L: **So it was good recording it, and you liked doing that then?**

P: Yeah. They can see you focussing, and every single day you're doing it, you know you're getting better and then you can look back on that week and think, God, I fastened my shoelaces…

P: ….. when you actually do those sheets; at first it's a mountain to climb and actually after a few days or a week you can look back and think, it took me seven minutes to tie my shoes and now it's only taken me forty seconds. It's a hell of a confidence booster, knowing that you're not struggling anymore, struggling like you did. And you can monitor yourself then which is quite pleasing and I'm over the moon that I did join it – the RAFTAS.

Code: Happy to practice programme independently or with therapist supervision

L: **You were saying you felt okay about practising on your own, you didn't have any problems with that.**

P: Oh, eye, nee bother, nee bother.

L: **Do you think, rather than sitting next to the therapist, practising it all with [therapist name]; do you think it was better practising it on your own or would you have preferred to have been sat with her?**

P: Again, it depends who you are, because with me under pressure, frustration, my choice of words were pretty bad, but she just told me to calm down, and sat there. For me, it depends on the person. If someone was laid back, that's brilliant, but for people like me, I wanted to run before I could walk. So [therapist name] sort of said, just in your own time, take your time.

L: **So did you find it better when you practising with [therapist name] rather than on your own?**

P: As I was saying, [therapist name] pushed me. She didn't – she wasn't forceful…

L: **Right.**

P: …But she knew I could do it.

L: **And did you prefer that to practising on your own, like in the evening?**

P: It didn't bother us whether I was on me own or not. I did get anxious when she used to come, asking, what's she going to make me do today. In my mind I was saying

can't do it but she was saying, you can, so it didn't really bother me [therapist name] being there.

P: But as I say, whether alone or with [therapist name] there or not, it was absolutely brilliant to do it, to get on with it.

Code: Independent activity practice – effect on confidence

L: And do you think it helped? Do you think it had an effect on your confidence, practising these things on your own?

P: Yes, definitely because I've seen a change and other people have seen a change in us. Like I say, being a grown man unable to hold a cup of tea in me hand like I'm doing now, I couldn't do that. I couldn't erm.... The same thing for my shoulders. It's just been brilliant.

P: P: ..... when you actually do those sheets; at first it's a mountain to climb and actually after a few days or a week you can look back and think, it took me seven minutes to tie my shoes and now it's only taken me forty seconds. It's a hell of a confidence booster, knowing that you're not struggling anymore, struggling like you did. And you can monitor yourself then which is quite pleasing and I'm over the moon that I did join it – the RAFTAS.

Code: Motivation to practice – Direct practice of functional activities to practice the programme

P: do you think the use of doing those very specific things that you'd chosen with [therapist name], those everyday tasks sort of motivated you more to do the program rather than just doing other things where you might just use weights or other things like that.

P: Yeah, because the things that were given to me everyday tasks to do. I mean, when you go out, you've got to fasten your shoelaces, you've got to fasten your zip.

L: So they're relevant to you aren't they?

P: Yeah, they're relevant for everybody, because you've god to be able to clothe yourself and hold a knife and fork. So you've got to, there's no way around it, you've got to those things, so every task that I done, was relevant.

Code: Practicing programme early after stroke better

L: So that was quite soon after you'd had your stroke, did that feel alright?

P: It was four days.

L: Yeah. When we start looking for people for the study, it's quite soon, between zero and fourteen days after the stroke. So do you think the timing for that was okay for you, it didn't feel too early or too late at four days or...

P: For me personally, because I know what happens with strokes anyway, I knew how it had affected my life and my parents. I wasn't willing to sit and just do nothing. I knew the sooner I got active and got my brain going, when it was three or four days afterwards. You know, you need it.

L: So that felt good, that it was earlier.

P: Yeah, the sooner the better.

Code: Time taken to complete practice

P: It dragged, the tasks dragged. I'm not the most patient man, but I knew I had to do it. For other people it would be great, but I'm dead impatient to get back on my feet, to do it, I was pushing. No, I think that everything was absolutely perfect the way that it worked out.

P: ..... when you actually do those sheets; at first it's a mountain to climb and actually after a few days or a week you can look back and think, it took me seven minutes to tie my shoes and now it's only taken me forty seconds

Code: Twice weekly therapist supervision appropriate

L: Do you think twice a week was about right?

P: I think twice a week was spot on. I think it's better you know for the likes of [therapist name] to come, to see me after a week to see how well I've done it.

Code: All in all – good

L: So just to summarise everything, what do you think was good about the programme?

P: Probably just everything. Like I say, I had [therapist name] who was pushing us...the confidence that she gave me and the sort of beady eye as well, you know, looking when I was doing these tasks. Holding the cup for a minute and then having to put it down, and then week later, I could pick up a cup normally

P: And I wasn't using my left arm, I wasn't using it and then [therapist name] said you've got to start using knives and forks. It's been, everything from the paperwork, everything...

P: But as I say, whether alone or with [therapist name] there or not, it was absolutely brilliant to do it, to get on with it.

Code: Activity log sheet layout could be improved

P: I did say to [therapist name] about the paperwork she gave me, it sort of had individual time and the layout of the paperwork, and some of it, I didn't think was correct, it was a bit of a struggle.

L: Right, how would you change that, what do you think could be improved?

P: I think it was just one of the boxes, I think one of the boxes was erm... I'm trying to remember.

P: I did tell [therapist name]. It had something to do with the paperwork, with the layout of the paperwork. It could have been, maybe different. You'll have to ask [therapist name], it was well before Christmas.

L: That's fine, that's fine.

P: I can't remember what it was, it was just something stupid.

L: Yeah, I hope she's made a note of it, because if we can improve it I'd be really interested in that.

P: She has yeah. I just think the boxes could have been laid out differently for a reason, but I couldn't tell you to tell the t[therapist name].

Code: Enhanced rehab outcome / benefitted from following the programme

P: Right, I mean, if it wasn't for the RAFTAS, and I didn't join the RAFTAS – I sort of, wanted the extra help – I wouldn't be half as advanced than what I was.

P: erm things were just, you know, I think everybody should made to do it, not a choice..... Six weeks, and I was fastening me shoelaces, I was using buttons, doing my belt. I hadn't worn a belt since I was bad, and I can do those things.

P: One week it took me seven to ten minutes to fasten one shoelace and a week later it took about a minute. Then obviously you get to a normal stage.

P: , I wouldn't be like this if it wasn't for the tasks.

L: Okay, do you think that practising those specific things in the program helped you then to do those things in everyday life?

P: Definitely,

<u>In-vivo codes – themes appealed to by the participants</u>

Code: Therapist guidance

P: Again, it depends who you are, because with me under pressure, frustration, my choice of words were pretty bad, but she just told me to calm down, and sat there. For me, it depends on the person. If someone was laid back, that's brilliant, but for people like me, I wanted to run before I could walk. So [therapist name] sort of said, just in your own time, take your time.

L: So did you find it better when you practising with [therapist name] rather than on your own?

P: As I was saying, [therapist name] pushed me. She didn't – she wasn't forceful...

L: Right.

P: ...But she knew I could do it.

Code: Participant attitude towards rehabilitation

P: I sort of, wanted the extra help

P: Because, six weeks after I came out of hospital – I've never been the kind of person who would sit there and say they couldn't do it, but

P: Definitely, I mean, if I hadn't been pushed by [therapist name], I think they've got a lot of patience these nurses, because I'm not the most patient person and I fly off the handle quite easily. She just said, "Don't say you can't, just focus on it," and the point is, when they do the paperwork, she would know if you're doing it or not because after three days of doing these repetitions and you still can't, you know, reach up and put something in the cupboard, or tie your shoelace, or do your buttons up, she would know I was doing it.

P: I didn't want the girls to help me walk or to eat with a knife and fork and I asked [therapist name] not to me. It didn't matter how long it was going to take me to do the task.

L: And when you were practising did you need a hand from anyone or did you do it on your own.

P: No, I refused help, if anything.

Code: Confidence

P: .....when you actually do those sheets; at first it's a mountain to climb and actually after a few days or a week you can look back and think, it took me seven minutes to tie my shoes and now it's only taken me forty seconds. It's a hell of a confidence booster, knowing that you're not struggling anymore, struggling like you did. And you can monitor yourself then which is quite pleasing and I'm over the moon that I did join it – the RAFTAS.

L: Do you think, when you practising stuff on your own, did that make you feel happier about doing those tasks in everyday life then because you'd been practising them on your own?

P: Eye, eye

P: It definitely gives you the confidence to go and do other things. You know, I keep going back to this fastening me shoe laces. I was thinking, once I can fasten me shoe laces, I can start going out. I didn't have the confidence to go out because when I can out of hospital, I fell. I fell twice in the same hour after I came out of hospital.

P: I fell outside a couple of times but that's only normal. I know I'm not back fully fit and I know that I'll struggle. So, to get back to putting my shoes on again and back to wearing something I can wear in order to move on.

L: Putting those things in places so you can go and do the things you want to do.

P: So I can put my zips on and my tops that I wear, or hoodies with zips on. I had to fasten them, to keep myself warm so I could go out.

Code: Part of routine care

P: I just think personally, if the people are there to help you, you shouldn't be asked to go on RAFTAS, you should be told. It should be part of the process.

L: Routine.

P: Yeah, it should be part of the process. Cause I've seen guys in there who haven't joined RAFTAS, and I looked at them and thought, I'm not half as good as them. Six weeks of what I was doing for RAFTAS, I bet they cannot do the same things now. It should be part of the whole recovery thing, if you know what I mean after a stroke?

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