Changing Consultation Behaviour in Healthcare Professionals and Physical Activity Behaviour in Adults with Type 2 Diabetes in Primary Care

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Thesis Abstract

Behavioural interventions targeting physical activity alone produce clinically significant improvements in long-term glycaemic control in adults with type 2 diabetes. Effective translation of physical activity behavioural interventions into routine primary care is hindered by the lack of evidence-based training resources to equip healthcare professionals with the knowledge, skills and confidence to deliver behavioural interventions to their patients.

This PhD thesis describes the development and open pilot testing of an evidence-informed multifaceted physical activity behaviour change intervention 'Movement as Medicine for Type 2 Diabetes' targeting: (i) consultation behaviour in primary healthcare professionals (online training programme); and (ii) physical activity behaviour in adults with Type 2 diabetes (patient toolkit delivered by primary healthcare professionals).

Informed by multi-methodological development work (workshops to identify information/support needs of patients and healthcare professionals; systematic review to identify effective physical activity behaviour change components; and usability testing), Movement as Medicine for Type 2 diabetes was piloted in two primary care practices over a two month period. A qualitative process evaluation and treatment fidelity assessment were used to optimise the intervention by identifying barriers and enabling factors to implementation and informed revisions to content and study procedures.

Six primary healthcare professionals completed the online training programme and delivered the toolkit to participating patients (N=30) during diabetes review appointments. Transferability of behaviour change techniques to other areas of practice was identified as a salient facilitator for healthcare professionals, although several implementation challenges were identified (e.g. previous negative experiences with supporting patients to increase physical activity behaviour). Intervention components were delivered by healthcare professionals to a satisfactory level of fidelity. Patients reported physical activity monitoring resources and review sessions as particularly beneficial components of the patient toolkit.

Movement as Medicine for Type 2 diabetes was found to be acceptable and feasible in the primary care setting. Open pilot methodology facilitated optimisation of the intervention ahead of a planned pilot randomised controlled trial.

Acknowledgements

Several people have been incredibly helpful and supportive during the process of conducting and writing up the research presented in this PhD thesis.

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I would also like to acknowledge Louise Taylor who conducted the initial exploratory work with me (phase 1a and 1b, presented in chapter 3), and provided design expertise throughout the development of Movement as Medicine for Type 2 Diabetes (MaM for T2D). Thanks also to Professor Jane Speight and Dr Kylie Mosely for their advice and input to the development of the MaM for T2D intervention (phase 2, presented in chapter 3).

The optimisation of the MaM for T2D intervention presented in this thesis was heavily reliant upon timely collection and analysis of good quality data. This was achieved with the help of my colleague, Dr Sarah Denton who played a key role in the collection and analysis of qualitative data as a second coder, presented in chapter 4. I would like to offer my sincere thanks to Sarah for going that extra mile, which made my life easier during the writing up of my thesis.

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Dedication

This PhD thesis is dedicated to a very special and inspirational lady, my Nana, Mrs Frances Fenwick. Without her influence, support and love I would never have made it this far.

Publications, Presentations and Awards

Publications

- Avery L, Sniehotta FF, Denton SJ, Steen N, McColl E, Taylor R, Trenell MI. Movement as Medicine for Type 2 Diabetes: Protocol for an Open Pilot Study and External Pilot Clustered Randomised Controlled Trial to Assess Acceptability, Feasibility and Fidelity of a Multifaceted Behavioural Intervention Targeting Physical Activity in Primary Care. *Trials* 2014, 15(46).

- Avery L, Flynn D, van-Wersch A, Sniehotta FF, Trenell MI. Changing Physical Activity Behavior in Type 2 Diabetes: A Systematic Review and Meta-Analysis of Behavioral Interventions. *Diabetes Care* 2012, 35(12), 2681-2689.

Conference Presentations

- Avery L, Flynn D, van Wersch A, Sniehotta FF, Trenell MI. What Behaviour Change Techniques used in Behavioural Interventions are Associated with Improvements in Physical Activity Behaviour and HbA1c in Adults with Type 2 Diabetes?. *In: Diabetes UK Professional Conference 2013*. 2013, Manchester: Wiley-Blackwell Publishing Ltd.

- Avery L, Flynn D, van Wersch A, Sniehotta FF, Trenell MI. A systematic review of behaviour change interventions targeting physical activity, exercise and HbA1c in adults with Type 2 diabetes. *In: Diabetes UK Annual Professional Conference*. 2012, Glasgow, UK: Wiley-Blackwell.

- Avery L, Taylor L, Lievesley M, Mosely K, Speight J, Sniehotta FF, Trenell MI. Development of a behavioural intervention targeting free-living physical activity in adults with type 2 diabetes in primary care: Movement as Medicine. *In: Diabetic Medicine: DUK Annual Professional Conference*. 2012, Glasgow, UK: Wiley-Blackwell Publishing Ltd.

- Avery L, Flynn D, van Wersch A, Trenell MI, Sniehotta FF. Systematic Review to identify active ingredients in behaviour change interventions targeting physical activity in adults with type 2 diabetes. *In: Psychology & Health: 25th European Health Psychology Conference*. 2011, Crete, Greece: Routledge.

Invited Talks

- Invited talk: 'Physical activity, where it fits in to diabetes care and the practicalities of changing behaviour using behaviour change techniques'. Joint Diabetes Management & Education Group (DMEG) and Dietitians in Obesity Management UK (DOMUK) study day "The war on weight", Newcastle, September 2013.

- Invited talk: 'Physical activity and Type 2 Diabetes: Changing behaviour using behavioural strategies'. Health Psychology Master Class. Northumbria Healthcare Foundation Trust. July 2013.

- Invited talk: 'Physical activity and exercise in Type 2 diabetes: Maximising glycaemic control'. 5th Annual Abracadabra Diabetes Nursing Conference; tackling the challenges of managing diabetes in Ireland: Pragmatic solutions for complex scenarios, Naas, Dublin, February 2013.

- Invited workshop: 'Using behaviour change techniques to increase physical activity behaviour'; Conference entitled: 'Helping people with diabetes better self-manage' hosted by NHS Grampian; Stirling Management Centre, University of Stirling, Scotland, November 2012.

Professional Group Invitations

- Invited member of the FUSE; The Centre for Translational Research in Public Health; Physical Activity Working Group. October 2013.

- Invited member of the Team Blood Glucose Professional Advisory Group (a not for profit social enterprise company) to provide expert opinion on the company

website and associated materials for people living with diabetes. May 2013. http://www.teambloodglucose.com/TeamBG/Home.html

Internal Seminars

- Development of a Behavioural Intervention Targeting Physical Activity in Adults with Type 2 Diabetes. Oral presentation delivered as part of the Institute of Cellular Medicine Seminar Series. May 2012.

Lay Presentations

- 'Movement as Medicine for Type 2 Diabetes' Oral presentation to Diabetes UK Newcastle Voluntary Group Members. May 2012.

- 'Movement as Medicine for Type 2 Diabetes' Oral presentation to Diabetes UK Tynedale Voluntary Group Members. April 2012.

Awards

- Interactive poster award winner: 'Systematic review to identify active ingredients in behaviour change interventions targeting physical activity behaviour in adults with type 2 diabetes'. 25th European Health Psychology Society (EHPS) Conference, Crete, Greece, Sept 2011.

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List of Abbreviations

BMI	Body Mass Index
CPD	Continuing Professional Development
DRN	Diabetes Research Network
GP	General Practitioner
HbA1$_c$	Glycated Haemoglobin A1$_c$
IQR	Interquartile Range
MaM	Movement as Medicine
MET	Metabolic Equivalent
MRC	Medical Research Council
NECS	North East Commissioning Service
PA	Physical Activity
PCRN	Primary Care Research Network
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-analyses
RCT	Randomised Controlled Trial
RCPs	Royal College of Physicians
SCT	Social Cognitive Theory
SMD	Standardised mean difference
TPB	Theory of Planned Behaviour
T2D	Type 2 Diabetes
WMD	Weighted mean difference

Thesis and Chapter Overview

Chapter 1. Introduction

The opening chapter provides a synopsis of key background topics directly relevant to this thesis. The first section describes the main types of diabetes, and the primary characteristics of Type 2 diabetes (and the diagnostic process) that is the focus of this work. This is followed by a synopsis of diabetes-related comorbidity and mortality, incidence and prevalence of Type 2 diabetes, including data on the economic cost of Type 2 diabetes. Risk factors for development of Type 2 diabetes are then presented along with an overview of the policy context, evidence on the quality of diabetes care and management options (diet, oral medication, insulin, with a focus on physical activity [PA]) for Type 2 diabetes in the UK, including currently available PA self-management options for people with Type 2 diabetes. The chapter concludes with a rationale for the development of a multifaceted behavioural intervention targeting PA/exercise in the primary care setting.

Chapter 2. Changing Physical Activity Behaviour in Type 2 Diabetes: A Systematic Review and Meta-Analysis of Behavioural Interventions

Chapter 2 reports on a systematic review and meta-analysis of published studies reporting on behaviour change interventions targeting PA/exercise in adults with Type 2 diabetes. Five electronic databases were searched up to January 2012. Two reviewers independently extracted data using a structured data extraction form to capture details of study characteristics; methodological quality; practical strategies for increasing levels of PA/exercise using a taxonomy of theory-linked behaviour change techniques; and treatment fidelity strategies important for internal and external validity.

Seventeen Randomised Controlled Trials (RCTs) fulfilled the review criteria (N = 1,152 adults with Type 2 diabetes). Behavioural interventions showed statistically significant increases in objective (SMD=0.39, CI=0.19 to 0.59) and self-reported PA/exercise (SMD=0.79, 95% CI=0.60 to 0.98) including clinically significant improvements in HbA1c (WMD= -0.30%, 95% CI= -0.41% to -0.20%) and body mass index (BMI) (WMD= -1.12 $kg/m^{2,}$ 95% CI= -1.36 to -0.87).

Ten behaviour change techniques were associated with statistically significant improvements in HbA1c. The three most commonly reported behaviour change techniques were goal setting (behaviour), prompt self-monitoring of behaviour and use of follow-up prompts. Only five studies provided details of treatment fidelity strategies to monitor/improve training of care providers, and none of the included trials attempted to assess the efficacy of the training on consultation behaviour. Intervention features (e.g., specific behaviour change techniques, interventions underpinned by behaviour change theories/models, and use of ≥10 behaviour change techniques) moderated effectiveness of behavioural interventions.

It was concluded that behaviour change interventions result in improved levels of PA and in turn clinically significant reductions in HbA1c in adults with Type 2 diabetes. Behavioural interventions utilising a greater range of behaviour change techniques have potential for yielding improved outcomes in routine diabetes care. These findings suggest that future interventions should be multifaceted and include structured training for diabetes care providers on the delivery of behavioural interventions.

Chapter 3. Intervention Development

Chapter 3 provides a comprehensive description of the systematic process used to develop the multifaceted behavioural intervention targeting PA behaviour, 'Movement as Medicine for Type 2 Diabetes (MaM for T2D)'. In accordance with the Medical Research Council (MRC) Framework for the Development and Evaluation of Complex Interventions, the development process involved an initial exploratory phase, a development phase and an open piloting testing phase. Intervention characteristics are appropriately described with reference to provider; format; setting; recipient; intensity; duration and information content in line with published guidance.

Initial exploratory work with general practitioners and adults with Type 2 diabetes informed the development of an initial draft version of the Movement as Medicine for Type 2 Diabetes (MaM for T2D) multifaceted intervention. This included an online training programme (facet 1) that was presented in modular format to fulfil the information and skills development needs of primary healthcare professionals (identified from semi-structured interviews).

The online training programme was developed to support the effective delivery of a person-centred behavioural intervention targeting PA/exercise to patients. Facet two was designed to fulfil the support needs of patients with Type 2 diabetes (identified from an interactive workshop) and included a suite of paper-based patient resources for use by primary healthcare professionals (during routine face-to-face diabetes review appointments) and served as a vehicle for diabetes self-management. The resources also included a DVD that would provide information to supplement and/or reinforce key information outside of consultations. Together these resources are referred to as the Patient Toolkit throughout this thesis. Collectively both of these intervention components are referred to as Movement as Medicine for Type 2 Diabetes (MaM for T2D).

The subsequent development phase involved identification of the optimal intervention process, information content and other active ingredients of both facets of the alpha prototype version of MaM for T2D, with reference to the findings of the systematic review reported in Chapter 2 and the wider research literature on the effectiveness of behaviour change interventions. A total of 15 behaviour change techniques were incorporated into the online training programme, that were associated with effectiveness and for reasons of pragmatism (as associations identified in the systematic review could not be considered definitive evidence of effectiveness). The explicit criteria used to select the Theory of Planned Behaviour and Social Cognitive Theory to underpin the development and evaluation of MaM for T2D are comprehensively described to provide an auditable development process.

The practicality and usability of the alpha prototype versions of the intervention components were assessed from the perspective of primary healthcare professionals (n=5, who reviewed both components of the intervention to elicit their views on the relevance of the content and general usability of the interventions using a structured feedback questionnaire) and patients with Type 2 diabetes. Patients (N=13), following routine diabetes review appointments were taken through a typical scenario with the patient toolkit, and structured interviews were used to identify any content and/or design and usability issues. Findings of usability testing were used to inform refinements to the information content and processes of the online training programme and patient toolkit materials for use in a subsequent pilot RCT. The chapter concludes with a summary of

the key findings, including potential strengths and weakness of the development process used to develop the intervention MaM for T2D.

Chapter 4. **Acceptability, Feasibility and Fidelity of Movement as Medicine for Type 2 Diabetes: An Open Pilot Study**

The penultimate chapter describes the design, conduct and results of a mixed methods open pilot study designed to optimise the acceptability, feasibility and fidelity of the MaM for T2D intervention. This included identification of barriers and facilitators to successful implementation of the intervention prior to use in a planned pilot RCT.

Primary healthcare professionals (n=6) completed the online training programme, and subsequently delivered the patient intervention toolkit to patients (n= 30) attending their routine diabetes review appointments.

All six healthcare professionals logged onto the online system and accessed the training programme. They spent a median of 3 hours and 35 minutes browsing the programme up to the point of completion (i.e. when a completion certificate was generated) over a median period of 5.5 days. The median time spent using the programme post-completion was 58 minutes over a median period of 4 days.

Theoretical Domains Framework based semi-structured interviews (n=9) were conducted with participating primary healthcare professionals (n=6) from two primary care practices, and adult patients with Type 2 diabetes (n=8) immediately following the initial MaM for T2D consultation (baseline) and at 1-month follow-up.

Content analyses identified 34 domain-specific beliefs across all 14 domains of the Theoretical Domains Framework, that were likely to positively (n=25 beliefs) or negatively (n=9 beliefs) influence acceptability and feasibility from the perspective of healthcare professionals. From the perspective of patients a total of 44 domain-specific beliefs across all 14 domains in the Theoretical Domains Framework, were likely to positively (n=40 beliefs) or negatively (n=4 beliefs) influence acceptability and feasibility of the patient toolkit in the clinical setting.

Coding of observations (video recordings) of consultations revealed that 11 out of 20 intervention components were delivered faithfully ≥50% of the time by primary healthcare professionals across 32 diabetes review appointments up until 1-month.

There was sufficient evidence to report that an online training programme is acceptable and feasible for use by healthcare professionals to provide them with the appropriate knowledge, skills and self-efficacy for delivery of a theory-based behavioural intervention targeting PA/exercise to adults with Type 2 diabetes. However, the current study identified a number of salient barriers to wider implementation. Informed by the findings of the open pilot study an optimised version of MaM for T2D has been developed which will be further tested for acceptability, feasibility and fidelity within a planned pilot RCT.

Chapter 5. Discussion and Conclusions

The final chapter of this thesis presents a comprehensive discussion of the implications of the findings arising from the work undertaken. Priority areas of further research on the development and evaluation of PA interventions targeting healthcare professionals and adults with Type 2 diabetes are discussed, with reference to theoretical and methodological challenges associated with development, evaluation and implementation in routine diabetes care.

Chapter 1. Introduction

Preface to Chapter 1

Chapter 1 was written wholly by the author of this PhD thesis. The sources of information presented are cited and referenced as appropriate.

1.1 What is Diabetes and how is it Diagnosed?

Diabetes affects 2.9 million people in the UK and represents a significant individual and societal burden [1]. Diabetes is a collective term given to two forms of a condition which arise from very different pathology and pathophysiology. Type 1 diabetes is an autoimmune disease that typically manifests during childhood and occurs when the body cannot produce insulin and accounts for approximately 10%-15% of diabetes cases. In contrast, Type 2 diabetes is a condition where the pancreas does not produce enough insulin, or when the body cannot effectively use the insulin it produces [2]. Type 2 diabetes accounts for the majority (85% to 95%) of diabetes cases [1] and is characterised by chronic hyperglycaemia (high blood glucose) and disturbances in fat, protein and carbohydrate metabolism, which is typically diagnosed in adults > 30 years [3]. Hyperglycaemia occurs as a result of uncontrolled diabetes and over time can lead to serious damage to many of the body's systems; especially the nerves and blood vessels, associated with a range of diabetes-associated morbidity [see Section 1.2].

In a report published by the World Health Organization in 1999, they recommended that a fasting plasma glucose test should be used as a diagnostic test for diabetes mellitus, where a level of less than 6.1mmol/l and a 2-hour plasma glucose of less than 7.8 mmol/l should be regarded as normal [4]. In an addendum to the diagnostic criteria published in the report 'Definition and diagnosis of diabetes mellitus and intermediate hyperglycaemia', the World Health Organization suggested that HbA1c could be used as a diagnostic test for Type 2 diabetes [5]. As a result an HbA1c level of 48 mmol/mol (6.5%) is currently recommended as the threshold for diagnosing Type 2 diabetes in people with symptoms and after repeated HbA1c levels above 6.5%. However, it should be noted that the addendum was not intended to invalidate the 2006 recommendations on the use of plasma glucose measurement to confirm diagnosis [5].

1.2 Morbidity and Mortality for Type 2 Diabetes

Type 2 diabetes is often associated with high blood pressure and/or cholesterol levels, excess body weight and fatigue at diagnosis. These factors combined with uncontrolled hyperglycaemia can cause microvascular (circulatory system dysfunction) complications such as diabetic retinopathy (damage to blood vessels in the retina with

the eyes); nephropathy (kidney disease); neuropathy (nervous system damage leading to chronic pain, and in men increased risk of problems with sexual function); lower limb problems (in particular of the feet) leading to amputation [6, 7]. Macrovascular (large blood vessels and arteries) complications are also associated with Type 2 diabetes such as coronary heart disease and stroke [7].

Increased risk of periodontal disease, Alzheimer's disease and vascular dementia are also associated with Type 2 diabetes [8, 9]. In addition, there are complex multi-factorial associations (with evidence of bi-directionality) between psychological disorders such as depression and diabetes[10-12,] which have a significant negative impact on quality of life and well-being.

The majority of adults with Type 2 diabetes have at least one diabetes-related complication at the time of diagnosis (with as many as 40% have at least three) [10, 11, 13]; which can have a negative impact on peoples' ability to self-manage their condition [14]. Not surprisingly given the increased risk of serious physical and psychological morbidity associated with Type 2 diabetes, those with this condition are also at an increased risk of premature mortality [1].

The majority of people with Type 2 diabetes are likely to die of cardiovascular disease such as heart disease (75%) or stroke (15%) [15], with mortality rates of between 2 and up to 5 times higher than people without diabetes [16]. Risk of death from diabetes also increases as a function of increasing age and HbAlc level in 1% intervals [17]. For example, for each 1% increase in HbA1c the relative risk of cardiovascular disease increases by 1.18% [18]. A 1% decrease in HbA1c has shown to be associated with a 37% reduction in microvascular complications and 14% reduction in myocardial infarction [19]. Furthermore, lowering HbA1c in patients with type 2 diabetes decreases the absolute risk of developing coronary heart disease by 5–17% and all-cause mortality by 6–15% [20].

1.3 Incidence and Prevalence of Type 2 Diabetes

The International Diabetes Federation estimate that in 2012 more than 371 million people worldwide had received a diagnosis of diabetes; although these figures were not specific in terms of Type 2 diabetes [21.] Applying the proportions reported by Diabetes

UK, this equates to approximately 315 to 353 million people globally with Type 2 diabetes (i.e. Type 2 diabetes accounts for approximately 90% of all diabetes cases).

In 2012 it was estimated that approximately 2.9 million people were diagnosed with diabetes in the UK which is projected to increase to 5 million in 2025, with the majority, 85% to 90% being Type 2 diabetes [1]. In terms of prevalence, in 2011 approximately one in 20 people in the UK had diabetes (diagnosed), with the prevalence of adults diagnosed with diabetes ranging from 5.5%, 5.0%, 4.3% and 3.8% in England, Wales, Scotland and Northern Ireland respectively. This equates to a mean prevalence of 4.4% in the UK adult population.

Prevalence of Type 2 diabetes is greater in males than females, and the proportion of people with the condition is largest in people aged > 65 [19].

As the increase in prevalence of Type 2 diabetes is most marked in younger adults, Type 2 diabetes is expected to inflict a devastating toll upon the future working age population in terms of diabetes-related morbidity and mortality [22].

1.4 The Economic Cost of Type 2 Diabetes in the UK

There are few data available on the costs of diabetes that differentiate between the two main sub-types (Type 1 and Type 2). A 2012 article published in Diabetic Medicine estimated that direct (diagnosis, lifestyle interventions, on-going treatment and management, and complications) and indirect (mortality, sickness absence, presenteeism [potential loss of productivity as a result of remaining in employment] and informal care) costs of Type 2 diabetes in 2010/11 was £8.8 billion and £13 billion respectively [23]. This cost (£21.8 billion) accounted for 10% of health spending during 2010/11, which according to Hex et al 2012 is projected to rise to 17% in 2035/36, with indirect and direct costs estimated to increase to £15.1 billion and 20.5 billion respectively during this period (overall costs = 35.6 billion).

1.5 Risk Factors for Type 2 Diabetes

Risk factors for developing Type 2 diabetes include a combination of genetic, lifestyle (behavioural) and environmental factors.

Genetic factors include familial (with a two to six-fold increased risk of being diagnosed with Type 2 diabetes when there is a positive history in family member) and ethnicity (people of South Asian, African and African-Caribbean origin being six and up to three times more likely respectively to develop the condition [1].

Obesity, (in particular visceral adiposity) is the most powerful lifestyle risk factor (heavily influenced by environmental factors) for Type 2 diabetes. Obesity accounts for 80-85% of the overall risk [24, 25] when combined with other environmental and behavioural factors, an ageing population, high levels of physical inactivity, limited energy expenditure and an unhealthy diet [1]. The latter two are the main causal risk factors for type 2 diabetes - an imbalance between energy expenditure (via PA/exercise) and energy intake through food consumption [26, 27].

Other environmental factors including social and economic deprivation have been linked with the development of Type 2 diabetes, due to increased risk of obesity in people residing within areas of highest deprivation [1].

1.6 Policy Context and Data on Quality of Diabetes Care and Outcomes in the UK

Standard 3 of the UK National Service Framework for Diabetes stated that all people with diabetes should receive a service which encourages partnership in decision making, provides support in managing their diabetes and helps them to adopt and maintain a healthy lifestyle [24]. Indeed, there has been a growing acknowledgment for some time that the emphasis in the NHS should shift from curative to preventative strategies that target lifestyle behaviours. Preventing illness and promoting healthy lifestyles was highlighted in 2004 by The White Paper "Choosing Health: Making Healthy Choices Easier" [28], which prioritised key areas for behaviour change as well as resources to increase individual responsibility for health (in particular for socially deprived groups) via greater provision of informed choice and personalised services that are flexible, convenient and sensitively tailored to the realities of peoples' lives.

National guidelines outlined the need for patient education models for the management of Type 2 diabetes [29, 30]. However, data published from the 2011-2012 National Diabetes Audit reported that very few people with diabetes are offered structured

education at the point of diagnosis (less than 3%). Of those who were offered structured education, even fewer attended [31]. These figures have improved from the previous year, however 31% of people with diabetes reported that they had never been offered structured education - even at the point of diagnosis [32]. The NICE public health guidance 6 on behaviour change [30] states "identifying effective approaches and strategies that benefit the population as a whole will enable public health practitioners, volunteers and researchers to operate more effectively, and achieve more health benefits with the available resources" (p6). Nevertheless, the reality is that evidence-based tools are lacking. This is especially the case with respect to advice on effective behaviour change techniques for use by diabetes primary care providers to support people with diabetes to make positive changes to their lifestyle behaviour to yield a concomitant positive impact on HbA1c.

The primary care setting is where the majority of people with Type 2 diabetes receive management advice on their condition, and the introduction of the Quality Outcomes Framework has provided a financial incentive for the delivery of evidence-based diabetes care by primary care teams [33]. Quality Outcomes Framework indicators related to Type 2 diabetes have improved since the introduction of the Quality Outcomes Framework, however the impact on outcomes such as improved long-term glycaemic control, decelerated progression, morbidity and mortality have yet to be fully elucidated.

Findings from the National Diabetes Audit in 2011/12 (87.9% of GP practices capturing information on 2,473,239 people with diabetes) found that NICE recommended glucose control (HbA1c ≤ 58mmol/mol) was recorded in only 65.8% of people with Type 2 diabetes [(29)]. Furthermore, this audit found that treatment target achievement for HbA1c <48mmol/mol (6.5%) was only 26.2% for patients with Type 2 diabetes in 2011/2012.

Other studies in UK primary care practices have reported that the majority of patients had not agreed a plan to manage their diabetes or received advice on PA [33]. This was further emphasised in a report published by Diabetes UK in 2013 entitled: 'State of the Nation 2013' where it was reported that only one third of patients with diabetes (35.5%) had agreed a care plan with a healthcare professional [34].

Clearly there is substantial room for improvement in the management of Type 2 diabetes in primary care settings. Indeed, the National Diabetes Audit stated that there is a "need to discover more effective diabetes care delivery systems for the future, they need to innovate" [p7] [31], which would suggest that the Quality Outcomes Framework may not be the solution to improved diabetes care. Furthermore, a review of quality improvement interventions in diabetes care emphasised a need for interventions to include components focused on professionals alongside patient-mediated strategies for maximal impact [35.]

1.7 Management Options for Type 2 diabetes in the UK

Effective management of Type 2 diabetes poses a significant medical and public health challenge, in particular with the projected increases largely attributable to an ageing population and unhealthy lifestyle behaviours [36]. Type 2 diabetes is generally regarded as a progressive condition [37]; however a plethora of evidence has demonstrated that a range of management options, in particular lifestyle behaviour modification (diet and PA) can result in improved glycaemic control. These in turn can decelerate, halt or even reverse progression of the disease and significantly reduce the risk of serious complications and premature mortality associated with Type 2 diabetes described in Section 1.2.

PA (regular movement such as walking) and exercise (structured activities such as running/cycling) and diet along with oral hyperglycemic medication and insulin therapy are the cornerstones of diabetes management [38], including appropriate combinations where indicated.

1.7.1 Oral medication

There are four main classifications of oral hypoglycaemic drugs (Metformin, insulin secretagogues [Sulphonylureas], rapid-acting insulin secretagogues [meglitinides], Acarbose and Thiazolidinedione's) [37]. The first line medical treatment for approximately 50% -90% of patients with Type 2 diabetes is Metformin. This is prescribed when patients are experiencing difficulty with self-management of glycaemic control (via diet and PA) for an extended period of time following diagnosis [17].

Other medications (with different potential adverse effect profiles) are typically used when Metformin is not tolerated well by patients (or is contraindicated) or augmentation to Metformin is necessitated (i.e., stepped-up poly-pharmacy), and their use are governed by various indications; e.g. if a person is not overweight then sulfonylureas are indicated [39].

Oral hypoglycaemic drugs have substantial evidence of effectiveness for reduction in HbA1c (0.5-1.5%) [40-43]. Most of this treatment effect is evident by 3–6 months following the start of medication, and meta-regression has established that when oral hypoglycaemic drugs are used for patients with higher baseline HbA1c levels they are associated with greater declines in HbA1c [43, 44].

1.7.2 Insulin therapy

Insulin (replacement) therapy in isolation or in combination with oral hypoglycaemic drugs is a third line treatment that is indicated when oral hypoglycaemic drugs are no longer effective at controlling HbA1c levels [37]. This should be offered alongside structured education, ongoing support from trained healthcare professionals, including determining the optimal dosing regimen and monitoring of HbA1c to determine when adjustments to the dosing schedule may be warranted [45].

1.7.3 Behavioural lifestyle modification: diet and physical activity / exercise

Dietary patterns (excess energy intake related to obesity) are a key risk factor for Type 2 diabetes [46]. Not surprisingly, behavioural interventions designed to support patients to make changes to dietary patterns implemented by healthcare professionals can yield significant benefits in terms of reduced body weight, improved insulin resistance and long-term (12 months) glycaemic control [47]. Therefore, diet is an important patient self-management strategy for halting/decelerating progression of Type 2 diabetes, including reducing risk of morbidity and mortality associated with the condition. A recent systematic review and meta-analysis [48] found evidence that four dietary regimens can result in clinically significant improvements in glycaemic control, with the Mediterranean diet producing the largest treatment effect (-0.47%), followed by high-protein, low-GI and low-carbohydrate (-0.28%, -0.14% and -0.12% respectively).

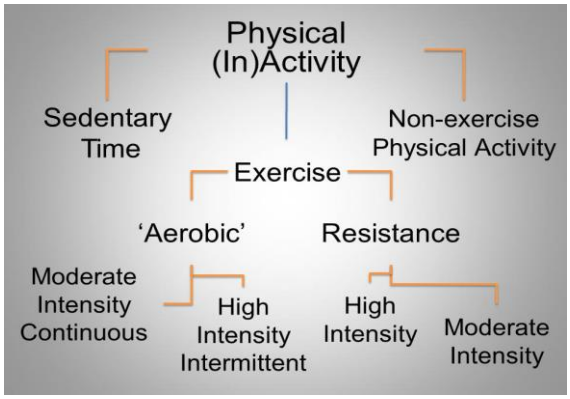
PA/exercise is a further important patient self-management option, but advice on PA/exercise is frequently omitted from management plans in primary care for patients with Type 2 diabetes [33]. Yet, energy expenditure is arguably most important, as the majority of people with Type 2 diabetes, or at highest risk for developing the condition, are relatively physically inactive compared with national norms [27]. Consequently, there is a need to focus exclusively on the development and implementation of effective behavioural interventions that target PA/exercise in primary care for two key reasons: (i) PA/exercise may be a more acceptable self-management option for glycaemic control for people with Type 2 diabetes who report poor adherence to dietary change and oral hypoglycaemic drugs; and (ii) PA/exercise can prevent the need for, or reduce the dosage of oral hypoglycaemic drugs - thus halting or decelerating progression to insulin therapy.

A 2006 Cochrane systematic review [49] reported that PA/exercise in isolation (i.e. in the absence of weight loss) produced clinically significant improvements in glycaemic control in people with Type 2 diabetes. The analyses revealed that PA/exercise can produce an average improvement in HbA1c of between -0.3% and -0.9 %. This improvement in glycaemic control is similar to the improvement seen in thiazoladinedione therapy [50]. However, drug-based interventions are unlikely to provide a self-management solution in the long-term as a result of progressive failure of insulin secretion over time [37]. Behavioural approaches aimed at increasing energy expenditure through PA/exercise can be an effective alternative, as the majority of people with type 2 diabetes are physically inactive compared with national averages [27]. Furthermore, effective self-management of Type 2 diabetes with PA/exercise would: (i) decelerate / halt progression to the stage when oral hypoglycaemic drugs are indicated, and thus avoid associated possible adverse effects associated with them; and (ii) for people already prescribed oral hypoglycaemic drugs to discontinue medication, including decelerate / halt progression to insulin therapy. In both cases, improved glycaemic control can reduce diabetes-related morbidity and promote manifestation of other benefits associated with increased PA/exercise. These include increased physical fitness, improved cardiovascular health, mental well-being, and improved body composition (reduced liver, visceral and intramuscular fat) [51]. Furthermore, there has been an accumulation of evidence highlighting the benefits of PA/exercise for improved quality of life and for reducing symptoms of depression in people with Type 2 diabetes[52-54]. With the prevalence of depression being increased in people with Type 2

diabetes and people with Type 2 diabetes having an increased risk of developing depression, supporting them to increase their levels of PA/exercise holds significant potential [55].

PA and exercise are often conflated and used interchangeably, which can cause confusion for both professionals and adults with Type 2 diabetes. An overview of the key characteristics and differences between PA and exercise are shown in Figure 1.1.

Figure 1.1. Overview of Physical Activity and Exercise



PA can be defined as any bodily movement that increases energy expenditure beyond resting; whereas exercise is typically planned, structured and repetitive with the aim of improving/maintaining physical fitness [56]. The Department of Health for England currently recommend that adults aged ≥19 years should accumulate a minimum of 150 minutes of moderate intensity PA each week to achieve tangible health benefits [51]; for example, regular movement such as walking, gardening and other non-exercise recreational activities such as dancing.

1.7.4 Currently available structured education programmes in the UK for people with type 2 diabetes that include support for physical activity

The National Service Framework for diabetes and NICE's technology appraisals of diabetes education models state that structured education should be provided to people with type 2 diabetes at the point of diagnosis and has to be part of their ongoing therapy [57].

There are currently only two widely available structured education programmes in the UK that include advice and support on PA for adults with Type 2 diabetes: The Diabetes Education and Self-management for Ongoing and Newly Diagnosed Programme (DESMOND) [58] and the X-PERT Diabetes Programme [59]. Key characteristics of these programmes are shown in Table 1.1.

Table 1.1 Structured education programmes available in the UK

	DESMOND	X-PERT
Eligibility	Patients diagnosed within 12 weeks or as Foundation Modules (for people with more established diabetes)	Anyone diagnosed with diabetes; although is aimed at people with established diabetes
Referral process	Primary care referral	Primary care or self-referral
Mode of delivery and setting	Structured group education (6-10 patients) in the community setting	Group education in the community setting
Content	• Thoughts and feelings of participants about diabetes. • Understanding diabetes and glucose • Understanding the risk factors and complications associated with diabetes. • Understanding more about monitoring and medication. • How to take control: Food Choices, Physical Activity. • Planning for the future.	• What is diabetes? • The eatwell plate and energy balance. • Carbohydrate awareness and glycaemic index. • The benefits of physical activity. • Supermarket tour and understanding food labels. • Possible complications of diabetes and their prevention. • Lifestyle experiment. • Are you an X-PERT? game. • Care Planning: the lifestyle experiment.
Duration	6 hours of structured group education: 1-day or 2 half-day sessions of teaching	2½ hour sessions over a 6 week period with annual follow-up sessions
Interventionists and accredited training	Healthcare professionals trained as DESMOND educators, with ongoing quality assurance assessment	Healthcare professionals and lay educators trained to deliver X-PERT

A multicentre cluster RCT of DESMOND (compared with usual care) involving 824 adults with newly diagnosed Type 2 diabetes reported statistically significant improvements in weight loss and smoking cessation at 12 months follow-up, but not HbA1c [58]. Strengths of this RCT include the large, sufficiently powered sample size that allowed results to be generalised to the larger newly diagnosed population; and high participant retention rates (less than 6% attrition in the intervention group and sample overall).

However, a key limitation acknowledged by the authors were the baseline differences in sex and HbA1c. While the differences in HbA1c were attributed to differential referral rates by more enthusiastic intervention practices (i.e. those with a higher HbA1c level were referred as they were considered in greater need), this introduces the possibility of selection bias and a subsequent threat to internal and external validity. Conversely, there is RCT evidence of the X-Pert diabetes education programme involving 314 adults with Type 2 diabetes where effectiveness at 14 months was reported for a number of key outcomes. These included glycaemic control, reduced total cholesterol level, improved BMI and waist circumference, reduced requirement for diabetes medication, increased consumption of fruit and vegetables, increased enjoyment of food, and improved knowledge of diabetes, self-empowerment, self-management skills and treatment satisfaction [59]. This study has several methodological strengths including a large adequately powered sample size increasing generalisability of the findings to the wider Type 2 diabetes population registered in primary care. While the attrition rate (approximately 20%) was higher than that reported in DESMOND, this was allowed for when calculating the sample size required to detect an absolute difference in HbA1c at follow-up.

Nevertheless, these structured education programmes are still not available to people with Type 2 diabetes in all parts of the UK [60]. Furthermore, both DESMOND and X-PERT are focused mainly on education and motivation regarding diet as opposed to PA, they are outsourced, costly and uptake rates are not recorded consistently. Moreover, evidence shows that not all patients are offered structured education [34], where it is offered there is a waiting list and patients are often required to travel considerable distances to attend sessions, and this means they are frequently not seen at the optimal time (i.e., immediately following diagnosis when arguably motivation is at its highest). The group-based approach may also not be the preferred mode of delivery by many patients.

Given that patients are seen regularly in primary care settings, there are multiple ‘ongoing’ opportunities for delivery of effective interventions by primary healthcare professionals, but these are lacking. The development of evidence-based PA approaches that provide care providers in the primary care setting with the necessary knowledge and skills to support adults with Type 2 diabetes to become more physically active are warranted.

1.8 Behavioural Approaches to Physical Activity Behaviour Change

Advice, fear appeals and direct persuasion can be used to encourage patients to become more physically active; however, these approaches are largely ineffective for overcoming non-adherence to chronic illness regimens [61]. A consequence of reliance on these types of approaches is that a small number of patients respond positively [62]. Crucially, a further consequence is that patients are not receiving the support they need from healthcare professionals to help them to identify optimal strategies for self-management of their PA levels. The latter is reflected in sub-optimal levels of treatment target achievement for HbA1c (26.2%) and management plans that include PA (~40%) in the UK [31, 33].

Moreover, the majority of adults with Type 2 diabetes are insufficiently active and healthcare professionals report significant barriers to supporting adults with Type 2 diabetes to make changes to lifestyle behaviours [63]. Overcoming these barriers requires healthcare professionals to possess knowledge on how to approach the subject of PA/exercise with patients, understanding the different types of PA and exercise and the impact on glycaemic control, and the competencies (skills) in behaviour change to support patients to become more physically active and maintain any changes over time [64]. Therefore it is important that behaviour change interventions targeting PA address both intention formation and action and bridging the gap between the two [65]. By addressing the 'intention-behaviour gap' by using a range of motivational and volitional strategies, the likelihood that patients will increase their PA/exercise behaviour is maximised [66].

Behaviour change theory and evidence-based behaviour change techniques provide effective strategies for addressing the intention-behaviour gap, by modelling the process of intervention development to impact positively on specific target behaviours such as PA/exercise and subsequent clinical outcomes (reduction in HbA1c). These concepts will be discussed in the subsequent sections.

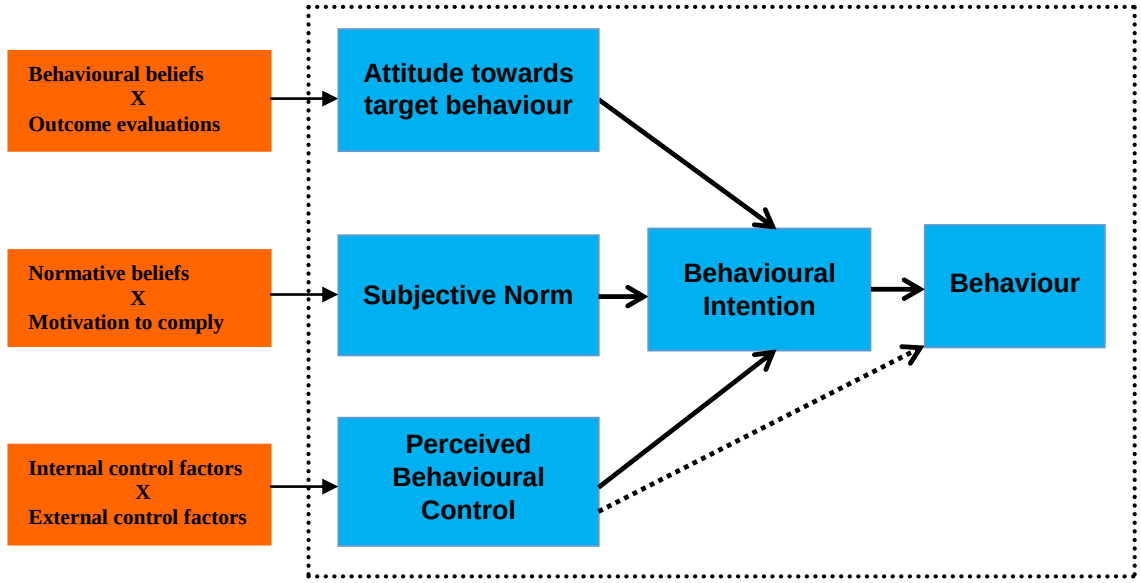
1.8.1 Behaviour change theory

There are a plethora of behaviour change theories in the literature. Armitage and Conner (2000) [67] distinguished between motivational (focus on the motivational factors that determine performance of behavioural intentions; for example, Social Cognitive Theory [68]), behavioural enactment (focus is on the action control strategies that facilitate motivation into action; for example, *the Rubicon Model of Action Phases* [69]) and multi-stage models (include variables that facilitate the adoption and maintenance of behaviour change; for example, the *Health Action Process Approach* [65]) of health behaviour; i.e., addressing the intention-behaviour gap that is a common feature identified across all human behaviour.

As a method to demonstrate the value of behavioural (health psychology) theory for supporting patients with Type 2 diabetes to modify and self-manage their PA/exercise behaviour, two models of health behaviour change will be used as exemplars: the Theory of Planned Behaviour (TPB) and Social Cognitive Theory (SCT). What follows is a synopsis of their key underlying assumptions and theoretical constructs/processes to highlight how they (and others) can model the process of intervention development to impact positively on target behaviours and subsequent clinical outcomes (e.g., increasing PA/exercise behaviour in adults with Type 2 diabetes to enable them to effectively self-manage their Type 2 diabetes).

The TPB (Figure 1.2) postulates that the most proximal determinant of behaviour is our level of motivation to change our behaviour – referred to as the strength of our behavioural 'intention' [70.]

Figure 1.2. Conceptual Diagram of the Theory of Planned Behaviour



Within the structure of the TPB three constructs directly influence the formation and strength of behavioural intentions: (i) attitudes toward the target behaviour (behavioural beliefs that a person holds about a target behaviour along with beliefs about outcome evaluations of performing the behaviour that can be positive or negative); (ii) subjective norms (perceived social pressure to perform the target behaviour) expressed as additive function of normative beliefs (significant others beliefs about the target behaviour such as work colleagues and relatives) and motivation to comply (extent to which the individual wishes to conform with the perceived normative beliefs of significant others); and (iii) perceived behavioural control refers the extent to which a person believes that the target behaviour can be implemented, and beliefs related to the extent that he/she can overcome internal (e.g., knowledge, refusal skills and will-power), and external barriers to implementation of a target behaviour (e.g., barriers and opportunities such as time, availability and co-operation of others). Perceived behavioural control can also directly influence behaviour as individuals with strong perceived behavioural control will continually strive towards implementing a target behaviour compared to individuals with low perceived behavioural control [71].

By targeting the three 'predictors' of behavioural intention described above, the TPB hypothesises that we increase the likelihood that motivation (intention) to perform a target behaviour will be developed, which in turn increases that the likelihood that the target behaviour will be implemented. For example, box 1 describes how the TPB could

be operationalised in the context of healthcare professional consultation behaviour while targeting Type 2 diabetes.

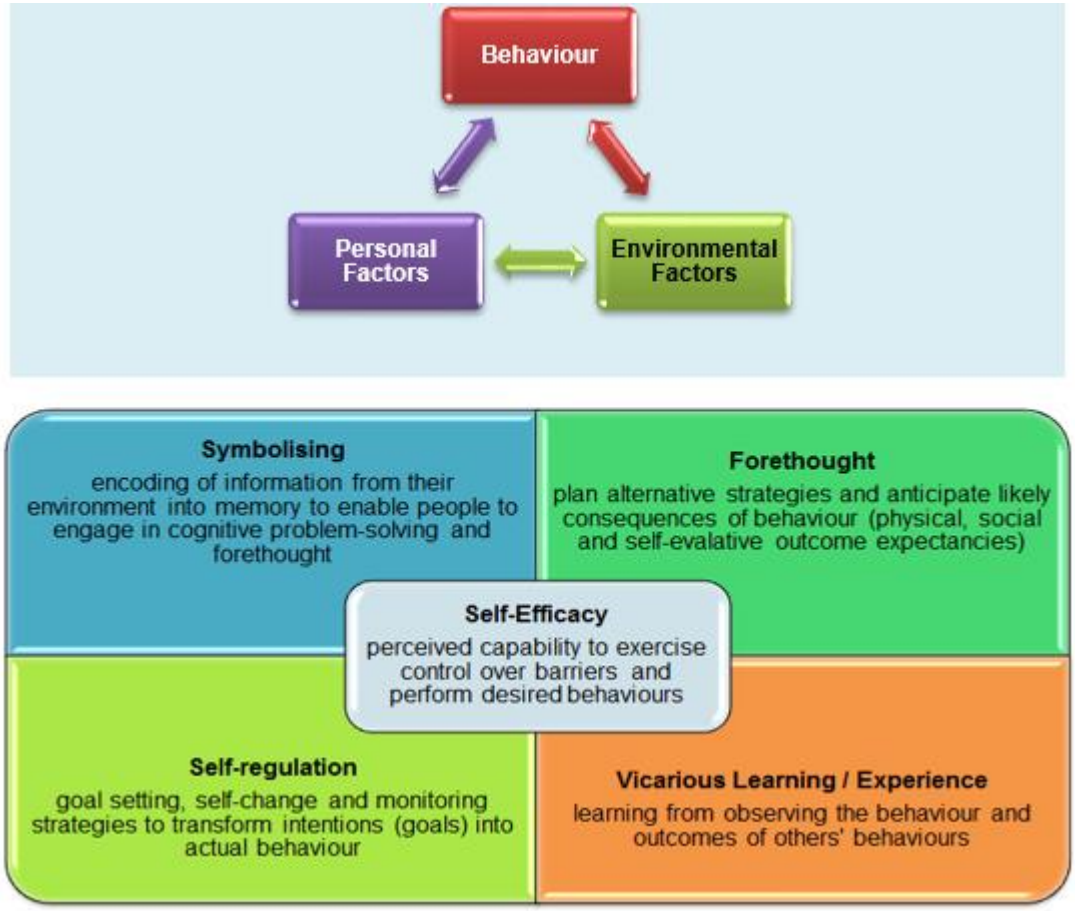
Box 1 - A patient with Type 2 diabetes attends their routine diabetes review appointment. Their diabetes is managed with oral medication; however their glycaemic control has worsened following their last review. Whether or not the practice nurse will target physical activity during the current appointment depends on their (motivation) ***intention*** do to so. The strength of intention formation depends on: i) the positive or negative ***attitudes*** about the value of physical activity for impacting positively on glycaemic control; ii) the extent to which they ***perceive social pressure*** from colleagues or others, including patients to discuss physical activity in the context of diabetes management (and the weight they attach to complying with their preferences); and iii) the extent to which they have the confidence (***perceived behavioural control beliefs)*** to overcome any internal (e.g., adequate knowledge and skills about behaviour change) and external barriers (e.g., availability of evidence-based tools to support the process of behaviour change) to discussing physical activity during the current review appointment with the patient.

SCT describes behaviour change as interactions between personal factors (e.g., outcome expectations, self-efficacy, and goals); environmental factors (e.g., availability of resources; social support); and behavioural factors (e.g., PA/exercise), which will differ as a function of the *individual*, the *target behaviour* and the *context* of the target behaviour – reciprocal triadic determinism [68].

SCT also posits that we have the following capabilities' (personal factors) that provide us with cognitive strategies for behaviour change: (i) **symbolising** (mental formation of images or words to provide meaning to our experiences); **forethought** (our ability to devise alternative strategies ahead of future events); **vicarious learning** (experience of observing others that can facilitate planning of alternative strategies); **self-regulation** (i.e. setting goals, self-monitoring, self-judgements and reactions to enable us to develop self-motivation to change); and **self-efficacy** (our ability to perform a target behaviour when faced with obstacles [68, 72]. Self-efficacy beliefs are core to SCT.

They are implicated in vicarious learning (acquisition of skills and knowledge), self-regulation (monitoring and evaluating success in achieving self-selected goals) and directly related to initiation and sustainment of behaviour change. A conceptual diagram of SCT is shown in Figure 1.3.

Figure 3. Conceptual Diagram of Social Cognitive Theory



Due to its complexity (the concept of reciprocal triadic determinism and the five capabilities), operationalising behavioural change strategies using SCT can be challenging. An illustrative example is presented in box 2 to demonstrate how key concepts from SCT can be used to understand PA behaviour change in the context of Type 2 diabetes.

Box 2 - A person is more likely to actually increase their level of PA/exercise (**target behaviour**) if they can encode health information in their memory efficiently (**symbolise**) via the use of accessible, trusted and reliable patient education on glycaemic control by increasing PA/exercise. The extent that health information is symbolised facilitates the capability of evaluating the pros and cons of change. If the outcomes of these deliberations are evaluated positively (i.e., increasing PA/exercise will help to control diabetes and halt/decelerate progression onto insulin therapy), then a plan for change will be formulated (**forethought**).

A personal self-selected goal (**self-regulation**) can then be set for change (e.g. embedding more walking into their regular routines such as taking the stairs at work instead of using the lift). The person's level of motivation to stick to their goal is strengthened by viewing a DVD with patient narratives (people similar to themselves) embedding more walking into their daily routines (**vicarious learning**) without any problems and receiving external and internal rewards (e.g. praise and improvements in fitness from the model) that will increase **self-efficacy**.

A general practitioner (GP) explains how a pedometer and activity planner can be useful for increasing PA/exercise. With the patients' agreement the GP demonstrates how to use the pedometer and activity planner to self-monitor their PA/exercise in order to achieve and maintain their personal goal for change (i.e. the GP is modelling the self-monitoring behaviours [**self-regulation]** needed to help them achieve their goal). The patient develops increased confidence in their ability to use the pedometer and activity planner (**self-efficacy**) that in turn will increase the likelihood that they stick to their goal and actually increase their PA/exercise behaviour.

The TPB has been widely applied to PA behaviour [73, 74] and is being increasingly used to target clinical behaviours of healthcare professionals [75]. There are several reasons why the TPB is an appropriate model to inform the development of intervention strategies for targeting PA/exercise in the context of Type 2 diabetes. Firstly, the TPB is among the most commonly used models for predicting intentions to perform behaviours as well as the actual behaviours themselves [76, 77]. Systematic reviews and meta-analyses of the TPB have provided empirical support in terms of its ability to predict PA/exercise behaviour, as well as many other health-related behaviours [73]. Secondly, meta-analytic

evidence suggests that augmentation of behavioural intention does lead to changes in actual behaviour [78]. Finally, a 2010 systematic review reported that the TPB, when used to underpin web-based behavioural interventions has substantial effects on behaviour [79.] However, several limitations of the TPB exist. A widely acknowledged limitation is that the majority of the evidence in support of the model and its predictive utility is cross-sectional thus limiting causality [80]. In a systematic review assessing the application of the TPB in behaviour change intervention studies, the authors report that intervention descriptions lacked clarity regarding how the theory had been applied. Where the TPB was used to underpin behavioural interventions, evidence has shown that rarely are all components of the model targeted and measured, and rarely had the TPB been applied to the development and evaluation of the interventions presented [81] A meta-analysis by McEachan and colleagues reported that the TPB is less predictive of behaviour when studies utilised a longitudinal design and objective assessment methods. However, following the outcome of systematic review by Hardeman and colleagues assessing the application of the model, it is difficult to determine whether all TPB constructs are targeted and utilised during the development and subsequent evaluation of the interventions. With this in mind there is a need for an intervention underpinned by the TPB that targets all constructs during the development process and subsequent evaluation.

Congruent with the TPB, SCT also has a strong evidence base for predicting and changing a number of behaviours [82] including PA/exercise, with perceived self-efficacy found to be a major determinant when forming an intention to become more physically active and when maintaining this behaviour over time [83, 84]. In intervention studies of adults aged over 60 years, an increase in PA/exercise behaviour at 12 months was found to be associated with beliefs about the ability to overcome barriers [85] and related to perceived environmental barriers and facilitators [86]. Furthermore, a systematic review published in 2008 [87] reported that the TPB has increasingly been used successfully to develop behaviour change interventions targeting healthcare professional behaviour.

Both the TPB and SCT can therefore be used to model the process of the intervention components (in line with the initial MRC Framework [88], to enable intervention developers / research teams to understand the complexity of the processes involved in behaviour change, and utilise evidence-based strategies that can effectively influence

modifiable antecedents of behaviour that are inherent within models/theories such as TPB and SCT.

Worthy of note is that there are several areas of conceptual similarity between the TPB and SCT. They are both considered to be 'social cognition models', i.e., theoretically they both assume that behaviour change efforts of individuals are 'goal-directed' and influenced by their cognitive abilities with regard to a target health behaviour in different contexts.

Other areas of 'conceptual overlap' are evident between the constructs of TPB and SCT. For example, outcome expectancies (forethought) are similar to attitudes (behavioural beliefs and outcome evaluations) in the TPB, whereas perceived behavioural control is closely related to self-efficacy in SCT. Ajzen the developer of the TPB, considers that the perceived behavioural control construct is identical to self-efficacy in SCT [70]. However, self-efficacy has been shown to be an independent contributor to behaviour [89] and several studies support this finding [90, 91]. However, differences in measurement traditions of self-efficacy and perceived behavioural control constructs may account for some of the observed disparities.

The TPB places a greater emphasis on motivation than action and has been criticised for the lack of available guidance on how to target the constructs of the model when developing behaviour change interventions, including a lack of in-built strategies to support people to bridge the intention-behaviour gap. In contrast, SCT emphasises the importance of both motivation and action and provides specific guidance on turning intentions into action via a range of in-built practical strategies for supporting intention formation (forethought / goals) and facilitating traversal of the intention-behaviour gap [92]. For example, the five capabilities are particularly useful for designing intervention strategies to facilitate observational learning to nurture the development of positive behavioural beliefs and outcome evaluations, as well as to increase self-efficacy / perceived behavioural control. Another example is the use of strategies such as goal setting and self-monitoring (as described in box 2) to increase self-regulation capability.

SCT also provides intervention developers with evidence-based strategies to target personal (health cognitions), as well as environmental and behavioural factors by addressing affective (i.e. emotional), cognitive or motivational processes as well as enhancing the innate capabilities of people (e.g., forethought). However, in contrast to the TPB, SCT places a greater focus and role on environmental factors (physical/structural and social) and processes of how cognitions change; whereas TPB focuses predominantly on social environmental factors that are limited to the presence of significant others in their environment.

Nevertheless, utilising two models/theories of behaviour change to underpin the development and evaluation of a complex behaviour change intervention can be complementary and viewed as a strength. Given the key limitation of the TBP (a lack of in-built strategies to support people to bridge the intention-behaviour gap), utilisation of a complimentary theory (i.e. SCT) enables the inclusion of additional evidence-based strategies for translating (motivation/intentions) into action (implementation of behaviour).

An alternative approach to elucidating effective strategies to support intention formation and subsequent performance of behaviour is afforded by the publication of a taxonomy of theory-linked behaviour change techniques that are consistently used across a range of behavioural interventions [93, 94]. Working around a theory/model of behaviour change may assist selecting, sequencing and communicating relevant behaviour change techniques to healthcare professionals and patients. Behaviour change techniques are therefore a particularly useful adjunct to the development of effective interventions as they describe the means of operationalisation, e.g., what interventionists 'do' to bring about change, regardless of the use of explicit theory.

Finally, much of the previous discussion (in particular the illustrative examples provided in boxes 1 and 2) focus on patient behaviour change. Alongside use of models/theories and delivery of specific theory-linked behaviour change techniques to design components of interventions, equal attention should be devoted to understanding the behaviour required of interventionists/care providers to effectively deliver behavioural interventions to a sufficient degree of fidelity in accordance with their theoretical underpinnings.

Effective delivery of interventions targeting health behaviour change underpinned by social cognition models (indeed all models of health behaviour change) relies heavily on the knowledge, skills and experience of the interventionists. For example, interventionists may be healthcare professionals with low-self efficacy for delivery of behaviour change interventions. Therefore training should be evidence-based and considered a behaviour change intervention in its own right with the target behaviour being the consultation behaviour of healthcare professionals needed to deliver the components of a theory-based intervention to patients. 'Training interventions' for interventionists to support them to change their behaviour (such as deliver the intervention) to maximise outcomes, should be considered in the development process for complex health behaviour change interventions.

1.8.2 Counselling techniques to support behaviour change interventions

Communication skills are a further important component of delivering behavioural interventions. For example, brief negotiation techniques have been used in a range of studies to engage people in discussions about behaviour change. These facilitate a non-threatening, person-centred and empathic environment to encourage individuals to resolve their own ambivalence about changing their behaviour, and in turn facilitate building of self-motivation via the medium of change talk [95]. The latter is a process whereby people are encouraged to make their own decisions about what to discuss and present their own arguments for changing their behaviour.

Brief Motivational Interviewing [95, 96] or Brief Negotiation Techniques developed specifically for behaviour change counselling of patients with diabetes [97, 98] have been used to good effect to maintain '*congruence with the changing needs of their clients on an ongoing basis during consultations'* about specific behaviours they may or may not wish to discuss or change [61]. Brief negotiation techniques are consistent with the 'spirit' of motivational interviewing [95], which has evidence of effectiveness as an intervention strategy [99, 100]. The effective use brief negotiation techniques are summarised with the acronym 'OARS' [95]: (i) **O**pen-ended questions ("what do you think about the amount of PA you currently do in a typical week?"); (ii) **A**ffirmation (highlighting personal strengths, values and goals and praising effort and reinforcing autonomy); (iii) **R**eflective Listening; and (iv) **S**ummarising. Reflective listening and summarising build rapport and therapeutic alliance.

Competencies for behaviour change have also been organised into a hierarchical framework (The Health Behaviour Change Competency Framework), designed to support an incremental approach to the development of knowledge and skills for delivery of behaviour change interventions with differing intensity [64]: (i) foundation competences (communication skills for fostering the development of an effective intervention alliance between patients and interventionists); (ii) behaviour change competences (theories and models of behaviour change and how they can underpin development / implementation of behavioural interventions); and (iii) behaviour change techniques (organised into motivation development, action on motivation and prompted behaviour in line with a taxonomy of theory-linked techniques utilised across behavioural interventions) [93, 94].

1.9 Rationale for the Development of a Multifaceted Intervention Targeting Consultation Behaviour of Healthcare Professionals and Physical Activity Behaviour of Adults with Type 2 Diabetes

The development and implementation of effective behavioural interventions targeting PA/exercise are warranted for use by primary healthcare professionals in routine diabetes care to help patients with Type 2 diabetes to self-manage their condition via increased levels of PA/exercise. With traditional advice-giving and direct persuasion approaches being largely ineffective for a majority of patients, behavioural interventions (along with effective behaviour change counselling techniques) that aim to increase PA/exercise to a degree sufficient to have a clinically significant impact on glycaemic control in the long-term are needed. Furthermore, targeting PA/exercise in the primary care setting is particularly promising because people with Type 2 diabetes have regular contact with their primary care team; therefore multiple opportunities exist for delivery of effective interventions by primary healthcare professionals.

Despite the known benefits of PA/exercise, there remains a shortage of effective interventions that can be offered by primary care professionals to adults with Type 2 diabetes to support them to achieve and sustain a physically active lifestyle [101]. This evidence-practice gap is seriously hindering the effectiveness of PA/exercise as a therapeutic intervention in routine diabetes care.

Although national guidelines outline the need for patient education models for the management of Type 2 diabetes [29] evidence-based tools are lacking. This is especially the case with respect to advice on effective strategies/techniques for use by diabetes care providers to increase levels of PA/exercise. It is recommended that people with Type 2 diabetes in the UK are offered some form of education/intervention (see Section 1.7.4), at least at the point of diagnosis; however, the length, information content and style of the interventions vary greatly between services where available. The majority of interventions do not include adequate support to help people with Type 2 diabetes to achieve PA/exercise recommendations, very few have been formally evaluated, and rarely have the individuals responsible for the delivery of these interventions been formally trained for this purpose [30].

There have been several published reviews and meta-analyses examining the effectiveness of interventions based on behavioural change theories / models for impacting on a range of health behaviour, including PA [76, 102.] However, there are a lack of published systematic reviews and meta-analyses investigating the efficacy of theories/models and theory-linked behaviour change techniques that are specifically aimed at providing adults with Type 2 diabetes with the knowledge, skills and confidence to increase their levels of PA/exercise that can have a positive impact on clinical outcomes such as HbA1c levels. The lack of evidence-based intervention techniques seriously hinders the effective use of PA as a patient self-management option for glycaemic control in diabetes care. Consequently, to inform both policy and practice, it is imperative to identify optimal strategies for facilitating behaviour change in people with Type 2 diabetes to enable them to become more physically active and maximise long-term glycaemic control.

The formulation of specific guidance on effective behaviour change that could be used as a basis for informing interventions and services for adults with Type 2 diabetes is compounded by the heterogeneity of behaviour change studies that makes it difficult to identify the optimal approach [80]. This was asserted further in a NICE-commissioned review [103] of four theories/models of health behaviour change (the Health Belief Model; the Theory of Reasoned Action; the Theory of Planned Behaviour and the Transtheoretical Model): "The heterogeneity of health psychology studies and inconsistencies in the way that models are applied often renders it difficult or

impossible to apply techniques such as meta-analysis in order to derive data on their predictive power and the effectiveness of alternative public health interventions" (p7).

Programmes available in the UK appear to omit structured evidence-based training for primary healthcare professionals on the delivery of evidence-based strategies for PA/exercise behaviour change. This could mean inconsistencies in the messages provided to patients, and a lack of impact on clinical outcomes. Behaviour change theory with reference to competency hierarchies [64] can be utilised to develop evidence-based interventions to target professional (clinical consultation) behaviour to equip healthcare professionals with knowledge, skills and confidence to effectively deliver evidence-based behaviour change interventions targeting PA/exercise to adults with Type 2 diabetes. However, interventions focused on healthcare professionals or patients alone will not be sufficient to address the intention-behaviour gap [35]. There is a need to focus on both sides of the consultation, and to systematically develop multifaceted interventions that address barriers to delivery and implementation of evidence-based PA/exercise interventions in the primary care setting for impacting positively on clinical outcomes in routine diabetes care.

A crucial first step in this development process is a rigorous review of the evidence to identify the optimal behaviour change techniques, modes of delivery and theoretical approaches to guide the design and evaluation of interventions targeting PA/exercise in diabetes care. This is the focus of Chapter 2 of this thesis.

Chapter 2. Changing Physical Activity Behaviour in Type 2 Diabetes: A Systematic Review and Meta-Analysis of Behavioural Interventions

Preface to Chapter 2

The author of this PhD thesis led on all aspects of the systematic review and meta-analysis presented in Chapter 2 under the direction of her supervisors and with advice from the wider systematic review team. This process involved the development of an initial protocol, including drafting and piloting of study selection and data extraction forms for use in the systematic review. Electronic searches were performed by the author with advice from a medical librarian. Study selection, data extraction and assessment of methodological quality of included articles were conducted by the author with input from the wider systematic review team to ensure rigor and reliability (i.e. all aspects of the review process [study selection, data extraction and methodological quality appraisal] were conducted independently by a member or members of the wider team). The meta-analyses and moderator analyses were conducted by the author of this thesis with advice from a statistician, before the final write-up of results, interpretation and conclusions.

A manuscript of this work was submitted and subsequently accepted for publication by the journal 'Diabetes Care' in December 2012. The reference is as follows:

Avery L, Flynn D, van-Wersch A, Sniehotta FF, Trenell MI. Changing Physical Activity Behavior in Type 2 Diabetes: A Systematic Review and Meta-Analysis of Behavioral Interventions. *Diabetes Care* 2012, 35(12), 2681-2689.

2.1 Introduction

PA (regular movement such as walking) and exercise (structured activities such as running/cycling) along with diet and medication are the cornerstones of diabetes management.[38] Several reviews [104, 105] and meta-analyses [38, 49, 106, 107] report that increased PA and/or exercise produce a significant improvement in glycaemic control in people with type 2 diabetes, yielding an average improvement in HbA1c of between -0.3% and -0.6%. Despite the clear benefits of increased PA/exercise upon glycaemic control, little is known about how clinical care teams should support people with Type 2 diabetes to achieve and sustain a physically active lifestyle. This evidence-practice gap is seriously hindering the effectiveness of PA/exercise as a therapeutic intervention in routine diabetes care.

Behavioural interventions targeting PA/exercise are heterogeneous in terms of content, implementation and effectiveness. Interventions differ on a range of dimensions, for example: (i) the theory of behaviour change used to underpin interventions; and (ii) the behaviour change techniques used to encourage change (e.g. goal setting, use of follow-up prompts); and 3) delivery of the intervention (e.g., frequency and duration of contact; one-to-one vs. group delivery). Working around a theory/model of behaviour change may assist selecting, sequencing and communicating relevant behaviour change techniques. Techniques, in turn, describe the means of operationalisation, e.g., what interventionists do to bring about change, regardless of the use of explicit theory. Despite the benefits of behaviour change theory and specific theory-linked behaviour change techniques [108, 109] historically behavioural interventions have frequently omitted adequate descriptions of both the specific theory/model of behaviour change used, and explicit detail on intervention content and how this was operationalised and evaluated [110] limiting both the efficacy of the intervention and replication outside the research setting. Elucidating the theory, content and delivery of interventions may help to explain the heterogeneity in effect sizes usually observed in systematic reviews and thereby identify what works and what does not, which provides the evidence needed to direct clinical care and research.

The objective was to conduct a systematic review to answer the following questions:

1) Are behavioural interventions more effective than standard clinical care for improving free-living PA/exercise and HbA1c in adults with type 2 diabetes in clinical or community settings?

2) What behaviour change theories or theory-linked behaviour change techniques (and other features of behavioural interventions) are associated with clinically significant improvements in HbA1c?

2.2 Research Design and Methods

This systematic review followed a published protocol [111] and Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines.[112]

2.2.1 Inclusion criteria: Studies were randomised controlled trials (RCTs) of behavioural interventions targeting free-living PA/exercise (i.e. interventions using behaviour change techniques to target an increase in PA/exercise behaviour outside of the research setting) in adults (≥18 years) with type 2 diabetes (controlled by diet/oral medication/insulin therapy), with a minimum follow-up period of one month from baseline. Where studies had a supervised exercise component they were only retained if participants received support to increase their PA/exercise behaviour outside of the supervised setting (i.e. a behavioural intervention). Interventions were delivered in clinical and community settings. Studies also included the following primary outcomes (i) change in level of PA/exercise and (ii) change in HbA1c.

2.2.2 Exclusion criteria: Studies were excluded if interventions targeted PA/exercise and diet, although studies were retained if all study participants received a dietary component that was consistent with usual care. Studies were also excluded if they targeted multiple chronic diseases or gestational diabetes or with no focus on engaging in free-living PA/exercise outside of supervised sessions. Studies that included the following components were also excluded: combinations of diet or pharmacological agents with PA/exercise in one arm of the trial, comparisons of pharmacological agents alongside and against PA/exercise or compared different behavioural interventions targeting PA/exercise that did not include a comparison arm that constituted usual care.

2.2.3 Search strategy: PsycINFO, Medline, CINAHL, EMBASE, Scopus and the Cochrane Library were searched using a combination of MeSH headings and keywords to identify potentially relevant literature (Appendix A). Searches were completed up to 23rd January 2012, and limited to RCTs published in the English language. Hand searching of reference lists and citation searching of studies fulfilling the eligibility criteria were also conducted.

2.2.4 Selection of studies: Two researchers independently screened the titles and abstracts of articles. Articles retained at the first stage were re-assessed independently for inclusion by the same two researchers using a study selection form (Appendix B) with disagreements resolved via discussion with the systematic review team.

2.2.5 Data extraction: Details on the study population, intervention(s), comparator(s) and outcomes were captured using a structured data extraction form (Appendix C). All included studies underwent independent assessment by at least two researchers and disagreements were resolved via discussion. Corresponding authors of included studies were contacted via email to request additional data where applicable. The Cochrane Collaboration risk of bias tool [113] was used to appraise methodological quality and assess overall risk of bias (low, unclear or high) within and across studies for each outcome. Data on treatment fidelity was assessed using published guidance.[114] Descriptions of intervention content were coded into specific theory-linked behaviour change techniques using a reliable and comprehensive taxonomy for intervention techniques targeting PA [94]. Behaviour change techniques utilised in both intervention and usual care groups were not coded to enable identification of those techniques that could be attributed to changes in outcomes.

2.2.6 Data synthesis: Data on changes in PA/exercise, HbA1c, and BMI were synthesised using meta-analytic techniques (RevMan v5.1). Studies reporting sufficient data to enable calculation of effect sizes were included in meta-analyses. Random effects models were selected to allow for between and within group differences [113]. Where studies included multiple trial arms, data on each intervention arm compared with the usual care arm were included in meta-analyses. Excessive weightings were controlled in studies with multiple intervention arms consistent with published guidance [113]. Heterogeneity was assessed using I^2 with values >50% considered heterogeneous [115].

Measures of intervention effects on PA/exercise, HbA1c and BMI are presented as a function of timing of follow-up measurements: ≥1 month to <6 months (short-term), 6 months (short- to medium-term); 12 months (medium-term); and 24 months (long-term). Overall measures of effect for interventions represent average effect sizes across these follow-up periods.

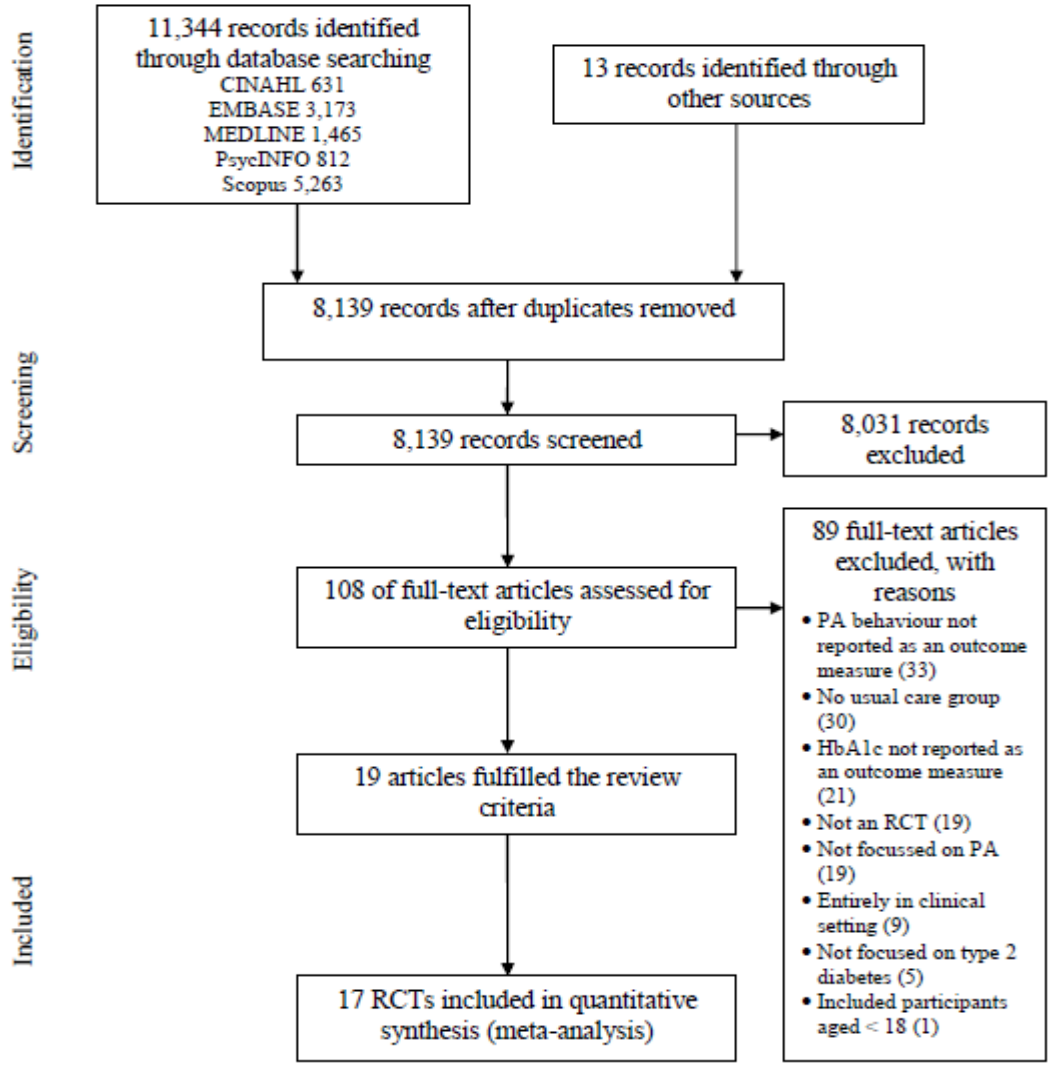
To account for variation in the methods used to assess PA/exercise across studies, objective measures (accelerometer [activity counts and/or minutes spent active] and pedometer [steps]) were combined in meta-analyses. Self-reported data on PA/exercise were combined, if sufficient information was provided about the content of the measures (i.e., 7-day recall of PA and conversion of activity intensity into MET values or minutes/hours spent active). Sensitivity analyses were undertaken by excluding outlying studies and studies with negative ratings on indices of methodological quality.

Moderator analyses were conducted on characteristics of behavioural interventions identified in a minimum of three studies to explore any impact on change in HbA1c (≥ -0.30% HbAlc as a cut-off value for a clinically significant improvement). These analyses should be considered exploratory, and were undertaken to identify any potential foci of future research and clinical practice.

2.3 Results

Nineteen articles reporting 17 RCTs [116-132] fulfilled the review criteria (Figure 2.1).

Figure 2.1 PRISMA Diagram showing the process used to identify RCTs



Two RCTs [122, 126] were reported across two articles [133, 134]. For four RCTs [116, 124, 131, 132] additional articles were consulted to obtain information on intervention content [19, 135-142].

Eleven RCTs were conducted in Europe, [116, 117, 119-123, 125-127, 132] two in Australia, [118, 130] three in North America [77, 128, 129, 131] and one in Asia [124]. Authors of 13 RCTs utilised a theory/model of behaviour change to develop and deliver interventions: Transtheoretical Model; [124-126, 132] Social Cognitive Theory; [116, 117, 122, 131] and Precede/Proceed Model [130].

Three studies stated that interventions were underpinned by multiple theories/models: (i) Transtheoretical Model and Social Cognitive Theory; [129] and (ii) Cognitive Behavioural Therapy, Motivational Interviewing, Social Cognitive Theory and theory-linked behaviour change techniques[119-121].

The studies had a combined total sample size of 1,975 participants. Eight studies conducted their intervention in clinical settings [116, 119-122, 124, 131, 132]; four in community settings [123, 127, 129, 130]; one study conducted their intervention in both a clinical and community setting (i.e. one arm utilised a clinical setting and a second arm a community setting) [128]; and one study was conducted in a University setting [125]. Three studies did not explicitly state the setting for their intervention[117, 118, 126]. Eight studies included approximately equal numbers of women and men, [120, 122-126, 131, 132] whereas nine studies had disproportionate numbers of women [118, 127-130] and men [116, 117, 119, 121, 143]. Participants were on average aged between 51-55 years, [124, 128, 131, 132] 58-59 years, [116, 126] 60-64 years [117, 118, 121-123, 125, 127, 129, 130] or 66-70 years [120]. One study included participants aged 35 to 75 years [119]. Information on time since diagnosis was described in 11 studies [116, 117, 119-122, 124, 125, 127, 129, 131, 144]. Twelve studies [116-118, 120-122, 124, 125, 127, 130-132] reported sufficient information on management of type 2 diabetes (diet, oral medication, and/or insulin therapy). For a summary of the key characteristics of the 17 included RCTs, see Appendix D.

2.3.1 Methodological quality assessment and treatment fidelity

Table 2.1 presents details of methodological quality assessment and overall risk of bias within and across studies for each outcome.

Eight studies provided sufficient information to establish the use of adequate randomisation sequences [116, 120, 122, 123 125, 126, 128, 129.] Six studies provided sufficient detail on the methods used to conceal allocation sequences[116, 119, 120, 125, 126, 128]. Seven studies provided explicit detail on the use of blinding of care providers [117, 132] or outcome assessors [116, 119, 120 125, 128] The majority of studies provided sufficient detail to establish the likely absence of selective outcome reporting, incomplete outcome data and other potential sources of bias.

Twelve studies reported a power calculation,[116, 117, 119-126, 128, 129] with nine reporting achievement of required sample sizes at final follow-up [116, 117, 121-126, 129] One study had an attrition rate of >20% at final follow-up [131]. Eleven studies reported using an intention to treat analysis ,[116, 117, 119-123, 125, 126, 128, 129]. The overall risk of bias for HbA1c, self-reported PA and BMI was graded as 'unclear', and 'low' for objectively assessed PA.

Table 2.1. Methodological quality assessment and grading within and across studies

				Methodological Quality Assessment							Outcomes			
Study ID	Power calculation (sample size at final follow-up)	Attrition rate	Intention to treat	A	B	C	D	E	F	Risk of bias within studies	HbA1c	Objective physical activity	Self-reported physical activity	BMI
Balducci et al 2010 [113]	Yes (Yes)	n=43 (7.1%)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Low	√	-	√	√
Balducci et al 2010 [112]	Yes (Yes)	n=5 (6.1%)	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Unclear	√	-	√	√
Cheung et al 2009 [114]	NR (NR)	n=3 (8%)	NR	Unclear	Unclear	Unclear	Yes	Yes	Yes	Unclear	√	-	√	√
De Greef et al 2010 [115]	Yes (No)	n=5 (12.2%)	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Low	√	√	-	√
De Greef et al 2011 [116]	Yes (No)	n=3 (4.5%)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Low	√	√	√	√
De Greef et al 2011 [140]	Yes (Yes)	n=4 (4.3%)	Yes	Unclear	Unclear	Unclear	Yes	Yes	Yes	Unclear	√	√	√	-
Di Loreto et al 2003 [118]	Yes (Yes)	n=3 (<1%)	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Unclear	√	-	√	√
Gram et al 2010 [119]	Yes (Yes)	n=3 (4%)	Yes	Yes	Unclear	Unclear	Yes	No	Yes	Unclear	√	-	-	√
Kim & Kang 2006 [120]	Yes (Yes)	NR	No	Unclear	Unclear	Unclear	Unclear	Yes	Yes	Unclear	√	-	√	-
Kirk et al 2004 [121]	Yes (Yes)	n=11 (16%)	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Unclear	√	√	√	√
Kirk et al 2009 [122]	Yes (Yes)	n=18 (13%)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Low	√	√	√	√
Ligtenberg et al 1997 [123]	NR (NR)	n=7 (12%)	NR	Unclear	Unclear	Unclear	Yes	Yes	Yes	Unclear	√	-	√	-
Plotnikoff et al 2010 [124]	Yes (Unclear)	n=7 (14.6%)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Low	√	-	√	√
Plotnikoff et al 2011 [125]	Yes (Yes)	n=8 (8.3%)	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Unclear	√	-	√	-
Samaras et al 1997 [141]	NR (NR)	NR	NR	Unclear	Unclear	Unclear	Unclear	Yes	Yes	Unclear	√	-	√	-
Tudor-Locke et al 2004 [127]	NR (NR)	n=22 (37%)	NR	Unclear	Unclear	Unclear	Yes	Yes	Yes	Unclear	√	√	-	-
Wisse et al 2010 [128]	NR (NR)	n=13 (18%)	NR	Unclear	Unclear	Yes	Yes	Yes	Yes	Unclear	√	-	√	√
									Risk of bias across studies		Unclear	Low	Unclear	Unclear

NR = Not Reported. A = adequate sequence generation; B = allocation concealment; C = blinding/masking; D = incomplete outcome data addressed; E = free of selective outcome reporting; F = study free of other problems.

The treatment fidelity assessment (Table 2.2) identified that all 17 studies provided sufficient detail to establish the use of treatment fidelity strategies related to study design (e.g., measures taken to ensure length/duration and frequency of contact within intervention groups).

Five studies referred to training of interventionists,[116, 120, 124-126] although only two studies explicitly described strategies for monitoring and improving interventionist training [116, 120] Fourteen studies described methods to improve delivery of interventions; [116, 117, 119-122, 124-126, 128-132](e.g., providing frequent supervision to interventionists, using scripted intervention protocols and taking steps to control contamination across intervention and usual care groups). All 17 studies provided sufficient detail to establish use of (i) strategies to monitor and improve the ability of patients to understand the intervention-related cognitive and behavioural skills, and (ii) strategies to monitor and improve enactment of intervention-related skills in relevant real-life settings (e.g., prompting participants to set goals, self-monitoring of progress, conducting follow-up discussions/telephone calls and opportunities for participants to review the effect of increased PA on blood glucose levels).

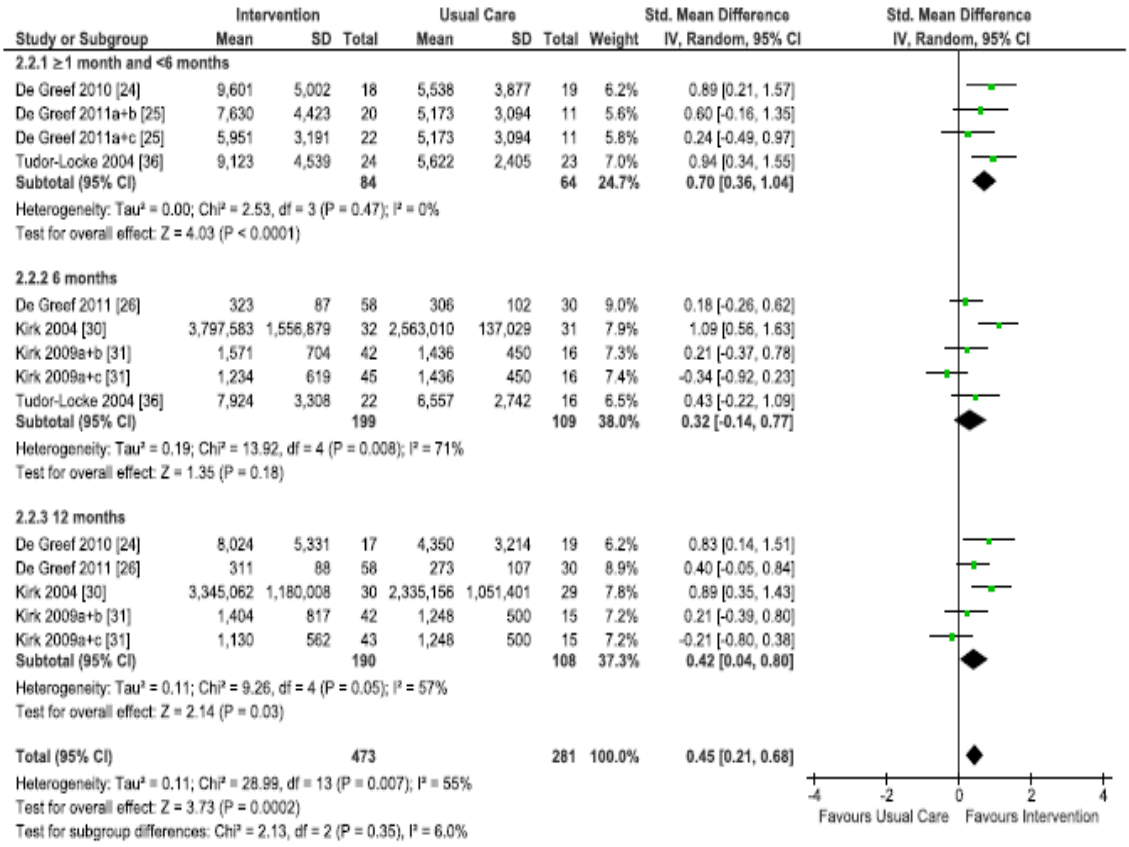
Table 2.2. Treatment fidelity assessment

	Treatment Fidelity Strategies				
Study ID	Design of study	Monitoring and improving provider training	Monitoring and improving delivery of treatment	Monitoring and improving receipt of treatment	Monitoring and improving enactment of treatment skills
Balducci et al 2010 [113]	Yes	Yes	Yes	Yes	Yes
Balducci et al 2010 [112]	Yes	No	Yes	Yes	Yes
Cheung et al 2009 [114]	Yes	No	Unclear	Yes	Yes
De Greef et al 2010 [115]	Yes	No	Yes	Yes	Yes
De Greef et al 2011 [116]	Yes	Yes	Yes	Yes	Yes
De Greef et al 2011 [140]	Yes	No	Yes	Yes	Yes
Di Loreto et al 2003 [118]	Yes	No	Yes	Yes	Yes
Gram et al 2010 [119]	Yes	No	Unclear	Yes	Yes
Kim & Kang 2006 [120]	Yes	Unclear	Yes	Yes	Yes
Kirk et al 2004 [121]	Yes	Unclear	Yes	Yes	Yes
Kirk et al 2009 [122]	Yes	Unclear	Yes	Yes	Yes
Ligtenberg et al 1997 [123]	Yes	No	Unclear	Yes	Yes
Plotnikoff et al 2010 [124]	Yes	No	Yes	Yes	Yes
Plotnikoff et al 2011 [125]	Yes	No	Yes	Yes	Yes
Samaras et al 1997 [126]	Yes	No	Yes	Yes	Yes
Tudor-Locke et al 2004 [127]	Yes	No	Yes	Yes	Yes
Wisse et al 2010 [128]	Yes	No	Yes	Yes	Yes

2.3.2 Changes in PA/exercise behaviour

Behavioural interventions when compared with usual care showed a statistically significant increase in levels of objectively assessed PA/exercise (SMD=0.45, 95% CI=0.21 to 0.68, I^2=55%) based on data from six studies [119-121, 125, 126, 131] (Figure 2.2). With the exception of 6 months, this effect was found for the follow-up period ≥1 month to <6 months (SMD=0.70, 95% CI=0.36 to 1.04, I^2=0%) and 12 months (SMD=0.42, 95% CI=0.04 to 0.80, I^2=57%). Sensitivity analyses (exclusion of one study with a high attrition rate [131] resulted in a slight decrease in magnitude of the overall effect (SMD=0.34, 95% CI=0.13 to 0.55, I^2=38%); and ≥1 month and <6 months follow-up period (SMD=0.59, 95% CI=0.18 to 1.00, I^2=0%).

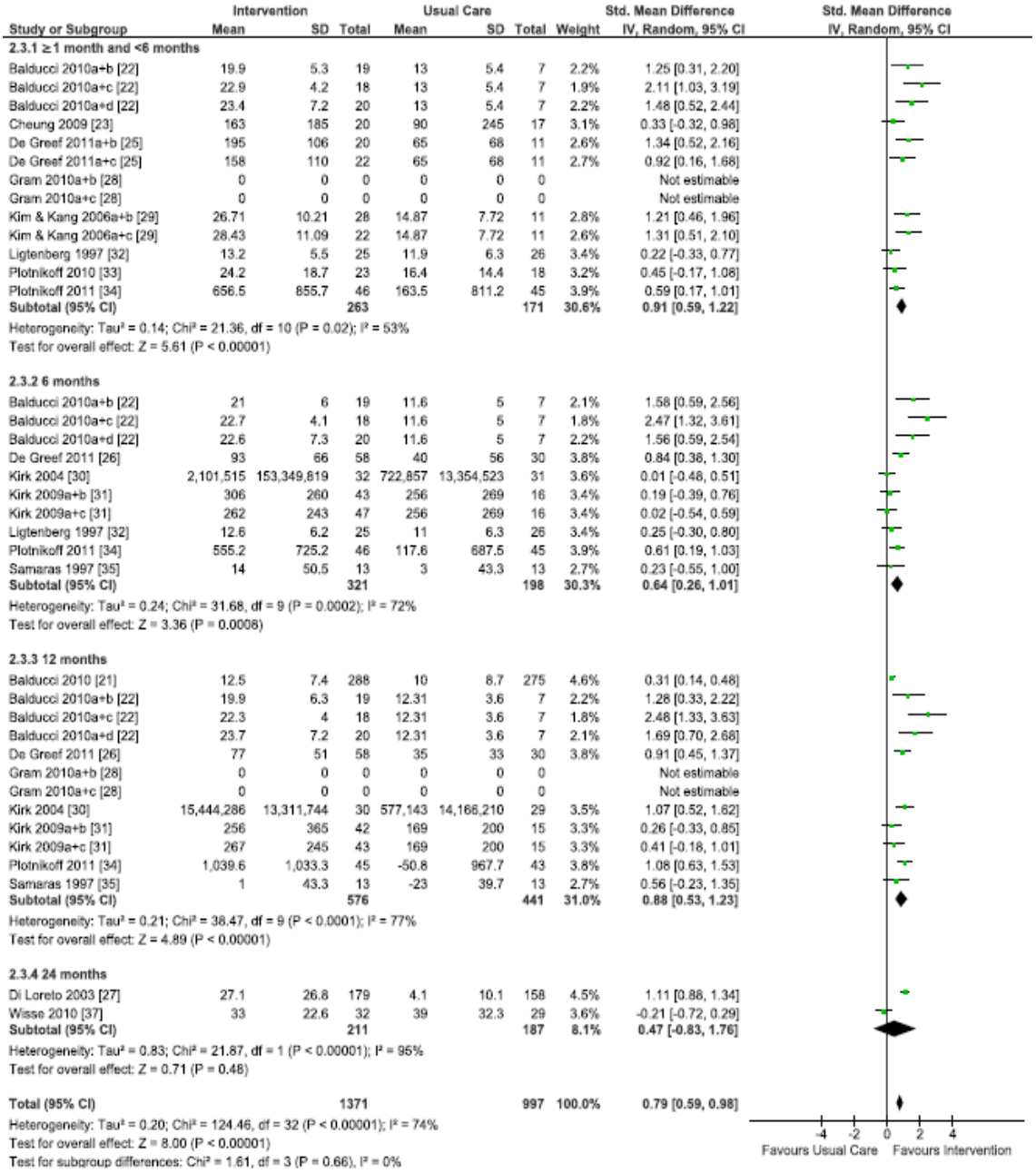
Figure 2.2: Forest Plot for Objectively Assessed Physical Activity Behaviour



Likewise, the 14 included RCTs providing self-reported PA/exercise data showed an overall significant positive intervention-effect (SMD=0.79, 95% CI=0.59 to 0.98;

I^2=74%) [116-118, 120-122, 124-130, 132] (Figure 2.3). These effects were maintained across all follow up periods, with the exception of 24 months.

Figure 2.3: Forest Plot for Self-reported Physical Activity Behaviour

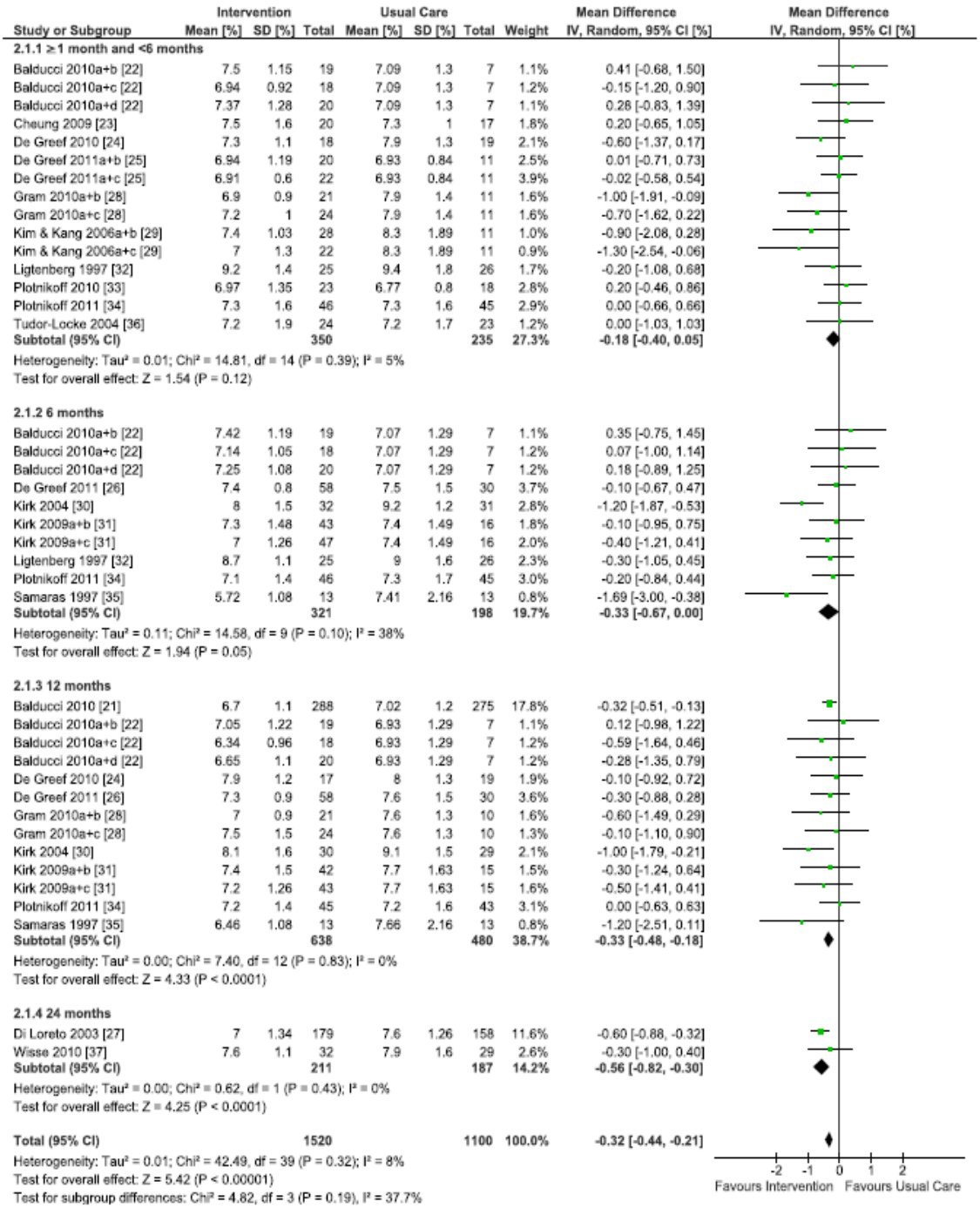


2.3.3 Changes in HbA1c

Behavioural interventions when compared with usual care showed both a statistically and clinically significant improvement in HbA1c (WMD= -0.32%, 95% CI= -0.44% to -0.21%, I^2=8%) based on data from 17 studies[116-132, 145] (Figure 2.4). With the exception

of ≥1 month to <6 months, statistically significant improvements were found across all follow-up periods: 6 months (WMD= -0.33%, 95% CI= -0.67 to -0.00%, I^2=38%); 12 months (WMD= -0.33%, 95% CI= -0.48 to -0.18%, I^2=0%); and 24 months (WMD= -0.56%, 95% CI=-0.82 to -0.30; I^2=0%). Removal of a study with a high attrition rate [131]did not change the conclusions regarding the overall effect.

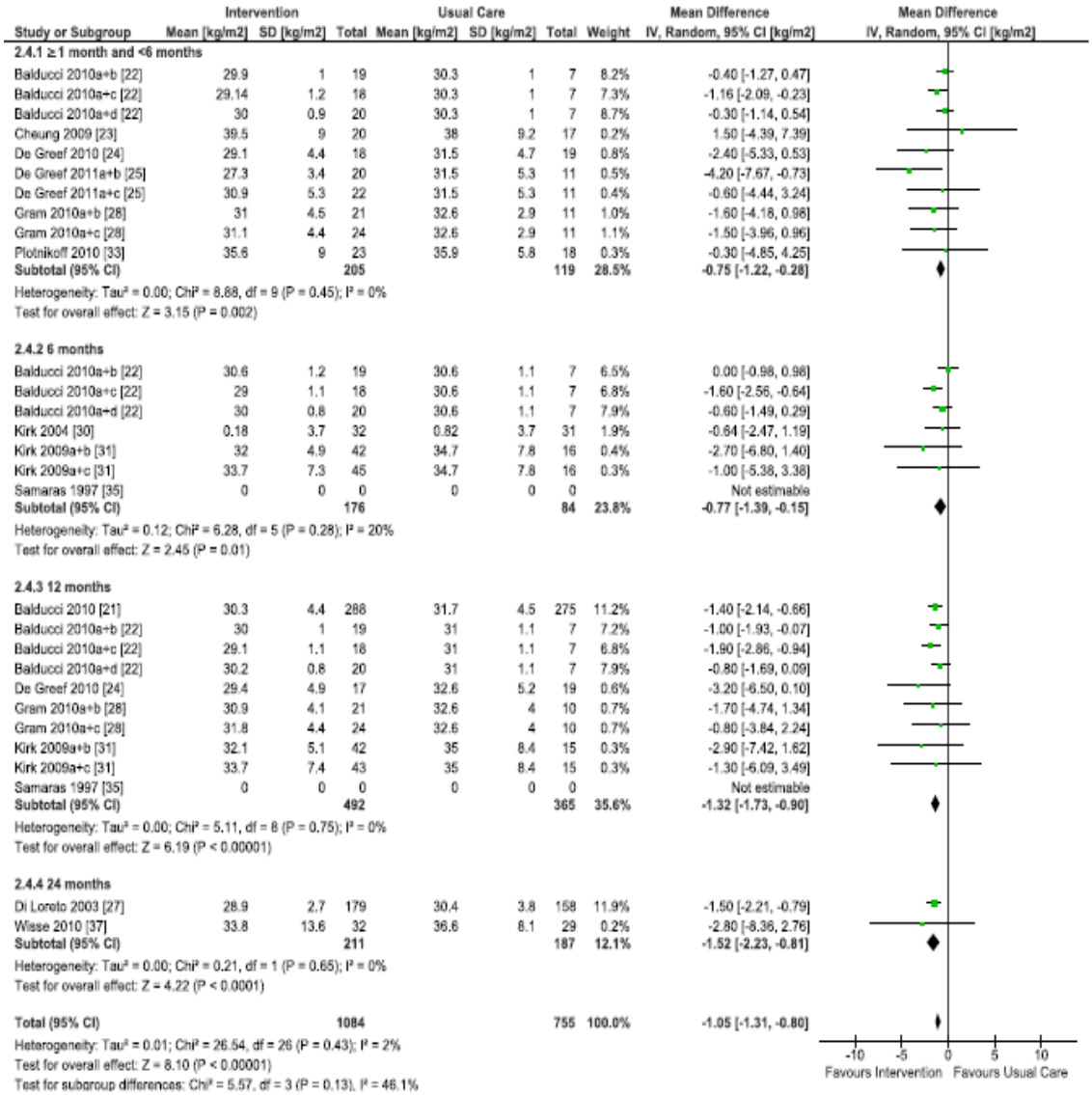
Figure 2.4: Forest Plot for HbA1c



2.3.4 Changes in BMI (Kg/m^2)

Behavioural interventions targeting PA/exercise when compared with usual care showed an overall statistically significant reduction in BMI based on data from 11 studies [116-120, 122, 123, 125, 126, 132] (WMD= -1.05 kg/m^2, 95% CI= -1.31 to -0.80, I^2=2%) (Figure 2.5). A decrease in BMI was evident across follow up periods: ≥1 month to <6 months (WMD= -0.75 kg/m^2, 95% CI -1.22 to -0.28, I^2=0%); 6 months (WMD= -0.77 kg/m^2, 95% CI -1.39 to -0.15, I^2=20%); 12 months (WMD= -1.32 kg/m^2, CI= -1.73 to -0.90, I^2=0%); and 24 months (WMD= -1.52 kg/m^2, CI= -2.23 to -0.81, I^2=0%).

Figure 2.5: Forest Plot for Body Mass Index



2.3.5 Moderators of intervention effects on HbA1c

Behaviour Change Techniques: Twenty five different behaviour change techniques were identified across the 17 studies (Table 2.3). The studies used a minimum of two and a maximum of fourteen behaviour change techniques (median of 10, IQR = 8).

Exploratory moderator analyses comparing effect size estimates for trials with or without a range of intervention features (i.e. behaviour change techniques, modes of delivery and theory use, (Table 2.4) suggested that effects varied considerably. While these differences do not equate to statistical significance, reflecting the limited power based on the current evidence, these analyses suggest that utilisation of 10 different behaviour change techniques within behavioural interventions may be associated with clinically significant improvements in HbA1c (≥ 0.3% HbA1c): prompting generalisation of a target behaviour, use of follow-up prompts, prompt review of behavioural goals, provide information on where and when to perform PA/exercise, plan social support/social change, goal setting (behaviour), time management, prompting focus on past success, barrier identification/problem-solving and provide information on the consequences to the individual.

Clinically significant improvements in HbA1c were also suggested for studies utilising more behaviour change techniques (≥ median of 10); interventions underpinned by a theory/model of behaviour change; and durations of ≥ 6 months. These analyses also suggested that different modes of intervention delivery; interventions utilising pedometers; interventions of greater intensity (≥ median of 14 contacts); and inclusion of a supervised PA/exercise component were not associated with clinically significant improvements in HbA1c.

Table 2.3. Behaviour change techniques utilised across 17 Randomised Control Trials targeting physical activity in adults with type 2 diabetes.

	Frequency
Goal setting (behaviour) [5]	17
Use of follow-up prompts [27]	16
Prompt self-monitoring of behaviour [16]	16
Barrier identification/problem solving [8]	15
Provide instruction on how to perform the behaviour [21]	15
Prompt review of behavioural goals [10]	14
Plan social support/social change [29]	13
Relapse prevention/coping planning [35]	11
Provide information on consequences of behaviour in general [1]	10
Set graded tasks [9]	10
Provide information on where and when to perform the behaviour [20]	10
Time management [38]	8
Provide feedback on performance [19]	7
Action planning [7]	6
Provide information on consequences of behaviour to the individual [2]	5
Prompting generalisation of a target behaviour [15]	5
Prompting focus on past success [18]	4
Teach to use prompts/cues [23]	4
Goal setting (outcome) [6]	3
Prompt rewards contingent on effort or progress towards behaviour [12]	3
Motivational interviewing [37]	3
Prompt self-monitoring of behavioural outcome [17]	2
Provide rewards contingent on successful behaviour [13]	1
Model/demonstrate the behaviour [22]	1
Prompt practice [26]	1
Provide information about others' approval [3]	0
Provide normative information about others' behaviour [4]	0
Prompt review of outcome goals [11]	0
Shaping [14]	0
Environmental restructuring [24]	0
Agree behavioural contract [25]	0
Facilitate social comparison [28]	0
Prompt identification as role model/position advocate [30]	0
Prompt anticipated regret [31]	0
Fear arousal [32]	0
Prompt self-talk [33]	0
Prompt use of imagery [34]	0
Stress management/emotional control training [36]	0
General communication skills training [39]	0
Stimulate anticipation of future rewards [40]	0

NB: The frequencies for BCTs include those from each intervention arm compared with the usual care arm across all 17 RCTs. Number in squared brackets corresponds with the code assigned to each behaviour change technique described in the taxonomy [(19)]

Table 2.4. Moderating effect of intervention features on HbA1c (%)

INTERVENTION FEATURE	Feature is present (absent)	Number of participants where feature is present (absent)	Effect Size (95% CI) Feature Present	Feature Absent	Difference
Behaviour Change Technique:					
Prompting generalisation of a target behaviour	5 (18)	190 (1644)	-0.73 (-1.16 to -0.31)	-0.29 (-0.44 to -0.15)	-0.44
Use of follow-up prompts	16 (7)	1056 (778)	-0.50 (-0.67 to -0.33)	-0.14 (-0.36 to 0.08)	-0.36
Goal setting (outcome)	3 (20)	123 (1711)	-0.65 (-1.23 to -0.07)	-0.32 (-0.46 to -0.17)	-0.33
Prompt rewards contingent on effort/progress towards behaviour	3 (20)	123 (1711)	-0.65 (-1.23 to -0.07)	-0.32 (-0.46 to -0.17)	-0.33
Prompt review of behavioural goals	14 (9)	920 (914)	-0.50 (-0.69 to -0.32)	-0.17 (-0.40 to 0.05)	-0.33
Provide information on where and when to perform the behaviour	10 (13)	747 (1087)	-0.54 (-0.74 to -0.34)	-0.24 (-0.39 to -0.09)	-0.30
Plan social support/social change	13 (10)	894 (940)	-0.50 (-0.69 to -0.32)	-0.20 (-0.41 to 0.01)	-0.30
Goal setting (behaviour)	17 (6)	1019 (815)	-0.44 (0.61 to -0.27)	-0.16 (-0.47 to 0.15)	-0.28
Prompting focus on past success	4 (19)	415 (1419)	-0.54 (-0.80 to -0.29)	-0.29 (-0.44 to -0.13)	-0.25
Provide information on consequences of behaviour to the individual	5 (18)	476 (1358)	-0.51 (-0.75 to -0.28)	-0.29 (-0.46 to -0.12)	-0.22
Barrier identification/problem solving	15 (8)	1016 (818)	-0.44 (-0.61 to -0.26)	-0.23 (-0.48 to 0.02)	-0.21
Time management	8 (15)	630 (1204)	-0.47 (-0.68 to -0.25)	-0.27 (-0.44 to -0.11)	-0.20
Teach to use prompts/cues	4 (19)	231 (1603)	-0.42 (-0.86 to 0.03)	-0.32 (-0.47 to -0.17)	-0.10

Table 2.4 (continued) Moderating effect of intervention features on HbA1c (%)

INTERVENTION FEATURE	Feature is present (absent)	Number of participants where feature is present (absent)	Effect Size (95% CI) Feature Present	Feature Absent	Difference
Behaviour Change Technique:					
Relapse prevention/coping planning	11 (12)	543 (1291)	-0.33 (-0.56 to -0.10)	-0.32 (-0.52 to -0.12)	-0.01
Provide feedback on performance	7 (16)	336 (1498)	-0.31 (-0.61 to -0.01)	-0.33 (-0.51 to -0.16)	0.02
Provide information on consequences of behaviour in general	10 (13)	417 (1417)	-0.24 (-0.50 to 0.02)	-0.36 (-0.55 to -0.16)	0.12
Provide instruction on how to perform the behaviour	15 (8)	1057 (777)	-0.29 (-0.47 to -0.10)	-0.42 (-0.64 to -0.20)	0.13
Action planning	6 (17)	339 (1495)	-0.23 (-0.53 to 0.07)	-0.37 (-0.53 to -0.22)	0.14
Set graded tasks	10 (13)	1252 (582)	-0.26 (-0.46 to -0.06)	-0.42 (-0.64 to -0.20)	0.16
Motivational interviewing	3 (20)	156 (1678)	-0.19 (-0.58 to 0.19)	-0.35 (-0.51 to -0.19)	0.16
Prompt self-monitoring of behaviour	16 (7)	656 (1178)	-0.18 (-0.38 to 0.02)	-0.47 (-0.68 to -0.25)	0.29
Use ≥ 10 Behaviour Change Techniques	13 (10)	864 (970)	-0.48 (-0.67 to -0.30)	-0.22 (-0.42 to -0.03)	-0.26
Mode of Delivery:					
Combination of individual face-to-face and group sessions	3 (20)	78 (1756)	-0.46 (-1.00 to 0.08)	-0.32 (-0.48 to -0.16)	-0.14
Individual face-to-face sessions only	12 (11)	1428 (406)	-0.33 (-0.52 to -0.14)	-0.32 (-0.57 to -0.06)	-0.01
Group sessions only	7 (16)	270 (1564)	-0.27 (-0.64 to 0.09)	-0.36 (-0.50 to -0.22)	0.09

Table 2.4 (continued) Moderating effect of intervention features on HbA1c (%)

INTERVENTION FEATURE	Feature is present (absent)	Number of participants where feature is present (absent)	Effect Size (95% CI)		
			Feature Present	Feature Absent	Difference
Theory or Model of Behaviour Change	18 (5)	1638 (196)	-0.37 (-0.49 to -0.25)	-0.21 (-0.72 to 0.29)	-0.16
Duration of intervention (≥ 6 months)	12 (11)	1378 (456)	-0.40 (-0.53 to -0.26)	-0.23 (-0.52 to 0.07)	-0.17
Pedometer	8 (15)	377 (1457)	-0.21 (-0.47 to 0.05)	-0.38 (-0.58 to -0.17)	0.25
Intensity of intervention (≥ 14 contacts)	11 (12)	1052 (782)	-0.23 (-0.40 to -0.07)	-0.46 (-0.66 to -0.26)	0.23
Supervised PA/Exercise Component	10 (13)	884 (950)	-0.28 (-0.48 to -0.07)	-0.39 (-0.58 to -0.19)	0.11

NB: moderator analyses include BCTs / features that were present / absent in each intervention arm when compared with the usual care arm across RCTs.

2.4 Discussion and Conclusions

This is the first systematic review of behavioural interventions targeting PA/exercise in adults with Type 2 diabetes detailing both clinical efficacy and guidance on potentially successful behavior change techniques. The analyses demonstrate that: (i) interventions targeting PA/exercise based on behaviour change theory deliver a significant increase in PA/exercise in community based intervention studies; (ii) increases in PA/exercise can be sustained for up to 24-months; (iii) changes in PA/exercise are accompanied by clinically significant improvements in HbA1c after 6-months; and (iv) specific behaviour change techniques may increase the likelihood of clinically significant improvements in HbA1c. Regarding utilisation of behaviour change techniques, more might be better. Combined, these results demonstrate that interventions targeting PA/exercise based on behaviour change theory can deliver increases in PA/exercise and improvements in diabetes control in community dwelling adults with established type 2 diabetes.

A strength of this dataset is that all studies were undertaken in clinical care/community settings, demonstrating potential clinical utility. The major implication of this review is that behavioural interventions have potential to effectively reduce HbA1c in adults with type 2 diabetes in routine clinical care.

The reductions in HbA1c of 0.20 to 0.41% are consistent with previous meta-analyses, including a wider collection of PA/exercise studies. [38, 49, 104-107.] Follow-up periods of < 6 months failed to show a significant impact upon HbA1c. However, < 6 months duration is not sufficient to elicit an observable effect on HbA1c, highlighting that longer behavioural interventions are needed if clinically meaningful changes in HbA1c are desired. The benefits to glycaemic control were sustained for up to 24 months (Figure 2.4) and were comparable to common long-term drug or insulin therapy.

Critically, all studies reviewed involved supporting adults with diabetes to undertake free-living PA/exercise. Despite the focus upon PA/exercise, meta-analyses reported significant heterogeneity for objective (Figure 2.2) and self-reported PA (Figure 2.3). Although there were individual differences in response, the variations in sensitivity and specificity in monitoring PA/exercise between the different objective and self-reported methods observed will have contributed to this heterogeneity. Furthermore, many

interventions reported reductions in BMI (Figure 2.5). As PA/exercise alone is generally insufficient to incur weight loss [146] this suggests an impact of behavioural interventions targeting PA/exercise upon calorie intake, and Hawthorne effects cannot be ruled out. Furthermore, there is a complex relationship between mode and intensity of activity, nutrition and the behavioural methods used to achieve these that is not addressed by this systematic review. However, the lack of detail about calorie intake or different modes of PA/exercise should not detract from the reported clinical utility of behavioural interventions targeting PA/exercise in terms of long-term glucose control.

The studies identified used a range of behaviour change theories and behaviour change techniques which may moderate the effectiveness of the behavioural interventions. While effect sizes found in moderator analyses do not differ significantly from the main findings, they help identify specific candidate behaviour change techniques most likely to be effective for future research and as potential foci for clinical practice. Ten behaviour change techniques [94] were associated with potential clinically significant improvements in HbA1c; prompting generalisation of a target behaviour (*e.g., once PA is performed in one situation, the individual is encouraged to try it in another*); use of follow up prompts (*e.g., telephone calls in place of face-to-face sessions to support maintenance*); prompt review of behavioural goals (*e.g., review whether PA goals were achieved followed by revisions or adjustments*); provide information on where and when to be active (*e.g., tips on places and times to access local PA/exercise clubs and classes*); plan social support/social change (*e.g., encourage individuals to elicit social support from others to help achieve a PA-related goal*); goal setting (*e.g., supporting individuals to formulate specific, measurable, achievable, relevant and timely PA-related goals*); time management (*e.g., freeing up time to be active*); prompting focus on past success (*e.g., identifying previous successful attempts at PA*); barrier identification/problem solving (*e.g., identifying potential barriers to PA and ways to overcome them*); and provide information on the consequences of PA to the individual (*e.g., information about the benefits and costs of PA to individuals*).

A number of published systematic reviews have aimed to identify the active ingredients of behaviour change interventions targeting PA behaviour in a range of populations. For example, a 2013 systematic review and meta-analysis by Olander and colleagues identified two behaviour change techniques (prompt self-monitoring of behavior and

‘plan social support/social change) associated with the largest effect sizes in PA behavior change in obese adults[147]. The following six behaviour change techniques ‘provide information on the consequences of behaviour in general’; ‘action planning’; ‘reinforcing effort or progress towards behaviour’; ‘provide instruction’; ‘facilitate social comparison’ and ‘time management’ were associated with the largest effect sizes in PA behaviour change in a sample of healthy community dwelling adults[148]. Most recently, French and colleagues reported that barrier identification/problem solving, provide rewards contingent on successful behaviour, and model/demonstrate the behaviour were associated with the highest levels of PA behaviour change when they were present in behavioural interventions targeting older adults aged 60 years and over[149].

The findings of these reviews are not directly comparable to the findings reported in the systematic review presented in this chapter (i.e. the findings from these three reviews were from populations of adults without Type 2 diabetes and report on behaviour change techniques associated with increases in PA and not improvements in HbA1c. However, they highlight the importance of selecting behaviour change techniques that are appropriate for specific target populations and outcomes (behavioural or physiological), even when interventions are targeting the same behaviour. For example, the behaviour change technique ‘prompt generalisation of a target behaviour’ was associated with the largest effect size in HbA1c in the systematic review presented in chapter 2 (targeting adults with Type 2 diabetes), whereas the same behaviour change technique was associated with the lowest effect size for PA behaviour change in the systematic review published by Olander and colleagues in 2013, which focused on obese adults. It could be inferred that individual or specific clusters of behaviour change techniques are associated with different magnitudes of change in PA/exercise behaviour (that will also be influenced by the type, duration and intensity of PA, including features of interventions such as intervention duration and the number of behaviour change techniques utilised. These in turn may have a variable impact on changes in physiological/biochemical outcomes such as improvements in HbA1c. Future work should therefore utilise factorial designs to further understanding of how behaviour change techniques impact on the type, intensity and duration of free-living PA/exercise that is maximally effective for sustaining improved physiological/biochemical outcomes in adults with diabetes.

The list of behaviour change techniques reported from the systematic review presented in this chapter is not definitive and is limited in terms of statistical power by the available body of evidence and by the small selection of techniques utilised within interventions versus those that are not. More research is needed to determine effectiveness of single or aggregated behaviour change techniques in RCTs and to investigate how clusters of these techniques could be individually-tailored for people with diabetes**.** In order to enhance reproducibility, attention should also be given to highlighting the utilisation of specific behaviour change techniques, with reference to a reliable taxonomy, [94] when describing intervention content. Exploratory moderator analyses suggested that the following intervention features were associated with clinically significant improvements in HbA1c: underpinning interventions with behaviour change theories/models (although no one model appeared to hold benefit over others), utilising ≥ 10 behaviour change techniques and intervention duration of ≥ 6 months. This provides evidence that behavioural interventions targeting PA/exercise may have a maximal impact on HbA1c when they are underpinned by a theory/model of behaviour change, utilise more (rather than fewer) BCTs and are at least 6 months in duration.

Further research is also required to determine what professional training enables care providers to effectively deliver behavioural interventions. Five studies reported that individuals delivering the interventions had been trained for this purpose, but only two studies provided information on mode, content and utilisation of strategies for monitoring and improving delivery of training. Professional training is a crucial component of behavioural interventions as it improves treatment fidelity and enhances reproducibility in routine practice. Both the mode of delivery and pathway of care provider training have a significant impact upon the cost of delivering the intervention, and as a result, the likelihood of implementation in routine care. Future studies, in addition to describing behaviour change theories, behaviour change techniques and how these were operationalised, should also report on how care providers were trained and aspects of treatment fidelity. This increased clarity will assist in addressing the current evidence-practice gap and serve to increase the efficacy of PA/exercise as a management option in routine diabetes care.

Potential limitations of this systematic review are the disparate definitions of 'usual care' across studies and the possibility of selection and/or performance and detection bias due to either absence/lack of reporting on allocation concealment and blinding respectively. However, blinding of participants and study personnel is inherently problematic in behavioural studies. Publication bias is possible, although an inspection of funnel plots for primary outcomes did not show any substantial asymmetry, indicating a low risk of publication or small study bias.

Combined these data reveal that behavioural interventions targeting increased PA/exercise in clinical care or community settings hold significant clinical utility. Although these observations are encouraging, there remains a pressing need for further research to understand how these should be optimised and implemented into routine clinical care. This need will be the focus of Chapter 3.

Chapter 3. Intervention Development

Preface to Chapter 3

The author of this PhD thesis was employed as a Research Associate at Newcastle University throughout her candidature as a PhD student to lead a project called 'Movement as Medicine for Type 2 Diabetes'. This role involved the systematic development of the evidence-informed behaviour change intervention presented in Chapter 3. The authors' contributions were as follows:

Exploratory Phase

The design of the 'exploratory phase', including methodological decisions about target population, setting, location, sample size, data collection and analyses were made prior to the author of this thesis joining the research team. This work was led by Louise Taylor, Interactive Designer on behalf of the Principal Investigator, Prof Mike Trenell. The authors' contribution during this phase involved interpretation of the data generated from semi-structured interviews with general practitioners and workshops with adults with Type 2 diabetes. The findings of this work were utilised by the author to inform the subsequent 'development phase'.

Development Phase

All aspects of the 'development phase' including key design and methodological decisions were made by the author of this thesis who subsequently led and conducted this work with guidance from her supervisory team. Development work included writing intervention content (online, paper-based resources and DVD) following the outcome of phases 1a, 1b and 2a, and revising the content following usability testing with primary healthcare professionals and adults with Type 2 diabetes (2c). Advice and input during phase 2b was provided by Prof Jane Speight and Dr Kylie Mosely. Assistance with usability testing was provided by Dr Sarah Denton.

3.1 Introduction

It is widely reported that PA/exercise is an effective management approach for glycaemic control in adults with Type 2 diabetes [49, 104-106.] However, despite the known benefits of PA/exercise, there remains a lack of effective evidence-based interventions that can be offered to adults with Type 2 diabetes in routine primary care. Furthermore, healthcare professionals report difficulties while trying to support their patients to increase their everyday levels of PA [150]. People with Type 2 diabetes have regular contact with their primary care teams and this setting is optimal for delivery of interventions targeting PA/exercise. However, primary care teams frequently do not receive adequate training that enables them to successfully target PA/exercise utilising effective behaviour change strategies [30, 151]. This makes supporting patients to increase their levels of PA/exercise to a magnitude sufficient for optimal glycaemic control a significant challenge in the primary care setting.

This chapter describes the systematic development of a theory-based multifaceted behaviour change intervention that targets both consultation behaviour in primary healthcare professionals and PA/exercise behaviour in adults with Type 2 diabetes: MaM for T2D. It will begin with an overview of the MRC framework and its value for guiding the development and evaluation of complex interventions. A discussion on the development process for MaM for T2D will then be presented with reference to three broad phases: an initial exploratory phase, a development phase and an open pilot testing phase. Findings from each phase will be described and how they informed subsequent phases to develop MaM for T2D.

The MRC framework for the development and evaluation of complex interventions highlights the need to clearly describe the development process and rigorously evaluate complex interventions [88, 108]. Behaviour change interventions are by their very nature complex (i.e. they contain multiple components); however details of the development process and reporting on specific details about their content is often lacking [110, 152].

Systematic reviews reporting on the effects of behavioural interventions targeting PA/exercise behaviour have concluded that both the interventions and associated effect sizes are extremely heterogeneous [153, 154].

While some interventions are found to be effective in changing PA/exercise behaviour and associated outcomes such as improved glycaemic control, other interventions fail to achieve positive effects. Identifying the reasons for these discrepancies between studies is difficult. Accumulation of evidence and its application and replication in practice relies on specific details about the content and delivery of an intervention being available and accessible [155]. Availability of such information makes identification of the 'active ingredients' of an effective intervention possible. Furthermore, it allows a better understanding of what works well; allows an assessment of whether intervention components can be successfully implemented; determines whether optimisation is required; allows replication of intervention development and delivery in future studies; and facilitates evidence synthesis to establish effective intervention features and overall effects on outcomes. Absence of specific detail about the development process and information content of complex interventions, including mode of delivery and details of interventionists (in particular the development process and information about the training they received to deliver an intervention) impacts negatively on their reproducibility and effective implementation in routine practice [151].

To maximise the success of an intervention, the authors of the MRC framework recommend that sufficient preliminary work is carried out to identify 'probable active components' that can be feasibly delivered in the target setting/context of the interventions. To facilitate this process a pre-clinical/theoretical phase of the framework is proposed. This involves a review of existing evidence that can provide guidance pertaining to the theoretical basis of an intervention, prior to the development of intervention components. This process facilitates the development or subsequent refinement of study hypotheses to ensure that behavioural predictors are adequately understood and appropriately targeted.

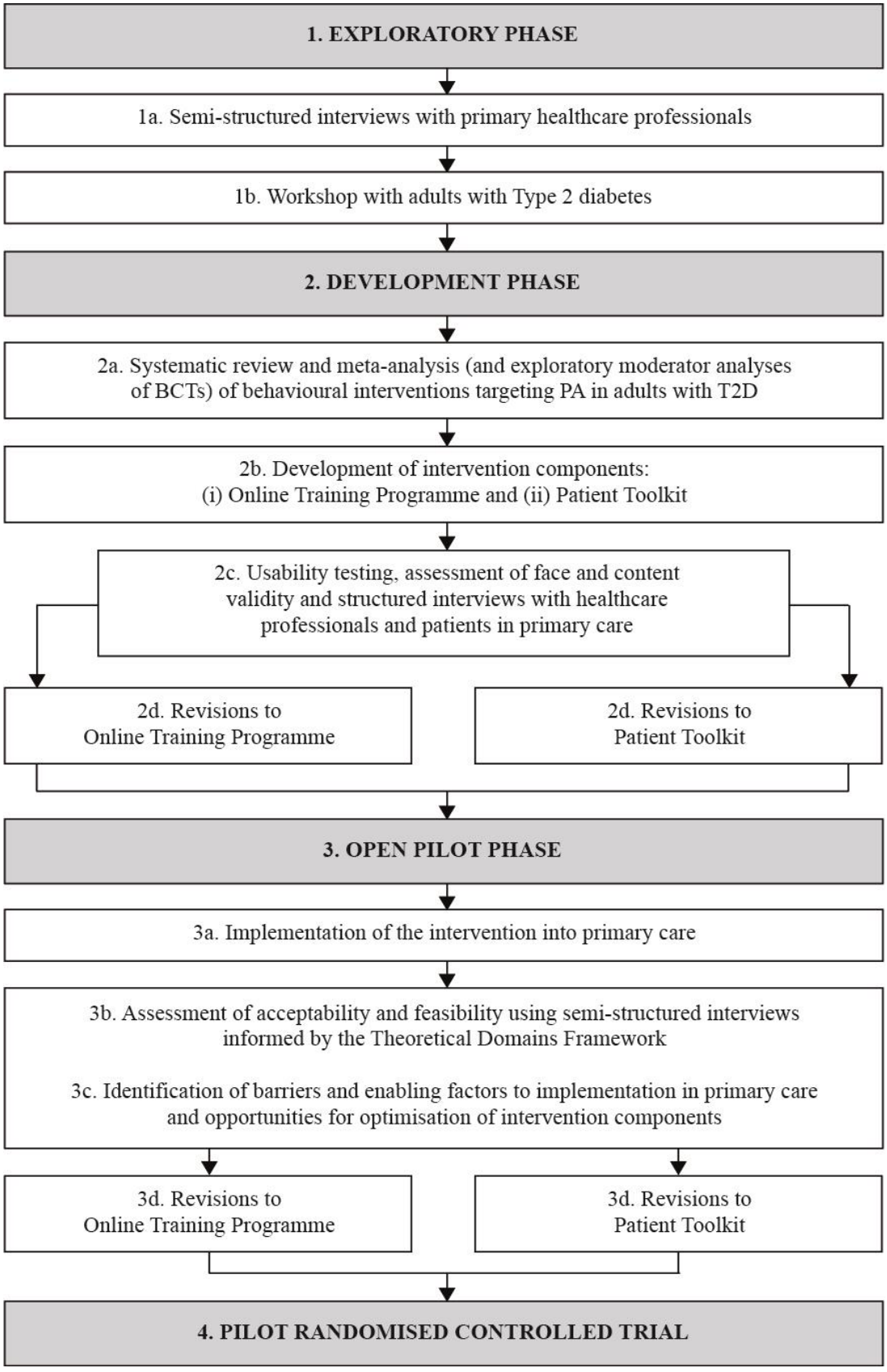
Phase I of the MRC framework, the 'modelling phase' emphasises the need to define components of an intervention to improve understanding of them, their interrelationships and potential for successful implementation. For example, carefully planned qualitative work with proposed recipients of an intervention can serve to identify barriers and enabling factors to behaviour change and implementation of an intervention prior to an exploratory trial. However, the MRC framework is not linear, i.e. the various phases proposed in the original framework should be considered an iterative process.

Indeed the updated MRC framework guidance published in 2008 [108] emphasises the need for an iterative development process. This is likely to involve movement back and forth between phases following the outcome of a pilot study for instance to facilitate refinement or optimisation ahead of a definitive trial.

Using the MRC framework a phased study consisting of participatory development work utilising a systematic development process was undertaken (see Figure 3.1). The aim was to develop a multifaceted behaviour change intervention that (i) was evidence-informed; (ii) met the needs of both primary healthcare professionals and adults with Type 2 diabetes; (iii) could be successfully integrated into routine primary care; and (iv) could be appropriately evaluated with an RCT design.

Guidance published by Davidson et al 2003 [156] was followed to ensure that intervention characteristics were appropriately described. These included intervention provider; format; setting; recipient; intensity; duration and information content. A taxonomy of behaviour change techniques [94] was used throughout the development and open pilot phases to ensure that techniques selected for inclusion in the intervention were adequately and consistently defined.

Figure 3.1. Summary of the intervention development process



Each distinct but interrelated phase of development work is described in the subsequent sections of this chapter.

3.2 Exploratory Phase

3.2.1 Understanding the training needs of primary healthcare professionals

Introduction

Chapter 2 reported on a systematic review and meta-analysis that provided sufficient evidence that behaviour change interventions targeting PA/exercise are effective in improving glycaemic control. However, a significant limitation of the majority of included studies was the lack of a standardised training component for care providers to enable them to effectively and consistently deliver behaviour change interventions targeting PA/exercise. Studies that did report a training component [116, 120, 124-126] often lacked detail on information important for replication (e.g., mode of delivery, duration, and specific content) or an assessment of the extent that the interventions were delivered to patients in accordance with the study protocol / content of training programmes for care providers (treatment fidelity). This creates uncertainty as to whether changes observed were attributable to the specific content of the interventions or to the quality of delivery. Training care providers to deliver the intervention competently and faithfully increases the likelihood that interventions are effective and that possible effects can be attributed to the intervention as specified in the protocol [114]. With so few studies reporting a standardised training component for care providers (and none of these reporting a formal evaluation), it is difficult to establish what was delivered to care providers, what worked well, the optimal mode of delivery and how/if training provision could be improved for use in future studies.

Aim and objectives

The aim of the semi-structured interviews (phase 1a) of the initial exploratory phase was to explore the views and experiences of primary healthcare professionals in the following areas:

(i) When and where they typically complete their continuing professional development
(ii) When and where they first and last completed training on diabetes and diabetes care
(iii) What are the most difficult topics to discuss with patients in relation to their diabetes
(iv) What in their view makes it difficult to deliver lifestyle interventions to patients with Type 2 diabetes
(v) How they currently support their patients to effectively manage their diabetes
(vi) Identify the training needs of primary healthcare professionals with regards to the delivery of behaviour change interventions targeting PA/exercise in the context of routine diabetes appointments, including their preferences on mode of training delivery and how much time they may have to complete training within a typical working week.

Method

A convenience sample of primary healthcare professionals (General Practitioners [GPs] and Practice Nurses) working in local practices were invited to participate in an exploratory semi-structured interview to inform the initial design of MaM for T2D.

Interviews elicited information on how their patients typically received diabetes education and advice on PA/exercise; (at what time points following diagnosis they received diabetes education and whether it was appropriate for their patients' needs); to what extent they believed patients engaged with the process of diabetes self-management; and approaches they currently used to target PA/exercise during diabetes review appointments and their views on whether they were effective.

To inform the content of a training programme, it was important to capture the specific training needs of primary healthcare professionals with regards to the delivery of behaviour change interventions targeting PA/exercise in the context of routine diabetes appointments. This included their preferences on mode of training delivery and how much time they may have to complete training within a typical working week.

An interview guide was developed (see Appendix E); however due to restrictions in time and availability of participating healthcare professionals, questions were selected from the guide that were most relevant to the individual healthcare professional that would serve to inform the design of an intervention. For example, a GP lead specialist in diabetes care was more likely to be asked questions about how they selected continuing professional development opportunities in the context of diabetes care and what areas of diabetes care they believed should be delivered by primary care practices; whereas a non-diabetes specialist was asked more generic questions such as 'what is the most difficult thing about delivering lifestyle interventions to patients?' The questions asked were guided by the experiences of the participating healthcare professionals and the time available. The aim was to address all questions from the topic guide across participating healthcare professionals to inform the initial design of MaM for T2D.

All interviews were audio recorded, transcribed and data analysed using a content analysis [157].

Results

Three general practitioners (male=2; female=1; specialists in diabetes/practice lead for diabetes (n=2) from three primary care practices in North-East England agreed to participate in a semi-structured interview.

General practitioners (GPs) reported feeling knowledgeable about the underlying physiological mechanisms of Type 2 diabetes, however they emphasised that it was sometimes difficult to communicate this complex information to patients. Furthermore, they expressed dissatisfaction that many of their patients do not act upon the advice they provide about increasing their PA/exercise levels. As such they felt that a different approach was required to effectively communicate information about diabetes to

patients, including the benefits of leading a physically active lifestyle that would be more flexible to patients' personal situations. They reported patients typically adopting a passive role during consultations, with a reluctance to engage in discussion about effective management of their diabetes and other co-morbidities by changing their behaviour. The latter was interpreted as evidence for patients *"not willing to take responsibility".* GPs reported that structured diabetes education was offered to their patients often by referral to a programme such as 'Diabetes Education and Self-Management for Ongoing and Newly Diagnosed' (DESMOND) [58] at the point of diagnosis. However, there are no regional / national data on uptake rates; and the GPs interviewed estimated that many of their patients either preferred not to take advantage of this service or choose not to attend scheduled diabetes review appointments: *"in Sunderland there's an introduction to diabetes at diagnosis…[the patients] are offered the education programme there. And I would say that probably less than 50% want to do that, which is a shame. It really is"* [GP #1]

The GPs reported the following as important considerations: being able to plan a programme of training in advance that can feed into their annual appraisal process, and training provision that is evidence-based and confers accreditation for the purposes of continuing professional development. Although a specific amount of time for training was not reported, GPs described time available for training as "limited" and only when they could acquire a locum to cover their clinics. Therefore, an online programme that allowed users to complete the content on multiple occasions (over a specified period of time) was considered to be the most feasible mode of training delivery.

The importance of being able to accurately identify a patient's current level of PA/exercise was emphasised by GPs (i.e. the need for tools to achieve this). Regarding targeting PA/exercise behaviour, the approach described by GPs was typically unsolicited advice giving combined with healthcare professional-centred goals for PA change. For example, *"I think with exercise… give them a very specific timetable for what I expect them to have done by the next appointment. Because… if you just say 'I'd like you to start exercising, do some swimming'? [No good]. You need to say 'How about you do 3 sessions of swimming?"* [GP, #1]

In general, prescribing drugs was considered as a more attractive and effective option than promoting PA lifestyle changes, *"If you've got somebody with a cholesterol of 6, and I have a target for it to be 5? If I get them to eat properly and I get them to exercise more, there's a chance that in 2 to 3 years their cholesterol might be 5. If I put them on a statin, their cholesterol's going to be 5 in 4 weeks' time." [GP, #3]*. When asked about the most difficult part of diabetes management, this was reported to be lifestyle behaviour change, *"I think it's the same thing that I find difficult – its behaviour change. Because at the end of the day, taking a tablet to help you lose weight and reduce your blood sugars, it's actually a bit easier than lifestyle change." [GP, #2].*

A variety of training needs specific to PA/exercise and Type 2 diabetes management were identified. The findings of the semi-structured interviews emphasised the need for a training programme designed to increase awareness of the value of PA/exercise as a form of management for Type 2 diabetes (It was reported that diet was targeted more consistently than PA/exercise due to the lack of knowledge about the type, duration, and frequency of PA/exercise to recommend), including type and intensity of PA/exercise. Furthermore, the dominance of healthcare professional-centred 'advice-giving' approaches indicated that a key focus of the training should be on skills development of healthcare professionals in the context of PA/exercise for Type 2 diabetes utilising effective health behaviour change strategies. The general consensus was that an online training programme would allow flexibility. The programme would be useful for demonstrating new ways for healthcare professionals to communicate to their patients about diabetes, in particular why it progresses without appropriate management and how to manage it effectively by making PA/exercise lifestyle changes.

Information content from interview transcripts were summarised and discussed within the wider research team to inform the initial development of the MaM for T2D intervention components.

3.2.2 Understanding the support needs of adults with Type 2 diabetes

Aims/objectives

The aim of the workshop was to collect information from adults with Type 2 diabetes (Phase 1b) on their views and perspectives on their information and support needs with regards to PA/exercise as a self-management option for their diabetes. That, together with the findings of phase 1a and the systematic review reported in Chapter 2, would inform the initial design and information content of the second facet of the intervention (a patient toolkit for delivery by healthcare professionals to facilitate the process of PA/exercise behaviour change) that would also inform the development of the first facet (online training for healthcare professionals) of the MaM for T2D intervention.

Method

The interactive workshop (utilising an open discussion format) focused on eliciting the views and perspectives of adult patients with a diagnosis of Type 2 diabetes on the following topics: (i) the value of the information provided by primary care teams on diabetes and their support needs to effectively manage their diabetes with PA/exercise; (ii) what they considered to be a definition of a 'great healthcare professional' in the context of diabetes care; (iii) whether they believed a family history of diabetes positively influenced their knowledge about the condition; (iv) who they would contact to request information and support about Type 2 diabetes when required; (v) how well informed they were about the use of PA/exercise as a management option for their diabetes; and (vi) how much information and support had they had received previously from primary care teams to help them to increase their levels of PA/exercise.

Field notes on salient points were summarised and discussed within the wider research team to inform the development of draft intervention components.

Results

Six adults with Type 2 diabetes (male=4; female =2) all aged ≥65 years, with a median time since diagnosis of 11 years (IQR = 8) agreed to take part in the interactive workshop.

Participants reported that in their view the primary healthcare professionals that they had contact with initially were not particularly knowledgeable about Type 2 diabetes in general, and as such felt unable to discuss their condition in any significant depth. *"…the first time I went to see her [practice nurse] she had no idea what my blood sugar levels should be…"* [P, #1]. This belief was reinforced when some participants were referred to secondary care specialists, and others referred to a diabetes specialist nurse at their practice. Several also reported educating themselves, their GP or practice nurse about their condition with regards to effective management strategies. One participant felt that that secondary care provided a better service, *"the problem I've got now is that I don't go to the diabetic clinic anymore. I'm back at the GPs, and I don't feel I'm getting the same attention. When I go to my GPs it's just going through the motions"* [P, #1].

Participants described very different experiences when receiving a diagnosis of Type 2 diabetes. A common scenario was that healthcare professionals would refer to the possibility of diabetes without explaining what it was or what it could mean for the patient. Subsequently participants were referred to a different healthcare professional for confirmation. One participant received a telephone call from the practice receptionist informing him that an appointment had been made for him to attend the diabetes clinic. This is not unusual, but in this case it was the first time the word diabetes had been mentioned to the participant: *"mine [the GP] never used the word [diabetes] at all"* [P, #1]. Participants expressed the opinion that diabetes was a low priority for their primary care practice. One factor contributing to this belief was that diabetes review clinics are generally nurse-led, *"You see your GP for many other conditions, but rarely for your diabetes….unless something goes wrong"* [P, #2].

Five of the six participants reported being advised to 'lose weight' and 'change their diet', although they weren't offered any specific support or advice on how to change their behaviour (i.e. how they could achieve this).

When asked 'what makes a good healthcare professional?', issues related to knowledge of diabetes was a consistent theme mentioned by participants, followed by one who is respectful towards patients. Some held the belief that the *"new breed"* of younger

healthcare professionals were more likely to communicate with their patients as equals than the *"old school"* doctors [P, #3].

While exploring family history and how this informed pre-existing knowledge of diabetes, participants stated that it was inevitable that they would develop the condition too; although the diagnosis for some still came as a surprise. The expectation was that their diabetes would likely progress in the same way as their parents (or other close relatives), despite the belief that *"treatment for diabetes has vastly improved…"* [P, #4].

Participants, when asked who they would go to as a first port of call for information about their diabetes, a majority would rely on friends with diabetes or information they came across in the media or press *"I'd ask [friends name] …she knows everything!"* [P, #2]. Some participants were determined to gather as much information as they could about their diabetes, whereas others were unwilling to question the information and advice given to them by healthcare professionals, *"I accepted what I was told"* [P, #4].

There was consensus that participants could not recall receiving any direct information about the potential of PA/exercise as a management option for Type 2 diabetes from primary care teams. However, some participants did have an awareness and knowledge of the value of increased PA/exercise for glycaemic control: *"I can't remember where I got the idea that exercise was good for blood sugar. It's only recently with my blood sugar levels increasing that I've started to walk perhaps an hour a day, which has had a beneficial effect…"*[P, #4]. When participants were asked what advice they had been given specifically about PA/exercise, they could not recall any specific examples other than being advised to simply reduce their weight and take plenty of exercise. However, with regard to the latter participants could not recall being provided with any specific information or guidance on recommended levels, type and duration of PA, including practical hints and tips on how to successfully make a change to their PA behaviour.

Finally, participants were asked their preferences on how they would like to receive information on diabetes-related topics and more specifically information on PA behaviour as a management option for diabetes, including their preferences on mode of delivery. Participants were given the option of several mediums of conveying information (including an online resource, mobile phone technology and interactive DVDs).

Printed booklets/leaflets were their popular choice followed by a DVD (all participants reported owning a DVD player). Despite reporting in some cases their dissatisfaction with the information they had received previously in primary care settings, a strong preference was elicited from patients for face-to-face delivery by a knowledgeable and respectful primary healthcare professional.

Conclusions of exploratory phase

Feedback from primary healthcare professionals identified in phase 1a was used to inform the development of an online training programme in accordance with their stated preference for mode of delivery. Although a specific maximal amount of time was not stated, it was agreed that the programme should be presented in modular format to allow completion in small manageable sections, due to the lack of time allocated for training purposes during a typical working week.

Training needs of primary healthcare professionals were identified in terms of different types, intensities, and duration of PA/exercise on health outcomes, in particular glycaemic control; the physiological effects of a physically active lifestyle in the context of Type 2 diabetes; and how utilisation of evidence-based behaviour change skills can be used to facilitate person-centred discussions with patients about increasing and maintaining their PA/exercise behaviour. In general, healthcare professionals reported lacking in confidence when tackling lifestyle issues with their patients, primarily due to frustration resulting from numerous unsuccessful attempts in the past. Consequently, modules on each of these topics were developed for inclusion in the online training component of MaM for T2D.

Adults with Type 2 diabetes in Phase 1b expressed a strong preference for individual face-to-face sessions with healthcare professionals who were knowledgeable about diabetes. Paper-based information and a DVD were identified as feasible methods of conveying information on diabetes to patients. The latter finding was attributable to participants either not having access to, and/or being unfamiliar with how to access or navigate the internet; although they reported familiarity and access to a DVD player.

The information gathered in the exploratory phases (1a and 1b) provided sufficient information to inform design of an initial prototype of both facets of 'MaM for T2D': (i) an online training programme to develop knowledge and skills in healthcare professionals; and (ii) a suite of draft paper-based patient resources for use by healthcare professionals during routine diabetes review appointments. These draft resources were designed to help patients to develop knowledge and skills for using PA/exercise as a vehicle for diabetes self-management, including a DVD that would provide information to supplement and/or reinforce key information outside of consultations. The specific evidence-based information content of the behaviour change components of the intervention were explored further and refined in the subsequent development phase.

3.3 Development Phase

3.3.1 Introduction

Prior to embarking on the development of a new intervention, the MRC framework encourage researchers to identify what is already known about other similar interventions (e.g., their theoretical processes of change) by drawing on existing evidence. Despite the growing number of RCTs examining the effect of behaviour change interventions on 'free-living' PA behaviour in adults with Type 2 diabetes, a systematic review examining the pooled effect size of these studies on PA behaviour and glycaemic control had not been published. Therefore the first stage of the intervention development process involved a systematic review and meta-analysis to assess the effectiveness of behaviour change interventions targeting PA/exercise behaviour upon long-term glycaemic control (Phase 2a). However, a pooled effect size does not provide any indication of what components (i.e., active ingredients) of the interventions are associated with their effectiveness. Chapter 2 described the process whereby candidate intervention components (behaviour change techniques and other features of interventions that were associated with clinically significant improvements in glycaemic control) were identified for inclusion in MaM for T2D via a series of moderator analyses (see Chapter 2, Table 2.4).

3.3.2 Aims/objectives

The development phase aimed to identify the optimal active ingredients of behaviour change interventions targeting PA/exercise behaviour (with evidence of effectiveness) to further inform the development and description of an alpha prototype of the multi-faceted intervention. This included specific intervention features and information content; underpinning theory to guide development and evaluation of both facets of the intervention, including the processes involved in the delivery of the draft paper-based resources by healthcare professionals to patients in routine diabetes consultations. Further aims of the development phase were to establish: (i) the practicality and usability of the prototype versions of the intervention components, from the perspective of primary healthcare professionals and patients with Type 2 diabetes, and to further refine the information content and processes of the online training programme and patient toolkit materials.

3.3.3 Selection of active ingredients for inclusion in the prototype interventions

Ten behaviour change techniques were selected for inclusion in MaM for T2D based on their association with improvements in HbA1c. These included: prompting generalisation of PA behaviour; use of follow-up prompts; prompt review of behavioural goals; provide information on where and when to perform PA behaviour; plan social support/social change; goal setting behaviour; prompt focus on past success; provide information on consequences of PA behaviour specific to the individual; barrier identification/problem solving; and time management.

However, these associations identified in the systematic review cannot be considered definitive evidence of effectiveness. Consequently, a further three behaviour change techniques that were shown to have a neutral effect (i.e. they had a positive association with HbA1c when both present and absent) in the moderator analyses within the review were also included: 'provide feedback on performance', 'relapse prevention/coping planning' and 'rewards contingent on effort/progress made towards PA behaviour'. These were included for pragmatic reasons to provide a balance of motivational and volitional behaviour change techniques to support intention formation and to promote post intention maintenance of PA behaviour [66].

Finally, a further two additional behaviour change techniques identified in the systematic review reported in Chapter 2 (i.e. action planning and prompt self-monitoring of behaviour) were selected for inclusion in MaM for T2D; despite the overall effect on HbA1c being larger when these techniques were absent. Given that these moderator analyses could not test associations between different combinations of behaviour change techniques, it was considered important to include combinations of techniques with strong evidence for increasing PA/exercise from the wider research literature. Two reviews reported that inclusion of self-regulatory techniques such as self-monitoring in PA behaviour change interventions improved effectiveness versus interventions not utilising self-regulatory techniques [158, 159]. Furthermore, the evidence suggests that PA/exercise interventions are optimised when self-monitoring is utilised and combined with at least one other self-regulatory technique [160]. Similarly, interventions utilising action planning and coping planning in combination were found to predict increases in PA/exercise [161].

Moreover, the inclusion of both action planning and coping planning at different stages of the behaviour change process (motivational and volitional) is reported to be an optimal strategy to employ when targeting PA/exercise behaviour change [162, 163].

The moderator analyses undertaken as part of the systematic review and meta-analysis reported in Chapter 2 were also able to guide selection of seven other features of MaM for T2D. Clinically significant improvements in HbA1c were associated with interventions utilising more behaviour change techniques (≥ median of 10); interventions underpinned by a theory/model of behaviour change; and intervention durations of ≥ 6 months.

Different modes of intervention delivery; interventions utilising pedometers; interventions of greater intensity (≥ median of 14 patient contacts); and inclusion of a supervised PA/exercise component were not associated with clinically significant improvements in HbA1c. In the absence of explicit guidance from the systematic review regarding mode of delivery of information to patients, the decision to use individual face-to-face sessions with a healthcare professional and patient was guided by preferences of patients during the exploratory work (phase 1a). To increase the likelihood of successful integration into routine primary care, the provision of information and support to patients was designed to be delivered during routine diabetes review appointments by a member of the clinical team who would usually be involved in the care of adults with Type 2 diabetes.

3.3.4 Theory selection

Moderator analyses reported in the systematic review suggested that interventions underpinned by a theory/model of behaviour change were associated with clinically significant improvements in HbA1c. Nonetheless, no single theory emerged as potentially superior over another. Therefore explicit selection criteria were applied to inform the optimal choice of theory to underpin the development of MaM for T2D in terms of form and specific intervention content and subsequent evaluative strategies.

These explicit criteria included a strong evidence-base for modelling the process of intervention components and outcomes that were the foci of MaM for T2D (i.e. changing consultation behaviour of primary healthcare professionals and increasing

PA/exercise in adults with Type 2 diabetes). Furthermore, exploratory work with primary healthcare professionals and patients identified the need to target motivational factors (e.g., attitudes/beliefs regarding the use of PA by healthcare professionals as a management option for people with Type 2 diabetes), and volitional factors (e.g., self-efficacy to increase and maintain increases in PA behaviour in adults with Type 2 diabetes; and self-efficacy of healthcare professionals for delivering a behavioural intervention in routine primary care). Therefore additional criteria for guiding theory selection included a theory that incorporated both motivational and volitional factors [66] and existence of in-built constructs and/or evidence-based strategies that can be used to effectively target both motivation/intention and actual PA/exercise behaviour to support maintenance. It was also important to select a theory/theories that had readily available, reliable and valid instruments to measure the theoretical constructs and postulated relationships between the constructs to inform the evaluation of MaM for T2D in a planned pilot RCT.

In accordance with these criteria, the Theory of Planned Behaviour (TPB) [70] and Social Cognitive Theory (SCT) [68] were selected to underpin the development and evaluation of the MaM for T2D intervention. The TPB has been extensively and successfully used to predict intentions to increase PA and actual PA behaviour [76, 164] including healthcare professional behaviour change [87]. However, the TPB does not provide guidance on how theoretical constructs can be targeted within interventions using evidence-based strategies, or how to address the frequent lack of concordance between motivation/intention and action, i.e. the 'intention-behaviour' gap [92]. Conversely, SCT is able to provide specific evidence-based strategies for translating motivation/intentions into action/behaviour in both healthcare professionals and patients (e.g., observational learning strategies such as modelling to support the acquisition of behaviour change skills and self-efficacy for the effective delivery of behaviour change techniques to patients). Furthermore, SCT has demonstrated utility in samples of people with diabetes when predicting PA behaviour [165]. Together with the theory-linked behaviour change techniques identified by the systematic review, the TPB and SCT provide a complimentary theoretical framework for guiding the development and subsequent evaluation of MaM for T2D.

3.3.5 Process for developing the alpha prototypes of intervention components

Findings from the initial exploratory work (phase's 1a and 1b) and the systematic review informed a subsequent participatory design process. This involved a multidisciplinary research team of behavioural scientists/health psychologists, primary healthcare professionals, adults with Type 2 diabetes, physiologists and interactive designers to produce an alpha prototype of the MaM for T2D multifaceted intervention. This included an online training programme for healthcare professionals (facet 1) and a range of resources for use by healthcare professionals during diabetes review appointments with patients to help them self-manage their diabetes with PA/exercise (facet 2), collectively referred to as the 'patient toolkit'.

Consistent with the needs of primary healthcare professionals, the training programme was designed as an online resource delivered in a modular format to facilitate flexibility and accessibility. The training was submitted to, and subsequently accredited by the Royal College of Physicians (RCPs). Completion of the online training programme prompted generation of a certificate awarding three continuing professional development (CPD) points (see Appendix F). This acted as incentive for healthcare professionals to complete the programme in full and fulfilled their requirement to have a training programme that could contribute towards their annual appraisal.

The content of the online training programme was designed to address the knowledge and skills gaps identified by healthcare professionals during the exploratory phase. Eight distinct but interrelated modules were developed. Table 3.1 presents an overview of the information content of each module. Also presented are the relationships between content of specific modules and associated behaviour change techniques with the theoretical constructs of the TPB and SCT. Module two presented healthcare professionals with information about the type of data to be collected from their practice and patients and data collection time points. As such it did not form part of the behaviour change intervention. Therefore it is not presented in table 3.1.

Table 3.1. Components of the MaM for T2D online training programme and their relationship to theoretical constructs within TPB and SCT

Module	Form and Information Content	Theoretical Constructs
Module 1: Introduction to MaM for T2D	Video recording of a professor of movement and metabolism introducing the programme, welcoming healthcare professionals and providing details of how and why MaM for T2D was developed. Video recording of a Consultant Diabetologist and a Diabetes Specialist Nurse providing an overview of why PA is important for the management of Type 2 diabetes	Symbolising Attitudes and beliefs (TPB) Subjective norms (TPB)
Modules 3 (Metabolism & Type 2 Diabetes), 4 (Physical Activity in the Care of Type 2 Diabetes); and 5 (Physical Activity & Exercise)	Evidence-based information about the role of metabolism, PA and exercise in the context of Type 2 diabetes. Modules contain interactivities to consolidate learning.	Symbolising (SCT) Attitudes/beliefs (TPB) Forethought (SCT) Intention (TPB)
Module 6: Using Psychology to Change Physical Activity Behaviour	Evidence-based information about the use of psychological theory and theory linked behaviour change techniques and counselling skills to change PA behaviour Module contains interactivities to consolidate learning.	Attitudes/beliefs (TPB) Forethought (SCT) Intention (TPB)
Module 7: Using Behaviour Change Techniques to Increase Physical Activity Behaviour	Video demonstrations of a Diabetes Specialist Nurse demonstrating the use of behaviour change techniques and behaviour change counselling techniques in practice with a mock patient	Symbolising (SCT) Observational Learning (SCT) Perceived Behavioural Control (TPB) and Self-efficacy (SCT) Subjective norms (TPB)
Module 8: Screening Before Physical Activity	Flowchart diagram demonstrating how to screen adults with Type 2 diabetes prior to PA and exercise	Self-regulation (SCT) Perceived Behavioural Control (TPB) and Self-efficacy (SCT)
End of Module 3, 4, 5 and 6 Quiz Questions	Provides feedback on performance	Perceived Behavioural Control (TPB) and Self-efficacy (SCT)
Flowchart summary (crib sheet with prompts) for use of the patient toolkit during diabetes review appointments	Prompts for healthcare professionals to use specific behaviour change skills and techniques	Symbolising (SCT) Perceived Behavioural Control (TPB) and Self-efficacy (SCT) Intention (TPB) Self-regulation (SCT)

The behaviour change techniques selected for inclusion in the patient toolkit component of the intervention were covered in detail within the content of modules 6 and 7. A series of audio-visual clips portrayed simulated interactions between a diabetes specialist nurse and a patient. These were used as a vehicle to demonstrate (via modelling) to healthcare professionals how to use specific behaviour change techniques to facilitate delivery of the patient toolkit. A full list is presented in table 3.2.

In addition, video clips demonstrating use of behaviour change counselling skills based on the principles of motivational interviewing (agenda setting; use of importance and confidence rulers to engage participants in change talk; active listening; and informing) [61] were incorporated into module 7. These specific counselling skills have considerable evidence for effectively engaging patients in collaborative decision making with healthcare professionals. They also serve as effective vehicles for placing the patient at the centre of the decision making process, and as such serve to maintain their autonomy when setting goals for PA/exercise behaviour change. Reflective listening and summarising are necessary for building rapport and communication to ensure that the healthcare professional understands what the patient is saying and to correct any misunderstandings. Furthermore, these skills serve to engage patients in "change talk" [166, 167], whereby they are encouraged to make their own decisions about what to discuss and present their own arguments for changing their PA behaviour. There is also emphasis on respecting a patient's decision to defer discussions about PA/exercise behaviour change to future consultations, including decisions not to make changes to their behaviour if this is their preference [61].

Table 3.2. Behaviour change techniques presented within Module 7 of the online training programme

Behaviour Change Technique	Definition	Aim(s) of the Technique	Rationale for Inclusion
Provide Information on the Consequences of the Behaviour to the Individual	Information about the benefits and costs of the action or inaction to the individual or tailored to a relevant group based on that individual's characteristics (e.g., demographics, clinical, behavioural, or psychological information). This can include any costs/benefits - not necessarily those related to health (e.g., feelings).	Raise awareness/dispel myths Initiate and maintain motivation for change	Systematic review evidence
Providing feedback on performance	This involves providing the person with data about their own recorded behaviour or commenting on a person's behavioural performance (e.g., identifying a discrepancy between behavioural performance and a set goal or a discrepancy between one's own performance in relation to others.	Raise awareness Reinforce positive behaviour changes to increase self-efficacy Maintain motivation for change	Pragmatic: ensure balance of motivational and volitional techniques to support intention and maintenance of PA
Goal Setting (Behaviour)	The person is encouraged to make a behavioural resolution (e.g., increase their levels of PA). This is directed towards encouraging people to decide to change or maintain change.	Promote autonomy Increase likelihood of translating intentions in to behaviour in combination with action planning	Systematic review evidence
Action Planning	Involved detailed planning of what the person will do including, as a minimum, when, in which situation and/or where to act. 'When' may describe frequency such as how many times per day/week or duration (e.g., for how long).	Increase likelihood of translating intentions in to behaviour in a format that is measurable (in combination with goal setting, self-monitoring and feedback provision)	Evidence that this technique combined with prompt self-monitoring of behaviour increases effectiveness
Providing information on where and when to perform the behaviour	Involves telling the person about when and where they might be able to perform the behaviour (e.g., tips on places and times participants can access local exercise classes). Can be in written or verbal form.	Specific information provision to increase awareness of activity options which can be used to develop an action plan	Systematic review evidence
Barrier Identification/Problem Solving	This technique presumes having formed an initial plan to change behaviour. The person is prompted to think about the potential barriers *and* identify the ways of overcoming them. Barriers may include competing goals and could be behavioural, cognitive, emotional, environmental, social and/or physical.	Promotes an increase in self-efficacy Equips participants with the tools and confidence to overcome barriers	Systematic review evidence
Prompt Review of Behavioural Goals	Involves a review or analysis of the extent to which previously set behavioural goals (e.g., increase PA over the next week) were achieved.	Facilitates a comparison of actual PA behaviour against previously set behavioural goals Encourages realistic, achievable goal setting Promotes self-efficacy upon goal attainment and following revision	Systematic review evidence

Table 3.2. Behaviour change techniques presented within Module 7 of the online training programme (Continued.)

Behaviour Change Technique	Definition	Aim(s) of the Technique	Rationale for Inclusion
Prompt Generalisation of a Target Behaviour	Once behaviour is performed in a particular situation, the person is encouraged or helped to try it in another situation. The idea is to ensure that the behaviour is not tied to one situation but becomes a more integrated part of the person's life that can be performed at a variety of different times and in a variety of contexts.	Promotes maintenance of PA behaviour	Systematic review evidence
Prompt Self-monitoring of Behaviour	Person is asked to keep a record of their PA behaviour as a method for changing behaviour. This could take the form of a diary in terms of type, frequency, duration and/or intensity of PA behaviour.	Raise awareness of current PA behaviour including frequency, duration, and intensity Identify opportunities for changing PA Monitor progress/achievement towards a pre-defined goal	Evidence that this technique combined with action planning increases effectiveness
Prompting Focus on Past Success	Involves instructing the person to think about or list previous successes in performing PA behaviour.	Initiate motivation Promotes self-efficacy	Systematic review evidence
Use of Follow-up Prompts	Intervention components are gradually reduced in intensity, duration and frequency over time (e.g., telephone calls instead of face to face and/or provided at longer time intervals.	Promote maintenance of PA behaviour	Systematic review evidence
Plan Social Support/Social Change	Involves prompting the person to plan how to elicit social support from other people to help him/her achieve their target behaviour/outcome. This will include support during the intervention (e.g., a buddy system or other forms of support and following the intervention including support provided by the individuals delivering the intervention, partner, friends and family.	Encourage participants to seek support to initiate and maintain PA behaviour (e.g., practical support – childcare; emotional support - opportunities to discuss issues; social support – eliciting support from friends and family members)	Systematic review evidence
Relapse prevention/Coping Planning	This relates to planning how to maintain behaviour that has been changed. The person is prompted to identify in advance situations in which the changed behaviour may not be maintained and develop strategies to avoid or manage those situations.	Raise awareness of situations that may prevent maintenance of PA Develop self-efficacy to deal with high risk situations	Pragmatic: balance of techniques to support intention and maintenance of PA
Time Management	This includes any technique designed to teach a person how to manage their time in order to make time for PA. These techniques are not directed towards performance of a target behaviour, but rather seek to facilitate it by freeing up times when it could be performed.	Encourage participants to plan a time where they could incorporate sufficient PA in to their daily lives to enable them to reach their goals (e.g., extending the duration or intensity of current PA if time is short, or setting aside a larger amount of time to start a new activity)	Systematic review evidence
Rewards contingent on effort/progress made towards PA	This involves receipt of rewards based on attempts or progress towards achieving a PA goal. This could include a self-reward.	Encourages participants to reward effort and progress towards a predetermined goal to promote sustainable behaviour change.	Systematic review evidence

The patient toolkit was designed for use by healthcare professionals to help patients with Type 2 diabetes to develop knowledge and skills for effective self-management of their diabetes with PA/exercise. The materials and resources were developed with reference to findings from initial exploratory work, the systematic review of behavioural intervention studies (behaviour change techniques and intervention features associated with clinically significant improvements in glycaemic control), theoretical constructs within the TPB and SCT and associated in-built strategies for bridging the intention-behaviour gap, and other relevant literature reporting on effective use of materials and strategies for PA behaviour change.

The patient toolkit (See Appendix I) included: (i) a discussion card comprising of a 7 day recall used to gauge current levels and patterns of PA/exercise; a decisional balance aid to discuss pros and cons for changing PA/exercise behaviour versus PA/exercise staying the same; and readiness rulers to gauge importance of PA/exercise and confidence for increasing PA/exercise; (ii) a booklet to support goal setting, action planning, barrier identification/problem solving, and self-monitoring; (iii) activity planners and trackers to facilitate time management and self-monitoring of PA/exercise; (iv) a DVD to promote observational learning and increase self-efficacy; (v) a pedometer to self-monitor PA/exercise behaviour; (vi) a record of progress pad to guide healthcare professionals through the process of intervention delivery and a mechanism for feedback provision to patients; (vii) a motivational postcard mailed out to patients at the 3-month time point to prompt increased PA/exercise and reduced sedentary behaviour; and (viii) a Diabetes UK leaflet entitled Keeping active: An essential part of managing diabetes [168]. Table 3.3 provides a synopsis of the patient toolkit resources and how their form and information content mapped onto theoretical constructs of TPB and SCT.

Healthcare professionals (following an initial assessment/discussion of current PA/exercise with patients with reference to the patient's extent of 'readiness' to change their PA/exercise behaviour) would be asked to select the most appropriate behaviour change techniques from those presented in modules 6 and 7 that would allow them to tailor delivery of the patient toolkit in accordance with the patient's needs (see Figure 3.2 for a procedural diagram of patient toolkit intervention processes and content).

A number of strategies are included to target motivation and confidence to support intention formation (e.g., provision of positive feedback on current levels of PA/exercise; a discussion of pros versus cons for increasing PA/exercise versus activity levels staying the same; an assessment of 'readiness' for change; prompting focus on past success). Once patients form an intention to change their levels of PA/exercise, a number of strategies are included in the process to help them to translate intentions into action (i.e. bridge the intention-behaviour gap' and make an actual change to their levels of PA/exercise and to sustain it over time and when faced with challenging situations). These include self-regulation strategies such as goal setting, action planning and self-monitoring). Figure 3.2 presents a flowchart summary of the intervention process for delivery of the patient toolkit incorporating both behaviour change techniques and behaviour change counselling skills. The latter based on the principles of motivational interviewing [95]. Figure 3.3 presents an image of version 1 of the intervention materials.

Table 3.3. Components of the MaM for T2D Healthcare Professional-Led Intervention (Patient Toolkit) and their relationship to theoretical constructs within TPB and SCT

Intervention Component	Form and Information Content	Theoretical Constructs
Discussion Card	Assessment of PA behaviour using a 7-day recall A decisional balance aid to assess the pros versus the cons for changing PA behaviour Rulers assessing importance and confidence for change	Attitudes/beliefs (TPB) Forethought (SCT) Intention (TPB) Perceived Behavioural Control (TPB) and Self-efficacy (TPB)
Booklet	Support to select an appropriate PA/exercise; set PA goals; consider means of social support; identify barriers/problem solve; set short and long-term goals; plan activity; self-monitor activity; prevent relapse	Forethought (SCT) Subjective norms (TPB) Intention (TPB) Self-regulation (SCT) Perceived Behavioural Control (TPB) and Self-efficacy (TPB)
Activity Planners/Trackers	Means to plan and monitor PA/exercise	Self-regulation (SCT)
DVD	Video recordings of adults with Type 2 diabetes engaging in PA/exercise and sharing their stories Information about the development of Type 2 diabetes	Symbolising (SCT) Attitudes/beliefs (TPB) Observational Learning (SCT) Subjective norms (TPB) Perceived Behavioural Control (TPB) and Self-efficacy (SCT)
Pedometer	Device to monitor the number of steps taken each day	Self-regulation (SCT)
Record of Progress pad	Record of readiness ruler outcomes; short and long-term PA/exercise goals; social support; potential barriers and ways to overcome them; self-monitoring method adopted; and activities of choice. Provides a mechanism for provision of feedback and an opportunity to monitor progress and recap during subsequent sessions	Perceived Behavioural Control (TPB) and Self-efficacy (SCT) Intention (TPB) Self-regulation (SCT)
Diabetes UK Leaflet	Leaflet entitled: Keeping active: An essential part of managing diabetes	Attitudes/beliefs (TPB) Perceived Behavioural Control (TPB) and Self-efficacy (SCT) Intention (TPB)
Postcard & Telephone call	A motivational postcard and telephone call aimed at prompting and maintaining PA/exercise and sedentary behaviour	Self-regulation (SCT) Attitudes/beliefs (TPB)

Figure 3.2. Flow diagram showing the intervention process (i.e. delivery of the Patient Toolkit)

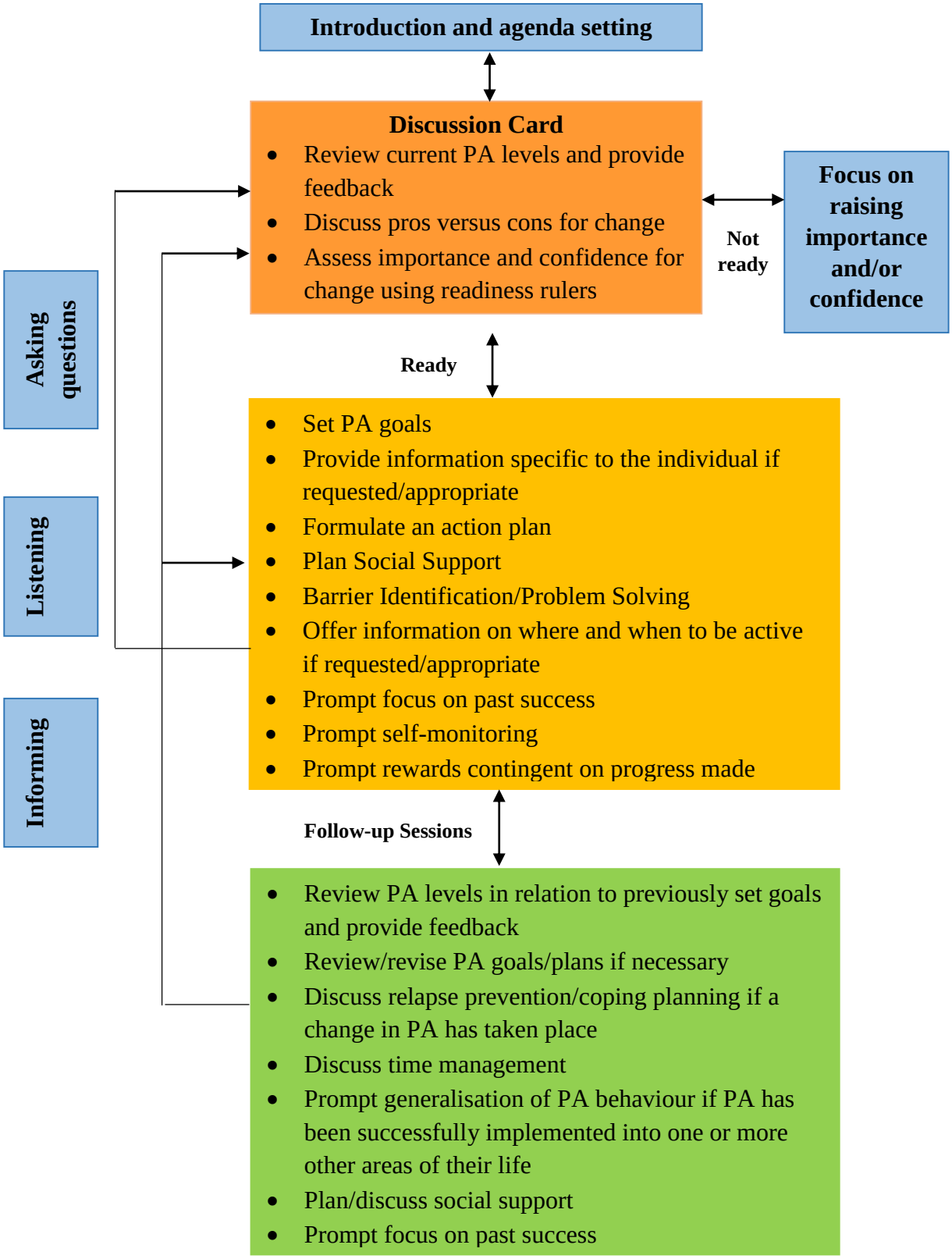


Figure 3.3 Version 1 of the patient toolkit (pre-usability testing)

3.3.6 Usability testing of an alpha prototype of MaM for T2D

Aims/objectives

The aims of phase 2c were to test the acceptability and usability of the online training intervention component and the patient toolkit materials (with patients with Type 2 diabetes). Findings of the Phase 2c were used to inform refinements to both facets of the intervention in phases 2d for use in a subsequent planned pilot RCT.

Methods

Phase 2c involved usability testing of the MaM for T2D intervention components with primary healthcare professionals and adults with Type 2 diabetes. Healthcare professionals and data managers at one local primary care practice were given access to version 1 of the MaM for T2D intervention to elicit their views on the relevance of the content and general usability of both the online training and patient toolkit components.

Although healthcare professionals were not asked to use the materials in actual consultations with patients, they were asked to consider while reviewing the intervention components whether they would work in practice. This included suggestions for improvement; identification of any technical issues; and to gauge overall satisfaction. Each participant completed a structured questionnaire (see Appendix G) asking specific questions about each module (e.g., module 1: does this module provide enough information about the purpose of the programme?; what did you like most about this module?; how could this module be improved?). Following a review of the responses provided to version 1 of the MaM for T2D intervention, informal follow-up discussions were carried out with healthcare professionals and one data manager. The purpose was to explore in more depth the points raised in relation to their expectations and anticipated experiences when using the components of MaM for T2D.

Structured interviews were also carried out with adults with Type 2 diabetes attending primary care diabetes clinics. Patients were approached following their diabetes review appointment with a healthcare professional to assess the face and content validity of the patient toolkit. During the interview, patients were taken through a typical scenario with the toolkit to identify any content and/or design and usability issues. Using a structured questionnaire (see Appendix H) specific questions were asked about each aspect of the toolkit. For example, 'based on the description written on the case, what did you expect this pack to do?', 'what would make it more attractive or appealing?'

Results: usability testing

Three healthcare professionals (one nurse practitioner; two practice nurses) and two data managers reviewed the content of both the online training programme and patient toolkit materials. Minor technical problems with the video footage (e.g., initial freezing of footage and inability to view the footage using early versions of internet explorer) and some of the interactive components of the online training programme (e.g., issues with functionality) were detected and subsequently resolved. Further information content was requested on appropriate advice to provide to people with chronic conditions such as arthritis when planning to undertake PA/exercise. This information was subsequently added to the online training programme in module 5.

Overall satisfaction was high with both intervention components and participants emphasised they would recommend MaM for T2D to their clinical colleagues. When asked how they would use the programme, they suggested that they would complete it in full, but would return to relevant sections if and when required. Therefore the need to have continuous access to the programme was emphasised and this was made a feature of the online training.

Thirteen adults with Type 2 diabetes (n=8 male, n=5 female, mean age = 58 years [SD=14], mean time since diagnosis = 5 years [SD=5], managed with diet [n=2], diet and oral medication [n=10], management unknown [n=1]) attending two routine diabetes clinic appointments agreed to participate in structured interviews. Although no significant issues were identified with the content of the patient toolkit, it was suggested by patients that the original 'intervention task cards' should be redeveloped into a booklet format. Patients also commented that pictures of physical activities should be added to the reverse side of the toolkit case, and that the booklet should include provision to record appointment dates and times as well as space to make notes of any questions to ask during subsequent appointments. Patients indicated that they would use the materials with the support of a healthcare professional as a mechanism to receive feedback and would be interested in taking part in the research. Mirroring the findings of the initial exploratory work, the latter was driven by a desire to learn more about PA/exercise, as the majority of patients reported that they did not recall having been advised specifically about PA/exercise to manage their diabetes or offered support to increase levels of PA/exercise.

Conclusions

Based on findings from the usability testing, version 1 of MaM for T2D was further developed (see Figure 3.4 for version 2 post-usability testing) to incorporate the comments and suggestions from healthcare professionals and patients for use in a subsequent open pilot study in the primary care setting (see Chapter 4). A copy of the toolkit is provided as Appendix I.

Figure 3.4 Version 2 of the patient toolkit (post-usability testing)

3.4 Discussion

This chapter has described the systematic development of the multifaceted behaviour change intervention MaM for T2D. Guided by the MRC Framework [88, 108], the different facets of the intervention were iteratively developed following four distinct but interrelated phases of work. An initial exploratory phase was conducted involving semi-structured interviews with healthcare professionals and focus group work with adults with Type 2 diabetes. This was followed by a development phase that involved reviewing and utilising existing evidence to guide theory selection and intervention content in terms of behaviour change techniques, and other intervention features such as mode of delivery, intervention duration and intensity. The outcome of this work has culminated in a theory-based intervention utilising the best available evidence from the literature combined with the needs and preferences of healthcare professionals and adults with Type 2 diabetes. The subsequent open pilot testing phase will optimise the content of the intervention and to identify barriers and facilitators to successful implementation prior to use in a planned pilot RCT. This is presented in chapter 4.

3.4.1 Potential strengths of the intervention and the intervention development process

The MaM for T2D intervention has several strengths. Guided by the MRC Framework it has been iteratively developed, incorporating a combination of systematic review evidence, alternative sources of published evidence and a high-level of user involvement.

Published intervention descriptions of studies included in the systematic review presented in chapter 2 have been examined to identify intervention features (e.g., behaviour change techniques) that are most likely to lead to effective outcomes (i.e. an increase in PA/exercise behaviour and concomitant improvement in glycaemic control). Combined this development process increases the likelihood that the intervention is fit for purpose and will impact positively on the target behavioural outcomes. In addition, intervention features (e.g., behaviour change techniques, intervention intensity and duration) have been explicitly reported and consistently defined using published guidance [94, 156]. This not only maximises the likelihood that the intervention can be replicated and components traced back to their original sources, but also allows a process of refinement (i.e. components can be identified and optimised). This systematic development process will increase the likelihood that the intervention will be both feasible and acceptable when piloted in an open pilot study and facilitate a process of optimisation where required. An open pilot study will be able to assess whether the components combined in to the MaM for T2D intervention are suitable for integration in to routine clinical care.

It should also be emphasised that MaM for T2D targets free-living PA/exercise behaviour. This is important firstly for promoting patient autonomy, however it also means that patients, through this programme are potentially being equipped with the skills to change their lifestyle in the long-term rather than relying on participation in supervised exercise sessions for a limited amount of time.

3.4.2 Potential drawbacks of the development process

The findings of the semi-structured interviews and interactive group workshops were derived from a small non-probability convenience sample of participants. Therefore, the findings may not be applicable to populations of healthcare professionals and patients in other primary care practices (i.e. findings may not be representative of the wider populations) [169]. However, the aim of the initial exploratory work was to collect information to inform the development of initial prototypes for further iterative development and testing with healthcare professionals and patients.

Furthermore, it is important to consider that behaviour change techniques and other intervention components were selected on the basis of what could 'potentially' be acceptable and feasible (to healthcare professionals and adults with Type 2 diabetes), and to maximise the impact on outcomes such as increased free-living PA/exercise behaviour and glycaemic control. However, a key limitation of this approach is that the selection of behaviour change techniques and other features are limited to those adequately described in studies included in the systematic review presented in Chapter 2. Therefore it is possible that behaviour change techniques not adequately described in published studies were missed by the coding process, and as such were not 'tested' in the moderator analyses.

Furthermore, currently there is insufficient evidence examining the effects of various 'clusters' of behaviour change techniques (as indicated by studies exploring the impact of combinations of specific behaviour change techniques) and this warrants further investigation. In addition, the taxonomy used to define and code behaviour change techniques presents 40 techniques in total. However, only 25 of these techniques were identified and coded across intervention descriptions. Therefore it is possible that those that were not identified or utilised hold the potential to increase PA/exercise behaviour in adults with Type 2 diabetes to a level that impacts positively on glycaemic control. Therefore the possibility of interaction between behaviour change techniques that were subsequently excluded from the intervention cannot be ruled out. Furthermore, the analyses conducted to identify candidate behaviour change techniques do not equate to statistical significance, and are associative at best; therefore a cause and effect relationship cannot be assumed. To assess the impact of specific techniques further investigation is required via randomised trials.

3.4.3 Conclusions

This chapter has described the systematic development of a behaviour change intervention in line with the MRC Framework [88, 108]. This process has utilised published systematic review evidence and expert opinion (healthcare professionals and adults with Type 2 diabetes) to develop an intervention that is likely to integrate into routine primary care and be both acceptable and feasible and delivered to a satisfactory level of fidelity.

The initial exploratory phase and subsequent development phase informed the development of version 2 of the intervention components that constituted MaM for T2D. Utilising a user-centred design process facilitated the intervention development process and increased likelihood that it would fulfil the needs of both healthcare professionals and adults with Type 2 diabetes. However, in order to determine whether this multifaceted behaviour change intervention 'MaM for T2D' was 'fit for purpose' and could be successfully integrated into the primary care setting, the next stage was to subject MaM for T2D to an open pilot evaluation (Phase 3). This study design would enable a preliminary assessment of acceptability, feasibility and fidelity and facilitate systematic adaptations and refinements of the intervention and study processes and procedures including outcome measures while being used in a real life setting [170]. A detailed overview of the open pilot study methodology and findings are presented in Chapter 4.

Chapter 4. Optimising Acceptability, Feasibility and Fidelity of Movement as Medicine for Type 2 Diabetes: An Open Pilot Study

Preface to Chapter 4

Open Pilot Study

All aspects of the open pilot study including key design and methodological decisions, data collection, analysis, interpretation and write-up were made by the author of this thesis with advice from her supervisory team. The author of this thesis subsequently led and conducted this work that involved data collection, analysis, interpretation and write-up.

Assistance with qualitative data collection was provided by Dr Sarah Denton who subsequently analysed a proportion of interview transcripts. Colleagues Dr Stephan Dombrowski and Dr Keegan Knittle assisted by coding a proportion of video recorded consultations to facilitate treatment fidelity assessment.

The study protocol providing details of the open pilot study and a pilot RCT was accepted by the journal 'Trials'. The reference is as follows:

Avery L, Sniehotta FF, Denton SJ, Steen N, McColl E, Taylor R, Trenell MI. Movement as Medicine for Type 2 Diabetes: Protocol for an Open Pilot Study and External Pilot Clustered Randomised Controlled Trial to Assess Acceptability, Feasibility and Fidelity of a Multifaceted Behavioural Intervention Targeting Physical Activity in Primary Care. *Trials* 2014, 15(46).

4.1 Introduction

Chapter 3 described the systematic development of the multifaceted behaviour change intervention 'MaM for T2D'. This involved identification of what were considered to be the most likely intervention components and features that would be associated with effectiveness (i.e. improvements in glycaemic control) and these were incorporated into MaM for T2D. The MaM for T2D online training programme targeted knowledge, skills and confidence (self-efficacy) of primary healthcare professionals to deliver a behaviour change intervention targeting PA/exercise to patients during diabetes review appointments. Using the intervention toolkit, this was designed to enhance patients' knowledge and skills for self-management of Type 2 diabetes via increased PA/exercise. Therefore it is important to determine whether healthcare professionals and patients believed the programme had achieved these objectives and how it could be improved. Even though the development of MaM for T2D involved a high level of user involvement (primary healthcare professionals and patients with Type 2 diabetes), it is still to be determined whether the components can be faithfully and consistently delivered in the primary care setting, and how they can be optimised to maximise implementation.

4.2 Aim

The aim was to conduct an open pilot study to optimise acceptability, feasibility and fidelity of the multifaceted intervention 'Movement as Medicine for Type 2 Diabetes' in the primary care setting. Intervention components were iteratively optimised incorporating feedback from primary healthcare professionals and patients throughout the intervention period of the open pilot study (baseline to 1-month follow-up). By systematically collecting information and refining the intervention, the aim was to optimise acceptability and feasibility of the intervention components for use in the primary care setting.

4.3 Methods/Design

4.3.1 Design

An open pilot study design was used to test the acceptability and feasibility of MaM for T2D during routine clinical care. Primary healthcare professionals and patients were interviewed throughout the intervention period. The information collected was used to systematically optimise and refine the intervention programme following feedback and improve delivery [170, 171]. The study was reviewed and given a favourable ethical opinion by Sunderland Research Ethics Committee (REC) (see Appendix J for letter from Sunderland REC).

4.3.2 Participants

Two groups of participants were recruited (i) adults with a confirmed diagnosis of non-insulin dependent Type 2 diabetes and (ii) primary healthcare professionals employed directly by participating practices. All participants provided informed written consent to participate. Inclusion criteria for these two groups and participating practices will now be detailed:

Inclusion criteria for primary care practices

Inclusion criteria for practices comprised of: willingness to be randomised to an intervention or control group; a commitment to participate over the duration of the study; to allow participation of at least two primary healthcare professionals in the study; capacity to identify and recruit up to 30 patients meeting the eligibility criteria; and willingness to complete the study as per the study protocol.

Inclusion criteria for patients

Patients aged 18 years and older with a confirmed diagnosis of non-insulin dependent Type 2 diabetes for a minimum of two years were eligible to participate in the study. Patients had to have the capacity to provide informed written consent and be able to write and converse in English.

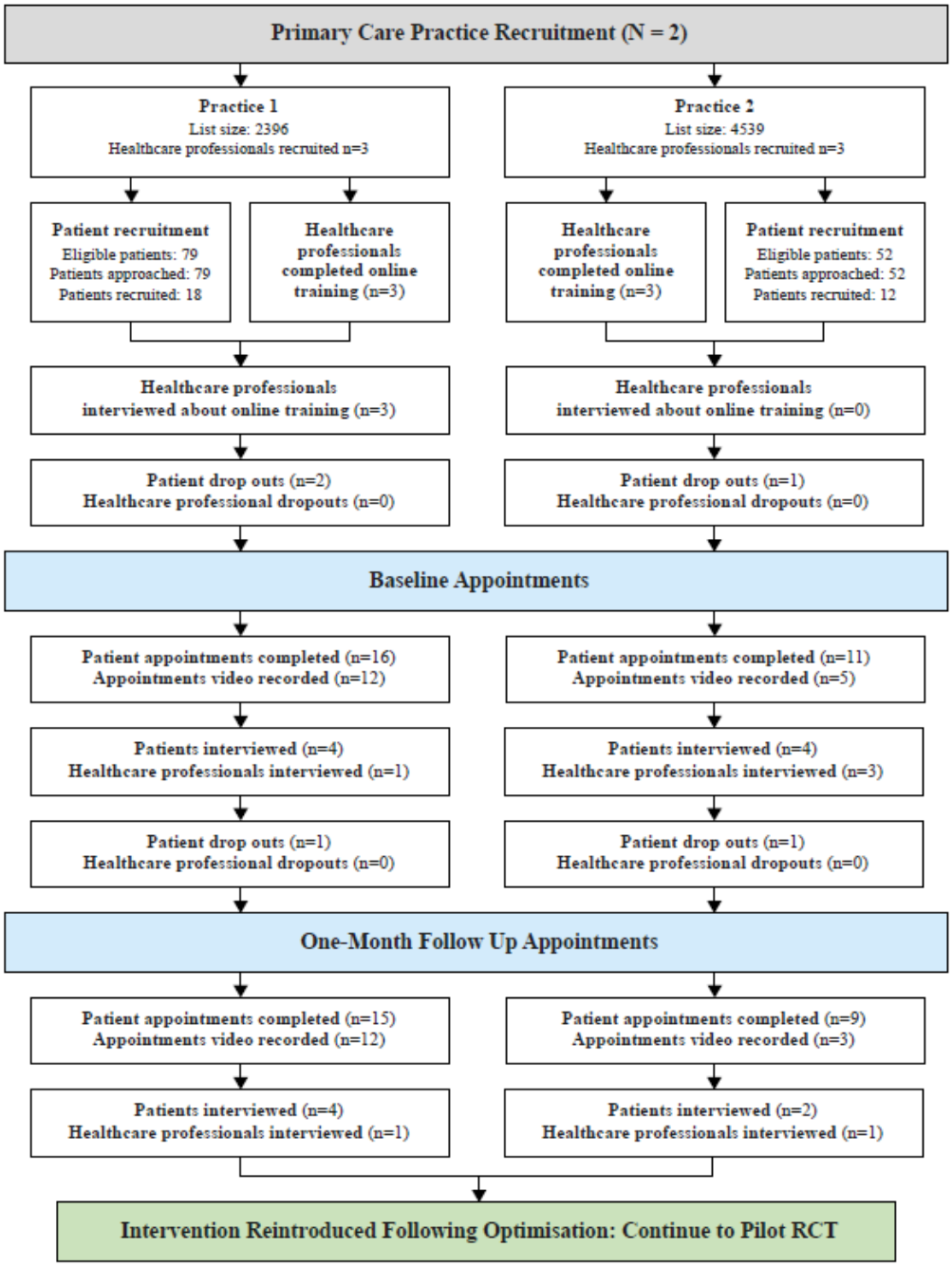
Exclusion criteria for patients

Patients were excluded if they were currently taking part in any other intervention research; were currently prescribed sulphonylureas; or had evidence of heart disease, musculoskeletal disorders or other disabling diseases that could be made worse by increasing levels of PA/exercise. Patients registered at each participating practice that fulfilled these pre-defined eligibility criteria were invited to participate in the study. The decision to exclude adults with Type 2 diabetes who are prescribed insulin and/or sulphonylureas was taken to reduce the likelihood of hypoglycaemia. The hypoglycaemic action of these agents is often enhanced when combined with exercise [172], and given the aims of this study (i.e. assessment of acceptability and feasibility) it was important to minimise risk.

4.3.3 Recruitment procedures

Figure 4.1 provides an overview of practice and participant recruitment, as well as fidelity and qualitative data collection activity.

Figure 4.1. Summary of practice, healthcare professional and patient recruitment and data collection activity.



All primary care practices in the County Durham and Darlington area of North East England were invited to participate in the study (N=87). The Primary Care Research Network (PCRN), and clinical leads from the North East Commissioning Service (NECS) facilitated practice recruitment by distributing postal invitations to all practices, and making personal contact with practice managers and clinical commissioning groups. 13 primary care practices responded positively by contacting the study lead and agreeing to participate. Due to time restrictions, the first two practices to agree to participate and provide informed written consent were enrolled into the open pilot study.

A minimum of two primary healthcare professionals from each participating practice were asked to provide informed written consent to take part in the study. Consent was sought from primary healthcare professionals to complete the online training intervention programme and subsequently to deliver the primary healthcare professional-led intervention (i.e. the toolkit) to patients recruited to the study. Separate consent was sought to video record consultations with patients for the purposes of treatment fidelity assessment; and to take part in one or more interviews with a researcher to identify barriers and enabling factors to effective implementation of the intervention in primary care. If primary healthcare professionals decided to opt out of the video recordings and interviews they were still permitted to participate in the planned pilot RCT. However, it was a requirement that at least one healthcare professional from each practice was willing and able to participate in video recordings and interviews to meet the aims and objectives of the open pilot study.

4.3.4 Data Collection

Acceptability and feasibility of the intervention by healthcare professionals was assessed both quantitatively and qualitatively. Usage of the online training intervention programme was monitored to establish whether healthcare professionals completed the training programme within the required time period (i.e. 4 weeks). Monitoring was also used to establish whether the programme was revisited following initial completion.

Healthcare professionals were also interviewed following completion of the online training intervention programme, and again following completion of the baseline and 1-month patient appointments.

Interview questions were constructed to determine whether healthcare professionals believed the programme had achieved its objectives and how it could be improved.

Interviews focused specifically on the acceptability and feasibility of the MaM for T2D intervention, including study processes and procedures. The interview topic guides were developed using the Theoretical Domains Framework [173] (See Appendix K). This approach enabled a range of personal, professional, and environmental challenges to implementation of the intervention to be explored. Furthermore, using the Theoretical Domains Framework to inform the development of a topic guide and for coding and analysis purposes enables the findings to be linked back to theory to facilitate an understanding of behaviour change processes that were inhibitors or drivers of implementation. Theory-driven refinements could then be made to optimise the intervention content and processes (i.e. beliefs within domain-specific categories informed changes / improvements to intervention components). The Theoretical Domains Framework is the result of a multi-disciplinary expert consensus approach that aimed to organise and simplify the theoretical literature on behaviour change by reviewing 33 behavioural theories. The 128 key constructs were organised into broad 'theory domains' based on commonalities [174]. After further validations, the Theoretical Domains Framework consists of 14 theory domains each providing broad explanations of why a behaviour was or was not performed: 'Knowledge', 'Skills', 'Professional Role and Identity', 'Beliefs about Capabilities', 'Optimism', 'Beliefs about Consequences', 'Reinforcement', 'Intentions', 'Goals', 'Memory, Attention and Decision Processes', 'Environmental Context and Resources', 'Social Influences', 'Emotions', and 'Behavioural Regulation' [173]. While the Theoretical Domains Framework is not a theory as such, it has been useful in organising narrative data to link findings of qualitative research back to theory [175, 176]. It was used in the current study to identify domain specific issues with the online training intervention programme (e.g., knowledge/skills gaps) and supporting materials that constituted the primary healthcare professional-led intervention for use with patients (i.e. the patient toolkit). In addition, healthcare professionals were asked to report their most and least favourite/useful components of MaM for T2D; and whether they would recommend MaM for T2D to a clinical colleague.

Acceptability and feasibility of the patient toolkit intervention from the perspective of patients was assessed quantitatively (review of appointment attendance rates for MaM for T2D sessions) and qualitatively using semi-structured interviews. Interviews were conducted with patients immediately following their diabetes review appointments incorporating MaM for T2D at baseline and at 1-month follow-up. Patients were interviewed using a topic guide developed using the Theoretical Domains Framework (see Appendix L) to establish comprehension, acceptability and feasibility of the primary healthcare professional-led 'patient toolkit' intervention and to detect any domain specific issues (e.g., information/support gaps).

The aim was to interview patients up until the point of data saturation (i.e. no new themes, findings or issues are observed in the data) [177]. In the absence of an explicit guidance regarding the optimal sample size for a study of this kind at the time of designing the study, the following process was used to guide the numbers of patients interviewed at each data collection time point.

The first four interviews were conducted with patients at practice 1 following baseline review appointments. Four interviews were then conducted with patients following the baseline data collection time point at practice 2. The decision to select equal numbers of patients for interview at each practice was pragmatic, however as the intervention was GP-led at practice 1 (a non-research active practice) and nurse-led at practice 2 (a research active practice) it was important to understand whether findings varied on the basis of these differences.

If no new findings or issues were observed from the data following completion of the first eight patient interviews (4 in each practice) at baseline, then no further interviews would be conducted at this data collection time point. Subsequent interviews were then conducted with patients following attendance at 1-month review appointments using the same process as described for baseline interviews.

4.3.5 Treatment fidelity for delivery of the intervention by healthcare professionals

Assessment of treatment fidelity is important to determine whether observed effects are a product of the intervention or non-intervention factors (i.e. to allow a judgement to be made as to whether intervention components were delivered as per the protocol) [114]. Furthermore, an assessment of treatment fidelity is important to facilitate optimisation of an intervention (e.g., specific components that don't translate well into practice) and to enable adaptations to be made to the study protocol to improve implementation [114]. If delivery of intervention components are not assessed (i.e. adherence to the protocol), this could potentially lead to conclusions that interventions are not effective when in reality they were not delivered as planned. The latter point is important because there is a risk that ineffective interventions are adopted into clinical settings in the place of potentially effective interventions [114, 145].

A standardised online training intervention programme was provided to ensure all primary healthcare professionals in the open pilot study received access to the same training content. Treatment fidelity assessment (using video recordings of MaM for T2D consultations with patients) was used to establish adherence of primary healthcare professionals to components of the patient toolkit intervention, in accordance with the content of the online training intervention programme and patient toolkit.

Several scales exist to assess performance of behaviour change skills. Most scales assess motivational interviewing skills (e.g., the Motivational Interviewing Treatment Integrity Code and the Motivational Interviewing Skills Code) [178, 179] and more general behaviour change counselling skills such as inviting patients to talk about change - assessed with the Behaviour Change Counselling Index [144]. Although these scales have been validated, they were not suitable for assessing treatment fidelity in the current study because they do not adequately cover the full range of specific components in the MaM for T2D intervention (for example performance of specific behaviour change techniques). In order to assess whether the patient toolkit intervention could be consistently and faithfully delivered in the primary care setting by healthcare professionals, a 20-item fidelity checklist was constructed to reflect the content and processes involved in delivery of the patient toolkit intervention by primary healthcare professionals. This checklist was used to assess the presence and absence of specific

intervention content, including the quality of delivery assessed using a 5-point scale (see Appendix M).

Measuring adherence to pre-defined intervention content and processes is quantifiable; however, adherence may not require all of these intervention features to be delivered during every individual session [180]. For example the use of the technique 'generalisation of PA behaviour' is unlikely to be used during a baseline session, therefore appropriate absence of this technique was recorded during the coding process by stating 'non-applicable'. Although the online training programme did not provide examples of when it would be inappropriate to use a specific intervention component, several examples were provided throughout modules 6 and 7 of when it would be 'appropriate' to use components. For example, the programme illustrated how specific behaviour change techniques could be used to increase motivation/form intentions to change PA/exercise behaviour when patients' stated that importance and confidence for change were low.

Where it was appropriate to use each of the 20 areas of specific intervention content or processes, a fidelity threshold was applied where ≥50% was considered to be 'sufficiently high' to continue with the study. While reviewing video footage of each consultation, coders recorded each intervention component as 'yes' (delivered), 'No' (not delivered) or 'N/A' (not applicable). Where it was applicable to use a specific intervention component during the consultation, the ≥50% fidelity threshold was applied (i.e. each intervention component had to be delivered faithfully at least 50% of the time across consultations). This assessment of fidelity enabled insights into potential adaptations or improvements to the patient toolkit and concomitant online training programme. If specific intervention components did not reach the ≥50% threshold, adaptations to the intervention were made to improve fidelity of delivery before continuing with the study.

A small smartphone sized video recording device was taken to each practice and set up ahead of each 'eligible' consultation by a researcher. Diabetes review appointments were video recorded and assessed for treatment fidelity only when both participating primary healthcare professionals and patients provided their informed written consent. Published guidance suggested that 20% to 40% of consultations should be video recorded, and where feasible equal numbers of consultations should be video recorded

at each intervention data collection time point to ensure representativeness of the data set [145].

In order to maximise treatment fidelity in other domains, a number of additional strategies were used, informed by published guidance [114].

4.3.6 Treatment fidelity strategies for study design

All patients received the same 'treatment dose' (i.e. the same number of contacts from primary healthcare professionals). To plan for implementation setbacks a minimum of two primary healthcare professionals were recruited (and trained) from each primary care practice.

4.3.7 Treatment fidelity strategies for monitoring and improving receipt of the intervention

Data on time spent completing the online training programme and modules reviewed post-training by healthcare professionals were collected from electronic logs embedded within the study website.

Monitoring receipt of the intervention by patients was undertaken by recording attendance at baseline and 1-month review appointments, including drop-out rates (and documenting reason for patient withdrawal).

4.4 Data Analysis

Theoretical Domains Framework based semi-structured interview transcripts were content analysed to identify domain specific beliefs likely to positively or negatively influence acceptability and feasibility of MaM for T2D in the primary care setting.

All healthcare professional interview transcripts (n=9) and patient transcripts (n=14) were content analysed [157] independently by the researcher [author of this thesis] using Nvivo 10 [181.] Twelve of the twenty three transcripts were independently coded and content analysed by a second coder. Discrepancies were resolved through discussion with a third coder.

Although the interview guides were developed using the Theoretical Domains Framework (i.e. specific questions were asked in relation to each domain), responses to questions regularly fell within more than one domain, for example, responses to questions relating to 'beliefs about capabilities' often overlapped with the responses provided by participants in relation to the domain 'optimism'.

Following completion of the coding of the first healthcare professional and patient transcript (Step 1), the researcher and the second coder met to discuss the results and resolve any discrepancies with coding. The researcher and second coder then independently coded the remaining transcripts and they each produced a list of beliefs they felt were generated by each of the 14 theoretical domains (e.g., 'MaM for T2D has improved my knowledge'). These are reported throughout as 'domain specific beliefs' and were derived from the data that were coded within each domain (Step 2). Once completed, the researcher and second coder met again to discuss overall results (Step 3). Following completion of steps one, two and three the researcher met with a third coder to finalise the list of domain specific beliefs and agree on those which were likely to positively and negatively influence the wider implementation (by impacting positively or negatively on acceptability and feasibility) of MaM for T2D in routine primary care (Step 5).

Domain-specific beliefs likely to positively influence acceptability and feasibility of MaM for T2D were agreed using the following criteria: (i) the frequency of specific beliefs across transcripts and within each theoretical domain; (ii) positively-framed domain-specific beliefs within each theoretical domain; and (iii) explicit statements of enabling factors to implementation. Domain-specific beliefs likely to negatively influence acceptability and feasibility of MaM for T2D were agreed using the following criteria: (i) the frequency of domain specific beliefs across transcripts and within each theoretical domain; (ii) negatively framed domain-specific beliefs within each theoretical domain; and (iii) explicit reporting of barriers to implementation.

Descriptive statistics (median and IQR, minimum and maximum values) were calculated for time spent (in minutes) by healthcare professionals to complete the online training programme and over what period of time (e.g., 7 consecutive or non-consecutive days).

In addition, a frequency analysis was used to determine how many times healthcare professionals revisited the online training programme, which modules they revisited, including how much time they spent browsing these modules in minutes (median and IQR, minimum and maximum values).

All video recordings of MaM for T2D consultations with patients were coded (a proportion were also double coded by researchers with expertise in health behaviour change to ensure reliability, and disagreements were resolved via discussion) using the 20-item fidelity checklist. Where appropriate, a fidelity threshold of ≥50% was considered to be 'sufficiently high' to be considered evidence of treatment fidelity for delivery of specific intervention content and processes by primary healthcare professionals.

Analyses of all data collected as part of the open pilot informed the overall decision as to whether the current version of MaM for T2D was acceptable and feasible in the primary care setting, or whether amendments were required to the form and information content of both intervention components. Suggestions for optimisation of MaM for T2D based on findings of the open pilot study were discussed during meetings with the wider research team and implemented, where feasible and appropriate.

4.5 Results

4.5.1 Participants

Six primary healthcare professionals from two primary healthcare practices (three from each practice) took part in nine face-to-face interviews (following completion of the online training programme [n=3], after initial baseline [n=4] and 1-month follow-up [n=2] appointments with patients). Healthcare professionals were two general practitioners (GPs), three practice nurses and one healthcare assistant. One GP and one practice nurse were specialists in diabetes. All six healthcare professionals were female and aged between 40 and 55 years (mean 47; SD 6) and had received no previous training on health psychology theory, and behaviour change generically. However, two healthcare professionals reported having attended a workshop on use of PA/exercise in primary care generally. None of the participating healthcare professionals had

previously been involved in diabetes or PA related research. Their baseline characteristics are presented in Table 4.1.

Table 4.1 Baseline characteristics of participating primary healthcare professionals (N=6)

Demographics	Frequency (% F)	Mean, SD (min/max)
Professional Role		
General Practitioner (Partner)	2 (34%)	
Practice Nurse	3 (51%)	
Healthcare Assistant	1 (17%)	
Specialist in diabetes care		
Yes	2 (34%)	
No	4 (68%)	
Employed		
Full-time	3 (50%)	
Part-time	3 (50%)	
Length of time in current role		9 years, 8 (0 to 23 years)
Gender		
Female	6 (100%)	
Male	0 (0%)	
Age		47 years, 6 (40 to55 years)
Currently hold an academic appointment		
Yes	0 (0%)	
No	6 (100%)	
Previously involved in diabetes research		
Yes	0 (0%)	
No	6 (100%)	
Previously completed training in diabetes		
Yes	6 (100%)	
No	0 (0%)	
Previously completed training specific to physical activity/exercise		
Yes	2 (34%)	
No	4 (68%)	
Previously completed training in health behaviour change and/or motivational interviewing		
Yes	1 (17%)	
No	5 (85%)	

Note; percentages may not total 100 due to rounding

Thirty adults with non-insulin dependent Type 2 diabetes were recruited from two participating primary care practices (eighteen from practice 1 and twelve from practice 2). This sample size was consistent with standard guidance relating to sample size for pilot studies [170, 171.] Their baseline characteristics are presented in Table 4.2. Briefly, patients were aged between 46 and 88 years (mean 68.9; SD 10.6); were 60% male (M/F, 18/12); had been diagnosed with Type 2 diabetes between 2 and 28 years (mean 6; SD 5.60) and 21 participants controlled their diabetes with oral medication. Patient progress throughout the study is presented Figure 4.1. It is worthy of note that exclusion

of adults with insulin-dependent Type 2 diabetes and those prescribed sulphonylureas reduced the number of eligible patients by approximately 50%.

Table 4.2 Baseline characteristics of participating patients (N=30)

Demographic	Frequency (% F)	Mean, SD (min/max)
Gender		
Female	12 (40%)	
Male	18 (60%)	
Age		69 years, 10 (46-88 years)
Employment Status		
Employed Full-time	3 (10%)	
Employed Part-time	1 (3%)	
Unemployed	1 (3%)	
Retired	22 (73%)	
Other	1 (3%)	
Missing data	1 (3%)	
Length of time since diagnosis of Type 2 diabetes		6 years, 5 (2-28 years)
Diabetes Management		
Diet only	8 (27%)	
Oral medication	21 (70%)	
Missing data	1 (3%)	

Note; percentages may not total 100 due to rounding

4.5.2 Outcome of semi-structured interviews with healthcare professionals

Thirty four domain-specific beliefs likely to positively or negatively influence acceptability and feasibility were identified from interviews with healthcare professionals. These are presented in Tables 4.3 and 4.4. Each domain-specific belief is supported by quotes and the number of healthcare professionals who expressed the domain specific belief is stated in the far right column.

4.5.3 Domains likely to have a positive influence on acceptability and feasibility from the perspective of primary healthcare professionals

A total of 25 domain-specific beliefs across all 14 domains in the Theoretical Domains Framework were likely to positively influence acceptability and feasibility of MaM for T2D within the primary care setting (Table 4.3).

Table 4.3. Theoretical domains and associated domain-specific beliefs likely to positively influence acceptability and feasibility of MaM for T2D from the perspective of healthcare professionals.

Domain	Domain-specific Belief	Example quote	Frequency
Knowledge	**MaM for T2D has improved my knowledge of diabetes and knowledge about the value of PA for glycaemic control**	'Have I learnt things? Definitely. I mean, I knew a fair amount but not all the nitty gritty…I think it has increased my knowledge definitely' #3 [Post training, pre BL] 'I knew it [PA] was a huge benefit but I wasn't aware of how small tweaks almost, little changes, can make a difference as much' #4 [Post 1 month]	**6/6**
Skills	**I have developed skills to help me engage patients in the process of decision making.**	'Well, I think the listening, you know, and letting them [patients] make a decision about things. Yeah. Trying to be positive' #2 [Post 1 month]	**3/6**
	I have developed new behaviour change skills as a result of participation in MaM for T2D that will benefit my practice	'Asking patients about previous things they've done it's actually brought out some surprising things about people who -- patients who I thought I knew quite well, and actually they've got a whole lot more to them that I didn't know about which is quite interesting' #3 [Post BL] 'I didn't know very much about it [Behaviour change]… I knew it was good but I didn't know how to implement it. I didn't have the skills. Doing this is a huge, huge benefit….' #4 [Post 1 month]	**5/6**
	MaM for T2D has provided me with skills that I can transfer into other areas of clinical practice	'….. I mean, ***** and I have said we're using it, we're using the principles on other things. We are, people come in with hypertension and things like that, and we're using the principles' #4 [Post BL]	**4/6**

#1 GP (Diabetes Specialist); #2 GP; #3 Practice Nurse 1 '#4 Diabetes Specialist Nurse; #5 Healthcare Assistant; #6 Practice Nurse

Table 4.3 (continued) Theoretical domains and associated domain-specific beliefs likely to positively influence acceptability and feasibility of MaM for T2D from the perspective of healthcare professionals.

Domain	Domain-specific belief	Example quote	Frequency
Social/Professional Role & Identity	**We are all well placed to use MaM for T2D. It is important to communicate a consistent message**	'I think it's good to have a consistent message from everybody' #1 [Post training, pre BL] 'I think we all have to intervene. Like it's all our role. I don't think any of us can say, "Oh, it's actually not my role to do that." #6 [Post BL]	**6/6**
	My own activity levels are likely to influence the extent that I encourage	'I enjoy exercising, being active, so I think that's been a positive thing in talking to people about being active'. #2 [Post training, pre BL]	**5/6**
Beliefs about capabilities	**Successful delivery of MaM for T2D will be achieved with practice in the clinical setting**	'I think we'll be more aware of how easy it is next time, at the next one…..It's the same as everything when you first start off, you're not sure you've done everything you were supposed to do'[#6, Post BL] 'It was easier [the second time] in that you felt a bit more confident…..I felt more confident going into it, whereas I absolutely would have stayed up in the middle of the night to do it for the last session..'#6 [Post 1 month] 'Oh, yeah, I feel more confident now than before, yeah. I was definitely more confident this week than I was last week' #3 [Post 1 month]	**6/6**

#1 GP (Diabetes Specialist); #2 GP; #3 Practice Nurse 1 '#4 Diabetes Specialist Nurse; #5 Healthcare Assistant; #6 Practice Nurse

Table 4.3 (continued) Theoretical domains and associated domain-specific beliefs likely to positively influence acceptability and feasibility of MaM for T2D from the perspective of healthcare professionals.

Domain	Domain-specific belief	Example quote	Frequency
Beliefs about consequences	**Using the techniques from MaM for T2D will result in better outcomes for my patients**	'I think I'll get better outcomes if I learn to do it [target PA] differently' #4 [Post BL] 'Before I delivered it, I didn't really know sort of, what I was getting into if you like, really. So, how's it differed? I mean, I'm.. I think people are trying to be more active. And what one guy's... his HbA1c has improved' #2[Post 1 month]	**4/6**
	The level of engagement shown by patients is surprising	'It's not necessarily a physical effect yet. I think it's a psychological effect, which is coming before the physical effect. Which is quite reassuring as well, that there is no physical manifestation of anything, but they're still interested in continuing as well. Because it's obviously shifted their mind-set' #6 [Post 1 month]	**3/6**
	MaM for T2D was easier to use in practice than I expected	'I thought once we had all the equipment, and we did all the training, I wondered if it was going to be a bit more hard work than it looked, but it wasn't' #5 [Post BL]	**3/6**
	The online training programme met my expectations	'Well, I think it pretty exceeded my expectations to be honest. Because yeah I found it useful and interesting and it was well-presented' #2 [Post training, pre BL]	**5/6**
Reinforcement	**There are personal incentives to use MaM for T2D if it increases the likelihood of positive outcomes for patients**	'Well, yeah. You know if it increases the likelihood of actually changing their lifestyle or doing what is going to improve their health, that's going to be an incentive' #2 [Post training, pre BL] 'It's almost like a little reward when you managed to achieve something with a patient and they'll want to go forth and do something, and that's what makes it seem worthwhile. Anything you do with nursing I suppose, you know, a rubbish day and then somebody says one nice thing, you think, so the day was rubbish. It's doing that with a patient when they're done it for themselves really, but you've prompted them along and it's quite rewarding' #3 [Post BL]	**5/6**

#1 GP (Diabetes Specialist); #2 GP; #3 Practice Nurse 1 '#4 Diabetes Specialist Nurse; #5 Healthcare Assistant; #6 Practice Nurse

Table 4.3 (continued) Theoretical domains and associated domain-specific beliefs likely to positively influence acceptability and feasibility of MaM for T2D from the perspective of healthcare professionals.

Domain	Domain-specific belief	Example quote	Frequency
Intentions	**Completing the training programme has increased the likelihood that I will target PA in future consultations**	'I think it will be very useful [in other areas of practice]. That's what I'm planning to do' #2 [Post training, pre BL] 'I think I'll probably carry on and use them, because I mean they get to be a habit anyway, and if they're successful we're going to keep it up' #5 [Post BL]	**4/6**
Goals	**I'm likely to use MaM for T2D to target high risk patients with and without diabetes**	'Well, I think, you know, with patients that I've seen that are overweight and things like that, and diabetics as well, I would be quite keen to use it. Yeah' #2 [Post 1 month]	**2/6**
Goals	**Competing priorities are something I am used to dealing with as part of my professional role**	[conflicting priorities] 'That's life. I do that every day' #4 [Post BL] 'Well, I should be alright. It happens all the time every day so you just get on with it and do it' #3 [Post training, pre BL]	**2/6**
Social influences	**I don't feel pressured to use programmes such as these. I see it as a good thing to do**	'Well, I don't think it's pressure I feel. It was sort of a good thing to do, so useful, the useful tools to use for anything in dealing with patients' #2 [Post training, pre BL]	**3/6**
	External pressures to target lifestyle influence my decision to use the programme (i.e. lifestyle has become a policy priority)	'…I think lifestyle is very much the on the agenda for all sort of different areas of care. I think all health professionals are really addressing that more and more' #1 [Post training, pre BL]	**3/6**

#1 GP (Diabetes Specialist); #2 GP; #3 Practice Nurse 1 '#4 Diabetes Specialist Nurse; #5 Healthcare Assistant; #6 Practice Nurse

Table 4.3 (continued) Theoretical domains and associated domain-specific beliefs likely to positively influence acceptability and feasibility of MaM for T2D from the perspective of healthcare professionals.

Domain	Domain-specific belief	Example quote	Frequency
Emotion	**I don't find delivering MaM for T2D stressful**	'I wouldn't say I feel uncomfortable with [using] any of it to be honest' #3 [Post 1 month] 'So, stress? No. Just awareness that there's a difference' #6 [Post 1 month]	**3/6**
Behavioural regulation	**I use prompts (e.g., crib sheets) to ensure I cover everything I need to during my consultations with patients**	'I've got crib sheet… to command and remind myself what I'm trying to do. Maybe just the sort of summary of the things I'm going to cover' #2 [Post training, pre BL]	**2/6**
	The programme has made me target physical activity in a different way with my patients	'I look at things differently. I think partly it's the general healthcare attitude that we used to talk about 30 minutes of aerobic work three times a week which seemed standard, but now I'm looking at just simple movement because there are people, who, as you know, who couldn't do ten minutes of walking. Now I'm looking at different things' #4 [Post BL]	**4/6**
Memory, attention & decision processes	**I'd be likely to use MaM for T2D with patients who are high risk**	'Well, I think, you know, with patients that I've seen that are overweight and things like that, and diabetics as well, I would be quite keen to use it' #2 [Post 1 month]	**2/6**
Environmental context and resources	**It is possible to integrate MaM for T2D in to practice**	'I think it [MaM for T2D] might take a bit longer than I thought it would. But I think it is manageable because we're a small practice...' #2 [Post training, pre BL]	**3/6**
Optimism	**I'm confident that with practice delivery of MaM for T2D will be easy**	'It's not easy at the moment because it's a new skill, but I think with practice it should be easy, but because it's new to me I'm having to think all the time. Wit I think it depends on the person to be honest. I mean but I will certainly spend a significantly longer time to actually talk about it [PA]. #2 [Post training, pre BL] 'With help and practice I'll become more fluent' #4 [Post BL]	**6/6**
	I am optimistic that use of the techniques will bring about change	'Yeah, I would say fairly optimistic; I certainly use techniques with other patients, so yeah' #3 [Post BL]	**4/6**

#1 GP (Diabetes Specialist); #2 GP; #3 Practice Nurse 1 '#4 Diabetes Specialist Nurse; #5 Healthcare Assistant; #6 Practice Nurse

An increase in knowledge about Type 2 diabetes and PA/exercise for the management of Type 2 diabetes was reported by all participating healthcare professionals (e.g., '*have I learnt things? Definitely. I mean, I knew a fair amount but not all the nitty gritty…I think it has increased my knowledge definitely')*. While healthcare professionals reported having previous knowledge to some extent about the importance of PA/exercise for management of Type 2 diabetes, they reported having focused on 'exercise' rather than free-living levels of PA. They agreed that a focus on free-living PA/exercise would be a more feasible approach to adopt with the majority of their patients (e.g., *'I think partly it's the general healthcare attitude that we used to talk about 30 minutes of aerobic work three times a week which seemed standard, but now I'm looking at just simple movement because there are people, who, as you know, who couldn't do ten minutes of walking [continuously]. Now I'm looking at different things').*

Primary healthcare professionals indicated that they had acquired skills required to deliver the patient toolkit intervention in practice. Responses in the skills domain were categorised into three groups of domain-specific beliefs:

(i) Development of skills that helped them to engage patients in the process of decision making about PA change (e.g., *'Well, I have learnt that you've really got to rather than just tell the patient what to do, you've got to get them on board and get them to come to that decision themselves really to support them through that')* whereas previously they acknowledged utilising a more didactic approach;

(ii) Development of behaviour change skills that would benefit them in their practice (e.g., *'I didn't know very much about it [Behaviour change].. I knew it was good but I didn't know how to implement it. I didn't have the skills. Doing this is a huge, huge benefit;*

(iii) Development of skills that were directly transferable to settings other than diabetes care (e.g., *'[GP] and I have said that we are actually using what we were taught in the online training in other settings'*).

A majority of healthcare professionals also had strong 'Intentions' to continue using the patient toolkit in routine practice, and had beliefs relating to 'Goals' (i.e. planned use for high-risk patients with and without diabetes) with positive assertions that presence of

competing demands would not conflict with these goals. 'Social influences' were not highlighted as facilitators per se, but there were domain-specific beliefs that delivery of MaM for T2D was consistent with a moral standard ''*Well, I don't think it's pressure I feel [to use interventions such as MaM for T2D]. It was sort of a good thing to do, so useful, the useful tools to use for anything in dealing with patients*' #2 [Post training, pre BL]"

All healthcare professionals expressed domain-specific beliefs associated with their 'Social / professional role and identity' as a driver/facilitator to use of MaM for T2D in practice. For example, they were well-placed to deliver the intervention as part of their role and considered that it was important to provide a consistent message. Others emphasised specific beliefs that their personal levels of PA/exercise had a positive influence on delivery of the patient toolkit.

With regard to domain-specific 'Beliefs about capabilities' all healthcare professionals indicated that the online training programme had improved their self-efficacy for discussing PA/exercise with patients, although opportunities for mastery (practice) of the patient toolkit was considered important. Regarding the latter, domain-specific beliefs associated with behavioural regulation were also elucidated (i.e., use of a crib sheet as a self-monitoring device that would also serve to reduce cognitive effort during delivery).

'Beliefs about consequences' generated five categories of domain-specific beliefs: improved patient outcomes (psychological/better patient engagement); improved clinical outcomes (behavioural and physiological); easier to use than expected; online training fulfilled expectations; and translation of learning to other areas of practice. Indeed, a majority expressed domain-specific beliefs associated with 'Optimism' (e.g. increased ease of use over time and concomitant improvements in long-term outcomes).

Domain-specific beliefs related to reliance on personal incentives such as expectations of better patient outcomes and engagement, in particular for high-risk patients were also identified within the domains 'Reinforcement' and 'Memory, Attention and Decision Processes' respectively. Furthermore, domain-specific beliefs related to the domains of 'Emotion' and 'Environmental Context and Resources' indicated that healthcare professionals possessed the psychological resources to cope successfully with the

demands of delivering MaM for T2D; e.g., *'So, stress? No. Just awareness that there's a difference' #6 [Post 1 month]*.

In addition, domain specific beliefs about the perceived value of MaM for T2D, goal formulation, intentions, capabilities (skills), self-efficacy and outcome expectancies (consequences) demonstrated evidence of a positive change over time (i.e., between interview time points). For example, prior to delivery of the patient toolkit intervention, healthcare professionals to some extent lacked (i) confidence for delivering the behavioural intervention to their patients; and (ii) positive outcome expectancies. However, following experience of delivering the intervention (after initial and 1 month appointments) an opposite and more positive pattern began to emerge (e.g., *'It was easier [the second time] in that you felt a bit more confident…..I felt more confident going into it, whereas I absolutely would have stayed up in the middle of the night to do it for the last session..'#6 [Post 1 month]; 'Before I delivered it, I didn't really know sort of, what I was getting into if you like, really. So, how's it differed? I mean, I'm... I think people are trying to be more active. And one guy... his HbA1c has improved' #2[Post 1 month])*.

4.5.4 Domains likely to negatively influence acceptability and feasibility from the perspective of primary healthcare professionals

Nine domain specific beliefs were identified across 6 domains in the Theoretical Domains Framework that could inhibit the wider implementation (negatively impact on acceptability and feasibility) of MaM for T2D (see Table 4.4).

Domain-specific beliefs associated with 'Memory, attention and decision processes' was the most frequently identified barrier to implementation of MaM for T2D; in particular beliefs about the amount of cognitive effort required to recall and deliver the various components of the patient toolkit at appropriate junctures in accordance with the protocol (e.g., *'I forgot to give a leaflet to one patient. I also forgot to keep a record of their progress, even though I went through it with them #3 [Post 1 month]).* In addition, domain-specific beliefs were expressed about the need to revisit the online intervention on multiple occasions to review information on specific skills and behaviour change techniques.

Given that domain-specific beliefs about opportunities to practice were identified as a facilitator to successful implementation, the small number of patients participating in one of the practices was considered as a potential barrier (Domain: memory attention and decision processes) to gaining sufficient opportunities for mastery of intervention processes and skills (e.g., *Well, I think because we've got such small numbers, you know, you forget sort of what you're meant to be doing. At least, I do. But, I mean, yes, I think it's reasonably easy to use. Yeah. #2 [Post training, pre BL]*.

Domain-specific beliefs associated with 'Optimism' indicated that past unsuccessful attempts at supporting patients to become more physically active had a negative impact on their perceived value of the patient toolkit for impacting positively on patient outcomes (e.g., *''I would like to think that it would make a difference, but you still never know because you're only giving people the tools. They don't necessarily have to go and build the shed in the garden with it..' #6 [Post BL]*).

Questions related to the domain 'Environmental context and resources' identified domain specific beliefs related to lack of time (as a barrier to implementation) to complete the online training programme and subsequent development of skills, but not additional time needed to deliver the patient toolkit in practice (e.g., *''To do a consultation with a pretendy patient might have been quite good, but we physically just didn't have the time….'. #4 [Post BL]*).

Additional evidence of barriers to implementation, were domain specific beliefs related to social influences (e.g., targets associated with the Quality Outcomes Framework taking priority over discussions about PA/exercise); social/professional role and identity (it was generally acknowledged that lifestyle advice and support was more within the remit of the practice nurse); and beliefs about consequences (five of six participants indicated that the MaM for T2D would be beneficial, but that this was potentially limited to *'a small amount of people open to change…..'#4 [Post BL])*.

Table 4.4. Theoretical domains and associated domain-specific beliefs likely to negatively influence acceptability and feasibility of MaM for T2D from the perspective of healthcare professionals.

Domain	Domain-specific Belief	Example quote	Frequency
Memory, attention & decision processes	**Using the skills I have learned in the clinical setting requires a lot of cognitive effort**	"It's not easy at the moment [to deliver MaM for T2D] because it's a new skill, and I think with practice it should be easy, but because it's new to me I'm having to think all the time" #4 [Post BL]	**5/6**
	Maximal retention of the MaM for T2D techniques is achieved when practitioners have revised the content a number of times	"..I think you probably need to do it more than once to get it into your head". #2 [Post training, pre BL]	**5/6**
	It's sometimes difficult to remember to use all MaM for T2D components at the appropriate times	"……when you are in the midst of talking to patients some of it goes out the window a little bit. I think that's probably just getting used to it….." #3 [Post BL]	**4/6**
Optimism	**Optimism is diminished by previous negative experience of trying to support patients to become more active**	"I would like to think that it would make a difference, but you still never know because you're only giving people the tools. They don't necessarily have to go and build the shed at the garden with it.." #6 [Post BL]	**3/6**
Environmental context and resources	**Lack of time to complete the training and deliver the intervention is the most likely barrier to implementation in practice**	"I don't think I'll be given a lot of time to do it" #3 [Post training, pre BL] "To do a consultation with a pretendy patient might have been quite good, but we physically just didn't have the time….". #4 [Post BL]	**3/6**

#1 GP (Diabetes Specialist); #2 GP; #3 Practice Nurse 1 '#4 Diabetes Specialist Nurse; #5 Healthcare Assistant; #6 Practice Nurse 2

Table 4.4 (continued). Theoretical domains and associated domain-specific beliefs likely to negatively influence acceptability and feasibility of MaM for T2D from the perspective of healthcare professionals.

Domain	Domain-specific belief	Example quote	Frequency
Social influences	**Diabetes care is usually target driven**	"I think in my role [nurse practitioner]… I've got the knowledge of diabetes but then you've got certain tasks that you need to complete, certainly things like QoF etc. So, although you know your general care, you've got to hit certain tasks and probably the exercise part of the tasks isn't highlighted enough" #4 [Post BL]	**1/6**
Social/Professional Role & Identity	**Practice nurses would be better placed than a GP to deliver MaM for T2D due to time constraints**	"I think anyone can do it, but given the time constraint of GPs, I would imagine it would be the nurses more likely that do it" #3 [Post BL] "….I think they all have a place to do it. I think, in a way...yeah, I think you can all do it. But, you know, if you talk about giving more time it's probably the nurses…."#2 [Post 1 month]	**5/6**
Beliefs about consequences	**The programme will only work with a minority of patients**	"So I think it's very beneficial but in reality I think there's only going to be a small amount of people open to change" #4 [Post BL] "I think with the right people it will work. I really do think it's going to depend on the individual because we have these discussions with patients all the time and you know the people who are going to make the effort and who aren't" #3 [Post BL]	**5/6**

#1 GP (Diabetes Specialist); #2 GP; #3 Practice Nurse 1 '#4 Diabetes Specialist Nurse; #5 Healthcare Assistant; #6 Practice Nurse 2

4.5.5 Time spent completing the online training programme and modules reviewed post-training by primary healthcare professionals

All six healthcare professionals logged onto the online system and accessed the online training programme. They spent a median of 3 hours and 35 minutes browsing the programme up to the point of completion (i.e. when a certificate was generated) over a median period of 5.5 days (see Table 4.5). The median time spent using the programme post-completion was 58 minutes over a median period of 4 days.

Table 4.5 Data on time spent browsing the programme (up to completion and post-completion)

	Number of days spent in training	Total hours/minutes	Number of days spent in training post completion	Total hours / minutes
Min	2.00	00:57	1.00	00:28
Max	9.00	07:02	10.00	06:42
Range	7.00	06:05	9.00	06:13
Median	5.50	03:35	4.00	00:58
IQR	3.25	01:21	5.50	02:33

All six healthcare professionals revisited the online training programme post completion. Four out of six healthcare professionals revised all modules, one healthcare professional revisited five of eight modules (including modules 6 and 7); and one healthcare professional revisited one module only (module 7).

Module 7 (using behaviour change techniques to increase PA behaviour) was revisited by all six healthcare professionals. Modules 2 (assessment of movement as medicine in routine primary care), 5 (PA and exercise) and 6 (using psychology to change PA behaviour) were revisited after completion of the training by 5 out of 6 healthcare professionals. Module 8 ‘screening before PA’ was the least revisited module.

Healthcare professionals spent the most time reviewing module 6, followed by (in descending rank order in median values) modules 7, 2, and 4 (PA in the care of Type 2 diabetes). The remaining modules were viewed for less than 10 minutes (median) post-training, with module 8 only being reviewed for a median time of only 1 minute, although it is worth nothing that this module consists of only one page.

Table 4.6. Modules in the online training programme that were reviewed post training by primary healthcare professionals (N=6) and time spent browsing each module in minutes and seconds

	Module 1 n =4	Module 2 n=5	Module 3 n =4	Module 4 n =4	Module 5 n =5	Module 6 n =5	Module 7 n =6	Module 8 n =3
Min	02:46	03:26	00:02	00:20	00:03	01:53	06:43	00:17
Max	11:42	25:15	20:35	28:59	62:13	78:51	185:09	06:01
Range	09:36	21:49	20:33	28:39	62:10	76:58	178:26	05:44
Median	06:37	18:25	07:34	12:18	04:22	41:06	28:30	01:24
IQR	05:14	11:14	14:28	24:32	13:43	43:18	79:38	02:52

All six healthcare professionals reported module 7 as the first component they would keep *"The videos and the stuff about the behaviour techniques and counselling [module 7]"; "definitely the behavioural module [module 6]"*. This is in line with findings from the online reporting system in table 6. Secondly the pedometer and PA/exercise planners/trackers *("I thought things like the pedometer thing and stuff like that. You know the step counter was a really good idea because you know, you never thought of using that with patients and it's actually quite good"; "I think it [the pedometer] would be a good motivator actually..."*

4.5.6 Patient attendance at baseline and 1-month review appointments

A total of 27 patients (out of 30 recruited) attended their baseline appointments. Twenty four patients attended follow-up appointments at one month (retention rate = 89%). One patient at 1-month follow-up did not attend a follow-up appointment as scheduled, and three patients left the study prior to attending the 1-month review appointment and reasons were documented. These included ill health; ill health of a relative; and one patient had passed away.

4.5.7 Theoretical Domain framework interviews: patients with Type 2 diabetes

Evidence from interviews informed by the Theoretical Domains Framework (n = 8 patients; 8 interviews conducted immediately following appointment 1 [at baseline]; and 6 interviews conducted immediately following appointment 2 [1-month follow-up]) indicated that 40 domain specific beliefs from across all 14 domains were likely to positively influence acceptability and feasibility of MaM for T2D.

Domains likely to positively influence acceptability and feasibility from the perspective of patients

Increased patient awareness/knowledge of Type 2 diabetes, including knowledge about the effectiveness of PA/exercise as a self-management option was identified for all eight patients *''I've gained enough [knowledge] to know doing a little bit more exercise is better for you than doing less exercise, so I've learned that and will try and keep it up..' #4 [1-month]*. In addition, a knowledge gain with regards to the complementarity of making positive changes to diet and PA/exercise for glycaemic control was emphasised by patients *'I know diet helps and activity helps and all that. But the two together help more than just diet or more than just activity' #7 [baseline]*.

In several cases, the MaM for T2D intervention highlighted information needs about Type 2 diabetes to which patients were previously unaware (e.g., positive impact of PA/exercise on glycaemic control*) '"I filled the form in [the study questionnaire], a massive form, and I felt a bit embarrassed not knowing as much as I should, which has made me look into this book you sent, which is fantastic, by the way" #8 [1-month]'*. Others described how the information content of the patient toolkit had reinforced their existing knowledge and provided them with the motivation to increase their PA/exercise levels *"I did know quite a bit about it because my dad was type 2 diabetic… This has been, if you don't mind me saying, a kick up the arse. I hadn't previously considered increasing physical activity" #2 [Baseline]*.

Importantly, the MaM for T2D intervention was reported to be associated with the initiation of intention formation (or strengthening of existing intentions) with regard to PA/exercise behaviour change in patients. Several patients emphasised that without participation in the programme (and by definition improvements in diabetes-related knowledge and more specifically the positive impact of PA/exercise as a self-management option), it is unlikely that they would have been sufficiently motivated to consider making and sustaining intentions to make positive changes to their PA/exercise behaviour *'I wouldn't have done [considered increasing my levels of PA before MaM for T2D]. No. Life would have just continued as normal, sort of thing. You know what I mean?" [#6 Baseline]*.

Skills development in self-management for Type 2 diabetes, in particular effective self-monitoring of PA/exercise and HbA1c levels, including coping planning to anticipate and overcome barriers to PA/exercise goals were evident from interviews with patients *"When I first started doing it, very well, until the wife took poorly and it took a big step back, although even then I was still monitoring the steps I was doing and writing a little bit of a diary, notebook and transferring it onto there" #8 [1-month]*. In some cases, the MaM for T2D intervention appeared to have served as a prompt to re-establishing PA/exercise as part of their social role and identity *"It's, sort of, rekindled my interest in activity and exercise…." #2 [1-month]*.

Patient 'beliefs about their capabilities' were expressed as a result of participation in MaM for T2D, and more specifically, exposure to the patient toolkit *"Well, the increase in activity and the sort of, you know, the monitoring and looking forward to achieving the goals, they go hand-in-hand. Each one, you know, has a knock-on effect on the other. I realise that the more I become able to increase activity, and actually do increase it, that I'm getting closer to my goals, and being closer to my goals makes me want to increase, you know" #2 [1-month]*. Moreover, the opportunity to set their own personal goals for PA change provided patients with a sense of control that impacted positively on their levels of confidence (self-efficacy) about PA behaviour change *"Yes [I prefer being able to select my own activity and goals]. Rather than being told that you've got to do it, because that's no good for me. I'd just rebel against it and say, "Well, I'm not." #6 [Baseline]*. Some patients reported that they managed to increase their PA/exercise levels with minimal difficulty *"I went up to Scotland for four days on holiday and I did quite a lot of walking around the shopping centres and garden centres and things like that. It was quite easy. I found it quite easy to increase that" #7 [1-month]*. One patient emphasised the difficulties with attempting to change multiple health behaviours simultaneously in an attempt to self-manage his Type 2 diabetes.

Concomitant positive beliefs about the consequences of participation in MaM for T2D were also elucidated relating to increases in patient PA behaviour. They involved reducing the risk of progression onto oral hyperglycaemic medication and insulin, and a range of other health benefits. These included improved glycaemic control, muscle tone/fitness, well-being, waist measurements, diet, weight control, as well as reduced blood pressure and risk of cardiovascular disease.

"I think it [MaM for T2D] has confirmed what I'd suspected. I'm desperate not to go onto medication and I thought movement would help, you know, exercise would help. It's confirmed that for me" #5 [1-month]. Indeed, patients reported already experiencing benefits after only 1 month of participating in MaM for T2D (e.g., well-being, improved glycaemic control, feelings of fitness, diet, weight and blood pressure control) which provided a further boost to their confidence *"Yeah, yeah. I've noticed that, you know, with having to tighten the belt up a bit more. I expected it to happen, but I think it's happened a bit quicker than I thought. And the result's been very positive, I'm pleased with it, you know" #2 [1-month]*. The majority of patients conveyed optimistic beliefs about the how MaM for T2D would help them to maintain changes in their PA behaviour to sustain the aforementioned health benefits.

Important reinforcers for sustaining patient engagement in the MaM for T2D programme and striving to increase and maintain levels of PA were a range of internal and external incentives (rewards). In particular, positive feedback/encouragement from healthcare professionals at the baseline and review appointments were emphasised as important incentives/rewards for sustained motivation *"Oh, seeing improvements coming along. If I didn't see improvements I wouldn't be motivated I think yeah" #1 [Baseline]*. Use of patient toolkit materials also provided powerful reinforcement opportunities such as use of the pedometers and activity trackers (that as well as a mechanism for self-monitoring also provided a mechanism for positive feedback on progress / fulfilment of their PA goals) *"I think this pushes me – the pedometer. I'm sure it does"* [#5, 1-month].

Closely related to the concept of rewards were beliefs about environmental context and resources. In particular the utilisation of the patient toolkit materials (pedometer and DVD) and the availability of active support from healthcare professionals with monitoring / feedback on PA and blood glucose levels at follow-up review appointments *"Oh, I think that it is important [to have the support of your GP to help you increase your PA levels] to the extent of making sure that you know, regular blood tests for feedback on sugar levels/ blood glucose levels, yeah" #1 [1-month]*. The latter were also reflected in domain specific beliefs about social influences *"It was very helpful seeing the nurse and reading the information, filling out the forms and thinking about my activity over the last week or so" #3 [Baseline]*.

Practical support with completion of paper-based materials in the patient toolkit and positive discussions involving feedback from 'trusted and knowledgeable' primary healthcare professionals on performance were described by patients as important for sustaining their motivation *"Well, I think it's good because I'm talking to somebody that's a bit more authoritative on things than I am, you know what I mean?" #6 [Baseline]*. Family members were also considered a valued and positive social influence (source of social and emotional support) on levels of motivation for PA behaviour change *"Yeah, it will [take a lot of effort], but as I said I've got the support, I've got family support, I sure we can do it. I can do it" #8 Baseline]*. In contrast (which highlighted the importance of taking into account of patients' personal preferences), a number of patients' stated a desire to 'go it alone' and preferred to rely on self-motivation to identify personally relevant strategies for making changes to their PA using the patient toolkit materials *"None whatsoever, if I can't do it on my own then I don't you know, I'll drive myself to do it. I don't need, I've never needed anybody else to jeer me along or anything like that. Something I can, you know I can motivate myself" #8 [1-month]*. The majority of patients reported not being interested in participating in structured PA/exercise classes or clubs *"No, I'm not a group kind of person. I like to do things on my own. I like to make my own mind up about my goals and things like that, whereas in a group you have to keep up with the group" #4 [1-month]*.

Patients also identified ill-health as a key barrier to increasing their level of PA within the domain 'environmental context and resources', *"I do suffer from depression, so if I have an illness that will disrupt everything, but thankfully it's under control at the moment" #3 [Baseline]*. However, several also indicated a capacity to overcome self-identified barriers such as poor weather conditions *"Er… not a lot [anticipated barriers], I can always turn my hand to doing something. I've got my, if the weather is that inclement I've got my sheds and workshops to get out into so I can always get my hands on something, tear it to bits and put it back together. [Laughter]" #2 [Baseline]*, and in one case getting back on track with their PA goal after a period of ill-health *"At the beginning of the week I was just getting over a cold and I found it quite hard work. I was puffing and panting a bit, my cold's going away now. I can breathe through my nose a lot easier again and I find it easier, so I was thinking of increase to four days a week or increasing the minutes or maybe doing two sessions" #7 [1-month]*.

Three patients did not anticipate that they would experience any salient barriers to PA due to the strength of their initial intentions *"....my time's my own from, you know, what I do in the house, or going shopping for myself and things like that. So, I've got the time to do it anyway, in that respect, you know what I mean?" #6 [Baseline]*. A further three patients considered that planning activity on a day-to-day 'temporal' basis was unnecessary for them to initiate positive changes to their PA levels, which indicated individual preferences for PA/exercise planning *"Well, yes, I mean, the business of filling in a day-to-day plan, I mean, it just doesn't appeal to me at all" #1 [1-month]*.

Domain specific beliefs about 'goals' were (via increased PA) improvements in blood glucose levels, level of fitness and well-being and reducing progression onto oral hypoglycaemic medication and insulin *"So I wouldn't want to go on any other medication if I could avoid it, because I've always had problems with every medication I've gone onto. It's been a nightmare, so I would like to avoid more medication" #5 [1-month]*. A majority of patients stated that the patient toolkit component (delivered by healthcare professionals) and accompanying materials had facilitated the process of identifying an appropriate PA goal. Of particular importance for patients was their engagement in an active and collaborative discussion with healthcare professionals, which along with support on how to use the patient toolkit materials, helped to identify 'personally-meaningful' SMART goals (e.g., increase physical activity to 10,000 steps per day, three days per week using the pedometer) for increasing their PA *"I think having goals and seeing what I achieve. I think that's been the most useful" #5 [1-month]*.

The positive impact of participating in MaM for T2D and making changes to PA on patients' mental well-being and vitality levels were identified in relation to domain specific beliefs about 'Emotion' *"I feel better for what I've done, with the increased activity. I feel better within myself" #2 [1-month]; "Participation has made me feel good. Optimistic that I can actually do something bit by bit #3 [1-month]*.

Domain specific beliefs with regard to 'Behavioural Regulation' were also apparent in Theoretical Domains Framework interviews with patients. They particular valued the patient toolkit materials (pedometers, PA/exercise planners and trackers) as tools for action planning, and self-monitoring.

"Oh, definitely. Yes, I mean, the toolkit , I don't know until I've seen the DVD but the pedometer, definitely, I intend to use it , as I say, seven days a week, depending on which days I'm most active and which days I'm not. And the days I'm less active, then take steps towards improving it.." #8 [1 month]. Several patients emphasised that these tools had enabled them to self-regulate to such an extent that behaviours such as self-monitoring of PA had become a routine (habitual) component of their day to day lives *"No real effort, No, no it's just becoming automatic now" #1 [1-month]*. Although as with personal preferences for goals, rewards and social influences, patients expressed individual preferences on action planning on a daily-basis for increasing PA *"I'm not a lover of writing. I've got to be honest, I hate writing" #6 Baseline]*.

Although not a theory domain per se, all patients interviewed expressed high levels of satisfaction with the MaM for T2D programme indicating that it had exceeded their expectations *"I'm very satisfied. I think that's got to be a maximum…." #1 [1-month]*.

Table 4.7. Domains likely to positively influence acceptability and feasibility of the MaM for T2D intervention with patients

Key: # patient number 1-8

Baseline = semi-structured interview following appointment 1; 1-month follow-up = semi-structured interview following appointment 2

Domain	Domain-specific Belief	Example quote	Frequency
Knowledge	**MaM for T2D has increased my awareness/knowledge about Type 2 diabetes including the use of physical activity as a self-management option**	"The fact that I know more about it [diabetes] than I've ever known before and I will be able to take steps to help prevent doing the things that make it worse" [#8, 1-month follow-up]	**8/8**
Knowledge	**I've learned that both physical activity and diet are important for effective self-management of my diabetes**	"Yeah. As I say, diet and physical activity, knowing that they're doing you good, and yeah it's good actually because as I say before, well since it was diagnosed I just thought, 'Oh diabetes, watch what I eat', but that's about it. I didn't' realise there was loads of more things you could do to help it" [#8, 1-month follow-up]	**4/8**
Knowledge	**I was aware that physical activity is good for managing my diabetes, but MaM for T2D has reinforced this knowledge and provided me with the motivation / an incentive to increase my physical activity levels**	"Well, I always had a vague notion that I should be more active, but I suppose never really had the incentive" [#1, Baseline] "It has increased my knowledge a bit. But more than that it's made me aware again, and conscious again, of what it can do when in the past I was an extremely active person, athletic, so you know I know what training's all about. Yeah, you know things have improved [#2, 1-month follow-up]	**4/8**
Skills	**MaM for T2D has equipped me with the self-management skills to monitor my PA/glucose levels, and to plan ahead so I can overcome barriers to physical activity**	"Well, basically relating the physical activity to blood glucose levels and also getting equipment like this to help you achieve your objectives you know, under this programme." [#1, Baseline] "Well, this information and this planning kit that I've got today [will help me to succeed]. I'm going to read through it tonight and the DVD and all that. All the information is helping, yeah" [#6, Baseline]	**7/8**
Social Role & Identity	**Being active was an important part of my life previously. MaM for T2D has prompted me to become more physically activity again**	"Er, I think the type of lifestyle I've slipped into basically reclusive, no activity and I sit and think a lot and I start thinking about what I used to be like, very active, until I started having problems maybe 15-20 years ago. And I want to change, I wanted to get back to the way it used to be and have a more fulfilling and rewarding life, you know, start enjoying life again instead of vegetating"[#8, Baseline]	**3/8**

Table 4.7 (continued) Domains likely to positively influence acceptability and feasibility of the MaM for T2D intervention with patients

Key: # patient number 1-8

Baseline = semi-structured interview following appointment 1; 1-Month follow-up = semi-structured interview following appointment 2

Domain	Domain-specific Belief	Example quote	Frequency
Beliefs about capabilities	**I have gained confidence to increase and maintain my levels of physical activity**	"It's put me back in charge. I am sort of planning and managing the way I'm going, which I wasn't doing before, I was just taking the day as it comes. But now I've got short-term goals, I've got sort of long-term goals as well. I know what I want to achieve" [#2, 1-month]	**7/8**
Beliefs about capabilities	**Increasing my levels of physical activity was not as difficult as I had anticipated**	"No real effort, No, no it's just becoming automatic now" [#1, 1-month follow-up] "I went up to Scotland for four days on holiday and I did quite a lot of walking around shopping centres and garden centres and things like that. It was quite easy. I found it quite easy to increase that" [#7, 1-month]	**4/8**
Beliefs about capabilities	**Being able to set my own goals (type of PA, including where and when) has given me a sense of autonomy and the confidence to increase my activity levels**	"Yes. Rather than being told that you've got to do it, because that's no good for me. I'd just rebel against it and say, "Well, I'm not." [#6, Baseline]	**5/8**
Beliefs about consequences	**Increasing my activity levels will help to reduce risk of progression onto medication for diabetes**	"I think it's confirmed what I'd suspected. I'm desperate not to go onto medication and I thought movement would help, you know, exercise would help. It's confirmed that for me" [#5, 1-month]	**2/8**
Beliefs about consequences	**Increasing my levels of physical activity will have important health benefits**	"Yeah. I mean, obviously, this blood test that has been taken today, what I hope will give us some indication when I get the results, is that maybe there has been a slight lowering of it" [#1, 1-month]	**7/8**
Beliefs about consequences	**I'm already starting to experience the health benefits of increasing my levels of physical activity**	"Yeah, yeah. I've noticed that, you know, with having to tighten the belt up a bit more. I expected it to happen, but I think it's happened a bit quicker than I thought. And the result's been very positive, I'm pleased with it, you know" [#2 1-month]	**3/8**

Table 4.7 (continued) Domains likely to positively influence acceptability and feasibility of the MaM for T2D intervention with patients

Key: # patient number 1-8

Baseline = semi-structured interview following appointment 1; 1-Month follow-up = semi-structured interview following appointment 2

Domain	Domain-specific Belief	Example quote	Frequency
Beliefs about consequences	**It is highly unlikely that I would have considered changing my levels of physical activity prior to participating in MaM for T2D**	"Oh, I just wouldn't have done it [without MaM for T2D]. I may have hopefully, reconsidered re-joining the gym but I must say, it wasn't high on my priority list" [#1, 1-month] "Realistically, not very likely. Certainly not to the same extent, no. You've given me information and incentives and I now have the figures to work with" [#3, 1-month]	**6/8**
Memory, attention & decision processes	**Support from the practice has helped me to make a decision to participate in MaM for T2D and understand how to use the toolkit**	"Knowing that an authority has told you this is a good thing to do rather than someone say, "Oh well I heard so and so", you know what I mean?" [#8, 1-month]	**4/8**
Optimism	**I am optimistic that MaM for T2D will help me to increase and maintain my levels of physical activity**	"Good. Optimistic that I can actually do something bit by bit" [#3, Baseline]	**7/8**
Reinforcement	**MaM for T2D has provided personal incentives to become more physically active**	"When I got it and read through it, yeah, I thought it's going to make me more active, so that was good. But to start with, that was my incentive" [#7, Baseline] "Just to keep fit and not to have to go into some old people's home. I love to be able to touch my toes and move around, whereas others my age possibly can't" [#5, 1-month]	**5/8**
Reinforcement	**Feedback and social support from healthcare professionals during consultations is an incentive to taking part in MaM for T2D**	"I think it depends on feedback [whether I will carry on using the toolkit]. Because, obviously, my activity levels are up but I've no feedback yet" [#1, 1-month] "Well, I think the nurse could be good moral support, being able to look at results and discuss them" [#3, Baseline]	**6/8**
Reinforcement	**Using a pedometer to self-monitor my activity serves to encourage me to increase and maintain my levels of physical activity**	"Well, I've had it for a few months, so I've had it since before our first meeting. So, yeah, it's been part of my awareness. I did 600 steps in 15 minutes the other day, and one of my new aims that [name of healthcare professional] and I agree on is to try and do that two or three times a week" [#3, 1-month]	**5/8**

Table 4.7 (continued) Domains likely to positively influence acceptability and feasibility of the MaM for T2D intervention with patients

Key: # patient number 1-8

Baseline = semi-structured interview following appointment 1; 1-Month follow-up = semi-structured interview following appointment 2

Domain	Domain-specific Belief	Example quote	Frequency
Intentions	**Participation in MaM for T2D has strengthened my intention to increase my levels of physical activity**	"This has been, if you don't mind me saying, a kick up the arse. I hadn't previously considered increasing my activity" [#2, Baseline] "Well, I think as I just mentioned, it concentrates the mind more on physical activity, you know, previously I just didn't give it any thought at all. Now, I am thinking about it" [#1, Baseline]	**7/8**
Intentions	**It is my intention to carry on being more physically active**	"I've gained enough [knowledge] to know doing a little bit more exercise is better for you than doing less exercise so I've learnt that and I intend to try and keep up" [#4, 1-month] "Well, yes, I suppose once you get into the routine, yes. Once you become a little bit more active. I don't know that I'll become very, very active, but I want to stop on the same level I am and maybe improve a little bit" [#7, Baseline]	**5/8**
Goals	**Setting my own goals is an important aspect of MaM for T2D**	"I think having goals and seeing what I achieve. I think that's been the most useful" [#5, 1-month] No, I'm not a group kind of person. I like to do things on my own. I like to make my own mind up about my goals and things like that, whereas in a group you have to keep up with the group" [#4, 1-month]	**5/8**
Goals	**Setting personal goals has enabled me to develop and adhere to an activity regime**	"Normally I've got this card where I write my number of steps down, what I've done. I look at that in the morning and if it's my day for doing the step up I do the 10 minute exercises and I do them in the afternoon, well, normally about 11 o'clock by the time I get up and wake up and do a little bit of work and then I do my step ups" [#5, Baseline]	**7/8**
Goals	**My goal is to improve my blood glucose levels via increased physical activity**	"I would like to lower my reading, which isn't particularly high, I don't think, but I'd like to not ever have to go onto medication. If I can achieve that, that would be great" [#5, Baseline] "Well, I would hope to become more active, lose a few pounds and hopefully improve my blood sugar levels" [#1, Baseline]	**3/8**

Table 4.7 (continued) Domains likely to positively influence acceptability and feasibility of the MaM for T2D intervention with patients

Key: # patient number 1-8

Baseline = semi-structured interview following appointment 1; 1-Month follow-up = semi-structured interview following appointment 2

Domain	Domain-specific Belief	Example quote	Frequency
Goals	**My goal is to avoid taking medication for my diabetes**	"So I wouldn't want to go on any other medication if I could avoid it, because I've always had problems with every medication I've gone onto. It's been a nightmare, so I would like to avoid more medication" [#5, 1-month] "I think the biggest goal is to keep me off medication, because I don't fancy going on medication" [#8, 1-month]	**2/8**
Environmental context and resources	**I've learned to overcome barriers to increasing and maintaining my levels of physical activity**	"When I first started doing it, very well, until the wife took poorly and it took a big step back, although even then I was still monitoring the steps I was doing and writing a little bit of a diary, notebook and transferring it onto there" [#8, 1-month]	**5/8**
Environmental context and resources	**MaM for T2D is a welcome addition to my usual review appointment**	"Well, I have my blood taken, I got weighed and I had my measurement, which you do. Apart from that, that's all you do on your review. All this, it's different" [#7, Baseline] "Normally review appointments are looking at the results of tests and just adjusting any medication so that didn't happen today. It was more looking forward to the actual use of the activity kit so it was a different sort of review" [#3, Baseline]	**4/8**
Environmental context and resources	**The toolkit has supported me to become more physically active**	"I think the pedometer's been great. I'm really attached to that now" [#5, 1-month] "Well, basically relating the physical activity to blood glucose levels and also getting equipment like this to help you achieve your objectives you know, under this programme" [#1, Baseline]	**4/8**
Environmental context and resources	**I don't anticipate any barriers to succeeding with increasing my PA from participating in this programme**	"Potential barriers?) Other commitments, sedentary commitments, but generally speaking, no, I feel committed to it as a task" [#3, 1-month]	**3/8**
Environmental context and resources	**Planning activity doesn't appeal to me**	"Well, yes, I mean, the business of filling in a day-to-day plan, I mean, it just doesn't appeal to me at all" [#1, 1-month] "I found it easier to make a little diary but not putting time to it" [#8, 1-month]	**3/8**

Table 4.7 (continued) Domains likely to positively influence acceptability and feasibility of the MaM for T2D intervention with patients

Key: # patient number 1-8

Baseline = semi-structured interview following appointment 1; 1-Month follow-up = semi-structured interview following appointment 2

Domain	Domain-specific Belief	Example quote	Frequency
Social influences	**Practical and emotional support from the practice and healthcare professionals is important for maintaining motivation to increase/maintain levels of physical activity**	"I will need a reasonable amount of support [to attain my goals] which I think coming back to the surgery will give me" [#3, Baseline] "Support definitely. Yeah. It's been a...it's given me the kick-start that I needed. I think the personal support more than anything, coming into the Practice, you know. Yeah" [#2, 1-month] "I think having the reviews are going to be useful because I think I'll be aiming all the time to lose a bit more weight, or another inch or so. I think that would help" [#5, 1-month]	**7/8**
Social influences	**I have confidence in the advice provided by the healthcare professionals**	"Well, I think it's good because I'm talking to somebody that's a bit more authoritative on things than I am, you know what I mean?" [#6, Baseline] "Knowing that an authority has told you this is a good thing to do rather than someone say, "Oh well I heard so and so", you know what I mean?" [#8, 1-month]	**4/8**
Social influences	**Social and emotional support from family is important for me to increase/maintain my activity levels**	"Well, my husband and my family do support me. If I said, "Look, they've told me I need to do this, I need to do that," they would definitely be up for it. And yeah, I get plenty of support from the practice, and like I say, this session has definitely helped me" [#7, Baseline]	**7/8**
Social influences	**I prefer to increase my activity in my own way. Structured classes and clubs don't appeal to me**	"Certainly not in a formal way [i.e. structured classes]. I've used my dogs to get me out" [#3, 1-month] "No, I'm not a group kind of person. I like to do things on my own. I like to make up my own mind up about goals and things like that, whereas in a group you have to keep up with the group" [#4, 1-month]	**5/8**

Table 4.7 (continued) Domains likely to positively influence acceptability and feasibility of the MaM for T2D intervention with patients

Key: # patient number 1-8

Baseline = semi-structured interview following appointment 1; 1-Month follow-up = semi-structured interview following appointment 2

Domain	Domain-specific Belief	Example quote	Frequency
Emotion	**Being more physically active as a result of participating in MaM for T2D has increased my energy levels and improved my general well-being**	"Yes, I think that more physical activity just leaves you feeling better about yourself" [#1, 1-month] "I like being active, you know, getting about is what I call being active, and if I wasn't, then I would be very moody" [#7, Baseline]	**5/8**
Behavioural regulation	**My physical activity levels have increased / maintained by using the patient toolkit materials to help me self-monitor my own activity levels**	"The motivation of this daily filling in and the daily recording of what I've achieved [will keep me on track]" [#1, 1-month] "I think they [activity planners and trackers] have been vital, I think" [#5, 1-month]	**7/8**
Behavioural regulation	**My physical activity levels have increased / maintained by using the patient toolkit materials to help me self-monitor my own activity levels**	"The motivation of this daily filling in and the daily recording of what I've achieved [will keep me on track]" [#1, 1-month] "I think they [activity planners and trackers] have been vital, I think" [#5, 1-month]	**7/8**
Behavioural regulation	**As a result of participating in MaM for T2D, physical activity has become part of my regular routine**	"It's just become an accepted part of life, you know. It's no imposition. It's just normal. What I normally do, I start off with waking up and the first thing I do is start recording, you know, take the readings of the previous day and setting the next day out and it's more or less just become automatic now, you know, just couple of minutes" [#2, 1-month] "it's becoming routine too, to put the monitor on, to reset it to record yesterday's figures and to stride into the day, aware of each step" [#3, 1-month]	**5/8**
Behavioural regulation	**MaM for T2D supports me to increase the amount of activity I want to do and at my own pace**	"I'd like to keep on going the way I am until the end of this month. Until my confidence and fitness level goes up. When I do start to really increase the level of activity, and the intensity of it, then I'll start keeping performance charts" [#2, 1-month] "I wrote everything down and the next week I decided that I would double the number of steps and I've done that and just this last week I've started on my step-up exercises, up a six-inch step" [#7, 1-month]	**3/8**

Table 4.7 (continued) Domains likely to positively influence acceptability and feasibility of the MaM for T2D intervention with patients

Key: # patient number 1-8

Baseline = semi-structured interview following appointment 1; 1-Month follow-up = semi-structured interview following appointment 2

Domain	Domain-specific Belief	Example quote	Frequency
Behavioural regulation	**Planning my activity using the materials provided is not necessary for me to change my levels of physical activity**	"Yes, yes. I don't, I've not done any of the planning. I don't feel that that's necessary. No, no, I mean, for me, filling in planning for the day or something you're going to do. I'm really not into that bit. I feel I can carry out the programme quite well without having do that. I plan to do this today or do that. I'm really not that kind of individual" [#1, 1-month]	**2/8**
Behavioural regulation	**Monitoring my activity has raised my awareness of physical activity**	"Yes, I'm being aware of the value of each step. They all count, so I am happier about going upstairs to fetch something rather than thinking, "Oh, if only I had picked that up last time."[#3, 1-month follow-up]	**1/8**
Satisfaction	**I am very satisfied with the delivery and materials used for MaM for T2D, and it exceeded my expectations**	"I didn't expect it to be as in-depth as this. In fact to what I expected and to now, it's much more than I expected." [#8 Baseline] "It is meeting my expectations I think, I wasn't absolutely sure what to expect today, but yeah" [#3, Baseline]	**7/8**

Domains likely to negatively influence acceptability and feasibility from the perspective of patients

Comparatively few domains were identified from the Theoretical Domains Framework guided interviews with patients that were likely to have a negative influence on acceptability and feasibility (barriers) of MaM for T2D. Four specific beliefs associated with three domains were identified: (i) ‘memory, attention and decision processes’ (i.e. some patients felt that it might take a while to fully understand MaM for T2D and believed it might help to focus on specific aspects of it to help increase levels of PA/exercise); (ii) ‘environmental context and resources (i.e. a period of ill-health and adverse health events such as stroke and planning activity were identified as salient barriers to increasing levels of PA/exercise) and (iii); ‘social influences’ (i.e. some patients preferred to complete the programme alone rather than rely on the support of others).

Table 4.8. Domains likely to negatively influence acceptability and feasibility of the MaM for T2D intervention with patients

Key: # patient number 1-8

Domain	Domain-specific Belief	Example quote	Frequency
Memory, attention & decision processes	**It may take a while to understand MaM for T2D and I will focus on specific aspects to help me increase my physical activity levels**	"No, I don't think so. Once I get it into my head, I'll be alright, but my head's a bit slow. Once I get it there, it'll be alright" [#7, Baseline] "Well, if I go in for something, I usually take it seriously rather than play with it. So I think I will definitely pay attention to it and I'll use the pedometer as often as I feel I should. I think at the moment, as I say, I will use it at least every day of the week so it's not just the days when I'm really active that I'll wear it, I'll use it on the days I'm lazy as well" [#8, 1-month]	
Environmental context and resources	**Illness is a barrier to increasing or maintaining levels of activity**	"[barriers] ...the time I usually get to sleep, which isn't good, unless I'm really exhausted. And I can feel my tummy going glug, glug, glug, and that stops you sleeping [IBS], so I really have to sort that out as well. But I do think tiredness is a big contributor to this" [#5, Baseline] "[Potential barrier] I mean I do suffer from depression, so if I have an illness that will disrupt everything, but thankfully it's under control at the moment" [#3, Baseline]	**6/8**
Environmental context and resources	**Planning activity doesn't appeal to me**	"Well, yes, I mean, the business of filling in a day-to-day plan, I mean, it just doesn't appeal to me at all" [#1, 1-month] "I found it easier to make a little diary but not putting time to it" [#8, 1-month]	**3/8**
Social influences	**I prefer not to rely on social support from others, I prefer to do this by myself**	"I'm likely to complete it by myself, yeah" [#3, Baseline] "I don't think I require anything [from the surgery]; it's up to me now" [#8, 1-month]	**3/8**

Baseline = semi-structured interview following appointment 1; 1-Month follow-up = semi-structured interview following appointment 2

4.5.8 Treatment fidelity assessment

A total of 32 diabetes review appointments involving healthcare professionals and patients were video recorded (17 at baseline and 15 at 1-month follow-up). Table 4.9 presents a summary of the assessment of fidelity for these 32 appointments. See Appendix N for a detailed summary table of the results of the treatment fidelity assessment. It is important to highlight that when observed, all intervention components delivered were done so appropriately (i.e. each healthcare professional delivered the components at an appropriate point during the consultation and did not attempt to use a component simply because it was available to them).

Table 4.9 Treatment Fidelity Assessment Summary

Video recordings N=32: Baseline n=17; 1 month follow up n=15

Intervention Component	*f* Baseline components delivered	*f* Follow-up components delivered	*f* Overall components delivered
Agenda Setting	**5**	**5**	**10**
Review Current PA	**16**	**16**	**32**
Discuss Pros and Cons	**9**	**9**	**18**
Confidence Ruler	**14**	**14**	**28**
Importance Ruler	**15**	**15**	**30**
Feedback	**13**	**13**	**26**
Information on Consequences for the Individual	**10**	**10**	**20**
Menu of PA options	**12**	**12**	**24**
Goal Setting	**12**	**12**	**24**
Plan Social Support	**14**	**14**	**28**
Action Planning	**10**	**10**	**20**
Barrier Identification/Problem Solving	**7**	**7**	**14**
Information on When and Where to be Active	**9**	**9**	**18**
Self-Monitoring	**16**	**16**	**32**
Prompt Rewards Contingent on Progress or Actual PA	**7**	**7**	**14**
Relapse Prevention/Coping Planning	**2**	**2**	**4**
Focus on Past Success	**3**	**5**	**8**
Time Management	**2**	**0**	**2**
Review of Behavioural Goals	**0**	**15**	**15**
Generalisation of PA Behaviour	**0**	**0**	**0**

Eleven out of 20 intervention components were delivered faithfully ≥50% of the time by primary healthcare professionals across the 32 diabetes review appointments. These were: review of current PA behaviour; use of the confidence ruler; use of the importance ruler; provision of feedback on current PA behaviour; provision of information on the consequences to the individual; goal setting behaviour; prompt social support; action planning; self-monitoring; prompt rewards contingent on effort or progress made towards PA behaviour; and prompt review of behavioural goals. Furthermore, these components were delivered when it was appropriate to do so (i.e. at the right time in the patient's journey towards PA behaviour change). Interestingly, half of the behaviour change techniques delivered faithfully were motivational techniques and half volitional techniques.

Observation of the video recordings highlighted a number of missed opportunities by healthcare professionals for utilisation of selected intervention components at appropriate times during the consultation. Most noticeable was the omission of agenda-setting. In addition, the following behaviour change techniques were frequently omitted: relapse prevention/coping planning; prompt focus on past success; time management and generalisation of PA behaviour. Although targeted consistently and appropriately, the behaviour change technique 'prompt rewards contingent on effort or progress made towards PA behaviour' did not transfer into the consultation effectively. Healthcare professionals were noticeably uncomfortable when utilising this technique.

4.5.9 Optimisation of intervention components

Amendments to the intervention or study processes and procedures were addressed following discussion of all data collected during the open pilot study with the wider research team.

The following changes were made to the online training and patient toolkit in order to optimise their acceptability and feasibility:

1) Restructuring of module 7. This module was subsequently broken down into sections in accordance with the specific behaviour change techniques and other intervention components to improve navigation.

2) Healthcare professionals reported difficulty with patients who already reported being active to a level recommended in the guidelines [51]. To address the latter a page was added on sedentary behaviour and how it was important for patients to reduce the magnitude of this type of behaviour to improve glycaemic control and derive a range of other health benefits. Greater clarity was provided online in terms of frequency, duration and intensity of PA/exercise [182].

3) The record of progress pad was redesigned to provide adequate space for documenting short and long-term goals. The content was broken down into 4 main sections to provide clarity and guidance to healthcare professionals regarding the intervention processes: (i) discussing readiness; (ii) goal setting; (iii) planning and monitoring PA; and (iv) overcoming barriers. Additional space was added to enable healthcare professionals to record clinical outcome measures such as HbA1c and weight. Healthcare professionals reported that this would be useful for some patients, but not all, and patients reported feedback on PA/exercise in relation to HbA1c, weight, blood pressure and other health outcomes as being an important motivator.

4) The behaviour change technique 'rewards contingent on progress towards PA behaviour' was removed from the online training programme, due to consensus amongst healthcare professionals that it was difficult to implement. Furthermore, patients expressed the opinion that they had no desire to strive towards a pre-set reward - they reported that feedback from a healthcare professional and/or a positive change in various health outcomes were the only motivators they needed and were striving towards.

5) Healthcare professionals reported that a checklist or flow diagram of intervention components would be a useful tool to refer to ahead of, and during appointments with patients. Furthermore, they indicated that such a tool would act as a prompt to utilise specific intervention components when it was appropriate to do so (see Appendix O for a copy of the checklist).

Following amendments to the intervention components, primary healthcare professionals were asked to revisit the online training intervention programme and materials to review any amended (or new) content before continuing to deliver the

intervention to patients. Where changes were made to the patient toolkit materials (e.g. the record of progress pad), patients were also asked to review this during semi-structured interviews. All amendments to the intervention and/or study processes and procedures were made prior to the 6-month time point.

4.6 Discussion

4.6.1 Summary of findings

The open pilot evaluation of MaM for T2D provided evidence that the theory-based online training programme is an acceptable and feasible approach for enhancing their knowledge, capability (skills), confidence (self-efficacy) and intentions to deliver a behaviour change intervention (patient toolkit) targeting PA/exercise to adults with Type 2 diabetes. The median time to complete the training was 3 hours and 35 minutes across a median period of 5.5 days. Arguably, the incentive of conferring 3 CPD points for completion of the online programme may have been a strong driving factor involved with browsing the entire content; although healthcare professionals revisited various modules (in particular the module on behaviour change techniques) within the online training following initial completion, which provides further evidence of acceptability.

Although the patient toolkit was not considered as a 'universally' acceptable intervention to support patients to change their PA/exercise behaviour, with the majority of participating healthcare professionals indicating that they believed it would only be beneficial for use with 'highly-motivated' patients, or those they consider would be successful in attempts to increase levels of PA/exercise. However, participation in this open pilot study appeared to engender positive outcome expectancies in healthcare professionals in terms of the consequences of MaM for T2D (improved patient engagement and clinical outcomes; e.g., glycaemic control), including optimism that their quality of delivery of the patient toolkit would improve with practice. Delivery of the patient toolkit (and PA/exercise support to patients generally) was considered consistent with their professional role, and personal incentives were important reinforcers for continued use of the intervention, with evidence of transferability of knowledge and behaviour change skills and techniques to other areas of behaviour change and different patient populations.

Crucially evidence was identified of translation of intentions into actual professional behaviour change. It emerged from the interview data that participating healthcare professionals had previously used a didactic 'advice-giving approach' to PA behaviour change with their patients, which has yielded limited success in the field of health behaviour change [61.] Moreover, 11 out of 20 intervention components were faithfully delivered (where appropriate) by healthcare professionals within a relatively short period of time. This provides evidence that the online training programme is a feasible platform for skills development, which is consistent with previous research evaluating the impact of online learning in non-clinical and clinical contexts [183, 184].

The mechanism of professional behaviour change appeared to be consistent with the theoretical underpinning of MaM for T2D with reference to the TPB and SCT. For example, exposure to the online intervention modules (in particular modules 6 and 7) facilitated the development of positive behavioural beliefs/outcome expectancies, normative beliefs and self-efficacy regarding use of the intervention skills and techniques, which combined additively to form sufficiently strong intentions to use the patient toolkit (alongside enhanced control of external [time demands] and internal barriers [stress]), which translated into actual use with their patients alongside a concomitant change in their consultation behaviour with patients.

Nevertheless, potential barriers to wider implementation of the patient toolkit by healthcare professionals in routine diabetes review appointments were identified, which were primarily focussed (directly or indirectly) on issues related to time constraints.

Primary care is a time pressured environment and interventions that are cognitively demanding and time-consuming in terms of pre-requisite training and delivery are barriers to implementation of PA/exercise, and novel interventions generally, in routine clinical practice [185.] In the current study issues directly related to time constraints included: (i) a lack of time to complete the online programme and few opportunities for mastery of intervention process and skills prior to implementation in practice with actual patients, which in some cases resulted in cognitive burden and necessitated more time to review of the online programme; (ii) beliefs of GPs associated with professional role and identity (i.e., the patient toolkit was considered to be more appropriately delivered by nurses due to time constraints); and (iii) the impact of social influences (i.e., pressure to

focus on targets related to diabetes care stated within the Quality Outcomes Framework were considered to be a competing demand on time to use of the patient toolkit intervention [186].

Interviews with patients demonstrated evidence that the patient toolkit provided a valued educational function in terms of improved diabetes-related knowledge and more positive attitudes towards use of PA/exercise as a self-management option for glycaemic control (and deceleration of progression of diabetes, in particular the need for insulin as well as wider health benefits of increased PA/exercise). Patients emphasised that the toolkit intervention supported them to form intentions to change their PA/exercise behaviour, along with development of prerequisite self-management skills (and self-efficacy for performing self-management behaviours) necessary for successful PA/exercise behaviour change (e.g., personalised goal-setting, self-monitoring [specifically with the use of pedometers as a form of self-monitoring and feedback on performance to gauge their progress / adherence towards a stated goal], overcoming barriers and development of plans to cope with difficult situations).

The value of a knowledgeable and supportive healthcare professional was emphasised by patients, in particular positive feedback and support with self-monitoring were considered to be powerful reinforcers for sustained motivation, PA related self-efficacy and goal attainment [187]. The latter was particularly important as goals were not exclusively focused on reductions in HbA1c levels, but also to other related outcomes considered 'personally important' to patients such as avoidance of the need for oral hypoglycaemic medication and insulin therapy.

The open pilot study had a more than satisfactory patient retention rate at 1-month follow-up, which is comparable to existing behaviour change interventions targeting PA/exercise in the context of clinical care [119, 120]. Several patients emphasised that they were experiencing the positive effects of PA behaviour change (again in a short period of time – 1 month), which provides further evidence of acceptability and feasibility of the mode of delivery and information content/materials of the patient toolkit intervention. Relatively few barriers were identified in the theoretical domain framework interviews with patients, although they tended to be related to individual preferences for levels of support from others, and uncontrollable factors such as periods of illness.

4.6.2 Limitations of the study

Despite the encouraging findings identified in the current study they must be interpreted with caution. Firstly, the current study focused on the perspective of healthcare professionals and patients with Type 2 diabetes. Domain specific beliefs of other key stakeholder groups such as relatives were not explored. Secondly, the small sample sizes of healthcare professionals and patients may have been insufficient to capture the full range of barriers and facilitators (including their relative importance) to implementation of MaM for T2D that exist in the primary care setting. It should also be acknowledged that all participating healthcare professionals were female. While all healthcare professionals from each participating primary healthcare practice were invited to take part in the study, it transpired during the initial consent meeting that the clinical team employed at practice one were all female, and the diabetes clinic at practice two was led by two female members of the clinical team. Therefore it cannot be ruled out that some of the views expressed may not reflect those of male healthcare professionals (i.e. there may be gender differences). Furthermore, the sample size was too small to draw any conclusions about differences in potential implementation challenges as a function of professional role (GPs [diabetes and non-diabetes specialists], healthcare assistants or practice nurses [diabetes and non-diabetes specialists]).

However, data saturation was reached (i.e., no further new domain-specific beliefs were identified), which if a stopping point had been stated a priori would have been indicative that an appropriate sample size was achieved [188].

Thirdly, it could be argued that the eligibility criteria for participating patients (i.e. exclusion of adults prescribed insulin and/or sulphonylureas) may have hindered the wide spread implementation of MaM for T2D. However, the aim of this study was to assess acceptability, feasibility and fidelity of MaM for T2D in routine primary care and to optimise the intervention based on feedback received. Taking the aims of the study into consideration, it could be viewed as unethical to increase the risk of hypoglycaemia in participating patients when the efficacy or effectiveness of the intervention was not under investigation.

The Theoretical Domains Framework has been useful in organising narrative data to link findings of qualitative research back to theory [175, 176], and in the case of the current study it has also emphasised that domain-specific beliefs within the Theoretical Domains Framework can be conceptualised as both drivers and inhibitors of successful implementation. However, it must be acknowledged that this study has also utilised the Theoretical Domains Framework for elucidating implementation difficulties with a view to optimising intervention components, processes and procedures [189]. Consequently, further research using larger samples across a greater number of primary care practices are warranted to provide more definitive accounts of barriers and facilitators to implementation in routine primary care practice.

While the Theoretical Domains Framework driven methodology has enabled a series of theory-linked modifications to the intervention to be made (and was able to preserve the underpinning theory of the intervention post optimisation), critics could argue that the structured topic guide may have constrained the responses of both healthcare professional and patient groups to those specific to the domains within the framework. However, one study utilised randomised designs to compare the findings of Theoretical Domain Framework based interviews, focus groups and questionnaires versus those utilising atheoretical methods and found a considerable degree of overlap. Furthermore, Theoretical Domain Framework based approaches were able to elicit beliefs that were not reported in the studies that had no theoretical basis. It was concluded that data generated using the Theoretical Domains Framework were more likely to elicit beliefs related to emotional factors and did not restrict investigation to rational cognitive processes [190]. In summary this suggests that the theoretical coverage of the Theoretical Domains Framework is comprehensive and inclusive rather than selective.

4.6.3 Future research

Future work will involve a consideration of domain-specific beliefs associated with potential barriers and facilitators to implementation of MaM for T2D from the perspective of larger samples of healthcare professionals and patients (and assessment of fidelity of delivery of the patient toolkit based on video-recordings of consultations with patients using the 20-item checklist) in a planned pilot RCT using an optimised version of MaM for T2D.

This will serve to determine whether use of the online training intervention training programme is associated with better patient outcomes (i.e. increased levels of PA/exercise in patients). The accompanying qualitative evaluation will include further Theoretical Domains Framework interviews that will utilise stopping rules and other procedures to ensure adequacy of sample sizes in such studies [185]. Theoretical Domains Framework interviews will also be undertaken with patients and healthcare professionals in both the intervention and control groups to better understand the nature of usual clinical care and what MaM for T2D provides over and above usual clinical care, in order to elucidate more precisely what helps support adults with Type 2 diabetes to become more physically active.

Finally, the postulated relationship between theoretical domains and behaviour change techniques within the optimised version of MaM for T2D will also be explored, guided by previous research [191]. For example, does the incorporation of further opportunities for self-monitoring by healthcare professionals reduce the potential influence of domain-specific beliefs associated with the memory, attention and decision processes**?**

Strategies and amendments to information content that could further optimise MaM for T2D in the planned pilot RCT arising from the findings of the current pilot study include:

- Provision of opportunities for practice (mastery experience – such as pre-intervention practice sessions with colleagues). Structured feedback on performance related to initial experiences of implementing the patient toolkit to augment self-efficacy and development of skills (and intervention-specific procedures and processes) is another possible solution.

- Ensuring that it is made explicit that focusing on PA/exercise would facilitate the achievement of the Quality Outcomes Framework targets that are well-below optimal levels for diabetes care [31, 33, 192], as well as strategies to emphasise the intrinsic personal rewards (as reinforcers) for delivering the patient toolkit.

- Build in additional behaviour change techniques to augment healthcare professionals beliefs about outcome expectancies/consequences associated with small increments in PA/exercise for all types of patients.

- Identification of clinical champions (GPs and/or practice nurses) could serve as 'role models and mentors' within primary care practices and this may facilitate uptake of MaM for T2D by the wider primary care team. Indeed the importance of clinical champions in the context of implementation of behavioural interventions targeting PA in primary care has been previously reported [193].

4.6.4 Conclusions

Increasing and maintaining levels of PA/exercise in adults with Type 2 diabetes of a sufficient magnitude to impact positively on long-term glycaemic control in routine primary care practice is a significant challenge. An open pilot study utilising Theoretical Domains Framework interviews has elucidated factors that may impede and facilitate the successful implementation of MaM for T2D in routine diabetes care within the primary care setting. There is sufficient evidence to report that an online training programme is acceptable and feasible for use by healthcare professionals to provide them with the appropriate knowledge, skills and self-efficacy for delivery of a theory-based behavioural intervention targeting PA/exercise to adults with Type 2 diabetes. However, the current study identified a number of barriers to wider implementation of MaM for T2D in routine primary care diabetes appointments. Informed by the findings of the open pilot study an optimised version of MaM for T2D has been developed which will be further tested for acceptability, feasibility and fidelity within a planned pilot RCT [194].

Chapter 5. Discussion and Conclusions

Preface to Chapter 5

Chapter 5 was written wholly by the author of this PhD thesis. It summarises the main findings of the research conducted for the purpose of this thesis including key strengths and limitations. The sources of information presented are cited and referenced as appropriate.

5.1 Summary of Key Findings and Contributions to the Literature on Behaviour Change Interventions

The findings of the systematic review and meta-analysis reported in Chapter 2 were instrumental for (i) establishing a robust rationale for the development of theory-based behaviour change interventions targeting PA/exercise in adults with Type 2 diabetes; and (ii) understanding how healthcare professionals can better support people with Type 2 diabetes to become more physically active in the primary care setting.

PA/exercise is a well-established management option for Type 2 diabetes [38, 49, 104] and is recommended internationally by healthcare professionals for use in routine diabetes care [41]. Prior to undertaking the systematic review, there was strong evidence for a clinically significant impact of PA/exercise on HbA1c levels (in the absence of significant weight loss, with additional positive effects on health-related quality of life and mood [195] from evidence syntheses of laboratory and hospital-based 'supervised' studies [49]. This effect was likely to be mediated by participation in a combination of aerobic and resistance exercise at a higher intensity [49 116], however evidence also shows that beneficial outcomes, (i.e. improvements in glycaemic control) can be achieved by maximising PA/exercise at a lesser intensity [196]. These findings are important because people with Type 2 diabetes are generally less active than people without diabetes who are likely to be unfamiliar with, and lack confidence for taking part in more intensive activities [197].

For the first time, the systematic review findings reported in Chapter 2 provided sufficiently strong evidence for the efficacy of PA/exercise for yielding a clinically significant impact on glycaemic control in community and clinical settings with the use of behavioural strategies. Notwithstanding the importance of this finding for providing a clear rationale for the design of interventions that promote patient autonomy in terms of choice of PA (as opposed to relying on participation in structured supervised exercise sessions for a limited amount of time), it also meant that there was now strong evidence for the potential of theory-based interventions targeting PA/exercise to support patients with Type 2 diabetes in the primary care setting to self-manage their diabetes in the long-term.

While oral antidiabetic drugs are effective at improving glycaemic control, many patients prescribed first round oral anti antidiabetic medication progress onto subsequent classifications of medication due to poor self-management of lifestyle behaviour (diet and PA) [198]. In addition, many people with Type 2 diabetes experience intolerable side-effects associated with diabetes medication that contributes to non-adherence and results in increased risk of progression and the onset of diabetes-related complications [199]. Therefore, targeting increased free-living PA with support from primary care professionals is an important self-management option for improved glycaemic control for people with Type 2 diabetes that report poor adherence to dietary change or oral antidiabetic drugs. Free-living PA may even provide benefit for those who do not wish to attend a structured education programme such as DESMOND [58] or structured supervised PA/exercise classes.

In addition, the systematic review in Chapter 2 highlighted the importance of providing evidence-based skills development training to healthcare professionals to facilitate delivery of intervention-concordant behaviour during encounters with patients, and the need to address fidelity as part of the evaluation strategy. The latter is necessitated to reliably establish the 'enactment' of knowledge and skills acquired by healthcare professionals as a result of completing a standardised evidence-based training programme, including subsequent 'receipt' of intervention content by patients with Type 2 diabetes. Undertaking this type of evaluation also enables the determination of any effects of MaM for T2D in subsequent trials to be more reliably attributable to the facets of the intervention - described as the theoretically expected treatment effect in the MRC Framework [94, 108, 200].

A series of moderator analyses of intervention features identified by the systematic review allowed identification of candidate 'potentially active' intervention components associated with clinically important improvements in glycaemic control. Informed by findings of exploratory work with GPs and patients with Type 2 diabetes to establish their training and support needs respectively (Chapter 3), the systematic review moderator analyses enabled evidence-based decisions to be made with regards to the underpinning theory, mode of intervention delivery and information content of the online training programme for healthcare professionals.

This included the underpinning theory, mode of delivery and concomitant evidence-based intervention processes, information content and other features to support adults with Type 2 diabetes to increase their levels of PA/exercise. The prototype version of MaM for T2D was further refined by eliciting the views and perspectives of primary healthcare professionals and patients on the intervention components to maximise the likelihood they were sensitive to their needs and complexities of primary care setting.

The exploratory and development phases of the intervention design process (reported in Chapter 3) addressed several important criticisms of previous behaviour change interventions targeting PA/exercise. These included the omission of specific information about the development process, and more specifically a detailed description of the rationale for selection of underpinning theory (in this case the use of both a model and theory of behaviour change provided a wealth of complimentary theory-concordant intervention strategies targeting both intention-formation and maintenance of PA/exercise behaviour), information content and both duration and intensity of interventions that prohibits replication [94, 200].

Chapter 4 reported on a phase II study that utilised an open pilot study design to explore the acceptability and feasibility of MaM for T2D. This included fidelity of delivery of intervention-concordant skills covered by the online training programme by primary healthcare professionals and receipt of intervention content by patients in the primary care setting. The mixed methods open pilot study provided evidence for acceptability in terms of the modes of delivery, and identified opportunities for optimisation of aspects of both intervention components. Crucially it was established that the online training programme did support the faithful delivery of intervention content that was consistent with use of the patient toolkit component by healthcare professionals. However, potential implementation challenges were identified prior to further evaluation in a planned RCT.

While a prodigious amount of work has gone into elucidating a taxonomy of behaviour change techniques, there has been less attention directed towards effective strategies to provide interventionists with the knowledge and skills to deliver theory-linked behaviour change techniques as described in the taxonomy. The current study adds to the current evidence base for behavioural interventions in terms of providing a theory-based means of operationalising the prerequisite behaviours involved with performance

of specific behaviour change techniques and conveying this knowledge visually to support 'vicarious skills development' via the medium of the internet. Moreover, this thesis provides an important proof of concept for delivery of behaviour change techniques by non-psychologists – which reflects one of the key aims of the developers of the behaviour change technique taxonomy [94].

The findings related to the use of the online training intervention component of MaM for T2D for improving knowledge and skills of primary healthcare professionals were consistent with the wider research literature on digital (internet-based) behaviour change interventions. A Cochrane review published in 2013 by Richards and colleagues [201] compared the effectiveness of web-based interventions for promoting PA behaviour in community dwelling adults against a control group exposed to a placebo, minimal intervention or no intervention. The authors reported evidence for the utility of online interventions to promote behaviour change. Indeed a systematic review published in 2010 aimed to determine which characteristics of internet health behaviour change interventions were most effective at promoting change. They assessed the use of theory, theory-linked behaviour change techniques and mode of delivery. The authors reported that interventions had a small but significant effect on health behaviour, and in particular interventions underpinned by the TPB and those incorporating more behaviour change techniques and using additional methods of communicating (e.g., text messaging) tended to report larger effects. [79]. These findings support the decision to utilise the TPB to underpin MaM for T2D, and add to the evidence-base for internet-based interventions to support professional behaviour change.

5.2 Methodological Strengths and Limitations

5.2.1 Methodological strengths

Inherent strengths of the work presented in this thesis include the high level of user involvement, and the use of a taxonomy [94] to ensure behaviour change techniques were defined consistently throughout the intervention development and evaluation process and when assessing treatment fidelity. This approach increased the likelihood that the behaviour change techniques selected met the needs and complexities of the primary care setting.

Although PA/exercise is a cornerstone of diabetes care, rarely are healthcare professionals trained to provide support to adults with Type 2 diabetes to become more physically active. Indeed the systematic review presented in chapter 2 identified that from 17 trials, only 5 referred explicitly to training for interventionists; and none of the trials included in the review formally evaluated the training provided. The research presented in this thesis was able to address this gap in the evidence base by developing a standarised training programme that was formally evaluated in terms of acceptability, feasibility and fidelity.

The advantage of using an open pilot study design is that it allows the gathering of feedback from study participants throughout the active intervention period [170]. The feedback obtained facilitates a process of systematic adaptation to intervention components and study procedures while the intervention is being used in a real life setting. While early development work (as described in chapter 3) is essential to make important decisions about intervention content and mode of delivery, often implementation issues cannot be identified until the intervention is utilised in practice. Therefore the open pilot study presented in chapter 4 allowed the intervention to be 'tested' and refined ahead of a planned pilot RCT. The main disadvantage of the open pilot study design is that data gathered from participants should not be included with 'main trial' data if the open pilot study forms the first phase of a larger study. Due to the high level of participant contact it is likely that effects observed as a result of the intervention with open pilot participants may be inflated when compared to participants that have not actively taken part in the open pilot phase of the study [171].

Integration of treatment fidelity strategies (e.g., each participant offered the same number of sessions over a given period of time) and assessment of fidelity of delivery of intervention components throughout the intervention period increases the likelihood that any effects observed can be attributed to the intervention delivered [114].

5.2.2 Methodological limitations

In the terms of methodological weaknesses, the relatively small sample sizes used during exploratory work and usability testing could be a potential limitation, although the aim was not to establish generalisability, but to inform iterative development of MaM for T2D for testing in a larger pilot RCT.

Behaviour change techniques identified by the systematic review were based on univariate analyses, and as such the review was unable to assess the effect of specific clusters of behaviour change techniques upon glycaemic control. Furthermore, the behaviour change techniques identified were limited to those utilised by the behavioural interventions included in the systematic review i.e. from the 40 behaviour change techniques included in the taxonomy, only 25 were utilised across studies, therefore it is yet to be determined whether utilisation of the 15 techniques omitted would have provided any additional benefit.

The Theoretical Domain Framework approach has been used to understand patient and professional behaviour and intervention implementation challenges in a variety of contexts such as witness response at acute onset of stroke; [176] implementation of a complex intervention for acute low back pain management in primary care [202]; hand hygiene behaviours [203]; implementation of family intervention recommendations within the NICE guideline for Schizophrenia [189]; and clinicians' behaviour about preoperative test ordering for anaesthesia management [204] and blood transfusion [205].

However, despite wide and successful use, there are several potential limitations of the Theoretical Domains Framework approach that should be acknowledged. The first is that it is a descriptive framework not a theory, therefore relationships between domains cannot be specified. Secondly, the Theoretical Domains Framework is frequently used in interview studies, however inter-coder agreement can be low [205]. This highlights the issue that it can be difficult to recognise the boundaries between the domains when using the Theoretical Domains Framework as a coding framework [190].

A common criticism levelled at behaviour change intervention studies is that the recruited participants were already highly motivated to change their behaviour. This possibility cannot be definitively ruled out in the research presented in this thesis. However, a key finding of the qualitative work undertaken was that patients reported that MaM for T2D provided them with the motivation/intention to increase their levels of PA/exercise. Without the programme they indicated that it was unlikely that they would have made a change. Equally healthcare professionals reported that without the MaM for T2D programme they would have been more likely to target diet in isolation

or make specific recommendations about the amount, frequency and type of PA/exercise their patients should undertake.

5.3 Further Research

As identified in Chapter 2 (systematic review of behavioural interventions targeting PA/exercise) there are variations in sensitivity and specificity between the different objective and self-reported methods used to assess PA/exercise. The lack of accurate, standardised and transparent methods for monitoring PA/exercise remains a significant barrier to accurately determining the efficacy of interventions targeting free-living PA/exercise. Moreover, it prohibits the elucidation of what participants are doing difficult, limiting specific options and advice that healthcare professionals can provide. This includes information about what type, intensity and frequency of PA/exercise are minimal and optimal to confer benefit for specific outcomes such as control of HbAlc and decelerating progression onto medication or insulin therapy. Future work could utilise factorial designs to further our understanding of the type and intensity of free-living PA that is minimally and maximally effective for improving diabetes-related outcomes.

The systematic review presented in chapter 2, and other systematic reviews [159, 160] have concluded that utilisation of multiple behaviour change techniques are associated with enhanced effectiveness of behavioural interventions (i.e. changes in behaviour and clinical outcomes). A better understanding of why this is the case needs to be explored. Furthermore, the systematic review presented in chapter 2 further suggested that interventions lasting at least 6 months in duration are more effective. By default it is likely that an intervention of longer duration will involve utilisation of more behaviour change techniques or indeed frequent use of specific behaviour change techniques, therefore a better understanding of whether it is the duration of the intervention or the frequent use of multiple and/or specific combinations of behaviour change techniques that leads to better behavioural and clinical outcomes is required.

MaM for T2D incorporated behaviour change techniques that were associated with improvements in glycaemic control. Therefore, arguably these behaviour change techniques are also associated with increases in PA/exercise at a higher level of intensity or greater duration; although this assertion was not tested in this thesis. Further work is required to identify whether utilisation of specific behaviour change techniques can increase PA/exercise behaviour to a magnitude sufficient for clinically significant improvements in diabetes-related outcomes.

Further avenues of research, which could be used to bolster the information content of MaM for T2D, include the provision of 'personalised' information to individuals with Type 2 diabetes on the likely benefits of increasing their levels of PA/exercise. However, there has been limited research on the impact of numerical and graphical information on risk in the context of Type 2 diabetes. The @Risk trial investigated the utility of theory-based methods of conveying absolute 10-year risk of cardiovascular disease to patients with Type 2 diabetes [206]. This trial found a positive effect on the accuracy of patients' estimate of cardiovascular risk perception (agreement between the patient's UK Prospective Diabetes Study risk engine score for cardiovascular disease and the patient's perceived risk) at 2 weeks, but not 12 weeks, with no significant impact on attitudes and intentions to make lifestyle behaviour changes. Further research is warranted to establish whether evidence-based information that transparently communicates the absolute risk reduction / benefit of developing complications and/or progressing to insulin treatment as a function of incremental changes to patients' current levels of free-living PA could further support the formation of positive outcome expectancies [in both patients and healthcare professionals]. In addition an assessment is needed as to whether this could serve as a further mechanism for supporting collaborative discussions with healthcare professionals about self-management strategies for increasing PA/exercise.

Fidelity assessment of delivery of MaM for T2D intervention processes by healthcare professionals provided an excellent insight into the extent that knowledge and skills from the online training intervention were translated into the primary care setting. Future research could explore the value of providing individualised feedback on performance to healthcare professionals as part of an enhanced training programme to establish any additional benefit in terms of treatment fidelity.

The MaM for T2D intervention did not provide an online platform for patients. Although internet use in older adults is still lagging behind that of younger adults, data on internet and social media use suggests that a high proportion of the population (including people aged > 65) regularly access these forms of media for health information [207]. A fruitful avenue of further research could be the development and evaluation of an online version of the MaM for T2D intervention for use by patients accessible via PCs and other electronic devices, including programmes analogous to MaM for T2D (utilising the development process described in this thesis) to support other self-management strategies for Type 2 diabetes such as medication adherence and diet.

With the recent inception of Clinical Commissioning Groups (CCGs), there is arguably a greater need to demonstrate cost-effectiveness as well as clinical effectiveness. The former should be a core component of future randomised studies. This will help us to better understand the improvement in outcomes as a function of cost savings to the NHS and as a function of cost of MaM for T2D per patient against the cost-savings of reduced diabetes related morbidity and mortality.

Threats to continued implementation of MaM for T2D following a successful definitive RCT need to be considered. These include the need for updating MaM for T2D over time as new evidence emerges on the effectiveness of behaviour change models / theory, theory-linked behaviour change techniques (as described above) and types of PA/exercise, including sedentary behaviour [208]. Otherwise the online training may be viewed in a relatively short period of time as 'out of date' that would impact negatively on use by healthcare professionals (and ultimately prevent patients from receiving the support they need to change their PA/exercise behaviour). Furthermore, the world of information computer technology is progressing rapidly, and there is a need to maintain the IT infrastructure needed to host the online training programme for healthcare professionals.

Finally, given the plethora of evidence for the use of PA/exercise as a management option for adults with Type 2 diabetes (and the systematic review presented in chapter 2 of this thesis providing evidence that the effects on HbA1c reported from laboratory-based studies can be replicated by effective use of behavioural strategies in community and clinical settings), further RCT evidence to demonstrate the efficacy of behavioural

interventions targeting PA/exercise may not be required. Perhaps a more fruitful avenue could be undertaking multi-centre service improvement and evaluation studies of behavioural interventions targeting PA/exercise – i.e. how we can successfully implement behavioural interventions targeting PA/exercise into the primary care setting?

5.4 Conclusions

Increasing and maintaining levels of PA/exercise in adults with Type 2 diabetes of a sufficient magnitude to impact positively on long-term glycaemic control in routine primary care practice continues to be a significant challenge. As evidenced in the introduction of this thesis, Quality Outcomes Framework targets are not enough to incentivise primary healthcare professionals to target PA/exercise if they feel they don't have the knowledge, skills and self-efficacy for targeting PA/exercise during routine care. Alternative approaches are warranted, and there is sufficient evidence that increasing PA/exercise can produce clinically important improvements in glycaemic control and that use of behavioural strategies in routine clinical care can replicate the effects observed in supervised laboratory settings.

In accordance with the recommendations in the MRC Framework for development of and evaluation of RCTs for complex interventions to improve health [108], this PhD thesis has described the pre-clinical (theoretical), modelling (phase I) and exploratory trial (phase II) phases that have informed the development of a clearly-defined complex multifaceted behaviour change intervention targeting free-living PA/exercise behaviour in the primary care setting (i.e. MaM for T2D). Following optimisation and a preliminary assessment of acceptability, feasibility and fidelity at 1-month follow-up, future work will compare MaM for T2D with standard clinical care in a pilot RCT. This thesis demonstrates not only that real world PA/exercise interventions provide benefit for people with Type 2 diabetes but also how these can be effectively delivered in routine clinical care. The thesis also shows how we can improve where we spend our energy, both physically and in service delivery, to optimise the management of Type 2 diabetes. The challenge ahead is no longer whether PA is useful in diabetes care but rather how we create and optimise services around moving more and sitting less.

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Appendices

Appendix A: Search strategy for PsycINFO

1.	Exp diabetes mellitus
2.	(type 2 diab* or T2D or T2DM or Type II Diab*).tw.
3.	non-insulin dependent diabetes mellitus
4.	(non insulin dependent diabetes mellitus or NIDDM).tw.
5.	(insulin dependent diab* or insulin-dependent diab* or IDDM).tw.
6.	1 or 2 or 3 or 4 or 5
7.	exp exercise/
8.	exp physical activity
9.	exp recreation
10.	7 or 8 or 9
11.	6 and 10

Appendix B: Study selection form for full text journal articles

Date: **Researcher Initials:** **Study ID:** **Bibliographic Details:**

INCLUSION CRITERIA	Tick if present
Study Design	
Randomised Controlled Trial	
Participants	
Adults ≥18 years	
Type 2 diabetes controlled by diet/oral medication/insulin	
Intervention	
Exclusive focus on physical activity/exercise	
Intervention duration/follow-up at least one month	
Delivered by healthcare & non-healthcare professionals in primary and secondary care, outpatients and community settings, including remotely via the internet or telephone	
Comparator	
Standard/Usual Clinical Care	
Primary Outcomes (must include both of the following)	
Change in physical activity/exercise behaviour	
Change in HbA1c	
EXCLUSION CRITERIA	**Tick if present**
Studies that target multiple behaviours (e.g., PA/diet); although retain when the dietary component was consistent with usual care	
Studies that target multiple chronic diseases	
Studies that target gestational diabetes	
PA/exercise interventions conducted entirely in the clinical setting (e.g., exercise laboratory or hospital-based gymnasium) supervised by personnel/clinicians, with no subsequent intervention activity outside the clinical/research setting	
Combinations of diet or pharmacological agents with PA/exercise in one arm of the trial	
Comparisons of pharmacological agents alongside and against PA/exercise	
Studies comparing different behavioural interventions targeting PA/exercise that DO NOT include a standard/usual care arm	

Include in review: YES NO UNSURE

Appendix C: Data Extraction Form

GENERAL INFORMATION	
Date of data extraction:	
Data extracted by:	
Full reference:	
Email address for corresponding author:	
Country of origin:	
Source of funding:	
STUDY CHARACTERISTICS	
Aims / objectives:	
Study design:	Factorial Cluster Cross-over Parallel Groups Other: Please state:
Number of study arms	
Inclusion criteria:	
Exclusion criteria:	

Recruitment procedures:	
Sampling strategy	

Number of participants screened	
Total study sample size	
Sample size informed by power calculation:	
Number randomised	
Intention to treat	
No in intervention group 1	
No in intervention group 2	
No in control / usual care group	
Follow-up time periods	**Time points:**

Loss to follow-up	
Ethical approval	

CHARACTERISTICS OF PARTICIPANTS				
Study targets adults with: NIDDM IDDM Both NIDDM and IDDM Not reported				
Type 2 diabetes is controlled by: Diet Oral Medication Both diet and oral medication Diet or Oral Medication Not reported				
Group / **Characteristics**	**Control / usual care Group**	**Intervention group 1**	**Intervention group 2**	**Overall**
Age • Mean (SD)				
• Median (IQR)				
• Min / Max (range)				
• None reported				
Gender • Number / percentage female • Number / percentage male				
• Not reported				
Length of time diagnosed with T2D • Mean (SD) • Median (IQR) • Min / max (range)				
• Not reported				

Race: n (%) White African American **Ethnicity**: n (%) Not Hispanic or Latino Hispanic or Latino				
• Not reported				
Socio-economic status • Number / percentage in each group				
• Not reported				
Education Higher degree and/or professional training College or University graduate Partial college education High school graduate Partial high school education				
• Not reported				
Marital Status: n (%) Single; Married; Divorced; Widowed; Not reported				

DETAILS OF THE INTERVENTION					
Mode of delivery	Attendance at one-to-one session with interventionist Yes	Attendance at exercise / PA class YES	Self-help information materials Yes	Information / support via website: No	Information / support via telephone: No
Is there a supervised component of the intervention (i.e. participant received supervision by study personnel/clinicians during physical activity/exercise)**?**					
Interventionist	Physician / Nurse / Researcher / Psychologist	Interventionist trained (received training on) in behaviour change? Yes / No If yes – please state**:**			
Duration of Intervention					
Type of exercise / PA targeted by intervention					
Description of Intervention					**Degree of personalisation:**
Details of control / usual care intervention(s)					
Explicit Reference to Theory					

Fidelity Measures

Does the paper report any treatment fidelity measures (See Bellg et al 2004 paper)	Yes / No	**Details**
1) Treatment fidelity strategies for design of study	Yes / No	
• Ensure same treatment dose within conditions	Yes / No	
• Ensure equivalent dose across conditions	Yes / No	
• Plan for implementation setbacks	Yes / No	
2) Treatment fidelity strategies for monitoring and improving provider training	Yes / No	
• Standardize training	Yes / No	
• Ensure provider skill acquisition	Yes / No	
• Minimize "drift" in provider skills	Yes / No	
• Accommodate provider differences	Yes / No	
3) Treatment fidelity strategies for monitoring and improving delivery of treatment	Yes / No	
• Control for provider differences	Yes / No	
• Reduce differences within treatment	Yes / No	
• Ensure adherence to treatment protocol	Yes / No	
• Minimize contamination between conditions	Yes / No	
4) Treatment fidelity strategies for monitoring and improving receipt of treatment	Yes / No	
• Ensure participant comprehension	Yes / No	
• Ensure participant ability to use cognitive skills	Yes / No	
• Ensure participant ability to perform behavioural skills	Yes / No	
5) Treatment fidelity strategies for monitoring and improving enactment of treatment skills	Yes / No	
• Ensure participant use of cognitive skills	Yes / No	
• Ensure participant use of behavioural skills	Yes / No	

Outcomes	Description (including details of data collection method[s])
Physical activity/ exercise behaviour	
Glycosylated haemoglobin A_{1c} (HbA_{1c}) level	
Attitudes/beliefs	
Self-efficacy	
Health-related quality of life	
Body weight	
Body mass index	
Waist circumference	
Hip circumference	
Fat distribution	
Total body fat	
Other – please state:	
Other – please state:	

RESULTS

Outcome:

	CONTROL / USUAL CARE Summary statistics					**INTERVENTION GROUP 1** Summary statistics					**INTERVENTION GROUP 2** Summary statistics				
	Baseline					Baseline					Baseline				
Mean (SD)															
Median (IQR)															
F (%)															
Details (e.g., mean difference and 95% CIs):															

Outcome:

	CONTROL / USUAL CARE Summary statistics					**INTERVENTION GROUP 1** Summary statistics					**INTERVENTION GROUP 2** Summary statistics				
	Baseline					Baseline					Baseline				
Mean (SD)															
Median (IQR)															
F (%)															
Details (e.g., mean difference and 95% CIs):															

METHODOLOGICAL QUALITY ITEMS[1] ***

	YES	NO	UNSURE
1. **Was the allocation sequence adequately generated?**			
2. **Was allocation adequately concealed?**			
3. **Was knowledge of the allocated interventions adequately prevented during the study?**			
4. **Were incomplete outcome data adequately addressed?**			
5. **Are reports of the study free of suggestion of selective outcome reporting?**			
6. **Was the study apparently free of other problems that could put it at a risk of bias?**			

*** also see Criteria for judgments YES, NO and UNCLEAR in the 'Risk of bias' assessment tool

NOTES

[1] Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.0.2 [updated September 2009]. The Cochrane Collaboration, 2009. Available at: www.cochrane-handbook.org (accessed 21 Feb 2011).

Behaviour Change Techniques	Yes (describe with page numbers in paper)	No	Unsure
1. Provide information on the consequences in general			
2. Provide information on the consequences for individual			
3. Provide information about others' approval			
4. Provide normative information about others' behaviour			
5. Goal setting (behaviour)			
6. Goal setting (outcome)			
7. Action planning			
8. Barrier identification/problem solving			
9. Set graded tasks			
10. Prompt review of behavioural goals			
11. Prompt review of outcome goals			
12. Prompt rewards contingent on effort or progress towards behaviour			
13. Provide rewards for behaviour			
14. Shaping			
15. Prompting generalisation of a target behaviour			
16. Prompt self-monitoring of behaviour			
17. Prompt self-monitoring of behavioural outcome			
18. Prompting focus on past success			

19. Provide feedback on performance			
20. Provide information on when and where to perform the behaviour			
21. Provide Instruction			
22. Model/demonstrate the behaviour			
23. Teach to use prompts/cues			
24. Environmental restructuring			
25. Agree behavioural contract			
26. Prompt practice			
27. Use of follow up prompts			
28. Facilitate social comparison			
29. Plan social support/social change			
30. Prompt identification as role model			
31. Prompt anticipated regret			
32. Fear Arousal			
33. Prompt self-talk			
34. Prompt use of imagery			
35. Relapse prevention/coping planning			
36. Stress management			
37. Motivational Interviewing			

38. Time management			
39. General communication skills training			
40. Stimulate anticipation of future rewards without necessarily reinforcing behaviour throughout the active period of the intervention			

Appendix D: Summary of Included Randomised Controlled Trials

Study ID, country of origin and setting	Details of Sample	Details of Intervention(s)	Mode of delivery	Interventionist	Assessment periods	Outcome Measures
Balducci et al 2010[112] Italy Diabetes Outpatient Clinic	N = 606 % male = 58% Mean age (SD): 58.8 years (8.6) Time since diagnosis: average of 6 years Management: Diet +/- Oral hypoglycaemic agent (OHA) = 88% Insulin = 12%	Intervention: Supervised aerobic and resistance exercise sessions and structured counselling targeting physical activity n=303 Duration: 12 months Intensity: Two supervised sessions per week for 12 months and structured counselling targeting physical activity (reinforced every three months) Supervised PA/Exercise Component: Yes Theory: Social Cognitive Theory Usual care: n=303	Individual face to face sessions	Physicians and exercise specialists	Baseline and 12 months	HbA1c Self-reported physical activity: MET-h/wk (Minnesota Leisure Time Questionnaire) BMI
Balducci et al 2010[113] Italy Setting not explicitly stated	N = 82 % Male = 59% Mean age range: 60.6 to 64.3 Time Since Diagnosis: on	Usual care (Group A): n=20 Intervention (Group B): Structured exercise counselling to perform aerobic physical activity of low-intensity n=20 Intensity: Not reported	Individual face to face sessions (Groups, A, B, C & D) Group sessions (Groups C & D)	Physician-delivered counseling It was unclear who supervised the exercise sessions in groups C and D	Baseline, 3, 6, 9, and 12 months	HbA1c Self-reported physical activity: MET-h/wk (Minnesota Leisure Time Questionnaire) BMI

	average this ranged from 7.8 to 10.1 years Management: Diet = not reported OHA = 80% Insulin = 15%	Intervention (Group C): Structured exercise counselling and supervised aerobic exercise n=20 Intensity: Supervised aerobic exercise (60 minutes; 70-80% Vo2Max) twice per week. Intensity of structured counselling was not reported. Intervention (Group D): Structured exercise counselling and supervised aerobic and resistance exercise n=22 Intensity: supervised aerobic (40 minutes; 70-80% Vo2Max) and resistance (20 minutes; 1 repetition maximum) exercise twice per week. Intensity of structured counselling was not reported. Duration: 12 months supervised PA/Exercise Component: Yes (Groups C and D) Theory: Social Cognitive Theory (groups B, C and D)				
Cheung et al 2009[114] Australia	N = 40 % Male = 32% Mean age = 59	Intervention: supervised resistance exercise with Dynabands, which was continued at home n=21	Group sessions	Fitness leaders and an exercise physiologist	Baseline and 4 months	HbA1c Self-reported physical activity: minutes/wk (Active Australia Questionnaire)

Setting not explicitly stated	years (intervention group) and 62 years (usual care) Time Since Diagnosis: Not reported Management: Diet = 8% OHA = 62% Insulin +/- OHA = 30%	Duration: 16 weeks Intensity: Five supervised sessions fortnightly for the first month (and monthly for the remainder of the study) with an additional 30 minutes at home 5 days per week. Supervised PA/Exercise Component: Yes Theory: Not reported Usual care: n=19				BMI
De Greef et al 2010[115] Belgium Endocrinology Department	N = 41 % Male = 68% Age range: 35 to 75 years Time Since Diagnosis:1 to 5 years (n=16) and ≥ 5 years (n=25) Management: not reported	Intervention: 12-week lifestyle intervention consisting of five cognitive-behavioural group sessions of 90 minutes duration n=21 Duration: 12 weeks Intensity: Five sessions over 12 weeks and one booster session at 23 weeks Supervised PA/Exercise Component: No Theory: Cognitive Behavioural Therapy & Motivational Interviewing Usual care: n=20	Group sessions	A physical education movement scientist and a clinical psychologist	Baseline, 12 weeks and 1 year	HbA1c Objectively assessed physical activity: Accelerometer minutes/day and pedometer steps/ day BMI
De Greef et al 2011[116] Belgium	N = 67 % Male = 50%	Intervention (Group 1): Individualised physical activity consultation using behavioural strategies	Group 1: Individual face to face sessions	Group 1: A General Practitioner Group 2: A	Baseline and 12 weeks	HbA1c Objectively assessed physical activity: pedometer steps/day;

Primary Care	Mean age (SD) = 67.4 (9.3) Time Since Diagnosis: >5 years (64.5%) and <5years (35.5%) Management: OHA = 90.3% Combined OHA and insulin = 8.1% Insulin = 1.6%	n=22 Intensity: Three 15 minute consultations (one session every three weeks) Intervention (Group 2): Interactive group counselling targeting physical activity n=21 Intensity: Three 90 minute sessions (One session every three weeks) Duration: 12 weeks supervised PA/Exercise Component: No (both intervention groups) Theory: Motivational Interviewing, Cognitive Behavioural Therapy & Social Cognitive Theory (both intervention groups) Usual care: n=24	Group 2: Group sessions	Behavioural Expert (Clinical Psychologist)		and self-reported physical activity: minutes/day (self-report diaries) BMI
De Greef et al 2011[117] Belgium Endocrinology Department	N = 92 % Male = 69% Mean age (SD); 62 (9.0) years Time Since Diagnosis: >5 years = 82% Management:	Intervention: A pedometer-based behavioural modification program with telephone support targeting physical activity and sedentary behaviour n=60 Duration: 24 weeks Intensity: One 30 minute face to face session and a supportive telephone call every 2 weeks for the first 4 weeks and every 4 weeks for the	One individual face to face session and 7 telephone calls	Psychologist	Baseline, 24 weeks and 1 year	HbA1c Objectively assessed physical activity: pedometer steps/day; accelerometer minutes/day; and self-reported physical activity minutes/day (International Physical Activity Questionnaire [IPAQ])

	Combination of oral medication and insulin = 44%	following 20 weeks supervised PA/Exercise Component: No Theory: Motivational Interviewing, Cognitive Behavioural Therapy & Social Cognitive Theory Usual care: n=32				
Di Loreto et al 2003[118] Italy Outpatient Diabetes Clinic	N=340 % Male = 47% Mean age (SD); 61.6 years (intervention group); 62 years (usual care) Time Since Diagnosis: mean 7.6 years Management: Diet = 10% OHA = 76% Insulin = 14% Insulin and Metformin = 21%	Intervention: Structured counselling targeting physical activity n=182 Duration: 2 years Intensity: One 15 minute appointment every 3 months and one telephone call at one month following the first consultation Supervised PA/Exercise Component: No Theory: Social Cognitive Theory Usual Care: n=158	Individual face to face sessions	Physicians	Baseline, 3 months and 2 years	HbA1c Self-reported physical activity: hours/wk and METs per h/week (Modifiable Activity Questionnaire [MAQ]) BMI
Gram et al 2010[119] Denmark	N = 68 % Male = 54%	Intervention (Group 1): Nordic Walking (NW) n=22	NW: Group sessions EP: Group	Physiotherapist	Baseline, 4 and 12 months	HbA1c Self-reported physical activity: hours spent on physical activity

Nordic Walking: Outdoors on forest paths Exercise Prescription: Gymnasium	Mean age across groups ranged from 59 to 62 years Time Since Diagnosis: Not reported Management: Not reported	Intensity: Participants trained twice per week for the first two months and once per week during the final 2 months. In total participants received between 25 and 27 sessions. Each supervised session lasted 45 minutes and included a 10-minute warm-up, 30 minutes of Nordic walking, and a 5-minute cool down. Participants were instructed to walk at a speed of at least moderate intensity (>40% of VO2max) continuously for a minimum of 30 minutes. Intervention (Group 2): Exercise Prescription (EP) n=24 Intensity: Participants trained twice per week for the first 2 months and once per week during the final 2 months. In total participants received between 25 and 27 sessions. Each supervised session lasted 45 minutes and included a 10-minute warm-up, 30 minutes of exercise and a 5-minute cool down. Training intensity was individually based; however, participants had to work continuously for a minimum of 30 minutes at a workload of at least moderate intensity (>40% of Vo2max). Prescription included both strength training and aerobic exercise. Duration: 4 months Supervised PA/Exercise Component: Yes (both NW and EP groups)	Sessions			and activities of daily living (unvalidated questionnaire) BMI

		Theory: No Usual Care: n=22				
Kim & Kang 2006[120] South Korea Outpatient Diabetes Clinic	N = 73 % Male = 53% Mean age (SD); 55.1 (7.42) years Time Since Diagnosis: mean (SD) = 7.3 (6.05) years Management: OHA = 68%	Intervention (Group 1; Web-based): Stage-based physical activity counselling intervention for use by care providers n=28 Intensity: Two clinic visits during the first 2 weeks and one further visit at the midpoint during the 12-week intervention period Intervention (Group 2; Printed Material): As above but in printed form n=22 Intensity: Two clinic visits during the first 2 weeks and one further visit at the midpoint during the 12-week intervention period Duration: 12 weeks Supervised PA/Exercise Component: No (both intervention groups) Theory: Transtheoretical Model (both intervention groups) Usual Care: n=23	Individual face to face sessions	Research Nurse	Baseline and 12 weeks	HbA1c Self-reported physical activity using a self report instrument adapted from a 7-day recall questionnaire: METs-h/wk
Kirk et al 2004[121]	N = 70 % Male = 50%	Intervention: Counselling targeting physical activity	Individual face to face sessions	Trained Research Assistant	Baseline, 6 and 12 months	HbA1c Objectively assessed physical

UK Setting not explicitly reported	Mean age (SD); 57.6 (7.9) years Time Since Diagnosis: Not reported Management: Not reported	n=35 Duration: 6 months Intensity: Two face-to-face sessions and four follow-up telephone calls at 1, 3, 7 and 9 months Supervised PA/Exercise Component: No Theory: Transtheoretical Model Usual Care: n=35				activity: Accelerometer counts and self-reported physical activity using a 7-day recall questionnaire: minutes/ wk spent active BMI
Kirk et al 2009[122] UK University	N = 134 % Male = 49% Mean age ranged from 59.2 to 63.2 years Time Since Diagnosis on average ranged from 9.8 to 12.4 years Management: OHA = 54% Insulin = 10% OHA and insulin = 5%	Intervention (Group 1; Physical Activity Counseling in person): Two 30-minute one-to-one consultations at baseline and 6 months where written physical activity packs were given to participants and used by the researcher to discuss relevant topics during the consultation n=47 Intensity: Two 30 minute sessions and four 5-10 minute telephone calls at 1 ,3, 6 and 9 months) n=47 Intervention group 2; Physical Activity Counseling in written form: A written physical activity pack was given to participants to work through in their own time n=52	Individual face to face sessions	Trained Research Assistant	Baseline, 6 and 12 months	HbA1c Objectively assessed physical activity: Accelerometer counts/ wk and self-reported physical activity using a 7-day recall questionnaire: minutes/wk BMI

		Intensity: Two 30 minute sessions and three 5-10 minute telephone calls at 1, 3, 6 and 9 months Duration: 12 months Supervised PA/Exercise Component: No (both intervention groups) Theory: Transtheoretical Model (both intervention groups) Usual Care: n=35				
Ligtenberg et al 1997[123] Netherlands Setting not reported for supervised exercise Participants continued to exercise at home	N = 58 % Male = 34% Mean age (SD); 61 (5.0) for usual care & 63 years (5.0) for intervention group Time Since Diagnosis: mean (SD) = 9.4 years (7.3) for control group & 6.6 years (4.6) for intervention group Management: Insulin = 34%	Intervention: A 4-phase physical training programme n=30 Duration: 26 weeks Intensity: Prior to training at home, study participants trained together three times per week for 6 weeks under direct supervision. In addition they received a telephone call once every two weeks over a 6 week period Supervised PA/Exercise Component: Yes Theory: Not explicitly stated Usual Care: n=28	Group sessions	Physician and physiotherapist	Baseline, 6, 12 and 26 weeks	HbA1c Self-reported physical activity using a validated questionnaire

Plotnikoff et al 2010[124] Canada Diabetes Clinics & Community	N=48 % Male = 33% Mean age = 55 years (intervention) and 54 years (usual care) Time Since Diagnosis: Not reported Management: Not reported	Intervention: Home-based resistance exercise three times per week n=27 Duration: 16 weeks Intensity: During the first 2 weeks the exercise specialist supervised all three sessions. This was reduced to twice per week during weeks 3–4, once per week during weeks 5–8 and once biweekly during the last 8 weeks. In total the exercise specialist supervised 18 of 48 sessions supervised PA/Exercise Component: Yes Theory: Not explicitly stated Usual care: n=21	Individual face to face sessions	Exercise specialist	Baseline and 16 weeks	HbA1c Self-reported physical activity: MET minutes/wk (Godin Leisure Time Questionnaire [GLTQ]) BMI
Plotnikoff et al 2011[125] Canada Community	N = 96 % Male = 40% Mean age (SD); 60 (27-78) years Time Since Diagnosis: mean (SD) = 6 (9.8) years Management: Not reported	Intervention: Diabetes Education Program (DEP) plus a supplemental theory based physical activity counselling intervention (DEPplusPAS) n=47 Duration: 8 weeks Intensity: Eleven group sessions over the duration of the intervention period were delivered as part of the DEP. Two face-to-face sessions and 13 supportive telephone calls were provided concurrently as part of the supplementary programme. Telephone support was offered weekly for the first two months and bi weekly for 2.5 months	DEP: group sessions Supplemental program (PAS): Individual face to face sessions	Diabetes Educator (DEP) Personal Trainer (DEPplusPAS) Nurse (Fitness testing)	Baseline, 3, 6 and 12 months	HbA1c Self-reported physical activity: MET minutes/wk (Godin Leisure Time Questionnaire [GLTQ]) BMI

		supervised PA/Exercise Component: No Theory: Social Cognitive Theory and Transtheoretical Model Usual care: n=49				
Samaras et al 1997[126] Australia Community Leisure Centre	N = 26 % Male = 38% Mean age = 60.5 years Time Since Diagnosis: Not reported Management: Diet and Metformin = 35% Sulfonylurea = 39% Insulin = 27%	Intervention Group: 6 month exercise support group programme targeting physical activity n=13 Duration: 6 months Intensity: Monthly 1 hour sessions with the group facilitator and one other team member. The exercise sessions remained available to participants within the intervention group. Supervised PA/Exercise Component: Yes Theory: Precede-proceed Model Usual Care: n=13	Group exercise with individual face to face sessions	Nurse Exercise physiologist Dietician Physician Group facilitator	Baseline, 6 and 12 months	HbA1c Self-reported physical activity: METs (validated questionnaire) BMI
Tudor-Locke et al 2004[127] Canada Diabetes education centre	N = 60 % Male = 55% Mean age (SD); 52.7 (5.2) Time Since Diagnosis: Mean = 2.7	Intervention: The First Step Programme targeting everyday levels of physical activity n=24 Duration: 16 weeks Intensity: Four weekly group meetings for the first 4 weeks that included a group walk. Motivational postcards were mailed at 6 and at	Group sessions	Physical activity experts/diabetes educators	Baseline, 16 and 24 weeks	HbA1c Objectively assessed physical activity: Pedometer steps/day

	years Management: Diet = 55.3% OHA = 47.4%	10 weeks. Supervised PA/Exercise Component: Yes Theory: Social Cognitive Theory Usual Care: n=23				
Wisse et al 2010[128] Netherlands Outpatient Diabetes Clinic	N = 74 % Male = 51% Mean age (SD): 54.3 years (intervention) and 51.3 years (usual care) Time Since Diagnosis: Not reported Management: Exogenous insulin treatment (100%)	Intervention: Personalized exercise prescription. An extended version of the Physician-based Assessment and Counselling for Exercise (PACE) project. n=38 Duration: 2 years Intensity: Two 1-hour consultations with a physical therapist and a 15 minute telephone call at 2 and 6 weeks. Over the 2-year follow-up period, a 30-minute consultation was alternated every 6 weeks with a 15 minute telephone call. Supervised PA/Exercise Component: No Theory: Transtheoretical Model Usual Care: n=36	Individual face to face sessions	Physical therapist	Baseline, 1 and 2 years	HbA1c Self-reported physical activity: METs/week (Tecumseh/Minnesota Scale) BMI

Appendix E: Exploratory work interview topic guide

Ongoing learning

1. Where do you get most of your CPD training?
   Online learning? Taught courses? Books? Journals
2. How do you choose the CPD training you undertake?
   Reviews? Recommendations? Info in the post? Practice manager choice?
3. Which of your CPD training experiences do you most vividly remember?
   Format? Subject? Tutor?
4. What was the worst/most ineffective CPD training you can remember?
   Format? Subject? Tutor?
5. When and where do you do most of your CPD learning?
   Break times at work? After hours at work? At home? Off site?
6. Have you ever done an online CPD course?
   Name? Subject? Good or bad?
7. How much time do you spend on a computer in an average day?
6. How would daily working life and CPD training decisions differ between:
   - a GP who is also a practice manager?
   - a locum/temporary GP?
   - a full-time salaried GP?

Learning about diabetes

1. Where did you FIRST receive training on diabetes & diabetes care?
2. When did you LAST receive training on diabetes & diabetes care?
   Where did you receive the training?
   Why did you undertake this training – requirement? Personal interest?
3. Where would you go to for answers, if you were asked a question about diabetes you couldn't answer?

Treating patients with diabetes

1. When did you last see a patient newly diagnosed with type 2 diabetes?
2. How many people with type 2diabetes do you see in average working week?
3. What are the defining features of a consultation with a patient with diabetes?
   Positive attitude? Negative attitude? Well-informed discussion? Bad news? Good improvement?
4. What's the most difficult thing to discuss with patients about their diabetes?
5. What % of diabetes care should be delivered by GP practices?
6. Which health professional is most responsible for supervising patient diabetes care and ongoing management?

Delivering lifestyle interventions

1. What's the hardest thing about delivering lifestyle interventions to patients?
2. What makes patients pay attention to lifestyle advice?
3. What's the best way to encourage people to make lifestyle changes?
4. Do you ever give patients leaflets or literature to take away?
5. Where do you get most of the leaflets or literature you give to patients / place in the waiting room?
   Who chooses it? Do you pay for it?
   Do you have a choice about using it?

Appendix F: Movement as Medicine for Type 2 Diabetes Online Training Programme Certificate

This is to certify that

Ms Leah Avery

Newcastle University, Newcastle upon Tyne

is trained to provide

Movement as Medicine for Type 2 Diabetes.

Accreditation details

Modules completed:	1. Introduction to Movement as Medicine for Type 2 diabetes 2. Assessment of Movement as Medicine in routine primary care 3. Metabolism and Type 2 diabetes 4. Physical activity in the care of Type 2 diabetes 5. Physical activity and exercise 6. Using psychology to change physical activity behaviour 7. Using behaviour change strategies to promote physical activity behaviour 8. Screening before physical activity
Date of completion:	06/08/2012
NHS CPD points:	3
Accredited by:	Royal College of Physicians

Appendix G: Usability Testing Feedback Questionnaire for Healthcare Professionals

Movement as Medicine for Type 2 Diabetes:

Feedback Questionnaire

1. **Module 1 – Introduction to Movement as Medicine**

Does this module provide enough information about the purpose of the programme?

Yes No (Please circle your answer)

Do you have any suggestions as to how it could be improved?

_____
_____

2. **Module 2 – Assessment of Movement as Medicine in Routine Primary Care**

Does this module provide sufficient information about how Movement as Medicine will be evaluated and why?

Yes No (Please circle your answer)

Following completion of this module, on a scale of 1-10 (with 10 being the most confident), how confident are you that you could describe Movement as Medicine and how it will be evaluated to a colleague? (Please circle your answer)

1 2 3 4 5 6 7 8 9 10

What did you like most about this module?

_____
_____

Do you have any suggestions as to how it could be improved?

_____
_____

3. **Module 3 – Metabolism and Type 2 diabetes**

Thinking about physical activity as a management option for adults with Type 2 Diabetes:

On a scale of 1-10 (with 10 being the most relevant), how relevant did you find the content of this module? (Please circle your answer)

1 2 3 4 5 6 7 8 9 10

On a scale of 1-10 (with 10 being the most useful), how useful did you find the content of this module? (Please circle your answer)

1 2 3 4 5 6 7 8 9 10

What did you like most about this module?

_____
_____

Do you have any suggestions as to how it could be improved?

_____
_____

4. Module 4 – Physical activity in the care of Type 2 diabetes

Did this module change your thinking about physical activity/exercise as a management option for Type 2 diabetes?

Yes No (please circle your answer)

What did you like most about this module?

_____
_____

Do you have any suggestions as to how it could be improved?

_____
_____

5. Module 5 – Physical Activity & Exercise

Did this module change your thinking about using physical activity/exercise to manage Type 2 diabetes?

Yes No (Please circle your answer)

Could you please explain your answer?

_____
_____

What did you like most about this module?

_____
_____

Do you have any suggestions as to how it could be improved?

_____
_____

6. Module 6 – Using psychology to change physical activity behaviour

Did this module change your thinking about the use of behavioural strategies to increase levels of physical activity in your patients?

Yes No (Please circle your answer)

Could you please explain your answer?

_____
_____

What did you like most about this module?

_____
_____

Do you have any suggestions as to how it could be improved?

_____
_____

7. Module 7 – Using behavioural strategies to promote physical activity behaviour

Following completion of this module, on a scale of 1-10 (with 10 being the most confident), how confident are you that you could successfully use this programme with your patients? (Please circle your answer)

1 2 3 4 5 6 7 8 9 10

What did you like most about this module?

_____
_____

Do you have any suggestions as to how it could be improved?

_____
_____

8. Module 8 – Screening before physical activity

Does this module provide enough information about screening patients before they become more physically active?

Yes No (Please circle your answer)

Do you have any suggestions as to how it could be improved?

_____
_____

9. General Programme Feedback

Was there a particular module that you found most useful?
Yes No (Please circle your answer)
If yes, could you please indicate which one?

_____
_____

Was there a module that you didn't find particularly useful?
Yes No (Please circle your answer)
If yes, could you please indicate which one?

_____
_____

Were there any topics **not** covered by the programme that you were expecting to see?
Yes No (Please circle your answer)

If yes, could you please tell us what they were?

_____
_____

Were there any topics covered by the programme that you did **not** expect to see?
Yes No (Please circle your answer)
If yes, could you please tell us what they were?

_____
_____

Do you believe the name of the programme reflects its content?

Yes No (Please circle your answer)
If no, could you please tell us why?

_____
_____

On a scale of 1-10 (with 10 being the most satisfied), how satisfied were you with the time it took to complete each module? (Please circle your answer)

1 2 3 4 5 6 7 8 9 10

How would you use this training programme in practice? (Please circle your answer(s)

1. Complete the programme all at once and **not** refer back to it once completed
2. Complete the programme all at once and refer back to it as and when needed
3. Complete the programme over a period of time and **not** refer back to it
4. Complete the programme over time and refer back to it when needed

Any further comments about how and when you would use this programme?

_____
_____

On a scale of 1-10 (with 10 being the most satisfied), how satisfied were you with the content of this programme? (Please circle your answer)

1 2 3 4 5 6 7 8 9 10

10. **Video clips**

On a scale of 1-10 (with 10 being the most useful), how useful did you find the video clips presented throughout this programme? (Please circle your answer)

1 2 3 4 5 6 7 8 9 10

Was there a particular video clip that you felt was most useful to your practice?

Yes No (Please circle your answer)

Could you please explain your answer?

_____
_____

11. Programme tasks

Did the quick tasks facilitate your understanding?

Yes No (Please circle your answer)

Could you please explain your answer?

_____
_____

On a scale of 1-10 (with 10 being the most helpful), how helpful did you find the interactive exercises presented throughout this programme? (Please circle your answer)

1 2 3 4 5 6 7 8 9 10

12. Quiz questions

On a scale of 1-10 (with 10 being most appropriate), how appropriate did you find the quiz questions presented at the end of each module? (Please circle your answer)

1 2 3 4 5 6 7 8 9 10

Do you believe the quiz questions helped to consolidate your learning throughout this programme?

Yes No (Please circle your answer)

Could you please explain your answer?

_____
_____

Could the module quiz questions be improved?
Yes No (Please circle your answer)
If yes, could you please tell us how?

_____
_____

Could you please tell us about any features of the programme that worked well or didn't work well for you?

_____
_____

Could you please tell us about any problems you encountered with the programme?

_____
_____

Would you recommend this programme to a colleague?

Yes No (Please circle your answer)

Could you please explain your answer?

_____
_____

Appendix H: Usability Testing Feedback Questionnaire for Primary Care Patients

Feedback Questionnaire

We have given you a case containing four task cards, an activity planner and tracker. We would be grateful if you would tell us what you think of these by answering the questions below. Your feedback is very valuable to us because it will help us to improve the look and content of the materials so that they can be used by people like you to become more physically active.

1) Please tell us what you think of the case

- Based on the description written on the case, what did you expect this package to do?

  _____
  _____
  _____

- Based on the description on the case, would you want to watch the DVD inside?

  ◯ Yes ◯ No

  - What might make it more attractive/appealing?

    _____
    _____

- If you were given this pack to take home, where would you keep it?

  _____

2) Please tell us what you think of the printed booklet and discussion card

Discussion Card – How am I doing right now? (Yellow)

- Is there enough space for you to write your answers? ◯ Yes ◯ No
- Would you find it difficult to complete any part of this card? ◯ Yes ◯ No
  - If yes, please tell us which part (A,B,C,or D) and why.

    _____
    _____

- **Do you think you would make use of Part 1 A of the booklet? (Orange)**

  ◯ Yes ◯ No ◯ Maybe

  - If you have answered 'no', please tell us why

    _____
    _____

- How might this section be improved?

  _____

Part 1 B and C of the booklet – How do I set myself goals? (Green)

- Is there enough space for you to write your answers? ◯ Yes ◯ No
- Would you find it difficult to complete any part of this card? ◯ Yes ◯ No
  - If yes, please tell us which part and why

    _____
    _____

- Do you think you would make use of Part 1 B and C ◯ Yes ◯ No ◯ Maybe
  - If you have answered 'no', please tell us why

    _____
    _____

- How might this section be improved?

  _____
  _____
  _____

Part 2 A, B and C– How do I track my progress? (Red)

- Is there enough space for you to write your answers? ◯ Yes ◯ No
- Would you find it difficult to complete the activity planner sheets? ◯ Yes ◯ No
  - If you have answered 'yes', please tell us why

    _____
    _____
    _____

- Do you think you would make use of Part 2 A, B and C? ◯ Yes ◯ No ◯ Maybe

- If you have answered ‘no’, please tell us why

  _____

  _____

- How might this section be improved?

  _____

  _____

  _____

Part 3 – How can I reward my good work? (Blue)

- Is there enough space for you to write your answers?? ◯ Yes ◯ No
- Would you find it difficult to complete any part of this card? ◯ Yes ◯ No
  - If yes, please tell us which part and why

    _____

    _____
- Do you think you would make use Part 3? ◯ Yes ◯ Maybe ◯ No
  - If you have answered ‘no’, please tell us why

    _____

    _____
- Which side of the sheet would you prefer to use?

  ◯ Tracking Activities ◯ Tracking Steps
  - Please tell us why

    _____

    _____
- Would you make use of the Activity Planner sheets? ◯ Yes ◯ No ◯ Maybe
  - If you have answered ‘no’, please tell us why

    _____

    _____

Please think about the pack overall and answer the following questions:

- Did the instructions throughout the pack make sense to you? ◯ Yes ◯ No
  - If not, please tell us which parts need improving

    _____

    _____
- Was any of the information in the pack difficult to read? ◯ Yes ◯ No
  - If yes, please tell us which part(s)?

    _____

    _____

- If you saw the pack in your GP surgery would you pick it up and look at it?

◯ Yes ◯ Maybe ◯ No

- If you saw the pack in your local library would you borrow it?

◯ Yes ◯ Maybe ◯ No

  - If you have answered ‘no’ to either of the questions above could you tell us why?

    _____

    _____
- If you could add ONE more thing to the pack what would it be?

  _____

  _____

  _____
- How likely is it that this pack could help you or someone like you to become more physically active? ◯ Not at all likely ◯ Unlikely ◯ Likely ◯ Very likely
- Could you please explain your answer?

  _____

  _____

Finally, please write any other suggestions or comments you have about the pack you have reviewed below. If you run out of space you can continue to write on the blank page at the end

_____
_____
_____

Thank you for the time you have taken to review this pack

Your feedback is very valuable to us. If you would like any further information about Movement as Medicine for Type 2 Diabetes, please contact Leah Avery by calling 0191 222 8264 or Email: leah.avery@ncl.ac.uk

Appendix I: Movement as Medicine for Type 2 Diabetes Intervention Toolkit Version 2 – Post usability Testing

Contents:

A: Discussion card

- grid to assess PA/exercise levels over the past 7 days
- decisional balance aid
- readiness rulers

B: Paper-based Activity Planners and Trackers

C: Patient Booklet

- goal setting
- action planning
- barrier identification / problem-solving
- relapse prevention / coping planning
- self-monitoring strategies of PA/exercise

D: A Patient DVD

- Patient narratives
- Vicarious learning of strategies to increase PA/Exercise
- Boosting self-efficacy

E: A record of progress (duplicate) sheet

F: Pedometer

Appendix J: Letter confirming a favourable ethical opinion

NHS
Health Research Authority

NRES Committee North East - Sunderland
Room 002
TEDCO Business Centre
Viking Business Park
Jarrow
Tyne & Wear
NE32 3DT

Telephone: 0191 4283563
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13 April 2012

Dr Michael I Trenell
NIHR Senior Research Fellow & Director:
MoveLab Physical Activity & Exercise Research
Newcastle University
Faculty of Medical Sciences
4th Floor, William Leech Building
Framlington Place
Newcastle upon Tyne NE2 4HH

Dear Dr Trenell

Study title:	**A cluster-based randomised controlled trial to assess feasibility, acceptability and effectiveness of a multi-faceted behavioural intervention targeting levels of physical activity in adults with Type 2 diabetes in primary care: Movement as Medicine for Type 2 diabetes**
REC reference:	**12/NE/0037**

Thank you for your letter of 12 March 2012, responding to the Committee's request for further information on the above research [and submitting revised documentation].

The further information has been considered on behalf of the Committee by myself as Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a **favourable ethical opinion** for the above research on the basis described in the application form, protocol and supporting documentation [as revised], subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Appendix K: Theoretical Domains Framework Interview Topic Guide for Healthcare Professionals

Interview schedule

Movement as Medicine for Type 2 Diabetes – Open Pilot

ONLINE TRAINING PROGRAMME

1. What are your views about online training programmes in general to prepare you to deliver a behaviour change intervention?

GENERAL

1. How has MaM been able to help you approach PA with your patients?
2. Has MaM made it any easier to discuss MaM with your patients? If so how?
3. Do you see any barriers to implementing this programme in routine practice?

KNOWLEDGE

1. Have you acquired any new knowledge from the programme that you have been able to use in practice so far?
2. What impact do you feel the training programme has had on your knowledge of physical activity?
3. What impact do you feel the training programme has had on your knowledge of behavioural strategies to help patients increase their levels of PA?

SKILLS

1. To what extent do you feel the online training programme has equipped you with additional skills to support your patients to become more physically active?
2. How confident do you feel about using counseling and behaviour change skills with your patients?
3. What have you learned (if anything) that you feel you could use when addressing other lifestyle issues?
4. To what extent do you believe your behaviour change skills will help patients to become more active?
5. Have you started to use anything from this programme in other areas of your practice?
6. Is there anything in the programme you have struggled with? And if so is there anything the research team could do to help you and others?

PROFESSIONAL ROLE AND IDENTITY

1. Now that you've used the programme, who do you feel is Who is best placed to use it in routine practice?

BELIEFS ABOUT CAPABILITIES

1. How easy is it to use the intervention in practice?
2. To what extent do you believe the intervention will help your patients to become more active?
3. How do you believe the first time you delivered the intervention compared to the subsequent times you delivered it?
4. Thinking about the first time you delivered the programme; do you believe you have got better over time? If so how?
5. Has your confidence when delivering the programme increased, decreased or stayed the same. If so why/how?
6. What else might you need to deliver the programme effectively?
7. How confident are you that you can deliver the intervention when faced with issues (e.g., running behind schedule, the intervention conflicts with other priorities etc)?
8. How well equipped do you feel to deliver the programme?
9. How comfortable do you feel about delivering the programme?
10. To what extent do you feel the online training programme has equipped you to deliver the intervention?

OPTIMISM

1. How optimistic do you feel about using this programme with your patients?
2. Now that you've completed the online training and had the chance to use the programme with patients, how optimistic do you feel about using it long term
3. How do you feel about using the programme with patients?

BELIEFS ABOUT CONSEQUENCES

1. Prior to delivering the programme, what were your expectations of it?
2. To what extent does it meet your expectations?
3. Do you expect patients to use the toolkit they have been given and to what extent?
4. What do you believe the outcome will be of patients completing this programme?
5. Do you feel the programme will be worthwhile?
6. To what extent do you enjoy using it?

REINFORCEMENT

1. Which aspects of the programme do you feel will help you succeed in delivering it?

INTENTIONS

1. Now that you've delivered the programme does it make you want to use it again?
2. Thinking about using this programme in routine practice, how far up the list of priorities would it be now that you've experienced using it?
3. To what extent do you intend to use what you've learned from the programme in other areas of practice?

MEMORY, ATTENTION AND DECISION PROCESSES

1. To what extent has MaM increased the likelihood that you will target PA in routine diabetes clinics?
2. Were you able to remember to deliver all aspects of the intervention appropriate to the individual patient?
3. How much attention do you feel you had to pay to deliver all aspects of the programme
4. How were you able to remember to deliver all aspects of the programme?
5. Did you have to leave anything out, and why?
6. Which aspects of the programme do you feel you delivered well?

SOCIAL INFLUENCES

1. How much discussion have you had with colleagues about this programme?
2. Have you been able to discuss among you which parts of the programme are most useful?

EMOTIONS

1. How stressful did you find delivering the programme?
2. Thinking about using it in routine practice, to what extent do you believe factors such as stress, tiredness or fear of delivering the intervention 'incorrectly 'will get in the way of you using the programme effectively?

BEHAVIOURAL REGULATION

1. You said last time that you had printed some materials from the IMPACT website. Did you prepare anything else?
2. Could the research team have provided you with anything else that would have helped you to deliver the programme?
3. Is there anything else needed to help prepare patients to engage with this programme?

NATURE OF THE BEHAVIOURS

1. To what extent do you feel you have developed any new skills by using the online programme and delivering the programme to patients?
2. How long do you believe it will take for you to incorporate the strategies learned from the training programme in to your routine practice?
3. How likely are you to return to the online training programme?

Appendix L: Theoretical Domains Framework Interview Topic Guide for Patients

Interview Questions

KNOWLEDGE

1. To what extent do you feel you've learned anything new about diabetes and physical activity since being in the study?
2. Now that you've attended your second appointment on a scale of 0-10 with ten being a lot, and zero being nothing at all, how much do you believe your knowledge has improved? Would you mind explaining your answer?
3. To what extent do you feel you have gained enough knowledge to understand what you could potentially gain from Movement as Medicine?
4. To what extent do you believe the practice (by using this programme) has given you the knowledge you need to use this programme?
5. Is there anything you feel you know now that you didn't know before you joined the study? Either about physical activity, diabetes or both?

SKILLS

1. To what extent has the Movement as Medicine toolkit supported you to become more physically active? (the DVD, contents of the box, pedometer and support of the practice
2. How confident are you that this toolkit will help you to stay active over the coming weeks or months?
3. Has being in this programme equipped you with any skills that you believe have made their way in to your regular routine?
4. How much have you used your toolkit?
5. On a scale of 0 to 10 with ten being the very likely, how likely are you to use the toolkit long-term?

SOCIAL ROLE AND IDENTITY

1. Have you told others (friends and family members for example) that you are taking part in this study? If so what was their reaction?
2. To what extent has physical activity become part of who you are?
3. Would you say being active has always been part of who you are?

BELIEFS ABOUT CAPABILITIES

1. What problems or difficulties have you encountered when using the toolkit?
2. Is there anything else you feel the practice or research team could have provided to help you become more active or maintain your activity levels?
3. How confident are you that you can become more active and maintain your activity levels by using the toolkit?
4. To what extent do you feel the support of your GP/practice nurse is needed to help you increase your levels of physical activity?

OPTIMISM

1. How optimistic are you that Movement as Medicine will help to increase your levels of physical activity:
   - Over the next couple of weeks?
   - Over the next 6-12 months?

BELIEFS ABOUT CONSEQUENCES

1. To what extent does Movement as Medicine meet your expectations so far?
2. Do you feel you are getting anything out of the programme so far?
3. What do you hope to get out of the programme long-term?
4. How likely do you think it is that you will get out of the programme what you want?
5. Have there been any disadvantages of taking part so far?

REINFORCEMENT

1. Which part of the programme do you think is most likely to help you stay on track? (e.g., a part of the toolkit or having review appointments at the practice?)
2. What is the main incentive for you carrying on with the programme?
3. How have you managed to fit this programme in to your everyday life?
4. Have you had to make any changes to your routine?

INTENTIONS

1. How likely is it that you would have thought about increasing your levels of physical activity before taking part in Movement as Medicine?
2. How has Movement as Medicine changed the way you think about physical activity so far?
3. To what extent do you intend to make physical activity part of your everyday life?

GOALS

1. How high up on your list of priorities is becoming more active?
2. How much support do you feel you need to reach your goal and from who?

MEMORY, ATTENTION AND DECISION PROCESSES

1. How much effort has it taken to stick to the programme?
2. Do you have to remind or prompt yourself to stick to the programme each day?
3. Is there anything that has or is likely to distract you from the programme?

ENVIRONMENTAL CONTEXT AND RESOURCES

1. Have you used the help of anything or anyone else to help you increase and sustain your levels of activity?
2. What (if anything) is likely to stop you from being more active?
3. What is likely to help you to maintain your level of physical activity?

SOCIAL INFLUENCES

1. Have you experienced any pressures that have got in the way of you progressing with the programme?
2. Have you worked through the programme by yourself or with the help of others?

EMOTIONS

1. How has taking part in the programme made you feel (e.g., more tired, stressed, happier, more energetic, more confident etc)?
2. How much does your mood influence your decision to follow the programme?

BEHAVIOURAL REGULATION

1. To what extent do you feel the activity planners, trackers and pedometer have helped you to increase and maintain your levels of physical activity?
2. Which have you used (activity planners [planning time}, trackers [tracking steps])?

OUTCOME MEASURES

1. How have you got on with completing the study questionnaires?
2. What was your experience of wearing the physical activity monitoring watch?

OVERALL

1. How confident are you after leaving your appointment today that you can carry o
2. n using your toolkit, increasing and maintaining your level of physical activity?
3. How confident are you that the programme will help you to manage your diabetes?
4. Which aspects of the programme do you like so far?
5. Which aspects of the programme would you change?
6. What do you think of the record of progress form that you receive at the end of each appointment?
7. What do you think of the programme so far?
8. On a scale of 0-10 with ten being most satisfied, how satisfied are you with the programme?
9. Finally we would like to hear how you get on with the programme.
10. Would you be willing to be interviewed again in a few months' time?

Appendix M: Fidelity Coding Checklist

Movement as Medicine for Type 2 Diabetes Intervention Content Coding Instrument

Coder: _____ Date:___/___/_____ Video Recording ID:_____

Consultation No. 1 2 3 4 (Please circle)

		Quality of delivery					
Intervention Component/ Behaviour Change Technique	Technique Utilised Yes/No/N/A	Low				High	Notes
Agenda Setting	Yes/No/N/A	0	1	2	3	4	
Discussion Card							
Review current physical activity behaviour	Yes/No/N/A	0	1	2	3	4	
Review of Pros and Cons	Yes/No/N/A	0	1	2	3	4	
Review of Importance ruler score	Yes/No/N/A	0	1	2	3	4	
Review of Confidence ruler score	Yes/No/N/A	0	1	2	3	4	
Provide feedback on performance	Yes/No/N/A	0	1	2	3	4	
Provide info on consequences of behaviour to individual	Yes/No/N/A	0	1	2	3	4	
Toolkit Booklet							
Discuss menu of options	Yes/No/N/A	0	1	2	3	4	
Goal setting (behaviour)	Yes/No/N/A	0	1	2	3	4	
Plan social support/social change	Yes/No/N/A	0	1	2	3	4	
Action planning	Yes/No/N/A	0	1	2	3	4	
Barrier identification/problem solving	Yes/No/N/A	0	1	2	3	4	
Provide information on where and when	Yes/No/N/A	0	1	2	3	4	
Prompt self-monitoring of PA behaviour	Yes/No/N/A	0	1	2	3	4	
Provide contingent rewards	Yes/No/N/A	0	1	2	3	4	
Relapse prevention/coping planning	Yes/No/N/A	0	1	2	3	4	
Not explicitly linked to intervention materials							
Prompt focus on past success	Yes/No/N/A	0	1	2	3	4	
Time management (i.e. freeing up time to be active)	Yes/No/N/A	0	1	2	3	4	
Prompt review of behavioural goals	Yes/No/N/A	0	1	2	3	4	
Prompt generalisation of physical activity behaviour	Yes/No/N/A	0	1	2	3	4	

Video recordings N=32: Baseline n=17; 1 month follow up n=15; Primary healthcare professionals N=6

Appendix N: Summary Table Presenting Results of Treatment Fidelity Assessment

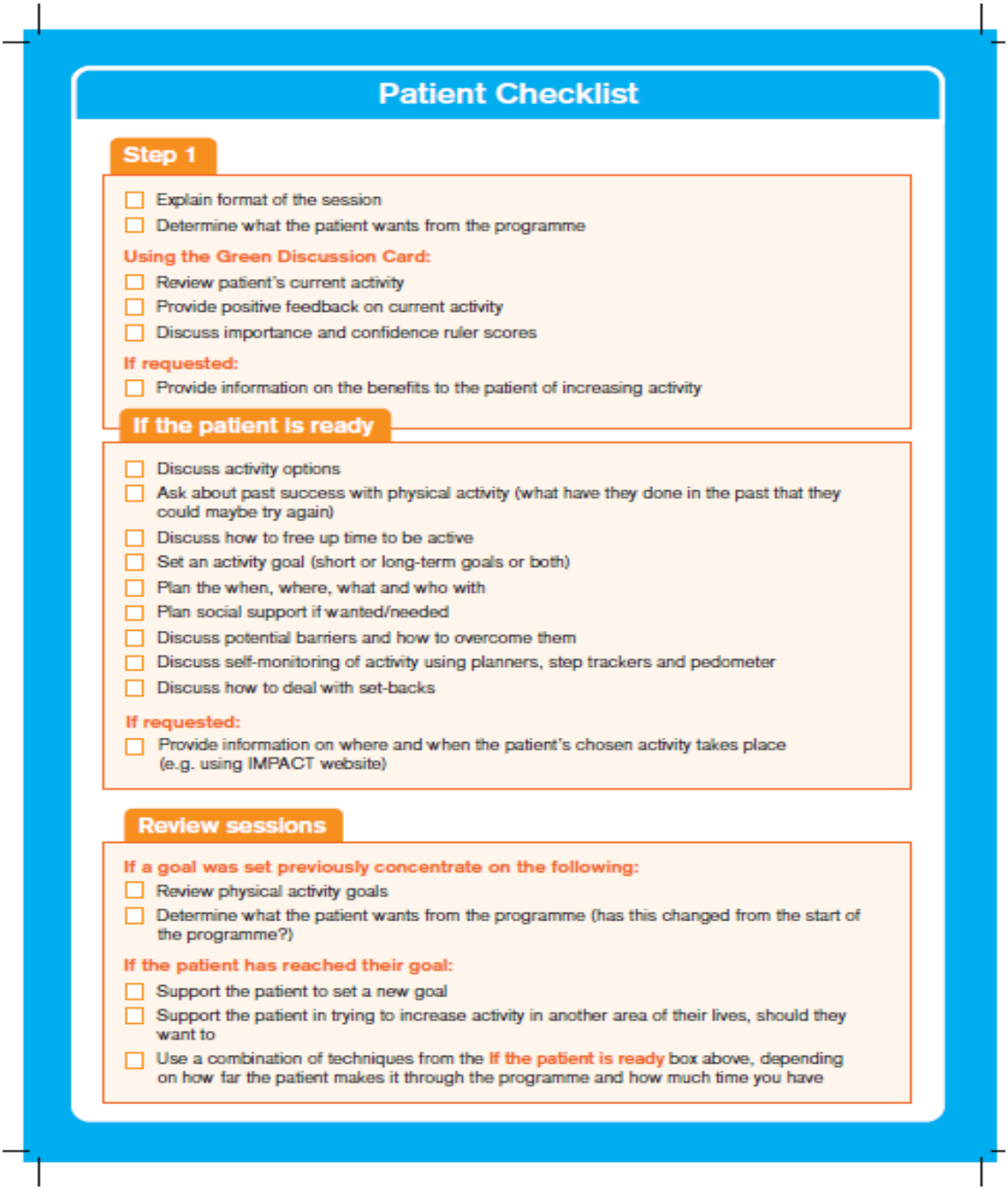
HCP	Video	Baseline / 1-Month	Agenda Setting	Review current PA	Pros & Cons	Ruler Importance	Ruler Confidence	Feedback	Info on consequences for individual	Menu of PA options	Goal setting	Social support	Action planning	Barrier Ident/problem solving	Info on where and when	Self-monitoring	Contingent rewards	Relapse prev/cop plan	Past success	Time management	Review of behavioural goals	Generalisation
1	1	DUROPT001	N	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	N	N	N	N	N	N
1	2	DUROPT001	N	Y	N	Y	Y	Y	N	N	Y	N	N	N	Y	Y	Y	N	N	N	Y	N
2	3	DUROPT002	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	N	N	N	N	N
2	4	DUROPT002	N	Y	N	N	N	Y	N	N	Y	N	N	N	N	Y	N	N	N	N	Y	N
3	5	DUROPT003	N	Y	Y	Y	Y	Y	N	N	Y	N	Y	N	N	Y	Y	N	N	N	N	N
3	6	DUROPT003	Y	Y	Y	Y	Y	Y	N	N	Y	N	Y	Y	N	Y	Y	N	N	N	Y	N
2	7	DUROPT004	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	N
2	8	DUROPT004	N	Y	N	N	N	Y	N	N	N	N	N	N	N	Y	N	N	N	N	Y	N
1	9	DUROPT005	N	Y	N	Y	Y	Y	N	N	Y	Y	Y	Y	N	Y	Y	N	N	N	N	N

HCP	Video	Baseline 1-Month	Agenda Setting	Review current PA	Pros & Cons	Ruler Importance	Ruler Confidence	Feedback	Info on consequences for individual	Menu of PA options	Goal setting	Social support	Action planning	Barrier Ident/problem solving	Info on where and when	Self-monitoring	Contingent rewards	Relapse prev/cop plan	Past success	Time management	Review of behavioural goals	Generalisation
1	10	DUROPT005	N	Y	N	Y	Y	Y	N	Y	N	Y	N	N	N	Y	Y	N	N	N	Y	N
2	11	DUROPT006*	N	Y	N	Y	Y	N	Y	Y	N	Y	N	N	Y	Y	N	N	Y	N	N	N
3	12	DUROPT007	Y	Y	Y	Y	Y	Y	N	Y	N	Y	N	N	Y	Y	N	N	Y	N	N	N
3	13	DUROPT007	N	Y	N	Y	Y	Y	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	N
3	14	DUROPT008	N	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	N	Y	Y	N	N	N	N	N
3	15	DUROPT008	N	Y	N	Y	Y	Y	N	N	Y	Y	N	N	N	Y	Y	Y	N	N	Y	N
3	16	DUROPT009	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
3	17	DUROPT009	N	Y	N	Y	Y	Y	Y	N	Y	N	Y	N	N	Y	Y	N	N	N	Y	N
1	18	DUROPT012	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	N	N	Y	Y	N	N	N	N	N	N
1	19	DUROPT012	N	Y	N	N	N	Y	Y	N	Y	Y	N	Y	Y	Y	N	N	Y	N	Y	N
2	20	DUROPT015	N	Y	Y	N	N	Y	N	Y	Y	Y	N	Y	Y	Y	Y	Y	N	N	N	N
2	21	DUROPT015	N	Y	N	Y	Y	N	Y	N	Y	N	N	N	N	Y	N	N	Y	N	N	N
1	22	DUROPT016*	N	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	N	N	N	N	N
1	23	DUROPT017*	N	Y	N	Y	Y	Y	Y	N	Y	N	N	N	N	Y	Y	N	N	N	Y	N

1	**24**	**DUROPT018***	N	Y	N	N	N	Y	N	N	Y	Y	Y	Y	N	Y	Y	N	Y	N	Y	N
4	**25**	**MAMOPT002**	Y	Y	Y	Y	Y	Y	Y	N	N	Y	N	N	N	Y	N	N	N	Y	N	N
4	**26**	**MAMOPT002**	N	Y	N	Y	Y	Y	N	N	Y	N	Y	N	N	Y	N	N	N	N	Y	N
4	**27**	**MAMOPT004***	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	N	N	Y	Y	N	N
5	**28**	**MAMOPT016**	N	Y	N	Y	Y	N	N	Y	Y	N	Y	N	Y	Y	N	N	N	N	N	N
5	**29**	**MAMOPT016**	Y	Y	N	N	N	Y	N	N	Y	N	N	N	N	Y	N	N	Y	N	Y	N
5	**30**	**MAMOPT017***	N	Y	N	Y	Y	Y	Y	N	N	Y	N	N	Y	Y	N	N	N	N	N	N
5	**31**	**MAMOPT076**	Y	Y	N	N	N	Y	Y	Y	Y	Y	Y	N	Y	Y	N	N	N	N	N	N
5	**32**	**MAMOPT076**	N	Y	N	N	N	Y	Y	N	Y	N	Y	Y	Y	Y	N	N	N	N	Y	N
		Total yes at baseline	**5**	**16**	**9**	**14**	**15**	**13**	**10**	**12**	**12**	**14**	**10**	**7**	**9**	**16**	**7**	**2**	**3**	**2**	**0**	**0**
		Total yes at 1-month	**2**	**15**	**1**	**10**	**8**	**14**	**5**	**1**	**13**	**5**	**6**	**5**	**5**	**15**	**8**	**2**	**5**	**0**	**15**	**0**
		Total	**7**	**31**	**10**	**23**	**23**	**27**	**15**	**13**	**25**	**19**	**16**	**12**	**14**	**31**	**15**	**4**	**8**	**2**	**15**	**0**

Video recordings were triple coded **Discrepancies between coders were discussed until consensus was reached**

Appendix O: Patient Checklist



Patient Checklist

Step 1

- ☐ Explain format of the session
- ☐ Determine what the patient wants from the programme

Using the Green Discussion Card:

- ☐ Review patient's current activity
- ☐ Provide positive feedback on current activity
- ☐ Discuss importance and confidence ruler scores

If requested:

- ☐ Provide information on the benefits to the patient of increasing activity

If the patient is ready

- ☐ Discuss activity options
- ☐ Ask about past success with physical activity (what have they done in the past that they could maybe try again)
- ☐ Discuss how to free up time to be active
- ☐ Set an activity goal (short or long-term goals or both)
- ☐ Plan the when, where, what and who with
- ☐ Plan social support if wanted/needed
- ☐ Discuss potential barriers and how to overcome them
- ☐ Discuss self-monitoring of activity using planners, step trackers and pedometer
- ☐ Discuss how to deal with set-backs

If requested:

- ☐ Provide information on where and when the patient's chosen activity takes place (e.g. using IMPACT website)

Review sessions

If a goal was set previously concentrate on the following:

- ☐ Review physical activity goals
- ☐ Determine what the patient wants from the programme (has this changed from the start of the programme?)

If the patient has reached their goal:

- ☐ Support the patient to set a new goal
- ☐ Support the patient in trying to increase activity in another area of their lives, should they want to
- ☐ Use a combination of techniques from the **If the patient is ready** box above, depending on how far the patient makes it through the programme and how much time you have