Keeping Adults Physically Active
Intervention development and randomised controlled feasibility study

Volume 1

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Thesis submitted to the University of Nottingham, School of Primary Care, for the Doctor of Philosophy Degree

February 2019

Thesis word count: 98,860

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Acknowledgements and Contribution by Author

I would like to express great thanks to my supervisor's Dr Liz Orton, Professor Denise Kendrick and Professor Pip Logan for their continued support throughout my PhD. Their expert knowledge, encouragement, insightful guidance and professional and emotional support helped me to finalise this PhD and the writing of this thesis.

I have been fortunate to have the support of many others throughout each stage of my PhD journey. I would like to thank my dear friend Dr Asiya Maula for the huge amount of time she spent in helping me conduct the systematic review and for the support she has given as a friend. I am also appreciative to my fellow co-worker and friend Natasher Lafond who has invested much time in teaching me qualitative research methods and helping me with my analysis. I am thankful to Clare Timblin who was very kind in supporting me with the administration of the study.

A great appreciation goes out to the NIHR School of Primary Care and the University of Nottingham's Medical School, as this work would not have been possible without their financial support. Additionally, I am grateful to the Keeping Active research group who allowed me to use the research data to help develop the KAPA intervention.

A special mention goes to Eileen Baron, Peter Riley and the physical activity service providers and members of the expert steering group, for freely giving me their time to help develop and implement the KAPA intervention. A huge thanks is owed to the PSIs and KAPA participants who kindly agreed to partake in the study. The feasibility study would not have been at all possible without their involvement.

Last, but by no means least, I would like to thank my family and friends who have believed in me and supported me emotionally throughout my PhD journey.

Contribution by author

The National Institute Health Research division of School of Primary Care Research funded me to complete this PhD study. I performed the systematic review, wrote the study protocol, consented the participants into the study and trained the Postural Stability Instructors to deliver the Keeping Adults Physically Active (KAPA) programme and collect the participant's field data. On completion of the intervention I collated the quantitive data, interviewed the participants, analysed the study findings and wrote the current thesis. I would like to acknowledge the following people who helped me with this study:

Dr Elizabeth Orton: Contributed to the systematic review by acting as a third reviewer in the article selection, data extraction and risk of bias (RoB) assessment stages. Dr Orton also performed a second eligibility check on the included studies. She contributed to the feasibility study by helping with the costing of the intervention in its development stages. She also helped to create the STATA "do files" needed for the statistical analysis of the socio-demographic and PA data. Dr Orton contributed to the writing of the thesis by reviewing and providing feedback on the chapters. She was also a member of the Keeping Active study research team who contributed the results of their study to help with the development of the KAPA intervention.

Professor Denise Kendrick: Contributed to the systematic review by performing second eligibility checks on the included studies. Professor Kendrick contributed to the feasibility study by creating STATA "do files" and running the statistical analysis of the PA data. She also contributed

to the writing of the thesis by reviewing and providing feedback on the chapters. Professor Kendrick was also the Chief Investigator on the Keeping Active study who contributed the results of their study to help with the development of the KAPA intervention.

Professor Pip Logan: Contributed to the systematic review by performing second eligibility checks on the included studies. Professor Logan contributed to the thesis writing by reviewing and providing feedback on the chapters. She was also a member of the Keeping Active study research team whose results were used to help with the development of the KAPA intervention.

Dr Asiya Maula: Contributed to the systematic review by acting as the second reviewer in the article selection, data extraction and RoB assessment stages. Dr Maula was also a member of the Keeping Active study research team who contributed the results of their study to help with the development of the KAPA intervention.

Jeanette Eldridge: Is a medical librarian who contributed to the systematic review by helping to create and test the sensitivity of the list of electronic search terms.

Natasher Lafond: Was a key member of the Keeping Active study research team who contributed the results of their study to help with the development of the KAPA intervention.

Dr Claire Blackmore: Contributed to the feasibility study by creating and providing the STATA “do files” that converted the raw Phone-FITT

questionnaire data into minutes of total physical activity (PA), strength and balance exercise and moderate-to-vigorous PA.

Clare Timblin: Contributed to the systematic review and feasibility study by providing administration support.

Eileen Baron: Eileen is an educational consultant who contributed to the development of the KAPA training package by reviewing and providing feedback on the learning outcomes, learner manual and learning materials.

Peter Riley: Peter is a PPI representative who provided feedback on the development of the KAPA intervention and participant manuals.

Physical Activity service providers: Contributed to the development of the participant manuals by creating a timetable of PA opportunities delivered within their localities.

Later Life Training: Contributed to the development of the participant manuals by permitting me to include the Later Life Training exercise booklet within the participant manuals.

List of Acronyms

Abbreviation	Acronym
AM	Asiya Maula
BCT	Behaviour change technique
BCW	Behaviour change wheel
BL	Baseline
CG	Control group
CHAMPS	Community Healthy Activities Model Program for Seniors
CI	Confidence interval
CMO	Chief Medical Officer
CO	Change objective
COM-B analysis	Capability, opportunity, motivation-behaviour analysis
EO	Elizabeth Orton
FaME	Falls Management Exercise
FTF	Face to face
ICC	Intra-class coefficient
IG	Intervention group
IM	Intervention Mapping
QR	Interquartile range
JE	Jeanette Eldridge
KAPA	Keeping Adults Physically Active
Kcal	Calories
KG	Kilogram
MDT	Multidisciplinary team
MET	Metabolic Equivalent
MPA	Moderate physical activity
NHS	National Health Service
NICE	National Institute of Clinical Excellence
NIHR	National Institute for Health Research
NL	Natasher Lafond
OR	Odds Ratio
PA	Physical activity
PAL	Physical activity level
PHISICAL	PHysical activity Implementation Study In Community-dwelling AduLts

PO	Performance objective
PPI	Patient and public Involvement
PSI	Postural stability instructor
QoL	Quality of life
RCT	Randomised Control Trial
REC	Research Ethics Committee
RoB	Risk of Bias
SA	Sarah Audsley
SCT	Social Cognitive Theory
SD	Standard Deviation
SDT	Self Determination Theory
SMART	Specific, Measurable, Attainable, Relevant and Time framed
SOP	Standard Operational Procedures
TPB	Theory of Planned Behaviour
TTM	Transtheoretical Model
UK	United Kingdom
ZL	Zena Lam

Abstract

Introduction

Physical inactivity contributes to disability and falls in community dwelling older adults. Regularly attending falls prevention exercise programmes improves health, physical function and reduces falling rates in older people. However, older adults rarely maintain moderate to vigorous physical activity (MVPA) beyond 12 months after exercise programmes end, which results in the beneficial health effects being lost. Research is needed to examine whether physical activity (PA) can be maintained in older adults exiting falls management exercise (FaME) programmes.

Aim

The aim of this PhD was to develop and investigate the feasibility of an intervention to maintain PA in community-dwelling adults aged 65 years and older exiting FaME programmes.

This aim was achieved by the following research objectives:

1. To identify effective intervention strategies for maintaining PA in older adults by conducting a systematic review.

2. To use the findings of the systematic review alongside an intervention development tool and an expert steering group to design an intervention that aims to maintain PA in older adults who have attended a FaME programme.

3. To conduct a study to test the feasibility, acceptability and fidelity of delivering the PA maintenance intervention to a group of older adults exiting the FaME programme. To examine the acceptability of, and adherence to the intervention by the participants and Postural Stability Instructors (PSI). To estimate the study parameters needed for a future definitive trial.

Methods

Systematic review: Controlled studies assessing interventions for maintaining PA, in people aged 65 years and older, were identified from electronic bibliographic databases and hand searching. Two researchers independently assessed for eligibility, risk of bias and extracted data. Only studies assessing community dwelling older adults aged 65 years old and older were included. Study characteristics, behaviour change strategies, intervention features, delivery modes and PA outcomes were synthesised narratively.

Intervention development: The Keeping Adults Physically Active (KAPA) intervention was developed using Bartholomew's intervention mapping (IM) framework. The IM process involved creating intervention objectives by reviewing qualitative data on older adults' PA determinants. Effective PA intervention strategies were identified in the systematic review and the National Institute of Clinical Excellence (NICE) guidelines for PA and behaviour change. The intervention strategies and programme design was built from the output of these initial stages. An expert steering group guided the design of the KAPA intervention and its implementation plan.

KAPA Feasibility study: A feasibility study was conducted in 8 FaME classes (4 intervention and 4 control groups) between January 2017 and January 2018. The study design was a two-arm, cluster randomised, multi-site feasibility study comparing the KAPA intervention with usual care controls. A sample of 10 PSIs and 50 community-dwelling adults aged 65 years old or older were recruited.

Quantitive and qualitative research methods were used to examine the KAPA intervention. Acceptability, feasibility, adherence and fidelity were assessed by:

i) Estimating study recruitment, retention and attendance rates.

ii) Examining acceptability by conducting semi-structured interviews with the participants in receipt of, and the PSIs delivering, the KAPA intervention.

iii) Investigating adherence by: a) analysing the PSI's completion rates of the class registers; b) examining class registers for the KAPA participants' adherence with the PA diaries and goals.

iv) Examining the fidelity of the KAPA intervention using class observations and PSI interviews.

v) Investigating parameter estimates for a future definitive trial by: a) estimating the potential effect size in terms of MVPA, b) estimating the intraclass correlation coefficient (ICC) for MVPA.

vi) Describing usual care by its intervention components.

vii) Identifying the data collection tools needed to cost the intervention in a definitive trial.

viii) Recording adverse events and assessing them for causality in relation to the delivery of the KAPA intervention.

Results

Systematic review: The search yielded 25,761 publications and 19 studies met the inclusion criteria. Of the 19 studies, 13 reported significantly maintaining PA. There was considerable heterogeneity between the studies and interventions delivered. Interventions delivered on a monthly, or quarterly basis over an intervention period of 6 months to 2 years most consistently maintained significant PA effects. Interventions were effective regardless of delivery mode, setting, intervention provider or whether delivered to groups or individuals. Providing pedometers, counselling and motivational interviewing helped to sustain PA. Most studies (n=17) were judged to be of an unclear or high risk of bias.

Intervention development: The KAPA intervention comprised of six group sessions of motivational interviewing, delivered by a trained and

mentor supported PSI. Participant manuals, illustrated exercise books and PA monitoring tools supported the KAPA intervention. KAPA sessions lasted between 60 to 90 minutes and were delivered in community-based venues over a 6-month duration. Participants unable to attend group sessions received the KAPA intervention via telephone.

KAPA Feasibility study:

Recruitment, retention and adherence rates: The aim of recruiting 120 participants was not achieved. Fifty of the sixty-seven participants (74.6%) invited into the study agreed to take part. Forty-five participants (92.3%) provided outcome data at the 6-month time point. Attendance rates to the KAPA intervention sessions were high as 94.2% of the total available sessions were attended.

Acceptability: Delivering KAPA was acceptable from the perspective of the PSIs. KAPA participants often expressed positive views about the venues and PSIs and talked about gaining enjoyment from group interactions. Many discussed the writing activities to be the least enjoyable element of the KAPA intervention. PA engagement was reinforced by peer support. During the interviews the KAPA intervention participants discussed increasing their walking and home-based exercise activities. Participants believed the illustrated home exercise booklet and the PA monitoring tools helped them keep active.

Adherence: Participant and PSI adherence with the KAPA intervention could not be assessed due to missing register data.

Fidelity: Fidelity observations showed that 75% of the intervention components were delivered. Three intervention PSIs discussed adapting KAPA during the semi-structured interviews.

Parameter estimates: The proportion of participants reporting at least 150 minutes of MVPA per week rose from 56.3% to 62.5% in the intervention arm and from 41.4% to 52.0% in the usual care arm (OR

1.25, 95% CI 0.26 to 5.88, p=0.78). The ICCs for reaching the target 150 minutes of MVPA weekly was 0.000 (95% CI 0.000 to 0.237).

Usual care descriptive: Usual care was described as the continued provision of FaME as an exercise maintenance class.

Data collection tool: Cost data relating to telephone usage was inaccurate. The current cost proforma needs adapting before its use in a definitive trial.

Adverse events: Three adverse events, possibly relating to KAPAs delivery, were reported.

Conclusion

The systematic review suggested that PA maintenance programmes can help older adults stay active. The findings suggested that intervention time periods and contact frequency may influence effectiveness. The knowledge gained from the review, NICE guidelines and the expert steering group helped to develop the KAPA intervention.

The KAPA intervention consisted of six-monthly group sessions of motivational interviewing, supported by written materials and self-monitoring tools. PSIs found the KAPA intervention feasible to deliver. Participants reported the illustrated home exercise booklet, peer support and the PA monitoring tools encouraged them to keep active. A definitive trial is needed to assess whether PA can be significantly maintained in response to the KAPA intervention.

Keywords: Behaviour change, PA maintenance, community-dwelling, older adults, feasibility, motivational interviewing, FaME.

READER'S NOTE: Please be aware that this thesis is presented in two volumes. The first volume contains the main text of the PhD thesis. The second volume contains an appendix of supplementary materials that support the main text. Please cross-reference volume 1 and volume 2 whilst reading the main PhD thesis.

Chapter 1. An Introduction to Physical Activity and Ageing Health

1.1 Summary of Chapter 1

Ageing is associated with deteriorations of health and physical function which increases disability and falling risk in older adults. Regularly performing physical activity (PA) improves older peoples' health and functional status. Falls Management exercise (FaME) programmes help increase PA levels, improve physical function and reduce falling risk in older adults. However, PA is rarely maintained after the completion of falls prevention exercise programmes. Over time, improvements in balance, strength and physical function are lost if people do not remain active after exercise programmes end. The purpose of this chapter is to discuss the evidence that highlights the need for the development of an intervention aiming to maintain PA in older adults exiting FaME.

1.2 Ageing, Physical Activity and Falls

1.2.1 Ageing population

Ageing is associated with declines in health, physical, cognitive and social wellbeing which has detrimental effects on independence and quality of life [1]. The increasing proportion of older adults in western populations is associated with the development of disability and many chronic diseases [1,2]. In the United Kingdom (UK) the percentage of the population aged 65 years and older has grown from 14.2% in 1976 to 18% in 2016 [3]. This proportion is predicted to increase to 24.7% by the year 2046 [3]. The number of UK citizens living with poor health is estimated to linearly rise with the ageing population which will amplify the stresses on health and social care resources and inflate long-term health care costs [4].

In an attempt to reduce the burden that ageing has on poor health, researchers and policy makers are increasingly focusing on developing interventions that influence the modifiable health behaviours that impact the aging process [1]. Particularly, interventions that encourage people to become more active have positive effects on ageing health as this delays, and in some cases can reverse, the onset of disability and age-related disease [1].

1.2.2 Physical activity and health

PA is defined as any bodily movement produced by contracting skeletal muscle that increases energy expenditure above basal resting levels [5]. PA is an umbrella term that includes planned activity, such as structured exercise and sport, and habitual activities like those performed during activities of daily living [5,6]. PA is characterised by the intensity of the activity performed (i.e. sedentary, light, moderate and vigorous) which is determined by the amount of energy expended (see text box 1) [6].

Epidemiological reports show that people are becoming less active which has contributed to an increased prevalence of over twenty chronic diseases and the recognition that physical inactivity is the fourth leading cause of early mortality worldwide [7-13]. Regularly performing moderate-to-vigorous PA (MVPA) benefits health as this reduces the risk of developing many non-communicable diseases including most cancers, cardiovascular, metabolic and musculoskeletal disease [7,14]. Therefore, promoting habitual PA is a disease prevention strategy is of increasing global importance [13].

Text box 1.

Definition of physical activity (PA) terms.

Sedentary behaviour occurs when people spend periods of time in reclining positions. Such behaviour requires no energy to be expended beyond baseline resting levels.

Light PA is an activity that requires small amounts of physical exertion and energy expenditure. Heart or breathing rate is not noticeably increased.

Moderate PA noticeably increases heart and breathing rate through more moderate efforts of movement.

Vigorous PA are activities that require maximum and sub-maximum efforts. This results in rapid heart rate and breathing rates.

Moderate-to-vigorous PA (MVPA) this is a term used to combine moderate and vigorous PA. The UK government advises on performing 150 minutes of MVPA per week.

1.2.3 Physical activity in older adults

Epidemiological studies show that older adults have the lowest PA levels of all populations. This has contributed to the disproportionate prevalence of chronic disease, disability and falls in people over 65 years old [2,6,15,16]. Such physical inactivity related conditions cost the National Health Service (NHS) over £1.06 billion per year, and a further £2.3 billion is spent on the treatment of falls [13,17,18]. Therefore preventing falls and disease in older adults is a public health priority [19,18].

Strategies aiming to modify older peoples' PA behaviours may help to support healthy ageing and mitigate the current demand on healthcare resources [12,20,21]. PA interventions are effective at reducing falls, improving function and health and modifying disease progression in older adults [22,23,24]. In an effort to improve the health of older adults the Chief Medical Officer (CMO) guidelines encourage people to perform 150 minutes of MVPA plus two sessions of strength and balance exercise weekly [4,13]. It is estimated that 44% of UK citizens aged 65 and over meet the MVPA target. However only 12% meet both the MVPA

and muscle strength target and 27% meet both the MVPA and balance targets [25]. The likelihood of disability, falls and disease is markedly increased in the older adults not meeting all three targets [4,13,25].

1.2.4 Physical activity and falling risk

Approximately one third of adults aged over 65 years old, and half of adults aged over 80 years old fall each year [26,27]. It is estimated that 5% to 20% of falls in community dwelling older adults result in injury or hospitalisation [28,29]. In England, falls in older adults contribute to 255,000 emergency hospital visits per year and the annual NHS spend on the treatment of falls related injury is estimated to cost £2.3 billion [19]. The human cost of falls includes injury, declines in physical function, confidence and loss of independence [28]. Loss of physical independence caused by severe injurious falls often results in premature admission into care-assisted living [29].

Multiple factors increase falling risk. These include visual impairment, environmental hazards, medications, dizziness, poor balance, muscle strength loss and mental capacity deterioration (e.g. dementia) [27-29]. Physical inactivity contributes to deterioration of physical health as this results in cumulative muscle weakness, poor balance, gait dysfunction and functional impairment that markedly increases the risk of falls and severe injury [30,31].

Often inactivity originates from a fear of falling that reduces older adult's confidence and self-belief in their ability to perform activities of daily living [32-35]. In an effort to avoid falls, older adults down regulate their activity levels which contributes to further deconditioning, fragility and social isolation [28,29,35]. Helping older adults to overcome PA barriers encourages PA engagement which improves muscle strength, balance, functional status and reduces falling risk [22,35,36].

1.2.5 Falls prevention exercise programmes

Multifactorial falls prevention programmes that contain exercise components helps with the avoidance of 400 hip fractures per year [37]. This saves the NHS £5 million per year as well as reducing the human cost of falls [37]. Evidence shows falls prevention exercise programmes that target strength, balance and flexibility reduce falling rates in community dwelling older adults by 21%, with the greatest outcomes seen in programmes lasting 3, or more, hours per week [22,38]. Reduced falling rates are a result of muscle strength, balance and physical function improvements that older adults experience in response to exercise [24,39,40]. Therefore government guidelines recommend that falls prevention programmes should include strength and balance exercise [18,28].

The Otago and Falls Management Exercise (FaME) programmes are the most commonly delivered falls prevention exercise schemes within the UK. Otago is a home-based strength and balance exercise programme that is delivered by trained professionals to community dwelling older adults at risk of falls. Otago recipients are encouraged to perform exercises thrice weekly over a 52 week time period [41]. A meta-analysis showed Otago helps approximately 36.7% of recipients to remain active three or more times a week over a 12 month period (Standard Deviation (SD) 15.8%, range 18 to 63%) [42]. Although the review concludes that participants adhered to the Otago programme, it is unknown what proportion meet the PA guideline targets, as the authors did not report the time spent in each PA domain.

FaME is a class-based exercise programme delivered by postural stability instructors (PSI) that consists of cardiovascular, balance, strength, Tai Chi and functional floor exercise. The ProAct 65+ clinical trial showed that a 24-week FaME programme resulted in 49% of

participants assigned to the FaME arm reached the CMO PA target of 150 minutes of MVPA per week when compared to the usual care arm (adjusted odds ratio 1.78, 95% confidence interval (CI) = 1.11 to 2.87, p=0.02). The FaME programme maintained PA for up to 12 months after FaME cessation and resulted in significantly lower falling rates (incidence rate ratio 0.74, 95% CI = 0.55 to 0.99, p= 0.042) [43]. However, 24 months after the trial ended many participants reverted back being less active [44]. If PA is not maintained after programmes end this results in the beneficial effects of exercise programmes to diminish [23]. Increased PA levels need to be maintained long after exercise programmes have ended so to preserve any improvements gained in strength, balance and health [23].

1.3 Physical Activity Maintenance

1.3.1 Importance of PA maintenance

Behaviour maintenance is defined as continued engagement in a behaviour over a given time period [45]. PA maintenance refers to the repetitive behaviour of regularly performing an increased volume of PA, otherwise known as habitual PA [45]. People who habitually perform PA inline with the CMO PA guidelines are referred to as being physically active [4].

Research shows that regularly performing PA modifies disease and improves physical function and quality of life in older adults [46-52]. Yet, if people do not continue to be active after exercise programmes have ended they will experience a period of detraining. A common phrase used to describe detraining is the “use it or lose it” principle whereby the lack of PA stimulus results in a partial or complete reversal of any physical performance or health benefits gained from exercise [53].

Research shows detraining in older adults results in a deterioration of bone and muscle mass, strength and balance, cardiovascular fitness and metabolic health [23]. Older adults need to engage with habitual PA inline with the PA recommendations so to maintain gains in cardiovascular health, balance and muscle strength after exercise programmes have ended [13].

1.3.2 PA interventions and PA maintenance in older adults

Community based PA interventions are commonly used to increase PA levels, modify disease and improve physical function and quality of life in older adults [46-52]. Maintaining PA and avoiding detraining after PA programmes have ended is critical to maximise clinical and cost effectiveness. Research surrounding this topic suggests that community dwelling older adults rarely maintain PA beyond twelve months after programmes have ended [43,47,52]. For this reason, researchers and service providers are increasing their focus on maintaining positive habitual PA behaviours after time capped exercise programmes have ended [54].

A systematic review published by Conn et al., [55] investigated PA behaviours in people aged 65 years and older in response to PA interventions. This review showed that supervised exercise and motivational strategies helped to increase peoples' PA levels in the short-term. No conclusions were drawn with regards to whether such interventions maintained long-term PA as very few longitudinal studies were found. A more recent meta-analysis by Hobbs et al., [47] synthesised the evidence to evaluate whether PA promotion interventions delivered to people aged 55 to 70 years of age are effective at sustaining long-term PA. The meta-analysis showed that PA interventions increased self-reported PA duration (SMD=0.19, 95% CI 0.10-0.28) and step count by 2,197 steps per day (SMD=1.08, 95% CI 0.16-1.99) at 12-

months, but not at 24-months. Currently it is unknown whether, or how, PA can be maintained beyond 12 months in people aged 65 years and older.

1.3.3 Behaviour change theories and techniques to support PA in older people.

Behaviour change theories and intervention effectiveness

The enactment of any given behaviour is dependent on individual state (i.e. motivations, intentions, habits and psychological resources) and environmental stimuli (i.e. opportunities, costs and cues) [56]. A behaviour performed in response to individual state or environmental stimuli is referred to as the "dominant response" [56]. Behavioural interventions aim to make good health behaviours the most "dominant response" as this encourages continued behaviour enactment regardless of a person's individual or environmental state [56].

Behaviour is complex and at least 83 behaviour change theories exist that aim to produce favourable health outcomes [57-59]. Behaviour change interventions have been found to be successful in initiating positive PA behaviours in older adults [47,60-62]. Theory based interventions are said to be more effective at changing health and PA behaviours compared to interventions without an underpinning theory [54,62-64]. Currently there is no consensus in the literature to support the use of one behaviour change theory over another to elicit the best PA responses in older people [60].

A systematic review assessing PA in older people reported that the Social Cognitive Theory and Transtheoretical Model based PA interventions produce larger effect sizes than those without a theoretical base [63]. Conversely, others report theoretically based interventions are

no more effective at producing favourable PA outcomes than those without a stated theory [62,65]. A meta-analysis assessing educational PA interventions found that Transtheoretical Model based interventions resulted in significantly smaller PA effect sizes when compared to those with other theoretical underpinnings [62]. The evidence base surrounding this topic appears very mixed. Hence, it is unsurprising that a recent systematic review of reviews concluded that the results were too mixed to link theory-based interventions with short and long-term PA effectiveness in older adults [60]. It is currently unknown whether theory-based interventions are superior to none theory-based interventions in helping older people to maintain PA.

Behaviour change techniques and intervention effectiveness

Behaviour change techniques (BCTs) are the active components delivered within interventions to encourage the enactment of desired behaviours [66]. The content of interventions, in terms of BCTs, is said to contribute to the success of health interventions [66]. Many systematic reviews report that PA interventions containing BCTs help to increase older people's PA levels [862,65,67]. However, there is a lack of consensus across the systematic reviews on which BCTs are effective at improving older peoples PA behaviours [60].

Evidence is consistent in suggesting BCTs relating to rewarding successful behaviour and demonstrating PA behaviours elicit positive PA outcomes in older people [60,68]. Otherwise, the body of evidence is inconsistent in identifying effective BCTs. French et al., [60] and Chase et al., [63] found barrier identification and problem solving techniques to improve older people's PA levels; whereas Conn et al., [62] found no effect and Zubala et al., [60] reported mixed effects on PA. Similarly, there are contradictory reports on relapse and prevention strategies [60,68]; goal setting [60,62,65,67,68]; feedback and self-monitoring [60,62,65,68]; motivational [62,67] and educational strategies [60,62]. Evidence has emerged suggesting that BCTs promoting self-regulation of behaviour (i.e. goal setting, self-monitoring, feedback and planning techniques) may negatively affect

older adults' PA levels [68]. Again contradictory evidence shows that MPA is increased at 18 months when clusters of self-regulatory BCTs are delivered to pre-diabetic populations [65]. Other authors have also reported self-regulatory strategies (i.e. goal setting) to be successful in helping older people to manage chronic disease [67].

It is unknown why there is a lack of agreement between systematic review findings. The vast majority of systematic reviews assessing PA in older people are considered to have high risks of bias, which may have influenced the outcomes reported in individual reviews [60]. Conn et al., [62] assessed the effect of PA interventions in older adults with chronic disease. The outcomes showed that older adults with arthritis generated larger PA effect sizes when compared to adults with diabetes or impaired cardiorespiratory health [62]. Therefore, it is possible that the lack of agreement within the literature is also due to different types of older people being included within studies.

Due to the diversity of systematic review findings, it remains unknown what behaviour change theories or BCTs are successful in promoting PA in older adults. There is also wide recognition that the evidence is absent, or at best unclear, on whether theory-based interventions and BCTs elicit PA maintenance in older people [47,60,65,68]. For this reason, investigating what intervention components may, or may not, encourage PA maintenance in older adults is of primary importance [47,60,69].

1.3.4 Theoretical explanations for behaviour maintenance

Behaviour change interventions are successful in initiating positive PA behaviours in older adults [47,60-62]. However, it is well known that the effects of behaviour change interventions diminish over time after a programme has ended [47,60,69,70]. Understanding why some people do,

whilst others do not, maintain good health behaviours can help to develop more effective interventions.

Kwasnicka et al.'s [56] recent systematic review synthesised 100 behaviour change theories to help improve the understanding of the theoretical explanations of behaviour maintenance. This review found that behaviours were more likely to be sustained if a person valued the behaviour and its outcomes. A person's level of self-efficacy and abilities in self-control, task switching, planning, evaluation and level of determination and willpower is also believed to affect behaviour maintenance [56]. Experiencing enjoyment and satisfaction from performing the behaviour also motivates a continual behaviour enactment [56].

Good social and physical environments help facilitate positive health behaviours [56]. Positive health behaviours remain more dominant when habits are formed in response to situational cues in people's social and physical environments. Conversely, environmental changes often result in the performance of non-habitual and negative health behaviours [56]. At times when poor health behaviours are performed a person's capacity to recover from lapses/relapses will affect whether behaviours are maintained [56]. Although these findings provide valuable information on what factors broadly influence behaviour maintenance the review did not specify which factors are more likely to affect specific behaviours or populations.

1.3.5 Potential explanations for PA maintenance in older adults

Literature emphasises that an older adult's cognitive processes such as perceived control, self-efficacy, motivation and health beliefs affect PA behaviours [71,72]. Such cognitions contribute to the development of multiple barriers towards being physically active. Cognitive barriers include fear of falling, reduced confidence and self-efficacy, reduced motivation, perceived lack of fitness, interest and belonging [33,73]. This helps to explain why increasing PA levels in older adults can be challenging. Yet, these factors do not explain the difficulties older adults face in maintaining PA after programmes have ended.

A recent qualitative study assessing PA maintenance behaviours in people who attended a 24 week falls prevention exercise programme reported very similar behaviour maintenance factors as those described in Kwasnicka et al's review [56] (Keeping Active Study paper currently under review). The recipients of the falls prevention programmes reported that they were more likely to continue to maintain PA if they valued the benefits of PA. Social environment played a large role in PA maintenance as people who enjoyed interacting with peers were more likely to continue attending exercise classes. PA was most likely to be sustained in people who were motivated by receiving positive reinforcement and feedback on their PA levels. The physical environment was also considered important. For example, the affordability and convenience of getting to class venues was said to affect whether people continued to attend classes. Using technology to monitor activity (i.e. pedometers and smart apps) also helped motivate PA participation (Keeping Active Study paper currently under review). This qualitative study provided a more specific understanding of factors influencing the continuation of PA after a falls prevention exercise

programme ended. Yet, at the point of initiating this PhD it was unknown how this information could be best used to develop interventions that aim to maintain the PA in older adults exiting FaME programmes.

1.4 Previous research contributing to the current thesis

Figure 1 depicts the previous research underpinning the Keeping Adults Physically Active (KAPA) study. The original FaME randomised controlled trial (RCT) showed falls rates were significantly lower in the FaME arm when compared to usual care [74]. During these early stages it was unknown whether FaME increased MVPA levels in its attendees. The ProAct 65+ trial addressed this research question by comparing changes in MVPA between FaME, OTAGO and usual care [43,44]. The ProAct 65+ results showed that the FaME participants significantly increased their MVPA levels and experienced significantly fewer falls at 12-months. Yet, these increases were not maintained at 24 months [44].

The evidence suggests that FaME is a clinically effective intervention [44,74]. However little was known about how well it could be implemented into local authority PA services [75]. There was also uncertainty surrounding whether the FaME service users could maintain PA beyond 12 months. The PHysical activity Implementation Study In Community-dwelling AduLts (PHISICAL) study examined the implementation of a FaME programme in commissioned PA services across Derby City, Leicestershire and Rutland Counties [75]. The PHISICAL study provided the opportunity to design, implement and test the feasibility of the KAPA PA maintenance intervention in the FaME participants. The KAPA feasibility study was approved as a sub-study and embedded into the PHISICAL implementation study to assess the feasibility and acceptability of an intervention aiming to maintain PA in the PHISICAL study participants.

The Keeping Active study qualitatively investigated the facilitators and barriers to PA maintenance in the ProAct 65+ trial participants (Keeping Active Study awaiting publication). The results showed that a range of physical, social, psychological and environmental factors influenced PA maintenance in the ProAct 65+ participants. These outcomes were subsequently used to help design the KAPA intervention, discussed in Chapter 3.

For the purpose of this thesis participants will be referred to as either being ProAct 65+, Keeping Active, PHISICAL or KAPA participants depending on which study they were recruited into last.

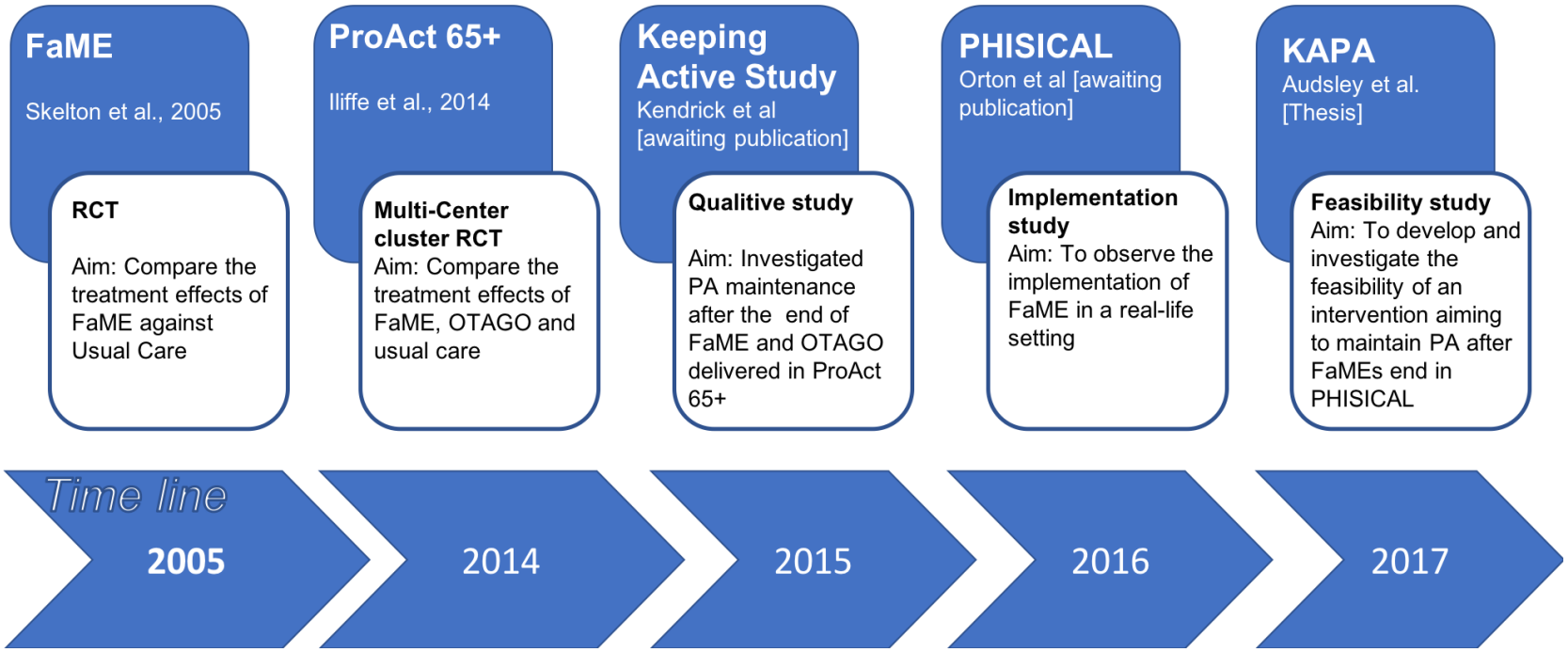


Figure 1. Previous research studies contributing to the rationale underpinning the KAPA feasibility study

1.5 Rationale for the current research

The 24-week FaME programme was investigated in the ProAct 65+ trial and was shown to increase the participants MVPA minutes [44]. Yet the longitudinal findings of the trial showed that between 12 to 24 months after FaMEs cessation 50.8% of participants no longer achieved the government guidelines of 150 minutes of MVPA and 15.5% performed no minutes of MVPA weekly [44]. Over time improvements in balance, strength and physical function gained from attending FaME programmes are lost and falls risks increase in older adults who do not remain active after FaMEs end.

Multiple controlled trials show PA maintenance interventions are effective in keeping older adults active [76-88]. The certainty is less on whether PA can be maintained in older adults exiting falls prevention exercise programmes [35,51,52]. This suggests that an intervention is needed to target the continuation of PA engagement after falls management exercises programme end.

The current study was designed to assess whether a PA maintenance intervention could help maintain PA in people aged 65 years and older exiting a community delivered FaME programme.

1.6 PhD Aims and Objectives

The aim of this PhD was to develop, implement and assess the feasibility and acceptability of an intervention aimed at maintaining PA in older adults exiting a FaME programme, in order to inform the conduct of a definitive randomised controlled trial.

The research objectives were:

- To understand which interventions are effective in maintaining PA in people aged 65 years and older by conducting a systematic review.
- To use the findings of the review alongside Bartholomew's intervention mapping framework to develop an acceptable intervention to maintain PA levels in people aged 65 years and older who have completed a 24- week FaME programme.
- To conduct a feasibility study to test the feasibility, acceptability and fidelity of delivering the intervention to a group of older adults exiting the PHISICAL FaME programme and to estimate the study parameters needed for a future definitive trial.
- To conduct a feasibility study to examine the acceptability and adherence with the PA maintenance intervention by the KAPA participants in receipt of, and the PSIs delivering, the KAPA intervention.

Chapter 2. What intervention components work best to improve physical activity maintenance in older adults? A Systematic Review

2.1 Summary of Chapter 2.

Chapter one rationales the need of a PA maintenance intervention to be developed to target FaME programme users. During this PhD's initial stages, it was unknown what intervention components would best work to help maintain PA in older adults. A systematic review was conducted to investigate the effects of PA maintenance interventions delivered to community dwelling older adults aged 65 years old and older. This chapter describes the systematic review's methodological processes and provides a critical appraisal of the evidence found. The systematic review increased our understanding on what intervention strategies and delivery modes best work to help older adults maintain PA. The important information found later informed the development of a PA maintenance programme aimed at older adults exiting the PHISICAL FaME programme. Please note that the current chapter has been submitted to the "Physiotherapy Journal" (in October 2018) for publication.

2.2 Systematic Review Introduction

Physical activity (PA) helps to modify disease and improve physical function and quality of life in older adults [46-52,89]. PA programmes increase older peoples PA levels which provides them with these added health benefits [46-52]. Yet, research shows that older adults PA levels wane between eight to twenty-four months after the completion of programmes. Subsequently, resulting in a reduction of any health benefits gained [43,47,52].

Maintaining good PA behaviours after the completion of PA interventions is important to help preserve older adults' health span, prevent disability and maintain quality of life. Understanding what intervention components work to maintain PA can help interventionists build more effective PA programmes. However, deciphering what intervention components work best can be difficult as the success of an intervention is determined by a complex matrix of behaviour change techniques (BCTs), intervention features and delivery modes.

To my knowledge, no systematic review has specifically explored which BCTs, intervention features and delivery modes work to help support PA maintenance in older people. The current systematic review aimed to increase our understanding of what works to improve the maintenance of PA in people aged 65 years old and older. The systematic review also explores whether interventions that aim to maintain PA are cost effective and affect self-efficacy and quality of life.

2.3 Systematic Review Methods

Method details are described in PROSPERO protocol: CRD42016038137.

2.3.1 Trial selection criteria

Study type and participants: Randomised and non-randomised controlled trials recruiting community-dwelling adults aged ≥65 years were included. Those recruiting participants with specific medical conditions (e.g. heart disease, hypertension, diabetes) were excluded. Non-controlled experimental trials and observational trials were excluded.

Intervention: PA maintenance interventions that were delivered at the end of, or were specifically embedded within, PA programmes were included. Physical activity and dietary changes are often targeted in healthy ageing interventions. Therefore, PA maintenance interventions that were delivered within, or as part of, a larger intervention that targeted multiple health risk factors (e.g. dietary control) were included.

Comparator: Only trials that compared the delivery of a "maintenance" intervention against a no maintenance intervention comparator group were included. Comparator groups were included if participants received no PA maintenance intervention, usual care or were placed on a waiting list.

Outcome: Included trials assessed subjective and/or objective measures of PA before and after the delivery of a PA maintenance intervention.

2.3.2 Search strategy

Five electronic databases (MEDLINE, EMBASE, PSYCInfo, CINAHL and PEDro) were searched. A previous systematic review [55] evaluated the delivery of PA promotion and maintenance interventions to people aged 65 years and older in literature published between 1960 to 2000. To avoid duplicating the efforts of these authors the database searches were limited to articles published during or after the year 2000. Databases were searched between January 2000 and January 2016. Searches were limited to human trials and to people aged ≥65 years and older but not by language.

A comprehensive list of search terms (Appendix 1) relating to PA, older people and controlled trials was created with the input from a medical librarian (JE). These were transformed into a Medline search strategy and modified for other databases. The reference lists of 39 published literature reviews reporting on PA interventions were hand-searched. The titles of the eligible papers found in the hand-searches were used to test the sensitivity of the electronic search strategy for each database. The citations found from the most sensitive search strategy were entered into endnote and duplicates removed.

2.3.3 Trial selection

Two reviewers (SA & AM) independently screened all titles and abstracts that the search yielded to identify eligible papers. Full text papers were retrieved when eligibility could not be determined from the abstract. The full texts of potentially eligible papers were independently assessed by both of the reviewers (SA & AM) against the eligibility criteria using a pre-piloted identification form. A third reviewer (EO) resolved any discrepancies or when eligibility could not be ascertained.

2.3.4 Data extraction

Two reviewers (SA and AM) independently extracted data from eligible trials using pre-piloted data extraction forms (Appendix 2). To avoid duplication, trials publishing multiple articles were grouped for data extraction. Data extracted included the trial type, participant characteristics, PA type (i.e. PA behaviour targeted) and interventions (described according to the TiDieR checklist [90]), comparator groups and outcomes. Direct quotes describing the BCT's used within the maintenance interventions were extracted by both reviewers on the data extraction form. Trial authors were contacted to request any missing data. A third reviewer (EO) resolved any discrepancies in the data extraction process.

2.3.5 Risk of bias assessment

Two reviewers (SA & AM) independently assessed the methodological quality of each randomised and non-randomised controlled trial using the guidance in the Cochrane Handbook for Systematic Reviews of Interventions [91]. As advised by the handbook, the researchers created a domain-based ROB assessment tool for RCTs which included an assessment of the following seven domains:

1. Random sequence generation
2. Allocation concealment
3. Blinding of the participants and personnel
4. Blinding of the outcome assessment
5. Incomplete outcome data
6. Selective reporting
7. Other bias

As advised by the Cochrane Handbook [91] for Systematic Reviews of Interventions a second ROB assessment tool was created for non-RCTs. This tool included an assessment for the following seven domains:

1. Allocation to the intervention / control arm
2. Blinding of the participants and personnel
3. Blinding of the outcome assessment
4. Risk of bias due to confounding
5. Incomplete outcome data
6. Selective reporting
7. Other bias

Each quality criterion was judged and assessed as a “low, unclear or high” risk of bias (RoB) across the seven RoB domains. To note, all self-reported measures of PA were categorised as a high RoB due to the inability to blind the participants to the outcome assessment. Objective PA measures were considered a low RoB if the outcome assessor was blinded or as a high risk of bias if there were no blinding procedures. The first and second reviewer compared and agreed on the RoB outcomes and a third reviewer resolved any disagreements in the critical appraisal process. The quality of the evidence was narratively summarised as the RoB across each separate domain [91].

2.3.6 Data analysis

A meta-analysis was planned but could not be performed due to the high heterogeneity between the PA interventions, PA measurement tools and outcomes reported. Therefore, the data was grouped and synthesised narratively. Interventions were categorised as booster interventions (delivered after a PA promotion programme) or integrated maintenance interventions (maintenance strategies incorporated within a PA promotion programme). A UK epidemiological report shows that the proportion of older adults achieving 150 minutes of MVPA weekly reduces from 55% in adults aged 65-74 years old to 27% in people aged 75 years and older [16]. Likewise, frail older adults spend less time performing MVPA when compared to non-frail adults [92]. Therefore, to explore the intervention effects in different populations, trials were categorised by participant age (<75 and ≥75 years) and participant group (i.e. frail older adults and fallers).

The delivery and features of each intervention was tabulated on an Excel spreadsheet using the TiDieR headings (i.e. behaviours targeted, intervention features, support, materials, provider, method of delivery, where delivered, dosage and intervention tailoring). Excerpts explicitly describing the BCTs used in the intervention in each trial were tabulated onto an excel spreadsheet. A researcher (SA) who had successfully completed the online training for coding BCTs (http://bct-taxonomy.com) coded the presence of BCTs within the texts using the v1 BCT taxonomy [93].

Trials were dichotomised and described as a significant effect or no significant effect on any measure of PA at each study's last data

collection point. The intervention features and delivery modes were then tabulated as being derived from a trial showing a significant or no significant effect on PA maintenance.

2.4 Systematic Review Results

2.4.1 Trial selection

The electronic search yielded 25,761 records. A further 91 articles were identified via hand searches. After removing duplicates and the titles and abstracts not meeting the inclusion criteria, 477 full texts were reviewed. Thirteen authors were contacted to provide further information on the participants [86,94-96], intervention components [78,82,97-99] or to provide outcome data [76,100-102]. Four authors did not provide the information requested [76,78,96,98,102] and nine provided information. Three articles were excluded due to insufficient information [96,98,102] and another three were excluded as the information received showed that there was no maintenance intervention comparison group [94,97,99]. After excluding these trials, twenty-nine articles reporting on nineteen trials fully met the eligibility criteria and were included in the review. The trial selection process is depicted in Figure 2.

Four of the nineteen trials had multiple published articles. Six articles reported on the LIFE-P trial [80], three on the SCAMOB Trial [77] and the Project LIFE trial [103] and two on the Green Prescription trial [85]. Table 1 lists the references of the included trials and articles.

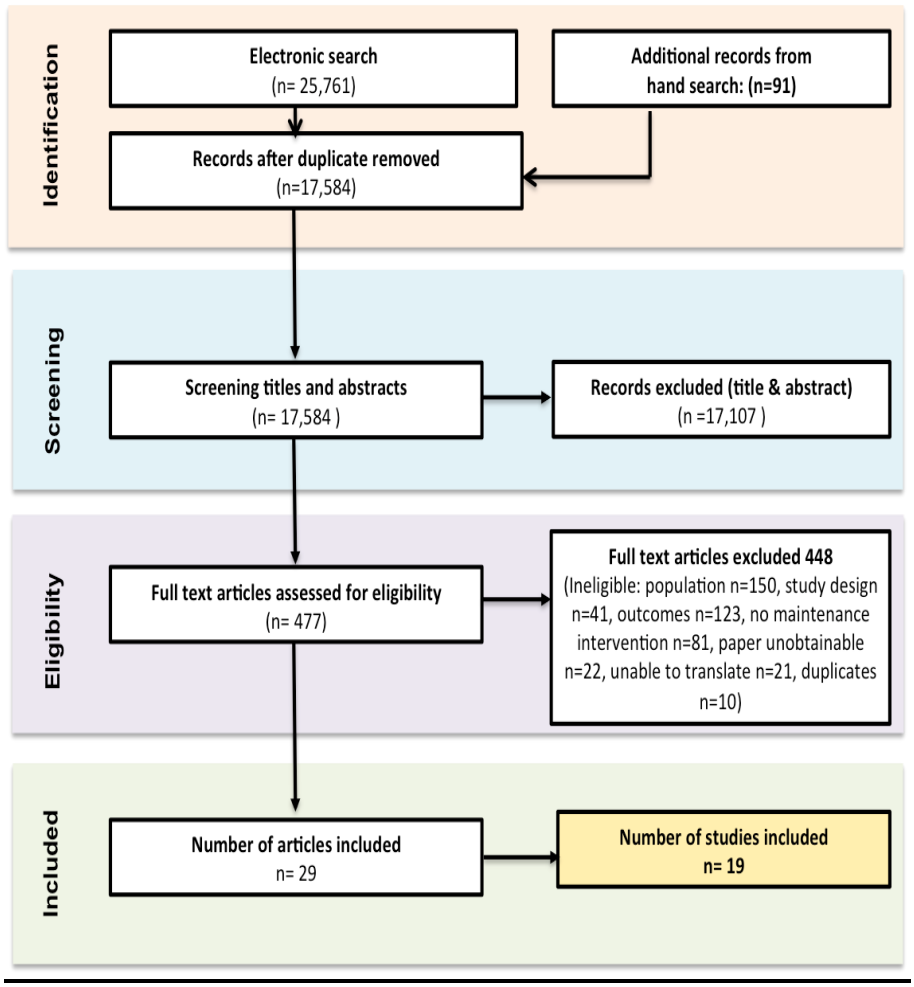


Figure 2. PRISMA Flow Chart

Table 1. Included Trials and Articles

Trial name or key author	Published articles
Active Adults Mentoring Programme	*Main article* Buman, M. P., Giacobbi Jr, P. R., Dzierzewski, J. M., Morgan, A. A., McCrae, C. S., Roberts, B. L., & Marsiske, M. (2011). Peer volunteers improve long-term maintenance of physical activity with older adults: a randomized controlled trial. *Journal of Physical Activity and Health*, *8*(s2), S257-S266
Easy Steps to Health	*Main article* Voukelatos, A., Merom, D., Sherrington, C., Rissel, C., Cumming, R. G., & Lord, S. R. (2015). The impact of a home-based walking programme on falls in older people: the Easy Steps randomised controlled trial. *Age and ageing*, *44*(3), 377-383. *Protocol* Voukelatos, A., Merom, D., Rissel, C., Sherrington, C., Watson, W., & Waller, K. (2011). The effect of walking on falls in older people: the 'Easy Steps to Health' randomized controlled trial protocol. *BMC public health*, *11*(1), 888.
Green Prescription	*Main article* Elley, C. R., Kerse, N., Arroll, B., & Robinson, E. (2003). Effectiveness of counselling patients on physical activity in general practice: cluster randomised controlled trial. *Bmj*, *326*(7393), 793. *Additional article(s)* Kerse, N., Elley, C. R., Robinson, E., & Arroll, B. (2005). Is physical activity counselling effective for older people? A cluster randomized, controlled trial in primary care. *Journal of the American Geriatrics Society*, *53*(11), 1951-1956.
Kraenzle Schneider, et al., (2008).	*Main article* Kraenzle Schneider, J., Cook Jr, J. H., & Luke, D. A. (2008). Cognitive-behavioural therapy, exercise, and older adults' quality of life. *Western journal of nursing research*, *30*(6), 704-723.
LIFE-P	*Main article* Pahor, M., Blair, S. N., Espeland, M., Fielding, R., Gill, T. M., Guralnik, J.M., …& Studenski,S. (2006). Effects of a physical activity intervention on measures of physical performance: results of the Lifestyle Interventions and Independence for Elders Pilot (LIFE-P) trial. *The Journals of Gerontology: Series A: Biological Sciences and Medical Sciences*.

	Additional article(s) Fielding, R. A., Katula, J., Miller, M. E., Abbott-Pillola, K., Jordan, A., Glynn, N. W., ... & Life Study Trial Investigators. (2007). Activity adherence and physical function in older adults with functional limitations. *Medicine and Science in Sports and Exercise*, *39*(11). Rejeski, W. J., King, A. C., Katula, J. A., Kritchevsky, S., Miller, M. E., Walkup, M. P., ... & LIFE Investigators. (2008). Physical activity in prefrail older adults: confidence and satisfaction related to physical function. *The Journals of Gerontology Series B: Psychological Sciences and Social Sciences*, *63*(1), P19-P26. Rejeski, W. J., Marsh, A. P., Chmelo, E., Prescott, A. J., Dobrosielski, M., Walkup, M. P., ... & Kritchevsky, S. (2009). The lifestyle interventions and independence for elders pilot (LIFE-P): 2-year follow-up. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences*, *64*(4), 462-467. Groessl, E. J., Kaplan, R. M., Blair, S. N., Rejeski, W. J., Katula, J. A., King, A. C., ... & Pahor, M. (2009). A cost analysis of a physical activity intervention for older adults. *Journal of Physical Activity and Health*, *6*(6), 767-774. Manini, T. M., Newman, A. B., Fielding, R., Blair, S. N., Perri, M. G., Anton, S. D., ... & Hsu, F. C. (2010). Effects of exercise on mobility in obese and nonobese older adults. *Obesity*, *18*(6), 1168-1175.
Luten et al., 2016	*Main article* Luten, K. A., Reijneveld, S. A., Dijkstra, A., & de Winter, A. F. (2015). Reach and effectiveness of an integrated community-based intervention on physical activity and healthy eating of older adults in a socioeconomically disadvantaged community. *Health education research*, cyv064.
Opdenacker et al., 2008.	*Main article* Opdenacker, J., Boen, F., Coorevits, N., & Delecluse, C. (2008). Effectiveness of a lifestyle intervention and a structured exercise intervention in older adults. *Preventive medicine*, *46*(6), 518-524.
PACE	*Main article* Harris, T., Kerry, S. M., Victor, C. R., Ekelund, U., Woodcock, A., Iliffe, S., ... & David, L. (2015). A primary care nurse-delivered walking intervention in older adults: PACE (pedometer accelerometer consultation evaluation)-Lift cluster randomised controlled trial. *PLoS Med*, *12*(2). *Protocol* Harris, T., Kerry, S., Victor, C., Ekelund, U., Woodcock, A., Iliffe, S., ... & Brewin, D. (2013). Randomised controlled trial of a complex intervention by primary care nurses to increase walking in patients aged 60–74 years: protocol of the PACE-Lift (Pedometer Accelerometer Consultation Evaluation-Lift) trial. *BMC Public Health*, *13*(1), 1.

PALs	*Main article* Jancey, J. M., Lee, A. H., Howat, P. A., Burke, L., Leong, C. C., & Shilton, T. (2011). The effectiveness of a walking booster program for seniors. *American journal of health promotion*, *25*(6), 363-367.
Pekkarinen et al., 2013	*Main article* Pekkarinen, T., Löyttyniemi, E., & Välimäki, M. (2013). Hip fracture prevention with a multifactorial educational program in elderly community-dwelling Finnish women. *Osteoporosis International*, *24*(12), 2983-2992.
Project LIFE	*Main article* Morey, M. C., Ekelund, C., Pearson, M., Crowley, G., Peterson, M., Sloane, R., ... & Bosworth, H. (2006). Project LIFE: a partnership to increase physical activity in elders with multiple chronic illnesses. *Journal of aging and physical activity*, *14*(3), 324-343. *Additional article(s)* Peterson, M. J., Sloane, R., Cohen, H. J., Crowley, G. M., Pieper, C. F., & Morey, M. C. (2007). Effect of telephone exercise counselling on frailty in older veterans: project LIFE. *American journal of men's health*, *1*(4), 326-334.
Rydwik et al, 2008	*Main article* Rydwik, E., Frändin, K., & Akner, G. (2010). Effects of a physical training and nutritional intervention program in frail elderly people regarding habitual physical activity level and activities of daily living—A randomized controlled pilot study. *Archives of gerontology and geriatrics*, *51*(3), 283-289.
SCAMOB	*Main article* Von Bonsdorff, M. B., Leinonen, R., Kujala, U. M., Heikkinen, E., Törmäkangas, T., Hirvensalo, M., ... & Rantanen, T. (2008). Effect of Physical Activity Counselling on Disability in Older People: A 2-Year Randomized Controlled Trial. *Journal of the American Geriatrics Society*, *56*(12), 2188-2194. *Additional article(s)* Mänty, M., Heinonen, A., Leinonen, R., Törmäkangas, T., Hirvensalo, M., Kallinen, M., ... & Rantanen, T. (2009). Long-term effect of physical activity counseling on mobility limitation among older people: a randomized controlled study *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences*, *64*(1), 83-89. Rasinaho, M., Hirvensalo, M., Törmäkangas, T., Leinonen, R., Lintunen, T., & Rantanen, T. (2012). Effect of physical activity counselling on physical activity of older people in Finland (ISRCTN 07330512). *Health promotion international*, *27*(4), 463-474.

	Protocol Leinonen, R., Heikkinen, E., Hirvensalo, M., Lintunen, T., Rasinaho, M., Sakari-Rantala, R., ... & Huovinen, P. (2007). Customer-oriented counseling for physical activity in older people: study protocol and selected baseline results of a randomized-controlled trial (ISRCTN 07330512). *Scandinavian journal of medicine & science in sports*, *17*(2), 156-164.
Seattle Protocol	*Main article* Teri, L., McCurry, S. M., Logsdon, R. G., Gibbons, L. E., Buchner, D. M., & Larson, E. B. (2011). A randomized controlled clinical trial of the Seattle protocol for activity in older adults. *Journal of the American Geriatrics Society*, *59*(7), 1188-1196.
Sisters in Motion	*Main article* Duru, O. K., Sarkisian, C. A., Leng, M., & Mangione, C. M. (2010). Sisters in Motion: A Randomized Controlled Trial of a Faith-Based Physical Activity Intervention. *Journal of the American Geriatrics Society*, *58*(10), 1863-1869.
Stand Up!	*Main article* Laforest, S., Pelletier, A., Gauvin, L., Robitaille, Y., Fournier, M., Corriveau, H., & Filiatrault, J. (2009). Impact of a community-based falls prevention program on maintenance of physical activity among older adults. *Journal of aging and health*, *21*(3), 480-500.
STEPS	*Main article* Dubbert, P. M., Cooper, K. M., Kirchner, K. A., Meydrech, E. F., & Bilbrew, D. (2002). Effects of nurse counseling on walking for exercise in elderly primary care patients. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences*, *57*(11), M733-M740.
Swanenburg et al., 2007	*Main article* Swanenburg, J., de Bruin, E. D., Stauffacher, M., Mulder, T., & Uebelhart, D. (2007). Effects of exercise and nutrition on postural balance and risk of falling in elderly people with decreased bone mineral density: randomized controlled trial pilot study. *Clinical Rehabilitation*, *21*(6), 523-534.
Veterans LIFE Study	*Main article* Morey MC, Peterson MJ, Pieper CF, et al. The Veterans Learning to Improve Fitness and Function in Elders Study: a randomized trial of primary care-based physical activity counseling for older men. *J Am Geriatr Soc* 2009; **57**(7): 1166-74. *Additional Article(s)* Hall KS, Sloane R, Pieper, CF, Peterson, MJ, Crowley, GM., Cowper, PA., ... & Morey, MC. (2010). Long-term changes in physical activity following a one-year home-based physical activity counselling program in older adults with multiple morbidities. *Journal of aging research*, *2011*.

	Protocol Morey M, Peterson M, Pieper C, et al. Learning to improve fitness and function in elders (Project LIFE): methods, design and baseline characteristics of a randomized trial. J Rehabilitation Research and Development 2008;45 (1):31–42.

Footnote: Protocol papers are not included within the PRISMA flowchart.

2.4.2 Description of trials

Fourteen RCTs [76-78,80,81,84,85,87,88,101,104-108], four controlled before and after trials [82,109-111] and one non-randomised controlled trial [86] were included. Eight trials were conducted in the United States of America (USA) [78,80,85-88,104,105,107], two in Australia [76,83], two in Finland [77,101] and one in each of the following: Canada [110], New Zealand [85], the United Kingdom [84], Sweden [106], Belgium [81], Switzerland [111] and the Netherlands [82].

2.4.3 Participants of included trials

Nineteen trials assessed 7,394 community-dwelling adults aged 65 years and older. Sample sizes ranged from 20 to 2178. The proportion of women across the trials was 65%. Three trials only included females [86,101,111] and two trials only included males [105] and the proportion of women across other studies ranged from 4% to 84%.

Sixteen trials reported age as a mean value that ranged from 65.3 to 83.5 [76-82,84-87,101,105,107,108,110,111]. Twelve trials reported the mean and standard deviation of the age of the intervention (72.5± 5.6 years) and the control group (72.7± 5.2 years) [76-78,81,82,85-87,101,105-107,110,111] and four reported mean age for the entire trial population (76.15 ±2.97 years) [80,105,107,108]. Three trials did not report age as a mean value but instead as the proportion of people in the sample aged 65 years old and older (range 52-100%) [83,84,88]. Six trials included people with a mean age of over 75 years old [77,78,80,105,106,108]. Eight studies reported ethnicity, with the percentage of ethnic minority participants ranging from 1.5% to 100%. Five studies recruited populations at risk of falls [101,110,111] or frailty [79,105]. The

characteristics of the included trials and the participants are shown in table 2 and 3.

2.4.4 Measurement tools and outcomes reported

Eighteen trials assessed self-reported PA. Self-reported tools included questionnaires [76,77,80-83,85,86,88,108,110], diaries [78,79,87,105,107,111] and interview questions [101]. Three used accelerometers [81,84,87] and two used pedometers [81,86] to quantify moderate physical activity (MPA) or step count. One trial examined PA using accelerometer readings [84].

The PA outcomes reported were: step count, calorie expenditure, time spent: walking, performing exercise, strength training, active transport (i.e. cycling or walking for transport), moderate physical activity (MPA) or MVPA. Two studies reported changes in a validated scoring system (i.e. PALs score and MET expenditure). Two studies presented PA as a pre-determined attainment of a specific level of PA (i.e. the proportion of people considered active).

2.4.5 Brief description and effects of the maintenance interventions

Booster interventions delivered after the provision of an initial PA promotion programme were used in ten trials. Interventions that integrated maintenance techniques within the initial PA promotion programme were used in nine trials. Seven booster and six integrated interventions (n=13) reported a significant increase in one, or more, PA outcomes between 9 to 36 months after the onset of PA maintenance interventions. This section

briefly synthesises the evidence of the PA maintenance interventions delivered within each trial. Tables 2 and 3 outline the outcome measures and results of each trial.

2.4.5.1 Booster interventions

Ten trials used "booster" interventions that were provided after the provision of the initial PA promotion intervention period had ended [77,78,81,83,85,87,101,103,106]. Seven of the ten trials showed significant effects on walking levels [83,87], exercise minutes [78,85], weekly calorie expenditure [85], daily step count [81], total PA levels [79,81] and the proportion of people remaining active [77].

Telephone delivered booster interventions showed significant effects on PA maintenance favouring the intervention group in five out of seven studies [77,81,83,85,87,103,108]. Participants in three studies were delivered maintenance interventions by phone after receiving a face-to-face consultation [77,85,87]. Practitioner endorsed telephone-counselling maintained PA for up to 12 months in three studies [85,87,108]. Yet, a follow up report on the Veteran Life Study showed that telephone counselling did not significantly maintain PA at 24 months [108,112]. Booster letters and review days resulted in no significant effects on the proportion of participants remaining active at 2 and 10 year follow-up [101]. Moving participants from supervised exercise in the PA promotion intervention to unsupervised PA in the maintenance intervention resulted in significant effects on PA maintenance to favour the intervention group in three studies [78,79,83]. Another study found delivering an unsupervised PA programme supported by booster telephone calls resulted in significant effects on PA maintenance to favour the intervention group [81]. Table 2 presents the data relating to the trial and the participants

characteristics, provides a brief intervention description and presents the follow-up data of each included study.

2.4.5.2 Integrated interventions

Nine trials integrated a PA maintenance strategy within the initial PA promotion intervention [76,80,82,84,86,88,107,110,111]. Six of the nine trials showed significant effects on PA maintenance [76,80,82,84,86,88].

Three out of four studies integrating relapse and prevention strategies into walking programmes reported significant effects on PA maintenance to favour the intervention group [76,84,88]. Falls prevention programmes integrating relapse and prevention strategies [110] and brief PA maintenance advice [111] reported no significant effect on PA maintenance. Integrating cognitive behavioural therapy into a supervised exercise programme resulted in no significant effect on METs at 12 months [107].

A follow-up report on the LIFE-P study showed integrating a 24-week "maintenance phase" consisting of home-based exercise and telephone support maintained significant effects on MPA for 36 months in the intervention group [80,113]. The continued provision of a multi-media PA promotion campaign during a maintenance phase resulted in significantly more minutes of active transport and leisure time PA in the intervention group at 12-months [82]. The continued provision of a multi-component faith-based intervention during a maintenance phase resulted in significantly higher daily step count in the intervention group [86].

Table 3 presents the data relating to the trial and the participants characteristics, provides a brief intervention description and presents the follow-up data of each included trial.

Table 2. Characteristics of included booster intervention studies

CHARACTERISTICS OF STUDY & SAMPLE	INTERVENTION FEATURES	OUTCOME MEASURES & RESULTS
Study characteristics: Green Prescription, Elley et al., [85] RCT (New Zealand) **Sample characteristics:** n= 270 **Subjects:** inactive adults (aged 40-80) recruited in GP practices. **Sex** (female): 63% **Ethnicity**: not reported **Ages:** years (mean, SD): IG: 71 (4.1); CG: 72.2	**Description:** clinician consultation and onward referral to exercise specialist **PA promotion strategies:** motivational interview consultation & exercise specialist referral **PA maintenance strategies**: motivational interviews delivered by telephone **Tailored:** to participant goals **CG:** usual GP care	**Outcome measure:** Auckland heart trial questionnaire. Reported between group differences of exercise minutes/week, total kcal (kg/week), leisure time kcal (kg/week). **Baseline** — **CG** Mean (SD) — **IG** — *P-value* Total Kcal/kg/week: 235.70 (45.30) — 237.50 (42.20) Leisure Kcal/kg/week: 6.50 (11.10) — 6.00 (12.20) Exercise mins/week: 12.00 (20.50) — 11.30 (21.70) **Post PA maintenance intervention (12 month)** — Mean (95% CI) — Difference between means (95% CI) Total Kcal/kg/week: 0.37 (−3.39, 4.14) — 9.76 (5.85, 13.68) — 9.38 (3.96, 14.81) — p=0.001 Leisure Kcal/kg/week: 1.29 (0.11, 2.47) — 4.32 (3.26, 5.38) — 2.67 (0.87, 4.47) — p=0.04 Exercise min/week: 54.60 (41.40, 68.40) — 16.80 (6.00, 32.40) — 33.60 (2.40, 64.20) — p=0.02
Study characteristics: Opdenacker et al., [81] RCT (Belgium) **Sample characteristics:** n= 180	**Description:** lifestyle PA programme **PA promotion strategies:** none **PA maintenance strategies**: lifestyle PA programme & motivational interviews delivered by telephone **Tailored:** participant needs and preferences	**Outcome measure:** Flemish PA computerized questionnaire, accelerometer and pedometer. Between group differences from pre-test to post-test and pre-test to follow up (steps/day and kcal expended/week on leisure PA, active transport and total PA). Significant findings are marked with an asterisk as the authors did not report the P-values. **Baseline** — **IG** Mean (SD) — **CG-1** — **CG-2** — *P-value* Steps: 6 765 (397) — 7 720 (392) — 7 390 (400) Leisure PA: 582 (166) — 809 (159) — 672 (165)

Subjects: healthy, inactive older adults recruited via advertisement **Sex** (females): 49% **Ethnicity:** not reported **Ages:** years (mean, SD) IG: 66.3 (4); CG-1: 70 (4.3); CG-2: 67.9 (5.3)	**CG-1:** no intervention **CG-2:** supervised exercise classes	Active transport: Total PA:	858 (104) 3 833 (313)	1 347 (100) 4 919 (301)	1 138 (104) 4 342 (313)	
		Post PA maintenance intervention (11 months)				
			IG versus CG-1	**IG versus CG-2:**	**CG1 versus CG2**	
			Difference between means (95%CI)			p-values
		Steps:	2 141 (1 028, 3 253)*	1 848 (736, 2 961)*	292 (-799, 1384)	unreported
		Leisure PA:	334 (−186, 855)	-513 (−1 039, 13)	847 (336, 1358)*	
		Active transport:	589 (257, 922)*	443 (106, 780)*	147 (-181, 474)	
		Total PA:	1 061 (169, 1 954)*	−12 (−918, 895)	1073 (194, 1953)*	
		Follow-up (23 months)				
		Steps:	952 (−273, 2177)	1 370 (169, 2 570)*	-417 (-1622, 787)	
		Leisure PA:	266 (− 322, 854)	33 (−544, 610)	233 (-343, 809)	
		Active transport:	444 (91, 798)*	195 (−153, 543)	249 (-97, 596)	
		Total PA:	758 (−413, 1929)	350 (−804, 1 504)	408 (-740, 1556)	
Study characteristics: PALs, Jancey et al., [83] Controlled before and after study (Australia) **Sample characteristics:** n= 573 **Subjects:** healthy, inactive older adults identified from the electoral register **Sex** (female): 64%	**Description:** mentor led walking programme and booster telephone calls **PA promotion strategies:** supervised walking programme **PA maintenance strategies**: unsupervised walking programme, pedometer & motivational interviews delivered by telephone **CG:** no booster intervention	**Outcome measure:** International PA questionnaire. Between group comparisons of total, recreation and habitual walking time minutes/week.				
			IG	**CG**		
		Baseline	Mean (SE)			*P-values*
		Recreation walking:	55.10 (6.20)	81.70 (7.70)		
		Walking for errands:	70.21 (8.77)	104.77 (10.62)		
		Post PA promotion intervention (6 month)				
		Recreation walking:	161.50 (9.20)	103.30 (8.90)		p>0.05
		Walking for errands:	119.58 (9.96)	109.32 (8.64)		p>0.05
		Post PA maintenance intervention (18 month)				
		Recreation walking:	109.50 (8.30)	99.00 (11.00)		unreported

Ethnicity: not reported **Ages:** years (range) 65-70 years		Walking for errands: **Follow-up (21 month)** Recreation walking: Walking for errands:	116.14 (12.25) 147.40 (13.60) 125.50 (17.93)	95.00(11.26) 92.00 (10.00) 99.90 (15.89)	unreported p<0.001 p>0.05
Study characteristics: Pekkarinen et al., [101] RCT (Finland) **Sample characteristics:** n= 2178 **Subjects:** females aged 60-70 years at risk of reduced bone mass density **Sex** (female): 100% **Ethnicity:** not reported **Ages:** years (mean, SD) IG: 65.3 (3.1); CG: 65.3 (3.1)	**Description:** multi-component PA programme **PA promotion strategies:** group education, individualised PA counselling & supervised exercise **PA maintenance strategies**: booster letters and review days **CG:** no intervention	**Outcome measure:** Self-reported PA in interview questions. Reported PA frequency and the percentage of people who exercised for 30 minutes+ per/week. **Baseline** 1 per/week: 2-4 per/week: 5-7 per/week: **Post PA promotion intervention (2 years)** 1 per/week: 2-4 per/week: 5-7 per/week: **Post PA maintenance intervention (5 years)** 1 per/week: 2-4 per/week: 5-7 per/week: **Follow-up 1 (8 years)** 1 per/week: 2-4 per/week: 5-7 per/week: **Follow-up 2 (10 years)** 1 per/week: 2-4 per/week: 5-7 per/week:	**IG** % of participants 10% 36% 54% 7% 33% 60% 7% 33% 60% 5% 36% 60% 7% 35% 58%	**CG** 14% 29% 57% 9% 32% 60% 6% 31% 63% 6% 33% 62% 7% 33% 60%	*P-value* p=0.45 p=0.38 p=0.37 p=0.80

Study characteristics:
Project LIFE, Morey et al. [103]
RCT
(USA)

Sample characteristics:
n= 165
Subjects: male veteran aged over 70years old at risk of frailty.
Sex (female): 0%
Ethnicity: not reported
Ages: years (mean, SD) 78.3 (SD not reported)

Description: PA counselling

PA promotion strategies: PA counselling

PA maintenance strategies: PA counselling via telephone

Tailored: stage of readiness to engage in PA

CG1: health counselling
CG2: usual care

Outcome measure: Community Healthy Activities Model Program for Seniors (CHAMPS) questionnaire.
Reported between group differences of MPA minutes/week, weekly kcals expended, walking/ bike minutes/week, total PA minutes/week.

	IG	**CG-1**	**CG-2**	*P-value*
Baseline	Mean (SD)			(Omnibus
MPA:	184 (233)	145 (210)	221 (294)	group x
Kcal:	2 629 (2 008)	2 579 (2 137)	2 663 (2 313)	time)
Walking/bike:	55 (88)	59 (85)	61 (112)	
Total PA:	616 (446)	596 (496)	600 (466)	
Post promotion intervention (3 month)				
MPA:	278 (295)	191 (236)	309 (406)	
Kcal:	3 393 (2 254)	2 815 (2 159)	3 694 (3 174)	
Walking/bike:	92 (116)	95 (138)	87 (103)	
Total PA:	760 (488)	630 (493)	815 (596)	
Post PA maintenance intervention (6 month)				
MPA:	210 (253)	172 (229)	144 (163)	p=0.17
Kcal:	3 054 (2 231)	2 054 (2 368)	2 368 (1 863)	p=0.054
Walking/bike:	67 (111)	90 (135)	49 (80)	p=0.67
Total PA:	685 (445)	697 (516)	543 (377)	p=0.45

Study characteristics:
Veterans LIFE Study, Morey et al. [108]
RCT
(USA)

Sample characteristics:
n= 398

Description: PA telephone counselling

PA promotion strategies: face-to-face PA counselling

PA maintenance strategies: PA counselling via telephone

Tailored: progress towards PA goals

Outcome measure: CHAMPS questionnaire.
Reported between group differences of MVPA minutes/week, strength minutes/week, percentage of people meeting the PA guidelines of 150 minutes MVPA/week.

	IG	**CG**	
Baseline	Mean (SD)		*P-value*
MVPA minutes:	37.9 (82.8)	35.8 (88.4)	
Strength minutes:	18.5 (43.4)	23.2 (54.7)	
Proportion of people active:	13%	14%	
Post PA maintenance intervention (3 month)			p-values
MVPA minutes:	65.1 (90.2)	38.8 (73.4)	unreported

Subjects: sedentary males aged over 70years old **Sex** (female): 0% **Ethnicity:** 77% **Ages:** years (mean, SD): 77.6 (4.9)	**CG:** usual care	Strength minutes: Proportion of people active: **Post PA maintenance intervention (6 month)** MVPA minutes: Strength minutes: Proportion of people active: **Post PA maintenance intervention (12 month)** MVPA minutes: Strength minutes: Proportion of people active: **Follow up (24 month)** MVPA minutes: Strength minutes: Proportion of people active:	56.3 (50.4) Not reported 69.3 (85.7) 58.4 (62.9) not reported 72.3 (114.8) 54.9 (54.9) 32% 52.4 (9.2) 37.3 (6.1) not reported	27.1 (61.0) 48.5 (100.1) 24.7 (54.0) 48.5 (100.1) 24.7 (54.0) 16% 43.2 (9.6) 33.8 (6.3)		 p-values unreported p=0. 002 p<0.001 p=0.22 p=0.01
Study characteristics: Rydwik et al., [106] RCT (Sweden) **Sample characteristics:** n= 94 **Subjects**: frail inactive older adults recruited via advertisement **Sex** (female): 58% **Ethnicity:** not reported **Ages:** years (mean, SD) IG: 83.5 (3.7); CG: 82.9 (4)	**Description:** combined physical training and nutrition programme **PA promotion strategies:** supervised gym-based PA programme **PA maintenance strategies**: unsupervised home-based PA programme & follow-up contacts **IG1:** training only **IG2:** nutrition & PA advice **CG:** no intervention	**Outcome measure:** PAL scores. Reported between group changes in PAL scores. **Baseline** PAL: **Post PA promotion intervention (3 month)** PAL: PAL: **Post PA maintenance intervention (9 month)** PAL: PAL:	**Training G** Median (IQR) 2 (1, 3) 3 (2, 3) 3 (2, 3) 3 (2, 3)	**Training nutrition G** 2 (2, 3) 3 (2, 3) 3 (2, 3)	**CG** 3 (2, 3) 3 (2, 3) 3 (2, 3) 3 (2, 3) 3 (2, 3)	*P-value* p<0.05 p<0.05 p>0.05 p<0.05

Study characteristics: SCAMOB, Von Bonsdorff et al., [77] RCT (Finland) **Sample characteristics:** n= 632 **Subjects:** sedentary to moderately active older adults living in Jyvaskyla, Finland **Sex** (female): 75% **Ethnicity:** not reported **Ages:** years (mean, SD) IG: 77.6 (1.9); CG: 77.6 (1.9)	**Description:** customer orientated motivational interviews for PA **PA promotion strategies:** motivational interviews **PA maintenance strategies**: lectures & motivational telephone calls **Tailored:** individual needs & preferences **CG:** exercise facility access	**Outcome measure:** Grimsby PA questionnaire. Changes in the percentage of people moving from sedentary to moderately active post intervention. **Baseline and post PA promotion intervention**: values not reported. **Post maintenance intervention (2 years)** 83% (IG) versus 72% (CG) OR=2.0, (95% CI 1.3, 3.0). Reported significant effects between groups.	p-value unreported
Study characteristics: Seattle protocol of physical activity, Teri et al., [78] RCT (USA) **Sample characteristics:** n= 273 **Subjects:** inactive older people, recruited from	**Description:** transition from supervised to unsupervised PA **PA promotion strategies:** supervised exercise **PA maintenance strategies**: unsupervised home-based exercise **CG:** routine medical care	**Outcome measure:** Physical Activity Scale for the Elderly. Reported the difference between means of exercise minutes/week. **Baseline** Data not reported **Post PA promotion intervention (3 month)** Exercise mins: Group data not reported **Post PA maintenance intervention (12 month)** Exercise mins: Post intervention data not reported **Follow-up (18 month)**	Difference between group means (95% CI) 39.3 (0.2, 78.4) *P-value* p=0.049 unreported

independent living retirement centres **Sex** (female): 62% **Ethnicity** (Caucasian): 91% **Ages**: years (mean, SD) IG-1: 80.3 (6.1); IG-2: 78.3 (5.3); CG-1: 79.6 (4.6); CG-2: 78.3 (4.2)		Exercise mins:	Group data not reported	31.4 (4.7, 58.1) p=0.02
Study characteristics: STEPS, Dubbert et al., [87] RCT (USA) **Sample characteristics:** n= 181 **Subjects**: inactive older adults, recruited from primary care **Sex** (female): 4% **Ethnicity** (Caucasian): 72% **Ages:** years (mean, SD) IG-1: 69.3 (4.7); IG-2: 68 (4.4); CG: 68.7 (5)	**Description:** nurse-led walking intervention **PA promotion strategies:** PA counselling **PA maintenance strategies**: IG-1: personalised booster telephone calls IG-2: personalised & automated booster telephone calls **Tailored:** stage of readiness to engage in PA **CG:** no maintenance intervention	**Outcome measure:** 7-day PA recall, accelerometer. Reported adherence to walking for >20 minutes, 3 days a week, walking minutes/week & MVPA hours/week. **Baseline** Data not reported. **Post PA promotion intervention (6 month)** *P-value* Walking adherence: IG-2 was significantly better than the CG, no figures reported. p=0.003 No significant differences were seen between IG-1, IG-2 and the CG, figures not reported. p>0.05 Walking time & MVPA: Data not reported. **Post PA maintenance intervention (12 month)** Walking adherence: IG-1 and CG: No significant difference, no figures reported. p=0.06 Walking adherence: IG-1 and IG-2: No significant difference, no figures reported. p>0.05 Walking adherence: IG-1 and IG-2 combined: significantly better than CG, no figures reported. unreported Walking adherence: IG-2 was significantly better than CG, no figures reported. p=0.04 Walking time & MVPA: Across time IG-2 walked for exercise more than IG-1 & CG, figures not reported. p=0.002	

Table 3. Characteristics of included integrated intervention studies

CHARACTERISTICS OF STUDY & SAMPLE	INTERVENTION FEATURES	OUTCOME MEASURES & RESULTS
Study characteristics: Active Mentoring Program, Buman et al., [88] RCT (USA) **Sample characteristics:** n= 81 **Subjects:** inactive older adults, recruited from the local community **Sex** (% female): 83% **Ethnicity** (Caucasian): 91% **Ages:** % of people over 65 years old. IG: 54%; CG: 50%	**Description:** peer led PA programme **PA promotion strategies:** supervised exercise **PA maintenance strategies**: relapse and prevention strategies and transition to home-based PA **CG:** standard exercise class provision	**Outcome measure:** The Leisure-Time Exercise Questionnaire. Reported between group differences in mean MPA minutes/week. **IG** **CG** **Baseline** Mean (SD) *P-value* MPA: 8.10 (9.30) 13.86 (23.62) **Post integrated intervention (16 weeks)** MPA: 106.10 (140.10) 94.41 (128.45) p>0.05 **Follow-up 18 months** MPA: 145.70 (246.40) 58.32 (103.58) p<0.05
Study characteristics: Easy steps to Health, Voukelatos et al., [76] RCT (Australia) **Sample characteristics:** n= 386	**Description:** walking programme **PA promotion strategies:** progressive walking programme **PA maintenance strategies**: relapse and prevention strategies **Tailored:** fitness capacity	**Outcome measure:** The incidental and planned exercise questionnaire. Reported between group differences of planned walking exercise & all planned exercise time (hours) per/week (median, IQR, p-value). **IG** **CG** **Post intervention (6 month)** Median (IQR) *P-value* Planned walking: 1.69 (2.63) 0.75 (1.69) p<0.0001 Planned exercise: 3.19 (3.19) 1.69 (3.38) p<0.0007

Subjects: healthy, inactive older adults recruited from the local community and electoral register **Sex** (female): 74% **Ethnicity:** not reported **Ages:** years (mean, range): 73.2 (65-90)	**CG: general** health information	**Follow-up**	Data not reported			
Study characteristics: Kraenzle Schneider, et al., (2008). [107] RCT (USA) **Sample characteristics:** n= 332 **Subjects:** healthy, sedentary older adults with transportation **Sex** (female): 76% **Ethnicity** (Caucasian): 96% **Ages:** years (mean, SD) IG: 71.6 (5.3); CG-1: 72.1 (4.8); CG-2: 71.6 (5.1)	**Description:** cognitive behavioural therapy **PA promotion strategies:** supervised exercise **PA maintenance strategies**: cognitive behavioural therapy sessions **CG-1:** health promotion education **CG-2:** no intervention	**Outcome measure:** Modifiable Activity Questionnaire. Reported METs hours/week.				
			IG	**CG-1**	**CG-2**	
		Baseline	Mean (SD)			*P-value*
		METs:	5.7 (7.3)	5.8 (8.8)	6.0 (8.2)	
		Post integrated intervention (6 month)				
		METs:	13.9 (9.9)	12.9 (10.4)	12.2 (10.7)	unreported
		Follow-up 1 (9 month)				
		METs:	11.5 (9.2)	12.6 (12.6)	12.4 (12.8)	unreported
		Follow-up (12 month)				
		METs:	12.9 (13.2)	14.7 (15.4)	12.4 (15.3)	unreported
Study characteristics: LIFE- P, Pahor et al., [80] RCT (USA) **Sample characteristics:** n= 424 **Subjects:** sedentary older adults at risk of disability	**Description:** structured PA and walking programme **PA promotion strategies:** centre based exercise **PA maintenance strategies**: transition to home-based PA & booster telephone calls	**Outcome measure:** CHAMPS. Reported between group differences in MPA minutes/week and kcal expended.				
			IG	**CG**		
		Baseline	Mean (SE)			*P-value*
		MPA:	119.7	119.7		
		Kcal:	655.0 (1 033.0)	596.0 (903.0)		
		Post integrated intervention (6 month)				
		MPA:	248.7 (33.3)	163.8 (34.0)		p=0.08

Sex (female): 69% **Ethnicity** (Caucasian): 76% **Ages:** years (mean, SD); 76.8 (4.2)	**CG:** healthy ageing advice	Kcal: **Follow-up 1 (12 month)** MPA: Kcal: **Follow-up 2 (36 month)** MPA: Kcal: not reported	1 248.0 (1 343.0) 233.5 (24.5) 1 001.0 (1 084.0) 165.5 (22.2)	772.0 (1 189.0) 103.1 (25.5) 710.0 (978.0) 99.3 (23.1)		p<0.001 p=0.002 p=0.042
Study characteristics: Luten et al., [82] Controlled before and after study (Netherlands) **Sample characteristics:** n= 643 **Subjects:** people aged over 55 years old, randomly selected from population registers **Sex** (female): 58% **Ethnicity:** not reported **Ages:** years (mean, SD) IG: 66.2 (7.8); CG: 67 (7.8)	**Description:** mass-media campaign **PA promotion strategies:** flyers, radio broadcasts, newsletters, posters **PA maintenance strategies**: continued promotion strategy provision with a reduced frequency of contacts **CG:** no intervention	**Outcome measure:** Short Questionnaire to Assess Health-Enhancing PA. Reported changes of time spent in different PA domains minutes /week (between groups). **Baseline** Total PA: Active transport: Household-related PA: Leisure-time PA: **Post PA promotion intervention (3 month)** Total PA: Active transport: Household-related PA: Leisure-time PA: **Post PA maintenance intervention (9 month)** Total PA: Active transport: Household-related PA: Leisure-time PA:	**IG** Group mean (SD) 1 691 (1 306) 168 (264) 626 (752) 564 (733) 1 738 (1 227) 162 (290) 587 (617) 576 (629) 1 771 (1 288) 219 (402) 666 (702) 546 (561)	**CG** 1 611 (1 292) 120 (222) 676 (765) 561 (726) 1 770 (1 277) 90 (148) 683 (747) 701 (789) 1 818 (1 112) 99 (153) 728 (739) 608 (579)	Overall effect size - 0.05 0.32 - 0.17 0.15	*P-value* p>0.05 p<0.001 p>0.05 p< 0.05
Study characteristics: PACE, Harris et al., [84] RCT (UK) **Sample characteristics:**	**Description:** nurse delivered walking programme **PA promotion strategies:** motivational interview consultations	**Outcome measure:** Accelerometer. Reported between group differences in MPA minutes/week and daily step count. **Baseline** Steps:	**IG** Mean (SD) 7 314 (2 693)	**CG** 7 380 (2 988)		*P-value*

n= 298 **Subjects:** community based older adults recruited from primary care **Sex** (female): 54% **Ethnicity** (Caucasian)**:** 99% **Ages:** (percentage people over 65 years) IG: 54%; CG: 73%	**PA maintenance strategies**: relapse and prevention & habit formation motivational interview strategies. **CG:** usual GP care	MVPA: **Post integrated intervention (3 month)** Steps: MVPA: **Follow-up (12 month)** Steps: MVPA:	296 (154) 7 903 (3 194) 333 (185) 7 514 (3 165) 319 (188)	301 (169) 6 904 (3 061) 278 (169) 6 872 (2 792) 285 (174)	Difference between means (95% CI) 1 037 (51, 1 560) 63 (40, 87) 609 (104, 1 115) 40 (17, 63)	p-value p< 0.001 p< 0.001 p=0.009 p=0.009
Study characteristics: Sisters in Motion, Duru et al., [86] Non-randomised controlled trial (USA) **Sample characteristics:** n= 62 **Subjects:** inactive African American women, recruited from church **Sex** (female): 100% **Ethnicity** (Caucasian): 0% **Ages:** years (mean, SD) IG: 73.3 (9.6); CG: 72.2 (5.8)	**Description:** faith-based PA programme **PA promotion strategies:** exercise classes provision, faith-based PA readings & incentive's **PA maintenance strategies**: exercise class provision **CG:** lectures on unrelated topics to PA, structured exercise classes	**Outcome measure:** CHAMPS & pedometer. Reported mean difference between the intervention and control group for MPA hours/week & weekly step count. **Baseline** Steps: MPA: **Post intervention (6 month)** Steps: MPA:	**IG** Mean (SD) 12 727 (9 387) 8.7 (8.9) Group mean (SD not reported) 9 883 9.5	**CG** 13 089 (8 636) 9.5 (8.9) 2 426 6.9	Difference between means (SE) 7 457 (3 020) 2.6 (3.8)	*P-value* p=0.02 p=0.5
Study characteristics: STAND UP!, Laforest et al., [110] Controlled before and after study (Canada) **Sample characteristics:** n=200 **Subjects:** pre-frail healthy older adults at risk of falls, recruited from community settings **Sex** (female): 84% **Ethnicity:** not reported	**Description:** community based falls prevention programme **PA promotion strategies:** supervised exercise **PA maintenance strategies**: integrated relapse and prevention session strategies and transition to home-based PA **CG:** waiting list	**Outcome measure:** CHAMPS. Reported weekly kcal expenditure. **Baseline** Kcals: **Post integrated intervention (3 month)** Kcals: **Follow-up (9month)** Kcals:	**IG** Mean (SD) 558 (922) 1 056 (883) 480 (691)	**CG** 518 (897) 518 (816) 325 (641)		*P-value* p< 0.001 p=0.84

Ages: years (mean, SD) IG: 73.6 (7.4); CG: 74.2 (7.4)					
Study characteristics: Swanenburg et al., [111] Controlled before and after study (Switzerland) **Sample characteristics:** n= 24 **Subjects:** older females with low bone mass density **Sex** (female): 100% **Ethnicity:** not reported **Ages:** years (mean, SD) IG: 71.8 (5.4); CG: 70.7 (8.1)	**Description:** exercise provision and nutrition supplementation **PA promotion strategies:** supervised exercise **PA maintenance strategies**: advice to continue exercising **Tailored:** fitness capacity **CG:** leaflet on home exercise	**Outcome measure:** Freiburger questionnaire for PA. Reported between group differences of weekly kcals expended.			
			IG Mean (SD)	**CG**	*P-value*
		Baseline	1 557 (647)	2 018 (1 036)	
		Post intervention (3 months)			
		Kcals:	2 586 (995)	2 098 (1 343)	
		Follow up 1 (6 months)			
		Kcals:	2 494 (1 376)	2 400 (1 360)	p=0.002
		Follow-up 2 (9 months):			
		Kcals:	1 914 (845)	2 334 (1 265)	p>0.05
		Follow up 3 (12 month)			
		Kcals:	1 821 (661)	2 200 (1 057)	p>0.05

Footnote table 2 and 3: n=number of participants; IG= intervention group; CG= control group; PA= physical activity; MPA= moderate PA; MVPA= moderate to vigorous PA; Kcal= calorie expenditure; No.= number, SD= standard deviation, CI = confidence interval, METs = metabolic equivalent, PALs= physical activity level, BL= baseline. PA promotion strategies refer to any interventions delivered prior to the maintenance intervention that promoted the onset of PA engagement. PA maintenance strategies refer to any intervention that specifically aimed to maintain PA after the intervention ended.

2.4.6 PA maintenance interventions features and delivery

The intervention within each trial was analysed using the TiDIER checklist to help improve our understanding of what intervention features and delivery modes work best to facilitate PA maintenance. The current section provides a narrative summary of the intervention features and delivery modes reported in Table 4.

2.4.6.1 Target behaviours

Six types of PA behaviours were categorised across the 19 trials.

Significant effects on PA maintenance favouring the intervention group were reported in twelve out of fifteen studies targeting walking; seven out of ten studies targeting resistance training; six out of seven studies targeting lifestyle PA; three out of six studies targeting cardiovascular exercise; five out of seven studies incorporating balance exercise and four out of five studies delivering flexibility training. Five out of six studies showed significant effects on PA maintenance favouring the intervention group when targeting a single PA type, i.e. walking or lifestyle PA, as did eight out of thirteen studies targeting multiple PA behaviours.

2.4.6.2 Intervention delivery and features

2.4.6.2.1 Intervention features

PA procedures: Significant effects on PA maintenance favouring the intervention group was reported in thirteen of nineteen studies encouraging unsupervised PA, one study providing supervised PA, twelve of thirteen studies promoting lifestyle PA and six of eleven studies prescribing home exercise.

Supporting activities: PA was maintained in the intervention group in five of eight studies providing professional support or counselling, five of six studies delivering motivational interviewing; two studies providing peer or mentor support and four of five studies improving accessibility to PA facilities.

Supporting Materials: Significant effects on PA maintenance were seen favouring the intervention group in seven of nine studies issuing pedometers and/or exercise equipment; nine of twelve studies providing written materials; three studies providing diaries and six of seven studies providing visual aids such as posters [82,110], illustrated exercise programmes [77,81,83] and videos [78,80].

Tailoring: Eight studies tailored interventions to participant goals [85,108], fitness capacity [76,111], individual needs and preferences [77,81] or stage of readiness to engage in PA [87,103]. Five of the eight studies reported a significant effect on maintaining PA to favour the intervention group.

2.4.6.2.2 PA delivery modes

Provider: Seven of nine studies used fitness professionals; four of six studies used healthcare professionals; one of four studies used behaviour therapists; one of three studies including medics and interventions delivered by researchers, mentors and volunteers all showed significant effects on PA maintenance favouring the intervention group.

Delivery modes: Seven out of eleven studies used face-to-face interactions; seven out of nine studies used telephone communication; seven out of nine studies used print materials; three out of four studies used visual or audio-recordings and two out of three studies delivering participant lectures reported significant effects on PA maintenance favouring the intervention group. Four out of eight studies used a single communication mode and nine out of eleven studies used a multi-modal communication approach reported significant effects on PA maintenance favouring the intervention group as did eight out of eleven studies delivering interventions to individuals and five out of eight studies delivering group interventions.

Setting: Significant effects on PA maintenance favouring the intervention group were found in nine out of twelve studies delivering interventions in home settings, four out of six studies delivering interventions in community venues and three out of four studies delivering interventions in clinics.

2.4.6.2.3 Dosage

Number of participant contacts: Seventeen studies reported the number of maintenance intervention contacts which ranged from 1 to 27. Significant effects on PA maintenance favouring the intervention group were reported in five of eight studies delivering between 1-3 contacts; four studies delivering between 4-7 contacts and two of five studies delivering ≥8 contacts.

Contact duration: Ten studies disclosed the duration of each participant contact which ranged between 5 to 90 minutes. Contact duration did not appear to influence intervention effectiveness.

Contact frequency: Twelve studies reported frequency of participant contacts. Six out of seven studies delivering monthly contacts and two studies delivering quarterly contacts reported significant effects on PA maintenance favouring the intervention group. No significant effects on PA outcomes were reported when delivering interventions weekly or bi-weekly.

Intervention period: Intervention length ranged from a single session to 8 years. Significant effects on PA maintenance favouring the intervention group were reported in one out of three studies delivering a single session; four studies delivering interventions over 1-3 months; five out of six studies delivering interventions over 6 months; three out of four studies delivering interventions for up to 12 months and one RCT delivering an intervention over 2 years.

Table 4 depicts the intervention features and the delivery of the PA maintenance intervention of each trial.

Table 4. Intervention features and delivery modes of included trials.

Trial/ first author name	BEHAVIOURS TARGETED							PA PROCEDURES					SUPPORTING ACTIVITIES				MATERIAL				PROVIDER							MODES OF DELIVERY							SETTING			DOSAGE			
	Lifestyle PA (not including walking)	Walking	Resistance training	Cardiovascular training	Balance training	Flexibility training	None PA behaviours	Exercise classes or gym	Home based exercise	Lifestyle PA advise/programme	Supervised	Unsupervised/ self directed	Counseling/ professional support	Motivational interviewing/ CBT	Social support (non professional)	Improving accessibility	Pedometers & exercise equipment	Written materials	Diaries	Visual aids (videos, illustrations)	Researcher	Fitness professional	Health care professional	nurse or medic	Behavioral therapist	Mentor or volunteer	Specially trained or supervised?	Face to face	Telephone	In print via post or computer	Lectures	Visual or audio recording	Delivered to an individual	Delivered in a group	Participant home	Primary care or hospital clinic	Community venue (indoors)	No. of contacts	Contact duration (minutes)	Frequency	Intervention duration
Active Mentoring		✓	✓					✓	✓	✓		✓			✓	✓										✓	✓							✓							4 w
Easy steps to Health		✓								✓		✓	✓				✓	✓			✓								✓	✓			✓		✓			2			23 w
Green Prescription	✓	✓							✓	✓		✓		✓				✓				✓		✓			✓	✓	✓	✓					✓	✓		3	10-20	m	3 m
Kraenzle Schneider		✕	✕						✕			✕		✕			✕								✕			✕							✕				8	60-75	w	8 w
LIFE- P	✓	✓	✓		✓	✓			✓	✓		✓	✓			✓	✓	✓		✓		✓							✓	✓		✓	✓		✓				6		m	6 m
Luten	✓						✓					✓						✓		✓		✓				✓				✓		✓		✓	✓	✓	✓				6 m
Opdenacker	✓	✓	✓	✓	✓	✓				✓		✓	✓	✓		✓	✓	✓		✓		✓			✓			✓	✓				✓	✓	✓			16		bi m to m	11 m
PACE		✓								✓		✓		✓			✓	✓	✓					✓			✓		✓				✓			✓			1	30		1 s
PALs		✓								✓		✓		✓			✓	✓		✓						✓	✓		✓	✓			✓		✓				2	8-10	m	3 m
Pekkarinen	✕						✕			✕		✕						✕				✕	✕	✕			✕			✕			✕		✕				2		3 y	8 y
Project LIFE		✕		✕					✕			✕	✕	✕			✕	✕							✕				✕				✕		✕				9	18	bi-m to m	6 m
Rydwik		✓	✓		✓		✓		✓	✓		✓							✓			✓	✓					✓				✓			✓				1			6 m
SCAMOB	✓	✓								✓		✓	✓	✓				✓		✓			✓				✓		✓	✓	✓		✓		✓				6	13	x3 y	2 y
Seattle protocol PA		✓	✓	✓	✓	✓			✓	✓		✓					✓	✓		✓		✓					✓	✓			✓			✓			✓	5	60	m to q	10 m
Sisters in Motion		✓	✓	✓	✓	✓		✓	✓	✓	✓	✓			✓	✓	✓				✓	✓					✓	✓					✓				✓	6	90	m	6 m
STAND UP!			✕		✕	✕			✕			✕								✕		✕						✕			✕	✕		✕			✕	1	30		1 s
STEPS		✓								✓		✓	✓			✕			✓					✓				✕	✓		✕	✓	✓		✓				20	5	w to m	12 m
Swanenburg			✕	✕	✕				✕			✕	✕										✕					✕					✓						1			1 s
Veterans LIFE Study		✕	✕	✕					✕			✕	✕					✕						✕	✕			✕	✕	✕			✕		✕				17		Bi-m to m	12 m

Footnote: ticks depict techniques in trials showing a significant effect on any PA outcome (e.g. MPA, walking or exercise time, Kcal expenditure, active transport) and crosses depicting techniques used in trials showing no significant effects on any outcome of PA maintenance. W= week/ly, m= month/ly, y= year/ly, q= quarter/ly, bi=twice.

2.4.7 Behaviour change techniques used in PA maintenance interventions

Twenty-nine BCTs within 12 domains were reported across trials. The following section provides a narrative summary of the BCTs that have been most frequently incorporated into interventions showing a significant outcome on a measure of PA. It should be noted that the interventions included in this review have been developed as a complex amalgamation of multiple components. Thus, it is unlikely that significant trial outcomes reported are solely related to the inclusion of a single BCT.

2.4.7.1 Goals and planning

"Problem solving" (e.g. relapse and prevention strategies) was described in seven trials with four reporting significant effects on multiple PA outcomes.

"Action planning" (e.g. physical activity plans) was outlined in five trials with three reporting significant effects on PA.

"Goal setting for behaviour" (e.g. walking goals), *"goal-setting for outcomes"* (e.g. step count) and "*reviewing behaviour goals"* were described in seven trials with five reporting significant effects on PA.

2.4.7.2 Feedback and monitoring

"Feedback on behaviour" was described in three of six trials showing significant PA effects.

"Self-monitoring behaviour" (e.g. diary completion) and *"self-monitoring outcomes of behaviour"* (e.g. step count via pedometer) was outlined in five of six trials showing significant effects on PA.

2.4.7.3 Social support

"Unspecified social support" (e.g. counselling, motivational interviewing) was described in nine of twelve trials reporting significant PA effects.

2.4.7.4 Shaping knowledge

"Instruction on how to perform a behaviour" (e.g. verbal instructions) was defined in nine of ten trials reporting significant PA outcomes.

2.4.7.5 Natural consequences

"Information about social and environmental consequences" (e.g. information on local PA services) was described in five of eight trials showing significant PA effects.

2.4.7.6 Comparison of behaviours

"Demonstration of how to perform a behaviour" (e.g. illustrated exercise sheets) was outlined in five trials showing a significant effect on a PA.

2.4.7.7 Comparison of outcomes

"*Credible source"* (e.g. nurse) delivered interventions were defined in nine trials with six reporting significant effects on PA.

2.4.7.8 Antecedents

"Adding objects into the environment" (e.g. pedometers, posters) was reported in nine trials with seven showing significant effects on various PA measures.

Table 5 depicts the BCTs used in each trial. Note that the BCTs presented do not include those used in the PA promotion period.

Table 5. Behaviour Change Techniques in Maintenance Interventions

Trial/ first author name	Behaviour change techniques																												
	1.1 Goal setting (behaviours)	1.2 Problem solving	1.3 Goal setting (outcome)	1.4 Action planning	1.5 Review behavior goal(s)	1.6 Discrepancy (behavior & goal)	1.7 Review outcome goal(s)	2.1 Behavior monitoring without feedback	2.2 Feedback on behavior	2.3 Self-monitoring of behavior	2.4 Self-monitoring outcome(s) of behavior	3.1 Social support (unspecified)	3.2 Social support (practical)	4.1 Instruction on how to perform a behavior	5.1 Information about health consequences	5.3 Info –social/ environmental consequences	6.1 Demonstration of the behavior	6.2 Social comparison	7.1 Prompts/cues	7.3 Reduce prompts/cues	8.1 Behavioral practice/ rehearsal	8.3 Habit formation	8.6 Generalization of a target behavior	8.7 Graded tasks	9.1 Credible source	11.2 Reduce negative emotions	12.1 Restructuring physical environment	12.5 Adding objects to the environment	15.4 Self-talk
Active Mentoring Program		✓		✓																									
Easy steps to Health		✓		✓	✓					✓		✓															✓	✓	
Green Prescription									✓					✓												✓				
Kraenzle Schneider	✕	✕		✕	✕	✕			✕			✕	✕					✕									✕		✕	✕
LIFE- P												✓		✓			✓					✓							✓	
Luten														✓	✓	✓	✓	✓	✓	✓						✓				
Opdenacker		✓	✓						✓	✓	✓	✓		✓		✓	✓												✓	
PACE	✓	✓			✓		✓					✓		✓	✓	✓	✓						✓			✓			✓	
PALs								✓	✓			✓		✓		✓	✓					✓			✓				✓	
Pekkarinen																✕										✕				
Project LIFE				✕						✕		✕			✕	✕													✕	
Rydwik											✓			✓												✓				
SCAMOB			✓	✓								✓		✓	✓		✓					✓				✓				
Seattle protocol of PA												✓		✓		✓													✓	
Sisters in Motion	✓								✓	✓		✓																	✓	
STAND UP!		✕														✕			✕				✕				✕			
STEPS												✓														✓				
Swanenburg														✕									✕			✕				
Veterans LIFE Study	✕	✕			✕	✕	✕		✕			✕			✕											✕				

Footnote: ticks depict techniques in trials showing a significant effect on any PA outcome (i.e.MPA, walking time, Kcal expenditure) and crosses depicting techniques used in trials showing no significant effects on any outcome of PA maintenance.

2.4.8 Age group data

Of the sixteen trials reporting mean age, six included people with a mean age of over 75 years old [77,78,80,105,106,108]. Six of the remaining ten trials that included participants with a mean age less than 75 years old reported significant effects on maintaining increased step counts [81,86], walking levels [76,87], time spent exercising or doing PA [76,81,82,85]. Whereas, four of the six trials including subjects with a mean age over 75 years old showed significant effects on sustained levels of weekly exercise [78], MPA, calorie expenditure [80], PAL scores [79] and keeping people active [77]. Only one of the five trials targeting people at risk of falls [101,110,111] or frailty [79,105] found significant effects in maintaining increased PAL scores in a frail population [79].

2.4.9 Secondary outcomes

2.4.9.1 Quality of life (QoL)

Six trials reported changes in QoL [76,78,85,87,107,108]. The effects of booster interventions alongside PA interventions on QoL are mixed. The Seattle Protocol for Activity Programme [78] found a telephone booster intervention to produce significant effects on improving QoL at 3 and 18 months. Likewise, the Green Prescription trial found telephone booster interventions to generate significant between group effects on QoL at 12-months [85]. Conversely, no significant effect was seen in QoL as a result of a nurse led walking program supported by booster telephone calls [87], nor a telephone counselling service [108] at 12-month follow up.

Trials integrating maintenance interventions into PA promotion programmes showed no significant effects on QoL. Incorporating relapse and prevention strategies into a 24-week maintenance phase showed no significant effects on QoL in the Easy Steps to Health trial [76]. Furthermore, incorporating cognitive behavioural therapy into a supervised PA programme may have a detrimental effect on health related QoL at 12 months post intervention [107].

2.4.9.2 Self-efficacy

One study investigated the effects of a telephone counseling service on levels of self-efficacy to perform MVPA and strength exercise. No significant effects were found between the intervention and control group's self-efficacy levels at 12-month follow up [108].

2.4.9.3 Cost effectiveness

The Life-P trial reported the cost-effectiveness of the intervention by calculating the costs saved via disability avoidance [114]. The cost effectiveness of the intervention at 12 months predicted that $28,206 would be saved through disability avoidance. A cost analysis was performed to calculate the cost of delivering and receiving the intervention and multiplying this by the USA national unit cost averages. The average participant cost for receiving the intervention was $1134.

The Veterans Project LIFE Study [108] used physicians to endorse their telephone counselling intervention during clinical consultations and by recording automated telephone calls. The cost of the physician's clinical time was estimated to cost $12.00 per participant for the intervention. All other intervention cost were unreported.

2.4.10 Risk of Bias (RoB) of included trials

The RoB results are presented in Table 6 and Table 7.

Most studies (n=17) were judged as a high or unclear RoB across at least 4 of the 7 sources of bias. The most common high RoB reported across trials (n=18) was the absence of blinding to the outcome assessment. Such findings are expected in PA trials due to the frequent use of self-reported PA measurement tools meaning that the participants cannot be blinded to the outcome assessment. Fourteen trials used self-reported PA measures and were classed as a high RoB on this basis. Four trials used objective outcome assessment tools in the form of accelerometers [84,87] and pedometers [81,86]. Yet, three of these trials did not blind the outcome assessor [81,84,86]. Only one trial reported objective PA measures that were collected by a blinded outcome assessor [87].

Nine of the fourteen RCTs used a random allocation sequence method. The allocation sequence methods were unclear in two trials and another two RCT's did not randomly allocate participants into groups. Overall, there was considered to be a low RoB across the majority of trials within this domain. Comparatively, the allocation of the participants in the non-RCTs was considered to have a high RoB overall. This was due to three of the five trials not randomly allocating participants into their groups.

There is an unclear RoB relating to the allocation concealment methods across all RCTs. Seven of the fourteen trials did not provide adequate information on the allocation concealment methods to assess RoB. Five RCTs were considered to be a low RoB as they clearly reported the allocation concealment methods. Two RCT's did not conceal the participant's group allocation.

It is rarely possible to blind participants to PA interventions as they usually require the participant to make a conscious effort to become more active. Therefore it was not surprising that no RCT could be scored as a low RoB on participant blinding. The majority of RCT's did not provide information on personnel blinding. Resulting in an unclear RoB overall. Two RCT's reported blinding staff and four RCTs clearly stated that they did not use blinding procedures. The results emerging from the non-RCTs was mixed. One mass media-campaign reported blinding of the participants and personnel [82]. Another reported blinding of the personnel only, two reported there was no participant and personnel blinding and one trial did not discuss blinding methods.

Most RCTs (n=12) were scored as a low RoB in the incomplete outcome data section as they provided acceptable reasons for missing data and/or performed an intention to treat analysis. The authors failed to report the reasons for the missing data and the attrition rates of one RCT [107] although the statistical analysis was adjusted for missing data. One trial did not provide sufficient information to accurately assess the RoB in this domain. Dealing with missing data in the non-RCTs was mixed. One trial reported the attrition rates, but gave no reason for dropouts and did not perform an intention to treat analysis. Another reported attrition rates and performed an intention to treat analysis but did not give the dropout reasons. Another trial limited the data analyzed to participants with a complete data set but failed to report the attrition rates. Two studies reported attrition rates, drop out reasons and performed an intention to treat analyses to account for missing data.

Generally, there was a high RoB scored in the domain relating to selective reporting of the outcomes that were outlined in the methods section or study protocols. Five RCTs and one non-RCT did not provide results on all of the pre-specified trial outcomes. Four RCTs and four non-RCTs did not publish sufficient information about the pre-specified outcomes to assess whether

all data had been reported. Five RCTs and one non-RCT clearly reported data on all pre-specified outcomes.

Lastly, no overall conclusions could be made on the RoB within the domain of “other bias”. Seven trials discussed study limitations whereas the other 11 trials did not acknowledge any additional bias risks. Two RCTs did not use validated tools to measure PA [79,101]. There was a low participation rate in another non-RCT which increased the risk of selection bias [82]. A further two trials were considered to be a high RoB as one used different recruitment methods across trial arms [81]. Another trial randomised the participants into groups after the intervention was administered [103].

Table 6 depicts the RoB of included RCT in each of the seven domains of the Cochrane RoB tool.

Table 6. Risk of Bias for included RCTs.

RCTs	1) Random sequence generation	2) Allocation concealment	3) Blinding of participants & personnel	4) Blinding of outcome assessment	5) Incomplete outcome data	6) Selective reporting	7) Other bias
Active Mentoring Program (Buman, Giacobbi et al. 2011)	+	?	?	−	+	?	?
Easy steps to Health (Voukelatos, Merom et al. 2015)	+	+	−	−	+	−	?
Green Prescription (Elley, Kerse et al. 2003)	+	+	−	−	+	−	?
LIFE- P (Pahor, Blair et al. 2006)	+	?	?	−	+	+	?
Morey et al. (2006)	+	?	?	−	?	?	−
Opdenacker, Boen et al. (2008)	−	−	?	−	+	?	−
PACE (Harris et al.,2015)	+	+	−	−	+	+	?
Pekkarinen, Loyttyniemi et al. (2013)	?	?	?	−	+	?	−
Rydwik, Frandin et al. (2010)	−	−	−	−	+	+	−
SCAMOB (Von Bonsdorff et al., 2008)	+	+	?	−	+	−	?
Schneider, Cook et al. (2008)	?	?	?	−	−	−	?
Seattle protocol of physical activity (Teri, McCurry et al. 2011)	+	?	?	−	+	+	?
STEPS (Dubbert, Cooper et al. 2002)	?	?	?	+	+	−	?
Veteran Project LIFE (Morey, Peterson et al., 2009)	+	+	−	−	+	+	+

Footnote: Crosses represent a low RoB, question marks represent an uncertain RoB and minus signs represent a high RoB. Blinding of the outcomes assessment is coded as high risk of bias in trials that only use self reported PA measures.

Table 7 depicts the RoB of included non-RCT in each of the seven domains of the Cochrane RoB tool.

Table 7. Risk of bias for non-RCTs

Non- RCTs	1) Allocation to the intervention/control	2) Blinding of participants & personnel	3) Blinding of the outcome assessment	4) Risk of bias due to confounding	5) Incomplete outcome data	6) Selective reporting	7) Other bias
Luten, Reijneveld et al. (2016)	+	+	−	+	?	?	−
PALs (Jancey, Lee et al. 2011)	−	−	−	−	−	?	?
Sisters in Motion (Duru, Sarkisian et al. 2010)	−	−	−	+	+	+	?
STAND UP! (Laforest, Pelletier et al. 2009)	−	?	−	+	?	?	−
Swanenburg, de Bruin et al. (2007)	+	?	−	+	+	?	−

Footnote: Crosses represent a low RoB, question marks represent an uncertain RoB and minus signs represent a high RoB. Blinding of the outcomes assessment is coded as high risk of bias in trials that only use self reported PA measures.

2.5 Systematic review discussion

Thirteen of nineteen trials reported a significant increase in one, or more, PA outcomes between 9 to 36 months after the onset of PA maintenance interventions. The evidence presented shows that PA maintenance programmes can help older adults preserve PA levels irrespective of increasing age [76-88]. Yet only one of five trials showed significant effects in maintaining PA in older adults at risk of falls [35,51,52] or frailty [79,105]. A potential explanation for this finding could be the greater risk of health conditions linked to frailty that influences peoples' ability to maintain PA over time [115].

Other systematic reviews assessing the longitudinal effects of PA programmes delivered to older adults report that PA can be sustained for between 12 [47] to 24 months [61]. The current review updates these conclusions as we found evidence showing that home-based PA and telephone support can help to sustain MPA levels for up to 36 months [80]. To our knowledge this is the first review incorporating evidence showing that older adults can maintain PA beyond a 24-month period.

Each PA maintenance intervention was reported as a complicated matrix of intervention features, delivery methods and BCTs that were unique to each trial. Due to the complex entanglement of multiple components it was impossible to confidently identify which intervention features, delivery modes or BCTs most consistently resulted in significant PA outcomes. For instance, there was very little distinction to whether booster components delivered at the end of, or maintenance components integrated within, PA interventions best maintained PA in older people. Likewise, the findings were unclear on what combinations of PA behaviours are best targeted by interventions.

It is possible that intervention outcomes are affected by interactions between the interventions BCTs, features and delivery modes. For example, “behavioural instructions” and “demonstration of how to perform a behaviour” are two separate BCTs. Yet when these two BCT’s were jointly delivered in interventions this often resulted in a significant PA outcome to favour the intervention group [77,80-83].

Segmenting interventions into BCT categories without disentangling the intervention features and delivery modes may lead to overly ambiguous results. Many BCT categories were vague and led to the inclusion of very heterogeneous group of interventions being placed in the same category. For example, motivational interviewing, counselling and cognitive behavioural therapy all fell within the BCT “unspecified social support”. This BCT category had to be disentangle to specifically find evidence that counseling [76,77,80,81,87] and motivational interviewing [77,81,83-85] could help encourage people to stay active. These specifics are important as other’s have also found motivational interviewing and counselling to improve the PA outcomes of adults [116,117] and specifically older people [47,55].

Some evidence suggests that including the BCT “adding objects into the environment” could encourage PA maintenance. Which objects are included may be of great importance. Again, unravelling the content of the BCT helped to identify that pedometers helped to encourage PA maintenance [29,35,37,42,44,48,50,57]. The benefit of including a pedometer within older adults PA programmes is well documented within literature reviews [47,61]. Printed materials and videos illustrating exercises may also help people to maintain PA [77,78,80-83]. This is similar to other systematic reviews and meta-analysis that found written materials [47,61] and PA instructions [118] to significantly improve older adults PA behaviours.

A recent meta-analysis proposed targeting a single PA behaviour may be more effective than targeting generic PA [47]. The outcomes of the current review are mixed. There is some evidence to suggest that solely targeting

walking helps to maintain older adults PA levels [76,83,84,87]. Yet numerous trials also reported maintaining significant PA levels when targeting multiple PA behaviours. Targeting lifestyle PA in programmes may be especially beneficial as 12 of 13 trials reported maintaining significant effects on PA.

A previous meta-analysis suggests that tailoring interventions with personal step count goals and information of local PA opportunities may be important to encourage sustained PA [47]. Our findings are similar to another review [61] whereby we found no conclusive evidence that tailored interventions are superior to non-tailored interventions in conserving older adults PA levels.

Authors have reported telephone communication supports the on-going effectiveness of PA interventions [47,61,119]. Although, we found evidence to support this supposition, we equally found no evidence to suggest that telephone calls were superior to face-to-face interactions. More importantly we found that a single communication mode (i.e. telephone calls alone) is not sufficient to maintain PA and that interventions should be communicated using multi-modal communication pathways.

The relationship between intervention dosage and PA outcomes remains unclear. A recent meta-analysis showed more intervention contacts did not lead to better PA outcomes [47]. However, our results differ from this whereby we found evidence to suggest that a single session of brief PA advice is not enough to maintain older people's PA levels. The frequency of intervention contacts appears to be more influential. Interventions delivered on a monthly or quarterly basis appear to be more effective than those delivered less often.

Another possible determinant of PA sustainability is intervention duration. Our findings show that the probability of PA being maintained is reduced when intervention time periods are less than two months. Whereas, intervention time periods of 6 months to 2 years may better predict the sustainability of PA in older people. This hypothesis is supported by a

published review that explored the theoretical explanations of behaviour maintenance whereby a new behaviour does not become focally dominant until 6 months after its initiation [56].

A previous meta-analysis found that exercise interventions have little effect on older peoples' quality of life [120]. Not enough QoL evidence was identified to neither support nor refute these findings. Similarly, conclusions on the cost effectiveness of interventions could not be made due to a lack of evidence.

It is almost impossible to blind participants to self-reported PA assessments. Therefore, it was unsurprising that the main RoB flaw related to lack of participant blinding. Where possible, future trials should endeavour to objectively measure PA whilst blinding the outcome assessor.

2.6 Strengths and limitations of the systematic review methods

The strengths of this review included two reviewers independently screened, extracted data and performed a RoB assessment using pre-specified methods. Authors were contacted to provide further information and missing data to help improve the accuracy of the results. A comprehensive list of PA search terms was created with the input from a medical librarian. It should be noted that the list did not include terms relating to non-formal physical activities (i.e. gardening and housework). Although wild cards and truncations were added to the included PA search terms it is possible that some studies investigating lifestyle PA were missed.

Appropriate databases were searched to answer the trial question. Although a range of databases were searched, this did not include the Cochrane Central Register of Controlled Trials (CENTRAL) or the Allied

and Complementary Medicine Database (AMED). The majority of trials in CENTRAL are also in MEDLINE and EMBASE, [91] and AMED was recently found to add little to study identification for systematic reviews of musculoskeletal conditions above MEDLINE, EMBASE and CENTRAL [121], it is possible that some eligible studies were missed.

This review was conducted to help evaluate which intervention components work best to encourage PA maintenance. As a result, each complex intervention was finely categorised by its intervention components. Therefore, the completeness of each individual intervention and the possible interactions between its various components were lost. Although the effects of such interactions are difficult to assess this does mean that we may have missed some valuable information.

Due to the large heterogeneity in the PA intervention components and outcomes reported a meta-analysis could not be performed. Therefore, the effectiveness level of specific intervention strategies could not be determined using pooled effect sizes. This limits our ability to provide objective answers to the research question “what intervention strategies work to improve PA maintenance in older people?”.

2.7 Limitations of included studies

Included studies used a range of measures to assess PA (e.g. frequency, duration, intensity or type) and most used self-reported outcome measures. Methods of converting questionnaire scores into calorie, MET and MVPA varied between studies. Some authors used published compendiums to estimate energy expenditure [85]; whereas others modified validated scoring systems to gain continuous measures of MVPA [108]. This variation in measures and outcome calculations may partly account for differences between study findings [122]. Recall and social desirability biases may have

occurred with self-reported PA [122,123] and only a small number of studies used objective PA measures (i.e. accelerometers and pedometers). Although self-reported questionnaires are highly accessible, researchers can improve the accuracy of PA outcomes using accelerometers [123,124].

Included studies randomly allocated participants to the PA promotion intervention. However, many booster studies did not subsequently randomly allocate participants into a maintenance group and a no maintenance comparator group. Consequently, our findings, in the most part, relate to the effect of the PA promotion intervention plus the maintenance intervention. To help assess the additional effect of the maintenance intervention future studies should reallocate participants into groups after the initial PA promotion programme. Additionally, some studies did not assess intervention effects beyond 6 months and longer follow-up periods are needed to describe the longitudinal health benefits. All studies took place in high-income countries, limiting generalisability to low or middle-income countries. Only one study took place in the UK, and caution may be needed in generalising findings from other high-income countries due to differences in PA opportunities between countries.

More adequately powered studies are needed to detect changes in PA as only ten calculated sample sizes using a PA outcome and only seven reported recruiting sufficient participants to meet the recruitment target. Some studies did not report baseline measures, p-values or group results. Therefore, more transparency is required when reporting research findings. More methodologically rigorous trials are needed as most studies were judged to be at high or unclear RoB across at least four sources of bias.

2.8 Implications for Future Research, Policies and Clinical Practice

Here we provide evidence showing that including PA maintenance strategies can help encourage older people to stay active for longer. This information is key for PA service managers and commissioners who develop and fund the provision of PA interventions in older adults. Intervention developers and clinicians can facilitate PA maintenance by delivering interventions for a period of 6 months or more on a monthly or quarterly basis. Interventions targeting walking or lifestyle PA and those that include pedometers, exercise equipment, counselling or motivational interviewing may help encourage PA maintenance.

Evidence was found showing PA maintenance interventions can be clinically effective, but there was a lack of studies performing economic evaluations of interventions. In the UK, commissioning of health interventions are based on their clinical and cost effectiveness [125]. Therefore, researchers should endeavour to perform an economic evaluation of interventions to help commissioners in their decision-making processes.

The current review illustrated how BCTs, intervention features and delivery modes work together to create outcomes. This complexity means that no single BCT or intervention feature can be analysed as a stand-alone component. Researchers of future systematic reviews should consider disentangling the content of BCT categories and interactions between BCTs and the intervention features. This may be of current importance due to the increasing numbers of published meta-analyses that are investigating health interventions in terms of BCTs without accounting for the potential effect of the intervention features and delivery modes [68,118,126].

Researchers investigating PA maintenance should consider using random allocation methods at the end of PA promotion programmes and use longer follow up periods to assess the extended effects of maintenance interventions. There is a current lack of research within UK systems therefore more research is needed.

2.9 Conclusion

The current review presents evidence showing that PA maintenance programmes can help older adults stay active. Both maintenance components that are integrated within and booster interventions delivered at the end of PA programmes maintain PA. Intervention time periods and the frequency that interventions are delivered appear to influence intervention effectiveness. Due to the complex matrix of components that make up interventions it is difficult to draw clear-cut conclusions on what BCTs and intervention features best encourage PA maintenance in older people. More methodologically rigorous trials with longer follow up periods are needed to assess the additional effect that PA maintenance interventions have on sustained PA.

Chapter 3. Keeping Adults Physically Active, Intervention Mapping and Development.

3.1 Chapter 3 Summary.

The purpose of chapter three is to detail and critically appraise the methods used to develop the Keeping Adults Physically Active (KAPA) intervention. Bartholomew's intervention mapping (IM) approach was employed to systematically design a theoretical and evidence-based intervention that aimed to maintain PA in participants exiting the PHISICAL FaME programme. The IM approach is a systematic step-wise process whereby the output of each stage contributed to the development of the final KAPA intervention. In summary, the resultant intervention was a PA motivational interviewing programme that aimed to help older adults remain physically active after the completion of the 24-week commissioned PHISICAL FaME programme. The acceptability and feasibility of the final KAPA intervention was later investigated using a mixed methods feasibility study.

3.2 An Introduction to Developing Theory Based Interventions

The initial stages of developing an intervention involves identifying the current evidence base by conducting a systematic review [64,127]. This helps develop a theoretical understanding of the research problem, identify effective strategies that have achieved change and hypothesise the expected outcomes. Literature review findings provide a menu of effective intervention strategies [128]. However, building interventions based on effective strategies alone may not be enough to provoke the best possible behavioural outcomes if the strategies identified do not address the determinants that drive specific behaviours.

Interventions designed to address behavioural determinants within specific populations have the greatest likelihood of success [54,59]. Identifying and understanding the factors that mediate behaviours can help interventionists to understand the nature and theoretical constructs of the problem at hand [128,129]. Linking behavioural determinants to specific theories can help ensure that the foundations of an intervention are in place. To increase the likelihood of the intervention working, links between behaviour determinants, theories and intervention strategies should be made during the intervention development process [130].

3.2.1 Intervention Development Tools

A number of tools and guidelines have been published to aid the intervention development process [64,127,131-135]. In the health field, intervention development tools either take an individual behaviour change or an ecological approach [131]. The PRECEDE-PROCEED model and Six steps in quality intervention development (6SQuID) tools use an ecological approach to create interventions [135,131]. The PRECEDE-PROCEED model assesses individual behaviours as well as societal and environmental factors and considers all to be potential intervention targets [135]. In contrast, the 6SQuID focuses on integrating behaviour determinants, theories and research findings and uses vast collaborative networks of practitioners, researchers, policymakers and service users to develop interventions [131]. Although ecological models are comprehensive, their drawbacks are that they consider a very broad range of complex factors which can be incredibly resource and time-intensive [135].

In comparison, individual approaches are less broad as they are concerned with targeting interventions at an individual level by assessing service-user needs [64,134]. Generally, individual needs remain core during the intervention

development process [134]. Centralising service-user needs is key in the Person-Based Approach [134]. This approach includes collecting and synthesising qualitative information from service-users to design intervention objectives and features [134]. The acceptability and feasibility of the intervention created is evaluated and modified using the service users perspectives [134]. Although this approach is designed to meet individual needs, alike other individual intervention development tools, it is not exhaustive in considering the operational stages of the intervention which can result in poor intervention implementation [127,132,133,134].

Similar to 6SQuID, Bartholomew's Intervention Mapping (IM) approach systematically integrates behaviour determinants, theory and research findings to develop interventions, implementation and evaluation plans [64,134]. Yet, the IM approach is less time and resource intensive as it does not require a multidisciplinary co-design approach [64]. The current study did not have the time and monitory resources needed to adopt a 6SQuID-approach. Therefore, the IM approach was selected as the most comprehensive and pragmatic approach to develop the KAPA intervention through to the implementation stage.

3.2.2 The Intervention Mapping Approach

Bartholomew's intervention mapping (IM) framework uses a systematic step-wise approach to guide the intervention development process. The IM process includes qualitative research methods as this helps one to identify the factors that mediate behaviour and highlight any potential barriers in the implementation process [64,127]. The information gathered during this systematic process is organised to help develop an optimum intervention and study evaluation plan [127]. Figure 3 outlines the six staged IM process and the types of information used at each intervention design stage. Using

the six domains, an IM protocol was used to outline the development of the KAPA intervention.

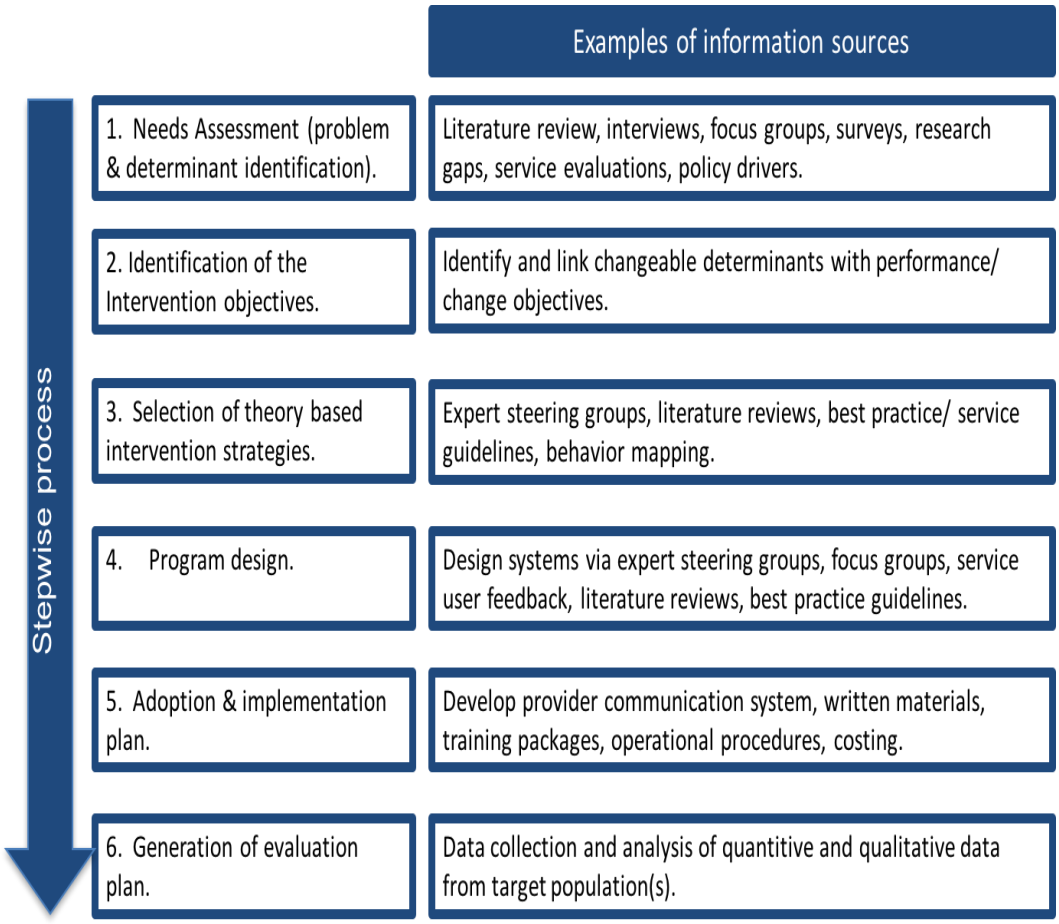
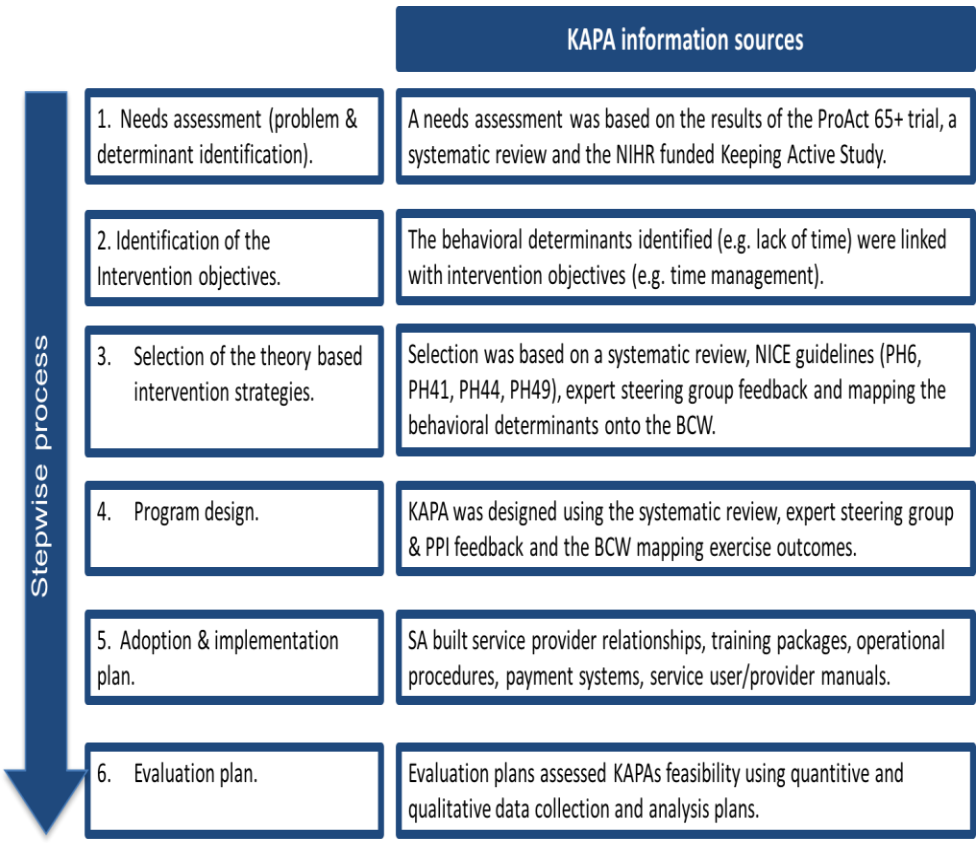


Figure 3. Bartholomew's Intervention Mapping Approach

3.3 KAPAs Intervention Development Process

The following sub-sections detail the methods used to help design the KAPA intervention using the IM approach. Figure 4 outlines the six-staged IM process and the resources used to design the KAPA intervention.



Footnote: NIHR – National Institute for Health Research, NICE - National Institute for Health and Care Excellence, BCW- Behaviour Change Wheel, PPI- People & Public Involvement, SA: Sarah Audsley

Figure 4. Outline of the KAPA Intervention Mapping Approach

3.3.1 Step 1. Needs assessment

The initial step of the intervention development process was to identify and analyse the problem and justify the need for the KAPA intervention. The need for the KAPA intervention has been outlined in Chapter 1 and is not discussed further in this chapter. During this initial stage interventionists need to identify the behavioural determinants that will encourage people to perform the target behavior.

Identifying the behavioural determinants

Behavioural determinants of the target population are most commonly identified using qualitative and quantitative research methods. The PA determinants of older adults exiting falls exercise programmes were identified using the results of the recently conducted Keeping Active Study (publication currently under peer review). This study used interviews with a number of the ProAct 65+ trial participants to identify the facilitators and barriers to PA maintenance in falls exercise programme users. Interviews investigated people's PA behaviours before and after the ProAct65+ trial and barriers and facilitators they experienced in relation to PA maintenance. The themes identified consisted of the barriers and facilitators relating to the physical, psychological, environment and social PA determinants. The PA determinants identified related to motivation, self-efficacy autonomy, enjoyment, positive feedback, positive evaluation of PA (i.e. physical benefits and social interaction) and the development of habitual PA behaviours.

For the purpose of developing the KAPA intervention the PA determinants reported in the study were extracted, tabulated and categorised in the themes of physical, psychological, environmental and social factors. The information table was used as a foundation to help identify the performance and change objectives in step 2. Table 8 shows the PA maintenance determinants derived from the Keeping Active study.

Table 8. Keeping Active study results showing the determinants of PA maintenance behaviours in older adults exiting falls prevention exercise programmes.

Determinant category	*Barriers*	*Facilitators*
Physical determinants	Deterioration in physical health Fatigue	Improved physical autonomy as a result of being physically active. Positively evaluated the benefits of PA. Improved physical function as a result of being physically active. Witnessing physical deterioration in friends and family members.
Social determinants	Caring roles prevented participation in structured organised PA Lack of time and PA not a priority Social isolation	Social interaction. Enjoyment of community based structured exercise programmes. Motivation gained by exercising with others. Partners motivating and encouraging one another. Positive feedback and evaluation of PA from friends and family.
Environmental determinants	Location and availability of exercise programmes Proximity to venues offering different types of exercise classes Technology (apps, smart phones and pedometers) provided motivation and encouragement. Having transport Cost or affordability	Distractions in the home reduced people's commitment towards home-based exercises. Lack of advertisement of local PA opportunities. Not having transport. Poor weather. Class times. Personal safety when attending evening classes. Uneven terrain or hard surfaces caused joint pain. Cost or affordability.
Psychological determinants	Beliefs that own health may not improve, possibly due to the ageing process Others' attitude towards ageing Depression/ low mood Memory impairment	Motivation gained by having easy access to PA programmes. Measurable activity with pedometers and tick charts. Increased self-efficacy. Development of a positive routine or habit Improved confidence relating to a reduction in falls.

3.3.2 Step 2: Identifying the performance and change objectives

In step 2, a researcher considered each PA determinant and translated them into potential solutions (i.e. performance objective) of what needed to happen at participant level to support PA maintenance. Performance objectives were used to identify the changes needed at service provider level (i.e. change objectives) in order to achieve changes in participant behaviour (i.e. meet performance objectives). The determinants and objectives were used to help identify appropriate behaviour change theories. The process of mapping performance and change objectives to relevant behaviour theories is important as the process outcomes are used to help identify the most appropriate intervention techniques to help change behaviours.

To create the matrix of performance and change objectives each PA determinant was broken down into sub-behaviours that affect PA engagement. For each PA determinant and sub-behaviour listed a feasible and accessible performance objective was identified by asking the question "what do the participants need to do to effect the sub-behaviour?" [136]. The change objectives were then specified by asking the question "what needs to change at service level to affect the performance objectives?". The performance and change objectives identified in this process were mapped against each PA determinant.

Next, relevant theories were linked with the performance and change objectives. Bartholomew et al.'s [137] information tables showing the associations between the behavioural determinants, theories and intervention techniques were used during this process to help ensure each performance and change objective was grounded in theory. During this stage only the objectives that the researcher deemed to have the potential to help older adults to maintain their PA levels and those that were feasible

to implement were selected. The matrix of determinants and performance and change objectives are shown in Appendix 3.

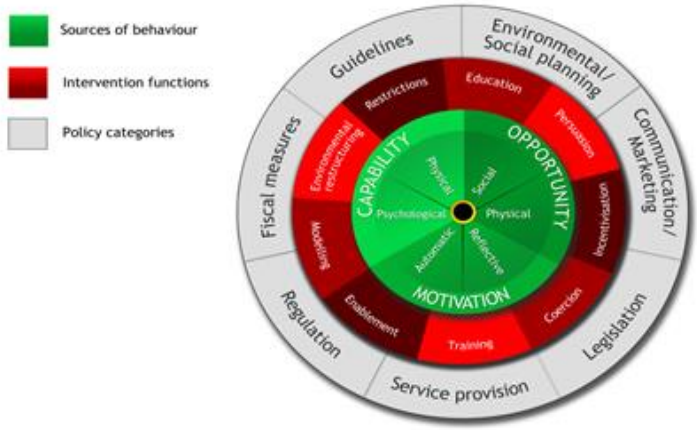
3.3.3 Step 3: Identifying intervention techniques

The goal of step three was to identify the most appropriate theory-based intervention techniques to affect the behavioural determinants and achieve the performance objectives. Determinants that mediate behaviour hold links with specific behaviour change or ecological theories. During the third stage behaviour change theories and their associated intervention techniques are chosen to ground the intervention.

There is very little evidence to support the use of one behaviour change theory over another to support PA interventions [54,138,139]. Thus, UK guidelines recommend that interventions should be built using more than one theory [54]. Choosing specific theories can be complex as the behaviour determinants identified may lie within many theoretical constructs, meaning that multiple theories need to be included. As each model has a different focus it can be problematic for interventionists to decide which model holds the most truth for their population [54,59]. Furthermore, no evidence exists to suggest which theoretical model(s) may best support PA maintenance in older people [60]. Due to these complexities it was difficult to identify which theories and associated strategies would best evoke behaviour change in terms of the KAPA intervention.

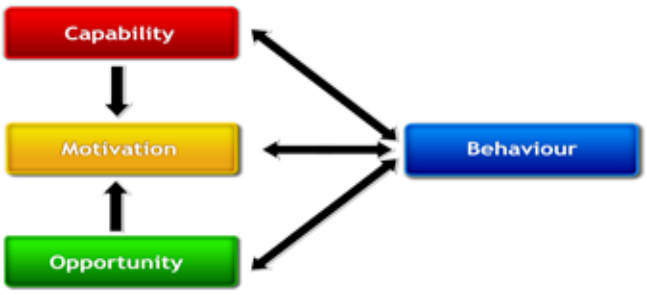
The behaviour change wheel (BCW) was developed using the constructs of multiple behaviour change theories to help link behavioural determinants with the most appropriate BCTs (see Figure 5) [58,59]. The BCW was chosen to underpin the KAPA intervention as it helped to resolve complications in deciding which theoretical model to choose to best evoke PA maintenance in older adults [58,59].

The BCW categorises behaviour determinants in terms of an individual's opportunity, capability and motivation to perform the behaviour which is centred at the core of the wheel (COM-B analysis, Figure 6). This generates a behavioural diagnosis that subsequently helps the interventionist to identify which category of intervention techniques may best support the behaviour change [59,140]. Due to the complexities relating to the selection of individual theories and methods the BCW was used to help identify appropriate intervention techniques for the KAPA intervention.



(taken from Michie et al., 2014)

Figure 5. The Behaviour Change Wheel (BCW).



(taken from Michie et al., 2014)

Figure 6. COM-B analysis

Permission was granted, from Mitchie S, Atkins L, West R. (2014). The BCW: A guide to designing interventions. London: Silverback Publishing (www.behaviourchangewheel.com), to use the images presented in Figure 5 and 6.

Each BCT selected was rationalised using a triangulation approach on whether the BCT was i) linked to having the potential to influence a performance or change objective on the matrix (Appendix 3); ii) highlighted as being evidence based (using table 9). All BCTs that met these three criteria and were practical to deliver within the PA services were included in the KAPA intervention. The only evidence based BCT listed on the matrix that was not included in the KAPA intervention was behavioural practice. This BCT was not included as the KAPA intervention was a talking therapy and the environment may not have been suitable for exercise. The following three-staged process details the triangulation methods used.

1: Linking BCTs with behavioural determinants using a COM-B approach.

Firstly, the behavioural determinants and the associated performance and change objectives, identified in Step 1 and 2, were categorised using the COM-B analysis. The COM-B analysis outcomes were mapped onto the BCW to identify the intervention functions and associated intervention techniques (i.e. BCT's) using the linking tables presented in Michie et al's (2014) guide to designing interventions [58]. All BCTs identified during this process were added onto the matrix of behaviour determinants, performance and change objectives (Appendix 3).

2. Selecting BCTs on the matrix of behaviour determinants, performance and change objectives (Appendix 3) using the evidence base.

The aim was to try and include only evidence based BCTs in the KAPA intervention. The BCTs identified in KAPAs systematic review (chapter 2) and the NICE guidelines for PA and behaviour change (PH6, PH41, PH44, PH49) were selected on the matrix to be included in the KAPA intervention. This was done using table 9 which contains the evidence based BCTs found in the systematic review and NICE guidelines.

3. Identifying additional BCTs to support behaviour maintenance.

The previous stage was important as it highlighted that the evidence based BCTs (outlined on Table 9) were not sufficient to affect all the behavioural determinants. In some cases, previous research had not investigated particular BCTs and PA maintenance [56]. Where the evidence base could not determine the effectiveness of a BCT on behaviour maintenance the BCT was selected on its potential to affect the behaviour determinant. For example, self-regulation is a determinant of behaviour maintenance [56]. Self-regulation is considered to be an active response, whereby emotions and desires are replaced with goal-orientated responses in an effort to control unwanted behaviour. Self-regulatory processes refer to the on-going process of self-monitoring, evaluation and reinforcement. Therefore, BCTs relating to monitoring people's behaviour outcomes and giving feedback on outcomes were selected on the matrix (Appendix 3) to address this determinant.

Managing impulses, temptations and breaking old habits is also a form of self-regulation. This is said to be supported by BCTs relating to conserving mental resources (e.g. stress management) [141], removing averse stimuli and substituting one behaviour for another [142,143]. People are said to be motivated to perform good health behaviours when trying to avoid negative health consequences [56]. BCT's highlighting good and bad health consequences (i.e. considering pros and cons and comparing future health outcomes) were selected on the matrix. Lastly, BCTs relating to past success, incentivisation and rewards were selected on the matrix, as these help to reinforce positive emotions that relate to enjoying performing the behaviour [144]. Table 9 contains the BCTs that were assumed to support behaviour maintenance from the Kwasnicka et al., review [56].

Table 10 (page 118) outlines the full and final content of the KAPA intervention and the BCT's (selected using the triangulation approach discussed in step 3) in the chronological order that they were delivered. The intervention strategies were fully described and numerically coded as the BCTs presented in v1 BCT taxonomy, developed by Mitchie et al., 2009 [93].

Table 9 Information sources supported the behaviour change techniques included in the KAPA intervention.

Information source supporting BCT for THE KAPA intervention development	Behaviour change techniques																												
	1.1 Goal setting (behaviours)	1.2 Problem solving	1.3 Goal setting (outcome)	1.4 Action planning	1.5 Review behavior goal(s)	1.6 Discrepancy (behavior & goal)	1.7 Review outcome goal(s)	1.8 Behavioral contract	1.9 Commitment	2.2 Feedback on behavior	2.3 Self-monitoring of behavior	2.4 Self-monitoring outcome(s) of behavior	2.5 Monitoring outcomes of behavior	2.7 Feedback on behavior outcomes	3.1 Social support (unspecified)	4.1 Instruction on how to perform a behavior	5.1 Information about health consequences	5.3 Info –social/ environmental consequences	6.1 Demonstration of the behavior	7.5 Remove aversive stimulus	8.2 Behavior substitution	8.3 Habit formation	9.2 Pros and cons	9.3 Comparative imagining of future outcomes	10.4 Social reward	10.7 Self incentive	10.9 self - reward	11.2 Reduce negative emotions	11.3 Conserving mental resources	12.5 Adding objects to the environment	15.3 Focus on past successes
Chapter 2 findings	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓				✓	✓	✓	✓	✓			✓								✓	
NICE PH6, Behaviour change general approaches [145]	✓	✓	✓	✓			✓			✓	✓	✓	✓	✓	✓															
NICE PH41, PA: Walking and cycling [146]	✓		✓								✓	✓	✓	✓	✓							✓							✓	
NICE PH44, PA brief advice for adults in primary care [147]	✓	✓	✓			✓											✓	✓												
NICE PH49, Behaviour change individual approaches [54]	✓	✓	✓	✓						✓	✓	✓	✓	✓	✓										✓	✓	✓			
Kwasnicka et al., [56]					✓	✓				✓	✓	✓	✓	✓						✓	✓		✓	✓	✓	✓	✓	✓		✓

3.3.4 Step 4: Programme design

The fourth step involved specifying, planning and organising the KAPA intervention package. This included the intervention strategies, delivery modes, training package and resources. It was important that the KAPA intervention programme was relevant and acceptable to both the PA service providers and participants. Therefore, an expert steering group provided feedback and guidance during the programme design process. Working with the expert steering group helped with the creation, operationalisation and reviewing of the KAPA intervention. The KAPA intervention was designed using the following three-step approach:

1. Identifying intervention features and delivery modes

A PA maintenance intervention framework, detailing the intervention features and delivery methods, was developed using the matrix created in stage 3 alongside the evidence base from the systematic review (chapter 2) and appropriate NICE guidelines (Figure 7) [54,147]. In brief, the systematic review suggested that interventions were most effective when delivered on a monthly or quarterly basis over a period of 6 months or more. Interventions that were delivered using multi-modal communication methods and a motivational interviewing approach were often found to be effective. Interventions supported by pedometers, exercise equipment and illustrative exercise sheets help to maintain PA (chapter 2). NICE guidelines for PA also advocate the use of pedometers in PA programmes that involve monitoring and goal setting [147]. Interventions targeting walking, lifestyle PA and multiple types of PA were often found to be effective in sustaining PA (chapter 2).

NICE guidelines for behaviour change recommend that staff delivering behaviour change techniques should be adequately trained. Mentors should also support staff delivering behaviour change interventions to aid their successful implementation [54]. All of the above information was collected and depicted in a KAPA intervention framework (Figure 7).

The KAPA intervention was developed with an expert steering group consisting of seventeen PA service managers, PSIs and a sport development officer from North West Leicestershire, Derby City and Rutland County councils. The KAPA intervention framework was presented in the meetings and formed the base of the discussions with the expert steering group. Discussions were held on which elements they believed were deliverable in the current services and those that they felt would best work to encourage PA in older people.

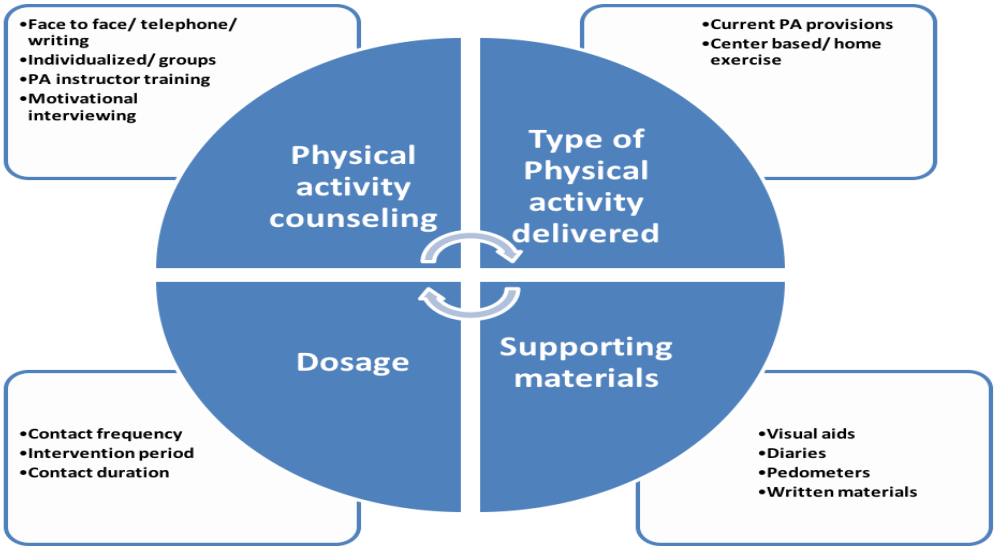


Figure 7. KAPA intervention framework developed from the systematic review and the NICE guidelines.

2. Selecting and specifying KAPAs intervention features and delivery modes

The expert steering group guided the development of the KAPA intervention during two service provider meetings. A researcher chaired the expert steering group meetings and provided information on the KAPA intervention framework, supporting literature and how these may help with the delivery of the KAPA intervention. During the process the expert panel provided guidance on how specific intervention features could best be delivered and implemented across each of the study sites.

Two stages of expert steering group meetings took place in total. The topics on the agenda for meeting one covered:

- Explore the KAPA intervention framework, research costs and proposed delivery methods.
- Explore what needs to happen at service provider level to make the KAPA intervention feasible.
- Identify the PA instructors' training needs.
- Identify the possible barriers and facilitators the service providers may face when delivering KAPA.

Meeting two's agenda covered:

- Shaping the final intervention
- Discuss any potential barriers and facilitators in delivering KAPA.
- Plan the PSIs training.

The following paragraphs provide a summary of the content discussed in the expert steering group meetings. The expert steering group used a consensus method in the decision-making process of how the KAPA intervention should be organised and delivered.

Time: It was highlighted that the KAPA intervention should have defined contact times as the PSIs and PA development officers have additional work within their roles that should not be impacted upon. The delivery of the KAPA intervention on one-to-one basis was considered too time intensive, but delivering the KAPA intervention within a group setting would help resolve timing issues. NICE guidelines [148] state that services should help create social opportunities for older people. Therefore, the expert steering group believed that a group setting would be fitting to meet this aim.

Development of PA action plans: Long discussions took place around how individualised PA plans could be developed during group sessions. The experts from Derby shared experiences of how they deliver group motivational interviews, but how they also complete individual forms and individual action plans. There were some concerns raised about confidentiality and sharing information in a group session and whether confidentiality maybe improved by running one-to-one sessions. The outcome of this conversation was that the expert group felt that action plans should be created within the group sessions as this would be more beneficial for time and cost. Each site was happy to create a menu of PA opportunities that were being run within the region to help participants select appropriate activities for their PA plans.

Follow up sessions: Discussions took place regarding the follow up sessions. The group felt it was important to emphasise the social element of the group meetings and discussed the possibility of including wider wellbeing topics. Questions were raised about whether the sessions had to be once a month or whether they should be more often. Conversations were had around whether follow up should be done via telephone or face-to-face. The group agreed that participants would be followed up face-to-face in a group setting. Yet those failing to attend a session would be followed up by telephone. It was agreed that to improve the time and cost efficiency of

face-to-face sessions they would be delivered once monthly for between 60 and 90 minutes. Telephone sessions would last no more than 20 minutes.

Discussions were had around appropriate venues to deliver KAPA. It was deemed important that the KAPA intervention should be delivered in an accessible venue because research suggests that the acceptability of PA interventions is affected by access to transport and venues [149,150]. Therefore, it was felt most appropriate to deliver the sessions monthly within the same venue that the original PHISICAL FaME classes had been held.

Training: A number of PSIs were trained in motivational interviewing ahead of delivering the KAPA intervention. It was agreed that the PSIs who were not trained in motivational interviewing would attend a one day *"Let's Get Moving"* motivational interviewing course at Loughborough College. It was also agreed that SA provided one day of training on behaviour change and how to deliver the KAPA intervention. It was decided that both e-learning and face-to-face training methods were viable options to deliver the KAPA training programme.

Supporting materials: The expert steering group were happy to contribute towards producing written materials for the participant manuals (i.e. timetables of local PA programmes). The group discussed the use of PA diaries and felt that an A5 or business card sized diary would be user friendly. The group were accepting of issuing pedometers to the KAPA participants. The final KAPA intervention features and delivery modes agreed in the expert steering group meeting is outlined in Table 10.

The research budget was key in considering the feasibility of the intervention features and delivery modes. Costing the KAPA intervention was based on the market value of the PSIs hourly rates and calculated with my PhD supervisor and Public Health Consultant Dr Elizabeth Orton. Various iterations of cost projections were created throughout the intervention development process to help continually ensure that the KAPA

intervention remained feasible from a cost perspective. The cost projections and intervention features and delivery methods agreed by the expert steering group was used to shape the final KAPA intervention (Figure 8).

3.3.5 Step 5: Developing an implementation plan

Once the KAPA intervention was finalised the next step was to develop an implementation plan. Creating an implementation plan is necessary to ensure that all PSIs were delivering the intervention correctly and with the same level of fidelity. Therefore, a key component of this stage was to develop:

1. A communication system between the researchers, service providers and users.
2. A standard operational procedures document (SOP) and writing materials to support the intervention delivery.
3. A training package and the mentoring system to support the PSIs delivering KAPA.

1. Creating a communication system

To help with implementation it is recommended that a communication system between the researchers, service providers and service users is created. The KAPA feasibility study communication system between these people was created during the initial PhISICAL study and was further reinforced during step 4 the KAPA study.

2. Developing the SOP and participant manual

The KAPA participant manual was developed to help layout the intervention and its practicalities. All participants and PSIs received a copy of the manual. The manual served two purposes. The first purpose was to help guide the KAPA participants through the KAPA intervention. Secondly, the manual was chronologically ordered in its KAPA programme activities (as outlined in Table 10) to help the PSIs to structure the sessions so to deliver the KAPA intervention with a good level of fidelity. Many of the BCTs selected were similar to those included in England's NHS Health Trainer service. Therefore, much of the content in the participant handbook, SOP and the PSIs training materials was structured and adapted from the NHS Health Trainer Handbook [151]. Feedback from a people and public involvement (PPI) representative (Peter Riley) on the participant handbook was gained during a two-hour meeting. The handbooks were amended to fit the feedback of the PPI representative. The finalised participant handbook can be viewed in Appendix 4.

The KAPA intervention was operationalized within a SOP. The document outlined the PSIs role and the confidentiality and health and safety procedures. The SOP also reiterated the content and procedures of the intervention strategies delivered within each of the six KAPA intervention sessions. A paper copy of the SOP was given to the PSIs during their training day. PSIs were encouraged to refer back to the SOP before

delivering each session to help improve fidelity. A copy of the SOP can be viewed in Appendix 5.

3. Creating the KAPA training programme

The learning outcomes, course syllabus and learning materials of the KAPA training package were developed by the intervention developer who was qualified and experienced in developing and delivering further education courses. KAPA's training content was designed using an outcome-based learning model which focused on the skills and knowledge that the PSIs would need to deliver KAPA. The types of learning outcomes developed were knowledge, application and skill-based. Bloom's Taxonomy of Educational Objectives [152] was used to help ensure that the learning outcomes were pitched at the right level of cognitive ability for the learners. An educational consultant (Eileen Baron) who specialises in health and fitness education reviewed the learning outcomes, course content and materials to ensure the course was suitable to meet the learners' needs.

The course syllabus developed was created using the NICE guidelines (PH6, PH41, PH44, PH49) and the literature on behaviour change and PA. The learning outcomes and activities related to the background knowledge and practical skills needed to deliver KAPA. A large emphasis of the training focused on how to deliver the BCTs selected in the KAPA intervention.

A seven-hour training programme was created and delivered face to face to groups of the PSIs assigned to delivering the KAPA intervention within either a work (i.e. local leisure centre) or education setting (Loughborough Sports Park). The PSIs training day was planned and delivered by the researcher. The learning outcomes included:

- Understanding behaviour in relation to change, maintenance and habit formation;

- Understand the concept and practical application of the COM-B analysis and motivational interviewing;
- Demonstrating an ability to effectively structure and deliver behaviour change interventions;
- Working within a professional capacity whilst delivering behaviour change interventions.

The educational package included written materials in the form of a trainee handbook, lecture slide print outs, case study learning activities, KAPA intervention standard operational procedures, data collection forms and a copy of the KAPA participant handbook. The precise details of the training manual and lesson plans can be viewed in Appendix 6.

To help support the delivery of the KAPA intervention two sessions were observed per PSI and feedback was provided on the KAPA intervention's delivery during a mentoring session. Mentoring sessions were given to each individual PSI in his or her place of work. Sessions were recorded in the PSIs' mentoring logbook and performance objectives were made to help the instructors to deliver the KAPA intervention to the best of their abilities. Each PSI had access to two mentoring sessions that were delivered on request. Mentoring sessions lasted between 30 and 45 minutes. Copies of the mentoring materials can be viewed in Appendix 6.

Together the researcher and the service providers arranged a convenient time to deliver the training, recruit participants into the study and launch the KAPA intervention.

3.3.6 Step 6: Generating an intervention evaluation plan

The final step was to generate an evaluation plan to test the intervention. It is usual for all performance objectives to be formulated as measurable concepts [153]. This helps the intervention designers to evaluate the intervention on its successes and failures so that elements of the intervention can be targeted for improvement at a later date. The intervention evaluation plan to assess the KAPAs intervention feasibility is outlined in chapter 4.

3.4 Resultant KAPA Intervention

The KAPA feasibility study involved two types of individuals. The first type of participant was the PSI who was recruited to receive the KAPA training programme and deliver the KAPA intervention. The second type of individual was the older adults who attended the 24-week PHISICAL FaME programme. These participants received six sessions of group motivational interviewing over a six-month period. Group sessions lasted between 60 to 90 minutes and were delivered in accessible community-based venues. Participants who were unable to attend group sessions received the KAPA intervention via telephone.

During the initial consultation the intervention group participants were presented with a file containing information about locally run PA services (e.g. exercise classes, walking groups, dances, sporting activities), a FaME home exercise booklet and written information on different types of lifestyle and transport related PA. The participants created a PA plan to meet the government recommendations of performing 150 minutes of MVPA and two sessions of strength and balance exercise per week after reflecting on their PA recall diaries. Participants set behaviour and outcome related goals and

were encouraged to monitor their progress towards their goals by completing PA diaries and monitoring their step counts with a pedometer.

The purpose of each subsequent follow-up session was to review the PA diaries and provide feedback on goal attainment. Participants were given opportunities to update PA plans and goals if they were later considered inappropriate or unobtainable. Various BCTs were delivered throughout each of the six sessions to help support participants in continuing to be active (as outlined in Table 10). The BCTs delivered aimed to resolve ambivalence about remaining active, encourage adherence to the KAPA intervention and build the self-regulation skills and long-term PA habits needed to remain active. Each session was guided by the standard operational procedures (Appendix 5).

Table 10. Intervention strategies, BCT code and order of delivery

Month	Session content	BCT code
1	**Initial consultation:** The aim of this session is to build a rapport with the participants, analyse their behaviours and develop effective action plans using motivational interviewing approach.	
1a	Review health status	
1b	Explore PA knowledge and provide information on the PA guidelines	5.1
1c	Reflect on current PA levels (strength, MVPA, balance) and compare with PA guidelines, problem solve how to meet the guidelines	1.2, 1.6, 2.2
1d	Decisional balance analysis with mental imagery of two possible futures	9.2, 9.3
1e	Provide PA education and information about the PA services within the local community	5.3
1f	Introduce home exercise booklet and demonstrate exercises	4.1, 6.1
1g	Write a weekly PA plan (how, what, when and who with approach)	1.4
1h	Identify the barriers and facilitators relating to a person's capability, opportunity and motivation to perform the plan	1.2
1i	Identify mechanisms of social support	3.1
1j	SMART goals for PA behaviours and outcomes	1.1, 1.3
1k	Modify goals and plans in accordance to self reported commitment and confidence ratings	1.9
1l	Introduce the use of monitoring tools (i.e. PA diaries and pedometers)	2.3, 2.4, 12.5
1m	Summaries the session, gain a signature of commitment and confirm date of next session	1.8, 1.9
2	**Follow-up session 1:** The first follow up meeting aims to facilitate adherence to the physical activity plan and goals.	
2a	Review health status	
2b	Review PA diaries, attainment of goals and revise/ adapt PA plans and goals.	1.4, 1.5,1.7, 2.2, 2.5
2c	Use a motivational interviewing approach to help problem solve high-risk situations where PA has not been performed and write "if then" plans.	1.2, 1.4, 3.1
2d	Encourage the use of diaries	2.3
2e	Reinforce social support mechanisms	3.1
2f	Summaries the session and confirm date of next session	
3	**Follow up session 2:** The aim of the second follow-up meeting is to facilitate PA adherence and introduce behaviour maintenance strategies.	
3a	Repeat steps 2a, 2b and 2c performed in the first follow-up meeting (i.e. session 2).	
3b	Relapse prevention strategies: i) continued use of monitoring systems, ii) reflecting on past successes iii) reflecting on lapses to identify high-risk situations and develop coping strategies	1.2, 1.4, (2.3, 2.4, 15.3)
3c	Building new habits: i) education of habit formation, ii) self review of poor PA habits, iii) record habits in diary	2.3, 8.3
3d	Use of rewards for enacting good PA behaviours and goal attainment	10.7, 10.9
3e	Reflecting on enjoyment and satisfaction levels of being more active	11.2
3f	Repeat steps 2d, 2e and 2f performed in the first follow-up meeting (i.e. session 2).	
4 & 5	**Follow up session 3 & 4:** The third and fourth follow-up meetings aim to help the participant build the self-regulation skills that they need to maintain the desired health behaviours.	
4a	Repeat steps 2a, 2b and 2c performed in the first follow-up meeting (i.e. session 2).	
4b	Problem solving and planning for possible future environmental and life changes	1.2, 1.4
4c	Reviewing habit diaries	2.2

4d	Problem solve and write plans to over-ride old habits (i.e. behaviour substitution plans and removing environmental triggers).	1.2, 1.4, 7.5, 8.2
4e	Identifying stress management strategies (e.g. rest breaks, Tia-Chi, mindfulness)	11.2
4f	Planning for times of low psychological resource levels (i.e. stress, grieving etc.)	1.4, 11.2, 11.3
4g	Repeat steps 2d, 2e and 2f performed in the first follow-up meeting (i.e. session 2).	
6	**Follow up session 5: The aim of the last session is to build on the skills needed to maintain healthier PA habits**	
6a	Repeat steps 2a, 2b and 2c performed in the first follow-up meeting (i.e. session 2).	
6b	Reflect on newly developed self-regulation skills	15.3
6c	Review PA plans and detail how people intend to maintain PA without further guidance	1.4
6d	Review achievements and provide praise	2.7, 10.4
6e	Close the session and sign a pledge of commitment	1.8, 1.9

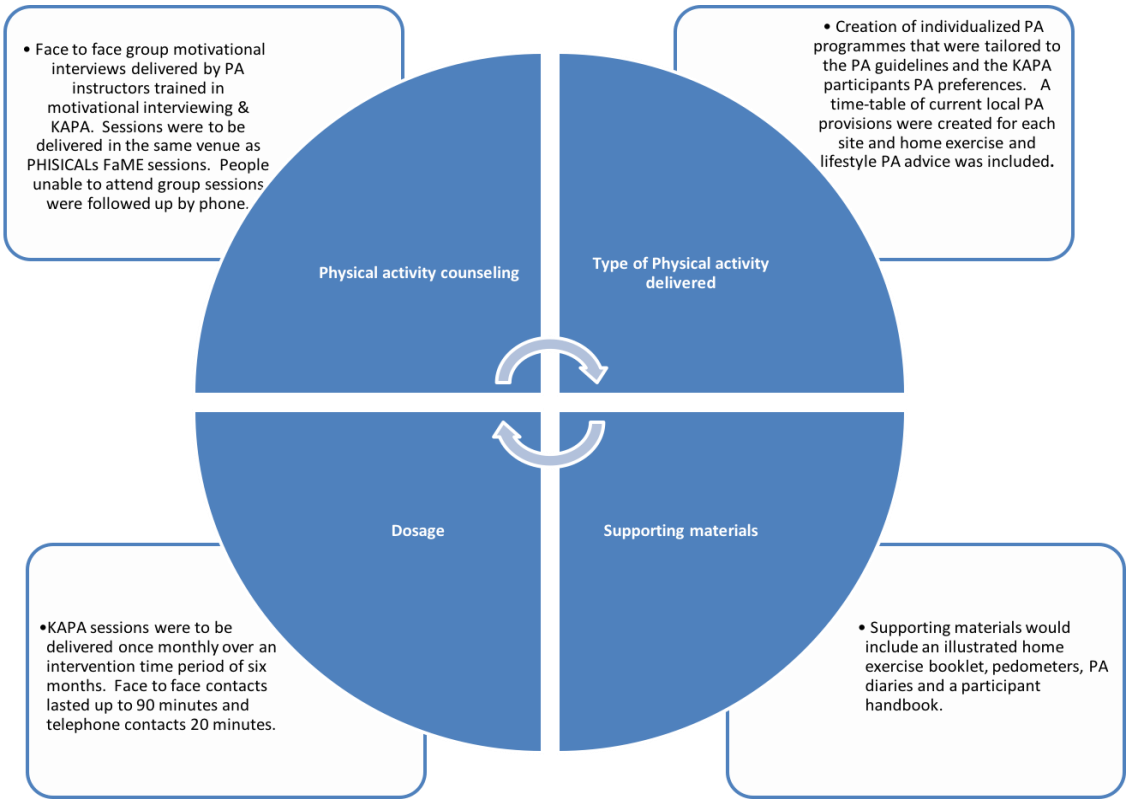


Figure 8. KAPA intervention features and modes of delivery as agreed with the expert group.

3.5 Discussion

3.5.1 Summary of KAPAs intervention development process

The purpose of the present chapter was to present the methodological process taken to develop the KAPA intervention. No study identified in the systematic review (Chapter 2) reported using an IM approach in the intervention development process. Therefore, the information presented provides a significant contribution to this field.

The KAPA intervention was created using a systematic step-wise process whereby the output of each of the IM stages contributed to the development of the final intervention and its implementation plan. The outcome of stage one highlighted a number of physical, social, environmental and psychological determinants that affect PA participation in older adults. In stage 2, matching thirty-six theoretically supported performance and change objectives against each determinant created the foundations of the KAPA intervention. It was the output of these initial two stages that underpinned the fundamental concepts of the KAPA intervention.

A large diversity of theories was identified in the stage 2 matrices. Each theory was based on a different premise. The concern at stage 3 was that selecting a small number of theories might have resulted in a lack of intervention strategies to match each performance or change objective. Selecting the BCW to underpin the KAPA intervention helped to overcome this conundrum as this allowed for a range of BCTs to be systematically matched against each of the change objectives. In addition, an intervention framework was created which encompassed a simplified version of the intervention delivery modes that were shown to be effective in the KAPA

systematic review. These outputs were carried forward into the intervention refinement stages (4 and 5).

The KAPA interventions programme design and implementation plan (stage 4 and 5) was heavily guided by the expert steering group's feedback. The expert steering group was predominantly made of service providers who subsequently delivered the KAPA intervention within their local authority services. It was during these meetings that the group adapted, refined and agreed on how they could best implement KAPA. This was an integral part of the KAPA intervention development as the input from the expert steering group helped to ensure that the intervention was feasible and acceptable to deliver within each separate PA service. Without the steering group's input, the consequence may have been that the intervention developed may not have been feasible to deliver.

The KAPA intervention was successfully developed using the IM approach. The resultant intervention was a PA motivational interviewing programme that aimed to help older adults remain physically active after the completion of the 24-week PHISICAL FaME programme. Inline with the Chief Medical Officers guidance for PA, the KAPA intervention's primary goal was to support participants to achieve 150 minutes of moderate to vigorous physical activity (MVPA) and two sessions of strength and balance exercise per week [12].

3.5.2 Comparison with the previous literature

Bartholomew's IM approach serves as a blueprint for developing, implementing and investigating complex theory based interventions [154]. The consensus with those that have used IM is that the approach is useful in building transparent evidence-based interventions [153-158]. Although IM is a methodical process the literature suggests that the application of each step is flexible, diverse and open to interpretation [137,154,156,157,159,160].

Step one of the intervention process requires intervention developers to identify the determinants that mediate a given behaviour. One study developing a return to work intervention used key stakeholders to brainstorm a list of service users' behavioural determinants [155]. In this case the behavioural determinants identified may have been incorrect due to being built on the assumptions of a third party. It is likely that these assumptions resulted in errors when identifying the performance and change objectives and subsequent intervention strategies. Thus demonstrating how significant the accuracy of step one may be when developing interventions.

It is most usual for researchers to collect qualitative information on behavioural determinants using focus groups or interviews with the potential service users [156,157]. If direct access to the population under investigation is not viable others have conducted a needs assessment and identified behavioural determinants using the previous literature base [136,153,158]. Constraints on time and finances meant that it was not feasible to collect data on older peoples' PA determinates within the confinements of the KAPA feasibility study. However, the data collected within the Keeping Active Study filled this void as it directly related to the determinates that

affect PA maintenance in older people exiting falls prevention exercise programmes.

Mapping theoretical strategies against the programme objectives was the first step in identifying potential intervention strategies. Authors have reported using different methods to select intervention strategies. For example one article reported basing strategies on the previous literature and conducting interviews with service providers [157]. Whereas others have based intervention strategies on the theoretical premise of the chosen behaviour change model [136] or using behaviour taxonomy tables alongside the literature base [153]. A mixed approach was used during the KAPA intervention development process whereby intervention components and modes of delivery were selected using the literature base, clinical guidelines and the feedback from an expert steering group. It was felt that this mixed approach would help ensure that effective intervention strategies were included whilst making the KAPA intervention feasible for the service providers to deliver.

The results of the systematic review supporting the KAPA intervention (chapter 2) suggest there is uncertainty on whether PA can be maintained in older adults exiting falls prevention exercise programmes [35,51,52]. Booster letters and invites to review days delivered after an initial “hip fracture prevention” programme resulted in no significant differences on the proportion of participants who kept active for more than 30 minutes per week at 2, 5, 8 and 10 years after the intervention ended [101]. Reductions in calorie expenditure at 9 month follow up were seen in another study that integrated relapse and prevention strategies into a falls prevention exercise programme [110]. Brief advice on remaining active after the completion of a falls programme did not result in PA levels being maintained at 9 and 12-month post intervention [111].

The KAPA intervention differs from these previous interventions as it contains 6 sessions of PSI delivered motivational interviewing that is

supported by workbooks, goal setting, PA monitoring and opportunities to socialise. Although no previous study has investigated these strategies for PA maintenance in older people exiting falls programmes many studies show motivational interviewing [47,77,81,83-85], PA monitoring tools, goal setting [47,63,76-88,161-163] and social support [23,87,150,164-166] helps older adults to remain active. These findings gave me confidence that the KAPA intervention had the potential to maintain PA increases in people exiting the PHISICAL FaME programme.

3.6 Strengths and Limitations

The IM approach provided a systematic step-wise process of linking determinants, theory and intervention strategies which help to develop a comprehensive intervention grounded in evidence and theory. The steps followed ensured that the intervention development process was methodical, logical and transparent.

KAPA's intervention strategies and training materials were largely built by triangulating the intervention matrix with the findings of the systematic review, NICE guidelines and reflecting back on the expert steering group meetings. Working in cooperation with the expert group was invaluable in helping to shape a practical intervention that was feasible to implement within each separate local authority organisation. These elements of the intervention development process were key to ensure that the KAPA intervention was not only grounded in theory and empirical evidence but that it was feasible for the service providers to implement from the offset.

Systematic review evidence is mixed regarding whether theory based interventions are more [63], less [62] or no more effective [62,65] than none theory based interventions to support PA in older adults. There is also no indication

as to whether theory-based interventions can maintain PA in older people [60]. To date, no study has underpinned the development of a PA maintenance intervention, for older adults exiting a falls prevention exercise programme using the BCW. This was a limitation in the intervention development process as it was unknown whether the BCW was suitable to underpin KAPA.

It is unknown whether BCTs support PA maintenance in older adults beyond 12 months [60]. A systematic review (Chapter 2) was conducted to assess what BCTs may support PA maintenance in older adults. The findings were used to help build KAPA's intervention strategies. Limitations may exist using this approach as a meta-analysis was not performed to assess the treatment effects of the BCTs included in the KAPA intervention. A recent meta-analysis suggested that self-regulatory BCTs negatively affect older adults PA levels [68]. Therefore, it is possible that the KAPA intervention includes BCTs that may evoke no behavioural response, or a negative behavioural response in the KAPA participants [68].

Expert steering group meetings were conducted using a non-formal consensus approach to build the KAPA intervention. A Nominal Group Approach would have better facilitated the intervention development process, as these include formal consensus methods (e.g. voting) to achieve participant agreement and make decisions [54,145-147,167]. As formal consensus methods weren't employed, the level of absolute agreement amongst the steering group members is unknown, making it possible that the KAPA intervention was built on the views of those dominating the group conversations [168]. Another study limitation was that there was no Patient and Public Involvement (PPI) member within the expert steering group. PPI members can provide unique perspectives and experiences to help ensure interventions are relevant and appropriate for service users [169]. Valuable PPI input was missed in the intervention development process which may

have limited the acceptability and relevance of the resultant KAPA intervention to the service users.

The IM approach has commonly been reported as being tiresome and resource and time intensive [153-158]. This was a key limitation of using the IM approach to develop the KAPA intervention as this involved conducting a literature review, chairing expert steering group meetings and much time spent creating a matrix of performance and change objectives.

The aim was to include intervention strategies to address each of the performance and change objectives. It was outside the scope of the current intervention to deliver intervention strategies for all the behaviour determinants identified. For example, it would have been difficult to address some of the socio-ecological mediators of behaviour such as social isolation, provide people with transport, improve people's memory or change the times of classes. Addressing these types of determinants would require interactions with many different collaborators across multiple levels. It should be noted that the effectiveness of the KAPA intervention maybe limited by the intervention not being able to provide a resolution for these determinants. For this reason, the development of interventions may benefit from including collaborators across multiple professions to help tackle issues that could limit the effectiveness of interventions.

3.7 Implications for Policy, Practice and Future Research

The process of developing interventions in research and clinical practice has been criticized for its lack of elaborate conceptualisation and planning [130]. Many interventions are developed through a process of conducting a literature review and creating interventions from a menu of effective strategies [128]. Selecting proven intervention strategies is important for the success of an intervention. However, the probability of achieving the desired behaviour change is reduced when an intervention is not firmly grounded in theory [170]. Failing to link the target populations' situational and personal behavioural moderators with appropriates theories and intervention strategies may part explain the mixed outcomes seen in prior intervention studies and clinical services [160]. Therefore, interventionists should consider conceptualising interventions by drawing associations between behavioural moderators, theories and effective intervention strategies during the intervention development process.

This chapter outlined an intervention development approach that links behaviour determinants, theories, intervention strategies and implementation planning. IM provides a transparent step-wise process whereby iterations are rationalised by theory and the end product of the previous stage. Although IM is a timely and complex process researchers and practitioners may take advantage from using this responsive and systematic approach to help develop more theoretically grounded interventions. The implication of using the IM approach in research is that the process is costly due to the increased demands on the interventionist's time and resources. However, this implication is outweighed by using an approach that increases the likelihood of developing a clinical and cost-effective intervention [130,154].

Published research and clinical guidelines should fully disclose intervention development processes as this improves the transparency of intervention reporting and helps clinicians to effectively implement interventions in real life settings [154]. Reports should highlight behavioural determinants to help guide researchers and clinicians in assessing whether a pre-made intervention meets the needs of their target population. Whereas, clearly describing the application and implementation of interventions will help clinicians to successfully deliver interventions. Thus, providing more robust accounts of the intervention development process will help guide the development of future services, clinical guidelines and policies.

3.8 Conclusion

Bartholomew's IM approach provided a helpful methodological process which helped with the comprehensive development of the KAPA intervention. The creation of the KAPA intervention benefited from the interactions with the expert steering group who used the evidence-based intervention framework to decide KAPA's intervention features and delivery modes. IM and the BCW helped to guide the selection of suitable theoretical strategies to address relevant behaviour determinants. The IM approach can be used to help with the development of more effective interventions that aim to change, or maintain, health behaviours.

Chapter 4. Keeping Adults Physically Active: Randomised Controlled Feasibility Study

4.1 Summary of Chapter 4.

The acceptability and feasibility of the final KAPA intervention was investigated using a mixed methods feasibility study. This chapter first outlines the KAPA feasibility study's quantitative methods and findings before moving onto detailing the qualitative research methods and results. The quantitative methods addressed the research objectives relating to feasibility, adherence, fidelity and the parameter estimates needed to inform a future definitive trial; whereas the KAPA interventions acceptability was investigated using qualitative methods. The chapter concludes with a discussion of the research findings, study limitations, generalisability of the research methods and findings and an interpretation of the current literature base. Please note the chapter is structured in line with the CONSORT 2010 statement for randomised pilot and feasibility trials [171].

4.2 Primary Study Objectives

The KAPA feasibility study aimed to examine the feasibility and acceptability of the KAPA intervention designed to encourage the continuation of physical activity (PA) following the completion of a Falls Management Exercise (FaME) programme.

The KAPA intervention was assessed by:

Objective 1: Feasibility of the research methods were assessed by estimating the recruitment and retention rates of the service providers (PSIs) and the PHISICAL FaME recipients to participate in the feasibility study.

Objective 2: Feasibility of the KAPA intervention was assessed by attendance rates and telephone response rates to the KAPA intervention as recorded in the class registers.

Objective 3: Assessing acceptability of the KAPA intervention by:

- Conducting semi-structured interviews with the participants in receipt of the intervention and the PSIs delivering the intervention, to assess the acceptability of the intervention features and delivery modes.
- To investigate the acceptability of the KAPA training day via the PSIs completing training evaluation forms.

Objective 4: Investigating intervention adherence by:

- Analysing the PSIs completion rates of the class registers.
- Evaluating whether the participants completed the PA diaries and achieved their PA goals as recorded in the monthly class registers.
- The KAPA participants were also asked whether they adhered to the KAPA intervention during semi-structured interviews.

Objective 5: Assessing fidelity through:

- Observations of the initial consultations and group sessions.
- PSIs were asked whether they made any modifications to the KAPA intervention during a semi-structured interview.

Objective 6: Investigating parameter estimates of moderate-to-vigorous PA (MVPA), usual care components and a data collection tool to cost the KAPA intervention to inform a future definitive trial by:

- Estimating the potential effect size of MVPA and percentage of the KAPA participants meeting the recommended 150 minutes of MVPA per week between the KAPA intervention and usual care arms.
- Estimating the intraclass correlation coefficient (ICC) for MVPA using the Phone-FITT questionnaire [172].

- Usual care was described by its intervention features, delivery modes and the behaviour change strategies included.
- Identifying tools and testing the feasibility of collecting the data needed to cost the KAPA intervention to enable a cost-effective analysis in a definitive trial.

Objective 7: Recording adverse events and assessing them for causality to determine if they are related to the delivery of the KAPA intervention.

4.3 Trial Design

A two-arm, cluster randomised (clustering at the level of Postural stability instructor (PSI)), multisite feasibility trial comparing the KAPA intervention with usual care controls conducted in 8 L FaME classes nested within the PHysical activity Implementation Study In Community-dwelling AduLts (PHiSICAL) study.

PA study participants can become disappointed if randomised to control arms which causes increased dropout rates and non-adherence to control arm protocols [173]. Upon initiating the KAPA feasibility study, the usual care protocol was unknown. A randomized controlled study design was chosen to investigate usual care procedures and monitor any confounding factors that may occur in the control arm as this information was considered important to inform the design of a definitive trial.

4.4 Ethical Approval and Protocol Changes

The study was conducted in accordance with the Declaration of Helsinki, 1996, Good Clinical Practice principles and the Department of Health Research Governance Framework for Health and Social Care, 2005. This study received ethical approval from the London-Chelsea Health Research Authority (REC reference: 16/LO/0396). The KAPA feasibility study protocol was made public on the ClinicalTrials.gov register on the 30th January 2019 (ClinicalTrial.gov Identifier: NCT03824015) [174]. The National Institute of Health Research funded this project.

The KAPA feasibility study was granted Research Ethic Committee (REC) approval in January 2017 and most PHISICAL FaME classes finished between October and December 2016. Permission was requested to recruit the PHISICAL FaME class attendees into the KAPA feasibility study during their 24-week commissioned FaME classes. This resulted in a low number of PHISICAL participants being available for recruitment into the study. Therefore, permission was requested from REC to undertake a second recruitment intake to enable the recruitment of the participants via postal, telephone or face-to-face methods up to six months after the completion of their PHISICAL FaME class.

4.5 Study Participants

There were two types of study participants:

1. Community dwelling PHISICAL FaME programme service users aged 65 years or older (referred to as KAPA participants).
2. PSIs who delivered Local Authority-commissioned PHISICAL FaME programmes in Derby City, Rutland or Leicestershire Counties (referred to as PSIs).

4.5.1 Eligibility criteria

4.5.1.1 PSI participants

Inclusion criteria:

- PSIs in Leicestershire, Rutland or Derby City who were delivering a Local Authority-commissioned FaME programme and were participating in the PHISICAL study.
- Able to provide written informed consent.

Exclusion criteria:

- PSIs delivering a falls prevention programme or FaME programme that was not commissioned within Derby City, Rutland or Leicestershire Counties and not participating in the PHISICAL study.
- Unable to provide written informed consent

4.5.1.2 KAPA participants

Inclusion criteria:

- Enrolled on a Local Authority FaME programme in Derby City, Rutland or Leicestershire Counties and participating in the PHISICAL study.
- Able to provide written informed consent.

Exclusion criteria:

- Enrolled on a falls prevention programme or FaME programme that was not commissioned within Derby City, Rutland or Leicestershire Counties and not participating in the PHISICAL study.
- Unable to provide written informed consent.

4.5.2 Recruitment methods

4.5.2.1 PSI recruitment

PSIs were recruited into the study prior to the PSI being randomised. PSIs were approached by a member of the research team, via e-mail and telephone to request their participation in the KAPA feasibility study. They were given oral and written information (via the participant information sheet) regarding their involvement in the study. This information detailed the procedures if randomised to the intervention group, delivering the KAPA intervention, attending the training day, the data collection methods and information about the interviews and observations. The participant information sheet was provided and a researcher answered any queries or questions. A researcher obtained informed written consent only after the

PSI had processed the information and expressed willingness to take part in the KAPA feasibility study.

4.5.2.2 KAPA participant recruitment

Recruitment Strategy 1: Recruitment took place during the 24-week commissioned PHISICAL FaME programme (between January and February 2017). Some PSIs ran two PHISICAL FaME classes. To avoid two levels of clustering, which would increase the required sample size, only one PHISICAL FaME class per PSI was selected. Where PSIs delivered two PHISICAL FaME classes in the PHISICAL study, one class was randomly selected for the feasibility study by tossing a coin.

The PSIs introduced the participants of the selected PHISICAL FaME classes to the KAPA maintenance intervention between weeks 20 to 24 of the commissioned PHISICAL FaME programme. The PSIs provided the participants with oral information about the study and a participant information sheet containing details of the KAPA intervention and feasibility study. A researcher attended the PHISICAL FaME classes to meet with the interested potential participants to discuss the study further and obtain consent to take part in the KAPA feasibility study.

Recruitment Strategy 2: Recruitment took place up to six months after the completion of the 24-week PHISICAL FaME programme (between June and July 2017). As described above, only one PHISICAL FaME class per PSI was selected. The PSIs sent participant information sheets detailing the KAPA intervention and the KAPA feasibility study together with an expression of interest slip to the PHISICAL participants via post. Some local authorities and PSIs continued to deliver self-funded exercise classes

beyond the initial 24-week commissioned period. The PHISICAL participants who continued to attend these classes were given an envelope containing the printed information and expression of interest slip by hand during their class. Participants were given a self-addressed freepost envelope to return the expression of interest slips back to the researcher. Alternatively, they handed the completed slips back to their PSI who forwarded these to the researcher. A meeting was arranged with the potential participants to discuss the study further and obtain consent to take part in the KAPA feasibility study.

4.5.3 Withdrawal of participants

Study withdrawals were defined as participants requesting to withdraw from the study and those developing contra-indications to exercise or experiencing an injury or a disease that would prevent them from being able to safely engage with PA. No participants withdrew from the KAPA feasibility study. The KAPA participants in both study arms were considered “lost to follow up” if they did not provide outcome data. Outcome data was collected in these participants by sending the Phone-FITT questionnaire by post with a freepost envelope and instructions to complete the questionnaire and send it back to the PSI.

4.5.4 Consent

Participation in the study was entirely voluntary. Participant informed consent was obtained in accordance with the REC guidance and Good Clinical Practice. All participants provided signed and dated informed written consent prior to entering the study and randomisation. Participants received participant information sheets from the PSIs and a researcher further explained the study details. Participants were given sufficient time to consider participating or not and were given the opportunity to ask questions about the study. The participant kept one copy of the consent form and a second copy was kept in the KAPA feasibility trial master file. No study data was collected before informed consent had been obtained.

4.6 Intervention Procedures

The intervention duration for the PSIs was 7 months and the KAPA participants 6 months.

4.6.1 KAPA training and mentoring programme procedures

Prior to delivering the KAPA intervention the PSIs assigned to the intervention group received training in the *"Let's Get Moving"* motivational interviewing course from Loughborough College. The KAPA training programme was subsequently delivered to the PSIs via face-to-face lectures 1 month prior to the KAPA intervention delivery. The training manual that supported the KAPA training can be viewed in Appendix 6.

To support their continued learning, the PSIs delivering the KAPA intervention were offered up to three, 1-hour, mentoring sessions as part of the KAPA training programme. Mentoring sessions took place either via phone, face-to-face (at their place of work) or email. The focus of the mentoring sessions was to explore and understand any problems that the PSIs experienced when delivering the KAPA intervention. The PSIs were given professional support and constructive advice that helped them develop plans to overcome or resolve any problems that arose.

4.6.2 Intervention procedures for KAPA participants

KAPA participants who completed the 24-week commissioned PHISICAL FaME programme received six sessions of PA motivational interviewing over a six-month period. KAPA intervention sessions were held in non-NHS, accessible, community venues located within the local authorities of Derby City, Leicestershire and Rutland Counties. The KAPA intervention was delivered face-to-face by PSIs, in a group setting, using motivational interviewing. Sessions lasted between 60 to 90 minutes. PSIs delivered KAPA intervention sessions by telephone if a participant did not, or was unable to, attend a face-to-face session. The intervention components delivered within each KAPA intervention session are outlined in Table 11. Full details of the KAPA intervention procedures can be found in chapter 3. Please note that the KAPA intervention group also had access to usual care.

4.6.3 Intervention procedures for usual care

Usual care was delivered for the duration of the KAPA feasibility study. The usual care participants finished the original PHISICAL FaME programme and went on to being offered the service provider's usual care package. Upon initiating the KAPA feasibility study, it was unknown what the service providers would deliver as usual care. Therefore, a study objective was to describe the usual care package delivered by the service providers. A description of usual care can be found under heading 4.8.10 "Description of Usual Care".

Table 11. Table outlining the individual intervention components delivered in each KAPA intervention session.

Month	Session content
1	**Initial consultation**
Review health status	
Explore PA knowledge and provide information on the PA guidelines	
Reflect on current PA levels and compare with PA guidelines, problem solve how to meet the guidelines	
Decisional balance analysis with mental imagery of two possible futures	
Provide PA education and information about the PA services within the local community	
Introduce home exercise booklet and demonstrate exercises	
Write a weekly PA plan	
Identify the barriers and facilitators relating to a person's capability, opportunity and motivation to perform the plan	
Identify mechanisms of social support	
SMART goals for PA behaviours and outcomes	
Modify goals and plans in accordance to self reported commitment and confidence ratings	
Introduce the use of monitoring tools (i.e. PA diaries and pedometers)	
Summarise the session, gain a signature of commitment and confirm date of next session	
2	**Follow-up session 1**
Review PA diaries, attainment of goals and revise/ adapt PA plans and goals.	
Use a motivational interviewing approach to help problem solve high-risk situations where PA has not been performed and write "if then" plans.	
Encourage the use of diaries	
Reinforce social support mechanisms	
3	**Follow up session 2:**
Review PA diaries, high risk situations, attainment of goals and revise/ adapt PA plans and goals.	
Relapse prevention strategies: i) continued use of monitoring systems, ii) reflecting on past successes iii) reflecting on lapses to identify high-risk situations and develop coping strategies	
Building new habits: i) education of habit formation, ii) self review of poor PA habits, iii) record habits in diary	
Use of rewards for enacting good PA behaviours and goal attainment	
Reflecting on enjoyment and satisfaction levels of being more active	
4 & 5	**Follow up session 3 & 4:**
Review PA diaries, high risk situations, attainment of goals and revise/ adapt PA plans and goals.	
Problem solving and planning for possible future environmental and life changes	
Problem solve and write plans to over-ride old habits	
Identifying stress management strategies	
Planning for times of low psychological resource levels	
6	**Follow up session 5**
Review PA diaries, high risk situations, attainment of goals and revise/ adapt PA plans and goals.	
Reflect on newly developed self-regulation skills	
Review PA plans and detail how people intend to maintain PA without further guidance	
Review achievements and provide praise	
Close the session and sign a pledge of commitment	

4.7 Quantitative Research Methods

4.7.1 Outline of the data collection for the KAPA intervention and usual care group participants

There were three different data collection time points in the KAPA feasibility study as depicted in figure 9.

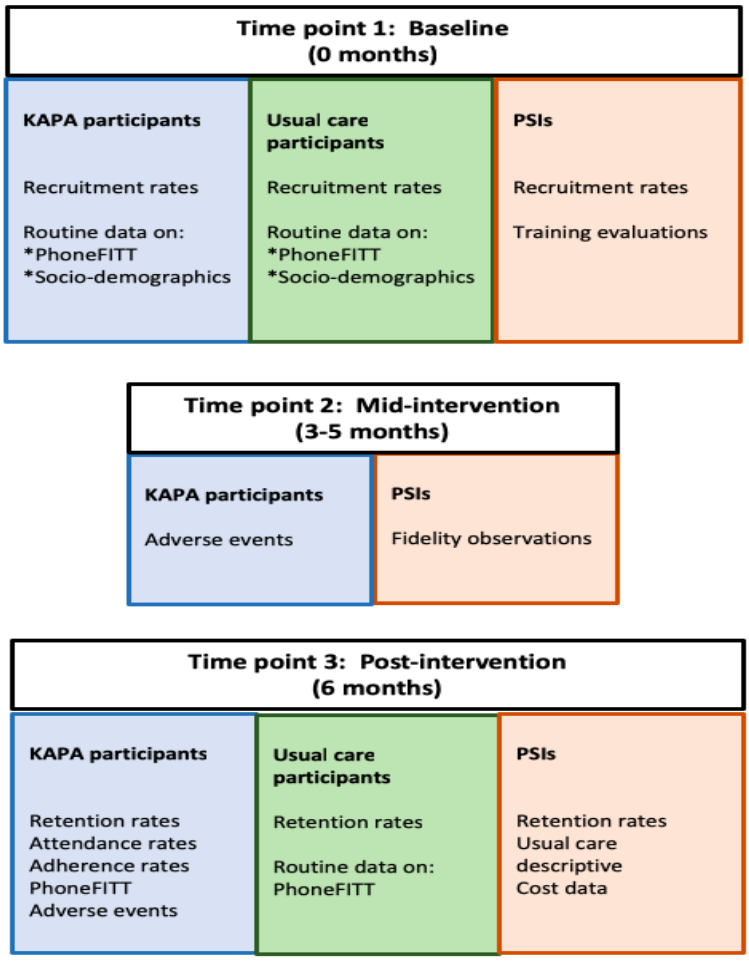


Figure 9. Data collection time points and data collected per participant group.

In recruitment strategy one, baseline quantitive data was collected between January and February 2017 and post intervention data between June and July 2017. Whereas in recruitment strategy two, baseline quantitive data was collected between June and July 2017 and post intervention data between January and February 2018. All data was collected within community-based venues, i.e. at the KAPA intervention delivery sites, which were located within Leicestershire and Rutland Counties and Derby City.

4.7.2 Data collection and outcome measures

4.7.2.1 Socio demographic information for the intervention and usual care group

The service providers routinely collected the participant's socio-demographic characteristics, health data and provided the participants' index of multiple deprivation (IMD) 2010 score based on their home address. IMD is a composite, area based score that measures and indexes the relative level of deprivation for small areas in England [175]. All socio-demographic data was collected prior to the KAPA feasibility study at community-based venues using each service provider's standard operational procedures. The details of the service provider's operational procedures were not shared with the researchers. The service providers gained verbal consent from the KAPA participants to share their routine data with the KAPA study researchers. Information sharing agreements were put in place between the Local Authority service providers and the University of Nottingham. Service providers sent the data to the researchers via email in password-protected documents.

4.7.2.2 Recruitment and retention rates in the intervention and usual care group (objective 1)

The researchers recorded the number of study sites, PSIs and PHISICAL participants invited and recruited into the KAPA feasibility study. Retention rates were recorded as the number of KAPA participants (i.e. intervention and usual care participants) who remained in the study and provided outcome data at the 6-month time point.

4.7.2.3 Attendance rates to the KAPA intervention sessions (objective 2)

The PSIs documented in the class registers the KAPA participants' attendance at each monthly telephone or face-to-face community-based KAPA session. Class registers were used to record the number of face-to-face and telephone interactions with the participants and the length of each telephone call. Registers were sent to the researchers in password-protected documents at the 6-month data collection time point.

4.7.2.4 Training evaluation of the KAPA training day (objective 3)

After receiving KAPAs training, the PSIs completed a training evaluation form to assess the suitability and acceptability of the training content and materials (see Appendix 7). The training evaluation forms contained questions relating to whether the training provided the following:

- Enough detail on the underpinning theory supporting the KAPA intervention, effective communication, health and safety procedures and the PSIs professional role.
- Whether the learning materials and delivery methods of the training met the learner's needs.

- Whether the PSIs felt confident in delivering the KAPA intervention after the training.

The training evaluation forms contained comment boxes and response options on 4 and 5-point Likert rating scales for each question. The trainer handed the training evaluation forms to each PSI directly after the KAPA training session and collected the forms back once fully complete. All training evaluation forms were completed at the training venue and took up to 20 minutes to complete.

4.7.2.5 Adherence to key KAPA intervention strategies (objective 4)

The KAPA participants' adherence to the KAPA intervention was measured via completion of the PA diaries and achievement of monthly PA goals. These were chosen as measures of intervention adherence, as PA monitoring and goal setting were key intervention strategies replicated in each KAPA intervention session. The PSIs asked the participants if they had completed their diaries and achieved their goal's during each face to face or telephone delivered KAPA intervention session. Participant responses were recorded by hand as a yes/no in the monthly class registers by the PSIs. The researchers did not collect any information recorded in the participant diaries or goal attainment logs. The premise on assessing diary and goal completion rates was purely based on investigating whether the participants adhered with these key intervention strategies.

The PSI's adherence with the data collection protocol was measured by identifying whether the class registers were fully complete. Adherence to the usual care procedures was not assessed in the feasibility study. All registers were sent in password-protected documents to the researchers at the 6-month data collection time point.

4.7.2.6 Fidelity observations of the KAPA intervention sessions (objective 5)

All PSIs entering the study provided informed written consent for being observed by a researcher twice during the 6-month intervention time period. Details of the intervention observations were included in the service provider participation sheet. Fidelity of the KAPA intervention delivery was ascertained by observations of an initial consultation and one of the monthly follow up sessions per PSI. Each KAPA intervention session observed was delivered within a community-based venue within one of the KAPA intervention sites. KAPA participants were notified verbally that a researcher would observe the following KAPA session. They were notified again on the day of the observation with assurance that the observations related to the delivery of the KAPA intervention rather than their participation. Fidelity observations lasted the duration of the class and were recorded on a fidelity checklist proforma that was based on the standard operating procedures (SOP) for delivering the KAPA intervention (Appendix 8). Checklist items under investigation related to the following intervention components:

- Preparing the environment and managing health and safety.
- Effective communication.
- Introducing each session and its content.
- Performing a behaviour analysis.
- Reviewing PA behaviours (via reflecting on diaries and goals).
- Delivering the behaviour change techniques.
- Summarising and closing the session.

The observer dichotomised each item as being either achieved or not achieved on the checklist.

4.7.2.7 Phone-FITT data collection for the intervention and usual care group (objective 6)

Phone-FITT is an interview-based questionnaire that measures frequency, duration, intensity and type of PA performed weekly. Differences between household, recreational and total activity are captured on the questionnaire to enable sub-scores of PA to be calculated. The reliability and validity of the Phone-FITT questionnaire has been established by comparing the Phone-FITT scores and accelerometer counts of community dwelling older adults attending exercise classes and falls prevention programmes [172]. The KAPA participants' levels of MVPA were collected using the Phone-FITT questionnaire at baseline and the 6-month time point.

KAPA participants self-completed the Phone-FITT questionnaire. The PSIs handed the Phone-FITT questionnaires to the participants during the face-to-face KAPA intervention or usual care sessions and collected the questionnaires back at the end of the sessions. The PSIs posted the Phone-FITT questionnaire to the participants who stopped attending these sessions to complete at home, which was to be returned to the PSIs in an enclosed self-addressed envelope. The PSI entered the data onto an excel spreadsheet and sent the data to the research team via email in a password protected document.

4.7.2.8 Data collection to describe usual care (objective 6)

An interview survey approach was used to collect the data relating to usual care. A researcher contacted each PSI assigned to usual care via email or telephone to ask if they would provide a usual care descriptive. PSIs were given the option of providing the details via telephone or during a face-to-face meeting with a researcher at their place of work (i.e. Local Authority PA service site) or over the phone.

The aim was to describe usual care according to the TiDIER Checklist for reporting interventions [90]. A usual care description form was created based on the TiDIER checklist. The checklist collected details on the following key elements:

- Provide a brief description of usual care.
- Describe the type of PA behaviours usual care targeted.
- Describe the materials used to help deliver usual care.
- Description of the usual care procedures and supporting activities.
- Describe who delivered usual care.
- Describe the modes of delivery.
- Describe the location where the intervention was delivered.
- Provide details on the duration, frequency, intensity and number of contacts that usual care was delivered.
- Provide any details on tailoring or modifications to usual care.

The researcher asked the PSIs open questions relating to each of these elements. The researcher completed the data collection form by hand with the PSIs responses (Appendix 9). The data was collected at the 6-month time point and the data collection forms took approximately 30 minutes to complete.

4.7.2.9 Cost data collection for the KAPA intervention (objective 6)

Data relating to how much it cost to deliver the KAPA intervention was collected using cost proformas (Appendix 10) completed by the service providers (i.e. PSIs and their managers). Cost proformas collected data on the costs incurred by the service providers to deliver the KAPA intervention. The data collected from the providers included costs relating to staff wages, travel expenses, administration costs, venue hire, consumables and expenses incurred to attend the KAPA training day. In addition, a

researcher recorded the research costs incurred to deliver the KAPA training day (i.e. venue hire, training manuals, trainer wages and trainer travel expenses).

A Local Authority perspective of costing the intervention was used. This means that direct costs to the local authority (e.g. staff salary, training, consumables, venue hire, administration) of the KAPA intervention was included. However, costs such as participant productivity and healthcare costs (including the cost of adverse events) were not collected. Proformas were delivered via email to the service providers at the 6-month time point and returned via email. Cost proformas were sent back to the providers to check for accuracy if the information on the form was incomplete or appeared incorrect.

4.7.2.10 Collecting data on adverse events in the KAPA intervention group.

Adverse events were recorded using the same procedures and forms as those used in the ProAct 65+ trial [43]. A researcher verbally defined an adverse event to each participant face-to-face whilst consenting the intervention participants into the KAPA feasibility study. Participants in receipt of the KAPA intervention were given a card containing contact details to report adverse events directly to the researcher. Participants were asked to contact the researcher immediately in the event of any serious adverse event. A researcher contacted the participants by telephone every three months to inquire if any adverse events had occurred. All adverse events were recorded and monitored until resolution, stabilisation, or until it was shown that the KAPA intervention was unrelated to the adverse event. An adverse events procedure was put in place whereby the Chief Investigator was informed immediately of any serious adverse events by the clinical leads (Denise Kendrick and Pip Logan) who determined the

seriousness and causality. Adverse events definitions, reporting procedures and the reporting form can be viewed in Appendix 11.

4.7.3 Sample Size

A sample size calculation was performed to derive the parameter estimates for a definitive trial, rather than to determine effect. A precision-based sample size calculation was performed so recruitment and retention proportions and error margins could be estimated to inform the recruitment targets to power a definitive trial [176].

Based on discussions with the service providers it was anticipated that there would be an average of 10 people per class and up to 30 classes, provided by 12 PSIs across all potential PHISICAL study sites. It was anticipated that 12 PSIs, each delivering one PHISICAL FaME class with 10 participants, would take part in the KAPA feasibility study, with 6 PSIs and their classes being randomised to the KAPA intervention and 6 PSIs and their classes being randomised to usual care.

With a total of 12 PSIs and 120 participants in 12 FaME classes, and an intra-class coefficient (ICC) of 0.05 [177]; the KAPA feasibility study would be able to detect a recruitment rate of 70% with a 95% confidence interval (CI) ranging from 60% to 80%. The ICC was based on a study by Elley et al reporting ICCs from RCTs evaluating PA interventions delivered within primary care. Elley at al found that ICCs for PA variables ranged from 0.00 to 0.072 for cluster sizes ranging from 5.8 to 20.6 [177]. Estimations for the KAPA feasibility study were calculated using Statulator: An online statistical calculator [178].

Intervention arm: The target was to recruit up to sixty participants to receive the intervention from 6 PSIs in 6 classes, with at least 2 classes located in each area (a) Leicestershire and Rutland Counties and (b) Derby City.

Usual care arm: The aim was to recruit up to sixty KAPA participants to receive usual care from 6 PSIs in 6 classes, with at least 2 classes located in each area (a) Leicestershire and Rutland Counties and (b) Derby City.

4.7.4 Randomisation

The KAPA feasibility study was a cluster randomised controlled study that randomised the PSIs and their classes to either the KAPA intervention or usual care arm. Individual participants were not randomised as randomisation occurred at class level. The PSIs and KAPA participants were recruited prior to the PSI being randomised. PSIs were randomised in a 1:1 allocation ratio to either deliver the KAPA intervention or usual care. PSIs were stratified by study centre (2 strata: (a) Leicestershire and Rutland Counties and (b) Derby City and randomly allocated within strata. There was one study site in Rutland and three study sites in Leicestershire therefore the districts were grouped. The random allocation sequence was computer generated by the study statistician (Denise Kendrick). The class randomisation procedure took place after the PSI's had been randomised into their study arm. One class per PSI was randomly selected for the feasibility study by tossing a coin. A researcher independent to the study performed the coin toss. The class allocation was documented and sent back to the research team via email.

4.7.5 Allocation concealment

PSI allocations were placed in numbered sealed opaque envelopes and grouped by stratum 1 & 2, Leicester and Rutland (stratum 1) and Derby (stratum 2). The PSIs were chronologically ordered and numbered depending on the date and time of their response. The content of the envelope indicated whether the PSI was allocated to delivering the KAPA intervention or usual care. The envelope opener (independent to the research team) opened each envelope in numerical order and matched it with the PSIs chronologically ordered number. Allocations were documented and the researcher was informed.

4.7.6 Blinding

The PSIs and participants were blinded to the group allocation until the PSIs had recruited all the participants. After the recruitment period the PSIs were told their group allocation assignment and this information was passed onto the KAPA participants via the PSI. Research personnel were not blinded to the group allocation or outcome assessment.

4.7.7 Data analysis

4.7.7.1 Recruitment and retention rates of the PSIs and participants in the KAPA intervention and usual care arms.

Recruitment rates were calculated as the percentage of the PSIs, KAPA and usual care participants who were recruited after being invited into the study. Retention rates of KAPA participants were calculated as the percentage of KAPA participants who provided follow up data at the 6-month time point. Recruitment and retention rates, over the six month KAPA feasibility study, for the PSIs and KAPA participants were described for each arm (number and percentage). The 95% confidence intervals for the proportions of participants recruited and retained were estimated using STATA and adjusted for clustering at the level of PSI.

4.7.7.2 Training evaluation of the KAPA training day

The PSIs in receipt of the KAPA training were asked to complete feedback questionnaires (see Appendix 7). Each of the four and five point Likert scales assessing PSI responses were described using numbers and percentages.

4.7.7.3 Adherence with the KAPA intervention and attendance rates to the KAPA intervention sessions

Participant adherence with the KAPA intervention was recorded in the class registers and assessed by the i) percentage of participants attending the initial and follow-up consultations ii) percentage of participants who completed the PA diaries and iii) percentage of participants meeting their PA goals.

4.7.7.4 Fidelity observations of the KAPA intervention

The fidelity observation checklist was sub-divided by its intervention components (Appendix 8). Single intervention items were grouped and categorized into criteria to be achieved, as listed below:

- Criteria 1: Preparing the environment and managing health and safety (4 items).
- Criteria 2: Communicating effectively with participants (5 items).
- Criteria 3: Introducing the session and its content (4 items).
- Criteria 4: Conducting a behaviour analysis (6 items).
- Criteria 5: Reviewing PA behaviour (8 items).
- Criteria 6: Delivering the behaviour change techniques outlined for the session (3 items).
- Criteria 7: Summarising and closing the session (4 items).

The sum of the criterion items for the initial consultation totalled a maximum fidelity score of 31 for each PSI to achieve within the observed session. Whereas the sum of the criterion items for the follow up sessions created a maximum fidelity score of 25 for each PSI to achieve. Summing the total number of items achieved, maximum number of items that could be achieved and the per cent of the maximum number of items achieved across all criteria was calculated to determine individual PSI scores. Criteria category scores were calculated by summing the total number of items achieved, maximum number of items that could be achieved and the percentage of the maximum number of items achieved for each criterion; followed by an average and the percentage across all PSIs.

4.7.7.5 Phone- FITT data analysis for the KAPA intervention and usual care group.

The KAPA feasibility study collected PA data using the Phone-FITT questionnaire as this was the data collection tool used by the service providers in routine practice. The Phone-FITT questionnaire measures household, recreational and seasonal activities. Yet it does not provide a scoring system to categorise PA intensity as being light, moderate or vigorous PA. Estimating MVPA was an outcome of interest in both the PHISICAL implementation and KAPA feasibility study. To meet the research objectives the PHISICAL research steering group created a method of calculating MVPA from the Phone-FITT scoring system. The CMO guidelines describe moderate PA to be any an activity that slightly increases breathing rate; whereas vigorous activity moderately to rapidly increases breathing rates [4]. Thus, the steering group categorised the Phone-FITT scoring system in terms of PA intensity across all household, recreational and seasonal PA as outlined in table 12.

Table 12. Table of PA intensity codes used in the KAPA feasibility study.

Codes	Phone-FITT description	PA category as defined by the KAPA study using the CMO guidelines.
0	Did not do the activity.	No activity
1	Breathing normally and able to carry on a conversation.	Light PA
2	Slightly out of breath but still able to carry on a conversation.	Moderate PA
3	Too out of breath to carry on a conversation	Vigorous PA

The Phone-FITT questionnaire utilises ranges to estimate PA duration (e.g. 1-15 minutes, 16-30 minutes etc.). To calculate minutes of MVPA the PHISICAL research steering group agreed that the median number within each range would be recoded to estimate minutes of PA per week, as outlined in Table 13. Frequency was recorded in its absolute values (i.e. x3 week). All codes were imputed into STATA and the variables for each activity were calculated by multiplying frequency and the recoded duration variable within each PA intensity code.

Table 13. Table of the PA duration codes used in the KAPA feasibility study.

Codes	Phone-FITT durations	PA durations used in the KAPA feasibility study.
0	Did not do the activity.	0
1	1-15 minutes	7 minutes
2	16- 30 minutes	23 minutes
3	31-60 minutes	46 minutes
4	1 hour +	90 minutes

The mean (standard deviation (SD)) and median (interquartile range (IQR)) were estimated for total MVPA minutes per week at baseline. The proportion meeting the target of 150 minutes of MVPA per week was estimated at the KAPA study baseline for each study arm. Depending on the distribution of the data either the mean (SD) or median (IQR) for MVPA, strength and balance exercise and total PA minutes were presented.

The minutes of MVPA minutes did not meet assumptions for random effects linear regression (residual values at level 1 and level 2 were not normally distributed with constant variance). Hence these were dichotomised into the proportion of participants undertaking ≥150 minutes of MVPA per week. The proportion of participants meeting the MVPA target was compared between treatment arms using random effects logistic regression model

with participant at level 1 and PSI at level 2 to estimate the odds ratio and 95% confidence interval (CI) and adjusting for study site and baseline value of the outcome measure.

Intraclass correlation coefficients for MVPA was estimated using one-way analysis of variance.

4.7.7.6 Describing usual care

Usual care was described according to the TiDIER Checklist for reporting interventions [90]. A researcher extracted the data from the usual care description form and tabulated it on an Excel spreadsheet using the TiDieR headings (i.e. behaviours targeted, intervention features, support, materials, provider, method of delivery, where delivered, dosage and intervention tailoring). The data was grouped and synthesised and described narratively.

4.7.7.7 Cost data to deliver the KAPA intervention

A Local Authority perspective of costing the intervention was used. Three local authority service providers and one community trust service provider across Leicestershire, Rutland and Derby delivered KAPA. The cost of delivering the KAPA intervention to each participant was calculated at service provider level. Costs were categorised and tabulated into either being related to:

i) Non-staff wages for delivering the KAPA intervention per study site (i.e. cost relating to travel, venue hire, intervention materials, telephone usage or administration).

ii) Staff wages to deliver the KAPA intervention per site (i.e. relating to delivering KAPA, administration and travel time).

iii) KAPA intervention training costs (i.e. PSI wages and expenses, training material cost, venue hire and trainer wages and expenses).

Where staff costing was required, the hourly wage of the member of staff was multiplied by the length of time taken to deliver the intervention, travel or perform administration tasks. This was then used to calculate the total study costs over the 6-month intervention period. For example, staff wages for delivering the KAPA intervention was calculated as the sum of:

Face to face delivery *(26.32 x 1x 6) + (28.64 x 1x 6) + (20.60 x 1.5 x 6) + (60.00 x 1.5 x6)* + Telephone contacts *(10.53 x 1 x 6) +(15.00 x0.5 x 2 x 6)* = ***£1208.34.***

Calculations of the non-wage related intervention delivery costs (i.e. venue hire, telephone usage and refreshments) were similar, whereby costs were summed and multiplied over the 6-month intervention time period.

Costs relating to consumables (i.e. pedometers, participant manuals and postage) were summed as one-off costs. Likewise, the consumables, venue hire and travel costs incurred in the KAPA training day were summed as a one off cost. Staff costs relating to the training day were calculated as the hourly wage of the member of staff and multiplied by the length of time taken to attend the training. Once the cost for each of these elements was calculated, the mean cost across all study sites and per participant was estimated. The cost of delivering the KAPA intervention was described.

4.7.7.8 Adverse events in the KAPA intervention group

A researcher contacted the participants by telephone every three months to inquire if any adverse events had occurred. Adverse events were recorded by the research team as the number of adverse events that occurred within the 6-month intervention duration alongside a description of each event. The KAPA study did not record adverse events in the usual care group.

4.8 Quantitative Research Results

4.8.1 Recruitment rates (objective 1)

4.8.1.1 PSI recruitment

In total 10 PSIs delivering PHISICAL FaME over 15 classes were identified as being eligible to enter the study. Teams of two PSIs jointly delivered the PHISICAL FaME classes in two study sites. In these sites both co-working PSIs were recruited into the study but were classed as a single unit. All 10 PSIs were invited and recruited into the study *(one-sided 97.5% CI, 69.0% to 99.7%)*. In recruitment strategy one (January to February 2017), five PSIs and the attendees of four classes were recruited and consented into the study. In recruitment strategy two (June to July 2017), five PSIs and the attendees of four classes were recruited and consented into the study. A total of 10 PSIs (n= 8 units) and the attendees from 8 classes (n=50 KAPA participants) were recruited and consented into KAPA. Figure 10 depicts PSI and PHISICAL FaME class recruitment.

4.8.1.2 KAPA participant recruitment

PHISICAL FaME class sizes ranged between 2 to 15 participants with the mean number of people per class being 5 (SD 3). Overall there were 67 eligible KAPA participants within the 8 recruited classes and all 67 were invited to enter the KAPA feasibility study. Of the 67 participants invited 50 participants *(74.6%: 95% CI 63.5% to 83.3%)* were recruited and consented into the study. No participants were excluded from the study. The breakdown of participants by recruitment strategy is as follows:

In recruitment strategy one, the class sizes of the selected 4 PHISICAL FaME classes ranged between 2 to 15 participants per PHISICAL FaME class. The mean number of people per class was 6 (SD 6). A total of 25 participants were considered eligible to enter the KAPA feasibility study and were invited to take part in the study. Twenty of the twenty-five participants *(80%; 95% CI 46.7% to 94.8%)* were consented and recruited into the KAPA feasibility study.

In recruitment strategy two, class sizes of the selected 4 PHISICAL FaME classes ranged from 8 to 12 participants per class. The average number of people per class was 11 (SD 2). A total of 42 participants were considered eligible and were invited to take part in the KAPA feasibility study. Thirty of the forty-two participants *(71.4%; 95% CI 51.5% to 85.4%)* were consented and recruited into the KAPA feasibility study. Figure 11 depicts the KAPA participant recruitment flow.

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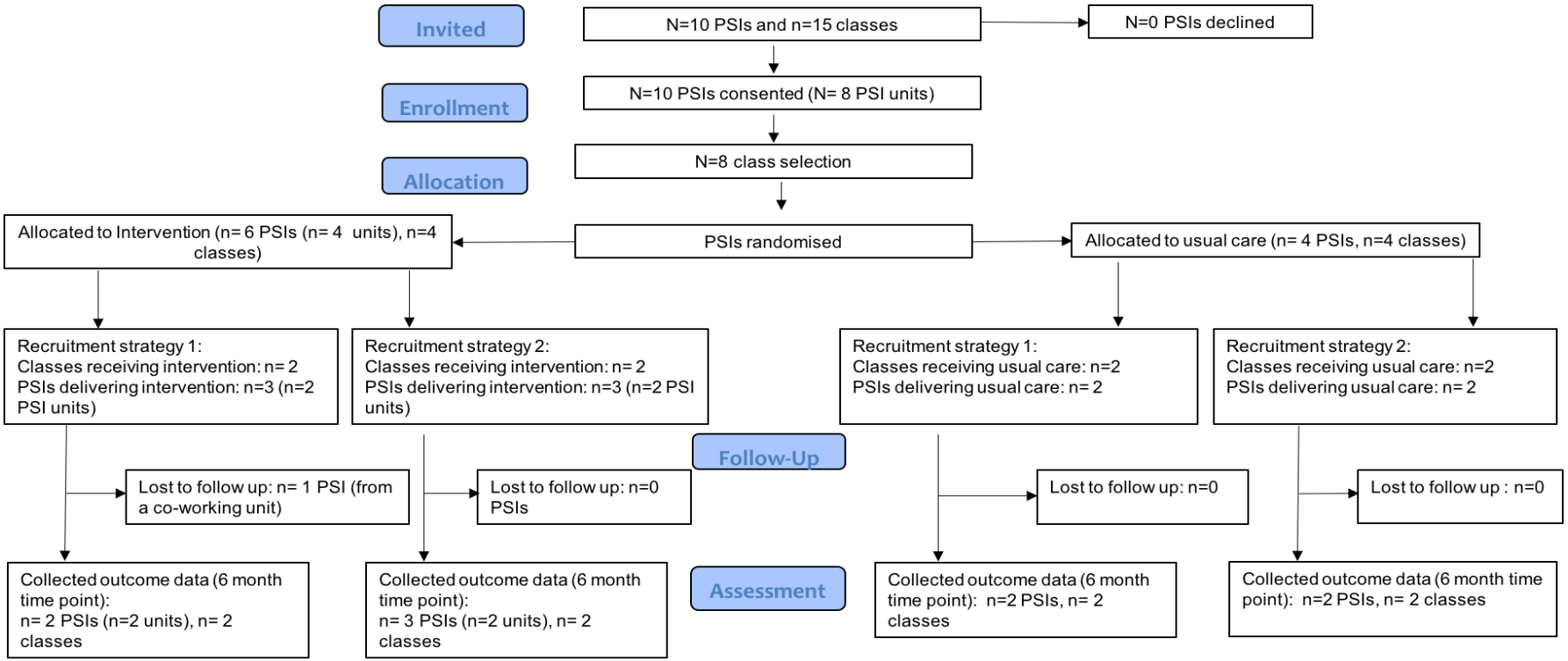

Figure 10. PSI and PHISICAL FaME class flow through the KAPA feasibility study.

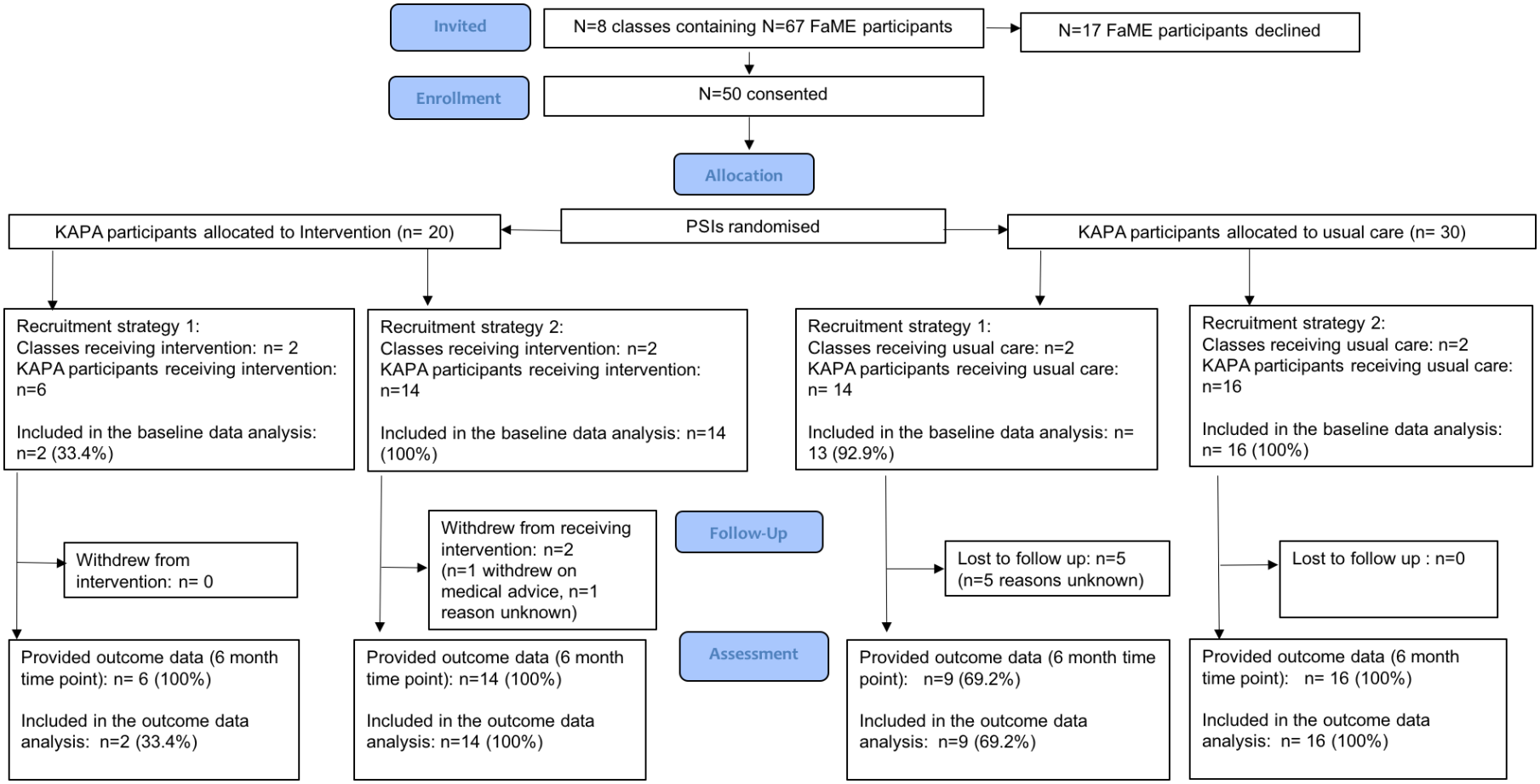

Figure 11. KAPA participant flow through the KAPA feasibility study.

4.8.2 Retention rates (objective 1)

Twenty-five *(83.3%; 95% CI 15.5% to 99.3%)* of the thirty participants randomised to the usual care group provided outcome data at the 6-month time point as five participants were lost to follow-up (reasons unknown). Of the 20 KAPA participants randomised to the intervention arm, 2 withdrew from receiving the intervention and 18 continued with the intervention receipt to the 6-month time point. One intervention participant withdrew from receiving the intervention after seeking health advice from a GP. Another participant withdrew from receiving the intervention and the reason was unreported. The two intervention participants that withdrew from receiving the intervention did so after the first KAPA intervention session. Although these two participants withdrew from receiving the intervention they remained in the KAPA feasibility study and still provided outcome data at the 6-month time point. Therefore, the data of 20 intervention participants *(100%; one sided 97.5% CI, 83.2% to 100%)* was collected at the 6-month time point.

Nine of the ten recruited PSIs were retained *(90%; 95% CI, 55.5% to 99.7%)* as one PSI from recruitment strategy one was lost to follow up due to a change of employment. However, the delivery of the KAPA intervention continued at this site as the PSI lost was a part of a co-working unit and the counterpart PSI continued to deliver the KAPA intervention. Five of six PSIs in the intervention arm *(83%; one-side 97.5% CI, 35.9% to 99.6%)* and all four usual care PSIs *(100%; 95% CI, 39.7% to 100%)* were retained at the 6-month time point.

4.8.3 Socio-demographic data

The routine data collected (i.e. socio-demographic and Phone-FITT [172]) was not available for four intervention and one usual care participants. Therefore, the data of 16 intervention participants (80%) and 29 usual care participants (97%) were included in the baseline data analysis. Five usual care participants were lost due to follow up and did not provide any outcome data. Twenty intervention participants (100%) and twenty-five usual care participants (83%) provided outcome data at the 6-month time point. The outcome data for 4 of the intervention participants (20%) was not included in the follow up data analysis due to missing baseline data. Therefore the outcome data of 41 participants (82%), 16 intervention participants (80%) and 25 usual care participants (83%), was included in the final outcome data analysis.

4.8.3.1 Socio demographic information

Due to differences in class sizes there was an imbalance between the numbers of participants in each study arm (see Table 14). Compared to the control group, intervention group participants were more likely to be female (81.3% versus 69.0%), have 6 or more comorbidities (12.5% versus 0.0%) and live in the least disadvantaged quintile of wards (45.4% vs 16.7%). Mean age, FRAT scores and education levels were similar between the two groups.

At baseline the intervention group reported achieving a higher amount of total MVPA minutes per week (median 160.0, IQR 57.5 to 532.5 versus median 46.0, IRQ 0.0 to 267.0) and the proportion of intervention group participants achieving 150 minutes of MVPA per week was also higher when compared to the usual care group (56.3% vs 41.4%).

Table 14. KAPA participants' socio-demographic and baseline PA information

	Intervention group n= 16	**Usual care group n= 29**
Age		
mean, (SD)	76.9 (7.0)	73.8 (6.4)
Gender n (%)		
Female	13 (81.3)	20 (69.0)
Male	3 (20.0)	9 (31.0)
Ethnicity n (%)		
White British	15 (93.8)	29 (100)
Asian Indian	1 (6.3)	0 (0.0)
Co-morbidities n (%)		
0 (None)	1 (6.3)	5 (17.2)
1	2 (12.5)	7 (24.1)
2	6 (37.5)	7 (24.1)
3	2 (12.5)	5 (17.2)
4	2 (12.5)	3 (10.4)
5	1 (6.3)	2 (6.9)
6 or more	2 (12.5)	0 (0.0)
IMD n (%)	(n=12)	(n=22)
Quintile 1 – most deprived	0 (0.0)	3 (13.6)
Quintile 2	2 (16.7)	7 (31.8)
Quintile 3	2 (16.7)	1 (4.6)
Quintile 4	1 (8.3)	2 (9.1)
Quintile 5 – least deprived	7 (58.3)	9 (40.9)
Education n (%)		
Secondary school (age 15/16)	10 (62.5)	20 (69.0)
Secondary school (age 17/18)	2 (12.5)	0 (0.0)
College	1 (6.3)	6 (20.7)
University	3 (18.8)	3 (10.3)
FRAT score n (%)		(n=28)
0	5 (31.3)	9 (32.1)
1	5 (31.3)	7 (25.0)
2	1 (6.3)	6 (21.4)
3	5 (31.3)	6 (21.4)
Physical activity		
Total minutes of MVPA - median, (IQR)	160.0 (57.5 to 532.5)	46.0 (0.0 to 267.0)
Total MVPA minutes:	7 (43.8)	17 (58.6)
0-149 minutes MVPA n, (%)	9 (56.3)	12 (41.4)
≥150 minutes MVPA n, (%)		

4.8.5 Attendance rates (objective 2)

Expected attendance consisted of attending 6 KAPA intervention sessions over the 6-month intervention period. KAPA intervention sessions could be attended either in person during a group session or via telephone with the PSI. A total of 120 KAPA intervention sessions were available to the 20 intervention participants recruited. The total number of sessions attended was 113 (94.2%). Ninety-seven (78.2%) of the 113 sessions were attended in a class environment and sixteen (21.8%) sessions were attended by phone. Eighteen individuals attended all 6 sessions, one person attended 3 sessions and another attended 2 sessions. Figure 12 depicts the number of participants attending each session over the six-month intervention period.

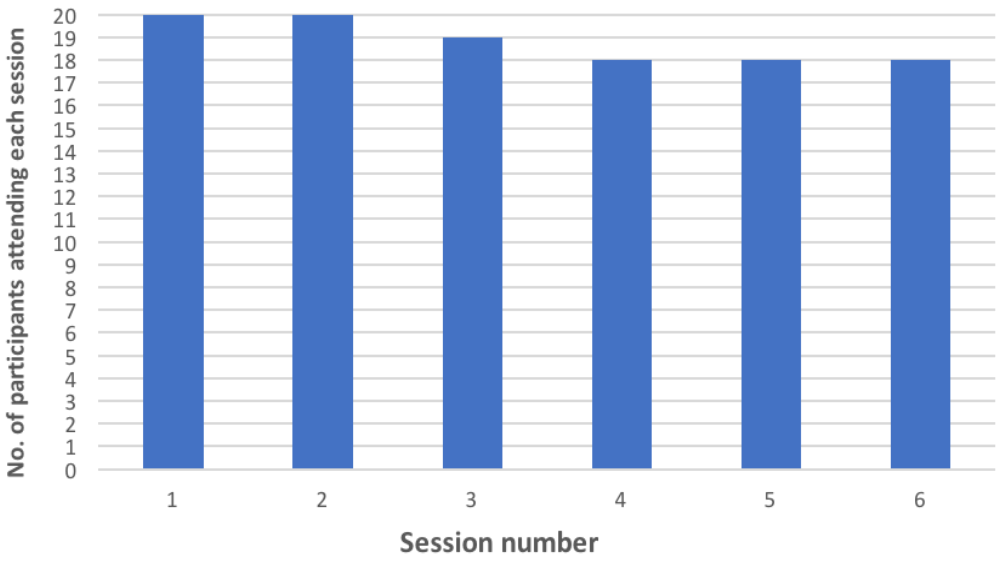

Figure 12. Figure showing the number of participants attending each of the six KAPA intervention sessions.

4.8.6 Training evaluation (objective 3)

All six PSIs recruited to deliver the KAPA intervention attended a KAPA training day. Usual care PSIs did not attend the KAPA training day. Evaluation of the training questionnaire showed that the content of the training day provided either comprehensive or adequate coverage of the theory and practical skills needed to deliver the KAPA intervention (Table 15). Overall, the delivery of the training day was well received as all six PSIs reported that the presentation style and lecture slides were adequate and the delivery of the training was easy to follow. However, the learning handbook and the learning tasks were less well received as only three PSIs (50%) found the learning handbook and the learning tasks helpful (Table 16).

Six PSIs reported that they were either very confident or quite confident in developing physical activity plans, reviewing goals and delivering the KAPA intervention follow up sessions. Three PSIs (50%) reported that they were only “quite” confident in delivering motivational interviewing techniques and four (66.7%) were quite confident in performing the behavioural assessments (Table 17).

Table 15. KAPA training evaluation, distribution of responses for training content

Responses	Comprehensive coverage N= (%)	Adequate coverage N= (%)	Some coverage N= (%)	No coverage N= (%)
Question: Did your training cover these aspects of the intervention in enough detail?				
Background knowledge of behaviour change	4 (66.7)	2 (33.3)	0	0
The concepts of the behaviour change wheel and motivational interviewing	4 (66.7)	2 (33.3)	0	0
Performing a behavioural assessment	4 (66.7)	2 (33.3)	0	0
Delivering behaviour change interventions	3 (50.0)	3 (50.0)	0	0
Self-monitoring and reviewing behaviour change	4 (66.7)	2 (33.3)	0	0
Structuring and delivering initial consultations	2 (33.3)	4 (66.7)	0	0
Structuring and delivering follow up sessions	2 (33.3)	4 (66.7)	0	0
Professional role and boundaries	4 (66.7)	2 (33.3)	0	0
Communication methods	4 (66.7)	2 (33.3)	0	0
Health and safety and data protection	4 (66.7)	2 (33.3)	0	0

Table 16. KAPA training evaluation, distribution of responses for training delivery

Responses	Strongly agree N= (%)	Agree N= (%)	Neither agree or disagree N= (%)	Disagree N= (%)	Strongly disagree N= (%)
Question: Did the delivery of the training and the learning materials meet your learning needs?					
The presenter's style was poor	0	0	0	2 (33.3)	4 (66.7)
The learning handbook was helpful	0	3 (50.0)	0	2 (33.3)	1 (16.7)
The lecture slides were poor	0	0	0	4 (66.7)	2 (33.3)
The learning tasks were helpful	1 (16.7)	2 (33.3)	0	2 (33.3)	1 (16.7)
There was not enough time to cover all the learning materials	0	1 (16.7)	0	4 (66.7)	1 (16.7)
I found it hard to follow	0	0	2 (33.3)	2 (33.3)	2 (33.3)

Table 17: Distribution of responses for PSI's confidence levels in their ability to deliver KAPA

Responses	Very confident N= (%)	Confident N= (%)	Quite confident N= (%)	Not very confident N= (%)	Not confident at all N= (%)
Question: How confident are you in your ability to:					
Use motivational interviewing techniques	1 (16.7)	2 (33.3)	3 (50)	0	0
Perform a behavioural assessment	0	2 (33.3)	4 (66.7)	0	0
Develop physical activity plans	2 (33.3)	4 (66.7)	0	0	0
Encourage people to self-monitor their behaviour	0	5 (83.3)	1 (16.7)	0	0
Review behaviours and goals	6 (100)	0	0	0	0
Deliver the content of follow up sessions	3 (50.0)	3 (50.0)	0	0	0

4.8.7 Adherence (objective 4)

4.8.7.1 PA diaries

Adherence with the KAPA intervention was measured by assessing the number and percentage of intervention participants who completed the weekly PA diaries and achieved their monthly PA goals. Adherence data was collected on the registers once per month over the 6 months intervention period. Where data was missing it was assumed that the participant had not completed their PA diaries. Register data was incomplete for 16 of the 20 participants (see Table 18). The register data showed that 4 participants (20% of the total group) were 100% compliant with completing the weekly PA diaries. Of the participants with incomplete data, 4 (20%) were 80% compliant; 1 (5%) was 60% compliant; 1 (5%) was 40% compliant; 7 (35%) were 20% compliant and 3 (15%) participants did not complete any of the PA diaries. Table 18 shows the PA diary completion rates. There was missing data in 35% of the diary completion boxes on the registers.

Table 18. Table showing participant adherence with completing PA diaries

Participant	Session no.					Sum adhered	%
	2	3	4	5	6		
1	-	-	✗	✗	✗	0	0.00
2	✓	-	✗	✗	✗	1	20.00
3	✓	-	✗	✗	✗	1	20.00
4	✓	-	✗	✗	✗	1	20.00
5	✓	✗	-	-	-	1	20.00
6	✗	-	-	-	-	0	0.00
7	✓	✓	✓	✓	✓	5	100.00
8	-	-	-	-	✓	1	20.00
9	-	-	-	-	✓	1	20.00
10	-	-	-	-	✓	1	20.00
11	-	-	✓	✓	✓	3	60.00
12	-	-	-	-	-	0	0.00
13	-	✓	✓	✓	✓	4	80.00
14	-	✓	✓	✓	✓	4	80.00
15	✓	✓	✓	✓	✓	5	100.00
16	✓	✓	✓	✓	-	4	80.00
17	✓	✓	✓	✓	✓	5	100.00
18	✗	✓	✓	-	✗	2	40.00
19	✓	✓	-	✓	✓	4	80.00
20	✓	✓	✓	✓	✓	5	100.00

Footnote: Ticks showing PA diaries completed, cross showing PA diaries not completed, dashes indicating missing data. The participants were tasked to complete the weekly PA diaries during the first KAPA session. Therefore, adherence rates were recorded five times between sessions 2 and 6.

4.8.7.2 PA goals

With regards to adherence with the PA goals, the register data showed that 3 participants (15%) met 80% of their PA goals. Where data were missing it was assumed that the participant had not adhered with meeting their PA goals. Register data was incomplete for 17 participants. The register data for the 3 participants with complete data showed that all 3 (15% of the total participants) were 80% compliant with the PA goals. Of the participants with missing data, 2 (10%) were 60% compliant; 1 participant (5%) was 40% compliant; 4 (20%) were 20% compliant and 7 participants (35%) did not achieve any PA goals. Table 19 shows the data relating to PA goal attainment. There was missing data in 37% of the PA goal attainment boxes on the registers.

Table 19. Table showing participant adherence with achieving PA goals

Participant	Session no.					Sum adhered	%
	2	3	4	5	6		
1	-	-	✗	✗	✗	0	0.00
2	✓	-	✗	✗	✗	1	20.00
3	✓	-	✗	✗	✗	1	20.00
4	✓	-	✗	✗	✗	1	20.00
5	✓	✗	-	-	-	1	20.00
6	✗	-	-	-	-	0	0.00
7	✓	-	✓	✓	✓	4	80.00
8	-	-	-	-	✗	0	0.00
9	-	-	-	-	✗	0	0.00
10	-	-	-	-	✗	0	0.00
11	-	-	✗	✗	✗	0	0.00
12	-	-	-	-	-	0	0.00
13	-	✓	✓	✓	✗	3	60.00
14	-	✓	✓	✓	✓	4	80.00
15	✓	✓	✓	✓	✗	4	80.00
16	✓	✓	✓	✓	-	4	80.00
17	✓	✓	✓	✓	✗	4	80.00
18	✗	✓	-	✗	✓	2	40.00
19	✓	✓	-	✓	✗	3	60.00
20	✓	✓	✓	✓	✗	4	80.00

Footnote: Ticks showing goals achieved, cross showing PA goals not achieved, dashes indicating missing data. The participants were tasked to set PA goals during the first KAPA session. Therefore, adherence rates were recorded five times between sessions 2 and 6.

4.8.8 Fidelity observations (objective 5)

Total fidelity scores achieved across all PSI remained similar between visit 1 (74.2%) and visit 2 (75.2%). The PSIs' communication scores (criteria 2) improved by 15 percentage points between visits 1 and 2 (85% vs 100%). Likewise, PSIs' fidelity scores relating to closing the KAPA intervention sessions (criteria 7) increased from 70% to 93% between the two visits. Between visits one and two a deterioration of scores was seen in criteria 3 (introducing the KAPA intervention session, 87.5% vs 65%) and criteria 6 (delivering the appropriate behaviour change techniques, 66.7% vs 43.3%). In the two visits the PSIs consistently achieved 100% in criteria 1 which related to setting up the environment and adhering to health and safety. Low scores documented in delivering the behaviour change techniques during the initial consultation (50% achieved) and follow up sessions (41.7% achieved) and when reviewing behaviour (56.3% achieved). All fidelity scores can be viewed in Table 20 and Table 21.

Table 20. Fidelity scores for the delivery of the initial consultation.

ID	**Criteria 01** Preparation Max score =4	**Criteria 02** Communication Max score =5	**Criteria 03** Session introduction Max score =4	**Criteria 04** Behaviour analysis Max score =6	**Criteria 06** Behaviour change techniques Max score =8	**Criteria 07** Closing the session Max score =4	**TOTAL FIDELITY SCORE per PSI** Total= 31 (%)
PSI01_site 1	1, 1, 1, 1	1, 1, 1, 1, 0	1, 1, 0, 1	1, 1, 1, 1, 1, 0	1, 0, 0, 0, 0, 0, 0, 0	0, 0, 0, 1	18/31 (58.1)
PSI02_site 2	1, 1, 1, 1	1, 1, 1, 1, 1	1, 1, 0, 1	1, 1, 0, 1, 1, 0	1, 1, 1, 0, 0, 0, 1, 1	1, 1, 1, 1	25/ 31 (80.6)
PSI03_site 3	1, 1, 1, 1	1, 1, 1, 0, 1	1, 1, 1, 1	1, 1, 0, 1, 1, 0	1, 1, 1, 1, 1, 1, 1, 1	1, 0, 1, 1	27/ 31 (87.1)
PSI04_site 4	1, 1, 1, 1	1, 1, 1, 0, 1	1, 1, 1, 1	1, 1, 1, 1, 1, 0	0, 0, 0, 0, 0, 0, 1, 1	1, 0, 1, 1	22/31 (80.0)
TOTAL (%)	**16/16 (100.0)**	**17/20 (85.0)**	**14/16 (87.5)**	**18/24 (75.0)**	**16/ 32 (50.0)**	**11 /16 (68.8)**	**92/124 (74.2)**
Average (%)	**4/4 (100.0)**	**4.3/5 (86.0)**	**3.5/4 (87.5)**	**4.5/6 (75.0)**	**4/6 (66.7)**	**2.8/ 4 (70.0)**	**23/31 (74.2)**

Footnote: Score for each criterion: 1 for achieved, 0 for not achieved. See Appendix 8 for a list of the criterion and items to be met in the fidelity observations.

Table 21. Fidelity scores for the delivery of the follow up sessions.

ID	**Criteria 01** Preparation Max score =4	**Criteria 02** Communication Max score =5	**Criteria 03** Session introduction Max score =2	**Criteria 05** Review behaviour Max score =8	**Criteria 06** Behaviour change techniques Max score =3	**Criteria 07** Closing the session Max score =3	**TOTAL FIDELITY SCORE** Total = 25 (%)
PSI01_site 1	1, 1, 1, 1	1, 1, 1, 1, 1	0, 1	1, 0, 1, 0, 0, 0, 0, 0	0, 0, 0	1, 1, 1	15/ 25 (60.0)
PSI02_site 2	1, 1, 1, 1	1, 1, 1, 1, 1	0, 0	1, 0, 0, 1, 1, 0, 0, 0	1, 0, 0	1, 1, 1	16/25 (64.0)
PSI03_site 3	1, 1, 1, 1	1, 1, 1, 1, 1	1, 1	1, 1, 1, 1, 1, 1, 1, 1	1, 1, 1	1, 1, 1	25/25 (100.0)
PSI04_site 4	1, 1, 1, 1	1, 1, 1, 1, 1	1, 1	1, 1, 0, 1, 1, 1, 0, 0	1, 0, 0	1, 0, 1	19/25 (76.0)
TOTAL per PSI (%)	**16/16 (100.0)**	**20/20 (100.0)**	**5/8 (62.5)**	**18/32 (56.3)**	**5/12 (41.7)**	**11/12 (91.7)**	**75/100 (75.0)**
Average (%)	**4/4 (100.0)**	**5/5 (100.0)**	**1.3/2 (65.0)**	**4.5/8 (56.3)**	**1.3/3 (43.3)**	**2.8/3 (93.0)**	**18.8/ 25 (75.2)**

Footnote: Score for each criterion: 1 for achieved, 0 for not achieved. See Appendix 8 for a list of the criterion and items to be met in the fidelity observations.

4.8.9 Parameter estimates (objective 6)

4.8.9.1 Parameter estimates of MVPA

The total MVPA minutes were dichotomised into whether or not the participants were achieving the target of 150 minutes of MVPA weekly.

At baseline the proportion of participants reporting at least 150 minutes of MVPA per week was 56.3% in the intervention group and 41.4% in the control group. Six-month follow up data showed the proportion of people reporting at least 150 minutes of MVPA per week rose in the intervention group (62.5%) and the usual care group (52.0%) (Figure 13).

Table 22 shows the odds ratios for comparing the intervention to the control arm at the 6-month time point, adjusted for baseline values. Odds ratios were above one, but none reached statistical significance (adjusted OR for achieving the MVPA target 1.25, 95% CI 0.26 to 5.88; p=0.78).

The ICCs for reaching the target MVPA minutes were 0.00 (95% CI 0.00 to 0.24).

Table 22. Table showing the proportion of participants and adjusted odds ratios for achieving 150 minutes of MVPA by study arm.

6-month time point	Intervention group (n=16) n (%)	Usual care group (n=25) n (%)	OR	95% CI	P-value
Total MVPA minutes					
0-149 minutes MVPA	6 (37.5)	12 (48.0)			
≥150 minutes MVPA	10 (62.5)	13 (52.0)	1.25	0.26 to 5.88	0.78

* Adjusted for baseline value

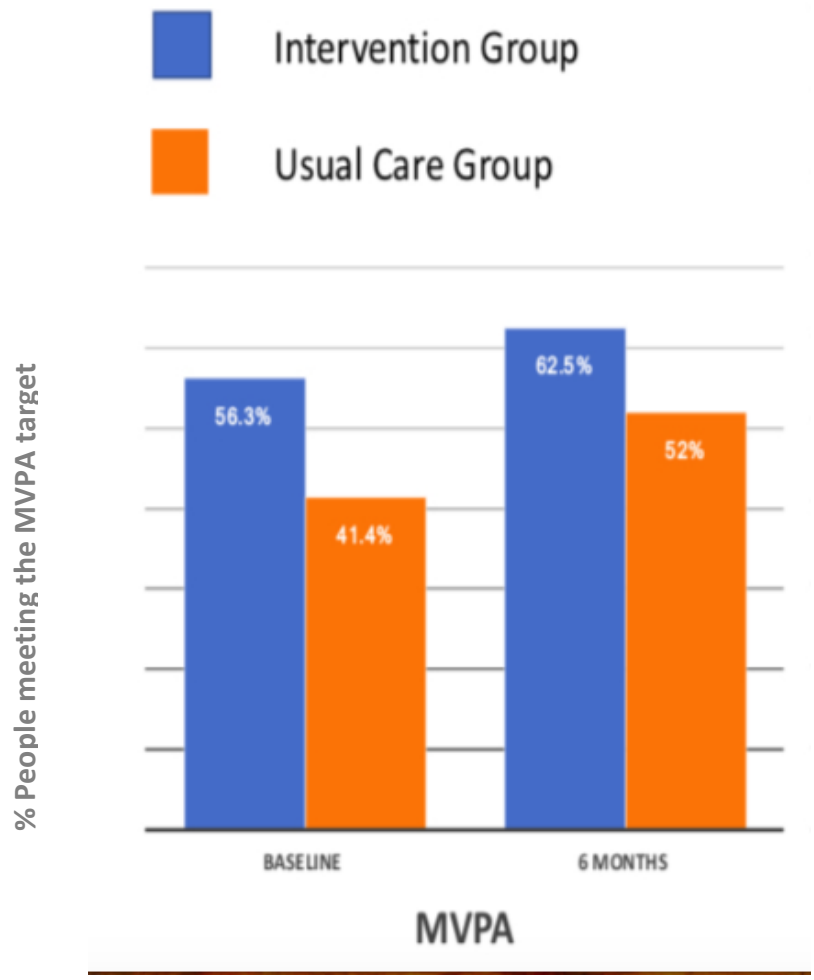

Figure 13. Figure showing the percentage of participants achieving 150 minutes of MVPA at baseline and at the 6-month time point.

4.8.10 Description of usual care (objective 6)

The service providers in 3 of the 4 usual care sites across North West Leicestershire and Derby provided descriptions of the content and delivery of usual care. All three usual care sites were active control groups and reported continuing to deliver supervised FaME classes after the end of the original 24-week PHISICAL FaME programme. The continued FaME classes contained a combination of resistance, cardiovascular, balance and flexibility exercises. All classes lasted 60 minutes and were delivered weekly in a community-based setting. FaME classes were delivered face to face by a PSI. All usual care providers encouraged home-based exercise that was supported by illustrated exercise materials. All sites reported following participants up by phone or text for none attendance. Tables 23 and 24 provide a visual and a written description of usual care at each of the three sites that provided information.

Table 23 Usual care delivery across sites (based on the TIDiER checklist).

Usual care site	BEHAVIOURS TARGETED					PA PROCEDURES					SUPPORTING ACTIVITIES		MATERIALS		PROVIDER		MODES OF DELIVERY						SETTING	DOSAGE			
	✓ Lifestyle PA (not including walking)	✓ Resistance training	✓ Cardiovascular training	✓ Balance training	✓ Flexibility training	✓ Exercise classes	✓ Home based exercise	✓ Lifestyle PA advise/program	✓ Supervised	✓ Unsupervised/ self directed	✓ Social support (non professional)	Improving accessibility	✓ Written materials	✓ Visual aids (videos, illustrations)	✓ Fitness professional	✓ Specially trained or supervised?	✓ Face to face	✓ Telephone	✓ In print via post or computer	✓ Visual or audio recording	✓ Delivered to an individual	✓ Delivered in a group	✓ Community venue (indoors)	No. of contacts	Contact duration (minutes)	Frequency	Intervention duration
SITE 6	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓			✓	✓	26	60	Weekly	Ongoing
SITE 7		✓	✓	✓	✓	✓	✓		✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	26	60	Weekly	Ongoing
SITE 8		✓	✓	✓	✓	✓	✓		✓	✓			✓	✓	✓	✓	✓	✓	✓			✓	✓	24	60	Weekly	Ongoing
Total	1	3	3	3	3	3	3	1	3	2	2	1	3	3	3	3	3	3	3	1	1	3	3	n/a	3	3	3

Table 24 Written description of the usual care strategies

Intervention site	*Usual care descriptive*
SITE 6	**Brief description:** FaME maintenance class. **Usual care strategies**: class-based graded exercise, later-life booklet illustrating exercises, timetable containing age-group specific PA classes in the locality. Follow up text for non-class attendance. **Tailored:** no
SITE 7	**Brief description:** Adapted FaME maintenance class (Fitness Stability Class for over 60's) **Usual care strategies**: class-based graded exercise, leaflets and multi media campaigns to advertise other local PA opportunities, once monthly coffee mornings. Follow up phone calls, emails and letters for non-class attendance. **Tailored:** no
SITE 8	**Brief description:** Adapted FaME maintenance class **Usual care strategies**: class-based graded exercise, illustrated home exercises, leaflets advertising local services for ageing health and safety and PA opportunities. Follow up phone calls for no attendance. **Tailored:** exercises modified for individuals' physical capabilities**.**

4.8.11 Study costs (objective 6)

4.8.11.1.1 Breakdown of the study costs per site.

The service providers of all eight sites provided data on the costs incurred to deliver KAPA. Table 25, table 26 and table 27 provide the breakdown of study costs for delivering the KAPA intervention per site.

Table 25. Break down of the study costs detailing the non-staff wages for delivering the KAPA intervention per study site.

	TRAVEL		KAPA INTERVENTION DELIVERY COSTS									ADMINISTRATION		
Intervention site	Fuel costs (total £)	Parking costs (session total £)	Venue hire (per session cost £)	Participant manuals (per manual £)	No. of manuals issued (Inc. PSI copy)	Pedometer (per item £)	No. of pedometers issued	Refreshment provision (per session £)	Telephone use (cost per minute £)	Average call length (minutes)	Average number of calls per month	Stationary (monthly cost £)	Postage (monthly cost £)	Postage cost for Phone-FITT questionnaire
SITE1	0.00	0.00	10.00	7.42	6	1.01	5	0.00	0.05	15	1	0.00	0.00	0.00
SITE 2	54.00	0.00	7.50	7.42	2	1.01	1	0.00	0.00	0	0	0.00	0.00	0.00
SITE 3	0.00	0.00	0.00	7.42	9	1.01	8	0.00	0.00	0	0	0.00	0.00	0.00
SITE 4 SITE 4	0.00	0.00	40.00	7.42	7	1.01	6	5.00	0.25	30	2	0.00	0.00	2.24

Table 26. Breakdown of study costs detailing the staff wages to deliver the KAPA intervention per site.

	STAFF SALARY											
Intervention site	Delivering KAPA session (£/ hour)	Time spent (minutes /session)	No sessions delivered per month	Telephone calls (£/ hour)	Time spent (minutes/ session)	No. Calls per month	Administration task rate of pay (£/ hour)	Time spent doing administration (min)	No. of sessions per month	Travelling to sessions (£/ hour)	Time spent travelling (minutes)	No. KAPA Sessions per month
SITE1	26.32	60	1	10.53	60	1	10.53	60	1	0.00	0	1
SITE 2	28.64	60	1	28.64	60	0	28.64	60	1	28.64	60	1
SITE 3	20.60	90	1	20.60	0	0	20.60	30	1	20.60	0	1
SITE 4	60.00	90	1	15.00	30	2	15	60	1	0	0	1

Table 27. Breakdown of KAPA Training Costs

	TRAVEL (PSI)		PSI WAGES				KAPA TRAINING DELIVERY COSTS				
Intervention site	KAPA training day fuel costs (£)	KAPA training day parking costs (£)	Attending KAPA training day (£/ hour)	Total time spent (minutes)	Mentoring session (£/ hour)	Total time spent (over 6 months)	PSI training manual (per manual £)	No. of manuals issued	Venue hire (cost per site)	Trainer wage (cost per site)	Trainer fuel and parking costs (cost per site)
SITE1	0.00	0.00	10.53	360	0.00	0	8.43	1	35.00	105.00	8.10
SITE 2	18.00	0.00	28.64	360	28.64	120	8.43	2	35.00	105.00	8.10
SITE 3	0.00	0.00	20.60	360	0.00	0	8.43	1	35.00	105.00	8.10
SITE 4	0.00	0.00	60	360	30	120	8.43	2	35.00	105.00	8.10

The staff wage range for delivering the KAPA intervention sessions was £20.60 to £60.00 per hour. Yet, it should be noted that the higher cost of £60.00 for delivering the KAPA intervention in site 4 was due to the KAPA intervention being delivered by two PSIs. The PSIs pay ranged £10.53 to £28.64 per hour for their administration time (Table 26).

The PSIs pay rate for delivering the KAPA intervention via telephone varied (£10.53 to £28.64). The PSIs at site 2 and site 3 were paid the class delivery rate (£28.64 and £20.60) to deliver the KAPA intervention by phone. However, the PSIs at sites 1 and 4 were paid an administration rate (£10.53 and £15.00) to deliver the KAPA intervention by phone. This payment scenario was similar for the PSIs who attended the KAPA training day as the PSIs from site 2, 3 and 4 were paid at class rate and site 1 PSI was paid an administration rate to attend the training day. Intervention sites 1 and 3 did not pay the PSIs for their time in attending the KAPA mentoring sessions. The reason for the PSI at site 1 not being paid for mentoring time is unknown. However, a possible reason for the lack of payment to site 3's PSI is that they received their mentoring via telephone and email, thus this information may not have been captured on the cost proforma.

Two providers (site 1 and site 2) delivered the KAPA intervention in community centers that were not the PSIs normal place of work. One of these sites (site 2) paid travel time and fuel costs to the PSI. The reason for site 1 not paying for travel time or fuel costs is unknown. Data relating to non-staff costs for the KAPA intervention is presented in Table 25.

The cost of venue hire where the KAPA intervention was delivered ranged between £0.00 to £40.00. The providers delivered 18 telephone calls. No intervention site had postage costs relating to collecting the Phone-FITT data. This suggests that the Phone-FITT data was collected during the KAPA intervention sessions.

4.8.11.1.2 Feasibility of collecting the cost data

The cost proformas were sent back to the providers to check for accuracy yet there were still some discrepancies in the information provided. For example, KAPA intervention delivery site 1 paid their PSI for an hour of their time (rate of pay £10.53) to deliver a single monthly KAPA intervention session by phone. However, the telephone usage costs would suggest the call delivered lasted an average length of 15 minutes.

4.8.11.1.3 Total study costs

The data presented in Tables 25, 26 and 27 was used to calculate the total study costs over the 6-month intervention period in both study arms. For example, staff wages for delivering the KAPA sessions were calculated as the sum of: Face to face delivery *(26.32 x 1x 6) + (28.64 x 1x 6) + (20.60 x 1.5 x 6) + (60.00 x 1.5 x6)* + Telephone contacts *(10.53 x 1 x 6) +(15.00 x0.5 x 2 x 6)* = ***£1208.34.***

The total cost for delivering the KAPA intervention was £3,987.85 and per participant the average cost was £199.39. Table 28 shows the total KAPA intervention costs incurred.

Table 28. Total costs for delivering the KAPA intervention

Service provider costing		
Category	**KAPA intervention (n=20)** No. of sessions delivered: 52 (n=24 group face to face classes and n=18 telephone calls)	
	Total cost (£)	Average cost per item per site (£)
DELIVERING KAPA		
Staff salary Intervention delivery time (face to face and by phone) Administration time Travelling time to classes	 1208.34 386.82 171.84	 302.09 96.71 42.96
Travel expenses (i.e. petrol and parking)	54.00	13.50
Venue hire	345.00	86.25
Refreshments	30.00	7.50
Administration consumables	2.24	0.56
Telephone usage	94.45	23.61
Pedometers and participant manuals	198.28	49.57
KAPA TRAINING		
Attending KAPA training and mentoring sessions (PSI wages)	835.90	208.98
Travel expenses (PSI)	18.00	4.50
Training manuals	50.58	12.65
Venue hire	140.00	35.00
Trainer wage	420.00	105.00
Travel expenses (trainer)	32.40	8.10
Total intervention cost **Total per person**	**£3,987.85** **£199.39**	

4.8.12 Adverse events (objective 7)

No serious adverse events were reported. There was one adverse event and two adverse reactions reported within the 6 months intervention time period. One participant experienced a fall-related adverse event during a planned supervised exercise class. The participant sustained a graze injury to the skin in the thoracic area. The clinical leads considered this was related to the KAPA intervention as the class attended had been written as one of the activities to perform in the participants' PA planner. The two adverse reactions were classified as musculoskeletal injuries. One participant was diagnosed with planter-fasciitis by a podiatrist after experiencing heel pain. The clinical leads believed this could be related to the study as the participant had increased their walking activity in response to the KAPA intervention. An orthopaedic consultant diagnosed another participant with an exacerbation of osteoarthritis of the knee. Again, this patient increased their daily walking activity in response to the KAPA intervention therefore the clinical leads considered that it could be related to the study. Table 29 summarises all of the adverse events that occurred during the KAPA feasibility study for the intervention arm.

Table 29: Description of the adverse events reported

Participant	**Place of event**	**Adverse event category**				**Adverse event type**	
	During KAPA activities	Adverse event	Adverse reaction	Relation to KAPA	Adverse incident	Musculoskeletal	Falling injury
1.	Yes	No	Yes	Possibly	No	Yes	No
2.	Yes	Yes	No	Definitely	No	No	Yes
3.	Yes	No	Yes	Possibly	No	Yes	No

4.9 Qualitative Research methodology and methods

4.9.1 Methodological approach

The KAPA feasibility study adopted a qualitative research approach to explore the acceptability of, and adherence with, the KAPA intervention from the perspective of the KAPA participants and PSIs. The KAPA feasibility study investigated the human experience of the KAPA intervention. Therefore, a phenomenological approach underpinned the KAPA feasibility study as this is concerned with investigating human understandings of particular experiences or experimental moments [179].

The researchers were specifically interested in gaining the PSIs and KAPA participant's experiential views on their engagement with the KAPA intervention. Therefore, a purposive sampling approach was employed as this focuses on selecting people who can provide rich information on specific experiences (e.g. the KAPA participants' experience of the intervention) [180]. Interview guides were based on asking questions to meet the research objectives and a deductive approach was used to create the framework to analyse the interview data [181].

4.9.2 Research methods

4.9.2.1 Sample

Qualitative data relating to adherence and acceptability was collected via semi-structured interviews with the KAPA participants across the three localities. All participants in receipt of the KAPA intervention were eligible to take part in the study interviews.

All intervention arm PSIs were eligible to take part in a semi-structured interview to discuss their perceptions of the acceptability and feasibility of receiving the KAPA training and delivering KAPA. PSIs were asked to describe any modifications that they made to the KAPA intervention or its delivery.

4.9.2.2 Recruitment

After the completion of the KAPA intervention all PSIs and the KAPA participants allocated to the intervention group were approached via email and telephone to request their participation in a one off semi-structured interview. Details of the KAPA feasibility study and the interviews were provided to the PSIs and KAPA participants in the participant information sheet. Written informed consent was sought prior to the interviews taking place.

4.9.2.3 Setting

Semi-structured interviews with the intervention group participants were arranged to take place either at the participants' homes or at a convenient

community location (e.g. at a leisure centre) to suit the participant. PSI interviews were held at local authority venues located within Derby City and Leicestershire and Rutland Counties.

4.9.2.4 Data collection

4.9.2.4.1 Interviews: KAPA's intervention group participants

Interview topics included questions relating to the participants' experiences of participating in the KAPA intervention (see Appendix 12 for interview schedules). Informed written consent was obtained on the day of interviews, prior to the interviews taking place. The interviews were audio recorded and lasted up to 60 minutes.

4.9.2.4.2 Interviews: PSI participants

Qualitative data relating to fidelity, acceptability and feasibility of delivering the KAPA intervention was collected via semi-structured interviews with the PSIs. For the PSIs delivering KAPA, interview topics included questions relating to the PSIs experiences in delivering the KAPA intervention and receiving the KAPA training. Fidelity of delivering the KAPA intervention was examined during the interviews by asking questions on whether the PSIs had modified the intervention or its delivery.

Semi-structured interviews with the PSIs took place up to 3 months after the completion of the KAPA intervention or usual care. Interviews took place in a convenient location and consent was obtained on the day of the interviews and prior to the interviews taking place. The interviews lasted up to 60 minutes.

Interviews were audio-recorded and transcribed verbatim. Transcribed data were handled using the NIVO10 computer software and coded. All interviews were analysed using a framework analysis approach [182]. This approach was selected to identify themes in the data to answer the research questions relating to feasibility, acceptability and fidelity. The first three interviews conducted were used as pilot interviews. The interview questions were amended to improve participant understanding of the questions or to improve the sensitivity of the questions to capture information relating to the KAPA interventions feasibility. The pilot interviews were included in the data analysis.

4.9.3 Data analysis

Data was analysed using a deductive thematic analysis approach. A predetermined framework was created based on answering the research questions. A separate framework was created for the KAPA study participants and the PSI interviews. The KAPA participant framework focused on investigating whether the participants adhered with the KAPA intervention and whether they found it acceptable. Whereas, the PSI framework analysis examined the feasibility and acceptability of delivering the KAPA intervention and the level of fidelity that the KAPA intervention was delivered.

The KAPA participant framework investigated:

- Whether the participants adhered with the intervention.
- Acceptability of the KAPA intervention to the participants.
- Suitability of the KAPA intervention to help keep participants active.
- The perceived benefits and disadvantages of the KAPA intervention.

The PSI framework analysis explored:

- The feasibility of the data collection methods to the PSIs.
- The acceptability and suitability of KAPAs training package.
- The acceptability and feasibility of the KAPA interventions delivery and implementation.
- The level of fidelity that the KAPA intervention was delivered.

The audio recordings of the interviews were listened to for familiarisation before generating the initial codes in the data set. The themes within the framework were developed from the coded transcripts. Once all the interview data was coded to the framework, the data most pertinent to the research aims and objectives was reviewed and identified. Clear definitions and names of each theme was generated before collecting the data to produce the report. These steps were performed systematically as outlined by Braun and Clarke, 2006 [182]. Due to a lack of research personnel, a single researcher (SA) coded the data and generated and defined the emergent themes.

4.10 Qualitative results

4.10.1 Recruitment

Sixteen of the twenty KAPA intervention participants were invited to interview as four participants did not respond to telephone calls and were not contactable. Fourteen of the sixteen participants agreed to be interviewed and two declined the interview invitation.

Five intervention PSIs were invited to interview and four agreed to take part. One PSI of the original six was not invited to an interview, as they were lost to follow up due to a change of employment and country of residence. An interview was not conducted with another PSI from a co-working unit as they declined an interview because their co-working PSI delivered five of the six KAPA sessions and they felt that they wouldn't be able to answer the questions on the KAPA interventions delivery. A PSI from each of the four KAPA intervention sites was interviewed.

4.10.2 KAPA participant demographics

Fourteen interviews with KAPA class participants and four interviews with the intervention PSIs were conducted between October 2017 and March 2018. The mean age of the KAPA participants interviewed was 75.6 years old (SD 7.09) and 64.3% of these were female.

4.10.3 Interview results

4.10.3.1 KAPA participant results (objective 3 and 4).

The areas of exploration (i.e. specific interview questions) and the themes (i.e. topics arising from the questions) identified in the participant interviews were:

1. Intervention adherence: This area of exploration investigated (a) the participant's motivation and emotional responses to goal attainment and (b) the participant's commitment to completing the diaries.

2. Acceptability of the intervention techniques was explored. The themes identified were (a) mental focus, reflection, self-feedback gained from completing the diaries and (b) feelings around acceptability of the participant manuals.

3. Acceptability of the KAPA intervention delivery features (objective 3): This area of exploration investigated (a) satisfaction with the venues; (b) PSI characteristics; (c) acceptability of the intervention duration and frequency and (d) social interaction, social comparison and feedback from others.

4. Suitability of the KAPA intervention to help participants keep active was explored. The two themes surrounding the KAPA interventions suitability were (a) self-monitoring, reflection and motivation and (b) memory recall and instruction for home exercise.

5. The last area of exploration evaluated participant's perceptions of the benefits and disadvantages of participating in KAPA.

Please note that the KAPA participant and PSIs names have been anonymised in the quotes by inserting the PSIs or KAPA participant's identification code.

4.10.3.1.1 Intervention adherence

Two areas of exploration investigated the participant's perception on how they adhered with KAPA. These areas of exploration were (a) motivation and emotional responses to goal attainment and (b) commitment to completing the diaries.

Motivation and emotional responses to goal attainment

Most KAPA participants reported either fully or partially completing their PA goals. Participants who fully met their goals reported being motivated by feelings of guilt if they had been inactive and the anticipation of gaining positive physical outcomes. Those reporting either partially completing, or not completing their goals discussed goal completion barriers to be laziness, spending time on other hobbies or having to spend time performing other life duties. Others discussed being motivated to achieve home exercise goals as this made their exercise classes "easier".

Interviewer: "Do you feel like you met your goals?".

"Oh yes, yes. Because I am well motivated you know and I want to make it easier when I get to the actual exercise classes itself so by doing exercises at home it does help." **PT05_Male, 74_site 3**

"Yes, I did on the whole, and I still do, I feel very guilty if I have sat all day and I either haven't done the exercises or I haven't gone for a walk. I have done more walking, I did walk but nowadays there is not many days go by that I don't walk." **PT07_Female, 84_site 3**

"I feel like I could possibly do more, that is probably a mental thing erm that is probably some laziness… yes I sometimes think you should be able to… oh I won't, I will do a crossword or something or go in the garden …" **PT03_Female, 69_site 1**

"I made a promise to do it every other day and every other day something else happened." **PT01_Male, 82_site 1**

Commitment and acceptability of completing the diaries

There were mixed feelings between participants about their commitment in completing the PA diaries. The majority of participants reported completing their PA diaries daily. Most did not have any reservations about completing the diaries as they found them important, motivating and helpful. Those who filled in the diaries discussed missing the odd day due to holidays or something else *"cropping up"*. A number of participants discussed completing the diaries to be an inconvenience. Participants who did not comply with the PA diaries reported that having to write and think acted as barriers to diary completion.

"Well there were odd days obviously when I was out, but it got done on a daily basis it never got left until the next day…. I really did put my heart and soul in it..." **PT03_Female, 69_site 1**

"I have a piece of paper on my dining room table and every time I eat a meal I write not only what I eat but the exercise that I have done so far. And then at the end of a week I take it upstairs and I put it all in to the computer and type it all out and then put it in my book ... I will continue the book because like I say I think it focuses your mind on how many steps you're doing and exactly what you're doing or not doing." **PT08_Female 67_site 3**

*"I did it for two or three weeks and then I just gave up, I did, yes I gave up**..."*** **PT13_Female, 85_site 4**

"As I say I missed the occasional day because something else had cropped up." **PT12_Male, 85_site 4**

"I did most of them, towards the end I didn't because I think we were away just before Christmas, so I didn't..." **PT06_Female, 70_site 3**

"I thought it was a bit of a pain filling in you know the sort of diary" **PT02_Female, 76_site 1**

"Some days I didn't do anything and some days I did a lot you know and I thought oh I can't sit and do the diary." **PT13_Female, 85_site 4**

4.10.3.1.2 Acceptability of the intervention components

Two themes emerged in regard to whether the participants found the KAPA intervention to be acceptable. The elements most discussed related to (a) mental focus, reflection, self-feedback gained from completing the diaries and (b) feelings around acceptability of the participant manuals.

Mental focus, reflection, self-feedback gained from completing the diaries

Those who filled in the diaries often reported being committed to completing the diaries as this focused their mind on their goals. They felt motivated and satisfied when writing down and reflecting back on their PA achievements.

"Interesting, it was quite interesting, trying to think of you know what to put and the diary… quite good I didn't have any reservations or anything." **PT04_Male, 86_site 2"**

"The big thing I suppose I found the most helpful was my diary, was the physical activity diaries, because you could take a look… well I used to take a look at the end of the week erm it felt good that I had done what I had done and at the end of the week I would think well I haven't done any better last week than the week before..." **PT03_Female, 69_site 1**

"Physical activity diaries, as I say they help concentrate your mind on what you're doing really, it makes you aware of everything you're doing or not

doing… I think it just makes you more aware of the exercise you weren't ever doing". **PT08_Female 67_site 3**

Feelings around acceptability of the participant manuals

Feelings were mixed about the acceptability of the participant manual. A number of participants discussed finding the manuals informative and the information and tasks useful. Yet there was a common theme whereby participants found the tasks and participant manual questions to be repetitive and over complicated. Participants often suggested that "simplifying" the manuals would help improve their acceptability. All participants agreed that including an illustrated home exercise booklet into the manual was beneficial as this helped to "remind" the participants how to perform the home exercises.

"Well I liked the files because they do make you do things, erm they nag you, it is like having a conscience there so that is good." **PT07_Female, 83_site 3**

"The manual was very good, very instructive yes, yes lots of suggestions and things and it all you know what you can do… erm that little bit of information that PSI01_site 1 gave about what is the guidelines, that information was useful for you to then be able to then look at what you were doing…" **PT02_Female, 76_site 1**

"Erm yes, they made me think a bit about it as to what I was doing which things were actually exercise and realised there were a lot more things that

were exercise than I sort of had first appreciated like just quite simply making the beds for example… I think the forms made me think… as I say I found that useful..." **PT12_Male, 85_site 4**

"The information was useful but all of this diary and you know I didn't find… If somebody wanted to write it for their own benefit then I suppose they can but information is good, information is very good." **PT03_Female, 69_site 1**

"Yes, I think just having to think... it seemed over complicated... I didn't particularly care erm but to have it simplified we thought. And maybe it is like this, my talking to you is far more beneficial to me, I much prefer that side to it." **PT11_Male, 73_site 4**

"*You know if it was more simplified... yes I think because you have got it all, everything down every week and then you have got another sheet telling you what you want to be doing and what… but it was like a bit too much sometimes, hmm."* **PT06_Female, 70_site 3**

"Yes, some of them are repeated questions and whatever you know? Yes, is I mean they were sort of semi-questions.... Sometimes if I wasn't sure, erm I would sit with PSI03_site 3 and the other girls and talked about it and then filled it in that way."

"Was there anything we could have done to have changed that to make it better for you?.."

" Simplify a bit, yes." **PT09_Female, 65_site 3**

"I liked the drawings they helped." **PT07_Female, 84_site 3.**

"I mean all of this, you know this was all very helpful, the exercises." **PT03_Female, 69_site 1**

"I found that useful that we got the exercise programme printed out for us, and when you come to do your exercises at home then you have got something just to remind you what you're doing so yes that was quite good and it helps you remind you when you come to fill your sheets in exactly what you have been doing." **PT10_Female, 79_ site 3**

4.10.3.1.3 Acceptability of the delivery features

Four areas of exploration were investigated about the acceptability of the KAPA interventions delivery. These exploration areas were (a) satisfaction with venues; (b) PSI characteristics; (b) acceptability of the intervention duration, frequency and timings; (c) social interaction, social comparison and feedback from others.

Satisfaction with the venues

All participants expressed high levels of satisfaction with the venues. Participants stated that the venues were “good” or “perfect” as they were accessible and had good facilities such as parking and refreshments. Being spacious was also often reported to be an advantageous feature.

"Erm the venue is perfect really." **PT02_Female, 76_site 1**

"No, no it is perfect, perfect for parking I mean a lot of places you go to you can’t park and there is a huge car park so you are always going to get in, erm walking in I know I don’t use the loos but people are very glad there is plenty of them around ... the coffee and sitting there is plenty of room." **PT07_Female, 84_site 3**

"Well I just think it is a good facility, you know everything is there that you need you know? The space, it is clean, it is… there is toilets, coffee and there is nice people… just everything about it is just right I think." **PT11_Male, 73_site 4**

PSI characteristics

Participants positively viewed the PSIs personality traits and professional characteristics as they spoke about the PSIs being motivating, encouraging, helpful and knowledgeable.

"Well she encourages you and I think it is quite a responsibility in a way, I said to her before about it and she really enjoys it. So yes, she is good. Couldn't better her really." **PT06_Female, 70_site 3**

"I think they are terrific, they are so understanding and helpful yes, no I think they are great…" **PT13_Female, 85_site 4**

"Well you have got a very good instructor, erm I think he did a good job... if you came up to a problem, PSI01_site 1 suggested how you could get round it." **PT01_Male, 82_site 1**

"*erm the instructor was perfect."* **PT02_Female, 76_site 1**

Acceptability of the intervention duration, frequency and timings

The majority of participants felt like the 6 months duration of the intervention was “long enough” and the monthly frequency of the intervention was “about right”. Most participants felt that they would not have benefited from more frequent KAPA intervention sessions or a longer intervention period. A few participants discussed inconvenience with the time of day that the KAPA intervention was delivered. Running the KAPA intervention over a lunchtime acted as a barrier to delivery as many participants wanted to “get back” home to have their lunchtime meal.

"I think a month is about right, weekly but weekly would be a chore… so I think a month is about right, especially if you make notes and you can look back and think oh yes I did do that." **PT07_Female, 84_site 3**

"No, I think it was… you have hit the nail on the head with it really and once a month and the group discussions." **PT08_Female, 67_site 3**

"No, I think meeting once a month was OK erm… I can’t see the point of going more frequently unless you are combining it with… I suppose what you could have done is have half an hour exercise and half an hour feedback." **PT02_Female, 76_site 1**

"Erm that was good, I think if you had just done it for one month you would have forgotten about it, I think the length of time it became a habit..." **PT07_Female 84_site 3**

"Erm… difficult to say really… I think it was long enough." **PT03_Female, 70_site 3**

"I think because there is a time… they finish at 1, you sort of want to get back to have a meal really…" **PT01_Male, 82_site 1**

"No, it is Monday now 1 until 2 which is a funny time because I don't like to eat before I go because it make some… that was 12 until 1:30, that wasn't bad because we eat in the evening anyway so but for some older people who have their lunchtime meals, have their main meal at lunchtime, erm anything between I think 12 and 2 is a bad time." **PT03_Female, 69_site 1**

"These discussions tend to take place after our class here don't they? Yes, so by the time you have done your class you are probably just about ready for your lunch…" **PT10_Female, 79_site 3**.

Social interaction, social comparison and feedback from others

All participants felt that an important feature of the KAPA intervention was the social interaction gained by participating in a group setting. Participants talked about experiencing feelings of encouragement and motivation from being part of a group and how they enjoyed communicating with and encouraging others. Participants who lived alone also found being given the opportunity to interact with other people helpful.

A number of participants reported that comparing themselves to others in the group helped to motivate them to be active. Participants also found that listening to other people's health problems and PA barriers reassured them about their own physical health.

"They were helpful, erm I mean a lot of us live on our own so to get in a group and start a conversation it is quite erm nice and you are obviously talking amongst other things you are talking about the actual course itself." **PT05_Male, 74_site 3**

"Because one of the important, to me important, features of those classes was the social interaction with other people." **PT12_Male, 85_site 4**

"Being a group, yes. Yes. And the fact that we see one person is doing something and if another one is ill and can't do it, we are there encouraging them and you know that they are doing the best they are able to within their abilities. So they don't feel that they are not achieving anything because we are encouraging them." **PT07_Female, 83_site 3**

"Yes, I mean I wouldn't say social but there were the four of us… how are you? what have you been doing? and so yes that part was good… I suppose in some ways it is encouraging other folk." **PT03_Female, 69_site 1**

"Yes, so it does help talking to other people and you know so there is oh there is hope for them as well… I struggle to do but I try to watch everybody else and say I will be able to do it next time." **PT09_Female, 65_site 3**

"A group keeps people going and then you think they are going to ask one if you have done… if we have done the work and you have got to keep up with them so you think yes I will go and do my exercises so you can say to PT05_Male, 74_site 3, well I didn't do them every day but I did do them three times last week and in isolation you wouldn't bother, you would have nothing to encourage you to do it other than being sensible and how many of us are?" **PT07_Female, 83_site 3**

"I have lost a lot of weight since I have been doing this, I have lost over four stones and I think it has motivated her, she has now lost four stone since she has been here, and you know erm a lot of well I say a lot of the others a couple of the others have started losing weight now and you know it has got to be good for you..." **PT05_Male, 74_site 3**

"Well it often helps me in funny ways in the sense that well I am not the only person who is suffering. So, it sort of calms me down a little bit when we

talk about all of our woes... And also when I… hear about the worse things that some other people have suffered you know, I shouldn't say that but it makes me a bit more cheerful about myself." **PT12_Male, 85_site 4**

4.10.3.1.4 Suitability of the KAPA intervention to help participants keep active

The next exploration area examined whether the KAPA intervention encouraged participants to continue to be physically active. Two themes arose in regard to what components of the KAPA intervention helped the participants to keep active. These themes included (a) self-monitoring, reflection and motivation (b) memory recall and instruction for home exercise.

Self-monitoring, reflection and motivation

Participants frequently discussed the benefits of using both the PA diaries and their own personal pedometers and those provided by the KAPA intervention to help motivate them to keep active and further increase their PA levels. Participants expressed that using the tools to monitor and reflect back on their daily and weekly step count and PA hours motivated them to increase the amount of walking and home exercise they performed. Participants who didn't enjoy completing the diaries discussed being more motivated by the pedometers. Whereas other participants believed the pedometers and diaries worked hand in hand. A number of participants reported that they were continuing to use the pedometers and diaries after the KAPA interventions completion as this helped them to stay focused on maintaining their PA levels.

"I think there was one week when it wasn't so good and I was a bit disappointed with myself I suppose and I think right next week I have got to up it again which you know so yes it was nice to look at it and see what I had done." **PT03_Female, 69_site 1**

*"I think they were worthwhile, at least you could you know see what was happening on a sort of day to day basis and you could look back and yes…. the only thing I think about those is that erm it could have motivated you more if you had somewhere on there to record the amount of steps you're doing.***" PT05_Male, 74_site 3**

"It is like because it is written down I think, it is there and you tend to look… you perhaps do a week and then you will have another week and look at the hours you spent doing whatever activity and compare them and think I haven't done much this week so I better get a move on. That sort of thing really." **PT06_Female, 70_site 3**

"Yes, you know they made me think a bit." …

"What kind of thoughts were you having when you were filling them in?"

*"Well you know, oh dear, I have not done anything for two days I better erm… go for a walk***." PT12_Male, 85_site 4**

"Oh I did, we got a little pedometer and I did used to walk around with those and check how many steps I had done, yes and I did use that... I was happy with that, something physical rather than paperwork." **PT13_Female, 85_site 4**

"I do much more walking, I normally have a Fitbit on, and erm I have put myself down for 6000 steps a day and erm that is my average."

"Does the Fitbit encourage you do you think?"

"Erm yes if you look at it at lunchtime and you have only done 1,200 you think oh I will go for a walk now." **PT07_Female, 83_site 3**

"Because it concentrates the mind on how much walking you're doing." **PT03_Female, 69_site 1**

"Oh yes, I will continue the book because like I say I think it focuses your mind on how many steps you're doing and exactly what you're doing or not doing." **PT08_Female, 67_site 3**

Memory recall and instruction for home exercise

Many participants talked about how the illustrated exercise booklet helped them to increase their PA levels at home. Some participants discussed how the illustrated exercises helped to remind them of the exercises and the technical instructions. Most participants reported continuing to perform the home exercises after the KAPA intervention had ended.

"Yes, we have got a whole list of drawings of what you can do at home… anything you know showing me what to do is good." **PT01_Male, 82_site 1**

“Yes, if you haven’t got the time you haven’t got the time to do the whole lot, you can do them as the day goes on.” **PT08_Female, 67_site 3**

"I didn’t used to do much exercise at home but we have done a bit more now at home and I have got the exercise book that I can do daily, those are always good, in fact I have had them quite a bit." **PT04_Male, 86_site 2**

"I have got the exercise sheet which I have adapted for myself... I felt… as I still feel that they are helpful. This is the reason why I do them every day." **PT05_Male, 74_site 3**

"Oh gosh yes, yes if I do… if I do home exercise I can’t always manage an hour but if I stand and exercise I usually do a good half an hour so I use those exercise sheets because it is a similar plan to what we have had in class so they are just to remind you what you could be doing." **PT10_Female, 79_site 3**

4.10.3.1.5 Perceptions of the benefits and disadvantages of participating in KAPA

The participants reported the main benefits of the KAPA intervention to be the feelings of enjoyment gained from interacting with others. When asked the only reported disadvantage of the KAPA intervention was completing the paperwork and having to “write”.

"Well you enjoy the… people there on the course with you, you certainly well exercise, I like to chat to people otherwise you tend to not see many people and when you can get in company it is good, you meet different people." **PT04_Male, 86_site 2**

"They were helpful, erm I mean a lot of us live on our own so to get in a group and start a conversation it is quite erm nice and you are obviously talking amongst other things you are talking about the actual course itself." **PT05_Male,74_site 3**

"I enjoy it and I love the banter with them and I like them all but it wouldn't worry me if tomorrow they stopped doing it... I say I do enjoy mixing with the people and doing it all." **PT11_Male, 73_site 4**

"I always enjoy sitting, chatting. Don't you? I mean you're not normal if you don't fancy a chat." **PT13_Female, 85_site 4**

"We are only a small group we still met up so it was nice to see other what other people were doing." **PT03_Female, 69_site 1**

"There is no disadvantages really, only the bother of writing it down but that is not too bad." **PT06_Female, 70_site 3**

"Well I don't think there are any disadvantages, but paperwork is always a bit of a pain isn't it?" **PT10_Female, 79_site 3**

"The only disadvantage is one doesn't like filling in forms but that was really all." **PT12_Male, 85_site 4**

"It was mostly paperwork and me and paperwork don't work… Just the fact there was so much of it, I mean the file there was one after the other, after the other, I thought no way am I going to do all of that yes. That was the amount of paperwork involved." **PT13_Female, 85_site**

4.10.3.2 PSI interview results (objective 3 and 5).

The PSI interviews specifically investigated four main areas of exploration:

1. Feasibility of the research methods: (a) barriers and facilitators to participant recruitment and (b) PSI experiences of collecting the data.

2. Acceptability and suitability of KAPAs training package: (a) perceptions of the KAPA training package, (b) on the job learning and usefulness of the mentoring support system and (c) transferable skill development and skill mobilisation.

3. Acceptability of the KAPA interventions delivery and implementation: (a) usefulness of the standard operational procedures (SOP), (b) barriers and facilitators to the KAPA intervention delivery (participant manuals, session duration, group setting) and (c) enjoyment gained from delivering KAPA.

4. Modifications to the KAPA intervention.

4.10.3.2.1 Feasibility of the research methods

Barriers and facilitators to participant recruitment

Two PSIs discussed experiencing no problems in recruiting participants into the KAPA feasibility study as their participant's eagerness to be involved facilitated the process. One instructor reported difficulties in recruiting participants into the KAPA intervention. This PSI described how FaME was delivered on a 12 months rolling programme whereby there is a constant turnover of participants entering and leaving PHISICAL FaME. The PSI felt this was a barrier to recruiting participants into the study as not all participants were at the 24-week time point in their PHISICAL FaME class.

Interviewer: "How easy did you find it to recruit participants in to the group?"

"Difficult... I think it is because with the group that we were using the clients had been on for quite a while so it was kind of an addition to our 12 month service programme and a lot of the clients had been on for a good four or five months beforehand so they just… they weren't in the mind frame to join in, they just wanted to come in, do the exercise and then drop off, It just seemed to fall during our 12 month programme where because it is a rolling programme it is always going to fall like that which is slightly difficult with the service we provide." **PSI01_site 1**

"They just… you know I asked them to do anything, would you like to be video interviewed for this? Would you like to be interviewed as part of the

research, would you like to be filmed as part of the research? They were just very excited about being part of it, they see they are getting a lot of benefit from it so they want other people to get the same benefit." **PSI03_site 3**

"We asked do you want to be part of this study? Most people were like yes, I will do that, explain that you are going to have to give up an hour once a month and we will do it on the last Thursday of the month, whatever it was we agreed, yes that is all fine. Erm so that was fine so to recruit them they were quite happy to come on board." **PSI04_site 4**

Experiences of collecting the data

Most PSIs reported that they had no problems in collecting the research data as they found it "straightforward". One PSI spoke of how the participants were "annoyed" with the repetitive nature of the Phone-FITT questionnaire.

Interviewer: "How did you find the data collection process?

"It wasn't a problem no." **PSI01_site 1**

"No that was straightforward… Erm and the Phone-FITT questionnaire they erm just did it and the fact that you know they were… I gave them a week and the people who couldn't come in that week they erm got their friends to bring them in, there is no… so I haven't had to follow anyone up." **PSI03_site 3**

"Well quite easy, straight forward… the answers are there, just tick the right box so it is quite easy." **PSI02_site 2**

"The stuff like the Phone-FITT questionnaire it is a lot of repeated… a lot of repeated questioning, again that is from the feedback from the participants, that is the bit that probably annoyed them the most, the repetitive nature of everything." **PSI04_site 4**

4.10.3.2.2 Acceptability and suitability of KAPAs training programme

The next area explored the degree to which the PSIs found the KAPA training programme acceptable and suitable to help deliver KAPA. Three themes arose in regard to how the training programme promoted learning and prepared the PSIs to deliver KAPA. These themes included (a) perceptions of the KAPA training package, (b) on the job learning and usefulness of the mentoring sessions and (c) transferable skill development and mobilisation.

Perceptions of the KAPA training package

All PSIs felt the content of the learning materials was “relevant”, “useful” and “helpful” and this expanded the PSIs theoretical knowledge to help them deliver KAPA. The PSIs felt that doing more role-play activities may have better prepared them to deliver KAPA. Some PSIs also discussed how the theoretical element of the training may have been better delivered as pre-course reading or as an “on-line” module.

"There was a lot in there erm to take in, some of it was you know relevant, quite highly relevant… the thing that we didn’t do particularly much of in the actual training was role play, erm so role play would be a good way of actually practising that technique before you actually you know put it over to the individual to explain erm how it works and yes." **PSI01_site 1**

"I think so especially the big folder with all of the paperwork, that was helpful in what needed to be done and when and how that was used in the programme but also how it related to the participants and the instructor, that was quite useful… I think it was done quite well the initial training pack and then the instructor pack as well and then having that mentoring session after delivering it in person… I felt confident delivering it because I knew if they did ask me a question I could answer it straight away." **PSI02_site 2**

"I think what you gave us with the two files, the blue file that participants have and the training file, they gave me everything I needed, it is just when you’re actually delivering it and you learn as you deliver anything, in any walk of life, the more you do it erm the more you learn and… the more

comfortable you feel. Yes. So you gave us everything… the tool kit was absolutely fine, it was just then how to apply it in practice… I went back and reread that after having done some and I thought oh yes how it absolutely ties in, I wonder whether that could be as pre read, some of it could be a pre read and then erm… go through a… I don't know whether it would be a summarised version on the actual day…" **PSI03_site 3**

"The amount of training that we received prior was significant, you know was OK, you came and showed us the folders and everything like that, that was all fine, there was no… erm we didn't feel like we were doing anything that we weren't equipped to do… I think for me, it might just be my personal way of learning but I didn't… I think maybe if you can give somebody some pre-course reading and get them to do a little bit of pre-course reading erm I don't know even if you could do some sort of online module as an alternative.... I think your day with us would be more valuable if we had done a little bit perhaps before." **PSI04_site 4**

On the job learning and usefulness of the mentoring support system

All PSIs positively discussed the mentoring sessions that they received. PSIs found the mentoring sessions useful and they liked having the support when delivering the intervention. PSIs also liked that the mentor was accessible. They felt the feedback that they received helped them to "develop and improve" their delivery skills.

"The feedback from that session was helpful erm highlighted things that you know you can address and improve on when you go and see the individuals

the following time and that did happen, we went when we did the follow up session from the initial session erm it went far better so that proved that the feedback I was given, I was able to you know to develop and improve basically yes." **PSI01_site 1**

"I think that was good, yes it was good… to get feedback on how we can improve that and especially for the participants." **PSI02_site 2**

"Yes, I knew you were there though, that was the thing that I… so that was interesting after the first running of it I did want to reflect and I did want to tell you what I thought had gone well and what had gone badly and that was really useful for me… I knew you were there so if I had sort of hit a real stumbling point that I could have rung you up or emailed you or whatever so… I liked the fact that you came out you know that first time and then also came out it ended up being the fifth time but I think you were thinking about doing one earlier so that was useful. And I liked the fact that I could erm email you and say well this is what I thought and also if I had hit a real problem that you were there so that was fine." **PSI03_site 3**

"Everything you have supported us with has been fine, it has been on point and anything that I have needed additional support with you have been there to help me with that and so yes, all of that, all of the mentoring, all of the support around the delivery has been just exactly what was needed." **PSI04_site 4**

Transferable skill development and skill mobilisation

Most PSIs believed the skills they learnt helped them with their wider working roles. Three of the PSIs discussed how they were implementing what they had learnt into different areas of their work.

"The benefits for me were firstly learning a new behaviour… you know that was important that I can use that across other areas of work that I do so that was great to learn something new." **PSI01_site 1**

"I think in my role now and in the future, I am going to take bits out of that intervention and use them because they are quite a good tool like the diary, planning the exercise and the goal setting." **PSI02_site 2**

"It has helped me… In my wider role yes… I like the techniques, they appeal to me which is why I am using them in erm… different classes." **PSI03_site 3**

4.10.3.2.3 Acceptability of the KAPA intervention delivery and implementation

Usefulness of the SOP

Most PSIs considered the SOP to be a useful document to follow when delivering each of the KAPA intervention sessions. The documents structure made the delivery process easier as it acted as a “good prompt”.

"I am just trying to think of the process whether that worked quite well, erm in following that, I think I didn’t seem to have any issues with that because it created a good prompt by having that there… erm you were able to follow through… to make sure nothing is missing as you go through so I think that process of doing it that way worked quite well that you can check everything off." **PSI01_site 1**

"That was really helpful, it was very comprehensive and easy to follow." **PSI03_site 3**

"Yes it is just a structure, for me I just needed that structure to work to, so the standard operational procedures if that was the right document that gave you that, the 1.1, the 1.2, this is what you kind of get through in each session, getting to session six you would have completed all of this, so that in a way that document, whichever one it was, erm was the tool I used if anything." **PSI04_site 4**

Barriers and facilitators to the KAPA intervention delivery

a. Barriers and facilitators to using the participant manuals

Most PSIs felt that the content of the participant manuals helped with the delivery of KAPA. One PSI discussed how different elements of the manual motivated participants. Two PSIs also expressed the benefit of including illustrated exercises in the manual. Another PSI discussed how the "paperwork" acted as a barrier to the KAPA intervention delivery. To help improve the KAPA interventions acceptability one PSI modified the intervention by giving the participants the option not to complete the paperwork. Only one of the four participants chose to complete the paperwork when given the option.

"The files were their own personal files and they were… you know they would always bring them along to the session, erm every month and they would document things in those erm participant files erm and it is something that became more personal to them what they were actually doing so it was really good yes... useful things were you know there was an exercise booklet in there for exercises that could be done at home so that is very useful." **PSI01_site 1**

"I think it made them think about other things they could be doing… I felt that… that… that some people were… motivated by the techniques, motivated by having the book, motivated by counting the steps and noting it down, whereas others weren't… so it was interesting to see that and it was also interesting to know how people sort of applied what they were doing so that was quite interesting in thinking about how to motivate people." **PSI03_site 3**

"One thing that was useful erm which I don't know if it is in this folder or the blue folder that we were given is the strength and balance exercises." **PSI04_site 4**

"The KAPA handbook didn't go down well, we had to change the way we delivered it." **PSI04_site 4**

b. Barriers to delivering the KAPA intervention (session duration)

Some PSIs felt like there was too much intervention content to deliver in the initial consultation time. In some cases, they felt this impacted on the quality of the KAPA intervention's delivery (i.e. not being able to complete the KAPA session or ask in depth questions within the given timeframe).

"The initial consultation erm in the first week I found quite difficult and in delivering that and that is why I thought probably some role play erm would have been good before that initial session... what happened in that initial session was I was talking more than what the participants were erm so we didn't manage to get through the initial consultation in one meeting erm so we had to extend that in to the second meeting." **PSI01_site 1**

"Initially the first meeting was… there was a lot to cover, I felt that was… yes there was quite a lot to cover in that. Erm… I found it difficult to really go in to as much detail as needed to be gone in to with the number of people in the time we had." **PSI03_site 3**

c. *Facilitators of the KAPA intervention delivery (group setting)*

The majority of the PSIs discussed the advantages of delivering the KAPA intervention in a group setting. PSIs talked about how the group dynamics helped to deliver the KAPA intervention as the participants helped and supported each other and problem solved together.

"What was also beneficial by being in a group situation, talking to the individuals as a group, they are able to discuss amongst themselves solutions to each individual's problem so erm… so yes erm it worked in that way as well yes... they were a very good group, a good sociable group, they talked well together and you know provided help to each other as far as you know different solutions to different issues." **PSI01_site 1**

"I think it worked better being part of erm the class because they were kind of all in that supportive, we are all in this together type of mind set… With the discussions they were having and how they were helping each other think through problems so that is why I think having a group discussion works." **PSI03_site 3**

'Having a positive group, you know that helped deliver the session knowing that erm the people involved are going to be quite positive about stuff and willing ... you know nobody was kind of clock watching… I think the group activity is erm… was what probably made it yes." **PSI04_site 4**

Enjoyment gained from delivering KAPA

PSIs expressed enjoying watching the participants positively respond to the intervention and seeing it “work”. Some PSIs also talked about enjoying delivering the intervention techniques such as goal setting, PA planning and PA monitoring.

"To see it work erm on the participants and then responding to that erm was really good." **PSI01_site 1**

"Just seeing how they were actually excited about doing more activity, I didn’t expect that.... I quite like doing the weekly erm like activity diaries, what they are going to do every week, I didn’t take much prompting to say what I want to do this, this and this so it was quite good." **PSI02_site 2**

"I like the techniques, they appeal to me... I think the highlight for me was when you were there, that session with all of those people just sort of helping that person think through her problems." **PSI03_site 3**

"I kind of enjoyed trying to bring a bit more out of them to get them to think about things a bit differently or challenge them to why they weren’t perhaps doing something or erm questioning if they were and it was a risk you know those kind of things, so I quite enjoyed that... I have got value from it because like I said I have enjoyed delivering it, I have enjoyed the group discussion, I have learnt from it, enjoyed challenging you know trying to stretch some people’s thinking around different subjects…" **PSI04_site 4**

4.10.3.2.4 Modifications to the KAPA intervention

Interview questions explored the extent to which the PSIs delivered the KAPA intervention in accordance with the SOP. Three of the four PSIs discussed making modifications to the KAPA intervention. One PSI discussed how they delivered the intervention content in the absence of completing the participant handbook to help make the KAPA intervention more tolerable for the majority of the participants. Another PSI discussed the benefits of delivering group exercise at the end of the KAPA session to maintain the participants' interest. Another PSI encouraged the participants to deliver the KAPA intervention to each other. This was aided by using break off groups and setting tasks which were listed on flip chart paper. All PSIs who discussed modifying the intervention considered the modifications to help improve the KAPA interventions delivery.

"It is quite a period of time sitting down, so what we did was an hour and a half session so I would tend to do a good hour or so on the talking part and then what I would do at the end is throw in… I would do a bit of exercise at the end... I think the split of the doing a bit of exercise at the end and the talking part as well, of establishing what they had done over the previous month erm the combination of the two worked quite well erm and it creates a bit of variation or a bit of interest that is different from erm just a sit down and chat so yes." **PSI01_site 1**

"Out of the five participants we had one person that would actively fill their folder out and they found it useful, the other participants didn't... we had a discussion and we agreed to do away with the folders and I would just

deliver erm the structure which was more or less the folder really but without the folder." **PSI04_site 4**

"Yes, put them in to break up groups, I used a flip chart so they got questions that they could all look at and then I tried to sort of like sit in on each of the groups and change it so they were trying to facilitate them, discussing it, but trying to let them lead the discussion... That worked well actually." **PSI03_site 3**

4.11 Discussion

4.11.1 Summary of the findings

To my knowledge, this is the first mixed methods feasibility study showing that booster sessions containing PA maintenance strategies are feasible to deliver, and acceptable for people exiting FaME programmes to receive, within local authority PA services. The original aim was to recruit 120 participants into the KAPA feasibility study. Due to small class sizes and a lack of available PSIs this target was not met and 50 participants were recruited. Ninety per cent of the intervention participants continued to receive the KAPA intervention until the 6-month time point and attendance rates were high (94.2%), suggesting that the participants found the KAPA intervention feasible to attend.

The current study demonstrates that the KAPA intervention is acceptable from the perspective of the participants in receipt of, and the PSIs delivering, the KAPA intervention. The PSIs believed that the training day, SOP document and mentoring support helped to facilitate the delivery of the KAPA intervention. The PSIs thought role-playing activities within the training day would have helped to better prepare them to deliver the KAPA intervention. The KAPA participants had positive views about the venues, PSIs and interacting with other group members. Participants discussed how the illustrated exercise booklets and self-monitoring tools encouraged them to keep active. Barriers to the KAPA intervention delivery included mixed feelings towards the participant handbook as participants felt there was too much content. The PSIs and participants agreed that simplifying the KAPA intervention would benefit its receipt.

Most KAPA participants reported regularly completing the PA diaries and meeting their goals, yet 35% of the PA diary completion data and 37% of

the goal achievement data was missing from the class registers. Therefore, participant adherence with these key KAPA intervention strategies could not be ascertained using the class register data. Approximately 75% of the fidelity checklist criteria were met during KAPA intervention class observations. Fidelity results suggested that the PSIs communicated well with the participants using a motivational interviewing approach but many of the behaviour change strategies in the initial consultation (33.3%) and follow up sessions (56.7%) were not delivered. Three PSIs reported making modifications to the KAPA intervention which compromised fidelity.

Parameter estimates of MVPA and ICC may be imprecise due to the low recruitment rate and small sample size. The ICC estimate of 0.000 (95% CI 0.000 to 0.237) suggests that there may be little clustering between the PSIs, although the wide confidence interval includes the possibility of a substantial degree of clustering. A higher proportion of the intervention group reported at least 150 minutes of MVPA per week (62.5% vs 52.0% respectively, OR 1.25, 95% CI 0.26 to 5.88, p=0.78), but the feasibility study was not powered to detect a significant difference. The KAPA feasibility study cost proformas were inaccurate in reporting telephone usage. Fifteen per cent of the intervention participants (n=3) reported an adverse event that could have been related to the KAPA intervention.

4.11.2 Interpretation of the findings

This section interprets the KAPA feasibility study results relating to each of the study objectives in terms of the current evidence base.

Objective 1: Recruitment and retention

Due to a lack of PSIs and classes available only 42% of KAPAs recruitment target was met (n=120). Ten PA booster intervention studies were found in KAPAs systematic review (Chapter 2) [77-79,81,83,85,87,101,103,108]. Recruitment rates in these studies ranged between 2.5% [79] and 71.8% [78] with the number of people invited ranging from 413 [83] to 3766 [79]. Only two of the ten studies recruited enough participants to meet their sample size requirements [77,78].

Generally, studies inviting people from primary care settings [85,87,103,108] and those using untargeted strategies (i.e. newspaper and radio advertisements) reached high numbers of people but high proportions were not recruited [76,79,81]. For example, Morey et al., [108] sent recruitment packs to 1917 people identified on primary care registers and achieved a recruitment rate of 20.8% (n=398). Rydwik et al's [79] recruitment methods (i.e. local advertisement and recruited from primary care clinics) reached a large number of older adults (n= 3766) but only 2.5% (n=96) of the people reached were recruited as many did not meet the rigorous eligibility criteria.

Studies meeting their recruitment aim used targeted recruitment strategies and less rigorous eligibility restrictions. For example, von Bonsdorff [77] invited people from population registers (n= 1310) and met their recruitment target (n= 657) as there were very few eligibility restrictions in place (i.e. older adults free from disability and contra-indications to exercise). Teri et

al, [78] also achieved their recruitment target as 71.8% (n=696) of the 969 people invited were recruited. These authors aimed to recruit inactive independently living older people and targeted their recruitment strategy by only inviting people from independent living centres. Therefore, targeted strategies coupled with less rigorous eligibility restrictions could help improve recruitment rates.

The KAPA feasibility study recruited 74.6% (n=50) of the participants invited (n=69). This suggests that the eligibility restrictions placed on participants were not too rigorous. It also suggests the recruitment methods (i.e. face to face and telephone interactions and letters from the PSIs) were effective at recruiting the participants. However, the recruitment strategy did not reach enough people, which is largely due to the restrictions placed on what FaME classes were eligible to be invited (i.e. FaME classes that took part in the PHISICAL study). Therefore, a future definitive trial needs to remove some of the eligibility restrictions placed on the FaME classes (i.e. only recruiting local authority classes delivered in the East Midlands) so that more FaME classes and participants can be reached and recruited.

Generally, studies investigating PA booster interventions delivered to older adult's report retention rates of 80% or more [77-79,81,85,87,103,108]. Studies with 6 month PA maintenance intervention periods report retention rates of between 88.7% [108] and 94.4% [103]. The KAPA feasibility study was similar as an 86.7% retention rate was achieved. However, it should be noted that longer intervention durations may lower retention rates as other authors have reported retention rates to be 85% during 12 month interventions [85,87], 80% during 18 month interventions [78] and 75.8% in interventions lasting 2 years [76,77]. It may therefore be helpful to use strategies shown to improve retention rates (i.e. giving people incentives and letter reminders [183]) more intensively in the later stages of studies.

Objective 2: Attendance rates

A recent systematic review proposes that older adults have sub-optimal attendance and adherence rates to PA programmes [184]. On the contrary, attendance at the KAPA sessions was high with a 94.2% attendance rate being achieved. Generally, attendance rates to the KAPA intervention were higher than those reported in other PA maintenance studies. A similar UK based motivational interview supported PA programme reported an attendance rate of 87% at four nurse led sessions [84]. Another study reported a 63% attendance rate at five face-to-face booster sessions delivered after the completion of a time-capped exercise programme [78]. Comparatively, the KAPA intervention had higher attendance rates which may partly be due to the KAPA participants already being at the intervention sites as attendees of the usual care exercise class, hereafter termed as the PHISICAL FaME maintenance class. The KAPA intervention may have had lower attendance rates if it had not been delivered directly after the PHISICAL FaME maintenance class.

The KAPA intervention attendance rates were higher than a cognitive behavioural therapy (CBT) supported exercise class which had an attendance rate of 83% (SD=0.22) [107]. Differences in programme durations may part explain the disparity between these findings and the KAPA feasibility study. The CBT supported exercise class was delivered over 10 weeks and older people are most likely to stop attending exercise programmes within the first 6 months as it takes this duration for health habits and new daily routines to form [166,185]. During the initial 6-month PHISICAL FaME programme all KAPA participants had formed weekly routines of attending a centre-based PA programme which likely enhanced the KAPA intervention's attendance rates. Thus, PA interventions of at least 6 months duration may achieve higher attendance rates in subsequent PA maintenance programmes as they can give people the opportunity to form new PA routines.

The LIFE-P Study [80] reported a 10% reduction in attendance rates at their centre-based exercise programme from the initiation period (70.9%) to the transition period (60.9%). Similarly, the KAPA intervention attendance rates reduced by 10% between the first (100%) and the last (90%) KAPA session, which was expected as two KAPA participants (10%) withdrew from receiving the intervention. The LIFE-P study sessions were delivered via face-to-face interactions whereas KAPA participants were given the option of receiving the intervention by class or phone. Attendance rates at KAPAs face-to-face group sessions were 78.2% and 21.8% at telephone sessions. Therefore, interventionists should consider delivering interventions via multimodal communication methods as this may help improve attendance rates to PA maintenance programmes.

Objective 3: Acceptability

Social network systems help to foster social engagement and good health in older adults [162,186,187]. Much evidence shows that social activities give older adults enjoyment and the motivation to exercise [23,87,150,164-166]. Similarly, the participants viewed the social network created within the KAPA intervention positively as they reported enjoying interacting with others, which motivated them to attend the KAPA sessions. Research has associated living alone with better programme attendance in older adults [184,149]. Likewise, many KAPA participants who lived alone highlighted the importance of the social interaction gained from attending group sessions. Social comparison is a fundamental element of social connectedness which promotes positive health behaviours in older adults [187]. Numerous KAPA participants discussed comparing their health and PA levels to others, which motivated them to become more active. Thus, fostering social networks maybe an integral component in the further development of the KAPA intervention and other PA maintenance interventions.

Participants reported that the PSI's feedback encouraged them to keep active. Others have also reported that fitness instructor feedback is key to encourage older people to comply with PA interventions [166]. Participants found the PSI's motivational interviewing skills encouraging. Many felt the PSIs provided helpful answers to questions and asked the right questions to help them overcome barriers. Participants discussed valuing the PSIs personality traits including being encouraging, helpful, caring and knowledgeable. Other authors have also reported fitness instructor personality and motivational interviewing skills improves the acceptability of, and older people's adherence to, PA programmes [149,166]. Motivational interviewing strategies can help older adults to remain physically active for up to 2 years [63,77,81,83-85,163,186]. Therefore it may be particularly beneficial to include motivational interviewing and fitness instructor feedback within PA maintenance interventions aimed at older people.

A substantial body of literature shows that older adults remain active after receiving PA interventions containing self-monitoring tools and goal-setting activities [47,63,76-88,161-163]. Comparably, KAPA participants often spoke of the emotional responses elicited by meeting or not meeting their goals. Monitoring tools and setting goals encouraged participants to reflect and focus on the activities they wished to perform. Achieving goals increased the participants' satisfaction levels, which motivated them to be active. Participants expressed feelings of guilt when their goals were not met.

The outcomes of multiple studies suggest that interventions containing illustrated exercise sheets and problem-solving strategies may help older people to remain active [76,77,81,83,84,88]. Most KAPA participants reported increasing their walking and home-based exercise activities in response to these specific intervention strategies. This suggests that the KAPA participants found these to be acceptable methods to encourage them to keep active. For this reason, these intervention components are likely to remain unchanged in future iterations of the KAPA intervention.

Although individual intervention components were found to be acceptable, a number of participants reported feeling that the KAPA intervention would be improved if the handbook was simplified. One PSI reported simplifying the KAPA intervention by not using the written materials. The PSI and the KAPA recipients reported that this helped to improve the KAPA interventions acceptability. A systematic review reporting on exercise interventions in older adults found intervention adherence improved in studies that simplified interventions to make them less demanding [184]. Intervention effectiveness has also been found to improve when participants find interventions simple and engaging [188]. Therefore, the KAPA intervention may benefit from being simplified.

Almost all participants believed the written materials were the least favourable part of the KAPA intervention. A number of participants found the participant handbook helpful as it was informative and increased their focus on their goals. Yet, an equal number reported the handbook being repetitive and involved too much writing. The authors of a nurse led walking intervention also found a mixed reception to their handbook whereby some participants found it helpful for goal setting, whilst others found it unhelpful [84]. Likewise, the participants in another nurse led walking study reported not enjoying writing in the PA diaries provided [87]. The literature is fairly consistent in suggesting that some older adults find writing activities helpful and acceptable in PA programmes whilst others do not. Thus, writing activities may need to be tailored to individual participants, as some older adults do not find writing activities acceptable in PA programmes.

Objective 4: Adherence

Previous PA maintenance studies have used a variety of methods to assess intervention adherence. Generally authors have measured intervention adherence via return of diaries [78,80] [79], PA questionnaires [77], completion of homework books [78], session attendance [78,79], goal attainment [87,108] and adherence with specific intervention elements [81].

Goal achievement was assessed as a measure of adherence with the KAPA intervention. Other authors have given participants specific goals to achieve during PA maintenance interventions (i.e. to perform 150 minutes of MVPA weekly [108] or perform 20 minutes of walking thrice weekly [87]). One author reported that 32% of participants reached their goals over the intervention period after receiving a telephone delivered PA counselling programme [108]. The "STEPs" study [87] found that goal achievement rates altered monthly and ranged between 43% and 58%. The KAPA feasibility study had similar findings as goal achievement rates varied from month to month (i.e. goal achievement rates were 50% in session 2, 40% in session 3, 35% in session 4, 40% in session 5 and 15% in session 6). This suggests that participants may experience relapses during a PA maintenance phase. During the interviews most KAPA participants reported fully or partially achieving their goals which does not fully agree with the register data. Much class register data was missing which may explain the disparity between the findings. Researchers and intervention providers should be attentive in accurately recording and monitoring adherence rates as the outcomes may be important so that PA maintenance techniques can be delivered to people as they are experiencing relapses.

Rydwik et al., [79] reported that 71% of people completed their training diaries throughout a 6 month intervention period. Teri et al. [78] reported PA diary adherence rates were 51% throughout a 10 month booster intervention

period. Much lower adherence rates were found in the KAPA feasibility study as the class registers showed that only 20% of participants completed all twenty-six PA diaries over the 6-month intervention period. During the interviews most participants expressed a mix of positive and negative feelings towards completing the diaries, even though most reported completing them daily. It is possible that the interview data is subject to social desirability bias and the participants overreported how often they completed their diaries. Equally, the adherence rates presented in the KAPA feasibility study are not accurate as 35% of the data relating to PA diary adherence was missing.

Adherence rates with KAPA's key intervention strategies and whether these could contribute to the future success of the KAPA intervention is unknown. More accurate outcome data in this area is needed as the research is mixed on whether goal setting and self-monitoring BCTs have a negative or positive influence on older people's PA behaviours [60,68]. Assessing adherence with these key strategies will be an area of interest in a future definitive trial.

Objective 5: Fidelity

No study author of the articles included in KAPAs systematic review (Chapter 2) attempted to quantify fidelity. The published research protocol [189] of one article [84] did discuss planning to use stringent methods to ensure fidelity (e.g. analysing audio recordings of telephone sessions, providing feedback at monthly supervisions, completing observational checklists). However, the authors did not quantify fidelity in the published research article. Therefore, the KAPA interventions level of fidelity cannot be compared with that of other published PA maintenance studies.

To improve intervention delivery it is advised that fidelity outcomes are used to identify service providers training needs and that outcomes are quantified

and fed back to providers to improve fidelity [188]. Treatment fidelity visits in the Exercise Plus programme were used to give performance related feedback to exercise trainers. This was reported to help improve intervention fidelity as "deviations" from the protocol were addressed and corrected immediately [190]. The Exercise Plus fidelity strategy was more comprehensive than the KAPA feasibility study strategy as the frequency and number of fidelity visits was greater and the exercise staff received informative monthly reviews [191].

The PSIs delivered 74.2% of the intervention content, showing that the KAPA intervention may not have been delivered entirely as planned. These findings are supported by the qualitative data as PSIs reported not having enough time to deliver all the intervention content. Equally, many PSIs also reported making vast modifications to the KAPA intervention which was not detected on the fidelity checklists (e.g. delivering the intervention in the absence of the participant manual). A future definitive trial may benefit from using similar strategies as the Exercise Plus trial [191]. Performing monthly observational visits would have helped to identify all deviations from the intervention protocol, which if fed back to the PSIs could have helped to improve the fidelity of the KAPA intervention delivery.

Objective 6: Parameter estimates, cost data collection tools and usual care descriptive

Parameter estimates (MVPA)

The KAPA intervention is unique in that a booster intervention consisting of group delivered motivational interviewing was delivered to older adults exiting a falls prevention exercise programme. There is a lack of studies investigating PA maintenance in falls prevention programmes (Chapter 2). Within the small number of existing controlled trials none have found a significant treatment effect on PA maintenance [35,51,52]. Booster letters and

review day invites after a “hip fracture prevention” programme resulted in no significant differences in the proportion of participants remaining active for 5 -7 days per week at 2 years follow up (IG 60% vs CG 60%, p=0.45) [101]. A 3 month falls prevention exercise programme with integrated relapse and prevention strategies resulted in no significant effect on calorie expenditure at 9 month follow up (*IG* 480 SD 691 vs *CG* SD 325 641, p=0.84) [110]. Comparably, brief advice to remain active after the completion of a 3 month falls prevention programme maintained significant effects on calorie expenditure at 6 months (IG 2494 SD 1376 vs CG 2400 SD 1360, p=0.002) but not at 9 months (IG 1914 SD 845 vs CG 2334 ±1265, p> 0.05) [111].

Previous study findings confirm that booster programmes consisting of motivational interviewing have positive treatment effects on maintaining exercise minutes (difference between group means 33.6 mins/week, *95% CI:* 2.5 to 64.2, p=0.02) [85], step count (difference between group means 1370 steps/day, *95% CI:* 169 to 2570) [81] and the proportion of people remaining active (IG 83% vs CG 72%, OR 2.0, *95% CI: 1.3 to 3.0, p-value not reported*) [77]. Generally, it is difficult to accurately compare the KAPA intervention with most previous trials as the term “physically active” is defined differently between studies.

The SCAMOB Study [77] investigating telephone delivered motivational interviews appeared to result in approximately 20% more of the intervention and control participants remaining “active” (IG 83% vs CG 72%, OR 2.0, *95% CI: 1.3 to 3, p-value not reported*) when compared to the proportion of KAPA participants adhering to the MVPA guidelines *(IG 62.5% vs CG 52%, OR 1.25; 95% CI 0.26 to 5.88, p=0.78)*. There are numerous potential explanations for the large disparity between these findings. Firstly, the SCAMOB study defined “physically active” to be the proportion of people remaining moderately active for 1-2 hours per week; whereas the KAPA feasibility study considered participant to be physically

active if they performed 2.5 hours of MVPA weekly. Secondly, the SCAMOB Study investigated a healthy older adult Finnish population who have the highest PA levels within the European Union [192]. Lastly, a smaller proportion of KAPA participants remaining active may be expected when compared to the SCAMOB study as those at risk of falls are more likely to avoid physical activity when compared to healthy older adults [35,193].

Parameter estimates (ICC)

Primary Care based PA studies recruiting older people have reported ICC results ranging from 0.00 to 0.12 at the level of primary care practices. The "Health Promotion for Older People trial" recruited 42 general practices and 267 older adults and estimated an ICC 0.00 (*95% CI* 0.00 to 0.085) for daily walking minutes [177,194]. The "Green Prescription Trial" recruited 42 general practices and 1,984 middle aged and older people. The parameter estimates showed ICC was 0.012 (*95% CI* 0.00 to 0.038) for weekly leisure exercise and ICC 0.014 (*95% CI* 0.00 to 0.041) for total PA calorie expenditure [85,177]. The KAPA feasibility study reported an ICC of 0.00 (*95% CI* 0.00 to 0.24) for the proportion of people achieving the target of 150 minutes of MVPA weekly. Although the KAPA feasibility study ICC estimate is similar to those from other studies the confidence interval is much wider due to the small number of participants and number of clusters [177]. In the KAPA feasibility study clustering was at the level of the PSIs, rather than study centre. Clustering at the level of PSIs resulted in a smaller number of people in each cluster when compared to clustering at the level of study site. Therefore, the KAPA feasibility study ICCs are likely larger than other studies where clustering is at the level of study centre, or GP practice. Further work would therefore be required to inform the ICC for a sample size calculation for a definitive trial of the KAPA intervention.

Usual care descriptive

The KAPA intervention was compared to the PHISICAL FaME maintenance class. Although, treatment effects were none significant, an increase of MVPA estimates were seen in both study arms at the 6-month time point (56.3% to 62.5% in the intervention group and 41.4% to 52.0% in the usual care group). It is likely that both study arms continued to be active in response to receiving a PA intervention, which may have reduced the estimations of the KAPA interventions treatment effect.

Other authors have also compared maintenance interventions to exercise group controls. Opdenacker et al., compared a motivational interview supported lifestyle PA programme to an exercise control group and found no significant effects on PA on completion of the intervention [81]. However, 24-month follow up data showed the intervention group performed significantly more daily steps when compared to the exercise controls *(*difference between group means *1370 steps/day, 95% CI: 169 to 2570).* Buman et al. [88] compared a peer supported exercise programme against standard exercise class provision. Alike Opdenacker et al, no statistical between group differences in PA were seen on completion of the intervention. Yet 18-month follow up data showed the intervention group performed significantly more minutes of MPA weekly when compared to the exercise controls *(145.7 SD 246.4 vs 58.32 SD 103.58, p< 0.05, respectively)*. Therefore, it is possible that a future trial assessing the KAPA intervention might be able to detect a significant effect on long-term PA maintenance even if the control group received continued exercise programme provisions. However, the treatment effect seen would likely be smaller than if a control group received no PA intervention.

Interestingly, the exercise class participants in Opdenacker et al's study reported having difficulties finding alternative PA opportunities after their structured exercise classes ended [81]. Therefore, continuing to provide PA

opportunities may be of particular importance when designing exit routes for PA programmes aimed at older adults.

Intervention costs

There is a lack of studies assessing the cost effectiveness of PA maintenance interventions delivered to older adults. Only one study, in KAPAs systematic review (Chapter 2) calculated economic costs [80]. However, the cost effectiveness of the maintenance component was not reported as the calculation included the PA promotion phase (i.e. walking programme) as well as the maintenance phase (i.e. transition to home exercise). Clinical interventions are commissioned in minimal doses which is determined by clinical and cost effectiveness reports [125]. Thus, maintenance interventions may not be commissioned if economic evaluations are absent. Researchers should perform cost evaluations of maintenance interventions to help commissioners with their decision-making processes.

Objective 7: Adverse Events

Three adverse events were recorded within the 20 KAPA intervention participants (15%). No serious adverse events were reported. One participant (5%) sustained a minor fall related injury and another two (10%) experienced lower limb injuries which were believed to be related to an increased amount of walking activity. These findings are consistent with other authors who have investigated nurse delivered walking maintenance programmes [87] [84]. In the study by Dubbert et al, [87] 14% of participants reported lower limb injuries and 6% reported experiencing a fall. Similarly, Harris et al, [84] found 6% of participants reported falls and 14% reported musculoskeletal injuries during the 3-month intervention period. Both study

authors reported that the types and numbers of adverse events were similar between groups and were considered unrelated to the intervention. Other authors have found the total number of adverse events of illnesses and injuries combined to be between 30% [77] and 69% [87] in participants receiving a maintenance intervention. Therefore, an adverse event rate of 15% is consistent with that of similar intervention studies. However, it is possible that our study did not identify all adverse events. Assuming that our study did identify all adverse events, it would suggest that the KAPA intervention does not require major modification to reduce potential harm to participants. However, adverse events would need to be monitored more regularly in a definitive trial. Asking the PSIs to record adverse events on the monthly class registers and reporting the occurrence of these back to the research team would achieve this aim.

4.11.3 Strengths and Limitations

This section discusses the KAPA feasibility study limitations and potential sources of imprecision and biases in the data.

Objective 1: Recruitment and retention

The KAPA feasibility study recruitment was confined to inviting participants exiting a small number of selected PHISICAL FaME classes within Derby City, Leicestershire and Rutland counties. These eligibility restrictions resulted in very few PSIs and participants being available for recruitment and the pre-specified recruitment target not being achieved. Furthermore, caution should be exercised when interpreting the confidence intervals due to the small number of clusters recruited.

A recent UK cluster randomised trial that incorporated PA maintenance strategies within a walking programme recruited 30.2% of participants invited from GP practices [84]. The KAPA feasibility study exceeded this proportion as 74.6% of the PHISICAL participants invited were recruited. Thus, suggesting that a large proportion of participants exiting FaME programmes may be agreeable to receive PA booster interventions. The KAPA feasibility study retention rates were high (86.7%). It is a study strength that the KAPA intervention has been shown to have the potential to retain a high number of participants, as high retention rates would be needed to maintain the statistical power in a definitive trial.

Objective 2: Attendance rates

Delivering the KAPA intervention directly after a PHISICAL FaME maintenance class (i.e. usual care sessions) may have affected the attendance rates in three of the four intervention sites. During the fidelity observations it became apparent that the intervention participants were also offered usual care and that the PHISICAL FaME maintenance class was delivered as an additional intervention to the KAPA intervention. Only one KAPA intervention class, containing five participants, didn't receive PHISICAL FaME maintenance class. Therefore, it is difficult to make any comparison to assess the extent that the additional intervention contributed to the high attendance rates seen in the KAPA intervention arm.

Objective 3: Acceptability

It is highly likely that multiple study outcomes were influenced by the PSIs modifying the KAPA intervention to improve acceptability and by delivering the PHISICAL FaME maintenance class directly before the KAPA intervention. It is hard to determine the extent to which these factors

impacted the KAPA interventions acceptability. As attendance rates were not monitored in the usual care arm comparisons cannot be made to assess whether the PHISICAL FaME maintenance programme contributed to the high attendance rates (94.2%) seen in the intervention arm.

It is difficult to identify feasible and acceptable strategies in multicomponent complex interventions. Interviews were conducted with the intervention participants to assess the value of each KAPA intervention component. This is a particular strength of the study as valuable information was gained to assess the KAPA interventions acceptability. However, the reliability of the data-coding scheme is unknown and coding errors may exist as the interview data was not second coded [195]. Thus, the research outcomes should be read with caution.

A single researcher delivered the training, mentoring sessions and conducted the interviews. The researcher was immersed in all research processes which may have unconsciously affected how the data was collected and interpreted. Additionally, the qualitative data pertaining to the PSI interview responses may be affected by social desirability bias as the PSIs may not have felt able to be critical about the KAPA intervention. Only four PSIs took part in the interviews and thematic saturation was not achieved. As a result, care needs to be taken in drawing conclusions about acceptability of the KAPA training package and mentoring sessions. To avoid such bias separate research staff should deliver the intervention training and conduct interviews. In larger studies, sufficient numbers of PSIs should also be recruited to interviews to help ensure thematic saturation is achieved.

Objective 4: Adherence

An objective of the KAPA feasibility study was to report intervention adherence by measuring the proportion of people completing the PA diaries and achieving their set PA goals. The qualitative findings suggest that a good number of participants adhered to completing their diaries and achieving their goals. However, we were unable to objectively assess this perception due to a substantial amount of missing data (35 to 37%) on the class registers relating to intervention adherence. To help overcome the deficiencies relating to the PSIs not recording high amounts of this data, a future definitive trial would benefit from the research team collecting the adherence data.

Objective 5: Fidelity

KAPA's intervention fidelity checklist assessed whether the intervention was delivered as planned. However, the checklist may not have accurately measured intervention fidelity as the PSIs reported making modifications to the KAPA intervention during the interviews, which was not detected in the observations. The same person who delivered the KAPA training performed the class observations and it is possible that this affected the PSIs' performance in delivering the KAPA intervention during the sessions observed. Therefore, a future definitive trial would benefit from using different people to deliver the training and perform observations. Observations of a larger proportion of KAPA sessions may also help to pick up additional modifications.

Objective 6: Parameter estimates

Parameter estimates (MVPA)

Detecting treatment effects is not a primary focus of feasibility studies as they commonly do not recruit enough participants to power statistical analyses [171]. It was therefore unsurprising that a significant treatment effect was not found in the KAPA study for MVPA. However, the odds ratios provide estimates of treatment effects that could be used in sample size calculations for a definitive trial.

A potential methodological flaw was that the PSIs and study participants were not blinded to the study objectives or outcome assessments. Lack of participant blinding influences self-reported PA outcomes as people tend to over exaggerate MVPA estimations [196]. It is impossible to blind participants to self-report PA outcome assessments as the person must consciously engage in recalling information. In PA studies it is also difficult to blind participants to their group allocation as they must, or must not, perform the act of being more physically active. This is similar for the PSIs who were either trained, or not trained, in delivering the intervention. For these reasons it is almost impossible to limit biases relating to blinding in PA studies. However, biases can be limited by collecting objectively measured PA instead of, or in conjunction with, self-reported PA.

It is important that PA is accurately measured when assessing intervention effectiveness [197]. It is well documented in the literature that self-reported PA data is less reliable when compared to objectively measured PA [197]. This is especially the case in older adults who are known to overestimate MVPA and underestimate sedentary time as a result of poor PA recall and

social desirability bias [163,198,197]. It would therefore be important in a definitive trial to include an objective measurement of PA.

The Phone-FITT questionnaire is a validated tool to collect self-reported data relating to household, recreational and total PA using an interview approach [172]. The KAPA feasibility study did not used the tool in its validated form. Firstly, the scoring system used to calculate the participants PA levels was modified to allow MVPA to be calculated. The approached used is not a validated method, therefore the results are only internally valid within the constraints of the KAPA feasibility study. Secondly, the study participants self-completed the Phone-FITT questionnaire, and it is unclear whether using a none interview approach affected its validity or reliability [197]. Therefore a definitive trial should collect Phone-FITT data using an interview approach and quantify the results using validated methods [172].

The recruitment period was extended to help increase participation numbers. As a result a number of participants (n=6) received the KAPA intervention directly after the 24-week PHISICAL FaME programme, whereas the KAPA intervention delivery to other participants (n=14) was delayed by 6 months. Directly after a PA interventions' completion it would be expected that those who completed the intervention would have reached a near ceiling effect. Treatment effects of exercise interventions are known to diminish after the intervention is discontinued [47,61]. As the KAPA intervention delivery was delayed by 6 months to some participants, they may no longer have been near a ceiling effect and the absolute increases in PA may have been greater which would result in a larger treatment effect in these people. Therefore, all participants would need to receive the KAPA intervention within the same timeframe to reduce baseline differences in PA in a future RCT.

Parameter estimates (ICC)

The ICC outcomes suggest there was no effect of clustering at the level of the PSIs. Recruiting too few participants and clusters reduces the precision of ICC estimates [199]. The ICC estimates in the KAPA feasibility study have wide confidence intervals because the recruitment targets for FaME classes (n=12) and participants (n=120) were not achieved. As a result the ICC estimates within the KAPA feasibility study should be interpreted with caution.

Usual care descriptive

The KAPA intervention was (unexpectedly) compared against a usual care group who received an exercise maintenance class. Both study arms continued to receive PA maintenance interventions and maintained MVPA increases. This will have reduced the point estimate of the KAPA interventions effectiveness (i.e. odds ratio) which may have lead to type 2 errors [200]. A number of KAPA intervention sites also received usual care, which will have also influenced the KAPA interventions treatment effect. Ultimately, it is unknown whether the treatment effect seen in the KAPA intervention arm was in response to the PHISICAL FaME maintenance class, the KAPA intervention, or both. Only three of the four intervention sites received usual care in addition to the KAPA intervention. Therefore, a comparison of whether KAPA had an additional treatment effect to usual care could not be made. To reduce the possibility of type 2 errors, future trials assessing the effects of exercise maintenance interventions should use a usual care group who doesn't receive an exercise class. If this is not possible, all intervention sites should receive usual care in addition to the maintenance intervention to determine the additional effect it has on usual care.

Cost proforma

The cost data was requested from the service providers after the KAPA interventions completion. The cost proforma may need adapting for a definitive trial as the telephone usage data was inaccurate. Service providers were not asked to record this throughout the KAPA feasibility study which may have resulted in reporting or recall biases. Collecting data from the service providers on a monthly basis may help to reduce the chance of recall biases in a definitive trial.

Objective 7: Adverse Events

During the intervention period participants were contacted by phone every three months to ask about the occurrence of any adverse events. Although participants were given contact details to report adverse events no participant reported any event, even though three were disclosed in the follow up calls. It is unknown why the participants did not contact the researcher to report these adverse events but this does suggest that asking participants to self-report events was not an effective research method. Additionally, the information may be subject to recall bias as the participants may not have recalled all events that occurred over a 3-month period. Therefore, it is also possible that some adverse events were not reported. In a future definitive trial the PSIs would be asked to record the occurrences of adverse events on the class registers and send these to the research team on a monthly basis.

The KAPA feasibility study only recorded adverse events in the intervention group. A limitation in the current study is that no information exists to assess whether the KAPA intervention increased the number of adverse events compared to usual care. A future definitive trial would also need to collect data in the usual care group so that between group comparisons can be made.

4.11.4 Generalisability

This section interprets the generalisability of the KAPA feasibility study research methods and trial findings.

The generalisability of the KAPA research findings are limited by a number of sampling biases. Firstly, all participants were recruited from a pre-selected consortium of local authority FaME providers within the East Midlands. Participants resided within a similar demographic area of England and were of a similar age. When compared to the general population of older adults living in the UK, the KAPA participant baseline results show that a lower proportion belonged to an ethnic minority group (2% vs 8%) [201] and a slightly higher proportion were female (73% vs 70%) [202]. Therefore, the KAPA participants may not be a true representative sample of all older adults aged 65 years or older within the UK.

Often interventions investigated within a controlled research environment are later found impractical to deliver in a real world setting [134,188,203]. The current study found that the KAPA intervention was feasible to deliver within a local authority setting in the East Midlands. Yet, local authority PA services delivered within the East Midlands may not be typical of those across the UK. Often FaMEs delivery is encompassed within GP referral schemes and at a cost to the service user. Thus, the KAPA interventions acceptability may not be generalizable to all local authority services within the UK. Especially those that do not have the means to subsidise FaME and the KAPA intervention delivery and those incorporating FaME (and the KAPA intervention) within an exercise on referral scheme.

Implementing the KAPA intervention directly into a local authority PA service was methodologically flawed from a research perspective as the subjects were exposed to an additional intervention (i.e. PHISICAL FaME maintenance class class) after the KAPA study had been designed. It is possible that the additional intervention impacted on attendance rates,

retention rates, intervention acceptability and the PA effect sizes. Therefore, the findings of the current study could not be generalised into a local authority service that does not have the provisions of a similar older adults' exercise class.

FaME classes are provided within a number of different settings (i.e. primary and secondary care) and some involve medical or healthcare professional referral systems. Different types of people may access FaME in each separate setting, for example frail older adults and frequent fallers are more likely to receive multifactorial falls risk assessments and attend classes through NHS care pathways [204]. Therefore, the KAPA feasibility study results cannot be generalised outside of classes being delivered within a local authority PA service. Furthermore, because the KAPA participants selected themselves into the original 24-week PHISICAL FAME class, and subsequently into KAPA, it is possible that the people who needed a PA maintenance intervention the most were not reached.

To help improve recruitment rates and resolve sampling biases future trials should aim to recruit older adults from a wider diversity of sources. Being less selective of the FAME classes invited into the study, recruiting from a wider variety of settings and widening the geographical area of recruitment will help to improve the generalisability of future study findings. However, adopting such recruitment methods may have implications for future trials in terms of cost, time and personnel, which may limit the feasibility of using these methods in a larger scale trial.

Lastly, parameter estimates derived from feasibility studies are likely to be imprecise unless a large number of clusters and participants are recruited [199]. Due to the KAPA feasibility study's low recruitment numbers and the imprecision of the ICC and intervention effect estimates, further work is required to inform sample size calculations for a definitive trial.

4.11.5 Recommendations for a future definitive trial.

This section discusses each of the study objectives and the proposed amendments that would be needed to investigate the KAPA intervention in a definitive trial.

Recruitment and retention strategy

Due to a lack of available PHISICAL FaME classes only 42% of the KAPA participant recruitment target (n=120) was met. The average number of participants within each PHISICAL FaME class was half the number initially anticipated. Recruiting 120 KAPA participants would have been unlikely even if the aim of recruiting 12 PSIs and classes were achieved. An extended recruitment period of six months was required to help increase participation rates. The study results suggest that an additional 12 classes (n=24) and double the time (12 months) were needed to recruit a sufficient number of participants into the KAPA feasibility study. Therefore, a definitive trial should base its anticipated number of classes and participants on the recruitment rates achieved in the KAPA feasibility study and should consider inviting more FaME classes and adopting longer recruitment durations.

The target of recruiting 70% of the people invited into the KAPA feasibility study was achieved. Inviting people face-to-face during an initial 24-week PHISICAL FaME programme was found to be the most favourable method (80% recruited) when compared to recruiting participants at a later date via letter or telephone invite (71.4% recruited). All participants were informed on the KAPA interventions rationale prior to being recruited. A recent Cochrane Review found that informing people on the rationale of interventions prior to recruitment enhances recruitment rates by

approximately 10% [205]. In the KAPA feasibility study the PSIs, rather than the researchers, informed the participants and recruited them into the study. It was hypothesised that this method would improve recruitment rates as other authors have found establishing good participant and service provider relationships improves recruitment [206]. It is believed that this combined approach helped to improve recruitment rates into the KAPA feasibility study. A definitive trial may benefit from using a similar approach to help augment recruitment numbers.

It is likely that the PSI - participant relationship influenced retention rates in the KAPA intervention as such relationships are believed to be fundamental in helping to retain older people in exercise programmes [166,184,206]. The KAPA intervention also had fairly intensive follow up contacts which also helps to retain older people in exercise programmes [206]. Both the KAPA intervention arm and the usual care arm had good retention rates (90% vs 83.3% respectively). Retention rates of 80% or more limit the risk of attrition bias [207]. However, to ensure that studies are free from attrition bias retention rates need to be at least 95% or more [207]. To meet this idealistic retention rate a definitive trial may benefit from employing strategies aimed to improve retention. A recent Cochrane Review found sending letter reminders and giving incentives improves retention rates within trials [183]. Therefore, a definitive trial should consider pre-defining and implementing such strategies to help maximise retention rates.

Addressing factors surrounding attendance

Recording attendance rates on class registers appeared to be successful as no attendance data was missing. Yet, during the KAPA feasibility study it became clear that the service providers delivered an additional PA intervention (i.e. the PHISICAL FaME maintenance class) directly before the provision of KAPA. It is possible that this distorted the attendance rate results. Revoking the PHISICAL FaME maintenance class from participants for research purposes maybe considered inappropriate and unethical as exercise classes have social as well as physical benefits for older people [162,186,187]. However, a definitive trial should seek to control when participants receive the KAPA intervention and other PA interventions (e.g. PHISICAL FaME maintenance class) as this will help to limit interactions between interventions so that the true effects of the KAPA intervention can be assessed.

Improving the KAPA interventions acceptability

KAPAs training package

A study objective was to investigate the KAPA interventions acceptability from the perspective of the PSIs who received the training and delivered KAPA. Service provider training should be well detailed and include concrete written instructions and supervisory systems as this promotes the successful implementation of interventions [203,208]. The PSIs believed the KAPA training package was comprehensive and the SOP facilitated the KAPA intervention delivery. Therefore, it is likely that the training materials would remain unchanged if the KAPA intervention were further investigated in a definitive trial.

Mentoring sessions, feedback on the fidelity assessments and action plans were provided to the PSIs to help strengthen the fidelity of the KAPA interventions delivery. The PSIs commended the mentoring sessions and found the feedback valuable to help improve their skills to deliver the KAPA intervention. Interventions are delivered with greater fidelity when monitoring and feedback loops are built into interventions [188,208]. Therefore, mentoring sessions supported by feedback on KAPA class observations should remain an integral part of the KAPA intervention in a definitive trial.

The consensus amongst the PSIs was that role-play activities and delivering KAPAs underpinning theory via virtual methods might have improved the training provision. Incorporating role-play activities has been found to improve intervention fidelity and should be included in further iterations of the KAPA training package [191]. However, interventions are implemented with greater fidelity when training is face to face rather than using virtual methods [203]. Therefore, the training package needs to be adapted in a manner that ensures intervention fidelity is not compromised.

KAPA intervention features and delivery modes

Participants found the PSIs delivering the KAPA intervention to be empathetic, motivating, helpful and knowledgeable, which promoted the acceptability of KAPA. The qualitative data emphasised that participants found the intervention setting and the dose and duration acceptable. Participants valued the self-monitoring tools, exercise illustrations, group connectedness and the motivational interviews delivered by the PSIs. Therefore, these components should remain unchanged in a definitive trial of the KAPA intervention.

Similar to the findings of other qualitative studies, the participants reported that procrastination and competing daily activities sometimes disrupted their plans to be active [209-212]. Considering how to mitigate such distractions

may be important in a definitive trial. Other authors have found that some older people report lacking daily structure, motivation and self-discipline which negatively impacts their PA intentions [209]. Qualitative researchers suggest creating daily routines and structuring in short bouts of purposeful PA might help older adults to build lasting PA habits [211,212]. Therefore, adding these intervention strategies into the KAPA intervention may help to improve the KAPA interventions effectiveness in a definitive trial.

Time of day appears to be important for intervention delivery. Authors of a systematic review assessing intervention adherence suggests that adherence to falls prevention programmes is negatively affected when older people's daily routines are disregarded [213]. Many participants reported dissatisfaction that the KAPA intervention was delivered over their normal meal times. Even though KAPA sessions were delivered at unsuitable times, high attendance rates were still achieved. Numerous participants were already at the venue to partake in the PHISICAL FaME maintenance class which may have affected the KAPA interventions attendance rates. If this is the case, it may be important to run the KAPA intervention to coincide with other activities people are attending at venues. Although when designing a definitive trial, researchers should still consider delivering PA interventions at a suitable time for the participant.

Based on participant feedback the written materials need simplified to help improve acceptability. It is unlikely that an intervention will be effective if recipients find components unacceptable [134]. The KAPA feasibility study's mixed methodology design was advantageous as this provided a means to investigate the acceptability of individual intervention components. It is recommended that a definitive trial should use a mixed methodology to also assess the acceptability of individual components so to refine PA interventions and improve efficacy.

Maintaining intervention fidelity in real life contexts can be difficult due to variations in service provider competences, resources and the competing

demands on the provider's time [188]. Interventions are often found impractical to deliver if they are not adapted to meet service provider needs [203]. Similarly, the PSIs reported modifying the KAPA intervention to make it more acceptable to deliver. Research suggests that service providers lack time to deliver falls prevention programmes as intended [213]. The consensus amongst the PSIs reports were similar whereby they felt that there was too much intervention content to deliver within the first KAPA session. Therefore, the KAPA intervention in its present form may benefit from being adapted in-line with the participant and service provider perspectives prior to testing in a definitive trial [134]. Focus groups should be conducted with KAPA service users and providers to help hone the KAPA intervention features so to optimise its acceptability and feasibility [134]. The modified intervention would then need to be investigated in a full scale RCT.

Measuring intervention adherence

Methods to measure adherence should be robust as poor intervention adherence can impact treatment outcomes [214]. Monitoring adherence throughout the duration of an intervention may be of particular importance as this can be used to help identify the people who are less likely to complete interventions so that additional support can be provided.

Much adherence data was missing, which suggests that using PSIs to record the data on the class registers was not an effective strategy. The semi-structured interviews took place before the quantitative analysis. Not being aware of the missing data resulted in a lost opportunity to explore why much adherence data was missing during the interviews. The consensus amongst the PSIs was that the data collection methods were "straightforward". This qualitative finding makes it difficult to interpret why much data was missing. Possible explanations could be that the PSIs

lacked time or motivation to collect the data or that the KAPA training package did not adequately cover the data collection methods.

Other authors have assessed intervention adherence by asking participants to post PA diaries directly to researchers on a monthly basis. Yet, this may be less effective than recording adherence in registers as diary return rates in older adults are between 50% and 60% [43]. A possible solution could be for PSIs to collect PA diaries and goal attainment sheets during the KAPA intervention sessions to forward to the research team. Opdenacker et al., collected adherence data verbally from the intervention participants during monthly telephone interviews [81]. All participants were contacted to collect data and 67% of the intervention participants were considered compliant with at least 80% of the intervention activities at the last data collection point (23 month follow up). Following participants up by phone could be a possible approach to collect adherence data, although it would have implications in terms of cost and research personnel time in a larger definitive trial.

KAPA intervention fidelity assessment methods

An objective of the feasibility study was to perform observational checks to evaluate deviations from the KAPA intervention's SOP. The class observation and interview data agreed that not all the interview content was delivered as a result of time constraints. The consistency between these two fidelity assessment methods suggests that these can both help to investigate fidelity with the SOP. Yet, the checklist failed to pick up some important data (i.e. data relating to intervention dosage, frequency and how well the participant handbook was used). The tool used a yes/no system to quantify fidelity with the SOP, rather than rating how well items were achieved. Feedback of rated outcomes may help improve provider skills [191]. A definitive trial wishing to assess the fidelity levels in delivering the KAPA

intervention should consider using a Likert scoring system to rate provider performance so this can be used for training purposes. The observational checklist should also be adapted to capture more data relating to adherence with the SOP.

Fidelity research protocols should evaluate a broad amount of information including provider training, intervention protocol adherence, quality of intervention delivery, interpersonal competence, programme differentiation and participant responsiveness [188,191,203]. It is important for fidelity evaluations to measure all these aspects as they can all impact intervention effectiveness [208]. Systematic reviews investigating the fidelity of health interventions report that fidelity indicators are often poorly assessed and reported [191,215-218]. It has been noted that very few articles assess fidelity issues relating to provider training, protocol adherence, service quality, interpersonal competence and participant responsiveness to treatments [203,188,191,217]. The KAPA feasibility study addressed a number of these fidelity issues as the training package; adherence to the protocol and the PSIs interpersonal skills were assessed. Yet the quality of KAPAs training package could be amended to improve fidelity. For example, the PSIs skill acquisition (e.g. role play examinations) was not assessed prior to delivering the KAPA intervention and methods to prevent skill drift (e.g. providing booster training sessions) were not included [191].

During interviews the PSIs reported that the mentoring sessions helped to improve their skills in delivering KAPA. However, the level of implementation support given to providers could have been improved via standardisation as PSIs received mentoring sessions on request rather than being provided at regular intervals [191,217]. It is advised that mentoring sessions should be standardised and the intensity of the sessions should be greatest at the beginning of an intervention when practitioners are in the process of learning new skills [191]. Therefore, standardising mentoring

sessions, giving follow up training and assessing skill acquisition would be modified prior to investigating the KAPA intervention in a definitive trial.

Fidelity assessment protocols need to measure all aspects of fidelity [208,215,219]. Borrelli et al., has created a comprehensive framework to help interventionists establish criteria to assess multiple aspects of intervention fidelity [191]. It is advised that a more robust fidelity assessment is created using this framework to ensure that all elements of fidelity are evaluated in a definitive trial.

Parameter estimates, cost data collection tools and usual care descriptive

Parameter estimates (MVPA)

The KAPA feasibility study would have benefited from collecting more accurate and precise measures of MVPA. The accuracy of measuring PA would be improved using accelerometers to measure the frequency, intensity and time of cardiovascular activity and sedentary time when compared to self-reported PA [63]. A definitive trial wishing to assess MVPA would benefit from using accelerometers. Although this method will increased the financial cost of collecting the PA data due to buying the accelerometers and researcher time to analyse accelerometer data [220]. Poor memory can affect wear-time adherence if accelerometers need to be worn over a number of days which often results in the data received being incomplete [220]. Thus, participants may need communication reminders to wear accelerometers. These methods would need to be factored in to designing a future definitive trial and research costs.

Lastly, at baseline the intervention group was older and had a higher proportion of women and participants with multiple morbidities when compared to the usual care group. It is possible that baseline differences were the result of only a small number of participants being recruited and an unequal number of participants between groups. Such baseline differences can be problematic in trials as these factors have been found to negatively affect people's PA levels [184,166,185]. The statistical analysis was adjusted for baseline PA, but not for age, gender and comorbidities. The analysis in the full trial should consider adjusting for baseline imbalances, in addition to baseline PA.

Parameter estimates (ICC)

A previous article evaluating sample size estimates for cluster trials suggest that ICC estimates derived from pilot studies should not be used as the sole parameter to calculate sample size estimates. A more reliable method of estimating ICCs is to use ICCs from a series of studies.[199], hence a definitive trial should use the KAPA feasibility study ICC in conjunction with those from other published studies to inform the sample size calculation.

Defining usual care

Usual care consisted of access to weekly PHISICAL FaME maintenance classes. If this was the case in a future trial, it would be more difficult to assess the treatment effect of the KAPA intervention than if a control group was used which did not receive an exercise intervention. It would be most ideal to compare KAPA against a no exercise control group. Yet, if usual care were an exercise class it would be unethical to revoke the exercise intervention for research purposes. A future definitive trial should compare

the KAPA intervention combined with usual care against usual care only as this would allow for the added effect of KAPA to be investigated.

Cost proforma

Even though cost proformas were returned to the service providers to correct errors many inaccuracies remained in the telephone usage data. This information is required to calculate the research funds needed to deliver the KAPA intervention in future trials. It is possible that these errors related to recall biases or the cost proforma.

In the current study, service providers managed their own research costs and were released money prior to the intervention being delivered. To reduce errors in data reporting the researchers would manage the research finances in a future trial. A definitive trial would also benefit from collecting cost data on a monthly basis (i.e. relating to telephone usage) to reduce the chance of recall bias. In doing so the service providers would be asked to refer back to telephone usage data recorded on the class registers to help improve the accuracy of the data submitted. Furthermore, data relating to quality of life needs to be ascertained in a definitive trial to allow an economic evaluation of cost utility.

Methods to assess adverse events

Adverse events were recorded using the same procedures and forms as those used in the ProAct 65+ trial [43]. The KAPA study did not record adverse events in the control group so it is unknown whether KAPA intervention resulted in more or less adverse events when compared to usual care. Therefore, a definitive trial would collect adverse event information from both study arms.

4.12 Conclusion

This study showed that the KAPA intervention is feasible to deliver in local authority PA services within the counties of Leicestershire, Rutland and Derby City. Attendance rates to the KAPA sessions and retention rates in the intervention group were high suggesting that the participants found the KAPA intervention acceptable to attend. Overall, participants reported finding the KAPA intervention acceptable, but findings also suggested the written materials may have been better received in a simplified format.

Fidelity assessments showed the PSIs effectively communicated with the participants using a motivational interviewing approach, although they did not always deliver all the KAPA interventions behavior change strategies. Participants reported that the illustrated home exercises and the PA monitoring tools encouraged them to keep active. Although MVPA levels were not significant, 62.5% of the intervention participants and 52.0% of the usual care group participants reported performing at least 150 minutes of MVPA per week. An adequately powered RCT is needed to assess whether the KAPA intervention can have a significant effect on maintaining PA.

Chapter 5. The lessons learnt during Keeping Adults Physically Active mixed methods study.

5.1 Summary of Chapter 5.

The Keeping Adults Physically Active (KAPA) study was a mixed methods study involving a systematic review. The review informed the development of an intervention that was investigated in a two-arm cluster-controlled feasibility trial. The primary study aim was to implement and investigate the feasibility and acceptability of the KAPA intervention within local authority physical activity (PA) services to inform a definitive trial.

Undertaking this research has been an invaluable learning experience. I have gained a good insight into many of the processes and complexities involved in designing and conducting clinical trials, and how these can impact the quality and creditability of research. This chapter provides a reflective discussion on the key challenges experienced and lessons learnt whilst addressing KAPA's study objectives.

5.2 Challenges faced in meeting the research objectives.

To inform the design of the KAPA intervention, the first research aim was to conduct a systematic review to identify effective intervention strategies for maintaining PA in older adults. KAPA's systematic review is the first to specifically investigate whether PA maintenance components help older adults to keep active. There was a large amount of heterogeneity between the intervention components and the PA outcomes reported across the included studies. Therefore, a meta-analysis was not possible and potentially effective intervention

components were identified using a narrative approach. The treatment effect of individual intervention components could not be determined as most included studies were not statistically powered to detect PA changes. Ultimately, there was a lack of statistical power underpinning the systematic review outcomes which made it difficult to confidently build a successful intervention based on the intervention components reported alone. Therefore, further evidence from the National Institute for Clinical Excellence guidelines for PA and behaviour change were also used to help develop the KAPA intervention [54,145,146,147].

A recent systematic review of reviews reported that the findings across the evidence base are too mixed to draw definitive conclusions on what specific intervention components can help older adults to keep active [60]. Conversely, a meta-analysis found associations between the delivery of specific intervention components (i.e. self-regulatory strategies) with lower levels of PA in older adults [68]. The previous research is mixed, which highlights the possibility that the KAPA intervention might include intervention components that have no effect, or a negative effect on older peoples PA levels.

An aim of the intervention development process was to design a theory-based intervention that was acceptable for PSIs to deliver and participants to receive. The KAPA intervention was co-produced with an expert steering group to help improve the interventions acceptability to deliver to the service users of local authority PA services. The expert steering group consisted solely of service providers and no Patient and Public Involvement (PPI) representative sat on the panel. There is an important distinction between the perspectives of service users, public members and service providers and these valuable insights are missed when PPI members are not included in research [221]. Therefore, the development of the intervention would have been strengthened by including PPI members within the expert steering group.

PPI involvement would have been valuable in all stages of the intervention development process (i.e. identifying the performance and change objectives and selecting and planning KAPA's intervention components, behaviour change techniques (BCTs) and delivery modes). A finding of the semi-structured interviews highlighted that a number of the participants did not enjoy writing in the handbooks. It is possible that a PPI member would have given some early insight into the acceptability of the handbook that may have helped to save research time and costs relating to the handbook's development. Involving PPI representatives in research requires additional time and costs which was not factored into the KAPA study [221]. The KAPA study had very tight deadlines and limited funds that largely impacted who was involved in the research processes. Regardless, this was a large limitation in the KAPA study. Therefore, in the design of future studies I will ensure that I factor in enough time and costs to enable PPI involvement in all research stages.

A research objective was to define usual care to inform a definitive trial. The FaME programme was a new service being trialled across local authority PA services within the East Midlands. My initial interactions with the service providers was to gain their interest in being involved in the KAPA study via educating them on PA maintenance exit strategies. During these early stages it became apparent that the providers had no predefined exit routes from FaME. However, the usual care descriptive showed usual care to be a complex intervention involving FaME's continued delivery which was supported by similar intervention strategies to KAPA (i.e. telephone calls, illustrated exercise sheets and timetables of age specific PA opportunities). The intervention and control arm service providers were involved in the expert steering group to develop the KAPA intervention. On reflection, their experience of this process likely influenced the usual care package they later developed.

Another confounding factor was that the intervention participants also accessed usual care. This meant that the intervention and control groups received very similar PA maintenance interventions; albeit the complexity of the KAPA intervention was greater due to the participants receiving a handbook, motivational interviewing and a wider mix of BCTs. Ethical approval was not gained to collect attendance rates, adverse events and intervention acceptability data in the usual care group. Therefore, a direct comparison of the effects of each PA maintenance intervention (i.e. KAPA vs usual care) could not be performed. Reflectively, in a full-scale trial I would ask the service providers to define the standard operational procedures of usual care before involving them in the research processes. I would also collect the same data in both study arms to determine the additional effect the KAPA intervention had on top of usual care.

Parameter estimates of MVPA were determined to inform the development of a definitive trial. The ProAct 65+ trial and the PHISICAL implementation study assessed FaME's treatment effects based on falls rates and MVPA estimates [44,75]. The KAPA feasibility study followed this research trajectory by investigating parameter estimates of MVPA in the research participants. Performing MVPA helps to manage numerous age related diseases (e.g. diabetes, cardiac disease and certain cancers [23]). However, engaging with MVPA does not improve balance or prevent age related muscle loss and is less important when managing falls [23]. Research shows that 15% of strength is lost, and falling risk increases by 2.5%, within 12 weeks of stopping performing resistance exercise [23]. Hence, measuring strength and balance exercise participation is particularly important in falls prevention exercise studies [23]. Therefore, a limitation of the KAPA feasibility study was that I did not pre-specify investigating strength and balance exercise participation and so this would be an outcome of interest in a definitive trial.

5.3 Reflective conclusion

This thesis presents a complex feasibility trial that involved the development and evaluation of an evidence-based intervention aiming to maintain PA in older adults. Clinical trials do not always go as entirely planned but presenting the lessons learnt can help inform future research [222]. The KAPA study incurred challenges that may have impacted the creditability of the research findings. However, the nature of a feasibility study is to identify the potential strengths and weaknesses of the research methods and interventions before progressing into a full scale trial [173]. Therefore, both the research results and the reflective evaluation of the KAPA study will be used to improve the quality and credibility of the research methods used in a definitive trial.

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