PHYSICAL ACTIVITY INTERVENTIONS FOR LONELINESS IN COMMUNITY-DWELLING OLDER ADULTS



By

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Abstract

This thesis addresses the important health concern of loneliness among community-dwelling older adults and attempted to contribute to the collective knowledge of interventions to reduce loneliness with a particular interest in PA interventions for loneliness, due to the current limited evidence. The first aim of this PhD was to systematically review the impact of physical activity interventions for loneliness among older adults, and conduct a meta-analysis of their effects. Developed from the findings of the systematic review of randomised controlled trials (RCTs), the next part of this PhD was to design a Physical Activity Intervention for Loneliness (PAIL) and protocol development. The next aim was to examine the acceptability and feasibility of the PAIL intervention in community-dwelling older adults at risk of loneliness. The PAIL intervention was a randomised controlled feasibility study and had a mixed-methods research design utilising quantitative and qualitative (i.e. focus groups) research methods. The systematic review found PA intervention effects on social functioning. The sensitivity analysis for social functioning obtained the strongest effects for solely PA interventions versus those with a social interaction component, (e.g. health education), among diseased versus healthy populations, in a group exercise setting versus individual, and delivered by a medical healthcare provider versus non-medical provider. However, coincident with the literature, no effect of PA was found for social support or social networks outcomes. Due to the lack of studies, it was not possible to review PA intervention effects for loneliness. From the intervention, based on responses of participants to interviews, the PAIL intervention was mostly accepted positively by participants who were seeking to increase their social networks and engage in PA. However, it was not feasible to recommend roll-out in a full-scale RCT in its present form. For example, the intervention design could be significantly improved by

providing transport, classifying groups by a level of walking (e.g. beginners, improver, advanced), adding group leaders, and delivering the healthy workshops as an extracurricular activity separately from the intervention. Similarly, the failure of the recruitment criteria shows the need to be improved possibly by recruiting through GPs and contacting the activity leaders of community organisations. The *a priori* recruitment criteria for progression to a large-scale RCT was not met, but the retention criteria were met and no adverse events occurred. Therefore, this thesis also discusses changes needed to support adequate recruitment of community-dwelling older adults at risk for loneliness and adherence into a definitive RCT.

I wish to dedicate this thesis to my parents, Liudmila and Vitaly Shvedko.

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I would like to admit that this PhD would not be completed without a help and support of those who was always present to listen and help during this PhD.

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Research contributions, funding and declaration of conflicts of interest

Research contributions

Prof. Anna Whittaker was the Primary Investigator of the PAIL research project, she reviewed stages of the systematic review, helped editing the manuscript for the publication, helped obtaining ethics approval and consequent amendments, helped with the registration of the study protocol, assisted at every stage of the conducting research experiment, facilitated patient recruitment, helped gaining access to the research sites, suggesting participation in the conferences, edited thesis drafts, structured my thesis and oversee all study procedures. Prof. Janice Thompson navigated through the appropriate resources for conducting the systematic review and oversee it's stages, helped with the structuring the PAIL research design, provided the heart rate monitor straps and a digital equipment required for the qualitative research analysis, assisted with the editing and publication of journal articles using the green route, provided the focus groups training and helped during the qualitative analysis, edited my thesis. Dr. Carolyn Greig helped to prepare for the ethical approval, provided the ActivPAL monitors for the research project, allowed access to the laboratory, advised regarding development of trial design and study protocol, edited my thesis. The doctoral research student, Anastasia Shvedko, obtained funding, conducted the systematic review, designed the PAIL study protocol, recruited and screened participants, provided health assessments, delivered the intervention, analysed the results, produced publications and wrote the thesis.

Dr Farhan Noordali, was a secondary reviewer of the systematic review and was a moderator of focus group interviews. PhD student, Meike Rosemeier helped with assisting focus group interviews. Lynne M. Harris (Academic Services, University of Birmingham) helped to conduct the database searches for the systematic review.

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Declaration of conflicts of interests

The author of this thesis declares that they have no competing interests.

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Abbreviations

AET	Aerobic Exercise Training
ANCOVA	Analysis of Covariance
AS	Doctoral Research Student Anastasia Shvedko, School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham
AW	Prof. Anna Whittaker, School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham
BDI	Beck's Depression Inventory
BMI	Body Mass Index
BP	Blood Pressure
BVSC	Birmingham Voluntary Support Centre: the Ageing Better Consortium
CG	Doctor Carolyn Greig, School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham
CHAMPS	Community Healthy Activities Model Programme for Seniors
CIs	Confidence Intervals
CONSORT	Consolidating Standards of Reporting Trials
COREQ	Consolidated Criteria for Reporting Qualitative research
CRBG	Cochrane Review Book Group
CRIS	Current Research Information System
DBP	Diastolic Blood Pressure
Delta2	Difference ELicitation in TriAls
EA	Evans Asamane, Doctoral Research Student, School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham
EE	Energy Equivalent

ES	Effect Size
FG	Focus Group
FN	Dr Farhan Noordali, School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham
GHD	General Health Questionnaire
GDS	Geriatric Depression Scale
GP	General Practitioner
h	Hour
HADS	Hospital Anxiety and Depression Scale
HR_{max}	Maximum Heart Rate
HRQL	Health-Related Quality of Life
ID	Identification
JT	Prof. Janice Thompson, School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham
K	Kappa Coefficient
kg	Kilogramme
LSNS-6	The 6-item Lubben's Social Network Scale
M	Mean
m	Metre
MCID	Minimum Clinically Important Difference
MeSH	Medical Subject Headings
METs	Metabolic Equivalents
MOCA	Montreal Cognitive Assessment
MOSSSS	Medical Outcomes Study Social Support Survey
MP	Mid-Point

MSPSS	Multidimensional Scale of Perceived Social Support
MVPA	Moderate-to-Vigorous Physical Activity
N	Number
NHS	National Health Service
ORs	Odds Ratios
PA	Physical Activity
PAIL	Physical Activity Intervention for Loneliness
PASI	Physical Activity Interventions with Social Interactions
PhD	Doctor of Philosophy
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROSPERO	the International Prospective Register of Systematic Reviews
PSPP	Physical Self Perception Profile
PURE	Publication and Research
QoL	Quality of Life
RCT	Randomised Controlled Trial
RET	Resistance Exercise Training
RPE	Ratings of Perceived Exertions
RRs	Relative Risk Ratios
SBP	Systolic Blood Pressure
SDs	Standard Deviations
SEE	Self-Efficacy for Exercise Scale
SEs	Standard Errors
SF-36	Short Form 36 item Health Survey
SMDs	Standardised Mean Differences

SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
SPPB	Short Physical Performance Battery
SPSS	Statistical Package for the Social Sciences
SSC	Satisfaction with Social Contacts
STEM	Science, Technology, Engineering and Mathematics
TIEDr	The Template for Intervention Description and Replication Checklist
UC	Usual Care
UCLA	University of California, Los-Angeles
UK	United Kingdom
ULS-20	The revised 20-item UCLA Loneliness scale
USA	United States of America
WHOQOL-BRIEF	World Health Organisation Quality of Life Assessment
WLC	Wait-List Control Group

Publications and conference presentations produced during this PhD

Journal Articles

1. Shvedko, A. V., Thompson, J. L., Greig, C. A., & Whittaker, A. C. (*under review*). Physical Activity Intervention for Loneliness (PAIL) in community-dwelling older adults: a randomised feasibility study. *Pilot and Feasibility Studies.*
2. Shvedko, A. V., Thompson, J. L., Greig, C. A., & Whittaker, A. C. (2018). Physical Activity Intervention for Loneliness (PAIL) in community-dwelling older adults: protocol for a feasibility study. *Pilot and Feasibility Studies*, *4*(1), 187. https://doi.org/10.1186/s40814-018-0379-0
3. Shvedko, A., Whittaker, A. C., Thompson, J. L., & Greig, C. A. (2018). Physical activity interventions for treatment of social isolation, loneliness or low social support in older adults: A systematic review and meta-analysis of randomised controlled trials. *Psychology of Sport and Exercise*, *34*, 128-137. https://doi.org/10.1016/j.psychsport.2017.10.003

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1. Shvedko, A.V., Whittaker, A.C., Thompson, J.L., Greig, C.A. (2018). Physical activity interventions for treatment of social isolation, loneliness or low social

support in older adults: A systematic review and meta-analysis of randomised controlled trials. Paper presented at the 24th *Nordic Congress of Gerontology*, Oslo, Norway.

Conference and meeting posters

1. Shvedko, A.V., Whittaker, A.C., Thompson, J.L., Greig, C.A. (2019). Physical Activity Intervention for Loneliness (PAIL) in community-dwelling older adults: a randomised feasibility study. Poster presented at the 77th annual scientific meeting of the *American Psychosomatic Society*, Vancouver, Canada.
2. Shvedko, A.V., Whittaker, A.C., Thompson, J.L., Greig, C.A. (2018). Physical activity interventions for treatment of social isolation, loneliness or low social support in older adults: A systematic review and meta-analysis of randomised controlled trials. Poster presented at the 5th joint annual Sport and Exercise Medicine conference of the *British Association of Sport Exercise Medicine*, Leeds, UK.
3. Shvedko, A.V., Whittaker, A.C., Thompson, J.L., Greig, C.A. (2018). Physical activity interventions for treatment of social isolation, loneliness or low social support in older adults: A systematic review and meta-analysis of randomised controlled trials. Poster presented at the *Agewell* public engagement conference, Birmingham, UK
4. Shvedko, A.V., Whittaker, A.C., Thompson, J.L., Greig, C.A. (2018). Physical activity interventions for treatment of social isolation, loneliness or low social support in older adults: A systematic review and meta-analysis of randomised controlled trials. Poster presented at the Royal College of Physicians CPD event, *British Geriatric Society*, London, UK.

5. Shvedko, A.V., Whittaker, A.C., Thompson, J.L., Greig, C.A. (2017). Physical Activity Intervention for Loneliness (PAIL) in community-dwelling older adults: a feasibility study. Poster presented at the *Agewell* public engagement conference, Birmingham, UK.
6. Shvedko, A.V., Phillips, A.C., Thompson, J.L., Greig, C.A. (2016). Physical activity interventions for treatment of social isolation, loneliness or low social support in older adults: a systematic review of randomised controlled trials. Poster presented at the *CRN West Midlands* ageing conference, Birmingham, UK.
7. Shvedko, A.V., Phillips, A.C., Thompson, J.L., Greig, C.A. (2015). Physical activity interventions for treatment of social isolation and loneliness in older people. Poster presented at the *PG research day*, University of Birmingham, UK.

CHAPTER 1. GENERAL INTRODUCTION

Background

Introduction to loneliness in ageing

According to the Office for National Statistics (Office for National Statistics, 2018a), the United Kingdom (UK) is increasingly an ageing population. In 2017, over 12 million people were aged 65 years and older, accounting for 18.2% of the total UK population in 2018 (Office for National Statistics, 2018a). The increased ageing of the UK population started over 30 years ago and continues to rise (Later life in the United Kingdom, 2018). To demonstrate, the population of the UK in 2018 was estimated to be 66.436 million people and is projected to reach over 74 million by 2039 (Office for National Statistics, 2018a). However, the highest increase of 23% for the last decade was registered in people aged 65 years and over estimating 10.6 million in 2018 (Office for National Statistics, 2018a). In addition, the birth rate dropped down and between 2017 and 2018 was the lowest since 2004 (Office for National Statistics, 2018a). Therefore, despite the increasing growth of the UK population, the higher proportion of older adults provides a new challenge for the government and society associated with increased concerns about the time spent in a good health for the average UK adult. With a shorter average life expectancy at birth for men (79.5 years) compared with women (83.2 years), men, in contrast to women, spend a higher proportion of their life in very good or good general health (79.7% versus 76.9% in females) (Office for National Statistics, 2018a). However, the maintenance of good health among older adults is increasingly difficult due to the number of health problems arising with ageing, that are often a result of an interaction of genetics, lifestyle factors and chronic diseases. With this, the risk of morbidity and mortality from common risk factors such as obesity,

cardiovascular diseases, physical inactivity, diabetes, cancer, and mental health problems, is significantly increasing in older adults (Bauman et al., 2016).

Almost a decade ago there was a relatively little information on consequences of loneliness for health (Adams et al., 2004). However, the ageing of the UK population has prompted an increase in research on loneliness and the number of interventions to prevent and treat loneliness, especially in older adults who are the most vulnerable. In recent decades there has been increased concern about the major negative health-related impact of social isolation and loneliness in older adults (World Health Organisation, 2008). Approximately 40% of older adults have low social contact and experience feelings of loneliness and social isolation (Lloyd et al., 2014). The statistics show that between 5 to 18% of UK adults feel lonely 'often' or 'always' (Office for National Statistics, 2018b). Almost a fifth of the UK population, over 9 million people, report feeling lonely (Jopling et al., 2017).

Social relations and networks are also very important for general quality of life and well-being, which has been defined as those aspects of one's living situation that make individuals feel better, function better on a daily basis, and live independently (Spirduso et al., 2001a). The high quality of social relationships needs to be maintained into old age to contribute to successful ageing (Department of Health, 2016). Older adults are especially affected by loneliness due to their experience of loss and deteriorating health conditions. With the ageing of the UK population, there is an increase in the government's concerns about the National Health Service (NHS) investments due to hospital admissions associated with loneliness and estimated to amount to £6000 per person over ten years (Jopling et al., 2017).

Loneliness is described as "a measure of a state of mind of a person and their negative feelings about their level of social contacts" (Wenger et al., 2004, p. 3). It is an

unpleasant subjective state of sensing the discrepancy between the desired amount of companionship or emotional support, and that which is available from the person's environment (Blazer, 2002). Loneliness is often associated with low satisfaction about social contacts and level of closeness with others (Wenger et al., 2004). In contrast to social isolation, which is mainly quantitatively defined as "a state in which the individual lacks a sense of belonging socially, lacks engagement with others and has a minimal number of social contacts" (Nicholson, 2009, p.1346), loneliness is associated with a deficiency in fulfilling quality social relationships (Steptoe et al., 2013). Social isolation can be both voluntary and involuntary, and is associated with the lack of social contacts and integration with other people (Wenger et al., 2004, Cattan et al., 2005). In contrast, loneliness is a subjective feeling and often defined as a perceived state and relates to minimal quantity and quality of social support or lack of desirable social contacts (Cattan et al., 2003, Dickens et al., 2011). Factors contributing to social isolation and loneliness in older people are multiple, and they often continue to be neglected by family members and the community as they age, but this could be avoided at early stages of the ageing process. Risk factors for loneliness include living alone (Cohen-Mansfield et al., 2016), being single or widowed (Victor et al., 2005, Hawthorne, 2008), living in remote and rural areas (Bartlett et al., 2013b), low education level (Victor et al., 2005), and being a member of a low income socioeconomic group (Dickens et al., 2011). Social groups mostly affected by loneliness are those who are isolated due to life obstacles, such as migrants from ethnically diverse backgrounds, or due to a specific profession, such as a caregivers, long distance drivers, etc. (Andersson, 1998). Recent research confirms that people with low quality social connections have a 50% greater risk for mortality due to the reduced likelihood of survival, and the impact of a lack of social relationships is in line with established

mortality risk factors such as obesity, increased alcohol consumption, and physical inactivity (Holt-Lunstad et al., 2010). Research shows that mortality is high among both socially isolated and lonely older adults, however, adjusted for baseline health and demographic factors, reducing social isolation is more likely to reduce mortality (hazard ratio (HR) 1.26, 95% CI, 1.08–1.48) versus loneliness (HR 0.92, 95% CI, 0.78–1.09) (Steptoe et al., 2013). Therefore, the mechanisms through which social isolation negatively impacts health are independent of the emotional experience of loneliness (Steptoe et al., 2013). As explained further, the mortality risk of social isolation was influenced by social disadvantage or poor health, while loneliness was rather associated with baseline health (Steptoe et al., 2013). This confirms previous findings which obtained a mediating effect of chronic disease and functional impairment on the association between loneliness and mortality in older adults (Sugisawa et al., 1994). Therefore, the experience of loneliness as an emotional state is prevalent among those with major health problems.

Loneliness in later life represents a serious health concern as it is directly associated with depression, dementia, stroke and Alzheimer's disease (Adams et al., 2004, Cacioppo et al., 2010, Jopling et al., 2017). In a study by Adams et al. (2004), loneliness accounted for 8% of the variation in depression scores and was found to be predicted from grieving for loss, the number of chronic health conditions, fewer visits from friends, and having a less extensive social network. Therefore, preventing loneliness at the early stages of its onset is important for prevention of serious mental health illnesses that are potentially harmful to quality of life (Cacioppo et al., 2010). Particular attention from policymakers and healthcare professionals has been placed on the implementation of effective physical activity (PA) interventions to promote active and healthy ageing (Franco et al., 2015, HM Government, 2019). The importance of

social connections and the negative health consequences of loneliness led the UK Government to introduce the government strategy for tackling loneliness in England (HM Government, 2019). With this, the £11.5 million Building Connections Fund and the Ageing Society Grand Challenge competition were aimed to support community, charity organisations, business and the voluntary sector to tackle this problem in society. The main aims of the UK Government guiding this strategy were: 1) assessment and building of an evidence base on loneliness; 2) implementation of loneliness reduction strategies in a number of policies for maintaining people's health and well-being; 3) contribution to national awareness and tackling the stigma of loneliness, which has often resulted in inconsistencies in loneliness reporting and associated barriers to social communication (HM Government, 2019).

Theories on social relationships in older age

The mechanism of association between PA and loneliness was related in existing studies to several theoretical concepts. Among such theoretical frameworks are the socio-emotional selectivity theory (Carstensen et al., 1999) and the continuity theory (Atchley, 1999). The socio-emotional selectivity theory (Carstensen et al., 1999), posits that, with the understanding of the limited time left to live in older age, the number and frequency of new and existing peripheral social contacts decreases and priority is given to existing close friends, partners and family (Nicolaisen et al., 2017). The feeling of loneliness is a subjective experience that is directly related to intimate social needs such as the need to belong (Baumeister et al., 1995). Older adults may remain connected to an informal social network, but desire less social stimulation and new social relations than younger adults, relying on close friendship connections to meet their social needs (Nicolaisen et al., 2017). New emotional attachments for older adults are not formed as

easily as for younger adults (Carstensen et al., 1999). Those living in independent living retirement communities may have greater access to a social network; however, this network does not guarantee access to quality relationships (Adams et al., 2004). Therefore, the question around the negative health consequences of social isolation should be only addressed to those experiencing a need for social interaction and expressing this need, causing evident health concern (Cacioppo et al., 2003, Hawthorne, 2008).

Although the number of emotionally close relationships does not decrease with age (Lang et al., 1994), their quality rises due to disengagement from unsatisfactory relationships and the loss of friends as a result of different lifestyle choices (Weiss, 1973). This is in line with the continuity theory (Atchley, 1999) that proposes that positive life experiences are maximised by continuous maintenance of quality of social relationships. This maintenance of socially close relationships with friends and family members serves a protective function from distress and a potential risk for negative experiences from new social relationships that is of crucial importance for cognitive health in older age (Carstensen et al., 1999). Active older adults retain cognitive function at a high level throughout their older years (Penedo et al., 2005, Haskell et al., 2007). A protective effect of social relationships on cognitive health is also supported by animal studies. For instance, it has been shown that social isolation may exacerbate the natural run-down of neuroplasticity that occurs in later life, defined as the ability of the brain to reorganise and refine the architecture of nerve cells into adulthood (Livingston et al., 2017). Diminished neuroplasticity increases the risk of developing dementia due to the lack of activation of neurone synapses which, in turn, are responsible for the coordination of human behaviour (Livingston et al., 2017). On the other hand, positive social relationships may boost brain neuroplasticity by forming new synapses and

prevent cognitive decline as demonstrated in experiments with mice (Livingston et al., 2017). Similarly, Silva-Gomez et al. (2003) found a decreased production of neurotropic factors within the brain and less dendritic arborization in the prefrontal complex and hippocampus in socially isolated animals.

Mechanisms of physical activity effects for psychological well-being

Studies continue to provide evidence of improved psychological well-being of lonely older adults leading an active lifestyle or who are exposed to regular exercise (Mazzeo et al., 2001, Taylor et al., 2004, Blake et al., 2009, Conn, 2010, Farrell, 2012).

The Oxford dictionary of Sport Science and Medicine defines psychological well-being (mental well-being) as 'a mental condition characterised by pleasant feelings of good health, exhilaration, high self-esteem, and confidence, also often associated with regular physical activity' (Kent, 2007, p. 410). Evidence of improved psychological health due to PA is often shown through better mood states, decreased levels of depression, anxiety, stress, improved self-esteem, explained in the literature by several underlying mechanisms that often act interchangeably (Lubans et al., 2016). Among them is a biochemical mechanism resulting in an exercise-related increase in serotonin, monoamine and neurotrophin production and reduction of the stress hormone cortisol (Armstrong et al., 2002, Biddle, 2011). Other effects are associated with the thermal mechanism of exercise-induced increased blood flow to inner organs and connected to this mechanism the effect of general body relaxation, that so-called 'feel good' effect (Biddle, 2011). Feelings of mastery and achievement during exercise performance were referred to a so-called 'social effect' of exercises (Lubans et al., 2013) associated with increased engagement in social connections. The social effect of feeling good is often via the social surroundings during exercise (e.g. accompanied

walk, one-to-one exercise or group exercise) (Biddle, 2011). Specific types of exercise (e.g. yoga, Pilates, meditation classes) also help divert negative emotions away due to the temporary distraction, teaching self-relaxation and mind peace and, as a result, reducing anxiety which is often a result of low self-regulation and self-esteem in lonely individuals (Cooney et al., 2013).

Mechanisms of physical activity effects for loneliness reduction

Despite the general beneficial effects of PA on psychological well-being, there is no consistent evidence of PA intervention effects for loneliness in older adults (Hagan et al., 2014, Pels et al., 2016, Smith et al., 2017). In addition, there is no clear guidance on the particular type of activity, or intensity and duration that result in effective interventions. The general UK PA guidelines for older adults recommend they spend a minimum 150 minutes engaging in moderate intensity PA, contributing to about two and half hours of activity a week (Mindell et al., 2012). In relation to activity bouts, the updated 2018 USA PA guidelines (2018 Physical Activity Guidelines Advisory Committee, 2018) suggest that any length of bouts lead to health related benefits rather than previously stated 10 minute bouts. Following the recommended PA minimum for older adults can contribute to the maintenance of physical health. In addition, to prevent the risk of falls, every older adult (65 years and older) is recommended to spend at least two 10 minute bouts on balance and coordination exercises a week, including muscle strengthening activity (Mindell et al., 2012). However, there are no PA guidelines for loneliness reduction in older adults due to the relative novelty of this research area (Jopling, 2015) and the lack of high quality evidence supporting that PA can reduce loneliness.

Any existing evidence related to effects of PA on loneliness is often sparse and contradictory (Hagan et al., 2014). For instance, a review (Pels et al. (2016) showed an effect of PA on loneliness was obtained in five intervention studies, and direct negative correlations between PA and loneliness were obtained in 50% of 25 cross-sectional studies and in one longitudinal study. In contrast, another systematic review (Smith et al., 2017) did not find any associations between loneliness and PA levels, or between general social support (SS) and PA. No reviews of PA interventions were published specifically for older adults residing in community settings and using only a RCT design. The review conducted by Shvedko et al. (2018a) (Chapter 2) showed that for loneliness there is a lack of PA interventions in community-dwelling older adults and this confirmed the need for further research.

As follows from the literature, PA as a health behaviour (Lubans et al., 2016) that is likely to reduce loneliness through facilitation of formation of social connectedness (Pels et al., 2016). In turn, social connectedness results in engagement in a healthy behaviours (healthy eating, discourage the use of alcohol) and increased PA (Cohen et al., 1985). This is supported by the literature, suggesting, that lonely adults are less likely to engage in healthy behaviours, such as healthy eating (Twenge et al., 2001) or to sustain PA with age (Jopling et al., 2017). In contrast, those who feel good emotionally led a more active and healthy lifestyle (Spirduso et al., 2001b). In addition, social connectedness and health status were independent predictors of change in PA (Clarke et al., 2017) and an independent predictor of older adults' health and well-being (Stathi et al., 2019). From a different angle, the presence of social relationships produced during PA may mediate the effect of psychological (e.g. stress, depression, anxiety) or behavioural processes (Cohen et al., 1985) on loneliness. For example, the presence of PA mediates the negative effect of stress on loneliness (as one component

of mental health difficulties) (Kwag et al., 2011). PA also increases the availability of perceived social support (associated with the perceptions and beliefs of availability of support from others), which was found to predict change in loneliness in experimental studies (McAuley et al., 2000a). In turn, the available support specific to PA, increases PA levels in older adults, especially when it comes from family members (Smith et al., 2017). Lastly, in accordance with 'the feel-good effect' of exercise (Lubans et al., 2013), the feeling of happiness moderates relationships between loneliness and a self-rated PA, specifically, the happier participants are, the lower loneliness is (Newall et al., 2013). Despite the possible mechanisms that underlie relationships between PA and loneliness, any independent effect of PA is difficult to decipher (Hagan et al., 2014) and it is likely that a combination of factors act simultaneously producing the common effect (Michie et al., 2009b).

The evidence-base for non-physical activity interventions for loneliness

According to the Promising Approaches framework (Jopling et al., 2017) effective approaches to reduce loneliness were as following: 1) supporting and maintaining existing social relationships, 2) enabling new social connections, and 3) changing the ways of thinking, referred to as a psychological mechanism. Related to the first approach, supporting and maintaining contacts with an existing social network as opposed to making new contacts in older adults was obtained through qualitative evidence (Pettigrew et al., 2008, Moyle et al., 2011). Coincident with the socio-emotional selectivity theory (Carstensen et al., 1999), older adults may give priority to *familiar* human relationships, such as close friends, partners and family and reduce the frequency of new social connections. This approach may emphasise the need for being valued and cared for which has a treatment effect on loneliness (O'Rourke et al., 2018),

which was demonstrated by interventions with living or robotic animals (Banks et al., 2002, Banks et al., 2008). Related to the second approach, keeping busy at all times and increasing social connections was found to be an effective strategy in studies using technology-based interventions Choi et al. (2012), video- and teleconferencing (Taylor et al., 2009, Tsai et al., 2011) as obtained in a systematic review by Hagan et al. (2014). Keeping busy either by engagement in daily activities or in purposeful activities, such as reading, gardening, cleaning, cooking, language learning, music classes, crafts and arts activities (regardless whether it was a solitude activity or in a contact with others) was associated with the feeling of accomplishing something or "killing time" (O'Rourke et al., 2018). This framework was coincident with the theory of active engagement (Lemon et al., 1972, Rowe et al., 1997), that generated a sense of purpose (purposeful activity/keeping busy) through increased social support and greater life satisfaction (Kahlbaugh et al., 2011). Regarding the third approach, there is evidence of loneliness reduction for interventions that influence negative perceptions and change an individual's outlook on life. For instance, the meta-analysis of Masi et al. (2010) obtained effect of interventions that addressed maladaptive social cognition through teaching behaviour management control with automatic negative thoughts and feelings (e.g. low self-confidence, low self-perception). Other effective mind-changing interventions were Cognitive Behavioural Therapy (CBT) (Theeke, 2014) through teaching to perceive the information from the environment not as facts but rather as a hypothesis, and a Mindfulness-Based Social Rehabilitation (MBSR) group programme (Creswell et al., 2012). CBT and MBSR were especially effective for adults with a depression and anxiety, which often goes along with the feeling of loneliness (Jopling et al., 2017). Among other successful non-PA approaches was an innovative community

project Men's Sheds that used woodwork and other activities to support older men from rural and urban areas who passed their skills on to others (Wilson et al., 2013).

Limitations of existing PA interventions for loneliness

An examination of existing interventions for loneliness shows that the majority of interventions were conducted with residents in institutional settings and not with community-dwelling older adults who make up the majority of the older population (Banks et al., 2002). Other reviews included non-PA interventions that did not allow for drawing any generalisations regarding the effectiveness of PA interventions or did not use a randomised controlled trial (RCT) design, which would significantly improve the methodological rigour of the research (Eldridge et al., 2016a). Loneliness in the majority of PA intervention studies was assessed as a secondary outcome, that does not allow assessing the effectiveness of the intervention. Limitations of studies for loneliness in older adults include a lack of high-quality studies which used a composite measure of social isolation and loneliness in addition to self-assessment tools of social health components versus a use of one standard tool (Spirduso et al., 2001a, Wenger et al., 2004, Hawkley et al., 2015). Moreover, existing RCTs in older adults were biased by high attrition rates (e.g. >20%) and low exercise adherence due to morbidity and mortality of participants, and difficulties of self-assessment due to impaired cognitive, mental or physical functioning (Wenger et al., 2004). Not many studies assessed barriers to PA or explored the association between motivation for PA and exercise behaviour, which seem to be of special importance for shifting the sedentary behavior of older adults (Bauman et al., 2016). Identifying barriers and ways to overcome them is important for identifying the sources of social support for treatment of loneliness in older adults through PA (MacMillan et al., 2011). Bearing in mind that the acute effect

of exercise is short-lived (Chodzko-Zajko, 2014a, Pels et al., 2016), the lack of long-term follow-up studies with high quality experimental data makes it difficult to draw any conclusions about the effectiveness of PA for loneliness. Therefore, it is important to systematically review the effect of existing PA RCT interventions for loneliness and other related social health outcomes in community-dwelling older adults and improve the methodological rigour of the research evidence as recommended by Eldridge et al. (2016a).

In an attempt to address these existing gaps in the literature, the first study of the current thesis presents the findings of a systematic review (Shvedko et al., 2018a) (Chapter 2). This systematic review demonstrated the intervention effects of PA for social functioning with meta-analyses which obtained stronger effects for: PA interventions versus PA with social interaction interventions; diseased versus healthy populations; group exercise settings versus individual or mixed group and individual settings; and delivery by medical healthcare provider (e.g. physiotherapist, nurse) versus non-medical (fitness) provider (e.g. personal trainer, fitness instructor). Due to the lack of available evidence, it was not possible to review PA intervention effects for loneliness. No effects of PA were found for social support and social networks, likely due to the small number of available studies for the meta-analysis (Shvedko et al., 2018a). This was also consistent with previous reviews on the topic (Cattan et al., 2005, Dickens et al., 2011, Hagan et al., 2014, Petitte et al., 2015, Cohen-Mansfield et al., 2016, Pels et al., 2016). The majority of studies were biased by using non-adequate or not fully described randomisation techniques, inability to blind health care providers delivering the PA intervention, inadequate blinding of outcomes' assessors and participants, and a low attendance rate, which can potentially result in the absence of any intervention effect in an absence of desired social engagement. Since the

publication of the review of Shvedko et al. (2018a), two systematic reviews have been published about PA effects on loneliness and socially related outcomes (Ayalon et al., 2018, Poscia et al., 2018). Poscia et al. (2018) reviewed PA interventions targeting loneliness and social isolation in older adults using quantitative (N=15) and qualitative (N=5) study designs examining people's experiences of loneliness. The review found that six out of 11 group interventions (55%), all three individual (100%) and one out of four mixed design interventions (25%) reported a significant effect for loneliness (Poscia et al., 2018). Coincident with previous reviews (Cohen-Mansfield et al., 2016, Pels et al., 2016, Shvedko et al., 2018a), Poscia et al. (2018) confirmed that complex programmes that included various approaches, such as educational, social and cognitive components, have a better effect on loneliness in community-dwelling older adults. In contrast, Ayalon et al. (2018) analysed the possibility of increasing the engagement in social connections in older adults in residential settings using non-PA interventions (N=10). The results of that systematic review suggest that the development of social networks in older adults from institutional settings was feasible even for older adults with mild-to-moderate dementia (Ayalon et al., 2018). However, the review was conducted using a narrative approach, and the majority of the included studies had a cross-sectional rather than longitudinal design (8/10, 80%) that limits the methodological rigour of the obtained findings.

The systematic review in the present thesis was the first to review the effects on loneliness, social support and other social health outcomes in community-dwelling older adults that explicitly included randomised controlled trials, comparing PA and non-PA interventions. The results of the review confirmed the limited evidence for PA interventions for loneliness in older adults and the need for a well-designed randomised controlled trial. The knowledge gained from the review confirms the lack of available

evidence of PA intervention effects for loneliness. Given this lack of evidence, it would seem appropriate that a feasibility study be conducted. The practicalities and feasibility of implementation of such PA interventions with older adults needed to be further tested, given the paucity of quality studies in this area. A feasibility study can save resources, time and effort that can be wasted on an inappropriately designed intervention and test the methods and tools to determine the feasibility of a full-scale intervention study (Arain et al., 2010). Before moving to the full-scale trial, it is still unclear whether PA intervention for loneliness should be with or without social interaction components, what feedback participants will give about a walking intervention, and what components of an intervention would be appropriate in a full-scale trial (e.g., health education workshops). It is also necessary to test the recruitment methods and time to recruit individuals into the study and whether it will be feasible to deliver this intervention with a given number of people and health care providers (e.g., walking group leaders). Lastly, it is important to define what is needed to improve PA interventions for loneliness.

As such, the second study in this thesis is the Physical Activity Intervention for Loneliness (PAIL) randomised controlled feasibility trial. The development of the trial methodology is presented in Chapter 3. The PAIL study utilised a mixed-methods research design, defined as the category of research where the researcher mixes or combines quantitative and qualitative research techniques, methods, approaches, concepts or language into a single study (Johnson et al., 2004). This research design allowed the addition of valuable knowledge into a feasibility study gained from the participants' experiences in the participation in the intervention (Eldridge et al., 2016b). This feasibility study had the following specific aims:

1. Recruitment rate, attendance and retention rates (number of participants completing the study as a proportion of those randomised).
2. The appropriateness and practicality of the designed intervention in the proposed settings.
3. The acceptability of the intervention by participants, and willingness to participate.
4. The appropriateness of the assessment tools.
5. The suitability of the statistical methods of data analysis used.
6. The power calculation of the likely required sample size for a future large-scale RCT.
7. The acceptability of measures, and the most suitable primary outcome measure for a future large-scale RCT.

Aims

The aims of this PhD were: 1) to systematically review the effects of physical activity intervention on loneliness (PAIL), social isolation or low social support in community-dwelling older adults; 2) to develop, implement and evaluate the feasibility of an RCT of a PAIL in community-dwelling older adults at risk of loneliness.

Chapter 2 of this thesis includes the systematic review and meta-analysis of randomised controlled trials of PA interventions for treatment of social isolation, loneliness or low social support in older adults, published in the *Psychology of Sport and Exercise* (Shvedko et al., 2018a). Chapter 3 details the protocol development and methodology of the PAIL in community-dwelling older adults: a randomised controlled feasibility study. Chapter 4 presents the feasibility and acceptability of the PAIL intervention, detailing the results of the implementation of the feasibility study and a discussion of the findings alongside limitations. Finally, Chapter 5 includes the overall

discussion of the research comprising this thesis along with strengths and limitations of the research, and recommendations for future research and practice.

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CHAPTER 2. PHYSICAL ACTIVITY INTERVENTIONS FOR TREATMENT OF SOCIAL ISOLATION, LONELINESS OR LOW SOCIAL SUPPORT IN OLDER ADULTS: A SYSTEMATIC REVIEW AND META-ANALYSIS OF RANDOMISED CONTROLLED TRIALS

This chapter is the systematic review of the evidence of PA intervention effects for loneliness, social support and other related outcomes in community-dwelling older adults published in the *Psychology of Sport & Exercise* journal (Shvedko et al., 2018a). The formatting of the chapter follows the publication format for this journal.

Abstract

Objectives: This article reviews the effects of physical activity (PA) interventions on social isolation, loneliness or low social support in older adults.

Design: Systematic review and meta-analysis of randomised controlled trials (RCTs).

Method: MEDLINE, EMBASE, PsycINFO, the Cochrane CENTRAL*, CINAHL*, were screened up to February 2017. RCTs comparing PA versus non-PA interventions or control (sedentary) condition were included. Risk of bias was assessed using the 12 criteria Cochrane Review Book Group risk of bias. The outcome measures were: social isolation, loneliness, social support, social networks, and social functioning. Standardised mean differences (SMDs) with associated 95% confidence intervals (CIs) were calculated for continuous outcomes. Meta-analysis was performed using a random effects model.

Results: The search strategy identified 38 RCTs, with a total of 5288 participants, of which 26 had a low risk of bias and 12 had a high risk of bias. Meta-analysis was performed on 23 RCTs. A small significant positive effect favouring the experimental condition was found for social functioning (SMD=0.30; 95% CI, 0.12 to 0.49; P=0.001) with strongest effects obtained for PA interventions versus PA with social interactions, diseased populations versus healthy, group exercise setting versus individual or mixed group and individual settings, and delivery by a medical healthcare provider versus a non-medical (fitness) healthcare provider. No effects of PA were found for social support and social networks. Due to the lack of available evidence, it was not possible to analyse PA intervention effects for loneliness.

Conclusion: This review shows, for social functioning, the specific aspects of PA interventions that can successfully influence social health. PA did not appear to be effective for social support and social networks.

Keywords: Systematic review; Randomised controlled trial; Loneliness; Social isolation; Older adults.

1. Introduction

The absence, or poor quality, of social relations has detrimental effects on mental health and well-being, negatively impacts quality of life (QoL) and leads to the feeling of loneliness (Netz et al., 2005, Masi et al., 2011). According to UK statistics, the prevalence of loneliness among older adults aged 65 years or older has been estimated to be between 6 to 22% in Great Britain in 2015 and is continuing to rise (Office for National Statistics, 2015). Older adults are considered a particularly vulnerable category of people because older adults experience an increased need in the meaningful social contacts that are consequently replaced by the family and close friends after retirement from work (Masi et al., 2011). Given this, special emphasis of healthcare professionals has been placed on the implementation of health promotion interventions to address this problem in society (Jopling, 2015).

Following the analysis of systematic reviews and meta-analyses (Cattan et al., 1998, Cattan et al., 2005, Dickens et al., 2011, Masi et al., 2011, Hagan et al., 2014, Snowden et al., 2014, Petitte et al., 2015, Cohen-Mansfield et al., 2016, Pels et al., 2016, Smith et al., 2017), there is a lack of available evidence for PA intervention effects for social health outcomes in community-dwelling older adults. Some reviews focus either on non-PA interventions in a wide diversity of participants and settings (Masi et al., 2011) or include non-experimental designed interventions, which reduce the methodological rigour of evidence (Hagan et al., 2014, Pels et al., 2016). Other are focusing on only certain social outcomes and do not consider social health as a multifaceted domain (Schechtman et al., 2001, Gillison et al., 2009, Masi et al., 2011). Limitations of current PA interventions include insufficient sample sizes and lack of adjustment for confounding factors resulting in an inability to provide sufficient information about the effectiveness of treatment.

The causal mechanisms that underlie the social health effects of PA are complex comprising many components (Michie et al., 2009b). The independent effects of interventions on social outcomes is difficult to determine due to the multidimensional structure of social health that is lacking the precise definition of its domains (Biddle et al., 2011). Sub-components of social health in addition to social isolation and loneliness include social support and its functional and structural domains (Dickens et al., 2011). Loneliness is defined as a discrepancy between a person's desired and actual social relationships (Peplau et al., 1980), that is typically assessed using the UCLA loneliness scale (Russell, 1996). Social isolation is a "a state in which the individual lacks a sense of belonging socially, lacks engagement with others, has a minimal number of social contacts, and they are deficient in fulfilling and quality relationships" (Nicholson, 2012, p. 138). Social support is the comfort, assistance, and information received and shared through formal and informal contacts with others (Wallston et al., 1983).

PA is a health behaviour that can influence social health through a number of mechanisms and behaviour change techniques (Michie et al., 2011). A recent meta-analysis showed that a "self-monitoring" technique combined with one or two other techniques (e.g. goal setting) were found to be most effective behavioural change strategies in PA or dietary interventions (Michie et al., 2009b). However, the causal mechanisms that underlie the social health effects of PA are complex comprising many components or moderating factors (Michie et al., 2009b). With this the type of PA intervention, residential settings, delivery format, comorbidity and others are important considerations which will be examined in the present review, where possible.

Mechanisms of how PA interventions might be particularly effective for improving social health outcomes have been suggested to be that, first, PA can facilitate social relationships through social connectedness arising from building friendly and

trusted relationships between people during activities (Lubans et al., 2016). In addition, PA removes the individual barriers to social interaction and generates a sense of self-esteem based on social acceptance and perceived emotional support, leading to further action (Baumeister et al., 1995, Masi et al., 2011). Second, PA changes perceptions of people's lives associated with direct effects on quality of life, sleep volume and self-regulation skills (Lubans et al., 2016). Third, at a biological level, the feel-good effect of PA is associated with the increases in serotonin, monoamine and neurotrophin production, reductions in the stress hormone cortisol, activation of the grey matter, and the release of endogenous opioids referred to the neurobiological hypothesis (Lubans et al., 2016). However, many PA interventions do not measure all of these aspects as potential mechanisms of effects on social health, or use them as a theoretical basis for intervention.

Several theoretical models that relate to the above mechanisms have been applied to loneliness reduction via PA interventions. Among them is *the social compensation model* described by Ferraro et al. (1995)'s model, according to which engagement in a variety of physical and leisure activities by older adults with a loss of meaningful social connections compensates for or replaces this loss by increasing their peripheral social networking. The related *theory of active engagement* explains loneliness reduction in older adults through engagement in an active lifestyle that generates a sense of purpose through increased social support and lowered depression (Lemon et al., 1972, Rowe et al., 1997). *The tripartite model of group identification* (Henry et al., 1999, Pels et al., 2016) associated with the exercise-induced change in the experience of living to an advanced age considers three aspects to explain the positive effects of physical activity: cognitive (social categorisation), affective (interpersonal attraction), and behavioural (interdependence) which seems to encompass much of the

aspects of the above theories. Finally, according to *the framework of "coping styles" of loneliness* (Fokkema et al., 2007b), PA may reduce loneliness in two ways: 1) by improving social skills and self-confidence by engaging in a variety of social contacts during PA programmes; and 2) by changing self-perception and "seeing things in perspective" (Fokkema et al., 2007b, p. 498). Among these, the most commonly utilised is the tripartite model, which has been successfully applied to a programme of PA in lonely seniors which increased their sense of identification (Henry et al., 1999, Pels et al., 2016). However, despite these convincing theories of how PA might influence health and wellbeing positively, there is a lack of available evidence regarding the effectiveness of PA interventions for psychosocial outcomes, and the available evidence is often contradictory and sparse (Hagan et al., 2014, Pels et al., 2016).

Given that the effect of PA interventions on social isolation, loneliness and low social support in community-dwelling older adults is not well documented, a novel systematic review of RCTs is needed in order to summarise the literature. This systematic review was aimed to examine physical activity intervention effects on loneliness, social isolation or low social support in community-dwelling older adults.

The protocol for this review was registered at PROSPERO; registration number 42016036013, available from: https://www.crd.york.ac.uk/PROSPERO/myprospero.php.

2. Material and methods

This systematic review was guided by the PRISMA statement (Moher et al., 2015). This is a 27-item checklist that ensures the transparency and clarity of a systematic review (Liberati et al., 2009).

Eligibility criteria

To be included in the systematic review interventions had to meet the following conditions (Appendix 1):

Population

1. Community-dwelling older adults with a mean age ≥ 60 years of age.
2. Healthy or with a comorbidity but physically mobile and able to walk without support;
3. Without dementia or moderate to severe cognitive dysfunction. Individuals with cognitive disabilities were excluded as this might confound the measurement of loneliness and social functioning.

Interventions

This review included any interventions that included PA (e.g. gym-based, home-based, community-based, web- or telephone-based) solely or in the combination with other social interaction components (PASI), such as education classes, social support or recreational activity and others.

Comparison

PA interventions were compared with a control (or sedentary) group without any exercise or undergoing another non-PA intervention (e.g. art therapy, cognitive behavioural therapy), which is reviewed as an active control condition.

Outcomes

The main outcomes for this review were: 1) loneliness; 2) social isolation; 3) social support; 4) social (support) networks; and 5) social functioning as a sub-domain of health-related quality of life (HRQL).

Study design

This review included only randomised controlled trials (RCTs) with a minimum of two comparison arms (PA versus a control (sedentary) condition or versus an active control condition undergoing another non-PA intervention).

Search strategy

The online search of articles using expanded medical subject headings (MeSH) and independent key words was conducted using the following databases: MEDLINE, EMBASE, PsycINFO, the Cochrane Central, CINAHL. Databases were searched twice, with the second search conducted in February 2017, to ensure that newly published articles were included (Moher et al., 2015) Appendix 2. Other resources included the grey literature (*System for Information on Grey Literature in Europe*, 2017, *Social care institute for excellence*, 2017, PQDT Global, 2017, World Health Organization, 2017), and a hand search of the reference lists of relevant reviews, citation tracking, peer reviewed journal articles, books, dissertation theses and conference proceedings. Searches of articles were limited to RCTs. No restrictions were applied to the publication period and the language. For articles awaiting publication, and for study protocols, e-mail alerts were set up. Further, we contacted a life sciences subject-expert librarian, plus physiotherapists and psychologists in our department with experience in systematic reviewing and physical activity interventions for advice on search terms, and reviewing and meta-analysis using software. All papers were screened by two reviewers independently at all stages of the review (i.e., titles/abstracts, full text) applying the screening-selection tool (Appendix 3). Any disagreements were resolved by a discussion with the third party until consensus was achieved. Levels of agreement are reported as Kappas. The selection of articles was

performed using The EndNote reference manager programme for Windows (version X7, Thomson Reuters).

Risk of bias

The risk of bias in individual studies was assessed independently by two reviewers using the 12-criteria Cochrane Review Book Group (CRBG) risk of bias assessment tool (Furlan et al., 2009) using responses: yes, no, or unclear (Furlan et al., 2009). The 12 criteria CRBG risk of bias assessment tool (Furlan et al., 2009) determines trial adequacy by assessing the reporting of the following outcomes: 1) randomisation; 2) allocation concealment; 3) similarity of baseline characteristics; 4) blinding of the allocated interventions to participants, 5) blinding of care providers; 6) assessment of co-interventions; 7) the acceptable compliance; 8) reporting of drop-out rates; 9) equal assessment of participants across randomised groups; 10) assessment of selective reporting of outcomes; 11) blinding of assessors; and 12) similarity of timing of outcome assessment (Furlan et al., 2009). The CRBG risk of bias tool was pilot tested between reviewers independently for three randomly selected studies. Any disagreements were resolved by a discussion with the third party until consensus was achieved (Milner, 2015). A minimum level of inter-rated agreement between reviewers was set at a 0.8 Kappa coefficient (κ) (Higgins et al., 2011). Interventions meeting a minimum six criteria and above (scored as "Yes" using CRBG tool) and without serious flaws (e.g., over 20% drop-out rate in one intervention group) were rated as having a low risk of bias (Furlan et al., 2009, Cramer et al., 2013). Interventions with fewer than six criteria met were considered to have a high risk of bias (Furlan et al., 2009).

Data extraction and coding of study characteristics

For dichotomous outcomes, relative risk ratios (RRs) or odds ratios (ORs) with 95% confidence intervals (CI) were extracted. For continuous outcomes, means (M)/mean change and standard deviations (SDs) based on the between group values derived from follow-up periods were extracted. If Ms or SDs were not available and instead studies reported SEs, CI, t- or p-values, effect sizes were computed based on the provided data from between group values (Furlan et al., 2009, Cramer et al., 2013). Where the study reported two interventions compared against the control group meeting the inclusion criteria both interventions were included in the analysis. The data extraction tool preliminarily was pilot-tested independently by two reviewers on 10 randomly selected studies to ensure clarity and transparency of the data reporting until consensus was achieved. Inter-rater agreement coefficients (without pilot studies) were as follows: for recruitment settings κ=1.000, sample size κ=1.000, age κ=1.000, gender κ=1.000, comorbidity κ=1.000, the settings (independent living versus supportive living) κ=1.000, the type of PA κ= 0.849, length of intervention κ=1.000, intervention content κ=1.000, control group comparison κ=1.000, format of delivery (group vs. Individual or mixed) κ= 0.949, information about provider (medical healthcare provider, non-medical (fitness) healthcare provider) κ=0.879, delivery settings κ=0.830, outcomes κ=0.839, assessment tools κ=1.000, validity of assessment tools κ=1.000, scoring of assessment tools κ=1.000, main findings κ=1.000. If any discrepancies were observed, the third party resolved discrepancies by discussion. For missing data, individual authors were contacted (N=8), with a 37.5 % response received. The following information was extracted and coded for each study (Appendix 4): a) study reference, country, recruitment settings; b) population characteristics (sample size, age, gender, comorbidity, residential settings); c) intervention characteristics (type of intervention, e.g. PA, PA and social interactions, length of the intervention, intervention content and

a control group comparison, format of the delivery, information about the treatment provider; d) methodological information (main outcomes, assessment tools, information about validation of assessment tools, study design); e) results related to effect size calculation (means or mean change, standard deviation, number of participants in each treatment group, measurement periods, e.g. immediate or follow up; and f) additional comments (a pilot study, translated from another language, author contacted).

Data analysis and reporting of findings

First, a narrative (descriptive) summary of participant and intervention characteristics containing detailed information about population (sample), interventions, outcomes, and results was made. Second, random effects model meta-analysis was performed if at least three studies quantitatively reported an effect of their intervention for each outcome. If two comparison arms were taken from one study, control group sample sizes were halved to avoid double counting of participants and underestimating the variance of the effect size. Analysis of data was conducted using Review Manager Software Version 5.3.5 (RevMan, 5.3.5; the Nordic Cochrane Centre, Rigshospitalet, Denmark). A random effects model assumes that different but, yet related treatment effects are incorporated by different studies (Furlan et al., 2009, Liberati et al., 2009, Higgins et al., 2011) and account for a heterogeneity (Thompson et al., 2002a). For continuous outcomes, SMD of 0.2 to 0.5 were deemed to indicate a small effect size, from 0.5 to 0.8, a moderate effect size, and more than 0.8, a large effect size (Cohen, 1988).

Subgroup and sensitivity analysis

If more than 10 studies were included for each outcome, this was deemed adequate (Thompson et al., 2002a), and subsequent sub-group analysis was performed to explore

effect of following covariates on intervention effects: the type of intervention (PA or physical activity with social interactions, e.g. health education, cognitive behaviour therapy, lectures, nurse counselling, etc.), delivery format (individual, group or mixed), residential settings (independent living or assisted living, e.g. retirement villages), comorbidity (healthy versus ill population), and information about healthcare provider (medical, non-medical (fitness), and non-healthcare provider). For the purpose of the review the medical health provider was considered to be any licenced or certified medical health professional (e.g. physiotherapist, nurse), a non-medical (fitness) healthcare provider was considered to be a qualified fitness professional, i.e. personal trainer, fitness instructor, or a qualified activity leader (e.g. walking group leader). A non-healthcare provider was considered to be anyone without a formal licence or a certificate (e.g. volunteer, research fellow, research assistant).

Statistical heterogeneity was examined by I^2 statistics as well as a visual analysis of forest plots. Based on I^2 statistics, heterogeneity was classified as moderate (I^2 >30%), substantial (I^2 >50%), or considerable (I^2 >75%); $P \leq 0.05$ (Hopkins, 2002). Effect size outliers were identified by examining the externally studentized residuals (Viechtbauer & Cheung, 2010) using SPSS for Windows (V.22, SPSS Inc., Chicago, IL). Subsequent sensitivity analyses was performed by removing high risk RCTs from the analysis (Furlan et al., 2009).

Assessment of publication bias

Publication bias was assessed by inspection of asymmetry measured by Egger's regression, i.e., the intercept from the regression of standard normal deviates on precision (Egger et al., 1997). Where publication bias emerged, "trim and fill" analysis

(Duval et al., 2000) was performed using the Stata for Windows (1C, 14.2, Stata Corp LLC, USA).

3. Results

Database search

The database search resulted in 3899 records (Fig. 1). After removing duplicates and screening records on titles, abstracts, and full texts, a total of 38 eligible RCTs with the corresponding number of 5288 participants (range 51-82 years) were included in this review (The reference list of included studies is shown in Appendix 5). Inter-rater agreement coefficients for screening on titles and abstracts K=0.878, for full text screening K=0.849. Key methodological study characteristics of included studies were categorised by the intervention type (i.e. PA or PA with social interaction component, e.g. health education, cognitive behaviour therapy, lectures, nurse counselling, etc.) are presented in Appendices 6 and 7). The majority of excluded studies were non-PA interventions. Among seven excluded interventions for non-community-dwelling older adults (e.g. for residents of institutional care) two were PA interventions.

Risk of bias

Risk of bias in individual studies revealed that 26 had a low risk of bias and 12 had a high risk of bias (Appendix 8). The average inter-rater agreement coefficient was κ = 0.855.

For item "Adequate random sequence generation" 24 out of 38 studies met the condition marked as "yes" answer on the data extraction sheet, 14 studies did not meet the condition marked as "no" or "unclear" answer (if the study only reported that it was the randomised study or participants were randomly allocated but the method of

randomisation was not given) (Appendix 8). For item "Adequate allocation concealment" nine studies met the condition and 29 studies did not due to an absence of information about the method of allocation concealment (e.g. sealed envelopes). For item "Similar baseline characteristics" 31 studies met the condition and seven did not provide the adequate information.

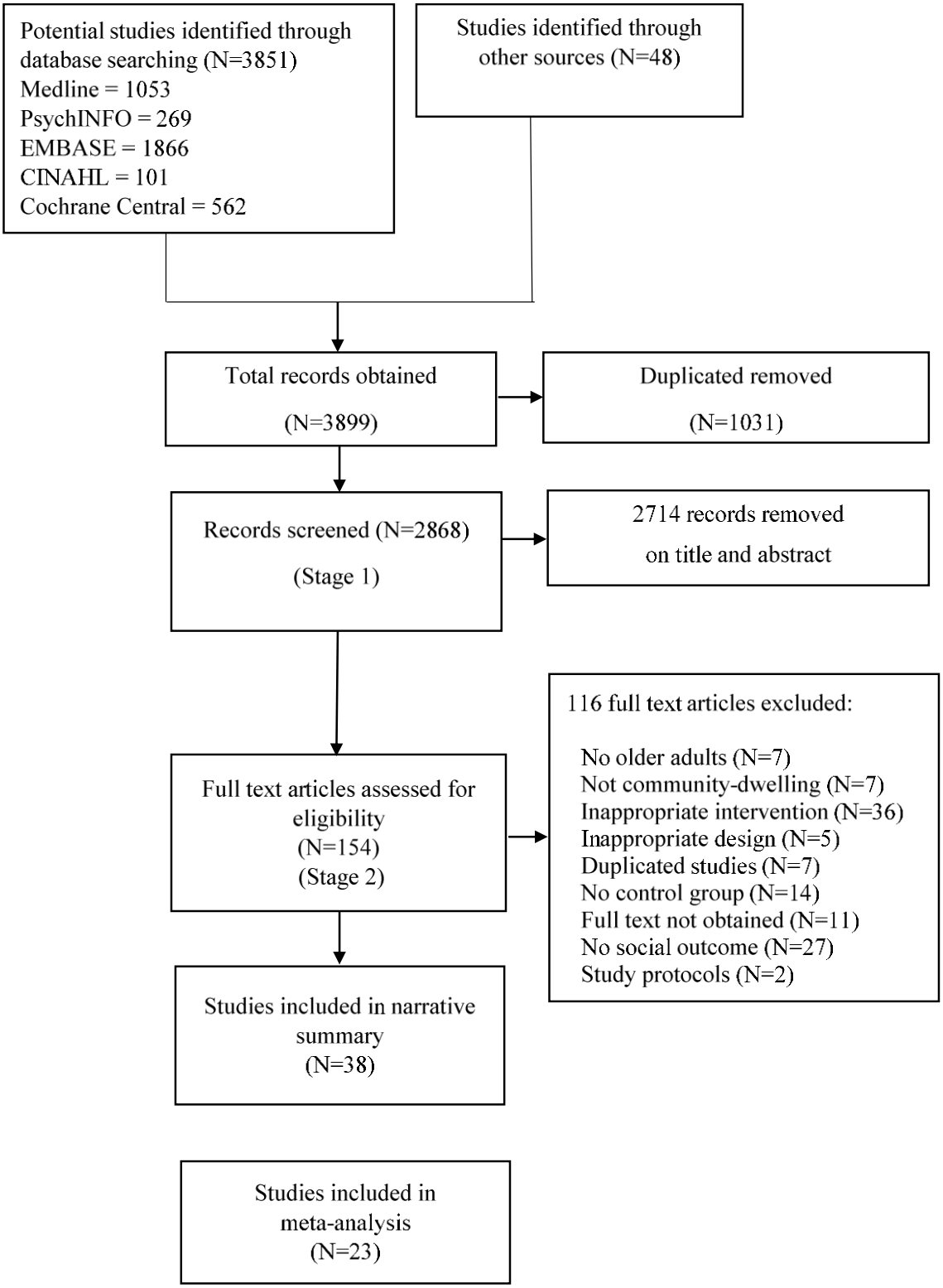


Fig. 1. Flow chart of the results of the database search.

For item "Adequate participant blinding" five studies met the condition and 33 studies did not provide the method of participant blinding. None of the studies could show

"Adequate provider blinding" and, therefore, did not meet this condition. For item "Similar or no cointerventions" 34 studies met the condition. For item "Acceptable compliance" 17 studies met the condition. For item "Acceptable and described dropout rate" 32 studies met the condition. For item "Inclusion of an intention-to-treat analysis" 14 studies met the condition. For item "No selective outcome reporting" 37 studies met the condition. For item "Adequate outcome assessor blinding" 11 studies met the condition (patients and those involved in the study could not reveal information about the allocation of participants, e.g., the outcome assessor was not involved in the treatment, or participants were instructed not to disclose the information about the allocation). For item "Similar timing of outcome assessment" 35 studies met the condition.

The most common biases were associated with inadequate information about the allocation concealment, lack of information about the compliance to the intervention and or non-acceptable drop-out rates. The intention-to-treat analysis was not reported in 24 interventions which limit the interpretation of the results in the included RCTs due to the low methodological rigour associated with a lack of information about adequate randomisation procedures. Detection bias (outcome assessor blinding, similar timing of outcome assessment) in included studies was mainly high due to the absence of information about adequacy of outcome assessor blinding. Another source of bias was inadequate blinding of the care provider, but it is likely this is not possible for this type of intervention (Eldridge et al., 2016a).

Narrative summary of participant and intervention characteristics

The key methodological study characteristics of included RCTs are presented in Appendices 6 and 7.

Population

The geographic spread of included studies showed that seven PA interventions were conducted in the USA, five of each in the UK and Japan, three of each in Australia and Taiwan, two of each in China, Canada and the Netherlands, and one of each in New Zealand, Korea, Sweden, Denmark, Finland, Turkey, Spain, Brazil, Hungary and Georgia (Appendix 6 and 7). The mean age of the participants in the included RCTs ranged from 51-82 years, with a higher percentage of females (67%). Twenty-five RCTs were conducted on older adults with common chronic diseases such as cardiorespiratory diseases, bone health diseases, depression, obesity, insomnia, and cancer. In contrast, 13 RCTs included relatively healthy community-dwelling older adults. Eleven studies included only female participants. All but one (Cress et al., 1999) included independently living residents, the latter included those in an assisted living village setting. Among the included RCTs, only one study explicitly targeted lonely or socially isolated people (Chan et al., 2017) which was a pilot study. Participants were recruited from general outpatient clinics, through integrated health care systems, a university medical centre, municipal services, community centres, through a breast screening programme, through the Fibromyalgia Association and retirement communities (see Appendix 4 for data extraction sheet).

Interventions

In terms of an intervention type, half of the included interventions (N=19) had a social interaction component as well as PA, such as health education, social support, sleep hygiene, and recreational activity (e.g. craft activity, cooking classes etc.), and social facilitation by trained ambassadors (Appendix 7). Interventions mainly consisted of

aerobic exercise training (AET) in 14 RCTs. Six PA interventions included resistance exercise training (RET). Others were of mixed aerobic and resistance exercises (e.g. swimming and Tai Chi exercises). Intervention length varied between six weeks (Turner et al., 2011) and one-year (Courneya et al., 2011), with majority of interventions lasting for 12 weeks or more (Appendix 6). Twenty-three interventions were conducted in a group setting, ten were conducted individually and five interventions were in mixed (group and individual settings) design settings.

The intensity of AET varied from light-to-moderate (50-65 % of HR_{max}) for people with chronic diseases and to vigorous (85% of HR_{max}) for healthy older adults based on the standard classification of intensity of aerobic exercises by the American College of Sports Medicine (2013). The workload for RET programmes varied from light-to-heavy with only one study quantitatively reporting the range of repetitions (5-10 repetitions per exercise) (de Vreede et al., 2006) (Appendix 4). The average frequency of PA interventions was set at three times a week (Chien & Tsauo, 2005) (Appendix 5). Other studies included exercise performed from once weekly (Maki et al., 2012; Oken et al., 2006; Stiggelbout et al., 2004) to five times or more weekly (Courneya et al., 2011; Evcik & Sonel, 2002; Hongo et al., 2007; Huang et al., 2011; Oken et al., 2006; Rejeski et al., 2014) (Appendix 4). The average duration of a single exercise session ranged between 45-60 min/session (Chan et al., 2017; Cress et al., 2006; Huang et al., 2011; Kamagaya et al., 2014; Kovaks et al., 2013; Kurtner et al., 1997; Oken et al., 2006; Stiggelbout et al., 2004; Appendix 4). The minimum duration of an intervention was 10 minutes performed in several bouts throughout the day (Evcik & Sonel, 2002) to over 80 min a day including warm-up and cool down periods (Turner et al., 2011). Interventions were delivered by medical healthcare providers (N = 22) and non-medical (fitness) healthcare providers (N = 16) and (Appendix 7).

Comparisons

PA interventions were compared to a control (sedentary) group or usual care (UC). Other comparisons included health education (attention-control group), social visits, recreational or educational activity and sleep hygiene for patients with insomnia (Reid et al., 2010) (Appendix 7). For social support and social networks, PA was compared only to control (sedentary) conditions not active conditions (non-PA control). For the social functioning outcome, PA was compared to control (sedentary) condition and active control conditions, combined into one group. As such, active control conditions included two interventions comparing PA with educational workshops (Singh et al., 1997, Stiggelbout et al., 2004) and one intervention comparing PA with a leisure activity (Reid et al., 2010).

Outcomes and assessment tools

Loneliness was assessed using a 1-item question: "Do you feel lonely?" (Pitkala et al., 2004), Russel's UCLA loneliness scale and De Jong Gierveld loneliness scale (Appendix 4). Social isolation was assessed using the Turkish version of the Nottingham Health Profile questionnaire and revised social support questionnaire. The majority of studies assessed social functioning (as a sub-domain of health-related quality of life) typically using the Short Form (SF-36) Health Survey (Ware et al., 1992), The World Health Organisation Quality of Life Assessment questionnaire (WHOQOL-BREF), and the 12-item Short Form Health Survey. Social support was assessed using the Multidimensional Scale of Perceived Social Support (MSPSS), the short version of the Medical Outcomes Study (MOS) Social Support Survey, and the Chinese version of the Inventory of Social Supportive Behaviours. Social networks

were assessed using the 6-item Lubben's Social Network Scale (LSNS) (Lubben et al., 2006).

Meta-analysis

Effects of physical activity interventions on social support (N=9)

For the social support outcome, the comparison group included only control (sedentary) conditions. The meta-analysis conducted for social support comparing the effect of PA interventions with control (sedentary) conditions showed a non-significant effect of PA (SMD = -0.05; 95% CI, -0.19 to 0.10; P=0.53, N=1384), heterogeneity was moderate (I^2 =34%, Chi^2 = 12.06, P=0.15) (Supplementary Fig. 1) as shown in Fig. 2. None of the included studies for social support had a high risk of bias.

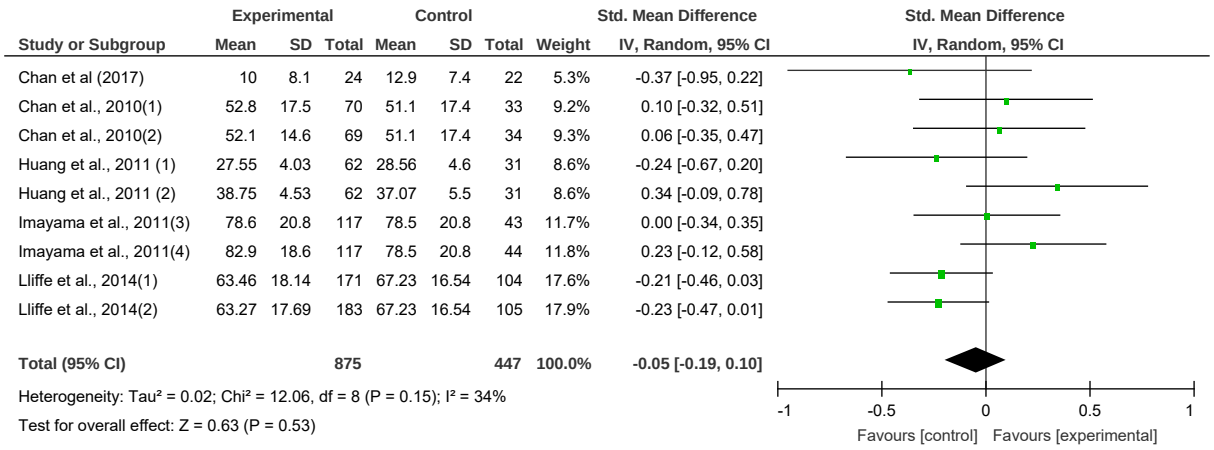


Fig. 2. Forest plot of the overall effect of physical activity interventions compared with control (sedentary) conditions on social support.

Effects of physical activity interventions on social networks (N=4)

For the social networks outcome, the comparison group included only control (sedentary) conditions. The meta-analysis conducted for social networks comparing the effect of PA interventions with control (sedentary) conditions showed a non-significant

effect of PA (SMD = -0.00; 95% CI, -0.28 to 0.27; P=0.99, N=773), heterogeneity was substantial (I^2 =68%, Chi^2 =9.35, P=0.02) as shown in Fig. 3. One out of four studies had a high risk of bias (Kamegaya et al., 2014).

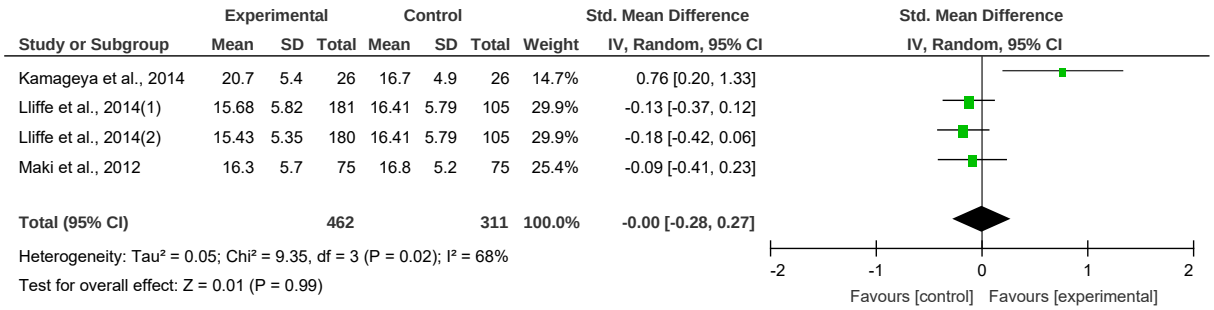


Fig. 3. Forest plot of the overall effect of physical activity interventions compared with control (sedentary) conditions on social networks.

Effects of physical activity interventions on social functioning (*N= 22)*

For social networks outcome control condition included three active (non-PA) controls (Singh et al., 1997, Stiggelbout et al., 2004, Reid et al., 2010) combined into one (mixed) comparison group. The meta-analysis conducted for social functioning comparing the effect of PA interventions with a mixed control group (comprised of sedentary and active control conditions) showed a small significant positive effect favouring PA interventions (SMD=0.30; 95% CI, 0.12 to 0.49; P=0.001, N=1625), heterogeneity was substantial (I^2 =63, Chi^2 = 56.50, P<0.0001) (Fig. 4). Nine out of 22 studies had a high risk of bias (Kutner et al., 1997, Singh et al., 1997, Stiggelbout et al., 2004, Oken et al., 2006, Salvetti et al., 2008, Park et al., 2011, Garcia-Martinez et al., 2012) (shown in Appendix 8).

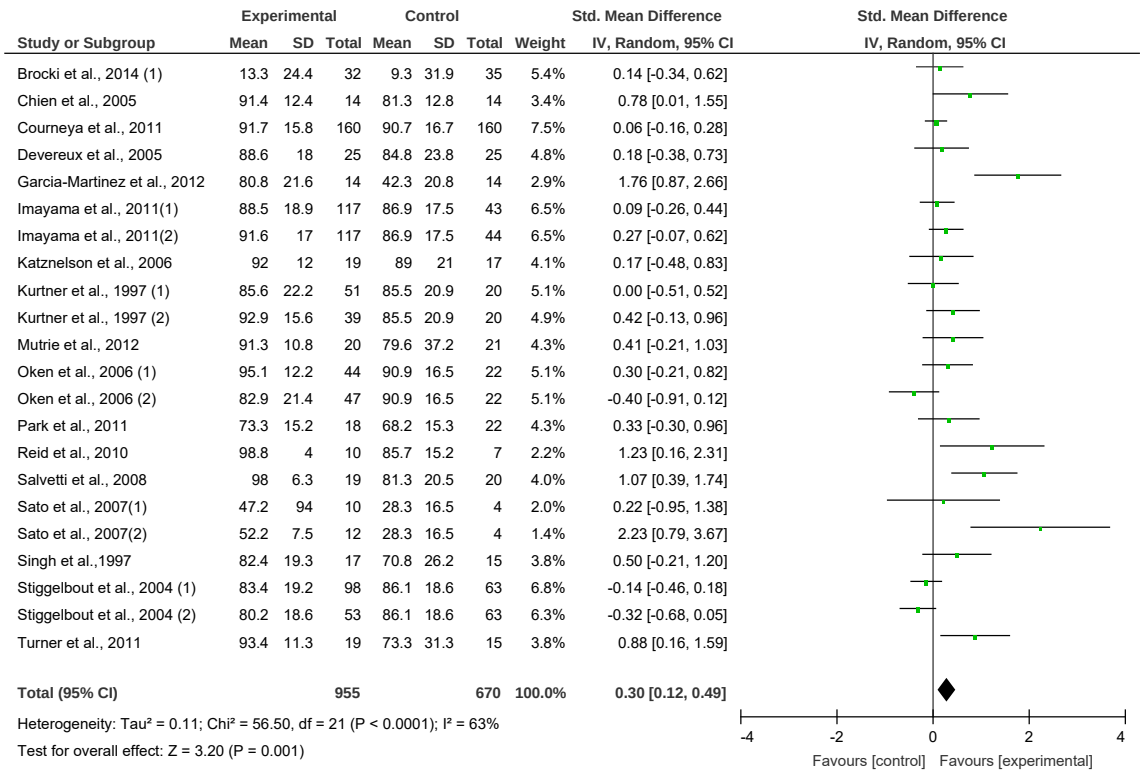


Fig. 4. Forest plot of the overall effect of physical activity interventions compared with mixed (sedentary and active control conditions) for social functioning.

Due to the lack of available data, meta-analysis for loneliness and social isolation outcomes was not performed.

The results of sub-group and sensitivity analysis

Sub-group analyses were performed for social functioning (Appendix 9). The forest plots are shown in Figures 5, 6, 7, and 8. A meta-analysis comparing PA interventions versus PASI revealed a significant small and positive effect for PA interventions (SMD=0.30; 95% CI, 0.10 to 0.51; P=0.003), but not for the PASI (SMD=0.33; 95% CI, -0.04 to 0.70; P=0.08) (Fig. 5); a significant moderate positive effect for diseased (SMD =0.55; 95% CI, 0.28 to 0.81; P<0.0001) but not for healthy (SMD =0.00; 95% CI, -0.19 to 0.19; P=0.99) populations (Fig. 6); a significant small positive effect for the group format of exercise delivery (SMD =0.34; 95% CI, 0.10 to 0.59; P=0.006) but not

for individual settings (SMD=0.21; 95% CI, -0.15 to 0.56; P=0.26) or mixed type (individual and group) settings (SMD=0.25; 95% CI, -0.15 to 0.65; P=0.21) (Fig. 7); and a significant small positive effect for medical healthcare provider delivery (SMD=0.42; 95% CI, 0.12 to 0.71; P=0.05) but not for non-medical (fitness) healthcare provider delivery (SMD=0.19; 95% CI, -0.04 to 0.43; P=0.11) (Fig.8). It was not possible conduct the sub-group analysis for residential settings (e.g. whether participants were independently living or in assisted living accommodation) as only one study (Cress et al., 1999) included assisted living residents.

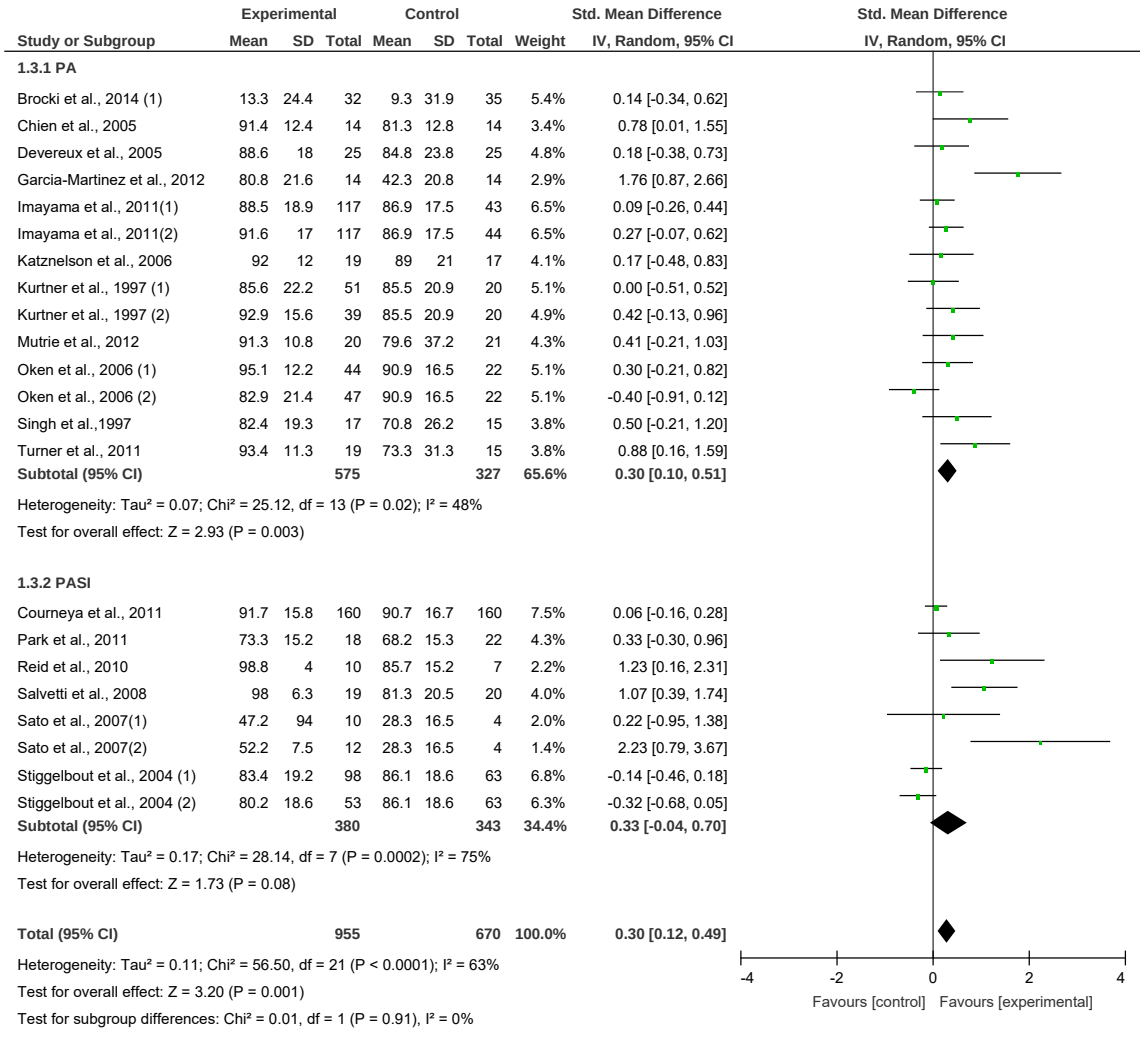


Fig. 5. Forest plot comparing overall effects of physical activity interventions (PA) compared with physical activity interventions with social interactions (PASI) on social functioning.

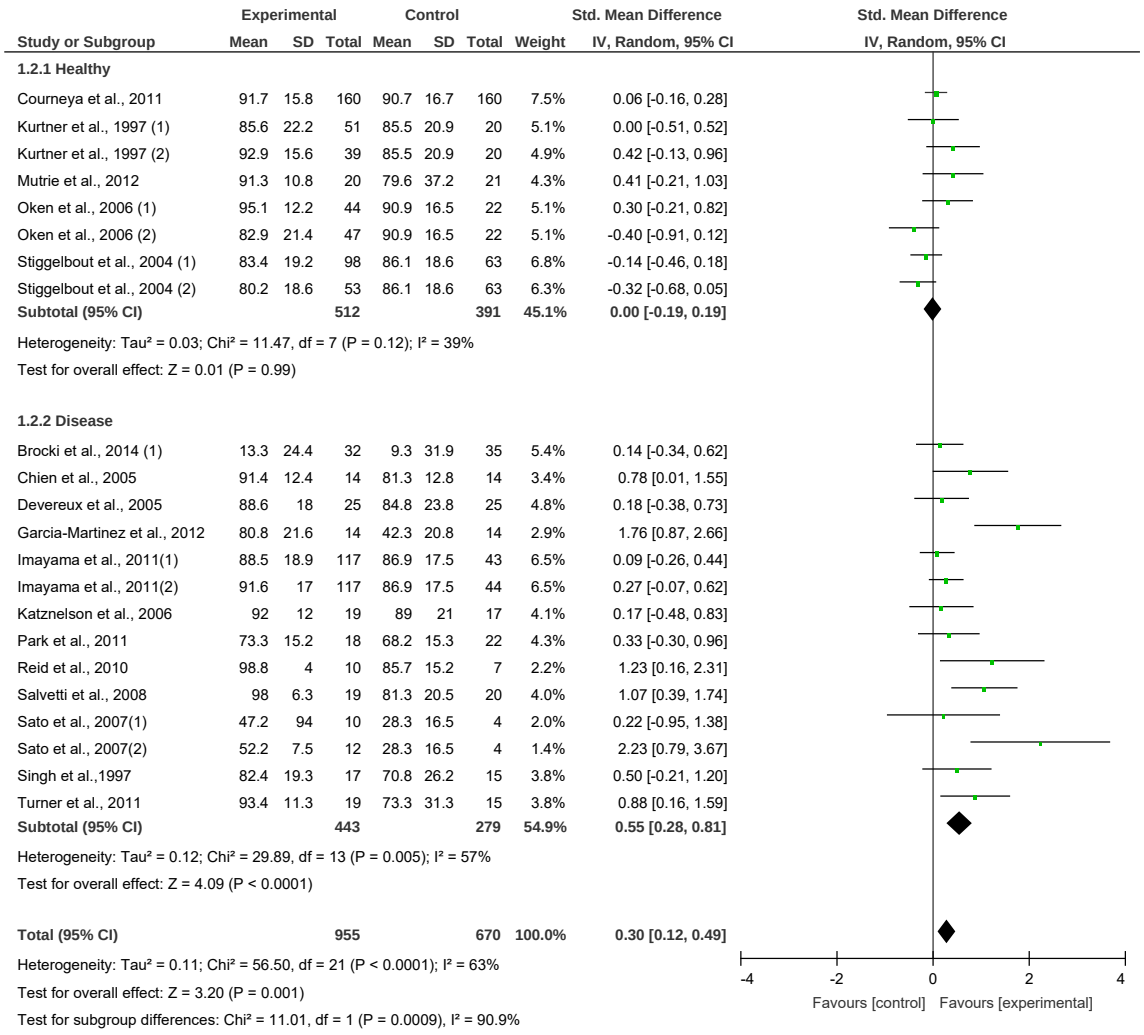


Fig. 6. Forest plot comparing overall effects on healthy compared with diseased populations on social functioning.

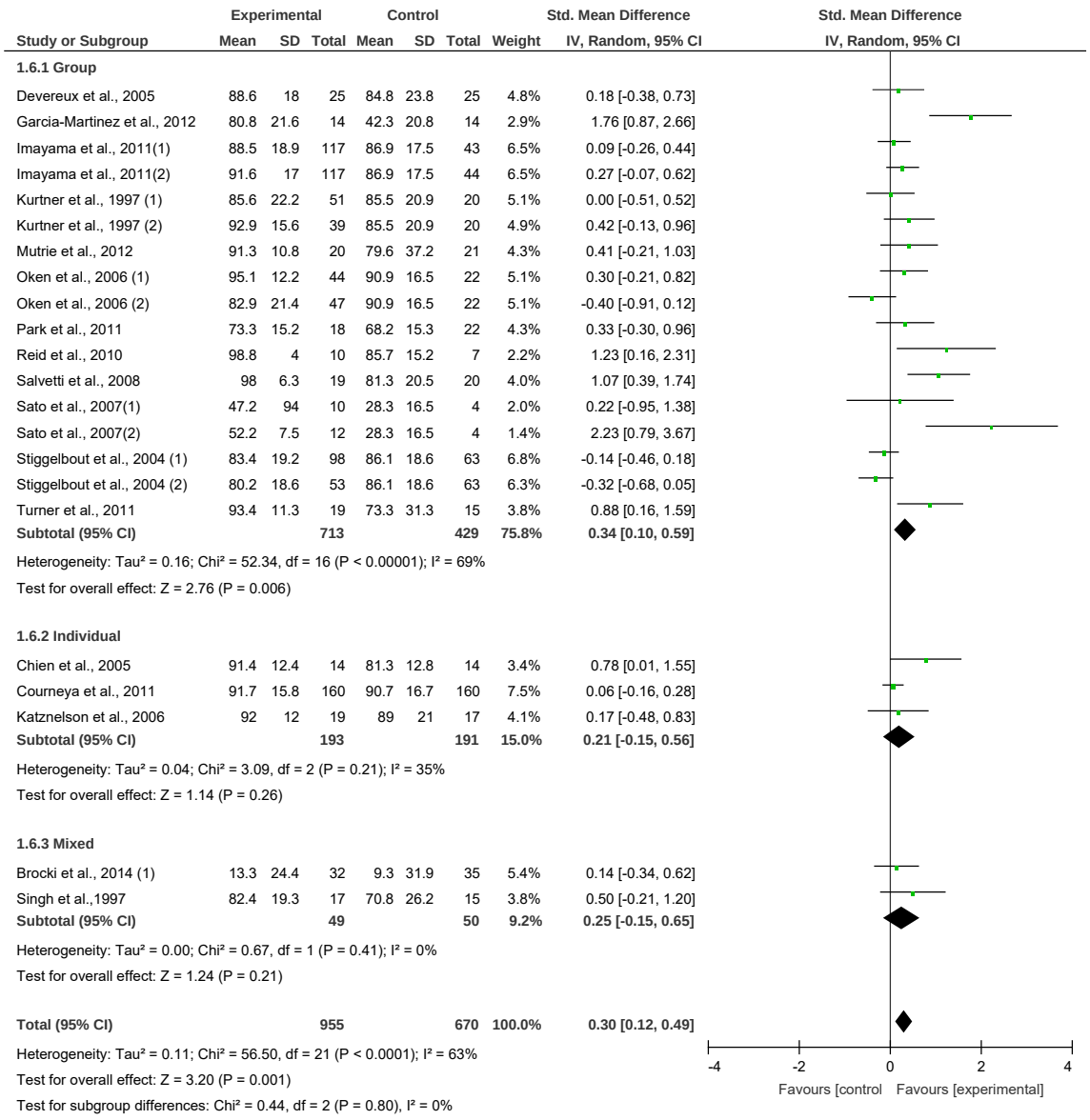


Fig. 7. Forest plot comparing overall effects of group settings compared with individual or mixed (group and individual) settings on social functioning.

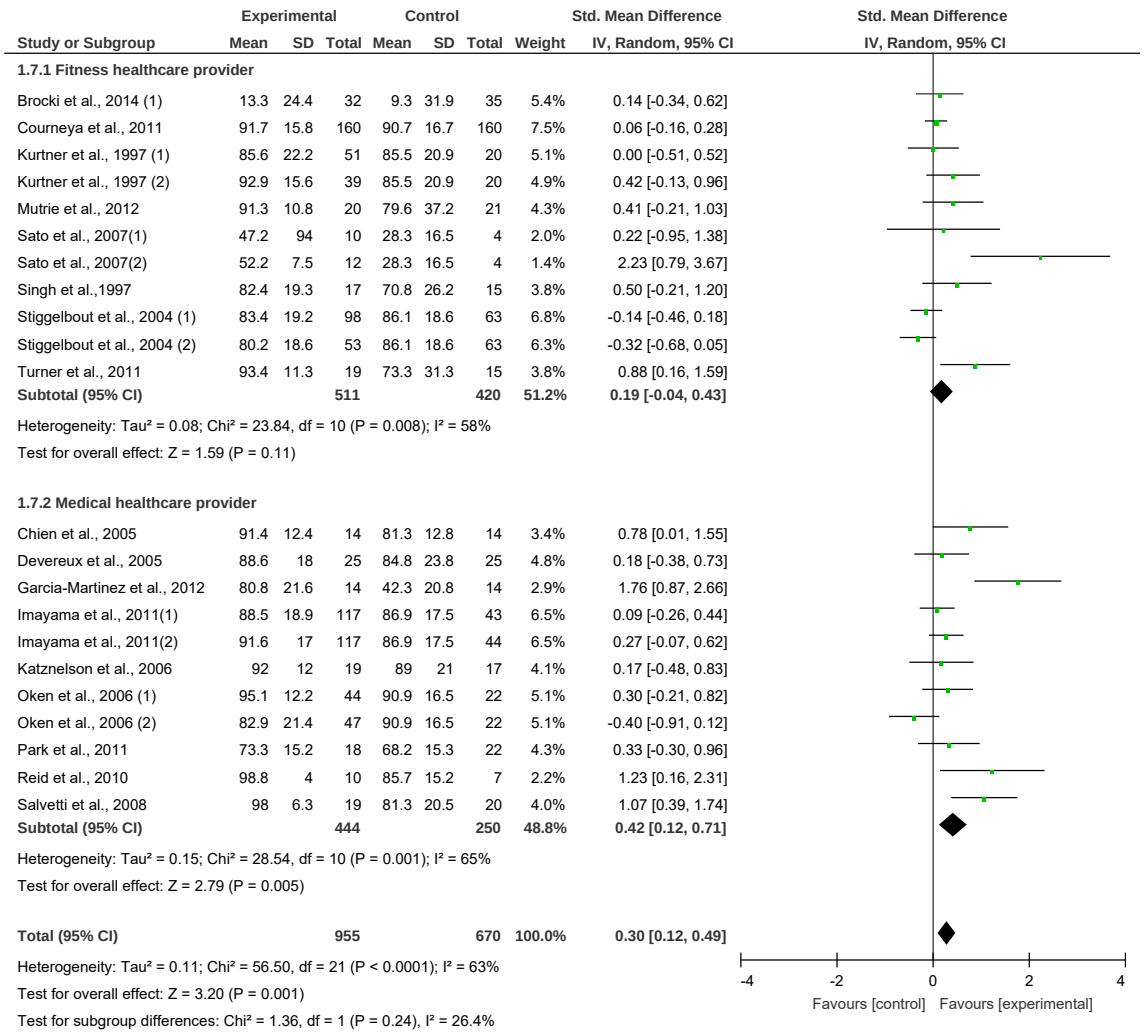


Fig. 8. Forest plot comparing overall effects of fitness healthcare provider compared with medical healthcare provider on social functioning.

The sensitivity analysis for social functioning without outliers (an extreme value that differs greatly from others in a set of values) (Aggarwal, 2015) revealed a small significant positive effect size (favouring the experimental group) and moderate heterogeneity (SMD =0.20, 95% CI, 0.05 to 0.36; heterogeneity: I^2=47, Chi^2 =35.95, P=0.02), N=20 (Appendix 10).

When high risk RCTs (N=9) were removed from the meta-analysis for social functioning, a small significant positive effect size was obtained (SMD=0.23; 95% CI,

0.08 to 0.39; P=0.004), and heterogeneity was small (I^2=15, Chi^2 =11.81, P=0.30) (Appendix 11).

The sensitivity analysis for social networks without outliers revealed a small non-significant negative (favouring the control group) effect size (SMD =-0.14, 95% CI, -0.29 to 0.01; heterogeneity: I^2=00, Chi^2 =0.19, P=0.07), N=3 (Appendix 12). For social support, no outlier effect sizes were identified.

Publication bias

For social functioning, the Egger's regression was significantly different from 1, suggesting asymmetry (2.76; 95% CI: 1.38-4.14, P<0.001), and thus publication bias was present. A consequent trim and fill analysis added eight new studies that increased the adjusted point estimate but yielded a non-significant p value (SMD= 1.07; 95% CI, 0.87 to 1.31; P=0.535; heterogeneity: Chi^2 = 56.50, P<0.0001). Therefore, the effect of publication bias on social functioning outcome is not trivial (Rothstein et al., 2006).

4. Discussion

The meta-analysis in this review demonstrated positive effects of PA interventions for social functioning. However, there was insufficient evidence of PA intervention effects on some social health outcomes in older adults, such as loneliness, and social isolation, which is consistent with previous reviews (Findlay, 2003, Cattan et al., 2005, Dickens et al., 2011, Hagan et al., 2014, Petitte et al., 2015).

Features of effective interventions

A higher effect of PA interventions for social functioning was obtained for delivery by medical healthcare professionals, and among diseased versus healthy older adults. Due

to the high correlation between health status and social health shown in the research literature (Hagan et al., 2014), it could be hypothesised that the effect of PA interventions on psychosocial outcomes might be more effective in specific vulnerable groups, which was the case for social functioning outcome. This review supports existing studies, which, in addition, identified effective interventions as being those enabling some level of participant or facilitator control, targeting specific population groups (e.g. sedentary, depressed, ill, with long term caring responsibilities) (Cattan et al., 1998, Cattan et al., 2005, Masi et al., 2010, Dickens et al., 2011, Hagan et al., 2014, Pels et al., 2016).

Intervention settings

Beneficial social health effects of group settings for social functioning were also shown. This is in line with the psychosocial hypothesis (Lubans et al., 2016) which associates intervention effects of PA with social connectedness between participants arising during activities based on shared needs and interests. It is hypothesised that exercise induces positive affective responses as a result of enhanced self-esteem and self-worth through group-based exercise activities (McAuley et al., 2000b). However, social health effects may also be influenced by the initial fitness of the participants, their age, baseline self-esteem, et cetera, as well as intervention variables (Rejeski et al., 1996, McAuley et al., 2000b, McAuley et al., 2003, Wenger et al., 2004) which need to be considered as potential confounders. In contrast to other studies, one-to-one settings using non-PA interventions were more effective in reducing loneliness in older healthy adults (Findlay, 2003, Banks et al., 2008, Kahlbaugh et al., 2011, Tsai et al., 2011), according to Hagan et al. (2014). In the present review, only two studies directly compared the effect of group-based and individual or one-to-one PA interventions on social isolation

and social networks (Evcik & Sonel, 2002; Lliffe et al., 2014). However, between group differences at follow-up were not significant in both interventions.

An overall significant small and positive effect for social functioning was obtained for PA interventions versus those with PA and social interactions. This seems somewhat at odds with the theories and mechanisms of how PA might be an effective intervention through increasing social connections, e.g., Lubans et al. (2016) discussed above, given that it would be expected that the more social interaction opportunities are integrated into the interventions, the more successful those would be. However, it is possible that this reflects the diversity of the different types of social interaction opportunities across the interventions which were PA with social interaction, and that not all of these interventions with social interaction components included this being in a group setting, but could be one-to-one. As shown, the sensitivity analysis for social functioning comparing PA with PASI, despite the significant and small effect obtained for PA interventions, the point estimate for PASI was greater albeit not significant (SMD=0.33; 95% CI, -0.04 to 0.70; P=0.08). This may be due to the grouping together PASI trials with different characteristics (Thompson et al., 2002b), and a significant effect favouring PASI may be obtained in a meta-analysis with another sample of studies.

Components of physical activity interventions

Five out of 13 PA interventions with significant results for psychosocial outcomes had a clear aerobic component of over 30 minutes a day (range 30-60 min) with intensities ranging from 60 to 85% HR_{max} (moderate-to-high) (Chan et al., 2013; Daley et al., 2007; Devereux et al., 2005; Garcia-Martinez et al., 2012; Rejeski et al., 2014) (Appendix G). The most common mode of aerobic exercise in included interventions was supervised walking (Chan et al., 2013; Daley et al., 2007; Rejeski et al., 2014; Sato

et al., 2007). Other beneficial PA interventions were resistance exercise training (Katznelson et al., 2006; Park et al., 2011; Singh et al., 1997). These findings are similar to observations of Rejeski et al. (1996) where the most effective PA interventions for QoL included aerobic exercise over 20 min (range 20-50 min) with intensities ranging from 45 to 85% of HR peak. Exploring the effect of dose or intensity of exercise, it has been hypothesised that exercise of lighter intensities (e.g. 55% maximum effort) induce exercise-related affective responses found to have a significant relationship with self-efficacy for exercise (McAuley et al., 2000b). However, these relationships do not appear to be maintained during vigorous intensity exercise (70% maximal effort), suggesting a blunted responsiveness at higher intensities (McAuley et al., 2000b). Further, exercise of light-to-moderate intensity intuitively provides better opportunities for social interaction, as shown in studies comparing exercise in different environments (Turner et al., 1997, McAuley et al., 2000b).

The duration of effective PA interventions in this review varied between six weeks and one year, with the majority of RCTs lasting for 12 weeks (N=13) (Appendix 6, 7). It was not possible to test the effect sizes of different durations, but given the paucity of significant overall effects, it could be considered that 12 weeks may not be sufficient time to see effects on social health.

Facilitation of intense social contact between participants was either through health education classes, recreational activity, cognitive behavioral therapy, social support and sleep hygiene (Appendix 6, 7).

With respect to the social functioning, there was substantial heterogeneity. Sources of substantial heterogeneity as shown in the sensitivity analysis were high risk RCTs (N=9) that resulted in small heterogeneity after removing these high risk RCTs

from the meta-analysis. Outcomes with non-significant effects (e.g. social support and social networks) had moderate and substantial heterogeneity, respectively.

Limitations and strengths of the review

Despite the significant small and positive effect of PA interventions obtained for social functioning, the results of this meta-analysis must be treated with caution. In the presence of publication bias for social functioning, the consequent trim and fill analysis reduced the previous social functioning effect size to being non-significant, which suggests that the effect of publication bias (or unpublished studies) is not trivial and the effect for social functioning that we report is affected by unpublished trials (Sterne et al., 2001).

A limitation of this review is that the meta-analysis for social support included only one RCT that explicitly targeted lonely or socially isolated people (Chan et al., 2017). Therefore, the effect size for social support may be larger if all included participants are lonely older adults. Included interventions rather targeted sedentary community-dwelling older adults where social outcomes were measured as secondary outcomes. Studies that address social health directly tend to be more behaviourally focused rather than looking at physical activity and might have more positive effects. One RCT targeted frail older adults whose physical health condition was assumed to lead to loneliness or social isolation due to the increased risk of institutionalisation (Ollonqvist et al., 2008). The relative lack of quantitative data and precise definitions of social health and determination of its domains (Rejeski et al., 1996) were limiting factors in reviewing the effects of PA interventions on the social health of older healthy adults.

A strength of the present review was the focus solely on community dwelling older adults, because there is a lack of available evidence particularly for older adults residing in community settings for loneliness. The majority of interventions are conducted on residents of institutional care (e.g. nursing home residents) as this is a potentially vulnerable group, thus we chose to focus on a different population who may also be in need of intervention. The present study also excluded individuals with cognitive disabilities, as this might confound the measurement of loneliness and social functioning. However, as vulnerable populations such as those with dementia might be more amenable to the effects of PA interventions, this would make an interesting comparison group and should be considered in future reviews.

One limitation is that the coding of the interventions could have been significantly strengthened by the use of a refined behaviour change taxonomy (Michie et al., 2011) in order to categorise the content of each intervention. However, as the focus of the current review included interventions that were therapeutic programmes for ill population or fitness interventions, these did not always include behaviour change techniques which this type of taxonomy is designed to code. However, it was possible to code the content of interventions to an extent, and to examine the impact of these factors such as PA alone, versus PASI. Unfortunately, meta-regression analysis to assess the effects of moderating variables could not be performed as there were insufficient studies for each social outcome to permit such testing (being fewer than 10 studies in each meta-analysis; (Thompson et al., 2002a). Also, it was not possible to examine whether differences in PA effect sizes predict the social outcome effect sizes as there were not enough studies for meta-regression. In summary, careful examination of trials showed that PA results were reported in a total of six studies (Courneya et al., 2003; Courneya et al. 2011; Daley et al.; 2007; DeVreede et al., 2007; Mutrie et al.,

2012; Park et al., 2011) (Appendix 5). Among these studies, only four studies report PA effects for social functioning (DeVreede et al., 2007; Courneya et al. 2011; Mutrie et al., 2012; Park et al., 2011). The remaining two presented results for the family well-being outcome (Daley et al., 2007; Courneya et al., 2003). Further, PA was measured in three different ways (METs, step counts, hour per week) across the social functioning studies.

It is possible that the residents of the retirement villages (i.e. assisted living) may be prone to more socialising due to the greater opportunities for structured social interactions (Park et al., 2012). However, we were unable to examine this as a potential moderating variable, as only one study in the current review included those in a retirement village setting (Cress et al., 1999) (Appendix 5). A further limitation is that three studies (Chien et al., 2005; Garcia-Martinez et al., 2012, lliffe et al., 2014) reported only completer analysis, thus the meta-analysis was not performed on solely intention-to-treat data. Further, this review did not include disease-specific analyses (e.g. cardiovascular, metabolic, bone health etc.) due to a limited number of studies and data available for each disease group, and subgroup analyses for exercise type were not performed for similar reasons. Indeed, the high heterogeneity in outcomes in addition to the high risk RCTs (e.g. for social functioning) may be a result of mixed-type exercises combined into one sub-group of PA. However, the inclusion of a broader variety of psychosocial outcomes made it possible to increase the number of available intervention studies.

There is also a limitation in the particular risk of bias tool used; the item "Appropriate blinding of care providers" would almost be possible for PA interventions. A limitation specific to several of the studies included in this review is that most of the interventions assessing psychosocial outcomes included these as secondary outcomes. However, this might be expected given that most studies of PA interventions are likely

to have primary outcome such as an increase in PA or fitness and physical function. Nonetheless, as PA can improve psychosocial outcomes as discussed above, it was still deemed important to systematically review the potential effects of PA on social health in order to inform future interventions focusing specifically on loneliness using PA as the intervention strategy.

Another issue is the use of non-composite measures of social health outcomes (i.e. only self-reported loneliness or social isolation without complex assessment of demographic characteristics, level of income, marital status, etc.). However, their use is advised to increase the specificity of self-assessment tools (Wenger et al., 2004). Some interventions were biased by the short duration of follow-up; it is known that the effect of a single exercise session is short-lived (Chodzko-Zajko, 2014a) and chronic adaptation is attenuated shortly after the cessation of an exercise programme. The average length of interventions in the included RCTs was 12 weeks (N=13). However, it is known that longer durations may be needed to allow participants to build upon transforming new contacts into meaningful relationships based on trust (McAuley et al., 2000b, Findlay, 2003), which might explain the lack of effects in some cases. Further, the majority of interventions included in this review did not assess potential mediators and moderators of PA and social health outcomes, such as social support and self-efficacy for exercise, although it is known that these factors may moderate the relationship between loneliness and physical activity (McAuley et al., 2000b, Fry, 2001, Fry et al., 2002, Taliaferro et al., 2010). Research shows that global (Bandura, 1993, Fry, 2001) and domain-specific self-efficacy (Fry et al., 2002) are moderating factors, and social support was found to be both a moderating (McAuley et al., 2000b) and mediating factor (Taliaferro et al., 2010). This review also did not consider the potential moderating effect of a residential setting (e.g. institutional versus community)

due to focusing solely on older adults residing in the community. It is likely that older adults from institutional settings (e.g. care homes) may be at increased risk of loneliness due to a lack of contacts with friends and family (Banks et al., 2002, Banks et al., 2008), and may also be more vulnerable due to dementia and other comorbidities than community-dwelling older adults (Banks et al., 2002, Banks et al., 2008). Future reviews might consider comparing across settings, taking into account comorbidities.

Despite the limitations of this review, to the authors' knowledge it is the first to assess the effects of PA interventions on variable domains of psychosocial health, and specifically to target a community-dwelling older adult population aged 60 years and over. Previous reviews have either included older adults as a sub-group of more diverse populations including children, adolescents or the general adult population (Gillison et al., 2009, Masi et al., 2011). Others included non-PA interventions only (Cattan et al., 1998, Cattan et al., 2005, Dickens et al., 2011, Petitte et al., 2015) or included mixed design studies for only one or two outcomes (e.g. RCTs, case-control studies, longitudinal etc.) (Smith et al., 2017). Compared with previously published systematic reviews (Cattan et al., 1998, Findlay, 2003, Cattan et al., 2005, Masi et al., 2011), the current review focused solely on RCTs which increased its methodological rigour, as advised (Masi et al., 2011). The results of this review confirm the need for further research estimating the effects of specific types of PA interventions on social health outcomes in specific groups of older adults to improve the specificity and effectiveness of targeted interventions.

5. Conclusions

Although this review obtained an effect of PA for the social functioning outcome, there is still insufficient evidence of any PA intervention' effects for loneliness and no

guidelines exist for any particular settings, population sub-groups, intensity, amount or types of activity (Rejeski et al., 1996). However, there are some indications that certain types of setting and intervention delivery can be beneficial, particularly for older adults with comorbidities, and specifically for social functioning. Future research should establish if there is any effect of PA on loneliness, social support, social networks and other related social health outcomes. If there is any effect of PA, further research is required to estimate mechanisms of association between PA and social health outcomes in older adults, using objective measures of PA and comprehensive methods of assessment of social health.

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Disclosure statement

The authors of this review declare that they have no known conflicts of interest.

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CHAPTER 3. PROTOCOL DEVELOPMENT AND METHODOLOGY

Maintenance of social connectedness throughout the lifespan is an important aspect of successful ageing (Cacioppo et al., 2014). The disruption of established social patterns or poor quality of social relationships negatively impacts quality of life and well-being in older adults and is highly associated with loneliness (Netz et al., 2005, Masi et al., 2010). Older adults are considered to be a particularly vulnerable category due to feelings of loss (Office for National Statistics, 2016). PA interventions could reduce loneliness and improve the psychological well-being of community-dwelling older adults, among other health benefits. Given this, the early prevention of loneliness and timely implementation of health interventions in a community setting to tackle the problem at its early onset seems prudent. However, as the systematic review in Chapter 2 shows, the available evidence for PA for loneliness is limited so further studies are needed to test the effect of PA interventions for loneliness in community-dwelling older adults (Eldridge et al., 2016b). This chapter contains a reference to the protocol for this feasibility study of Physical Activity Intervention for Loneliness (PAIL) in community-dwelling older adults, that was published in the *Pilot and Feasibility Studies* journal (Shvedko et al., 2018b).

This chapter presents a detailed overview of the main research paradigms and philosophical assumptions underpinning the feasibility study, followed by the research methodology of the mixed-method research study including qualitative and quantitative phases. It gives a detailed description of procedure and methods for quantitative and qualitative data collection.

The nature of research paradigm

As follows the literature (Guba et al., 1994), before any knowledge is obtained during research, it must have the appropriate research paradigm necessary, first, to approach the data and, consequently, analyse it based on the chosen paradigm (or strategy). This is also crucial for justifying the methodological strategies and methods of research (Guba et al., 1994). A research

paradigm is defined as a set of basic beliefs or worldview that guides the investigator (Guba et al., 1994), allow observing and measuring the particular research phenomena using a specific approach (Fossey et al., 2002). The choice of a defining research paradigm must be based on its utility and appropriateness for the research rather than on the proof (Guba et al., 1994). However, due to the interrelated link between the theory and methodology of the study (Gray, 2013), the choice of research paradigm as the foundational research criteria must be appropriately justified (Corbin et al., 2008). Consequently, the research paradigm is presented through main perspectives or questions: ontological (or the nature of the reality), epistemological (what it means to know) and methodological (set of methods or how the reality is investigated) (Gray, 2013).

Research paradigm and philosophical assumptions of the quantitative aspects of the study

From an ontological perspective the theoretical paradigm of the quantitative phase of study was positivism that assumes that reality exists independently (or external) of the researcher and from those who investigate this inquiry (Guba et al., 1994, Gray, 2013). Positivism using the deductive approach (e.g. from general to the particular) tries to test or verify the research hypothesis through the experimental study involving rigorous methods (Gray, 2013). It is different to a post-positivism theoretical perspective based on attempts to falsify the hypothesis and operated by critical constructivism that rejects the worldview obtained through the human knowledge (Gray, 2013). From an epistemological perspective, a theoretical perspective linked to positivism is objectivism, which assumes that reality is not constructed (i.e. constructivism) and therefore objectively exists (Gray, 2013). This objective reality operates objective methods of data collection, such as, questionnaires. From a methodological perspective, this feasibility study is an experimental study which includes methods of sampling, questionnaires, and statistical data analysis.

The perspective of mixed method research

The mixed method research design includes quantitative (positivist/post positivist) and qualitative (e.g. constructivism) methods which has philosophical assumptions as well as methods of enquiry (Creswell et al., 2017). Therefore, combining multiple philosophical assumptions (or worldviews) into one study is valuable for comparing and contrasting the interferences obtained from qualitative and quantitative studies (Creswell et al., 2007). It also maximises the strengths of one research design and minimises the weaknesses of another.

The main perspective of this mixed method research was pragmatism that emerges from the research questions being studied (Creswell et al., 2007). This perspective "is taken by individuals who approach mixed methods research from a social foundation perspective" (Creswell et al., 2007, p. 305). It acknowledges the value of the interpretation process by the researcher and the investigation of the truth, "what works" and "what does not" instead of exploring existing "truth" and "reality" (Teddlie et al., 2009, p. 713). Rather it looks at philosophical assumptions brought by the researcher, who investigates the truth, rather than testing methods or a process of research. It is a relevantly new paradigm for research, which has faced criticism due to merging different philosophical assumptions that, in the opinion of critics, should not be mixed into one study, and that paradigms (as worldviews) cannot be changed during a study (Creswell et al., 2007). As follows, many paradigms may be used in mixed research study, researchers have to describe each paradigm, and any tensions and contradictions they reflect (Greene et al., 1989). In the field of PA and behaviour change, the mixed methods research design allows researchers to understand more deeply the complex phenomenon (e.g. a phenomenon of loneliness) using a broad range of methods rather than a single method (Stathi et al., 2012).

Research paradigm and philosophical assumptions of the qualitative aspects of the study

The theoretical paradigm of the qualitative phase of study was constructivism which "believes in pluralistic, interpretive, open-ended and contextualized (e.g. sensitive to place and situation)

perspectives toward reality" (Creswell et al., 2000, p. 125). In constructivism, researchers believe that reality is socially shaped and therefore, meaning about the world is socially constructed. Qualitative research via the inductive approach allows the development of theories or models, which is opposed to the hypothesis or theory testing through positivism.

Study design

The details of design and methods are described elsewhere (Shvedko et al., 2018b). PAIL was a 12-week randomised controlled feasibility trial with a wait-list control group (WLC) delivered in Birmingham, United Kingdom, and ran in two waves: from February to April 2018 (Intervention Wave 1), from June to August 2018 (Intervention Wave 2). The PAIL feasibility study had a mixed-methods research design (including quantitative and qualitative research methods using focus group interviews). The trial was approved by the STEM Research Ethics Committee of the University of Birmingham, UK (ERN_16-1419A) (Appendix 13). The amendments to the ethical application were due to the updates in the chart of study visits and the eligibility criteria. The study protocol was registered at ClinicalTrials.gov (NCT03458793) and published in the *Pilot and Feasibility Studies* journal (Shvedko et al., 2018b). The reporting of the trial was guided by the Consolidated Standards of Reporting Trials (CONSORT) statement (Eldridge et al., 2016a). Written informed consent was obtained from all participants prior to entry into the study (Appendix 14).

Participants

Recruitment

Participants were recruited in two waves: from September 2017 to January 2018 (Recruitment Wave 1) and from January to May 2018 (Recruitment Wave 2) from local neighbourhood (households) and communities in Birmingham via posters (Appendix 15) and distribution of leaflets (Appendix 16) about the study (left for collection and not handed out to participants personally). Additional recruitment was facilitated during the eligibility screening where potential participants

were given a copy of the information sheet (Appendix 17), and a leaflet about the study and were asked to invite anyone else they know and who might be interested in the project i.e., using snowball or chain recruitment by word of mouth (Miles et al., 1994).

Eligibility

Participants were older adults living in Birmingham, United Kingdom. *The eligibility criteria* for study participation were:

1) community-dwelling older adults aged 60 years and older;

2) previously sedentary (i.e. as defined by a lack of regular involvement in more than 20 minutes exercise per week over the past month that increased breathing significantly and was considered moderate) (Stevens et al., 1998). Moderate intensity activity that is noticeable accelerates the heart rate and is equal to approximately 3-6 metabolic equivalents (METs) (American College of Sports Medicine, 2013);

3) at risk of loneliness and having ≥6 out of 9 points on the 3-item loneliness scale during the phone screening (Hughes et al., 2004) (Appendix 18). Those who scored ≥6 out of 9 points were classified as lonely.

4) physically mobile as measured using the Short Physical Performance Battery (SPPB) (Guralnik et al., 1994) with a score ≥ 9 out of 12 (Pahor et al., 2014);

5) healthy or having one or more common chronic diseases not precluding their participation in the exercise programme (e.g. ambulatory);

6) without a cognitive disability as assessed by the Montreal Cognitive Assessment (MOCA) (Nasreddine et al., 2005) with a score ≥ 22 out of 30 (Freitas et al., 2013);

7) able to give written informed consent;

8) English speaking and able to complete paper and pencil questionnaires.

***Exclusion criteria* were:**

1) <60 years old;

2) currently taking part in another physical activity intervention;

3) socially active or not lonely based on the phone screening tool by Hughes et al. (2004);

4) regularly physically active;

5) moderate to severe cognitive disability with cut-off below 22 for MOCA or clinical diagnosis of dementia or Alzheimer's disease;

6) not ambulatory, i.e., not able to walk 4 meters;

7) not literate in English (speaking and reading) as this precludes taking pen and paper tests.

Excluded participants based on moderate to severe cognitive disability received a telephone call from the research team to sensitively explain reasons for exclusion associated with: 1) reliability of data, e.g. high-level of cognitive capacity and initiative required to communicate during social club discussions and to provide adequate answers on questionnaires (Taylor et al., 2012), 2) and inability to conduct the telephone-based eligibility screening, comprehend the information sheet, consent form and other important materials of the study. The research team also advised the participant to discuss any health-related discovery (in person or by the phone call) with their GP. This information is also provided in the information sheet.

Intervention development and delivery

The development of the PAIL intervention was a result of collaborative work of research group (AS, AW, JT, CG). Although, the theory of active engagement (Lemon et al., 1972) influenced the development of the intervention content by enhancing a feeling of social connectedness and self-confidence during engagement in group physical activity, a specific model of behaviour change was not used in this intervention, as the main focus was not on the behaviour change but rather on the novelty of whether PA could alter loneliness. In addition, the existing theories for loneliness do not explicitly specify how to modify the intervention design to target the factors which can be the most effective. Therefore, rather than linking any existing theory into practice, we have attempted

to deliver the intervention and consequently refine it based on study limitations and data gathered. This will allow addition of an element of innovation to behaviour change from the constructivist philosophical assumption of multiple realities, and contrast it to any fixed theory "delivered to interventionists for implementation" (Rothman, 2004, p. 3). The intervention was a group walking intervention with an education workshop on healthy ageing topics alongside each walking session once per week. After the pilot of the entire intervention with five people and feedback obtained at a focus group interview conducted in March 2018, minor changes were needed to modify the delivery approach of the intervention. Firstly, it was suggested to facilitate recruitment of participants by contacting the 1000 Elders group (The Birmingham 1000 Elders group, 2017) and the BVSC consortium (Birmingham Voluntary Service Council, 2016) to advertise the intervention for the summer period. Due to a small number of participants per group, the intervention was lacking the necessary social interactions between participants. Therefore, it was suggested to add new participants who were eligible to join the current groups, and identify the start date of their 12-week intervention from the day they joined (e.g. on a rolling basis). It was also suggested to modify the way of delivering group workshops using a less formal chat in the coffee shop rather than formal presentations at the university facility. Based on participants' responses during the focus group interview and concerns about the continuity of the walking after the intervention ends, participants who completed the 12-week intervention continued walking in a separate group with another walking group leader (an ex-participant who volunteered to become a walking group leader). This group did not merge with controls and therefore, did not affect the responses of control group on questionnaires etc. In order to assess the follow-up attendance rate for the voluntary walking group, the walking group leader was asked to complete a weekly attendance checklist (Appendix 19) and report the attendance to the primary researcher (a PhD student, AS) during informal meetings and copy the primary researcher into group e-mailing list informing about the location and times of walks. Additionally, free access was gained to Winterbourne House and Gardens (Birmingham, UK) once every three weeks for healthy workshop sessions, which included free beverages

(external funding was obtained from the School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham). Participants started to receive a weekly e-mail with the information about the next walking route and a topic of the workshop to set appropriate expectations and help them prepare for the discussion (based on a feedback received during the mid-point focus group with participants of Wave 1 in March 2018). Information about social events was e-mailed weekly to support local engagement with activities and facilitate within group social interaction. The walking leader attended monthly supervisory meetings with the research team to discuss the progress of the intervention and any arising challenges.

Intervention

A brief description of intervention is given elsewhere (Shvedko et al., 2018b). The full description is presented below. The template for intervention description and replication (TIDieR) checklist guided the research reporting to ensure the clarity and transparency of the intervention reporting (Hoffmann et al., 2014) (Appendix 20). The PAIL (Physical Activity Intervention for Loneliness) was a 12-week intervention consisting of group walks and health educational/social interaction workshops performed once weekly for a duration of up to 90 minutes in total per session. The possible mechanisms of association between PA and improved social relationships are described in Chapter 1.

The design of the PAIL was based on the characteristics of effective interventions obtained from the existing systematic and meta-analytic evidence on the topic (Cattan et al., 1998, Cattan et al., 2005, Hagan et al., 2014, Petitte et al., 2015, Pels et al., 2016, Smith et al., 2017). Additionally, the systematic review described in Chapter 2 (Shvedko et al., 2018a) confirmed the limited evidence for PA for loneliness and revealed features of effective interventions for social functioning. Therefore, where possible, the narrative participant and intervention characteristics were added to confirm or expand on the existing evidence of effective PA intervention characteristics from the researched literature:

1. A *walking-based intervention over 30 minutes' duration.* Following the systematic reviews of interventions to treat loneliness and social isolation, beneficial interventions had a clear aerobic component of over 30 minutes per day in the older adult population (Pels et al., 2016). Supervised walking was the most common mode of aerobic exercise intervention (Shvedko et al., 2018a), it has a low cost and accessible to all levels of physical fitness, and has been shown to be effective in increasing PA levels in community-dwelling older adult populations (Mutrie et al., 2012a) and clinical settings (Long et al., 2012).

2. A s*mall group setting (up to 9 people)*. Small group activity was shown to facilitate the sense of belongingness and social acceptance of activity group members (Baumeister et al., 1995). In this regard, as noted by Masi et al. (2010), what seems to work with lonely individuals to treat their loneliness is not the gathering of people who are unfamiliar to each other in the group intervention, but the building of relationships arising from common experiences during enjoyable and group-based activity based on trust. Consequently, small group-based PA interventions are necessary for building friendly relationships based on trust and respect and are essential to exercise participants' mastery followed by improved self-efficacy for exercise associated with decreased loneliness (McAuley et al., 2000b, Masi et al., 2010).

3. *Centre-based interventions.* Centre-based PA or cultural interventions may facilitate the reasons participants have to attend any intervention with an aim of making friends and improving their social networks. This was clearly seen in a friendship enrichment intervention for loneliness reduction in the study of Stevens (2001) where women were hoping to meet a new local resident for companionship and find a friend for a specific activity (e.g. walking or swimming). Similarly, community-based primary care PA interventions were shown to reduce loneliness in older adults (Mutrie et al., 2012a) versus less effective individual home-based interventions (Chan et al., 2010).

4. *Intensity of the intervention*. Exercise of light-to-moderate intensity (up to 70% of predicted HR $_{max}$) was chosen as it has been shown to induce exercise-related affective responses which were significantly related to self-efficacy for exercise and intuitively provide better opportunities for

social interaction (Turner et al., 1997, McAuley et al., 2000b). These effects did not appear to be maintained during vigorous intensity exercise (over 80% HR $_{max}$), suggesting a blunted responsiveness at higher intensities (McAuley et al., 2000b).

5. *Duration of the intervention 12 weeks.* Treatment of loneliness requires a longer time to allow participants to build upon transforming new contacts into meaningful relationships based on trust. This is particularly due to quality of social contacts as opposed to simply expanding social connections (quantity of contacts) required to reduce the feeling of loneliness, which takes longer time to develop (McAuley et al., 2000b, Findlay, 2003). As shown in the the 12-week friendship enrichment programme for lonely older women (Stevens, 2001), the first friendship gains were obtained only after fifth lesson of the programme. Thus, an adequate follow-up period is required to obtain any changes in psychosocial outcomes, with the treatment effect of any intervention observed in some studies five months after termination of the intervention (Masi et al., 2011) to six month follow-up (Anderson, 1985). On the other hand, it may be difficult for older adults to commit to an intervention over 12 weeks. This was supported by literature, showing that approximately one third of those who initiate an exercise programme drop out by this time (Ettinger et al., 1997). On contrast, interventions less than 12 weeks were found to be not effective particularly for loneliness reduction (Pels et al., 2016). Although the majority of interventions were 12 weeks or more, obtained in the systematic review conducted as the first stage of this PhD (Shvedko et al., 2018a), the treatment effect of PA for loneliness was not able to be analysed due to the lack of studies. Therefore, for the purposes of the PAIL feasibility study, a minimum 12-week intervention was chosen to complete the intervention to fit with existing studies, and the limited time frame of a PhD study and available resources.

6. Delivery of intervention by experienced staff. Experienced staff (e.g. experienced walking group leader, certified gym instructor, run leader) with a thorough knowledge of exercise and preferably having a knowledge of working with the required sample (i.e. lonely participants or older adults) may ensure the effective delivery of exercises in accordance with the health and safety standards to

minimise the likelihood of any harm or injuries first (Pels et al., 2016), and, secondly, to improve the effectiveness of the delivered intervention by facilitation of the required skills (e.g. improvement of social relationships between participants during the intervention by friendly discussions) (Hawkley et al., 2007, Pels et al., 2016). Therefore, the PAIL intervention was delivered by the trained walking group leader (i.e. Level 3 certified personal trainer and a group exercise instructor, who was the PhD student, AS).

7. Activity engagement. Following the systematic reviews (Dickens et al., 2011, Hagan et al., 2014, Petitte et al., 2015, Pels et al., 2016), beneficial interventions to reduce loneliness in older adults in addition to having a PA component, used the facilitation of intense social contact between participants through a variety of non-PA interventions, for example, health education classes or small group social workshops. In the published systematic review (Shvedko et al., 2018a) (Chapter 2), the effects for social functioning were obtained for PA versus PA with social interactions (PASI), which contradicts to the literature above. Therefore, bearing in mind the limitations of the studies that used PASI included in the review (Devereux et al., 2005, Sato et al., 2007, Salvetti et al., 2008, Park et al., 2011, Chan et al., 2013) (as shown in Appendix 5), which are likely to be associated with the discrepancies in participants and settings, and differences in PA programmes, the PAIL intervention included healthy workshops to assess the feasibility of such intervention and discuss the ways to receive support for exercise from others on being physically active. In addition, participants' feedback about healthy workshops was asked during focus group interviews.

The walking intervention was used to: 1) increase the daily amount of walking by walking up to 45 minutes per week and reduce sedentary time (Stevens et al., 1998); 2) improve the social skills of participants and decrease feelings of loneliness and social isolation; 3) reduce depression and anxiety and improve the psychological well-being and confidence. Group workshops were aimed to facilitate the social skills of the participants, provide social support, and improve skill building. Thus, the combined benefits of physical activity and a socially supportive and enriched group environment during the intervention were expected.

The PAIL was delivered once weekly using a face-to-face method in small groups (up to 8-9 people per group) and run in various locations and parks in Birmingham, UK (Appendix 21). The research team informed participants about the dates and times of walks (conducted once a week on Wednesdays, at 11.30 am) and meeting points in advance by e-mail or individual phone calls/messages. Additionally, participants were reminded of the dates of the next meeting at each session. Prior to the first walking session, participants received a copy of a General Practitioner (GP) letter to inform their doctor of participation and were asked to complete the "Par-Q and You form" (Shephard, 1994). During guided walking, the instructor will be acting as a facilitator of social contact by using in-session talks and friendly discussion between participants to reduce psychosocial tension. Walking sessions were based on the principles of gradual progression and adaptation to PA (American College of Sports Medicine, 2013) (Appendix 22). The intensity of the walks was light-to-moderate and was monitored objectively by heart rate monitors using the age-predicted heart rate maximum (HR_{max}) method (Fox et al., 1971) and subjectively using the talk test (Persinger et al., 2004) and the 0-10 Borg Ratings of Perceived Exertion scale (RPE) (Borg et al., 2006). Participants had to be able to speak comfortably during exercise using the talk test (Persinger et al., 2004), and rate their RPE from 2 to 4 on the 0-10 Borg RPE scale (Borg et al., 2006). Participants followed a trained walking leader via a specific route (Appendix 21). A warm-up was performed at the beginning of each session for 7-10 minutes and will include preparatory dynamic and static stretches standing, performed for the major muscle groups and walking at a leisurely pace maintaining an upright pose. Each session included balance exercises to reduce the risk of falls: knee bends, heel and toe walking, heel-toe backward walk, walking and turning around tightrope walking, standing on one leg, sit to stand, sideways walking, tandem stance, semi-tandem stance, one leg stand) performed at the end of the walking session recommended for older adults to reduce frailty (Department of Health, 2011) performed in three sets of 10 seconds each exercise. A further cool down was performed for 5-7 minutes, consisting of stretching exercises for upper and lower body (head, neck, trunk, back extension, ankle movement) and breathing exercises while standing.

Group walks were followed by health education/social interactions workshops on a variety of healthy ageing topics including health, well-being, health hygiene derived from "A practical guide to healthy ageing" (NHS England and Age UK, 2015) (Appendix 23 is showing the content of healthy workshops). Additionally, participants received a weekly e-mail with information about local events at Birmingham city and social activities in the community (Birmingham City Council) to facilitate social networking and socially active behaviour in their free time.

Intervention group

After randomisation, participants in the intervention group started the 12-week intervention.

Wait-list control group

Participants in the WLC group (delayed intervention) started the intervention after their follow-up measures were completed approximately 13 weeks post-randomisation.

Measures

All measures were conducted at the host academic institution at baseline and immediate post the intervention period.

Phone-based eligibility screening

The phone-based eligibility screening participant form included five sections (Appendix 18):

A. *Eligibility screening section.* Participants with any negative answer on questions 1-2 or any positive answer on questions 3-4 will be ineligible to take part in the intervention.

B. *The risk of being socially isolated* or lonely was conducted using the 3-item loneliness scale for the phone screening. Participants who scored ≥ 6 out of 9 points were considered at risk of feeling socially isolated or lonely and were eligible to take part in the intervention.

C. *Physical mobility* was assessed using questions that were adapted from the 10-item The CONFbal scale for balance confidence (Simpson et al., 2009). Participants who were unable to walk

across the room without support or answered “Very difficult” or “Unable” on any of the questions were considered as ineligible to take part and were excluded.

D. *Assessment of physical activity behavior.* Sedentary individuals were defined by a lack of regular involvement in more than 20 minutes exercise per week over the past month that increased breathing significantly and was considered moderate) (Stevens et al., 1998) using modified short form of the CHAMPS physical activity questionnaire adopted for use in older adults population (Stewart et al., 2001).

E. *Confidence in ability to get to sessions* was assessed using the question: “How confident do you feel that you would usually be able to attend a PAIL session once a week for the next three months?” providing responses: “Quite confident”, “Not sure” and “Not at all confident”.

Socio-demographic characteristics and medical conditions

Participants provided socio-demographic information about their age, gender, ethnicity, marital status, living arrangements, level of education, any children, employment status and any medical conditions. The total number of chronic medical conditions was classified into three categories: 0 (none), 1, 2 or more.

Cognitive function

Cognitive function was assessed using a Montreal Cognitive Assessment scale (MOCA) designed to test mild cognitive impairment (Nasreddine et al., 2005). It is a 30-point tool displayed on one page that requires approximately 10 minutes to complete assessment of the following: 1) short-term memory using two trials of recalling five words (5 points); 2) visuospatial abilities using a clock-drawing task (3 points) and a copy of the three-dimensional cube (1 point); 3) executive functioning using an alternation task (1 point), a phonemic fluency task (1 point), and a 2-item verbal abstraction task (2 points); 4) attention, concentration, and working memory using a sustained attention task (target detection using tapping; 1 point), a serial subtraction task (3 points), and digits

forward and backward (1 point each); 5) language using a 3-item confrontation animal naming task (3 points), repetition of two syntactically complex sentences (2 points), and the aforementioned fluency task; 6) orientation to time and place (6 points). One point was added for 12 years or fewer of formal education. Cut-off ≥ 22 points for MOCA (Freitas et al., 2013) was required to be eligible for study participation.

Physical functioning

The physical functioning of participants was assessed using the Short Physical Performance Battery (SPPB) (Guralnik et al., 1994). The scale consisted of three fitness tests: gait speed test for 4 meters, a standing balance test and sit-to-stand (rise from the chair) test, using a tape, chair and a stopwatch. The scoring was provided by summing the category scales for all tests and ranging from 0 (low mobility) to 12 points (high mobility). Participants with a score ≥9 out of 12 were eligible to take part in PAIL (Pahor et al., 2014). The summary performance scale has shown high internal consistency of 0.76 (Guralnik et al., 1994) and test-retest reliability of 0.72 (Ferrucci et al., 1999).

Anthropometric and health-related measurements

Stature to the nearest 0.1 cm was measured using a stadiometer (Seca AG, Reinach, Switzerland) and recorded in metres (m). The body mass of participants was assessed using weighing scales (Tanita UK Ltd., Middlesex, UK) to the nearest 0.1 kg. BMI ($kg \cdot m^{-2}$) was calculated by dividing mass (kg) by height squared (m^2).

Resting blood pressure (BP rest) (mm Hg) was measured using a portable semi-automatic OMRON sphygmomanometer (OMRON HEM705IT sphygmomanometer; Omron Matsusaka Co Ltd, Japan). Participants were asked to sit for 5 minutes upright with the blood pressure cuff placed around the non-dominant arm and the mean of three readings with a 5 min interval were recorded.

Physical activity

Physical activity was measured using ActivPAL accelerometers (PAL Technologies Ltd. Glasgow, UK) over a continuous 7-day period of awake and sleeping (24 hours a day) except when bathing or swimming (Chastin et al., 2010) with a minimum of 5-day continuous recording period. This is a light (15g) small uni-axial accelerometer-based monitor (3.5 x 5.3 x 0.7 cm) worn on the anterior surface of the thigh and secured with the waterproof dressing (3M Tegaderm Film, 10 x 12 cm, 3M Health Care, USA). Data were recorded in 10-second epochs and extracted from outputs for time sitting/lying (h), time standing (h), time stepping (h), daily average step counts, sit-to-stand transitions (n) and energy equivalent (EE, MET/h). The ActivPAL monitor has been validated for the use with older adults (Grant et al., 2008). Participants received written instructions about the use of ActivPAL monitors and were asked to contact the research team in case of any discomfort or if there was any issue about the use of ActivPAL (e.g. discomfort, problem) via the contact information of the research team as displayed at the end of the ActivPAL information sheet. Participants were asked to sign in the log sheet asking for the information about how they would like monitors to be collected (at home or in the centre at the next visit) and provide the preferred way of contacting them by the research team to remind them to take off the monitors at the end of the seven days.

Questionnaires

All questionnaires and documents were written in 14 font with the adequate spacing between lines as recommended to meet the needs of most older adults (Stewart et al., 2001).

Loneliness was assessed using the 8-item UCLA (University of California at Los Angeles) Loneliness Scale (Hays et al., 1987). This is a short form version of the revised 20-item UCLA Loneliness Scale (ULS-20) (Russell, 1996). The exploratory factor analysis of ULS-20 revealed that eight items were substantially loaded (median loading =0.48, range 0.31-0.73) on the first factor (Hays et al., 1987). These eight items represent the key characteristics loneliness (Peplau et al.,

1980) and the 8-item UCLA scale is a better substitute of the ULS-20 than a 4-item short form UCLA (Hays et al., 1987). Items were rated on the 4-grade Likert scale ranging from 1 (never) to 4 (often). The total scoring was ranged from 8 to 32 with the higher score indicating more loneliness considered to be a worse outcome. Questions "I am an outgoing person" and "I can find companionship when I want it" were reverse scored. The UCLA-8 has demonstrated high internal consistency of 0.79 (Hays et al., 1987).

Social support was assessed using the 20-item Medical Outcomes Study Social Support Survey (MOSSSS) (Sherbourne et al., 1991). The questionnaire consisted of 20 items including the assessment of a structural social support (number of close friends – item 1) and assessment of functional social support (items 2-20). Participants were asked to complete the questionnaire using the five-point Likert scale ranging from low social support "None of the time" (1 point) to a high social support "All of the Time" (5 points). The total score was the sum of the scores. Higher scores of support showed better social support. The MOSSSS is the most comprehensive tool for assessment of various dimensions of functional support (emotional/informational, tangible, affectionate, and positive social interaction), focused around perceived availability as most essential component of social support (Cohen et al., 1983). The observed correlations between subscales were high (r's range from 0.69 to 0.82) (Sherbourne et al., 1991). The scale was developed in people with chronic health conditions, therefore items are short and easy to administer, with one question related to the one concrete meaning (Sherbourne et al., 1991). The confirmatory analysis supported the distinction of support measures of MOSSSS from the related concepts, such as loneliness ($r=-0.67$) and family functioning ($r=0.53$) at $p<0.01$ (Sherbourne et al., 1991). The MOSSSS has shown a high internal consistency of > 0.91 and a high test-retest reliability from 0.72 to 0.78 (Sherbourne et al., 1991).

Social networks were assessed using the 6-item Lubben's Social Network Scale (LSNS-6) (Lubben et al., 2006). The LSNS-6 is also used to screen for social isolation and was specifically designed for use with the older population (Lubben et al., 2006). The LSNS-6 has total 6 items

divided into two subscales: family and friendship (three items for each). The LSNS-6 is particularly designed to identify a population at risk of social isolation as a gold standard test does not exist (Lubben et al., 2006). The LSNS-6 was based on the concept of lack of redundancy (Fuhrer et al., 2002) and has determined clinically defined cut-off points (e.g.< than 12) for interventions targeting social isolation. The total score was calculated by sum of the six items with scores ranging from 0 to 30. A sum of scores for six items less than 12 indicated that the respondent had fewer than two people for social interactions, and therefore at risk for social isolation. Similarly, a cut-point score of 6 on the three-item indicated as being at risk for social isolation (Lubben et al., 2006). The family subscale indicated that the participants had less than two family members to perform social interactions, similarly for the friendship subscale. The LSNS-6 has shown good internal validity from 0.84 to 0.89 (Lubben et al., 2006).

Depression and anxiety were assessed using the 14-item Hospital Anxiety and Depression Scale (HADS) (Zigmond et al., 1983). The scale was designed specifically to assess the caseness of anxiety (as centered on emotion of fear) and depression (centered on emotion of sadness) in non-psychiatric patients with the specific aim to distinguish between these two constructs (Zigmond et al., 1983), both of which were of interest in the PAIL intervention as closely linked to loneliness (Cohen-Mansfield et al., 2016). The review of Bjelland et al. (2002) supported the two factor structure in 11 (total N=14,588) out of 19 studies using factorial analysis. The HADS showed high correlation with General Health Questionnaire (from 0.50 to 0.66) (Bjelland et al., 2002) and Beck's Depression Inventory (BDI) (from 0.62 to 0.73) (Bjelland et al., 2002). The questionnaire consisted of 14 items with the assessment on four-point scale (0-3). The cut-offs for the total score for each sub-scale were: 0-7 – normal, 8-11 – mild, 12-14 – moderate, 15 and over – severe. Despite the 30-item Geriatric Depression Scale (GDS) (Yesavage et al., 1982) being more frequently used in exercise interventions with the geriatric population, the HADS is much shorter and has been shown to be a valid and reliable questionnaire for use in both hospital and community settings for the assessment of anxiety ($r=0.41$ to 0.76, $P<0.01$) and clinical depression ($r=0.30$ to 0.60, $P<0.02$)

(Zigmond et al., 1983).

Self-efficacy for exercise was measured using the revised 9-item Self-Efficacy for Walking/Exercise Scale (SEE) in a paper-and-pencil format (Resnick et al., 2000). Based on the Social Cognitive Theory (Bandura, 1986), self-efficacy expectations predict exercise activity, with the higher self-efficacy scores relating to stronger and more persistent efforts, which informed the choice of this tool. The SEE scale contains self-efficacy expectations which significantly correlated to ability to participate in exercise, coincident with the PAIL study. Using numbers from 0 (not confident) to 10 (very confident) participants were asked to rate their confidence in their ability to walk/exercise for 20 minutes three times per week (Resnick et al., 2000). The scoring was calculated by summing the numerical ratings for each response and dividing by the total number of items. The SEE score indicated the strength of efficacy expectations and has shown high internal consistency of 0.92 in a sedentary older adult population, which was higher than for the Physical Self-Worth subscale of the commonly used Physical Self Perception Profile (PSPP) (internal consistency 0.89) (Fox et al., 1989). The squared multiple correlation coefficients ranged from 0.38 (Item 6) to 0.76 (Item 2) (Resnick et al., 2000).

Satisfaction with level of social contacts was measured with the question "How satisfied are you with your social contacts?" (Fokkema et al., 2007a). Participants rated their answer on a scale from 0 (entirely dissatisfied) to 10 (entirely satisfied).

Expected outcomes and barriers for exercise were administered using the Expected Outcomes and Barriers for Habitual Exercise scale (Steinhardt et al., 1989) adapted for the older adult population (Appendix 24). This scale was developed based on the self-efficacy theory of Bandura (1997) with the expected outcomes referring to two constructs: *the self-efficacy expectations* related to belief in ability to perform specific behaviour, and *outcome expectations* relating to a specific behaviour that lead to specific expectations. The identification of adults with low expectations from exercise using this tool can help to predict low attendance or a likelihood of drop out (Resnick et al., 2000). In contrast, those who exercised regularly were shown to have

higher expected outcomes based on this scale ($F=31.3$, $p<0.05$, eta squared $=0.15$) (Resnick et al., 2000). Four questions related to sport competence from expected outcomes and question "Interferes with work" from expected barriers have been deleted due to irrelevance for this population group (Steinhardt et al., 1989). Participants replied using the five-point Likert scale ranging from "Strongly disagree" (1 point) to "Strongly agree" (5 points). Scoring for each subscale was provided by summing all numerical ratings for each item and divided by the total number of items. The total score of expected outcomes and barriers for exercise was ranged from 1 point (low) to 5 points (high). The Expected Outcomes and Barriers for Habitual Exercise scale has demonstrated good internal consistency from 0.66 to 0.85, and a high test-retest reliability of 0.78 in previous research (Steinhardt et al., 1989).

Feasibility outcomes

The following feasibility outcomes will be assessed in this study:

1) Attendance will be calculated as the total number of attended sessions divided by the total number of sessions of the intervention and recorded as a percentage;

2) Recruitment rate was based on the absolute numbers of participants and was calculated as the number of individuals randomised into the intervention out of a total number of approached individuals. Recruitment rate was recorded as a percentage, e.g. 62.5% (25/40). It is acknowledged that advertisements may reach a large number of individuals, but it is impossible to quantify this. Therefore, the method based on formal invitations given/advertisements placed (including web-based advertisements, advertisements placed in the local cohort groups and poster and leaflet material disseminated in the community) was not used in this study for a calculation of the recruitment rate. The complete recruitment rate could not be accurately estimated;

3) Retention rate was calculated as number of participants completing the study as a proportion of those randomised;

4) The appropriateness, practicality and acceptability of the designed intervention in the proposed settings was assessed using focus group interviews. The focus group transcripts were analysed using a thematical analysis (Fossey et al., 2002), and these data were used to help the research team to improve the quality of the delivered intervention by informing positive changes in the methodology and design of the intervention for the future implementation in a consequent study;

5) The assessment rate of questionnaires was evaluated as the total number of completed questionnaires divided by the total number of questionnaires and recorded as a percentage;

6) The appropriateness of assessment tools for primary efficacy outcome measures were investigated using reliability analysis. Internal consistency reliability analysis, using a Cronbach's alpha test, was calculated for baseline and post-intervention measures for loneliness, social support (only for items 2-20 referring to functional support), social networks (a total value, family and friends' sub-scales), depression, anxiety, self-efficacy for exercise, and the Expected Outcomes and Barriers for Exercise. For the Expected Outcomes and Barriers for Exercise additional test-retest reliability analysis using Pearson's product-moment correlations was conducted at baseline within a week between measures, and coefficients of correlation (r) were reported with coefficient 0.3 – a weak, 0.5 – moderate and 0.7 and above –a strong correlation;

7) The potential sample size for the main study was calculated based on the target difference (the desired between group difference) using the ES for one or two potentially meaningful outcomes (e.g. loneliness) obtained from the literature as specified by the Delta2 guidance (Cook et al., 2018).

PHASE I. Quantitative data collection

Interested participants contacted the research team by phone or e-mail and arranged the phone-based eligibility screening with the researcher. After providing baseline eligibility screening, potential participants were offered a total five visits for health assessments at the University facility (Figure 9). Participants in the intervention group had an additional visit (Visit 4 at week 6) for

attending the mid-point focus group to assess the participants' feedback on the intervention and see if any changes were needed to modify the methods or delivery approach of the intervention. All assessments were conducted within the School of Sport and Exercise Sciences, University of Birmingham.

Visit 1 (centre-based). During the first visit potential eligible participants were asked to give initial consent to being screened for the study (Appendix 19) and completed the assessment of cognitive and physical function as the second stage of the eligibility screening. Potential eligible participants based on the assessment of cognitive and physical function completed assessment of anthropometry (stature, body mass, used to calculate Body Mass Index, BMI) and resting blood pressure. They were given the demographics and medical conditions form, and questionnaires for the assessment of loneliness, social support, social networks, anxiety and depression, self-efficacy for exercise, a level of social contacts and the Expected Outcomes and Barriers for Exercise to be completed at home. They received a copy of an information sheet that was also e-mailed prior the phone-based screening (Appendix 18) and a leaflet or a leaflet about the study (Appendix 16) and were asked to invite anyone else they know who is eligible and that might be interested in the project, in order to snowball recruiting. To assess physical activity, ActivPAL accelerometer (PAL Technologies Ltd. Glasgow, UK) was attached to the front thigh and secured with the waterproof Tegarderm dressing. Participants were given written instructions about the use of ActivPAL to take home. All participants were instructed to continue with their normal PA patterns.

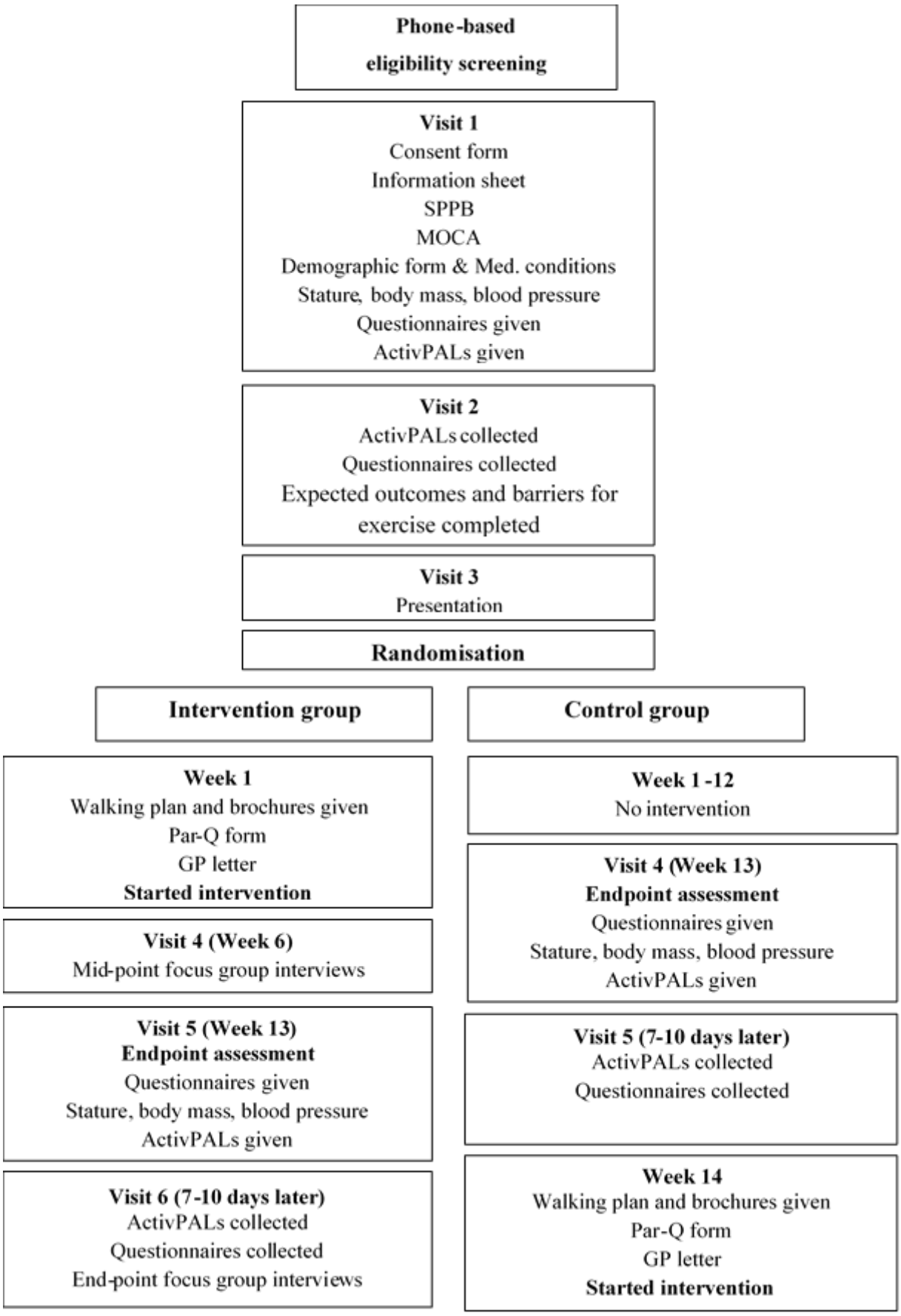


Figure 9. Chart of study visits.

Visit 2 (centre-based). During the second visit (7-10 days after Visit 1) ActivPAL monitors and completed questionnaires along with the demographic form were collected. Participants were asked to complete Expected Outcomes and Barriers for Exercise questionnaire (Steinhardt et al., 1989) for a second time (with a week interval in between) for a consequent test-retest reliability and validity analysis.

*Visit 3 (*centre-based). Potential eligible participants were invited to the centre (University of Birmingham) for the group presentation containing the detailed information about the PAIL study, had a chance to ask any questions and meet other participants. This was delivered at the University by the main researcher (AS), and included a detailed description of the project aims, methods and procedures, and a Question and Answer session. The research team registered everyone who came for the meeting using the log sheet to keep the contact information and register of the number of people who attended the presentation to gauge retention rate. Randomisation was performed using a computer-generated random sequence using list of participants' IDs performed on the Microsoft Office Excel 2016 software for Windows (Microsoft Corporation, Redmond, Washington, USA) and the intervention commenced prior to visit four this is detailed below.

Visit 4 (centre-based). During the fourth visit mid-point focus group interviews were conducted with participants of the intervention group (Week 6).

Visit 5 (*centre-based*). Participants in the intervention group had post-intervention assessments of anthropometry (stature, body mass, BMI calculation), resting blood pressure and were given ActivPAL monitors and questionnaires to be completed at home (Week 13).

Visit 6 (*home or centre-based*). 7-10 days after the end-point assessment at Visit 5, the ActivPAL monitors and completed questionnaires were collected. End-point focus group interviews were conducted with participants from the intervention group.

The control group had the post-intervention assessments of anthropometry (stature, body mass, BMI calculation), resting blood pressure and were given ActivPAL monitors and questionnaires to be completed at home at Visit 4 (*centre-based*) to coincide with the same

assessments in the intervention group. 7-10 days after the end-point assessment (Visit 5), the ActivPAL monitors and completed questionnaires were collected.

PHASE II. Qualitative data collection

Focus groups

To understand participants' experiences of taking part in the PAIL feasibility trial, focus groups were conducted with the intervention group at mid-point (Week 6) (Visit 4) and at the end of the 12 week intervention (end-point, Visit 6) using semi-structured discussions in small group (4-9 people per group) of the mixed gender (Appendix 26; Appendix 27). Focus group interviews were aimed to help the research team to improve the quality of the delivered intervention by making changes in the methodology and design of the intervention for the future implementation in a consequent study. The 32-item checklist for reporting qualitative research guided the researcher to ensure clarity and transparency of focus groups methodology (Tong et al., 2007) (Appendix 25). Participants were asked to verbally respond to a series of open-ended questions and were provided with hot beverages during discussions.

Mid-point focus group interviews (Approximate duration 1 hour) were aimed to gather participant's experience and attitudes of taking part in the PAIL study so far for a process assessment (Appendix 26). Research assistant checked if any alterations were required based on the participants feedback using the notes taking.

Endpoint focus group interviews (Approximate duration 1 hour) were aimed to explore participants' experiences for the participation in the PAIL study overall, patterns and motives for participation as well as the acceptability of instruments and questionnaires used in the intervention, overall content and delivery of the intervention, adherence of participants, and barriers to participation (Appendix 27). Additional questions were related to the participants' feedback and suggestions. Focus group interviews were conducted at the study or focus group rooms of the University of Birmingham. All focus groups were run by a trained focus group leader who was not

the intervention group lead to avoid any biasing effect on participants' responses (Elder et al., 1995). A trained focus group leader acted as a moderator and a facilitator of the group interactions on broad questions before asking focal questions aimed to make focus groups more informative (MacDougall et al., 2001).

Participants were asked not to discuss co-participants' contributions after the focus groups. Focus groups were audio recorded using a digital recorder and transcribed verbatim (and anonymised). Focus group questions and the audio recorder were pilot tested prior to their use to ensure the appropriateness of questions and the clarity of sound of the recorder (Tong et al., 2007). In case of withdrawals, reasons for withdrawal were recorded to avoid reporting of inappropriate statements (Altheide et al., 1994). Another research team member (PhD student) not involved in delivery of intervention was present by availability to make additional field notes during participant answers required for cross-checking the collected data during analysis in case of any doubts. Field notes and observation of participants (non-verbal information) were used for data analysis, interpretation of qualitative data and some alterations to the focus group interview questions (Bluff, 1997, Fossey et al., 2002). Attendance of participants were recorded in the attendance form.

Data monitoring

The data monitoring committee for this project was the supervisory research team (three academic supervisors, AW, JT, CG) who were independent from the trial sponsor, and from the funder of the PhD student. They were responsible for checking data accuracy upon assembly of the final database following completion of data collection prior to data analysis. The PhD student was responsible to monitoring and reporting spontaneous adverse events or any unintended trial effects to the supervisory team, and the PI (AW) was responsible for reporting these to the Sponsor. The trial was also subject to independent audit request by the sponsor, the University of Birmingham, by a team independent to the supervisory/research team. The sponsor contact details are given below.

Dr Sean Jennings, Head of Research Governance, University of Birmingham (e-mail: s.jennings@bham.ac.uk).

Sample size

As this was the feasibility study using the small RCT design, a sample size calculation is not normally required (Arain et al., 2010). Rather, the sample size was required to be adequate for the estimation of the critical parameters of the study, such as a primary feasibility outcomes: recruitment and retention rates (Arain et al., 2010). Based on the flat rule of thumb method for setting the sample size to minimise the sample size across studies (Kieser et al., 1996), using 80% upper confidence limit approach they calculated a total target sample of up to 40 participants for a two-arm trial (e.g. with 20 in the intervention group and 20 in WLC group) was required to minimise the overall sample size of 80-250 corresponding to standardised effect sizes of 0.4-0.7 and 90% power. Therefore, approximately up to 40 participants (20 per treatment arm) were required to be recruited in this study.

Randomisation and concealment

The information about the randomisation and concealment is described elsewhere (Shvedko et al., 2018b). Randomisation was conducted 1 week after completion of baseline measures using a computer-generated random sequence using list of participants' IDs performed on the Microsoft Office Excel 2016 software for Windows (Microsoft Corporation, Redmond, Washington, USA) performed by an external researcher not involved in the delivery of the intervention or outcome assessment. Participants were informed about the group allocation by e-mail or a phone call by a person not involved in assessments or delivery of the intervention. At the outcome assessment level, participants who were assessors of their own psychosocial outcomes using questionnaires, were blinded to their group allocation at the time of completing the initial questionnaires. Intervention providers who were responsible for outcome assessments were not blinded to the intervention

delivery as this would not be possible, given that the study and walks were conducted by the PhD student (AS) who was the researcher.

Recruitment and retention rates

Recruitment was aimed to be at a rate of 10 participants a month (to a minimum of 40 participants over each recruitment period) for estimation of the critical parameters of the feasibility study (Arain et al., 2010). If the number of recruited participants was less than 75% by the end of the four months recruitment period or if the retention rate was less than 75 % at 12 weeks (endpoint period), changes were required to be made to the recruitment strategy and the intervention was run again a few months later. No targets were set for other feasibility outcomes, e.g., questionnaire completion rates or attendance at the intervention sessions.

Progression criteria

As suggested by El-Kotob et al. (2018) feasibility studies are not adequately powered to test the hypothesis of efficacy of physical activity intervention and, therefore, *a priori* criteria for progression to the definitive large-scale RCT is advisable to consider future efforts. The progression criteria to a definitive large-scale RCT in this study was: 1) no any serious adverse events, such as hospitalisation, life-threatening condition, death and any adverse events associated with the exercise intervention experienced by less than 5% of participants per group; 2) recruitment rate of no less than 75% by the end of the four months recruitment period; and 3) retention rate of no less than 75% in each group at 12 weeks (end-point). To compare, in a 12-week Pilot Randomised Controlled Trial of a pedometer-based walking intervention, 90% (37/41) of randomised participants completed the intervention, which demonstrated a high retention rate (Mutrie et al., 2012a). If any out of three criteria were not met, there would be insufficient evidence to justify proceeding to the definitive RCT. Changes were required to be made to the intervention with the consequent re-

running of the intervention a few months later with the decision: proceed or proceed with changes. No stopping guidelines for the intervention were applied.

Attendance

To estimate the attendance rate (required for the future large-scale trial and outlined as a feasibility outcome) the research team completed the attendance logs at every session during the 12-week intervention period (Appendix 19). Attendance was calculated as the total number of attended sessions divided by the total 12 sessions of the intervention and recorded as a percentage; it was estimated by the verbal report of participants and confirmed by the attendance logs completed each week and kept by the walk leader.

Participant withdrawal

During the intervention participants could withdraw at any time without giving a reason by contacting the research team. Participants were offered to complete the withdrawal form to understand the reasons. If they did not like to be contacted about future research, they were asked to let the research team know. Any data pertaining to the participant was still used unless requested to be destroyed. This was stated in the information sheet.

Anonymity and confidentiality

To ensure anonymity, participants' names were not mentioned in any publications. However, participants were not anonymous during the intervention and their names were known to research team. During the focus group interviews, participants were called by name, however, their initials were used for transcription (e.g. NK, PA). Participants were asked not to discuss co-participants' contributions after the focus groups which was also stated in the information sheet. All data were treated as confidential. To ensure confidentiality, each participant was assigned a numeric ID code used for transcription. Documents containing personal data (signed consent forms, interview

transcripts and digital information from interviews) were stored in locked filing cabinets/on password protected university computers accessible only to the research team. Only the researchers had access to the master list linking personal data to other data coded only by unique ID number. Digitally recorded interview transcripts were stored securely on a password protected computer that only the researchers had access to. Audio recordings were destroyed after the recordings were transcribed verbatim. All other data (e.g. eligibility screening forms, activity data and questionnaire data) were pseudo-anonymised with a unique ID number and stored in locked filing cabinets/on password protected university computers.

Statistical methods

Quantitative data analysis

Quantitative data was analysed using SPSS version 25.0 for Windows (SPSS Inc., Chicago, IL) employing an intention-to-treat analysis (based on their treatment allocation and irrespective of participants' adherence or withdrawal) (Gupta, 2011). For missing or incomplete data, the code "9999" was used in SPSS software to enable efficient data screening and cleaning. Only descriptive statistics or estimates with 95% confidence intervals (CI) were reported for all outcomes. No statistical warning rule was applied to this feasibility study according to CONSORT (Eldridge et al., 2016a). Recruitment, retention and attendance rates were calculated as a number (%) and analysed relative to *a priori* criterion for progression. Means and SD were reported for continuous variables (e.g. age, stature, body mass, BMI, physical function, cognitive function, number of comorbidities, and outcomes of questionnaires). Nominal data (e.g. gender, ethnicity, marital status, living arrangements, level of education, children, and employment status) were presented as number (N) and percentage (e.g. N and % married). Differences in secondary outcomes were analyses using unadjusted mean differences at follow-up with 95% CIs using independent samples t-tests as well as a calculated mean differences and 95% CI adjusted for baseline score conducted using ANCOVA.

The accelerometer data was analysed using the ActivPAL software V8.10.3.8 (PAL technologies, Scotland, UK) (*PAL software*). Recorded data was downloaded to a computer for average daily time lying and sitting (h) in increments of 15 s, time standing (h), time stepping (h), step counts (n), and energy expenditure (EE, MET/h).

Internal consistency reliability analysis using Cronbach's alpha test in SPSS was calculated for baseline and post-intervention measures for loneliness, social support (only for items 2-20), social networks (a total value, family and friends' sub-scales), depression, anxiety, self-efficacy for exercise and the expected outcomes and barriers for exercise. The calculation of internal consistency (reliability) for satisfaction with level of social contacts and structural social support (item 1 from MOSSSS) was not relevant as it has only one item in the dimension. Data were reported for each time point of assessment (baseline and post-intervention) and an average value. A Cronbach's alpha of ≥ 0.8, a high reliability, was regarded as acceptable (Streiner et al., 2015). For the Expected Outcomes and Barriers for Exercise an average between two baseline measures were taken to report baseline Cronbach's alpha. To allow for test-retest reliability using Pearson's product-moment correlations, for the Expected Outcomes and Barriers for Exercise baseline measures were completed twice with a week difference between measures and coefficients of correlation (r) were reported with coefficient 0.3 – a weak, 0.5 – moderate and 0.7 and above – a strong correlation.

The potential sample size for the main study was calculated based on the target difference (the desired between group difference) using the ES for one or two potentially meaningful outcomes (e.g. loneliness), obtained from the literature as specified by the Delta2 guidance (Cook et al., 2018). Using the target difference, the sample size was calculated using *a priori* method for a future trial using α=0.05 and 80% power using the G-power software Version 3.1 (Erdfelder et al., 1996).

Qualitative data analysis

The qualitative data (focus group interviews) were analysed using inductive thematic analysis by two researchers (AS, JT) independently. Thematic analysis refers to analysis of data by identifying, analysing and reporting patterns (themes) (Braun et al., 2006). It includes the comparative method (Lincoln et al., 1985) which involves processes of clarifying, comparing, grouping and refining grouping of text segments to create the definition categories (or themes). Therefore, thematic analysis develops categories derived from the data rather than *a priori* theory for the interpretation of data (Fossey et al., 2002, Tesch, 2013). During analysis, segments were coded, sorted and organised to look for patterns, or connections, between them (Tesch, 2013). Digitally recorded interviews were transcribed verbatim using the foot pedal controlled Express Scribe Transcription Software (NHC Software Ink., USA). Transcripts were returned to participants for comments/correction to ensure transparency and trustworthiness of the data (member checking) (Fossey et al., 2002, Tong et al., 2007). Validated transcripts were read several times by two independent researchers to obtain an overall meaning. Then, themes and subthemes with important meanings common for all participants were derived from the obtained data. Results were compared through discussion between reviewers. Coding (labelling segments of data for examination) (Fossey et al., 2002) was conducted using a qualitative data indexing package QSR NVivo V.12 for Windows. The research team members who coded data was different from the focus groups leader. Quotations illustrating a particular point were highlighted and assigned a specific code (or a subtheme). Direct quotes from each group were grouped under thematic headings (and assigned a participant number who made the quote, gender and age) for a better classification of phrases and identification of frequency of mentioning these themes by participants. Grouped results were consequently analysed in-depth to provide a narrative description of core elements of participants' experiences. Themes were refined through comparison across different phrases. Finally, the summary of data containing the main themes was presented. Minor themes or diverse cases were discussed between the researchers during informal discussion. Maps with main themes and

subthemes from mid- and end-point focus groups, and a word map with the barriers were created using the N-Vivo Version 12 software for Windows.

Trustworthiness

Mid-point (N=2) and end-point (N=2) focus group interview transcripts were re-read several times by the main researcher (AS) to ensure the clarity and transparency of the qualitative data allowing to gather the meaning. To ensure consistency, the main researcher (AS) had a discussion and thorough analysis of notes produced by the focus group assistant. The transcripts were coded by two researchers independently (AS, JT), followed by a subsequent discussion and comparison of results and identification of main themes and subthemes. Initially, the set of coding was developed which formed the basis for data analysis. Following this, mind-maps with main themes and subthemes were made, and refined until agreement was achieved and confirmed by the citations obtained from the transcripts. In any doubts regarding the understanding of the colloquial expressions (e.g. "Englishness") the main researcher (AS) had a third party involved (AW) to resolve any issues regarding the understanding of the meaning to maximises the reliability. The reliability in qualitative study is referred to "generating of understanding" (Stenbacka, 2001, p. 551) or gathering the meaning to prevent the situation to become confusing or enigmatic (Golafshani, 2003). Additionally, the description of the study methodology includes the information about participants, settings, procedure, methods and data analysis, which enable transferability of the research in other similar settings (Creswell et al., 2000). Fieldnotes produced during interviews were discussed and used for determining any bias produced during interpretation of the data. The researcher produced the notes with her thoughts and past experiences, that could cause bias during the data analysis and kept them throughout the data collection and analysis in a form of a personal journal. This self-disclosure allows minimisation of inequalities between researcher and participants, that is often experienced by participants in interventions (Creswell et al., 2000).

The validity in qualitative research instead is described as "how accurately the account represents participants' realities of the social phenomena and is credible to them" (e.g. credibility) (Creswell et al., 2000, p. 124). It was established in this study through the following three processes. Firstly, through the lens of the researcher as to whether the data was fully saturated to derive themes or categories; the researcher was coming back to transcripts over and over again to see if derived themes, categories and meanings made sense, referred to as "validity-as-reflective-accounting" (Denzin, 1994, p. 489). Also, through the lens of the researcher, validity was maximised through the process called "disconfirming evidence" or a search for negative evidence (Creswell et al., 2007). During this process, main themes were defined and then the data searched for disconfirming evidence or a consistency with the established themes. The search for disconfirming evidence helps to establish credibility and is in agreement with the complex reality of the constructivism approach adopted in this study. Secondly, validity was ensured through the lenses of participants of the study who ensured the reality was interpreted in the final account as accurately as they presented it by checking the obtained meanings with what they actually said (Creswell et al., 2000). Also, transcripts were returned to participants for verification to ensure transparency and trustworthiness of the data (member checking). Thirdly, through the interpretations of reality from other experts, not involved in the intervention design or delivery but familiar with the researched phenomenon (e.g. loneliness in ageing) and familiar with the research. This was aimed at improving the understanding of constructed reality by others referred to as peer debriefing (Creswell et al., 2000). During the peer debriefing, the external researcher (EA) was asking questions about methods and interpretations, challenged the researcher's assumptions to add more ideas to the data analysis and add credibility to the study (Creswell et al., 2000).

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CHAPTER 4. FEASIBILITY AND ACCEPTABILITY OF THE PAIL INTERVENTION

This chapter presents the results and discussion of the implementation of the PAIL intervention and focuses on the feasibility and acceptability of the intervention. As is common in feasibility studies, both quantitative and qualitative methods were employed. The results related to implementation, feasibility and acceptability are presented first, followed by a discussion of the findings in relation to the existing literature on the topic. Study limitations and future recommendations are given to inform a future larger scale randomised controlled trial, and information is provided for healthcare professionals, individual researchers, public organisations and community services with a broad knowledge of the research problem. Given that the qualitative data cover several of the initial aims (Chapter 1 Introduction), the data supporting each of the original aims are not presented in numerical order as described in the Methodology (Chapter 3) but are addressed in each section describing the quantitative and qualitative analyses applied to address those aims. This chapter has been submitted as a paper to the *Pilot and Feasibility Studies* journal and is under review. The submitted manuscript can be found in Appendix 28 of this thesis.

Quantitative Feasibility and Acceptability Primary Outcomes

PAIL was a two-arm, 12-week randomised feasibility trial with a WLC group delivered in Birmingham, United Kingdom, from in two Waves from February, 2018 to April 2018 (Wave 1) and from June 2018 to August 2018 (Wave 2). Quantitative data analyses were completed in November 2018; qualitative data analyses were conducted iteratively over the data collection period from March 2018 onwards.

Participant characteristics

Participants were 25 (mean age 68.5(8.05) years, range 60-92) healthy, inactive, community-dwelling older adults, 14 (56%) female, and 18 (72%) white. Baseline descriptive statistics classified by intervention and control group are shown in Table 1. Baseline group characteristics for questionnaires and functional tests are shown in Tables 2 and 3.

Table 1. Baseline socio-demographic, anthropometric and health-related characteristics of study participants by group (n=25).

Variable	**Intervention (n=12)**	**Control (n=13)**
Age, years	68.4(5.9)	67.3(11.5)
Range, years	61-76	60-92
Male to female	5:12	6:13
White, n (%)	7(58.3)	11(84.6)
Marital status, n (%)		
Married	4(33.3)	2(15.4)
Single/never been married	4(33.3)	4(30.8)
Divorced/separated	2(16.7)	5(38.5)
Widowed	2(16.7)	2(15.3)
Living alone, n (%)	8(66.7)	9(69.2)
Education, n (%)		
No qualification	2(16.7)	1(7.7)
Secondary education	2(16.7)	4(30.8)
College degree	3(25)	2(15.4)
University degree or higher	5(41.7)	6(46.2)
Having children, n (%)	7(58.3)	10(76.9)
Not employed /retired, n (%)	10(83.3)	8(61.5)
Comorbidities, n (%)		
0	3(25)	3(23.1)
1	5(41.7)	2(15.4)
≥2	4(33.3)	8(61.5)

Physical function (SPPB score ≥ 9 points)	10.3(1.2)	10.8(1.0)
Cognitive function (MOCA score ≥ 22 points)	28.3(1.9)	27.5(2.4)
Stature, m	1.7(0.1)	1.7(0.1)
Body mass, kg	68.2(12.8)	68.8(14.2)
Body mass index, kg/m^2	24.7(3.0)	24.7(3.4)
Systolic blood pressure, mmHg	128.9(7.9)	133.1(16.6)
Diastolic blood pressure, mmHg	75.7(8.9)	77.9(11.9)

Values are the mean (SD) unless stated otherwise.

Abbreviations: n- number; SPPB – short physical performance battery, MOCA – Montreal cognitive assessment scale.

Table 2. Baseline psychosocial characteristics of study participants by group (n=25).

Questionnaires	**Intervention (n=12)**	**Control (n=13)**
UCLA-8	18.2(5.8)	17.8(5.1)
Structural SS	4.8(2.7)	5.5(5.5)
Functional SS	62.1(19.8)	63.7(20.5)
LSN (Total)	14.6(5.2)	12.5(5.3)
LSN (Family)	6.7(3.8)	6.5(2.9)
LSN (Friends)	7.9(3.7)	6.0(4.7)
Depression	6.7(2.8)	5.1(3.4)
Anxiety	7.6(3.2)	6.8(3.0)
SEE	7.1(1.8)	6.3(1.8)
SSC	6.8(3.2)	5.4(3.6)
Expected outcomes	4.2(0.6)	3.9(0.5)
Barriers for exercise	2.8(0.9)	2.9(0.7)

Values are the mean (SD) unless indicated otherwise.

Abbreviations: n- number; UCLA- 8 – 8-item University of California, Los Angeles loneliness scale; LSN – Lubben's Social Networks, SEE – Self-Efficacy for Exercise; SS – Social support; SSC – Satisfaction with Social Contacts. For loneliness, depression, anxiety and barriers for exercise, lower values indicate better scores (e.g. less loneliness).

Table 3. Baseline physical activity characteristics of study participants by group (n=25).

Average daily physical activity	**Intervention (n=12)**	**Control (n=13)**
Time lying/sitting (h)	17.1(2.5)	16.9(1.6)
Time standing (h)	5.4(1.9)	5.4(1.5)
Time stepping (h)	1.7(0.7)	1.7(0.6)
Step counts	7956.5(3381.3)	7752.8(3218.1)
Sit to stand transitions (n)	43.3(11.3)	57.6(15.8)
Energy Equivalent (METs/h)	33.9(1.4)	33.9(1.3)

Values are the mean (SD) unless indicated otherwise.

Abbreviations: h-hour; n- number; METs – metabolic energy equivalents.

For ActivPAL measurements, for every individual at each visit attended from a total of 2 visits, 7 days' continuous wear time was available (Table 4). Of the 280 days of data in total 9 (3.2%) days recorded showed less than 1000 steps.

Table 4. Missing values for ActivPAL step counts.

	Missing days of ActivPAL data	
	Intervention (n=12)	**Control (n=13)**
Baseline, N (%)	3/280 (1.1%)	4/280 (1.4%)
12 weeks follow-up, N (%)	2/280 (0.7%)	

For ActivPAL wear time, the proportion of participants providing valid data for a minimum of 5 days of continuous wear time is shown in Table 5.

Table 5. The ActivPAL wear time.

	Wear time (days)	
	Intervention (n=12)	**Control (n=13)**
Baseline, N (%)	12/12 (100%)	12/13 (92.3%)
12 weeks follow-up	10/12 (83.3%)	13/13 (100%)

a- To be valid a minimum of 5 days of continuous ActivPAL wear time was required.

Feasibility outcomes

Recruitment and retention

Participant recruitment was in two waves from September to January, 2018 (recruitment Wave 1) and from January, 2018 to May, 2018 (recruitment Wave 2) before the randomisation of the second wave of participants. The intervention was advertised using 145 leaflets and 47 advertisement posters (N=192) in the local community, which yielded 45 individuals expressing interest. An additional three individuals were recruited through referrals from friends. In total, 48 potential participants showed an initial interest in the intervention and the phone-based screening was arranged (52.1% recruitment rate; 25/48).

The flow of participants through the study is shown in Figure 10. From an initial pool of 48 potential participants, two declined to participate before completing the phone-based screening. Forty-six potential participants were assessed for eligibility using the phone-based screening with 21 excluded due to not meeting the eligibility criteria (N=18), declined to participate (N=2) and no response (N=1). Reasons for not eligibility were: already physically active or taking part in another intervention (N=11) or not at risk of loneliness (as assessed using the phone-screening tool) (N=7).

Reasons for declining to participate were: pressures of work/lack of time (N=1) and health reasons (N=1). A total of 31 participants (31/46, 67.4%) attended the further eligibility screening at Visit 1, and 25 were eligible to proceed with baseline assessment (Visit 2). This resulted in a total sample of 25/46 (54.4%) starting the 12-week intervention. Consent was obtained prior the baseline screening from 100% (25/25) potential participants (details of ethical approval were reported in Chapter 3 Methodology). Twenty-five eligible participants (25/46, 54%) were invited to attend the presentation about the PAIL intervention (Visit 3).

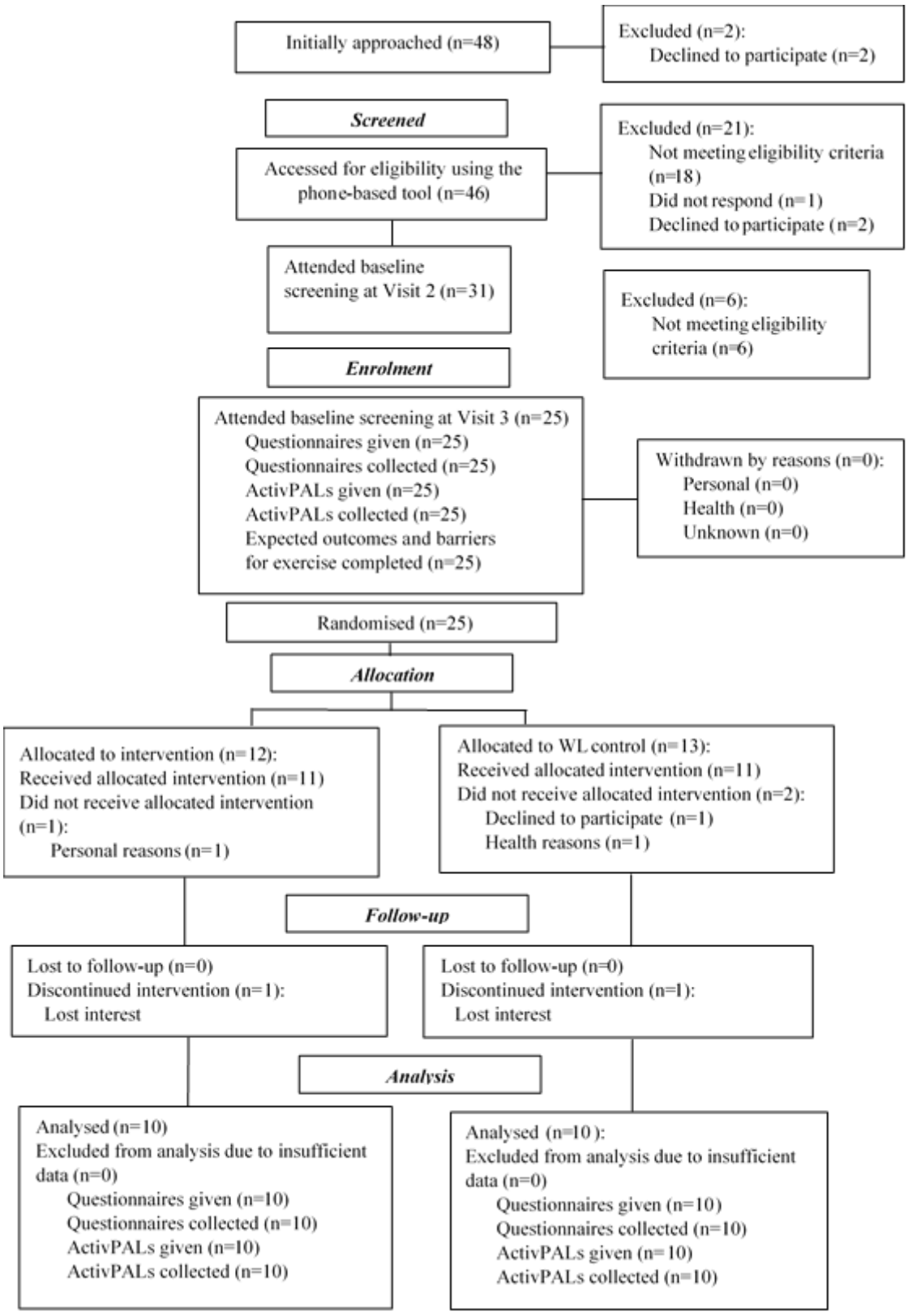


Figure 10. CONSORT flow diagram of Physical Activity Intervention for Loneliness (PAIL) intervention.

The attendance rate was 28% (7/25) at the initial information presentation session; reasons given for not attending were lack of time or other personal reasons. The 25 participants were then randomised into the intervention (N=12) and WLC group (N=13) using computerised random-sequence generation. No participants objected verbally to randomisation at this point, when the opportunity was given to discuss their views on randomisation. Withdrawals occurred post-randomisation due to mainly personal and health reasons (e.g., knee or hip pain limiting their ability to walk). One participant from WLC group dropped out prior to completing end-point measures due to not wishing to wait for the start of the intervention. One intervention group participant discontinued the intervention due to loss of interest. Using Wilson's 95% confidence interval, at 12 weeks, 10/12 (83.3%; 95% CI 55.20 to 95.30) intervention and 10/13 (76.9%; 95% CI 49.74 to 91.82) control participants completed final assessments (Wilson, 1927). The retention rate satisfied the criteria of the study, e.g. > 75% of participants at 12 weeks (end-point period), although the recruitment rate of 52.1% by the end of the four months was somewhat lower than was initially proposed at 75% (see Chapter 3). There were no serious adverse events, or any adverse events observed related to study participation.

Attendance

The average attendance rate for the total of 12 sessions of the walking intervention was 69.2% for the intervention group, with attendance ranging from 25% to 91.7%; Figure 11 shows the weekly average attendance rate (%) for the 12-week walking intervention. The average attendance rate for WLC group was 55%, with attendance ranging from 25% to 91.7%. The mean (SD) number of attended sessions per person was 8.3 (2.5) and 6.6 (2.6) in the intervention and WLC group, respectively. After completing the 12-week intervention, a total of 7/10 participants from the intervention group and 6/10 participants from WLC group continued walking (Chapter 3). The follow-up attendance rate assessed during the 12-week post-intervention period was 54.8% (from 25% to 83.3%) for the intervention group and 62.5% (from 33.3% to 83.3%) for the wait-list control

groups, respectively (Figure 12). The mean (SD) number of attended follow-up walking sessions per person was 6.6 (2.2) in the intervention group and 7.5(2.4) in the WLC group out of a maximum of 12 sessions.

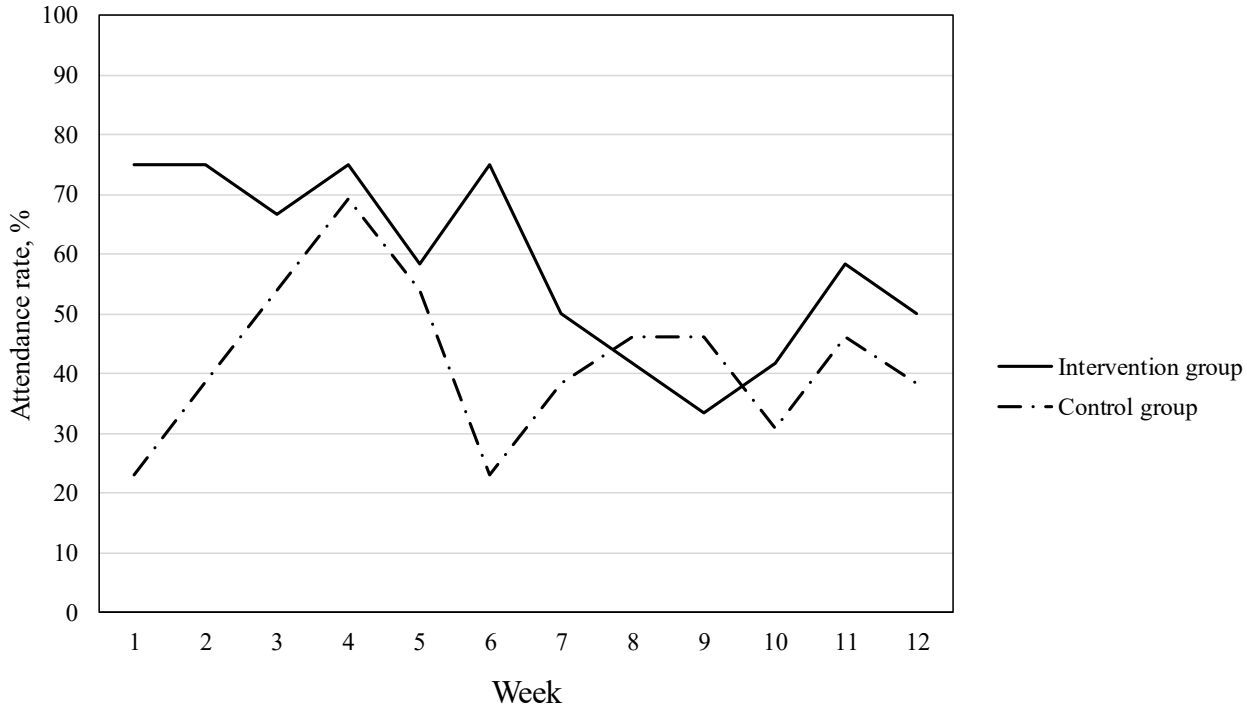


Figure 11. Weekly average attendance rate (%) for the 12-week walking intervention

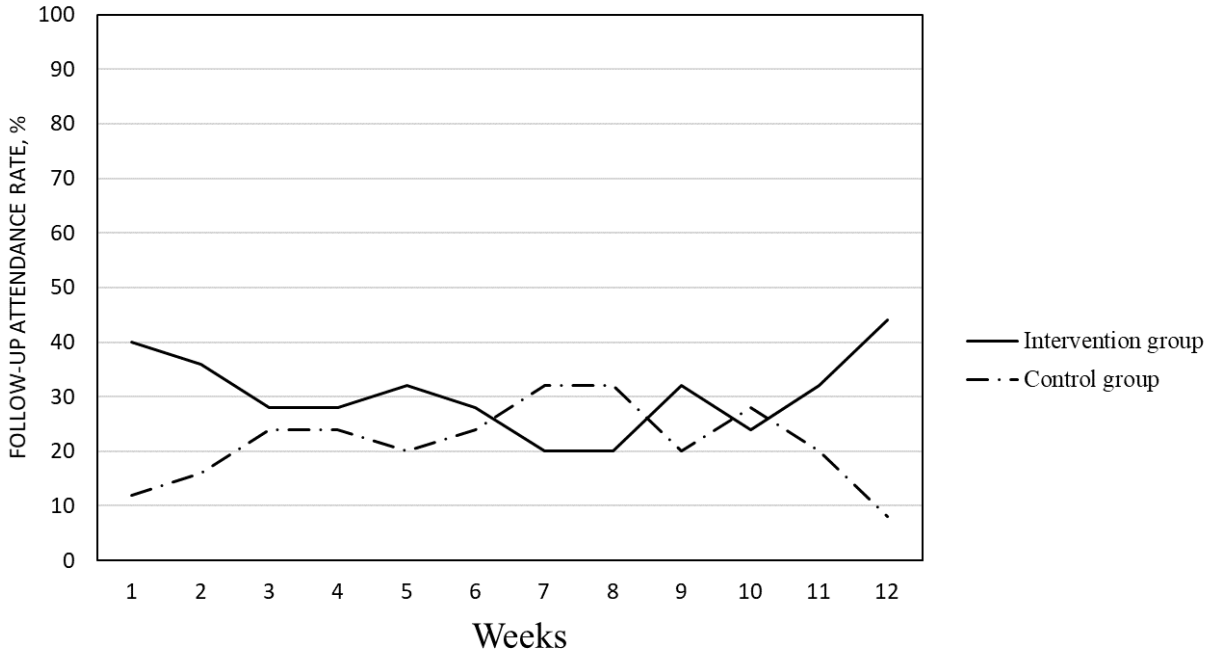


Figure 12. Weekly follow-up attendance rate (%) for the 12-week walking intervention

The assessment rate of questionnaires

Baseline questionnaires and accelerometer data were provided by 100% (25/25) of participants recruited into the study. After the initial information presentation, no participants declined to take part in the intervention. Post-intervention questionnaires and end-point accelerometer data were provided by 83.3% (10/12) experimental and 76.9% (10/13) control group participants.

The appropriateness of the assessment tools

The appropriateness of assessment tools for primary efficacy outcome measures was investigated using Internal consistency reliability analysis (Cronbach's alpha test), calculated for baseline and post-intervention measures for loneliness, social support (only for items 2-20), social networks (a total value, family and friends' sub-scales), depression, anxiety, self-efficacy for exercise and the Expected Outcomes and Barriers for Exercise. Data were reported for each time point of assessment (baseline and post-intervention) and an average value. For the Expected Outcomes and Barriers for Exercise an average between two baseline measures were taken to report baseline Cronbach's alpha. To allow for test-retest reliability using Pearson's product-moment correlations, for the Expected Outcomes and Barriers for Exercise baseline measures were completed twice with a week's difference between measures. The average internal consistency reliability was high for all psychosocial outcomes: loneliness (Cronbach's alpha 0.857), social support (Cronbach's alpha 0.975), Lubben's social networks (Cronbach's alpha 0.721), depression (Cronbach's alpha 0.744), anxiety (Cronbach's alpha 0.693) and self-efficacy for exercise (Cronbach's alpha 0.925) (Table 6).

The expected outcomes for the exercise sub-scale of the Expected Outcomes and Barriers for Exercise questionnaire showed high internal consistency reliability at baseline, with Cronbach's alpha equalling 0.926 (a week before) and 0.938 (a week after); at post-intervention the value was 0.976. Barriers for the exercise sub-scale of the Expected Outcomes and Barriers for Exercise questionnaire showed high internal consistency reliability at baseline, with Cronbach's alpha

equalling 0.888 (a week before) and 0.924 (a week after); at the post-intervention period the value was 0.943.

Table 6. Internal consistency reliability (Cronbach's Alpha) coefficients for psychosocial outcomes.

Variable	Cronbach's alpha		
	Baseline	Post-intervention	Average
Loneliness	0.858	0.856	0.857
Social support	0.973	0.976	0.975
LSN (Total)	0.692	0.750	0.721
LSN (Family)	0.821	0.905	0.863
LSN (Friends)	0.945	0.911	0.928
Depression	0.718	0.769	0.744
Anxiety	0.629	0.756	0.693
SEE	0.919	0.931	0.925

Notes: LSN – Lubben's social networks, SEE – self-efficacy for exercise.

Findings from the qualitative study

The appropriateness, practicality and acceptability of the intervention by participants

Focus group interviews were conducted only for participants in the intervention group (Figure 9, Chart of study visits), as their purpose was to explore the feasibility and acceptability of the PAIL intervention. The 32-item Consolidated criteria for Reporting Qualitative research (COREQ) (Tong et al., 2007) (Appendix 25) were used to guide the researcher to ensure clarity and transparency in the focus group methodology.

Due to practicality issues, the second coder was not available and an independent researcher (JT) was cross-checking the main themes and sub-themes to ensure the transparency of the research. During the search for disconfirming evidence the researcher had to consult with the independent

researcher (JT) for the understanding of the right interpretation of meanings of "Englishness" and that the member checking the main researcher (AS) has received the correct interpretation of the meaning of the "finesse (from French)" and the meanings regarding the terminology of 'older' adults. The original understanding of the researcher was that the hoops are too tight referring to the strict eligibility criteria. Participants believed that older adults at 60 years of age should not be called "old" or "older". However, the corrected meaning was that the older age is not about the number of years, but about the experiences that people have at this age and their emotional and intellectual capacities for social interactions. A person a hundred years old can participate in the intervention, but won't be able to pass the physical testing defined *a priori*.

I. Mid-point focus groups

A total of 5/12 (42%) participants in the intervention group attended two mid-point focus group interviews conducted in March 2018 (for the Wave 1 Intervention group) and July 2018 (for the Wave 2 Intervention group). The attendance rate at the focus groups was 41% (5/12) at each mid-point period. Participants ranged in age from 62-76 years, 60% (3/5) female, 80% white, with 60% (3/5) living alone, having a university degree, having children, being retired and having one medical condition (Table 7).

The responses of participants are summarised under three main themes and displayed graphically for: 1) study design and recruitment (22 subthemes), 2) healthy workshops (17 subthemes), and 3) walking sessions (14 subthemes) (Figures 13, 15, 16). Participants were given pseudonyms.

Theme 1: Study design and recruitment

The study design and recruitment themes from the mid-point focus group interviews are shown in the Figure 13.

Table 7. Summary of participant characteristics of mid-point focus groups.

Pseudonyms	**Age (years)**	**Sex**	**Ethnicity**	**Marital status**	**Living arrangements**	**Level of education**	**Any children**	**Employment status**	**Number of chronic medical conditions**
Andrew	68	Male	White	Married	Living with others	University	No	Retired	0
Ben	65	male	white	single	living alone	university	no	employed	1
Alison	75	female	white	divorced	living alone	college	yes	retired	1
Sarah	76	female	white	widowed	living alone	secondary school	yes	retired	2
Kate	62	female	Other	married	living with others	university	yes	Full time	1

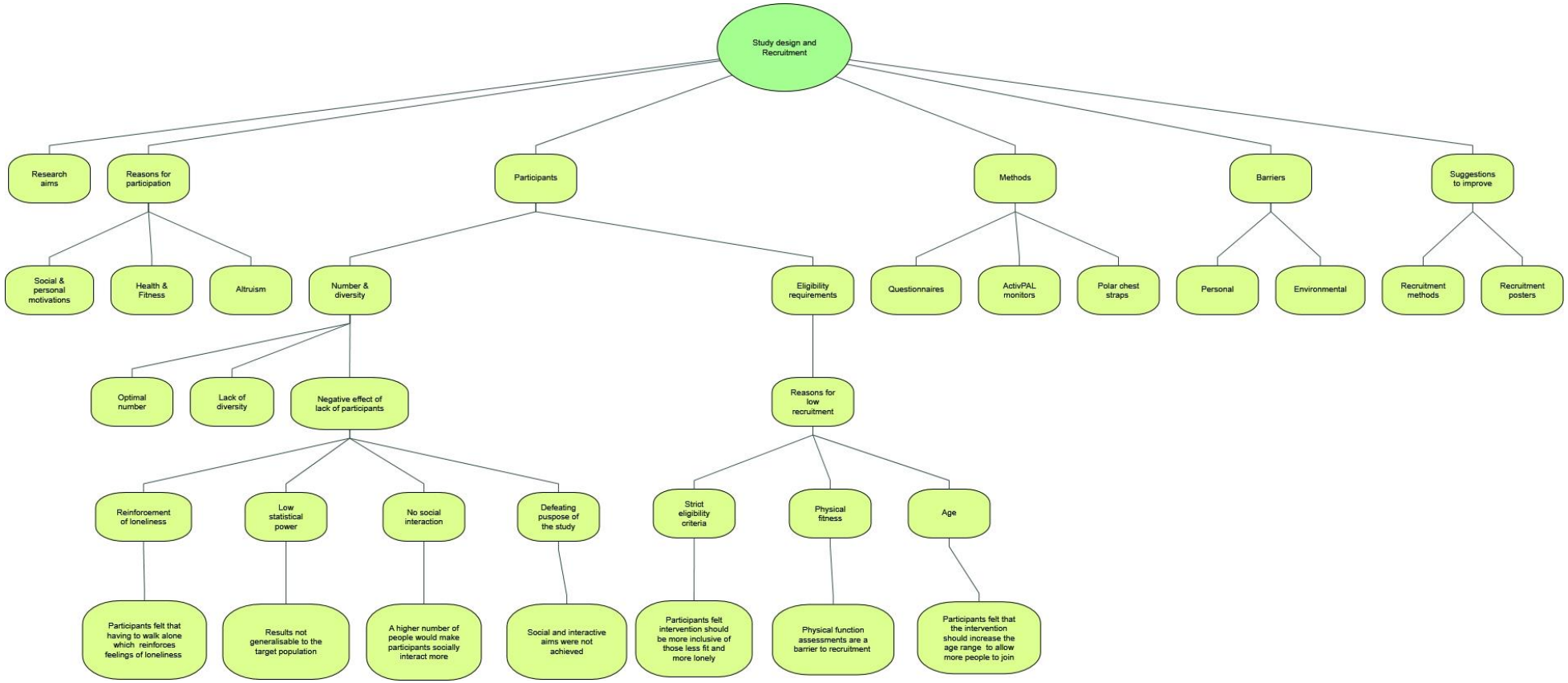


Figure 13. Study design and recruitment themes from the mid-point focus group interviews.

Reasons for participation

One main reason for participating in the intervention was to 'keep going' and make an effort to get out and about to be active and healthy:

"(.) I think you know there are all these motivations and keeping going, you have got to keep going. You have got to keep going. And it is an effort, and as you get older it is more of an effort, that you have got to do it if you want to be well" (Alison, 75, female).

Participation in the walking intervention for some participant was a diversion from stress:

" (.) the reason that I really joined this group, it is because I am given a chance by my work manager, that if it is for the sake of (.) because last year we had a rough year. My husband had a heart attack, so I have to look for something diversional to take all the stress out of this world and myself. He is not back to work" (Kate, female, 62).

Others experienced worries associated with the retirement period and the need to find a hobby to do something in their free time:

"We are already retired, yes, I still have a plan to retire. However, they said: "You should have a hobby before you retire and you should have an interest to do first before retiring". Oh, I said, I am doing it now (.) *It opens my mind that I should have one of these things first before I retire, because maybe you will be feeling bored. I don't know, I haven't been there, but it is an opening up to myself and I am an opener"* (Kate, female, 62).

The appropriateness and practicality of the designed intervention in the proposed settings

Research aims

Participants had the impression that PAIL intervention was too formal at the start of the project and was lacking social engagement between participants:

"It is an impression we have got. What purpose is it for, it is just an academic thing? It is going to help people, or it is an academic exercise?" (Andrew, 68, male).

Due to a low number of participants engaging in the intervention at Wave 1, the project aims were questioned by participants as this was "defeating the purpose" of the PAIL project, which was to decrease feelings of loneliness. This led to them question the benefits of participation in the intervention:

"I am just getting more of an impression it is just the academic exercise, you know (.) so I don't feel I am getting anything out of it (.)" (Ben, 65, male).

Negative effects of low number of participants

The participants' lack of understanding about the aims of the intervention combined with the low number of participants during Wave 1 (February to April 2018) appeared to reinforce feelings of loneliness at the beginning of the project, and led to participants' uncertainty about the continuation of the walking intervention after the formal intervention period of 12 weeks (during follow-up):

"Yeah, but you know at the same time, you may have [a lot of things] in common with a couple of, [people] you know (.) It's not just like finishing and you are going away and just all going to a separate place, you know (.) That just reinforces the fact that you are on your own to some extent" (Ben, 65, male).

*"I would, I can't see this having any relevance when you have the (.) the stretching round. It makes the whole study rather irrelevant. I mean statistically it is meaningless. Unless you got probably at least a dozen it is still statistically quite low" (*Andrew, 68, male).

Focus group participants speculated that the reasons for lack of participants in Wave 1 were associated with what they perceived as strict eligibility criteria, such as age limitations, physical fitness, and diversity of participants. Some expressed that, in particular, a wide range of ages and cultural diversity makes a significant difference in participants' experiences and can enrich the group both socially and culturally:

"You need to select, I think you need a range of people basically, and range of ages" (Ben, 65, male).

"You will learn more. You know, from different people. I mean, I lived all over the world, but you learn more from different people and different cultures and different attitudes" (Andrew, 68, male).

The terminology of 'older' adults, in the opinion of some, was underestimating their biological age and intellectual abilities and it was suggested to define the older adult category using other additional methods, such as memory tests, or to broaden inclusion criteria:

"My father is a hundred and he can't walk anymore but he is pretty fit, and he is still doing research projects here, but half the research projects in a medical school won't take everybody over 80. There are more and more and more people over 80, so why they aren't including them in the research?" (Andrew, 68, male).

"I know lots of people who use computers every day. They use computers even in their 70's or 80's. It is a question of addressing groups of people who was interested" (Andrew, 68, male).

Barriers for participation

The word map of barriers to participation is shown in Figure 14. Among barriers for participation in the PAIL intervention were personal and environmental barriers. Environmental barriers were transportation, the weather and the walking routes. Participants found it difficult to get to the location by public transport, or to find the nearest parking area if the meeting point was on campus:

" (.) it is time-consuming. And it is actually difficult to get here. I have to take a bus. A car park is about 20 minutes away, so it is physically difficult. On one Saturday I couldn't get in [to the campus] and I spent about half an hour waiting for someone to get me out and let me in" (Andrew, 68, male).

"And some of the walks, like [the place of the walk], although it wasn't that particularly early, it's getting there… [an issue] on public transport" (Sarah, 76, female).

Delivering the intervention during spring-summer was perceived to be more pleasant than delivering during the winter:

*"Yeah, I thought It would be probably more pleasant doing it in the summer and there will be like, more people doing it maybe (.) you know we were being in an early group and it's winter you know, and it does make it [difficult] (.)"(*Ben, 65, male).

Participants felt that walking on the hilly footpath with tree branches may be not safe and can become a potential barrier for participation for those with poor balance:

"The only other barrier I had was the (location of the walk) one, where we joined forces with the [name of the walking group] you meet every Thursday. It was because it is (location of the walk) and it's self-explanatory (laughs), it was hilly and it wasn't a footpath, it was a route through oak trees and it wasn't an easy path to follow. So, I spent most of the time looking down in case I fell over tree roots. So, I wasn't taking in any surroundings, so I had to be careful because I don't know whether it's because I was (.) and I wear glasses, when I looked down [Nick: You were dizzy?] I had to be careful. I was very aware that I could easily trip so whether that would apply to other people as well I don't know" (Sarah, 76, female).

Personal barriers included lack of time associated with family and community celebrations, holiday, home refurbishments, and carer responsibilities:

"Yes, it is difficult. You have to decide which is the priority, don't you? Are you the priority in walking in the group, or what is your consequence of doing the priority? You just have to decide what the priority is" (Alison, 75, female).

"There is also one who is taking care of a father, he is a carer maybe, he is with a father" (Kate, 62, female).

For others one of the personal barriers was lack of time associated with their job before they joined the intervention:

"The only thing that gives me some area that I cannot attend is my work and my commitment before I joined this" (Kate, 62, female).

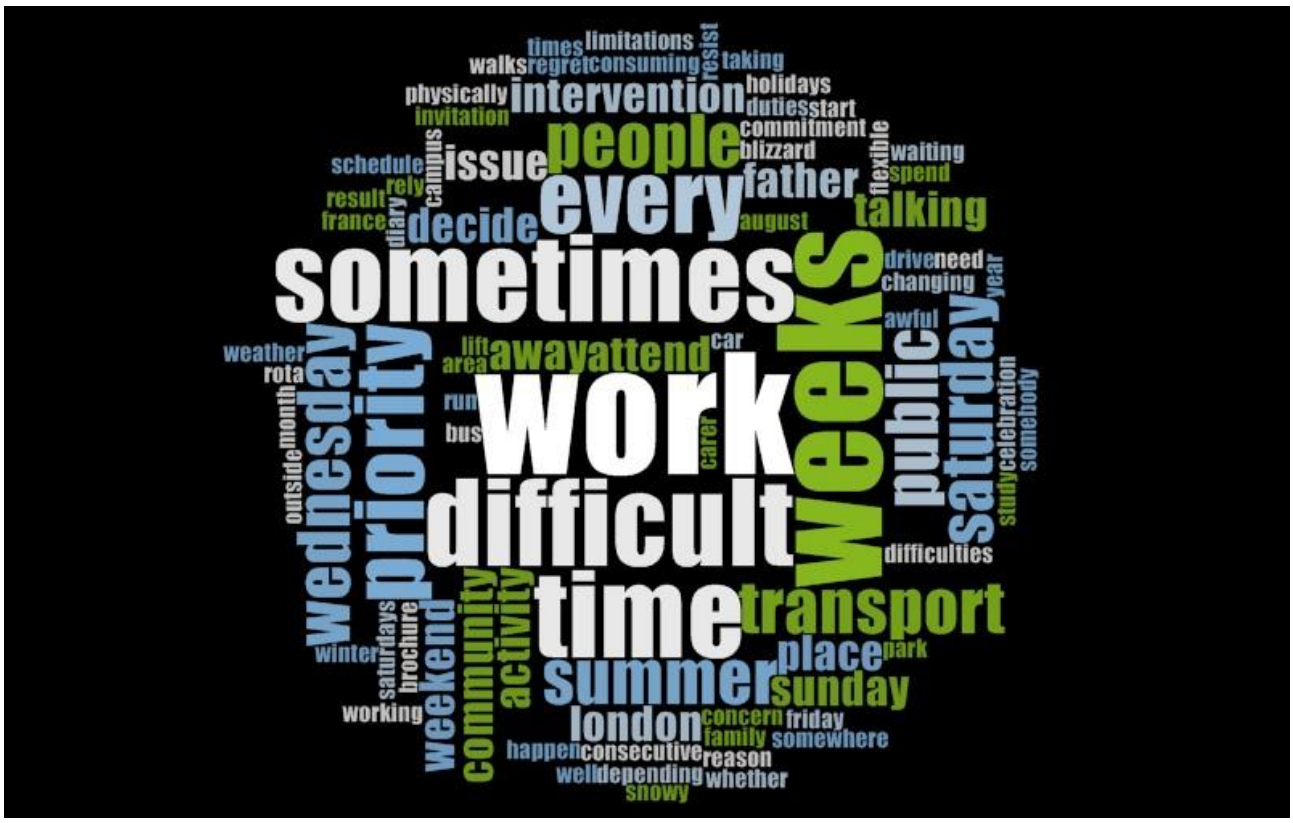


Figure 14. Word-map of barriers for attending the PAIL intervention from mid-point focus group interviews.

Commitment to 12 weeks for the walking sessions was named as one of the barriers for some participants, and it was suggested to highlight and remind participants about the total length of the intervention prior to their participation and to highlight the intervention length more visibly in the recruitment posters.

"I wonder whether on the brochure you could say actually it would have been three months' time, and we would like you to spend 12 consecutive weeks doing it, that would be the ideal. I think if that's made clear you will then clear your diary (.) so what I can do at that time because I then have got 12 weeks I can actually do. Because when you are actually coming to do the pilot study, and are going to need people to be there most of the weeks, aren't you?" (Alison, 75, female).

There were no emotional barriers identified that affected their ability to attend the intervention:

"Well we just said what is practical. But for emotional (.) none really" (Ben, 65, male).

The appropriateness of questionnaires

In general, participants did not experience any difficulties with completing the questionnaires and most stated that the set of questionnaires they were asked to complete was what they would expect. However, one participant stated that there were quite a lot of questionnaires to be completed:

"I don't mind doing paper work, but I was a bit surprised about the initial set of them, I thought it was quite a lot of them" (Ben, 65, male).

For participants with low literacy or whose native language was not English, one participant emphasised that extra help may be needed with interpreting the questions:

"That may not be for people with the language difficulties" (Alison, 75, female).

ActivPAL monitors

The ActivPAL monitors were viewed as relevantly easy to wear and in general, participants did not report any negative feedback regarding wearing the monitors. Participants were provided with the information sheet about the use of the ActivPal monitors and were asked to report any discomfort or to give any feedback about the monitors. However, they felt that using other types of activity monitors, especially those worn on the wrist that show readings about activity performed on the display, would be more advantageous and could encourage participants to increase their daily physical activity:

"I have all sorts of monitors, so I got used to it. But there are better ones than this model. You can get heart monitors that are watches so you don't have to bother about them, less of a fuss. I have one that I keep in my pocket (better)" (Andrew, 68, male).

" (.) we have no idea what are they recording. What did they achieve, no idea" (Andrew, 68, male).

Polar chest straps

Polar chest straps were not quite acceptable due, to technological requirements, however, they were viewed highly positively by those participants who could connect them to their phones. By connecting to the mobile phone via the Bluetooth app, the Polar chest straps informed participants about their activity zones both visually and audibly (with a voice recorder) and gave instructions to increase the speed or slow down during walks to keep participants "updated". They were instructing participants to slow down or move faster based on the pre-set HR zones. The only limitation was that Polar chest straps have to be connected to the phone via Bluetooth and require participants to be "techy" or have the latest models of phones (Android or Mac) which is not always feasible. Only 4 out of 25 participants were willing to wear chest straps and could connect them to their phone, however all four of these individuals had a very positive view of this technology and wanted to continue wearing the monitors after the programme ended:

"I was given this monitor [talking about the chest strap to measure heart rate during walks]. That is the best that I experienced (.) It is telling me to slow down and it tells me also (.) these calories that I burn, I am happy about that. I always said when I walk home, it is beneficial to me. That's what I like as well" (Kate, 62, female).

The acceptability of the intervention by participants and willingness to participate

Suggestions to improve study design and recruitment

Among suggestions to improve the study were some related to recruitment methods, such as more widely advertising in the community, through hospitals and university resources:

"(.) but the other thing I suggested to her was there is a group that, there are physios at the [local hospital] who do special sessions for people who just have had a heart surgery. Why not tagging to them? (.) if you could spoke to the physio, they'd say this is a great idea (.) I mean they have people because I had heart surgery last year. They have people and they are only giving them, they are only allowed to give them eight sessions. This will be a natural continuation for those people and they have ten to fourteen people for each group. Some of them will probably love it. And then you get more people" (Andrew, 68, male).

Some of participants suggested placing advertisements for participant recruitment at "the place of the worship", e.g. churches and mosques, to reach ethnically diverse population groups.

"And they tend to have a [name of the magazine], you know churches, and they tend to advertise in [name of the magazine] that reaches a lot of people as well" (Alison, 75, female).

Recruitment posters were suggested to be redesigned to contain more condensed information about the intervention to attract participants and outline the 12-week intervention more visibly:

"The only thing I can think is from what we have discussed today, some of it can be condensed down and put it on the promotion sheet that you have sent out, so (contain) a bit more information on the posters to encourage people, you know. "Do you want to meet more friends, do you want to (.)", - I don't know. Just to condense what we just have said really" (Sarah, 76, female).

Theme 2: Walking sessions

The map of walking sessions themes from the mid-point focus group interviews is shown in Figure 15.

Health effects or benefits

Overall, participants had very positive views of the walking intervention, naming among the benefits of walking, its cost-effectiveness in terms of the economic benefits for older adults who lived their adult lives as single parents:

"And because I am on a fixed income now, you know I can't just go out and earn a bit more money to do something, it does limit you a little bit in what you can do and you have got all this time, but you haven't got the money. Err, you know, and I brought up a child on my own so she took quite a lot of my salary when I was working [Kate laughs], you know I have never got a lot of money (all

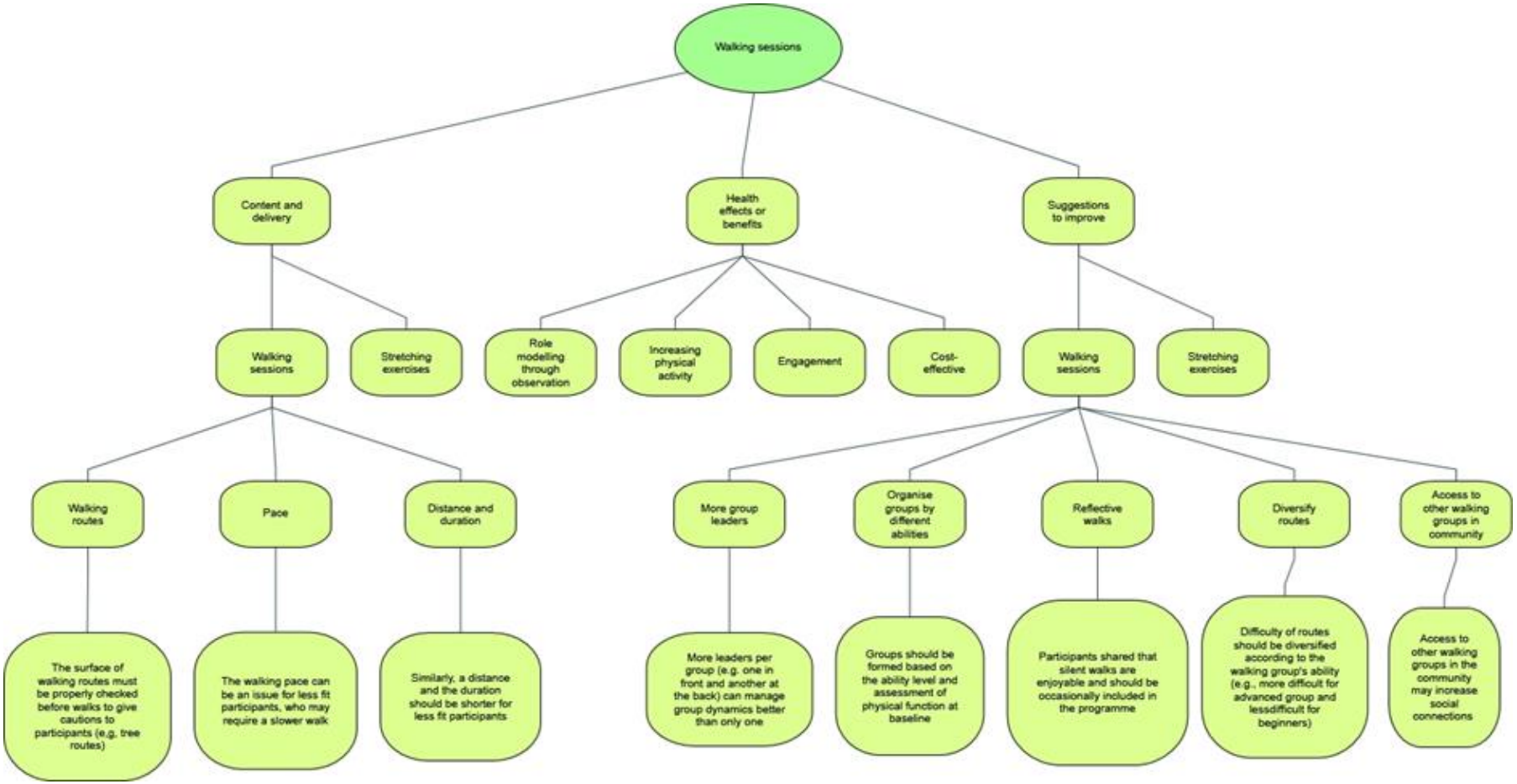


Figure 15. Map of walking sessions themes for mid-point focus group interviews.

laugh) to do what I would really like to do. So, you have to work within that (.)" (Alison, 75, female).

Walking was the most enjoyable part of the intervention for most and it was also an opportunity to meet others:

"I mean walking is good because it loosens everybody up a bit, gets people to know each other (.)" (Andrew, 68, male).

"Well I thought that it (walk) was so pleasant. The last time it went along the canal and run by the halls of residence and that was really quite pleasant, and then we had a session of doing stretches and exercises, some of which I sort of knew already but that was helpful as well, quite enjoyable, yeah" (Ben, 65, male).

Walking was seen to promote the bonding of participants and improved their aspirations for friendship-based relationships. They stated that particularly for ethnically diverse groups it is important to feel a sense of belonging, and the walking intervention was seen to provide some extra social support that they needed while being distanced from their country of origin:

*"The more we meet each other, the more we discuss things, we can see that we have the same likes, the same dislikes, so it will become (.) the friendship hopefully will be established and maybe yeah, it will be great support. We will be supporting each other"(*Kate, 62, female).

"(.) because we are not from here (referring to the country of origin), we are very far from here [meaning far from country of origin], we only see each other for the whole week, not really the whole week…for, five days, together as a group and we create some kind of activities for the

[country of origin], that's why it is an important for us to do some bonding as well" (Kate, 62, female).

Also, the walking intervention stimulated an increase in habitual physical activity for some participants:

"It really gave me the energy to walk after work. I don't walk in the morning (.) I don't walk towards the work, towards the job to the work place in the morning, because I am not a morning person, I am an afternoon person, so I have the energy (in the evening). But it really gives me (.) I am really happy to say, I am, actually, until now even despite it is too hot, too cold, I am walking (laughs). This what I am doing" (Kate, 62, female).

Content and delivery

Participants enjoyed the variable routes and walking routes, many of which were undiscovered for some. They enjoyed walking in parks that were new to them, however, they identified that some routes were slightly hilly or had tree roots which posed a problem for older adults with deteriorating physical balance or worries about the loss of balance during walks:

"I have discovered loads of different things in [referring to the walk in the park] I have not been to (.)"(Kate, 62, female).

"And you are watching your feet because there are tree roots all over the place" (Alison, 75, female).

"Yeah, yeah" (Kate, 62, female).

"Which is probably why I felt shattered at the end, because I was (.) (tired)" (Sarah, 76, female).

"Yes, yes. And it is quite hilly, it is quite hilly too" (Alison, 75, female).

In terms of the walking pace and a distance of walks, most participants felt the speed and intensity were optimal. The intensity of the walks was regulated based on perceptions of exertion during walks (using Borg's RPE scale of 0-10). However, some participants felt a slower pace (lower intensity of walk) or less distance was more suitable based on their health conditions, however, for others a slower pace was deemed unsuitable it could lead to back pain:

"I don't walk fast particularly, but if I walk too slow, I get really bad back pain, so (.)" (Sarah, 76, female).

"I have found that personally a bit of a struggle and another lady did as well, and someone took her off and did the shorter walk which was lovely. So, a little bit like that, and then Alison [referring to one participant] said the pace could be an issue" (Sarah, 76, female).

"*So maybe for you, Sarah [referring to one participant], it is the time rather than the pace. It is the amount you are doing"* (Alison, 75, female).

Stretching exercises were viewed very positively. By being conducted in the small group, stretching exercises encouraged participants to explore different exercises and improved the feeling of support and self-esteem due to a feeling of mastery:

"Yes, initially I thought that when we stopped to do some [Kate: exercises], oh my God, I can't do that, but I was (.) obviously there was more of us to do this and I saw you doing it and I thought if they can do it (everyone laughs) then I can do it, yeah. Yes, so that was (.) you can really get into the way of thinking you can't do things, whereas actually you can do that, or you can try it, yeah" (Sarah, 76, female).

"You can do it, and it is encouraging us, yes" (Alison, 75, female).

Suggestions to improve

Bearing in mind some health conditions of older adults which limit their physical ability to sustain walks of longer distances (e.g. over 40-45 minutes), one of the suggestions was to organise walks for different activity levels (e.g. beginners, improvers, advanced level). Participants felt this would motivate people to finish one level and start another to increase their activity motivation.

"So, you know when the Researcher does the assessment and the Researcher asks you to walk backwards and forwards, how fast can you walk and you do that. And at that point you could divide into three (categories), what people are comfortable at doing "(Alison, 75, female).

"*And hopefully, if initially you are quite a slow walker, but you can up (.) your challenge will be to get on the next walk (.) (laughs)*" (Alison, 75, female).

However, this categorisation based on levels of activity could potentially affect the primary aim of the intervention of reducing loneliness among community-dwelling older adults and could lead to the rejection of those in most need, which would compromise the aims of the intervention:

"But my only concern is it's too (.) how we will be categorised? That is what I was thinking. Because it is accepting everyone. I don't know, maybe there is no category in this kind of activity that we are doing. That is what I have only in my mind. The only thing is we will be breaking this loneliness, we want to meet I (.) I am being objective (.) we will meet people, we will just walk, will be active and that's it. I mean not to categorise us into slow, medium and fast walkers" (Kate, 62, female).

Another suggestion was to have more group leaders participating in the walks and have a more rigorous initial physical and memory testing of participants including a second independent assessor or a group of assessors.

"(.) and it was only (the Researcher). But if (the Researcher) had two other people on our walk … You can do a slow one slightly less (distance), a medium one slightly further and a faster one even further. I don't know how you would organise that, but that would take care of the pacing (.) The Researcher will need help. You can't do that with one person because you got to lead, so she actually does need somebody to lead a group" (Alison, 75, female).

One of the interesting ideas was to attend other walking groups in the community to share the experiences of leading walking groups. Taking participants to other walking groups may be useful in terms of increasing their social connections and give them the opportunity to meet other like-minded people:

"*I think there are a lot of walking groups within [the city] and they do set up different groups for different abilities (.) so that would be a good thing to know, what we were talking about"* (Sarah, 76, female).
"*Yes, so that would suit you after we have done this feasibility study, yeah"* (Alison, 75, female).
"*Yeah, look what they do and where they go and how (.)"* (Sarah, 76, female).

Attending such walks provides the opportunity to walk at different paces with different people and find out more about each other through friendly conversation:

"And on the actual walks, it is interesting because we walk at different paces, you may get to chat to different people, you know, they may go ahead then and we might be at back of it [referring to

the walking group], so you get to speak and realise why other people are there and this (.) I shared there are quite a lot of different reasons (.)" (Sarah, 76, female).

One of the suggested alternatives to the regular group walks was engaging in 'reflecting walks':

"(.) the other thing is that it is quite difficult though it is when a whole group, at the middle of this big group going around and you are all talking there is no wildlife as a result. You know, we could do silent walks until you get to the coffee you know, it's something I (.) when you walk a dog, which I have done for years (.) it is lovely to be silent in the countryside and the dog doesn't talk (Kate laughs). It is actually quite a relief (.)" (Alison, 75, female).

Theme 3: Healthy workshops

The map of healthy workshops themes for mid-point focus group interviews is shown in Figure 16. Healthy lecture workshops were conducted as a part of the PAIL intervention after the walks, and were aimed to facilitate the social skills of the participants, provide social support, and improve skill building. Each week participants were given a health-related topic with an educational aim and were given an opportunity to share their opinions. Healthy workshops were initially offered in a University-based meeting room during the first four weeks of the intervention, and then were delivered in later weeks in various locations on and off the University campus over a cup of tea.

Delivery

The acceptance of healthy workshops was expressed via two contrary opinions. First, they were not well accepted by some participants who thought that the workshops were too formal and lengthy,

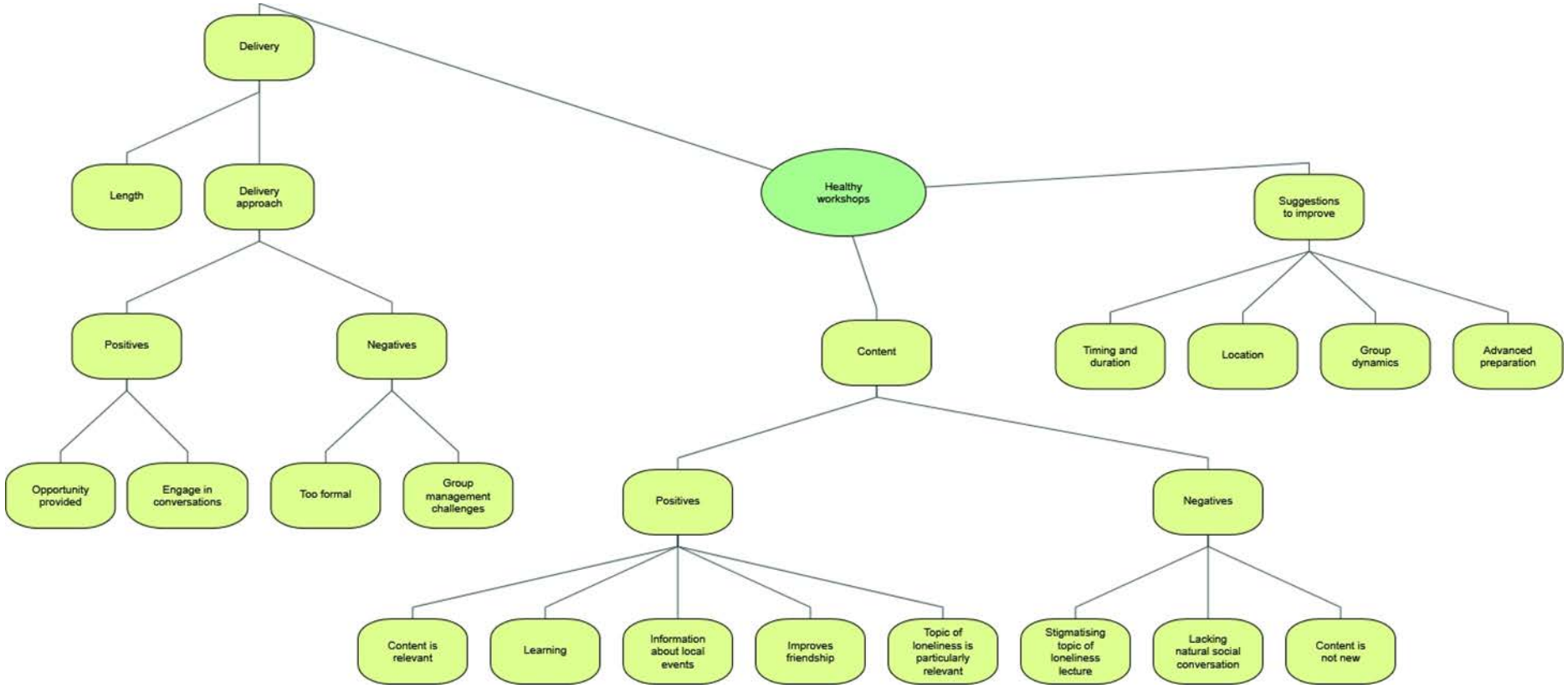


Figure 16. Map of healthy workshop themes from mid-point focus group interviews.

and that the content of workshops was not new. Due to the structure of the workshops, the delivery of the healthy workshops was viewed as too formal and was associated with the feeling of "going back to school" (Andrew, 68, male). This was due to PowerPoint slides being projected on the wall in the classroom or being given as a handout during coffee chats after walks.

"I think using the slides like that actually stilts the conversation" (Andrew, 68, male).

Providing notes during the workshops was identified as a good option by some, as this provided the opportunity to read and remember information when they returned home or read to others. However, the notes or projector slides (as delivered during the first four weeks of the intervention in a classroom setting) did not allow participants to have informal conversations with each other.

"I agree because I just feel the slides just govern completely the workshops, because you know, you just are going through the promotions of them, and you have to get through them (.) you know, in a set time, and but we don't need them. Although we are both able to talk for ourselves and express opinions, which we are doing today, so it doesn't need slides as an incentive for us to talk. We know all what's on the slides" (Ben, 65, male).

In contrast, other participants (particularly female participants) thought that the healthy workshops as delivered were very useful for discussing the topics of interest as well as for bonding and making friendship connections:

"The more we meet each other, the more we discuss things, we can see that we have the same likes, the same dislikes, so it will become (.) the friendship hopefully will be established and maybe yeah, it will be great support. We will be supporting each other" (Kate, 62, female).

The most advantageous features of the workshops, according to participants, were as a means to get people talking, find out more about each other, and "get other people's points of view on [things]" (Alison, 75, female):

"(.) and the thing is that it starts us all talking together, doesn't it, and that's where we are making friends perhaps, isn't it? We are sorting out who you want to be friends with because that's what we do, and so maybe it serves two purposes: one is information, one is actually talking, sitting down, not just walking because you don't get always to talk to everybody" (Alison, 75, female).

However, the time devoted to workshops after the walking session was seen as too brief to cover all aspects of the topics presented. Additionally, the topics included detailed information that some did not know before they attended, despite the general topic area not being new to them:

"I think, it's (.) actually everything is relevant, we have one of these (.) we had one of each at the end of each session [referring to workshops]. If you go through it there will be some stuff that is not relevant, you have gone through it before or discussed that before or (.) ermm (.), but there is always usually something there that you can relate to" (Sarah, 76, female).

Specifically, the topic of loneliness was identified as one of the most desired phenomena to discuss. It uncovered feelings, particularly for female participants, associated with loneliness and they were willing to share these feelings during the focus group interview (being unable to discuss it in more depth during the workshop):

There is one particular leaflet which I brought with me and I think it would open up a lot of conversations, a lot of it's (.) a lot of the others are information about websites you can get to for various things, but this one I thought (.) there is various topics within that, which (.) I put pin marks on the ones that I think would be useful for me (.), but really that I think the stuff in here [referring to the discussion notes] would be really useful to people" (Sarah, 76, female).

"What I have learned is that I have spent a lot of time alone, not that I am necessarily lonely, but I do spend a lot of time alone (.). And you can be like that, married, and having to look after someone, so you actually do feel very alone actually" (Alison, 75, female).

Loss of meaningful others was identified by participants as being associated with feelings of despair and a lack of the purpose. They missed the 'sharing moments' with colleagues and loved ones:

"That is something I have noticed from my point of view, is it is probably because I have been alone loads, you don't really know what your goal is anymore. [Alison: yes]. Because you are not working, you haven't got your work colleagues, you are not involved, you know, in organisations. If your own children are grown up, your grandchildren don't really need you anymore and there (.) but I don't need looking after since no care is involved. And the other big thing, if you are on your own, as someone mentioned the other day (.), although I

have read it that somebody said (referring to slides) (.) I really miss (.) this is only been recently that I have lost my husband (.). I miss this (.), what was this (looking at the window) [Alison: the day to day talking] sharing moments [Alison: yes just saying: "What do you think about that or what do you think about that?" or discussing a television programme or, you know, you have lost your partner, you have lost your best friend]. Yes, you have missed that sharing moment (.)" (Kate, 62, female).

Content

One unexpected outcome was the participants' identification of the educational benefits of the healthy workshops for older adults as an increased awareness that followed from the loneliness topic, specifically that someone can be alone or live alone but not experience a negative feeling of loneliness associated with the lack of desirable social relations:

"I mean some people they would like to think that they were lonely, that there was a loneliness (.) and I have said to myself before, I feel alone but not lonely, that [concept of loneliness] is incorporated in your posters that you put out "Are you alone or lonely?" [referring to the workshop on loneliness] that one might think oh (.) the thing is for a lot of really lonely people" (Sarah, 76, female).

"I think it was a sort of light bulb moment you know, realising that actually we spend a lot of time alone [Kate: but not lonely], and there can be a resentment about that because I have to do everything. If the lawn needs cutting, I have to cut it, if someone is coming for lunch (.) I don't have somebody to help me to prepare lunch (.) it (.) you know, everything is done on my own! I have to do everything (.)" (Alison, 75, female).

"But you can be alone, and people are around you" (Sarah, 76, female).

"I agree with you, especially at work" (Kate, 62, female).

"When my husband first died, I was a (.) they said go out and do things, do what you normally do, go shopping, this you know (.) but you can still be in the crowd of people and still be alone and I find it so difficult (.)" (Sarah, 76, female).

Presumably due to the stigmatising nature of the loneliness topic, and how people might have very individualised views and responses to this topic, it was viewed by some that it may not be a desirable topic to discuss and listen to for every participant.

"You suggest a separate session for loneliness?" (Focus group lead).

"A separate [Kate: a separate session yeah (.)] without so many leaflets" (Alison, 75, female).

"Yeah, so that will be a little bit (.) it will be a good focus for each of us to learn, to share (.)" (Kate, 62, female).

"Maybe not everybody, every group needs that (.)" (Alison, 75, female).

With this it was suggested perhaps to devote a separate day for attending the workshops (one session per day) in a format such as an open seminar and invite external experts to discuss these topics and share opinions.

"And the other thing that would be related to your question or not (.) [referring to the focus group leader] is at the end of the walk, we sit and have a coffee and a chat, and the Researcher gives us an informational handout. But because with (.) I find, because with the end of the walk you think: "Ah! I can't really discuss this and (.)", you know, it's a few pages

through (as if not finishing the workshops fully), and I am just wondering if the end of the walk is the right time to discuss the thing [referring to the topic being discussed in the workshops]" (Sarah, 76, female).

"Maybe, I would suggest if that's the case we have a separate time for discussion rather than walking, I agree with you (referring to Alison) because I last time after we have been at [the place for a walk], we were talking about food rather than the discussion topic (.)" (Kate, 62, female).

It was found that some participants were more independent than others in their approach to life, and they expressed the opinion that the opportunities for engagement are provided and it is an initiative of each individual to take advantage of these opportunities for socialisation. These individuals viewed themselves as being more prone to social interaction and bonding.

"It is there, it is there (information) [Sarah: It is there] and then you have to go and get it yourself" (Alison, 75, female).
"Yes, it is creating independence, but all the information is there" (Sarah, 76, female).

"I am taking this seriously myself, do you know I just feel a little bit, oh come on, you must to make a little bit more of an effort" (Kate, 62, female).

Suggestions to improve healthy workshops

Other suggestions of how healthy workshops could be improved included having a more advanced management of the group dynamics, suggesting the necessity of the training experience for the group leader of any future intervention:

"I have to say I think there could be more interaction rather than just listening to the slides and sorry, what's the name of the lady, [referring to participant], [name] is it? [Andrew: Yeah]. She is sort of constantly trying to give her [Andrew: Yeah, she goes, yeah, she goes on a bit]. She goes on a bit because of a need for attention, which is no criticism [Andrew: just the way she is]. Just the way she is, but it does tend to make things more drawn out and I feel that her interventions are getting in the way of what the Researcher wants to get on with (laugh)" (Ben, 65, male).

"Yeah, I have remembered there are other members of the group who do not want to discuss things. They have a wall [around them] and some will be open, so yeah" (Kate, 62, female).
"And some are just quiet and don't say anything" (Alison, 75, female).

Participants suggested it would be beneficial to use a less structured approach to workshops, make them shorter in duration and more precise:

"I think it should be more casual, laid back and more general you know, the walk loosens everybody up, puts them in the good mood hopefully, and then ermm you just come back, have a cup of coffee and maybe like Andrew said, half an hour, an hour talks" (Ben, 65, male).

"(.) but if it was all free and easy like this, she would be less stressed because she could just sit there and (.) we would get more out of it (.) People would be more relaxed, and it will be an interaction. I mean walking is good because it loosens everybody up a bit, gets people to know each other (.)" (Ben, 65, male).

With this it was suggested to offer healthy workshops in coffee shops, not at the University or any other classroom setting:

"It could be a coffee shop somewhere in [name of the district] for instance" (Andrew, 68, male).

Participants expressed a desire to be informed about the topic of upcoming workshops, requesting they be informed in advance by e-mailing the topic of the next sessions or slides prior to the session so they can read and formulate questions:

"Well I mean, for instance, if you are going to have to go through lectures like that you could actually e-mail the slides out and then we would understand them better in our own way, and then we could use questions in our own way and we wouldn't have to sit, you know, go through slide by slide err, which is becoming very long winded " (Andrew, 68, male).

II. End-point focus groups

A total of 5/12 (42%) participants in the intervention group attended two end-point focus group interviews conducted in April 2018 (Wave 1) and August 2018 (Wave 2). Participants ranged in age from 65-76 years, 20% (1/5) female, 80% white, 60% (3/5) living alone, 40% (2/5) with university degree, 60% having children, retired and having one or more medical condition (Table 8).

Table 8. Summary of participant characteristics of the end-point focus groups.

Pseudonyms	**Age (years)**	**Sex**	**Ethnicity**	**Marital status**	**Living arrangements**	**Level of education**	**Any children**	**Employment status**	**Number of chronic medical conditions**
Andrew	68	Male	White	Married	Living with others	University	No	Retired	0
Ben	65	male	white	single	living alone	university	no	employed	1
Leo	60	male	white	divorced	living with others	college	yes	employed	2
Sarah	76	female	white	widowed	living alone	secondary school	yes	retired	2
Nick	73	male	Asian	widowed	living alone	secondary school	yes	retired	2

Responses of participants were summarised under three main themes during the analysis of interviews and displayed graphically for: 1) study design and recruitment (16 subthemes), 2) healthy workshops (12 subthemes), and 3) walking sessions (8 subthemes) (Figures 17, 18, 19).

Theme 1: Study design and recruitment

The study design and recruitment themes from the end-point focus group interviews are shown in Figure 17.

Benefits of participations

Reasons for participations were coincident with benefits in participation. Motivation to do things was one of the main reasons to join the study which was improved after participation in the intervention:

"*I think for me the fact that my main aim for joining was social plus motivation. Motivation to get out and do things for the last couple of years. There has been quite a lot, loads of things I wanted to do, and I am interested in (.) (doing) but just getting up and doing it was really difficult. When I say really difficult (.) it is difficult to explain, so the motivation is a 12-week commitment to the Researcher. For me, I needed to do that first, not necessarily just for me. I did not want to let people down"* (Sarah, female, 76).

"You have to just try and keep motivating [yourself], just keep going I suppose, rather than just sitting at home. I don't know how (.) for me like, I am working four days a week at the

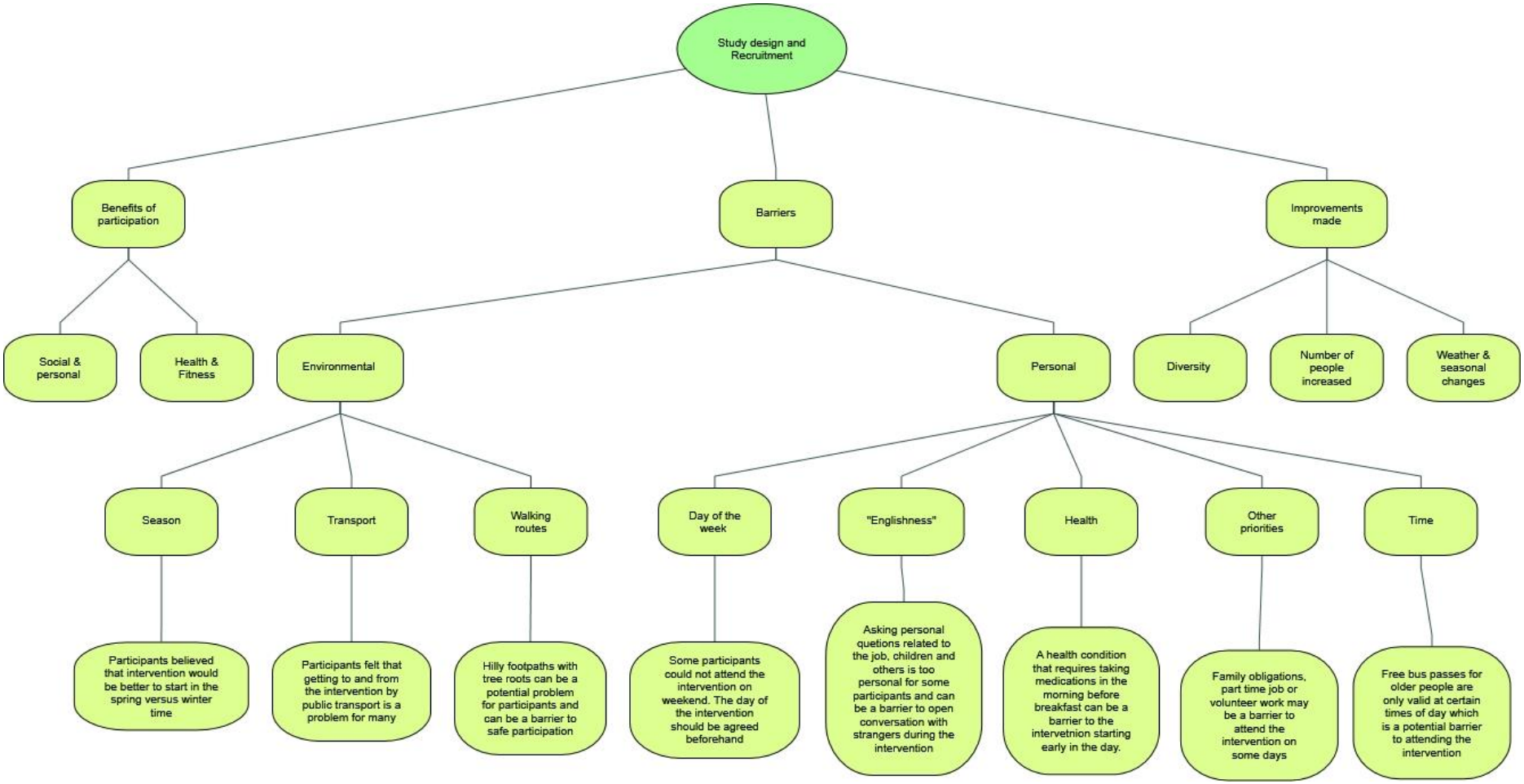


Figure 17. Map of study design and recruitment themes from end-point focus group interviews.

moment, so I don't know how I would feel when I retire, which is going to happen next year so (.)" (Ben, male, 65).

1. Social and personal benefits

"I have definitely made new friends, enjoyed meeting new people and you gel with some people which is a human nature, so (.)" (Sarah, 76, female).

"Exchange of views" (Nick, 73, male).

"So yeah, I have enjoyed it" (Sarah, 76, female).

"I have enjoyed the walks. My aim of improving my motivation to do things has worked a little bit, yeah, and it's sort of filtered out to other aspects of my life and getting a little bit more doing stuff" (Sarah, female, 76).

For others it was a chance to meet new people and share feelings and knowledge:

"It is meeting the group of people, yeah, introducing them and meeting is for the health while it is walking which is (.) and you do get addicted to it, yeah? You can continue it. That's the main object was it? (.) And mixing with the people" (Nick, male, 73).

It was also considered to be free time activity and an opportunity to get out of the house and meet people and add a bit of "finesse" in their life:

"It makes you go out of the house, the main thing" (Nick, male, 73).

"Because it is a bit of something that could be also something new, interesting, meeting new people instead of doing the same thing repeatedly and meeting the same people repeatedly which is also important" (Leo, male, 60).

The intervention was described as a way to allow one to divert their mind away from things and to avoid losing out on social opportunities due to the tight schedule setting of others:

"I would say that sometimes I am focused on my diary too much, say today, there is this to be done and day after tomorrow I have to remember about that (.) I am very strongly focused on the subject. But I think what our walking and meetings (.) what it gave me is mainly to remember that if I do this as a part of my good routine, do what should be according to my plan, I can easily [Sarah: Tweak it a bit] yes [Sarah: Tweak it a bit because you don't have to do] yes so don't be afraid to (.) so do not lose a chance to meet people [by sticking too tightly to his schedule]" (Leo, male, 60).

2. Health and fitness benefits

Participants felt that participation in the intervention helped them to become more physically active, which was one of their aims:

" (.). Yeah, yeah. Main thing for [me] was the health" (Nick, male, 73).

"Ermm, well it has driven home you have to make things happen, you can't just sit at home. I suppose the only thing is just the physical you know, what comes with age is just the physical side and not be able to do quite as much, so that I suppose is something about so (.)" (Ben, male, 65).

"(.) it was enjoyable for me as well, both, I mean physical activity and a chance to express my opinion on the subjects which have been passed to us by the Researcher, and well, I am trying to be active, so another chance to go to the park, and actually I had to go to the park which I have never been before, and I found a surface perfect for my private purpose which was a roller skating (laughs), so another benefit of being a member of a group errr (.)" (Leo, male, 60).

Barriers

Among barriers to participation were environmental and personal barriers.

Environmental barriers were season of the year, transport difficulties and walking routes.

In the opinion of most participants, it would be best to start the walking intervention is in the spring throughout the summer season:

"*I think it started really too early in the year, because (.) [Andrew: Yeah, and it was winter] and it was winter. So, it would have been better really to start it maybe in spring. More people will be interested in joining* (.)" (Ben, male, 65).

Getting to and from the intervention location was difficult using public transport:

"*Transport [is a challenge] for me as I need a little bit more time to get here because I don't drive, so I used to have to get two buses and I only have to get one now because they have changed its routes. So today it was easier* (.)" (Sarah, female, 76).

"*Transport (.) there was no proble*m (.)" (Nick, male, 73).

The surface of walking routes was a challenge for those participants who had problems with physical balance and had to watch tree roots along the way so as not to trip/ fall down:

"*The only other barrier I had was the (name of the place) one, where we joined forces with the [name of the walking group] you meet every Thursday. It was because it is (the name of the place) and it's self-explanatory (laughs), it was hilly and it wasn't a footpath, it was a route through oak trees, and it wasn't an easy path to follow. So, I spent most of the time looking down in case I fell over tree roots. So, I wasn't taking in any surroundings, so I had to be careful because I don't know whether it's because I was (.) and I wear glasses, when I looked down [Nick: You were dizzy?] I had to be careful. I was very aware that I could easily trip so whether that would apply to other people as well I don't kno*w (.)" (Sarah, female, 76).

Among personal barriers were time of the intervention coincident with use of public transport, late night hobbies and health reasons. It was suggested that an 11:00 start was best for most participants:

"No 11 o'clock (in the morning) is just right. That's why we did say when we came at 10 o'clock, because on weekdays I cannot use my pass (referring to the free bus pass) by half past nine, Saturday is not problem, but on weekdays we cannot use our pass before half nine" (Nick, male, 73).

"(.) in our age in the morning we are not fast. It takes time in the morning. We cannot rush. Then on top of it we could take medication you know, like everybody (.) I take triple tablets and you can't just (.) it takes time" (Nick, male, 73).

"I do read during the night so from this point of view it is better if it starts [referring to walks] not earlier than 11 o'clock" (Leo, male, 60).

An 11:00 start was also suitable for those taking morning medicine required to be half an hour before their first meal:

"Timing is little bit [difficult] with me (.) We were meeting at [Nick: 11 o'clock, in the beginning, a couple of days we have met at 10 o'clock] yeah, we were meeting at 10 o'clock which was too early for me and I have personal health problem. So 11 o'clock is better for me, much better" (Sarah, female, 76).

"Right, a similar situation that Sarah [referring to participant] just mentioned is health conditions. I had a heart attack, so I start my day with my medications, which have to be taken in a certain order so one before the breakfast, and other after, so I have to give myself a bit of extra time when I start my day. So, 11 o 'clock from this point of view is better for me, I could give enough time for myself to start the day" (Leo, male, 60).

Another major barrier was the presence of a health condition that precluded participation at an older age:

"In my age group a lot of people will have health issues, which you have to be aware of. (.) some people may have a health issues, physical issues which means they can't take part in a certain walk. We had one person with real arthritis in her hip so that made it difficult for her

a little bit, so, and myself as well. I couldn't come one time because I had a pain in my hip" (Sarah, female, 76).

Some were restricted by work and could not attend the intervention on weekends. However, others were flexible and could easily accommodate the intervention day depending on their schedule:

"Depends on the day, say when we are trying to move [the day to meet]. Yesterday we were trying to move from Saturday back to Wednesday, but I can't do Wednesdays at the moment, so it's probably very difficult to have a good day for everybody" (Andrew, male, 68).

"I am following the schedule (.) let's say, I guess I got something to do every day and there are other physical activities like table tennis, swimming, I am involved in to keep myself busy in a way, so (.) but if I know in advance about our walks I can easily pop in and take part. So, from this point of view I would say I am "flexy". I do also care when I change my plans to participate in walks in the park and I well, as I said before, I really enjoy [the walks] so no regrets" (Leo, male, 60).

Some had a lot of time associated with other things to do:

"Well I have got other things to do - it is that simple. Someday, I can do [referring to attending the programme], some days no, but on other days I have something else to do apart from going on a walk" (Andrew, male, 68).

The opinion of others was that a specific barrier precluding participation in the interventions

was a social component related to being British/ English:":

"From my point it is, it might be a sort of British, English thing. It is knowing that point that it is a sort of the British, English thing is that point when you can ask personal questions. When I say personal, it is about what they have done for a job, do they have children and initially you don't feel that you can ask (.). You don't bombard them, yeah. Does it make sense? I mean in some cultures they jump at you with both feet, don't they (laughs). Do you agree [referring to one of participants]?" (Sarah, female, 76).

Improvements made

Improvements which could be made to the intervention that were identified by participants included an increase in participant number, as well as participants being more diverse, and increasing opportunities for social interaction and establishing friendly connections:

1. Increase in the diversity of the participants:

"We had yes, we had met friends. And the most (.) the thing is mixing with different age groups and different people, yeah. This definitely helps. I meet with different people throughout the season" (Nick, male, 73).

Male participants noted that the majority of the group were female, so the group was not balanced in terms of the gender:

"(.) It is more female-based now" (Ben, 65, male).

"Oh yeah, there are more women as they live longer, don't worry about it, Ben [laughs]. Gender-biased" (Andrew, 68, male).

2. Increase in the number of participants:

"Lack of people?" (Andrew, 68, male).
"Yeah, but this has improved" (Ben, 65, male).
"Now she [referring to the Researcher] has got about a dozen people it is much more interesting, but initially we (.) most of the time it was just two of us" (Andrew, 68, male).

The optimal number of people in the group, in the opinion of the participants, is 6 to 12 people to allow participants to repeatedly socialise with each other and establish friendship connections:

"This is probably about right. What is it, seven or eight?" (Ben, 65, male).
"Yes, seven or eight" (Andrew, 68, male).

*"Ten to twelve people will be good" (*Nick, male, 73).

"But there wasn't an opportunity socially with that many people err (.) for me I would have thought probably eight to ten would be the most (suitable) for me, if you want to make it social thing as well as exercise things" (Sarah, 76, female).
"I agree, more than ten [is not ideal], yes, yes" (Leo, 60, male).

3. With the number of people increased, social interaction improved as well:

"People talk more" (Andrew, 68, male).

"More interaction, it has been more social (.). I mean when we went for a coffee or things like that. I mean yesterday, last two times it has been like, we have gone for coffee it has been quite pleasant, isn't it?" (Ben, 65, male).

"(.) the other week we went to a (place) and had a coffee so that became social, and yesterday we were at the (place of the park) and that was quite sociable, and it was bigger group" (Andrew, male, 68).

4. Weather and seasonal changes:

The intervention group that ran during the summer months was perceived as more positive by participants versus the intervention conducted during winter, which was less enjoyable:

"Ermm, it is more pleasant doing it now because the weather is better. It wasn't pleasant in the winter at all" (Ben, 65, male).

"That is what I am saying. Especially the weekend we had to give up because it was snowing" (Andrew, 68, male).

"It (the weather) has been lovely, isn't it?" (Sarah, 76, female).

"Ever since we started the walking group, weather has been tremendous, weather has been very nice, yeah all these weeks" (Nick, 73, male).

Theme 2: Walking sessions

The map of walking session themes from end-point focus group interviews is shown in Figure 18.

Benefits

The benefits of walking sessions from the end-point focus group interviews included social engagement:

"Enjoyed the walks, enjoyed the conversations with people that we have met on the walks (.) Leo, Nick [referring to participants by names] so yeah, it's been interesting. And it, sort of the conversations evolve (the topic that the Researcher gives us) it evolves into things (laughs) that (.) which is fun, yeah (.)" (Sarah, female, 76).

Another benefit was access to other walking groups in the community:

"(.) I have exchanged the contact right at the beginning with a lady called [a name of the member of other walking group lead] and she leads several walks across Birmingham for various abilities, so she has given us three walks [referring to walking groups], well she gave me and then she gave to the Researcher the names of these walks that she leads, so you can join those or join one of them" (Sarah, female, 76).

Participants especially valued stretching exercises for health reasons:

"I enjoyed the exercise thing. It is quite, you know (.) it is just (.) She sort of said, you know, made us aware of sort, of what sort of exercise is good for, what parts of your body and so forth. So, I mean it is important, isn't it to keep moving, keep active and this is what part of the programme is about, isn't it?" (Ben, male, 65).

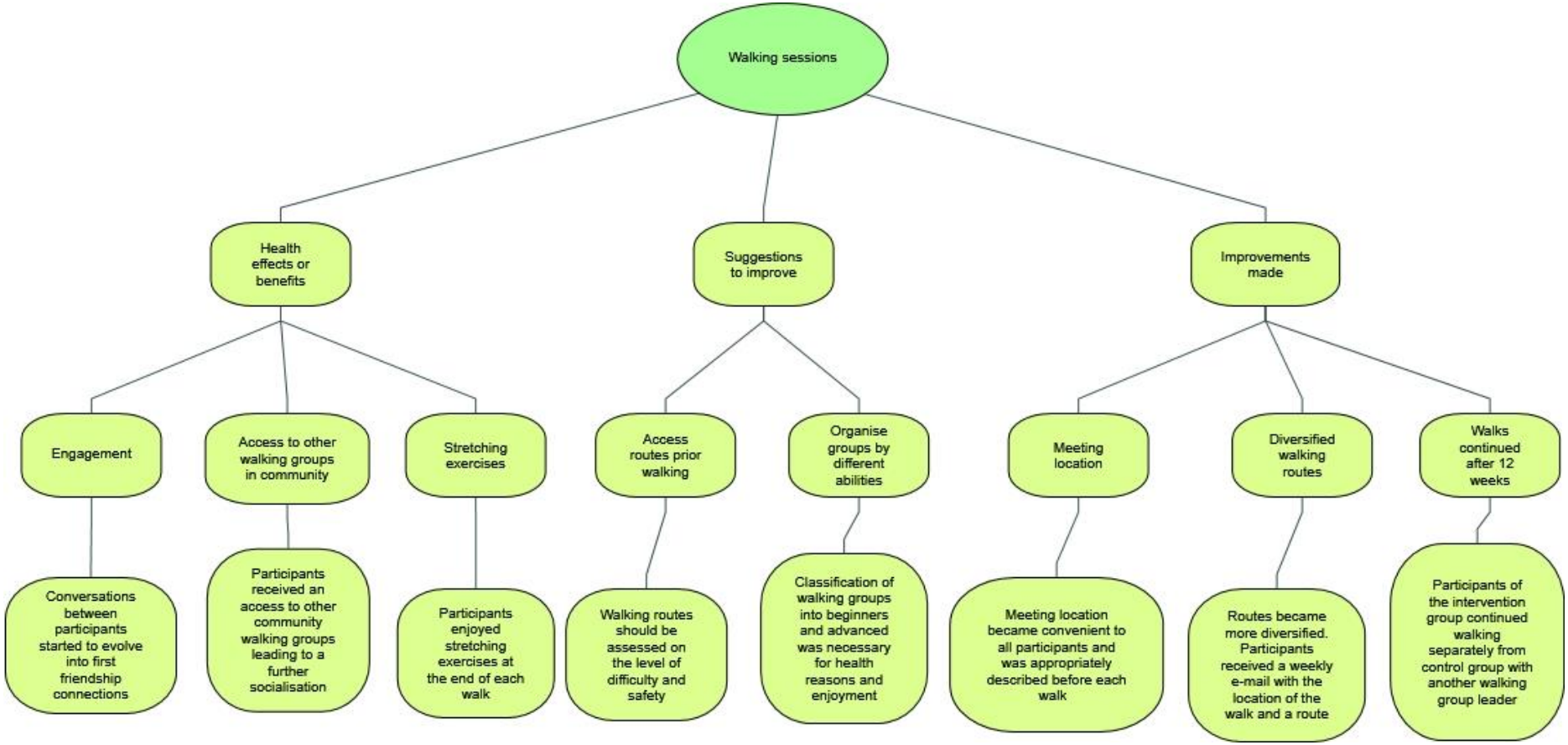


Figure 18. Map of walking sessions themes from end-point focus group interviews.

Improvements made

The improvements made since the beginning of the intervention that were identified included:

1. Change in meeting location from a University facility to a local park or a community centre near the walking route:

I prefer to move and meet somewhere [else] rather than coming here [the university] because we waste time coming here first, and then going on somewhere else (.) whereas yesterday we just met straight at the park and it was a lot of (.) we were there on the spot and we started. It was less time wasting" (Ben, male, 65).

2. Diversified walking routes:

"And now she is also, instead of just walking around the university, we started walking around other places" (Andrew, 68, male).

"I mean there is a whole programme now. She [the Researcher] organised it all now" (Ben, 65, male).

"Yeah, she works out where we are walking for the next three months almost" (Andrew, 68, male).

3. Walks continued after 12 weeks:

Intervention participants were offered the opportunity to continue walks separately from control group with another walking leader (an ex-member volunteered to lead walks) based on their concern about the follow-up as followed from the mid-point interviews:

"It will be interesting to see whether at the end there will be any continuation (.) I mean already you can see like one lady, the lady seems to get very friendly very quickly, and there is one lady already bringing one in and picking her up from [location] or the rest of it, so yeah, it seems to be (.)" (Ben, male, 65).

"I was talking to one of the participants and he said that he has been doing this for nearly 6 months" (Nick, male, 73).

Suggestions for improvement

1. Participants suggested that the walking leader should inform better about possible difficulties of routes prior to walking in the future in order to advise participants about the possible route difficulties and an overall distance:

"They have to assess the mode of the walk, the mode of the road at the first place (referring to the walking group leader)" (Nick, male, 73).

2. Organise groups by different abilities:

"I think possibly from people that are joining for an exercise point of view, people's abilities need to be looked at (.). What they are capable of physically. So, if it's, if you got people that walk regularly and walk quite quickly, you may also have people who walk very slowly (.) it can be a little bit, not frustrating but you know, the difference is too much" (Sarah, female, 76).

"Some people can walk more, or some people cannot do that" (Nick, male, 73).

"Not far away from here to the other side of [local University], we had a walk there. We started a walk for some physical exercises, but anyway firstly the leader gave us a sort of warm up and secondly, which is more important for our leader (referring to the group leader by name) to get a picture of every one of us, what we can and for her I think it is important to know about our ability, what (physical) level we have (referring to physical abilities of participants)" (Leo, male, 60).

Based on suggestions of participants classification of groups based on ability level can be an option for the future study, however this may require a more rigorous approach to the selection process and a larger sample size.

Theme 3: Healthy workshops

The map of healthy workshop themes from the end-point focus group interviews is presented in Figure 19.

Benefits

1. Social engagement

Benefits of participation in the healthy workshops were social engagement and opportunity to meet others, as well as sharing opinions regarding the topics of interest:

"(.) we had a chance to talk about something interesting (for me it was very interesting) about our dental hygiene and it is an important thing to remember to take care of (.) to get into any community and to say start the conversation or to be involved into the conversation (.) I think all of us, we know what I am talking about to avoid bad smell (referring to the breath smell) so hygiene is really important, a vital thing I would say, to mention our last subject of our discussion" (Leo, male, 60).

2. Friendship gains

First friendship gains started from as early as the second or third walk:

"I have definitely made new friends, enjoyed meeting new people and you gel with some people which is a human nature, so (.)" (Sarah, female, 76).

"Second or third walk? Yeah" (Sarah, female, 76).

"On the first session we had introduced each other anyway, so we started to know each other maybe at the second (session)" (Nick, male, 73).

The 12 weeks of participation was viewed as inadequate for the majority of participants to make strong friendship connections and consider going out or meeting outside of the walking intervention:

"I have met with one person only once because this is still quite a short time, isn't it? (.) [This is] something that evolves really isn't it? It takes time to make friends that you want to do other things with. (.) It grows slowly, you know" (Sarah, female, 76).

Common interests raised during the walks were a main reason for some to establish friendships more quickly or consider becoming friends in a shorter period of time:

"Yes, mainly, basically I do agree. However, I have to say that for me, surprisingly for myself, I have started talking to one of the [referring to the group leader from another walking group], the big one, don't remember exactly the name. We jumped into the discussion and we started touching

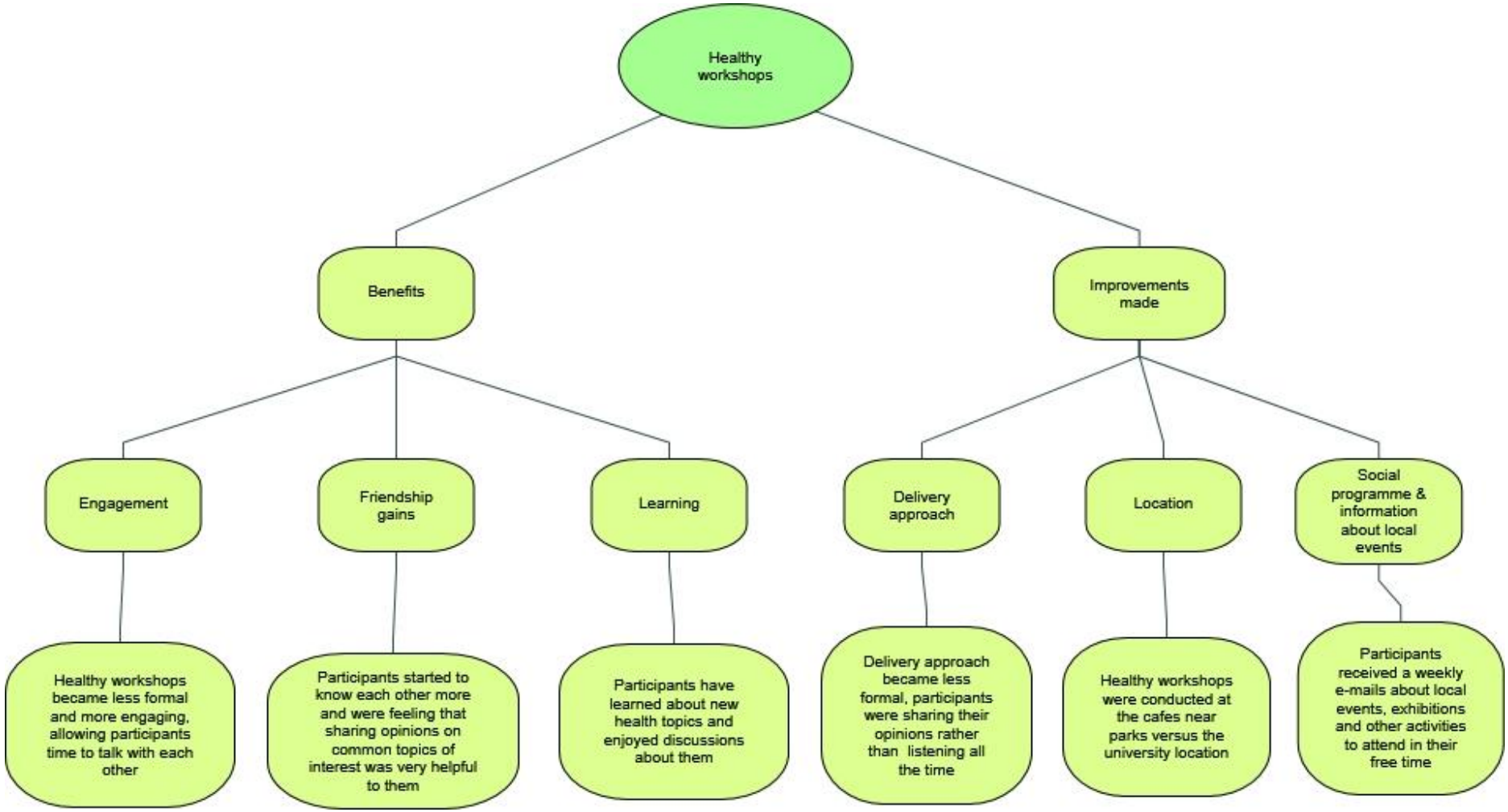


Figure 19. Map of healthy workshop themes from end-point focus group interviews.

rather private issues, so I was surprised because I am normally not like this, and it was sort of direct communication that touched every subject we wanted, so it was nice (.) It was like we are good friends for I don't know how many years. Whilst we just met" (Leo, male, 60).

3. Learning

Healthy workshops also provided an opportunity to learn which expanded during the talks:

"See yesterday, I think after you had gone we got onto a very useful discussion about tinnitus a bit and one of the ladies she had a useful thing about it and it was very interesting" (Ben, male, 65).

Improvements made during the project

1. Delivery approach

The delivery approach was changed after the mid-point focus groups from note or slides-led to a less formal approach where participants were more engaged in a conversation about the topic and beyond over hot beverages:

"I could feel relaxed and just enjoyed walks and discussion [Sarah: Yeah, yeah]" (Leo, male, 60).

2. Location of healthy workshops:

"I think the things did notably change after the mid-focus group because after that, then it was less classroom based [activities] and then basically we were out more. That dropped completely almost, wasn't it? [Andrew: Yeah] But now it is the beginning of the next group, so the Researcher is repeating the procedure except it is not classroom-based now, it is outside-based" (Ben, male, 65).

3. Social programme and information about local social events.

Among improvements made was a weekly social programme and information about local social events which was added in a form of weekly e-mails as addition to the intervention:

"Well I suppose that to try organise some social programmes, I suppose. But to be honest, [the Researcher] has widened it out, hasn't she? She seems to have been organising quite few things. She mentions along the way, "you know you could do this, or this is available" (,) so she is putting in (.) there is a little bit of input" (Ben, male, 65).

"The same, but the main thing I would like to say is the information which the Researcher provided us, what's happening round about [in the surrounding area] you know, that is something that we did not know (referring to events and activities in the city)" (Nick, 73, male).

"She [the Researcher] has a lot of information about (things)" (Sarah, 76, female).

The impact of the qualitative findings on the future intervention design

The findings from focus group interviews significantly improved understanding and insight into the experience of participation in the intervention and its delivery. Firstly, that the walking intervention would attract more people by providing a transport to and from locations, delivering an intervention in a larger group and the possibility of conducting shared walks with other community walking groups. To provide safe participation, the group should be classified by abilities and include a clear description of possible hazards for health and safety. Walking groups should be classified by physical ability level (e.g. beginners, advanced) for health reasons and to ensure everyone can walk the required distance and at the same pace. Based on the views of participants, though healthy workshops were informative and allowed opportunity to share opinions about various topics, for some they were taking too much time and were not what they were necessarily looking to attend. Therefore, a suggestion for the future study would be to include healthy workshops as an additional

optional activity not included in the main programme. The intervention is also easier to organise in the spring-summer season to avoid any weather difficulties in the winter time (e.g. snow, strong wind).

Changes in outcome measures

Pre-post differences in secondary outcome measures

Table 9 shows the post-intervention between group statistics for secondary outcomes. A preliminary normality data check showed no assumptions of normality were violated for all outcomes. Controlled for baseline score, at 12 weeks follow-up the intervention group decreased self-efficacy 1.4 (95% CI 0.09 to 2.7), more than the control group, p=0.04 (Table 9). Based on the unadjusted mean difference, the control group had -15.0 (-25.7 to -4.4) more sit-to-stand transitions compared with the intervention group at follow-up (p=0.01). Figure 20 demonstrates sit-to-stand transitions between the intervention and control groups at follow-up.

Table 9. Follow-up data for anthropometric, health-related, physical activity and psychosocial outcomes in the intervention and control group.

Variables	Intervention (n=12)	Control (n=13)	Unadjusted mean difference (95% CI)	P values	Difference[a] (95% CI)	P values
Stature, m	1.7 (1.6 to 1.7)	1.7 (1.6 to 1.7)	0.0 (-0.1 to 0.1)	0.98	0.0 (-0.0 to 0.0)	0.24
Body mass, kg	67.9 (59.9 to 76.0)	68.5 (60.7 to 76.1)	-0.5 (-11.6 to 10.7)	0.93	0.2 (-0.3 to 0.7)	0.49
BMI, $kg.m^{-2}$	24.3 (22.4 to 26.2)	24.5 (22.7 to 26.4)	-0.2 (-2.9 to 2.4)	0.86	-0.2 (-0.6 to 0.2)	0.36
SBP, mmHg	124.4 (118.8 to 130.1)	128.8 (123.4 to 134.2)	-6.6 (-16.1 to 2.9)	0.16	-4.4(-12.3 to 3.5)	0.26
DBP, mmHg	74.1 (68.6 to 79.6)	74.5 (69.1 to 79.8)	-0.4 (-8.1 to 7.3)	0.92	1.1 (-4.1 to 6.3)	0.68
Loneliness	18.1 (15.1 to 21.2)	18.6 (15.6 to 21.6)	-0.5 (-4.8 to 3.8)	0.80	-0.8 (-3.7 to 2.1)	0.59
Structural SS	5.7 (2.5 to 8.8)	6.4 (3.0 to 9.7)	-1.4 (-5. 8 to 3.0)	0.50	0.0 (-1.7 to 1.7)	0.98
Functional SS	63.9 (51.8 to 76.0)	59.8 (49.2 to 71.5)	4.1 (-12.7 to 20.9)	0.62	5.1 (-7.9 to 18.1)	0.42
LSN (Total)	15.4 (12.0 to 18.9)	12.0 (8.7 to 15.3)	3.4 (-1.3 to 8.2)	0.15	1.9 (-1.7 to 5.5)	0.29
LSN (Family)	6.9 (4.48 to 9.4)	5.9 (3.6 to 8.3)	1.0 (-2.4 to 4.4)	0.55	0.9 (-1.3 to 3.0)	0.42
LSN (Friends)	8.5 (6.1 to 10.9)	6.1 (3.8 to 8.4)	2. 4 (-0.9 to 5.7)	0.14	1.0 (-1.0 to 2.9)	0.33
Depression	6.5 (4.5 to 8.5)	5.5 (3.5 to 7.4)	1.0 (-1.8 to 3.9)	0.46	-0.1 (-2.3 to 2.2)	0.96

Anxiety	6.9 (4.8 to 9.0)	7.4 (5.4 to 9.4)	-0.5 (-3.4 to 2.5)	0.74	-0.9 (-3.5 to 1.8)	0.51
SEE	7.1 (5.9 to 8.3)	5.2 (4.1 to 6.3)	1.9 (0.3 to 3.6)	0.02	1.4 (0.09 to 2.7)	0.04
SSC	6.5 (4.7 to 8.8)	5.3 (3.2 to 7.3)	1.5 (-1.4 to 4.4)	0.29	0.2 (-1.5 to 2.0)	0.79
Expected outcomes	3.8 (3.2 to 4.4)	3.9 (3.3 to 4.4)	-0.1 (-0.9 to 0.7)	0.87	-0.2 (-0.9 to 0.5)	0.57
Barriers for exercise	2.6 (2.0 to 3.2)	2.9 (2.3 to 3.4)	-0.3 (-1.0 to 0.5)	0.51	-0.2 (-1.0 to 0.6)	0.57
Time lying/sitting (h)	16.8 (15.7 to 17.9)	17.1 (16.0 to 18.1)	-0.3 (-1.8 to 1.2)	0.70	-0.5 (-1.4 to 0.5)	0.32
Time standing (h)	5.5 (4.62 to 6.5)	5.1 (4.2 to 6.0)	0.5 (-0.9 to 1.7)	0.46	0.5 (-0.4 to 1.3)	0.24
Time stepping (h)	1.9 (1.5 to 2.3)	1.8 (1.4 to 2.3)	0.1 (-0.5 to 0.7)	0.87	0.0 (-0.5 to 0.5)	0.90
Step counts	9067.5 (6539.632 to 11595.4)	8575.6 (6146.861 to 11004.3)	491.9 (-3013.6 to 3997.5)	0.78	320.4 (-2392.5 to 3033.2)	0.81
Sit to stand transitions (n)	45.3 (37.7 to 53.0)	60.3 (53.0 to 67.7)	-15.0 (-25.7 to -4.4)	0.01	-3.5 (-9.8 to 2.8)	0.26
Energy Equivalent (METs/h)	34.4 (33.4 to 35.4)	34.1 (33.2 to 35.1)	0.3 (-1.1 to 1.7)	0.67	0.3 (-0.8 to 1.3)	0.62

Values are means (95% CI) unless indicated otherwise.

a- adjusted for baseline score.

Abbreviations: BMI - body mass index, DBP – diastolic blood pressure, n- number, SBP – systolic blood pressure, SEE – self-efficacy for exercise; SS – Social support, SSC – satisfaction with social contacts, LSN – Lubben's social networks; $P<0.05$

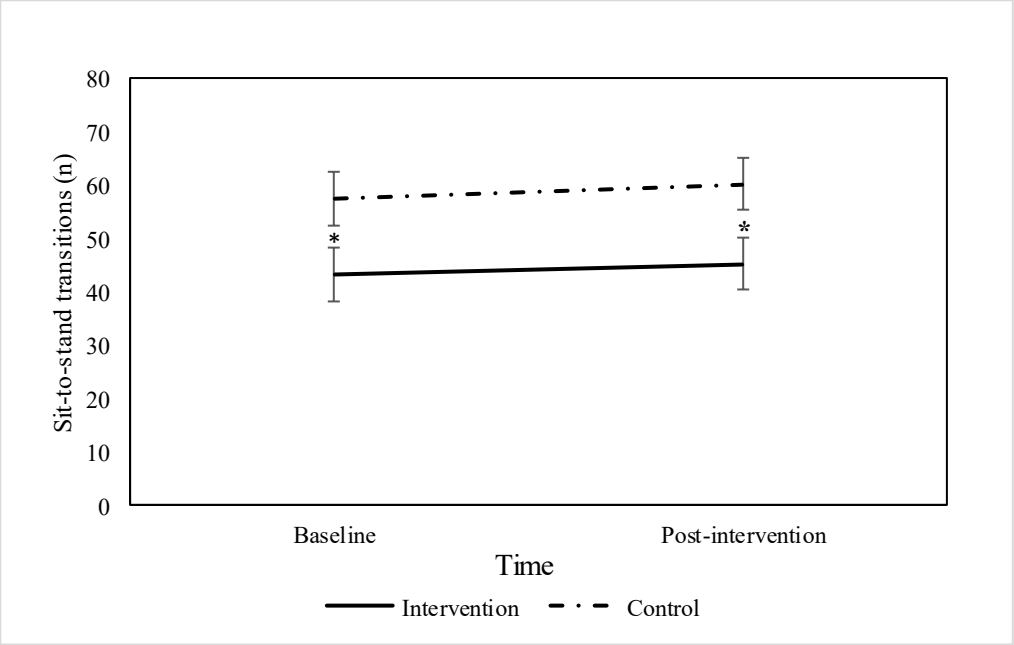


Figure 20. Baseline to post-intervention means for mean daily sit-to-stand transitions (n) between intervention and control groups.

Power Calculations

The potential sample size for the main study was calculated for loneliness (as a potentially future meaningful outcome) based on the target difference for between group differences (Cook et al., 2018). Using the ES obtained from the study of Mutrie et al. (2012a), the ES of 1.2 (95% CI -1.2 , 3.6) was considered to be a minimum target group difference at follow up for loneliness. The sample size was calculated using the *a priori* method for t tests and a difference between two independent groups for a future trial using the $\alpha = 0.05$ and power 80% and 90% using the G-power software Version 3.1 (Erdfelder et al., 1996). Observed power is shown in Table 10. Following this, a sample size required for loneliness at 80% power and $\alpha = 0.05$ was 24 people. The attrition rate was 20%, as 5/25 dropped out (3 after randomisation before the intervention and 2 at follow-up). Accounting for attrition rate, a total of 29 people was required in total.

Table 10. Sample size calculation for loneliness.

Variables	ES[a] (95% CI)	Power (1-β)	Level of significance	N required for significant effects	N required accounting for 20% attrition
Loneliness	1.2 (-1.2 to 3.6)	0.80	$\alpha = .05$	24	29

a – the ES obtained from Mutrie et al. (2012a)

Abbreviations: N- total sample size, LSN – Lubben's social networks, HADS – hospital anxiety and depression scale, SEE – self-efficacy for exercise, SSC – satisfaction with social contacts.

Discussion

This study assessed the feasibility of the Physical Activity Intervention for Loneliness (PAIL) intervention in community-dwelling older adults at risk for loneliness. Due to the exploratory nature of the study and the lack of the obtained power in the feasibility study to test the efficacy hypothesis of the intervention, the predetermined progression criteria were implemented into this study as advised by others (El-Kotob et al., 2018). Based on the progression criteria, the retention rate satisfied the criteria of the study, e.g. >75% of participants at 12 weeks (end-point period), as well as no adverse events during the intervention. The recruitment rate of 52.1% by the end of the four months was somewhat lower than was initially proposed at 75% (see Chapter 3 Methodology). Therefore, only two out of three criteria of progression to the definitive RCT were satisfied, meaning that the study was not feasible to deliver in its present form and changes were required to be made. These findings are not surprising based on the fact that it is difficult to access socially isolated older adults who may be less interested in joining an intervention than those who are more socially engaged. As such, the recruitment of lonely individuals can be quite challenging based on what is typically seen in research with hard-to-reach population groups (Mutrie et al., 2010). Therefore, it is recommended that any future large-scale trial should utilise a variety of recruitment methods, and include GP referrals (e.g. letters from GP) to recruit older adults at high risk of loneliness or social isolation in addition to the universally available mass media advertisement approach recommended in the literature (Jopling, 2015, Age Concern UK, 2016, Shvedko et al., 2018a).

All participants who consented to participate in this study agreed to randomisation, however, the attendance rate was low (69.2% for the intervention group, 55% in WLC group). These results are not necessarily surprising, as the physical activity intervention is considered to be a behaviour change strategy, and it is recognised that behaviour change is

not easily initiated or consistently maintained, especially in older adult populations (Horne et al., 2018). One of the possible reasons for low attendance in PAIL can be attributed to impaired self-regulation, which is a typical consequence of loneliness, that was also found to influence adherence to physical activity in other studies (Hagger et al., 2010). Consequently, the intervention effect can be reduced due to low attendance and decreased opportunities for social interactions between participants.

Bearing in mind the barriers to participation (as described in Chapter 4, Qualitative results) including transportation difficulties, a firm commitment to attend every session of the 12-week intervention weekly was not feasible for all participants. However, similar to Mutrie et al. (2012a), those who did attend regularly enjoyed the intervention that corresponded to their needs as shown in the focus group interviews. Delivering the intervention during the summer months was perceived by participants as more enjoyable than during the winter months, which is consistent with the literature as weather was one of the most commonly reported barriers to regular engagement in physical activity (Wu et al., 2017). Some participants struggled to remember the aim of the research project, which led to confusion about the need for regular participation. Therefore it may be necessary in a future trial to ask them in their own words to repeat the purpose of the research and the need for regular engagement, with the goal to improve compliance as recommended by El-Kotob et al. (2018). To stimulate participant motivation and adherence, additional "self-monitoring" techniques of behaviour change (Michie et al., 2009a), such as pedometers or other movement assessment devices, may be advisable for inclusion in future studies. In addition, providing transport to and from walking session locations may also improve adherence, particularly within this population due to health issues that may affect their mode of transport, and participants' desire to have the walks in various locations to maintain their interest.

In terms of establishing friendly relationships between participants, for some the development of friendships started from the second or third session. The majority of participants stated that 12 weeks is of insufficient duration to establish friendships; but they made acquaintances as follows from the end-point focus group interviews. As noted by Stevens (2001), lonely people often lack essential social skills to develop relationships with strangers and have been shown to have unrealistic friendship expectations. It is recognised that it is not just enough to have social interactions to reduce loneliness, but it is also necessary to have meaningful social relationships arising during shared and enjoyable activities between people and their experiences. It is particularly the quality of relationships that matters most. In contrast, some participants noted that they exchanged numbers and made friendship connections from the first-to-second session, which they stated occurred naturally to them based on common interests and viewpoints arising between participants during walks. Within the current PA intervention, the beneficial effects may be indirect through increased social support in general and social support for exercise, lower depression and/or improved self-esteem, however it was not obtained in this research. As reported in the literature, the acute exercise effect is brief (Chodzko-Zajko, 2014b) and without an adequate follow-up period it may be impossible to detect any changes. A longer duration intervention may be needed to allow participants to build upon transforming new contacts into meaningful relationships based on trust, which previous studies suggest may be up to 5 months (McAuley et al., 2000b, Findlay, 2003). Therefore, a future trial may need to include follow-up assessments of social connections between participants using a reliable tool, in addition to conducting focus group interviews and assessments of social satisfaction with programme participation during the course of intervention delivery.

With regards to acceptability of questionnaires, the internal consistency and test-retest reliability for all questionnaires was moderate to high (Cronbach's alpha from ranged 0.69 to

0.98), however moving forward, for some participants in a future trial additional support may be required with completion of the questionnaires due to lack of clarity and limited English literacy, which was also suggested during the focus group interviews. It was also noted that participants were surprised at the number of questionnaires, thus participant burden would need to be considered in the future and a reduction in the number of questionnaires to those shown to be most likely to indicate important changes due to the intervention, from the power calculations reported in this study. Given that the initial aim of the intervention was to see if loneliness could be impacted, and the observed power and estimated sample size for this seems achievable, this could be recommended as a future primary outcome. However, a feasibility study, by its very nature, may be under powered to achieve statistical significance at α=0.05 (Lee et al., 2014). Therefore, any interpretation based on significance levels should be treated with caution. Post-hoc sample size calculations were possible, however not advisable for feasibility studies (Walters, 2009). Effect size (ES) is usually taken from the pilot studies to make an informed guess about the reasonable effect in a full-scale trial. Typically, the effect size is set with $\beta = 0.2$, meaning there is an 80% chance of finding a significant association of this size between the outcomes (power = 0.80) and 20% chance of missing this association, as was the case in the present study. However, if no data are available from other studies, a minimal possible value can be used such as 0.1 to find a 10% chance of an association of this size between the outcomes. There was no effect of the intervention on psychosocial outcomes in the PAIL study, so the power calculations, although possible, are not particularly informative and cannot be used for sample size calculations for a future trial. Instead, the sample size for the future study was calculated based on the target difference using the ES for loneliness obtained from the study of Mutrie et al. (2012a) as specified by the Delta2 guidance (Cook et al., 2018). The results show, that for loneliness a sample size at 80% power was 24 people. Accounting for the attrition rate, a total of 29

people was required in total. Given that larger effect sizes result in lower number of people, there is a possibility of obtaining a larger sample size based on calculations taken from other studies. However, due to underdevelopment of the topic of loneliness and PA, further research and a discussion with experts in this field is required for more justified calculations.

Assessment of physical activity using ActivPAL accelerometers was both feasible and acceptable in the present study. Participants reported that it was comfortable to wear the unit during a 7-day data collection period. However, participants would have preferred to wear a more informative device, one that shows readings of actual physical activity performed and that can be worn on the wrist as opposed to be secured by adhesive tape to the thigh. Previous studies have shown that these accelerometers capture periods of lying/sitting, standing, walking and are reliable for use in older adult populations (Chastin et al., 2010, Mutrie et al., 2012a). However, the accelerometers do not capture other forms of activity such as balance training, cycling, or swimming and, therefore, the studies that may choose to employ a non-walking intervention will need consider these limitations of technology. It can be suggested to use a pedometer during the trial and an accelerometer to capture activity data pre-post intervention. Also, direct monitoring cannot capture type of activity so there may be a case for incorporating both self-report and direct monitoring measures in future interventions.

Participants shared the most positive feedback in relation to the Polar heart rate monitors, which were used in addition to methods of subjective assessment of rating of perceived intensity, such as the Borg RPE scale and the talk test. Connecting the monitor via Bluetooth to the mobile device of participants resulted in a visual display of the amount of activity performed and could also give audio instructions to participants to maintain their heart rate within a given target zone (e.g. aerobic, for weight loss, etc.). However, only 4 out of 25 participants were willing and able to use heart rate monitors due to the specific requirements for connecting to their mobile device. The use of a heart rate tracking watch

was not available due to resource constraints. Future studies could explore various methods of assessment of objectively measured exercise intensity to determine the most preferred technology for this population group.

As this was a feasibility study, the primary aim was to assess feasibility and acceptability of the intervention, study design and methodological tools (Eldridge et al., 2016b, NIHR, 2018). As such, this study was not sufficiently powered to assess or detect treatment effects (Eldridge et al., 2016b). Although there was a general trend toward a pattern of improvement across the various psychosocial and physical activity outcomes, these changes were not statistically significant making it difficult to determine a future primary outcome. It would be informative to suggest whether the intervention group changed by a MCID, but the outcome measures used do not have clear indications of what this would be. Due to the unrepresentative sample sizes and the imprecision of estimates common for feasibility trials, CONSORT (2010) suggests exercising caution in relying on calculated effect sizes from feasibility studies for estimation of future sample sizes for a large scale RCT (Eldridge et al., 2016a). Efficacy outcomes of the current feasibility study may be used in exploratory analyses, and further changes in the intervention design and methods are required before proceeding to a definitive trial.

Strengths and limitations

This study included the features of effective physical activity interventions for treatment of loneliness and social isolation in community-dwelling older adults based on the results of a published systematic review (Shvedko et al., 2018a). Walking was chosen as it has been shown to be the most feasible and cost-effective method of physical activity for older adults (Mutrie et al., 2012a, Townsend et al., 2012). Other strengths of this study include objective measurement of PA, use of reliable methods of assessment of psychosocial outcomes in older

adults, and the mixed method research design that allowed for collecting feedback from participants during and at the end of the intervention. This approach provided the opportunity to make improvements while the intervention was ongoing, and also provided evidence to direct the design and methods used in a future full-scale trial.

Study limitations included selection bias associated with recruitment being done through self-referral. Due to the "stigmatising nature of loneliness," GP referrals may be a more effective recruitment approach, as GPs have access to and can reach more individuals at risk for loneliness and social isolation, a group who are less likely to respond to the advertisements for participation in physical activity interventions (Peplau et al., 1982, Stevens, 2001, Wenger et al., 2004, Griffin, 2010). Evidence from systematic reviews suggests that lonely but socially active, moderately fit participants or those with relatively good physical function are typically more likely to volunteer to participate in a physical activity intervention (Stevens, 2001, Cattan et al., 2003, Masi et al., 2010, Shvedko et al., 2018a). This may be the case in the current feasibility study which included physically mobile participants as measured using the Short Physical Performance Battery (SPPB) (Guralnik et al., 1994) with a score ≥ 9 out of 12 (Pahor et al., 2014) based on the eligibility criteria. Therefore, any treatment effect of this feasibility study may be blunted by this selection bias (Stevens, 2001, Masi et al., 2010) and inclusion of higher functioning older adults. With this, the characteristics of those who volunteered to participate in the PAIL study can suggest about those who were most responsive to participation in the intervention who may be only a particular subset of the targeted population (El-Kotob et al., 2018).

Another issue associated with the selection bias in the present study is exclusion of potential participants who may have been participating in forms of physical activity not related to walking, e.g. resistance exercise or yoga. Sedentary participants in the PAIL study were defined as regularly engaging in less than 20 minutes of moderate intensity PA in the

last four weeks, and less than 125 minutes per week of moderate intensity PA for the past month (Stevens et al., 1998). This was done using the modified short form of the CHAMPS physical activity questionnaire adopted for use in an older adult population (Stewart et al., 2001) (Chapter 3, Methodology). A total of eleven participants were excluded from the study based on this criterion during the phone-based eligibility screening. However, for future studies it is advisable that instead of using this general normative definition of a sedentary individual, this exclusion criterion could be exclusive to walking. For instance, Mutrie et al. (2012a) excluded from their walking intervention those whose baseline step count was >7000 steps/week based on study by Tudor-Locke et al. (2011). To avoid this limitation, future studies should consider using objective methods of assessment of PA (e.g., pedometers or accelerometers) in older adults as a screening tool for eligibility.

Related to the participant selection it is difficult to measure loneliness using phone-based screening tool (Hughes et al., 2004) and use of complex assessment of social demographic characteristics, such as level of income, marital status, living conditions, education, any children and other information must be included in the eligibility to increase the specificity of self-assessment tools (Wenger et al., 2004).

Another limitation of the present study was the high risk for detection bias due to the PhD student researcher also having to serve as walking group leader, which resulted in the researcher not being blinded to the treatment allocation. Appropriate blinding of the researcher was not possible in the present study due to a lack of resources available to pay an independent person to deliver the intervention and collect all of the data. However, the focus groups were conducted by a trained independent researcher in an effort to ensure participants could be candid in sharing their views about the intervention. As such, it is recommended that future studies are resourced to allow for the recruitment of a trained walking leader to deliver the intervention and an independent assessor of outcomes to allow for adequate blinding and

reduce detection bias. It was not possible to conduct regression analyses due to the low power. Therefore, it was not possible to assess potential moderating effects between outcomes.

Implications for the future research

A more extensive and robust strategy is needed moving forward to support adequate recruitment to a definitive RCT, such as via GP recruitment. Future studies should employ an independent trained walking leader to deliver the intervention and blinded personnel to perform assessments of outcomes. In addition, transport to and from walking locations may also improve the adherence and give access to a variety of walking locations. To increase the motivation of participants, pedometers could be provided for the duration of the intervention to help to monitor gradual progression of steps counts per week, as well as being used as a screening tool for inclusion into the study.

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CHAPTER 5. GENERAL DISCUSSION

Overview

Chapter 1 of this thesis reviewed the evidence base for loneliness and social isolation in later life and a rationale for the need of this PhD research. Chapter 2 presented the systematic review and meta-analysis of PA intervention effects for social isolation, loneliness, low social support and other related social outcomes in community-dwelling older adults published in the *Psychology of Sport & Exercise* journal (Shvedko et al., 2018a). Chapter 3 described the research methodology of the PAIL intervention, providing an overview of the main research paradigms and philosophical assumptions underpinning the feasibility trial as well as the progression criteria for proceeding to the future full-scale RCT. Chapter 4 contains the results, and their discussion, from the PAIL feasibility study that is currently under review with the *Pilot and Feasibility Studies* journal (Appendix 28).

The conducted systematic review and meta-analysis showed evidence of intervention effects for social functioning with strongest effects obtained for PA interventions versus PA with a social interactions, diseased populations versus healthy, group exercise setting versus individual or mixed group and individual settings, and delivery by a medical healthcare provider versus non-medical (fitness) healthcare provider. No effects of PA were found for social support and social networks. Due to the lack of available evidence, it was not possible to analyse PA intervention effects for loneliness. Thus, the evidence of PA interventions for loneliness in community-dwelling older adults remains limited. Therefore, coincident with the review results, a novel intervention was required to examine the feasibility of PA interventions for loneliness and other related social health outcomes in community-dwelling older adults. The purpose of this thesis was to consider whether PA is viable as an intervention to alleviate loneliness, from the literature thus far, and, using what has been

learned from the results of previous studies, design, conduct, and examine the feasibility of a Physical Activity Intervention for Loneliness (PAIL) in community-dwelling older adults at risk for loneliness.

Methodologies used in this thesis

A range of research methodologies were used in this thesis, including systematic reviewing and meta-analysis of PA interventions for loneliness; a mixed-methods research design utilising quantitative and qualitative (i.e. focus groups) research methods; a systematic review of evidence and a meta-analysis.

The systematic literature review described in Chapter 2 (Shvedko et al., 2018a) incorporated specific inclusion criteria within the older adult population to summarise the effects of existing PA interventions. The conducted review was strengthened by inclusion of only randomised controlled studies as advised to improve the methodological rigour of the evidence (Hagan et al., 2014). Secondly, only older adults 60 years of age or over, healthy or having chronic health conditions and residing only in community settings were included as being a targeted and a less-researched population category than residents of institutional settings. Thirdly, all possible social health outcomes related to loneliness were included, such as social isolation, social support, social networks, and social functioning as a sub-domain of health-related quality of life for the broader multi-perspective approach of the researched phenomenon. This also increased the number of available PA interventions for analysis, as these were in the minority among other interventions. Additionally, this review was strengthened by a sub-group comparison of PA interventions for social functioning outcome.

The mixed-methods research approach in the PAIL intervention was utilised due to being highly recommended in feasibility studies to contribute new knowledge in under-researched or complex phenomena, such as loneliness (Gardiner et al., 2018). It was aimed

to elaborate an in-depth understanding of issues emerging from the PAIL trial (Fossey et al., 2002, Tong et al., 2007). The mixed-method intervention design aimed to increase the strengths and minimize weakness of two different research paradigms, such as the positivism of quantitative research) and the constructivism and pragmatism perspective of qualitative research in this intervention (Creswell et al., 2007). A feasibility study, with a randomised controlled trial design, was chosen to test the appropriateness of the methods used in the intervention as well as to see if the study can be executed (not necessarily obtaining significant results), before proceeding to a large-scale RCT in the future. This was an important step in the research process in order to save time and resources that could be wasted on an inappropriately designed intervention (Eldridge et al., 2016b).

Summary of research findings from the systematic review and meta-analysis of PA interventions for loneliness, social isolation or low social support

As indicated in Chapter 1 (General introduction), due to the increased ageing of the UK population and the growing prevalence of loneliness in older adults (Office for National Statistics, 2018a), the focus of health specialists has been addressed towards the early prevention and treatment of loneliness in the society as a major public health concern. The analysis of existing literature to date suggested that older volunteers involved in community-based programmes benefit from social engagement through creating the socially supportive environment that generate a sense of belonging (Jopling et al., 2017, Gardiner et al., 2018). While leisure activities reduce loneliness by keeping occupied, spending time interacting with others and maintaining acquired social contacts, relatively little has been achieved in identifying the mechanism of PA intervention effects and features of effective PA interventions, and any existing evidence is often contradictory (Bartlett et al., 2013a, Pels et

al., 2016, Jopling et al., 2017, Stojanovic et al., 2017). Literature analysis showed that existing systematic reviews on the topic included variety design interventions, such as experimental, longitudinal and cross-sectional studies, that makes it difficult to draw any generalisations regarding the benefits of experimental interventions (Petitte et al., 2015, Poscia et al., 2018). This knowledge highlighted the need for further research. Consequently, the systematic review and meta-analysis of randomised controlled PA interventions was conducted as a first step of this PhD thesis to fill the gaps in the literature and advance the knowledge in this field (Shvedko et al., 2018a). Thus, the aim of this systematic review was to examine PA intervention effects on loneliness, social isolation or low social support in community-dwelling older adults.

This review showed effects of PA interventions for social functioning outcome, no effects were obtained social support, or social networks. There was a lack of evidence to review the effects of PA for loneliness due to an insufficient number of available studies, coincident with the existing literature (Hagan et al., 2014, Petitte et al., 2015). Among 38 trials included in the systematic review in total, loneliness was only included in three (Ollonqvist et al., 2008, Mutrie et al., 2012b, Chan et al., 2017). All three included studies assessed loneliness as a primary outcome, however the meta-analysis for loneliness was not performed due to not sufficient or a missing data and differences in assessment methods of loneliness. Many existing reviews on the topic reported a low methodological quality, high attrition rate, non-representative samples (e.g. not lonely individuals) and a short duration of intervention period and results of these reviews should be treated with caution (Hagan et al., 2014, Ayalon et al., 2018, Gardiner et al., 2018, Lim et al., 2018). This was the case for the current systematic review. Risk of bias assessment of included interventions showed that over half of interventions (26/38 RCTs) had a low quality due to a high risk of bias. A common bias was due to inadequate allocation concealment, absence of intention-to-treat concept as

well as inappropriate blinding of health care providers, that is rather not feasible for PA interventions where a care provider is aware of the group allocation. Social health outcomes included in the review were assessed using validated tools. For instance, loneliness was assessed using as Russel's UCLA loneliness scale (Russell, 1996) and De Jong Gierveld loneliness scale (de Jong-Gierveld, 1987), and using a single item tool, such as a 1-item question: "Do you feel lonely?" (Pitkala et al., 2004). This is in line with the previous review that found the majority of studies used validated assessment tools for loneliness (Gardiner et al., 2018). However, inclusion of one-item assessment tool was recommended as it was strongly correlated with more complex measures, such as demographic characteristics, health conditions and other outcomes required for a consequent analysis (Victor et al., 2008). Loneliness, as a social health outcome, is a complex concept, and mechanisms of interventions often act together at once (Pettigrew et al., 2008). Therefore, any treatment effect is difficult to decipher without analysis of other related factors and inclusion of wider assessment methods of social outcomes which were not always included in the studies as coincident with previous findings.(Smith et al., 2017, Gardiner et al., 2018). This suggests that studies incorporating loneliness as a key outcome should also include measurement of other social outcomes.

The performed sub-group analysis for social functioning showed the strongest effect obtained for PA interventions versus PA with a social component, diseased populations versus healthy, group exercise setting versus one-to-one or individual settings, and delivery by a medical healthcare provider versus untrained health provider. Related to first, this seems somewhat odd bearing in mind that social interactive environment provides better opportunities for building socially friendly relationships triggering a feeling of perceived emotional support, leading to further action (Baumeister et al., 1995, Masi et al., 2011). However, for the social functioning outcome, PA was compared to control (sedentary)

conditions and active control conditions, which were combined into one group. Therefore, the findings of this meta-analysis should be accepted bearing in mind the aforementioned limitations.

PA interventions with social component in this review included health education classes, recreational activity, cognitive behavioral therapy, social support and sleep hygiene (Shvedko et al., 2018a). Based on the review of Poscia et al. (2018), multicomponent programmes, including educational, cognitive and social support programmes are highly recommended to tackle loneliness. However, it may be that due to the stigmatising nature of loneliness and a high demand for a reciprocity required to influence social health outcomes, interventions for lonely older adults may not always work. This was also obtained in qualitative review of Gardiner et al. (2018), where social facilitation interventions did not provide a mutual response. Related to obtained effect of subgroup-analysis for social functioning outcome for diseased populations versus healthy, it can be hypothesised, that the specific vulnerable groups, such as a diseased population, have a higher need in socially enriched PA interventions due to deteriorating health conditions, which may explain the findings of this review coincident with others (Lim et al., 2018, Poscia et al., 2018). Related to benefits obtained for group interventions are in line with the previous research that highlighted a treatment effect of a sense of companionship during group interventions (Cattan et al., 1998, Cattan et al., 2005, Pettigrew et al., 2008, Petitte et al., 2015, Poscia et al., 2018). However, contrary to the previous research evidence, one-to-one settings using non-PA interventions, such as a use of robotic dog, videoconferencing and others, were more effective in reducing loneliness in older healthy adults, but required more financial resources (Findlay, 2003, Banks et al., 2008, Kahlbaugh et al., 2011, Tsai et al., 2011). Related to effects obtained for group exercise settings versus individual or mixed settings, similar to previous findings (Smith et al., 2017, Gardiner et al., 2018), the involvement of a trained

healthcare providers who act as a gatekeepers between the community and health organisation, benefit in interventions for loneliness which provides opportunities to feel accepted to the community and increase interest in participation. Performed meta-analysis in this systematic review reported a moderate heterogeneity for social support and a substantial heterogeneity for social functioning and social networks. According to previous research (Smith et al., 2017, Stojanovic et al., 2017, Lim et al., 2018), a high heterogeneity is often reported due to differences in intervention design and settings specifically among diseased populations. In this review the majority, 25 out of 38 interventions, were for older adults with chronic diseases, which is likely to predispose the high heterogeneity in this population group.

The narrative summary of participant and intervention characteristics of this review allowed distinguishing of specific features of beneficial PA interventions (see Chapter 3).

1. A walking-based intervention over 30 minutes' duration.
2. A small group setting (up to 9 people).
3. Centre-based interventions.
4. Light-to-moderate intensity of the intervention.
5. 12-week average duration of the intervention.
6. Delivery of intervention by experienced/qualified staff.
7. Facilitation of intense social contact between participants through active engagement in social activities (e.g. healthy workshops).

Bearing in mind that available evidence for PA for loneliness was limited, although it was possible to observe some of the features of effective interventions, further research was needed to test the effect of PA interventions for loneliness in community-dwelling older adults in a feasibility study (Eldridge et al., 2016b).

Summary of approach and research findings from the PAIL feasibility study

The observed features of effective interventions from the systematic review, listed above, and limitations of the included experimental studies were considered and implemented into the design of the novel feasibility study 'Physical Activity Intervention for Loneliness (PAIL)' in community-dwelling older adults at risk of loneliness as assessed using the 3-item loneliness scale during phone screening (Hughes et al., 2004). Those who scored ≥6 out of 9 points were classified as lonely (N=25) and were eligible to study participation. As follows from the literature (Chapter 1) Risk factors for loneliness include living alone (Cohen-Mansfield et al., 2016), being single or widowed (Victor et al., 2005, Hawthorne, 2008), living in remote and rural areas (Bartlett et al., 2013b), low education level (Victor et al., 2005), and being a member of a low income socioeconomic group (Dickens et al., 2011). Therefore, these and other additional characteristics (e.g. any children, and comorbidities) were added into the baseline demographic assessment of included participants to give a characteristic of participants taking part in the experiment (see Chapter 4). The trial was conducted as a 12 week small group outdoor walking intervention with healthy workshops designed specifically to engage older adults in social conversations to increase the possibility of making a friendship connections. The inclusion of qualitative methods (e.g. focus group interviews) into the design of the PAIL intervention allowed to get the participants' feedback on the intervention, reasons for participation, feedback on healthy workshops, and suggestions for improvement. According to the observed beneficial features of interventions from the systematic review (Shvedko et al., 2018a), the PAIL feasibility trial was delivered by a trained health care provider who had a knowledge in PA training for older adults as well as received a training in analysing focus group interviews, but was not involved in the delivery of focus groups. The inclusion criteria of the PAIL feasibility study was assessing loneliness

using both: validated tools, such as the 8-item UCLA (University of California at Los Angeles) Loneliness Scale (Hays et al., 1987), and socio-demographic characteristics of participants for a detailed representation of the targeted population group. The PAIL study included a number of social health outcomes, such as social support, social networks, depression and anxiety, self-efficacy for exercise, satisfaction with level of social contacts and barriers and outcomes for exercise as it is recommended for a feasibility studies underpowered to decide on best future primary outcomes but rather to focus on the feasibility outcomes. The primary aim of the PAIL feasibility study was to estimate: recruitment, retention and attendance rates; the appropriateness of the intervention design and its practicality; the acceptability of the intervention by participants. Process and outcome evaluations were conducted using focus groups interviews and were thematically analysed using a phenomenological inductive approach by two reviewers independently. As the PAIL was a feasibility RCT, the implemented progression criteria was required to decide if the study was possible to progress into definitive large-scale RCT (Eldridge et al., 2016a) or if any changes were required. The *a priori* recruitment and retention criteria for progression were not met as the recruitment rate was 52.1% by the end of the four months was somewhat lower than was initially proposed at 75% despite no serious adverse events. Therefore, the study was not able to progress on the future RCT before requiring some modifications to the trial design.

Although, in general, a pattern of improvement was seen across all outcomes in the intervention group, but not reaching the criterion for statistical significance. This was coincident with the previous literature that confirmed that small sample sizes, poorly designed interventions and short duration of studies often fail to obtain positive influences of interventions (Bartlett et al., 2013a, Gardiner et al., 2018). It is common that experimental studies fail to obtain a reduction in loneliness, however, some report improvements in other

associated outcomes other outcomes such as friendship connections (Routasalo et al., 2009, Gardiner et al., 2018) or levels of helplessness (Bergman-Evans, 2004). In addition, this study did not assess the effect of co-variates, such as an initial level of loneliness, BMI or other factors due to unrepresentative sample. Therefore, the future study will be aimed to address these issues for an adequate correlation analysis.

Focus group interview questions assessed the acceptability and feasibility of the intervention, personal experiences of the intervention, and barriers to participating in the intervention. Using thematic analysis, this study gained insights of participants from participation in the PAIL intervention and barriers to participation. The focus group results showed that the main reason for participation in the intervention was the opportunity to meet new people and get access to local community groups (Chapter 5). Due to limited resources and time constrains, walking was a practical (feasible) physical activity that was well accepted by participants, especially those with some health conditions and associated with its positive, albeit not statistically significant, health effects. This was also in line with the aim which participants had to become physically active. However, the transportation to the location of walks (some of these were off-campus) could be a problem for the majority using public transport. Similarly, the other barrier was weather conditions. It was suggested to run the intervention between the spring-summer seasons. Another suggestion was to organise groups by different abilities (i.e. beginner, improver), have more group leaders per group, and assess routes prior to walking carefully for the level of difficulty and surface quality. Therefore, walks in park with tree branches should not be recommended for older adults with impaired physical balance. Additional assistance of the walking group leader is required during walks to increase the support and self-confidence.

Regarding the healthy workshops, overall, participants had positive feedback. They found the healthy workshop topics to be relevant and led to broad discussions between

participants sharing their opinions. However, due to the lack of time devoted to the workshops (up to 45 minutes) over hot beverages it was not always long enough, and it was suggested to run workshops only for those who were interested and to run them separately from the walks. It was noted that the first friendship gains started from as early as the second or third walk and continued after the programme's end at 12 weeks. Participants wished to continue walks after the termination of the programme and were enquiring about the continuation of the programme as it was very valuable to them. Regarding the experience of living with loneliness, the intervention was particularly important for lonely adults who missed sharing good times. The new connections, arising during the intervention, were helpful for them in terms of expressing their feelings during the shared activity. Therefore, it is recommended in the future study to offer social workshops in the separate days from the main programme to those who wish to attend and share their feelings.

As this was a feasibility study, it was not designed to confirm that the PAIL intervention, being a complex multicomponent PA programme including health education social workshops, could have any positive effect on loneliness. Neither was it was designed to detect an effect of the PAIL intervention for other social health outcomes. However, there was a tendency towards improvement in the experimental group. With this, the study limitations are discussed here, as well as potential suggestions made for future research.

Study limitations included selection bias associated with recruitment being done through self-referral. With lonely adults being a "hard-to-reach" population (Mutrie et al., 2010), group interventions conducted only for lonely older adults may increase "the tendency of negativity" in lonely individuals (Hawkley et al., 2007, p. 571), and, therefore, reduce the effectiveness of the physical activity programmes. With this, a longer intervention (up to 5 months) with adequate follow-up may be needed to transform into friendly relationships between participants based on trust during PA interventions (Minkler et al., 2005, Steptoe et

al., 2013). Another issue was the selection bias associated with recruitment via posters and flyers. Due to the "stigmatising nature of loneliness," GP referrals may be a more effective recruitment approach, as GPs have access to and can reach more individuals at risk for loneliness and social isolation, a group who are less likely to respond to the advertisements for participation in physical activity interventions (Peplau et al., 1982, Stevens, 2001, Wenger et al., 2004, Griffin, 2010). Evidence from systematic reviews suggests that those who are lonely but socially active, moderately fit participants or those with relatively good physical function are typically more likely to volunteer to participate in a physical activity intervention (Stevens, 2001, Cattan et al., 2003, Masi et al., 2010, Shvedko et al., 2018a) Therefore, this selection bias may blunt the treatment effect of the intervention (Stevens, 2001, Masi et al., 2010). In order to avoid selection bias it is advised to use GP referral to recruit older adults at high risk of loneliness or social isolation in addition to the universally available mass media advertisement (Jopling et al., 2017). In the present study this was difficult due to the additional time and resources needed to involve the NHS in this way within the scope of a PhD trajectory, but future studies with more resources should seek to incorporate recruitment via the NHS. This may be the case in the current feasibility study which included physically mobile participants as measured using the Short Physical Performance Battery (SPPB) (Guralnik et al., 1994) with a score $\geq$ 9 out of 12 (Pahor et al., 2014) based on the eligibility criteria. Therefore, any treatment effect of this feasibility study may be blunted by this selection bias (Stevens, 2001, Masi et al., 2010) and inclusion of higher functioning older adults. With this, the characteristics of those who volunteered to participate in the PAIL study can suggest about those who were most responsive to participation in the intervention who may be only a particular subset of the targeted population (El-Kotob et al., 2018).

To provide some commitments to the PAIL intervention, participants in addition to providing consent to study participation could be promised an availability of future references

(by paper or e-mail). Instead of posters, invitations for a participation could be in a form of a personalised invitation card delivered by post to recruit the hard-to-reach population. However, this may require additional resources and time for recruitment.

The lack of change in PA may be due to the low frequency of exercise (once a week walking) in the study or a low duration of walking. The previous studies suggested a mixed effect of such PA interventions (Petitte et al., 2015, Ayalon et al., 2018, Poscia et al., 2018), and even high quality RCTs with improved designs have not obtained robust results as there is not guidelines for treatment of loneliness using the PA (Baker et al., 2008).

Despite the absence of any effect on social health outcomes, the study had advanced features of an intervention that were cumulatively obtained from the systematic review (Shvedko et al., 2018a) and the research literature to date. Due to the stigmatising phenomenon of loneliness, recruiting lonely adults to PA interventions is extremely difficult (Mutrie et al., 2010), therefore, the study had a recruitment strategy comprised of the mass media recruitment through posters and advertisements (see Chapter 3) and word of mouth. The intervention had a mixed method design, combining quantitative with qualitative methods to investigate the experience of participation in the PAIL trial that is valuable and only examinable via feasibility studies (Gray, 2013). In addition to the reliable assessment methods of loneliness using questionnaires, the socio-demographic characteristics, loneliness characteristics and living conditions of participants were assessed as recommended by others (Fry et al., 2002, Wenger et al., 2004). PA was assessed by the objectively measured ActivPAL accelerometers that are widely recommended for use with older adults (Chastin et al., 2010, Mutrie et al., 2012a). The reporting of the design and the results of the PAIL study were in accordance with the CONSORT guidelines for feasibility studies (Eldridge et al., 2016a) to enhance the quality of reporting of this type of research.

Limitations of the PAIL trial and implications for the future research

This study included the features of effective physical activity interventions for treatment of loneliness and social isolation in community-dwelling older adults based on the results of a published systematic review (Shvedko et al., 2018a). Walking was chosen as it has been shown to be the most feasible and cost-effective method of physical activity for older adults (Mutrie et al., 2012a, Townsend et al., 2012). Other strengths of this study include objective measurement of PA, use of reliable methods of assessment of psychosocial outcomes in older adults, and the mixed method research design that allowed for collecting feedback from participants during and at the end of the intervention. This approach provided the opportunity to make improvements while the intervention was ongoing, and also provided evidence to direct the design and methods used in a future full-scale trial.

The small sample size and the design of the current research limit obtaining research evidence within this thesis. The PAIL intervention failed apriory criterion for recruitment requiring modification before proceeding to the large-scale RCT. Future studies should aim to assess moderating factors such as self-esteem and self-worth on the relationship between PA and loneliness, as previous research suggests that there could be exercise-induced positive affective responses through group-based exercise activities (McAuley et al., 2000b). Additionally the trial may include assessment of the first friendship gains as well as the association of loneliness with other outcomes, such as number of friendship connections and levels of helplessness (Bergman-Evans, 2004) to enrich the research applications. Studies show that emotional assistance during PA interventions (or contextual social support) can reduce loneliness suggesting that it can moderate the relationship (the strength of influence) between PA and loneliness in older adults (McAuley et al., 2000a). Similarly a potential confounder can be the physical fitness of the participants, as well as their age, BMI and comorbidities in addition to intervention variables, such as type of exercise, intensity,

duration of each session, and settings (Rejeski et al., 1996, McAuley et al., 2000b, McAuley et al., 2003, Wenger et al., 2004). Related to this, coincident with the theory of active engagement (Lemon et al., 1972, Rowe et al., 1997), PA interventions may generate a sense of purpose through increased social support and greater life satisfaction (Kahlbaugh et al., 2011). Therefore, the assessment of moderating factors would be useful in future research to relate any intervention effects to certain mechanisms and to help improve consequent interventions (Pels et al., 2016). Understanding these moderators (affecting the strength of the relationship between PA and loneliness) or mediators (driving the influence of PA on loneliness) could inform a logic model on how the various key factors might interact to influence loneliness, as well as helping inform a power analysis of the likely sample size needed for a full-scale trial. Therefore, further research is needed to explore the association between loneliness, self-efficacy and social support in a PA intervention for older adults.

Because of the resource constraints and difficulty of recruitment of lonely participants into the intervention due to the stigmatising nature of loneliness, the WLC group condition was chosen in the PAIL feasibility study. It is known that the invitation to participation in the intervention specially designed to reduce loneliness may increase personal barriers in lonely individuals (Peplau et al., 1982, Stevens, 2001, Wenger et al., 2004, Griffin, 2010). However, there are certain limitations associated with the WLC condition, such as opposed to no treatment or placebo condition such that the WLC condition may generate a nocebo effect (a worsening symptom of disappointment, e.g., anxiety, worsening psychological well-being) (Furukawa et al., 2014). One of the explanations for this can be that those assigned to the WLC group may remain motivated but inactive if they have negative psychological wellbeing (e.g. depression symptoms) and may wait to receive a promised intervention later, while participants in a ‘no treatment’ condition may start actively seeking advice of others to receive another treatment (Furukawa et al., 2014). The expectation of intervention that will be

delivered later may also induce frustration in participants (Gold et al., 2017). Such a reaction, in turn, may influence their answering of the questionnaires. Moreover, the intervention effect specific to PA may be blunted (Gold et al., 2017). A network meta-analysis of Furukawa et al. (2014) showed the higher effectiveness of an intervention effect with a no treatment control condition versus a WLC condition (OR=2.9, 95% CI: 1.3-5.7). Therefore, a future study may consider using a no treatment control condition instead of a WLC.

Bearing in mind the time needed to recruit participants and the difficulty of recruiting lonely individuals into research, the time required to recruit participants in a follow-up trial would have to be increased to 6 months or more. Additionally, recruitment rate may be increased by changing inclusion criteria for PA, for instance inclusion older adults whose SPPB<9 and who is able to walk with some support. This group can be compared to those, whose SPPB was 9 or above as it was in this study. Similarly, recognising the relatively low attendance rate in the intervention group, it could be suggested that the intervention can be modified to provide a range of available PA programmes to suit the interests and diverse needs of older adults. Additionally, attendance may be improved by increasing the number of face to face contacts with participants per week or the number of sessions per week. One major limitation of the PAIL Intervention is the absence of PPI (Patient and Public Involvement) involvement. Therefore, the future study may include a phone call or a home visit from a member of local community group (or activity leader) to motivate participants on maintaining behaviour change associated with their participation in PA intervention. Additionally, the inclusion of older adults as peer volunteers into the intervention may help to overcome any occurring barriers and provide extra support (Stathi et al., 2016). The PAIL intervention did not use any particular behavioural change technique, due to the main focus of the research on assessing the *feasibility* of the intervention rather than *effectiveness* of the walking intervention. The systematic review evidence found that use of a step-diary or setting

step goals in a walking intervention resulted in an increase in walking duration by 54 minutes per week (Greaves et al., 2011). Moreover, the use of pedometers in PA interventions may not be effective without inclusion of self-regulatory behavioural change strategies. Therefore, the inclusion of such techniques as a goal setting, a self-monitoring of progress, and providing feedback on performance is recommended for a stronger impact on the maintenance of the behaviour change strategy (e.g. PA) (Greaves et al., 2011). For instance, participants may be given Polar chest straps connected via Bluetooth to a mobile phone or pedometers with number of steps visible for constant use during the whole period of the intervention (which was expressed by one participant during the focus groups).

Further, it would be sensible to measure not the number of walks undertaken but the amount of movement via accelerometry or pedometry during the intervention as an assessment of attendance. The current study did not analyse how change in objectively measured PA predicted change in loneliness, social support or health status. Therefore, future research is recommended to analyse this to confirm previous findings of a direct negative correlation between PA and loneliness obtained in experimental studies (Pels et al., 2016). Additionally, for people with low physical balance more leaders per group is required and routes should be carefully assessed prior to walking for the level of difficulty and surface quality, including tree roots. Groups have to be classified by the levels of difficulty based on their physical functioning and previous history, e.g. beginner, intermediate. As for social workshops, they rather should be offered as a part of the programme (not compulsory) and conducted at the separate times from the walks to increase the feeling of social support and allow participants share their feelings and thoughts on the topics of interest at each lecture. Related to the focus groups, the future study may need to include focus groups or interviews for the control group to understand their experience of participation in the intervention and methods, e.g., what was their experience of waiting for the start of the intervention and how

this may have influenced their answering of the questionnaires, although responses about this latter issue may be susceptible to social desirability bias. Moreover, research shows that the opinion of participants may be inhibited by the group dynamics (Smithson, 2000), and therefore a future study could include individual interviews in addition to focus groups to avoid any bias.

Another issue associated with the selection bias in the present study is exclusion of potential participants who may have been participating in forms of physical activity not related to walking, e.g. resistance exercise or yoga. Sedentary participants in the PAIL study were defined as regularly engaging in less than 20 minutes of moderate intensity PA in the last four weeks, and less than 125 minutes per week of moderate intensity PA for the past month (Stevens et al., 1998). This was done using the modified short form of the CHAMPS physical activity questionnaire adopted for use in an older adult population (Stewart et al., 2001) (Chapter 3, Methodology). A total of eleven participants were excluded from the study based on this criterion during the phone-based eligibility screening. However, for future studies it is advisable that instead of using this general normative definition of a sedentary individual, this exclusion criterion could be exclusive to walking. For instance, Mutrie et al. (2012a) excluded from their walking intervention those whose baseline step count was >7000 steps/week based on study by Tudor-Locke et al. (2011). To avoid this limitation, future studies should consider using objective methods of assessment of PA (e.g., pedometers or accelerometers) in older adults as a screening tool for eligibility.

Related to the participant selection it is difficult to measure loneliness using phone-based screening tool (Hughes et al., 2004) and use of complex assessment of social demographic characteristics, such as level of income, marital status, living conditions, education, any children and other information must be included in the eligibility to increase the specificity of self-assessment tools (Wenger et al., 2004).

Another limitation of the present study was the high risk for detection bias due to the PhD student researcher also having to serve as walking group leader, which resulted in the researcher not being blinded to the treatment allocation. Appropriate blinding of the researcher was not possible in the present study due to a lack of resources available to pay an independent person to deliver the intervention and collect all of the data. However, the focus groups were conducted by a trained independent researcher in an effort to ensure participants could be candid in sharing their views about the intervention. As such, it is recommended that future studies are resourced to allow for the recruitment of a trained walking leader to deliver the intervention and an independent assessor of outcomes to allow for adequate blinding and reduce detection bias.

After the pilot testing of the PAIL intervention, it was suggested to add new participants who were eligible to join the current groups, and identify the start date of their 12-week intervention from the day they joined (i.e., on a rolling basis). A limitation associated with this may be an influence on their answering of the questionnaires (e.g., participants who continued walking may be more socially and physically active and therefore, may increase the social barriers of newly started participants. This in turn, may negatively influence questionnaire responses.

Lastly, as physical function (measured in this intervention using SPPB) can be a health indicator, it is possible to assess the correlation between SPPB and PA from baseline. Therefore, the future research should include assessment of SPPB at follow-up in addition to the baseline assessment.

Implications for policy and practice

Given that the problem of loneliness and poor social relations are considered to be risk factors for morbidity and mortality in older adults due to greater overall survival skills (Holt-

Lunstad et al., 2010), the focus of healthcare professionals has been placed on the implementation of health promotion interventions to address this problem in society. However, despite the close link between social isolation and mortality in older adults, the health-related effect is independent of the emotional experience of loneliness (Steptoe et al., 2013). Although the effects of other non-PA interventions are well reported (Poscia et al., 2018), there is mixed evidence regarding the effectiveness of PA interventions, and results of reviews are contradictory. A lack of high-quality studies and differences in the assessment of PA, use of non-validated tools for the assessment of social health outcomes, and mixed age groups, make the results of even well-designed studies less credible.

In line with this, the present study was aimed to design and implement the PAIL intervention for older adults at risk for loneliness in a community setting, as this population has been less explored in comparison to residents of care facilities (Jopling et al., 2017). The findings from the feasibility study (Chapter 4) suggest that the PA intervention with social health workshops was safe but would require some alterations before proceeding to a large-scale RCT. A more extensive and robust strategy is needed moving forward to support adequate recruitment to a definitive RCT, such as GP improvement in addition to the widely advertisement, recruitment of gatekeepers to provide the access to community and social engagement based on interest groups in addition to the multicomponent PA programmes. However, the focus group interviews highlighted that the research was relevant and participants felt they benefited from the inclusion of PA as it was associated with older adults' primary need to increase PA, and, secondly, served their goal of making friends and becoming a part of a community. The present PhD research showed that the intervention was valuable to participants. The current study raises many issues that can affect the outcomes of the health promotion interventions of this kind. Among them, personal barriers that predispose older adults with loneliness from taking part in participation such an intervention

due to the stigmatising nature of loneliness. In addition, transport to and from walking locations may also improve the adherence and give access to a variety of walking locations. Group interventions were shown to be beneficial for the treatment of loneliness in older adults in previous reviews (Petitte et al., 2015, Poscia et al., 2018, Shvedko et al., 2018a). However, individual barriers may limit social interaction in PA group interventions requiring perceived emotional support for a feeling of social acceptance, leading to further action (Baumeister et al., 1995, Masi et al., 2011). Given this, future interventions may need to take into consideration the challenges associated with a lonely older aged population. Future PA interventions would benefit from access to local leisure centres and transportation to local parks that might potentially increase participants' interests, corresponding to their needs. As a behaviour change concept (Mutrie et al., 2010), PA interventions in the future may include digital technologies, such as digital activity monitors to motivate participants to perform more daily activity and self-monitoring behavioural change techniques. Future studies should employ an independent trained walking leader to deliver the intervention and blinded personnel to perform assessments of outcomes. To increase the motivation of participants, pedometers could be provided for the duration of the intervention to help to monitor gradual progression of steps counts per week, as well as being used as a screening tool for inclusion into the study. The findings from this feasibility study could be used to promote health interventions in community centres for lonely or socially isolated older adults.

Conclusions

To conclude, this thesis supports the existing inconclusive effects of PA interventions for lonely older adults both from the systematic review and the feasibility trial. As obtained by the systematic review, the beneficial effect of PA was found for social functioning and it is sensitive to comorbidities, exercise settings, content and delivery. However, the evidence for

loneliness, social support and social networks was not found, requiring the further research. Although some aspects of the PAIL study were not feasible to deliver in its present form, it may be plausible with some alterations suggested above. Some major alterations should be incorporated to adapt the intervention to the population needs, such as an improved recruitment strategy including GP recruitment and a longer duration of follow-up to obtain any changes between groups. The findings from this thesis are useful for the development of a protocol for future research and have been strengthened by having a design based on the features of effective interventions based on the systematic review of RCTs. Future studies would need to implement a robust methodology to conduct a high quality RCT with a primary social health outcome.

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Appendix 1

PICOS statement

Population	**Include** ☐ Community-dwelling older adults ≥ 60 years of age ☐ Healthy or with a comorbidity but mobile ☐ Without dementia or moderate to severe cognitive dysfunction	**Exclude** ☐ Adults ≤ 60 years of age ☐ Not community residing ☐ Dementia or moderate to severe cognitive dysfunction ☐ Non-ambulatory patients
Interventions	**Include** 1) Physical activity interventions (gym , outdoor, home, web, or telephone-based)	**Exclude** ☐ Multicomponent interventions ☐ Health promotion and exercise-counselling interventions ☐ Exercise referral schemes
Comparison intervention	**Include one of the following** ☐ Control (sedentary) group without any exercise or other non-PA intervention	**Exclude** ☐ Interventions comparing different exercise intensity (e.g. high intensity versus low intensity exercise) ☐ Interventions with control group performing stretching or toning exercise
Outcomes	**Include one of the following outcomes:** ☐ Loneliness ☐ Social isolation ☐ Social support / social support for exercise	**Exclude** ☐ Quality of life (or HRQL) ☐ Social/ family well-being ☐ Happiness

Appendix 2

The example of the Medline search strategy (February 2017)

Database(s): **Ovid MEDLINE(R)** 1946 to February Week 1 2017
Search Strategy:

#	Searches	Results
1	"physical activity".mp. or Exercise/	127913
2	Loneliness/	2724
3	Social Isolation/	11897
4	Social Support/	59955
5	social network.mp.	5081
6	quality of life.mp.	227749
7	2 or 3 or 4 or 5 or 6	295123
8	Aged/	2635232
9	elderly.mp.	190879
10	8 or 9	2670225
11	1 and 7 and 10	3992
12	limit 11 to ("middle aged (45 plus years)" and randomized controlled trial)	1053

Appendix 3

The screening-selection tool

	Variables																								
	Study design		Participants		Settings		Regime of patients with disease		Intervention		Comparison		Outcome					Other reasons for exclusion					Overall decision (A.S.)			
	Include	Exclude	Include	Exclude	Include	Exclude	Include	Exclude	Include	Exclude	Include	Exclude	Include	Include	Include	Include	Include	Exclude	Exclude	Exclude	Exclude	Exclude other)	INCLUDE	EXCLUDE	DOUBTS	REASONS FOR DOUBTS (A.S.)
Author (year)	RCT	Non-RCT	≥ 60 yrs old	Not ≥ 60 yrs old	Community-dwelling	Not community-dwelling (e.g. care homes, hospital)	Ambulatory	Non-ambulatory	PA	Non-PA	Control group or non-exercise intervention	Other PA comparison or no comparison group	Social isolation	Loneliness	Support/social support	Social network/size of network	Social functioning/quality of life	No control group	No full text obtained	Intervention not described	No social health outcome	Inappropriate intervention (e.g. no PA or PA within multicomponent programme)				
McAuley et al. (2000b)	X		X		X		X		X			X		X	X			X						X		
Ollonqvist et al. (2008)	X		X		X		NA		X		X			X									X			
Routasalo (2009)	X		X		X		NA		X		X			X		X						X		X		This is a psychosocial group rehabilitation programme (PGR) with PA components included in a range of activities: 1) art and inspiring activities, 2) therapeutic writing and group therapy, 3) group exercise: dancing, swimming and walking countryside, discussion of health topics interested to participants. All these three groups were combined in one intervention group during stat analysis.Thereore there was no comparison between PA and other non-PA activities or to control condition. Randomisation method is not described.
Mutrie et al. (2012)	X		X		X		NA		X		X			X			X						X			
ery and Blumenthal (199	X		X		X		NA		X		X										X			X		No assessement of social health
Maki (2012)	X		X		X		NA		X		X					X							X			
Iliffe et al. (2014)	X		X		X		NA		X		USUAL				X	X							X			
Kamegaya et al. (2014)	X		X		X		NA		X		X				X		X						X			
Brassington (2002)	X		X		X		NA		X			X			X			X						X		
McAuley et al. (2003)	X		X		X		NA		X			X			X			X						X		
Bowen (2006)	X		X		X		NA		X			X			X			X						X		Control group performed stretching classes once weekly
Littlecott (2014)	X		X		X		X		X		X							X		X		Multicentre intervention		X		No control group not performing exercises. Control group was offered priority access to exercise facilities. Also there was social support for exercise (not general social support).

Appendix 4

Data extraction sheet

		Methods				Participants							Interventions								Outcomes					
Study ID	Reference	Country	Recruitment settings (C, PC, CPC) *	Sample size (N)	M age ± SD/ age range	Male/ female (%)	Targeted population: women only (Y/N)	Population group (H, D)	Type of diasease (if applicable)	Residential settings (IL, AL)	Type of intervention (PA, PASI)	Length of the intervention (weeks)	Experimental group(s)	Control group	Delivery settings (health club/home/centre)	Format of delivery (GF, IF, GIF)	Provider (HP - healthcare provider, MHP - medical healthcare provider, non-HP - non	Outcomes (L, SI, SS, SN, SF, other)	Assessment tool	Validity and reliability of assessment tool (Y, N)	Scoring (range, coding) e.g. social functioning:VAS 0-100, higher score = improvement	Study design (RCT, quasi-RCT, CRCT - randomised clinical trial)	Main findings **a) immediate; b) follow-up assessment**	Additional information (pilot study, translated from another language, author contacted)
129	Brooki et al. (2014)	Denmark	PC (hospitals)	78	64.47±91	59.5% male, 40.5% female	N	D	Lung cancer	IL	PA	10	1) Intervention group (aerobic exercises, muscle strength and stretching exercises): 60 min x 1 time/week	one individual instruction in exercise training	hospital	GIF	HP	SF	SF-36 questionnaire (version 2) (Bjorner, 1997)	Y	VAS 0-100, higher score = improvement	RCT	a) NS; b) NS	
43	Chan (2010)	China	PC (general outpatient clinics)	206	72. 95 ± 7.7 yrs (age range 55-88 yrs)	91% male, 8.6% female	N	D	chronic obstructive pulmonary disease (COPD)	IL	PA	12	1) Tai Chi Qigong (TCQ) group: 60 min x 2 times/week + advised on individual practice at home 60 min/most days of the week; 2) Exercise group (various breathing & walking exercise): 60 min x every day of the week.	UC	centre and home	GIF	HP	SS (perceived social support)	Chinese version of the12 - item Multidimensional scale of perceived social support (MSPSS-C) (Chou, 2000)	Y	VAS 12-84, higher scores = improvement	RCT	a) NS vs control group; b) NS	
169	Chan (2017) Effects of Tai Chi	China	CPC	48	77.3 ± 7.4	76% female, 24% male	N	H	NA	IL	PASI (social facilitation by trained ambassadors)	12	Tai Chi: 60 min ±2 times/week.	UC (home visits by social workers, information about local facilities)	centre	GF	HP	1) L; 2) SN; 3) SS	1) De Jong Gieveld loneliness scale (Leung et al., 2008); 2) Lubben social network scale (LSNS-6) (Lubben et al., 1988); 3) Revised social support questionnaire (RSSQ) (Sarason et al., 1987)	Y	2) Score range 0-30 (higher - better SN)	RCT	Loneliness: a) NS; b) S; Social networks: a) NS; S; 3) Social support: a) NS, b) NS	Pilot trial
130	Chan et al. (2013)	USA	PC (outpatient clininos)	23	54±11	100% female	Y	D	Pulmonary hypertension	IL	PASI (AEROBIC +EDUCATION)	10	1) exercise + education group (treadmill walking): 30-45 min, intensity 70-80% HRR. 24-30 sessions total.	Health eductaion	NG	GF	HP	SF	SF-36 questionnaire (version 2) (Gomberg-Maitland, 2008)	Y	VAS 0-100, higher score = improvement	RCT	a) Significant improvement in exercise group; b) NA	
168	Chien (2005)	Taiwan	PC (outpatient departments of medical centre)	28	60.3 ± 9.3 yrs	100% female	Y	D	osteoporosis or osteopenia	IL	PA	12	1) Home-based trunk strengthening exercise program: 1 set x 10 reps, 3 times/day, 7 days/week.	UC	home	IF	MHP	SF	SF-36 questionnaire (Ware, 1993)	Y	VAS 0-100, higher scores = improvement	RCT	a) NS vs control group; b) NA	Pilot trial
36	Courneya (2003)	Canada	PC (outpatient clinic)	102	60.32 ± 10.47 yrs	59.6% male, 40.4 % female	N	D	colorectal cancer	IL	PA	16	1) Home-based personalized exercise program (preferred mode e.g. swimming, cycling): 20-30 min, moderate intensity 65-75% HR max, 3-5 days/week.	no exercise prescription	home	IF	HP	social/family well-being (sub-domain of QoL)	36-item Functional assessment of cancer therapy-colorectal (FAC-T) scale (Ward, 1999)	Y	VAS 0-112, higher scores = better quality of life	RCT	a) NS vs control group; b) NA	
30	Courneya (2011)	Canada	PC (Alberta Breast Screening Program)	320	82.5±6.36 yrs	100% female	Y	H	NA	IL	PASI (facility-based session, health education, telephone calls, plans for vacations, regular newsletters)	1 year	1) Aerobic exercise group: 45 min/day, moderate-to-vigorous intensity 70-80% HRR, 5 days/week.	no exercise prescription	fitness facility	IF	HP	SF	the Medical Outcomes Study short form survey (SF-36) (Ware et al., 2002)	Y	VAS 0-100, higher scores = improvement	RCT	a) NS vs control group; b) NA	

16	Crees (1999)	USA	C	49	76.0 ±4.0 yrs	both genders, 96% female	N	H	NA	AI	PA	24	1) Combined endurance-resistance exercise training program: 60 min/day, intensity 75-85% HRR for aerobic exercise (kayak and stepper equipment), 75-8-% HRmax for resistance training (gym equipment), 3 days/week.	no exercise prescription	centre	IF	HP	SF	QF-36 questionnaire (Ebergner, 1991)	Y	VAS 0-100, higher scores = improvement	RCT	a) NC vs control group; b) NA	missing data (author contacted)
35	Daley (2007)	UK	PC (outpatient clinics/cancer groups)	109	51.0 ± 9.7 yrs	100% female	Y	D	breast cancer	IL	PA	9	1) Aerobic exercise therapy group: 50 min/day, intensity 65-85% HRmax, 3 days/week; 2) Exercise placebo group (body conditioning): 50 min/day, low intensity (<40% HR max), 24 times total.	UC	university centre	IF	HP	social/ family well-being (sub domain of QoL)	the Functional Assessment of Cancer Therapy General (FACT-G) (Piper, 1998)	Y	not stated	RCT	a) significant between exercise group and control; NS between body conditioning group and control; b) NS	missing data (author contacted).
145	De Vreede (2007)	Nethelands	C	98	74.2 ± 3.59 yrs	100% female	Y	H	NA	IL	PA	12	1) Functional tasks exercise group: 40 min, 5-10 reps for each exercise, 3 days/week; 2) Resistance exercise group: 60 min/day, moderate to hard intensity 7-9 RPE (Borg), 3 days/week.	no exercise prescription	leisure centre	GF	MHP	SF	SF-36 questionnaire (Ware, 1993)	Y	VAS 0-100, higher scores = improvement	RCT	a) NS vs control group; b) NS	missing data (author contacted)
39	Devereux (2005)	Australia	C (community health centres/senior centres)	50	73.3 ± 3.9 yrs (age range 65.5-82.5 yrs)	100% female	Y	D	osteopenia/osteoporosis	IL	PA	10	1) Water-based and mixed land-based exercise + education: total 60 min/day, 2 days/week	no exercise prescription	community aquatic centre	GF	MHP	SF	SF-36 questionnaire (Hall et al., 1999)	Y	VAS 0-100, higher scores = improvement	RCT	a) significantly higher from control group; b) NA	
79	Evcik (2002)	Turkey	PC	90	56.24 ± 6.50 yrs (age range 40-71 yrs)	47% male, 53% female	N	D	knee osteoarthritis	IL	PA	12	1) Home exercise program (isometric and isotonic quadriceps exercises): duration NG, 10 reps/exercise, 2 times/day, most days of the week; 2) Walking exercise program, 10-30 min/day, 3 days/week.	no exercise prescription	home	IF	MHP (physiotherapist)	GI	Turkish version of the Nottingham Health Profile questionnaire (Kucukdeveci, 2000)	N	scoring not given	RCT	a) NS vs control group; b) NA	
60	Garcia-Martinez (2012)	Spain	PC (Fibromialgia Association)	28	58.86 ± 8.64 yrs	100% female	Y	D	fibromyalgia	IL	PA	12	1) Exercise group (aerobic, strengthening and flexibility exercises): 60 min/day, intensity from 60-70% HRmax to 75-95% of HRmax, 3 days/week.	no exercise prescription	not stated	GF	MHP	SF	Spanish version of the SF-36 questionnaire (Ware, 1992)	Y	VAS 0-100, higher scores = improvement	RCT	a) significantly higher vs control group; b) NA	
74	Hongo (2007)	Japan	PC (university, outpatient clinics)	80	67.0 ± 6.03 yrs	100% female	Y	D	osteoporosis	IL	PA	16	1) Home exercise group (the single isometric back strength exercise prescription): 3-5 min/exercise, 1 set x 10 reps, 5 days/week.	no exercise prescription	home	IF	MHP	recreation and social activity (sub-domain of QoL)	Japanese Osteoporosis Quality of Life Questionnaire (Miyakoshi, 2003)	Y	VAS 0-152, higher scores=improvement	RCT	a) NS vs control group; b) NA	
27	Huang (2011)	Taiwan	C	186	Age range 60-71 (Mage not given)	41.4% male, 58.6% female	N	H	NA	IL (registered household)	PASI (cognitive behavioural therapy)	8	1) Cognitive behavioural therapy group (CB): 60-90 min x 1 day/week for 8 weeks; 2) LLB + Tai Chi exercises: 60 min x 5 days/week. 1) OEP: Home-based exercise program and walking exercise: 30 min/day, progressing intensity, 3 days/week; 2) FaME: community-based group-exercise program (group	no exercise prescription	centre	GF	HP (trained facilitators - cognitive therapy, professional instructors	1) SS behaviour; 2) SS satisfaction 1) social network	Chinese version of the Inventory of Social Supportive Behaviours (Huang, 2004) 1) Lubben Social Network Scale (LSNS) (Lubben,	Y	VAS not reported, higher scores = improvement 1) VAS 0-20, higher scores	RCT	a) significant improvement vs control group; b) significant improvement vs control group. 1) Social network: a) NS vs	

8	Lilffe (2014)	UK	PC (integrated health care systems)	830	M age 73, Age range = 65-94 yrs.	62% female	N	D	various chronic diseases	IL	PA	24 weeks	1) OEP: Home-based exercise program and walking exercise: 30 min/day, progressing intensity, 3 days/week; 2) FaME: community-based group-exercise program (group exercise training): 2 x 30 min/day, home exercises (based on OEP) + walking exercise: 30 min x 2 days/week, flexibility training, adapted Tai Chi complex, functional skills training.	no exercise prescription	community centre	GF	HP	1) social network size; 2) perceived SS	1) Lubben Social Network Scale (LSNS) (Lubben, 2006); 2) Multidimensional Scale of Perceived Social Support (MSPSS) (Zimet, 1988).	Y	1) VAS 0-30, higher scores = better social network; 2) scoring not given	multicentre cluster RCT	1) Social network: a) NS vs control group; b) NS; 2) Social support: a) NS vs control group; b) NS	
14	Imayama (2011)	USA	C	439	57.93 ± 5.03 yrs	100 % female	Y	D	obesity or overweight	IL	PA	12 months	1) Aerobic exercise group: 45 min/day, moderate-to-vigorous intensity 70-85% HRmax, 5 days/week; 2) Dietary weight-loss group: consultations with the dietitian 1-2 times/week; 3) Diet + exercise group: 45 min/day, moderate-to-vigorous intensity, 5 days/week.	WL	exercise facility	GF	MHP	1) SS; 2) SF	1) short version of the Medical Outcomes Study (MOS) Social Support Survey (Derogatis, 1983); 2) SF-36 questionnaire (Ware, 1993)	Y	1) VAS 0-100, higher score =improvement; 2) VAS 0-100, higher score = improvement	not stated	1) Social functioning: a) NS vs control for all groups; b) NA. 2) Social support: a) NS vs control for all groups, b) NA.	
9	Kamageya (2014)	Japan	C (municipal services)	52	74.9 ± 5.9 yrs	53% male, 47% female	N	H	NA	IL	PASI (cooking, handcraft competitive games)	12	1) Exercise group + leisure activities (strengthening exercises, aerobic exercises & flexibility exercises): 45 min/day weekly for exercise, total duration of a session 2 hours/weekly.	no exercise prescription	community centre/home	GIF	HP	SN	Lubben Social Network Scale Revised (Lubben, 2006)	Y	VAS 0-30, higher scores = better social network	RCT	a) NS vs control group; b) NA	
61	Katznelson (2006)	USA	CPC (outpatient clinics/communities)	70	72.24 ± 5.18 yrs	100% male	Y	D	testosterone insufficiency	IL	PA	12	1) Resistance exercise group (exercises with elastic bands of various resistance): duration not stated, intensity from very light to heavy, 3-4 days/week.	UC	home	IF	MHP	SF	SF-36 questionnaire (Ware, 1992)	Y	VAS 0-100, higher score = improvement	RCT	a) significantly higher vs control group; b) NA	
131	Kerse (2010)	NEW ZEELAND	PC (outpatient clinics)	193	81.10±19.14 yrs	41.5% male, 58.5% female	N	D	depression	IL	PA	24	1) exercise group (moderate-intensity balance retraining, progressive resistance lower limb-strengthening exercises, and walking): 30 min x 3 times/week, progressing intensity.	non-PA (social control group)	home	IF	MHP (trained nurse)	SF	SF-36 questionnaire (Brazier, 1992)	Y	VAS 0-100, higher score = improvement	RCT	a) NS; b) NA	
65	Kovaks (2013)	Hungary	C	76	68.4 ± 5.87 yrs	100% male	Y	H	NA	IL	PA	25	1) Exercise group (mixed exercises): 60 min/day x 2 days/week.	no exercise prescription	sport centre	GF	HP	SF	SF-36 questionnaire (V2) (Walters, 2001)	Y	VAS 0-100, higher score = Improvement	parrallel two-arm RCT	a) NS vs control group; b) NA	
19	Kurtner (1997)	Georgia	C	200	Mean age 76.2 yrs (SD not stated)	19% male, 81% female	N	H	NA	IL	PA	15	1) Tai Chi group: 45 min/day x 2 days/week; 2) computerized balance training: 45 min/weekly.	SI (attention-control group - education): 45 min/weekly)	facility/home	GF	HP	SF	SF-36 questionnaire (Ware, 1992)	Y	VAS 0-100, higher score = improvement	RCT	a) NS vs control group; b) NS vs control group	
7	Maki (2012)	Japan	munnicipal centre/community	150	72.0 ± 4.0 yrs	29.3% male, 73.7% female	N	H	NA	IL	PA	12	1) Walking program: 90 min/weekly.	attention-control group (education): frequency not	not stated	GF	HP	SN	Lubben Social Network Scale (Lubben, 1988)		VAS 0-30, higher scores = better social network	RCT	a) NS vs control group; b) NA	
5	Mutrie (2012)	UK	PC	41	70.81 ± 5.24 yrs	32 % male, 68% female	N	H	NA	IL	PA	12	1) Individualized walking program: duration various, intensity various, 2 days/week.	no exercise prescription	outdoors /community	GF	HP	1)SF; 2) L	1) SF-36 questionnaire (version 2) (Kenkinson, 1999); 2) the UCLA loneliness scale (version 3) (Russell, 1996)	1) Y; 2) Y	1) VAS 0-100, higher score = improvement; 2) VAS 1-80, higher scores = higher loneliness (reversed)	RCT	Loneliness: a) NS; b) NS. Social functioning: a) NS; b) NS.	missing data (author contacted).

82	Okamoto (2007)	Japan	C	200	64.2±6.18 yrs;	22.5% male, 77.5% female	N	H	NA	IL	PA	32	1) Aerobic walking group: ≥ 20 min/day, 50-60% of relative exercise intensity, ≥2 days/week.	no exercise prescription	outdoors /community	GF	HP	SF	SF-36 Japan version questionnaire (Fukuhara, 1998)	Y	VAS 0-100, higher score = improvement;	RCT	a) NS; b) NA	missing data (author contacted)
22	Oken (2006)	USA	C	135	72.13 ± 4.81 yrs	75 % male, 25% female	N	H	NA	IL	PA	32	1) Yoga group: 90 min/week; 2) aerobic exercise group (walking 400m): 60 min/day, 70% HR max, 5 days/week.	no exercise prescription	centre	GIF	MHP	SF	SF-36 questionnaire (Ware, 1993)	Y	VAS 0-100, higher score = improvement;	RCT	a) significant improvement for yoga group vs control group; b) NA	
3	Ollonquist (2008)	Finland	PC (health services)	708	78.35 ± 6.6 yrs	14.5 % male, 85.5% female	N	D	frailty	IL	PASI (group discussions and lectures)	32	1) Exercise rehabilitation program (exercises in sitting position, pool exercises or resistance training in the gym): total time for group activity 20-56 hours, frequency not given.	no exercise prescription	rehabilitation centre	GF	HP	L	1-item question: "Do you feel yourself lonely?": 0=never, 1- seldom, 2 – sometimes, 3- often, 4- always) (Pitkala et al., 2004).	Y	Rating: lonely/not lonely (dichotomous), higher scores = higher loneliness (reversed)	randomised controlled multicentre trial	a) NS vs control group; b) NA.	missing data (author contacted)
85	Park (2011)	Korea	C	40	71.0 ± 5.64 yrs	33.3% male,66.7 % female	N	D	hypertension	IL	PASI (education, councelling, and exercise)	12	1) Health education + exercise program (elastic band exercise): 30 min, 2-3 sets x 15 reps, 2 times/week.	no exercise prescription	senior centre	GF	MHP	SF	SF-36 questionnaire (Version 2) (Brodie, 2008)	Y	VAS 0-100, higher score = improvement	RCT	a) significantly higher vs control group; b) NA	
86	Reid (2010)	USA	C (community centres)	17	61.6 ± 4.3 yrs	77.2 % male, 22.8% female	Y	D	insomnia	IL	PASI (sleep education)	16	1) Aerobic physical activity(walking, cycling, treadmill exercises) + sleep hygiene: 30-40 min/day, progressing intensity from 55 to 75% HR max, 2-4 times/week.	non -PA (recreational or educational activity + sleep hygiene) group: 45 min x 3-4 time/week	not stated	GF	MHP	SF	SF-36 questionnaire (Ware, 1992)	Y	VAS 0-100, higher score = improvement;	RCT	a) NS vs control group; b) NA	
132	Rejeski (2014)	USA	newspapers, radio advrtisement, mailed postcards	17	70.66±9.45	59.44 % male, 50.56% female	N	D	Peripheral arterg disease	IL	PASI (CBT)	24	1) cognitive behavioural walking intervention and group discussion.: 90 minutes total x 1 time/week: walking 45 min, 12-14 RPE, with gradual progression to 50 min on 5 days/week, 45 min group discussion.	SIG (health education group)	indoor facilities	IF	MHP	SF(social integration sub-domain)	Cutrona and Russell's Social Provision Scale (SPS) (Cutrona, 1987)	Y	VAS =NG, higher scoere= improvement	CRCT	a) Significant improvement vs control group; b) NA	ES PROVIDED
110	Salvetti (2008)	Brazil	PC (university medical centre)	39	53.51 ± 8.52 yrs	25.5% male, 74.5% female	N	D	coronary disease	IL	PASI	12	1) Home-based exercise (walking, stretching) and group walking + education: 60 min, intensity 60-80% HR peak, 3 times/week.	no exercise prescription	gymnasium/ home	GIF	MHP	SF	SF-36 questionnaire (Ware, 1992)	Y	VAS 0-100, higher score = improvement	RCT	a) significantly higher vs control group; b) NA	
93	Sato (2007)	Japan	C (day services)	30	77.21 ± 5.94 yrs	both gender, the numebr is not given	N	D	frailty	IL	PASI	12	1) Once weekly water exercises + exercises for daily living: 60 min/day, 11 RPE (Borg); 2) twice-weekly water exercises + exercises for daily living: 60 min/day, 11 RPE (Borg), 2 times/week.	no exercise prescription	day service facility	GF	HP	SF	Japanese version of SF-36 questionnaire (Fukuhara, 2002)	Y	VAS 0-100, higher score = improvement	single-blind RCT	a) S; b) S	Pilot study
97	Saxton (2011)	UK	PC (general hospital)	104	M age 68 yrs (SD not reported)	77.8 % male, 22.2 % female	N	D	intermittent claudication	IL	PA	24	1) Upper-limb aerobic exercise group: 40 min/day, 85-90% limb-specific peak oxygen consumption, 2 times/week; 2) Lower-limb aerobic exercise group: 60 min/day, 85-90% limb-specific peak oxygen consumption, 2 times/week.	no exercise prescription	not given	GF	HP	SF	British version SF-36 questionnaire (Version 2) (Ware, 1992)	Y	VAS 0-100, higher score = Improvement	RCT	a) NS vs control group; b) NS vs control group	missing data (author contacted)

112	Sims (2006)	Australia	PC (general practices)	38	74.30 ± 5.87 yrs	28% male, 72 % female	N	D	depression	IL	PASI (telephone calls each week)	10	1) Progressive resistance training program (strengthening exercises for upper/lower limbs): moderate intensity (resistance 80% 1 reps max), 3 sets x 8-10 reps, 3 times/week.	no exercise prescription	local facility	GF	HP	Social health	The World Health Organisation Quality of Life Assessment questionnaire(WHOQOL-BREF) (The WHOQOL group, 1995)	Y	range for sub-domain 4-20, total scoring not given	RCT	a) NS ; b) NS	Pilot study
101	Singh (1997)	UK	PC (health center databases)	32	71.3 ± 1.2 yrs	37.5% male, 62.5 % female	N	D	depression	IL	PA	10	1) Progressive resistance training program (strengthening exercises for whole body muscle groups): 45 min/day, high intensity (resistance 80 % 1 reps max), 3 sets x 8 reps, 3 times/week.	non-PA (health education)	not stated	GIF	HP	SF	SF-36 questionnaire (Stewart, 1988)	Y	VAS 0-100, higher score = improvement	CRCT	a) S; b) NA	
111	Stiggelbout (2004)	Netherlands	C (municipal registers of the cities)	277	71.0 ± 4.1 yrs	37 % male, 63 % female	N	H	NA	IL	PASI (social club)	10	1) More exercise for seniors program once a week (mixed exercises): 45 min/weekly; 2) More exercise for seniors program twice a week (mixed exercises): 45 min/day, 2 times/week.	attention-control group (health education): 1.5 hour/month total	gumnasium in community centre	GF	HP	SF	the TNO Leiden Academic Hospital Adults Quality of Life questionnaire (TAAQOL, Singh, 1997)	Y	Range not given, higher score = improvement	Multicentre RCT with cross-over design	a) NS vs control group; b) NA	
125	Tang (2010)	Taiwan	PC (oncology outpatient clinics)	71	51.8 ± 12.13 yrs	23.9 % male, 76.1% female	N	D	cancer	IL	PA	8	1) Walking exercise group: 30 min/day, intensity 11-13 RPE, 3 times/week.	UC	university-based medical centres	not given	MHP	SF	SF-36 questionnaire (Ware, 1992)	Y	VAS 0-100, higher score = improvement	RCT	a) NS vs control group; b) NA	missing data (author contacted)
114	Turner (2011)	Australia	PC (general practices)	35	67.8 ± 10.6 yrs	44.1% male, 55.9 % female	N	D	asthma	IL	PA	6	1) Exercise training group (walking, cycling, strength exercises): 80-90 min x 3 times/week.	UC	hospital centre	GF	HP	SF	SF-36 questionnaire (Juniper, 1992)	Y	VAS 0-100, higher score = improvement	RCT	a) NS vs control group; b) NS	

Note: * Refer to the coding manual (page 2).

Appendix 5

Reference list of included studies

Brocki, B. C., Andreasen, J., Nielsen, L. R., et al. (2014). Short and long-term effects of supervised versus unsupervised exercise training on health-related quality of life and functional outcomes following lung cancer surgery–A randomized controlled trial. *Lung Cancer*, *83*(1), 102-108. doi:http://dx.doi.org/10.1016/j.lungcan.2013.10.015

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Appendix 6

The methodological study characteristics of included RCTs

Reference	N	M age ± SD/ age range, % female	Population group	Duration of intervention (weeks)	Residential settings	Format of delivery	Care provider	Outcomes	Results: a) I; b) FU
PA interventions									
Brocki et al. (2014), Denmark	78	64.47±91, 40.5% female	D	10	IL	GIF	FP	SF	a) NS; b) NS
Chan (2010), China	206	72.95±7.7, 8.6% female	D	12	IL	GIF	FP	SS	a) NS; b) NS
Chien (2005), Taiwan	28	60.3±9.3, 100% female	D	12	IL	IF	MHP	SF	a) NS; b) NA
Courneya (2003), Canada	102	60.32±10.47, 40.4 % female	D	16	IL	IF	FP	SFW	a) NS; b) NA
Cress (1999), USA	49	76.0 ±4.0, both gender, 36% female	H	24	AL	IF	FP	SF	a) NS; b) NA
Daley (2007), UK	108	51.0±8.7, 100% female	D	8	IL	IF	FP	SFW	a) S; b) NS
De Vreede (2007), Netherlands	98	74.2±3.59, 100% female	H	12	IL	GF	MHP	SF	a) NS; b) NS
Devereux (2005), Australia	50	73.3±3.9, 100% female	D	10	IL	GF	MHP	SF	a) S; b) NA
Evcik (2002), Turkey	90	56.34±6.50, 53% female	D	12	IL	IF	MHP	SI	a) NS; b) NA

Garcia-Martinez (2012), Spain	28	58.95±6.64, 100% female	D	12	IL	GF	MHP	SF	a) S; b) NA
Hongo (2007), Japan	80	67.0±6.03, 100% female	D	16	IL	IF	MHP	RSA	a) NS; b) NA
Imayama (2011), USA	439	57.93±5.03, 100 % female	D	12 months	IL	GF	MHP	1) SS; 2) SF	SS: a) NS, b) NA; SF: a) NS, b) NA
Katznelson (2006), USA	70	72.24±5.18, 100% male	D	12	IL	IF	MHP	SF	a) S; b) NA
Kerse (2010), New Zeeland	193	81.10±19.14, 58.5% female	D	24	IL	IF	MHP	SF	a) NS; b) NA
Kovaks (2013), Hungary	76	68.4±5.87, 100% male	H	25	IL	GF	FP	SF	a) NS; b) NA
Kurtner (1997), Georgia	200	Mean age 76.2, 81% female	H	15	IL	GF	FP	SF	a) NS; b) NS
Mutrie (2012), UK	41	70.81±5.24, 68% female	H	12	IL	GF	FP	1)SF; 2) L	L: a) NS; b) NS; SF: a) NS; b) NS
Okamoto (2007), Japan	200	64.2±6.18, 77.5% female	H	32	IL	GF	MHP	SF	a) NS; b) NA
Oken (2006), USA	135	72.13±4.81, 25% female	H	32	IL	GIF	MHP	SF	a) S; b) NA
Saxton (2011), UK	104	M age 68,	D	24	IL	GF	FP	SF	a) NS;

		22.2 % female							b) NS
Singh (1997), UK	32	71.3±1.2, 62.5 % female	D	10	IL	GIF	FP	SF	a) S; b) NA
Tang (2010), Taiwan	71	51.8±12.13, 76.1% female	D	8	IL	GF	MHP	SF	a) NS; b) NA
Turner (2011), Australia	35	67.8±10.6, 55.9 % female	D	6	IL	GF	FP	SF	a) NS; b) NS
PA interventions with social interactions									
Chan (2017), China	48	77.3 ±7.4, 76% female	H	12	IL	GF	FP	1) L; 2) SN; 3) SS	L: a) NS; b) S; SN: a) NS; b) S; SS: a) NS, b) NS
Chan et al. (2013), USA	23	54.0±11.0, 100% female	D	10	IL	GF	FP	SF	a) S; b) NA
Courneya (2011), Canada	320	82.5±6.3, 100% female	H	1 year	IL	IF	FP	SF	a) NS; b) NA
Huang (2011), Taiwan	186	Age range 60-71, 58.6% female	H	8	IL	GF	FP	SS	a) S; b) NA
Lliffe (2014), UK	830	M age 73, 62% female	D	24	IL	GF	FP	SN, SS	SN: a) NS; b) NS; S S:

									a) NS; b) NS
Kamageya (2014), Japan	52	74.9 ±5.9, 47% female	H	12	IL	GIF	FP	SN	a) NS; b) NA
Maki (2012), Japan	150	72.0±4.0, 73.7% female	H	12	IL	GF	FP	SN	a) NS; b) NA
Ollonquist (2008), Finland	708	78.35±6.6, 85.5% female	D	32	IL	GF	FP	L	a) NS; b) NA
Park (2011), Korea	40	71.0±5.64, 66.7 % female	D	12	IL	GF	MHP	SF	a) S; b) NA
Reid (2010), USA	17	61.6±4.3, 22.8% female	D	16	IL	GF	MHP	SF	a) NS; b) NA
Rejeski (2014), USA	17	70.66±9.45, 50.56% female	D	24	IL	IF	MHP	SF	a) S; b) NA
Salvetti (2008), Brazil	39	53.51±8.52, 74.5% female	D	12	IL	GIF	MHP	SF	a) S; b) NA
Sato (2007), Japan	30	77.21±5.94, mixed gender (% NG)	D	12	IL	GF	FP	SF	a) S; b) S
Sims (2006), Australia	38	74.30±5.87, 72 % female	D	10	IL	GF	FP	SH	a) NS; b) NS
Stiggelbout (2004), Netherlands	277	71.0 ±4.1, 63% female	H	10	IL	GF	FP	SF	a) NS; b) NA

Note: H – healthy, D – disease population, IL -independent living, AL-assisted living; IF – individual format, GF – group format, GIF - mixed group and individual format, FP – fitness (non-medical) healthcare provider, MHP - medical healthcare provider, L- Loneliness, SI- Social isolation, SS – Social support, SN – social networks, SFW- Social/family well-being, RSA- Recreational and social activity, SH- Social health, I-immediate, FU – follow-up, S – significant, NS - not significant; NA - not applicable; NG – not given.

Appendix 7

Intervention characteristics of included RCTs

Reference	N	M age ± SD/ age range, % female	Population group	Duration of intervention (weeks)	Residential settings	PA intervention group(s)	Format of delivery	Care provider	Outcomes	Results: a) I; b) FU
PA interventions										
Brocki et al. (2014), Denmark	78	64.47±91, 40.5% female	D	10	IL	Aerobic exercises, muscle strength and stretching exercises: 60 min x 1 time/week	GIF	FP	SF	a) NS; b) NS
Chan (2010), China	206	72. 95 ± 7.7, 8.6% female	D	12	IL	1) Tai Chi Qigong (TCQ) group: 60 min x 2 times/week + advised on individual practice at home 60 min/most days of the week; 2) Exercise group (various breathing & walking exercise): 60 min x every day of the week.	GIF	FP	SS	a) NS; b) NS

Chien (2005), Taiwan	28	60.3 ± 9.3, 100% female	D	12	IL	Home-based trunk strengthening exercise programme: 1 set x 10 reps, 3 times/day, 7 days/week.	IF	MHP	SF	a) NS; b) NA
Courneya (2003), Canada	102	60.32 ± 10.47, 40.4 % female	D	16	IL	Home-based personalised exercise programme (preferred mode e.g. swimming, cycling): 20-30 min, moderate intensity 65-75% HR max, 3-5 days/week.	IF	FP	SFW	a) NS; b) NA
Cress (1999), USA	49	76.0 ±4.0, both gender, 36% female	H	24	AL	Combined endurance-resistance exercise training programme: 60 min/day, 3 times/week with 75-85% HRR for aerobic exercise (kayak and stepper equipment), 75-8-% HR_{max} for resistance training (gym equipment).	IF	FP	SF	a) NS; b) NA

Daley (2007), UK	108	51.0 ± 8.7, 100% female	D	8	IL	1) Aerobic exercise therapy group: 50 min/day, intensity 65-85% HR_{max}, 3 days/week; 2) Exercise placebo group (body conditioning): 50 min/day, low intensity <40% HR max, 24 times total.	IF	FP	SFW	a) S; b) NS
De Vreede (2007), Netherlands	98	74.2 ± 3.59, 100% female	H	12	IL	1) Functional tasks exercise group: 40 min, 5-10 reps for each exercise, 3 days/week; 2) Resistance exercise group: 60 min/day, moderate to hard intensity 7-8 RPE (Borg), 3 days/week.	GF	MHP	SF	a) NS; b) NS
Devereux (2005), Australia	50	73.3 ± 3.9, 100% female	D	10	IL	Water-based and mixed land-based exercise + education: total 60 min/day, 2 days/week.	GF	MHP	SF	a) S; b) NA
Evcik	90	56.34 ± 6.50,	D	12	IL	1) Home exercise	IF	MHP	SI	a) NS;

(2002), Turkey		53% female				programme (isometric and isotonic quadriceps exercise): duration is NG, 10 reps/exercise, 2 times/day, most days of the week; 2) Walking exercise programme: 10-30 min/day, 3 days/week.				b) NA
Garcia-Martinez (2012), Spain	28	58.95 ± 6.64, 100% female	D	12	IL	Aerobic, strengthening and flexibility exercises: 60 min/day, intensity from 60-70% HR_{max} to 75-85% of HR_{max}, 3 days/week.	GF	MHP	SF	a) S; b) NA
Hongo (2007), Japan	80	67.0 ± 6.03, 100% female	D	16	IL	Home exercise group (the single isometric back strength exercise prescription): 3-5 min/exercise, 1 set x 10 reps, 5 days/week.	IF	MHP	RSA	a) NS; b) NA
Imayama	439	57.93 ± 5.03,	D	12 months	IL	1) Aerobic	GF	MHP	1) SS;	SS:

(2011), USA		100 % female				exercise group: 45 min/day, 70-85% HR_{max}, 5 days/week; 2) Dietary weight-loss group: consultations with the dietitian 1-2 times/week; 3) Diet + exercise group: 45 min/day, moderate-to-vigorous intensity, 5 days/week.			2) SF	a) NS, b) NA; SF: a) NS, b) NA
Katznelson (2006), USA	70	72.24 ± 5.18, 100% male	D	12	IL	Exercises with elastic bands of various resistance: duration NG, intensity from very light to heavy, 3-4 days/week.	IF	MHP	SF	a) S; b) NA
Kerse (2010), New Zeeland	193	81.10±19.14, 58.5% female	D	24	IL	Moderate-intensity balance exercises, progressive resistance lower limb-strengthening exercises, and walking: 30 min x	IF	MHP	SF	a) NS; b) NA

						3 times/week, progressing intensity.				
Kovaks (2013), Hungary	76	68.4 ± 5.87, 100% male	H	25	IL	Exercise group (mixed exercises): 60 min/day x 2 days/week.	GF	FP	SF	a) NS; b) NA
Kurtner (1997), Georgia	200	Mean age 76.2, 81% female	H	15	IL	1) Tai Chi group: 45 min/day x 2 days/week; 2) Balance training: 45 min/weekly.	GF	FP	SF	a) NS; b) NS
Mutrie (2012), UK	41	70.81 ± 5.24, 68% female	H	12	IL	Individualised walking programme: duration various, intensity various, 2 days/week	GF	FP	1)SF; 2) L	L: a) NS; b) NS; SF: a) NS; b) NS
Okamoto (2007), Japan	200	64.2 ± 6.18, 77.5% female	H	32	IL	Aerobic walking group: ≥ 20 min/day, 50-60% of relative exercise intensity, ≥2 days/week.	GF	MHP	SF	a) NS; b) NA
Oken (2006), USA	135	72.13 ± 4.81, 25% female	H	32	IL	1) Yoga group: 90 min/week; 2) aerobic exercise group (walking 400m): 60 min/day, 70% HR max, 5 days/week.	GIF	MHP	SF	a) S; b) NA
Saxton	104	M age 68,	D	24	IL	1) Upper-limb	GF	FP	SF	a) NS;

(2011), UK		22.2 % female				aerobic exercise group: 40 min/day, 85-90% limb-specific peak oxygen consumption, 2 times/week; 2) Lower-limb aerobic exercise group: 60 min/day, 85-90% limb-specific peak oxygen consumption, 2 times/week.				b) NS
Singh (1997), UK	32	71.3 ± 1.2, 62.5 % female	D	10	IL	Strengthening exercises for whole body muscle groups): 45 min/day, high intensity (resistance 80 % 1 reps max), 3 sets x 8 reps, 3 times/week.	GIF	FP	SF	a) S; b) NA
Tang (2010), Taiwan	71	51.8 ± 12.13, 76.1% female	D	8	IL	Walking exercise group: 30 min/day, intensity 11-13 RPE, 3 times/week	GF	MHP	SF	a) NS; b) NA
Turner (2011),	35	67.8 ± 10.6, 55.9 %	D	6	IL	Exercise training group (walking,	GF	FP	SF	a) NS; b) NS

Australia		female				cycling, strength exercises): 80-90 min x 3 times/week.				
PA interventions with social interactions										
Chan (2017), China	48	77.3 ± 7.4, 76% female	H	12	IL	Exercise + social support: Tai Chi: 60 min x2 times/week.	GF	FP	1) L; 2) SN; 3) SS	L: a) NS; b) S; SN: a) NS; b) S; SS: a) NS, b) NS
Chan et al. (2013), USA	23	54.0 ± 11.0, 100% female	D	10	IL	Exercise + health education: treadmill walking: 30-45 min, intensity 70-80% HRR. 24-30 sessions total.	GF	FP	SF	a) S; b) NA
Courneya (2011), Canada	320	82.5±6.3, 100% female	H	1 year	IL	Exercise + health education: home-based personalised exercise programme (preferred mode e.g. swimming, cycling): 20-30 min, moderate intensity 65-75%	IF	FP	SF	a) NS; b) NA

						HR max, 3-5 days/week.				
Huang (2011), Taiwan	186	Age range 60-71, 58.6% female	H	8	IL	Exercise + cognitive behavioural therapy: 1) Cognitive behavioural therapy group (CB): 60-90 min x 1 day/week for 8 weeks; 2) CB + Tai Chi exercises: 60 min x 5 days/week	GF	FP	SS	a) S; b) NA
Lliffe (2014), UK	830	M age 73, 62% female	D	24	IL	Exercise + support: 1) OEP: Home-based exercise programme and walking exercise: 30 min/day, progressing intensity, 3 days/week; 2) FaME: community-based group-exercise programme (group exercise training): 2 x 30 min/day, home exercises	GF	FP	SN, SS	SN: a) NS; b) NS; S S: a) NS; b) NS

						(based on OEP) + walking exercise: 30 min x 2 days/week, flexibility training, adapted Tai Chi complex, functional skills training.				
Kamageya (2014), Japan	52	74.9 ± 5.9, 47% female	H	12	IL	Exercise + recreational activity: strengthening exercises, aerobic exercises & flexibility exercises: 45 min/day weekly for exercise, total duration of a session 2 hours/weekly.	GIF	FP	SN	a) NS; b) NA
Maki (2012), Japan	150	72.0 ± 4.0, 73.7% female	H	12	IL	Exercise + health education: walking exercise 90 min/weekly.	GF	FP	SN	a) NS; b) NA
Ollonquist (2008), Finland	708	78.35 ± 6.6, 85.5% female	D	32	IL	Exercise + health education: Exercise rehabilitation programme (exercises in	GF	FP	L	a) NS; b) NA

						sitting position, pool exercises or resistance training in the gym), total time for group activity 20-56 hours.				
Park (2011), Korea	40	71.0 ± 5.64, 66.7 % female	D	12	IL	1) Exercise + health education: elastic band exercise, 30 min/day, 2-3 sets x 15 reps, 2 times / week.	GF	MHP	SF	a) S; b) NA
Reid (2010), USA	17	61.6 ± 4.3, 22.8% female	D	16	IL	Exercise + sleep education: 1erobic physical activity (walking, cycling, treadmill exercises) 30-40 min/day, progressing intensity from 55 to 75% HR_{max}, 2-4 times/week.	GF	MHP	SF	a) NS; b) NA
Rejeski (2014), USA	17	70.66±9.45, 50.56% female	D	24	IL	Exercise + cognitive behavioural therapy: walking intervention and group discussion 90 minutes total x	IF	MHP	SF	a) S; b) NA

						1 time/week: walking 45 min, 12-14 RPE, with gradual progression to 50 min on 5 days/week, 45 min group discussion.				
Salvetti (2008), Brazil	39	53.51 ± 8.52, 74.5% female	D	12	IL	Exercise + education: Home-based exercise (walking, stretching) and group walking 60 min, intensity 60-80% HR peak, 3 times/week.	GIF	MHP	SF	a) S; b) NA
Sato (2007), Japan	30	77.21 ± 5.94, mixed gender (% NG)	D	12	IL	Exercise + support: 1) Once weekly water exercises + exercises for daily living: 60 min/day, 11 RPE (Borg); 2) twice-weekly water exercises + exercises for daily living: 60 min/day, 11 RPE (Borg), 2 times/week.	GF	FP	SF	a) S; b) S

Sims (2006), Australia	38	74.30 ± 5.87, 72 % female	D	10	IL	Exercise + telephone calls: strengthening exercises for upper/lower limbs, moderate intensity (resistance 80% of 1 RM), 3 sets x 8-10 reps, 3 times/week.	GF	FP	SH	a) NS; b) NS
Stiggelbout (2004), Netherlands	277	71.0 ± 4.1, 63% female	H	10	IL	Exercise + health education: 1) More exercise for seniors programme once a week (aerobic, strengthening, coordination exercises): 45 min/weekly; 2) More exercise for seniors programme twice a week (aerobic, strengthening, coordination exercises): 45 min/day, 2 times / week.	GF	FP	SF	a) NS; b) NA

Appendix 8

Risk of bias assessment

Bias	Selection bias			Performance bias			Attrition bias			Reporting bias	Detection bias		
Reference	Adequate random sequence generation	Adequate allocation concealment	Similar baseline characteristics	Adequate participant blinding	Adequate provider blinding	Similar or no cointerventions	Acceptable compliance	Acceptable and described dropout rate	Inclusion of an intention-to-treat analysis	No selective outcome reporting	Adequate outcome assessor blinding	Similar timing of outcome assessment	Total (/ 12)*
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	
Brocki (2014)	yes	yes	yes	unclear	unclear	yes	yes	yes	yes	yes	yes	yes	10
Chan (2010)	yes	yes	no	no	unclear	yes	yes	yes	yes	yes	yes	yes	9
Chan (2013)	yes	yes	no	yes	unclear	yes	yes	yes	no	yes	yes	yes	10
Chan (2017)	yes	no	yes	unclear	unclear	yes	yes	yes	yes	yes	unclear	yes	8
Chien (2005)	yes	unclear	yes	no	unclear	yes	yes	yes	no	yes	unclear	yes	7
Courneya (2003)	yes	unclear	yes	unclear	unclear	yes	unclear	yes	unclear	yes	yes	yes	7
Courneya (2011)	yes	unclear	yes	unclear	unclear	yes	unclear	yes	yes	yes	no	yes	7

Cress (1999)	unclear	unclear	yes	unclear	unclear	yes	unclear	yes	yes	yes	unclear	yes	6
Daley (2007)	yes	unclear	yes	unclear	unclear	yes	yes	yes	no	yes	no	yes	7
De Vreede (2007)	yes	unclear	no	unclear	unclear	yes	yes	yes	no	yes	unclear	unclear	5
Devereux (2005)	yes	unclear	no	unclear	unclear	yes	unclear	yes	no	yes	yes	yes	6
Evcik (2002)	unclear	unclear	yes	unclear	unclear	yes	no	yes	no	yes	no	yes	5
Garcia-Martinez (2012)	yes	unclear	yes	unclear	unclear	yes	no	yes	no	yes	unclear	unclear	5
Hongo (2007)	unclear	unclear	yes	unclear	unclear	yes	no	yes	no	yes	yes	yes	6
Huang (2011)	unclear	yes	yes	unclear	unclear	yes	no	yes	yes	no	yes	yes	7
Lliffe (2014)	yes	unclear	yes	yes	unclear	yes	unclear	unclear	no	yes	no	yes	6
Imayama (2011)	yes	yes	no	no	unclear	yes	unclear	yes	yes	yes	no	yes	7
Kamageya (2014)	unclear	no	yes	no	unclear	yes	unclear	yes	no	yes	no	yes	4
Katznelson (2006)	yes	unclear	yes	unclear	unclear	yes	yes	unclear	no	yes	unclear	yes	6

Kerse (2010)	yes	yes	no	yes	unclear	yes	yes	yes	no	yes	yes	yes	9
Kovaks (2013)	yes	yes	yes	no	unclear	unclear	unclear	yes	yes	yes	yes	unclear	7
Kurtner (1997)	unclear	no	yes	no	unclear	no	unclear	no	no	yes	no	yes	3
Maki (2012)	unclear	no	yes	no	unclear	yes	unclear	yes	yes	yes	no	yes	6
Mutrie et al., (2012)	yes	unclear	yes	no	unclear	yes	yes	yes	yes	yes	unclear	yes	8
Okamoto (2007)	unclear	no	yes	no	unclear	yes	unclear	yes	no	yes	no	yes	5
Oken (2006)	unclear	unclear	yes	unclear	unclear	yes	unclear	unclear	no	yes	unclear	yes	4
Ollonquist (2008)	yes	yes	yes	yes	unclear	yes	no	no	no	yes	yes	yes	8
Park (2011)	no	no	yes	no	unclear	yes	no	no	no	yes	no	yes	4
Reid (2010)	unclear	no	yes	no	unclear	yes	yes	yes	no	yes	no	yes	6
Rejeski (2014)	yes	yes	yes	unclear	unclear	yes	yes	unclear	no	yes	unclear	yes	7
Salvetti (2008)	unclear	unclear	yes	no	unclear	yes	yes	no	no	yes	no	yes	5
Sato (2007)	unclear	unclear	yes	unclear	unclear	yes	yes	unclear	no	yes	unclear	yes	5

Saxton (2011)	yes	unclear	yes	yes	unclear	unclear	yes	yes	yes	yes	unclear	yes	8
Sims (2006)	yes	unclear	yes	no	unclear	yes	yes	yes	yes	yes	no	yes	8
Singh (1997)	yes	unclear	yes	unclear	unclear	unclear	unclear	yes	no	yes	unclear	yes	5
Stiggelbout (2004)	no	no	no	no	unclear	yes	yes	no	no	yes	yes	yes	5
Tang (2010)	yes	unclear	yes	unclear	unclear	yes	unclear	yes	yes	yes	unclear	yes	7
Turner (2011)	yes	unclear	yes	unclear	unclear	yes	no	yes	yes	yes	unclear	yes	7

Note: * low risk of bias if ≥ 6 criteria scored as “Yes”, high risk of bias if < 6 criteria scored as “Yes”.

Appendix 9

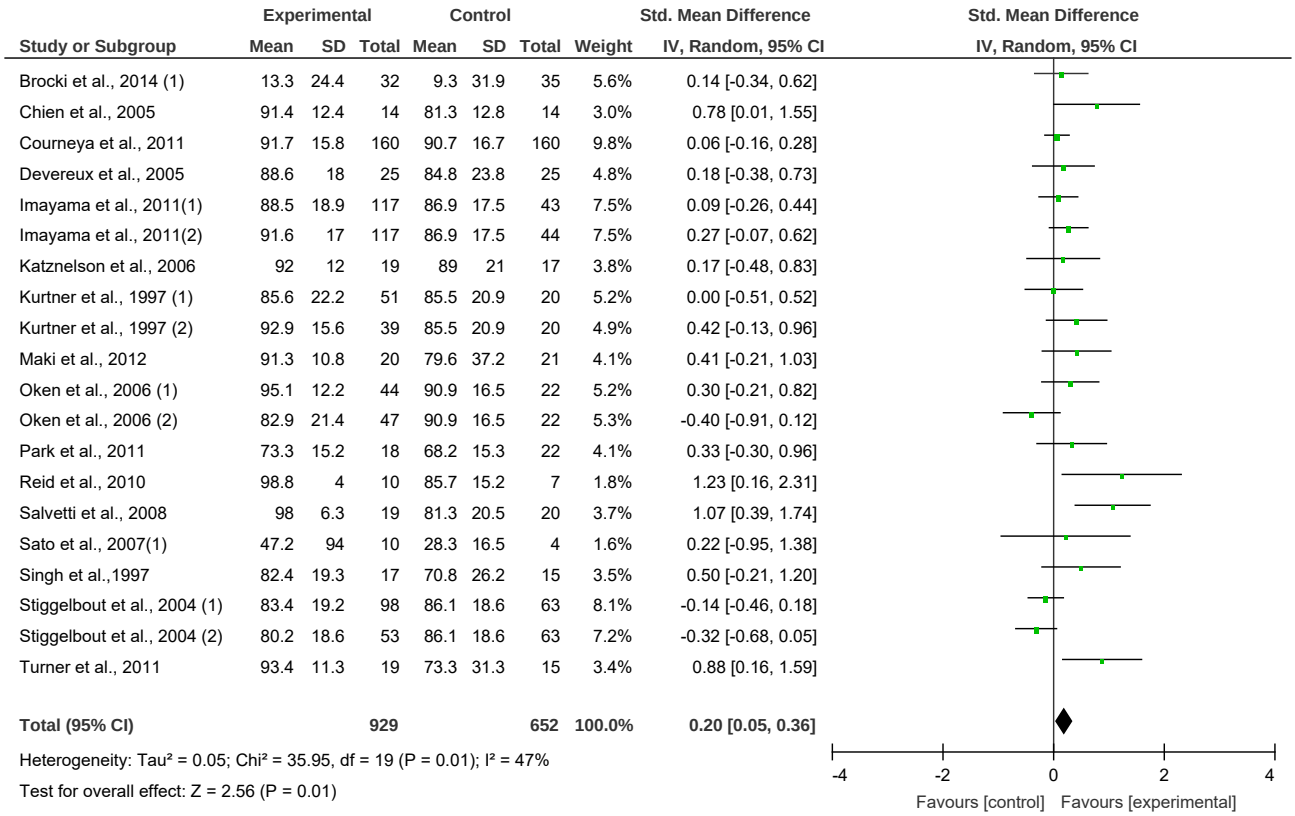
The sub-group analysis for the selected study and intervention characteristics for the social functioning outcome

Social functioning outcome								
Covariate	**Classification**	**K**	**N**	**ES (95% CI)**	**P**	**I^2**	**Chi^2**	**P-value**
	Overall effect	22	1625	0.30 (0.12 to 0.49)	0.001	63	56.50	<0.0001
Type of intervention	PA	14	899	0.30 (0.10 to 0.51)	0.003	48	25.12	0.02
	PASI	8	723	0.33 (-0.04 to 0.70)	0.08	75	28.14	0.0002
Population type	Healthy	8	903	0.00 (-0.19 to 0.19)	0.99	39	11.47	0.12
	Diseased	14	722	0.55 (0.28 to 0.81)	<0.0001	57	29.89	0.005
Format of delivery	GF	17	1142	0.34 (0.10 to 0.59),	0.006	69	52.34	<0.00001
	IF	3	384	0.21 (-0.15 to 0.56)	0.26	35	3.09	0.21
	GIF	2	99	0.25 (-0.15 to 0.65)	0.21	0	0.67	0.41
Healthcare provider	FP	11	931	0.19 (-0.04 to 0.43)	0.11	58	23.84	0.008
	MPH	11	694	0.42 (0.12 to 0.71)	0.005	65	28.54	0.001

Note: PA – physical activity interventions, PASI – physical activity interventions with social interactions, IF – individual format, GF – group format, GIF - mixed group and individual format, FP – fitness (non-medical) healthcare provider, MHP - medical healthcare provider.

Appendix 10

The sensitivity analysis for social functioning when outliers were removed



Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Brocki et al., 2014 (1)	13.3	24.4	32	9.3	31.9	35	5.6%	0.14 [-0.34, 0.62]
Chien et al., 2005	91.4	12.4	14	81.3	12.8	14	3.0%	0.78 [0.01, 1.55]
Courneya et al., 2011	91.7	15.8	160	90.7	16.7	160	9.8%	0.06 [-0.16, 0.28]
Devereux et al., 2005	88.6	18	25	84.8	23.8	25	4.8%	0.18 [-0.38, 0.73]
Imayama et al., 2011(1)	88.5	18.9	117	86.9	17.5	43	7.5%	0.09 [-0.26, 0.44]
Imayama et al., 2011(2)	91.6	17	117	86.9	17.5	44	7.5%	0.27 [-0.07, 0.62]
Katznelson et al., 2006	92	12	19	89	21	17	3.8%	0.17 [-0.48, 0.83]
Kurtner et al., 1997 (1)	85.6	22.2	51	85.5	20.9	20	5.2%	0.00 [-0.51, 0.52]
Kurtner et al., 1997 (2)	92.9	15.6	39	85.5	20.9	20	4.9%	0.42 [-0.13, 0.96]
Maki et al., 2012	91.3	10.8	20	79.6	37.2	21	4.1%	0.41 [-0.21, 1.03]
Oken et al., 2006 (1)	95.1	12.2	44	90.9	16.5	22	5.2%	0.30 [-0.21, 0.82]
Oken et al., 2006 (2)	82.9	21.4	47	90.9	16.5	22	5.3%	-0.40 [-0.91, 0.12]
Park et al., 2011	73.3	15.2	18	68.2	15.3	22	4.1%	0.33 [-0.30, 0.96]
Reid et al., 2010	98.8	4	10	85.7	15.2	7	1.8%	1.23 [0.16, 2.31]
Salvetti et al., 2008	98	6.3	19	81.3	20.5	20	3.7%	1.07 [0.39, 1.74]
Sato et al., 2007(1)	47.2	94	10	28.3	16.5	4	1.6%	0.22 [-0.95, 1.38]
Singh et al.,1997	82.4	19.3	17	70.8	26.2	15	3.5%	0.50 [-0.21, 1.20]
Stiggelbout et al., 2004 (1)	83.4	19.2	98	86.1	18.6	63	8.1%	-0.14 [-0.46, 0.18]
Stiggelbout et al., 2004 (2)	80.2	18.6	53	86.1	18.6	63	7.2%	-0.32 [-0.68, 0.05]
Turner et al., 2011	93.4	11.3	19	73.3	31.3	15	3.4%	0.88 [0.16, 1.59]
Total (95% CI)			**929**			**652**	**100.0%**	**0.20 [0.05, 0.36]**

Heterogeneity: Tau² = 0.05; Chi² = 35.95, df = 19 (P = 0.01); I² = 47%

Test for overall effect: Z = 2.56 (P = 0.01)

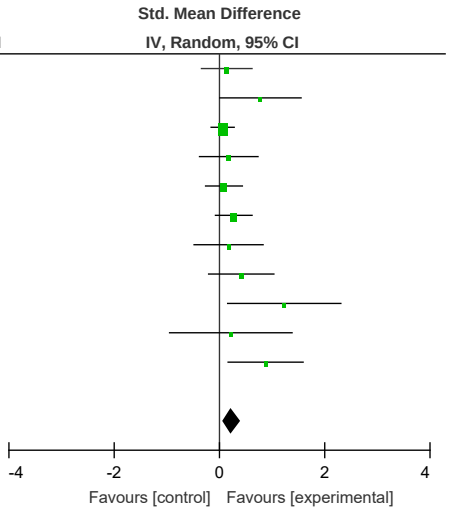
Appendix 11

The sensitivity analysis for social functioning when high risk RCTs were removed

	Experimental			Control				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Brocki et al., 2014 (1)	13.3	24.4	32	9.3	31.9	35	9.3%	0.14 [-0.34, 0.62]
Chien et al., 2005	91.4	12.4	14	81.3	12.8	14	4.0%	0.78 [0.01, 1.55]
Courneya et al., 2011	91.7	15.8	160	90.7	16.7	160	28.4%	0.06 [-0.16, 0.28]
Devereux et al., 2005	88.6	18	25	84.8	23.8	25	7.2%	0.18 [-0.38, 0.73]
Imayama et al., 2011(1)	88.5	18.9	117	86.9	17.5	43	15.5%	0.09 [-0.26, 0.44]
Imayama et al., 2011(2)	91.6	17	117	86.9	17.5	44	15.6%	0.27 [-0.07, 0.62]
Katznelson et al., 2006	92	12	19	89	21	17	5.4%	0.17 [-0.48, 0.83]
Mutrie et al., 2012	91.3	10.8	20	79.6	37.2	21	6.0%	0.41 [-0.21, 1.03]
Reid et al., 2010	98.8	4	10	85.7	15.2	7	2.1%	1.23 [0.16, 2.31]
Sato et al., 2007(1)	47.2	94	10	28.3	16.5	4	1.8%	0.22 [-0.95, 1.38]
Turner et al., 2011	93.4	11.3	19	73.3	31.3	15	4.6%	0.88 [0.16, 1.59]
Total (95% CI)			**543**			**385**	**100.0%**	**0.23 [0.08, 0.39]**

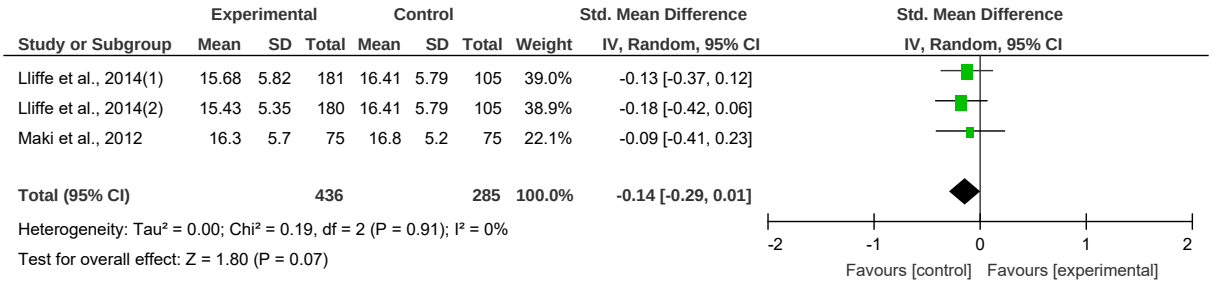
Heterogeneity: Tau² = 0.01; Chi² = 11.81, df = 10 (P = 0.30); I² = 15%

Test for overall effect: Z = 2.89 (P = 0.004)



Appendix 12

The sensitivity analysis for social networks when outliers were removed



Appendix 13

Ethical approval form

Dear Professor Whittaker

Re: "Physical Activity Intervention for Loneliness (PAIL) in community-dwelling older adults: a feasibility study"
Application for amendment ERN_16-1419A

Thank you for the above application for amendment, which was reviewed by the Humanities and Social Sciences Ethical Review Committee.

On behalf of the Committee, I can confirm that this amendment now has full ethical approval.

I would like to remind you that any substantive changes to the nature of the study as now amended, and/or any adverse events occurring during the study should be promptly bought to the Committee's attention by the Principal Investigator and may necessitate further ethical review. A revised amendment application form is now available at https://intranet.birmingham.ac.uk/finance/accounting/Research-Support-Group/Research-Ethics/Ethical-Review-Forms.aspx . Please ensure this form is submitted for any further amendments.

Please also ensure that the relevant requirements within the University's Code of Practice for Research and the information and guidance provided on the University's ethics webpages (available at https://intranet.birmingham.ac.uk/finance/accounting/Research-Support-Group/Research-Ethics/Links-and-Resources.aspx) are adhered to and referred to in any future applications for ethical review. It is now a requirement on the revised application form (https://intranet.birmingham.ac.uk/finance/accounting/Research-Support-Group/Research-Ethics/Ethical-Review-Forms.aspx) to confirm that this guidance has been consulted and is understood, and that it has been taken into account when completing your application for ethical review.

Please be aware that whilst Health and Safety (H&S) issues may be considered during the ethical review process, you are still required to follow the University's guidance on H&S and to ensure that H&S risk assessments have been carried out as appropriate. For further information about this, please contact your School H&S representative or the University's H&S Unit at healthandsafety@contacts.bham.ac.uk.

If you require a hard copy of this correspondence, please let me know.

Kind regards

Susan Cottam
Research Ethics Officer
Research Support Group
C Block Dome
Aston Webb Building
University of Birmingham
Edgbaston B15 2TT
Tel: 0121 414 8825
Email: s.l.cottam@bham.ac.uk
Web: https://intranet.birmingham.ac.uk/finance/RSS/Research-Support-Group/Research-Ethics/index.aspx

Appendix 14

Consent form

UNIVERSITY OF BIRMINGHAM

Participant's Consent Form *[Office use only: ID _____]*

Physical Activity Intervention for Loneliness (PAIL) in community-dwelling older adults: A feasibility study

Please read the following statements and sign if you agree to take part in the study.

I have read the information sheet (version 1, 12.4.17) concerning this study and understand what it is about. All my questions have been answered to my satisfaction. I understand that I am free to request further information at any stage. Please initial each box.

1. My participation in the study is entirely voluntary. ☐
2. I agree to participate and consent to my data being used and stored against a unique ID number for 10 years ☐
3. I understand I will be required to answer questions about my feelings. ☐
4. I understand that I can withdraw from the study at any time without giving reason, but that any research data will still be used unless I request otherwise. ☐
5. I know that the information that I give will be treated as confidential and my name will not be used in any publications. ☐
6. I know that I may ask that any data pertaining to me be destroyed at any time up until research publication with no penalty. ☐
7. I agree to my GP being informed that I am taking part in this study ☐
8. I am happy to be contacted about future research. ☐

I agree to the above statements.

Signed

……

Print name

…….. Date ……

The study has been reviewed and approved the Ethics Committee of the University of Birmingham. Thank you for your time and consideration.

Anastasia Shvedko
Doctoral Researcher
School of Sport, Exercise & Rehabilitation Sciences
axs1235@student.bham.ac.uk
Tel: [redacted]

Prof Anna C Whittaker
Principal Investigator
School of Sport, Exercise & Rehabilitation Sciences
A.C.Whittaker@bham.ac.uk
Tel. 44 121 414 4398

Appendix 15

Recruitment poster

UNIVERSITY OF BIRMINGHAM



We would like to invite you to the

12 WEEK OUTDOOR GROUP WALKING PROGRAMME

Organised by doctoral research students from the University of Birmingham, UK

The programme is free of charge. You will be invited to attend once weekly walking group sessions with the trained walk leader. As a part of the course you will attend healthy workshops for older adults and a social club discussion over a cup of tea. This is an opportunity for you to make new friends, increase your physical activity and have a good time.

WHO ARE WE LOOKING FOR?

- Older adults aged 60 years or over;
- Inactive (less than 20 minutes of a regular exercise per week for the past month);
- At risk of loneliness or social isolation (e.g. living alone, recently widowed, with a long-term care responsibility, etc.);
- Able to walk without support (walking stick is acceptable);
- Healthy or having one or more common chronic diseases but ambulatory;
- English speaking and able to complete paper and pencil questionnaires.

WHAT DO I HAVE TO DO?

Health assessments usually take about 30-minutes and include a total of 5 visits for assessment of height, weight, resting blood pressure, physical activity, **questionnaires** and **two focus group interviews.**

For more information, please call at [redacted] or e-mail: axs1235@bham.ac.uk (Doctoral research student Anastasia Shvedko)

Appendix 16

Recruitment leaflet



UNIVERSITY OF BIRMINGHAM

Aged 60 and over?

Looking for friends?

Need some exercise?

12 WEEK OUTDOOR GROUP WALKING FOR OLDER ADULTS

Organised by doctoral research students from the University of Birmingham, UK

You are invited to attend

- Once a week walking group sessions with a trained walk leader on campus
- Healthy workshops and a social club discussion over a cup of tea at the University of Birmingham facility, B15 2TT
- The programme is free of charge. This is an opportunity for you to make new friends, increase your physical activity and have a good time.

Health assessments

You will have a total of 5 assessments of height, weight, blood pressure, physical activity, questionnaires and two focus group interviews.

For more information contact Anastasia Shvedko
Mob. [redacted] **E-mail: axs1235@bham.ac.uk**



UNIVERSITY OF BIRMINGHAM

Physical Activity Intervention for Loneliness (PAIL) in community-dwelling older adults: a feasibility study

INFORMATION SHEET

Investigators: Prof Anna Whittaker, Dr Carolyn Greig, Prof Janice Thompson, Doctoral Research Student Anastasia Shvedko (University of Birmingham).

You are being invited to take part in the current study that is looking to see if it is possible to do a group walk and health education workshops to increase levels of physical activity in older adults residing in the community. This information sheet explains purposes of the study, the reasons why you may be asked to take part and conditions of your participation. Please, take the time to read this information sheet and decide if you wish to consent to take part in the study.

1. What is the purpose of the study?

This study will address the following aims:

1. To assess the feasibility and practicality of the Physical Activity Intervention for Loneliness (PAIL) in community-dwelling older adults.

2. To assess the effect of the PAIL on loneliness reduction.

3. To analyse the associations between loneliness, self-efficacy for exercise and social support in terms of the impact of the PAIL.

2. Who are we looking for?

You have been invited because you are:

- Community-dwelling older adult aged 60 years or over;
- Inactive (i.e. engaged in less than 20 minutes per week of regular physical activity for the past month or <125 minutes per week of moderate physical activity). Moderate intensity aerobic exercise is where you are working hard enough to raise your heart rate and break into a sweat (e.g. activity like walking at a fast pace). You are able to talk but unable to sing the words to a song;
- You may sometimes feel lonely or socially isolated;
- Physically mobile and able to walk without support (walking stick is acceptable);
- Healthy or having one or more common chronic diseases but mobile;
- Without a cognitive disability;
- English speaking and able to complete paper and pencil questionnaires.

3. What does this study include?

You will take part in the 12-week outdoor group walking with the trained walking leader (Doctoral Research Student of the University of Birmingham) and will listen to a series of health education workshops. During walks you will be following the walking leader by the specified route starting from the University of Birmingham facility. You will receive the walking plan and walking brochures to facilitate exercise activity in your free time.

4. Do I have to take part?

- Your participation in the study is entirely voluntary.

- You can withdraw from the study at any time without giving a reason. However, we would still like to use any data you have provided by this point, unless you specifically request for it to be destroyed.
- You are guaranteed the security and confidentiality of data collected during research.

5. What will happen if you decide to take part?

If eligible, you will be scheduled a meeting at your preferred location (at home or in the University of Birmingham facility) for you to give initial consent to the study and to obtain information about your health and physical mobility at **Visits 1 and 2**. You also will be asked to complete a demographic information form and a medical conditions you may have using the form.

If eligible to proceed, you will be invited to group meeting in the University of Birmingham facility (**Visit 3**) to listen to the presentation about the study and meet other participants over a cup of tea. You will be asked to complete self-reported questionnaires to assess your feelings. We will also measure your height, weight and resting blood pressure and give you an activity monitor (small gadget to be worn on the thigh and secured with waterproof dressing) to measure your physical activity over a continuous 7-day period (24 hours a day) except for bathing/swimming (showering is okay) (Picture 1).



Pic. 1. Activity monitor.

We will also inform you if we find any results during the study which are of clinical significance.

Focus group interviews

Focus group interviews will be conducted in small groups (up to 9 people in the group) of mixed gender twice between week 4 and 5 and at the end of the 12-week course using semi-structured discussions. The duration of a single interview is approximately 1 hour (range 1-1.5 hours). In the group you will be asked to discuss a series of open-ended questions over tea and biscuits with the trained focus group leader. The aim of focus groups will be to gather your experiences of taking part in the study, overall content and delivery of the course, and other questions to help the research team to improve the study in the future based on your honest feedback.

6. What are the possible disadvantages and risks of taking part?

There are minimal risks to taking part In the PAIL study. During the guided walking of a moderate intensity you may feel tired or out of breath, but this is normal and safe.

7. What are the potential benefits of taking part in the study?

Your feedback on the study will be used to make some alterations and design an effective study in the future to increase physical activity and prevent loneliness and social isolation in older adults. You will also receive a summary of the study findings upon completion of the 12-week programme.

8. What will happen if I do not want to carry on with the study?

You can withdraw up to 2 weeks after final session. During the study, you can withdrawal at any time without needing to give a reason by contacting the research team. You will be offered to fill up the withdrawal

form to us to identify the possible reasons for your withdrawal and asked if you would like to be contacted in the future.

9. What will happen to the results of the research study?

The results of the study will be a part of the dissertation research project of the postgraduate student and will be published in the journal paper. Authors of the study guarantee the anonymity in any published information; names of participants will not be given. Where opinions stated in the focus groups are quoted in publications, we will change names to preserve anonymity. Research data will be stored labelled with a unique ID number in locked filing cabinets/on password protected university computers accessible only to the research team and only the researchers will have access to information linking you to your unique ID number in order to contact you to
arrange the visits during the study. Research data will be kept for 10 years in line with UK data protection regulations.

10. Who has reviewed this study?

The study has been reviewed and approved by the Ethics Committee of the University of Birmingham.

11. What happens now if I decide to take part?

If you wish to participate, please contact Anastasia Shvedko on [redacted] or e-mail to axs1235@bham.ac.uk. You will be arranged the date and the time for the phone-based eligibility screening for the study participation which takes only 15 minutes. We will be glad to answer any questions you have about the study.

This information sheet is yours to take home.
Thank you for your time. It is appreciated.

Anastasia Shvedko
Doctoral Researcher
School of Sport, Exercise &
Rehabilitation Sciences
axs1235@bham.ac.uk
Mob: [redacted]

Prof Anna Whittaker
Principal Investigator
School of Sport, Exercise &
Rehabilitation Sciences
A.C.Whittaker@bham.ac.uk
Tel. 44 121 414 4398

Appendix 18

Phone-based eligibility screening form

Physical Activity Intervention for Loneliness (PAIL) in community-dwelling older adults: Participant Screening

Hello, thank you for showing an interest in the walking programme for adults. My name is Anastasia and I am a Doctoral Research student at the University of Birmingham.

I am doing a research on the impact of physical activity on well-being and health of older adults. As a part of my project, you are invited to take part in the 12-week outdoor group walking with a trained walk leader and a social club over a cup of tea. This is an opportunity for you to increase your physical activity and make new friends. The programme is free of charge and will be held at variety of locations around the Edgbaston campus based on the preferences and time that we arrange. The full information will be given to you later that is provided in the information sheet, so you can take it with you and share with your friends or family.

To take part, first, we need to check if you fit the study during the phone-based screening that will only takes **10 minutes of your time**.

If you fit then we will invite you for a second eligibility testing that will check your ability to walk and your cognitive abilities, such as logic, memory and a language.

We will need to have your verbal consent to the telephone-based screening.
Do you have any questions before we proceed?

Would you like to start our phone assessment? Yes | No ☐

We would need to take your contact information:

Name

Telephone

E-mail

Date of Screening:

Verbal consent for telephone screening given	Yes	No
Gender	Male	Female

How did you hear about **the PAIL**?

1. Advertisement
2. By word of mouth (i.e. referred by a friend)
3. Other (please state)

_____

"Now I'm going to run through a series of questions and when we get to the end, I'll explain whether you could be eligible to take part in PAIL study and if you are we'll go onto a few more questions."	Yes	No
A. Eligibility criteria		
1. Are you 60 years old or over?	Yes	No
2. Do you live in the community residence (e.g. private housing)?	Yes	No

3. Have you been diagnosed by your GP with Alzheimer's disease or dementia? Yes No

4. Are you currently enrolled in another physical activity research project or physical activity intervention? **If yes:** Yes No

Study name: _____

Study end date:_____

Did the participant fall into any of the shaded boxes, or involved in any other physical activity intervention or research study? Yes No

If 'Yes', explain that:

"Unfortunately, we can't include you in the intervention PAIL at the moment because you are not eligible for the participation in the study, but if you are happy for us to do so, we will contact you to inform about any other opportunities in the future".

*If "**No**" you may proceed with the eligibility screening.*

B. Assessment of feeling socially isolated or lonely (3-item tool of Hughes et al., 2004 for the phone screening)

The next questions are about how you feel about different aspects of your life.
For each one, tell me how often you feel that way using responses: "Hardly ever", "Some of the time" or "Often".

5. First, how often do you feel that you lack companionship: "Hardly ever", "Some of the time", or "Often"?	Hardly ever 1	Some of the time 2	Often 3
6. How often do you feel left out: "Hardly ever", "Some of the time", or "Often"?	Hardly ever 1	Some of the time 2	Often 3
7. How often do you feel isolated from others? (Is it "Hardly ever", "Some of the time", or "Often"?)	Hardly ever 1	Some of the time 2	Often 3

Provide **the total scoring for questions 5-7** by the sum of answers.

Total sum of points _____

If the loneliness score is **≥*6 points*** *the participant is at risk of feeling socially isolated or lonely and is **eligible** to participate. You can proceed with the screening and may go **to section C**.*

If No explain that:

"Unfortunately, we can't include you in the intervention PAIL at the moment because you are not eligible for the participation in the study, but if you are happy for us to do so, we will contact you to inform about any other opportunities in the future".

C. Assessment of physical function

Now I will ask you questions related to your health"

17. Do you have any chronic illness or a medical condition?			Yes	No
18. If you answered **yes** on previous question, are you physically mobile and able to walk without support?			Yes	No
"*A few more questions related to your health…"*				
19. A) Do you use a wheelchair?		Yes		No
B) Do you use a Zimmer frame?		Yes		No
20. How would you find walking across a room? *(With a walking stick is OK. If needs a zimmer **tick" Very difficult")***	Easy	A little difficult	Very difficult	Unable
21. How easy would you find getting out of a low chair?	Easy	A little difficult	Very difficult	Unable

a) If response is "Easy" ask: Would you normally use your arms to help you get up from the chair?	Yes / No			
22. How easy would you find walking up a flight of stairs with no handrail or wall to lean on?	Easy ▼	A little difficult	Very difficult	Unable
23. How easy do you find walking on an uneven pavement without losing your balance?	Easy ▼	A little difficult	Very difficult	Unable
Do any of the participant's answers fall into any of the <u>shaded boxes</u>, or they find <u>all four activities very difficult or unable</u>?			Yes ▼	No

If 'yes', explain that:

"Unfortunately, we can't include you in the PAIL trial at the moment because your level of physical function is not appropriate for the participation in the study, but if you are happy for us to do so, we will contact you again in a few months to re-assess the situation."

*If **No** participant is eligible to take part in the study and you may proceed with the eligibility screening*

Date to call back (time and date) if needed: _____

D. Assessment of physical activity and exercise behaviour

"I will just continue to ask a few more questions about your level of physical activity and participation in any exercises"

24. Can you remember, during the past 4 weeks (past month), did you do any regular exercise **over 20 minutes/week?**	Yes	No

If the answer is **NO** go to section E**.** Participant is eligible to take part in the study.

If the answer is **YES** proceed asking more question and go to question 25.

25. Can you remember, in a typical or normal week during the past 4 weeks, did you spend at least 20 minutes a week getting regular exercise **that increased breathing significantly and considered to be moderate, I will give you examples:** (*Circle the appropriate answer below*).

a) Dance? (for example, square, folk, line, ballroom) (*Interviewer Note: **Do not count aerobic dance)***	Yes	_____ mins	_____ times/week
b) Walk uphill or hike uphill?	Yes	_____ mins	_____ times/week
c) Walk fast or briskly for exercise?	Yes	_____ mins	_____ times/week
d) Water exercises? (*Such as aqua aerobics <u>NOT</u> leisure swimming)*	Yes	_____ mins	_____ times/week
e) Other _____ (if this exercise significantly increased breathing. You can talk but you can not sing the words).	Yes	_____ mins	_____ times/week

***If any YES answer:** "Can you say how much time did you do this exercise and how often did you do this exercise a week for the past four weeks? (write in columns above)?" (refer to the section above and fill the answers)*

Sum of all items (a,b,c,d,e)

_____
Total minutes a week

Total sum is* ≥ 125 minutes/week *for the past four weeks (past month)?	Yes	No

If the answer is **YES, explain** that "unfortunately you seem to be active at the moment and you are ineligible to participate in the study". Would you like us to call you back in four weeks' time?

Due to call back (date and time) _____

If answer is NO participant is eligible to take part in the study. **Go to section E.**

E. Confidence in ability to get to sessions:

"None of us can predict exactly what will happen over the next year, holidays, illnesses and minor operations may crop up unexpectedly, but in general if you were allocated to the physical activity sessions how confident do you feel that you would usually be able to attend a PAIL session once a week for the next three months."

Quite confident	Not sure	Not at all confident

If not at all confident ask and record the reason(s) why:

_____

If <u>NOT</u> confident because of the location of the venue or days of the week explain: *"Other venues/days will become available later this year, which may be more convenient for you. Would you like us to call you back then?*

Due to call back (date and time) _____

If still not confident, suggest that: *"Would it be better if we called you back in a few months to see if you are feeling more capable of attending sessions?"*

Agreed to be called back Date and time : _____	Preferred not to be called back

Thank you. That's all I have to ask you at the moment, is there anything you'd like to ask me?".....
"From what you have told me so far you could be eligible to take part in our study so what we would like to do now is invite you to attend a session at (venue)_____ so that we can meet face to face and conduct a few more simple screening tests such as asking you to walk 4 metres and answer a few more questions."

Are you still happy to attend?	Yes	No
If 'No': "*We will be running PAIL in other areas around the city later this year. Would you prefer to be put on the waiting list for these other sessions?*	Yes	No
If 'Yes', set date and time of the call: _____		
If still 'No': *'That is not a problem at all, if you change your mind, please do get back in touch with us by telephone, or e-mail.*		

Explain further details of the screening session.

"It's been nice talking to you. That's it for today. If there are any more questions you want to ask you can call me anytime. Thank you very much for your time. Preliminary screening shows that you are eligible to take part in our study.
At the next stage of the screening we need to arrange the meeting with you to check your cognitive skills and physical mobility. We can do it at home or in our facility".

At University facility ☐

At home ☐

Date Time Address

Researcher:- ☐ Enter details onto database Date _____

Appendix 19

Attendance log form

Wave ___ walking group

			Week											
No	**Name**	**ID**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**

TIDieR Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	____79_____	_____
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	____79_____	_____
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	_____82_____	_____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	__82-83_____	_____
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	_____81____	_____
	HOW		

6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	_____82____	_____
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	____82-83_____	_____
	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	____82____	_____
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	___N/A_____	_____
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	____77-78_____	_____
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	__77-78___	_____
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	____80____	_____

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

Appendix 21

12 week walking programme



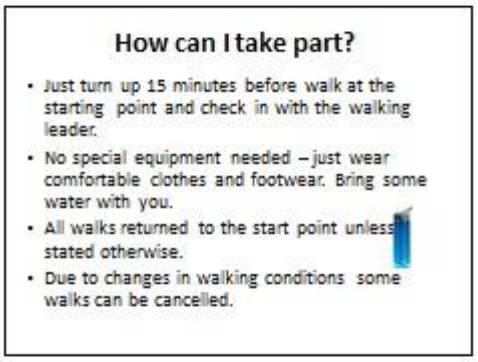
1



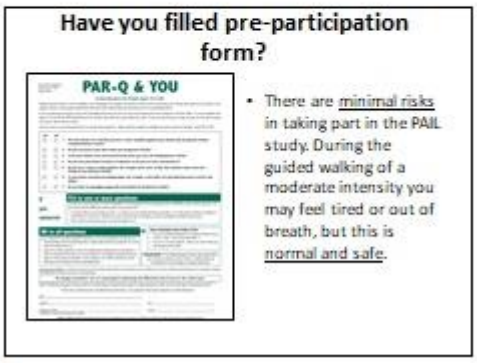
2



3



4



5



6

What if I would like to withdraw?

- The participation is entirely voluntary
- Everyone can withdraw from the study at any time point without giving a reason
- Any feedback will be valuable

7

Parking

- The University has two main pay and display car parks:
- **North East Car Park** (access via Pritchatts Road). Sat Nav Postcode: B15 2SA
  Please note that this car park is multistory and does not have a lift.

  Pritchatts Road Car Park (at junction with Vincent Drive). Sat Nav Postcode: B15 2QU
- Free parking for Blue Badge holders is available on campus. Please drive up to the security barriers at East Gate (access off Edgbaston park Road, near to the Barber Institute of Fine Arts) for assistance.

8

Week 1- Vale & Winterbourne House and Gardens



- Saturday 10.00am
- 9th of June,
- Start and endpoint: University of Birmingham train station
- Walk along the canal up to the Vale
- Getting there: All bus and train routes to the University train station
- Parking available free of charge near University train station. Use car pooling due to limited places if you are parking at Winterborne House and Gardens (not free of charge).

* *Coffee stop at Winterbourne Gardens (free entry)*

9

Vale & Winterbourne House and Gardens



10

Topic for discussion

Healthy ageing



UNIVERSITY OF BIRMINGHAM

11

Wale and Winterbourne House and Gardens.. Coffee stop



12

Week 2 - Cannon Hill park



- Saturday 10.00am
- 16th of June,
- Start and endpoint:
  MAC, the Cannon Hill Park
- Getting there: From Selly Oak – bus No63 (Bristol Road/Dawlish road) to Bristol Road/Priory Road.
- Bus X61, 144 from Bristol Road.
- Parking: There are two car parks, one by the MAC off Edgbaston Road £2 up to 4 hours, and a smaller car park off the Russell Road.

* *Coffee stop the Mac cafe.*

13

Mac, Cannon Hill park



14

Walk in Cannon Hill Park





15

Topic for discussion

Healthy eating: nutritional guidelines for older adults



UNIVERSITY OF BIRMINGHAM

16

Week 3 –Warley Woods Park



- Saturday 10.00am
- 30th of June
- Start and endpoint:
- Near Pavilion cafe The Pavilion, 101 Lightwoods Hill, Smethwick B67 5ED located off the Lightwoods Hill.

Getting there: From the University bus No48 to Hagley Road West and a short walk to the park.

Car parking: The car park off Lightwoods Hill, near The Pavilion.

* *Coffee stop at Pavilion cafe. The cafe is open 9am – 3pm weekdays*

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Warley Woods Park



18

Walk at Warley Woods Park



19

Topic for discussion

Loneliness



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20

Richmond Park & Isabella Plantation (London) – Week 3 (optional)*

- Sunday 12.00am
- 1st of July,
- Start and endpoint:

Kingston Gate
(Richmond park)



Getting there: Trains available from Vauxhall or Clapham Junction to Norbiton station (from there it is 10 minutes walk away to Kingston Gate
Parking is available at Kingston Gate (Richmond park). Sat nav KT2 5JN

* Coffee stop at Pavilion cafe. The cafe is open 9am – 3pm weekdays

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Richmond Park & Isabella Plantations



22

Kingston Gate (Richmond park)



23

Lickey Hills Country park– Week 4

- Thursday 10.30-11.30am
- 5th of July,
- Start and endpoint:

Visitor centre,
Warren Lane, Lickey, B45 8ER



Getting there: Train from University to Kings Norton, then bus 47 from Kings Norton to Rednal Island. Walk 5 minutes to the destination.

24

Lickey Hills Country park



25

Walk at Lickey Hills Country Park



26

Walk at Lickey Hills Country Park





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Week 4 - Topic for discussion

Social support



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28

Week 5 - Vale & Winterbourne House and Gardens

- Saturday 10.00am
- 14th of July,
- Start and endpoint: University of Birmingham train station



- Walk along the canal up to the Vale
- Getting there: All bus and train routes to the University train station
- Parking available free of charge near University train station

* Coffee stop at Winterbourne Gardens (free entry)

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Vale & Winterbourne House and Gardens



30

At Winterborne House and Gardens



31

Week 5 - Topic for discussion

Physical activity for older adults



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Week 6 – Woodgate Valley Country Park

- Saturday 10.00am
- 21st of July,
- Start and endpoint:
  Woodgate Valley Visitor's centre, B32 3DS
- Getting there: All bus and train routes to the University train station
- Parking available at the car park B32 3DS

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Topic for discussion
Local events and exercise activities

https://marketplace.mycanalbirmingham.org.uk/Activity/Category/13

Local Events
across Birmingham and beyond

34

Woodgate Valley Country Park



35

Walk at Woodgate Valley Country Park





36

Walk at Woodgate Valley Country Park



37

Focus group interview

1. *Mid-point focus group interview (Approximate duration 1 hour)*
   - To gather participants' experience and attitudes of taking part in the PAIL study

Where:
Room G05 (ground floor left block, School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham)



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Week 7 – Vale & Winterbourne House and Gardens



- Wednesday 11.00am
- 25th of July,
- Start and endpoint: University of Birmingham train station
- Walk along the canal up to the Vale
- Getting there: All bus and train routes to the University train station
- Parking available free of charge near University train station

* *Coffee stop at Winterbourne Gardens (free entry)*

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Vale & Winterbourne House and Gardens



40



Topic for discussion

The importance of the 'flu vaccination

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41



42

Week 8 – Walk and Pizza at Plough (Harborne)



- Wednesday 11.00am
- 1st of August,
- Start point: University of Birmingham train station
- Walk to Metchley Park & Groove Park and up to Harborne
- Pizza at Plough bar (Harborne High street) 21 High St, Harborne, Birmingham. B17 9NT

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Topic for discussion

Mental health and Wellbeing



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44







45

Week 9 - Cannon Hill park



- Wednesday 12.00am
- 9th of August,
- Start and endpoint: MAC, the Cannon Hill Park
- Getting there: From Selly Oak – bus No63 (Bristol Road/Dawlish road) to Bristol Road/Priory Road.
- Bus X61, 144 from Bristol Road.
- Parking: There are two car parks, one by the MAC off Edgbaston Road £2 up to 4 hours, and a smaller car park off the Russell Road.
- *Coffee stop the Mac café.*

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Cannon Hill park walk

Mac, Cannon Hill Park Queen's Ride, Birmingham B12 9QH



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Topic for discussion

Dental hygiene

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Week 10 – Walk to the Vale

- Saturday 10.00am
- 18th of August,
- Start and endpoint:
  University of Birmingham
  train station



- Walk from the University station along the canal up to the Vale
- Getting there: All bus and train routes to the University train station
- Parking available free of charge on campus

* Coffee stop on the campus

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Topic for discussion
Eye hygiene

50

Walk along the canal





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Week 11 –Sandwell Valley Park



- Friday 11.30-12.30
- 24th of August
- Start and endpoint:
- Near RSPB Sandwell Valley B43 5AG, Panhouse Avenue

Getting there: Bus No16 from Priory Queensway to Tanhouse Avenue, B43 5AG (£4 day saver or free with a senior bus pass)

Car parking: The car park at RSPB cost £2.

* Coffee stop at RSPB cafe.

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Bird watching at RSPB Sandwell Valley



Photos by Patrick Anderson patrick@vanl.com

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Bird watching at RSPB Sandwell Valley





Photos by Patrick Anderson patrick@vanl.com

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Walk around Forge Mill Lake



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Walk around Forge Mill Lake







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Topic for discussion

Keep active



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Week 12 - Vale & Winterbourne House and Gardens

- Wednesday 11.00am
- 29 of August
- Start and endpoint: University of Birmingham train station
- Walk along the canal up to the Vale
- Getting there: All bus and train routes to the University train station
- Parking available free of charge near the University train station

* Coffee stop at Winterbourne Gardens (free entry)



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Vale & Winterbourne House and Gardens



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Topic for discussion
Preventing the risk of falls

60

Focus group interview

1. *End-point focus group interview (Approximate duration 1 hour)*
   - To gather participants' experience and attitudes of taking part in the PAIL study

Where:
Room G05 (ground floor left block, School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham)



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Thank you for being with us all this time!

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Anastasia Shvedko
mob. 07490392720
e-mail: axs1235@bham.ac.uk

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Appendix 22

12-week walking plan

Please contact us if you would like more information about 12 week walking programme:

Anastasia Shvedko

Mobile phone: [redacted]

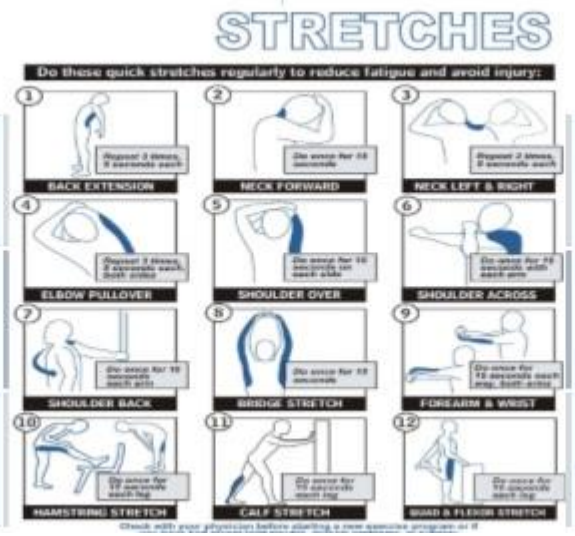
e-mail: axs1235@student.bham.ac.uk

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12 week walking programme



12 week walking plan

Week 10 40 min brisk walk Borg 4-5, 65-70% Heart rate maximum		
Week 11 45 min brisk walk Borg 4-5, 65-70% Heart rate maximum		
Week 12 45 min brisk walk Borg 4-5, 65-70% Heart rate maximum		

12 week walking plan

This walking programme is designed to get just about anyone off the couch and gradually work them up to walking for 45 minutes a day, in just 12 weeks. It is designed for absolute beginners using a mixture of walking routines to gradually increase your physical activity.

Week 1 15 min brisk walk Borg 2, up to 55% Heart rate maximum	**Week 4** 20 min brisk walk Borg 3, up to 60% Heart rate maximum	**Week 7** 30 min brisk walk Borg 3-4, 60-65% Heart rate maximum
Week 2 15 min brisk walk Borg 2, up to 55% Heart rate maximum	**Week 5** 25 min brisk walk Borg 3, up to 60% Heart rate maximum	**Week 8** 30 min brisk walk Borg 3-4, 60-65% Heart rate maximum
Week 3 20 min brisk walk Borg 2, up to 55% Heart rate maximum	**Week 6** 25 min brisk walk Borg 3, up to 60% Heart rate maximum	**Week 9** 35 min brisk walk Borg 3-4, 60-65% Heart rate maximum

Appendix 23

Content of healthy workshops



Appendix 24

Expected Outcomes and Barriers for Habitual Exercise scale

Expected outcomes and barriers for exercise Steinhard & Dishman, 1989

We would like to ask you about your expected outcomes and barriers for participation in the PAIL study using this questionnaire.

Please read through the questions below and respond using: strongly disagree, disagree, neither agree nor disagree, agree, or strongly agree.

First, answer questions about expected outcomes for engaging in physical activities.

I would like to participate in the exercise programme to:

Expected outcomes	Strongly disagree	Disagree	Neither agree not disagree	Agree	Strongly agree
1. Improve health					
2. Stay in shape					
3. Release of tension					
4. Maintain or lose weight					
5. Enhancing self-image and appearance					
6.Improved physical attractiveness					
7.Positive psychological effect					
8. Sense of accomplishment					
9. Enjoyment of activity					
10.Improved mental alertness					
11. Fun and enjoyment					
12. Cope with life's pressures					
13. Time spent with close friends					
14. Sense of being					

member of the team					
15. Time spent with family and members					

Total scoring for expected outcomes

_____

Now, answer questions about *barriers for exercise*.

What are your major reasons for not doing exercise?

Barriers	Strongly disagree	Disagree	Neither agree not disagree	Agree	Strongly agree
1. Too busy					
2. Not enough time					
3. Family obligations					
4. Lack of motivation					
5. Too lazy					
6. Too tired					
7. Bad weather					
8. Illness					
9. Exercise is boring					
10.Too inconvenient					
12.Too fatigued by exercise					
11. Physical disability					
12.Limiting health reason					
13. Lack of facilities					

Total score _____

Scoring: Strongly disagree (1), disagree (2), neither agree nor disagree (3), agree (4), or strongly agree (5). Summarise all numerical ratings for items and divide by the total number of questions. Total scoring ranges from 1 (low barriers and low outcome expectations) to 5 (high barriers and high outcome expectations).

Appendix 25

32-item checklist for reporting qualitative studies (COREQ)

Domain 1	**Research team and reflexivity**	
Personal characteristics		
1. Interviewer/facilitator	Which author/s conducted the focus group?	Farhan Noordali
2. Credentials	What were the researcher's credentials (*e.g. PhD.*)?	Doctoral Researcher & Trainee Health Psychologist (FN)
3. Occupation	What was their occupation at the time of the study?	Focus group moderators were Doctoral Researcher (FN) and full time PhD students (by the availability). Another PhD student (MK) was an assistant.
4. Gender	Was the researcher male of female?	Male
5. Experience and training	What experience or training did the researcher have?	All focus groups were run by a trained focus group leader who was not the intervention group lead to avoid any biasing effect on participants' responses: FN (Doctor of Philosophy, focus group lead) has 7 years of experience in qualitative research and facilitating focus groups for post-graduate/doctoral level research. He has been trained by qualitative research experts and has read extensively about the running of focus groups and managing participants before, during and after focus groups. MR (PhD student, focus group assistant) has received Bachelors and Master degrees in Psychology in Germany and learned about qualitative as well as quantitative research. She has been working as an assistant in a focus group evaluating a Diabetes Prevention Programme. AS (PhD student, leading researcher) has received the Master

		degree in Sport and Health Sciences and had a training in conducting a qualitative analysis with the Professor JT who has an experience of conducting and analysing focus group interviews.
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	Participants did not have a knowledge about the focus group moderator.
7. Participants knowledge of the interviewer	What did the participant know about the researcher? *e.g. personal goals, reasons for doing the research*	Participants were familiar with the project aims during the initial presentation. They also had an information sheet which outlined aims and methods of the research.
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? *e.g. Bias, assumptions, reasons and interests in the research topic*	Focus group moderator was an experienced researched in healthy ageing and mindfulness.
Domain 2	**Study design**	
Theoretical framework		
9. Methodological orientation and theory	What methodological orientation was stated to underpin the study?	The study did not have an established theoretical framework. The main theoretical paradigm of focus group interviews was a constructivism.
Participants selection		
10. Sampling	How were participants selected? E.g. purpose, convenience, consecutive, snowball	Participants were selected via widely mass advertisements and using snowball or chain recruitment by word of mouth.
11. Method of approach	How were participants approached?	Participants were approached using the phone-based eligibility screening and face-to-face during the university-based eligibility screening assessments.
12. Sample size	How many participants were in the study	This feasibility study included 25 participants in total.
13. Non-participation	How many people refused to participate or dropped out? Reasons?	Two participants withdrawn from the wait-listed control group: one - by the reason of too long wait till the start of the intervention, another – by the health reasons. Two participants dropped out form the intervention group by

		personal reasons.
14. Setting of data collection	Where was the data collected?	The data collection was conducted at the University of Birmingham, School of Sport, Exercise and Rehabilitation Sciences
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	A trained focus group leader (Doctor of Philosophy) acted as a moderator and a facilitator of the group interactions. Additionally, assistant was present by the availability (another PhD student or a research assistant).
16. Description of the sample	What are the important characteristics of the sample? *e.g. demographic data, date*	Participants were older adults aged 60 years or older, male and female, residing in the community settings and living in Birmingham, United Kingdom
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Focus group questions and the audio recorder were pilot tested prior to their use to ensure the appropriateness of questions and the clarity of sound of the recorder.
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	No
19. Audio/visual recording	Did the research use audio or visual recording to collect data?	Focus groups were audio recorded using a digital recorder and an I-phone voice recorder.
20. Field notes	Were field notes made during and after focus group interviews?	Another research team member (PhD student or a research assistant) not involved in delivery of intervention was present by availability to make additional field notes during participant answers required for cross-checking the collected data during analysis in case of any doubts.
21. Duration	What was the duration of focus group interviews?	Interviews lasted on average 1-1.5 hours.
22. Data saturation	Was data saturation discussed?	Immediately after focus groups, leader and assistant verified key points of each focus group interview followed by the debriefing using field notes made during interviews. In case of any doubts, recordings were checked.
23. Transcripts returned?	Were transcripts returned to participants for	Transcripts were returned to participants for verification to

	comment and/or correction?	ensure transparency and trustworthiness of the data (member checking).
Domain 3	**Analysis and findings**	
Data analysis		
24. Number of data codes	How many data coders coded the data?	Qualitative data were thematically analysed by two research team members independently (AS, JT). Segments were coded (labelling segments of data for examination), sorted and organised to look for patterns, or connections, between them (Fossey et al., 2002).
25. Description of the coding tree	Did the authors provide a description of the coding tree?	Mind maps with main themes and subthemes were produced by the authors for each category.
26. Description of themes	Were themes identified in advance or derived from the data?	The themes and sub-themes were derived from the collected data using thematic analysis. Each subsequent groups were compared to earlier groups and emerged new codes (sub-themes) were added to already existing.
27. Software	What software, if applicable, was used to manage the data?	Coding was conducted using a qualitative data indexing package QSR NVivo V.12 for Windows.
28. Participant checking	Did participant provide feedback on the findings?	Yes, participants did provided the feedback on findings and validated the transcripts.
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? *e.g. participant number*	Quotations were illustrating the particular point and were assigned a specific code (respondent ID number). Then, themes with important meanings common for all participants were derived from the obtained focal data. Direct quotes from each group were grouped under thematic headings (and assigned a participant number who made the quote) for a better classification of phrases and identification of frequency of mentioning these themes by participants.
30. Data of findings consistent	Was there consistency between the data presented and the findings?	Results were compared through discussion between reviewers.

31. Clarity of the major themes	Were major themes clearly presented in the findings?	Grouped results were consequently analysed in-depth to provide a narrative description of core elements of participants' experiences. Themes were refined through comparison across different phrases. Finally, the summary of data containing the main themes was presented.
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Minor themes or diverse cases were discussed between the researchers during informal discussion.

Mid-point focus group questions

Date:

Place:

Preparation:

1. Have few copies of participants' questionnaire printed (Attachment - Case report)
2. Printed copies of information sheet, and leaflets about the study (Attachments – Information sheet, Recruitment poster)

The welcome

- Introduce moderator and assistant:

Good morning and welcome to our session. Thanks for taking the time to join us to talk about experience in taking part in the Physical Activity Intervention for Loneliness. My name is … and I am going to lead a focus group with you today. Assisting me is ….

The overview of the topic

The topic is Physical Activity Intervention for Loneliness (PAIL) in the community-dwelling older adults: a feasibility study.

You have been given the information sheet about the project before participation and had a presentation about the project. Do you clearly understand what are aims of the project to make you feel more focused about the purpose of the project and its implication?

The aim of the project is to examine the feasibility of Physical Activity Intervention for Loneliness (PAIL). The study is aimed to assess the appropriateness and practicality of the designed intervention in the proposed settings.

The ground rules

- There are no wrong answers:

  There are no wrong answers but rather differing points of view. Please feel free to share your point of view even if it differs from what others have said. Keep in mind that we're just as interested in negative comments as positive comments, and at times the negative comments are the most helpful.

- We are tape recording, one person speaking at the time:

  You have probably noticed the microphone. We are tape recording the session because we don't want to miss any of your comments. People often say very helpful things in these discussions, and we can't write fast enough to get them all recorded.

- We are on a first name basis:

  We will be on a first name basis today and we won't use any names in our reports. You may be assured of complete confidentiality. The reports will go back to the country extension staff to help them plan future programmes.

- You don't need to agree with others, but please listen respectfully as others share their views

- Rules for cellular phones:

We ask that you turn off your phones. If you cannot and if you must respond to a call please do so as quietly as possible to re-join us as quickly as you can.

- Me role as moderator will be guide the discussion

- Talk to each other

The opening question

Well. Let's begin. You had participated in walking intervention. Tell us a bit about your experience so far of taking part in the study. Please be honest. Your opinion is valuable to us and helps us to improve our research in the future.

1. Was there any particular reason or goal you had which led you to participate in this intervention?	
2. Tell us about your experience of participation in the intervention. How has it been so far? What specifically did you like and why?	
3. What part of sessions did you least enjoy and why? Probe question: Are there any improvements that can be made to the walking intervention?	
4. Is there anything that you would change about walking intervention?	

Probe question 1: Any views on the length of walking and other exercises? Probe question 2: How satisfied are you with the number of people in the group and diversity of people?	
5. Do you think that the content of the social workshops is relevant to you? Probe question: What would you suggest to include/exclude in the future if this walking intervention were to be delivered more widely in the future?	
6. What do you think would be make it more interesting for people to engage with and attend the walking intervention? If you feel that the intervention needs to be changed, how would you suggest it be improved?	
7. What do you think about the questionnaires that you have completed for this study (all of them)? 8. Were they easy to answer?	
9. Did you experience any specific	

difficulties when filling out the forms? (have the copy of questionnaire on the table to help support their memory about what they've completed)?	
10. How did you find the activity monitors? Did you have any problems with wearing them? Is there anything you would like to suggest about using these monitors in future interventions?	
11. Did you experience any barriers to regularly participating in the walking intervention? Probing question: If, so what specific barriers affected your ability to attend regularly (e.g., physical, personal, transport, health reasons, motivation)?	
12. Do you feel the instructor was well prepared for the walking intervention? Probe question: What do you think about the leader's approach (delivery of walks and stretching exercise, communication skills)?	
13. Has participating in this walking	

intervention helped you to engage with people in conversations and make new friends? *Note: need to explore here whether they've made new friends within the walking intervention, and also if this has made them more confident to make friends and socialise outside of the walking intervention. Probe: If not, why? (e.g., do you feel that you need more time to build relationships? Do you feel there more could be offered in the walking intervention to help you socialise and make new friends?	
14. What has been the most useful or meaningful experience for you during the intervention and what do you feel you will take away from this experience?	

Thank you for your time. Your opinion is very important to us. Your answers will be confidential, and your name will not be mentioned anywhere where direct quotes are published in order to illustrate this research study.

Endpoint focus group questions

Date:

Place:

Preparation:

3. Have few copies of participants' questionnaire printed?
4. Printed copies of information sheet, and leaflets about the study

The welcome

- Introduce moderator and assistant:

Good morning and welcome to our session. Thanks for taking the time to join us to talk about experience in taking part in the Physical Activity Intervention for Loneliness. My name is … and I am going to lead a focus group with you today. Assisting me is ….

The overview of the topic

The topic is Physical Activity Intervention for Loneliness (PAIL) in the community-dwelling older adults: a feasibility study.

You have been given the information sheet about the project before participation and had a presentation about the project. Do you clearly understand what are aims of the project to make you feel more focused about the purpose of the project and its implication?

The aim of the project is to examine the feasibility of Physical Activity Intervention for Loneliness (PAIL). The study is aimed to assess the

appropriateness and practicality of the designed intervention in the proposed settings.

The ground rules

- There are no wrong answers:

  There are no wrong answers but rather differing points of view. Please feel free to share your point of view even if it differs from what others have said. Keep in mind that we're just as interested in negative comments as positive comments, and at times the negative comments are the most helpful.

- We are tape recording, one person speaking at the time:

  You have probably noticed the microphone. We are tape recording the session because we don't want to miss any of your comments. People often say very helpful things in these discussions, and we can't write fast enough to get them all recorded.

- We are on a first name basis:

  We will be on a first name basis today and we won't use any names in our reports. You may be assured of complete confidentiality. The reports will go back to the country extension staff to help them plan future programmes.

- You don't need to agree with others, but please listen respectfully as others share their views

- Rules for cellular phones:

We ask that you turn off your phones. If you cannot and if you must respond to a call, please do so as quietly as possible to rejoin us as quickly as

you can.

- Me role as moderator will be guide the discussion

- Talk to each other

The opening question

Well. Let's begin. You had participated in walking intervention. Tell us a bit about your experience so far of taking part in the study. Please be honest. Your opinion is valuable to us and helps us to improve our research in the future.
Tell us a bit about your experience.

1. Tell us about your experience of participation in the walking intervention. How has it been? What specifically did you like and why?	
2. What would you suggest to include/exclude in the future if this walking intervention were to be delivered more widely in the future?	
3. Did you experience any barriers to regularly participating in the walking intervention? <u>Probing question</u>: If, so what specific barriers affected your ability to attend regularly (e.g, physical, personal, transport, health reasons, motivation)	
4. Do you think you made new friends?	

If yes, how many and at what session did you start feeling this?	
5. What has been the most meaningful experience for you and what do you feel you will take away from this experience?	

This is the end of the interview. Thank you for your time. This is very important for us. Your answers will be confidential, and your name will not be mentioned anywhere.

Appendix 28

PAIL feasibility study results manuscript submitted to *Pilot and Feasibility Studies*

Physical Activity Intervention for Loneliness (PAIL) in community-dwelling older adults: a randomised feasibility study

Anastasia V. Shvedko[1], Janice L. Thompson[1], Carolyn A. Greig[1,2,4] and Anna C. Whittaker[1,3*]

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[1]School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, Birmingham, UK

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[3]Faculty of Health Sciences and Sport, University of Stirling, Stirling, UK

[4]NIHR Birmingham Biomedical Research Centre, University Hospitals Birmingham NHS Foundation Trust and University of Birmingham, UK

Background: Low quality social relationships in older adults are strongly associated with feelings of loneliness. Physical activity interventions could reduce loneliness and improve psychological well-being, among other health benefits. The aim of this study was to examine the feasibility of a Physical Activity Intervention for Loneliness (PAIL) in community-dwelling older adults at risk of loneliness.

Methods: Study design was a 12-week randomized controlled feasibility trial (RCT) conducted in Birmingham, United Kingdom (February to August 2018). Participants were 25 healthy, inactive, community-dwelling older adults at risk for loneliness, aged 60-92 years. The intervention included: once weekly group walk and health education workshop up to 90 minutes per session in total, with a wait-listed control group. The primary feasibility outcomes were to estimate recruitment, retention and adherence rates. Secondary outcome measures (not blinded assessment) were body mass index, blood pressure, physical activity, and psychosocial variables. Process and outcome evaluations were conducted using focus groups interviews.

Results: Forty-eight participants were recruited over 4 months with a recruitment rate of 25% (48/195); 52% (25/48) met the inclusion criteria and 100% (25/25) were randomised into the intervention (N=12) and wait-listed (WL) control groups (N=13). At 12 weeks, 10/12 (83.3%; 95% CI 55.20 to 95.30) intervention and 10/13 (76.9%; 95% CI 49.74 to 91.82) control participants completed the final assessments. The average attendance rate was 58.3% for the intervention group (range 33.0%-75.0%) and 42.3% (range 23.1%–69.2%) among controls. The *a priori* recruitment criteria for progression were not met. The retention rate satisfied the criteria of the study. No serious adverse events occurred. The focus group results identified three themes which showed overall positive experiences of participation in PAIL in terms of: 1) study design and intervention; 2) walking sessions; and 3) health education workshops.

Conclusions: The findings suggest that community-dwelling older adults at risk of loneliness found the intervention and measures acceptable and could safely participate. However, a more extensive and robust strategy would be needed to support adequate recruitment of lonely older adults and adherence into a definitive RCT.

Trial registration: Clinicaltrials.gov Identifier: NCT03458793.

Keywords: Feasibility study, Physical activity, Loneliness, Older adults, Randomised Controlled

Trial.

Background

Maintenance of social connectedness throughout the lifespan is an important aspect of successful ageing (Cacioppo et al., 2014). The disruption of established social patterns or poor quality of social relationships negatively impacts quality of life and well-being in older adults and is strongly associated with loneliness (Poscia et al., 2018). According to the Office for National Statistics (Office for National Statistics, 2018a), the United Kingdom (UK) is increasingly an ageing population. In 2017 over 12 million people were aged 65 years and over, accounting for 18.2% of the total UK population in 2018 (Office for National Statistics, 2018a). Defined as a discrepancy between a person's desired and actual social relationships (Peplau et al., 1980), loneliness and a lack of social relations are considered to be high risk factors for morbidity and mortality, and the negative impact of loneliness can be as harmful as smoking fifteen cigarettes a day (Holt-Lunstad et al., 2010). Bearing in mind the ageing of the UK population, with a sharp increase in the proportion of adults aged 65 years and older over the last 30 years (Later life in the United Kingdom, 2018), health professionals have placed special emphasis on the promotion of "Active Ageing" enabling older adults to increase participation in "social, economic, cultural, spiritual and civic affairs" to maintain quality of life (World Health Organisation, 2002, p. 12). Further, promotion of a variety of campaigns to prevent loneliness may reduce or slow the burden on National Health Service (NHS) expenses, with potential economic benefits estimated at around £900 per annum per person associated with loneliness reduction and thus reduced bed hospitalisation (Bernard et al., 2013). Given this, the early prevention of loneliness and timely implementation of health interventions in a community setting to tackle the problem at its early onset seems prudent.

Physical activity (PA) is defined as any bodily movement produced by the contraction of skeletal muscles that results in a substantial increase over resting energy expenditure (American College of Sports Medicine, 2013). It is a health behaviour that can facilitate meaningful social relationships and serve as an alternative to medical treatments which may have negative side effects (Pels et al., 2016). Compared with other forms of treatment therapies (e.g. mindfulness therapy, art and craft therapy), PA interventions, especially in small groups (up to 8-9 people), can assist in building friendly and trusted relationships between participants based on shared interests and similar needs, as demonstrated by previous research (Stevens, 2001).

Mechanisms of the effectiveness of PA interventions are suggested to relate to loneliness reduction models, stress reduction, and increased social support during activities. The social compensation model (Ferraro et al., 1995) suggests that PA can work via compensation for lost meaningful social connections due to increased peripheral social networking during friendly conversations between participants (Stevens, 2001). The hypothesis of the broaden-and-build theory of positive emotions (Fredrickson, 2004) posits that enjoyable forms of PA generate happiness and bring positive emotions, which in turn could be associated with loneliness reduction (Newall et al., 2013). The tripartite model of group identification was found to be effective, particularly among lonely seniors, based on the sense of identification and social attraction to group members with shared interests and goals, arising during engagement in physical activities (Henry et al., 1999). Based on the stress/social support model (Cohen et al., 1985), social networks promote well-being that is associated with loneliness reduction in older adults. Among the mechanisms named above, only the

tripartite model of group identification has been shown to be successfully applied in the treatment of loneliness directly in the context of PA.

Based on the analysis of existing randomised controlled trials (RCTs), few PA interventions for loneliness reduction have been conducted in community settings (Shvedko et al., 2018a). This is also consistent with previous systematic reviews and meta-analyses (Masi et al., 2010, Pels et al., 2016, Smith et al., 2017, Poscia et al., 2018). A subsequent analysis of other loneliness-related social outcomes has shown that for social functioning (as a sub-domain of health-related quality of life), specific aspects of PA interventions can successfully influence social health (Shvedko et al., 2018a) with the strongest effects being obtained for group setting exercise interventions, with delivery by a health/medical professional, and in a diseased rather than healthy population. PA interventions did not appear to be effective for increasing social support or social networks (Shvedko et al., 2018a). In addition, the majority of studies used a cross-sectional or longitudinal design, which does not allow determination of causality and limits the rigour of the research evidence (Pels et al., 2016). Nevertheless, it is important to emphasise that the majority of existing PA interventions assess loneliness as a secondary outcome within a number of other psychosocial outcomes, which limits the ability to fully examine the effectiveness of these interventions for reducing loneliness (Fry, 2001).

Further, a number of moderating (affecting the strength of the relationship between PA and loneliness) and mediating (driving the influence of PA on loneliness) factors are not consistently considered in intervention studies, making the outcomes of even well-conducted interventions less credible (Pels et al., 2016). As such, exploring the number

of moderating and mediating factors between loneliness and PA may help to determine additional pathways of any PA intervention effects. Research shows that global (Bandura, 1993, Fry, 2001) and domain-specific self-efficacy (Fry et al., 2002) are moderating factors, and social support was found to be both a moderating (McAuley et al., 2000a) and mediating factor (Taliaferro et al., 2010) of the impact of PA on loneliness. Also, perceived self-efficacy in one study (Fry et al., 2002) was found to be a superior predictor of loneliness and psychological distress in older adults when compared with demographic factors, physical health, and support networks. Further, personal (self-efficacy) and environmental (social support) variables moderating relationships between loneliness and PA have a bidirectional link with each other (Holahan et al., 1987). Perceived social support is a moderator of self-efficacy, and increased self-efficacy leads to better social support (McAuley et al., 2000a).

Bearing in mind the limitations of the current literature, understanding the mechanisms of association between loneliness and PA may bring new insights to the design of novel and effective PA interventions (Pels et al., 2016). Further research is needed to explore the association between loneliness, self-efficacy and social support in the context of PA interventions for older adults. However, before the mechanisms can be fully understood, the practicalities and feasibility of implementation of such interventions with older adults should be tested in a feasibility trial (Eldridge et al., 2016b) before proceeding to a definitive RCT. In order to assess participant experiences of such interventions, the present study utilised a mixed-methods research design, defined as the class of research where the researcher mixes or combines quantitative and qualitative research techniques, methods, approaches, concepts or language into a single study (Johnson et al., 2004). This research design can add valuable knowledge into a feasibility study. The

aim of the study was to examine the feasibility of the Physical Activity Intervention for Loneliness (PAIL) intervention in community-dwelling older adults at risk for loneliness. For the planned future large-scale RCT, the primary hypothesis was that, compared with the inactive control group, participants in the intervention group would report a greater decrease in loneliness. The secondary hypothesis was that participants in the intervention group would significantly increase their amount of physical activity engagement per week, and this would be associated with greater positive changes in other psychosocial and health outcomes compared with the control group participants.

Study objectives

The following specific aims of this feasibility study were to estimate:

1. Recruitment rate, attendance and retention rates (number of participants completing the study as a proportion of those randomised).
2. The appropriateness and practicality of the designed intervention in the proposed settings.
3. The acceptability of the intervention by participants, and willingness to participate.
4. The appropriateness of the assessment tools.
5. The appropriateness of the statistical methods of data analysis used.
6. The required sample size for a future large-scale RCT derived from a power calculation.
7. The acceptability of measures, and the most suitable primary outcome measure for a future large-scale RCT.

In addition, to reflect the aims of a future large-scale RCT that this feasibility study was seeking to inform, the effect sizes between the intervention and control groups were

examined, however the analysis was exploratory due to feasibility studies not being adequately powered to test the effectiveness of the intervention (Eldridge et al., 2016a).

Methods/design

The full description of methods is published elsewhere (Shvedko et al., 2018b). A brief description is presented here. PAIL was a two-arm, 12-week randomised feasibility trial with a wait-listed control group delivered in Birmingham, United Kingdom, from February 2018 to August 2018 and ran in two waves of data collection. Quantitative data analyses were completed in November 2018; qualitative data analyses were conducted iteratively over the data collection period from March 2018 onwards. The trial was approved by the Science, Technology, Engineering and Mathematics (STEM) Research Ethics Committee of the University of Birmingham, UK (ERN_16-1419A). This feasibility study was guided by a populated CONSORT Extension to Pilot and Feasibility Trials (Table 1, Additional file 1). Written informed consent was obtained from all participants prior to entry into the study.

Participants

Recruitment

A total of 25 (aged 60 years and older) community-dwelling older adults were recruited in two waves from September 2017 to January, 2018 (recruitment Wave 1) and from January, 2018 to May, 2018 (recruitment Wave 2) from local neighbourhoods (households) and community centres across the wide geographic area of Birmingham, United Kingdom via widely distributed advertisements about the study in local media resources, posters and leaflets. Additionally, potential participants received an information sheet about the study during the eligibility screening to facilitate

recruitment by word of mouth (Miles et al., 1994). Recruitment was aimed to be at a rate of 10 participants a month (to a minimum of 40 participants) for estimation of the critical parameters of the feasibility study (Arain et al., 2010).

Interested participants contacted the research team by phone or e-mail. Further the phone-based eligibility screening was arranged. Potential participants who appeared to be eligible based on the phone interview were invited to attend a presentation meeting about the study. Those agreeing to participate, after providing informed consent, were invited for further eligibility screening prior the entry into the study. Eligible participants were screened at baseline and randomised into the intervention or a WL control group using a computer-generated random sequence. Details of the randomisation and concealment are reported elsewhere (Shvedko et al., 2018b).

Eligibility

Participants were eligible if they were: 1) community-dwelling older adults aged 60 years and older; 2) previously sedentary (i.e. as defined by a lack of regular involvement in more than 20 minutes exercise per week over the past month that increased breathing significantly and was considered moderate) (Stevens et al., 1998); 3) at risk of loneliness and having ≥6 out of 9 points on the 3-item loneliness scale during the phone screening (Hughes et al., 2004); 4) physically mobile as measured using the Short Physical Performance Battery (SPPB) (Guralnik et al., 1994) with a score ≥ 9 out of 12 (Pahor et al., 2014); 5) healthy or having one or more common chronic diseases but ambulatory; without a cognitive disability as assessed by the Montreal Cognitive Assessment (MOCA) (Nasreddine et al., 2005) with a score ≥ 22 out of 30 (Freitas et

al., 2013); 6) able to give written informed consent; and 7) English speaking and able to complete paper and pencil questionnaires.

Interventions

The PAIL feasibility study was a 12-week intervention consisting of group walks and health educational/social interaction workshops performed once weekly for a duration of up to 90 minutes per session. The design and features of the PAIL intervention were derived from the findings from a systematic review of PA interventions for loneliness by Shvedko et al. (2018a). Prior to the first walking session, participants received a copy of a General Practitioner (GP) letter to inform their doctor of participation. Walking sessions were based on the principles of gradual progression and adaptation to PA (American College of Sports Medicine, 2013). Participants followed a trained walking leader via a specific route. A warm-up preceded each session followed by an end of session cool-down and breathing exercises. Group walking sessions were followed by health education/social interactions workshops on a variety of healthy ageing topics such as eye hygiene, mental health and well-being, preventing falls, social support, nutritional guidelines, and PA recommendations for older adults where participants shared their knowledge and experiences about the topics discussed.

Intervention group

After randomisation, participants in the intervention group started the 12-week intervention.

Wait-listed Control group

Participants in the WL control (delayed intervention) group started the intervention after their follow-up measures were completed, approximately 12 weeks post-randomisation.

Measures

All measures were conducted at the host academic institution at baseline and immediately post the intervention period. Participants provided socio-demographic information about their age, gender, ethnicity, marital status, living arrangements, level of education, any children, employment status and any medical conditions. *Cognitive function* was assessed using a Montreal Cognitive Assessment scale (MOCA) designed to test mild cognitive impairment (Nasreddine et al., 2005). *Physical functioning* was assessed using the Short Physical Performance Battery (SPPB) (Guralnik et al., 1994). *Height* was measured to the nearest 0.1 cm using a stadiometer (Seca AG, Reinach, Switzerland) and recorded in metres. *Weight* was assessed using weighing scales (Tanita UK Ltd., Middlesex, UK) to the nearest 0.1 kg. *Body Mass Index* (BMI, $kg \cdot m^{-2}$) was calculated by dividing mass (kg) by height squared (m^2). *Resting blood pressure* (BP rest, mm Hg) was measured using a portable semi-automatic OMRON sphygmomanometer (OMRON HEM705CP sphygmomanometer; Omron Matsusaka Co Ltd, Japan). *Physical activity* was measured using ActivPAL accelerometers (PAL Technologies Ltd. Glasgow, UK) at baseline and immediately post intervention over a continuous 7-day period of awake and sleeping (24 hours a day) except when bathing or swimming (Chastin et al., 2010).

Questionnaires

Loneliness was assessed using the 8-item UCLA Loneliness Scale (UCLA-8) (Hays et al., 1987). *Social support* was assessed using the 20-item Medical Outcomes Study

Social Support Survey (MOSSSS) (Sherbourne et al., 1991). *Social networks* were categorised using the 6-item Lubben's Social Network Scale (LSNS-6) (Lubben et al., 2006). *Depression and anxiety* were assessed using the 14-item Hospital Anxiety and Depression Scale (HADS) (Zigmond et al., 1983). *Self-efficacy for exercise* was measured using the revised 9-item Self-Efficacy for Walking/Exercise Scale (SEE), using a paper-and-pencil format (Resnick et al., 2000). *Satisfaction with level of social contacts* (SSC) was measured with the question "How satisfied are you with your social contacts?" (Fokkema et al., 2007a). *Expected outcomes and barriers for exercise* were measured using the Expected Outcomes and Barriers for Habitual Exercise scale (Steinhardt et al., 1989) adapted for the older adult population. Four questions related to sport competence were deleted from the expected outcomes sub-scale due to irrelevance for this population group (Steinhardt et al., 1989). The expected outcomes and barriers for exercise scale has demonstrated good internal consistency from 0.66 to 0.85, and a high test-retest reliability of 0.78 in previous research (Steinhardt et al., 1989).

Qualitative assessments

To understand participants' experiences of taking part in the PAIL feasibility trial, focus groups were conducted at mid-point (between week 4 and 5) and at the end of the 12-week intervention using semi-structured discussions in groups of 4-9 people per group of mixed gender (Additional files 2, 3). The research team iteratively analysed the mid-point data to identify if any alterations in the intervention were required based on the participants' feedback. The 32-item checklist for reporting qualitative research guided the researcher to ensure clarity and transparency in focus group methodology (Tong et al., 2007). Focus groups were audio recorded using a digital recorder and transcribed verbatim. An independent trained focus group leader acted as moderator and facilitator

of the focus groups (MacDougall et al., 2001).

Feasibility outcomes

The following feasibility outcomes were assessed:

1) Attendance was calculated as the total number of attended sessions divided by the total number of sessions of the intervention and recorded as a percentage;

2) Recruitment rate was calculated as the number of individuals responding to advertisements and friends' referrals out of a total number of formal invitations given/advertisements placed (including web-based advertisements, advertisements placed in the local cohort groups and poster and leaflet material disseminated in the community). Recruitment rate was recorded as a percentage, e.g. 25% (48/195). It is acknowledged that advertisements may reach a large number of individuals, but it was impossible to quantify this;

3) Retention rate was calculated as number of participants completing the study as a proportion of those randomised;

4) The assessment rate of questionnaires was evaluated as the total number of completed questionnaires divided by the total number of questionnaires and recorded as a percentage;

5) The appropriateness of assessment tools for primary efficacy outcome measures was investigated using reliability analyses. Internal consistency reliability (Cohen's alpha) was calculated at each time point (pre and post) and averaged to give overall reliability. The expected outcomes and barriers for exercise questionnaire was completed twice at baseline, with a week between measures, to allow for test-retest reliability analysis.

6) The appropriateness, practicality and acceptability of the designed intervention in the proposed settings was assessed using focus group interviews. The focus group

transcripts were analysed using a phenomenological inductive approach (Creswell, 2012), and these data were used to guide the research team in improving the quality of the delivered intervention by informing positive changes in the methodology and design of the intervention for the future implementation in a consequent study;

7) Statistical power and sample size estimation was calculated for meaningful potential future primary outcomes (e.g. loneliness or social support) using a method based on the differences in means between the intervention and control groups, using G-power software (Erdfelder et al., 1996);

8) An effect size (ES) was calculated for loneliness, social support, social networks, anxiety and depression, self-efficacy for exercise, satisfaction with level of social contacts, and the expected outcomes and barriers for exercise. Means (M) and standard deviations (SD) were used to investigate the effect size for change in loneliness using mixed between (intervention group vs. control group) and within (over time) repeated-measures analysis of variance (ANOVAs) with post-hoc comparisons.

Data monitoring

The data monitoring committee for this project was the supervisory research team (three academic supervisors). They were responsible for checking accuracy of quantitative data upon assembly of the final database following completion of data collection prior to data analysis. The qualitative data were analysed iteratively by AS with independent analysis and oversight by a member of the supervisory team with expertise in qualitative and mixed methods research (JT). AS was responsible for monitoring and reporting spontaneous adverse events or any unintended trial effects to the supervisory team, and the primary supervisor (AW). The trial was also subject to independent audit request by

the sponsor, the University of Birmingham, by a team independent of the supervisory/research team.

Data collection

Data were collected at the university facility at screening, baseline and post-intervention period (12 weeks after the start of the intervention). After providing baseline eligibility screening, potential participants were offered a total of five visits for health assessments at the university facility. Participants in the intervention group had an additional sixth visit for attending the mid-point focus group.

Sample size

As this was a feasibility study to inform the design of the future large-scale RCT, a total targeted sample of 40 older adult participants was considered necessary to be recruited for estimation of the critical parameters (Arain et al., 2010) with 20 in the intervention group and 20 in the WL control group.

Progression criteria

The progression criteria to a definitive large-scale RCT were: 1) no any serious adverse events, such as hospitalisation, life-threatening condition, death and any adverse events associated with the intervention experienced by less than 5% of participants per group; 2) recruitment rate of no less than 75% by the end of the four months recruitment period; and 3) retention rate of no less than 75% in each group at 12 weeks (end-point). If all three criteria were not met, there would be insufficient evidence to justify proceeding to the definitive RCT. No targets were set for other feasibility outcomes, e.g., questionnaire completion rates or attendance at the intervention sessions.

Data analysis

Quantitative data were analysed using SPSS version 22.0 for Windows (SPSS Inc., Chicago, IL) employing an intention-to-treat analysis (based on their treatment allocation and irrespective of participants' adherence or withdrawal) (Gupta, 2011). The level of significance was set at $p < .05$, however any hypothesis testing was preliminary, and any results were interpreted with caution as this feasibility study is underpowered and the analyses based on small numbers. Baseline differences between groups for continuous data (e.g. age, BMI, resting blood pressure, number of comorbidities, cognitive and physical functioning, and outcomes of questionnaires) were analysed using one-way ANOVA. Chi-squared tests were applied for nominal data (e.g. gender, ethnicity, marital status, living arrangements, level of education, children, and employment status). For descriptive statistics, data were presented as means (M) and standard deviations (SD). Nominal data were presented as number (N) and percentage. Mixed between (group) and within (time) repeated-measures ANOVAs with post-hoc comparisons were applied to investigate the effect of the intervention versus control on psychosocial outcomes (loneliness, social support, support networks, depression, anxiety, self-efficacy for exercise, satisfaction with level of social contacts), expected outcomes and barriers for exercise, and accelerometer data. The accelerometer data were analysed using the ActivPAL software V7.1.18 (PAL technologies, Scotland, UK). Recorded data were downloaded to a computer, and data for average daily amount of stepping (step counts), average time lying and sitting (h) in increments of 15 s, average time standing (h), and energy expenditure (EE, MET/h) were analysed using mixed between (intervention group) and within (time) ANOVAs. For the Expected Outcomes and Barriers for Habitual Exercise scale (Steinhardt et al., 1989), additional test-retest

reliability was calculated via correlation. In order to explore which outcome measures are likely to be most important for the main trial, Pearson's correlations were performed between calculated change scores over time in the experimental group for all psychosocial outcomes (Lubben's social networks, loneliness and self-efficacy for exercise) and change scores for averaged daily physical activity (time lying/sitting (h), time standing (h), time stepping (h), step counts, sit to stand transitions (n) and energy equivalent (METs/h)). Statistical power and sample size estimation for a future large-scale RCT were calculated for meaningful outcomes (e.g. loneliness or social support) using the method based on the differences in means between the intervention and control group using the G-power software Version 3.1 (Erdfelder et al., 1996).

Qualitative study

Qualitative data were thematically analysed by two research team members independently using a phenomenological inductive approach (Creswell, 2012). Transcripts were returned to participants for comments/correction to ensure transparency and trustworthiness of the data (member checking) (Fossey et al., 2002). Validated transcripts were read several times by the two independent researchers to obtain an overall meaning. Then, themes and subthemes with important meanings common across all participants were derived from the obtained data. Results were compared through discussion between reviewers (Tesch, 2013). Data were pseudo-anonymised with a unique identification number (ID) and stored confidentially in locked filing cabinets/on password protected university computers accessible only to the research team. Audio recordings were destroyed after the recordings were transcribed verbatim. Digitally recorded interview transcripts were stored securely on a password-protected computer that only the researchers had access to.

Results

Participant characteristics

Participants were 25 (mean age 68.5(8.05) years, range 60-92 years) healthy, inactive, community-dwelling older adults, 14 (56%) female, and 18 (72%) white. Baseline descriptive statistics of participants are shown in Table 2.

Feasibility and safety

Recruitment and retention

The flow of participants through the study is shown in Figure 1. The intervention was advertised using 192 advertisements (145 leaflets and 47 advertisement posters), which yielded a total of 48 potential participants (45 expressing the initial interest and three recruited through friends' referrals). The recruitment rate was 25% (48/195). Two declined to participate before completing the phone-based screening. Forty-six potential participants were assessed for eligibility using the phone-based screening with 21 excluded due to not meeting the eligibility

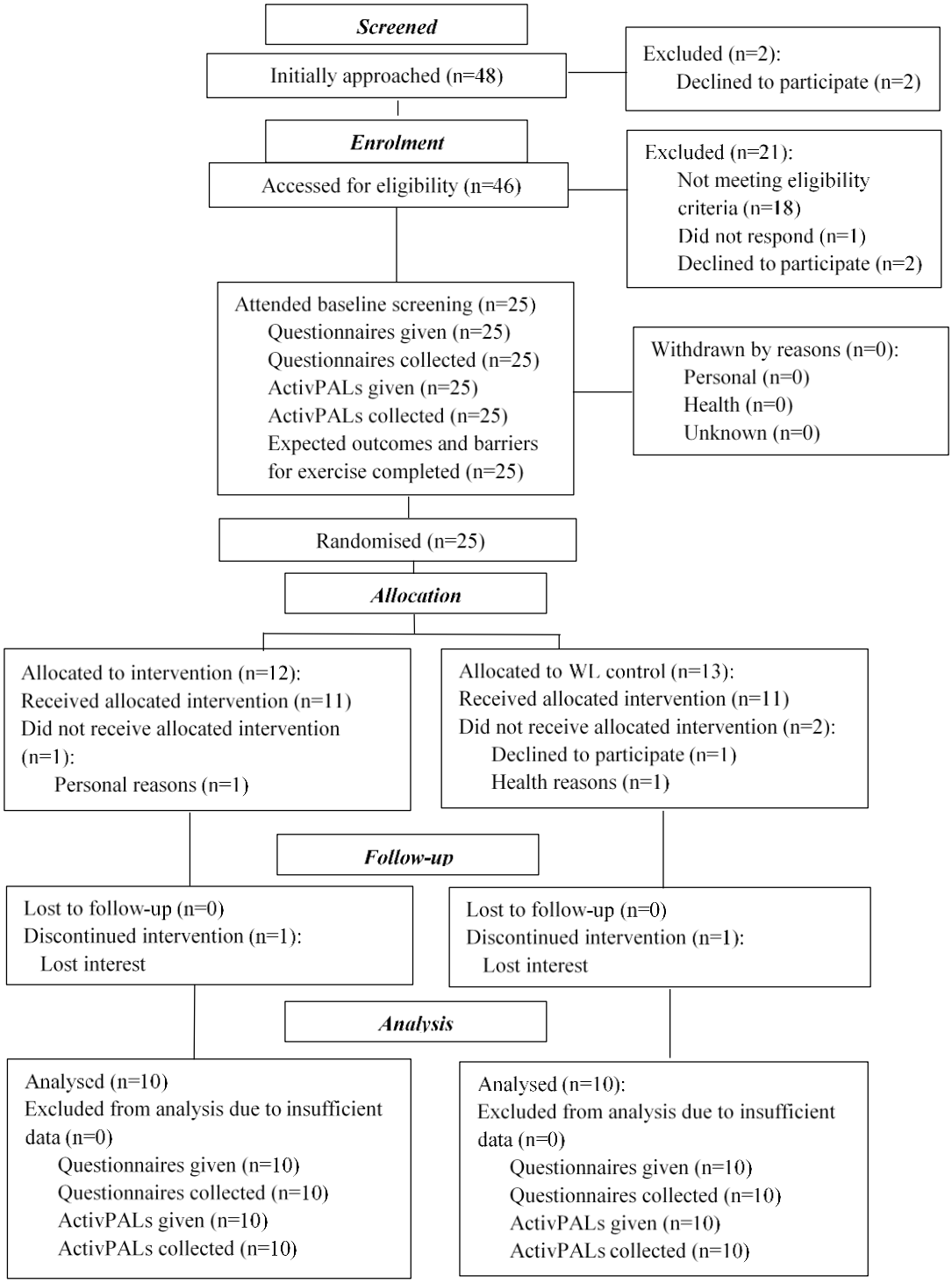


Fig. 1. CONSORT flow diagram of Physical Activity Intervention for Loneliness (PAIL) intervention.

criteria (N=18), declined to participate (N=4) and no response (N=1). Reasons for not being eligible were already physically active or taking part in another intervention (N=11), or not at risk of loneliness (as assessed using the phone-screening tool) (N=7).

Reasons for declining to participate were pressures of work/lack of time and health reasons. A total of 31 participants (31/46, 67.4%) attended the further eligibility screening at Visit 1, and 25 were eligible to proceed with baseline assessment (Visit 2). Using Wilson's 95% confidence interval (Wilson, 1927), at 12 weeks, 10/12 (83.3%; 95% CI 55.20 to 95.30) intervention and 10/13 (76.9%; 95% CI 49.74 to 91.82) control participants completed final assessments. The retention rate satisfied the criteria of the study, e.g. > 75% of participants at 12 weeks (end-point period), although the recruitment rate of 25% by the end of the four months was somewhat lower than was initially proposed at 75%. There were no serious adverse events, or any adverse events observed related to study participation.

Attendance

The average attendance rate for the total of 12 sessions of the walking intervention was 58.3% for the intervention group, with attendance ranging from 33.0% to 75.0% (Additional file 4). The average attendance rate for the WL control group was 42.3%, with attendance ranging from 23.1% to 69.2 %. The mean (SD) number of attended sessions per person was 8.6(2.8) and 6.6(2.6) in the intervention and wait-list control group, respectively. After completing the 12-week intervention, 7/10 participants from the intervention group and 6/10 participants from the wait-list control group continued walking. The follow-up attendance rate assessed during the 12-week post-intervention period was 48% for the intervention and 52% for the WL control group.

The assessment rate of questionnaires

Baseline questionnaires and accelerometer data were provided by 100% (25/25) of participants recruited into the study. Post-intervention questionnaires and end-point

accelerometer data were provided by 100% (10/10) of the intervention and 100% (10/10) WL control group participants.

The appropriateness of the assessment tools

The average reliability was high for all psychosocial outcomes: loneliness (Cronbach's alpha 0.857), social support (Cronbach's alpha 0.975), Lubben's social networks (Cronbach's alpha 0.721), depression (Cronbach's alpha 0.744), anxiety (Cronbach's alpha 0.693) and self-efficacy for exercise (Cronbach's alpha 0.925). The expected outcomes for the exercise sub-scale of the Expected Outcomes and Barriers for Exercise questionnaire showed high internal consistency reliability at baseline, with Cronbach's alpha equalling 0.926 (a week before) and 0.938 (a week after); at post-intervention the value was 0.976. Barriers for the exercise sub-scale of the Expected Outcomes and Barriers for Exercise questionnaire showed high internal consistency reliability at baseline, with Cronbach's alpha equalling 0.888 (a week before) and 0.924 (a week after); at the post-intervention period the value was 0.943.

Findings from the qualitative study

The appropriateness, practicality and acceptability of the intervention by participants

A total of 5/12 (42%) participants in the intervention group attended two focus group interviews, at the mid-point and end-point intervention periods. The responses of participants during the focus groups were summarised in the main themes for mid-point and end-point intervention periods and presented below.

1. Mid-point focus groups

The main themes were: study design and recruitment (3 subthemes), healthy workshops (3 subthemes) and walking sessions (3 subthemes) (Additional file 2).

Mid-point focus group results showed that in terms of the appropriateness and practicality, the spring-summer seasons were a better to start the intervention than winter time. Overall, participants had very positive views of the walking intervention, particularly the benefits of walking, its cost-effectiveness in terms of the economic benefits for older adults and direct positive health effects:

"And because I am on a fixed income now, you know I can't just go out and earn a bit more money to do something, it does limit you a little bit in what you can do and you have got all this time, but you haven't got the money. Err, you know, and I brought up a child on my own so she took quite a lot of my salary when I was working [Kate laughs], you know I have never got a lot of money (all laugh*) to do what I would really like to do. So, you have to work within that (.)"* (Alison, 75, female).

For others, it was a chance to meet new people and get access to local community groups:

"I mean walking is good because it loosens everybody up a bit, gets people to know each other (.)" (Andrew, 68, male).

The content of the healthy workshops was relevant and allowed them to share feelings and knowledge. However, the main barriers to attend walks were: 1) personal, such as lack of time associated with family and community celebrations, holiday, home refurbishments, and carer responsibilities; and 2) environmental barriers, such as transportation and the weather (Additional file 3). Participants found it difficult to get to

the location by public transport, or to find the nearest parking area if the meeting point was on campus:

"And some of the walks, like [the place of the walk], although it wasn't that particularly early, it's getting there (.) [an issue] on public transport" (Sarah, 76, female).

2. End-point focus groups

The main themes were: study design and recruitment (3 subthemes), healthy workshops (3 subthemes), and walking sessions (2 subthemes) (Additional file 3). Participants felt that participation in the intervention helped them to become more physically active, which was their initial aim:

"You have to just try and keep motivating [yourself], just keep going I suppose, rather than just sitting at home. I don't know how (.) for me like, I am working four days a week at the moment, so I don't know how I would feel when I retire, which is going to happen next year so (.)" (Ben, male, 65).

"I enjoyed the exercise thing. It is quite, you know (.) it is just (.) She (referring to the exercise leader) sort of said, you know, made us aware of sort, of what sort of exercise is good for, what parts of your body and so forth. So, I mean it is important, isn't it to keep moving, keep active and this is what part of the programme is about, isn't it?" (Ben, male, 65).

Common interests raised during the walks allowed first friendship gains that started from as early as the second or third walk and continued after the programme's end at 12

weeks. Walking was seen to promote the bonding of participants and improved their aspirations for friendship-based relationships:

"I have definitely made new friends, enjoyed meeting new people and you gel with some people which is a human nature, so (.)" (Sarah, female, 76).

Future recommendations included more group leaders per group and classification of walks by ability level (e.g. beginner, improver):

"(.) and it was only (the Researcher). But if (the Researcher) had two other people on our walk (.). You can do a slow one slightly less (distance), a medium one slightly further and a faster one even further. I don't know how you would organise that, but that would take care of the pacing (.) The Researcher will need help. You can't do that with one person because you got to lead, so she actually does need somebody to lead a group" (Alison, 75, female).

Another suggestion was to conduct healthy workshops during a separate session/time:

*"-You suggest a separate session for loneliness? (*Focus group lead).

-A separate [Kate: a separate session yeah (.)] without so many leaflets (Alison, 75, female).

-Yeah, so that will be a little bit (.) it will be a good focus for each of us to learn, to share (.)" (Kate, 62, female).

Changes in outcome measures

There were no significant differences between the intervention and control groups at baseline in all measures except for number (n) of sit-to-stand transitions (p=.02), which were 14.4 points lower in the intervention group (mean 43.3(11.3)) compared with

controls (mean 57.6(15.8); 95% CI 2.91, 25.81). Table 3 shows the between group differences for secondary outcomes. A mixed repeated between-within subjects' ANOVA showed that there were no significant between (group) or within (time) interaction effects during the study for all outcomes (Table 3). Although in general a pattern of improvement was seen across all psychosocial and physical activity outcomes in the intervention group. All correlations performed for psychosocial outcomes are shown in Table 4. Correlation analysis performed for calculated change scores over time in the experimental group for all psychosocial outcomes showed no significant correlations between any other psychosocial outcomes except for a moderate negative correlation between self-efficacy for exercise and loneliness, r(10)=-.71 (p=.01) and a moderate negative correlation between self-efficacy for exercise and the family sub-scale of Lubben's social networks, r(10)=-.65 (p=.02). A moderate positive correlation emerged between self-efficacy for exercise and the friendship sub-scale of Lubben's social networks, r(10)=.66, n=12 (p=.02), such that an increase in self-efficacy for exercise was associated with a larger family and friends social network size.

Power Calculation

The potential sample size for a future large-scale trial was calculated for each psychosocial outcome using *post-hoc* analyses first to estimate the observed power based on the effect sizes from the repeated measures between-within ANOVAs on the 25 participants using the partial eta-squared from the interaction effect (η^2). Following this, a sample size was calculated *a priori* for a future trial using $\alpha = 0.05$ and power at 80% for each measure: loneliness (N=77, η^2=.014), social support (N=48, η^2=.030), Lubben's social network (N=48, η^2= .026), depression (N=378, η^2=.008), anxiety (N=68, η^2=.032), SEE (N=12, η^2=.122), expected outcomes (N=60, η^2=.033), and

barriers for exercise (N=172, η^2=.011) (Additional file 5). The calculation of estimated sample size for SSC was not possible as η^2=.000 (insufficient power).

Discussion

This study assessed the feasibility of the Physical Activity Intervention for Loneliness (PAIL) intervention in community-dwelling older adults at risk for loneliness. Based on the progression criteria, the retention rate satisfied the criteria of the study, e.g. >75% of participants at 12 weeks (end-point period), as well as no adverse events during the intervention. The recruitment rate of 25% by the end of the four months was somewhat lower than initially proposed at 75%. Therefore, only two out of three criteria of progression to the definitive RCT were satisfied, meaning that the study was not feasible to deliver in its present form. However, these findings were not surprising based on the inability to accurately estimate recruitment rates in the present study, as well as the fact that it is difficult to access socially isolated older adults who may be less interested in joining an intervention than those who are more socially engaged. Therefore, recruitment from GPs may be more advantageous than advertisement via mass media resources such as leaflets or advertisement posters in a future large-scale trial to recruit older adults at high risk of loneliness or social isolation (Jopling, 2015, Age Concern UK, 2016, Shvedko et al., 2018a).

The low attendance rate (58.3% for the intervention group, 42.3% in the WL control group) in this study is not surprising given that the physical activity intervention is considered to be a behaviour change strategy that is not easily initiated or consistently maintained in older adult populations (Horne et al., 2018). Based on participant responses, providing transport to and from walking session locations may significantly

improve adherence and provide easier access to various locations of walks to maintain interest of older adults.

No significant changes in outcome measures were found after 12 weeks of the PAIL intervention. As reported in the literature, the acute exercise effect is brief (Chodzko-Zajko, 2014a) and a longer duration intervention as well as an adequate follow-up period of the future intervention may be needed to allow participants to build upon transforming new contacts into meaningful relationships based on trust, which previous studies suggest may be up to 5 months (McAuley et al., 2000b, Findlay, 2003).

Given that the initial aim of the intervention was to see if loneliness could be impacted, and the observed power and estimated sample size for this seems achievable, this could be recommended as a future primary outcome. However, a feasibility study, by its very nature, may be under powered to achieve statistical significance at $\alpha=0.05$ (Lee et al., 2014). Therefore, any interpretation based on significance levels should be treated with caution. Post-hoc sample size calculations were possible, however are not advisable for feasibility studies (Walters, 2009). The results show that, for instance, for loneliness the obtained power ($1-\beta$) was 0.96 which is high and supports that post-hoc sample size calculations are not advisable (in this case not possible) for this feasibility study (Walters, 2009). Given the small effect sizes for SCC, a sample size calculation was not possible, thus this should be omitted from any future trial. The efficacy outcomes of the current feasibility study may be used in exploratory analyses, but further changes in the intervention design and methods are required before proceeding to a definitive trial. For example, a larger sample and more rigorous recruitment strategy, as well as easier access to walking locations may significantly improve the quality of future research. A future intervention would also be advised to: 1) classify walking groups by ability level; 2) add more group leaders per group; 3) conduct healthy workshops during a separate

session/time; and 4) provide transport to walking locations in order to maintain high adherence and diversity of routes.

Strengths and limitations

This study included the features of effective physical activity interventions for treatment of loneliness and social isolation in community-dwelling older adults based on the results of a published systematic review (Shvedko et al., 2018a). Walking was chosen as it has been shown to be the most feasible and cost-effective method of physical activity for older adults (Mutrie et al., 2012a, Townsend et al., 2012). Other strengths of this study include objective measurement of PA, use of reliable methods of assessment of psychosocial outcomes in older adults, and the mixed methods research design that allowed for collecting feedback from participants during and at the end of the intervention.

Study limitations include selection bias associated with the recruitment of physically mobile participants as assessed during the eligibility screening. Therefore, any treatment effect of this feasibility study may be blunted by this selection bias (Stevens, 2001, Masi et al., 2010) and inclusion of higher functioning older adults. The identification of sedentary individuals in this study was done using the modified short form of the CHAMPS physical activity questionnaire adopted for use in an older adult population (Stewart et al., 2001). For future studies it is advisable that instead of using this general normative definition of a sedentary individual, this exclusion criterion could be exclusive to walking. Future studies should consider using objective methods of assessment of PA (e.g., pedometers or accelerometers) in older adults in addition to the phone-based screening for a rigorous eligibility process. Appropriate blinding of the researcher was not possible in the present study due to a lack of resources available to

pay an independent person to deliver the intervention and collect all of the data. As such, it is recommended that future studies are resourced to allow for the recruitment of a trained walking leader to deliver the intervention and an independent assessor of outcomes to allow for adequate blinding and reduce detection bias.

Conclusions

The present study suggests that community-dwelling older adults at risk for loneliness can successfully complete a 12-week walking intervention programme, reporting enjoyment and benefits, and they were keen to share their knowledge and experiences during the healthy/social workshops. The efficacy outcomes of the current feasibility study may be used in exploratory analyses, but the changes suggested above to the intervention design and methods would be necessary before proceeding to a definitive trial.

Abbreviations

ANOVA: the repeated-measures analysis of variance; B: the standardised regression coefficient; BMI: Body Mass Index; BP rest: Resting blood pressure; CHAMPS: Community Healthy Activities Model Programme for Seniors; CI: Confidence Intervals; EE: energy expenditure; ES: the effect size; GP: General Practitioner; HADS: Hospital Anxiety and Depression Scale; LSNS-6: 6-item Lubben's social network scale; M: means; MET: the metabolic equivalent; MOSSSS: the Medical Outcomes Study Social Support Survey; MOCA: the Montreal Cognitive Assessment; N: number; NHS: National Health Services; PA: physical activity; PAIL: Physical Activity Intervention for Loneliness; R: correlation coefficient; RCT: Randomised Controlled Trial; RPE: Ratings of Perceived Exertion; SD: standard deviations; SEE: Self-efficacy for exercise

scale; SSC: Satisfaction with level of social contacts; SPPB: the Short Physical Performance Battery; STEM Ethical Review Committee: the Science, Technology, Engineering and Mathematics Ethical Review Committee; UCLA-8: the 8-item The University of California, Los Angeles Loneliness Scale; UK: The United Kingdom; WL: wait-listed control group.

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Availability of data and materials

Not applicable.

Authors' contributions

AW, JT and CG advised regarding development of trial design and study protocol, assisted obtaining ethics approval and amendments, helped in facilitating patient recruitment, register study protocol, structure the research stages and oversee all study procedures. JT also helped to design and analyse focus group interviews. FN helped to conduct and analyse focus group interviews. The doctoral research student (AS) obtained funding and was involved in the design of the study protocol, participant recruitment, health assessments and implementation of the intervention.

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Competing interests

The authors of this review declare that they have no competing interests.

Consent for publication

Not applicable.

Disclosure statement

The authors of this review declare that they have no known conflicts of interest.

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Pilot and Feasibility Studies

Physical Activity Intervention for Loneliness (PAIL) in community-dwelling older adults: a randomised feasibility study

--Manuscript Draft--

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Abstract:	Background: Low quality social relationships in older adults are strongly associated with feelings of loneliness. Physical activity interventions could reduce loneliness and improve psychological well-being, among other health benefits. The aim of this study was to examine the feasibility of a Physical Activity Intervention for Loneliness (PAIL) in community-dwelling older adults at risk of loneliness. Methods: Study design was a 12-week randomized controlled feasibility trial (RCT) conducted in Birmingham, United Kingdom (February to August 2018). Participants were 25 healthy, inactive, community-dwelling older adults at risk for loneliness, aged 60-92 years. The intervention included: once weekly group walk and health education workshop up to 90 minutes per session in total, with a wait-listed control group. The primary feasibility outcomes were to estimate recruitment, retention and adherence rates. Secondary outcome measures (not blinded assessment) were body mass index, blood pressure, physical activity, and psychosocial variables. Process and outcome evaluations were conducted using focus groups interviews. Results: Forty-eight participants were recruited over 4 months with a recruitment rate of 25% (48/195); 52% (25/48) met the inclusion criteria and 100% (25/25) were randomised into the intervention (N=12) and wait-listed (WL) control groups (N=13). At 12 weeks, 10/12 (83.3%; 95% CI 55.20 to 95.30) intervention and 10/13 (76.9%; 95% CI 49.74 to 91.82) control participants completed the final assessments. The average attendance rate was 58.3% for the intervention group (range 33.0%-75.0%) and 42.3% (range 23.1%–69.2%) among controls. The a priori recruitment and retention criteria for progression were not met. No serious adverse events occurred. The focus group results identified three themes which showed overall positive experiences of participation in PAIL in terms of: 1) study design and intervention; 2) walking sessions; and 3) health education workshops. Conclusions: The findings suggest that community-dwelling older adults at risk of loneliness found the intervention and measures acceptable and could safely participate. However, a more extensive and robust strategy would be needed to support adequate recruitment of lonely older adults and adherence into a definitive RCT. Trial registration: Clinicaltrials.gov Identifier: NCT03458793. Keywords: Feasibility study, Physical activity, Loneliness, Older adults, Randomised Controlled Trial.
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Covering letter concerning your manuscript	Dear Sirs, Please find attached a manuscript of a feasibility study titled: "Physical Activity Intervention for Loneliness (PAIL) in community-dwelling older adults: a randomised feasibility study". We hope that the manuscript is within the research interest and scope of the Pilot and Feasibility Studies journal and is suitable for publication. This feasibility study for the research intervention aiming to prevent loneliness among community-dwelling older adults is designed to estimate key feasibility outcomes to inform the future large scale randomised controlled study. The design and features of the PAIL intervention are based on analysis of the most effective interventions obtained from the systematic review analysis of the existing evidence published in Psychology of Sport and Exercise journal in January 2018 by authors of this project. The results of this feasibility trial provide insights for the practise of day care centers, community organisations and independent health professionals as to the most appropriate and effective intervention of early prevention and treatment of impaired social health in older aged community residents. The protocol of the present study entitled "Physical Activity Intervention for Loneliness (PAIL) in community-dwelling older adults: a protocol for the feasibility study" was published in the Pilot and Feasibility Studies journal in December 2018. PAIL is original research and has not been published or submitted elsewhere. We look forward to hearing from you. Regards, Anastasia Shvedko
Declarations Have you included a 'Declarations' section in your manuscript including all of the subheadings listed below and the relevant information under each? • Ethics approval and consent to participate • Consent for publication • Availability of data and material • Competing interests • Funding • Authors' contributions • Acknowledgements Click here for information on what should be included under each heading. Please use the 'Contact Us' link above if you require further assistance	I confirm I have provided a complete 'Declarations' section in my manuscript
<b>Is this study a clinical	Yes

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trial?<hr>A clinical trial is defined by the Word Health Organisation as 'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'.	
We require registration of all clinical trials that are reported in manuscripts submitted to the journal. More information about trial registration, including the trial registries that currently meet all of the ICMJE guidelines, can be found in the FAQ section of "About ICMJE" at http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/.<p>Please provide the following information where prompted:<hr>Enter the Trial Registration Number: as follow-up to "Is this study a clinical trial?<hr>A clinical trial is defined by the Word Health Organisation as 'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'."	NCT03458793
Enter the name of the registry: as follow-up to "Is this study a clinical trial?<hr>A clinical trial is defined by the Word Health Organisation as 'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'."	Clinicaltrials.gov
Enter the URL of the trial registry record: as follow-up to "Is this study a clinical trial?<hr>A clinical trial is defined by the Word Health Organisation as 'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'."	https://clinicaltrials.gov/ct2/show/NCT03458793
Enter the date that you registered your trial (in mm/dd/yyyy format): as follow-up to "Is this study a clinical trial?<hr>A clinical trial is defined by the Word Health Organisation as 'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'."	03-01-2018
Enter the date of enrolment of the first participant to the trial (in mm/dd/yyyy	12-09-2018

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format): as follow-up to "Is this study a clinical trial?<hr>A clinical trial is defined by the Word Health Organisation as 'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'."	
Was your trial registered before the first participant was enrolled? (i.e. prospectively registered) as follow-up to "Is this study a clinical trial?<hr>A clinical trial is defined by the Word Health Organisation as 'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'."	Yes
Within your manuscript, have you also included details of your trial registration at the end of your abstract? • Name of the registry • Trial registration number • Date of registration • URL of trial registry record *Example: Trial registration: ISRCTN, ISRCTN12345678. Registered 28 September 2014, http://www.isrctn.com/ISRCTN12345678* as follow-up to "Was your trial registered before the first participant was enrolled? (i.e. prospectively registered)"	I confirm I have provided trial registration details at the end of the abstract

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