Protocol

Full Project title: A feasibility study and pilot RCT of a peer-led walking programme to increase physical activity in inactive older adults: "Walk With Me Study"

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Grant number: PHR 12/133/04

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Abbreviations

BCT	Behaviour change techniques
BMI	Body Mass Index
EPAQ-2	EPIC Physical Activity Questionnaire (Version 2)
EuroQol-5D	European Quality of life (5 Dimensions)
GHQ-28	General Health Questionnaire (28 items)
GP	General Practitioner
MRC	Medical Research Council
MVPA	Moderate and vigorous physical activity
NI	Northern Ireland
PHA	Public Health Agency
RCT	Randomised controlled trial
UCLA	University of California, Los Angeles
UK	United Kingdom

Background

The UK is currently faced with a rapid increase in the proportion of the population aged 65 years or older.[1] Ageing is associated with changes in health that predispose older adults to functional decline, morbidity, disability, poor quality of life, and increased mortality, and these health problems emerge earlier in older adults from socio-economically deprived backgrounds.[2] The anticipated declines in physical health, functional ability and mental wellbeing[3] that accompany ageing may be offset or delayed by the adoption of more active lifestyles.[4] As with middle-aged adults, a physically active lifestyle in older adults leads to a reduced risk of developing numerous chronic non-communicable diseases[6-7] and all-cause mortality,[8] as well as improvements in balance and a reduction in the risk of falls[9] and sarcopenia.[10] In addition to the physical health benefits, regular activity has been linked to improved cognitive function and mental health and wellbeing[11-12] and higher levels of health-related quality of life.[13] These associated physical and mental health benefits may lead to lower utilisation and cost of healthcare services.[15]

With the number of older adults set to rise in coming years, and half of our lifetime spend on healthcare accounted for in old age,[16] there is a need to develop effective interventions that promote active ageing. Declining physical activity levels are a major public health concern in the UK due to the associated increase in morbidity and mortality,[20] and the associated costs, estimated to be £1.06 billion per year.[21]

Levels of inactivity increase with age, with approximately 75% of adults aged 50 or older not meeting recommended levels.[23] Factors associated with the successful maintenance of physical activity in older age include being male and unmarried, higher levels of education, absence of chronic conditions and functional limitations, lower BMI, higher social support, absence of other unhealthy behaviours and lower levels of psychological distress.[24] A decline in physical activity with age is often coupled with changing social circumstances: low levels of activity are associated with increased social isolation (fewer interactions with others) and loneliness (feeling of being alone) in adults aged over 65.[25]

Previous systematic reviews have summarised the findings from studies designed to evaluate the effectiveness of interventions, to increase self-reported physical activity among community-dwelling older adults.[29-33] The majority of the interventions reviewed compared the effect of either group based or individual home based physical activity with a non-exercise control, ranging in duration from six weeks to four years, with the majority being 4-6 month interventions. In general, the interventions encouraged older adults to perform some type of aerobic activity, of which walking was the predominant form. Previous walking interventions have resulted in health benefits and high adherence rates,[34-35] little risk of injury and high acceptability as it is a no-, or low-cost activity that can easily be incorporated into daily life.[36] Although interventions in these reviews demonstrated promising short term increases in physical activity, longer term follow up was often absent. A more recent systematic review of the effect of physical activity interventions in older adults that included follow-up of longer than 12 months has demonstrated that changes in physical activity can be sustained for one year.[32]

These systematic reviews have also highlighted that many of the interventions do not reach the people who would benefit the most.[30-31] Evidence is needed from interventions targeting groups who are least active, such as the socio-economically disadvantaged.

These ‘hard to reach’ groups have their own unique needs that should be considered in designing an intervention.

The barriers and motivators for physical activity reported by older adults are different from those in younger people. For older people, poor health and a lack of knowledge of and belief in the health benefits of moderate physical activity are most frequently cited as the major barriers to regular exercise.[39] Focus groups of inactive older adults have reported their desire for individually tailored physical activity programmes, which take place outside of intimidating settings such as gyms and which avoid the concern of slowing others down in group exercise.[40]

The majority of the interventions included in the reviews above have been effective at producing short-term changes in physical activity, but levels decline substantially in studies that include longer term follow up (>6 months). Individual factors (positive affect and self-efficacy)[43] and social factors (such as social support)[44] are associated with long-term maintenance of changes in physical activity. More recent focus has been on how these factors interact with the potential influence of neighbourhood environments to support physical activity in older adults. A recent study concluded that a supportive physical environment (one which is more ‘walkable’) was associated with higher levels of physical activity, especially in individuals who also had higher self-efficacy and social support.[45] This suggests that an intervention designed on an ecological model, to address multiple levels of influence on physical activity behaviours (including individual, social and environmental factors), is likely to be more effective at delivering sustained changes in activity than interventions targeting individual influences only. However, there are few studies designed to address these multiple influences in community dwelling older adults. Interventions with multiple components addressing the various levels in the ecological model are required. There is need for research to test the feasibility and acceptability of multilevel interventions, before a substantive trial is undertaken.[46]

Peer-led interventions offer a model that would help overcome many of the barriers identified above. Peer-led behaviour change interventions are a common and effective means of encouraging behaviour change, including physical activity.[47] Peer mentors are trained, nonprofessional individuals, who share similar demographic characteristics to the target population (e.g. age and cultural background) and possess experiential knowledge of the target behaviour.[48] They may provide emotional support, motivation through positive reinforcement, and knowledge regarding problem solving strategies.[49] Peer mentors would be able to deliver tailored information about changing physical activity and its benefits, in a sociable manner. Peer mentors provide positive role models who can dispel the stereotypes of ageing more effectively than younger professionals who may be involved in the health or social care of older adults. In addition, they could provide the necessary social support for behaviour change,[50] outside of perceived intimidating settings (e.g. gyms). The recent UK physical activity guidelines highlight the lack of evidence of the effect of physical activity interventions for increasing social engagement.[20] In addition to the environmental and social support for changing physical activity, previous systematic reviews have shown that individual self-monitoring combined with goal setting and reviewing and providing feedback on performance are effective strategies for increasing physical activity in the general adult population.[32, 51-53] Previous peer-led walking programmes such as the “First Step” programme[54] and other walking based programmes in older adults [55-56] have included tools to assist in goal setting and self-monitoring. We therefore will use pedometers to set individually tailored goals and self-monitor progress using weekly step diaries.

Aims and Objectives

The study aims to bridge the evidence gap by developing and testing the feasibility of a complex peer-led, multi-component physical activity intervention, derived from a socio-ecological model of health, in socio-economically disadvantaged community dwelling older adults.

The objectives of the study are to:

1. identify components for inclusion in a peer-led walking intervention
2. to develop a protocol for the content and delivery of a peer-led walking programme for older adults that addresses multiple levels of the socio-ecological model
3. to pilot recruitment, training and management of a group of peer mentors, working in collaboration with community partners
4. to test the feasibility of a peer-led walking programme targeting inactive older adults in a randomised controlled pilot study, in order to inform the design of a main trial

Methods

Using the MRC framework for complex interventions,[46] we will design and test the feasibility of a multilevel peer-led physical activity intervention for older adults, tailored to meet the needs of the local community. The intervention package will be developed after defining appropriate behaviour change techniques (BCTs). BCTs are the replicable, active component of an intervention (e.g. goal setting).[57] They will be used to inform the intervention design by: (i) identifying BCTs used in previous peer-led interventions. To identify these from previous peer-led interventions, it will be necessary to conduct a rapid review of the literature; (ii) conducting interviews with members of the target population to explore their preferences for, and the perceived feasibility of particular BCTs.

Based on the outcome of these stages, we will then; (iii) conduct a pilot Randomised Controlled Trial (RCT). The trial will provide information on recruitment and attrition rates, intervention fidelity, data on the variability in objective physical activity measurements and the resources needed to support the development of a definitive trial.[58]

Phase 1: Identification of approaches used in previous peer-led interventions

The first phase in the complex intervention model is to gather relevant evidence and theory to develop a logic model for the implementation of the intervention, which will include the proposed causal pathways and relevant outcome measures. A rapid review[59] approach will be used to update a systematic review[47] of peer-led physical activity interventions in adults aged over 18 years. The review will not be restricted to interventions only targeting older adults as there have been very few peer-led interventions in this age group, and this would limit the inclusion of potentially useful components. We will adopt the same search strategy as that used in the Webel et al. review.[47]

The purpose of the rapid review will be to extract the BCTs from the intervention descriptions. BCTs will be independently identified from the intervention descriptions by both researchers using the recently published BCT Taxonomy (v1).[60] Inter-rater reliability will be calculated and any discrepancies resolved through discussion. Additional details such as intervention setting, target participants, dose, duration, mode of delivery (e.g. individual, group, website, written materials etc.) and country will be extracted and used to inform intervention development. The BCTs will be mapped[61] onto theoretical domains[62] and to the determinants of physical activity in older adults, and will be used to help identify causal pathways linking interventions to behaviour change using the approach taken in a previous review by Michie et al.[63] and will inform the choice of additional measures (possible mediators of change) for the pilot RCT. The socio-ecological model will provide a framework for a multilevel intervention design[64] that addresses multiple levels of determinants including individual, social and environmental factors. In addition to individual factors (such as feedback on current behaviour), we plan to address social factors, by providing peer mentors to act as a social support for change, and environmental factors by matching the programme to local environmental opportunities. The Behaviour Change Wheel[65] will be used to map promising BCTs (those that are effective and feasible to deliver within the proposed context) on components of behaviour which reflect these multiple levels: motivation (reflective and automatic), opportunities (physical and social environment) and capability (physical and psychological). The main output at this stage will be a shortlist of proposed BCTs to be included in the design of a pilot RCT.

Phase 2: Feasibility and acceptability of proposed BCTs
We will then explore the perceived feasibility and preferences for particular BCTs through face to face semi-structured interviews with a purposive sample of 15 older adults from our target communities. This sample will include both genders, a range of ages (from 60 to 70 years) and individuals living in different residential locations and with varying levels of physical activity.

As in a previous study in socio-economically deprived adults,[66] participants will be presented with a range of hypothetical strategies to promote physical activity. These strategies will be presented and explained to participants in interviews, in order to explore their opinion and how these strategies could best be incorporated into the intervention package. Participants will be asked to indicate the most and least appealing of strategies. For each strategy, they will be asked what they like and do not like about it, whether they think it would result in them being more active and sustaining that activity, what they perceive as potential problems or barriers to its uptake, and where appropriate, how and when the strategy would best be delivered.

In addition to exploring the acceptability of specific evidence based BCTs, the interviews will investigate older people's experiences of walking, identifying barriers and facilitators which will inform the intervention design.[67] These interviews will allow exploration of views on how the specific behaviour of walking may be promoted in their peer group. Attitudes, beliefs and social perspectives on BCTs may influence engagement with the intervention and these will be explored prior to its design. Taking account of the interview findings will enable the intervention design to avoid or overcome potential barriers, and to incorporate elements which are perceived to facilitate walking.

The interviews will be conducted on a one-to-one basis, semi-structured and contain between 5-8 questions. This semi-structured construct will allow participants to focus on specific topics but to express themselves freely in their comments. The number of interviews required, proposed as 15, will be defined when data saturation is reached (no new themes or issues arising). Analysis will be based on a theoretical framework and will use constant comparative methods, so that issues arising in early interviews may be explored in more detail in later interviews.

Phase 3: Pilot RCT
We will conduct a pilot RCT with 60 inactive, community dwelling older adults aged 60-70 years, residing in socio-economically disadvantaged communities. The aim of the pilot RCT is to test the feasibility of conducting a trial of a peer-led walking programme in promoting sustained increases in objectively measured physical activity in order to enhance health, mental wellbeing, increase social engagement and improve quality of life in community dwelling older adults.

<u>Participants</u>
Community dwelling older adults living in areas of disadvantage aged 60-70 years, will be targeted by this study. Most previous interventions have targeted older adults aged 65 years and older. However health problems in older adults from socio-economically disadvantaged areas are likely to emerge earlier and they are likely to experience age related declines in physical activity at a younger age than their peers from other socio-economic groups.[68] It is therefore necessary to intervene at a younger age in this group.

Previous research has recognised the value of physical activity interventions at points of transition such as changes in social (loss of companions), economic (retirement) or health circumstances in older adults.[69] Li et al[70] acknowledged that this 'transition' is not necessarily an abrupt change, but may involve a gradual change over time. Whilst retirement from paid employment may lead to change in employment and income, these transitions may not be applicable to many people in disadvantaged communities. Thus, in addressing the identified research priorities of inequalities in health and physical activity participation in socioeconomically disadvantaged communities, we will include all 60-70 year olds in such communities in our target population, rather than focusing on retirement.

In their seventh decade, adults from socio-economically disadvantaged areas often transition from good health to poor health, from being fit to being unfit, from independence to dependence and may transition from employment to retirement.[69] This age range (60-70 years) therefore can be seen as a transition period, as older adults from socio-economically disadvantaged areas transition from good health to poor health.

For this study, socio-economically disadvantaged communities are defined as those falling within the lowest quartile of super output areas, based on the Northern Ireland (NI) Multiple Deprivation Measure (http://www.nisra.gov.uk). For ease of administration, the feasibility study will be conducted in the South-Eastern Health & Social Care Trust, which covers a large geographical area and a mix of urban and rural settings. The feasibility study will be designed to maximise the potential for roll-out in this setting, by engaging the voluntary and community sector in designing and delivering the intervention. In doing so, the intervention would fill an identified gap in preventive service provision for older adults who may need support to increase their physical activity levels in order to maintain physical function and independence in daily living.

Recruitment

Previous research has identified difficulties in recruiting participants from socio-economically disadvantaged communities,[71] and that a wide range of active and passive strategies are required to successfully recruit participants. To identify eligible participants, we will initially use a mix of active and passive recruitment strategies. Active strategies will include identification and referral of potential participants through the project partners. Passive recruitment methods will include sending study information, along with a letter from their General Practitioner (GP), to suitable patients from 15 GP practices in target communities; distribution of leaflets and posters through GP surgeries, community centres, libraries, health centres, faith based groups and churches; and the email lists and social media outlets of project partners. Those eventually recruited will be asked how they learned of the study. Individuals who wish to participate will be asked to contact the study team by telephone, in writing, by email or via a study website.

Eligibility Criteria

Inclusion criteria:

- Living in a socio-economically disadvantaged community in the South Eastern Trust (defined as the lowest quartile of super output areas according to the NI Multiple Deprivation Measure)
- Competent to give informed consent
- Not currently physically active (assessed using the General Practice Physical Activity Questionnaire[74])
- Community dwelling (i.e. living in their own home)
- Planning to stay in the current residence during the next year

- Able to communicate in English
- No self-reported recent history of myocardial infarction or stroke or physical limitations that would limit ability to participate in a walking programme (assessed using the Physical Activity Readiness Questionnaire[75])

Randomisation

All participants who consent to participate will be contacted by a local community organisation and, following the completion of baseline outcome measures, will be randomised to an intervention or control group using computer generated random numbers, by an independent statistician.

All participants will be posted a brief health promotion booklet on physical activity. This leaflet is made available to interested individuals in primary care and contains brief information on the benefits of regular physical activity and motivational messages to help identify and overcome common barriers to increasing physical activity.

Control group

Those assigned to the control group will not receive any additional support to change their activity over the course of the intervention period. At the outset of the trial, they will receive the same booklet as the intervention group, and will be informed that after the six month data collection point, they will be offered a choice of opportunities to engage in physical activity. These opportunities will include an offer of a pedometer and instructions on how to begin a self-directed walking programme (similar to what is offered by the Public Health Agency (PHA) www.choosetolivebetter.com/content/getting-active). They will also be offered referral to the local exercise referral scheme and local walking groups in their area, both of which the Health and Social Care Trust are responsible for delivering. They will be asked to complete outcome measures at baseline and all follow-up timepoints. A sample of participants in the control group will be invited to attend one of four participant post-study focus groups to explore their views on engaging older adults in physical activity research, and on the feasibility and acceptability of the intervention to other adults aged 60 years and over.

Intervention group

The intervention will be delivered by the PHA, utilising existing partnerships with the community sector. Members of the intervention group will be invited to participate in a 12-week, peer-led walking programme.

During this period the participant will have regular contact with the peer mentor, and be encouraged to increase their time spent in moderate intensity physical activity. This period will begin on the occasion of the first face-to-face meeting between the peer mentor and participant. After 12-weeks, the formal peer-led component will finish, and participants in the intervention group will be signposted to other activity programmes in the community to encourage maintenance of their activity level.

The precise contents of the 12-week programme (e.g. BCTs, how they are delivered, determinants of physical activity targeted) will be defined during the development phase, however, typically this type of programme involves a phased approach, with an initial period of trust building, identifying current levels of physical activity and facilitators and barriers to increasing activity, and identifying strategies to overcome these barriers and increase activity (e.g. discussing opportunities in the local environment, social support). This is followed by individually-tailored goal setting, where weekly targets are discussed,

agreed and reviewed.[76-77] This will be done using pedometers to set individually tailored goals and self-monitor progress using weekly step diaries, as in previous peer-led physical activity interventions.[54-56]

Peer mentors will be encouraged to make weekly contact with participants, either in person or by telephone, with a minimum of fortnightly face-to-face contacts. Mode, duration and reason of contact will be recorded by the peer mentors in a diary. To encourage behavioural rehearsal, during the face-to-face meeting, the mentor and participant will undertake a 15-30 minute walk in the participant's own local neighbourhood, to contextualise the new physical activity behaviour. This will familiarise the participant with local opportunities for activity in the neighbourhood environment, demonstrating where these are, how to access them and what to use them for. The nature and destination of these walks will be tailored to the individual's stated preferences for types of activities (for example, walking in a park, to the shops or to the house of a friend or family member) and opportunities available in their local neighbourhood environment. For example, a peer mentor may take a participant for a walk to their local park. They would demonstrate the best route to take, what facilities are available, and encourage the participant to consider using this environment for more regular activities. This will be supplemented with information such as maps of local walking amenities and tips for safe walking. Previous research has shown that features that promote walking include feelings of familiarity of the local neighbourhood, safety from crime, good access to shops and services, well-maintained walking facilities, aesthetically appealing places, streets with little traffic and places for social interaction.[78]

Peer Mentors

The intervention will be delivered by trained peer mentors. Six peer mentors will be recruited de novo from among participants of previous initiatives run by partner organisations. The inclusion criteria for the peer mentors are that they are aged 60-70 years and will reside within the target communities. They will be paired with participants of the same sex and from a similar community. During the pilot RCT, peer mentors will be given access to a research team member for advice/support and will be contacted by the project manager at least once per fortnight, to identify any problems with the programme delivery or participant contact and engagement.

Outcome Measures

The outcomes to be assessed have been chosen in order to inform the development of a future definitive study. We plan to assess the feasibility and acceptability of employing these measures.

The primary outcome measure will be minutes of moderate and vigorous physical activity (MVPA) objectively measured using an Actigraph GT3X accelerometer (physical activity monitor) over seven days. Participants will be asked to wear the activity monitor on an elasticated belt, during waking hours, for seven consecutive days.

To explore the context of changes in physical activity, a validated self-reported physical activity questionnaire (EPAQ-2)[80] will also be completed. Other health related outcomes will include mental health and wellbeing using the General Health Questionnaire (GHQ-28)[81-82] and the Warwick-Edinburgh Mental Well-being Score[83-84] respectively. Health-related quality of life will be assessed using EuroQol-5D.[85] Social engagement will be measured with the UCLA Loneliness Scale[86] and the Lubben Social Network Scale.[87]

Though the pilot is not designed to estimate cost effectiveness, we will pilot the use of participant health and social care services resource use instruments (health service use logs and questionnaire), which will inform the design of a future economic evaluation, developed using items from the Annotated Cost Questionnaire.[89]

Assessment and follow up

Outcome measures will be assessed at baseline, post-intervention (12 weeks) and 6 months after baseline, in person, by the project manager, who will be blind to group allocation. Mean daily minutes of MVPA will be recorded using an Actigraph GT3X accelerometer, issued and collected in person by the project manager. MVPA will be calculated using a previously validated level of >2000 counts per minute.[90] To be included in the analysis, standard cleaning rules will be applied (at least five valid days defined as 600 minutes of wear time per calendar day).[91]

Fidelity

To assess fidelity of the intervention, for each peer mentor, one randomly selected first meeting and another randomly selected follow-up meeting will be audio-recorded and assessed by the research team for content and delivery fidelity using a quality assurance form. Feedback on fidelity will be given to each peer mentor during the intervention to assist them in delivering the intervention. Completeness in the dose of delivery of the intervention will be assessed using previous methods,[92] including asking the peer mentors and a sample of 10 pilot trial participants to record a diary of contacts (both face-to-face and telephone). This diary would include information on the number of attempts to make contact and the duration of each successful contact.

Assessment of Acceptability of the Intervention

The acceptability of the intervention will be assessed using two approaches. Firstly, all participants will be asked to complete a post-study exit questionnaire, as used in a previous physical activity intervention.[93] This questionnaire asks the participants to rate their experience of the intervention and provide reasons for the decision. If the majority of responses are positive, we would assume that the study is acceptable, otherwise we would not proceed. Sample questions include: overall were you satisfied with your involvement in this study? (if not, why not?); were you satisfied with the advice / information you received about this study (including the participant information sheet)?; how helpful do you think the peer mentor was in encouraging you to undertake more physical activity? (if not helpful, why not?); how helpful do you think using the pedometer to monitor your activity was in encouraging you to undertake more physical activity? (if not helpful, why not?); how helpful do you think going for a walk with your peer mentor was in encouraging you to undertake more physical activity? (if not helpful, why not?); how easy / difficult was it for you to stick to your physical activity programme? (why?); would you recommend this programme to a friend or family member? (why/why not?); would you be happy to be involved in this type of programme again (if not, why not?); If we were to run this programme again, which features did you like and would want us to keep the same?; if we were to run this programme again, what changes do you think could be made that would improve it?

We will further explore acceptability in the post-study interviews with participants and peer- mentors, to allow us to capture greater depth of detail in the explanations of their responses than may have been captured on the questionnaire. All participants in the intervention group, and a sample of participants in the control group, will be invited to attend one of 4 focus groups, to explore reasons for success and failure to change activity

and their views on the feasibility and acceptability of the intervention. These focus groups will further inform the development and design on a fully powered trial, allowing an in-depth examination of barriers to and compliance with the implementation of the protocol. The qualitative data thus obtained will help to explain quantitative data regarding recruitment and retention, collected during the process of the intervention, and responses written in the exit satisfaction questionnaire (described above). Both participants and peer-mentors will be invited to discuss and provide feedback on their experiences of the intervention. Primary questions will relate to the different BCTs employed, reviewing each in turn, considering what worked to increase engagement in walking for some individuals and what did not work for others. Focus group participants will be asked what they would change about the intervention if they were to take part in it again. This information will provide high quality feedback and allow appropriate refinement of the intervention's components and delivery for future study. Peer mentors will be asked to recall any expenses they incurred in delivering the intervention or additional health service resource use. This will contribute towards the assessment of the feasibility of an economic evaluation as part of a future trial.

Expecting approx. 50% uptake of invitation, we aim to include at least 20 participants (5 per group) after the 6 month follow up. Their views of the programme length, design of materials, difficulties encountered and how they used facilitators and overcame barriers to increasing their activity and influence of seasonality on programme compliance will be explored. Two separate focus groups will be conducted with the peer mentors and representatives of community organisations to gather their views on what would be required to increase the intervention's acceptability to the community, enhance its effects and simplify implementation. Transcripts from audio recordings will be analysed thematically. Focus groups have been used previously to evaluate and provide feedback on the effectiveness of community led walking interventions.[94-95]

Assessment of harms

We do not anticipate any serious adverse events from a walking intervention. Adverse events reported by participants will be recorded on a standard proforma used in a previous walking intervention.[96] All adverse event reports will be reviewed by one of the co-investigators (who are trained physicians) who will confirm the coding assigned.

Sample size

As this is a feasibility study, no formal sample size calculation has been carried out (as the information required is not available), but we anticipate that recruitment of 60 participants will provide sufficient information to estimate a predicted effect size and its variability, which will inform a sample size calculation for a potential future definitive, fully powered trial.

Statistical analysis

As this is a feasibility study, significance tests will not be performed. Intervention effects will be represented by point estimates, and 95% confidence intervals will be estimated at each follow-up time point. Recruitment, retention and adherence rates will be reported and any adverse events recorded and, alongside effect size, will be used to estimate a sample size required for a definitive trial.

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