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Protocol

The Effectiveness and Cost-Effectiveness of the 'Walk with Me' Peer-Led Walking Intervention to Increase Physical Activity in Inactive Older Adults: Study Protocol for a Randomised Controlled Trial

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Abstract: Background: The proportion of the population aged 65 years or older is increasing. Typically, physical activity and health decline with age, which is why action to promote active ageing is a major public health priority, particularly due to health inequalities in older adults. The aim of this study is to assess the effectiveness and cost-effectiveness of the Walk with Me peer-led walking intervention for older adults. Methods: This study is a two-arm, assessor-blind, randomised controlled trial. The intervention is a 12-week peer-led walking intervention based on social cognitive theory. Participants in the control group will receive information on active ageing and healthy nutrition. The study will target 348 community-dwelling older adults, aged 60 years or over living in areas of socio-economic disadvantage communities. Trained peer mentors will deliver the intervention. The primary outcome will be a mean between-group change in moderate-to-vigorous physical activity at 12 months from baseline, measured using an Actigraph accelerometer. Secondary outcomes will include quality of life, mental wellbeing, blood pressure, BMI and waist circumference. An embedded process evaluation will involve focus groups and participant diaries. Discussion: Evidence-based, cost-effective interventions to promote physical activity in older adults living in socio-economically disadvantaged communities are needed to address health inequalities.

Keywords: older adults; peers; physical activity; randomised controlled trial

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1. Introduction

Globally, the population of people aged 65 years and over is set to double by 2050 [1]. It is, therefore, a public health priority to promote healthy ageing [2], by helping older people maintain their physical function, independence and quality of life. Regular physical activity makes a vital contribution to preventing or delaying age-related declines in function, health

and all-cause mortality in older adults [3], which may lead to lower utilisation and cost of healthcare [4].

However, approximately one-third of older adults in the United Kingdom do not meet the recommended levels of physical activity [5]. Declining levels of physical activity with age are often coupled with changing social circumstances, and low levels of activity are associated with increased social isolation and loneliness in older adults [6]. In addition, older adults from socio-economically disadvantaged backgrounds engage in less activity [7]. There is a need for research on the effectiveness of physical activity interventions targeting socio-economically disadvantaged older adults [8].

A recent umbrella review indicated that effective interventions in this population included tailored information on activity levels and opportunities, encouragement of walking and using a pedometer to self-monitor [8]. However, there are few physical activity interventions that both incorporate these components in older adults and demonstrate longer-term maintenance [9]. Individual psychological factors, such as positive affect and self-efficacy [10] and social factors, such as social support [11] are associated with the long-term maintenance of physical activity [12]. Peer-led interventions offer a model that may enhance social support and promote physical activity. Peer mentors are trained, nonprofessional individuals, who share similar demographic characteristics to the target population. They can uniquely contribute to intervention delivery through their ability to share, relate and empathise with participants, offering more social support in a way that non-peers are unable to [13]. In a systematic review of peer-supported interventions, retention rates were consistently above 75% for most studies, with some studies reporting retention rates of 90% and above [13].

The Walk with Me intervention was developed in response to a recognised need for an intervention tailored to inactive older adults living in socio-economically disadvantaged communities and has been shown to be acceptable and feasible to deliver [14].

The aim of this study is to assess the effectiveness and cost-effectiveness of a peer-led walking programme to increase moderate-to-vigorous physical activity in adults aged 60 years and over living in socio-economically disadvantaged communities.

2. Materials and Methods

2.1. Study Design

The study (Protocol version 1 August 2022) is a two-arm parallel-group randomised trial involving older adults aged 60 years or over living in socio-economically disadvantaged communities. It has been prospectively registered on the International Traditional Medicine Clinical Trial Registry (ISRCTN73367347). A SPIRIT 2013 checklist is included as Supplementary File S1 to describe the minimum reporting recommended protocol items for a clinical trial. Further details of the trial oversight, data management and dissemination plans are available from the funder's website (https://fundingawards.nihr.ac.uk/award/NIHR131550, accessed on 22 February 2024).

While 65 years and older is often used to define older adults, in the UK physical activity recommendations target individuals aged 60 years and over, which is historically the first retirement age.

Individuals will be randomised to either a 12-week peer-led walking intervention group or a minimal intervention control group. An internal pilot is included with pre-specified stop-go criteria using a 'traffic light' system recommended by Avery et al. [15] and assessed by an independent trial steering committee. Progression will be based on the percentage of the target sample achieved after six months. These criteria are: (a) proceed: $\geq$50% of the total sample of peer mentors and participants recruited; (b) modify: 25–49% of the total sample of peer mentors and participants recruited; or (c) stop: <25% of the total sample of peer mentors and participants recruited. After six months, any required changes in the recruitment strategy and/or introduction of new recruitment pathways will be agreed with the trial steering committee. The flow of participants through the study is described in Figure 1.

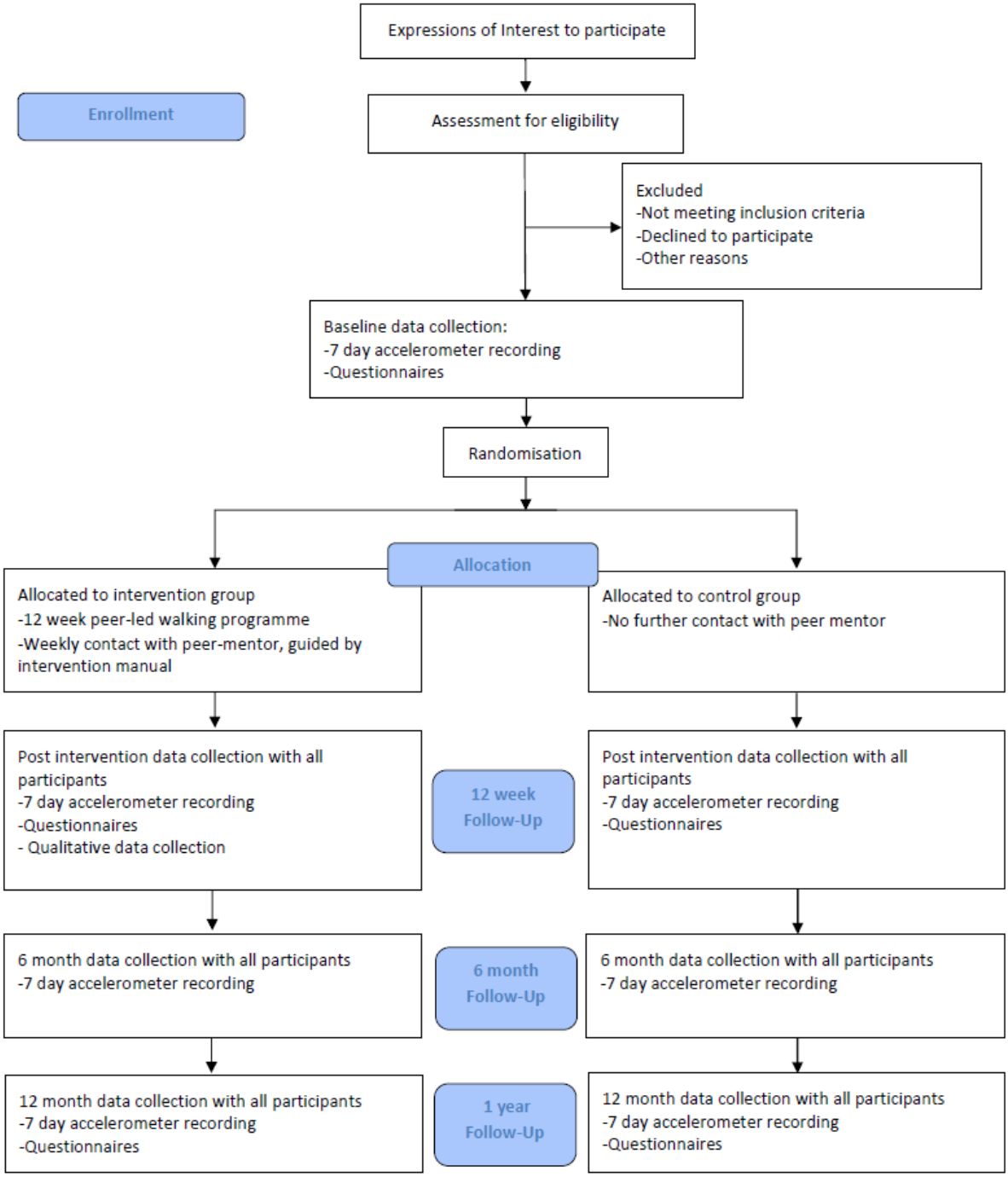

Figure 1. Flow of Participants in the Walk With Me Study.

2.2. Study Setting and Recruitment

The study will target community-dwelling older adults, aged 60 years or over living in areas of socio-economic disadvantage, defined as the most disadvantaged quartile of electoral wards in Northern Ireland, based on the NI Multiple Deprivation Measure (NIMDM) [16].

A mixture of strategies will be used to recruit participants. Up to 12 general practices based in target areas of deprivation will send a postal invite to identify potentially eligible participants. The postal invites will be sent directly from the general practices by authorised practice staff, to comply with GDPR. Interested individuals will be invited to contact the study team if they wish to participate, using a reply slip and a stamped addressed envelope,

or by telephone or email. In recognition of their role, practices will receive £50 per patient recruited to the study. No incentives are offered to participants.

We will also disseminate information about the study through community organisations and centres, libraries, faith-based groups and churches and the email lists and social media outlets of project partners. In addition, to boost the recruitment of men, we will also specifically target existing men's groups, such as sporting organisations. Individuals who wish to participate will be asked to contact the study team by telephone, in writing by returning a reply slip, or by email. Interested individuals will be screened for eligibility over the telephone by a trained researcher. Reasons for exclusion and the route of recruitment will be recorded.

2.3. Eligibility Criteria

Participants will be eligible if they meet the following inclusion criteria:

- Males or females aged 60 years or over.
- Currently physically inactive, according to the most recent physical activity recommendations [17], assessed using the General Practice Physical Activity Questionnaire [18]. Individuals classified as inactive, moderately inactive or moderately active will be eligible for inclusion.
- Living in a socio-economically disadvantaged community, defined as the most disadvantaged quartile of electoral wards in Northern Ireland according to the NIMDM.
- Able to communicate in English and live independently in the community (i.e., at home), including those residing in independent living facilities. We will also only include individuals planning to stay in their current accommodation during the next year, to try and ensure they will be available for follow-up assessment.
- Individuals not in employment at the outset will be included provided they are not planning on returning to work over the following 12 months. This is to mitigate against the potential interaction between returning to work and changes in physical activity.
- Competent to give informed consent, assessed as a score of 24 and higher on the Mini-Mental State Exam [19]
- Non-frail, assessed as a score of <3 using the PRISMA-7 questionnaire [20]
- Individuals who report no recent medical history in the last six months that would limit the ability to participate in a walking programme are assessed using the Physical Activity Readiness Questionnaire [21]

Individuals who do not meet the inclusion criteria, decline to participate, or who are living with a learning disability will be excluded.

2.4. Allocation and Randomisation

Individuals deemed eligible to participate will be posted/given a study pack containing an information sheet and consent form. Individuals who agree to participate will be asked to provide written informed consent following a minimum 24-h cooling off period to allow them to consider participating. With the participant's permission, a letter will be sent to their General Practitioner to inform them of their participation.

An independent statistician will generate the randomisation sequence using a computer program and randomly permuted block randomisation with mixed block sizes. After written consent to participate is received and baseline outcome measures have been collected, participants will be randomised to the intervention or the control group. On entry to the study, a participant's group allocation will be provided to a member of the study team via telephone.

2.5. Walk with Me Intervention

The Walk with Me intervention is based on social cognitive theory (SCT) [22], utilising the Behaviour Change Wheel as an overarching framework [23]. Behaviour change techniques (BCTs) [24] identified from previous evidence were mapped onto the core set of

intervention functions of SCT. The socioecological model was used to provide a framework for a multilevel intervention design [25].

The initial 12-week intervention is comprised of three stages. During the activation stage (weeks 1–4), intervention components support the building of rapport between the mentor and participant, which is necessary for successful peer mentoring. The participant will record their initial daily step counts during the first week of the intervention, using a pedometer (Yamax SW-200, Yamax Corp, Tokyo, Japan) [26]. Following this, the participant, with the support of their mentor, will set an initial step goal based on the average steps per day achieved during the first week. This will be used as the basis for mutually agreeing on a suitable goal in the second and subsequent weeks [27]. The participant will be encouraged to increase their daily steps by a minimum of 500 steps per day and to maintain this daily increase on each day of the subsequent week. The mentor and participant will discuss how many more steps per day would be practical, whilst supporting the self-efficacy of the participant by setting a goal that they are confident that they can achieve. An action plan for each participant will be drawn up, outlining how the participant will incorporate additional physical activity into their weekly schedule.

The second stage (weeks 5–8) of the intervention will focus on behavioural practice. The participant and mentor will meet regularly (once a week) to discuss goals/barriers to increasing physical activity and going for a walk. These meetings will enable the mentor to demonstrate the appropriate walking pace to achieve moderate-intensity physical activity and enable the participant to review progress and set individual physical activity goals, taking into consideration their capabilities. If the participant is having difficulty increasing their physical activity, they will discuss strategies to overcome barriers to increasing physical activity (e.g., by discussing opportunities for physical activity in the local neighbourhood environment). During this period, the mentor and participant will begin to discuss local opportunities to continue physical activity after the programme. This may be in the form of a local community or leisure centre-based walking group, or through other local physical activity opportunities that might help the participant maintain their activity level when the structured component of the intervention comes to an end.

During the final four weeks of the initial intervention, in the 'habit formation' stage (weeks 9–12), the peer mentor will prompt rehearsal and repetition of physical activity by meeting with the participant, discussing and reviewing physical activity goals, reviewing the benefits achieved, discussing their satisfaction with behaviour change and planning participation in local physical activity opportunities to facilitate the maintenance of physical activity behaviours after the intervention. Thereafter, the participant will be encouraged to utilise these local opportunities for physical activity to maintain their activity. To support this transition, participants will be given specific advice on maintenance at the end of the intervention, which includes information about the health benefits of keeping their activity up and they will be encouraged to make individual plans to avail of specific physical activity opportunities in the form of group exercise or a personal physical activity plan [28].

Between months three to six from the outset of the intervention, participants will be encouraged to continue to use the pedometer to monitor their activity levels and return their pedometer diary to their peer mentor [29]. This will be reinforced through a monthly telephone or online video call from their peer mentor between months three and six to encourage maintenance and review their ongoing engagement in activity [30,31]. Health reasons are often cited in older adult physical activity research as a main contributor to attrition [32]. Therefore, any participant experiencing short-term health issues that affect their participation in physical activity will be encouraged to pick up again when they are able to. Where appropriate, participants will also be encouraged to utilise technology to support their physical activity, such as wearable devices or online exercise videos. During the final six months participants will continue with the programme unsupported in what will be termed an 'independent' phase [33].

2.6. Peer Mentors

To deliver the intervention, peer mentors (n = 35) will be recruited, prior to and concurrently with participant recruitment. Peer mentors are nonprofessional individuals who are similar to the target population with the exception of being sufficiently physically active [34]. We will recruit them using similar methods to those used for participant recruitment. Peer mentors will receive two half-day face-to-face training sessions one week apart, delivered by a Public Health Improvement officer based at the Institute of Public Health in Ireland, based in Northern Ireland. This person will be responsible for training the peer mentors and will support them throughout the delivery of the programme. The aim of these training sessions is to develop their skills, knowledge and confidence to promote physical activity among their peers. The training will include evidence and theoretical concepts underpinning the Walk with Me intervention, information on the roles and responsibilities of the peer mentor, including participant confidentiality; knowledge and education about physical activity; behaviour change techniques, including setting goals and monitoring performance and problem-solving and practical approaches to overcome potential barriers to physical activity. During the training sessions, mentors will receive information on the 'Walk with Me' programme, including the main tasks and requirements; information about physical activity guidelines for older adults; education about BCTs and their role in the programme; how to model physical activity behaviours; helping their peer complete and record programme activities and reporting on activities or providing feedback to the project team. This study is not being implemented in a climate that experiences extremes of weather conditions. Peer mentors are trained to utilize strategies to tailor the delivery to the circumstances participants face. This includes the potential to use indoor walking venues (e.g., shopping centres) if the weather is inclement or icy. This is part of the advice given around safety, including choosing appropriate walking destinations and an awareness of the signs and symptoms of an adverse event.

Peer Mentors will also be trained in how to build and sustain an effective relationship with a participant, as well as communication skills such as active listening and providing social and emotional support. In addition to the training, peer mentors will receive an intervention manual to promote intervention fidelity. The manual includes information on the areas of the programme covered in the training sessions and copies of all the materials they need to deliver the intervention.

Peer mentors will be offered ongoing support from the Public Health Improvement Officer via telephone or online video as well as online resources and access to a closed Facebook group to access support from other peer mentors. Additional follow-on support will be delivered to mentors during the programme. The Public Health Improvement Officer will meet with the peer mentors three times (once a month, during the first three months) to ensure that they are still comfortable with the content of the intervention, briefly refresh the original training, including the techniques of goal-setting and monitoring, address any technical problems which may arise, e.g., issues which may have arisen with participants (such as not turning up), and discuss the focus for the next phase of the intervention. They will be offered a certificate following training and will be reimbursed for all expenses such as mileage. They will be paired with participants of the same sex and from a similar community. Each mentor will have "responsibility" for up to five intervention participants. Before starting, peer mentors will be provided with a study information sheet and asked to provide written consent before they are invited to complete the same outcome measures that the participants complete at the outset of the programme and again at 12 weeks, six months and 12 months.

2.7. Control Group

Individuals allocated to the control group will be contacted by a Public Health Improvement Officer based at the Institute for Public Health. They will be thanked for their participation and informed that they will be contacted at 12 weeks, 6 months and 12 months for follow-up assessments. They will be given a copy of standard public health information

booklets on active ageing and healthy eating but will not receive any additional physical activity support over the course of the research study. To encourage retention, they will be contacted again by a Public Health Improvement Officer in nine months to confirm contact details. Participants in the intervention group will be contacted at the same time to encourage retention. After the final data collection point, they will be given the opportunity to discuss with a member of the research team the availability of local physical activity opportunities (e.g., local walking groups) and offered a pedometer and physical activity diary to begin a walking programme.

2.8. Outcome Measures

Outcome measures will be collected by researchers blind to group allocation at baseline (before randomisation), 12 weeks (post-intervention), six months (primary outcome only) and 12 months. Outcome measures will be collected at the participant's home, at a local community centre/venue, or at their general practice if the participant would prefer.

The primary outcome will be daily minutes of moderate-to-vigorous physical activity per day (>1951 counts per minute (CPM)) at 12 months [35], measured using a waist-worn Actigraph wGT3X+ accelerometer (ActiGraph, LLC, Pensacola, FL, USA) and worn for a minimum of five days out of seven [36]. To be included in the analysis, standard cleaning rules will be applied (at least five valid days defined as 600 min of wear time per calendar day) [37]. Non-wear time will be defined as a run of zero counts lasting > 60 min.

Secondary outcomes will include mental well-being measured using the Warwick-Edinburgh Mental Well-being Scale [38,39], quality of life using the EuroQol-5 Dimensions, five-level version (EQ-5D-5L) questionnaire [40], and loneliness and social engagement using the UCLA Loneliness Scale [41] and the Lubben Social Network Scale respectively [42]. Changes in physical health will be recorded using measures of resting blood pressure, height, weight, body mass index, waist circumference and physical functioning measured using the short physical performance battery [43]. Light intensity physical activity (>100 and $\leq$1951 CPM) and sedentary behaviour per day ($\leq$100 CPM) will be calculated from the accelerometer data.

In addition, we will measure potential mediators of our intervention aligned to the theoretical basis of the intervention. These will include physical activity and social activity self-efficacy [44] and physical activity and social activity outcome expectancies [45]. We will also assess physical activity self-regulation [46], which assesses the use of BCTs included in the intervention such as self-monitoring, goal setting and social support. These outcomes will aid the understanding of the mechanisms through which the intervention works as part of the process evaluation.

2.9. Health Economic Evaluation

A cost-consequence analysis will be conducted, where key costs and consequences/outcomes will be presented in a comparable and disaggregated form. We will present the analysis as a summary table which will display the incremental costs and various incremental health and non-health outcomes. These will be presented separately in their natural units without combining them into a single measure such as a cost-effectiveness ratio. The consequences presented will include the primary outcome, physical activity, and secondary outcomes (mental wellbeing, physical activity and social activity self-efficacy, physical activity and social activity outcome expectancy, physical activity self-regulation, loneliness and social engagement and physical functioning).

The cost-effectiveness of the intervention will be assessed via a within-trial cost-effectiveness at 12 months and a long-term model, estimating the cost per quality-adjusted life year (QALY). Interventions with an incremental cost-effectiveness ratio of less than £20,000 per QALY gained are generally considered by NICE to be cost-effective [47]. Current guidelines for conducting [48] and reporting [49] economic evaluations will be followed. The base-case analysis will be from a health service and personal social service perspective and a sensitivity analysis will be from a societal perspective and include non-NHS costs

such as formal and informal care, private health care, out-of-pocket expenses related to the use of leisure services and productivity costs. Our base case will discount costs and health outcomes at the same annual rate of 3.5% followed by a sensitivity analysis of 1.5% which is appropriate for interventions with potentially long-term effects such as public health interventions.

For the within-trial cost-utility analysis, participants' use of health and social care services, use of leisure services and any paid/unpaid working hours will be collected using a concise study-specific questionnaire at baseline, 12 weeks and 12 months. Participants will also be provided with a brief diary to allow them to record their data contemporaneously. Costs associated with delivering the intervention, such as those incurred by the peer mentors, will also be collected. Methods for collecting the economic data were piloted in the pilot study and we have adapted our tools following participant feedback accordingly. Standard unit costs will be used to cost resources. Responses to the EQ-5D-5L at baseline, 12 weeks and 12 months will be converted to utilities using the tariff recommended by NICE at the time of analysis [50]. We will use the area under the curve method to calculate QALYs [51]. To deal with missing data, we will explore the quantity of missing data and report on the missing rates for the different cost components and outcomes, by study group. We will also explore the nature of the missing data.

Since the relatively short time horizon of the trial will not capture the potential long-term health impact of the intervention, trial data will be incorporated into a long-term economic model with a lifetime horizon. We will conduct a literature review prior to designing the model to ensure we have the most up-to-date data on lifetime disease incidence, utilities and costs related to physical activity. The model is most likely to be a Markov state-transition model as these are particularly useful for modelling lifetime costs and health outcomes and have been used previously to assess the long-term cost-effectiveness of other physical activity interventions [52–55].

For both within-trial and long-term analyses, we will perform deterministic sensitivity analysis to explore key assumptions and probabilistic sensitivity analysis (PSA) [56] to account for uncertainty arising from imprecision in the economic data. The PSA will generate bootstrapped replications of the incremental cost effectiveness ratio which will be plotted on the cost-effectiveness plane and used to construct a cost-effectiveness acceptability curve: this will depict the probability of the Walk with Me intervention being cost-effective compared to usual care at different willingness-to-pay per QALY thresholds. We will consider performing subgroup analyses and this will be in keeping with the main statistical analyses.

2.10. Statistical Analysis

The primary analysis will be conducted on an intention-to-treat basis once the primary outcome data collection is complete, with all randomised participants being analysed in the group to which they were allocated, regardless of the subsequent treatment they received at an a priori significance level of $p = 0.05$ and reported in accordance with Consolidated Standards of Reporting Trials guidance [57]. The analysis will be undertaken by a statistician with no role in decision-making about the ongoing conduct of the trial. We will describe the baseline characteristics and follow-up measurements using suitable measures of central tendencies: means and medians with the associated standard deviations/interquartile ranges for continuous data, and frequencies and proportions for categorical data.

We will compare the primary outcome between groups adjusting for baseline within a generalised linear mixed model including mentor as a random effect to account for possible clustering. Similar methods will be used for the other time points and secondary outcomes. Exploratory analyses will be reported using 99% confidence intervals using interaction terms (treatment group by subgroup) for the subgroup of high and low household income to look at the moderating effect of individual-level socio-economic position. The analysis will explore the moderating effect of gender, age, seasonality and physical environment features on the results.

2.11. Sample Size

Based on the findings from our pilot study [14], and recent systematic reviews [58,59], a sample size of 133 in each group will have 90% power to detect an effect size of 0.4 based on a two-group t-test. This is equivalent to an increase of approximately 50 min/week of MVPA in the intervention group compared to the control group. Based on data from another physical activity study in older adults [29], we have assumed an ICC of 0.01 with a cluster size of five participants per mentor, the design effect was estimated as 1.04, resulting in a sample size of 139 per group. Allowing for 20% dropout, a sample size of 174 per group or a total sample size of 348 individuals would be required. Reasons for dropout will be recorded.

2.12. Process Evaluation

A nested theory-driven process evaluation, guided by the MRC Process Evaluation guidelines [60] will be undertaken to explore the impact of intervention implementation, mechanisms of action and context on the study outcomes.

At 12 weeks and six months, we will invite a purposeful sample of 30 intervention group participants to a focus group. A mixture of males and females across different age groups will be invited. We will run between four and six focus groups depending on participants' availability and location. We will also invite their mentors to one of four separate focus groups. The aim of these focus groups will be to (1) understand the experience of participants and mentors; (2) explore if SCT and the logic model describe the experience of participants; (3) explore the barriers and facilitators to longer-term maintenance of activity; (4) explore the intervention BCTs used as part of making the initial changes in physical activity and to maintain activity at six months. Anonymity and confidentiality for reporting will be ensured. Topic guides will facilitate discussions. Audio recordings of focus groups will be transcribed and uploaded into QSR NVivo along with field notes.

2.13. Implementation

To assess implementation fidelity, an audio recording of one randomly selected first meeting and a follow-up meeting for each peer mentor will be made. This will be assessed for content, delivery fidelity and the receipt and enactment of the intervention by participants, by comparing the content to the intervention manual. Audio recordings will be made in a total of 70 participants sampled across different locations and in a mixture of ages and sex. Intervention fidelity will be further assessed by asking all mentors and a sample of 35 participants (one from each peer mentor) to record a diary of the frequency and content of contacts. Intervention fidelity will also be explored in the 12-week focus groups to explore perceptions of the delivery, receipt, and enactment of intervention components (e.g., BCTs such as monitoring progress). This information will be summarised at the end of the intervention. Any adaptations and modifications to the intervention will be recorded using the FRAME methodology to capture adaptations or modifications made by the peer mentors or participants [61].

2.14. Mechanisms of Impact

To assess the mechanism of intervention effects, we will assess changes in the physical activity self-regulation scale, physical activity and social activity self-efficacy and outcome expectancies using statistical mediation analysis. Furthermore, the use of BCTs by participants will be assessed in focus groups, and the delivery of BCTs by peer mentors will be assessed using a coding framework from included BCTs in audio recordings described above.

2.15. Contextual Factors

Contextual factors that may influence implementation and variation in outcomes, such as participant characteristics and physical environment features that may impact

walking will be explored in the post-intervention focus groups with participants and mentors. Based on previous research [62], questions regarding the physical environment will include the impact of feelings of safety while walking; access to recreational facilities, parks/public open spaces and shops; greenery and aesthetically pleasing scenery; walk-friendly infrastructure and access to public transport. To prompt discussion, we will present each focus group participant with a screenshot from the WalkScore (https://www.walkscore.com, accessed on 22 February 2024) output for their local neighbourhood. In addition, we will assess the moderating effect of the physical environment on the results, using WalkScore as a proxy for neighbourhood walkability, and by sourcing area-level data on crime and the living environment using relevant indicators from the Northern Ireland Multiple Deprivation Measure [16].

2.16. Assessment of Harms

Walking is a low-risk intervention, and we do not anticipate any serious adverse events [63]. Participants will be encouraged to report adverse events (e.g., musculoskeletal problems or falls) to the study team. Adverse events reported by participants will be recorded on a standard proforma.

3. Discussion

This study aims to assess the effectiveness and cost-effectiveness of a peer-led walking programme. Evidence-based, cost-effective interventions to promote physical activity in older adults living in socio-economically disadvantaged communities are needed to address health inequalities. Peer-led interventions have the potential to provide a timely response to this urgent problem.

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/jal4010003/s1, File S1: SPIRIT 2013 Checklist: Walk with Me Study.

Author Contributions: M.A.T., F.K., M.E.C., W.H., E.E.A.S., M.H.M., R.O., C.B., A.A., C.M., B.L., S.C. and S.M.M. have made a substantial contribution to the conception and design of the study. They are named co-investigators on the funding for the project. C.C. (Conor Cunningham), M.O., R.D.N., M.A. and C.C. (Chris Callaghan). subsequently have made substantial further refinements to the intervention, outcome assessment and process evaluation methodology and are responsible for data collection. M.A.T., C.C. (Conor Cunningham), M.A. and M.O. wrote the first draft of this manuscript. F.K., M.E.C., W.H., E.E.A.S., M.H.M., R.O., C.C. (Chris Callaghan), R.D.N., C.B., A.A., C.M., B.L., S.C. and S.M.M. have critically reviewed the manuscript's content. As co-investigators, all authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of the work are appropriately investigated and resolved, as per the funding agreement. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement: The study will be conducted in accordance with the Declaration of Helsinki, and approved by the North of Scotland NHS Research Ethics Committee (Ref: 22/NS/0056) on 25 May 2022. The study is sponsored by Ulster University.

Informed Consent Statement: Written informed consent will be obtained from all participants involved in the study.

Data Availability Statement: No new data were created or analysed in this study protocol. Data sharing is not applicable to this article.

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Conflicts of Interest: The authors declare no conflicts of interest.

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