RESEARCH PROTOCOL

Effectiveness and cost-effectiveness of a peer-led walking programme to increase physical activity in inactive older adults: "Walk with Me Study"

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Summary

Background

The proportion of the population aged 65 years or older is increasing. Typically, physical activity and health declines with age, which is why action to promote active healthy ageing is a major public health priority, particularly in socio-economically disadvantaged older adults. This trial builds on our Walk with Me pilot study. The aims of the project are to: (1) conduct a full-scale randomised controlled trial of the Walk with Me peer-led walking intervention to estimate changes in physical activity at 12 months for older adults living in socio-economically disadvantaged communities; (2) assess differences between groups in secondary outcomes; (3) assess the cost-effectiveness of the Walk with Me intervention compared to a minimal intervention control group; and (4) understand older adults' and peer mentors' experiences of the intervention.

Methods

Two-arm, assessor blind, randomised controlled trial recruiting 348 older adults using a GP invitation letter (85%) or from community groups (15%). The Walk with Me intervention is a 12-week peer-led walking intervention based on social cognitive theory comprising three stages. Stage 1 (weeks 1–4) involves the participant setting initial pedometer step goals. Stage 2 (weeks 5–8) involves setting short- and long-term physical activity goals. Finally, stage 3 (weeks 9–12) emphasises behaviour rehearsal and practice and signposting participants to other activity programmes in their community. Participants in the control group will receive information on active ageing and healthy nutrition. 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. Trained peer mentors (n=35) will deliver the intervention. These are nonprofessional individuals who are similar to the target population, but sufficiently physically active. The primary outcome is the mean between-group change in accelerometer measured moderate-to-vigorous physical activity at 12 months from baseline, powered to detect 50 mins/week difference in moderate-to-vigorous physical activity. Secondary outcomes include SF-12; EQ-5D-5L; Warwick-Edinburgh Mental Well-Being Scale; blood pressure, body mass index and waist circumference; adverse events. In addition, focus groups with 30 intervention participants and their mentors at 12-weeks (post-intervention) and 6 months about their experiences. The primary economic outcome will be incremental cost per quality adjusted life year (QALY). We will assess the potential benefits and return on investment via cost-consequence analysis, within-trial cost-utility analysis and a long term model. Using intention-to-treat approach, we will compare the primary outcome between groups within a generalized linear mixed model including mentor as a random effect.

Background

The proportion of the population aged 65 years or older is increasing in the UK, with the largest projected increases in Northern Ireland (NI) and globally the population of older adults is set to double by 2050.[1] Maintaining physical function, independence and quality of life (QoL) among older adults are public health and economic imperatives, all of which are influenced through physical activity and sedentary behaviour.[2,3] Our recent review showed that regular physical activity is associated with reduced risks of a range of health conditions and all-cause mortality in older adults,[4,5] which may lead to lower utilisation and cost of healthcare.[6]

Approximately 30% of older adults do not meet recommended levels of physical activity.[7] In the UK, physical inactivity is estimated to cost the NHS £1.06 billion per year due to associated healthcare costs.[8] 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.[9] In addition, we have demonstrated that declines in physical activity during the COVID-19 lockdown have been associated with poorer mental health and wellbeing,[10] emphasising the importance of offering support to individuals. Older adults from socio-economically disadvantaged backgrounds engage in less activity.[11] There is a need for research on the effectiveness of physical activity interventions targeting socio-economically disadvantaged older adults.[12] A recent 'review of reviews' 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.[12]

Future research into physical activity interventions should be designed with maintenance in mind.[13] Individual psychological factors, such as positive affect and self-efficacy[14] and social factors, such as social support[15] are associated with long term maintenance of physical activity.[16] There is a need for studies to assess the effect of enhancing social support on physical activity in older adults.[13] Peer-led interventions offer a model that would enhance social support and promote physical activity. Peer mentors are trained, nonprofessional individuals, who share similar demographic characteristics to the target population and have an enhanced capacity to share, relate and empathise, and therefore have the potential to offer support in a way that non-peers are unable to.[17] In a systematic review of peer supported interventions, adverse events were rare and retention rates were consistently above 75% for most studies, with some studies reporting retention rates of 90% and above.[17]

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. In a pilot study,[18] participants in the intervention group reported very high rates

of satisfaction with the intervention and the helpfulness of their peer mentor. They noted that the intervention was useful in establishing a physically active lifestyle habit. The a priori progression criteria for a fully powered RCT were met.

Research Questions

Primary research question: What is the effectiveness and cost-effectiveness, compared with a minimal intervention control condition, 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?

Primary objectives

1. To conduct a full-scale randomised controlled trial of the Walk with Me intervention with data collection at baseline, 12-weeks, 6 months and 12 months follow-up.
2. To conduct a full economic evaluation to estimate the cost-effectiveness of the Walk with Me intervention compared to a minimal intervention control group.

Secondary objectives

1. To compare changes in time spent in sedentary behaviour, light intensity physical activity, steps taken per day between the intervention and control groups
2. To compare changes in cardiovascular risk factors (blood pressure, waist circumference, weight, BMI) between the intervention and control groups
3. To compare changes in mental wellbeing between the intervention and control groups
4. To compare changes in loneliness and social engagement between the intervention and control groups
5. To conduct a process evaluation involving a mixed methods approach, following the MRC process evaluation guidance, to assess contextual influences, implementation and mechanisms of effect.
6. To evaluate the impact of volunteering in the intervention on the physical activity and health of the peer mentors.

Secondary research question: Compared with the control group, do participants allocated to the Walk with Me intervention significantly increase their levels of light intensity physical activity, health-related QoL, mental well-being, cardiovascular risk factors and physical function at 12 months?

Research Methods

Study Design

This Walk with Me study is a two-arm parallel-group randomised trial involving 348 older adults aged 60 years or over living in socio-economically disadvantaged communities. Individuals will be randomised to either a 12-week peer-led walking intervention group or a minimal intervention control group. Baseline measures will be collected before randomisation, at 12 weeks (post-intervention), six months (accelerometer only) and 12 months. An internal pilot will be included with pre-specified stop-go criteria. The independent Trial Steering Committee (TSC) will assess the feasibility of progressing past the first 6-month internal pilot period based on the recruitment rates of peer mentors and participants. Using a 'traffic light' system previously recommended,[19] progression will be based on the percentage of the target sample achieved half way through the recruitment period (6-months): (a) proceed: ≥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 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 TSC and the funder. The participants recruited in the pilot study will be included in the overall analysis. Qualitative data will also be collected at 12 weeks and six months. Process and economic evaluations will be nested within the trial.

Setting and Participants

The study will target community-dwelling older adults, aged 60 years or over living in areas of socio-economic disadvantage, defined as most disadvantaged quartile of electoral wards in NI, based on the NI Multiple Deprivation Measure (NIMDM) (www.nisra.gov.uk), which covers a large geographical area.

Recruitment

A mixture of recruitment strategies will be used. To identify potentially eligible participants for postal receipt of study information and an invitation to participate from their general practice, 12 practices will be invited to collaborate. The recruitment of these practices, based in target communities, will be conducted by the NI Clinical Research Network (Primary Care). Staff in collaborating practices will be asked to identify potential participants. This could be achieved by practice staff through a computerised search of patient records for individuals aged 60 years or over, or the identification of known individuals who would be eligible to participate. The practice will send a letter (Appendix 1) to potential participants on practice headed paper and an invitation to contact the study team if they wish to participate, using an enclosed reply slip (Appendix 2) and a stamped addressed envelope. As in the pilot study,[18] practices will

receive a payment of £50 per recruited participant in recognition of the additional work for practice staff that recruitment involves.

We will also disseminate information (Appendix 3) 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 men's sheds, Men's Health Forums, Farmer's Unions, and sporting organisations such as the Irish Football Association, Ulster Rugby and the Ulster Gaelic Athletic Association). Individuals who wish to participate will be asked to contact the study team by telephone, in writing by returning an opt-in card, or by email.

Screening

Following initial contact with the study team, interested individuals will be screened for eligibility over the telephone by a trained researcher, following the Participant Eligibility Form (Appendix 4). Reasons for exclusion and the route of recruitment will be recorded.

Eligibility Criteria

The inclusion criteria are:

- Living in socio-economically disadvantaged community, defined as most disadvantaged quartile of electoral wards in NI according to the NIMDM.
- Able to communicate in English and living independently in the community (i.e. at home). This will include those residing in independent living facilities that meet the threshold for participation, but not those in institutions such as care homes. 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.
- For individuals not in employment at the outset, they will be included as long as 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 the outcome measures, which was observed in the pilot study.
- Males or females aged 60 years or over.
- To screen participants' competency to give informed consent, we will use the Mini-Mental State Exam.[20] This is an assessment of cognitive function, including attention and orientation, memory, registration, recall, calculation, language and ability to draw a complex polygon. Lower scores indicate more severe cognitive problems, and we will only include participants who score 24 or higher, as this indicates 'normal' cognitive function.[20] We will also screen for frailty using the PRISMA-7 questionnaire.[21] Individuals scoring three or more will be excluded.

- Only those who are not currently physically active, according to the current physical activity recommendations,[3] will be included. This will be assessed using the General Practice Physical Activity Questionnaire,[23] which is designed to screen inactive individuals and takes approximately 30 seconds to complete. Individuals classified as inactive, moderately inactive or moderately active will be eligible for inclusion.
- Individuals who report no recent medical history in the last six months that would limit ability to participate in a walking programme will be included. This will be assessed using the Physical Activity Readiness Questionnaire,[24] which is commonly used in physical activity programmes to limit the potential of adverse events occurring. Typically, individuals who would not be eligible due to their recent medical history require a tailored rehabilitation programme.

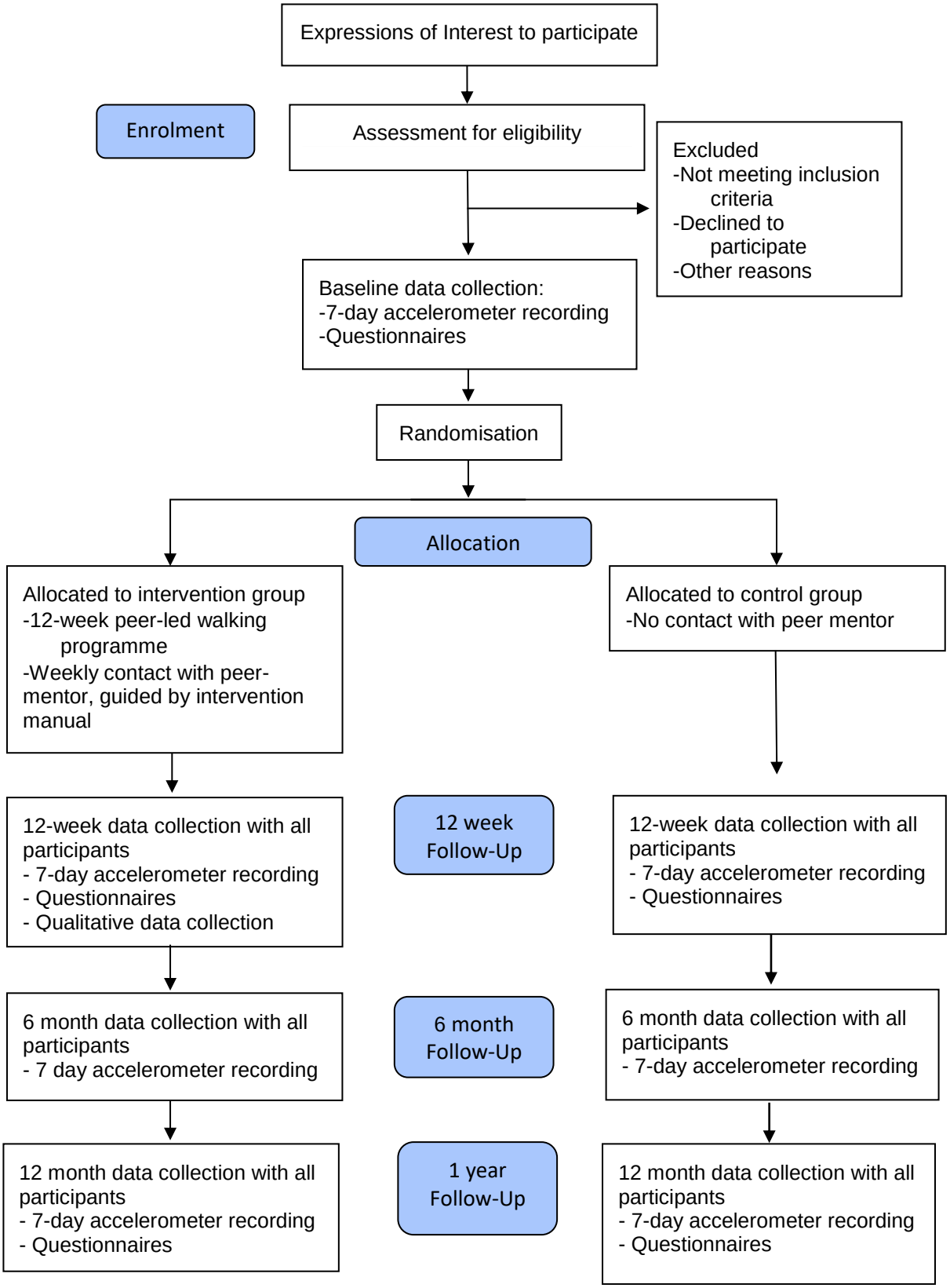
The exclusion criteria are:

- Individuals who do not meet the inclusion criteria
- Individuals who decline to participate
- Individuals with learning disabilities will be excluded
- Individuals unwilling to give informed consent
- Unable to communicate in English

Informed consent

The flow of participants through the study is described in Figure 1. Individuals deemed eligible to participate will be posted / given a study pack containing an information sheet (v1: 6th November 2021; Appendix 5) and consent form (v1: 6th November 2021; Appendix 6) along with a stamped addressed envelope. The information sheet will contain the contact details of the research team should the individual have any further questions they wish to ask. Individuals who agree to participate will be asked to provide the project manager with written informed consent following at least a 24 hour cooling off period to allow them to consider participating. They will be given a duplicate of the consent form which will also contain the details of the researcher should they wish to ask any further questions about the study. With participant's permission, a letter will be sent to their GP to inform them of their participation (Appendix 7).

Figure 1: Study flowchart for the Walk with Me RCT



Randomisation

A statistician from the Northern Ireland Clinical Trials Unit (NICTU) 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 outcomes measures have been collected, participants will be randomised to the intervention or the control group. The Research Project Manager will phone the NICTU and provide confirmation of the participant's consent, eligibility and participant ID number. The NICTU will provide the Research Project Manager with the participant's group allocation.

Sample Size

Based on the findings from our pilot study,[18] and recent systematic reviews,[25-26] 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 minutes/week of MVPA in the intervention group compared to the control group. A previous trial of a walking intervention in older adults has demonstrated that this would be a clinically significant change in terms of a reduction in the risk of fatal and nonfatal cardiovascular events, reduction in the risk of fractures and reductions in systolic and diastolic blood pressure.[27]

In our pilot study, we did not identify clustering of the results by peer mentor, with no obvious pattern in the data. However, as there were relatively few peer mentors involved, this may not be a fair reflection of what might happen in a larger trial. Therefore, based on data from another physical activity study in older adults, we have assumed an ICC of 0.01;[28] with a cluster size of 5 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. This adjustment for clustering thus inflates the estimate derived from the findings of our pilot study.

Walk with Me Intervention

The theoretical design of the Walk with Me intervention is based on social cognitive theory (SCT)[29] and the Behaviour Change Wheel is used as an overarching framework.[30] Behaviour change techniques (BCTs)[31] identified from previous evidence were mapped onto the core set of intervention functions of SCT (Figure 2). The socioecological model was used to provide a framework for a multilevel intervention design.[32]

Peer mentors and participants will meet once per week in an environment (community centre/coffee shop/library) close to a location where they can also go for a walk together, chosen jointly by the mentor and participant. In choosing a location, any public health or social measures in place due to COVID-19 will be accounted for so that the location is safe to meet

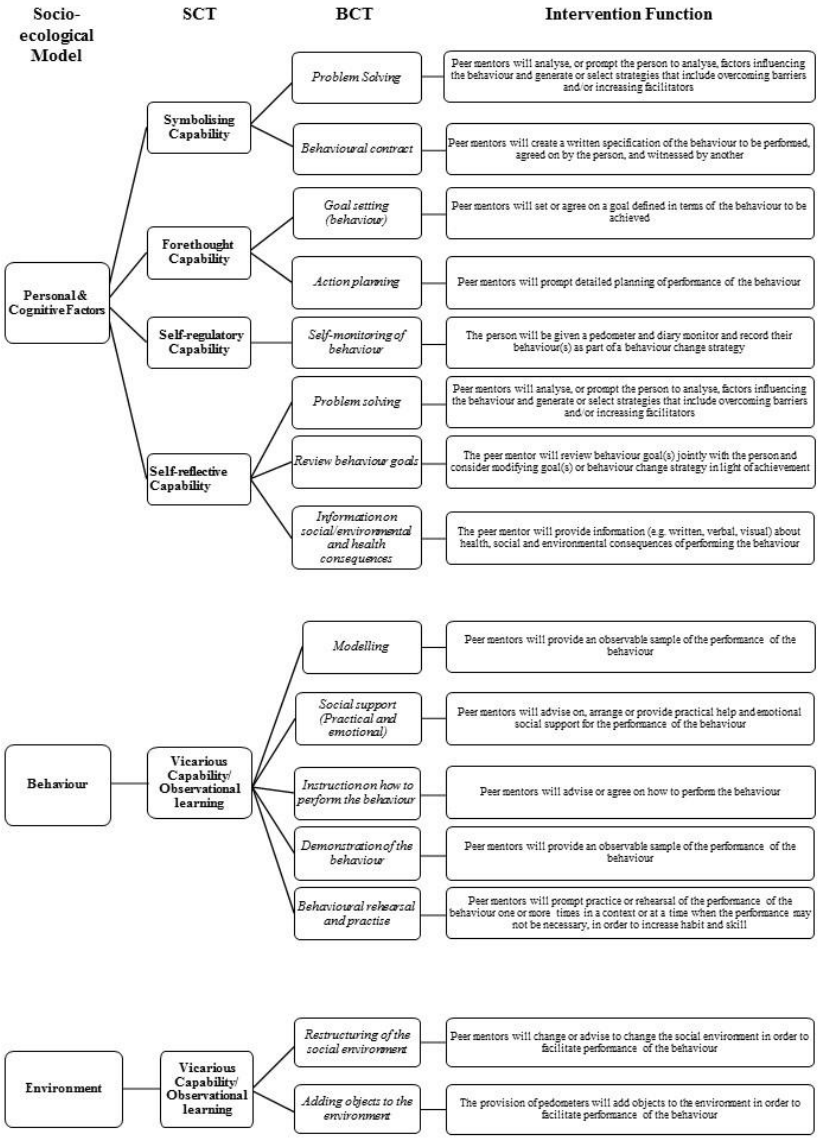
in. This may include meeting outside, physical distancing when inside, or indeed meeting online if necessary. During this meeting, the participant and mentor will engage in a structured discussion involving a review of the previous week's activity, discuss goal-setting and problem-solving, and set goals for the coming week. Joint decisions will be recorded using weekly templates (Appendix 8). The structure for a typical meeting will be outlined during an initial introductory session between the participant and the mentor, and they will be encouraged to continue this format to help establish a rapport with one another and to facilitate the delivery of the intervention content. Following this discussion, mentors and participants will take part in a walk in the local environment/park. At the end of the session, plans will be made to meet (online if necessary) the following week to progress the programme. As recommended in the pilot study,[18] we will run an event in the local community every three months to allow mentors and participants to meet each other, thus promoting social interaction. The organisation of this event will take account of relevant public health and social measures and will be online if necessary.

The 12-week intervention is comprised of three stages. The activation stage (weeks 1–4) is designed to build rapport between the mentor and participant. The goal of this first stage is to build a trusting relationship between the mentor and participant that is necessary for successful peer mentoring. The participant will record their initial step counts per day during the first week of the intervention, using a pedometer. Following this, the participant, with the support of their mentor, will set an initial step goal based on the average steps per day during the first week. This will be used as the basis for discussion of a suitable goal in the second and subsequent weeks.[33] 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 (approximately 5 minutes/day), and 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 (online if necessary) regularly to discuss goals/barriers to increasing physical activity and go 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 set individual physical activity goals by taking into consideration their capabilities. Weekly activity targets will be reviewed and agreed. 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 other local physical activity opportunities that would help the participant maintain their activity level when the structured component of the intervention comes to an end. In the case where attending these types of opportunities in person are not possible due to COVID-19 public health and social measures, other opportunities will be offered, such as online groups and home-based programmes such as the recently launched AGENI 'Move with Mary' programme, an exercise programme designed for older adults shielding due to COVID-19 and delivered by a local sporting celebrity (https://www.ageuk.org.uk/northern-ireland/information-advice/coronavirus-covid-19/movewithmary/).

Figure 2: Behaviour change techniques[31] mapped to intervention functions, SCT and socioecological model.



During the final 4 weeks of the intervention, 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. They will attend one of these places/groups together so the participant can become familiar with location, what takes place, and be introduced to the people that run it. In the event that COVID-19 public health and social measures prevent meeting in person, this session will be conducted through online video platforms (e.g. Zoom) or via the telephone.

After this, 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.[34] Between months three and six, participants will be encouraged to continue to use the pedometer to monitor their activity levels and return their pedometer logs (Appendix 9) to their peer mentor.[28] 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.[35-36] Health reasons are often cited in older adults physical activity research as a main contributor to attrition.[37] 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 the Active 10 mobile phone app that helps individuals monitor their activity, and they can be signposted to other digital supports, for example, physical activity programme websites such as the 'Move with Mary' initiative detailed above. During the final six months participants will continue with the programme unsupported in what will be termed an 'independent' phase.[38]

Peer Mentors

Peer mentor recruitment

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 but are sufficiently physically active.[39] We will recruit them using the methods successfully utilised in our pilot study.[18] We will seek volunteers from local community organisations, leisure centres and general practices through in person presentations at groups; via flyers, posters or social media posts, or through personal recommendation from group leaders to their members. Physical activity officers based in the Health and Social Care Trusts will also invite trained walk leaders to volunteer to become peer mentors. In addition, individuals who volunteer to take part in the intervention but are not eligible as they are already sufficiently physically active (i.e. meeting the current recommended level of 150 minutes of moderate-to-vigorous physical activity per week) will be invited to participate and undergo training to deliver the programme as a peer mentor. They will also agree to having an Access NI criminal records check before commencing in the role, as in our pilot study.

Strategies to enhance fidelity of intervention delivery will include standardised training (Appendix 10), the use of manuals (Appendix 10), and ongoing support from a health promotion officer based at the Institute of Public Health. Feedback on fidelity, and tailoring to individual participants, and any adaptations to preserve fidelity will be given to each peer mentor.

Peer mentor training

Peer mentors will receive two half-day face-to-face training sessions, one week apart, delivered by a health improvement officer based at the Institute of Public Health. A health improvement officer will not only be responsible for training the peer mentors, but will support them throughout the delivery of the programme and will report progress to the research project team through the Project Steering Committee. These training sessions have been developed and successfully delivered in our pilot study.[18] If COVID-19 public health and social measures prohibit face-to-face training, they will be delivered online, with didactic elements pre-recorded as videos for the peer mentor to watch on their own and the interactive elements completed in an online video call or via telephone.

The aim of these sessions is to develop their skills, knowledge and confidence to promote physical activity among their peers. The training will include training on the evidence and theoretical concepts underpinning the Walk with Me intervention, information on the role 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 (Appendix 10), 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. Case studies will be included in the training on each BCT, based around scenarios that the peer mentor may face (e.g. overcoming potential barriers to increasing physical activity). Emphasis will be placed throughout the training sessions on interactive components, as we have found previously that mentors learn most from putting knowledge into practice. These will include role play to help mentors practise the use of BCTs and observational learning where they engage with the programme as the participant would, including using the pedometer to monitor their own steps and to set goals.

Mentors will also be trained in how to build and sustain an effective mentoring relationship with a participant, as well as skill-building in the areas of active listening, communication and providing social and emotional support. In addition, peer mentors will receive a training and support manual (Appendix 10) that was developed for the pilot study, 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 in order to deliver the intervention. If a mentor decides to quit, a new mentor will engage with their participants promptly (with their mutual consent and ongoing support of the health improvement officer). If necessary, we can train more peer mentors, to step in if a mentor is ill, on holiday, or decides to withdraw from the programme. Support and training for new mentors, recruited during later stages of the study, will be tailored as required.

Ongoing support for peer mentors

Peer mentors will be offered telephone or online video access to a health improvement officer for advice or support 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. A health improvement officer will meet (online if necessary) with the peer mentors three times (once a month) 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. when using online video calls, and any 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. As in the pilot study, peer mentors will be provided with a Peer Mentor Participant Information Sheet (v1: 6th November 2021; Appendix 11) and individuals who agree to participate will be asked to provide written consent (v1: 6th November 2021; Appendix 12) before they 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. This will give them an insight into what participants have experienced as well as offer the opportunity to evaluate the potential impact of the programme on the physical activity and health of the peer mentors themselves.

Matching peer mentors to participants

As in the pilot study,[18] mentors and intervention group participants will be matched by sex, geographic location and other information such as their activity likes, dislikes and habits.

During their initial meeting, the structure for a typical meeting will be outlined and participants and mentors will be encouraged to continue this format in order to support the development of a rapport between them and to facilitate delivery of the intervention content.

Control group

Individuals allocated to the control group will be contacted by a 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 the Public Health Agency's information booklets on active ageing (Appendix 13) and healthy eating (Appendix 14). They 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 health improvement officer at 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). In line with approaches used in our pilot study[18] and other interventions in older adults,[13] they will also be offered a pedometer and physical activity diary during this meeting.

Outcome Measures

Demographic and outcome measures will be measured across four time points, as presented in Table 2.

Table 2: Outcome assessment according to the Walk with Me logic model and pilot study.

Data Collection	Baseline	3M	6M	12M
Socio-demographic: age, sex, marital status, car ownership (Appendix 15)	✓			
Actigraph accelerometer	✓	✓	✓	✓
Anthropometry – weight, body mass index (BMI), waist circumference	✓	✓		✓
Resting blood pressure	✓	✓		✓
Short physical performance battery (SPPB)[40]	✓	✓		✓
Warwick-Edinburgh Mental Well-Being Scale (WEMWBS)[41-42] (Appendix 16)	✓	✓		✓
EQ-5D-5L questionnaire[43] (Appendix 17)	✓	✓		✓

UCLA Loneliness Scale[44] (Appendix 18) and the Lubben Social Network Scale[45] (Appendix 19)	✓	✓		✓
Physical activity self-regulation scale[46] (Appendix 20)	✓	✓		✓
Physical activity and social activity self-efficacy[47] (Appendix 21)	✓	✓		✓
Physical activity and social activity outcome expectancy[48] (Appendix 22)	✓	✓		✓
Service use questionnaire (Appendices 23-25)	✓	✓		✓
Unintended consequences or adverse events		✓		✓

The primary outcome will be daily minutes of moderate-to-vigorous physical activity per day (>1951CPM) at 12-months,[49] measured using a waist-worn Actigraph wGT3X+ accelerometer (ActiGraph, LLC, Pensacola, FL, USA) and worn for a minimum of four days out of seven.[50] 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).[51] Non-wear time will be defined as a run of zero counts lasting > 60 minutes.

Secondary outcomes, which were found to be acceptable and feasible in our pilot study, were measures of mental well-being, using the Warwick–Edinburgh Mental Well-being Scale (WEMWBS),[41-42] and quality of life using the EuroQol-5 Dimensions, five-level version (EQ-5D-5L) questionnaire.[43]

In our logic model (Appendix 26) we define physical activity and social activity self-efficacy (10-point Likert scale, rating confidence in the ability to remain physically or socially active despite circumstances such as bad weather, boredom and pain),[47] and physical activity and social activity outcome expectancies (five-point Likert scale rating likelihood of outcomes such as good health, improved appearance, reduced stress, companionship and motivation),[48] as intermediate outcomes and possible mediators of the intervention, to aid the understanding of the mechanisms through which the intervention works as part of the process evaluation. We will also assess physical activity self-regulation (PASR),[46] as it indicates the processes through which change is hypothesised to occur. The PASR questionnaire assesses the use of BCTs included in the intervention such as self-monitoring, goal setting and social support. In addition, loneliness and social engagement will be measured with the UCLA Loneliness Scale[44] and the Lubben Social Network Scale.[45] As requested by participants in the pilot study, we will also measure resting blood pressure, height, weight, body mass index (BMI) and waist circumference, as these have been shown to be associated with increased physical activity in

older adults.[52] Physical functioning will also be measured using the short physical performance battery (SPPB).[40] Light intensity physical activity (>100 & ≤1951 CPM) and sedentary behaviour per day (≤100 CPM) will be calculated from the accelerometer data.

Health economic evaluation

A full economic evaluation will be conducted. We will assess the potential benefits and return on investment generated by Walk with Me via:

Cost-consequence analysis (CCA)

A CCA 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 (i.e. they will be disaggregated). 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).

Cost-utility analyses (CUA)

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). We will consult NICE guidance for economic evaluations of public health interventions[53] and other available guidelines including those related to the reporting of economic evaluations.[54-57] 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. In line with NICE guidance 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 public health interventions.[53]

For the within-trial CUA 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 prospectively. 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.[58] We will use the area under the curve method to calculate QALYs.[59] 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.[60-63]

For both within trial and long term analyses we will perform deterministic sensitivity analysis to explore key assumptions and probabilistic sensitivity analysis (PSA)[64] 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 the performing subgroup analyses and this will be in keeping with the main statistical analyses. A detailed health economic analysis plan will be written in advance.

Methods for data collection

Outcome measures will be assessed at baseline, post-intervention (12 weeks from the start of the intervention in the intervention group or equivalent timing for the control group), 6 months (accelerometer only) and 12 months after baseline, in person, by a Research Assistant, who will be blind to group allocation.

Outcome measures will be collected at the participant's home, at a local community centre/venue, or their general practice if the participant would prefer. The meeting will adhere to COVID-19 public health and social measures that are in place at the time, such as wearing face coverings and physical distancing.

Participants will be asked to complete self-reported questionnaires (Appendices 15-25), with support from the Research Assistant if needed. When these are complete, resting blood pressure will be measured using an Omron M6 digital sphygmomanometer. In line with the American College of Sports Medicine guidelines, blood pressure will be recorded after the participant has been seated for at least five minutes, and measured twice, separated by at least one minute, and averaged.[65]

Weight will be measured using a Seca weight scale and height measured using a portable stadiometer, and used to calculate body mass index. Waist circumference will be measured as the midpoint between the lowest rib and the iliac crest, using a fibre glass tape.

The SPPB includes three tests of balance and gait:

1) Chair Rise Test

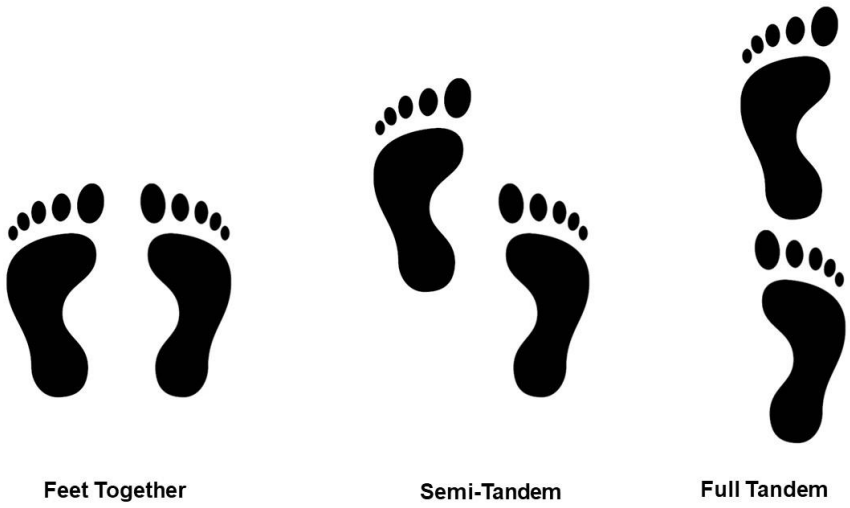
For the chair stand test, whilst seated, the participant is asked to stand up and sit down as quickly as possible five times, without stopping. Whilst completing this, the participant should keep their arms folded across their chest. The movement will first be demonstrated by the Research Assistant. Timing, using a digital stopwatch, begins as soon as the participant bends forward at the hips, and ends when they sit back down after completing the fifth stand. The test is stopped if the participant starts to use their hands, or after one minute if they have not completed 5 rises, and if the Research Assistant is concerned about the participant's safety. If the test is stopped early, the time is recorded and the number of chair rises completed, along with the reason for stopping the test. If the participant is unable to complete 5 chair rises, they are given a score of 0 points. If they complete 5 chair rises in 16.70 seconds or more they score 1 point; in 13.70 to 16.69 seconds they score 2 points; in 11.20 to 13.69 seconds they score 3 points; and in 11.19 seconds or less they score 4 points.

2) Standing Balance Test

This test assesses the participant's ability to stand unaided for 10 seconds with their feet in three different positions. After demonstrating these positions (Figure 3), the participant is first asked to stand unsupported, feet together for 10 seconds. They are permitted to use their arms, bend their knees, or move their body to maintain their balance, but they will be asked to try to not move their feet. The research assistant stands next to the participant, allowing them to hold onto their arms to get their balance. Timing begins when the participant has their feet together and let's go of the supporting arm. If they can complete the 10 seconds, they progress to the semi-tandem stand. In the semi-tandem stand, the participant is asked to stand for up to 10 seconds with the heel of one foot placed by the big toe of the other foot. If they complete the semi-tandem stand, the participant completes the final balance test, the

full tandem stand. In this, one foot is placed directly in front of the other. The time balance is maintained for each test is recorded, to a maximum of 10 seconds. For each balance test not completed, a participant is given 0 points. If they hold the feet together and the semi-tandem balance for at least 10 seconds, they score 1 point each. If they hold the full tandem balance for at least 10 seconds, 2 points are awarded.

Figure 3: Feet Positions for Standing Balance Test



3) Usual walking speed

A distance of 3 metres is measured with a tape measure and a marker cone is placed at either end. The participant is asked to walk at their normal walking speed between the two cones and the time taken to complete the walk is recorded. The participant is allowed to use a walking aid if they normally use one when walking. The test is repeated twice and averaged. One point is awarded if the average time across the two tests is more than 6.52 seconds. Two points are awarded if the time is between 4.66 and 6.52 seconds; three points are awarded if the time is between 3.62 and 4.65 seconds, and four points are awarded if the time is <3.62 seconds.
At the end of the test period, participants will be fitted with an accelerometer and given an instructional guide on how to use it (Appendix 27) and a diary to record wear time (Appendix 28). They will be asked to wear the accelerometer during waking hours for 7 days. A pre-paid envelope will be provided to return the accelerometer to the study team.

In the case where COVID-19 public health and social measures make it impossible to meet face-to-face, a pack with outcome measures will be posted to participants in advance of an online video call or telephone call. This will include the accelerometer with instructions on how to fit and wear it, a measuring tape to measure waist circumference and self-completed measures. Participants will be asked to measure their weight using their own scales if they

have them and estimate their height. We will measure as many of the components of SPPBon the video call as is feasible.

Data management and statistical analysis

The primary analysis will be conducted on an intention-to-treat basis once primary outcome data collection is complete, with all randomised patients 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.

The analysis will be undertaken by a statistician from the NICTU with no role in decision making about the ongoing conduct of the trial. We will describe 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 generalized linear mixed model including mentor as a random effect to account for possible clustering. Similar methods will be used for 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. We will also explore the moderating effect of gender, age, season and physical environment features on the results.

Process evaluation

A theory-driven process evaluation will be guided by the MRC Process Evaluation guidelines,[66] including an understanding of the impact of implementation, mechanisms of impact and context on the study outcomes.

Implementation

To assess implementation fidelity, we will assess an audio-recording of one randomly selected first meeting and a follow-up meeting for each peer mentor for content, delivery fidelity and the receipt and enactment of the intervention by participants, by comparing the content to the intervention manual (Appendix 10).[67] Audio-recordings will be made in a total of 70 participants sampled across different locations and a mixture of ages and sex. If the meetings are via online video call or telephone, they will be recorded with only the audio-file saved for fidelity

assessment. These will be analysed iteratively, and ongoing feedback given to peer mentors to enhance intervention fidelity, which will be carefully documented.[68]

Intervention fidelity will also be 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 (Appendix 29). 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.

Mechanisms of Impact

To assess the mechanism of any intervention effects (see logic model, Appendix 26), we will assess changes in physical activity self-regulation scale, physical activity and social activity self-efficacy and outcome expectancies using 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.

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, and those resulting from changes in COVID-19 public health or social measures (Appendix 30).[69]

Contextual factors

Contextual factors[66] that may influence the implementation and variation in outcomes, such as participant characteristics and physical environment features that may impact on walking will be explored in the post-intervention focus groups with participants and mentors.

Based on previous research,[70] these will include the impact of feelings of safety while walking; access to recreational facilities, parks/public open space 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 screen shot from the WalkScore (https://www.walkscore.com) output for their local neighbourhood. WalkScore is freely available tool that reports walkability within a 30-minute walk from a person's house. The score is a measure of pedestrian friendliness and the number of amenities in the neighbourhood, measured on a scale of 0 to 100. As well as the score, a map is available,

highlighting a variety of local amenities such as parks and shops as well as roads. This will prompt individuals to describe where they walk and what barriers and facilitators to walking they may encounter in their locality.

In addition, we will assess the moderating effect of the physical environment on the results, using WalkScore as a proxy for neighbourhood walkability and area level data on crime and the living environment using relevant indicators from the Northern Ireland Multiple Deprivation Measure (https://www.nisra.gov.uk/statistics/deprivation/northern-ireland-multiple-deprivation-measure-2017-nimdm2017).

At 12 weeks and 6 months, we will invite a purposeful sample of 30 intervention group participants to a focus group. A mixture of males and females and 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. They will be provided with a Peer Mentor Participant Information Sheet (v1: 6th November 2021; Appendix 11). Individuals who agree to participate will be asked to provide written consent (v1: 6th November 2021; Appendix 12).

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 (Appendix 31) will facilitate discussions. Audio recordings of focus groups will be transcribed and uploaded into QSR NVivo (v12) along with field notes. Analysis will explore the logic model, guided by the five stages of the Framework approach:[71] familiarisation; identifying a thematic framework; indexing; charting; mapping and interpretation.

Assessment of unanticipated outcomes

This is a low risk intervention, and we do not anticipate any serious adverse events. Adverse event reporting will follow the Health Research Authority guidelines on safety reporting in non-clinical trial investigational medicinal product studies (CTIMPs). 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 (Appendix 32).[72]

Serious adverse events, defined as an unexpected occurrence resulting in death, threat to life or hospitalisation or otherwise considered medically significant by the investigators will be recorded and assessed by clinical members of the study team who are not directly involved in the day-to-day running of the trial for causality and expectedness, using the definitions provided in Table 3.

Table 3: Serious Adverse Event (SAE) causality definitions	
Causality assessment	**Description**
Unrelated	There is no evidence of or rationale for any causal relationship.
Likely to be related	There is evidence, and a rationale, to suggest a causal relationship and other possible contributing factors can be ruled out.

If, in the opinion of the clinical co-investigator, an SAE occurring to a research participant is classified as related to the intervention, then the Chief Investigator will be responsible for reporting it to the Sponsor and to the research ethics committee which issued the favourable ethical opinion, using the SAE report for non-CTIMPs (published on the Health Research Authority website) within 15 days of becoming aware of the event.

Dissemination of Findings

We will target programme commissioners, general public and primary care clinicians with targeted outputs, using plain English summaries to ensure all resources are accessible to a wide audience. We will produce a range of outputs for different audiences, including a study website with regular updates, newsletters for participants, stakeholders and policy makers, lay summaries of evidence, peer reviewed publications and conference presentations at national and international conferences. We will prepare papers for publication in the public health literature.

To disseminate the ongoing progress of the study, and the study findings to members of the public and the wider public health community, we will distribute lay summaries of evidence and circulate these via social media channels (Twitter, Facebook). We will also seek three intervention participants to volunteer to keep a regular vlog of their experience of the programme. They will be asked to record a short 30 second video on their mobile phone, describing their experience as they progress through the intervention and to reflect on the process and what they have learnt. These will be collated and shared via Youtube and social media, with the participants' permission (Appendix 33).

Project Timelines

This project will last for 36 months. It is anticipated that all participants will be recruited between April 2022 and March 2023. This will allow for post-intervention assessments to take place between July 2022 and June 2023, 6-month assessments to take place between October 2022 and September 2023, and 12 month assessments between April 2023 and March 2024, leaving nine months for analysis, write-up and dissemination.

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