ISRCTN11235176 https://doi.org/10.1186/ISRCTN11235176

A feasibility study to test the effect of a set of behavioural change strategies in improving physical activity levels in adults aged 45 and over

Submission date
07/05/2018

Recruitment status
No longer recruiting

Registration date
10/05/2018

Overall study status
Completed

Last Edited
09/06/2025

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
It is well known that being physically inactive is good for mental and physical health and that adults who are involved in regular physical activity are protected from heart disease, cancer and other illnesses. On the other hand, adults who are inactive are more likely to get mental and physical health conditions. Inactive adults tend to have poorer balance and mobility and fall more often and often they become socially isolated. Many countries worldwide are trying to implement national strategies to get older adults moving and success has been limited. Research has shown that behavioural change strategies can result in improved physical activity levels for adults in community settings. Move For Life (MFL) is designed to improve and maintain physical activity levels. MFL is an intervention comprised of a set of behavioural change techniques and will be delivered by an instructor who is trained in these strategies. The instructor will then train a member of the community in the skills necessary to sustain the class in the future. This peer-mentor may then train up more members of the community in time. Before any intervention like this can come about, there must be evidence that it works and this is typically done by a trial. The aim of this study is to establish if it is feasible to conduct this type of trial and to measure the outcomes. The primary outcome is measuring time spent in daily physical activity.

Who can participate?
People aged over 45 years

What does the study involve?
Participants will be invited to attend a recruitment evening where they will be asked questions about their age and ability to participate in the physical activity programmes to ensure that they are suitable for the trial. Any participants deemed unsuitable will be asked to leave the study at this point. After participants have been screened to ensure they are suitable for the trial, they will be enrolled on the trial. All the participants in each local sports partnership hub will be allocated to the same arm of the study.

Group 1: Move For Life Intervention. Participants will be given a choice of four different physical activity programmes: Men on the Move is a 12-week structured physical activity class for men; Women on Wheels is an 8-week structured cycling class for women; Get Ireland Walking is an 8-week walking initiative for inactive men and women; Go for Life is a 8-week structured physical activity class for women and men aged 50 and over. Each programme will be run by a professional instructor who has been trained in behavioural change techniques. The instructor will train a 'peer mentor' who will be chosen from the local community to help to facilitate the group. The participants will have data collected before they commence the physical activity programme and which will run for 8-12 weeks. Repeat data will be collected at 3 and 6 months.
Arm 2: Usual care group. Participants will be enrolled in their preferred option of the four physical activity programmes described above. All classes are run by a professional instructor. The instructor will not have been trained in behavioural change techniques and will not have a 'peer-mentor' in the group. The participants will have data collected before they commence the physical activity programme and which will run for 8-12 weeks. Repeat data will be collected at 3 and 6 months.
Arm 3: True control. Participants will be given information about physical activity and will be offered entry into programmes when the trial has finished. They will have data collected after enrolment and at 3 and 6 months.

What are the possible benefits and risks of participating?
The benefits of physical activity and are well documented and it is hoped that the participants in the intervention arm in particular will become more active and will maintain physical activity levels for life. There may be a risk of injury as with any form of exercise. However, all of the physical activity classes are run by a professional instructor and have a proven track record in safety. Participants will be allocated to suitable levels of physical activity at enrolment. Participants may leave the classes or the trial at any stage.

Where is the study run from?
University of Limerick

When is the study starting and how long is it expected to run for?
March 2018 to November 2019

Who is funding the study?
Health Service Executive

Who is the main contact?
Dr Andrew O'Regan, andrew.oregan@ul.ie

Study website
https://moveforlife.ie/

Contact information

Type(s)
Scientific

Contact name
Dr Andrew O'Regan

Contact details

Graduate Entry Medical School
Faculty of Education and Health Sciences
University of Limerick
Limerick
Ireland
V94 YDE9

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2018_02_15_EHS

Study information

Scientific Title
An evaluation of a peer mentoring intervention designed to help inactive 45+ become more active: a cluster randomised feasibility trial of the Move for Life Programme.

Acronym
Move for Life

Study objectives
As this is a feasibility study we do not have a null hypothesis. We are testing the feasibility of measuring an improvement in moderate to vigorous physical activity levels in adults.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Limerick Faculty of Education and Health Sciences Research Ethics Committee, 09/04/2018, 2018_02_15_EHS

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Feasibility of increasing physical activity in people aged over 45 years

Interventions
Move for Life (MFL) is a feasibility cluster randomised control trial (RCT) where the Local Sports Partnership (LSP) hubs are the units of randomisation (the clusters), and individuals within the hubs are the units of analysis (the participants). The advantage of a cluster RCT is that it overcomes contamination problems that arise if simple random allocation is used. When testing a complex intervention, randomisation of participants risks contamination if individuals from both arms attend the one group. This study will enrol a total of eight hubs and randomise physical activity groups to each of three arms. This framework is in line with the recommendations of Eldridge et al. (Eldridge et al. 2016a) and the CONSORT (Eldridge et al. 2016b) guidance on the minimum number of clusters required to obtain accurate estimates of rates and proportions in pilot and definitive cluster RCTs respectively. The first arm is the intervention (three hubs); the second is usual exercise classes (three hubs) and the third is a no-physical activity control (two hubs). It is a complex intervention focussed on behavioural change that will use the cascade training model to augment existing programmes and will involve the professional instructor training up one (or more) of the group participants to be a peer-mentor, using an evidence-based educational toolkit. Assessments will be completed at baseline, 3 and 6 months follow up and include a physical health battery, completion of a MFL questionnaire and the monitoring of physical activity and sedentary behaviour over a 7-day period using an ActivPAL accelerometer.

After participants have been screened to ensure they are suitable for the trial, they will be enrolled on the trial. All the participants in each local sports partnership hub will be allocated to the same arm of the study. The study has three arms as described below:
Arm 1: Move For Life (MFL) Intervention.
Participants will be given a choice of four physical activity programmes: Men on the Move is a 12-week structured physical activity class for men; Women on Wheels is an 8-week structured cycling class for women; Get Ireland Walking is an 8-week walking initiative for inactive men and women; Go for Life is a 8-week structured physical activity class for women and men aged 50 years and over. Each programme will be run by a professional instructor who has been trained in behavioural change techniques. The instructor will train a ‘peer mentor’ who will be chosen from the local community to help to facilitate the group. The participants will have data collected before they commence the physical activity programme and which will run for 8 to 12 weeks. Repeat data will be collected at 3 and 6 months.
Arm 2: Usual care group.
Participants will be enrolled in their preferred option of the four physical activity programmes described above. All classes are run by a professional instructor. The instructor will not have been trained in behavioural change techniques and will not have a ‘peer-mentor’ in the group. The participants will have data collected before they commence the physical activity programme and which will run for 8 to 12 weeks. Repeat data will be collected at 3 and 6 months.
Arm 3: True control.

Participants will be given information about physical activity and will be offered entry into programmes when the trial has finished. They will have data collected after enrolment and at 3 and 6 months.

Intervention Type
Behavioural

Primary outcome measure
Time spent in daily moderate to vigorous physical activity. This will be measured by a sophisticated accelerometer that will be worn by the patients for 7 days at baseline, 3 and 6 months. The accelerometer data will then be uploaded by the research team for analysis.

Secondary outcome measures
1. Participant recruitment outcomes include demographic profile and the success of each of the recruitment strategies, based on the number, profile and reasons of participants who drop out, which will be recorded by the data collection team.
2. Measures relating to attendance at classes, retention of participants, characteristics of drop outs and refusals. Data will be collected on attendance, and safety and adverse events will be recorded by the LSP tutor.
3. Physical health assessments, including body mass index (BMI) and waist circumference. Validated tests of functional ability including balance and strength testing will be carried as well as height, weight and grip strength.
4. Participant experience. Participants will be asked to complete a MFL questionnaire comprising of four modules: behavioural change techniques, well-being, cost effectiveness, and process evaluation. After the trial a subset of participants will be asked to undertake interviews to investigate their experience. NVIVO version 11, a qualitative research software package, will be used to assist analysis of the data with thematic analysis (Braun & Clarke, 2006) used to analyse the findings.
5. Description of how concealment of allocation from participants, data collectors and data analysis team was achieved
6. Feasibility of measuring number of minutes of moderate to vigorous physical activity

Overall study start date
02/03/2018

Completion date
30/11/2019

Eligibility

Key inclusion criteria
Adults aged 45 years and over

Participant type(s)
All

Age group
Mixed

Lower age limit

45 Years

Sex
Both

Target number of participants
576

Total final enrolment
733

Key exclusion criteria
Aged under 45 years

Date of first enrolment
01/04/2018

Date of final enrolment
30/11/2018

Locations

Countries of recruitment
Ireland

Study participating centre
University of Limerick
Castletroy
Limerick
Ireland
V94 YDE9

Sponsor information

Organisation
University of Limerick

Sponsor details
Castletroy
Limerick
Ireland
V94 YDE9

Sponsor type
University/education

Website
www.ul.ie

ROR
https://ror.org/00a0n9e72

Funder(s)

Funder type
Government

Funder Name
Health Service Executive - Healthy and Positive Ageing for All (HaPAL)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
30/06/2022

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date. Full ethical approval has been granted. At enrolment each participant will be assigned a number and all data will be anonymised.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	09/07/2019	25/07/2019	Yes	No
Results article		15/05/2024	30/05/2024	Yes	No
Other publications		18/03/2025	09/06/2025	Yes	No