ISRCTN26786857 https://doi.org/10.1186/ISRCTN26786857

A randomised controlled trial of the effectiveness of pedometers plus systematic advice to increase physical activity levels in sedentary older women

Submission date
29/05/2007

Recruitment status
No longer recruiting

Registration date
03/08/2007

Overall study status
Completed

Last Edited
17/05/2018

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Studies have shown that increasing physical activity levels, especially through increasing walking, can protect older people from developing mobility loss. Increasing physical activity can also reduce the risk of diseases like obesity, diabetes, stroke, heart problems, osteoporosis, depression and Alzheimer's disease. It is not known which way is the best to change people's behaviour and help them to become more active. The aim of this study is to see whether simple measures including advice about how to increase activity levels and setting out an activity plan will help people increase their physical activity. The study will also check if using a pedometer (a small device that is worn around the neck or at the waistband that counts the number of steps taken) to set targets will help people further increase their activity levels.

Who can participate?
Women aged 70 or over who are insufficiently active or sedentary

What does the study involve?
The study lasts for 6 months during which time the study nurse and research assistant will arrange to visit participants at home on five occasions. Participants are randomly allocated to one of three groups. Participants in the first group are asked to wear a pedometer for 6 months and to fill in a daily activity diary. They are also given advice on how to increase their physical activity levels and an activity plan designed to suit their needs. Participants in the second group are given the advice and activity plan only. Participants in the third group receive nothing. At the beginning of the study, the middle and again at the end of the study 6 months later, all participants undergo a walking test, a balance test, and a standing and sitting down test, and complete four questionnaires about how well they feel, how often they need to attend their GP surgery, their mood, and how well they have managed to follow their 'Activity Plan'. These take about ten minutes to complete with the research assistant. Participants keep a record of any falls and what might have caused these. Participants who receive a pedometer are asked to walk 100 steps to check whether the pedometer works best worn on the waistband or around the

neck. They are also asked to keep a record of the number of steps recorded each day on the pedometer. They are encouraged to gradually increase the number of steps they take every day. At the end of the study they are allowed to keep the pedometers for their own use. Irrespective of whether or not they are asked to wear a pedometer, all the women in the study are asked to wear a second device called an accelerometer on three occasions for periods of one week during the first, middle and last weeks of the study. The accelerometer is a small device about the size and shape of a small matchbox which tells us about their overall total activity. Participants have five home visits over the course of the study that last about 40 minutes each, two visits from the study nurse and three from the research assistant. Between the first and last visit, the study nurse contacts them by telephone to find out about how they are managing with their activity plan. For the first month they contact them every week and for the rest of the study they telephone fortnightly.

What are the possible benefits and risks of participating?
Increasing physical activity levels, especially through increasing walking, can protect older people from developing mobility loss. Increasing physical activity can also reduce the risk of diseases like obesity, diabetes, stroke heart problems, osteoporosis, depression and Alzheimer's disease. It is hoped that the physical activity advice will prove beneficial. This study aims at increasing physical activity levels. Too rapid an increase can lead to mild tiredness. Participants are encouraged to increase their physical activity levels gradually and appropriate targets are set.

Where is the study run from?
University of Dundee (UK)

When is the study starting and how long is it expected to run for?
August 2007 to October 2009

Who is funding the study?
Chief Scientist Office (UK)

Who is the main contact?
Prof. Marion McMurdo
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A randomised controlled trial of the effectiveness of pedometers plus systematic advice to increase physical activity levels in sedentary older women

Acronym
METM Pedometer study

Study objectives
To evaluate the use of pedometers plus brief systematic advice and individualised activity plans in assisting sedentary older women to accumulate increasing amounts of physical activity, mainly through walking.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Tayside Committee on Medical Research Ethics B, ref: 07/S1402/33

Study design
Randomised controlled trial.

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Sedentary women over 70 years of age

Interventions
The participants will be randomised to one of the following 3 arms:
Arm 1: Advice and pedometer
Arm 2: Advice only
Arm 3: Control group

Arms 1 and 2 receive tailored advice at the baseline session from a nurse visiting the participant at home. They will be encouraged to incorporate more walking into their daily routine. They will be given monthly targets to achieve (in pedometer counts for Arm 1 and in time spent walking outdoors for Arm 2). Both arms will be given daily activity diaries to complete (of pedometer

count for Arm 1 and of time spent walking outdoors for Arm 2). They will receive telephone support weekly for the first month then fortnightly thereafter. The control group receives no intervention.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Change in daily activity levels by accelerometry

Key secondary outcome(s))
The following will be assessed at baseline, 3 and 6 months:
1. Lower limb function (a validated 12-point performance score)
2. Health related quality of life (the Euroquol questionnaire)
3. Depression (the Hospital Anxiety and Depression Scale ([HADS])

Completion date
14/10/2009

Eligibility

Key inclusion criteria
1. Women aged 70 years or over
2. Insufficiently active or sedentary (no participation in moderate-intensity physical activity of at least 30 minutes at least 5 days per week, or at least 20 minutes of continuous vigorous-intensity activity 3 or more times per week)

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Senior

Sex
Female

Key exclusion criteria
1. Women fulfilling recommended physical activity recommendations
2. Resident of institutional care
3. Housebound (so unable to increase outdoor walking)
4. Moderate to severe cognitive impairment precluding informed consent
5. Visually impaired (unable to read pedometer count)
6. Wheelchair bound
7. Unwilling to participate

Date of first enrolment
13/08/2007

Date of final enrolment
14/10/2009

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
University of Dundee
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
University of Dundee (UK)

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office (UK)

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The protocol is available from the authors on request but is not available online. Study data are available for non-commercial, bona-fide academic analyses in collaboration with the authors; decisions on data access will be made between the investigators and the Sponsor (University of Dundee). Participant consent for unrestricted sharing of individual participant data was not obtained. Contact for data sharing: Dr Catrina Forde (c.forde@dundee.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2010		Yes	No
Basic results		17/05/2018	17/05/2018	No	No