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A pedometer intervention to increase walking in adults: Pedometer And Consultation Evaluation - UP (PACE-UP) trial

Submission date 29/02/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/03/2012	**Overall study status** Completed	
Last Edited 29/10/2019	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Physical activity is vital for health, yet most adults are inactive and do not achieve the recommended 30 minutes of moderate intensity activity on 5 or more days per week. Adults' most common physical activity is walking, light intensity if strolling, moderate intensity if brisker. Pedometers measure step-count and have been shown to increase walking. However, most pedometer trials have had short-term outcomes, they have not separated out pedometer effects from other support and they have reported only step-counts, not time spent at different physical activity intensities. The aim of this trial is to investigate whether 993 inactive patients aged 45-74 years from 6 London general practices can increase their physical activity as a result of being given a pedometer with a diary and written guidelines, and whether additional tailored support from a practice nurse increases any benefits.

Who can participate?
To take part you need to be aged 45-74 years, registered with one of the six general practices in South West London taking part in the trial, and doing less physical activity than recommended by UK guidelines, i.e. usually doing less than half an hour of moderate or vigorous activity (such as walking or a sport) on five or more days of the week.

What does the study involve?
If you are invited to take part you will be invited to meet with one of the researchers at your GP practice. This meeting will take about 30-45 minutes. You will be asked to :
1. Sign a consent form and fill in a questionnaire about your health.
2. Have your height, weight and waist circumference measured.
3. Record your physical activity in a diary for a week.
4. Wear a belt with two small monitors on, an accelerometer and a pedometer, during the day for a week (the monitors will accurately record your physical activity levels, but will be sealed for the baseline measurements, so they will not give any direct feedback).
5. Return the belt and monitors to the practice when you have finished wearing them.
Participants will be divided into three groups. The groups will be decided randomly, like tossing a coin.

The first group will carry on with their usual activity (the usual physical activity group). If you are in this group you will be contacted by post 3 months after your first visit and asked to wear the accelerometer again for 7 days. You will be asked to visit the practice 12 months after your first visit and to monitor your activity with the accelerometer for 7 days before that visit. You will be offered a pedometer and guidance on a 12-week walking programme at the end of the study.
The second group will be sent a pedometer, a physical activity diary and instructions for a 12-week walking programme through the post (pedometer by post group). If you are in this group you will be contacted by the researcher one week after you receive the pedometer to check it is working and that you understand the instructions and then you will be contacted at 3 months and 12 months, exactly as for the usual physical activity group.
The third group will meet with the practice nurse and will receive their pedometer, physical activity diary and 12-week walking programme instructions from her (the pedometer plus nurse support group). If you are in this group you will be invited to see the nurse three times over three months, and each visit will last around 20-30 minutes. The nurse will encourage you to make a physical activity plan and will encourage you to monitor your activity, set goals, overcome barriers to change and increase your confidence to become more active. You will also be contacted by the researcher at 3 months and 12 months, exactly as for the other groups.

What are the possible benefits and risks of participating?
There are many proven benefits from walking more and becoming more active. You will be offered feedback on your individual activity levels and a pedometer to keep at the end of the study and a physical activity consultation with the nurse, if you would like one. This is a very low risk study. If you are in the pedometer by post group or the pedometer plus nurse support group you will be advised to gradually increase your walking in a safe way. However, there is a small risk that you could fall or get pain from unaccustomed walking or you could make a condition that you already have, like arthritis, worse. If you develop new symptoms you should report these to your GP.

Where is the study run from?
It is being organised by St George's University of London. Six general practices in South West London will be recruited, patients will see the researcher and nurse at their own practice

When is the study starting and how long is it expected to run for?
October 2012 to September 2014

Who is funding the study?
The study is being funded by the Health Technology Assessment programme of the National Institute of Health Research

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HTA 10/32/02

Study information

Scientific Title
Randomised controlled trial of a pedometer-based walking intervention with and without practice nurse support in primary care patients aged 45-74 years

Acronym
PACE-UP

Study objectives
Does the provision of pedometers with physical activity diaries and written guidelines increase physical activity (average daily step-counts) over the short term (3 months) and longer term (12 months) in inactive primary care patients aged 45-74 years and does additional, individual, tailored support from a practice nurse increase any benefits?

More details can be found at: https://www.journalslibrary.nihr.ac.uk/programmes/hta/103202/#/

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London- Hampstead, ref: 12/LO/0219: approval pending

Study design
Three-arm randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Inactive primary care patients

Interventions

Nature of the complex intervention: 12 week pedometer-based walking intervention delivered either by post with written instructions or delivered in the context of three brief physical activity consultations with a practice nurse, based on a cognitive behavioural approach.

There are 3 groups: control (usual physical activity); pedometer by post group; pedometer plus nurse support group.

Components of the complex intervention
1. Pedometers
Yamax Digi-Walker SW-200 (Tokyo, Japan) is the criterion pedometer with best accuracy. It provides direct step-count feedback to participants. Step-counts need daily manual recording and re-setting. The pedometer will be delivered by post along with written instructions on its use to the pedometer group, it will be given by the nurse directly to patients in the pedometer plus support group.

2. Written instructions and physical activity diaries for a 12-week pedometer based walking intervention (delivered by post to pedometer group, provided in consultations for pedometer plus nurse support group)

We will have participants baseline step-count from their blinded pedometer assessment. They will be given feedback on this and information about the fact that adding in 3000 steps/day in 30 minutes on five or more days weekly to their baseline would help them to achieve the recommended daily physical activity guidelines and that this can be built up gradually. They will be given advice on the benefits of at least moderate intensity physical activity for health and informed that moderate intensity PA makes you feel warm and makes you feel a bit breathless and increases your heart rate, but that you should still be able to talk. A suggested walking plan will be provided as follows:
Weeks 1-2: Add in 1500 steps in 15 minutes 3 or more days per week
Weeks 3-4: Add in 1500 steps in 15 minutes 5 or more days per week
Weeks 5-6: Add in 3000 steps in 30 minutes (or 2 x 15 minute bouts) on 3 or more days per week
Weeks 7-8: Add in 3000 steps in 30 minutes (or 2 x 15 minute bouts) on 5 or more days per week
Weeks 9-12: Maintenance, continue adding on 3000 steps in 30 minutes on 5 or more days per week.
They will be given diaries for recording their daily step-count on so that they can see if they are acheiving their target for that week. They will be given written advice on how to maintain their activity, and how to anticipate and manage setbacks.

3. Physical activity consultations with a practice nurse based on a cognitive behavioural approach. The cognitive behavioural model includes patient-led goal setting based on behaviour change principles, including motivational language, problem-solving, self-monitoring, SMART goals, social support, relapse prevention, addressing barriers, use of written tools including diaries. These techniques have been successfully used by non-specialists in primary care after brief training and are emphasized in the NHS Health Trainer Handbook. Pedometer measurement and diary recording of step-counts provides clear material for physical activity goal-setting, self-monitoring and feedback and should fit very well with this approach. Practice nurse training in a cognitive behavioural approach to increasing PA based on the NHS Health Trainer handbook, combined with training in advising on a 12-week pedometer based walking intervention will be provided.

1. David L. Using CBT in General Practice. The 10 minute consultation. Oxfordshire: Scion; 2006.
2. British Psychological Society. Improving Health, Changing Behaviour: NHS Health Trainer Handbook. 2008.

Intervention Type
Behavioural

Primary outcome(s)
Change in average daily step-count, assessed objectively by accelerometry (Actigraph GT3X+ Manufacturing Technology Inc, Fl USA), measured over 7 days, between baseline and 12 months

Key secondary outcome(s))
1. Change in time spent in:
1.1. At least moderate intensity physical activity and
1.2. Sedentary physical activity, measured over 7 days by accelerometry, between baseline and 12 months
2. Change in average daily step-count, time spent in at least moderate physical activity and time spent sedentary, assessed objectively by accelerometry measured over 7 days, between baseline and 3 months
3. Cost-effectiveness, incremental cost of the intervention to the NHS and incremental cost per change in step-count and per quality-adjusted life year
4. Acceptability of the interventions (qualitative interviews and focus groups)
5. Change in self-reported physical activity from the questionnaire [General Practice Physical Activity Questionnaire (GPPAQ), International Physical Activity Questionnaire (IPAQ)]
6. Change in other patient reported outcomes from the questionnaire (exercise self-efficacy, anxiety, depression, perceived health status including mood and pain (EuroQol 5D [EQ-5D])
7. Change in anthropometric measurements (weight, body mass index, waist circumference, body fat, bio-impedence (Tanita scales)
8. Adverse outcomes (data on falls, injuries, major cardiovascular disease events and deaths will be collected as part of safety monitoring for the trial, through participant and nurse reporting, questionnaires at 3 and 12 months and primary care records
9. Health service use - number of and diagnoses for all primary care consultations during the 12 months of the trial, as well as any out of hours, A&E or in-patient attendances related to falls, injuries, fractures etc from computerised primary care records at the end of the study given participants consent
10. There will be a range of outcomes from qualitative interviews and focus groups for both participants and practice nurses involved in implementing the intervention. We will gain an in-depth understanding of the acceptability and challenges with the interventions for participants and practice nurses, as well as valuable insights into the factors influencing why people opt not to participate in the intervention

Completion date
30/09/2014

Eligibility

Key inclusion criteria
1. Patients aged 45-74 years registered at one of the six general practices within the South West London cluster of primary care trusts (PCTs) where the research is being undertaken
2. Able to walk outside the home and with no contraindications to increasing their moderate intensity physical activity levels

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Those reporting achieving the Chief Medical Officers' guidelines of at least 150 minutes of at least moderate intensity physical activity weekly. We anticipate that there will be a few participants who will be found on subsequent baseline accelerometer assessment to be above this level of physical activity (our previous pilot work suggests this number will be small as most people tend to overestimate their physical activity levels). They will not be excluded from the study, as this is a pragmatic trial and if this intervention were to be rolled out, exclusion would be on the basis of the screening question alone.
2. Liiving in a residential or nursing home
3. Housebound
4. Three or more falls in previous year or one or more fall in previous year requiring medical attention
5. Terminal illness
6. Dementia or significant cognitive impairment (unable to follow simple instructions)
7. Registered blind
8. New onset chest pain
9. Myocardial infarction
10. Coronary artery bypass graft or angioplasty within the last 3 months
11. Medical or psychiatric condition which the general practitioner (GP) considers excludes the patient (e.g. acute systemic illness such as pneumonia, acute rheumatoid arthritis, unstable or acute heart failure, significant neurological disease or impairment, unable to move about independently, psychotic illness)
12. Pregnant women

Date of first enrolment
01/10/2012

Date of final enrolment
30/09/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

St George's University of London
London
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Sponsor information

Organisation
St George's University of London (UK)

ROR
https://ror.org/040f08y74

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme (10/32/02)

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	results	15/12/2014		Yes	No
Results article	results	12/12/2015		Yes	No
Results article	results	01/04/2016		Yes	No
Results article	results	03/01/2017		Yes	No
Results article	results	22/01/2018		Yes	No
Results article	results	23/01/2018		Yes	No
Results article	results	09/03/2018		Yes	No
Results article	results	01/06/2018		Yes	No
Results article	results	25/06/2019	27/06/2019	Yes	No
Protocol article	protocol	05/12/2013		Yes	No
Other publications	cost effectiveness analysis	17/10/2018	29/10/2019	Yes	No