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RCT of a complex intervention by primary care nurses to increase walking in patients aged 60-74 years (PACE-Lift Pedometer Accelerometer Consultation Evaluation trial)

Submission date
21/06/2011

Recruitment status
No longer recruiting

Registration date
21/06/2011

Overall study status
Completed

Last Edited
27/06/2019

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Physical activity is essential for older peoples physical and mental health, yet most older adults are inactive and do not achieve the recommended 30 minutes of moderate intensity activity on 5 or more days weekly, despite most being able to. Older adults' most common physical activity is walking, light intensity if strolling, and moderate intensity if brisker. Effective techniques for changing behaviour and increasing physical activity include strategies such as goal setting, self-monitoring, building confidence and preventing relapses. Primary care physical activity consultations with a nurse allow individual tailoring of advice. Pedometers measure step-counts and accelerometers measure physical activity intensity. The aim of this study is to investigate whether 300 patients aged 60-74 years from 3 general practices can increase their physical activity, particularly walking, as a result of having physical activity consultations with a nurse using behaviour change techniques and providing feedback on physical activity levels using pedometers and accelerometers.

Who can participate?
To take part you need to be:
1. Aged 60-74 years
2. Registered with one of the 6 general practices in Oxfordshire or Berkshire West taking part in the trial
If there is a reason why you should not increase your physical activity levels (e.g. recent heart attack or stroke, recurrent falls) you will not be able to participate in this study. If you have dementia or learning difficulties, or you are suffering from a terminal illness, or you are living in a residential or nursing home you will also not be able to take part.

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:
i) Sign a consent form and fill in a questionnaire about your health.

ii) Have your height and weight and waist circumference measured.
iii) Record your physical activity in a diary for a week.
iv) Wear a belt with a monitor called an accelerometer on, during the day for a week. (The monitor will accurately record your physical activity levels, but will be sealed for the baseline measurements, so they will not give any direct feedback).
v) Drop back the belt and monitor to the practice, when you have finished wearing them.
There will be 2 groups of people taking part in the study. The groups will be decided randomly, like tossing a coin.
One group will carry on with their usual activity (the usual physical activity group). If you are in this group you will be contacted 3 months after your first visit and asked to wear the accelerometer again for 7 days and visit the practice again. You will also be asked to wear the monitor again 12 months after your first visit. You will be offered a pedometer and guidance on how to use it to increase your walking at the end of the study.
One group will meet with the practice nurse and will receive a pedometer, physical activity diary and patient handbook from her (the nurse support group). If you are in this group you will be invited to see the nurse 4 times over 3 months, each visit will last around 30 minutes and you will be asked to wear the accelerometer before each meeting and you will receive feedback on your activity levels measured on the accelerometer and pedometer during the meetings. 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 usual physical activity group.

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.
This is a very low risk study. If you are in the 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?
St Georges University of London. 3 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?
The study will be open to participants from approximately October 2011 until September 2012.

Who is funding the study?
Research for Patient Benefit programme of the National Institute of Health Research.

Who is the main contact?
Dr Tess Harris
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
9885

Study information

Scientific Title
RCT of a complex intervention by primary care nurses to increase walking in patients aged 60-74 years (PACE-Lift Pedometer Accelerometer Consultation Evaluation trial)

Acronym
PACE-Lift

Study objectives
Physical activity (PA) is vitally important for older peoples health. Guidelines recommend at least 30 minutes daily, 5 days weekly, of at least moderate intensity PA. Older peoples most common PA is walking, light intensity if strolling, moderate if brisker. Less than a fifth of the UK's 60-74 year olds report achieving the guidelines, despite most being able to. Effective PA interventions include cognitive-behavioural strategies, primary care nurse PA consultations allow individual tailoring of advice. Pedometers measure step-counts and accelerometers measure PA intensity, but no studies have assessed if feedback on this combination can increase PA levels in older primary care patients.

Aim:
The PACE-Lift trial will evaluate the potential for increasing PA in older people using primary care nurse PA consultations based on a cognitive behavioural approach and using pedometer and accelerometer feedback.

Ethics approval required
Old ethics approval format

Ethics approval(s)
11/H0606/2

Study design
Randomised, interventional, prevention, treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Generic Health

Interventions
1. Randomised controlled trial with intervention and control arms
2. Target population: 300 people aged 60-74 years registered with 3 practices in Oxfordshire or Berkshire, who can walk outside and have no contraindications to increasing activity
3. Three month pedometer and accelerometer based intervention with practice nurse PA consultations
4. Individual PA plans based on increasing walking and other existing physical activities will be developed, considering baseline steps, time spent in different PA intensities, health problems and personal circumstances and using strategies such as goal-setting and self-monitoring
5. Physical activity consultation, 4 individual physical activity consultations with a primary care nurse over 3 months
6. Individual physical activity plans based on increasing walking and other existing physical activities will be developed, considering baseline steps (from pedometer), time spent in different physical activity intensities (from accelerometer), health problems and personal circumstances
7. The nurse will use cognitive behavioural strategies such as goal setting, self-monitoring and boosting motivation
8. Follow up length: 12 months, single randomisation only

Intervention Type
Other

Phase
Phase II

Primary outcome measure
1. Change in accelerometer step-count at 3 months
2. Change in average daily steps (primary outcome) and average time spent in at least moderate intensity PA weekly at 3 months (main outcome) and 12 months (for maintenance)
3. Self-reported PA, depression scores, pain, quality of life and body size variables will also be assessed

4. A qualitative evaluation will explore the interventions acceptability and perceived barriers and benefits to increasing PA

Secondary outcome measures
No secondary outcome measures

Overall study start date
03/10/2011

Completion date
30/09/2012

Eligibility

Key inclusion criteria
1. Registered at one of the 3 practices recruited into the trial (in Oxfordshire or Berkshire)
2. Age 60-74 years and able to walk outside the home
3. Male or female

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
UK Sample Size: 300

Key exclusion criteria
1. Living in a residential or nursing home
2. Housebound
3. Dementia or significant cognitive impairment (unable to follow simple instructions)
4. Three falls in last year or fall in previous year requiring medical attention
5. Terminal illness
6. Registered blind
7. New onset chest pain
8. Myocardial infarction
9. Angioplasty or coronary artery bypass graft in the last 3 months
10. Medical or psychiatric condition which the GP considers as exclusion criteria for the patient:
10.1. Acute systemic illness such as pneumonia
10.2. Acute rheumatoid arthritis
10.3. Unstable or acute heart failure
10.4. Significant neurological disease or impairment
10.5. Unable to move independently,
10.6. Psychotic illness

Date of first enrolment

03/10/2011

Date of final enrolment
30/09/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cranmer Terrace
London
United Kingdom
SW17 0RE

Sponsor information

Organisation
St George's University of London (United Kingdom)

Sponsor details
Cranmer Terrace
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SW17 0RE

Sponsor type
University/education

Website
http://www.sgul.ac.uk/

ROR
https://ror.org/040f08y74

Funder(s)

Funder type
Government

Funder Name
NIHR Research for Patient Benefit, ref: PB/PG/0909-20055 (United Kingdom)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	04/01/2013		Yes	No
Results article	results	17/02/2015		Yes	No
Results article	results	12/12/2015		Yes	No
Results article	results	25/06/2019	27/06/2019	Yes	No