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Physical activity after cardiac events (PACES)

Submission date
27/02/2017

Recruitment status
No longer recruiting

Registration date
27/02/2017

Overall study status
Completed

Last Edited
05/01/2022

Condition category
Circulatory System

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

Plain English summary of protocol

Current plain English summary as of 13/02/2019:
Background and study aims
Coronary heart disease (CHD), also known as ischemic heart disease, is one of the leading causes of death worldwide. CHD develops because of the build-up of fatty deposits (plaque) on the walls of the coronary arteries (the arteries that supply the heart with oxygen-rich blood). When arteries are blocked or narrowed, the heart does not receive enough blood to function properly, which can lead to a cardiac event such as a heart attack. After experiencing one cardiac event, the risk of experiencing one again is increased unless there is intensive management of risk factors such as physical activity, smoking, diabetes, hypertension (elevated blood pressure levels), hyperlipidaemia (elevated fat levels in the blood) and obesity. This usually involves being offered a structured education and exercise programme of cardiac rehabilitation, after which risk factor management is done by a GP. The aim of this study is to look at the effectiveness of an education programme with text messaging support for increasing physical activity, specifically walking, in individuals who have had a cardiac event in the past 12 to 48 months.

Who can participate?
Adults who have had a cardiac event 12-48 months ago.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive usual care, which involves being given general health advices in the form of a standard information leaflet and will be returned to standard care delivered by their GP. Those in the second group also receive the standard information leaflet as well as being invited to take part in two group-based structured education sessions. These education sessions are delivered by trained facilitators approximately two weeks apart. Following this, participants receive regular text messages providing support for a year. Participants in both groups have their physical activity levels assessed at the start of the study and then again after six and 12 months.

What are the possible benefits and risks of participating?
By taking part, both groups will benefit from a health assessment and physical activity advice. Individuals will also receive information on their general fitness levels. Most importantly participants will add to evidence-based lifestyle information that may improve the treatment and support for people 12 months after a cardiac event in the future. During any physical activity there is always an increased risk of a heart event or injury. The walking test is being performed

before participants start the study to ensure the risks to an individuals health is very low. These risks are also lowered because the education sessions target the increase of daily physical activity levels rather than vigorous physical activity. There will also be a trained researcher undertaking all aspects of the study. If there are any contraindications individuals will not participate and their GP will be informed. All clinic measurements are carried out by qualified members of the research team. Some people experience minor discomfort and slight bruising during blood tests. A fully qualified research team member will carry out the blood test to ensure any pain is kept to a minimum. If 'abnormal' blood results are found, participant's GPs will be contacted so that they can investigate further.

Where is the study run from?
Leicester Diabetes Research Centre (UK)

When is the study starting and how long is it expected to run for?
February 2017 to January 2020

Who is funding the study?
1. East Midlands Academic Health Science Network (UK)
2. National Institute for Health Research (UK)
3. National Institutes of Health (USA)

Who is the main contact?
Dr Louisa Herring
PACES@uhl-tr.nhs.uk

Previous plain English summary:
Background and study aims
Coronary heart disease (CHD), also known as ischemic heart disease, is one of the leading causes of death worldwide. CHD develops because of the build-up of fatty deposits (plaque) on the walls of the coronary arteries (the arteries that supply the heart with oxygen-rich blood). When arteries are blocked or narrowed, the heart does not receive enough blood to function properly, which can lead to a cardiac event such as a heart attack. After experiencing one cardiac event, the risk of experiencing one again is increased unless there is intensive management of risk factors such as physical activity, smoking, diabetes, hypertension (elevated blood pressure levels), hyperlipidaemia (elevated fat levels in the blood) and obesity. This usually involves being offered a structured education and exercise programme of cardiac rehabilitation, after which risk factor management is done by a GP. The aim of this study is to look at the effectiveness of an education programme with text messaging support for increasing physical activity, specifically walking, in individuals who have had a cardiac event in the past 12 to 36 months.

Who can participate?
Adults who have had a cardiac event 12-36 months ago.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive usual care, which involves being given general health advices in the form of a standard information leaflet and will be returned to standard care delivered by their GP. Those in the second group also receive the standard information leaflet as well as being invited to take part in two group-based structured education sessions. These education sessions are delivered by trained facilitators approximately two weeks apart. Following this, participants receive regular text messages providing support for a year. Participants in both groups have their physical activity levels assessed at the start of the study and then again after six and 12 months.

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Contact information

Type(s)
Scientific

Contact name
Dr Louisa Herring

Contact details
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LE5 4PW
+44 1162 588964
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Additional identifiers

Protocol serial number
32603

Study information

Scientific Title
Developing and evaluating an education programme aimed at increasing physical activity in individuals with diagnosed coronary heart disease: a randomised controlled trial

Study objectives
Current study hypothesis as of 13/02/2019:
The aim of the study is to implement an acceptable and cost-effective education programme with text message support and to test the effectiveness of this programme for increasing total daily physical activity, specifically walking activity measured using accelerometry, in individuals 12 to 48 months after diagnosis of a cardiac event.

Previous study hypothesis:
The aim of the study is to implement an acceptable and cost-effective education programme with text message support and to test the effectiveness of this programme for increasing total daily physical activity, specifically walking activity measured using accelerometry, in individuals 12 to 36 months after diagnosis of a cardiac event.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - Solihull Research Ethics Committee

Study design
Randomised; Interventional; Design type: Treatment, Prevention, Education or Self-Management, Psychological & Behavioural, Complex Intervention

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Diabetes, Primary sub-specialty: Both; UKCRC code/ Disease: Cardiovascular/ Other forms of heart disease

Interventions
Eligible participants will be randomised, apart from those in the same household, using a block design and stratified by gender (men; women), and ethnicity (White European; other) to one of two groups.

Control group: Participants will be provided with general health advice in the form of a British Heart Foundation standard information leaflet and will be returned to standard care delivered by their general practitioner.

Intervention group: Participants will receive the British Heart Foundation standard information leaflet and will be invited to attend two group-based structured education sessions. Theses education sessions will be delivered by trained facilitators approximately two weeks apart and will receive subsequent reinforcement via text message support thereafter (section 3.2). These structured education sessions have been developed and refined in conjunction with PPI work and through the use of existing infrastructure consisting of Diabetes Education and Self-Management in on-going and Newly Diagnosed (DESMOND) groups and a network of trained facilitators. The participants will receive 82 physical activity related text messages at different weekly frequencies following the second education session to the 12 month follow-up assessment.

Participants in both groups will be followed up after 6 and 12 months.

Intervention Type
Other

Primary outcome(s)
Average daily physical activity is assessed using an accelerometer (Average daily physical activity - Milligravities [mg]) worn for eight days at baseline, 6 and 12 months.

Key secondary outcome(s))
1. Aerobic fitness is assessed using an Incremental Shuttle walk test (metres) at baseline and 12 months
2. Anthropometric measures of height, body mass, BMI, waist circumference, hip circumference and waist to hip ratio are measured using standard techniques at baseline and 12 months
3. Blood pressure (mmHg) & resting heart rate (bpm) are measured using standard techniques at baseline and 12 months
4. Lipid profile (Cholesterol, HDL, LDL, Triglycerides) is measured via venepuncture at baseline and 12 months
5. HbA1c (mmol/mol, %) is measured via venepuncture at baseline and 12 months
6. Self-efficacy for exercise expectations is measured using the Jenkins self-efficacy for exercise expectations scale at baseline, 6 and 12 months
7. Anxiety and depression is measured using the Hospital Anxiety and Depression scale (HADS) at baseline, 6 and 12 months
8. Self-reported physical activity is measured using the Recent Physical Activity Questionnaire (RPAQ) at baseline, 6 and 12 months
9. Quality of life is measured using the EuroQoL EQ-5D-5L at baseline, 6 and 12 months
10. Chronotype is measured using the Morningness- Eveningness Questionnaire at baseline, 6 and 12 months
11. Biomarkers of inflammation, proteomics, metabolomics and novel markers of cardiovascular health are measured via venepuncture at baseline and 12 months
The following secondary outcome measure was added on 13/02/2019:
12. Health service use data at 12 months using routinely used questions (approved by a health economist) is collected annually for 5 years using GP, hospital records and/ or NHS Digital.

Completion date
02/01/2020

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 13/02/2019:
1. Aged 18 years or older
2. 12-48 months post confirmed diagnosis of a cardiac event (myocardial infarction, angina or acute coronary syndrome)
3. Able to speak and read English to participate effectively in a group education programme
4. Willing and able to attend the education sessions and clinic visits
5. Willing and able to give informed consent
6. Access to a mobile phone in order to receive text messages
7. Willingness to allow GP notification of their participation in study and access to patient records for purpose of study
8. Able to take part in moderate physical activity as assessed using Incremental Shuttle Walk Test (ISWT) (Level three or above)

Previous participant inclusion criteria:
1. Aged 18 years or older
2. 12-36 months post confirmed diagnosis of a cardiac event (myocardial infarction, angina or acute coronary syndrome)
3. Able to speak and read English to participate effectively in a group education programme
4. Willing and able to attend the education sessions and clinic visits
5. Willing and able to give informed consent
6. Access to a mobile phone in order to receive text messages
7. Willingness to allow GP notification of their participation in study and access to patient records for purpose of study
8. Able to take part in moderate physical activity as assessed using Incremental Shuttle Walk Test (ISWT) (Level three or above)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
291

Key exclusion criteria
1. Individuals with a diagnosis of heart failure where the underlying primary cause is not myocardial disease as a result of atherosclerosis will be excluded from this study
2. Musculoskeletal limitations that would limit physical activity (e.g. musculoskeletal injury)
3. Participation in another clinical intervention study in the past 12 weeks
4. Lacks capacity to give informed consent

5. Severe life-threatening co-morbidity (e.g. malignancy)
6. Poor exercise capacity, (< level three on the ISWT [120 metres]), these individuals will be directed back into cardiac rehabilitation (good practice)
7. Housebound or immobile
8. Unstable symptoms (chest pain or breathlessness at rest; unstable stage II hypertension [160 /100mmHg], not on necessary medications)
9. Individuals with no or limited understanding of written or verbal English

Date of first enrolment
14/03/2017

Date of final enrolment
30/09/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leicester Diabetes Research Centre
Leicester General Hospital
Gwendolen Road
Leicester
United Kingdom
LE5 4PW

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Government

Funder Name
East Midlands Academic Health Science Network

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
National Institutes of Health

Alternative Name(s)
US National Institutes of Health, Institutos Nacionales de la Salud, NIH, USNIH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

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?
Results article	results	01/02/2021	01/03/2021	Yes	No
Protocol article	results	04/10/2018		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan	version V1.0	20/03/2019	24/04/2020	No	No