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Movement as medicine for cardiovascular disease prevention

Submission date	Recruitment status	[X] Prospectively registered
29/08/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/10/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/06/2022	Circulatory System	

Plain English summary of protocol

Background and study aims:
Research has demonstrated that physical activity has a clear protective effect on cardiovascular disease (CVD). What is not well understood is how best to support people who are at increased risk of cardiovascular disease to become more physically active and maintain this over time. This study aims to find out whether the use of structured support provided by healthcare professionals in primary care is feasible, acceptable and effective for increasing levels of physical activity in patients with increased risk of CVD.

Who can participate?
All primary care organisations within County Durham and Darlington will be invited to take part in the study. Patients aged 18 years or over who have been identified as at increased risk of cardiovascular disease or as 'inactive' or 'moderately inactive' in a recent NHS Health Check.

What does the study involve?
All primary care organisations in the County Durham and Darlington region are invited to take part in the study. Healthcare professionals are given access to the online intervention which comprises 11 distinct yet inter-related modules on topics such as physical activity and sedentary behaviour in relation to CVD, and the processes involved in behaviour change. The course aims to equip healthcare professionals working in primary care with knowledge and skills to deliver a behavioural intervention designed to increase levels of physical activity of their patients. Patients have three conversations (one face-to-face and two via telephone) of up to 30 minutes each with their healthcare professional at the start of the study (baseline), and after 2 and 4 months. They are also provided with access to an online behaviour change 'toolkit'. This website provides them with information on physical activity, but also tools for them to set physical activity goals, plans and monitor their progress.

What are the possible benefits and risks of participating?
The time taken for the healthcare professionals to complete the online intervention, the survey questionnaires and participate in interviews as well as delivering the intervention could be considered burdensome. However, the knowledge and skills potentially gained following successful completion of the intervention are considered to outweigh the burden of taking part. Additionally, professionals receive CPD credit for completing the intervention. The time taken

for the patients to have additional consultations with their healthcare professional, complete paper-based survey questionnaires and wear an accelerometer for 7 days during each data collection time point (baseline, 3 and 6 months) may be considered burdensome. However, the potential benefits the patients may experience if they increase their physical activity are anticipated to outweigh the burden of taking part and any inconvenience encountered.

Where is the study run from?
The study is run by Newcastle University; however, it will be carried out in primary care organisations across the County Durham and Darlington region.

When is the study starting and how long is it expected to run for?
June 2014 to June 2015

Who is funding the study?
County Durham Sport

Who is the main contact?
Dr Mike Trenell
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Feasibility, acceptability and effectiveness of a multi-faceted behavioural intervention targeting levels of physical activity in adults at increased risk of cardiovascular disease in primary care: movement as medicine for cardiovascular disease prevention

Study objectives
A theory-based behavioural intervention will be more effective than standard clinical care for impacting positively on levels of free living physical activity on risks of developing cardiovascular disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North East - Newcastle & North Tyneside 1, 25/03/2014, 14/NE/0062

Study design
One-group exploratory trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Increased risk of cardiovascular disease

Interventions
Current interventions as of 27/05/2014:
A theory-based accredited online training programme for primary care practitioners. An online toolkit consisting of physical activity promotion materials, activity planners and trackers and a pedometer for patients. Patients will have three conversations (one face-to-face and two via telephone) of up to 30 minutes each with their healthcare professional at baseline, 2 and 4 months.

Previous interventions:
A theory-based accredited online training programme for primary care practitioners and a toolkit physical activity promotion materials, activity planners and trackers and a pedometer.

Intervention group: Patients will attend face to face review appointments over a 12-month period (baseline, 1, 6 and 12 months) where they will be supported using the toolkit to increase their levels of physical activity.
Control group: Standard clinical care.

Both the intervention and control group will receive a telephone call at 3 months.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 27/05/2014:
Primary care practitioners:
Use of behaviour change techniques and counselling skills

Patients:
Engagement in the programme

Previous primary outcome measures:
Primary care practitioners:
Use of behaviour change techniques and counselling skills

Patients:
Objectively and subjectively assessed physical activity behaviour

Secondary outcome measures
Current secondary outcome measures as of 27/05/2014:
Primary care practitioners:
1. Cardiovascular disease and physical activity-related knowledge and attitudes/beliefs
2. Self-efficacy for delivering physical activity-related counselling to adults at increased cardiovascular disease risk
3. Use of online course materials

Patients:
1. Theoretical predictors of physical activity
2. Sedentary behaviour patterns
3. Use and evaluation of intervention materials

Previous secondary outcome measures:
Primary care practitioners:
1. Cardiovascular disease and physical activity-related knowledge and attitudes/beliefs
2. Self efficacy for delivering physical activity-related counseling to adults at increased cardiovascular disease risk

Patients:
1. Cholesterol
2. Blood pressure
3. Body mass index (BMI) and waist circumference

4. Cardiovascular disease and physical activity related knowledge and attitudes / beliefs
5. Physical activity related self efficacy
6. Health-related quality of life
7. Sedentary behaviour patterns
8. Achievement of physical activity goals

Overall study start date
01/06/2014

Completion date
01/06/2015

Eligibility

Key inclusion criteria
Current inclusion criteria as of 27/05/2014:
1. Age between 18-75 years
2. Have the capacity to provide informed written consent
3. Able to read, speak and understand English without the support of an interpreter
4. Have access to the internet and therefore all intervention materials
5. Deemed fit to partake in physical activity/exercise by the Physical Activity Readiness Questionnaire (PAR-Q)
6. Have been identified as physically inactive with the General Practice Physical Activity Questionnaire (GPPAQ) during an NHS Health Check OR identified as having at least a 20% risk of CVD in the next 10 years

Previous inclusion criteria:
1. Adults aged ≥18 years
2. Identified to be at increased cardiovascular disease risk
3. Physical activity/ exercise is below recommendations (i.e. 30 minutes per day three times per week)
4. Capacity to provide informed consent
5. Ability to write and converse in English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants

200

Total final enrolment
83

Key exclusion criteria
Contra-indications to performing physical activity

Date of first enrolment
01/06/2014

Date of final enrolment
01/12/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newcastle University
Newcastle Upon Tyne
United Kingdom
NE2 4HH

Sponsor information

Organisation
Newcastle Upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Current sources of funding as of 27/05/2014:

Funder Name
County Durham Sport (UK)

Funder Name
Previous sources of funding:

Funder Name
County Durham and Darlington Primary Care Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/06/2022	30/06/2022	Yes	No
HRA research summary			28/06/2023	No	No