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A randomised controlled trial of the efficacy and cost-effectiveness of a very brief intervention to increase physical activity when delivered in a primary care setting

Submission date
17/07/2014

Recruitment status
No longer recruiting

Registration date
17/07/2014

Overall study status
Completed

Last Edited
01/07/2020

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Not doing enough physical activity is the 4th leading cause of preventable vascular diseases such as diabetes and heart disease and in the UK it represents a direct and indirect cost to society of £8.2 billion. GP and nurse/healthcare assistant consultations have been identified as the most effective place to give physical activity advice but time and resources are a limiting factor. There is therefore a need to develop interventions that are brief but effective at promoting an increase in physical activity. We have developed and tested several promising very brief interventions (VBI) lasting about 5 minutes and this trial will test the best of these during routine NHS Health Checks. We want to see whether a short intervention will encourage people to be a little more active.

Who can participate?
Participants are able to take part in the study if they are between 40 and 74 years old, have not already been diagnosed with any vascular disease, their GP surgery is taking part and they have received a study invitation.

What does the study involve?
During the NHS Health Check participants will be randomly allocated to receive either the NHS Health Check on its own or to receive the Health Check with the very brief intervention (VBI). The VBI includes a discussion on the physical activity recommendations and how the patient might increase their physical activity by encouraging the use of a pedometer to count steps and to set a plan for making small increases. All participants will complete a short questionnaire and participants receiving the VBI will be encouraged to take the material home. Three months following the Health Check all participants will be asked to wear an accelerometer (a small device that detects and measures movement) for 1 week and complete two questionnaires. We also wish to obtain the 10-year vascular risk score of all participants. This information along with the rest of the information collected will help us understand why some people increase their physical activity more than others.

What are the possible benefits and risks of taking part?
The NHS Health Checks measure the 10-year risk of developing vascular disease and so taking part can improve a participants health. There are no major risks to taking part in the trial. The VBI has been designed to encourage an increase in activities such as brisk walking, swimming and cycling which carry only a small risk of harm.

Where is the study run from?
The participants are recruited from 23 surgeries in the East of England.

When is the study starting and how long is it expected to run from?
It is expected that recruitment will start in the summer of 2014 and complete at the end of 2015. A participants total length of involvement will be about 3 1/2 months.

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Chief Investigator: Professor Stephen Sutton, srs34@medschl.cam.ac.uk
Trial Coordinator: Ms Jo Mitchell, jm294@medschl.cam.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
16952

Study information

Scientific Title
A randomised controlled trial of the efficacy and cost-effectiveness of a very brief intervention to increase physical activity when delivered in a primary care setting

Acronym

VBI

Study objectives
Do patients increase their levels of Physical Activity (PA) in the short term as a result of receiving a Very Brief Intervention (VBI) to promote PA during a routine NHS Health Check?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire Research Ethics Committee, 14/EE/1004

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Prevention

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Topic: Primary Care; Subtopic: Not Assigned; Disease: All Diseases

Interventions
The NHS Health Check is an assessment of a patients' 10-year risk of developing vascular disease. The treatment group will have this assessment as well as the VBI. The VBI includes a discussion on the physical activity recommendations and how the patient might increase their physical activity by encouraging the use of a pedometer to count steps and to set a plan for making small increases. The VBI lasts a maximum of 5 minutes and is given at the end of the NHS Health Check. All participants are sent an accelerometer and questionnaires months following the Health Check.
Step It Up: The Pedometer Intervention will be delivered at the end of the Health Check and consists of the following three components:
Face-to-face discussion in which the practitioner:
1. Gives the patient feedback on their current activity
2. Gives information about the current physical activity recommendations (30 minutes of moderate-intensity activity on 5 or more days a week OR 10,000 steps per day)
3. Shows the patient how to wear/use the pedometer and encourages them to use it to monitor t;

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Physical activity at 3-month follow-up, as measured by accelerometer counts p

Key secondary outcome(s)

Not provided at time of registration

Completion date
31/12/2015

Eligibility

Key inclusion criteria
Participants will be adults aged 40-74 who are eligible to be invited for a NHS Health Check and who are able to give consent for participation in the trial.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
1007

Key exclusion criteria
The GP practice will exclude patients they consider unsuitable for the trial (i.e., any patient where receiving an invitation will cause unnecessary stress due to mental health issues or a diagnosis of terminal illness for example)

Date of first enrolment
01/08/2014

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Institute of Public Health
Cambridge
United Kingdom
CB2 2SR

Sponsor information

Organisation
University of Cambridge (UK)

ROR
https://ror.org/013meh722

Funder(s)

Funder type
Government

Funder Name
NIHR Programme Grants for Applied Research (UK); Grant Codes: RP-PG-0608-10079

Results and Publications

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?
Results article	results	23/05/2016		Yes	No
Results article	results	06/03/2020	01/07/2020	Yes	No
HRA research summary			26/07/2023	No	No