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Potential efficacy, fidelity, feasibility and acceptability of techniques to promote physical activity for use in very brief interventions in primary care

Submission date
03/10/2012

Recruitment status
No longer recruiting

Registration date
05/10/2012

Overall study status
Completed

Last Edited
10/10/2016

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Physical activity can delay or prevent chronic diseases such as vascular disease, which includes heart disease, stroke, diabetes and kidney disease. The majority of adults in England do not meet the government recommendation of at least 30 minutes per day of moderate-intensity activity on at least five days per week. The NHS is conducting Health Checks, in which everyone between 40 and 74 years is invited for an assessment of their risk of vascular disease and offered appropriate management of risk. The Health Checks are an ideal opportunity to deliver brief interventions to promote physical activity to large numbers of people. The present study forms part of a larger programme of on-going (and inter-related) research, funded by an NIHR Programme Grant, which aims to develop and evaluate very brief interventions to increase physical activity in primary care. In the present study we will test several brief interventions which aim to promote physical activity that could be delivered by a practice nurse or health care assistants (HCA) in five minutes during a Health Check consultation. It is anticipated that the findings of the present study will indicate what intervention should be selected (out of the several brief interventions piloted in the present study) to be taken forward for robust evaluation in a larger study.

Who can participate?
Adults aged 40-74 who are invited for an NHS Health Check (The NHS Health Checks are designed for adults who have not been previously diagnosed with vascular disease).

What does the study involve?
In Phase 1, the nurse (or HCA) will pilot each intervention within the Health Check consultation. The consultations will be audio-taped to check fidelity to the intervention protocol and the time taken to deliver the intervention. Participants will be interviewed immediately after the consultation by a researcher to assess the acceptability of the intervention. In Phase 2, the nurse (or HCA) will deliver 1 intervention per week (these will be refined and modified based on the findings of Phase 1). Feasibility, fidelity and acceptability will be assessed as in Phase 1 using

audio-tapes of consultations and interviews with the nurses/HCAs and a random sample participants. The outcome measures, assessed at 4 weeks (post intervention), will be objective physical activity (assessed by accelerometers), self-reported physical activity and relevant mediators.

What are the possible benefits and risks of participating?
Physical activity can delay or prevent chronic diseases such as vascular disease (which includes heart disease, stroke, diabetes and kidney disease). By providing patients with advice on how to become more active, they could improve their health. The potential risks to participants in this study will be negligible. The interventions used in the study are behaviour change interventions that aim to encourage moderate physical activity such as brisk walking which carries a very low risk of injury.

Where is the study run from?
The Primary Care Unit, University of Cambridge (UK)

When is study starting and how long is it expected to run for?
October 2012 to December 2013

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
13157

Study information

Scientific Title
Potential efficacy, fidelity, feasibility and acceptability of techniques to promote physical activity for use in very brief interventions in primary care: a feasibilty study

Study objectives
The objective of this research is to test several brief interventions which aim to promote physical activity, that could be delivered by a practice nurse (PN) or healthcare assistant (HCA) in five minutes during a Health Check consultation. Initially, the interventions will be piloted in a small number of practices in order to assess their feasibility, acceptability and fidelity, via recordings of consultations and through interviews with PNs (or HCAs) and participants. Following this, the interventions will be tested in a randomised controlled trial whereby PNs (or HCAs) will deliver different interventions to participants within the Health Checks, in order to determine whether these brief interventions increase participants physical activity levels four weeks after the Health Check. It is anticipated that the findings of the present study will indicate what intervention should be selected (out of the several brief interventions piloted in the present study) to be taken forward for robust evaluation in a larger explanatory trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridge Central, 25/04/2012, ref: 12/EE/0200

Primary study design
Interventional

Study design
Both; Interventional; Design type: Prevention

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Promoting physical activity

Interventions
Phase 1:
Participants will receive usual care for NHS Health Check PLUS one of four brief behaviour change interventions for increasing physical activity:
1. Brief motivational intervention OR
2. Action-planning intervention OR
3. Pedometer intervention OR
4. Activity diary (self-monitoring) intervention

Phase 2: (Up to) Eight groups to be compared
Control Group: Participants will receive usual care for NHS Health Check

Intervention Group: Participants will receive usual care for NHS Health Check PLUS one of (up to) seven brief behaviour change interventions to increase physical activity:
1. Brief motivational intervention OR

2. Action-planning intervention OR
3. Pedometer intervention OR
4. Activity diary (self-monitoring) intervention OR
5-7 A combination of intervention

Intervention Type
Behavioural

Primary outcome(s)
Phase 1
Fidelity of the intervention delivery by the PN (or HCA) e.g. adherence to protocol, competency

Key secondary outcome(s)
Phase 2
Physical activity (assessed by self-report questionnaire and accelerometer counts per day)

Completion date
01/10/2013

Eligibility

Key inclusion criteria
Participants will be adults aged 40-74 who are invited for an NHS Health Check (The NHS Health Checks are designed for adults who have not been previously diagnosed with vascular disease).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
As this study is a feasibility trial to pilot and test several interventions, participants who do not have a working knowledge of English (and thus cannot participate in an interview without the aid of a translator) will also be excluded from the study.

Date of first enrolment
17/09/2012

Date of final enrolment
01/10/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Primary Care Unit
Cambridge
United Kingdom
CB2 0SR

Sponsor information

Organisation
University of Cambridge (UK)

ROR
https://ror.org/013meh722

Funder(s)

Funder type
Government

Funder Name
NIHR (UK) - Central Commissioning Facility (CCF)

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	08/04/2015		Yes	No
Results article	results	30/09/2016		Yes	No

Other publications	erratum	17/11/2015	Yes	No