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Sheffield physical activity booster trial

Submission date 12/02/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/02/2009	**Overall study status** Completed	
Last Edited 11/05/2016	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Adults who increase their physical activity can improve their health and reduce future risks to health, but long-term changes are difficult to sustain. This study assesses whether it is worth providing further support, 3 months after giving initial advice, to those who have managed to do more physical activity. The research will be carried out in 20 of the most deprived neighbourhoods in Sheffield. These locations have large, ethnically diverse populations, high levels of economic deprivation, low levels of physical activity, poorer health and shorter life expectancy. Participants will be recruited through general practices and community groups, as well as by postal invitation to ensure the participation of minority ethnic groups and those with lower levels of literacy.

Who can participate?
Residents of the 20 most deprived neighbourhoods in the city of Sheffield, aged 40 to 64, who are not achieving the current recommended activity level.

What does the study involve?
All participants are initially given an interactive DVD. A researcher contacts them twice at one month intervals to assess their physical activity levels. Only those who have increased their physical activity at this point remain in the study. These participants are randomly allocated to receive either a "mini booster", a "full booster" or no booster. The "mini booster" consists of a two telephone calls one month apart to discuss physical activity and usage of the DVD. A "full booster" consists of a face-to-face meeting with the facilitator at the same intervals. The purpose of these booster sessions is to help participants to maintain their increase in physical activity. After 3 and 9 months we measure the differences in physical activity, quality of life and costs associated with the booster interventions.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University of Sheffield (UK)

When is the study starting and how long is it expected to run for?
April 2009 to March 2013

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
Dr Elizabeth Goyder
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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
NCT00836459

Secondary identifying numbers
HTA 07/25/02; 120243

Study information

Scientific Title
A randomised controlled trial and cost-effectiveness evaluation of "booster" interventions to sustain increases in physical activity in middle-aged adults in deprived urban neighbourhoods

Acronym
Booster Study

Study objectives
This study assesses whether it is worth providing further support, 3 months after giving initial advice, to those who have managed to do more physical activity.

Further details can be found at: http://www.nets.nihr.ac.uk/projects/hta/072502
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0005/51746/PRO-07-25-02.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
North Sheffield Local Research Ethics Committee, approval pending as of 12/02/2009

Study design
Open-label parallel-group randomised controlled single-centre trial, with a feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Physical activity levels in middle-aged adults

Interventions
The participants will be individually randomised to the following three arms:
1. Mini Booster: Two telephone-based physical activity consultations, delivered in a motivational interviewing style, at one month and two months from randomisation. Duration of treatment 2 months, duration of follow-up 9 months.
2. Full Booster: Two face-to-face physical activity consultations, delivered in a motivational interviewing style, at one month and two months from randomisation. Duration of treatment 2 months, duration of follow-up 9 months.
3. Control: No Intervention. Duration of follow-up is 9 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Physical activity measured by 7-day accelerometric assessment (recoded as counts per week) at 3 months post-randomisation.

Secondary outcome measures
1. Physical activity measured by 7-day accelerometric assessment (recoded as counts per week) at 9 months post-randomisation
2. Self-reported moderate or strenuous physical activity using the SSPAQ (incorporating Stage of Change information) which records type and duration of activities in the previous week (at 3 and 9 months post randomisation)
3. Health-related quality of life using the Sheffield Version SF-12v2 plus 4 survey instrument (at 3 and 9 months post randomisation)
4. Self-reported use of community facilities for physical activity (at 3 and 9 months post randomisation)
5. Self-reported health and social care contacts (at 3 and 9 months post randomisation)
6. Psychological measures of motivation, intentions, attitudes, beliefs, social influences and self-efficacy towards physical activity, measured using the Theory of Planned Behaviour. Exercise stages of change, and self-determination will be assessed using Behavioural Regulation in Exercise Questionnaire (BREQ-2) (at 3 and 9 months post randomisation)

Overall study start date
01/04/2009

Completion date
31/03/2013

Eligibility

Key inclusion criteria
1. Residents of the 20 most deprived neighbourhoods in the city of Sheffield
2. Both males and females, aged 40 to 64 years
3. Not achieving the current recommended activity level (30 mins of moderate activity on at least 5 days) assessed using the Scottish Physical Activity Questionnaire (SPAQ) and wishing to have support to become more active

Participant type(s)
Other

Age group
Adult

Sex
Both

Target number of participants
600

Key exclusion criteria

1. Have increased their physical activity level by at least 30 mins of moderate or vigorous activity per week (assessed using the SPAQ) since initial assessment of activity level
2. Capacity to give written informed consent to trial participation

Date of first enrolment
01/04/2009

Date of final enrolment
31/03/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Sheffield
Sheffield
United Kingdom
S1 4DA

Sponsor information

Organisation
University of Sheffield (UK)

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Research Office
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Sponsor type
University/education

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

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
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	04/01/2010		Yes	No
Results article	results	01/02/2014		Yes	No
Results article	results	24/02/2016		Yes	No