

Sheffield physical activity booster trial

Submission date 12/02/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 16/02/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/05/2016	Condition category Other	<input type="checkbox"/> Individual participant data

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

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00836459

Protocol serial number
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

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

University of Sheffield

Sheffield

United Kingdom
S1 4DA

Sponsor information

Organisation

University of Sheffield (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, Health Technology Assessment (HTA), HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2014		Yes	No

Results article	results	24/02/2016	Yes	No
Protocol article	protocol	04/01/2010	Yes	No