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Booster Study

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.

RESEARCH PROTOCOL
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Authorised by:	**Liddy Goyder**

Sheffield Clinical Trials Research Unit (CTRU)

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.

Booster Activity Trial

This document describes a clinical trial, and provides information about procedures for entering participants. The protocol is not intended for use as a guide to the treatment of other patients. Amendments may be necessary; these will be circulated to known participants in the trial.

Contents

Abbreviations

A&E	Accident and Emergency
ANCOVA	Analysis of Covariance
BMI	Body Mass Index
BREQ-2	Behavioural Regulation in Exercise Questionnaire
CONSORT	Consolidated Standards of Reporting Trials
CI	Confidence Interval
CTRU	Clinical Trials Research Unit
DMEC	Data Monitoring and Ethics Committee
EXERT	Exercise Evaluation Randomised Trial
GCP	Good Clinical Practice
HRQoL	Health Related Quality of Life
HTA	(National Institutes for Health Research) Health Technology Assessment programme
IMD	Index of Multiple Deprivation
MI	Motivational Interviewing
NICE	National Institute for Health and Clinical Excellence
QALY	Quality-Adjusted Life Year
RA	Research Assistant
ScHARR	School of Health And Related Research
SD	Standard Deviation
SF-12v2 plus 4	16-item Short Form Health Survey of the Medical Outcomes Study
SF-6D	Short Form Health Survey – 6 Dimensions
SMART	Specific, Measurable, Achievable, Realistic, Time-related goals
SPAQ	Scottish Physical Activity Questionnaire
TMG	Trial Management Committee
TSC	Trial Steering Committee
TTM	Trans-Theoretical Model

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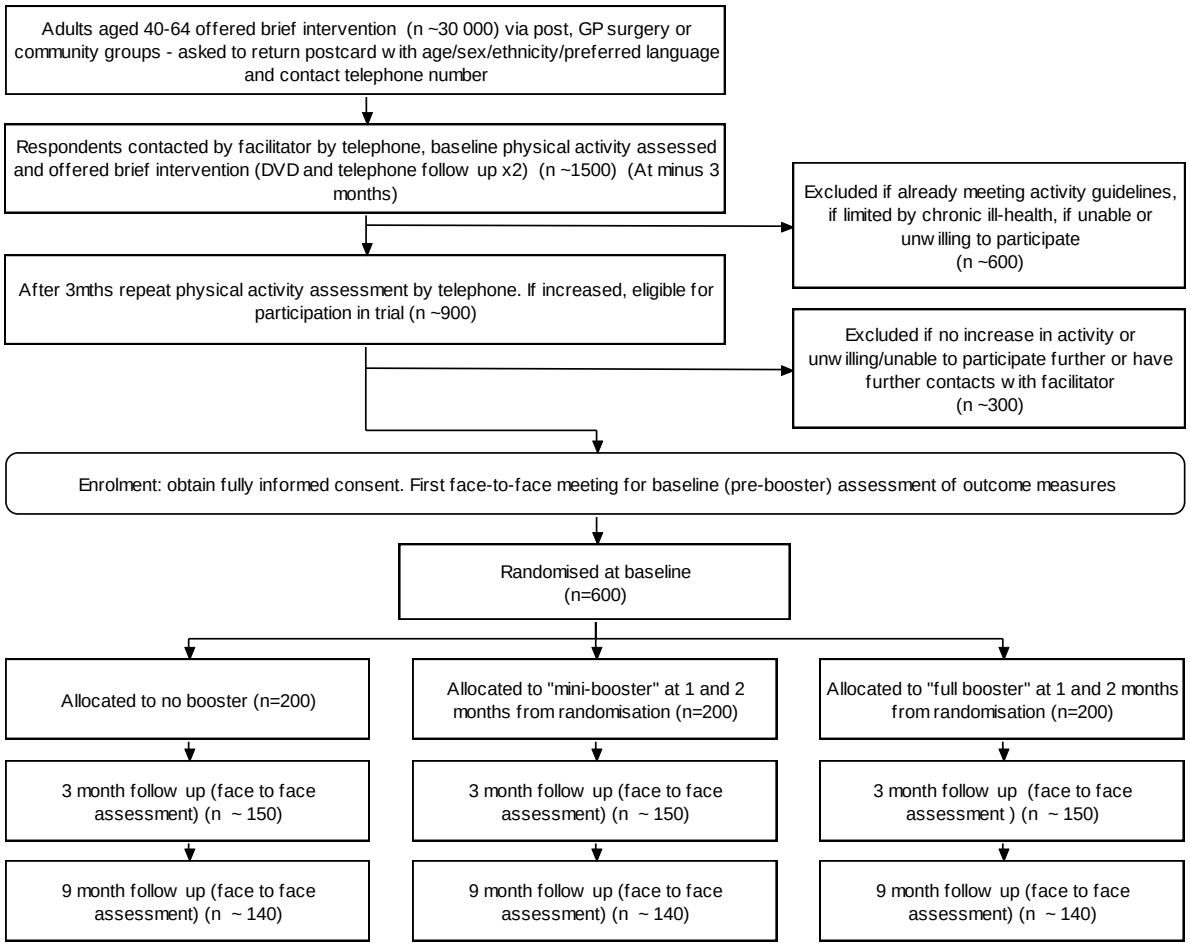
Trial Summary

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. All participants will initially be given an interactive DVD, supported by advice from a trained facilitator. The facilitator will provide two telephone follow ups at one month intervals. Only those that have increased their physical activity at this point will remain in the study. These participants will receive 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 the individual to maintain their increase in physical activity. We will measure the differences in physical activity, quality of life and costs, associated with the booster interventions, 3 months and 9 months from randomisation. 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. Sheffield City Council and Primary Care Trust fund a range of facilities and activities to promote physical activity and variations in access to these between neighbourhoods will make it possible to examine whether the effectiveness of the intervention is modified by access to community facilities.



1. Introduction

Rationale

There are a number of published systematic reviews of evidence for interventions that increase physical activity (Hillsdon et al, 2005; Eaton and Menard, 1998; Lawlor and Hanratty, 2001; Kahn et al, 2002; Humpel et al, 2002). More recently the evidence base for brief interventions in primary care has been reviewed (NICE, 2006). This review identified a sufficient evidence base for NICE to recommend the use of brief interventions to promote physical activity but also identified specific evidence gaps that this trial will be able to address, particularly in relation to the value of follow up beyond three months, for the longer term maintenance of physical activity.

Searches of the National Research Register and ClinicalTrials.gov for research in progress confirm that although there are a number of physical activity intervention trials in progress in specific patient groups and in older age groups or in children, there are few trials including “healthy” middle-aged participants and no other trials specifically examining the value of further intervention after an initially successful “brief intervention”.

Investigational interventions

The trial will compare a "mini booster" of two telephone physical activity consultations and a "full booster" of two face-to-face physical activity consultations, offered four and five months after an initial brief intervention, to a standardised three month brief intervention alone. The purpose of these booster sessions is to help participants to sustain their physical activity levels and prevent relapse. The brief intervention will involve provision of an interactive DVD based on a MI approach that is directive, client-centred and replicates the style of other successful behaviour change programmes (Miller and Sovereign, 1989; Schippers, Brokken and Otten, 1994). All interventions, including the initial brief intervention, will be delivered by trained facilitators (employed as research assistants and trained by the research team) to ensure consistent delivery.

Theoretical underpinning of interventions

Meta-analytical and systematic reviews of physical activity and behaviour change (Marcus & Forsyth, 2003; Marshall & Biddle, 2001) suggest that the transtheoretical model (TTM) (Prochaska & DiClemente, 1983) is the most commonly adopted theoretical framework for promoting physical activity. The TTM has demonstrated effectiveness as an approach to increasing exercise adoption and adherence in adults (Marshall & Biddle, 2001; Nigg & Courneya, 1998; Prochaska & Marcus, 1994; Woods, Mutrie, & Scott, 2002). The TTM (Prochaska & DiClemente, 1983; Prochaska, DiClemente & Norcross, 1992; Prochaska & Velicer, 1997) describes how people modify problem behaviours or acquire positive new ones. The TTM determines behaviour change as a process rather than a single event and offers practical suggestions for how individuals can change behaviour. The TTM consists of the following constructs: stages of change (describes when people change), processes of change (outlines techniques for helping people to change), decisional balance (weighing up the pro's and con's of change) and self-efficacy (increasing one's confidence to change behaviour) (Prochaska & DiClemente, 1983). The TTM offers practitioners a common, validated framework for guiding participants through periods of change and proposes strategies for maintaining positive behaviours. We will also adopt a client centred approach to all interventions based upon the style of motivational interviewing.

Motivational Interviewing and its use in promoting physical activity: Motivational interviewing (MI) is a directive, client-centred counselling style for eliciting behaviour change by helping clients to explore and resolve ambivalence (Rollnick & Miller, 1995). Motivational interviewing has been used in many settings and ethnic groups and meta-analysis suggests effect sizes from motivational interviewing-based interventions are larger in ethnic minority populations (Hettema et al, 2005). A MI approach has been shown to impact positively on lifestyle and health outcomes including physical activity behaviours in adults (Berg-Smith et al, 1999; Bennett, 2007; Knight, 2006; Hettema, Steele & Miller, 2005; Britt, 2003). MI has been applied in a number of formats including technology-based, such as internet and video (Atkinson & Gold, 2002; Hester, Squires & Harold, 2005; Miller and Sovereign, 1989; Schippers, Brokken and Otten, 1994), telephone (Stotts, DiClemente & Dolan-Mullen, 2002) and face-to-face consultations (Bennett et al, 2007). An example of a technology-based intervention adopting an MI approach is The Drinker's Check-up (Hester, Squires & Harold, 2005; Miller and Sovereign, 1989; Schippers, Brokken and Otten, 1994). The Drinker's Check-up offers a comprehensive assessment of the client's drinking and related behaviours. A key element of the programme is providing feedback that matches the user's individual circumstances, motivational readiness and confidence for changing their behaviour.

Justification of use of interactive DVD: The use of video format in the promotion of physical activity has been shown to increase self-reported physical activity (Tate, 2001; Tate, 2003; Pinto, 2002), positively influence user engagement and self-efficacy and yield health benefits in low-income populations (Campbell, 1994; Skinner, 1999). Survey data (Mintel, 2007) reveals that at least 80% of adults aged 35-64 own a DVD player. Furthermore, 84% of households classified as 'hard pressed' (which includes: inner city adversity, high rise hardship, burdened singles, struggling families, ACORN classification, 2007) own a DVD player. The DVD clearly represents an opportunity to reach a wide audience, at relatively low cost, using a medium that is familiar and accessible. We will ensure participants without home access to a DVD player have community access by arranging that DVD players are provided and accessible in community venues including neighbourhood centres, libraries and GP surgeries. The content of the DVD has already been developed based on existing materials already used for face-to-face interventions and the first phase of the trial will include translation, production, and piloting of the DVD. This potentially offers a very cost-effective way to promote change and utilises technology that will already be familiar to most participants. Practical support with using the DVD will also be available from local library staff in libraries where the DVD can be played on public access computers.

Content of the Brief Intervention (Interactive DVD and telephone follow up)
Consistent with NICE guidance on physical activity interventions (NICE, 2006), the brief intervention will aim to help middle age adults consider, initiate and maintain physical activity behaviours. The DVD represents an interactive tool that is based on the style of motivational interviewing and the principles of the TTM. The DVD offers individuals the opportunity to choose information on the following: the benefits (social, health, environmental) of physical activity; current physical activity recommendations; things to consider before starting; different types of physical activity; building confidence and efficacy to become physically active; myths and misconceptions about physical activity; staying motivated; sign-posting of opportunities to be physically active in Sheffield/South Yorkshire and example case studies.

Compliance with NICE guidance and UK practice

A. NICE Physical Activity Guidance (March 2006)

"identify inactive adults and advise to aim for 30 minutes of moderate activity on 5 days of the week (or more)". The DVD will allow individuals to assess their own physical activity relative to current physical activity recommendations that will be provided on the DVD. Information will be provided that will help individuals to understand what is meant by "active" and "moderate intensity".

"When providing physical activity advice, primary care practitioners should take into account the individual's needs, preferences and circumstances. They should follow them up at appropriate intervals over a 3 to 6 month period". The DVD offers trainers a tool to support individuals in making healthier lifestyle choices regarding positive change in physical activity. The DVD is theoretically underpinned by the Trans-theoretical model of behaviour change and the Theory of Planned Behaviour - which both place emphasis upon the individual considering their perceived behavioural control, subjective norms and attitudes when initiating behaviour change -such as increasing physical activity. The DVD asks the individual to reflect upon their individuals needs, preferences and circumstances and this is done within an evidence-based stage matched approach - meaning that greater emphasis will be placed on those factors (such as circumstances and needs) that mediate behaviour change at the early stages of change adoption (pre-contemplation) and factors that mediate sustaining the new behaviour such as reinforcement management that will be more salient for those individuals who have already decided to take action but need help to implement change.

"Practitioners should agree goals with them" Goal setting, what it means and examples of goal setting for physical activity will be given in the DVD. This will put the potentially abstract theory of goal setting into a real life context. Appropriate language will be used to facilitate understanding and relevance.

"They should also provide written information about the benefits of activity and the local opportunities to be active". The DVD will provide a comprehensive list of physical activity opportunities within the Sheffield area with contact details. These will include activities that have already been found to be popular with minority ethnic groups eg. dance activities.

"Local policy makers, commissioners and managers, together with primary care practitioners, should pay particular attention to the needs of hard to reach and disadvantaged communities, including minority ethnic groups, when developing service infrastructures to promote physical activity." The information given within the DVD will have been discussed with local ethnic minority community groups to ensure it is culturally and contextually appropriate. The local strategic partnership will be consulted about current service provision for disadvantaged and ethnic minority groups.

B. NICE Behaviour Change Guidance (October 2007)

"Employ a range of behaviour change methods and approaches, according to the best available evidence. These concepts could be used to structure and inform interventions." Action planning, implementation-intention action plans, promoting user- autonomy, providing tips and practical strategies to develop physical activity self-efficacy, adopting a client centred approach, information giving, expert based advice, peer modelling, engaging in reflective tasks, contingency planning are all features of the DVD intervention that comply with the list of concepts that are advocated by NICE to structure behaviour change interventions. Through engagement with the DVD, individuals will be able to devise their own personal physical activity plan, understand the benefits of physical activity, be given information regarding safe physical activity, how to monitor intensity, myths about activity, information re the difference between activity for health and fitness.

"It should be taken into account behaviour is embedded in social, cultural & material circumstances." The complexity of an individual's personal circumstances, their

socioeconomic and cultural context and their interactions with health behaviours will be considered in the content of the DVD and in ensuring associated advice is realistic and culturally appropriate.

Compliance with pragmatic practice

The brief intervention will be delivered as part of the local strategy for promoting physical activity in more deprived neighbourhoods within the Enhanced Public Health Programme which is based on a comprehensive needs assessment and targets specific neighbourhoods with poorer health outcomes. The use of DVDs is in line with the strategic approach and methods developed locally by Active Sheffield and supported by the partnership of bodies that deliver support for increasing physical activity across Sheffield. Use of DVDs is already being introduced in other areas with anecdotal success but without systematic evaluation. Health First, the specialist health promotion agency for Lambeth, Southwark and Lewisham, has recently produced a DVD designed to promote physical activity. This DVD includes similar content to that in our proposed intervention, tailored for a local population. The DVD 'Choosing Physical Activity' is in the public domain and can be viewed using http://video.google.co.uk.

The main reasons for not using existing community or primary care practitioners to deliver an initial brief intervention were both to ensure fidelity to the intervention protocol (so an ineffective intervention can be distinguished from inadequate delivery of an effective intervention) and also because in practice, if the intervention is effective and introduced into practice, it will need to be delivered consistently and efficiently across a large population with capacity to benefit by a range of health trainers and other community staff as well as primary care staff. The proposed DVD has the potential to reach a wide targeted audience at minimal cost compared to a one to one based intervention with a health professional.

Content of the Full Booster: The full booster will comprise two 20-30 minute face-to-face physical activity consultations that aim to promote and sustain change in physical activity status. The full booster sessions will take place in community venues. The consultation will be underpinned by the principle of the TTM (Prochaska et al, 1992) and replicate a brief version of motivational interviewing based on a method designed for time limited consultations in medical settings (Rollnick, Heather & Bell, 1992). Such an approach has been successfully employed to change health-related behaviours previously (Britt et al, 2003). This approach also mirrors that adopted by the health trainer initiative which provides a current model of face-to-face promotion of healthy behaviours. For the Full booster, a menu of six strategies has been developed (based on Rollnick, Heather & Bell, 1992) to guide the 30-minute consultation. Each strategy is suitable for participants who are in the maintenance stage of motivational readiness for physical activity behaviour change. They are:

Assessment of motivation and confidence for maintaining physical activity

Increasing knowledge of the benefits of physical activity; awareness of the risks of a sedentary lifestyle; increasing awareness of physical activity opportunities; increasing awareness of the current recommendations for physical activity

Increasing confidence to be physically active - self-efficacy

Goal setting and tracking using SMART (specific, measurable, achievable, realistic, time-related) goal principles

Strategies for staying motivated

Relapse prevention strategies

During the full booster consultations, strategies will be worked through at a pace dictated by the participant and the menu used to structure information exchange without being prescriptive.

Content of the Mini Booster: Although face-to-face interventions have been found to be efficacious in promoting physical activity (Britt et al, 2003), many of the barriers associated with this approach, including time and financial costs, highlight the need for pragmatic alternatives that are both relatively cheap to deliver and may make it easier for the participant to access the intervention. The Mini Booster will consist of two 20-minute telephone based physical activity consultations. The telephone consultation will follow the same menu of six behaviour change strategies as the Full Booster (outlined above) and aim to promote and sustain change in physical activity status. A number of studies using telephone support for physical activity in older adults have been carried out (Humpel et al, 2004; Ball et al, 2005). A telephone based approach has been effective in increasing physical activity participation at six months compared to no telephone support (Green et al, 2002) and has also been shown to increase physical activity participation to a greater extent than standard reading materials in adult populations (Ball et al, 2005). The telephone consultations will follow a script of known efficacy that has been implemented in previous physical activity promotion studies delivered by members of this research team.

Quality assurance: The proposed interventions will adhere to an intervention fidelity framework based on the Behaviour Change Consortium (Bellg et al, 2005; Resnick et al, 2005). This framework provides quality assurance parameters based on the intervention design, training, delivery, receipt and enactment. Further detail of this can be found elsewhere (Bellg et al, 2005). A recent review has highlighted inconsistent delivery and levels of competence of physical activity interventionists reporting to deliver a physical activity counselling components (Breckon, Johnston & Hutchison, in press) and it has been suggested that the effectiveness of behaviour change counselling is predicted by the length, the intensity, the content of interventions and the competence of the deliverer (Tulloch et al, 2006). The sessions will therefore be delivered by a team of four research assistants trained in MI and behaviour change techniques and assessed to ensure their competency. A framework will be developed for each session to ensure consistency of advice across sessions and between participants. All research assistants (RAs) will be trained (by JB, HC and RC) using a training package and a detailed manual to ensure standardised delivery of the booster interventions. All booster interventions will be audio-recorded. A random selection of 5% of all booster consultations (20 telephone and 20 face-to-face) will be reviewed and assessed by an independent clinical psychologist (LJ) using a pre-determined check list. The RAs will be provided with individual feedback if required, to ensure intervention fidelity is maintained.

Population
Men and women aged between 40 and 64 who have increased their physical activity by at least 30 minutes per day.

This trial will be conducted in compliance with the protocol, GCP and regulatory requirements.

2. Aims and objectives

The overall aim is to measure the effectiveness and cost effectiveness of “mini" and "full" booster sessions, as an adjunct to a brief intervention, in sustaining physical activity in middle-aged adults.

Primary objective
To determine whether physical activity measured by accelerometry three months after randomisation (six months after a brief intervention) is significantly increased in

participants allocated to two intervention groups (receiving two booster physical activity consultations, delivered in a motivational interviewing style, either by telephone or face-to-face) compared to participants allocated to a control group (receiving no further contact after the baseline assessment).

Secondary objectives

1. To determine whether physical activity nine months after randomisation (12 months after the brief intervention) is significantly increased in participants allocated to the two intervention groups compared to participants allocated to the control group.

2. To compare physiological measures of fitness (12 minute walk test) and self-reported physical activity (SPAQ instrument) between allocated groups.

3. To compare health related quality of life, resource use (including health and social care contacts) and economic costs between allocated groups.

4. To investigate whether the impact of the intervention may be modified by gender, ethnicity or the types of physical activity undertaken (including use of community facilities for physical activity).

5. To undertake a process evaluation to identify, using both quantitative and qualitative methods, psychosocial and environmental factors that may mediate or modify the effectiveness of the intervention.

3. Trial Design

Design

This is a three-arm, parallel group, randomised controlled trial with a feasibility study.

Feasibility study

In the first year a pilot trial will be undertaken to assess the feasibility of both trial recruitment plans and the proposed interventions (Birkett & Day, 1994; Wittes & Brittain 1990). A total of 3000 mailshots will be sent to the patients of a general practice situated in a “typical” deprived ward (Manor Ward), at least 150 will receive the brief intervention and 60 randomised to the three trial arms. This will allow outcome measurement in 15-20 individuals in each study arm to estimate a mean and standard deviation for the primary outcome, total energy expenditure per day (averaged over a 7-dayaccelerometry assessment period in each group using the Actiheart Device). The main risks to trial success identified by reviewers that the feasibility trial will test are:

1. Recruitment targets for the brief intervention will not be met;

2. The brief intervention will not be effective enough to generate sufficient individuals eligible for the trial;

3. Insufficient eligible individuals will consent to participate in the trial

These three issues in combination will determine whether the trial recruitment rate is adequate.

The success criteria for the feasibility study will therefore be:

A. At least 60 patients recruited to the pilot trial and 45 having 3 month follow-up measurements including accelerometry completed on the basis of an initial mailshot to 3000 individuals. (We will not use community recruitment at this stage since it may represent a more limited pool for recruitment that we can use to booster participants from "hard-to-reach" groups as required in the main trial)

B. At least 70% of those randomised to booster interventions actually receiving the interventions per protocol

C. On the basis of the pilot primary outcome (accelerometry) data collected, the sample size for the main trial will be re-calculated. The trial will not proceed if the revised sample size calculation suggests a total sample size >600 will be required. Assuming the protocol and intervention remain unchanged, the participants recruited during the feasibility phase will be included in the full trial population.

Main trial

The trial participants will be recruited from the 20 most deprived neighbourhoods of the city of Sheffield, based on Index of Multiple Deprivation (IMD) 2004 and health indicators. Average life expectancy is six years lower in lowest versus highest quintile of IMD (based on data from www.neighbourhoodstatistics.gov.uk). Up to 30 000 middle-aged residents, (aged 40 to 64 years at recruitment), will be invited to participate in a brief intervention to help them get more physically active. Up to 1500 residents who respond to the invitation will receive an initial assessment telephone call to determine their physical activity status. Eligible participants (i.e. those not already meeting current recommendations of 30 minutes moderate activity, 5 times a week) will then receive an interactive DVD and supporting written materials through the post. Follow up telephone contacts will be made one month and two months from initial contact. Active Sheffield, the organisation responsible for promoting physical activity in Sheffield, will ensure participants have access to a range of community facilities for exercise and will provide regularly updated information on current provision.

After three months, the Study Introduction letter will be sent to all DVD recipients and a further telephone assessment will establish whether they are eligible to participate in the booster trial (i.e. have increased their activity by at least 30 minutes per week and are willing to have further assessment and follow up). Eligible participants will then be invited to attend a baseline assessment appointment at a community venue and they will be randomly allocated to one of three groups:

1. a control group who will be assessed at randomisation, after three months and after nine months and receive no additional intervention between those assessments;

2. a "mini booster" group also receiving an intervention comprising two telephone-based physical activity consultations, delivered in a motivational interviewing style, at one month and two months from randomisation;

3. a "full booster" group also receiving an intervention comprising two face-to-face physical activity consultations, delivered in a motivational interviewing style, at one month and two months from randomisation.

Written consent to trial participation will be obtained at the start of the trial baseline assessment meeting. All randomised participants will be assessed at baseline, 3 months and 9 months from randomisation (i.e. 3 months, 6 months and 12 months from the initial contact for the brief intervention). Where possible, staff conducting

assessments will not know participants' group allocation and participants will be asked not to tell them.

Endpoints

1. Objective measure of physical activity including:
    a. Total Energy Expenditure (TEE), in Kcal per day, from seven-day accelerometry and heart rate monitoring using Actiheart
    b. Physical activity counts (PAC) per week;
    c. Minutes of moderate/vigorous physical activity per day;
    d. Meeting the current physical activity recommendation of at least 30 min per day (continuous or in bouts of at least 10 min] of at least moderate intensity) for at least 5 days a week (yes or no).

2. Self-reported moderate or strenuous physical activity using the Scottish Physical Activity Questionnaire (SPAQ) which records type and duration of activities in the previous week;

3. Health-related quality of life using the Sheffield Version of the 16-item Short Form health survey instrument (SF-12v2 plus 4);

4. Self-reported use of community facilities for physical activity;

5. Self-reported health and social care contacts;

6. Psychological measures of motivation, intentions, attitudes, beliefs, social influences and self-efficacy towards physical activity, measured using the Theory of Planned Behaviour (Azjen, 2002). Exercise stages of change (Marcus et al, 1992), and self-determination will be assessed using Behavioural Regulation in Exercise Questionnaire (BREQ-2: Mullan et al, 1997) and questions used in the HTA-funded Exercise Evaluation Randomised Trial (EXERT) (Isaacs et al, 2007). This will allow comparison with results from other physical activity trials including EXERT.

7. Body weight and height (to allow calculation of BMI)

8. Physiological measures of fitness (12 minute walk test - McGavin et al, 1976)

Design measures to avoid bias

The allocation schedule will be concealed through the use of a centralised web-based randomisation service. The randomisation sequence is computer-generated. Data analysts will be blind to treatment allocation, but the study manager, participants (who are also outcome assessors) will not be blinded. Analysis will be by intention-to-treat. Where individuals are lost to follow-up or data is missing, imputation methods will be employed, which will be described in the statistical analysis plan.

Randomisation codes and allocation concealment

The randomisation schedule is generated prior to the study by the Clinical Trials Unit Randomisation Service. On identification of an eligible volunteer, the study manager or data manager will randomise and inform the patient and their general practitioner on the treatment allocation.

4. Selection and withdrawal of participants

Inclusion criteria for brief intervention

1. Residents of the 20 most deprived neighbourhoods in the city of Sheffield
2. Aged 40 to 64 years
3. Not achieving the current recommended activity level (30 minutes of moderate activity on at least 5 days) assessed using the SPAQ (Lowther, 1999) and wishing to have support to become more active

Additional inclusion criteria for booster trial:

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

Exclusion criteria

Individuals with chronic conditions who can benefit from physical activity will not be excluded unless their condition significantly impairs their ability to exercise. They will be asked to consult their GP if they have a condition that increases their risk of adverse events during exercise (i.e. chronic cardiovascular or pulmonary disease).

Criteria for withdrawal from trial treatment

Participants may withdraw from active participation in the study on request. If a participant experiences chest pain or severe breathlessness during the 12-minute walk test, then the researcher will advise the GP directly and immediately, and will also advise the participant to make an appointment with their GP at their earliest convenience.

If analysis of Actiheart (accelerometer) readings suggests pre-existing arrhythmias, this information will be shared with the participant and their GP.

Subjects removed from active participation will not be replaced and, with their consent, will be followed up for all outcome information.

5. Randomisation and enrolment

We will use a remote web-based randomisation service. Eligible participants will be randomised to one of the three arms by the study manager, after receiving the consent form, via a centralised telephone randomisation service provided through the Clinical Trials Research Unit (CTRU).

6. Assessments and procedures

Procedures required at screening or before randomisation

Letter 1. Up to 30 000 middle-aged residents will be sent a letter and business response envelope inviting them to enroll in a programme to help them get more physically active.

Scottish Physical Activity questionnaire. The research team will send this out to potential participants with Letter 1. It will be administered face-to-face by a member of the research team at screening and sent out again by post on two subsequent occasions to participants (3 months and 9 months after randomisation).

Brief intervention
Interactive DVD and supporting written materials, delivered through the post. The research team will send this out to potential participants who respond to Letter 1.

Procedures required at initial follow-up
Follow up telephone contacts, one month and two months from initial contact to assess DVD usage and offer advice on physical activity. A member of the research team will contact the individual at home by telephone.

Procedures required at screening
After three months, the Study Introduction letter will be sent to all DVD recipients and eligibility to participate in the booster trial will be assessed by telephone. Eligible participants will be invited to attend a baseline assessment.

Procedures required before randomisation
Participant information sheet sent to potential participant at home. The research team will send this out to potential participants who are eligible and willing to participate in the trial (see above).

Visit to a community venue for informed consent, baseline assessment and randomisation. A member of the research team will meet and consent the individual, take baseline assessments and randomise them. A member of the research team will administer:

- Scottish Physical Activity questionnaire;
- Short-Form 12v2 plus 4 questionnaire, plus one wellbeing question;
- Behavioural Regulation in Exercise Questionnaire (BREQ-2);
- Exercise Evaluation Randomised Trial (EXERT) questionnaire'
- Personal information questionnaire (Questionnaire 1).
- Questions about use of community facilities for physical activity, and about health and social care service contacts; and,
- Measurement of weight and height.

Procedures required at three month follow-up
A member of the research team will meet the individual, take baseline assessments and randomise them. A member of the research team will administer:

- Scottish Physical Activity questionnaire;
- Short-Form 12v2 plus 4 questionnaire, plus one wellbeing question;
- Behavioural Regulation in Exercise Questionnaire (BREQ-2);
- Exercise Evaluation Randomised Trial (EXERT) questionnaire'
- Questions about use of community facilities for physical activity, and about health and social care service contacts;
- Measurement of weight and height.
- Twelve-minute walk test; and,
- Seven-day accelerometry using Actiheart.

Procedures required at nine month follow-up
A member of the research team will meet the individual, take baseline assessments and randomise them. A member of the research team will administer:

- Scottish Physical Activity questionnaire;
- Short-Form 12v2 plus 4 questionnaire, plus one wellbeing question;

- Behavioural Regulation in Exercise Questionnaire (BREQ-2);
- Exercise Evaluation Randomised Trial (EXERT) questionnaire'
- Questions about use of community facilities for physical activity, and about health and social care service contacts;
- Measurement of weight and height.
- Twelve-minute walk test; and,
- Seven-day accelerometry using Actiheart.

List procedures for attempted follow-up of patients "lost to follow-up"
Patients will be considered lost-to-follow-up if they fail to respond to questionnaires, one reminder letter and two telephone calls. There are no procedures for further follow-up.

Procedures required when closing a trial (premature or planned).
At the point at which all questionnaires have been collected (or participants have failed to respond despite reminders) and all data have been entered and cleaned, the management group will approve closure of the database. Further details will be presented in the data management protocol.

Procedures required to record serious adverse events
At each follow-up, participants will be asked if they have experienced any event or illness which:

- has required unscheduled hospitalisation; or,
- has resulted in persistent or significant disability / incapacity.

The details of serious adverse events will be confirmed with the participant's general practitioner before classification.

It is the Chief Investigator's responsibility:

1. To follow the procedure outlined in the study protocol for the reporting of SAEs;
2. To assess each event for causality and AE category;
3. To provide the Dean of ScHARR and the University Research Office (in their capacity as representatives of the sponsor) with details of all SAEs identified within agreed timeframes;
4. To notify the Trial Steering Committee and Data Monitoring and Ethics Committee of any SAEs; and,
5. To submit the annual safety report to the REC.

7. Statistics

Number of patients to be enrolled
600.

Reason for choice of sample size
The original sample size calculation assumed that physical activity would be measured using a simple hip-mounted accelerometer. It was also assumed that a mean difference of 400,000 PAC per week between the intervention and control groups at three months was the smallest clinically and practically important difference and that the SD of this outcome was 1.2 million counts/per week. Hence with 450 participants (300 intervention: 150 control), the main trial was determined to have 90% power to detect this mean difference or greater between the intervention and control arms as statistically significant at the 5% (two-sided) level using a two

independent samples t-test. Assuming an approximate 25% loss to follow-up by three-months, it was proposed to recruit and randomise 200 participants per group giving total sample size of 600. The Actiheart accelerometer measures physical activity counts per week on a different scale of magnitude to a simple hip mounted accelerometer with a considerably lower mean and standard deviation.

When re-estimating the sample size using data from an internal pilot study the revised sample size estimate either stays the same or increases (it cannot be less than the original estimate). The original sample size calculation of 450 subjects with valid outcome data at 3 months post-randomisation, was based on detecting a standardised effect size of 0.33 or a mean difference of one-third of a standard deviation in the outcome measures between the intervention and control groups. This equates to an estimated mean difference between the Booster and Control groups, based on the observed standard deviation from the feasibility stage of 34,465 PAC per week and 102 kcal per day for TEE.

To have a 90% power of detecting a mean difference of 102 kcal in mean TEE per day is between the groups would require 426 participants in total with evaluable data (control=142; intervention=254). Similarly, the total required sample size under the above conditions to detect a mean difference of a 34,465 PAC per week is 429. Therefore since the re-estimated sample size, of around 430 participants, is lower than the original estimate of 450 participants the trial will proceed with the original sample size estimate of 450 participants with evaluable data.

Statistical criteria to terminate the trial
There are no statistical criteria for stopping the trial early; as the intervention is considered low risk, there is no DMEC and decisions to stop the trial will be made on safety grounds by the Trial Steering Committee.

Procedure for accounting for missing data
The primary analysis will be an ITT analysis with participants with complete accelerometry data at three months post-randomisation. A sensitivity analysis will be undertaken to impute missing accelerometry data using baseline and follow-up data from the group of patients with valid accelerometry data at three months post-randomisation. As this is an ITT analysis, withdrawals and protocol violations will be analysed in their groups as randomised.

Analysis of primary objective
As the trial is a parallel group RCT data will be reported according to the revised CONSORT statement (Moher et al 2001). The statistical analyses will be performed on an intention-to-treat basis. All statistical exploratory tests will be two-tailed with alpha = 0.05. Baseline demographic variables (age, gender), physical measurements (e.g. weight, height, BMI), and health-related quality of life data (SF-36) will be summarised with appropriate summary statistics, tabulated and assessed for comparability between the treatment groups. For example, categorical variables (e.g. gender, the number and percentage who are male and female will be reported). For continuous variables, e.g. age, depending on the distribution of the data, if it is symmetric, the data will be summarised with a mean and standard deviation; if it has a non-symmetric distribution it will be summarised with a median and inter-quartile range.

The primary aim is to compare the intervention (Full or Mini Booster) versus control treatment (No booster). Secondary aims are to compare the two interventions (Full versus Mini booster). The primary comparison will be between the mean physical activity levels from the Actiheart accelerometer (average Total Energy Expenditure

per day in Kcal, from a seven-day assessment)) in the two "booster" arms combined compared with the mean physical activity levels in the control arm at 6 months follow-up (3 months post-randomisation). This difference in means, between the intervention and control groups, will be compared using a two independent samples t-test and a 95% confidence interval for estimated mean difference between the groups will also be calculated. In the event of differences between the Booster and Control groups with respect to baseline demographic, physical, and health-related quality of life and accelerometer measurements, multiple regression will be used to adjust the treatment effect for these variables. The ordinary least squares adjusted regression coefficient estimate for the treatment group parameter along with its 95% confidence interval (CI) will then be reported.

The research hypothesis is that the booster interventions will have greater levels of physical activity than the control. The statistical and null hypothesis is that there are no differences between the intervention and control groups at follow up. The alternative hypothesis is that there is a difference in physical activity levels between the intervention and control groups at follow up.

Secondary aims are to compare the effect of the two interventions (Full versus Mini booster). This will be done using the same methods as for the primary endpoint as described above. Interim analyses will not be required. An exploratory sub-group analysis using multiple linear regression, with the primary outcome the mean physical activity levels from the Actiheart accelerometer (average Total Energy Expenditure per day in Kcal, from a seven-day assessment) at 6 months (3 months post-randomisation), will look for an interaction between treatment group (Booster or control) and sub-groups defined by gender, ethnicity and access to community facilities (self reported use versus no use of community facilities).

Analysis of secondary outcomes

Analyses will identify any significant different between groups for each outcome measure, at three months and nine months from randomisation:

1. Objective measures of physical activity from the Actiheart:
    a. Physical activity counts (PAC) per week;
    b. Minutes of moderate/vigorous physical activity per day;
    c. Meeting the current physical activity recommendation of at least 30 min per day (continuous or in bouts of at least 10 min of at least moderate intensity) for at least 5 days a week (yes or no).
2. Physiological measures of fitness (12 minute walk test) and types of physical activity (self report) and change in self-reported physical activity levels
2. Change in health-related quality of life measured by changes in SF-12v2 plus 4 (converted to SF-6D)
3. Health and social care contacts
4. Changes in psychological measures of motivation, intention and stages of change, and self-efficacy

Secondary categorical outcomes such as the proportions maintaining (or increasing) their weekly duration of physical activity in the two "booster" arms combined compared with the proportion in the control arm at 6 months follow-up (3 months post-randomisation), will be compared between the intervention and control groups, using a continuity corrected chi squared test and a 95% confidence interval for estimated differences in proportions will also be calculated. In the event of differences between the groups with respect to baseline demographic, physical, and health-related quality of life measurements, multiple logistic regression will be used to adjust the treatment effect for these variables. The maximum likelihood estimated

regression coefficient for the treatment group parameter (odds ratio) along with its 95% confidence interval (CI) will then be reported.

Secondary outcomes such as HRQoL (SF-12v2 plus 4 dimension scores) and distance walked on 12 minute walk test, at six month follow-up, will be assumed to be continuous outcomes. A two independent samples t-test will be used to compare mean outcomes between the Booster and control groups in this parameter. A 95% confidence interval (CI) for the mean difference in this parameter between the groups will also be calculated. In the event of differences between the Booster and Control groups with respect to baseline demographic, physical, and health-related quality of life measurements, multiple regression or analysis of covariance (ANCOVA) will be used to adjust the treatment effect for these variables. The ordinary least squares adjusted regression coefficient estimate for the treatment group parameter along with its 95% confidence interval (CI) will then be reported. Twelve month outcomes will be analysed in a similar way. We shall also compare the effect of the two interventions (Full versus Mini booster) on these secondary outcomes at 3 and 9 months post-randomisation, using the same methods as described above.

Economic analysis

The basic design of the health economic component of the study will be to estimate the incremental cost effectiveness of the mini-booster and full booster interventions compared to no booster. It will include an estimation of the cost effectiveness of the intervention from a NHS perspective in terms of their incremental cost per quality adjusted life year (QALY) and a broader societal assessment of efficiency that includes costs for other Government agencies and productivity (inside and outside the home). It uses similar methods to those used in the successfully completed evaluation of a community exercise programme (Munro et al, 2004).

There will be two components to the costing. The interventions will be costed, as well as the consequences for the use of health and social services in general. The costs of the booster consultations will be assessed in a micro costing study. The costs will include enrolment of participants, training and time of facilitators, travel and telephone calls. Actual cost data will be collected for consumables and facilitator time will be costed using national grades. Despite being a highly pragmatic trial, there are some features of the programme which are specific to the research study and it will be necessary to adjust for these in order to make the results generalisable. Care will also be taken to compare costs assuming a routine level of throughput, rather than that achieved in the trial. Any research related costs will be excluded.

The consequences for use of health and social services will use resource data collected from participants. Use of primary, secondary, community and social services will be obtained using a self-completed resource questionnaire administered to participants at each assessment at baseline, three months and nine months. Resources will be costed using the best available national estimates. Where appropriate, national unit costs will be used (Netten and Curtis, 2005).

SF-12v2 plus 4 data will be converted into health state utility values using the SF-6D preference-based algorithm (Brazier and Roberts, 2004). The area under the curve between assessments will be used to provide an overall estimate of the QALY difference between the intervention arms and the control arm after adjusting for significant baseline variables (Mathews et al, 1990). Given cost and benefit data will only be collected for nine months, the on-going costs and health benefits will not be discounted, though start-up costs, including training costs, will be annuitised over a five year period. The sensitivity of the results to possible uncertainties in key parameters will be explored by a full sensitivity analysis, including a probabilistic sensitivity analysis.

8. Trial supervision

Details of the composition of the Trial Steering Committee (TSC) and Trial Management Group (TMG) are given at the front of this protocol. Sheffield CTRU standard operating procedures Gov001 and Gov002 apply. Sheffield CTRU trials require an independent Chair for a TSC.

There is no interim analysis. The responsibility of the TSC is to evaluate serious adverse events and make decisions about the continuation or discontinuation of the trial on safety grounds. In the event that any women consented into the trial are, or become pregnant, the safety of these individuals will also be monitored by the TSC.

There is no Endpoint Review Committee.

9. Data handling and record keeping

Data from the study will be stored in accordance with the Archiving Standard Operating Procedure (Shef/CTRU/DM002) for at least 5 years following completion. It will be stored in a commercial archive in Sheffield, which will protect the data from damage by fire, water, etc. The data will be packed into boxes and labelled with a number, the study title/reference no., the sponsor, the investigator and date until which it is to be archived. Named individuals will be responsible for archiving the data and for retrieving data from the archives. It will be necessary for the named individuals to go to the commercial archive to physically retrieve the data. Access will be restricted to the investigator and regulatory authorities. Details of what is kept in the archive will be logged on a register. These details will be the same as is detailed on the archive box labels. When data is removed from the archive, this is also logged on a register by one of the named individuals. Electronic data will be stored in an 'archive' area of the secure CTRU server for a minimum of five years to ensure that access is future−proofed against changes in technology. Electronic data may also be stored (e.g. on a compact disc) with the paper files.

The detailed data management and data quality issues will be set out in a data management and monitoring protocol in conjunction with the CTRU database manager.

10. Publication

Dissemination will be undertaken through peer reviewed scientific journals and clinical and academic conferences.

11. Ethics approval

The protocol will be approved by North Sheffield Research Ethics Committee.

12. Indemnity / Compensation / Insurance

The University of Sheffield has in place insurance against liabilities for which it may be legally liable and this cover includes any such liabilities arising out of this research project.

13. Changes from Protocol Version 4

Deleted text: Protocol v4 page numbers	Replacement text: Protocol v5 page numbers
Page 13: After three months, a further telephone assessment will establish whether they are eligible to participate in the booster trial…	Page 13: After three months, the Study Introduction letter will be sent to all DVD recipients and a further telephone assessment will establish whether they are eligible to participate in the booster trial…
Page 16: After three months, eligibility to participate in the booster trial will be assessed by telephone.	Page 16: After three months, the Study Introduction letter will be sent to all DVD recipients and eligibility to participate in the booster trial will be assessed by telephone.

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