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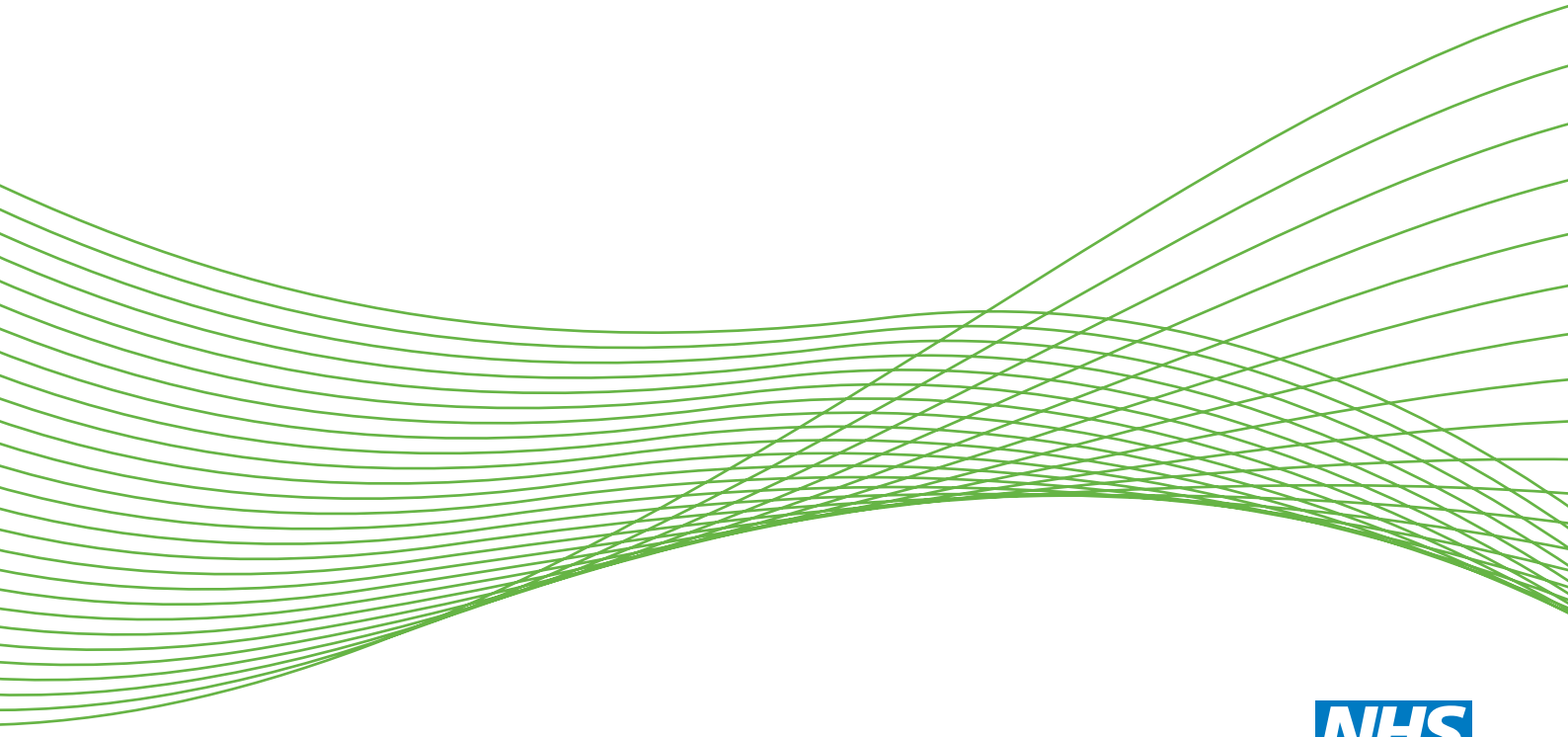

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Abstract

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

Elizabeth Goyder,[1] Daniel Hind,[2]* Jeff Breckon,[3] Munyaradzi Dimairo,[2] Jonathan Minton,[1] Emma Everson-Hock,[1] Simon Read,[1] Robert Copeland,[3] Helen Crank,[3] Kimberly Horspool,[1] Liam Humphreys,[3] Andrew Hutchison,[3] Sue Kesterton,[3] Nicolas Latimer,[1] Emma Scott,[1] Peter Swaile,[3] Stephen J Walters,[1] Rebecca Wood,[3] Karen Collins[4] and Cindy Cooper[2]

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Background: More evidence is needed on the potential role of 'booster' interventions in the maintenance of increases in physical activity levels after a brief intervention in relatively sedentary populations.

Objectives: To determine whether objectively measured physical activity, 6 months after a brief intervention, is increased in those receiving physical activity 'booster' consultations delivered in a motivational interviewing (MI) style, either face to face or by telephone.

Design: Three-arm, parallel-group, pragmatic, superiority randomised controlled trial with nested qualitative research fidelity and geographical information systems and health economic substudies. Treatment allocation was carried out using a web-based simple randomisation procedure with equal allocation probabilities. Principal investigators and study statisticians were blinded to treatment allocation until after the final analysis only.

Setting: Deprived areas of Sheffield, UK.

Participants: Previously sedentary people, aged 40–64 years, living in deprived areas of Sheffield, UK, who had increased their physical activity levels after receiving a brief intervention.

Interventions: Participants were randomised to the control group (no further intervention) or to two sessions of MI, either face to face ('full booster') or by telephone ('mini booster'). Sessions were delivered 1 and 2 months post-randomisation.

Main outcome measures: The primary outcome was total energy expenditure (TEE) per day in kcal from 7-day accelerometry, measured using an Actiheart device (CamNtech Ltd, Cambridge, UK). Independent evaluation of practitioner competence was carried out using the Motivational Interviewing Treatment Integrity assessment. An estimate of the per-participant intervention costs, resource use data collected by questionnaire and health-related quality of life data were analysed to produce a range of economic

models from a short-term NHS perspective. An additional series of models were developed that used TEE values to estimate the long-term cost-effectiveness.

Results: In total, 282 people were randomised (control = 96; mini booster = 92, full booster = 94) of whom 160 had a minimum of 4 out of 7 days' accelerometry data at 3 months (control = 61, mini booster = 47, full booster = 52). The mean difference in TEE per day between baseline and 3 months favoured the control arm over the combined booster arm but this was not statistically significant (–39 kcal, 95% confidence interval −173 to 95, $p = 0.57$). The autonomy-enabled MI communication style was generally acceptable, although some participants wanted a more paternalistic approach and most expressed enthusiasm for monitoring and feedback components of the intervention and research. Full boosters were more popular than mini boosters. Practitioners achieved and maintained a consistent level of MI competence. Walking distance to the nearest municipal green space or leisure facilities was not associated with physical activity levels. Two alternative modelling approaches both suggested that neither intervention was likely to be cost-effective.

Conclusions: Although some individuals do find a community-based, brief MI 'booster' intervention supportive, the low levels of recruitment and retention and the lack of impact on objectively measured physical activity levels in those with adequate outcome data suggest that it is unlikely to represent a clinically effective or cost-effective intervention for the maintenance of recently acquired physical activity increases in deprived middle-aged urban populations. Future research with middle-aged and relatively deprived populations should explore interventions to promote physical activity that require less proactive engagement from individuals, including environmental interventions.

Study registration: Current Controlled Trials ISRCTN56495859, ClinicalTrials.gov NCT00836459.

Funding: This project was funded by the NIHR Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 18, No. 13. See the NIHR Journals Library website for further project information.

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Glossary

Accelerometer Instrument for measuring physical activity (such as Actiheart – see below).

Actiheart Chest-worn device that records heart rate, interbeat interval and physical activity. It calculates and measures activity energy expenditure.

Bootstrapping A simulation method for deriving non-parametric estimates of variables of interest (e.g. the variance in the incremental cost-effectiveness ratio) from a data set.

Cost-effectiveness acceptability curve A graph that plots a range of possible cost-effectiveness thresholds on the horizontal axis against the probability (chance) that the intervention will be cost-effective on the vertical axis. In technology appraisals, cost-effectiveness acceptability curves are a means of representing the uncertainty surrounding the cost-effectiveness estimates in relation to the decision.

'Full booster' Two 20- to 30-minute face-to-face physical activity consultations, delivered in a motivational interviewing style, 1 month apart. This included an exploration of barriers and motives to change, decisional balance, agenda setting, action planning and relapse prevention.

Incremental cost-effectiveness ratio The ratio of the difference between the mean cost of a technology and the cost of the next best alternative technology to the difference in the mean outcomes.

'Mini booster' Two 20-minute telephone physical activity consultations, delivered in a motivational interviewing style, 1 month apart. This aimed to promote and sustain increased physical activity levels, focusing on exploration of relevant physical activity experience and action planning, and to discuss physical activity and usage of the DVD.

Motivational interviewing A directive, client-centred counselling style for eliciting behaviour change by helping clients to explore and resolve ambivalence.

Motivational Interviewing Treatment Integrity code The Motivational Interviewing Treatment Integrity code is a behavioural coding system, the use of which produces a score on a global scale indicating how well or poorly a practitioner is using motivational interviewing.

Probabilistic sensitivity analysis A way of representing uncertainty in the results of economic evaluations. Uncertainty may arise from missing data, imprecise estimates or methodological controversy. A sensitivity analysis repeats the main analysis using different assumptions to examine the effect on the results. In probabilistic sensitivity analysis, probability distributions are assigned to the uncertain parameters and are incorporated into evaluation models based on decision-analytical techniques (e.g. Monte Carlo simulation).

Research assistant In this study research assistants were employed to conduct research activities (screening candidates for study eligibility, collecting baseline and follow-up data) and as interventionists (delivering the motivational interviewing 'booster' interventions).

Self-determination theory A theory of motivation concerned with supporting supposedly intrinsic or natural tendencies to behave in effective and healthy ways.

Transtheoretical model Defines behaviour change as a process rather than a single event and offers practical suggestions for how individuals can change behaviour. The transtheoretical model offers practitioners a common, validated framework for guiding participants through periods of change and proposes strategies for maintaining positive behaviours.

Utility score A measure of the strength of a person's preference for a specific health state in relation to alternative health states. The utility scale assigns numerical values on a scale from 0 (death) to 1 (optimal or 'perfect' health). Health states can be considered worse than death and thus have a negative value.

List of abbreviations

A&E	accident and emergency
ANCOVA	analysis of covariance
ANOVA	analysis of variance
BMI	body mass index
BREQ-2	Behavioural Regulation in Exercise Questionnaire
CEAF	cost-effectiveness acceptability frontier
CI	confidence interval
CONSORT	Consolidated Standards of Reporting Trials
CTRU	Clinical Trials Research Unit
DMEC	data monitoring and ethics committee
EXERT	Exercise Evaluation Randomised Trial
FAB	Feedback, Awareness and Behaviour
FIT	Food and Immunity Trial
GIS	geographical information systems
GP	general practitioner
HRQoL	health-related quality of life
ICER	incremental cost-effectiveness ratio
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IMD	Index of Multiple Deprivation
IQR	interquartile range
ITN	Integrated Transport Network™
ITT	intention to treat
LSOA	lower super output area
MCID	minimum clinically important difference
MCS	mental component summary score
MET	metabolic equivalent of task
MI	motivational interviewing
MITI	Motivational Interviewing Treatment Integrity
NEJM	*New England Journal of Medicine*
NICE	National Institute for Health and Care Excellence
OA	output area
OARS	Open ended questions, Affirmations of change talk, Reflective listening and Summarising
ONS	Office for National Statistics
PAC	physical activity counts
PARS	Physical Activity Referral Scheme
PCS	physical component summary score
PSA	probabilistic sensitivity analysis
QALY	quality-adjusted life-year
RA	research assistant
RAI	Relative Autonomy Index
RCT	randomised controlled trial

RR	relative risk	SF-6D	Short Form questionnaire-6 Dimensions
ScHARR	School of Health and Related Research	SPAQ	Scottish Physical Activity Questionnaire
SD	standard deviation	TEE	total energy expenditure
SF-12v2 plus 4	16-Item Short Form health survey instrument		

Scientific summary

Background

The benefits of increasing levels of physical activity for people with sedentary lifestyles and those at increased risk of chronic disease are well established. Systematic reviews have identified a need for further research on the clinical effectiveness and cost-effectiveness of interventions intended to increase and maintain physical activity levels. In 2006, the National Institute for Health and Care Excellence recommended brief interventions in primary care. They also called for more work to understand how recent increases in physical activity could be sustained in formerly sedentary people, as studies with longer follow-up times had suggested high levels of relapse. Systematic reviews also suggest that dependence on self-reported measures of physical activity and the difficulty of blinding participants mean that treatment effects may have been exaggerated in previous primary research studies of interventions that support people to be more active.

Objectives

The Sheffield physical activity booster trial aimed to recruit participants who had already received a brief intervention to evaluate different intensities of booster intervention. The primary objective was to determine whether objectively measured physical activity, 6 months after a brief intervention, is increased in those receiving physical activity 'booster' consultations delivered in a motivational interviewing (MI) style, either face to face or by telephone. Secondary objectives included comparisons after longer follow-up (12 months after the brief intervention); physiological measures of fitness and self-reported physical activity; analyses of mediators (interventionist fidelity) and moderators (demographics and access to facilities) of treatment effect explored quantitatively and qualitatively; and a cost-effectiveness analysis.

Design

Three-arm, parallel-group, pragmatic, superiority randomised controlled trial with nested qualitative research fidelity and geographical information systems (GIS) and health economic substudies. Treatment allocation was carried out using a web-based simple randomisation procedure with equal allocation probabilities. The principal investigator and study statisticians were blinded to treatment allocation until after the final analysis only.

Setting

The 55 most deprived neighbourhoods in Sheffield, UK.

Participants

Between May 2009 and June 2011 NHS Sheffield sent letters with postage-paid reply cards to 70,388 people inviting them to enrol in a programme to help them become more physically active. A brief intervention was targeted at people not already meeting the current recommendations of 30 minutes of moderate activity, five times a week. Previously sedentary people aged 40–64 years, living in deprived areas of Sheffield, UK, who had increased their self-reported physical activity levels by 30 minutes per week after receiving a brief intervention, were randomised.

Interventions

1. A 'full booster' group receiving two face-to-face physical activity consultations, provided in a MI style, 1 and 2 months after randomisation.
2. A 'mini booster' group receiving two telephone-based physical activity consultations, provided in a MI style, 1 and 2 months after randomisation.
3. A control group who received no intervention after randomisation.

Interventions were underpinned by self-determination theory and used the relational and technical aspects of MI. Session content considered client background, typical day, readiness to change, decisional balance, importance for change and action planning. Follow-up telephone calls explored progress to date and reviewed agreed action plans with a view to modification when necessary.

Main outcome measures

The primary outcome was total energy expenditure (TEE) in kcal per day from 7-day accelerometry, measured using an Actiheart device (CamNtech Ltd, Cambridge, UK) at 3 months. The mean TEE in the combined booster group and in the control group was compared using a two independent samples *t*-test and 95% confidence interval (CI), with the associated *p*-value for the estimated mean difference between the groups calculated. Secondary outcome measures included self-reported moderate or strenuous physical activity using the Scottish Physical Activity Questionnaire (SPAQ); health-related quality of life (HRQoL) using the 16-item Short Form health survey instrument (SF-12v2 plus 4); self-determination using the Behavioural Regulation in Exercise Questionnaire (BREQ-2); body weight and height and physiological measures of fitness (12-minute walk test).

An estimate of the per-participant intervention costs, resource use data collected by questionnaire and HRQoL data were analysed to produce a range of economic models from a short-term NHS perspective. An additional series of models were developed that used TEE values to estimate the long-term cost-effectiveness.

Qualitative research elicited information on potential effect moderators at 3 months post randomisation. The survey questionnaire asked participants about the type and location of physical activity they had undertaken during the previous 3 months, reasons for staying physically active, factors that influenced their physical activity behaviour and social support from significant others. Booster recipients were asked about intervention acceptability. Questionnaire completers who received a booster were invited to a semistructured interview lasting about 20 minutes and conducted over the telephone or face to face. The topic guide covered questions about participants' physical activity views and habits as well as their opinions of the intervention. Interviews were digitally recorded, transcribed verbatim and analysed using the 'framework' approach.

The GIS analysis used network distance analysis and univariable linear regression models to test the association between mean TEE in kcal per day at 3 months and potential geographical moderators (pedestrian access to municipal green space and leisure facilities).

In the fidelity assessment, interventionists ($n = 4$) were assessed for their competence after training and at 9 and 18 months using the Motivational Interviewing Treatment Integrity (MITI) assessment to evaluate global ratings of evocation, collaboration, autonomy/support, direction and empathy. Counts of MI adherent and non-adherent behaviours were made. Sessions were independently coded by a qualified MITI coder. We employed analysis of variance to test the null hypothesis that physical activity measured by mean TEE at 3 months was the same across all of the interventionists who delivered the MI intervention.

Two types of cost-effectiveness model were developed, which used different approaches and sources of data to estimate the health effect, in quality-adjusted life-years (QALYs), of the interventions. A short-term cost-effectiveness model incorporated trial-based estimates of the effect of the study interventions – mini booster and full booster – on participants' use of NHS resources during the trial period. It also incorporated trial-based estimates of the effect of the interventions on participant utility using responses from participants who completed the SF-12v2 plus 4 HRQoL questionnaire at baseline and 9 months. Twelve scenarios were evaluated to account for structural uncertainty. Approximate costs of the interventions were incorporated in the model alongside the estimates of the effect of the interventions on resource use.

Another individual sampling model considered the effect of the interventions over a much longer time horizon than the trial duration and assumed that any potential QALY benefits of the interventions are mediated through the clinically measurable health benefits of increased physical activity. We populated a hypothetical cohort of 500,000 individuals with the age and gender variability of the trial population at baseline. Office for National Statistics life tables were used to define and simulate the ongoing mortality hazard in the simulated population. We used a regression equation to adjust QALYs by age and gender, discounting QALY gains at a rate of 3.5% per annum. Three alternative scenarios used different assumptions about the longevity of the effect of the interventions and about the causal relationship between physical activity and mortality hazards. We estimated the mean incremental treatment effect on patient utilities using a differences-in-differences and a simple differences approach.

Results

We randomised 282 participants (control = 96; mini booster = 92, full booster = 94) of whom 160 (control = 61, mini booster = 47, full booster = 52) had a minimum of 4 out of 7 days' accelerometry data at 3 months. There were no marked differences in baseline characteristics between arms or between those followed up and those lost to follow-up. The mean difference in TEE per day between baseline and 3 months favoured the control group (2266 kcal) over the combined booster groups (2227 kcal), but was not statistically significant (−39 kcal, 95% CI −173 to 95 kcal, $p = 0.57$). There was also no significant difference in the primary outcome when the full booster and mini booster groups were compared. A difference in TEE per day of 112 kcal, favouring the full (face-to-face) booster, was observed, but this result was not statistically significant and of borderline clinical significance. There was no statistically significant difference between groups on any secondary outcome measure, at 3 or 9 months, apart from the 12-minute walk test (adjusted mean differences 90.8 m, 95% CI 14.5 to 167.1 m at 3 months and 115.9 m, 95% CI 1.1 to 230.7 m at 9 months). Results were consistent after adjusting for age, gender, body mass index, SF-12v2 plus 4 scores and total minutes of physical activity at brief intervention and baseline.

Postal questionnaire respondents ($n = 75$) and interviewees ($n = 26$) reported physical activity that was mainly private and individual in character, with a minority participating in structured exercise classes or competitive sports. Under half reported exercising with others. Participants felt that social support was important, exercising with others was encouraging and motivating oneself in isolation was difficult. Non-family members were sometimes seen as better support than family, who were often perceived as a barrier. Musculoskeletal injuries were a frequently cited barrier to becoming more active whereas chronic physical conditions were often a motivator. The autonomy-enabled MI communication style was generally acceptable, although some participants wanted a more paternalistic approach and most expressed enthusiasm for monitoring and feedback components of the intervention and research. The face-to-face intervention was seen as preferable to the telephone booster. Self-reported moderate to vigorous physical activity often appeared to be at odds with the objective data.

Global ratings were mostly characterised as proficient for direction and competent for other global MI measures. The use of technical aspects of MI, including the use of open questions, increased across all interventionists from baseline. The global rating of 'direction' was consistently high across all interventionists at phase 1 and phase 2. The reflection to question ratio increased across the

four interventionists who completed delivery of the intervention from phase 1 to phase 2. The use of directional and deeper complex reflections was rated moderate or below competence across all interventionists. MI fidelity was associated with physical activity as measured by mean TEE per day in kcal at 3 months ($p = 0.027$).

The GIS analysis found wide variations in pedestrian access to municipal green space and leisure facilities. However, there was no statistical association observed between access and TEE at 3 months.

Two alternative modelling approaches, evaluating a large number of scenarios, both suggested that neither intervention was likely to be cost-effective. The main economic evaluations indicated that neither the mini booster intervention nor the full booster invention is cost-effective at any willingness-to-pay threshold. An additional analysis based on the long-term model, however, which incorporated data on physical activity differences in differences between arms in a different way from the main analysis, suggested that the full booster intervention might be cost-effective, assuming a willingness-to-pay threshold of £20,000 per QALY, if the cost of the intervention is less than approximately £300 per participant. This additional analysis assumes that all participants who receive the intervention increase their physical activity levels by equal amounts. This assumption may be unwarranted given that those participants who are already comparatively physically active may increase their physical activity levels most.

Conclusions

Although some individuals find a community-based, brief MI 'booster' intervention supportive, the low levels of recruitment and retention and the lack of impact on objectively measured physical activity levels in those with adequate outcome data suggest that it is unlikely to represent a clinically effective or cost-effective intervention for the maintenance of recently acquired physical activity increases in deprived, middle-aged urban populations. The lessons learnt in undertaking this trial should inform both the design of future physical activity intervention trials and the development of more effective interventions that not only are feasible and affordable but also have sufficient reach to have an impact in the most deprived, and most sedentary, populations who could benefit most from sustained increases in their physical activity levels. Future research with middle-aged and relatively deprived populations should explore interventions to promote physical activity that require less proactive engagement from individuals, including environmental interventions. The design of studies to evaluate interventions should include both objectively measured, and self-reported, levels of physical activity as outcomes, given the lack of agreement between these measures.

Study registration

This trial is registered as ISRCTN56495859 and ClinicalTrials.gov NCT00836459.

Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.

Chapter 1 Background

Regular physical activity is associated with reductions in all-cause mortality, risk of cardiovascular disease and some types of cancer.[1–3] Frequent exercise has a role in both the prevention and the management of hypertension, type 2 diabetes and obesity as well as a variety of mental health conditions.[4–6] However, most of the UK population do not attain levels of physical activity sufficient to confer such benefits.[7] For the last 10 years, a key Department of Health policy objective has been encouraging the population to undertake a total of at least 30 minutes of at least moderate intensity physical activity on 5 or more days of the week.[8]

Brief interventions delivered in primary care can increase physical activity levels and are recommended as effective and cost-effective interventions by the National Institute for Health and Care Excellence (NICE).[9,10] However, the evidence base largely consists of studies with short-term follow-up post intervention and that use self-reported increases in physical activity by trial participants as a primary outcome. Maintenance of recommended physical activity levels is understood to be essential to achieve the reported health benefits. As a result, NICE identified that further research was warranted on the long-term sustainability of such treatment effects.[10] At the time, the few studies that had followed participants over the long term suggested that approximately half of those who initiate a physical activity programme relapse and return to their previous sedentary lifestyle within 6 months.[11]

In the last 6 years, since the publication of the original NICE guidance in March 2006 recommending the use of brief interventions in primary care to encourage physical activity,[10] a number of additional primary studies and relevant systematic reviews have been published. These recent reviews of effectiveness and cost-effectiveness evidence are further discussed in *Chapter 8* (see *Other recent evidence for the effectiveness and cost-effectiveness of 'brief' and 'booster' interventions for increasing and sustaining physical activity*). The availability of further evidence on the use of brief interventions has led to the initiation of a programme to update the original NICE guidance and this new guidance was published in May 2013.[12]

In the meantime, the Sheffield physical activity booster trial was funded and undertaken to address one of the major gaps in the evidence base identified by the original NICE guidance.[10]

The booster trial was designed to evaluate the effectiveness and cost-effectiveness of motivational interviewing (MI) 'booster' interventions to help previously sedentary people maintain recently increased physical activity levels acquired following a brief intervention. MI[13] is one of the behaviour change interventions recommended by NICE for health promotion.[14]

The brief intervention involved provision of an interactive DVD based on a MI approach that is directive, is person centred and replicates the style of other successful behaviour change programmes and was underpinned by the theoretical construct of self-determination theory.[15,16] All interventions were delivered by trained facilitators whose competence was independently assessed using a treatment fidelity framework to ensure consistent delivery.[17,18]

Chapter 2 Methods

Methods for the main trial

This report is concordant with the extension of the Consolidated Standards of Reporting Trials (CONSORT) statement to improve the reporting of pragmatic trials.[19] An internal pilot trial, conducted between May 2009 and March 2010 and focusing on feasibility outcomes, is reported elsewhere.[20] The final protocol can be found in *Appendix 1* and a table of changes made to the protocol over the course of the project is presented in *Appendix 2*.

Participants

To identify potentially eligible study candidates we worked with NHS Sheffield (Sheffield Primary Care Trust), the health service organisation responsible for commissioning health services for the local population (until April 2013). Between May 2009 and June 2011 NHS Sheffield sent letters with postage-paid reply cards to 70,388 people inviting them to enrol in a programme to help them become more physically active. Six general practices were also given a total of 305 marked recruitment packs to distribute. These packs were identical to those sent from NHS Sheffield with the exception that the covering letter was not personalised. An unknown number of packs were also given to four community centres to be distributed by health trainers and health champions. Mail-outs and responses were allocated to output areas (OAs) according to the National Statistics Postcode Look-up table [November 2010 version; see http://geoconvert.mimas.ac.uk/help/documentation/10nov/nspd-version-notes-november-2010.pdf (accessed 21 November 2013)]. The response rate for each OA was calculated as the total number of allocated responses divided by the total number of allocated mail-outs. We performed a post hoc analysis to investigate whether response rate was related to population transience. Transience rate was calculated using information obtained from the 2001 census (small area statistics, Table CAS008), specifically the outgoing population divided by the outgoing population plus the static population.[21] An unweighted Spearman's rank correlation test between response rate and transience was performed in R version 2.15.0. (R Foundation for Statistical Computing, Vienna, Austria; see www.R-project.org/).

The physical activity programme involved a 'brief intervention' combining an interactive DVD and area-specific written information about local facilities and opportunities for physical activity. The DVD was developed by a team at Sheffield Hallam University using MI principles, which are consistent with NHS guidance on physical activity and behaviour change interventions.[10,14] The content and development of this DVD are provided more fully in *Appendix 1*.

Research assistants (RAs) telephoned respondents and administered the Scottish Physical Activity Questionnaire (SPAQ).[22] Those eligible to receive the brief intervention (DVD and information sheet) were (1) residents of the 55 most economically deprived neighbourhoods in the city of Sheffield (out of 100), (2) those aged 40–64 years and (3) those not achieving the recommended activity level (30 minutes of moderate activity on at least 5 days) assessed using the SPAQ and wishing to have support to become more active. RAs telephoned those sent a DVD 3 months later to assess their eligibility for participation in the trial. Eligible candidates (4) had increased their physical activity level by at least 30 minutes of moderate or vigorous activity per week (assessed using the SPAQ) over the 3-month brief intervention (DVD) period and (5) were capable of giving written informed consent for trial participation. Individuals with chronic conditions who could benefit from physical activity were not excluded unless their condition significantly impaired their ability to exercise.

The validated SPAQ contains a series of questions assessing physical activity behaviour over the previous 7 days and also asks whether or not this level of weekly activity is typical. When observed weekly activity was reported as atypical, SPAQ asks participants to clarify what constitutes a more typical week in terms of

an increased or reduced number of minutes of physical activity. Before and after the brief intervention period the RAs were asked to interpret the observed minutes of physical activity (as assessed using SPAQ) and to include any additional minutes of activity that were felt to be typical for study candidates who reported that the previous week had been atypical.

Interventions

Candidates who were assessed as eligible during the telephone assessment described in the previous section were invited to attend a baseline assessment at a community venue. Those who consented were randomly allocated (see *Randomisation and blinding*) to one of three groups:

1. a 'full booster' group receiving two face-to-face physical activity consultations provided in a MI style, 1 and 2 months after randomisation
2. a 'mini booster' group receiving two telephone-based physical activity consultations provided in a MI style, 1 and 2 months after randomisation
3. a control group who received no intervention after randomisation.

Both booster interventions are fully described in the study protocol, which can be found in *Appendix 1*. The full booster involved two face-to-face consultations, intended to last between 20 and 30 minutes, which took place in community venues. The consultations replicated a brief MI method designed for time-limited consultations in medical settings and which had already been successfully employed to change health-related behaviours.[23,24] During the full booster consultations, strategies were worked through at a pace dictated by the participant and the menu used to structure information exchange without being prescriptive.

The mini booster involved two physical activity MI consultations delivered by telephone, each intended to last approximately 20 minutes. The telephone consultations followed a script of known efficacy that has been implemented in previous physical activity promotion studies delivered by members of this research team.[25,26] It is thought that telephone counselling can provide an alternative to face-to-face contact that is relatively inexpensive in time and financial terms.[14] In previous studies in adult populations, telephone-based approaches have increased physical activity participation at 6 months compared with no telephone support and to a greater extent than standard reading materials.[27,28]

Objectives

The primary objective of the main study, a parallel-group randomised controlled trial (RCT), was to determine if physical activity assessed using an Actiheart device (CamNtech Ltd, Cambridge, UK) 3 months after randomisation (6 months after a brief intervention) increases in participants allocated to two intervention groups (receiving two booster physical activity consultations, delivered in a MI style, either by telephone or face to face) compared with participants allocated to a control group (receiving no further contact after the baseline assessment). Secondary objectives were to:

1. determine whether physical activity 9 months after randomisation (12 months after the brief intervention) is significantly increased in participants allocated to the two intervention groups compared with participants allocated to the control group
2. compare physiological measures of fitness (12-minute walk test[29]) and self-reported physical activity (SPAQ instrument) between allocated groups
3. compare health-related quality of life (HRQoL), resource use (including health and social care contacts) and economic costs between allocated groups
4. 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. 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.

Outcomes

Table 1 shows the timing of assessments and interventions, all made at community venues. The primary end point was the level of physical activity measured at 3 months post randomisation using Actiheart [specifically, the mean total energy expenditure (TEE) in kcal per day over a 1-week period]. Secondary end points were:

1. objective measures of physical activity including:
   i. TEE in kcal per day from 7-day accelerometry and heart rate monitoring using Actiheart (at 9 months)
   ii. physical activity counts (PACs) per week
   iii. minutes of moderate/vigorous physical activity per day
   iv. meeting the current physical activity recommendation of at least 30 minutes per day (continuous or in bouts of at least 10 minutes 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 SPAQ, which records type and duration of activities in the previous week
3. HRQoL 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 (see *Methods for the health economic analysis* for the analysis plan)
6. self-determination using the Behavioural Regulation in Exercise Questionnaire (BREQ-2)[30]
7. body weight and height [to allow calculation of body mass index (BMI)]
8. physiological measure of fitness (12-minute walk test).

The primary outcome was measured at 3 months post randomisation whereas the secondary outcomes were measured at 3 and 9 months post randomisation.

A decision was made to abandon the analysis of self-reported physical activity based on a questionnaire adopted from the HTA-funded Exercise Evaluation Randomised Trial (EXERT) trial.[31] This was because completion errors remained high even after repeat training of those administering it. The decision to abandon the use of this form was made in consultation with the trial steering committee and the HTA programme manager and the EXERT team and is fully documented elsewhere.[32]

Sample size

The sample size was originally based on a primary outcome that was subsequently superseded by the use of Actiheart, that is, a physical activity measure based on the mean physical activity levels from the 7-day accelerometric assessment (recorded as counts per week) at 3 months post randomisation (6 months after initial contact). Before progression to the main trial, an internal pilot was undertaken to estimate the variability of the outcomes and the minimum clinically important difference (MCID) based on one-third of the standard deviation (SD) of the primary outcome from the observed data and power estimation (conditional on the initial proposed sample size of 600 subjects). From the feasibility phase, the estimated effect size based on one-third of the SD was 34,464.7 PACs per week and 101.5 kcal per day TEE.[32] 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).[33,34]

Assuming a mean difference in TEE of 101.5 kcal per day between the intervention group and the control group as the smallest difference of clinical and practical importance that is worth detecting, then with 450 subjects (300 intervention, 150 control) the trial was originally determined to have 92% power to detect this mean difference or greater between the 'booster' arm and the control arm (assuming a SD of 304.6 kcal per day) as statistically significant at the 5% (two-sided) significance level using a two independent samples *t*-test. With 300 subjects in the booster intervention (150 mini booster, 150 full booster) the trial would also have had approximately 82% power to detect a similar mean difference in

TABLE 1 Timing of assessments and interventions

Assessment/intervention	Minus 3 months	Minus 2 months	Minus 1 month	~ Minus 1 week	Baseline	1 month	2 months	3 months	9 months
Brief intervention screening checklist	✓								
SPAQ	✓			✓				✓	✓
Brief intervention questionnaire 1	✓								
DVD (if eligible)	✓								
DVD usage assessment/advice		✓	✓						
Booster trial screening checklist				✓					
Participant information sheet				✓	✓				
Participant consent form					✓				
BREQ-2					✓			✓	✓
Booster trial questionnaire 2					✓			✓	✓
Questionnaire 3 (SF-12v2 plus 4)					✓			✓	✓
Height and weight					✓			✓	✓
Randomisation					✓				
Booster intervention (booster groups only)						✓	✓		
12-minute walk test								✓	✓
7-day accelerometry								✓	✓

TEE of 101.5 kcal per day between the two booster arms as statistically significant at the 5% (two-sided) significance level using a two independent samples *t*-test. Assuming an approximate 25–35% loss to follow-up by 3 months post randomisation, we proposed to recruit and randomise 200 subjects per intervention group to give a total sample size of 600 participants, giving the study power of between 87% and 92% to detect a mean difference in TEE of 101.5 kcal per day.

Randomisation and blinding

A Sheffield Clinical Trials Research Unit (CTRU) statistician, not on the trial team, used a simple randomisation procedure to generate the randomisation sequence, with each participant having a one-third probability of being allocated to one of the three intervention arms. We used a block size of 200 with no stratification. Eligible participants were randomised to one of the three arms using a central web-based randomisation service delivered by Sheffield CTRU after patient eligibility and informed consent were confirmed by a RA. Participants and outcome assessors were not blind to treatment allocation because of the practical nature of the intervention. However, the primary outcome was objectively assessed using the Actiheart device. Most other outcomes were self-reported. Study statisticians and the principal investigator were blinded to the treatment allocation codes until after the final analysis.

Statistical methods

Analysis population

The intention-to-treat (ITT) data set included all participants who were randomised according to randomised treatment assignment (ignoring anything that happened after randomisation, including non-compliance, protocol deviations and withdrawals); participants also had to have a valid 3-month post-randomisation Actiheart accelerometry measurement of physical activity.

A valid Actiheart accelerometry measurement was defined as having at least 4 complete days (of the 7 days) of measurements of physical activity. We used the 'auto-fill' option on the Actiheart to minimise the amount of missing data. The 'auto-fill' option fills the gaps, of up to 2 hours, with the average value calculated from the recorded portion of the same day.[35] If the device identified > 2 continuous hours of missing data then, even using the 'auto-fill' option, this was classified as an incomplete day. When data were obviously missing because the participant had taken the accelerometer off to sleep, imputation of 'sleeping' values was employed by using the mean values during sleeping times. The decision about which data were missing as a result of 'sleeping' was made by study team members blind to the treatment allocation. After discussion with the trial management group and steering committee, incomplete days were classified as having > 1000 minutes (16.7 hours) of lost or missing activity per day as measured by the Actiheart. Although the manufacturers assert that there should be no issue with missing data, few studies report the majority of participants returning complete data sets. A brief review of published studies shows that a 'complete day' of Actiheart data is typically considered to be 500–600 minutes of recording.[36,37] Although many studies do not report the thresholds used, in the absence of advice from the manufacturers or definitive studies to determine the optimal threshold, researchers must determine an appropriate cut point to maximise both data validity and participant inclusion.

In addition to the ITT set, two other data sets were analysed as part of the sensitivity analysis. A complete cases data set was a subset of the ITT data set that included randomised participants with all 7 complete days of physical activity measurements at 3 months post randomisation. A per-protocol data set was defined as including those who received the intended two booster sessions (either face to face or by telephone) among participants in the booster intervention arm. Participants who did not receive the booster sessions as intended were excluded from this data set. Additional data sets were also analysed for the primary outcome as part of the sensitivity analysis assuming different missing mechanisms using regression and multiple imputation approaches.

Handling incomplete days or missing daily counts measurements

Exploratory analysis of potential risk factors associated with not having evaluable data (at least 4 complete days of Actiheart data) was undertaken using logistic regression. Spaghetti plots stratified by intervention arm were also used to explore the missing pattern of the primary end point with respect to the measurements during days of the week. To achieve 80% reliability with respect to activity counts and time spent in moderate to vigorous activity in adults, at least 3–4 days (of the 7 days) of activity monitoring are required.[38,39] In this regard, the primary outcome measure (mean TEE in kcal per day) was calculated as the mean TEE over 7 days among those with at least 4 complete days of evaluable Actiheart data.

The primary method to deal with missing data on the secondary outcome, activity counts per week, was to scale up complete observed daily measurements to 7 days using the following formula:

$$\text{PAC7}_i = \frac{\textit{Total Physical Activity counts per day (complete days)}}{\textit{Number of observed complete days}} \times 7 \text{ days} \quad (1)$$

where PAC7_i is the new standardised physical activity measurement for 7 days for participant *i*. The number of PACs per day was calculated by multiplying PACs per minute by 1440 (24 hours in a day multiplied by 60 minutes in an hour). This approach was used for patients who have at least 4 complete days measured after imputation using 'auto-fill' and 'sleeping' time as described earlier.

Statistical analysis

Multiple logistic and linear regression was used to compare the baseline characteristics [i.e. gender, ethnicity, employment status, age, BMI, weight, height, SF-12v2 plus 4 physical component summary score (PCS), SF-12v2 plus 4 mental component summary score (MCS), Relative Autonomy Index (RAI) of the BREQ-2, and SPAQ change scores] of the completers (≥ 4 days of valid Actiheart data at 3 months post randomisation) and non-completers (< 4 days). An interaction term was included in the regression model to see whether the characteristics of the completers and non-completers were different between the booster and the control groups. The purpose was to explore whether the missing data mechanism was related to the intervention or whether there are observed characteristics that might predict whether or not a randomised participant would have valid and complete Actiheart data at 3 months post randomisation.

For sensitivity analysis, multiple imputation was used to obtain a complete data set for the primary outcome by filling incomplete daily measurements. Twenty multiple imputation data sets were created and we imputed, at most, 3 incomplete days of the week per participant (among those with at least 4 complete days). The multiple imputation model took into account participants' baseline characteristics (such as age, gender, weight, height, HRQoL and BMI) and longitudinal time sequence as well as total physical activity at baseline and 3 months before randomisation. In addition, for participants with at least 1 complete day of the outcome measure, multiple imputation was also used to impute the missing daily measurements as part of further sensitivity analysis using the same multiple imputation model as described above but imputing at most 6 incomplete days of the week per participant.

Baseline characteristics

The baseline demographic characteristics and physical measurements were summarised and assessed for comparability between the booster and the control arms.[40–42] Age, weight (mass), height (stature), BMI, SPAQ change score, BREQ-2 RAI dimension score and SF-12v2 plus 4 PCS and MCS scores were presented on a continuous scale. For these continuous variables, summary statistics such as the minimum, maximum, mean, SD, median and interquartile range (IQR) were presented. Numbers of observations used with number and percentages in each category are presented for categorical variables (e.g. gender, marital status, ethnicity and stage of change). Summary statistics are presented by treatment group and assessed for comparability. No statistical significance testing has been carried out to test baseline imbalances between the intervention arms but any noted differences are descriptively reported.[43,44]

Data completeness

Reporting of data completeness is an integral part of clinical trial reporting. Hence, summaries of data completeness are shown on a CONSORT flow chart from participants' enrolment, during follow-up and at the end of the trial. Data completeness is based on the primary outcome (mean TEE in kcal per day) and having a valid measurement at 3 and 9 months post randomisation.

Effectiveness analyses

The primary aim was to compare the intervention group (full or mini booster) with the control group (no booster). The primary comparison was between the mean physical activity levels from the accelerometer (mean TEE in kcal per day) in the two 'booster' arms combined compared with the mean physical activity levels in the control arm at 3 months post randomisation. This difference in means between the intervention group and the control group was compared using a two independent samples *t*-test; a 95% confidence interval (CI) for estimated mean difference between the groups was also calculated and reported with its associated *p*-value. The research hypothesis was that the booster intervention groups will have greater levels of physical activity than the control group. In all of the analyses the control group was treated as the reference for comparisons.

An adjusted analysis using multiple regression was also conducted to estimate the effect of the intervention adjusted for baseline covariates (such as age, gender, HRQoL, BMI and SPAQ at baseline and 3 months before randomisation). The ordinary least squares adjusted regression coefficient for the intervention effect was presented and reported with its associated 95% CI and *p*-value.

A secondary objective of the study was to compare the effect of the two interventions (full booster vs. mini booster) at 3 months post randomisation using the primary outcome, mean TEE per day. Therefore, we repeated the above analysis to compare the effects of the full and mini booster interventions.

The analysis outlined above for the primary outcome was also repeated for the main secondary outcome, PACs per week at 3 months post randomisation, and for the TEE and PAC outcomes at 9 months post randomisation.

Analysis of secondary outcomes

The following continuous secondary outcome measures were assessed at 3 and 9 months post randomisation:

- PCS, MCS and Short Form questionnaire-6 Dimensions (SF-6D) scores from the SF-12v2 plus 4
- average minutes per day spent on moderate activity [3–6 metabolic equivalents of task (METs)]
- average minutes per day spent on vigorous activity (> 6 METs)
- average minutes per day spent on moderate and vigorous activity (≥ 3 METS)
- BREQ-2 dimensions (amotivation, external regulation, introjected regulation, identified regulation, intrinsic regulation, RAI)
- BMI
- distance walked (in minutes) during a 12-minute walk test.

Mean outcomes were compared between the combined booster groups and the control group using two analysis of covariance (ANCOVA) multiple regression models: a simple model that adjusted for the baseline value of the outcome only and a more complex model that adjusted for several covariates including age, gender, BMI, total minutes of physical activity at 3 months and 1 week before randomisation and the baseline outcome measurement. The mean differences in outcomes between the groups and their associated 95% CI and *p*-value from the two models were reported.

Secondary binary categorical outcomes were the number and proportion maintaining (or increasing) their weekly duration of physical activity (based on the self-reported SPAQ) and the number and proportion meeting the current recommendations of at least 30 minutes of moderate physical activity (MET level ≥ 3)

on at least 5 days of the week. We compared these outcomes between the booster groups and the control group at 3 and 9 months post randomisation using a continuity-corrected chi-squared test; 95% CIs for the estimated differences in proportions between the booster groups and the control group were also calculated.[45]

Gender, ethnicity and access to community facilities (self-reported use of community facilities vs. no use of community facilities) were predefined as subgroups that we wished to test for evidence of effectiveness in an exploratory analysis. An additional post hoc exploratory subgroup evaluation was undertaken to assess the impact of the timing of the initial mail-out (summer/spring vs. winter/autumn). The exploratory subgroup analysis used multiple linear regression with the primary outcome, the mean TEE (per day) levels from the Actiheart at 3 months post randomisation, as the response. We used an statistical test for interaction between the randomised intervention group and the subgroup to directly examine the evidence for the treatment effect of the combined booster groups varying between subgroups.[43,46,47] Subgroup analyses were performed regardless of the statistical significance of the overall intervention effect (booster vs. control). The model below was used to assess the interaction:

$$\text{Outcome} = \text{randomised group} + \text{subgroup} + \text{randomised group} \times \text{subgroup interaction} \quad (2)$$

A graphical plot of mean profile subgroups with intervention group was used to display the interaction effect.[48]

Methods for the process evaluation

The aim of the process evaluation was to (1) assess how acceptable and appropriate participants found the intervention and (2) identify psychosocial and environmental factors that may modify the effectiveness of the intervention. The study contained two components: (1) a survey by postal questionnaire, incorporating closed and open questions, and (2) a semistructured interview conducted individually face to face or over the telephone, depending on the preference of each participant.

Our methodological and theoretical approach is that adopted by Snape and Spencer,[49] characterised by a subtle realism, interpretivism and pragmatism: we understand our subject matter through participants' contextually situated perspectives; we strive for neutrality and objectivity during data collection and analysis and we attempt to be as transparent as possible as we move beyond the data during interpretation to serve the needs of policy-makers.

Survey

Survey questionnaires were sent to participants before their 3-month research assessment and they were asked to completed the questionnaire before the assessment and return it in a sealed envelope. If the survey was not completed participants were asked if they would be willing to complete it at the 3-month research assessment, after which the participant sealed it in an envelope and handed it back to the RA. Because of delays in regulatory approvals, questionnaires were sent out from April 2010 only and the first 47 randomised participants were not invited to complete it.

The survey questionnaire asked participants about the type and location of physical activity that they had undertaken during the previous 3 months, reasons for staying physically active, factors that influenced their physical activity behaviour and social support from significant others. The versions of the questionnaire sent to participants in the full and mini booster arms of the trial also contained questions on the intervention received. Participants were asked why they chose to participate; their preferred format for such an intervention; their expectations of the intervention and the extent to which these were met and whether they found the intervention easy, convenient, non-judgemental and non-confrontational. Participants were also asked their opinion about the amount of contact time with the project worker, the extent to which they felt encouraged to set their own goals for physical activity and the extent to which

they felt that the intervention had helped them to resolve their barriers to physical activity, expand their knowledge of physical activity, increase their awareness of local facilities and opportunities and increase their confidence to stay active. Finally, participants were asked whether they had become more physically active than they were before participating and what had helped them achieve this. The questionnaire sent to those in the full booster arm of the trial can be found in *Appendix 4*. The questionnaires distributed to the mini booster and control arms are available from the team on request.

In-depth interviews

Those receiving a booster intervention who also responded to the survey questionnaire (see *Survey*) were given the option of participating in an in-depth interview. Because of the poor response there was no scope for purposive sampling; as a result, we interviewed a sample comprising all of the 26 people who volunteered. We did not elicit reasons for declining a research interview. Three RAs performed the interviews: Andrew Hutchison PhD (male) and Kimberly Horspool MSc and Sue Kesterton MSc (both female). KH and SK had both studied qualitative research techniques as part of their MSc but were novice interviewers. AH was more experienced having conducted a number of qualitative research interviews as part of his doctoral research. None of the interviewers delivered the intervention to the interviewees but interviewers may have been involved in collecting baseline data for the RCT component from some interviewees. Interviewees would have known that interviewers were on the research team and were from Sheffield Hallam University and may have associated them with exercise science and delivery of the intervention. The interviewers were asked to withhold their own opinions and to make it clear that this interview was separate from the intervention motivational interviews. No field notes were taken and no repeat interviews were undertaken.

Semistructured interviews lasted between 9 and 32 minutes (median 21 minutes) and were conducted over the telephone or face to face in a quiet room at a community venue, according to each participant's choice. For most interviews no one was present except for the participant and the researcher. In one case a participant chose to conduct the interview on a mobile phone and, for part of the time, in a public place.

A topic guide was provided to interviewers (see *Appendix 5*); this was not pilot tested. This guide included questions on participants' levels, choice and prioritisation of physical activity as well as the benefits and costs associated with staying physically active. It also included questions on participants' experiences of the booster sessions and why they had or had not helped them to stay active and why participants felt that the booster sessions were or were not a good way to give them the support that they needed.

Interviews were digitally recorded and transcribed verbatim. Transcripts were not returned to participants for comment or correction. Daniel Hind conducted the initial data analysis in NVivo version 10 (QSR International, Southport, UK) using a constant comparative method to identify themes. We used a 'framework' approach to analysis in which a priori and emergent themes were identified using the following stages: familiarisation, identifying a thematic framework, indexing, mapping and interpretation (charting was not undertaken).[50] For instance, a theme of a priori interest was the perceived effectiveness of the booster sessions; subthemes within this category were derived inductively from familiarisation with the transcripts.[50,51] The results were used to explore insights into the mechanisms that may have contributed towards the quantitative findings and to identify any other emerging issues or factors that may have influenced the uptake of the boosters and which had not previously been documented.[52] Data saturation was achieved[53] with no substantively new themes emerging in the last 10 interview transcripts. Participants were not asked to provide feedback on the themes.

Having indexed transcripts using our own thematic framework, we undertook a rapid review of the literature to find existing frameworks to evaluate dimensions of (1) prior conditions experienced by the participants; (2) barriers to and facilitators of adoption of new behaviours or technologies; and (3) the acceptability/appropriateness of the interventions. For prior conditions (see *Chapter 4*, *Prior conditions*) we used dimensions described by Rogers (p. 172).[54] We adopted, with modifications, the dimensions of the Motivators of and Barriers to Health-Smart Behaviors Inventory, developed by Tucker and colleagues[55]

(see *Chapter 4*, *Barriers to physical activity* and *Physical activity: motivators*). Our dimensions of intervention acceptability are based on those described by Nastasi and Hitchcock[56] (see *Chapter 4*, *Motivational interviewing: perceived effectiveness*, *Motivational interviewing: consistency with perspectives or world views*, *Motivational interviewing: perceived feasibility* and *Motivational interviewing: perceived importance*).

Methods for the fidelity study

Background

Although a small number of studies assessing the efficacy of physical activity counselling have reported the content, frequency and duration of training of those delivering the physical activity counselling intervention, the majority do not, and it is not uncommon for most clinical trials to fail to even report the content of the counselling intervention.[57,58]

Although physical activity counselling based on MI has been rolled out across the UK through the *Let's Get Moving* education programme,[59] it remains unclear whether those delivering the training and those delivering the intervention to patients are doing so according to the approach intended. This failure to embed assessments of competence has raised questions over the value of short-term workshops with little or no ongoing supervision and professional practice reflection. It is clear that programmes such as this offer a potentially valuable additional education framework but few studies are currently being published that have clearly assessed the fidelity of those delivering the intervention.

It has therefore been suggested that behavioural interventions should clearly report (1) the content of or elements of the intervention, (2) the characteristics of those delivering the intervention, (3) the characteristics of the recipients, (4) the setting [e.g. Physical Activity Referral Scheme (PARS)], (5) the mode of delivery (e.g. face to face or by telephone), (6) the intensity and contact time (e.g. number of sessions) and (7) participant adherence to delivery protocols.[60] The booster trial embedded these principles into its design along with treatment fidelity frameworks intended to provide standardisation of the behavioural intervention without losing innovation and flexibility within the two intervention arms.[17,18] Furthermore, the action planning and maintenance phases in both experimental arms used behaviour change techniques, as recommended by Michie and colleagues,[60] which are thought to enhance self-regulation towards change. The assessment of the existing competence and subsequent training of those delivering the MI interventions was evidence based and built on recent reviews of training in MI.[61]

Motivational interviewing content and delivery

The MI component was delivered by RAs trained by a member of the Motivational Interviewing Network of Trainers and followed existing frameworks for MI in physical activity contexts.[62,63] The key phases and content of the intervention are provided in *Table 2* and follow the phases of MI.[64] The relational aspect (or 'spirit') of MI is pivotal to the approach and emphasises participant 'autonomy' as opposed to

TABLE 2 Motivational interviewing content and session structure

MI content	MI phase
Opening exchange/agenda setting	Engagement
Decisional balance	Focusing
Importance of change (agreed target behaviour)	Evoking
Readiness to change (agreed target behaviour)	
Action planning	Planning
Maintenance phase	Maintenance

'imposing authority'; 'evocation' rather than 'education'; and 'collaboration' instead of 'confrontation'. Once underpinned with the relational approach, the technical skills of MI were delivered, which included open-ended questions, affirmations, reflective listening and summarising.[13] Those delivering the intervention received 6 days of formal training over the first 12 months of the study in addition to follow-up supervision for the remainder of the study using audio recordings for reflective feedback.

Treatment fidelity assessment and methods

To ensure that the criteria for treatment fidelity were met, those delivering the MI physical activity booster interventions (RAs) were assessed for their competence in delivering MI before and throughout the intervention period. The assessment of practitioner competence used was the Motivational Interviewing Treatment Integrity (MITI) assessment.[65] Minimum practitioner levels will be based on the levels of 'competence' as stated in the MITI coding system. To account for practitioner competence 'drift' (post training), follow-up reviews of practitioner MI competence were carried out at appropriate intervals (approximately every 9 months).

The MITI assessment was used to measure the interventionist application of key facets of MI, which included 'global ratings' of evocation, collaboration, autonomy/support, direction and empathy. In addition, 'behaviour counts' were recorded, which included giving information, MI adherent behaviours (e.g. asking permission, affirming, emphasising personal control), MI non-adherent behaviours (e.g. advising, confronting, directing), open compared with closed questions and simple and complex reflections. The calculations for MITI were based on existing standards,[65] as seen in *Table 3*.

The relationship between motivational interviewing fidelity and levels of physical activity: statistical methods

We employed analysis of variance (ANOVA) to test the null hypothesis that physical activity measured by mean TEE at 3 months was the same across all of the RAs who delivered the MI intervention. We plotted the means of mean TEE with their associated 95% CIs stratified by the RA who delivered the MI intervention to show how physical activity varies across RAs ranked by their global proficiency ratings. A further ANOVA model was fitted with RAs with the same global proficiency rating grouped together. We dropped from the analysis RAs who delivered very few sessions. In addition, for the few sessions in which MI was delivered by two RAs, we allocated the session to the RA who delivered more sessions.

Methods for the geographical information systems study

Aim

The aim of this substudy was to explore whether access to green space and leisure facilities influenced the effectiveness of the intervention. We used network distance analysis to produce a set of variables for each of the 282 trial participants, which represents his or her pedestrian access to municipal green space and any relevant leisure facilities.

TABLE 3 Motivational Interviewing Treatment Integrity treatment fidelity results

Clinician behaviour count or summary score thresholds	Beginner proficiency	Competency
Global clinician ratings (average)	3.5	4.0
Reflection to question ratio (R : Q)	1	2
Per cent open questions (% OQ)	50	70
Per cent complex reflections (% CR)	40	50
Per cent MI adherent (% MIA)	90	100

Network distance analysis

Euclidean (straight line) distance is the simplest measure of distance between two points. However, in a city it is rarely possible to follow a straight line between two points. Moreover, rivers, railway lines and sometimes roads force pedestrians to take routes that may deviate considerably from a straight line. To gauge the realistic walking distance between two points in a city, it is necessary to build a network representation of the pedestrian-accessible routes within the city and surrounding area. The shortest route between any two points on the network can then be calculated mathematically.

The most labour-intensive step is creating the network. The Integrated Transport Network™ (ITN) in OS MasterMap® [Ordnance Survey, Southampton, UK; see www.ordnancesurvey.co.uk/oswebsite/products/os-mastermap/itn-layer/index.html (accessed 10 October 2012)], can be used for this purpose, but unfortunately it is not possible to download a single portion of the ITN covering all of Sheffield and the surrounding area. Instead, we downloaded the data for this area from OpenStreetMap (see www.openstreetmap.org). In a certain respect, OpenStreetMap is actually more useful to us than the ITN; it is created (in part) by local volunteers, walking on foot and recording data with global positioning system (GPS) devices, and therefore provides information on pedestrian access that is more detailed than a typical OS map.

Roads and footpaths, etc. in OpenStreetMap are stored in a simple vector format that makes it relatively easy to extract the information required to build a network. The only problem is that the labelling of pedestrian accessibility for roads (especially trunk roads) is not consistent and is occasionally inaccurate. It was therefore necessary to manually exclude the following sections of road:

- A61 Dronfield bypass
- Sheffield Parkway
- Mosborough Parkway
- A57 (section linking Mosborough Parkway to the M1)
- A616 Stocksbridge bypass
- Park Square roundabout
- Tinsley roundabout and Tinsley viaduct.

Crossing points for non-pedestrian roads, for example bridges and underpasses, are well detailed in OpenStreetMap.

Although the shortest distance between points within the network can be calculated very accurately, there is the potential for error when calculating the network distance between features that do not lie within the network. Unfortunately, the centroids of postcode areas, and the polygons representing municipal green space boundaries, do not lie within the network. Here it is necessary to spatially ‘join’ these features to an appropriate point on the network. This is best done manually; however, because of the large amount of work that this would require it was necessary to automate the joining process, as follows.

Each postcode centroid was linked to the closest point on the network and the Euclidean distance between the centroid and the network point added to the network distance.

Each green space polygon was linked to all network points falling inside it, with the minimum network distance to any of these points deemed to be the minimum network distance to the polygon itself. As pedestrian entry points to green space are well detailed in OpenStreetMap, this means that the network distance mostly takes the entry points into account.

The major limitation of the automated joining process is that sometimes the network point that the feature is linked to is not always the most appropriate. For example, a postcode area may include adjacent houses that face onto different streets so that an address may be attributed to a network point on a street from which there is actually no access to the property. Similarly, for green space, points on the network

outside the green space polygon may sometimes be closer to the actual entry points than those inside the polygon. This can result in network distance errors of ≥ 100 m, in some cases substantially more if the difference in network distance between the automated choice of point and the optimum choice of point is large. Fortunately, very large anomalies appear only in rural areas where the road network is sparse and therefore were not a significant concern in this analysis.

Green space measures

All municipal green spaces in Sheffield were considered, excluding certain types of land use inappropriate for exercise. Sheffield City Council classifies these spaces as 'city', 'district' or 'local' according to their catchment areas. We used 'city' as a proxy for high-quality space and 'district' as a proxy for medium-quality space in terms of attractiveness. Local spaces were too ubiquitous for a meaningful spatial analysis. Of municipal green spaces belonging to other authorities, only Rother Valley Country Park was included (designated high quality).

Digitised boundary data for municipal green spaces in Sheffield were provided by the Sheffield City Council Parks and Countryside team. As well as boundary information, these data included a classification of the usage and catchment area categorisation of each space. These are explained fully in a Sheffield City Council Parks and Countryside report[66] but are summarised here as follows:

- Usage type:
    - parks
    - gardens
    - sports sites (e.g. tennis courts)
    - playing fields
    - playgrounds
    - playground/open space
    - woodlands
    - moorland/heathland
    - open spaces
    - allotments
    - churchyards/cemeteries
    - other site types – specified:
        - golf courses
        - farms
        - show grounds
        - depots
        - ancillary sites to other leisure facilities (e.g. car parks).
- Catchment area categorisation:
    - city wide
    - district (up to 1.3 km)
    - local (up to 0.4 km).

We decided to disregard the following usage types: playgrounds (because our participants are middle-aged), allotments (as nearby allotments are relevant only to the minority of local residents who rent them), churchyards/cemeteries (less likely to be appropriate places for exercise), farms, depots and ancillary sites.

Inclusion of the catchment area categorisation information is more problematic than inclusion of usage type as it is not clear on what research, if any, it is based. However, disregarding the categorisation is equally problematic as 'local' municipal green space is ubiquitous. For example, our preliminary study

considered all municipal green spaces in Sheffield of the appropriate usage type and the size of a football pitch or greater and found very few postcodes in the city that were further than 1 km from such a space, with roughly 50% falling within 500 m and roughly 30% falling within 300 m. This tallies with the findings of Barbosa and colleagues.[67] Also, most distances > 500 m fell in the most affluent parts of the city, which were not included in the booster trial (this also tallies with the findings of Barbosa and collegaues[67]). Because of random errors inherent in our network distance measurements (see *Network distance analysis*), such small network distances would contain an unacceptable amount of uncertainty. It was also felt that it was important for us to take some account of the attractiveness of municipal green spaces.

Therefore, we decided to make use of the catchment area categorisation as a proxy for the quality/attractiveness of the space, using an ordinal scale in which citywide represents the highest quality, district represents medium quality and local represents the lowest quality. Disregarding all green spaces with unsuitable usage types (see earlier) we measured the shortest network distance to:

(a) high-quality municipal green spaces of appropriate types
(b) high- or medium-quality municipal green spaces of appropriate types.

We excluded Sheffield's three municipal golf courses; these have citywide catchment areas but this is clearly based on their attraction as a leisure facility (as defined in leisure facility measures) offering golf, rather than as a green space, and the booster participant questionnaire responses indicated that very few participants played golf.

One potential problem with using the green space data for Sheffield is that many of the booster participants live on the edge of the city and could be using municipal green spaces belonging to surrounding authorities (Barnsley Metropolitan Borough Council, Rotherham Metropolitan Borough Council, Derbyshire County Council or North East Derbyshire District Council). This was a matter of sufficient concern for us to request green space boundary data from these authorities. However, because of the green belt around Sheffield, there are actually few important municipal green spaces belonging to these authorities that are close to the borders of Sheffield. The exception to this is Rotherham, with the two conurbations forming a continuous urban area. However, this area is heavily industrialised and there are few important municipal green spaces. One very important exception is Rother Valley Country Park, which borders south-east Sheffield; a boundary polygon for this park was added manually to the set of green spaces having a citywide catchment area.

All green space measures in this study are shortest distance measures. So far we have decided not to use a gravity model for green space as the need to include an arbitrary distance decay parameter would be a potential source of bias. However, this remains an option for future work. Regarding the more sophisticated floating catchment area gravity model, this may actually be inappropriate for green space: unlike a capacity-constrained service such as a health practitioner, a green space that is heavily used (and thus full of people) may be more attractive and more likely to be perceived as appropriate for recreational exercise or as a walking route than one that is less well used.

Leisure facility measures

Leisure facilities, as distinct from green spaces, are defined here as places where a physical activity is facilitated by some kind of organisation, usually in return for payment. For example, we define a tennis club as a leisure facility but an unsupervised tennis court within a park as part of a green space. Similarly, a publicly accessible playing field is considered a green space rather than a leisure facility, unless it is part of a sports club. Data on leisure facilities are easier to collect than data on green spaces because leisure facilities can be treated as point locations. Even though these facilities may cover a large area, there is usually an office where people must go to pay, and this is typically also the building to which the address of the facility relates. Therefore, noting the limitations of geocoding accuracy explained in *Network distance analysis*, it is credible to use the postcode centroid of the facility's address as a point location.

The chief problems in collecting data on leisure facilities were twofold:

- deciding which types of leisure facility were relevant to the booster participants
- ensuring that all leisure facilities of these types, located within a reasonable distance of the study area, were included.

To address the first point we had the benefit of the questionnaires completed by the booster participants (see *Outcomes* and *Survey*). These data suggest that the main physical activities relevant to the participants were walking, gardening, swimming and gym-based activities. Walking relates to municipal green space rather than leisure facilities and gardening relates to neither, so we considered only leisure facilities offering a gym and/or swimming.

To address the second point we used the Sport England online 'active places' database,[68] which provides an authoritative list of sports facilities, with each facility listed as offering one or more types of activity. Two of these types of facilities, 'health and fitness suite' and 'swimming pool', correspond directly to gyms and swimming respectively. The postcode of each facility is also included on the database, as is an indicator of how the public can access the facility (those open only to sports clubs or community associations, rather than individuals, were excluded). For each facility postcode we calculated the network distance to every other postcode within Sheffield, and for each Sheffield postcode we recorded the shortest network distance to:

- a unisex gym
- a female-only gym
- a swimming pool.

As with green space, we did not implement any of the more sophisticated 'gravity' models for leisure facilities. The basic gravity model is additive, meaning that having three gyms a 500-m network distance from one's home would be scored three times better than having one gym 500 m away. This is clearly inappropriate as gyms are often paid for on a membership basis, and it is unlikely that a participant would join several gyms. Although swimming may be offered on a pay-per-session basis more frequently than gym facilities, it is still questionable whether having three local pools is exactly three times better than having one local pool.

Here, the floating catchment area gravity model is potentially more useful than the basic gravity model as it links the usefulness of local facilities to local demand.[69] A gym may be less desirable if it is frequently crowded and one has to wait to use particular exercise machines, and the same may also apply to lane swimming in pools. In this context having multiple local facilities can be beneficial, as greater provision of facilities means that they are less likely to be crowded. Unfortunately, the problem with interpreting this model is determining local demand; although the size of the local population can be easily obtained from census data, people often choose leisure facilities close to where they work rather than where they live, so using population data could be misleading, particularly in the city centre.

Given these issues, and for consistency in the analysis methods, we have used straightforward minimum distance analysis.

With leisure facilities there is also the issue of affordability. Some facilities are expensive and may not be realistically accessible to the more deprived communities targeted by the booster recruitment strategy. However, pricing information is not included in the Sport England database and it was not possible within the timescale of this project to obtain pricing information separately for each facility. Restricting the analysis to municipal facilities was considered but in Sheffield some privately run leisure facilities are less expensive than municipal ones. It is therefore important to recognise that affordability may be an additional barrier to accessing local leisure facilities, even when they are geographically close, which this analysis does not address.

Statistical methods

We constructed crude scatter plots of mean TEE per day (kcal) at 3 months against potential moderators generated from the geographical information systems (GIS) analysis and other continuous baseline potential moderators to explore any univariable linear relationships. In addition, we stratified these plots by intervention arm to explore whether the univariable linear relationships were consistent within the intervention arms. Univariable linear regression models were fitted with amount of physical activity measured by mean TEE per day (kcal) as the response and potential moderator as an explanatory variable to explore whether a potential moderator was a predictor of physical activity at 3 months.

To explore the moderation effect, we fitted multivariable linear regression models on the same response variable with intervention group, potential moderator and interaction between treatment group and potential moderator as explanatory variables (as given by *Equation 3*). Plots of the fitted regression line stratified by booster treatment group were constructed to explore any potential interactions. In addition, hypothesis testing on the interaction term was also undertaken using *Equation 3* to test the moderation effect of GIS variables on physical activity. Variables were classified as being moderators of physical activity if they had a significant interaction effect with treatment at 3 months.

$$\begin{aligned}\text{Mean TEE per day (kcal)} = {} & \text{potential moderator} + \text{treatment group} \\ & + \text{potential moderator} \times \text{treatment group}\end{aligned} \tag{3}$$

Methods for the health economic analysis

Introduction

As part of the trial data collection, participants answered questions on their use of NHS facilities at 3 months and 9 months post randomisation. Participants also completed the SF-12v2 plus 4 HRQoL questionnaire, allowing SF-6D HRQoL scores at 3 and 9 months to be produced.[70] Together with an estimate of the intervention cost, such data allow a simple estimate of the effect of the intervention on mean HRQoL and average cost to be produced by comparing costs and utility scores at the end of the intervention with those before the intervention.

A potential problem with using this approach in the case of the booster intervention is illustrated in *Figure 1*. *Figure 1a* illustrates a typical pharmaceutical RCT. The patient population is recruited on the basis of suffering from a particular disease, which has a progressive effect on their HRQoL. The intervention reduces disease progression and so a difference in HRQoL emerges between the intervention arm (dashed line) and the control arm (solid line) by the end of the trial. *Figure 1b* indicates the potential effect on HRQoL of a lifestyle intervention. Both the control arm and the intervention arm are generally in good health initially but because of low levels of physical activity both are at an increased risk of developing a range of diseases and conditions related to sedentary behaviour. As the intervention is not intended to modify a disease but instead modify a lifestyle factor that predisposes people over the long term to increased morbidity and mortality risks, a straightforward comparison of before-and-after levels of resource use and HRQoL may be misleading as it may have been too soon for the mediating effect of physical activity on health to have become apparent.

For this reason, the cost-effectiveness of the interventions was assessed using two distinct modelling approaches. Alongside a short-term model comparing participants' self-reported HRQoL and NHS resource use at 3 and 9 months, a long-term epidemiological model was also developed in which differences in the primary physical activity measure recorded in the trial, TEE, were mapped onto effects on mortality reported in epidemiological literature. This approach better allows the complex mediating effects of physical activity on health to be formally represented but also increases the dependence of the modelling results on strong assumptions about this physical activity–health relationship.

In the rest of this section overviews of the methods used to produce the two models are provided.

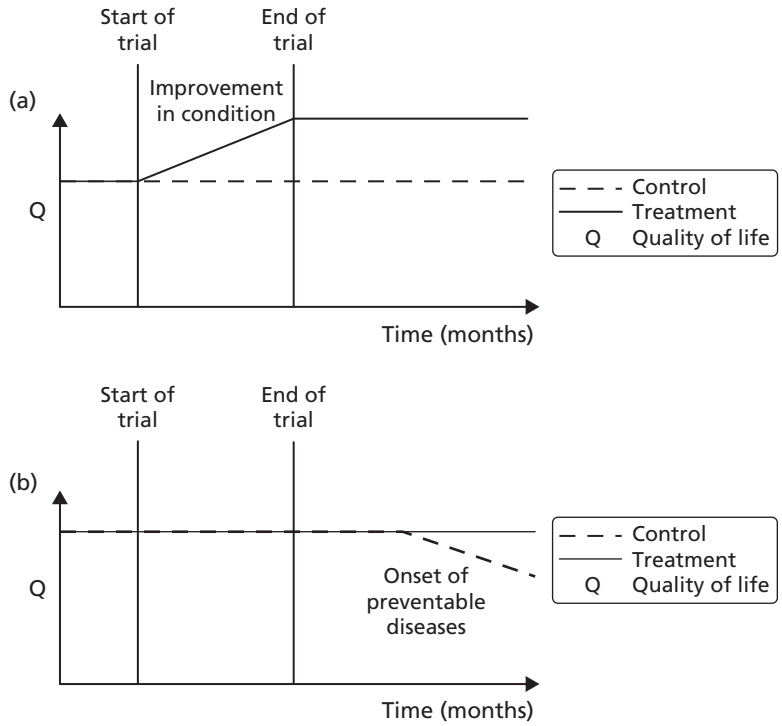


FIGURE 1 Timing of HRQoL benefits. (a) Curative intervention; and (b) preventative public health intervention.

Cost-effectiveness modelling overview

Two types of cost-effectiveness model were developed, which used different approaches and sources of data to estimate the health effect, in quality-adjusted life-years (QALYs), of the interventions. Both types of model are described in more detail below.

Short-term questionnaire-based model

A short-term cost-effectiveness model has been constructed that incorporates trial-based estimates of the effect of the two interventions – mini booster and full booster – on participants' use of NHS resources during the trial period. It also uses trial-based estimates of the effect of the interventions on participant utility using responses from participants who completed the SF-12v2 plus 4 HRQoL questionnaire at baseline and 9 months.[70] Approximate costs of the interventions are also incorporated in the model alongside the estimates of the effect of the interventions on resource use.

Resource use data collected and used

Data were collected at randomisation and at the end of the trial on participant use of NHS facilities. This included all face-to-face and telephone consultations with general practitioners (GPs) and other primary care staff, attendance at hospital accident and emergency (A&E) facilities, use of hospital outpatient facilities, number of hospital day cases and number and duration of hospital stays. With these data it is possible to produce an estimate of the effect of the intervention on resource use from an NHS perspective. Uncertainty in the true frequency with which each type of NHS resource was accessed was represented using a Dirichlet distribution with a non-informative prior of 0.5 added to each cell count.

For each trial arm – control, mini booster and full booster – the number of times that each participant had been to A&E, used hospital outpatient facilities, been a hospital day case and stayed overnight in hospital was recorded at both randomisation and up to 9 months later. Along with the reason for each resource use event, the number of times that type of resource was accessed for that reason was also recorded. For example, some participants may stay 2 nights in a hospital for a particular reason, others may have three hospital day appointments for another reason. What is of interest from a resource use perspective is the number of resource use units – such as nights in hospitals, day appointments, A&E admissions – rather than number of events. For this reason the number of resource use units of each resource use type

was calculated by multiplying the number of resource units represented by an event by the frequency of each event. Costs for each type of resource use unit were estimated from a standard source[71] to produce estimates of the cost of each type of resource use at the start and end of the trial and in each trial arm. These were divided by the number of participants in each arm to produce an estimated cost per participant.

Estimating costs from a societal perspective

These data were also used to provide estimates of the effect of different health conditions from a broader, societal perspective, which are presented as separate analyses. From this broader perspective, each use of a NHS facility was assumed to incur an additional cost. This additional cost was calculated as the national minimum wage for older people of working age multiplied by an assumed amount of time that it would take a patient to make use of each particular service type. The number of working hours foregone in making use of each type of NHS resource is shown in *Table 4*.

Although a significant proportion of the patient population was close to, or older than, retirement age and so may not be expected to be in full-time employment, the same opportunity costs were applied to all patients. This is to account for the societal value of services that people who are not in employment can be assumed to provide to friends and family, such as looking after children, home maintenance, looking after pets and so on. Each of these services can be bought and so has a market value at or above minimum wage. These simplifying assumptions are more likely to overestimate than underestimate the true societal costs and so could be considered an upper range of the cost-effectiveness of the interventions from a societal perspective.

Estimating health-related quality of life

Responses from participants who completed the SF-12v2 plus 4 questionnaire were used to derive an SF-6D utility score.[70] Differences in differences between an intervention arm and the control arm are used to produce an estimate of the incremental effect of each intervention on participant utility over this period.

Deterministic results

A version of the model is presented that provides a single best estimate of the mean incremental cost and mean incremental QALY gain for both the mini booster and full booster interventions. These best estimates combine resource use and utility values estimated from trial data with approximate intervention costs elicited from report authors involved in conducting the interventions. These estimates are somewhat approximate and are intended more to be illustrative than authoritative. The effect of the high level of uncertainty in these estimates on decision uncertainty is explored through probabilistic sensitivity analysis (PSA).

Probabilistic sensitivity analysis

Within PSA, instead of a single best estimate of the incremental cost and QALY gain of each intervention being used, the effect of uncertainty around these values was assessed by drawing 1000 plausible values

TABLE 4 Assumed number of hours of labour or equivalent foregone from each use of a NHS facility

Resource type	Assumed working hours foregone
Visit to A&E	15 (2 days)
Hospital day case	7.5 (1 day)
Hospital outpatient	7.5 (1 day)
Hospital overnight stay	7.5 (1 day)
GP telephone consultation	1
Visit to GP surgery	3.75 (half a day)

from joint distributions of the mean costs and mean QALYs of each intervention. These are shown on scatterplots, with different plotting symbols representing estimates from different arms.

Cost-effectiveness acceptability frontiers

Cost-effectiveness acceptability frontiers (CEAFs) were used to translate the joint incremental cost and incremental QALY estimates ('scatter') produced from the PSA into an indication of decision uncertainty. This involved calculating the incremental cost-effectiveness ratio (ICER) implied by each joint estimate of incremental cost and incremental QALYs and identifying the proportion of ICERs that are below a given willingness-to-pay threshold (λ). The horizontal axis of a CEAF indicates how the proportion of ICER estimates below the threshold varies across different values of λ. Within this analysis, the range of λ values considered was between £0 and £50,000 per QALY. CEAFs differ from cost-effectiveness acceptability curves in that only the option estimated to be optimal, that is, with the greatest net mean benefit, is plotted.

Long-term epidemiological model

As stated previously, interpretation of the short-term cost-effectiveness model can be problematic as the intervention is preventative rather than curative and the participants are not selected from a population characterised by a particular disease. Because of this, it may be more valid to consider the effect of the intervention over a much longer time horizon than the trial duration and to assume that any potential QALY benefits of the intervention are mediated through the clinically measurable health benefits of increased physical activity. This is the rationale for presenting a long-term epidemiologically based model alongside the short-term questionnaire-based model described in the previous section. Unfortunately, adopting this approach requires making a number of strong assumptions about how the physical activity measures recorded within the trial translate into an impact on population health. The long-term model was an individual sampling model constructed in the R statistical programming language (version 2.14.2). The approach taken to develop this model, together with the assumptions made, are described in the following section.

Populating a hypothetical cohort of individuals

As the population who participated and were eligible for the intervention were drawn from a fairly general working age population, an individual sampling model was constructed to represent variability in terms of age and gender of the population at baseline. After discussion amongst project members, it was decided that the age distribution of the hypothetical population considered in the long-term model should be drawn from the age distribution of the booster trial participants rather than the population eligible for the trial. This is because trial participants did not appear to be uniformly drawn from the population eligible to participate but were disproportionately drawn from the upper end of the age range eligible to participate. For simplicity, it was assumed that trial participants were drawn equally from both genders.

Hypothetical population size

Within these analyses, the size of the simulated cohort was selected to be 500,000 individuals. Increasing the number of individuals sampled in the simulation will lead to greater stability in estimates of mean effect but will substantially increase the computing time that models need to run.

Defining and simulating the ongoing mortality hazard in the simulated population

Once the hypothetical cohort of individuals was constructed, the aim was to simulate their clinical experiences over their lifetime. Beginning at their initial age, the probability that they die in the following year was estimated using Office for National Statistics (ONS) life table data.[72] If they survive the following year, their age is increased by 1 year and the probability of them dying in the following year is updated to reflect their new age. The mathematical model involves applying this process iteratively for each of the

individuals in the cohort until death, producing a series of simulated initial ages and ages at death. *Table 5* provides a simple illustration of this:

TABLE 5 Illustration of results from a simple patient natural history simulation

Person number	Initial age (years)	Gender	Age at death (years)
1	51	Male	82
2	45	Male	75
3	59	Female	84
4	48	Female	90
5	52	Male	86

Column 2 is drawn from trial participants' ages. Column 4 is estimated from life tables.

Calculating quality-adjusted life-years

The purpose of simulating each individual 1 year at a time is to estimate the accrual of QALYs over the life course. Recent work by the School of Health and Related Research (ScHARR) at the University of Sheffield has indicated that the QALYs associated with living another year differ according to the age and gender of the patient and to reflect this it has produced a regression equation that allows age- and gender-adjusted QALYs to be calculated.[73] This equation has been used within the mathematical model to produce more accurate estimates. Each additional year lived by a simulated individual therefore results in an increment to the number of QALYs accrued by that individual but this amount differs each year according to this equation.

In adjusting QALYs according to the age and gender of an individual, the different levels of morbidity that typically affect people at different ages and which differentially affect men compared with women are implicitly accounted for and so the model incorporates morbidity effects alongside mortality effects. For simplicity, however, it was assumed that different levels of physical activity do not have a mediating effect on the degree of morbidity that an individual experiences relative to other people of the same age and gender.

Discounting

As is standard practice in UK-based health-care economic modelling, QALYs gained are discounted at a rate of 3.5% per annum.[74]

Assumptions about the longevity of the effect of the intervention

An intention of the long-term model was to represent a plausible decline in physical activity levels in the years following the trial, returning to baseline levels for participants in each of the three trial arms after 2 years. As baseline levels of physical activity were not recorded using Actiheart, three alternative scenarios using the long-term model were used. One scenario used the 9-month activity levels relative to the 3-month activity levels and two other scenarios compared differences between arms at 3 months and 9 months post randomisation. The implications of these different assumptions about the appropriate comparators are discussed below, see *Problems with inferring causal effects from the data*.

Assumptions about the causal relationship between physical activity and mortality hazards

A number of sources of epidemiological research exist which suggest that a monotone relationship exists between how physically active people of working age are and their all-cause mortality rates.[75–80] However, no source could be identified that related directly to the population eligible for the intervention (those aged between 40 and 64 years inclusive), those who participated in the intervention (who tended to be drawn disproportionately from the older ages within the pool of those eligible) or the particular physical activity measures recorded by the Actiheart system.

Because of this a number of assumptions had to be made to relate the epidemiological results to the outcomes reported in the booster trial. The main epidemiological source used to inform the assumed relationship between physical activity measures and adjusted mortality risks was a US-based study published in the *New England Journal of Medicine* (NEJM) in 2002.[81] In this study the peak exercise capacity, as measured in METs, for older men of working age (mean age 59 years) was assessed through standardised treadmill-based testing. The paper presents a figure showing the relationship between relative risk (RR) of death and quintile of exercise capacity. The risk ratio for the highest exercise capacity quintile was chosen as the reference category. These data are presented in *Table 6*, as well as values adjusted to have the third quintile as the reference category.

Although initially it was assumed that the risk ratio to MET relationship could be mapped directly from the NEJM results to the Actiheart data, as both the data in the NEJM article and the booster trial data were categorised according to METs, it was recognised that this was not appropriate. This is because the contexts in which these METs were recorded were not equivalent. In the case of the NEJM article, METs were of physical exercise capacity and involved trying to identify an upper physical limit to patients' physical performance over a short period of time. In the case of the Actiheart data the METs were of typical activity over a period of 1 week. Instead, an indirect approach to mapping the relationship was used. This involved making the additional assumption that the relationship between quintiles held, even if the unit of measurement was different.

The outcome measure used from the booster trial to estimate the relationship between exercise quintile and RR was mean daily TEE, which was recorded using the Actiheart device at both 3 months and 9 months. The median TEE score from both time periods combined was identified and all scores recorded were converted to a proportion of this median score. The central proportional TEE score within each of the five quintiles was calculated by sorting all values from lowest to highest and identifying the values 10%, 30%, 50%, 70% and 90% of the way across this distribution, to identify proportional TEE values associated with each quintile. The relationship between TEE (as a proportion of the median TEE) and exercise quintile is presented in *Table 7*. This shows that someone whose TEE was approximately 80% of

TABLE 6 Reported relationship between exercise capacity quintile and RR of death

Quintile	Risk ratio[a]	Centralised risk ratio[b]
1 (lowest)	4.5	2.5
2	2.5	1.4
3	1.8	1.0
4	1.4	0.8
5 (highest)	1.0	0.6

a Quintile 5 was the reference category.
b Quintil 3 was the reference category.
Source: Myers and colleagues.[81]

TABLE 7 Mapping between quintile and TEE as a proportion of the median

Quintile	Mean TEE per day (kcal)	TEE as proportion of the median
1 (lowest)	1703	0.77
2	1998	0.90
3	2224	1.00
4	2434	1.09
5 (highest)	2839	1.28

the median is in the lowest physical activity quintile and someone whose TTE was approximately 30% more than the median was in the highest quintile. Participants' TEE levels at 3 months and 9 months are also presented graphically in *Figure 2*.

Data from *Tables 6* and *7* were combined to produce a regression equation mapping proportional TEE against RR of death. A good fit was found by assuming a power law relationship between these variables. The data and mapping equation identified are shown in *Figure 3*. The best fit equation identified was $y = 1.056x^{-2.951}$, where y is RR and x is TEE as a proportion of the median.

Using Actiheart data to adjust mortality risks in the simulated cohort

By using the power law mapping equation shown in *Figure 3*, an estimated RR for each proportional TEE value determined from the Actiheart data can be produced. The procedure for this within the

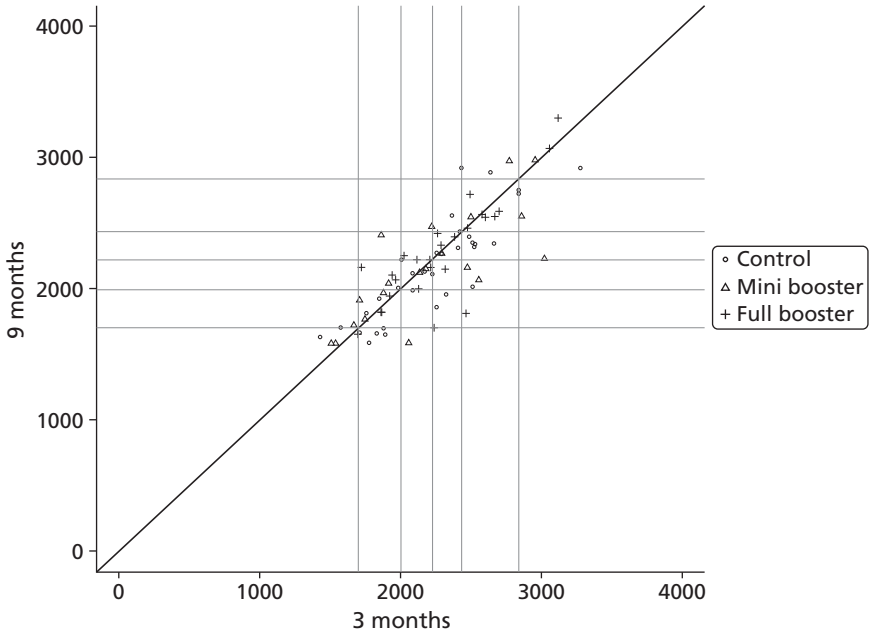


FIGURE 2 Relationship between mean daily TEE at 3 months and mean daily TEE at 9 months by intervention group. Grey lines indicate the centre of each quintile.

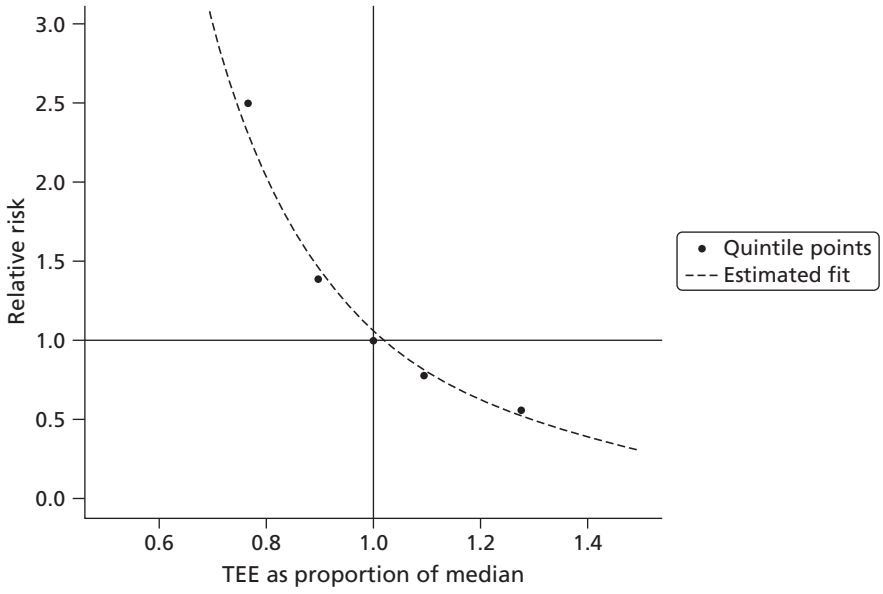


FIGURE 3 Mapping equation between assumed RR of death and TEE as a proportion of the median.

mathematical model involved first duplicating the initial simulated cohort of individuals produced using the ONS population data and then applying TEE scores drawn from the final observations in treatment arms combined to one of these cohorts and TEE scores drawn from the final observations in the control arm to the other of these cohorts. TEE scores were sampled with replacement from each respective arm. The RR associated with the particular proportional TEE assigned to that individual was then assumed to apply to him or her. An illustration of this is provided in *Table 8*.

The risk of death in the following year for each individual is then calculated by finding the estimated probability of death in the following year using life table data adjusted for age and gender and then multiplying that risk by that individual's estimated RR. Within the mathematical model the positive effect of the treatment can operate only through this life table adjustment, although as described above other positive clinical relationships between physical activity and mortality risk could also be incorporated in later additions of the model.

Problems with inferring causal effects from the data

There are two fundamental challenges to the validity of the long-term model: first, the main physical activity outcome recorded in the booster trial, TEE, is a surrogate or proxy from the perspective of the long-term model, in which the outcome is QALYs; second, it is difficult to judge what is the counterfactual or baseline, that is, what would have happened to those participants who were assigned to the intervention arms of the trial if they were assigned to the control arm.

The previous section has shown the degree of potential model dependence on a number of assumptions that had to be made to link TEE with mortality. Some of these assumptions are strong, such as the assumption that quintiles of exercise capacity in one population correspond directly to quintiles of physical activity in another population. The validity of such assumptions therefore has a knock-on effect on the validity of the model outputs.

The issue of estimating the counterfactual is a fundamental challenge in the case of the booster trial for a number of reasons:

1. Actiheart measurements including TEE and PACs were not recorded at the start of the trial ('baseline'). Instead, the first measures were recorded at 3 months post intervention. Additionally, subjective measures of physical activity such as the SPAQ were known to have only very slight correlation with the objective measures so cannot be reliably used to impute the objective scores at baseline.[82]
2. The level of attrition within the trial was high, meaning that the sample of participants who completed the trial may not be representative of those who started the trial, and so there is a significant potential bias issue.
3. The number of participants who had valid and complete Actiheart measures at 3 months and 9 months post randomisation is significantly smaller than the number who completed the booster trial.

TABLE 8 Illustration of how proportional TEE (pTEE) and RRs are linked to simulated individuals in the mathematical model

'Control' cohort					'Treatment' cohort				
Person number	Initial age (years)	Gender	pTEE	RR	Person number	Initial age (years)	Gender	pTEE	RR
1	51	Male	1.1	0.80	1	51	Male	0.9	1.45
2	45	Male	0.9	1.45	2	45	Male	1.1	0.80
3	59	Female	0.9	1.45	3	59	Female	1.3	0.49
4	48	Female	0.8	2.05	4	48	Female	1.0	1.06
5	52	Male	1.0	1.06	5	52	Male	1.7	0.22

Because of the high level of attrition and low number of participants with complete Actiheart data, it may be wrong to assume that the population mix in each arm is similar at 3 months and 9 months after the start of the trial, because of patterns of selective attrition. This means that it may be problematic to assume that differences in the outcome measures between the control arm and the treatment arm observed at 3 months and 9 months are due to the treatment effect.

For this reason, a differences-in-differences approach was used. This involves comparing change over time in the outcome in the treatment group with change over time in the outcome in the control group. As no TEE measurements were recorded at baseline, the 3-month scores were used as proxies for the baseline levels and the 9-month scores were assumed to be the longer-term post-intervention levels.

It may be argued that using the 3-month post-intervention scores as the baseline scores is a very strong assumption because a significant treatment effect may be present at 3 months post intervention. In theory, a highly effective intervention could appear to be less effective than a less effective option because the more effective intervention is most effective at 3 months whereas the less effective option is more effective at 9 months than at 3 months. This is illustrated in *Figure 4*, in which the more effective intervention is indicated by the solid line and the less effective intervention by the dashed line. Because of this potential problem with using the 3-month scores as the baseline scores in the differences-in-differences approach, separate analyses using a simple differences approach were also carried out. These analyses involved comparing the TEE levels at 3 months in the intervention arms with the TEE levels at 3 months in the control group, and the 9-month TEE levels in the intervention arms with the 9-month TEE levels in the control group.

The fundamental problem with the simple differences approach is that differences between groups at either 3 months or 9 months could be due to differences between the groups that were present at randomisation, rather than differences as a result of the intervention. This is illustrated in *Figure 5* in which the intervention had no effect on the physical activity levels of either arm (the solid or dashed lines), but comparing scores in arms at either 3 months or 9 months would suggest a treatment effect. In this study, although the participants were randomly assigned to each of the three arms and so on average can be assumed to have similar baseline characteristics at randomisation, because of the degree of attrition in the study the composition of the three arms cannot be assumed to be the same at 3 months or 9 months because the attrition may have been selective. For example, participants who were least inclined towards additional physical activity may be more likely to leave the treatment arms but may stay in the control arm.

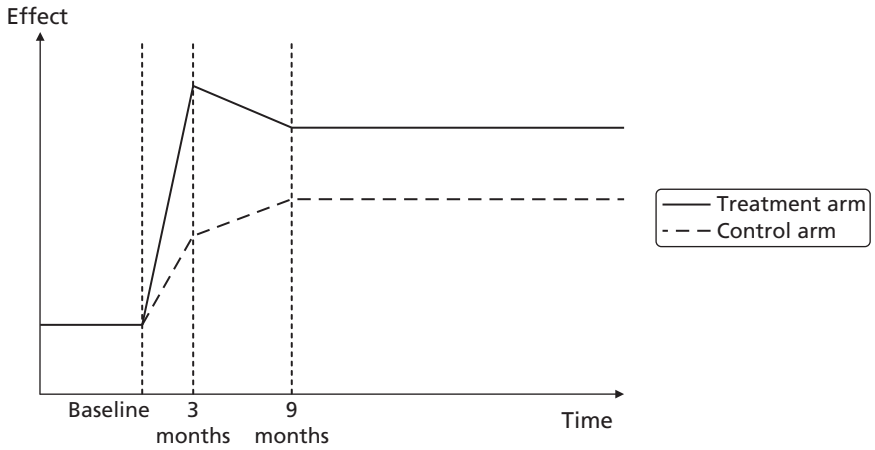


FIGURE 4 Illustration of a scenario in which it would be wrong to attribute differences in differences (9 months vs. 3 months) between the treatment arm and the control arm to a treatment effect.

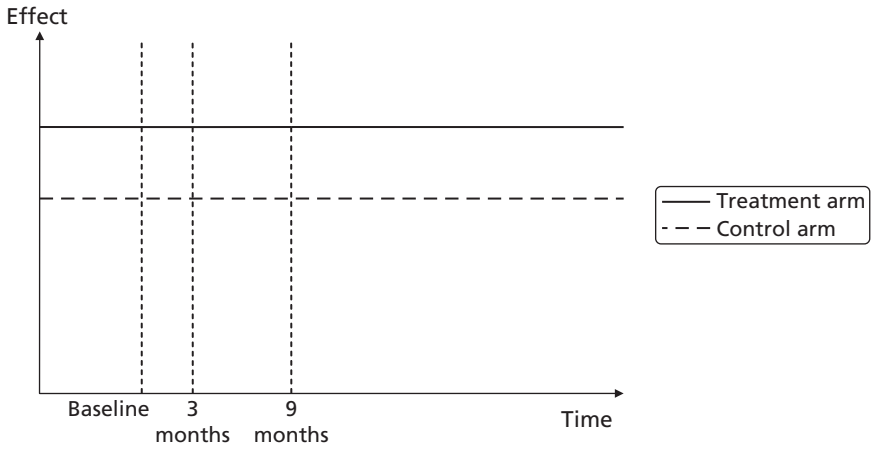


FIGURE 5 Illustration of a scenario in which it would be wrong to attribute differences between the treatment arm and the control arm at 3 months or 9 months to a treatment effect.

Estimating the mean incremental treatment effect on patient utilities using a differences-in-differences approach

In the differences-in-differences approach, four out of six hypothetical groups with the same initial age and gender profiles were compared. The six groups are:

- F_T – the 'treated' full booster arm. All individuals' scores were sampled with replacement from the scores of participants who were assigned to the full booster group and provided valid Actiheart data at 9 months and 3 months. The RRs associated with the individuals' 9-month scores were used for the first 2 years, then the RRs associated with individuals' scores at 3 months were used thereafter. This represents the assumption that any treatment effect of the intervention is unlikely to last much longer than the duration of the trial.
- F_U – the 'untreated' full booster arm. The same as for F_T but with the 3-month RRs used throughout.
- M_T – the 'treated' mini booster arm. The same as F_T but drawing from participants in the mini booster arm rather than the full booster arm.
- M_U – the 'untreated' mini booster arm. The same as F_U but drawing from participants in the mini booster arm rather than the full booster arm.
- C_T – the 'treated' control arm. As with F_T and M_T but using 9-month control group scores for 2 years instead. Using scores from this group helps to control for trends over time and any effect on physical activity of being part of the trial even if not assigned to one of the treatment arms.
- C_U – the 'untreated' control arm. As with F_U and M_U.

The utility effect of the intervention was therefore estimated as $(M_T - M_U) - (C_T - C_U)$ for the mini booster group and $(F_T - F_U) - (C_T - C_U)$ for the full booster group.

Estimating the mean incremental treatment effect on patient utilities using a simple differences approach

Using notation similar to that presented above, the six groups are:

- F_3 – scores at 3 months in the full booster arm
- F_9 – scores at 9 months in the full booster arm
- M_3 – scores at 3 months in the mini booster arm
- M_9 – scores at 9 months in the mini booster arm
- C_3 – scores at 3 months in the control arm
- C_9 – scores at 9 months in the control arm.

The utility effects of the interventions were therefore estimated as $F_9 - C_9$ (full booster) and $M_9 - C_9$ (mini booster) using 9-month data and $F_3 - C_3$ (full booster) and $M_3 - C_3$ (mini booster) using 3-month data.

Primary and secondary models

Because both the simple differences approach and the differences-in-differences approach require that problematic assumptions be made, neither the simple difference models nor the differences-in-differences models should be considered preferable to each other. Instead, they should all be considered equal primary models.

In addition to these primary analyses, a secondary model was also produced. This model involved assuming that the changes in physical activity levels recorded between 3 months and 9 months in each arm were equally distributed. This means that a mean increase in physical activity between 3 and 9 months will translate into a mean increase in survival and longevity. Because the primary long-term models are individual-level models and make use of a separate single observation from the trial and involve mapping changes in physical activity to changes in annual risks, this does not necessarily occur in these models. The approach used in this 'value-added' model is described in more detail in the following section.

The 'value-added' model

If F_{9i} defines the level of activity recorded in the individual in the full booster arm at 9 months and F_{3i} defines the level of activity recorded in that same individual at 3 months, then in the differences-in-differences model the physical activity level change in each individual at the end of 9 months is calculated as $F_{9i} - F_{3i}$ and so is different for each individual. In the 'value-added' model, however, an equal increase is assumed for all participants in each arm. This increase, Δ_F, is the mean difference between 9-month and 3-month scores observed in individuals in the full booster group. The increases in the control group, Δ_C, and the mini booster group, Δ_M, are calculated similarly.

'Value added' means that the direction of effect in terms of estimated effect on mean utility should always be in the same direction as the estimated effect on mean activity level and so may appear to produce more plausible estimates when trial results indicate a mean increase in physical activity but the economic model indicates a mean decrease in estimated utility. The cost of doing this, however, is to not make use of some available individual-level data relating level of physical activity at 3 months to level of physical activity at 9 months.

Additional assumptions about the physical activity–mortality relationship

As assuming that RRs related to physical activity levels applied indefinitely produces implausible estimates of the mortality effects of the intervention (such as indicating that a substantial proportion of those in the highest exercise quintile will live to > 140 years), and as the available results are for middle-aged individuals, it was additionally assumed that the relationship between physical activity and mortality rate stopped when participants reached 70 years of age and that uniform risks applied from that age onwards.

For simplicity, and because of a paucity of data in those above this age, it was also assumed that no individual would live longer than 99 years.

Additional scenario analyses

Assessing the effect of baseline physical activity on additional benefits of additional physical activity

As the relationship between exercise quintile and mortality RR appears to follow a power law, it seems important to consider how estimates of cost-effectiveness vary as a function of baseline levels of physical activity. This is because a given increase in physical activity for people already relatively active is likely to provide less additional health benefit than the same increase in physical activity in a very sedentary population. As a supplementary analysis, the long-term model was therefore used to estimate the effect of an intervention that increased people's physical activity from the first to the second quintile, the second to the third quintile, and so on.

Chapter 3 Results of the main trial

All tables relating to results from the main trial can be found in *Appendix 6*.

Recruitment of trial participants

Figure 6 provides a detailed flow chart showing participant recruitment and follow-up during the study. Between May 2009 and June 2011 a total of 70,388 postal invitation letters with prepaid reply cards were sent to residents aged 40–64 years in our study neighbourhoods inviting them to enrol in a programme to help them become more physically active. Response and randomisation rates from the six mail-outs are detailed in *Appendix 6*, *Table 16*. Mail-out 6 was sent in June 2011 in a final attempt to boost recruitment but with the expectation that 9-month follow-up results would not be available. The trial was closed to recruitment in November 2011, the last opportunity within the funding envelope to recruit and follow participants up for 3 months (the primary outcome assessment). No marked reply cards distributed by GPs were returned; the team have no information on whether those distributed through community sources were returned but it is assumed that most if not all respondents were approached through the primary care trust mail-out (see *Chapter 2*, *Methods for the main trial*).

Of the invitation letters sent, only 4964 (7.1%) replies were received indicating an interest in taking part in the trial. Of these potential participants, 2502 (50.4%) were contactable and were screened for eligibility for the brief intervention. A total of 568 (22.7%) of those screened for the brief intervention were ineligible to take part for various reasons (three were too young, 16 were too old, 470 were too active and already achieving the current recommended activity levels of at least 30 minutes of at least moderate activity on at least 5 days a week, 21 did not wish to be more active and 58 were ineligible for other reasons).

A total of 1934 participants wishing to have support to become more active and meeting the inclusion criteria and eligible for the brief intervention were sent a DVD focused on increasing physical activity in general. Three months after receiving the brief intervention, 1094 (56.6%) were contactable and their physical activity levels were reassessed.

Of these, 556 (50.8%) successfully increased their physical activity levels and were eligible to be randomised into the booster intervention trial, of whom 282 consented and were randomised into the three arms of the trial in a ratio of 1 : 1 : 1 (control = 96, mini booster = 92 and full booster = 94).

Retention of participants during follow-up and evaluable data

Participants were followed up between August 2009 and February 2012. Of the 282 participants who were randomised, 201 (71%) were followed up and assessed at 3 months after baseline (control = 76, mini booster = 63 and full booster = 62). However, evaluable data on the primary outcome, mean daily TEE, which was defined as data from those with at least 4 complete days (lost not more than 1000 minutes in a day) of Actiheart measurements, were available for only 160 (57%) of the randomised participants, which translated to an attrition rate of 43%. Therefore, 160 participants were available for the ITT analysis on the primary outcome.

At 9 months post randomisation 50% (140/282) of the participants had an assessment, of whom 91 had evaluable primary outcome data at 9 months of follow-up [a 9-month response rate of 32% (91/282)]; 80 had evaluable data at both 3 and 9 months and the remaining 11 had evaluable data only at 9 months.

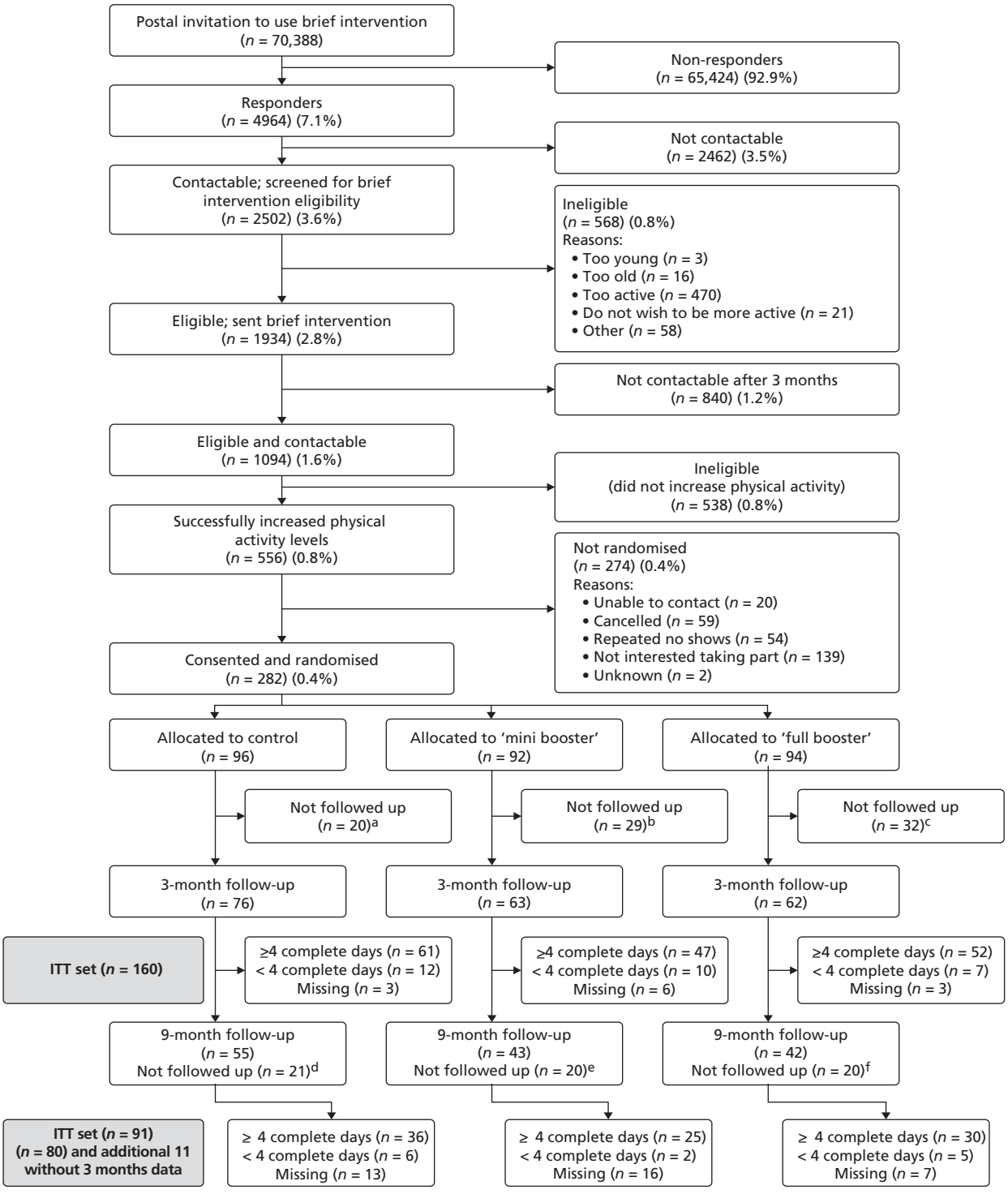


FIGURE 6 Participant flow. a, 10 withdrew consent (one disappointed at allocation, two found it too time intensive, two because of ill health, five for other reasons), one did not attend assessment, nine were lost to follow-up (uncontactable); b, nine withdrew consent (three found it too time intensive, one because of ill health, five for other reasons), four did not attend assessment, 16 were lost to follow-up (uncontactable); c, 14 withdrew consent (10 found it too time intensive, one because of ill health, three for other reasons), one died, three did not attend assessment, 14 were lost to follow-up (uncontactable); d, one withdrew consent (because of ill health), three did not attend assessment, five were lost to follow-up, 12 were randomised with insufficient time for 9-month follow-up; e, two withdrew consent (too time intensive), one did not attend assessment, six were lost to follow-up, 11 were randomised with insufficient time for 9-month follow-up; and f, two withdrew consent (one found it too time intensive, one for other reasons), two did not attend assessment, three were lost to follow-up, 13 were randomised with insufficient time for 9-month follow-up.

Figures 7 and *8* show the crude distributions of evaluable primary outcome data at 3 and 9 months of follow-up respectively.

Intervention received per protocol

Of the 186 participants who were randomised to the mini booster and full booster interventions, 73% (136/186) received the intervention as per protocol [77% (71/92) in the mini booster arm and 69% (65/94) in the full booster arm].

Baseline characteristics of participants

The baseline characteristics of the randomised and ITT participants are shown in *Appendix 6*, *Tables 17* and *18*, respectively. The distributions of participants' characteristics were fairly similar between the control and intervention arms in both sets of data. There were 28 participants among those randomised who did not show an increase of at least 30 minutes of physical activity based on the SPAQ at brief intervention screening and pretrial screening. Of these, 23 reported atypical activity at either brief intervention screening or pretrial screening (see *Chapter 2*, *Participants*). However, the remaining five reported typical activity on both assessments and reported an increase of less than the required amount of at least

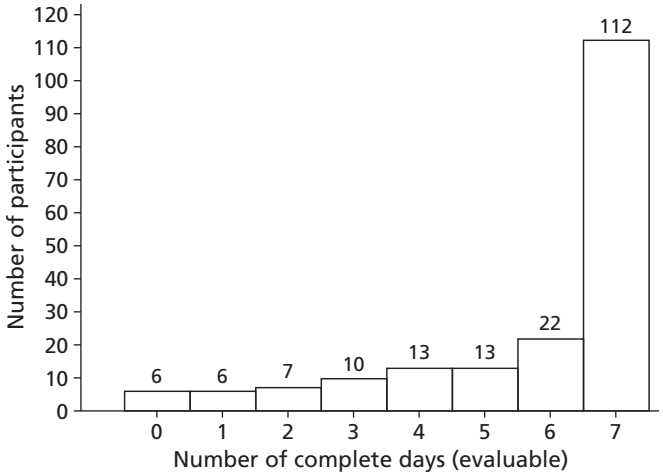


FIGURE 7 Crude distribution of the number of complete days (evaluable data) at 3 months.

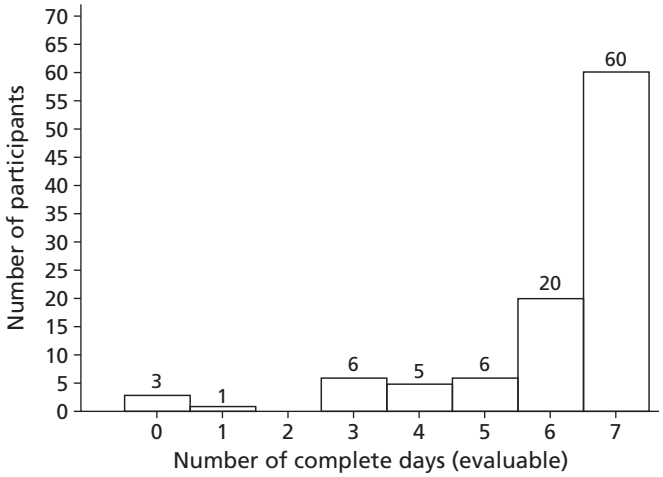


FIGURE 8 Crude distribution of the number of complete days (evaluable data) at 9 months.

30 minutes but were randomised into the study in violation of the protocol (see *Chapter 8*, *Recruitment and retention*). Four of these participants contributed 3-month Actiheart data and were retained in the ITT analysis but excluded from a post hoc sensitivity analysis to assess their likely impact on the treatment effect (see *Effectiveness of the booster intervention at 3 months*).

Figures 9 and *10* show Index of Multiple Deprivation (IMD) 2010[83] overall scores and income scores, respectively, for booster participants based on the lower super output area (LSOA) corresponding to their postcode. High scores indicate high levels of deprivation.

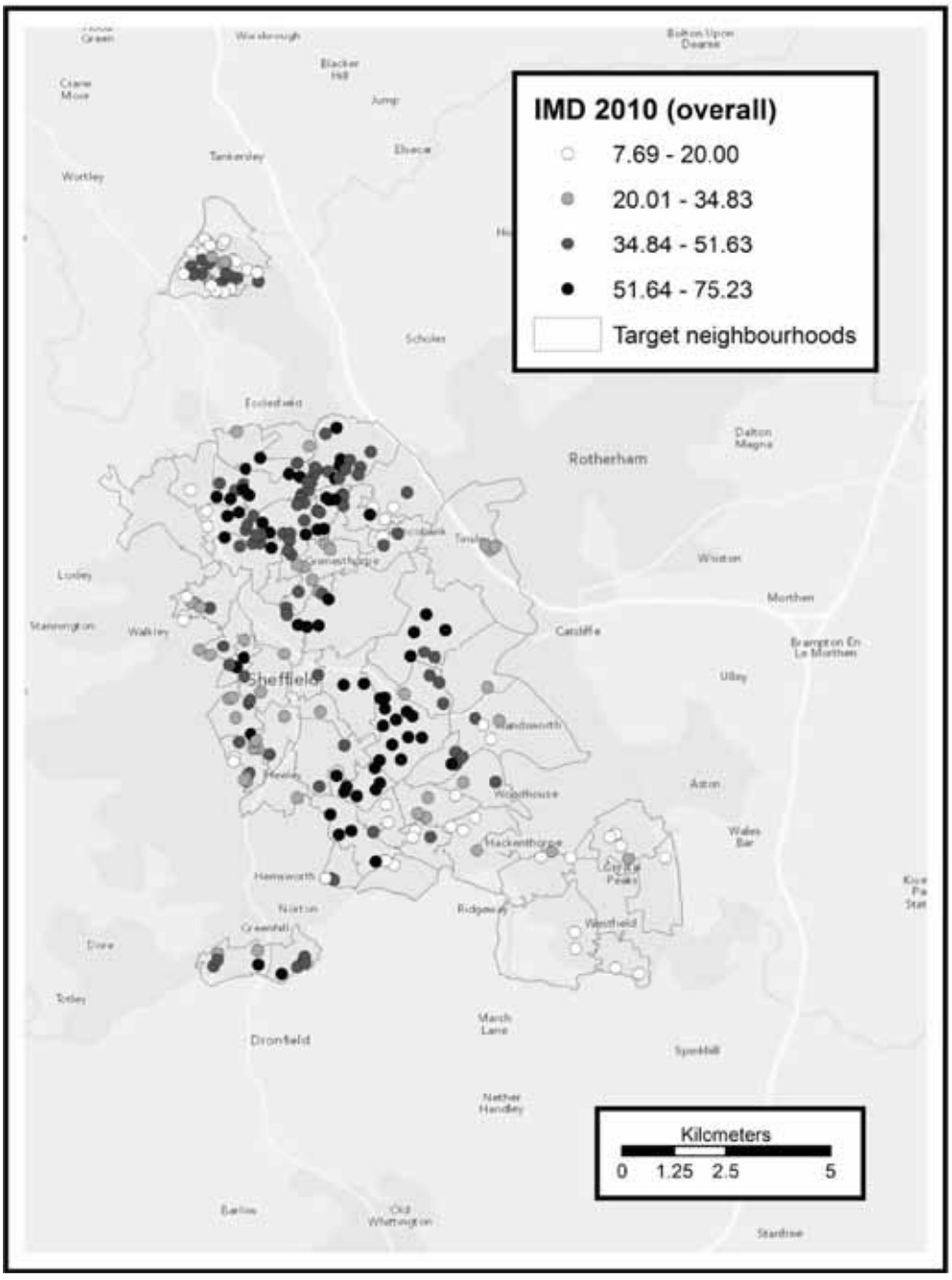


FIGURE 9 Index of Multiple Deprivation 2010 overall scores for randomised participants.

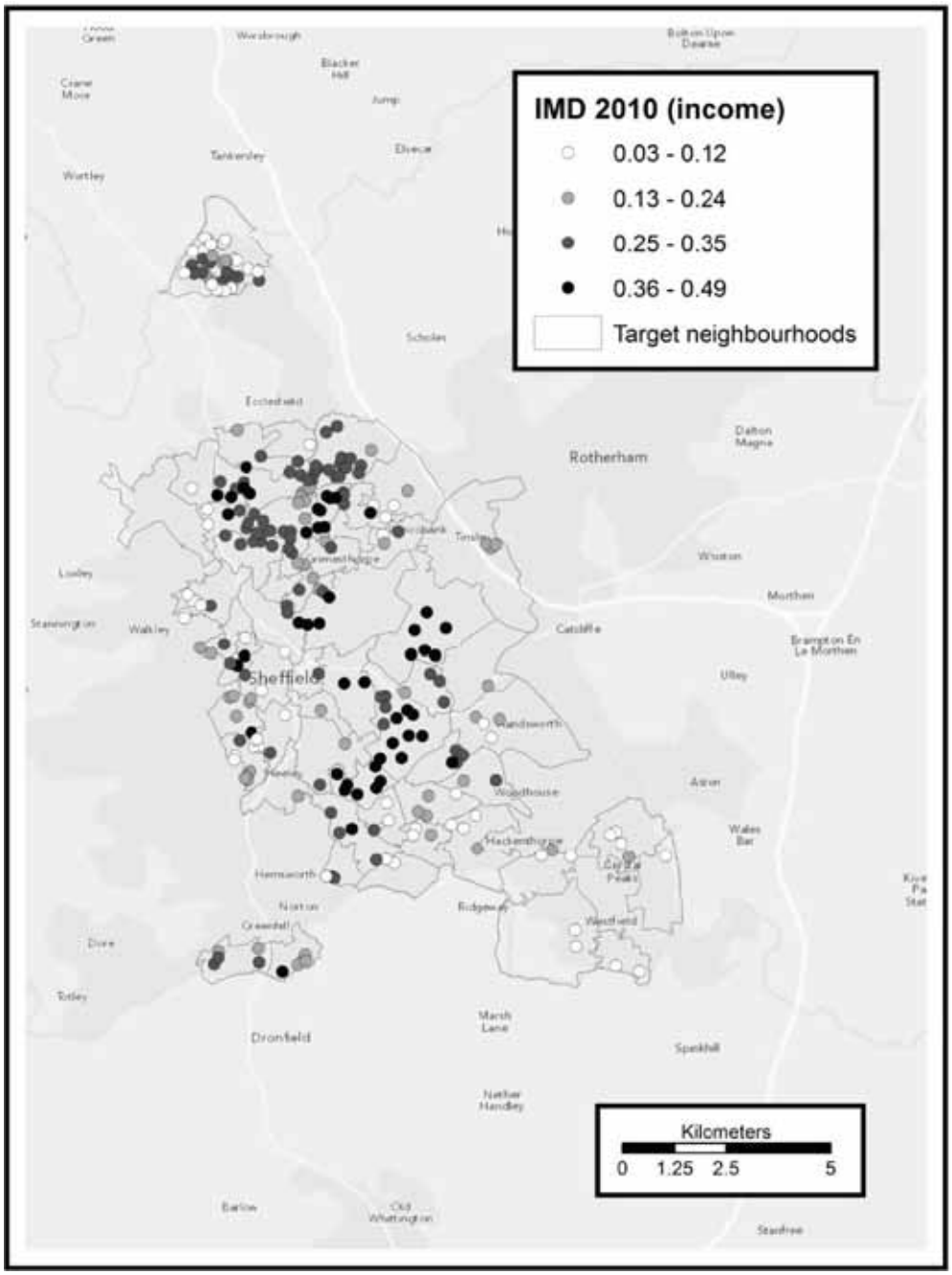


FIGURE 10 Index of Multiple Deprivation 2010 income scores for randomised participants.

Figure 11 shows the results of a preliminary geospatial cluster analysis using SaTScan™ version 9.1 [see www.satscan.org/ (accessed December 2013)]. Clusters of high response rates were present in High Green and the Longley area of the city. Clusters of low response rates were present in the north and central-south parts of the city. In a post hoc analysis we aggregated the number of mail-outs and the number of response rates at LSOA level. A negative Spearman rank correlation of –0.22 was found between the two factors. This indicates that people living in LSOAs with higher levels of deprivation were less likely to respond to the initial mail-out (see *Chapter 8*, *Recruitment and retention*, for discussion).

Response rate was not found to be related to population transience, with the Spearman rank correlation test between response rate and transience reporting a very weak correlation. The unweighted correlation was –0.005 and the weighted correlation was 0.030. With $n = 687$, the correlation must have a magnitude > 0.075 to be significant at the 5% level.

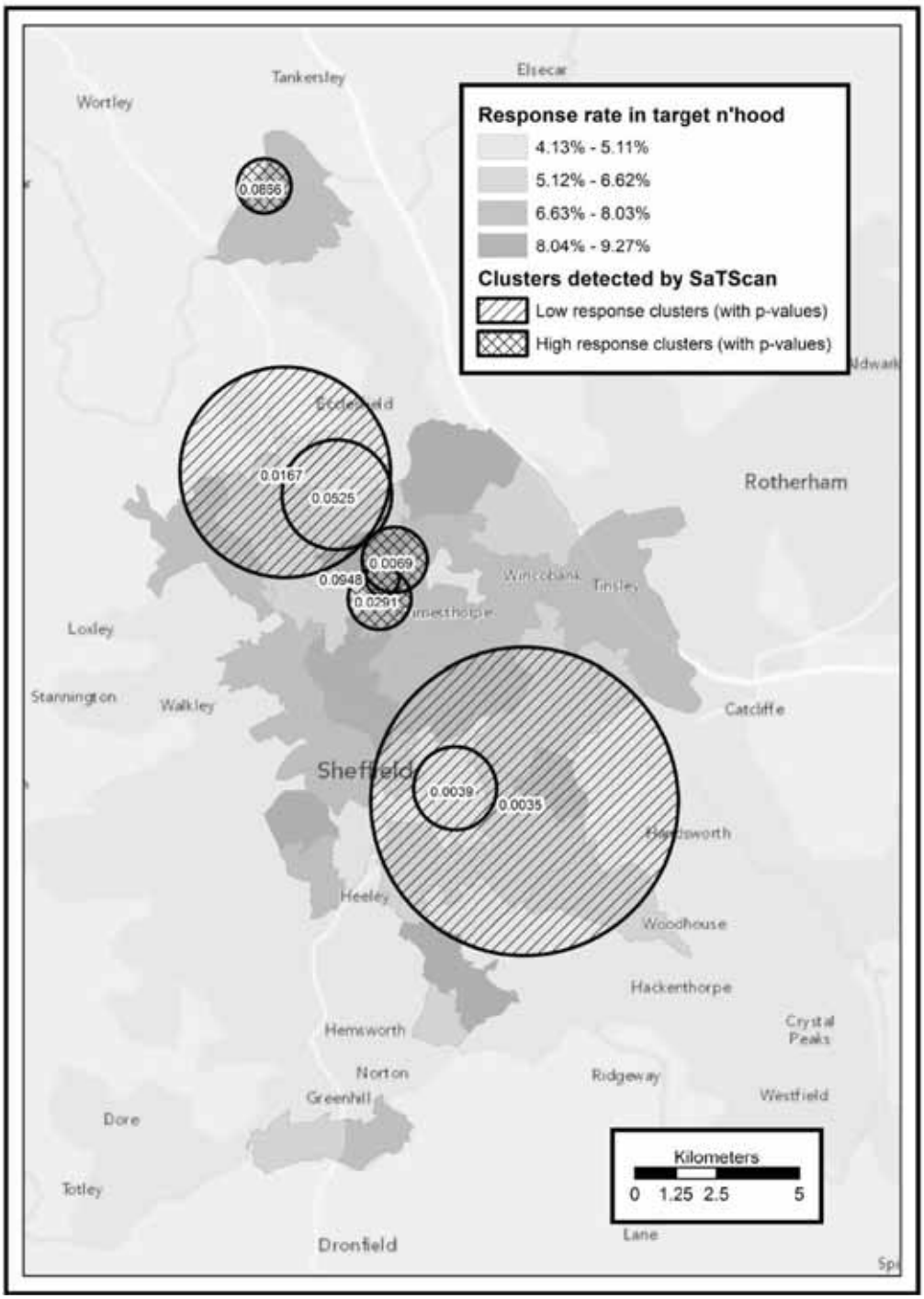


FIGURE 11 Map showing response rate by neighbourhood to booster mail-outs. Mail-outs from April 2009 to November 2010 together with clusters of high/low response rates identified by SaTScan.

Factors associated with having evaluable data at 3 months of follow-up

The descriptive statistics of completers (with evaluable data) and non-completers (for any other reason) are shown in detail stratified by intervention group in *Appendix 6*, *Table 19*. Non-completers had higher values than completers for BMI (mean 31.5 kg/m^2 and 29.4 kg/m^2 respectively; mean difference −2.0 kg/m^2, 95% CI −3.4 to −0.6 kg/m^2; $p = 0.005$; see *Appendix 6*, *Table 21*) and weight (mean 89.4 kg and 82.0 kg respectively; mean difference −7.4 kg, 95% CI −11.7 to −3.1 kg; $p = 0.001$; see *Appendix 6*, *Table 21*).

However, there was no evidence of an interaction between the intervention and the completers group. This means that, even though the overall distribution of completers and non-completers was slightly different with respect to weight, BMI, PCS scores and RAI between the booster group and the control group, their within-group distributions were similar and in the same direction across these treatment groups (see *Appendix 6*, *Tables 19* and *21*). There was some evidence to suggest an interaction between gender and the completers group with a high proportion of male non-completers in the booster group [51 (58.6%)] compared with completers [42 (42.4%)] (interaction $p = 0.034$; see *Appendix 6*, *Table 20*). In addition, the odds of having evaluable data were slightly lower in the mini and full booster intervention arms although this was not statistically significant at the 5% significance level. There was no sufficient evidence to indicate an association between having complete evaluable data at 3 months and other variables (see *Appendix 6*, *Tables 19–21*).

Appendix 6, *Table 18* shows that the baseline characteristics of the ITT sample ($n = 160$) were broadly similar despite the 43% (122/282) attrition rate from the original randomised sample.

Distribution of the primary outcome at 3 months of follow-up

Figures 12 and *13* show the distribution of mean TEE per day (kcal) stratified by intervention arm, which was fairly normally distributed. The pooled SD of the mean TEE per day at 3 months was 417.4 kcal.

Effectiveness of the booster intervention at 3 months

At 3 months the observed mean TEE per day was 2266 kcal and 2227 kcal in the control and booster intervention arms respectively (see *Appendix 6*, *Table 22*), which translated to a mean difference of −39 kcal (95% CI −173 to 95 kcal; $p = 0.6$) in favour of the control arm and less than the expected MCID of 102 kcal in favour of the booster intervention. After adjusting for age, gender, BMI, total minutes of physical activity at brief intervention and pretrial screening and HRQoL based on SF-12v2 plus 4 total scores (see *Appendix 6*, *Table 22*), the adjusted mean difference in mean TEE per day was similar (–40 kcal, 95% CI −117 to 37 kcal; $p = 0.3$) and still in favour of the control group. The wide CIs around the observed treatment effect indicate the uncertainty in the effectiveness estimates but the results are not statistically significant, potentially of some clinical or practical importance as the CIs include the MCID of 102 kcal but the point estimates clearly show that the control group had the better outcomes.

A forest plot (*Figure 14*) summarises the treatment effect and its direction, which is in favour of the control arm in five analysis sets (including the primary analysis) under different assumptions except using imputations including all participants with at least 1 complete day of evaluable data, which was slightly in favour of the intervention. However, this observed effect was very small, only 20% of the expected MCID

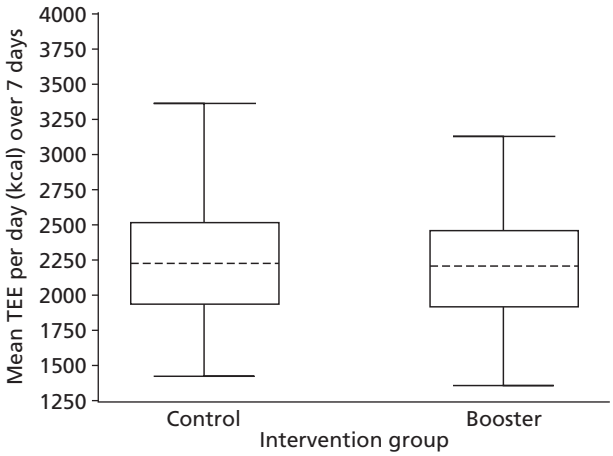


FIGURE 12 Box plot of mean TEE per day (kcal) at 3 months stratified by intervention arm ($n = 160$).

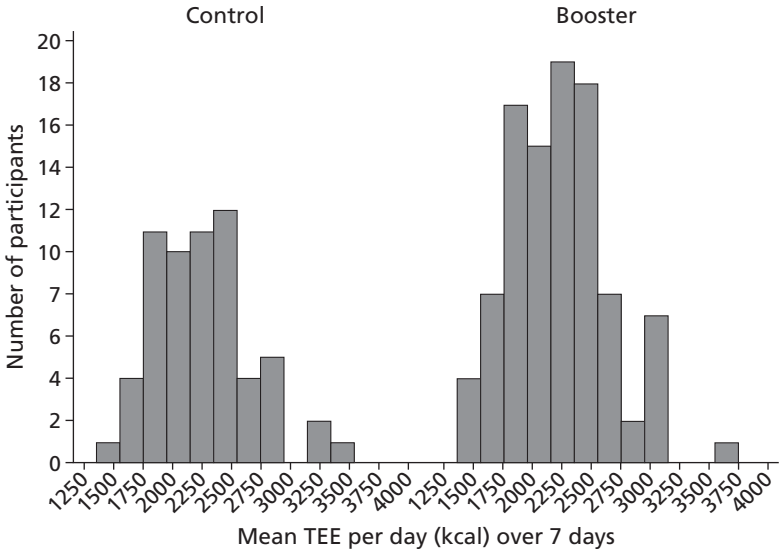


FIGURE 13 Histogram showing distribution of mean TEE per day (kcal) at 3 months stratified by intervention arm ($n = 160$).

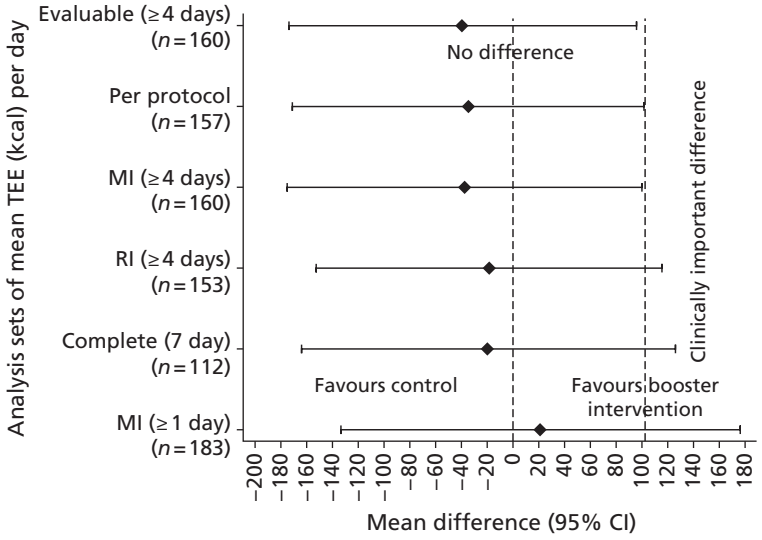


FIGURE 14 Different analysis sets: clinical effectiveness at 3 months. MI, multiple imputation; RI, regression imputation.

of 102 kcals, and diminishes after adjusting for age, gender, BMI, total minutes of physical activity at brief intervention and pretrial screening and SF-12v2 plus 4 total scores (see *Appendix 6*, *Table 21*). Details of sensitivity analysis on the primary analysis in *Appendix 6*, *Table 22* are shown in *Appendix 6*, *Table 21* and graphically displayed in *Figure 14*.

Figure 15 shows the distribution of mean daily TEE for the cohort of participants at 3 and 9 months. The treatment effect (mean difference) excluding the four protocol violators, described in *Baseline characteristics of participants*, was −51.2 kcal (95% CI −185.7 to 83.3 kcal; $p = 0.453$) in favour of the control group.

Effectiveness of the mini booster intervention compared with the full booster intervention at 3 months

At 3 months post randomisation we observed a mean TEE per day of 2168 kcal and 2280 kcal in the mini booster ($n = 47$) and full booster ($n = 52$) intervention groups, respectively, which translated to a mean difference of 112 kcal (95% CI −57 to 280 kcal; $p = 0.2$) in favour of the full booster group. After

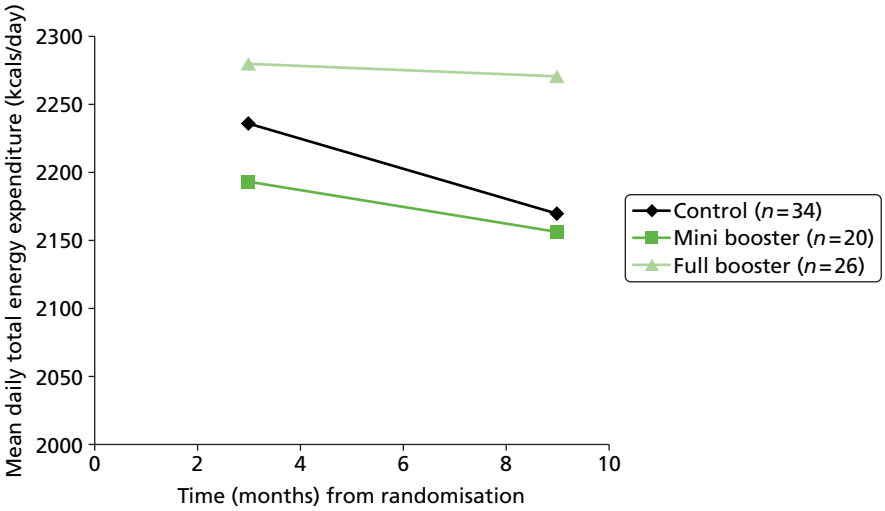


FIGURE 15 Mean daily TEE per day (kcal) over time for participants with valid 3- and 9-month post-randomisation outcome data ($n = 80$).

adjusting for age, gender, BMI, total minutes of physical activity at brief intervention and pretrial screening and HRQoL based on SF-12v2 plus 4 total scores, the mean difference was 56 kcal (95% CI −38 to 149 kcal; $p = 0.4$). Again, the wide CIs around the observed treatment effect indicate the uncertainty in the effectiveness estimates and the results are not statistically significant. However, as the CIs do include the MCID of 102 kcal, and the point estimates clearly show that the full booster group had the better outcomes at 3 months, we cannot rule out a significant difference between the mini booster group and the full booster group.

Secondary outcomes at 3 and 9 months

Appendix 6, *Table 24* shows the effectiveness of the full booster (face-to-face) intervention compared with the control. We observed a small increase in physical activity of 14 kcal in favour of the full booster intervention at 3 months although this is not statistically significant and far from being clinically important. The wide CI around this estimated effect indicates huge uncertainty and is compatible with no difference in effectiveness between the control and the full booster intervention. The direction of the effect changed in favour of the control group after adjusting for potential confounders (see *Appendix 6*, *Table 24*).

As shown in *Appendix 6*, *Table 25*, we observed a decrease in physical activity of approximately 98 kcal in the mini booster intervention group compared with the control group at 3 months, although this was not statistically significant and the uncertainty around the estimated effect was also large. The direction of the effect was consistent even after adjusting for age, gender, BMI, total minutes of physical activity at 3 months and 1 week before randomisation, and HRQoL (SF-12v2 plus 4 total scores). Similarly, the differences at 9 months in TEE are not statistically or clinically significant, as illustrated by *Figures 15* and *16*.

For the other continuous secondary outcomes – PACs (see *Appendix 6*, *Tables 30* and *32*), PCS, MCS and SF-6D scores from the SF-12v2 plus 4 (see *Appendix 6*, *Tables 34* and *35*), average minutes per day spent on moderate activity (3–6 METs), average minutes per day spent on vigorous activity (> 6 METs) and average minutes per day spent on moderate and vigorous activity (≥ 3 METS) (see *Appendix 6*, *Tables 36* and *37*) and BMI (see *Appendix 6*, *Tables 44* and *45*) – we found no reliable statistical evidence of a difference in outcomes between the booster group and the control group at 3 and 9 months post randomisation. There was insufficient evidence to support differences in self-reported levels of physical activity between the booster group and the control group at 3 and 9 months. However, based on the ITT set (see *Appendix 6*, *Table 46*), participants in the booster group reported increased physical activity of around 49 minutes and 74 minutes over a 1-week period at 3 and 9 months, respectively, although this was not statistically

significant at the 5% significance level. In addition, there was a very weak correlation to support a positive linear association between the objective measure (based on accelerometry) and the self-reported measure of physical activity (based on the SPAQ) at 3 months of follow-up (Pearson correlation coefficient = 0.03, 95% CI −0.13 to 0.19; $p = 0.686$), as shown in *Figure 17*. Some studies elsewhere reported similar results of a weak association between objective and subjective measures of physical activity.[82] In light of the very weak association between the objective and the self-reported measures of physical activity, we urge that results based on the self-reported SPAQ measure are interpreted with caution (see *Figure 17*).

Similarly, for the following binary categorical outcomes, we found no reliable statistical evidence of a difference in outcomes between the booster group and the control group at 3 and 9 months post randomisation: the number and proportion maintaining (or increasing) their weekly duration of physical activity (based on the self-reported SPAQ; see *Appendix 6*, *Tables 38* and *39*) and the number and proportion meeting the current recommendations of at least 30 minutes of at least moderate physical activity (MET level ≥ 3) on at least 5 days of the week (see *Appendix 6*, *Table 50*). *Figure 18* shows a clustered bar chart of the distribution of the number of days with at least 30 minutes of at least moderate physical activity.

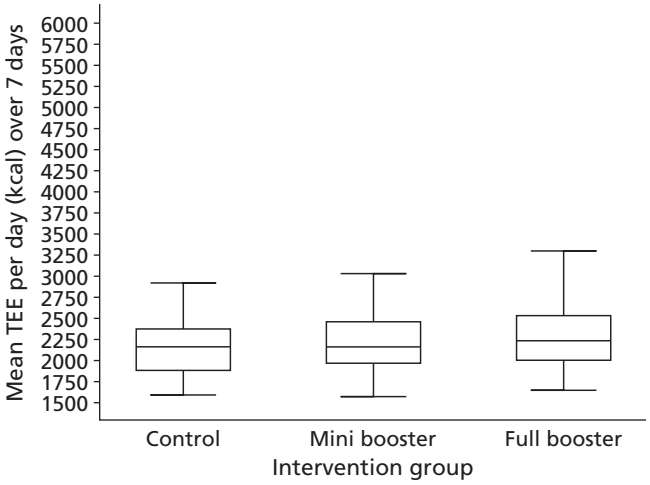


FIGURE 16 Mean TEE per day (kcal) at 9 months stratified by intervention arm ($n = 91$).

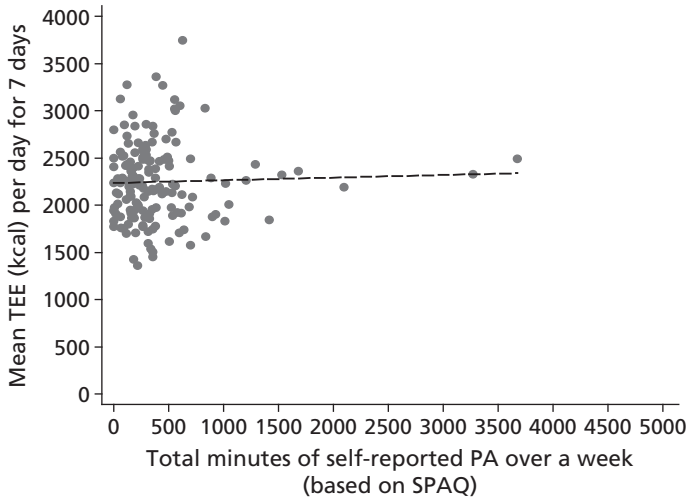


FIGURE 17 Scatter plot and regression line showing the correlation between mean TEE per day and self-reported minutes of physical activity (based on the SPAQ) at 3 months. Correlation coefficient = 0.03; p-value = 0.686; $n = 156$. Dots represent mean values for individuals for whom data were available; the dotted line represents the regression line.

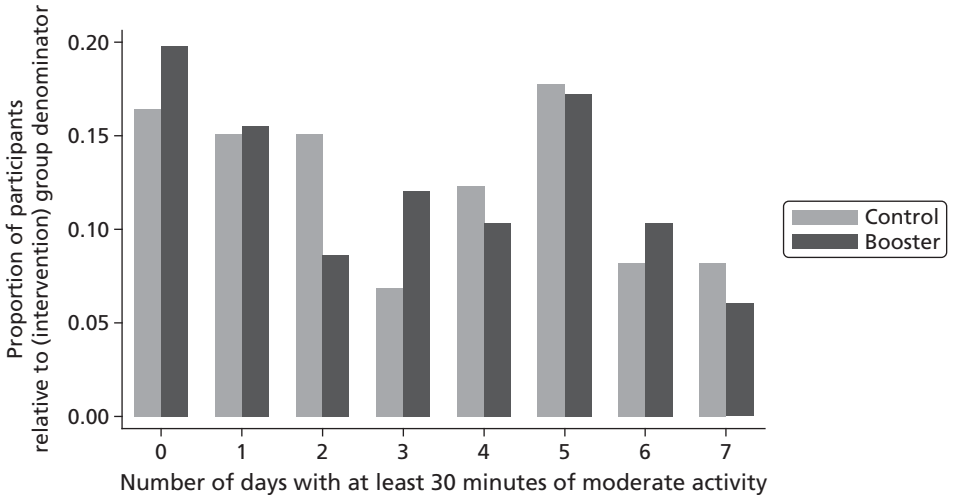


FIGURE 18 Crude distribution of the number of days with at least 30 minutes of at least moderate physical activity based on the Actiheart device ($n = 189$).

Only for the distance walked (in metres) during a 12-minute walk test (see *Appendix 6*, *Tables 48* and *49*) and the BREQ-2 dimensions (introjected regulation, identified regulation and intrinsic regulation; see *Appendix 6*, *Table 40*) did we find any reliable or borderline statistical evidence of a difference in outcomes between the booster group and the control group at 3 and 9 months post randomisation at the 5% significance level.

Subgroup analyses

Gender, ethnicity and access to community facilities (self-reported use vs. no use of community facilities) were predefined as subgroups that we wished to test for evidence of effectiveness in an exploratory analysis. As the majority of participants with valid 3-month primary outcome data were white British [89% (143/160)], we could not test for an ethnicity subgroup effect. We found no reliable statistical evidence of any (gender or access to community facilities) subgroup effects or interactions between the booster group and control group at 3 and 9 months post randomisation (*Figures 19–24* and see *Appendix 6*, *Tables 51–54*). In addition, there was no reliable statistical evidence to suggest that the timing of the initial mail-out had an impact on the response of participants at 3 months (see *Appendix 6*, *Tables 55* and *56*). However, there was some indication (with respect to direction of the effect) that participants who were approached to take part in the summer or the spring were performing slightly better in the full booster arm than their counterparts who were approached in the winter or the autumn, although there was huge uncertainty in the estimated effect (see *Appendix 6*, *Table 55*).

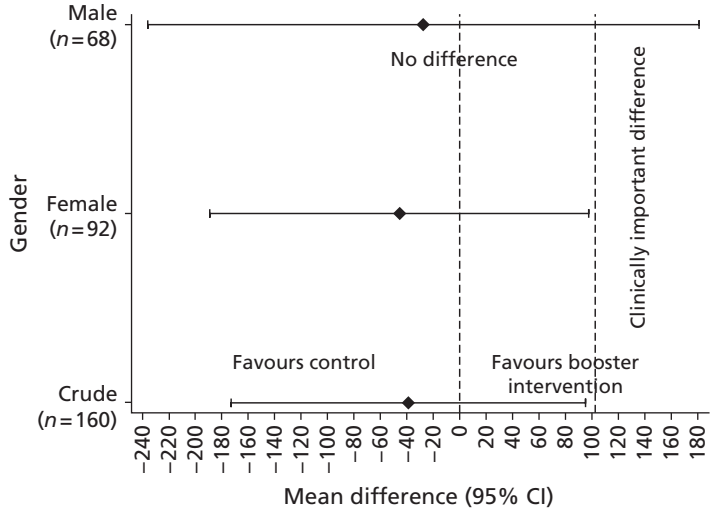


FIGURE 19 Subgroup evaluation for the primary outcome at 3 months stratified by gender ($n = 160$).

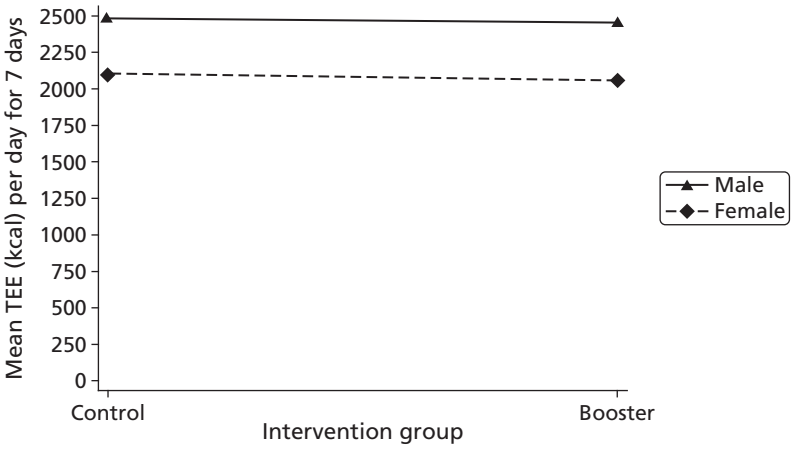


FIGURE 20 Interaction effect of the intervention and gender at 3 months. Interaction = –18.2 (95% CI –260.6 to 224.3; $p = 0.882$).

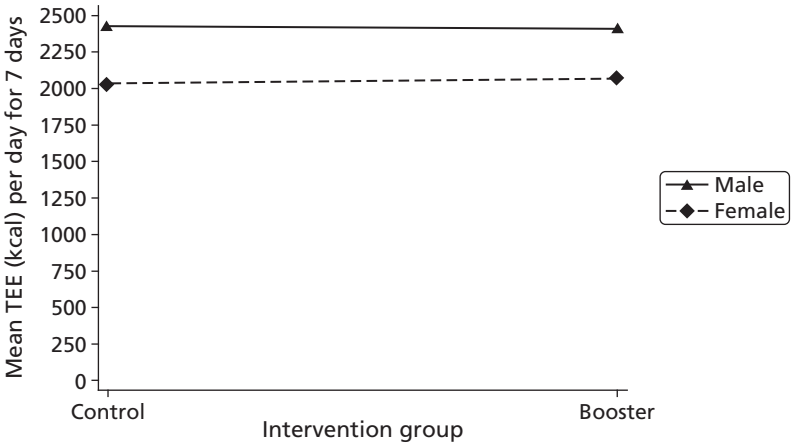


FIGURE 21 Interaction effect of the intervention and gender at 9 months. Interaction = 49.2 (95% CI –262.6 to 361.0; $p = 0.755$).

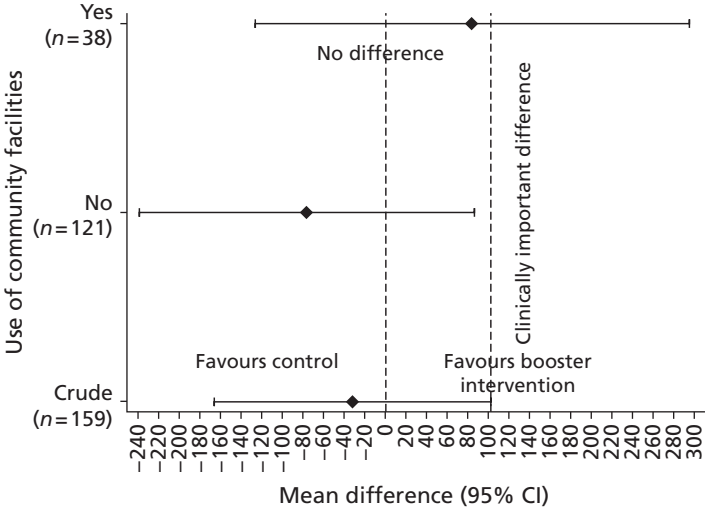


FIGURE 22 Forest plot of the effect of the intervention stratified by use of community facilities in the last month at 3 months.

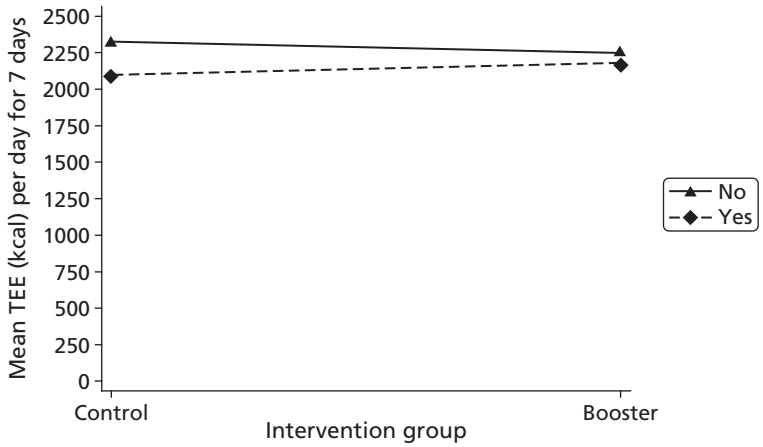


FIGURE 23 Interaction plot of the intervention and use of community facilities in the last month at 3 months. Interaction = −160.2 (95% CI −469.1 to 148.7; $p = 0.307$).

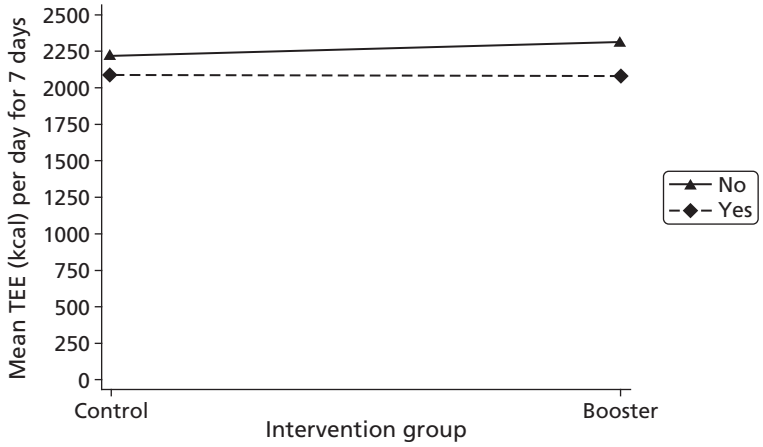


FIGURE 24 Interaction plot of the intervention and use of community facilities in the last month at 9 months. Interaction = 100.3 (95% CI −264.8 to 465.3; $p = 0.586$).

Chapter 4 Results of the process evaluation

All tables relating to the process evaluation can be found in *Appendix 7*.

Results of the survey

The sample

In total, 239 people were sent and 75 returned the survey questionnaire. The baseline characteristics of the survey population are compared with the baseline characteristics of trial participants who did not take part in the survey in *Appendix 7*, *Table 57*. The only variable that shows a difference between groups worth highlighting was the change in SPAQ score between –3 months and baseline, with non-responders reporting larger changes than survey responders. Formal significance testing for baseline comparability was not performed.

Closed questions

The responses to the process evaluation closed questions are presented in *Appendix 7*, *Table 58*. Over the 3 months before they were surveyed, 64 respondents (84.2%) reported taking part in recreational/leisure activities (e.g. gardening, cycling), 10 (13.2%) in competitive sports/exercise, 26 (34.2%) in structured exercise (e.g. an exercise class) and 54 (71.1%) in active commuting (e.g. walking/cycling to work). In total, 37 (48.7%) respondents reported undertaking physical activity at home, 41 (53.9%) in a local open space (e.g. a park), 34 (44.7%) in a facility (e.g. a gym, pool, community centre or track), 52 (68.4%) as part of their daily activities (e.g. in work, shopping, walking the dog or commuting) and 11 (14.5%) in other places. The most common reasons given for staying physically active were to improve health and get fitter or to stay fit, with 59 respondents (77.6%) reporting that this was very much the case. The most commonly reported influence on being able to perform their chosen activity was a respondent's own health ($n = 56$, 73.7%). In total, 34 respondents (44.7%) reported that they did physical activity with other people, of whom most ($n = 29$, 38.2%) said that they found this fairly or very useful. The most commonly reported partners for physical activity were a spouse ($n = 19$, 25.0%), friend ($n = 15$, 19.7%) or other family member ($n = 10$, 13.2%). If further physical activity 'booster' advice had been available in the future, more people would have preferred it to be delivered face to face ($n = 29$, 58.0%) than over the telephone ($n = 13$, 26.0%) or by written advice ($n = 12$, 24.0%).

Overall, 43 (86.0%) of those who received physical activity 'booster' advice said that it met their expectations, with more in the face-to-face full booster group reporting so ($n = 24$, 96.0%) than in the telephone mini booster group ($n = 19$, 76.0%). The majority ($n = 38$, 76.0%) agreed or strongly agreed that the 'booster' counselling/advice sessions fitted easily into their daily schedule, with no obvious difference between the mini booster ($n = 19$, 76%) and full booster ($n = 19$, 76%) participants. The majority of respondents who were full booster recipients ($n = 21$, 84.0%) agreed or strongly agreed that the 'booster' counselling/advice sessions had been conducted at a convenient location.

In total, 41 respondents (82.0%) who received booster interventions agreed or strongly agreed that the project worker was non-judgemental and 39 (78.0%) agreed or strongly agreed that the booster counselling/advice sessions were non-confrontational in nature. A total of 44 participants (88.0%) agreed or strongly agreed that, throughout the 'booster' counselling/advice sessions, the project worker understood what they were saying. Overall, 22 respondents (44.0%) said that they spoke more than the project worker and 21 (42.0%) spoke roughly the same amount as the project worker. In total, 45 respondents (90.0% of those receiving the intervention) said that the amount of contact time with the project worker was about right. The majority ($n = 42$, 84.0%) agreed or strongly agreed that they were encouraged to set their own goals for physical activity and 31 (62.0%) agreed or strongly agreed that, as a result of the 'booster' counselling/advice sessions, they had been able to resolve their barriers towards physical activity. Overall, 33 (66.0%) agreed or strongly agreed that, as a result of the 'booster' counselling/advice sessions, they now knew more about the benefits of physical activity. The same number

agreed or strongly agreed that, as a result of the 'booster' counselling/advice sessions, they now knew more about the risks associated with living an inactive lifestyle. In total, 32 (64.0%) agreed that, as a result of the 'booster' counselling/advice sessions, they were now more aware of available physical activity facilities and opportunities and 41 (82.0%) agreed or strongly agreed that, as a result of the 'booster' counselling/advice sessions, their confidence to stay active had increased.

Open questions

Recreational/leisure activities over the previous 3 months

Common recreational/leisure activities reported were gardening ($n = 38$), walking (including walking the dog) ($n = 24$) and swimming ($n = 10$). Housework/DIY ($n = 7$), gym-based activities ($n = 5$), cycling ($n = 5$), rambling/hillwalking ($n = 4$), running ($n = 3$), football ($n = 2$), badminton ($n = 2$), Wii/Wii Fit ($n = 2$) and yoga ($n = 2$) were also reported. The following activities were listed by one respondent each: Zumba, tai chi, diving, camping, bowling, snooker and golf. Some people reported more than one activity. Few people reported activities relating to competitive sports and there was significant overlap with activities classified as recreational/leisure activities. Football, walking/rambling, gym-based activity, badminton and golf were all included in both categories.

Common forms of structured exercise reported were gym-based exercise ($n = 8$), dance-based exercise (including at home) ($n = 7$), low-impact exercise classes ($n = 6$), cardiovascular exercise classes ($n = 5$), home-based exercise (not including dance/dance videos) ($n = 4$) and swimming ($n = 2$). Some people reported more than one activity in this category.

The most commonly reported form of active commuting was walking ($n = 33$). Walking activities that did not involve commuting ($n = 9$) or in which it was unclear whether or not they formed part of a commute ($n = 10$) were also reported. One participant reported cycling and one responded 'yes' without any further details. Some people reported more than one activity in this category.

Location of activities

Commonly reported facilities used included a leisure centre (including a gym and/or pool) ($n = 28$), a rural location ($n = 6$), a community centre ($n = 2$), a football facility ($n = 2$), a physiotherapy centre ($n = 2$) and shops ($n = 2$). The following locations were listed by one respondent: dancing, local area, school lessons, tennis courts, local neighbourhood, friend's home and allotment. Some people reported the use of more than one location.

Reasons for staying physically active

Several people stated that a reason for staying physically active was that a health professional recommended that they should do so. This included a doctor ($n = 4$), consultant ($n = 2$), nurse ($n = 1$), dietitian ($n = 1$) and the booster research team ($n = 1$). Under 'other', one person reported that the decision to stay physically active was prompted by a wellness advisor at work.

Reasons for taking part in the project

Using thematic analysis, we grouped the reasons that people gave for participating in the project into the following categories: self-improvement, altruism and curiosity. Responses concerning the wish for self-improvement were the most numerous and thematically diverse: respondents wished to improve or maintain their health or well-being, weight level, medical prognosis, fitness level, motivation to do physical activity, performance or practice in particular physical activities or their knowledge about what activities and levels of activities were best for them as individuals. A minority of respondents also discussed their wish to challenge or better understand themselves. Responses that we categorised as 'curious' included comments to the effect that the project sounded interesting, respondents wanted to know more or to see what was 'on offer' and respondents were looking for new ideas or wanted to try something new. Responses classified as 'altruistic' conveyed a desire to help with the research, to advance science and to help other people in the future.

Prior expectations of the 'booster' physical activity sessions

Participant reports of prior expectations of the booster sessions overlapped considerably with reports of the reasons for participating in the study, perhaps indicating that they were not making a clear distinction between the contacts made by RAs for the purposes of research study data collection and the contacts made by RAs as part of the intervention (see *The importance of monitoring and feedback*). Although many of the answers categorised in the previous section under self-improvement, altruism and curiosity were reiterated, there were responses that were conceptually distinct. For instance, respondents reported hoping that the intervention would increase their confidence. A number of respondents reflected on needing encouragement to set, achieve and maintain goals, targets or standards. Respondents also wanted information about their own fitness levels (see *The importance of monitoring and feedback*) and this included advice on physical activity that would meet or suit their existing medical needs (see *Previous conditions*, *Barriers to physical activity* and *Physical activity: motivators* on medical health issues).

What helped people become more physically active than they were before the study?

Participants from all three groups listed similar factors contributing to an increase in their physical activity levels since the onset of the study. The largest number of reasons given related to the booster intervention. Some respondents felt that the booster intervention had given them help, advice and support and confidence. A number of respondents reported the role played by their newly increased awareness of the health benefits of physical activity, including weight loss, and the dangers of being inactive. A number mentioned the motivation or encouragement provided by the RAs, including that provided by a desire to achieve goals and targets set with the counsellor. Participants reported responding to prompts to think about an active daily routine, discussing the need and different ways to keep fit, as well as an increased awareness about their own activity levels. Aside from the engagement with the RAs, respondents reported other, wide-ranging, extrinsic factors affecting changes in physical activity levels including the adoption of flexible working hours, having appropriate footwear, the receipt of a medical diagnosis and support from family or friends. A few reported more intrinsic reasons, with some crediting themselves for becoming more proactive. These individuals talked about their self-motivation, their own desire to improve their fitness or reduce their weight.

Results of the in-depth interviews

The sample

In total, 26 people participated in the in-depth interviews between December 2010 and February 2012. The baseline characteristics of the interview population are compared with the baseline characteristics of the trial participants who did not take part in the interviews in *Appendix 7*, *Table 59*. Participants in full-time employment were under-represented (15% in the interview population compared with 35% of those not interviewed). As with the survey population, increases in self-reported physical activity in the 3 months before baseline were lower for those interviewed than for those not interviewed.

Actiheart data were not available for six interviewees. Of the remaining 20, 17 contributed 7 days of data, one contributed 4 days of data and two contributed 3 days of data (see *Appendix 7*, *Table 60*). We have no evidence that any of the participants met the national guidance of at least 30 minutes of moderate/vigorous exercise on at least 5 days per week, although it is highly likely that one participant would have done so as he did > 5 hours of at least moderate activity on each of the 3 days over which he contributed data. Two people met the target of 30 minutes of moderate/vigorous exercise on 3 days; two people met the target on 2 days; three people met the target on 1 day; and the remaining 13 people did not meet the target on any day for which they provided accelerometry data.

Participants noted that they preferred the following physical activities: walking, swimming, cycling, gardening, walking the school run, football, running, yoga, gym, badminton, physical jobs, playing on the Wii and dancing. Some participants also declared a strong dislike for the gym and one declared a strong dislike for jogging.

Previous conditions

Previous practice

Two distinct groups of people seemed to emerge as salient in the sample. First were people with positive past experiences of physical activity whose commitment to an active lifestyle had been disrupted by the time that they were contacted by the trial team. This disruption frequently involved medical conditions, environmental factors, such as a change in working patterns, or a change in priorities, such as new commitments brought on by family (see also *Barriers to physical activity* and *Physical activity: motivators*):

> *Yeah, but I did do quite a bit of walking in my working life. I've cut back on the work and eventually retired . . . and suddenly it hits you that yes, all you're doing is sitting round all day.*
>
> *Co-habiting male, 65 years*

> *Because I suffer from vertigo and I kept going dizzy – it's the Raynaud's [syndrome] – I'd stopped cycling for five years.*
>
> *Married male, 65 years*

> *I'd more or less retired from running because I've been doing sport all my life and I just thought, coming up to 50, I thought, 'Give it up' because I wasn't, because we've got twins and . . . we were up early in the morning and you were breaking your sleep pattern . . . So I just thought, I'll give up the running and just look after the kids.*
>
> *Divorced male, 49 years*

Second were those who did not discuss previous positive experiences and for whom the uptake of physical activity was related to morbid introspection brought on by the birth of children, grandchildren or ageing (see also *Physical activity: motivators*):

> *Well I've been going to the gym for 10 years and I can't say I really enjoyed any of that time. I've never been a particularly sporty person all through my life but I got to about 52 and I thought well if you don't get you know . . . I was doing a lot of driving and a lot of sitting behind a desk, so I thought if you don't do something now, it's never going to happen because it's all downhill from 60 so . . .*
>
> *Married male, 64 years*

> *My main motivation is the fact I've stopped smoking and well, my girls . . . At the end of the day it is as much for me as it is for them . . . I'm sure they don't want to lose their dad when they've just turned 20 do they?*
>
> *Married male, 48 years*

Many people in the sample, but especially those with previous positive experiences of physical activity, were revising their expectations of what they were capable of after injury, the onset of a chronic physical condition or just the ageing process more generally. This was clearly difficult for many and the subject of intense rumination:

> *I did used to be a very, very good squash player, played up at [. . .] many times against the masters . . . the first operation stopped me playing squash . . . the same surgeon, promised me that it would get me back doing everything . . . and it didn't, you know. I could have done with [the motivational interviewing] then, you know, saying, 'Don't do this; move onto something else'.*
>
> *Co-habiting male, 65 years*

> *I'm not doing what I did some 12 months before . . . I know now I'm not going to be able to return to that level.*
>
> *Divorced male, 55 years*

Yes. Yes. I realise I can't be what I was, so I'll never be doing a marathon again, but at least . . . every five miles is a marathon to me now, between start and finished.

Married male, 65 years

Felt needs or problems

Many participants simply wanted 'to feel fitter'. Of these, a number were looking for advice on tailoring a physical activity regimen to their lifestyle: 'I didn't want to join any gyms or anything . . . I wanted some other options and something that if I didn't fancy going one week I didn't have to' (married female, 52 years).

Many were motivated by goals or perceived benefits which they hoped that increased physical activity levels would deliver (see *Physical activity: motivators*). For some, these anticipated benefits were urgent because of changing life circumstances:

I wanted to build my strength up, My husband became ill and I was having to do a lot of . . . physical work and I was finding it very difficult because I suffer with arthritis myself. So I needed to lose weight . . . to build my muscle up as well.

Married female, 64 years

Long-term conditions

At least half of those interviewed had a chronic condition that affected their attitude to physical activity in one way or another (see *Barriers to physical activity* and *Physical activity: motivators*), including traumatic stress; high blood pressure and high cholesterol; arthritis and depression; obesity, stress and depression; depression; asthma plus a family history of diabetes, mental illness and obesity; breast cancer, high cholesterol and pre-diabetes; a history of total knee surgery; arthritis and knee problems; chronic lung disease; chemotherapy-related neuropathy; shoulder injury; hypertension, diabetes and a history of heavy drinking; Raynaud syndrome and a history of transient ischaemic attacks.

Social norms

Although not prevalent, there were at least three instances of participants reporting that physical activity was not socially normative in their community:

I think so yeah. I think some of it is being on your own, if you know what I mean? If you are on your own and your friends don't do exercise it doesn't encourage you much.

Married female, 52 years

And that's the thing; a lot of pressures get put on people that they can't, because their peers will say: 'Oh you don't want to be doing that, you want to be coming down the pub and having a few beers like we normally do' . . . then they feel pressurised to actually say, 'Well I'd better not do that because I'll upset them'.

Divorced male, 55 years

People have said to me, 'Oh . . . you've done Sheffield round walk – which is about 16 mile – you must be daft!'

Married male, 65 years

Barriers to physical activity

Preferred alternatives

At least 10 people explicitly mentioned that they had preferred alternatives to physical activity, including college classes and work; watching television; looking after their children and going to work and running

their own business. A number of people also mentioned 'personal' or 'family situations' that had disrupted or prevented the uptake of physical activity routines:

> *I find it more difficult to keep motivated, cos I don't really like exercise. I could . . . I'm one of these people that could just sit and watch telly all day and enjoy it.*
>
> *Divorced female, 65 years*

> *Yeah . . . my personal life has been a bit different in these last 12 months or so, I think that's, you know, made more of an impact on my fitness . . . I can't get down to the gym, I won't have time, coz I run my own business, you see, I have my own shop.*
>
> *Widowed male, 60 years*

> *Cos I do still do some part time work – I look after a lady with dementia – so I'm not free every day by any means. So the main thing is, sort of fitting it in around . . . Once a week is fine. Fitting in twice or three times can be difficult sometimes to find that bit of free time.*
>
> *Single female, 62 years*

Medical health issues

At least 10 interviewees had chronic health issues (see *Physical activity: motivators*) and a number of other more acute episodes were also declared, including muscle strains and trauma leading to sepsis; knee injury; muscle pain – non-specific; back pain; foot pain; severe depression and pain in the side and leg. Those with acute injuries often described difficulty maintaining their existing programme of exercise: 'I was doing an hour's session with a personal trainer. She gave me a programme to do. But the trouble is I was finding with these injuries . . . I couldn't do all of it' (married male, 64 years).

Those who have had surgical treatment or aggressive treatment for a chronic disease often reported constraints placed on them by caregivers so as not to aggravate their condition:

> *I'm not allowed to . . . as much as I hated running on me own, it always had to be done for stamina, didn't it? . . . After you've had total knee surgery . . . you can't go pounding on the road and you've got to be careful, she says to me, cos I had it done at such a young age, they said, you know, 50, you've got to look after it cos it'll last 25 years if you want, but they just said to me, 'you know if there's any problems, you'll have to have remedial surgery'.*
>
> *Married male, 58 years*

> *Oh yeah, I was always active . . . Well, I was working as well before I went off on the sick, so everything fell – because of the illness [cancer] and whatnot, everything sort of stopped for a while.*
>
> *Married male, 57 years*

Psychosocial conditions such as depression and heavy drinking presented participants with barriers to starting physical activity that were more related to apathy, lethargy or procrastination:

> *Yeah, because my doctor recommended the exercise for severe depression, it's the depression . . . vicious circle . . . it's the depression that stops the motivation, you know, I can sort of very easily think, 'Can't be bothered' or 'Let's not bother'.*
>
> *Single female, 62 years*

Environmental support

Earlier we introduced the idea that maintaining physical activity levels might be difficult when it was not socially normative (see *Previous conditions*, *Social norms*). Some people also found their family to be a barrier. Societal and personal budgetary constraints were mentioned by a number of people. Some had experienced cherished physical activity programmes being cancelled because of local authority cuts:

'They've got a group, a dad's group, and I do the 5-a-side, but that's kind of stopped due to lack of funding' (married male, 48 years).

Others saw their own financial situation as constraining their options:

> *Well, I do want . . . I'd like a lifestyle that is more active, but . . . until I earn more money [laughs] . . . But at the moment, I've got very little coming in and very little being spent . . . membership for gyms costs a fortune, I can't even entertain the idea really.*
>
> *Divorced male, 50 years*

> *I mean, this is the other thing about my lifestyle, because of the severe restrictions on income, I have to spend most of my time at home so I'm not wearing down my shoes too often . . . And that's the thing: it's very easy, you know, when you're on your own, on a low income, it's very easy to get depressed and get down. You can spend a lot of time wasting a lot of time just not doing anything, you can just sit down, feel absolutely miserable.*
>
> *Single male, 51 years*

Those who did work often found that a constraint, especially when shift work prevented access to facilities and establishment of a routine (see also *Barriers to physical activity*, *Preferred alternatives*). Threats to personal safety were not a common concern, except among those who had aspired to cycle:

> *I thought, 'God, to ride a bike on these streets is going to be terrifying'.*
>
> *Single female, 47 years*

> *I don't feel confident riding on the roads . . . so I've decided I'm not doing cycling.*
>
> *Divorced female, 65 years*

> *Roads are a nightmare in the morning on a bike, you know, when there's lots of cars on the road.*
>
> *Married male, 58 years*

A number of people cited bad weather as a barrier to physical activity. For some, this was specifically related to chronic conditions or the side effects of aggressive medical treatment. For most, it was simply a self-evident fact that cold, wet weather was not appropriate for exercise:

> *Yeah, so, what I need is one of those cycle machines in my flat during the winter time, during the grotty weather, then I'll have no excuse at all!*
>
> *Single male, 51 years*

> *I am a summer cyclist because, when it's cold and wet and you're on a bike . . . we havn't got the weather, have we?*
>
> *Married male, 58 years*

> *The problem I have, in England of course we have the weather in the winter . . . come spring, like now, I'm increasing my energy and my exercise regime.*
>
> *Co-habiting male, 61 years*

Self-consciousness

Self-consciousness was not a widely cited problem; the following two instances were noted:

> *There's a gym outside, I think she called it a green gym, it's the one at Millhouses Park . . . I think my problem is, I'm not really a great fan of gyms . . . I suppose I'm just too self-conscious about these things.*
>
> *Single male, 51 years*

The fact that I am getting older and I feel more embarrassed about going to the swimming baths and things, or a gym, [deterred me] whereas it never used to bother me in the past.

Single female, 56 years

Physical activity: motivators

General commitment and priorities

As many as 15 interviewees expressed views that could be characterised as commitment to physical activity. For about one-third of these, the commitment seemed intrinsic or part of their identity:

To anybody that doesn't walk and they're quite capable . . . I find that as alien as what they find me doing them sort of things, not doing anything when you're quite capable that you could do something.

Married male, 65 years

Everybody should be involved in sport.

Divorced male, 49 years

Yeah, like I say I've always either gone to a gym . . . for, god knows how long . . . I've never been idle about it.

Widowed male, 60 years

For the majority, especially those without previous positive experiences of physical activity, it seemed extrinsic – a response to received understandings about the need to ward off infirmity, to stay in a condition to live independently or to discharge one's responsibilities and to be a role model to one's family:

Staying alive [is my main goal]. I've got two babies. Two and a half and three and a half, you know, it would be nice to see them have kids. You know, so pretty much that singularly would be my main goal I would say.

Married male, 48 years

It would be nice if [my children] could enjoy sport the way I enjoyed sport growing up.

Divorced male, 49 years

I have to be as self-reliant as I can.

Single male, 51 years

I lied to [my children] as much as I wasn't involved in any sports activities with them when they were young, and they've taken it up themselves and enjoying it, I have now found in sport activities something that's helping me to stay healthy and I'm getting more benefits out of it now at this age.

Single female, 47 years

I have experience of people in the family who've not been active and how quickly they've deteriorated, health wise and they just couldn't get about any more, because they weren't prepared to push their selves and that sort of scared me into thinking, 'I'm not going to get like that'.

Married female, 62 years

Goals or benefits

Most interviewees (at least 20) described their motivation to maintain physical activity levels in terms of anticipated benefits or goals, including wanting to feel fitter and not so lethargic in the long term; knowing that exercise will make you feel good during and afterwards; for social contact; being a role model; warding off illness, disease or infirmity and living longer; dealing with stress or depression; gaining

in self-confidence; wanting to lose weight for 'vanity', a holiday, a wedding outfit or health purposes; wanting to remain independent and wanting to try other activities previously thought too taxing:

> *It's like if you're a runner you never feel like going out for a run do you? But then when you're out there, as soon as you've even got your trainers on, you're feeling better, do you know what I mean? . . . Yeah you feel better when you have done it, you feel a bit sluggish when you go and when you come back you feel more energetic. I mean you feel a bit tired, but it's a nice feeling.*
>
> *Married female, 52 years*

> *The thing is that, it's a way I've had to deal with stresses throughout my life, if I had a particularly stressful time, I usually get out for a nice brisk walk up a hill or two. I've been on benefits for a very, very long time so I've, the only way to handle such stress is actually to do lots of exercise.*
>
> *Single male, 51 years*

> *The cycling has a sort of almost immediate effect, when I've done sort of 20 minutes/half an hour on the bike. You can actually sort of feel a bit of mood lift. It's strange.*
>
> *Single female, 62 years*

> *You live longer and I think you just feel better if you do even if you don't want to do it, you just feel better, look better.*
>
> *Divorced female, 65 years*

> *I've got to build the body up, you know. My wife laughs at me . . . when she sees the bingo wings and whatnot.*
>
> *Married male, 57 years*

Personal preference

Only two people explicitly made the point that they actively preferred physical activity to other activities and embraced it as part of their identity:

> *Your body is made to work, not just to sit and watch television like my brother . . . There is other things to do than watch television all day.*
>
> *Married male, 65 years*

> *To anybody that doesn't walk and they're quite capable . . . if they've got an injury or disabled etc., I find that as alien as what they find me doing them sort of things.*
>
> *Married male, 65 years*

Medical health issues

Although illness and injury could often be a barrier to uptake or maintenance of physical activity, it was also cited in response to questions about motivation by at least 20 interviewees. Those with mental health problems were driven by their perception that physical activity could alleviate symptoms of stress, anxiety or depression, either somatically ('I really do find that there's an immediate lift') or psychologically ('it takes your mind off it'). In at least one case a person with depression had been prescribed exercise for the management of depression. Prescribed exercise was much more common among those with chronic physical conditions. Most of those with a long-term physical condition (see *Previous conditions*) talked about clinic visits when asked about what motivated them to become or stay active. However, nobody explicitly claimed that doctors had recommended exercise to them, although conversations such as the following often suggested that this was the case:

> *[My cholesterol] went up to 5.7 and the doctor said we do prevention now . . . and she's put me on to 10 mg of Eprinel now . . . because she said my blood pressure were a bit higher than it had been so that's a big motivation to keep fit.*
>
> *Single male, 54 years*

Environmental and social support

For some, having support and advice from someone who was not a friend or family member, such as a supportive personal trainer, was critical (see also *Motivational interviewing: perceived importance*). Some people reported getting support from their families, particularly children or grandchildren, or neighbours. For others, the experience of exercising with other people, with whom one could talk, was motivating, with buddying up for swimming, joining classes and cycling, walking or running in groups or clubs all being mentioned:

> *I suppose if you get somebody who motivates you as well, that goes with you or join a group or something, that's when it's enjoyable more I think.*
>
> *Married female, 52 years*

> *[You] buddy up with someone . . . So that you get a bit of talk. I've made friends I've had from walking and it's made a difference.*
>
> *Single female, 56 years*

Sociable sentiments were not ubiquitous with some people reporting choosing physical activities or times and locations to avoid their family and friends. Ready access to facilities was also important for some. One person reported being encouraged to make regular use of the exercise bike and step machine in their GP's summerhouse. Easy access to countryside where it was pleasurable to walk was encouraging for a number of people.

Motivational interviewing: perceived effectiveness

Only three people said that they thought that the booster sessions had no impact on them. All expressed the sentiment that they continued to do what they would have done anyway. Two of these achieved 0 and 5 minutes of moderate levels of activity during 7 Actiheart days. The other did not contribute Actiheart data.

> *nothing that was said over the phone or through interview made the slightest bit of difference.*
>
> *Married male, 48 years*

Seven people expressed ambivalence about whether the booster sessions were effective, through convoluted, contradictory, evasive or indirect answers:

> *Well it's ticking boxes, yes . . . there's things I mentioned to [motivational interviewer] which I haven't quite got round to doing yet . . . I don't know if I can get down to it. I think my problem is, I'm not really a great fan of gyms.*
>
> *Single male, 51 years*

Of these seven, three contributed no Actiheart data and three achieved 0, 3 and 9 minutes of moderate/vigorous activity over 7 Actiheart days. The last had 3 days where they met (43 minutes) or almost met (27 and 28 minutes) the national target of 30 minutes of moderate/vigorous activity a day.

In total, 15 people said that they thought that the booster sessions had been effective. Of these, 11 met the national target of 30 minutes of moderate/vigorous activity on at least 1 day. Three exhibited fairly sedentary activity levels on all days.

Motivational interviewing: consistency with perspectives or world views

At least four people, were, at best, ambivalent about MI. At least two explicitly said that they had hoped for an exercise programme or some kind of physical activity provision:

> *I would have expected more of a, shall we say, physical challenge? . . . I thought there would have been more physical activity to be measured and said, 'Well, yeah, you did this when you came on the programme, you were able to do this by the time you'd got to the end of the programme'.*
>
> *Co-habiting male, 65 years*

Two disliked the autonomy-supported communication style used in MI (see *Chapter 8*, *Views on physical activity and motivational interviewing 'boosters'*, for discussion):

> *Just two people chatting really, you know, I'm trying to give her some answers and she's doing the best to give me some advice . . . it's just like same old same old.*
>
> *Married male, 48 years*

> *I wanted to be told what the opinion was of my state of fitness. I want some results, you know, and being told off or being told that, 'Well, it's what you actually do in your day to day work keeps you reasonably fit, if necessary, or . . .' . . . I wanted somebody to say, 'Well, we've done your blood pressure' or 'We've measured you, we've weighed you and so we think', blah blah blah.*
>
> *Divorced male, 50 years*

However, at least 10 people expressed enthusiasm for the autonomy-supported communication style. Common themes that emerged were that people liked the question-and-answer format and the informality. They found it businesslike and characterised the approach as encouraging, supportive and to do with fact finding rather than being 'pushy' or judgemental:

> *Well I was encouraged, but not pushed . . . So it's obviously a lot better than virtually being told, what about this or no sorry, do this or this or this. So it was open and it enabled me to do it at the pace I wanted it to.*
>
> *Widowed female, 65 years*

At least 10 people made comments to the effect that they found the advice appropriate and flexible to their context. Clients frequently made statements to the effect that MI was thought-provoking or that it helped them focus on the importance of and barriers to physical activity. It gave them ideas that they could not have come up with themselves and pushed them to think about how much exercise they actually did. For many, the assistance in setting realistic goals was critical:

> *We set little goals for me to achieve . . . sort of saying, build your exercise up from 15 minutes to 30, 40 and I managed to get up to an hour a day on some days . . . he sort of set me targets for me to achieve, not too big, and goals and I found that because I knew that I was meeting him again . . . I made myself do them. I enjoyed the exercise once I got into it . . . I didn't want to go and say, oh I didn't achieve what we'd set out because the goals weren't big goals and I think that's the key, not to set a goal too big that it's impossible to reach, so you think well I'm never going to do it, so I'll not bother. You know, you can give up if the goal is too far ahead . . . I knew that I could achieve it. If I thought it was impossible to do, then human nature being as it is, I thought well I'm never going to do that, so I'm not even going to try.*
>
> *Married female, 52 years, achieving recommended activity levels on 3/7 Actiheart days*

> *It's gradually making the changes . . . it's about not drastic changes, it's about taking one step at a time and gradually make the changes towards setting the goals that you want . . . make the changes to achieve the goals that you want to set yourself. So it's helping people to achieve realistic goals.*
>
> *Single female, 47 years*

Motivational interviewing: perceived feasibility

For the vast majority of participants, the timing, duration and periodicity of booster sessions was highly convenient. Complaints were infrequent but focused on continuity of care ('I don't think I've seen the same person twice have I?') and the need for more sessions. Suspecting that lack of funding might explain the limited provision (two sessions), one participant suggested that introducing clients into a peer-support ('self-help') group would be better than the current 'abrupt' end to the programme.

Seven out of 13 people interviewed who received MI by telephone believed that face-to-face booster sessions would have been preferable. One man with his own business and children found it difficult to protect time either at work or at home:

> *because I work for myself, you know, if someone walks in, you know, I've got to see to them straight away . . . so it's easier for me to make a time [for a face-to-face meeting] and, you know, I'll be there . . . at 6 o'clock, when I get home, it's like 'Daddy, Daddy' and . . . I'm being followed into every room, can't go anywhere!*
>
> *Divorced male, 49 years*

Those receiving face-to-face MI often said that they thought that the physical presence of the person made the MI more effective (see *Motivational interviewing: perceived importance* and *The importance of monitoring and feedback*):

> *Actually seeing the individuals who come and talk to you, so it's like a one-to-one communication, the physical contact I think is very important . . . What difference would it make to me – somebody just over the telephone, ticking a box? Why can't they just meet me?*
>
> *Single female, 47 years*

Motivational interviewing: perceived importance

A majority of people expressed the view that they felt that MI was important in some way, for instance because it met some acknowledged need. Sixteen people used language to the effect that the MI gave them encouragement, motivation, 'a push', impetus, a boost to their confidence or similar. For some, it helped them keep motivated in a situation of social isolation or disliking exercise or preferring alternatives:

> *Because I live on my own, I find it more difficult to keep motivated, cos I don't really like exercise. I could . . . I'm one of these people that could just sit and watch telly all day and enjoy it.*
>
> *Divorced female, 65 years*

Many people said that they needed help with ideas for alternative physical activity strategies or help with overcoming barriers or thinking through life changes, especially retirement. People frequently claimed that the sessions helped them 'focus' or reinforced knowledge or goals:

> *I did start to try and look for ways and means of filing my time in, after I'd retired. Most of my immediate family were worried that I wasn't going to survive this winter with not being able to go to work, so I was looking to broaden my horizons.*
>
> *Co-habiting male, 65 years*

At least four people mentioned that they enjoyed the social contact of the booster session. Sometimes this was because they were able to engage in a depth of conversation about an issue that was important to them that they did not feel able to do (or would not be productive) with a friend or family member:

> *Well it's good to have a chat with someone. I don't get much opportunity at home . . . I mean, it's a welcome break to my day, having a conversation along those lines. It's a sort of a change . . . having to think about something different.*
>
> *Single male, 51 years*

> *Because your family and your friends know you too well and they have got a preconceived idea of you, whereas [the motivational interviewer] hadn't, ya know, it was just me.*
>
> *Married female, 62 years*

In summary, participants claimed that the MI met a number of needs, including providing encouragement and the opportunity to think laterally about problems and solutions with a professional removed from their

normal social context. However, as the next section discusses, interviewees often framed these views in terms of altering their behaviour because of an awareness that they were being observed:

> *It's little things that you can talk through which you probably wouldn't have thought of and it seems to be important, but who would you talk to about it? Like, how do I fit in the jobs that I've got and fit in what I want to do, and is the diet I've got important and should I be doing this, and things like, 'Oh for goodness sake, I can't be bothered with it', but because I've had to think about it, because I'm going to talk to someone about it and then . . . It appears to have worked very well.*
>
> *Married female, 65 years; our emphasis*

The importance of monitoring and feedback

Around half ($n = 13$) of the participants expressed enthusiasm not for the motivational interview per se but for the opportunity to be monitored and have feedback on their performance. For some, this involved the expected pleasure of receiving objective feedback from the researcher or the Actiheart on their level of activity over a week or during particular activities, as well as how that compared with national guidance or other people:

> *to be honest, one of the reasons I participated in this is because I did want some feedback. I wanted to be told what the opinion was of my state of fitness.*
>
> *Divorced male, 50 years*

> *I just wish I'd been able to carry on with the monitor, just to see what the heart monitor showed through my normal week . . . I was quite disappointed I couldn't just keep it on.*
>
> *Single female, 62 years*

> *I wanted to be able to see that result, to see what kind of exercise I did over that time, how much calorie did I burn, you know, things like that. I would love to have something like that. I think that generate a greater interest to go out and do something.*
>
> *Single female, 47 years*

Others reported that arranging to meet a researcher in 3 months' time, for the research study primary outcome follow-up, motivated them to increase their physical activity. This may indicate possible confusion between research and intervention procedures and possible contamination of the intervention by the research procedures (see *Strength and weaknesses of the study*). Some thought that they would feel ashamed to admit it if they had not achieved their goals. Others actively looked forward to reporting achievements that they had made:

> *the fact that you know you're going to a session . . . you think I've got to do something because she's going to say, 'what have you done since last time?' If you sit there and say, 'well, actually, nothing' . . . [it] increases the guilt value [laughs].*
>
> *Married male, 64 years*

> *It's sort of saying, I realise that I remember you saying I'd do this and I haven't done that yet, sort of thing, and I'm always disappointed with myself when I say things and I don't do them.*
>
> *Single male, 51 years*

> *The very fact that I actually told [the motivational interviewer] I was going to go swimming meant I had to do it. There was no pressure on me to do it from her but the very fact that I actually told somebody I was going to do it meant I had to do it . . . because I'd actually told her I was going to do it, it made me want to do it.*
>
> *Married female, 56 years*

in the nicest possible way, I was having to report to somebody and . . . I know me: that is what I need. I don't mean that I was being told off or anything like that . . . Just to have to report that, yes I'm doing this, or I've started doing that and getting a bit of praise. I think we all like praise don't we, deep down, and that helped.

Widowed female, 65 years

you keep that pressure on by saying, 'Right, you've got an appointment in 4 weeks' time and we're going to put this on, and blah-di-blah', so you know, people think, 'Ah, I must do it, I must do it'.

Widowed female, 65 years

Of these, a number of people expressed how important it was that the person holding them to account was a relative stranger rather than a friend:

It could've been a friend, but it's not as easy with a friend to do it . . . And it kept my mind focused, just the fact that I was talking to someone, someone who obviously knew what they were talking about as opposed to, I mentioned a friend before, where a friend wouldn't know the same, wouldn't have the same knowledge.

Widowed female, 65 years

Yeah, yes, cos day-to-day people, they're with you all day, they're either bored of it or they can see it for themselves, or you know, you might catch them when they're not particularly interested. You know, so it's not quite so easy, whereas with somebody else who is a stranger as well, I quite liked that, rather than, sort of, if it hadn't gone well, it's not, you know, somebody judgemental.

Married female, 53 years

The prevalence of optimistic self-assessment

We have already noted earlier that self-reported physical activity from the SPAQ correlated poorly with objective physical activity (see *Figure 17*) and the low numbers of people meeting physical activity targets of 30 minutes of moderate to vigorous physical activity on any particular day (see *Appendix 6*, *Table 50*). However, some interviewees made very explicit and detailed claims to the effect that they were very physically active when the Actiheart data suggested otherwise:

Well don't forget, my work involves me running around after a tower crane up buildings that were anything from 6 to 18 floors up that had no lifts in them, and you know so that's kind of pretty physical all by itself.

Married male, 48 years, who met physical activity guidance on 1/7 Actiheart days; median (range) minutes per day of moderate activity = 0 (0–40)

Chapter 5 Results of the fidelity assessment

Assessment of interventionist motivational interviewing experience and competence

Those delivering the intervention (RAs) typically had approximately 3 years' experience of delivering physical activity interventions; in addition, two had formal psychological or counselling workshop training prior to this trial. However, all RAs had experience of physical activity programming training in a range of settings. This was predominantly in local authority, gym, health or university contexts and did not focus on health behaviour change. All of the RAs had an educational background in sport and exercise science, psychology, physical activity and wellness at undergraduate and postgraduate level.

At the initial MI training sessions an evaluation was made of the competence of the RAs in delivering the technical and relational components of MI. All of the RAs were able to competently describe and demonstrate the level 1 skills of MI, which focused on a higher ratio of open to closed questions, increased client talk time, simple reflections and summarising. In addition, the RAs were able to identify the components and characteristics of the 'spirit' of MI. By the end of the first training block (2 days equivalent) the group could identify the use of affirmation compared with praise although found it more difficult to apply this consistently in practice and still tended to fall into a 'righting reflex' of problem-solving rather than eliciting opportunities and resources from the client.

At the first formal assessment, independently coded using MITI (see *Appendix 7*, *Table 61*; first assessment), the RAs were consistently using level 2 MI skills, which included reflective listening, directional open questions (e.g. optimism for change, intention to change, advantages and disadvantages of change) and tools such as decisional balance, readiness and confidence rulers and action planning. This level of proficiency was in line with the clinician behaviour scores reported in *Table 3*.

The global rating scores (evocation, collaboration, autonomy/support, direction and empathy) across both assessment period 1 (9 months from first training) and assessment period 2 (18 months from first training) were consistent and the mean scores reflected a level of competence in all RAs with respect to 'direction' and a level of proficiency/competence in respect to 'evocation' and 'empathy'. The per cent MI adherent clinician behaviours were all at 100% at phase 1 and/or 2.

With regard to behaviour counts (e.g. per cent complex reflections, per cent open questions and reflection to question ratio), the per cent open questions increased across all RAs from baseline, the reflection to question ratio increased from phase 1 to phase 2 across all RAs and the open questions to complex reflections ratio was higher than anticipated across all RAs.

Independent assessment of interventionist delivery (Motivational Interviewing Treatment Integrity assessment)

The MITI coded sessions were independently assessed by a qualified MI coder and a number of aspects were highlighted as positive and effective in addition to there being areas for enhancement. Although 'direction' scored as proficient on the global ratings scale, feedback indicated a need for greater recognition of individual participants' level of readiness, values and the strength of change talk.[84] This was highlighted as requiring a greater use of more challenging complex reflections and a greater use of strategies to elicit and strengthen change talk. The RAs scored highly for levels of empathy, however, and similarly demonstrated a high level of client engagement, which is a common aspect of MI 'spirit'.

Although the use of 'direction' across all RAs was consistently high, most RAs did not sufficiently demonstrate empathy and autonomy support, which are global MI measures.

The relationship between motivational interviewing fidelity and levels of physical activity

There is moderate evidence to suggest that MI fidelity is associated with physical activity as measured by mean TEE per day (kcal) at 3 months ($p = 0.027$), that is, the level of physical activity of participants at follow-up was associated with the overall fidelity of delivery of the RA who delivered their MI intervention.

Figure 25 shows the means of mean TEE per day at 3 months with their associated 95% CIs stratified by RA ranked by their global fidelity rating. It should be noted that RA1, RA2 and RA3 had a similar global proficiency rating of 3.5. Grouping these RAs together showed a stronger association between MI fidelity and mean TEE per day at 3 months ($p = 0.003$). As observed from *Figure 25*, RAs with a higher global proficiency rating are associated with higher physical activity levels at 3 months. These results should be interpreted with caution, however, given that some RAs delivered a lower number of sessions, as observed by huge uncertainty around their estimated means. Moreover, the sessions were brief and it was not possible to demonstrate all MI processes in some RA sessions that were coded. RA6 does not appear in *Figure 25* because she delivered very few sessions and was subject to MITI recording only over a short period after initial training.

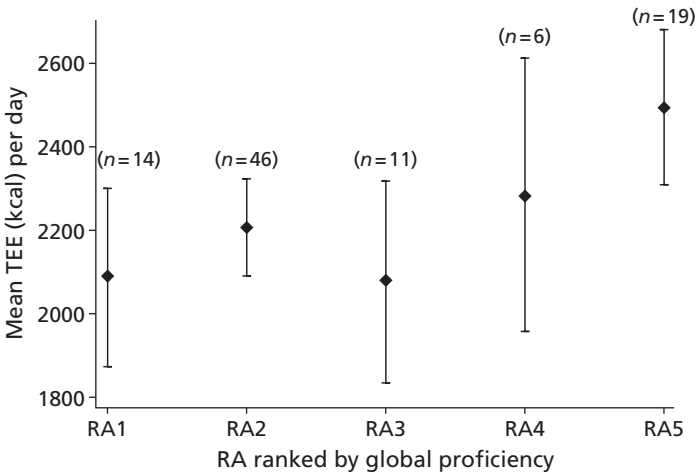


FIGURE 25 Means of mean TEE per day (kcal) stratified by RA who delivered the MI sessions.

Chapter 6 Results of the geographical information systems analysis

Distance from municipal green spaces

Chapter 2 (see *Green space measures*) described the subdivision of municipal green spaces based on their catchment area classification (as determined by Sheffield City Council) and certain other criteria. This led to two sets of polygons, one representing the highest-quality green spaces and the other representing medium- and high-quality green spaces. We calculated the shortest network distance from the home postcode centroid of each participant to the nearest polygon in both sets. This resulted in two variables for each participant, which are shown in *Figures 26* and *27*, respectively, using quantile colour-coded circles placed at each of the randomised participants' home postcode centroids.

The most striking feature of *Figures 26* and *27* is that participants in High Green (the cluster of points in the upper part of the map) live much further from these municipal green spaces than other participants located more centrally within Sheffield, despite being surrounded by open countryside. This is an issue that has been encountered in other studies linking green space and exercise.[85,86]

Although there is a case for including all forms of green space in an analysis of access to spaces for physical activity, it is also likely that municipal green space is, or is perceived to be, more accessible than the green space that is available in the countryside. More specifically, municipal spaces typically offer a 'tame' version of nature that may be more attractive to those unused to active outdoor pursuits, with better-marked paths and routes and not requiring any specific clothing or footwear such as walking boots.

Regarding the differences between *Figure 26* and *Figure 27*, it is noticeable that, aside from Rother Valley Country Park (the large park in the south-east corner of both maps), there are no high-quality green spaces in the east or south-east of the city, despite these areas being well provided with medium-quality green space. This aside, the two sets of data do not differ strongly.

Regarding the measuring of green space, it is worth noting that the greenery comes in many forms, not all of which can be measured by land usage. For instance, many public roads in the Victorian areas of Sheffield are lined with mature deciduous trees, lending these areas a 'green' feel, even though these do not count as municipal green spaces. However, it is beyond the scope of this study to address this issue.

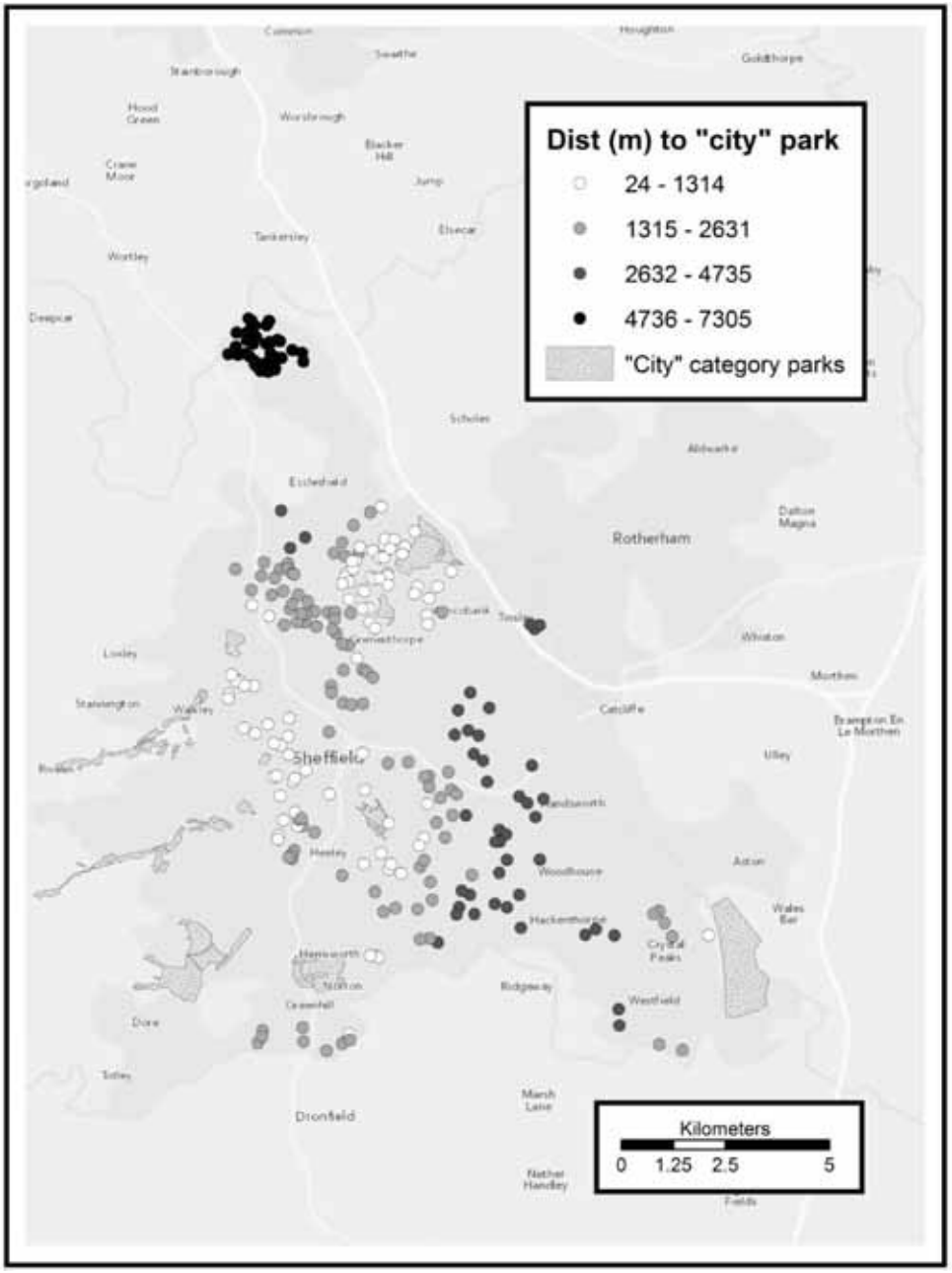


FIGURE 26 Shortest pedestrian network distance to high-quality green space (randomised participants only), as determined using a citywide catchment area.

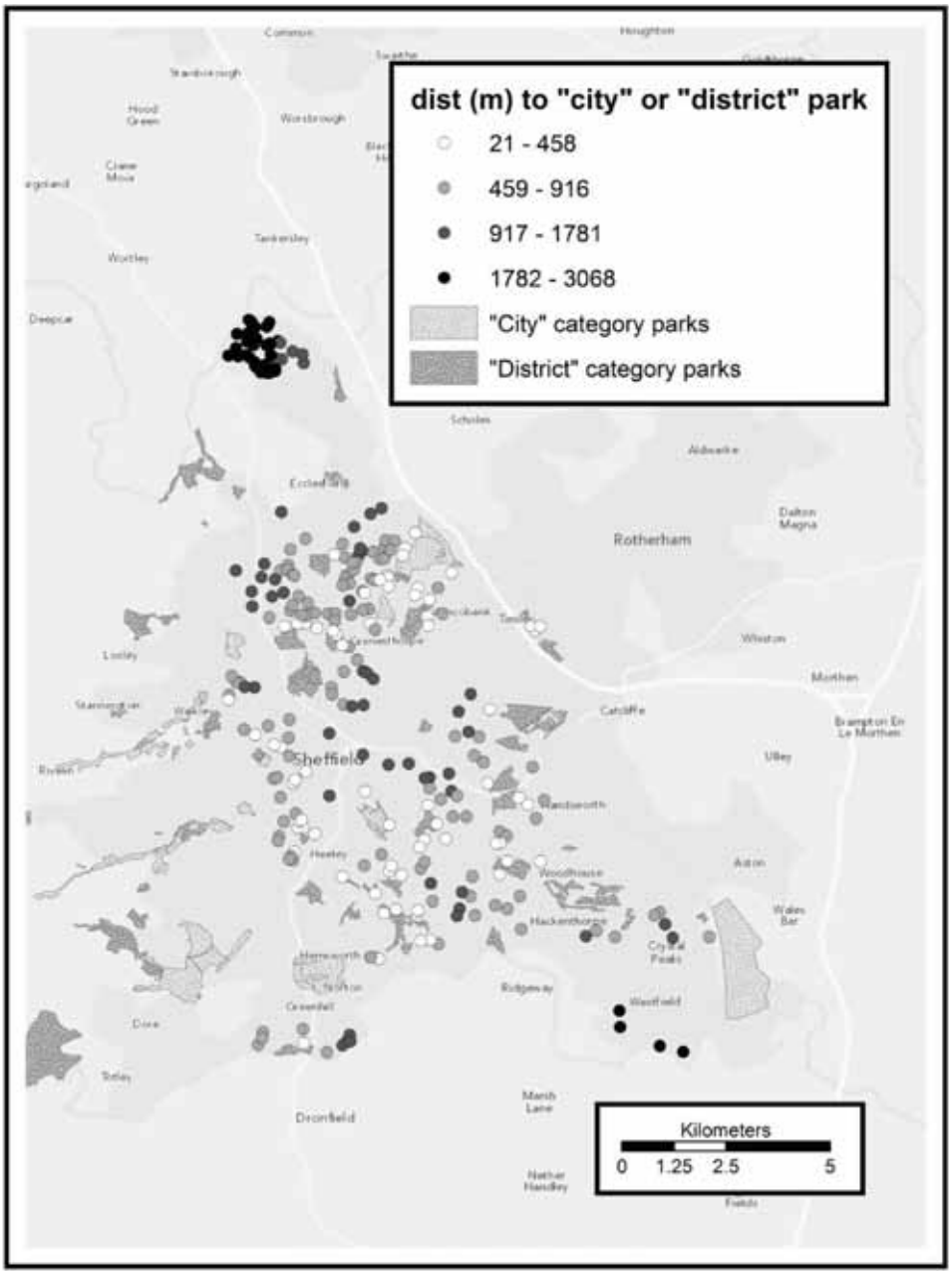


FIGURE 27 Shortest pedestrian network distance to medium or high-quality green space (randomised participants only), as determined using a district or citywide catchment area.

Distance from leisure facilities

Chapter 4 (see *Leisure facility measures*) described the identification of gyms and swimming pools in the local area. Based on survey and interview data from the booster participants, these facilities were felt to be the most relevant to the study. *Figures 28* and *29* show the location of gyms and swimming pools, respectively, in Sheffield and the surrounding area, together with the network distance to the nearest facility for each of the randomised participants. Note that as some gyms are female only, the set of locations used for calculating network distance was different for male and female participants. In *Figure 28*, female-only gyms are represented by a black star, with a white star for unisex gyms.

Regarding *Figure 28*, as with *Figures 26* and *27*, there is a noticeable difference in the results for participants in High Green (the cluster of points in the upper part of the map). This is especially true of the northern-most part of High Green, despite a gym being present at Tankersley Manor (the star just above High Green on the map). This is because there is a high-speed trunk road (the A616 Stocksbridge bypass) between the two, which is not suitable for pedestrians; the relatively high network distances here reflect a detour across fields to reach a footbridge over the road.

The presence of female-only gyms does not have a large effect on the results, as these are mostly in areas where other gyms are present.

In contrast to *Figure 28*, *Figure 29* shows a marked absence of swimming pools in the east and south-east of the city, except for the far south-east. *Figure 29* also shows an apparent 'corridor' of mid-grey points (indicating a relatively high network distance to the nearest swimming pool) in the north-west of the city; however, this is an artefact resulting from the participant locations happening to fall in a line.

Association between trial outcomes and proximity to green space and leisure facilities

The main purpose of mapping proximity to both green spaces and leisure facilities was to explore whether geographical access to opportunities for physical activity was a predictor of activity levels in trial participants. However, there was no statistical association observed between TEE at 3 months and proximity to the above variables in trial participants and we found no evidence therefore to support the hypothesis that geographical access to either municipal green space or swimming pools and gyms was an independent predictor or moderator of physical activity. As the booster intervention was not shown to be effective (a necessary condition for mediation analysis) and use of community facilities by participants (a planned subgroup analysis) was not a moderator of intervention effect, we did not further explore the hypothesis that geographical access or any other variables could be mediators of the impact of a booster intervention.

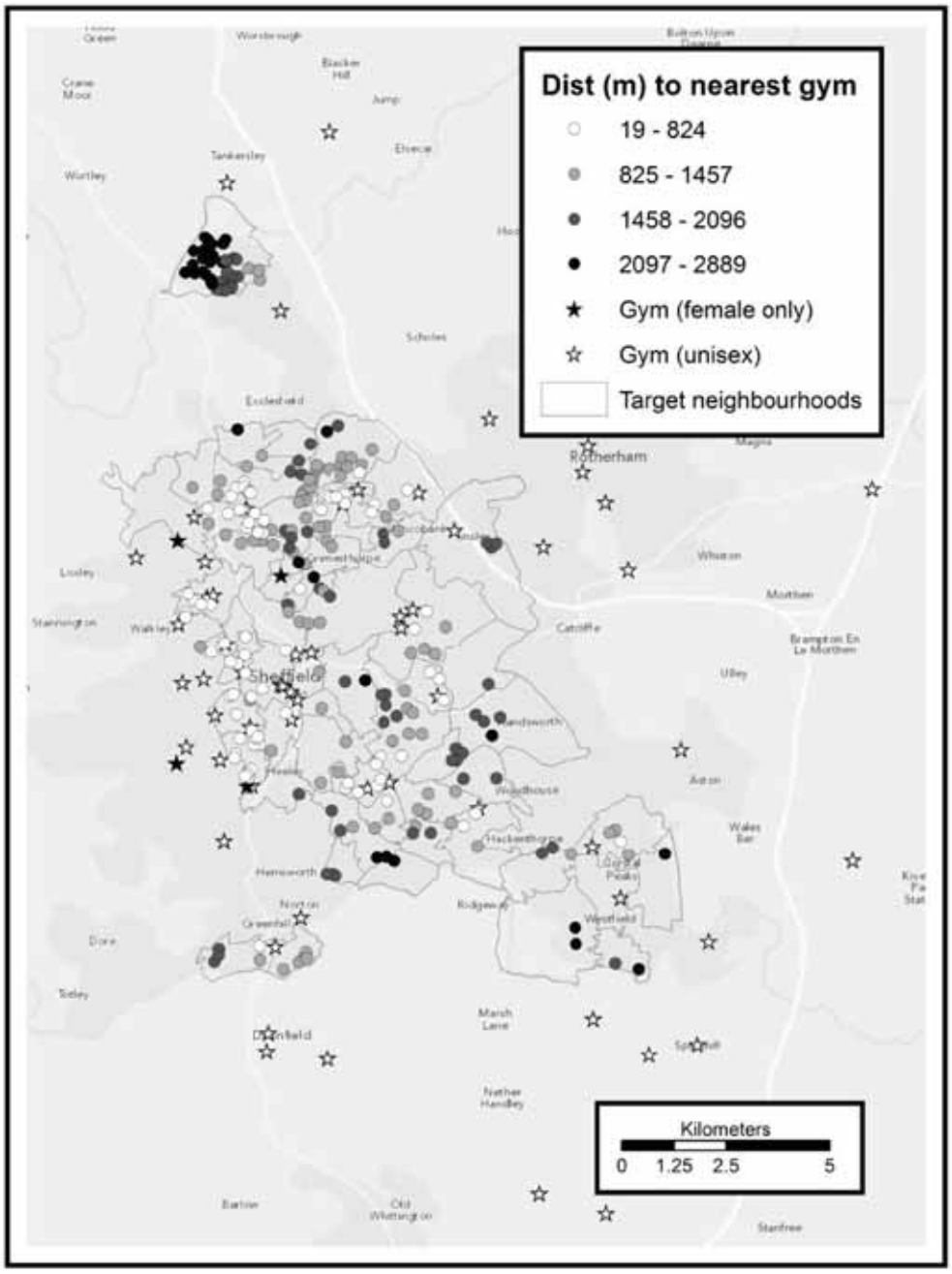


FIGURE 28 Shortest pedestrian network distance to a gym (randomised participants only). This was dependent on the gender of the participant as some gyms are female only.

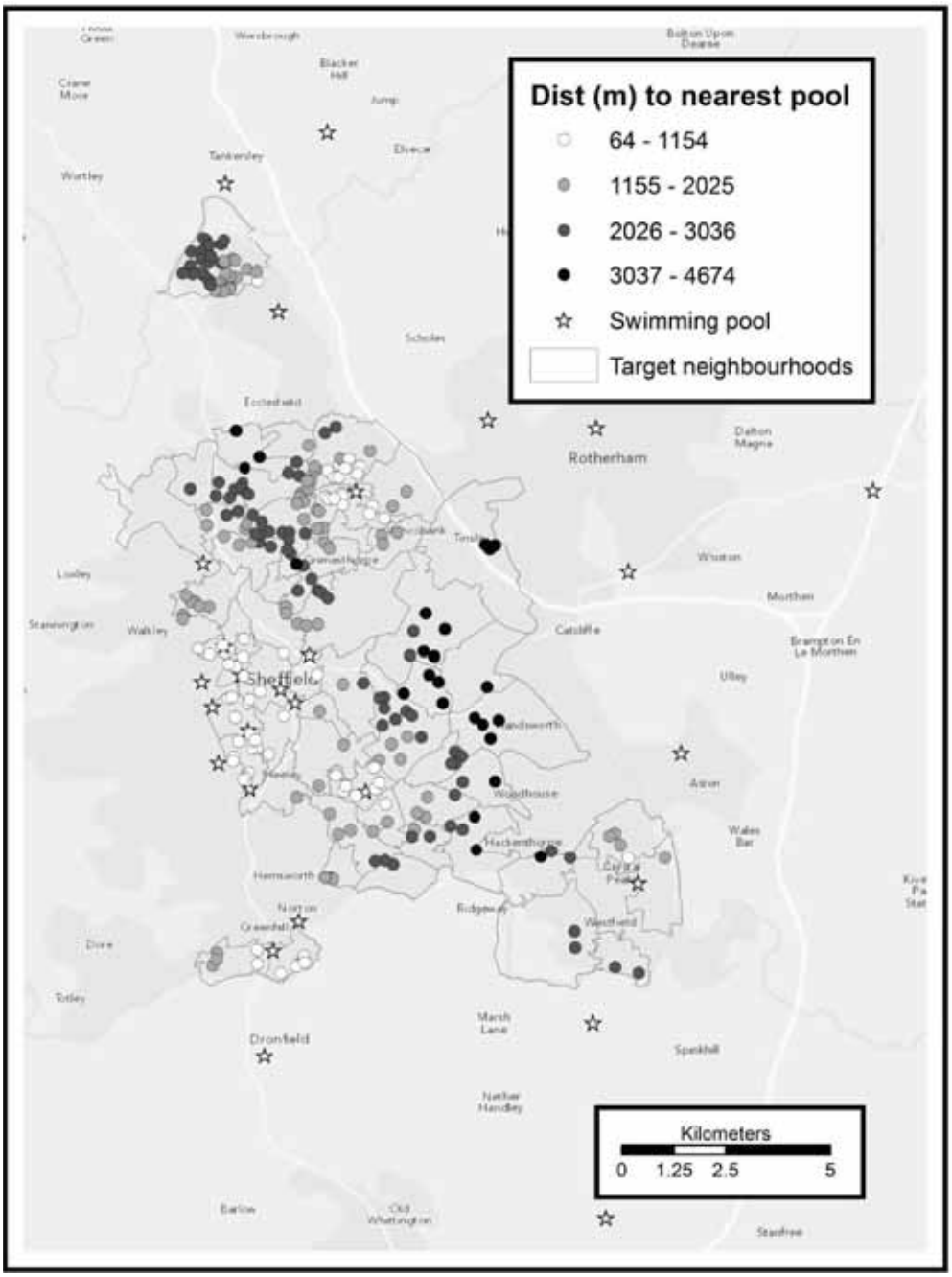


FIGURE 29 Shortest pedestrian network distance to a swimming pool (randomised participants only).

Chapter 7 Results of the health economic analysis

Scenarios modelled

As discussed in *Chapter 2*, a range of sources of structural uncertainty exist when attempting to infer the long-term clinical and cost-effectiveness implications of the booster trial results, based largely on the Actiheart data (as the primary outcome assessing differences in physical activity between trial groups). For this reason it was decided to consider two different types of model and a number of scenarios within each model type:

1. short-term model [see *Short-term (directly elicited) model*]:

   - perspective: NHS, societal
   - comparison: baseline compared with 3 months; baseline compared with 9 months; 3 months compared with 9 months
   - data: all available data; completers only

2. long-term model [see *Long-term (epidemiological) model*]

   - primary
     - individual-level differences-in-differences approach
     - 3-month differences only
     - 9-month differences only
   - secondary
     - 'value-added' differences-in-differences approach
     - quintile effects.

A total of 12 separate short-term model scenarios are considered, involving all combinations of the three variables listed above. Each of these scenarios is numbered as shown in *Table 9*.

Short-term (directly elicited) model

Resource use analysis

An analysis of the NHS resources consumed by participants in each of the trial arms indicated that participants in the intervention arms had greater increases in NHS resource consumption at 9 months compared with baseline than participants in the control arm, as indicated in *Table 10*.

Cost of the intervention

Estimates of the cost of the intervention were arrived at taking into account a range of factors including number of sessions per completer; number of completer sessions per RA; numbers of completers at 3 and 9 months in the mini and full booster intervention arms; numbers of participants in the mini and full booster arms; estimates of the duration of sessions in the mini and full booster arms; RA training and monitoring costs; venue hire (full booster) and telephone call (mini booster) costs; and the ratio of participants who completed a full or mini booster course to those assigned to the course.

Following discussion with RAs, the average duration of a mini booster session was estimated to be 20 minutes and the average duration of a full booster session was estimated to be 30 minutes.

TABLE 9 Key to economic modelling scenarios

Scenario no.	Perspective	Time comparison	Data used
1	NHS	Baseline to 3 months	All
2	Societal	Baseline to 3 months	All
3	NHS	Baseline to 9 months	All
4	Societal	Baseline to 9 months	All
5	NHS	3 months to 9 months	All
6	Societal	3 months to 9 months	All
7	NHS	Baseline to 3 months	Completers
8	Societal	Baseline to 3 months	Completers
9	NHS	Baseline to 9 months	Completers
10	Societal	Baseline to 9 months	Completers
11	NHS	3 months to 9 months	Completers
12	Societal	3 months to 9 months	Completers

TABLE 10 Differences-in-differences NHS resource use estimates

Differences in differences between control arm and . . .	Mean value (per participant) (bootstrapped 95% CI) (£)
Mini booster arm	26.68 (26.59 to 27.12)
Full booster arm	190.91 (190.56 to 191.25)

The cost per minute of a mini booster session was estimated to be lower than the cost per minute of a full booster session as the latter required venue hire and RA travel time. Rates of attrition were similar in both intervention arms at 3 months but were higher in the mini booster arm at 9 months. Because of this the average total cost per completer (someone who attended two booster sessions and provided valid Actiheart data) was estimated to be slightly higher in the mini booster arm at 9 months than in the full booster arm at 9 months. Because of the high level of uncertainty in estimating the cost of the intervention, eight different intervention cost estimates were produced for both the mini booster arm and the full booster arm using different plausible assumptions. The assumptions made to produce these estimates are shown in *Appendix 7*, *Table 62*; 2011 prices were assumed.

The range of estimates appeared to follow a log-normal distribution with a mean (SD) cost per completer of £216 (£88) for the mini booster and £205 (£76) for the full booster. Because of the similarity of these numbers the booster intervention was assumed to cost approximately the same irrespective of whether it was the full booster or the mini booster. The two pairs of eight estimates were combined to produce a mean (SD) cost per completer of £211 (£91), also assuming a log-normal distribution. Within the deterministic analyses the mean estimate of £211 was used. Within PSA 1000 values were drawn from an appropriately parameterised log-normal distribution.

Health-related quality of life data used

The trial outcome data used to populate the short-term model are patient-estimated utilities based on SF-12v2 plus 4 questionnaire data recorded at baseline and at the end of the trial. These data are presented in *Figure 30* for participants who provided valid 9-month Actiheart data ('completers').

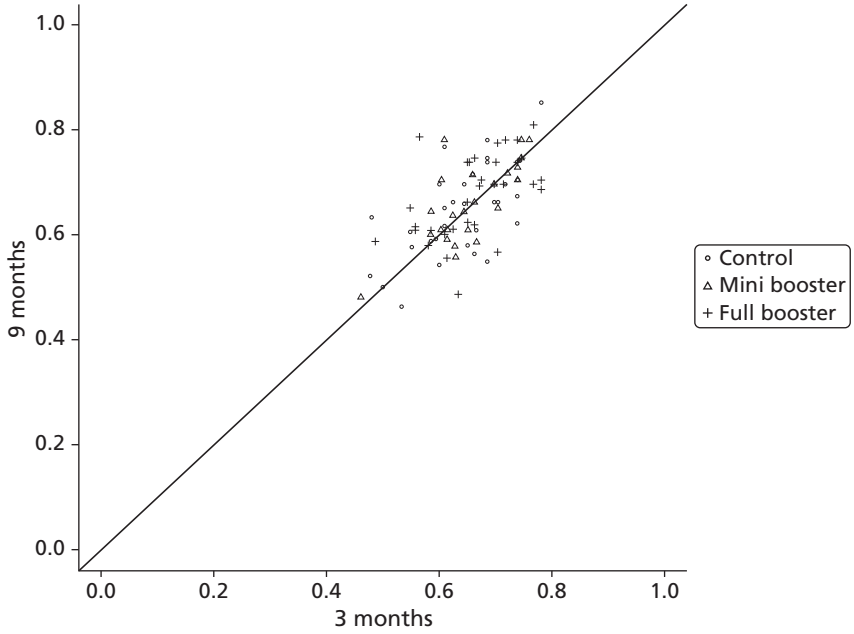


FIGURE 30 Estimated utility scores reported at 3 and 9 months by allocation group (trial completers only).

Within scatter plots of this form, an overall trend over time would be indicated by the scatter deviating from the diagonal line: above the line in the case of an upwards trend and below the line in the case of a downwards trend. A difference between groups would be apparent if the three sets of scatter, indicated by the three plotting symbols, tended to cluster in different places. It is seen from this plot that there does not appear to be either a trend over time or a difference between groups.

Table 11 shows the mean (SD) change in HRQoL from baseline to 9 months by allocation group. Differences-in-differences estimates, comparing the control group with either the mini booster group or the full booster group, are also presented. These differences are very close to zero in all cases but very slightly favour the control group over either of the intervention groups.

This approach was adopted for each of the analyses.

Simple threshold analysis

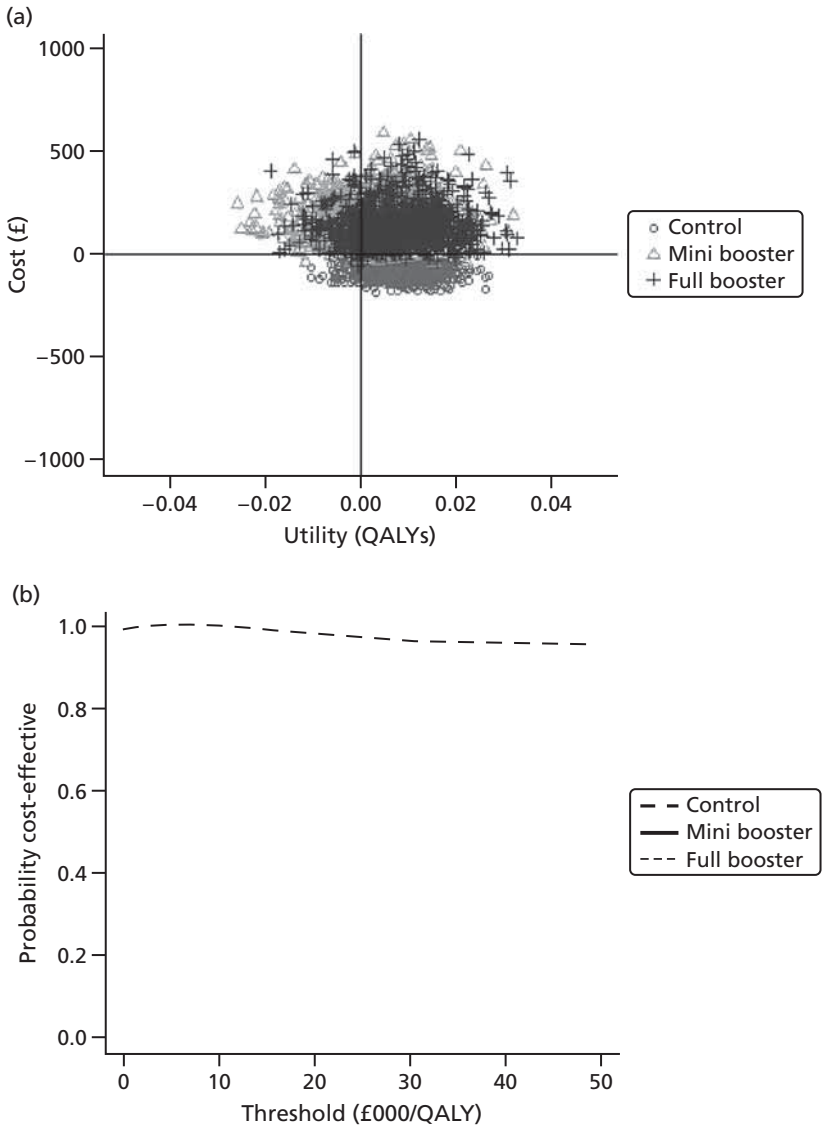
Given an estimated cost of the intervention of £211 per participant, and assuming a willingness-to-pay threshold of £20,000 per QALY, the intervention would have to provide an additional 0.01055 QALYs to be considered cost-effective.

Short-term scenarios

Figures 31–42 present scatter plots, CEAFs and tables summarising mean scores and ICERs for each of the 12 scenarios described in *Table 9*.

TABLE 11 Mean (SD) change in HRQoL scores from 3 to 9 months

		Differences in differences compared with the control group	
Group	Mean (SD) change in HRQoL from 3 to 9 months	Mean	Bootstrapped mean 95% CIs
Control	0.018 (0.010)		
Mini booster	0.001 (0.015)	–0.016	–0.018 to –0.016
Full booster	0.016 (0.014)	–0.002	–0.002 to –0.000

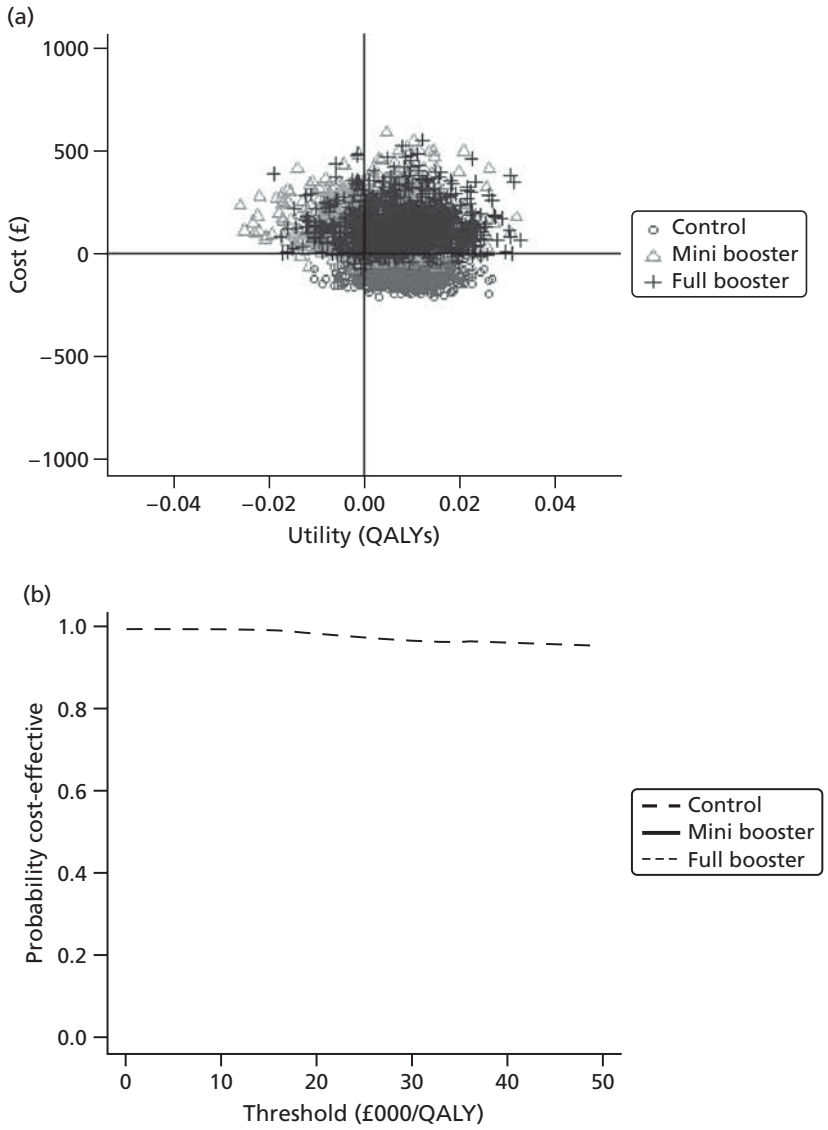


(c)

Scenario 1	Mean cost (£)	Mean QALY
Control	−81	0.01
Mini booster	169	0.00
Full booster	148	0.01

ICER (£/QALY)	Mean	Jackknifed 95% credible intervals
Mini vs. control	Dominated	Dominated to dominated
Full vs. control	Dominated	Dominated to dominated

FIGURE 31 Scenario 1. (a) Scatter plot of difference in costs (£) against differences in QALYs; (b) CEAF; and (c) mean costs, QALYs (to two decimal places) and ICERs.

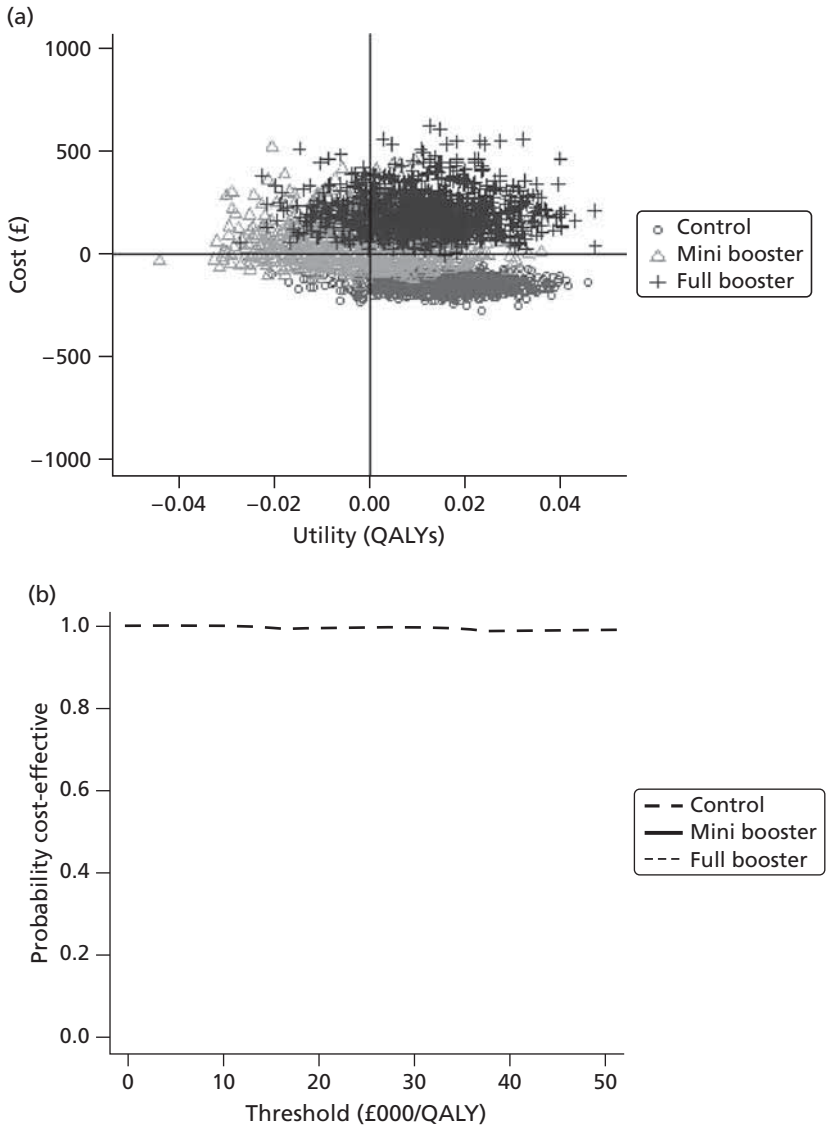


(c)

Scenario 2	Mean cost (£)	Mean QALY
Control	−96	0.01
Mini booster	155	0.00
Full booster	132	0.01

ICER (£/QALY)	Mean	Jackknifed 95% credible intervals
Mini vs. control	Dominated	Dominated to dominated
Full vs. control	Dominated	Dominated to dominated

FIGURE 32 Scenario 2. (a) Scatter plot of difference in costs (£) against differences in QALYs; (b) CEAF; and (c) mean costs, QALYs (to two decimal places) and ICERs.

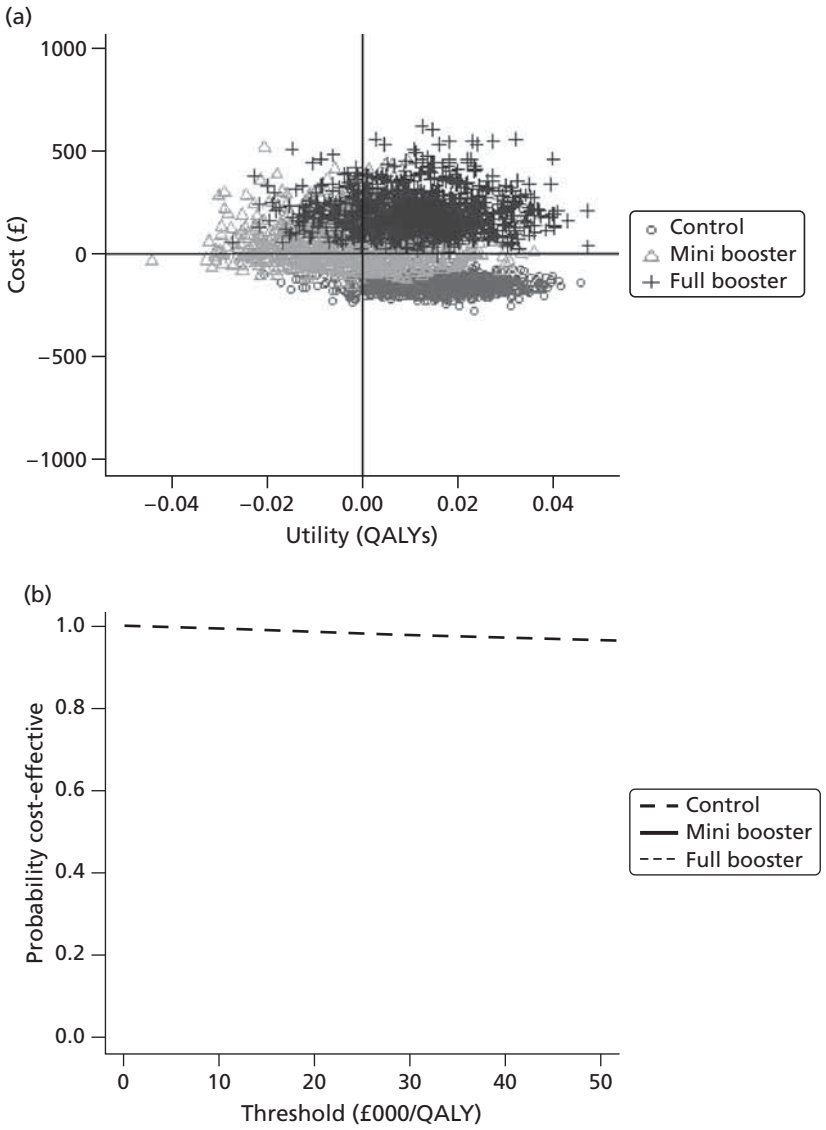


(c)

Scenario 3	Mean cost (£)	Mean QALY
Control	−146	0.02
Mini booster	63	0.00
Full booster	203	0.01

ICER (£/QALY)	Mean	Jackknifed 95% credible intervals
Mini vs. control	Dominated	Dominated to dominated
Full vs. control	Dominated	Dominated to dominated

FIGURE 33 Scenario 3. (a) Scatter plot of difference in costs (£) against differences in QALYs; (b) CEAF; and (c) mean costs, QALYs (to two decimal places) and ICERs.

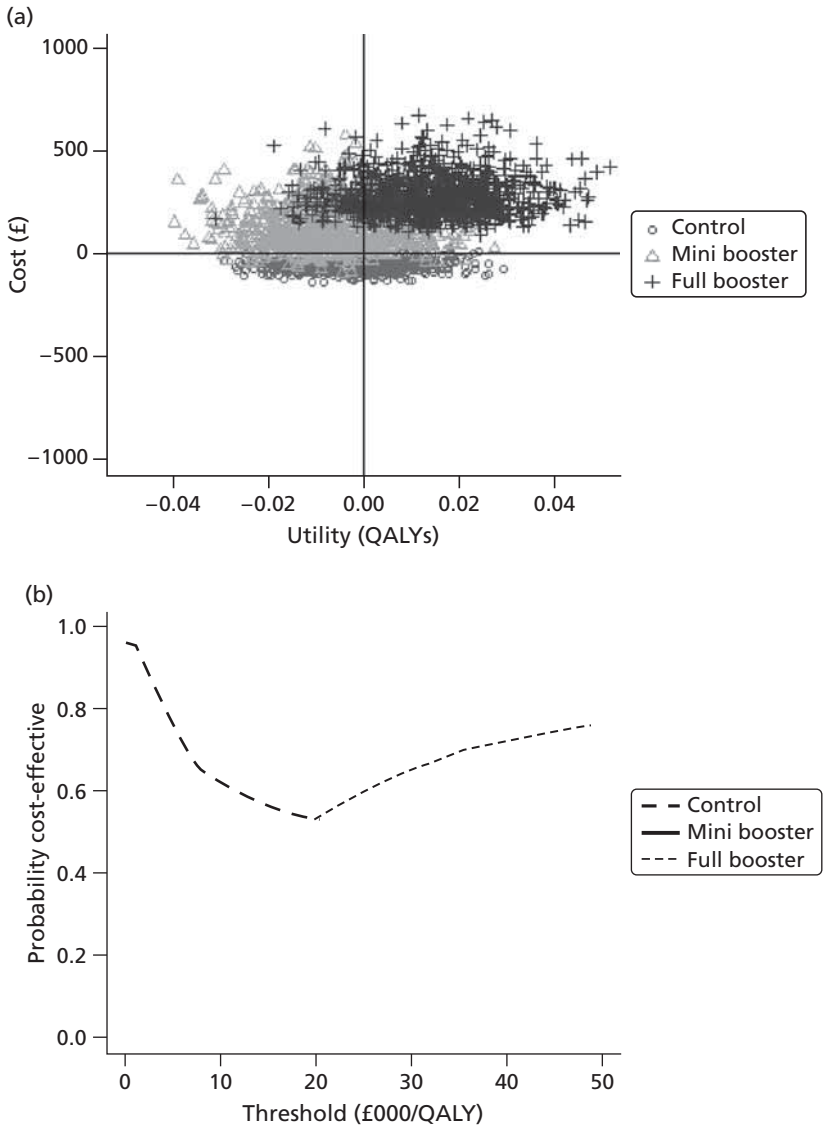


(c)

Scenario 4	Mean cost (£)	Mean QALY
Control	−146	0.02
Mini booster	63	0.00
Full booster	203	0.01

ICER (£/QALY)	Mean	Jackknifed 95% credible intervals
Mini vs. control	Dominated	Dominated to dominated
Full vs. control	Dominated	Dominated to dominated

FIGURE 34 Scenario 4. (a) Scatter plot of difference in costs (£) against differences in QALYs; (b) CEAF; and (c) mean costs, QALYs (to two decimal places) and ICERs.

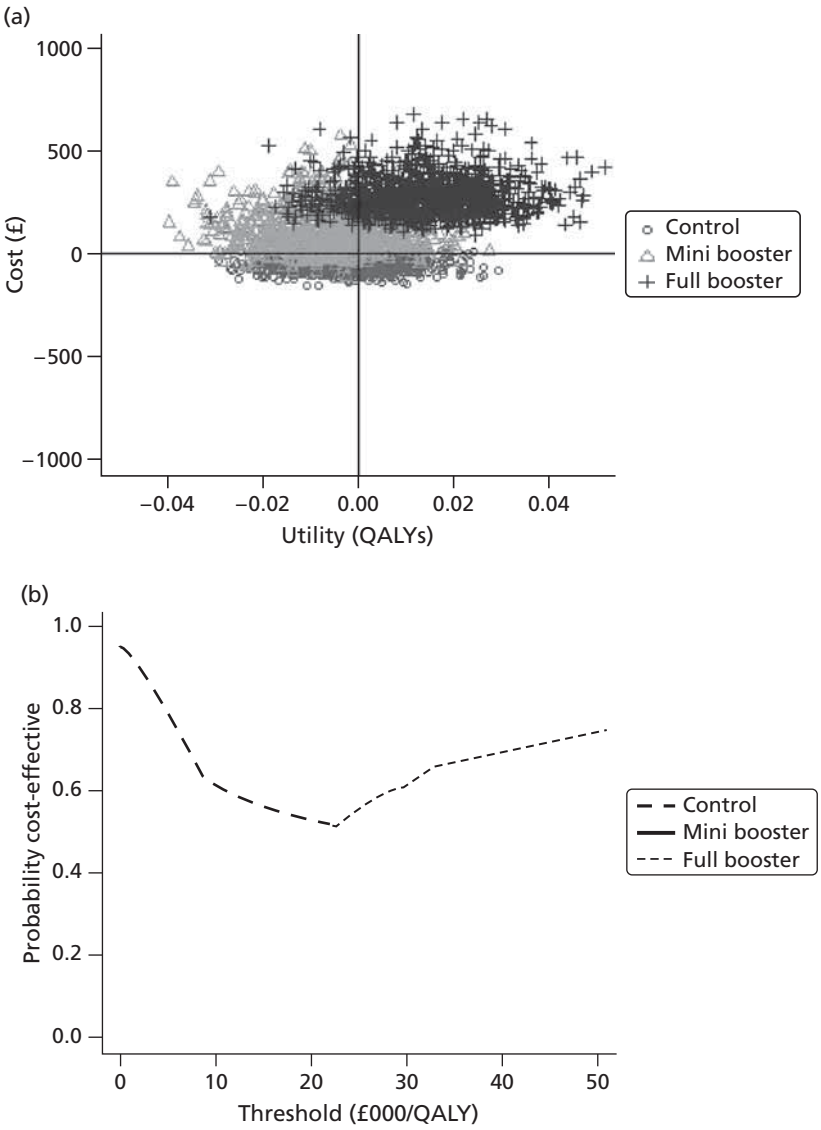


(c)

Scenario 5	Mean cost (£)	Mean QALY
Control	−47	0.00
Mini booster	129	−0.01
Full booster	279	0.01

ICER (£/QALY)	Mean	Jackknifed 95% credible intervals
Mini vs. control	Dominated	Dominated to dominated
Full vs. control	£20,417	£20,376 to £20,458

FIGURE 35 Scenario 5. (a) Scatter plot of difference in costs (£) against differences in QALYs; (b) CEAF; and (c) mean costs, QALYs (to two decimal places) and ICERs.

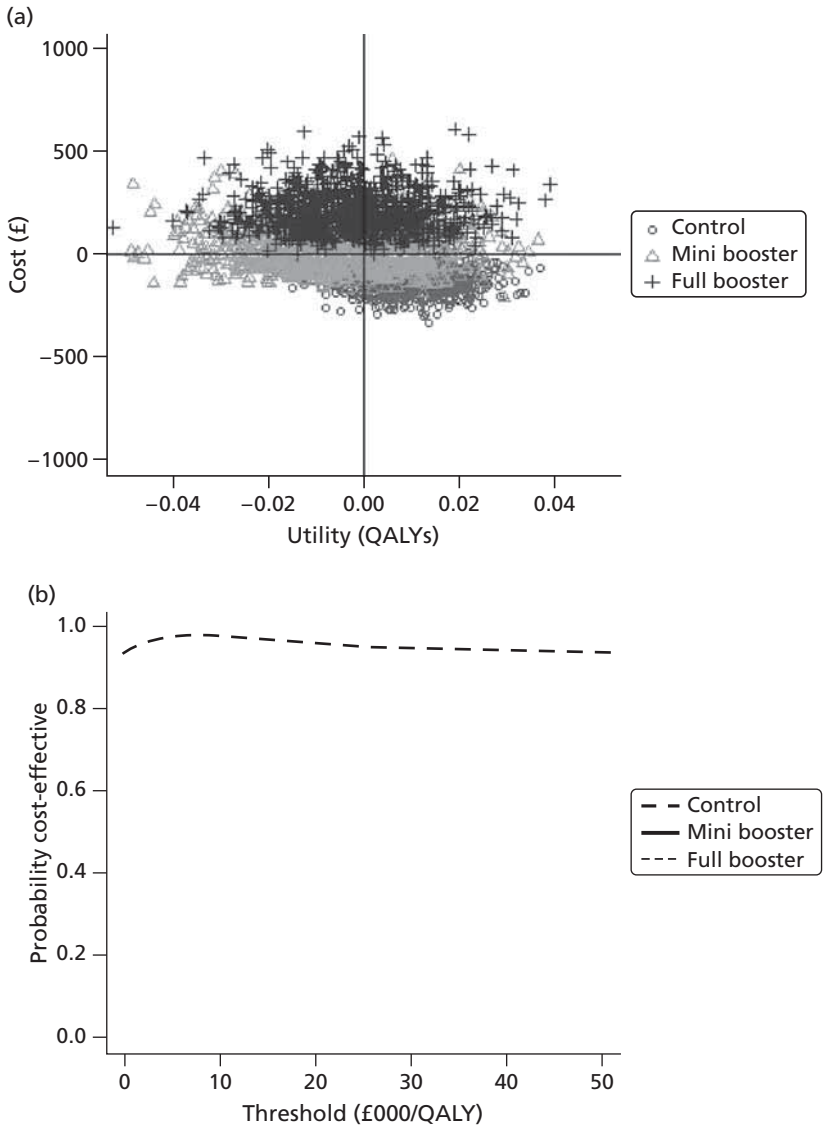


(c)

Scenario 6	Mean cost (£)	Mean QALY
Control	−50	0.00
Mini booster	121	−0.01
Full booster	289	0.01

ICER (£/QALY)	Mean	Jackknifed 95% credible intervals
Mini vs. control	Dominated	Dominated to dominated
Full vs. control	£20,843	£20,801 to £20,884

FIGURE 36 Scenario 6. (a) Scatter plot of difference in costs (£) against differences in QALYs; (b) CEAF; and (c) mean costs, QALYs (to two decimal places) and ICERs.

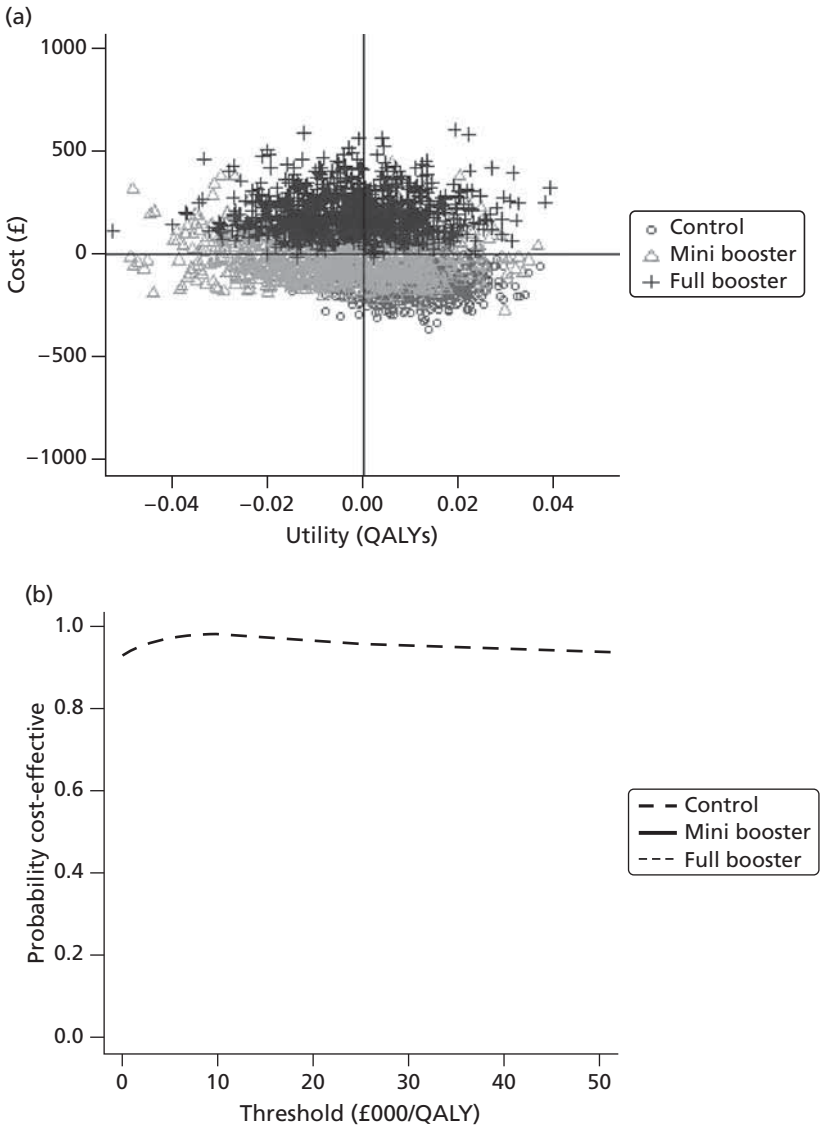


(c)

Scenario 7	Mean cost (£)	Mean QALY
Control	−105	0.01
Mini booster	34	−0.01
Full booster	207	0.00

ICER (£/QALY)	Mean	Jackknifed 95% credible intervals
Mini vs. control	Dominated	Dominated to dominated
Full vs. control	Dominated	Dominated to dominated

FIGURE 37 Scenario 7. (a) Scatter plot of difference in costs (£) against differences in QALYs; (b) CEAF; and (c) mean costs, QALYs (to two decimal places) and ICERs.

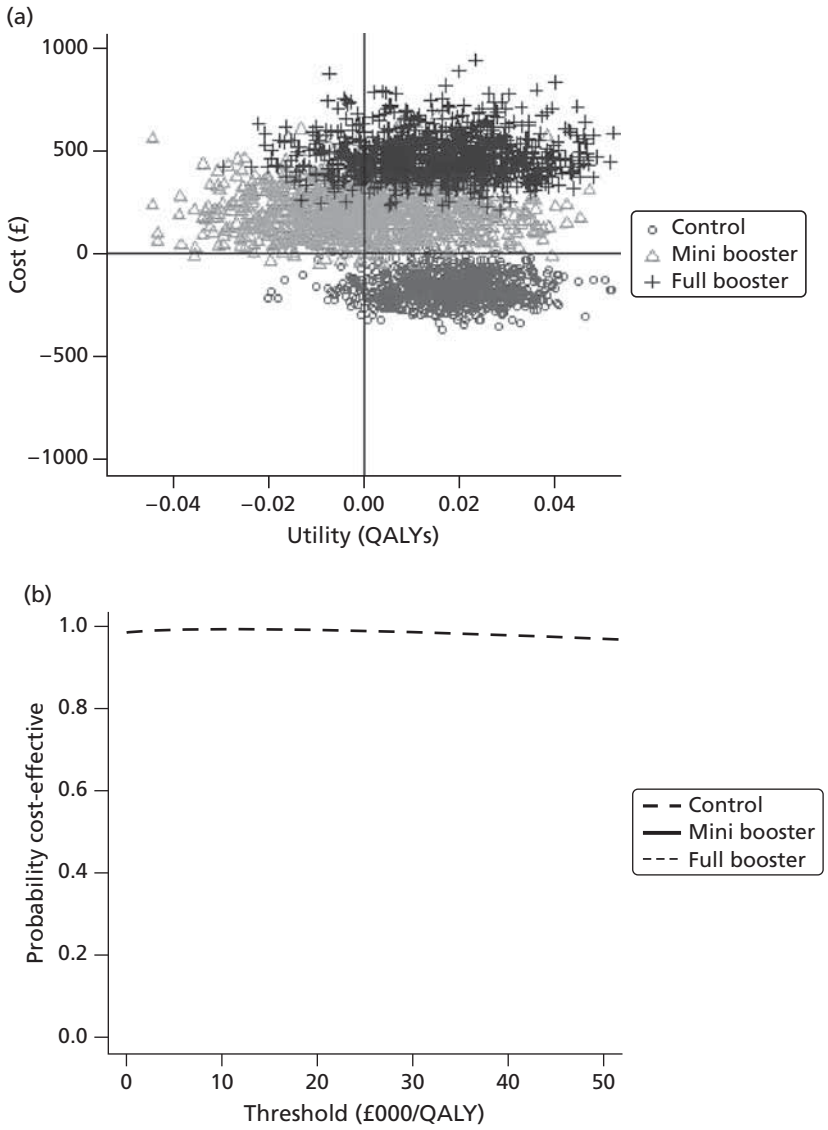


(c)

Scenario 8	Mean cost (£)	Mean QALY
Control	−112	0.01
Mini booster	0	−0.01
Full booster	198	0.00

ICER (£/QALY)	Mean	Jackknifed 95% credible intervals
Mini vs. control	Dominated	Dominated to dominated
Full vs. control	Dominated	Dominated to dominated

FIGURE 38 Scenario 8. (a) Scatter plot of difference in costs (£) against differences in QALYs; (b) CEAF; and (c) mean costs, QALYs (to two decimal places) and ICERs.

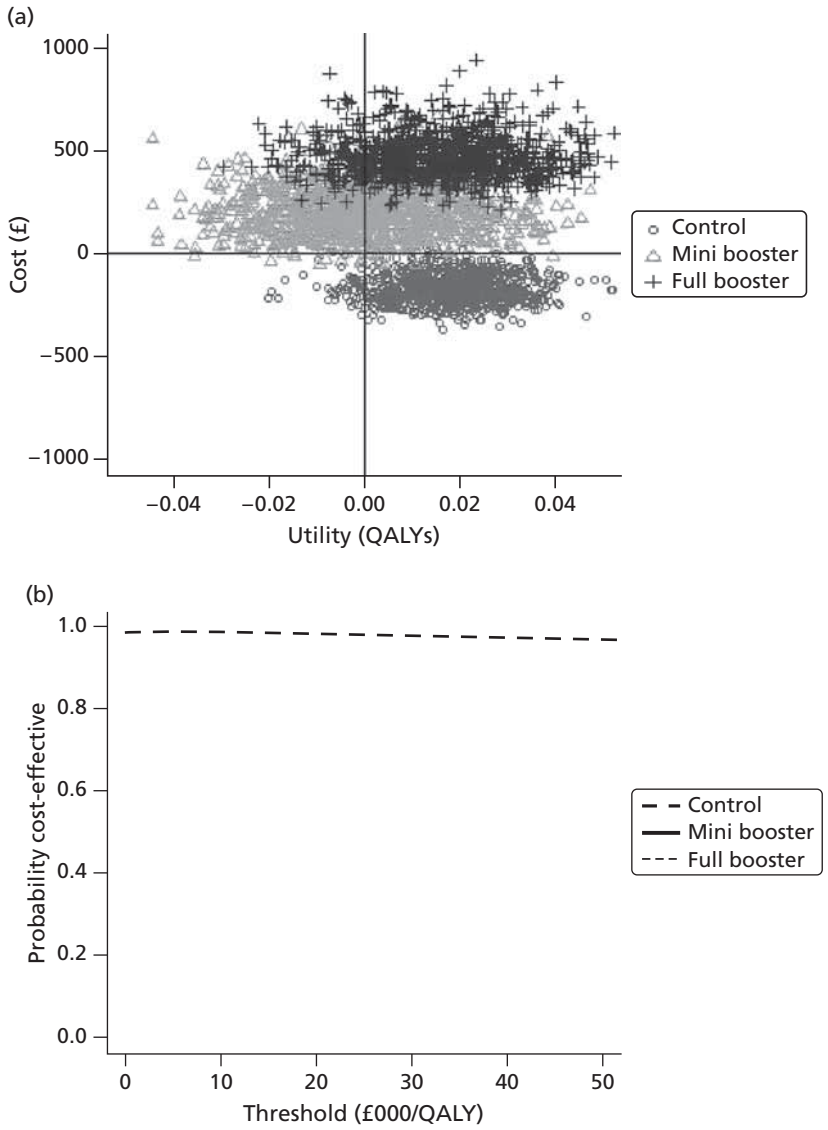


(c)

Scenario 9	Mean cost (£)	Mean QALY
Control	−168	0.02
Mini booster	211	0.00
Full booster	473	0.02

ICER (£/QALY)	Mean	Jackknifed 95% credible intervals
Mini vs. control	Dominated	Dominated to dominated
Full vs. control	Dominated	Dominated to dominated

FIGURE 39 Scenario 9. (a) Scatter plot of difference in costs (£) against differences in QALYs; (b) CEAF; and (c) mean costs, QALYs (to two decimal places) and ICERs.

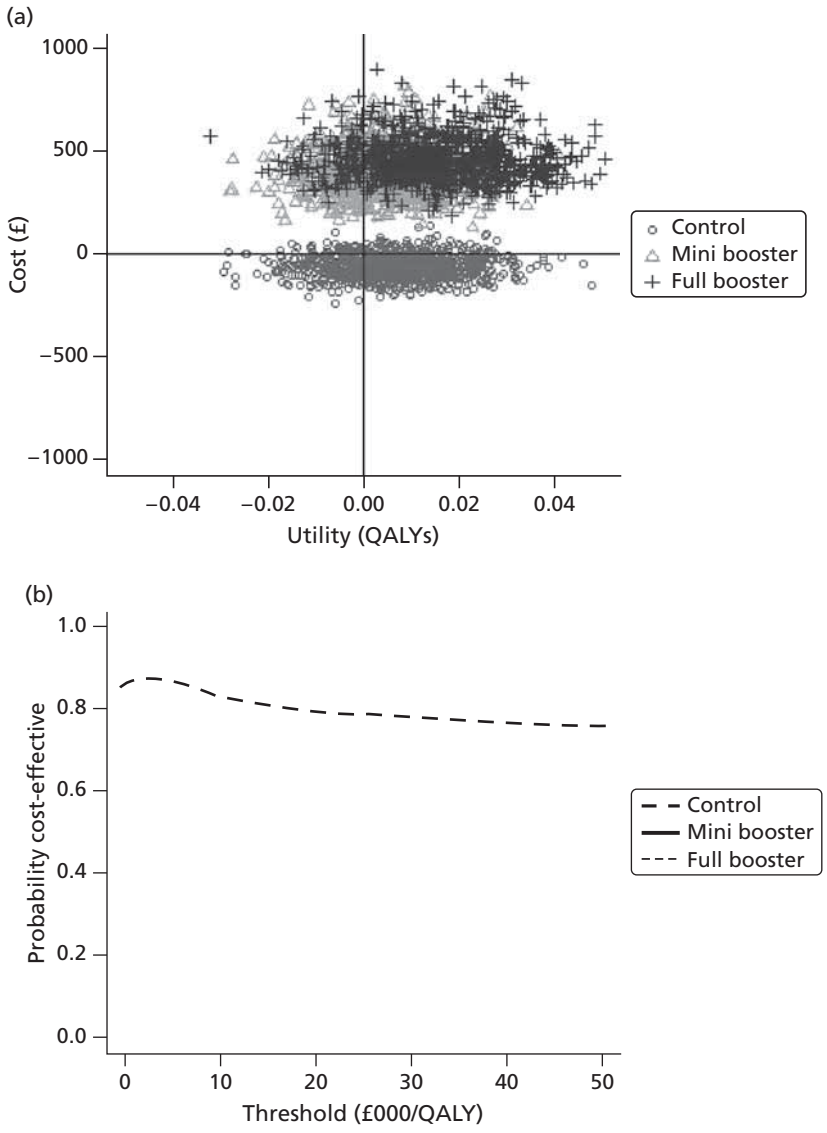


(c)

Scenario 10	Mean cost (£)	Mean QALY
Control	−168	0.02
Mini booster	211	0.00
Full booster	172	0.02

ICER (£/QALY)	Mean	Jackknifed 95% credible intervals
Mini vs. control	Dominated	Dominated to dominated
Full vs. control	Dominated	Dominated to dominated

FIGURE 40 Scenario 10. (a) Scatter plot of difference in costs (£) against differences in QALYs; (b) CEAF; and (c) mean costs, QALYs (to two decimal places) and ICERs.

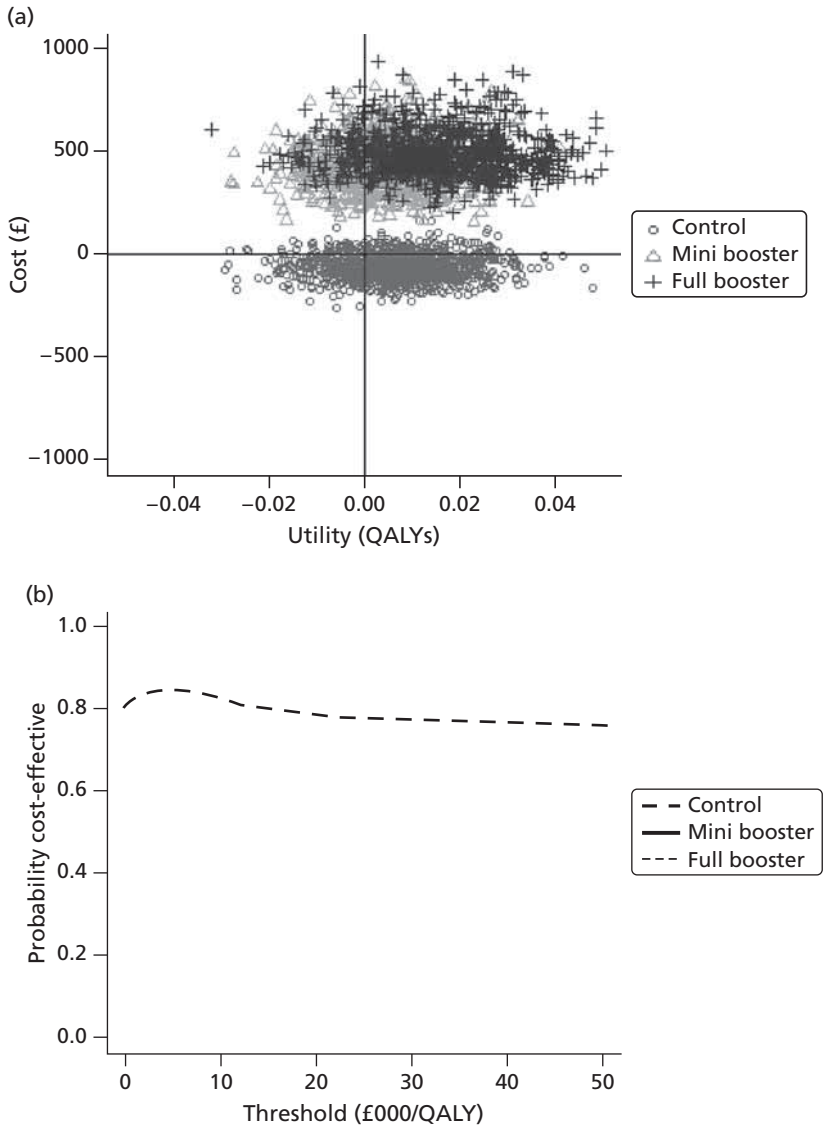


(c)

Scenario 11	Mean cost (£)	Mean QALY
Control	−59	0.01
Mini booster	390	0.01
Full booster	454	0.02

ICER (£/QALY)	Mean	Jackknifed 95% credible intervals
Mini vs. control	Dominated	Dominated to dominated
Full vs. control	£60,155	£59,928 to £60,397

FIGURE 41 Scenario 11. (a) Scatter plot of difference in costs (£) against differences in QALYs; (b) CEAF; and (c) mean costs, QALYs (to two decimal places) and ICERs.



(c)

Scenario 12	Mean cost (£)	Mean QALY
Control	−56	0.01
Mini booster	420	0.01
Full booster	486	0.02

ICER (£/QALY)	Mean	Jackknifed 95% credible intervals
Mini vs. control	Dominated	Dominated to dominated
Full vs. control	£63,470	£63,231 to £63,726

FIGURE 42 Scenario 12. (a) Scatter plot of difference in costs (£) against differences in QALYs; (b) CEAF; and (c) mean costs, QALYs (to two decimal places) and ICERs.

Summary of the short-term model results

The results of the separate scenarios for the short-term, questionnaire-based cost-effectiveness model suggest that the estimated cost-effectiveness of the intervention is subject to a high degree of structural uncertainty and depends on factors such as which data are used and which time periods are compared. In the majority of the scenarios, the control intervention, no booster, appears both the optimal choice and the option with the highest probability of cost-effectiveness at all willingness-to-pay thresholds considered. However, if the assumptions involved in scenarios 5 and 6 are made, there is an indication that the full booster may be the optimal choice when assuming a willingness-to-pay threshold of ≥ £20,000.

Looking at the estimated mean costs and mean QALYs for each arm in each scenario, it is apparent that the differences in costs and QALYs are marginal for all scenarios. For QALYs, the differences in mean values between arms are typically around or < 0.01 QALYs. The cost of the booster intervention is just one of a number of costs to the NHS and society that the participant population incurred and, compared with the costs of other NHS resources accessed by the participants over the trial period, it is not large. As the mean costs and QALYs observed in all arms are very similar, and the ICER is a ratio of two numbers, even slight decreases in costs or increases in QALYs could lead to very different indications of the cost-effectiveness of either intervention and so all results presented are potentially very dependent on statistical noise.

As previously discussed, the approaches taken to estimate the causal effect of the intervention on mean resource use and mean utility should be considered cautiously. This is partly because of the small sample sizes involved but mainly because the population considered does not as a rule suffer from any particular NHS resource-consuming and quality of life-reducing disease that the intervention is specifically designed to treat. Because of this, changes in HRQoL or NHS resource consumption over the relatively short time horizon of the trial are unlikely to be directly related to the effect of the intervention. As the intervention is more preventative than curative, the effect of the intervention on NHS resource consumption and HRQoL is likely to be relatively indirect, mediated by the effect of increased physical activity on lifelong morbidity and mortality risks, and to operate over a much longer time horizon. The long-term model results presented in the following section attempt to take these factors into account.

Long-term (epidemiological) model

Individual sampling model results

In the long-term model, 9-month and 3-month mortality RRs associated with individuals within each intervention arm are based on TEE scores sampled directly from individual participant trial data. Because of the power law mapping equation used to associate individual TEE scores with mortality RRs, and slight differences in the age and gender distribution of the trial arms, the mean incremental effects of the intervention on HRQoL may differ from the effects on TEE. This is particularly likely to be the case when the distribution of baseline levels of physical activity differs by group, as the mapping equation assumes that the most sedentary individuals have much higher mortality RRs than slightly less sedentary individuals.

As discussed earlier, a number of separate primary scenarios were considered to investigate the impact of structural uncertainty on the model results. These are shown in *Table 12*, which shows mean incremental life-years and QALYs in each arm, and *Table 13*, which shows, to two decimal places, estimated incremental differences in effectiveness in the intervention arms compared with the control arm in each of the scenarios.

As *Table 12* indicates, all estimates for the number of additional life-years lived and QALYs accumulated are very similar, with all values differing by < 1 life-year and < 0.5 QALYs. As *Table 13* indicates, this in turn leads to very small estimates for incremental differences, of < 1 life-year and < 0.33 of a QALY. Because of the stochastic qualities of the models, and the effect of initial ages on QALYs and annual QALY increments, the direction of the incremental differences in life-years and QALYs is different for some of the

TABLE 12 Summary of mean additional life-years and QALYs within different arms and scenarios

Arm	Long-term physical activity scenarios assumed[a]	Extra years lived		QALYs accrued	
		Mean	SE	Mean	SE
Control	Scenario A	26.73	0.02	12.75	0.01
	Scenario B	26.73	0.02	12.75	0.01
	Scenario C	26.90	0.02	12.81	0.01
Mini booster	Scenario A	26.71	0.02	12.73	0.01
	Scenario B	26.82	0.02	12.78	0.01
	Scenario C	26.14	0.02	12.52	0.01
Full booster	Scenario A	26.58	0.02	12.69	0.01
	Scenario B	26.67	0.02	12.72	0.01
	Scenario C	26.18	0.02	12.53	0.01

SE, standard error.
a Scenario A: 9-month activity levels for 2 years, then 3-month activity levels thereafter; scenario B: 3-month activity levels throughout; scenario C: 9-month activity levels throughout.

TABLE 13 Summary of estimates of effectiveness

Scenario	Comparison	Extra years lived		QALYs accrued	
		Mean	SE	Mean	SE
Individual-level differences in differences	Control vs. mini	–0.10	0.03	–0.05	0.01
	Control vs. full	–0.09	0.03	–0.04	0.01
3-month differences	Control vs. mini	–0.09	0.02	0.03	0.01
	Control vs. full	0.06	0.02	–0.02	0.01
9-month differences	Control vs. mini	0.76	0.02	–0.29	0.01
	Control vs. full	0.72	0.02	–0.27	0.01

SE, standard error.

scenarios, highlighting how marginal the differences between the trial arms were and the resulting influence on random variation of the estimated results.

Secondary analyses

In addition to the main long-term model results, two supplementary analyses were also conducted. In the first series of analyses, the levels of physical activity of all participants were set to fixed values. These fixed values were varied from the first (lowest) quintile to the fourth quintile observed in the trial. The mean additional utility that resulted from shifting up by one quintile was estimated for each of these baseline levels of physical activity so that the relationship between additional physical activity and baseline activity could be explored. The second series of analyses adopted a similar approach but used a level of physical activity gain based on the mean differences-in-differences estimates for TEE in the full booster group compared with the control group.

Scenarios assuming gains of one quintile

Given the power law relationship that appears to exist linking physical activity with mortality RRs, it is important to consider the effect of the baseline level of physical activity in estimating the cost-effectiveness of an intervention. Given that the least physical active quintile has the highest mortality risk, it can be assumed that a given improvement in physical activity is likely to be disproportionately effective in terms of reduced mortality in this population compared with less sedentary baseline populations. Within the scenario analysis it was assumed for simplicity that the intervention led to an improvement in physical activity of one quintile for 2 years. The effect of this temporary increase in physical activity was modelled when assuming that the entire population was initially in the first (most sedentary) quintile, the second quintile, the third quintile and then the fourth quintile. The results of this analysis are shown in *Table 14* and *Figure 43*. The maximum acceptable intervention cost for each of these quintiles is presented, assuming a standard willingness-to-pay threshold of £20,000 per QALY.

'Value-added' model

Analyses of available data comparing mean daily TEE levels at 3 months and 9 months, and in the control arm, mini booster arm and full booster arm, suggest that those in the control arm used on average 66.64 kcal less per day at the end of the trial than at 3 months. In comparison, those in the mini booster arm used 36.37 kcal less per day at the end of the trial than at 3 months and those in the full booster arm used 8.85 kcal less at the end of the trial than at 3 months. This indicates a difference of 30.27 kcal favouring the mini booster over the control and a difference of 57.78 kcal favouring the full booster over the control. These differences are very small but positive. Because of the non-linear relationship between TEE gain and baseline TEE level, the main economic model, which used individual-level data from all

TABLE 14 Shift in physical activity quintile

Quintiles moved between	Mean utility gain	SE	Maximum acceptable intervention cost (£)
1 (most sedentary) to 2	0.122	0.0119	2430.70
2 to 3	0.046	0.0102	914.36
3 to 4	0.043	0.0094	853.83
4 to 5 (most physically active)	0.032	0.0088	649.66

SE, standard error.

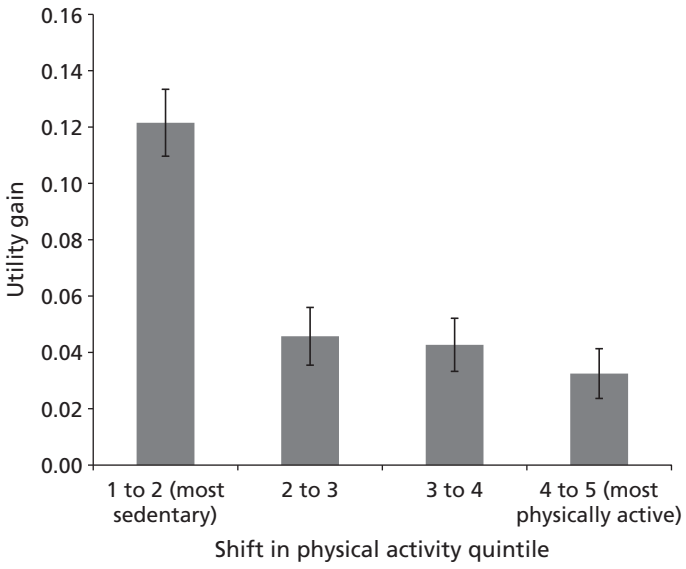


FIGURE 43 Shift in physical activity quintile.

participants, produced utility estimates that very slightly favour the control arm over either of the booster interventions. Within this additional series of analyses, the implications of assuming that the mean relative gains of the intervention groups relative to the control group were applied equally to all participants was explored. To do this it was noted that 30.27 kcal is equal to 1.36% of the 3-month median TEE score and 57.78 kcal is equal to 2.53% of the 3-month median TEE score. Just as in the previous series of analyses an intervention was assumed to lead to a 20 percentage point increase in activity for 2 years relative to no intervention (i.e. shift activity levels from the first to the second quintile, the second to the third quintile, and so on), so in this series of analyses the full booster was assumed to result in a 2.53 percentage point increase and the mini booster was assumed to result in a 1.36 percentage point increase.

With these assumptions it appears that the full booster may be cost-effective, assuming a willingness-to-pay threshold of £20,000 per QALY, if the intervention costs < £332 per participant (95% credible interval dominated to £725 per participant), as shown in *Table 15*. However, the clinical differences between the control arm and the mini booster arm appear so marginal that the mini booster and control arms appear largely indistinguishable in terms of QALYs and so the central estimate suggests that the mini booster is ruled out by simple dominance compared with the control (although the 95% credible intervals of the maximum acceptable intervention cost vary from not acceptable/dominated to £299 per participant).

TABLE 15 Scenario analyses

Scenario	Extra years lived, mean (SE)	QALYs accrued, mean (SE)
Control		
Untreated	26.70 (0.0175)	12.74 (0.00610)
Treated	26.74 (0.0175)	12.75 (0.00608)
Mini booster		
Untreated	26.83 (0.0174)	12.79 (0.00605)
Treated	26.86 (0.0174)	12.80 (0.00605)
Full booster		
Untreated	26.70 (0.0175)	12.74 (0.00610)
Treated	26.77 (0.0174)	12.77 (0.00605)
Differences-in-differences		
Control vs. mini booster	−0.008 (0.0291)	−0.0047 (0.0100)
Control vs. full booster	0.033 (0.0292)	0.0166 (0.0100)

SE, standard error.

Chapter 8 Discussion

Effectiveness of motivational interviewing 'boosters'

Overall, despite the low recruitment rate and significant loss to follow-up in the trial cohort, it is possible to draw some useful, and relatively robust, conclusions from the results of this randomised trial. The statistical analysis and economic modelling suggest that the interventions are unlikely to be effective or cost-effective whilst the process evaluation suggests some potential explanations for both the poor uptake and the lack of overall effectiveness in this relatively deprived and middle-aged population.

We found no evidence of a difference in TEE between the booster groups and the control group and the point estimates suggested that the combined booster group was less active than the control group. Even allowing for sampling uncertainty because of the small sample size, the confidence limits do not cross 101.5 kcal, the clinically important difference on which the trial was re-powered following the internal pilot/feasibility phase. This effect size represents about 4% of a typical energy expenditure of 2400 kcal per day.[87,88] In the comparison of the two forms of booster, we observed a difference in TEE per day of 112 kcal favouring the full (face-to-face) booster, although this result was not statistically significant and of borderline clinical significance.

Although there may be major concerns about the generalisability of the findings from such a small group of trial completers relative to the population targeted, the 160 (60%) participants who contributed data to the primary end point do still represent the target population: they are resident in deprived areas; aged between 40 and 64 years (if skewed towards the upper end of the range) and mostly highly sedentary at baseline (with a minority who have previous positive experiences of physical activity). If a similar intervention was offered outside the context of a trial, we have no reason to suppose that those taking up the offer of 'booster' interventions would differ significantly from those who volunteered to participate in this trial and complied with the intervention.

Views on physical activity and motivational interviewing 'boosters'

A wide range of leisure activities were reported in the open-ended survey responses, with few sports and competitive activities being reported. Locations also varied, encompassing facilities, domestic contexts, the local area and rural locations. Reasons for taking part in the study were also varied, including wanting to help with the research; being advised by medical staff to increase activity; wanting to improve or gain knowledge of health and well-being, physical activity levels and fitness; and to gain personal benefit.

Medical health issues were frequently cited as both barriers to and motivators for being physically active. Musculoskeletal injuries were a prevalent barrier whereas chronic physical conditions were often a direct cause of people wanting to become more active than previously. Social support was important with many people saying that they found exercising with other people encouraging and motivating oneself in isolation difficult. Friends and strangers from outside of the home were sometimes seen as better support than family, who were often perceived as a barrier, especially in younger participants who had young children.

Most people found some benefit from the MI although some people would have liked something more action oriented (see *Chapter 4*, *Motivational interviewing: consistency with perspectives or world views*). The setting for delivery was generally considered convenient and many people talked about MI meeting some unmet need, particularly an occasion to talk about goals and barriers relating to physical activity with

an informed and non-judgemental person (in contrast to family and sometimes friends). The term 'counsellor' was used by several participants to describe the MI practitioners, reflecting a perception of the relationship as impartial and supportive.

A prevalent theme was that people were keen to receive feedback (both verbal and accelerometry) on their performance and strove to meet goals so as not to disappoint the MI practitioners. Monitoring and normative feedback is an important part of ongoing motivation to maintain behaviour change.

More participants who received a booster intervention said that a face-to-face (full) booster would be preferable to a telephone (mini) booster, which was seen as less easy to prioritise. This is corroborated in the literature: specifically in MI, a face-to-face intervention is identified as an effective way of developing client engagement.[89] This, together with accurate empathy, is consistently highlighted as an important factor in supporting health behaviour change and, as technology attempts to substitute this level of contact with potentially cheaper and more convenient platforms such as smartphone apps, the telephone, DVDs and online alternatives, trade-offs between cost and efficacy might be expected.

Self-reported moderate to vigorous physical activity often appeared to be at odds with the objective data, both for individuals, as illustrated in *Chapter 4* (see *The prevalence of optimistic self-assessment*), and for the participant population as a whole, for whom the correlation between self-report (SPAQ) and objective (Actiheart) data at 3 months was almost non-existent. This incongruence is common in the measurement of health behaviours and is widely reported in the literature.[90] In terms of physical activity, participants typically over-report moderate and vigorous activities and under-report low-intensity activities.[91] Concerns are often raised about participants altering their behaviour in response to the knowledge that they are being monitored, the 'Hawthorne effect'.[92] Reactivity of this kind causes a change in actual behaviour, rather than a discrepancy between different methods of measurement. Over-reporting of activity may occur out of a desire to please the researcher and meet with perceived expectations, that is, social desirability bias, whereas it has been suggested that the under-reporting of lower-intensity activities, such as walking, may be due to a simple lack of awareness of undertaking them as many instances occur as part of everyday living rather than as planned activities.[93]

There are some parallels between the findings of the process evaluation and the findings of other qualitative research examining physical activity in older adults. For instance, engaging in a lifelong habit of being physically active was a motivator for physical activity in a systematic review of physical activity during the transition to retirement, and relates to previous practice and also commitment to physical activity found in the current study.[94] Some of the barriers to physical activity identified in the current study, that is, preferred alternatives and lack of social support (for certain types of activity), were also identified in the review by Barnett and colleagues.[94] In both pieces of research physical activity was adopted in response to felt needs or problems and had social benefits that could be motivational.

The importance of the social context as both a barrier and a facilitator was also identified in a recent systematic review of physical activity perceptions among older adults of South Asian origin.[95] Specifically, 'lack of time' (encompassed by 'preferred alternatives' in the booster study) was a barrier that related to people's obligations to others; taking time out from these obligations to exercise could be perceived as culturally inappropriate behaviour.

Monitoring and feedback have also been found to be desirable in a process evaluation of a primary care-based walking intervention for older adults. Mutrie and colleagues[96] found that pedometers were perceived as easy to use and were popular as a motivational tool. Unlike the booster study, however, they found good correspondence between reported and measured increases in physical activity levels.

In a process evaluation of telephone health mentoring for chronic obstructive pulmonary disease patients (mean age of 65 years) in Australia, Walters and colleagues[97] found that the experience of engaging in telephone health mentoring was valuable to most people and enabled them to reassess their activities of

daily living, including physical activity. There was a perceived motivational element, with some people finding that the health mentoring served as a useful reminder to perform the relevant health behaviours. As in the booster study, some participants found the anticipation of speaking to someone about their health behaviour generally, and physical activity in particular, a motivator.

In another study[98] the anticipation of mental and physical health benefits motivated the initiation of physical activity in South Asians aged 60–70 years and motivation for adherence also came from a drive to maintain good physical and mental health, which were among the reasons given by booster study participants for maintaining physical activity. In addition, Horne and colleagues[98] found social support from family, friends, peers and statutory and voluntary workers to be important in motivating people to initiate and maintain physical activity, often through the impact of the social environment on their confidence. The self-confidence in their own physical ability gained from mastering a specific activity also served to motivate maintenance of physical activity among some people, and similarly confidence was given as a motivator for maintenance in the current study. Another recent study[99] exploring the views of older Slavic immigrants in the USA about physical activity found that motivators included the desire to be active and go for walks and the anticipated benefits for existing medical health issues (including pain, poor sleep and use of medication). Anticipated benefits also included greater independence as well as social support, as physical activity was seen to provide a way of engaging with other family members, especially grandchildren. Some similar barriers to those in the current study were also reported, namely lack of desire, limitations imposed by medical health issues such as tiredness, pain and specific chronic conditions, and environmental issues such as safety concerns, bad weather and heavy traffic.

Geographical information systems analysis

The primary aim of the GIS analysis was to produce a set of variables for each of the 282 participants in the booster study that represented their pedestrian access to municipal green space and relevant leisure facilities (gyms and swimming pools). We found wide variations in pedestrian access across Sheffield, most notably with regard to proximity to swimming pools and the highest-quality green space. However, there was no statistical association observed in trial participants between mean TEE per day at 3 months and proximity to the above variables.

It is unlikely that proximity to either green space or leisure facilities was an important determinant of activity levels in our participants, which equally suggests that lack of access to green space and facilities was not a significant barrier to activity in trial participants. This is consistent with the qualitative evidence from the in-depth interviews, which suggests a range of other pertinent barriers.

Cost-effectiveness of motivational interviewing ‘boosters’

Because of the complex processes by which changing levels of physical activity lead to changes in HRQoL, two qualitatively different approaches to estimating the cost-effectiveness of the interventions were adopted. One of these approaches utilised resource use and SF-6D utility scores elicited directly from participants at 3 months and 9 months following the intervention to produce cost-effectiveness estimates over the short term. The other approach combined data on changes in levels of physical activity recorded using the Actiheart system with epidemiological data linking exercise capacity to relative mortality risks to produce individual-level simulations estimating long-term HRQoL effects resulting from the effect of changing levels of physical activity on participant mortality rates.

Despite adopting qualitatively different approaches and methodologies, both main models indicated that both the mini booster and the full booster appear to be ruled out by simple dominance and so do not appear cost-effective at any willingness-to-pay threshold. An additional variation of the long-term model, however, which incorporated data on physical activity differences in differences between arms in a

different way from the main analysis, indicated that the full booster intervention may be cost-effective assuming a willingness-to-pay threshold of £20,000 per QALY as long as the cost of the intervention is below approximately £300 per participant. The additional assumption made in this model, however, is that all participants who receive the intervention increase their physical activity levels by equal amounts, which may be a particularly strong assumption given that it may be those participants who are already comparatively physically active who increase their physical activity levels most, and the least physically active who increase their physical activity levels the least. Given that it appears that the greatest health benefits for a given increase in physical activity are in people who were initially the most sedentary, patterns of selective take-up of additional physical activity may mean that the health benefits of a mean increase in physical activity may be less than initially assumed.[81]

Other recent evidence for the effectiveness and cost-effectiveness of 'brief' and 'booster' interventions for increasing and sustaining physical activity

While the booster trial has been ongoing a number of other trials and non-randomised evaluations of physical activity interventions have reported, but none with a specific focus on maintenance. A team at ScHARR have recently conducted a review of the evidence for the effectiveness of brief interventions in promoting physical activity in primary care[100] and this comprehensive systematic review, together with an associated review of the cost-effectiveness evidence, has informed an update of the NICE guidance on this topic,[12] which is currently out to consultation (http://www.nice.org.uk). In the NICE-commissioned review the current evidence base for brief interventions was synthesised and it was found that, although there is evidence (based mainly on self-reported outcomes) that brief interventions are effective at increasing physical activity, there is not consistent evidence to suggest a 'dose–response' effect with more intensive or repeated interventions having a greater impact than a simple brief intervention (defined by the review inclusion criteria as one lasting up to 30 minutes).

Three other recent systematic reviews[101–103] provide evidence that interventions in primary care, including brief interventions and telephone interventions, may be effective and/or cost-effective. The review by Orrow and colleagues[103] also mainly synthesised trials with self-reported activity as the primary outcome, but included all primary care interventions with at least 12 months' follow-up. This review found evidence for an impact of a range of interventions on self-reported activity, but similarly reported that there was no robust evidence that more intensive interventions (such as exercise on referral) were more effective than a simple brief intervention. A systematic review by Goode and colleagues[102] included eight studies evaluating maintenance of physical activity behaviour change up to 12 months after a telephone intervention. The majority of telephone interventions involved > 12 contacts and took place over a period of > 6 months, with many interventions involving significantly more frequent and longer contacts than the mini booster intervention in our trial. The review defined successful maintenance as between-group differences in at least 50% of reported outcomes in favour of the telephone intervention group at least 3 months after completion of the intervention. Of the eight studies reporting on the maintenance of behaviour change, two reported a maintenance effect for at least 50% of outcomes over 3 months without the intervention. Garrett and colleagues[101] reviewed cost-effectiveness studies of physical activity interventions in primary care and found that interventions involving advice (in person, by telephone or by mail) were more cost-effective than supervised exercise interventions. This review did not examine the marginal benefit of additional interventions to maintain behaviour change as the included studies all compared a specific intervention with usual practice or no intervention.

Considering the findings from the booster trial and the implications of the cost-effectiveness modelling in the context of these reviews suggests that simple, brief interventions targeting sedentary populations are likely to be more cost-effective than more expensive and intensive interventions, including 'boosters'. A major caveat in assuming the generalisability of the effectiveness of brief interventions is that the majority of the evidence of effectiveness comes from self-reported outcomes in unblinded studies. The booster trial

is one of the few trials with objectively measured energy expenditure (or physical activity) as the primary outcome measure and this confirmed the poor correlation between objectively measured activity levels and self-reported activity levels in trial participants. Future cost-effective modelling should also take account of the baseline physical activity levels (and fitness) of participants who achieve an increase in activity levels, given the exponential relationship between baseline risk and impact on mortality.

Strengths and weaknesses of the study

Recruitment and retention

The principal shortcoming of this study was its failure to recruit 600 participants and retain 450 within the allotted time and budget. This is a common experience as only 31% of Medical Research Council- and HTA-funded trials that recruited participants between 1994 and 2002 met their recruitment target on time and within budget, with 45% closing to recruitment having reached < 80% of their target and 54% requiring a time extension.[104] Furthermore, there is considerable evidence that recruitment to trials evaluating preventative interventions is considerably more difficult than recruitment to those evaluating therapeutic interventions, with typical rates of those randomised as a proportion of those screened cited of 1–5% and 20–27%, respectively, according to one overview.[105] High levels of deprivation are known to predict poor consent rates in trials evaluating behavioural interventions for sedentary people.[106,107] It may be particularly difficult to recruit healthy participants in deprived communities for an intervention that may have significant costs to participants, including both the costs of behaviour change and the time and travel costs of attending for the intervention as well as recruitment, baseline data collection and follow-up. We were also recruiting participants from an age group (40–65 years) in which many people have both work and family responsibilities, which may make it particularly likely that perceived costs will outweigh the perceived benefits of participation.

Our study needed to recruit patients who had already received and responded to a brief intervention but was hampered by the absence of access to patients already being given a brief intervention in the local primary care setting whom we could recruit. For this reason the study team had to devise and distribute a brief intervention (see *Chapter 2*, *Participants*) and deliver it in partnership with the local primary care authorities but outside of the routine NHS care setting. The principal method of approaching participants was through personalised letters, electronically signed by the local director of public health, inviting people to contact the study team. This method generated 4964 responses from the 70,388 letters sent, a response rate of 7.1%. It is possible that we could have generated more responses by recruiting GPs to carry out the mail-outs. However, this method would have been much more expensive and there is little evidence that it would have been more effective. The Food and Immunity Trial (FIT), another South Yorkshire-based public health study, recruited people aged 65–85 years using mail-outs from general practices.[108] Its response rate was 528 out of 7482 (7.1%), identical to our own. The FIT study team used a wide range of other methods to recruit participants but GP mail-outs accounted for 90% of consented participants. It is worth noting that there is no good-quality evidence for the superiority of direct face-to-face recruitment compared with mail-outs in this population.[109] Even had there been it is unlikely that we would have had the reach or the resources required to reach full accrual using face-to-face accrual. We attempted to recruit through a range of other stakeholders, including GPs, health trainers and health champions, but this was not successful (see *Chapter 3*, *Recruitmant of trial participants*). This suggests that direct recruitment through primary care and community networks may not have improved recruitment yields. Previous research comparing targeted mail-outs with recruitment through general practices has found that mail-outs are more effective and cost-effective, even when there are strong collaborative links with GPs.[110]

The brief intervention devised by Sheffield Hallam University reached 1934 (2.7%) of the 70,388 people who were invited to apply for it, although a further 568 who contacted and were screened by us were excluded from using the brief intervention, mostly because they were already physically active (see *Chapter 3*, *Recruitmant of trial participants*). Of those who received the brief intervention, 840 (43%) were

not contactable at 3 months, 538 (28%) were contactable but had not increased their self-reported physical activity levels sufficiently to be eligible for the trial and 274 (14%) who were eligible could not be randomised (half of whom actively refused consent; the other half did not attend consent appointments). The concept of the 'funnel effect', in which a pool of potential patients who are contacted about entering a clinical trial becomes progressively smaller as it passes through successive screens and the informed consent process, is relevant here.[105] It is widely believed that the lower the percentage recruitment yield, the more questionable it is to generalise from the study findings to the target population.[111] We would assert that the results of this study are generalisable. Although we found it difficult to identify participants who had benefited from receipt of the brief intervention (the key eligibility criterion), we randomised 51% (282/556) of those we were able to identify (see *Figure 6*). The issue is the willingness to take up and respond to a brief intervention of those who could benefit, as supported by the published evidence. Of the four published RCTs evaluating brief interventions delivered to UK populations,[112–115] none reported statistically significant improvements in self-reported physical activity. For the same reason it is fair to say that the MI boosters cannot be seen as public health interventions, because they cannot be rolled out at a community level. Rather, individuals will identify whether the offered intervention is appropriate and acceptable to them, and only a minority of sedentary individuals are likely to take such an intervention up.

Impact of area deprivation on recruitment

We aimed to recruit people from deprived neighbourhoods. We knew from the outset that there were pockets of affluence within the predominantly deprived areas that we surveyed. In a few areas people from LSOAs that were less deprived were recruited to the study (see *Figure 9*). However, the majority of the study participants were from relatively deprived LSOAs. Out of 147 LSOAs targeted, 102 were in the bottom 20% of national IMD 2010 overall scores.

The contact details for each recipient were confirmed as current by the NHS in the week before each mail-out. Despite this we received 1117 letters (1.6%) returned to sender because of the addressee being unknown at that address. There were undoubtedly more letters that were not returned to us, suggesting that a sizable minority of invitations were not received and reflecting the inaccuracy of the primary care databases that depend on patients reliably informing their current general practice when they move. Registers will be less accurate for more transient populations and this population characteristic may have had an impact on recruitment in more deprived neighbourhoods. We tested the hypothesis that the impact might be more severe in areas with transient populations but an exploratory GIS analysis using a simple linear model found no evidence that response rate was correlated with indicators of population transience (see *Chapter 2*, *Participants*, and *Chapter 3*, *Baseline characteristics of participants*). However, as noted in *Chapter 3*, there was a statistically significant difference in the response rates from different neighbourhoods, with fewer responses from more deprived LSOAs. It is important to stress that none of the areas approached was affluent in national terms and that this finding indicates relative resistance to recruitment from very deprived communities compared with only moderately deprived communities.

Of the randomised participants, 165 out of 282 were living in LSOAs in the bottom 20% of national IMD 2010 overall scores. This may indicate that, although we surveyed neighbourhoods that are normally understood to be deprived, the study population from these areas is likely to have been relatively more affluent. This is most visible in *Figure 10* in which the plot for High Green, the geographical outlier to the north of the city, shows a 'halo' of participants from relatively affluent LSOAs.

Operationalisation of eligibility criteria

Four protocol violators (2.5% of the ITT population) were included in the ITT analysis (see *Chapter 3*, *Baseline characteristics of participants*). These participants did not meet the eligibility criterion of increasing self-reported physical activity by 30 minutes per week over the previous 3 months and did not signal, in the final SPAQ question, that the amount of physical activity that week was atypical. Academic opinion is divided on the utility of post-randomisation exclusions. For some, 'the only safe way to deal with [protocol violations] is to keep all randomized patients in the trials' (p. 464).[116] Others advise excluding 'ineligible patients from analysis, provided that the eligibility criteria are absolutely clear and objective' (p. 176).[117]

Guideline E9 of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) also makes provision for the exclusion of participants if a 'major' eligibility criterion was violated.[118] Although ICH E9 fails to define 'major', commentators have suggested that it might include criteria that, the violation of which, produce 'a less homogeneous set of patients (a possible loss of power)' (p. 885).[119] With the benefit of hindsight we can see that the SPAQ was a far from objective screening tool: the reports of physical activity provided by those to whom it was administered correlated poorly with objective measures of physical activity (using the Actiheart device) during follow-up. Further, the use by RAs of negative answers to the final question ('Was the last week typical of the amount of physical activity in minutes you usually do?') to provide a basis for exemption from the eligibility criterion and an argument for randomisation was probably inconsistently and subjectively applied across randomised and non-randomised participants. For this reason it is unlikely that the presence of these four individuals seriously affects the homogeneity of the analysis set. A post hoc sensitivity analysis also suggests that the treatment effect was unaffected by their presence (see *Chapter 3*, *Effectiveness of the booster intervention at 3 months*). Although the concurrent use of the SPAQ as a screening tool is clearly problematic, it is not clear what the alternative might have been, given the need to screen 2502 unconsented members of the public at 3 months before randomisation to randomise just 282. The SPAQ also has a level of external validity that accelerometry might not, in that it, or self-report measures like it, are in use by the kind of local services to which our findings were intended to be generalisable.

Impact of the use of the Actiheart system on the collection of primary outcome data

The trial design team anticipated a participant attrition rate of up to 25%. In practice, the trial lost 81 participants (29%) to follow-up at the primary outcome assessment time point of 3 months (see *Figure 6*), despite deploying many of the preventative measures described by Brueton and colleagues.[120] Although this was disappointing, the loss of a further 18% of participants from the main analysis because of missing Actiheart data was entirely unexpected. The majority of early Actiheart studies were focused on the validation of the device for use in young people and healthy adults in controlled laboratory conditions. There are more recent studies in which Actiheart has been used in hospital settings, free-living environments and community settings.[121–123] However, few provide comments on its acceptability or suggest the kind of poor compliance observed in this study. The best available evidence on its acceptability comes from a recent study comparing instruments for the objective assessment of physical activity frequency and intensity.[122] In this study of Native Hawaiian participants, the Actiheart device was deemed more comfortable than ActiTrainer (an accelerometer and a Polar heart rate monitor; ActiGraph, Pensacola, FL, USA) and was worn for 6.5 days out of 7 for an average 12 hours per day. However, only 17 people wore the Actiheart in this study and two participants (12%) reported skin irritation. Although only a few people in our study reported irritation from the electrodes, many found that the electrodes did not adhere for the full week. As a result of this, and after trying several different brands of electrodes in addition to the ones recommended by the manufacturer, all participants were issued with spare electrodes so that they could replace them during the week as necessary. It is also interesting to note that the manufacturer of Actiheart, CamNtech, now offer a belt as an alternative to electrodes for holding the Actiheart in place.[124] As far as we are aware, this study is one of the first studies to suggest problems with the acceptability of the device in community settings and with repeated measures, with most published studies having asked participants to use the device on one occasion only. Our relatively large sample and limited involvement in placing/replacing the device means that this study provides a novel insight into the use of the Actiheart as a device for community-based assessment of physical activity.

The most problematic characteristic of accelerometer data is that activity is not measured over a uniform period each day and therefore determining the minimum number of monitoring days with valid accelerometry measurements is always a challenge in practice, especially in pragmatic trials.[38] Ideally, at least 7 days of physical activity monitoring using the Actiheart device is recommended to achieve estimates of physical activity in adults of approximately 90% reliability.[39] However, in practice, there is a balance between achieving the required degree of reliability in physical activity estimates and the number of days with valid accelerometry data required to optimise retention of study participants in the ITT population.

To achieve 80% reliability with respect to activity counts and time spent in moderate to vigorous activity in adults, at least 3–4 days (of the 7 days) of activity monitoring are required.[39,125] In this regard, in this study, participants were required to have carried the Actiheart monitor for at least 4 days (of the 7 days) and have a minimum of approximately 7 hours (not lost > 1000 minutes) of accelerometry measurements each day.

This meant that a significant number of participants, despite completing the study, did not provide primary outcome data at 3 and 9 months and it is impossible to rule out information bias being introduced because of differences in physical activity levels between those who successfully used and returned the Actiheart monitor and those who did not.

Potential impact of trial participation on physical activity levels independent of the trial intervention

The phenomenon of behaviour modification caused by the act of being observed (the Hawthorne effect[126]) has been reported in some studies[127,128] but not in others.[129]

A specific concern that influenced the design of the booster trial was the perceived risk that the objective measurement of baseline activity (Actiheart) would have an effect on all participants' physical activity levels because of their awareness of being monitored, potentially reducing the likelihood of observing an intervention effect in those also receiving booster interventions over and above this. In other words, the very act of measuring participants' baseline activity levels, although an element of the research data collection process and not part of the intervention, might in itself act as an intervention, thus reducing the potential to have a 'true' control group with no intervention.

In theory we might expect this type of Hawthorne effect, but at least expect it to be similar between the booster group and the control group if Actiheart devices are administered in all arms. Therefore, we would not expect the estimated treatment effect, the difference in 3-month post-randomisation energy expenditure, to be affected by the Hawthorne effect in this scenario, mitigating any potential concern about an intervention effect masking the measurable impact of the face-to-face or telephone MI sessions.

However, it is possible that a Hawthorne effect did still occur during the study, as several participants reported in interviews that the expectation of seeing a researcher for their 3-month research study outcome assessment provided a motivation for staying physically active (see *Chapter 4*, *The importance of monitoring and feedback*). Although the same RA was never used for both the intervention and the research procedures, visual cues (such as Sheffield Hallam University Centre for Sports and Exercise Science logos on polo shirts) might have blurred the distinction in the minds of participants.

Lack of objective measurement of physical activity at baseline

The main rationale for not collecting baseline Actiheart data in our trial was to reduce the possibility of encountering the Hawthorne effect as discussed in the previous section. However, we acknowledge that baseline measurements could have had three potential advantages in this trial. First, the availability and utilisation of baseline Actiheart data would have improved the precision around the estimated treatment effect (the difference in outcomes between the booster group and the control group). Second, in hindsight, with a baseline assessment of energy expenditure we would have predicted problems with the Actiheart devices at an earlier stage of our study. We could have then developed strategies to minimise attrition and improve retention of participants with valid Actiheart data at 3 months. Third, baseline measurements of activity levels might have provided additional information about whether any differences between groups at follow-up were due to differential retention in the three arms, rather than intervention effects (which is always a potential source of bias when participants cannot be blinded to their intervention group).

Strengths and limitations of the process evaluation

Neither the process evaluation survey nor the topic guide for the interviews was piloted, although the response to questionnaire closed items was generally good. Another weakness was that, because of sickness and maternity leave, interviews were conducted by Sheffield Hallam University researchers who

also delivered the intervention. However, no participant was interviewed by the same person who delivered their intervention and the analysis was conducted independently by University of Sheffield researchers not involved in the delivery of the intervention.

The use of qualitative research allowed for a nuanced interpretation of the quantitative elements and raised several supplementary questions that we were able to address through additional analyses, for instance the importance of relative autonomy in participants' responses to the intervention.

Strengths and limitations of the trial intervention

The booster trial applied a humanistic counselling approach that attempted to action plan based on participant readiness, values and perceived resources. The approach was manualised and fidelity calibration of those delivering the intervention was attempted. This was a clear strength of the study intervention, which is rarely seen in physical activity counselling settings.[18] The theoretical approach (self-determination theory[15]) underpinned the cognitive and behavioural intervention in line with the treatment fidelity framework. This ensured a consistent rubric, based on empirical evidence, providing justification for the content and delivery of the counselling intervention (MI). Measurement of the cognitive effect of factors such as exercise motivation (measured using the BREQ-226) on behavioural adaptations to physical activity (measured using accelerometers) also provides evidence for the effectiveness of an MI approach. In the process evaluation the use of empathy and engagement was reported by the participants throughout, which is a fundamental part of MI.[89] These concepts are clearly distinct from a traditional medical model in which advice giving, warning and confronting with evidence are often found to generate the opposite result.

The MI counselling intervention, measurement of behavioural change using objective instruments (accelerometer) and measurement of epidemiological change (physical markers such as BMI) were again a strength of the trial in attempting to clearly assess and report the link between cognitive, behavioural and epidemiological interventions and outcomes. Although objective measures of behaviour change are difficult to achieve, this is likely to be improved as technology enables smaller and less intrusive instrumentation. Correlating the cognitive (or affect) and behavioural change pre–post allows inference of the change in cognitive affect (motivation) mediating a corresponding change in behaviour. Moreover, process evaluations can provide greater explanations of the reasons for this change.[130]

The identification of the target behaviour (e.g. physical activity, diet or other lifestyle behaviours such as smoking) is fundamental to MI and yet is challenging to achieve and manage in a brief session (approximately 30 minutes) such as that delivered in the trial. Moreover, the duration of the full (face-to-face) and mini (telephone) booster sessions was more akin to the duration of a brief MI intervention, whereas longer and more frequent sessions are often found to be significant in other health settings.[131] The duration of the sessions was usually dictated by the participant, although the RAs' limited use of deeper reflections and extended exploration of issues and participant values, as reflected in the MITI scores, could also have contributed to sessions being briefer than might be optimal. Multifaceted behaviours often emerged, which are rarely discrete, and combinations such as diet, alcohol, physical activity, smoking and medication adherence are challenging to manage in such a short period. Therefore, a longer period of time would be useful to explore the agenda, target behaviour and carry out action planning as a result. Lundahl and colleagues[131] and Hettema and colleagues[132] have suggested that MI interventions including up to six repeated sessions are the most significant and, although briefer interventions have been found to show positive results, these are more reliant on interventionist effects and influence. In the current trial the duration of the individual intervention sessions limited the opportunity to fully explore client values within the level of MI skillfulness of the RAs.

There was limited opportunity to explore maintenance and relapse prevention with participants within the mini and full booster MI sessions primarily because of the limited time available for the interaction. It is clear that action planning in physical activity contexts rarely embeds maintenance strategies (which include relapse prevention) and these need to be considered in future trials and community-based interventions.

Although the action plan did attempt to account for setbacks and managing relapse this was not perhaps explicit enough and specific 'active' compared with 'passive' follow-up sessions would support this.[60] In addition to the value of specific cognitive–behavioural 'maintenance' strategies, a number of components were delivered (e.g. monitoring and normative feedback) although these were not made explicit enough in the intervention.

More generally, the complexity of the intervention could not be managed sufficiently in the short time available. 'Adoption' behaviours such as physical activity and diet change involve multifaceted lifestyle adaptations over a long duration and the current trial had a limited intervention duration with what could be described as a 'passive' follow-up. There was also limited opportunity for the use of explicit maintenance strategies that would have embedded cognitive–behavioural content such as adapting change goals, active follow-up and normative feedback. Future studies should make more explicit the use of maintenance strategies based on client readiness and changes in levels of motivation and opportunity for change.

Motivational interviewing training and assessment of practitioner competence

The current trial also demonstrated the value of detailed documentation and reporting of both the MI training and assessment of MI competence, which identified both strengths and limitations in these key factors that influence intervention delivery and effectiveness.

The trial applied a theoretical underpinning for the intervention in line with treatment fidelity, which was based on empirical studies and contemporary evidence at the time of conception.[16] Since that time the evidence on the link between MI and self-determination theory has become even more robust, which has justified its use.[64] This study is one of the first to apply a treatment fidelity framework with a clear description of the design (theoretical underpinning using self-determination theory), training (MI component and assessment of competence), delivery (to the participant, recorded and reviewed), receipt (by the participant) and enactment (behavioural change measured using objective and self-report methods) in a physical activity counselling intervention.

A significant strength of this study was the application of a validated and reliable assessment tool to indicate the competence of those delivering the intervention. This sat comfortably within the treatment fidelity framework and was a robust approach rarely seen in previous physical activity counselling trials.[17,18] The treatment fidelity framework itself provided a sound basis for the design and delivery of the intervention with an appropriate theoretical framework (self-determination theory[16,64]) and facilitated a clear link between the cognitive intervention and the outcome measure using BREQ-2.[15,30] No other MI studies in physical activity settings have attempted this level of assessment and it provides a number of lessons for future studies that are likely to train and assess those delivering the intervention in situ (health professionals already positioned in health-care settings as opposed to additional RAs).

One key implication of the trial has been the importance of the assessment of the baseline ability of the RA before the start of a trial as well as the need for ongoing assessments and self-reflection to account for 'drift' in counselling competence. Although the RAs were trained in foundation practitioner skills, it was not possible to optimise the level of competence through specific 'real-world' reflective practice in the run up to intervention delivery to trial participants because the RAs were heavily involved in the recruitment phase of the study. Practitioners in an existing service might have been less likely to experience this lag period in skill development (although the risk of skill drift might have been greater).

Other studies in health contexts, such as studies on medication adherence and management and prevention of transmission of human immunodeficiency virus, have assessed the competence of practitioners at interview stage and filtered out those who do not meet strict criteria. This was not possible in this study as the practitioners had to be experienced in both physical activity programming and lifestyle change, which meant that the chance of them also being experienced MI practitioners was limited. In the current austerity climate there has been a move towards training existing practitioners in health services as

opposed to attaching practitioners from outside this setting. Although this will increase the ecological validity and context-specific nature of the training, existing practitioners are likely to have a broader range of abilities.

Although a number of studies have emerged in recent years assessing the efficacy of MI in promoting physical activity behaviour change, few have clearly reported the content, frequency and duration of the MI intervention; the heuristic value of this trial is therefore the clear reporting for future adaptations.

Those delivering the mini and full booster (RAs) were not existing health professionals, which may challenge the ecological validity of the intervention and the relevance of the direct inferences for health-care settings. Although the use of RAs allows for bespoke training and focused attention on the trial, their awareness of specific care pathways was limited.

The amount of time required for ensuring MI fidelity and applying self-reflection (and accounting for practitioner competence 'drift') was a challenge in the current trial as the RAs were also heavily involved in the recruitment process and the lead-in time between training and delivery to participants was short. As a result the RAs trained 'on the job' and had little opportunity for group supervision and full-day workshops followed by reflective practice. However, one could argue that this is likely to be similar for any other practitioner delivering physical activity MI sessions alongside or as part of their full-time job.

Although the use of a treatment fidelity framework provided an outline for all stages of the trial, there is a risk of a 'pure' application of such a framework, constraining the adaptability and innovation often seen in a health-care setting.[133] The value of internal validity and process awareness of training, for example, is unquestionable, although they may be seen as a 'dictate for provider adherence to a set of therapist behaviours rather than as adherence to the delivery of the "active" treatment component' (p. 454).[133] Leventhal and Friedman[133] suggest that 'such manualised approaches can discourage functional analysis of the complexities of individual cases' (p. 454).

Strengths and limitations of the geographical information systems analysis

The main strengths of the GIS analysis are the use of network distance rather than straight line distance and the use of the Sports England database for comprehensive coverage of local leisure facilities. Unlike some other studies in this field, which use Euclidean distance as a proximity measure (including a well-cited study by Maas and colleagues[86]), we have calculated walking distance using network information extracted from OpenStreetMap, which provides extensive coverage of pedestrian access routes.

The main weaknesses are the use of automated geocoding (rather than more precise but labour-intensive manual geocoding) and the use of a 'distance to nearest' measure rather than a more sophisticated 'gravity' distance model. A more sophisticated 'gravity' measure (such as that used in the study by Dai[134]) can take into account multiple facilities in the local area and it is possible that it could be used in future work; however, the required assumptions meant that it was not suitable for all of the facilities that we studied in this trial.

Strengths and limitations of the health economic modelling

Because of considerable structural uncertainty and difficulties in translating from the measures recorded in the booster trial to QALYs and costs, two alternative models were developed and within each model a wide range of scenarios was considered. The majority of these scenarios indicated that both the full booster intervention and the mini booster intervention appeared to be ruled out by simple dominance, although a small number of scenarios provide weak indications that the full booster may be the optimal choice assuming willingness-to-pay thresholds of approximately £20,000 per QALY or more. All scenarios were reflections of the evidence of the trial, indicating that in substantive terms there were only marginal differences between trial arms.

Although the short-term model has the benefit of being heavily based on evidence collected during the trial, it remains an open matter whether a lifestyle intervention such as the booster intervention is likely to produce a clinically significant effect in terms of either participant HRQoL or use of NHS resources over the duration considered. This is because the intervention is primarily preventative rather than curative and participants were not selected on the basis of suffering from a particular disease adversely affecting their HRQoL and NHS resource use. Because of this it may not be plausible to assume that increasing physical activity now will lead to systematic changes in HRQoL or resource use in the short term. Instead, positive health effects of the intervention may emerge over a much longer time horizon, reducing the risk of a range of diseases developing and so improving health outcomes indirectly.

It was because of this concern that the long-term model was developed to be considered alongside the short-term model. In this modelling approach, the HRQoL gains from increased physical activity result from the mediating effect of physical activity on relative mortality risks, meaning that a cohort of more physically active people should be expected to live for slightly longer on average than an otherwise identical cohort of slightly less physically active people and so experience slightly higher average HRQoL. The model implicitly incorporates the effect of morbidity on HRQoL, by using age- and gender-specific mean HRQoL scores, but does not incorporate an additional mediating effect of physical activity on either the onset or the severity of non-fatal diseases. As such, it is similar in its approach to the economic model developed by Brennan and colleagues.[135] The Brennan and colleagues' model uses work by Andersen and colleagues[75] to map physical activity levels onto relative mortality risks, whereas this model uses work by Myers and colleagues for the same purpose.[81] Both mapping exercises indicate qualitatively similar relationships between physical activity and relative mortality risk, suggesting that the greatest benefit of a given increase in physical activity is likely to be in people who are the most sedentary and that the marginal benefit of additional physical activity is less in people who are already relatively physically active.

The report by Brennan and colleagues[135] contains a review of existing papers on the cost-effectiveness of physical activity interventions, as well as a brief review of existing model frameworks. Readers are directed to this publication for further information.

The economic model in this report does not yet directly consider the relationship between physical activity levels and morbidity risks. Morbidity is indirectly handled through the changing mortality risk ratios and also by adjusting HRQoL scores for age and gender (e.g. because of differences in disease burden at different ages). However, specific disease states are not considered in the model. A further iteration of the model could consider the additional cost and utility implications of different diseases by modelling annual probabilities of developing particular conditions and combining these with RR modifiers related to physical exercise levels. In theory, a physical activity intervention could then appear cost saving if the additional cost of the intervention is outweighed by the additional reduction in NHS resource use costs as a result of a reduced burden of disease. An important example of such a disease would be type 2 diabetes mellitus, whose onset is known to be linked to lifestyle factors and whose treatment represents a significant and increasing annual cost to the NHS.[136]

Given the complex array of mediators and moderators involved in translating changes in physical activity into changes in mortality and morbidity risks, HRQoL and NHS resource use over the short, medium and long term, it is important that economic models are based on a solid clinical and epidemiological foundation. Models should incorporate current expert opinion on how physical activity interventions lead to sustained changes in lifestyle behaviour and through this to changes in health-related utility and costs, as well as the range of other mediating and moderating factors that need to be taken into consideration so that the model represents the patient experience with sufficient accuracy. The paths of causal influence linking individual- and ecological-level factors to short-term and long-term mortality and morbidity risks should be established through extensive consultation with clinical experts and used to establish flexible public health models that can be used to consistently model a wide range of interventions affecting different parts of the aetiological pathways. This process of attempting to understand the clinical and epidemiological consensus in understanding causal processes could be used to form directed acyclic graphs

and influence diagrams, which can be used as the basis for economic models.[137] When it is identified that consensus between clinical experts does not exist with regard to certain causal pathways, the effect of different structural assumptions could be explored by constructing separate models that reflect alternative clusters of opinion.

Implications for practice and commissioning

The uptake of both the brief intervention and the booster intervention suggests that the potential impact on population-level change of these types of recruitment approaches and interventions is limited. The overall findings suggest that neither the mini booster nor the full booster is likely to be an appropriate population-level approach to promote physical activity in middle-aged populations in deprived areas. Better integration in local primary care services, such as GP clinics and IAPT (Improving Access to Psychological Therapies) programmes, might yield improved take-up and results, although even with better integration these types of interventions are unlikely to enable sufficient throughput of participants to have the reach of a true public health intervention.

The qualitative research component identified large numbers of people who wished to maintain physical activity levels in the hope of managing chronic disease symptoms. In particular, those with mental health issues (depression and anxiety) expressed a belief that physical activity would provide symptom relief, although the same people were often exercising alone in private spaces, were unenthusiastic about doing so and reported problems maintaining exercise levels. The social element of exercise may mediate some of the mental health benefits and those making exercise referrals should be aware of this. The needs of people with long-term injuries are different again; these people are typically seeking highly tailored exercise advice to suit their physical abilities. Referrers and advisors should be sensitive to these diverse needs.

The duration of both the mini booster and the full booster was approximately 30 minutes, which is more akin to a 'brief' MI session. Longer MI sessions have been found to be more effective and therefore a greater response might be expected from a higher dose, similar to the findings in contexts in which MI is more commonly applied, such as addictions settings and behaviour adoption (e.g. smoking and alcohol).[97] Although the current trial attempted to provide an ecologically valid intervention period, delivering a bespoke, person-centred intervention in this time frame that explored and set the client agenda, managed resistance and ambivalence and set appropriate goals with effective relapse prevention strategies was challenging, and delivering a greater number of sessions would be a realistic mechanism for managing this in the future. It is unlikely that delivering a greater number of sessions would be possible within existing care pathways, although the *Let's Get Moving* programme[59] proposes more than two sessions.

Face-to-face contact was more acceptable than telephone contact. More evidence is needed on relative costs and effectiveness as the results of this trial suggest that neither intervention is cost-effective at conventional levels of statistical significance and willingness-to-pay threholds. At present, PARSs are being decommissioned by a large number of primary care providers and their local council partners. PARSs provide a face-to-face physical activity promotion intervention that typically consists of up to 12 practical sessions, although not all of these are delivered on a one-to-one basis. Currently, the preferred option for physical activity promotion within the NHS is *Let's Get Moving*, which involves multiple one-to-one contacts regarding physical activity that are either integrated into existing health-care contacts or delivered by the primary health-care team as standalone appointments.[59] This is arguably a cheaper way of delivering an intervention. It does, however, rely on individuals initiating contact with a member of their health-care team who is trained to provide the intervention.

Some people seemed to like the MI approach but others seemed to want, or had expected, a more didactic delivery approach. On the surface this seems counterintuitive and is at odds with the premise that MI can foster intrinsic motivation, which is linked to longer-term maintenance of activity, whereas more didactic advice-giving approaches would provide extrinsic motivation for being active. Many people we interviewed appeared to be extrinsically motivated, with few expressing thoughts about exercising for enjoyment, despite using a maintenance intervention designed to foster intrinsic motivation.

This may be related to participants' stage of readiness to be regularly active. Those in a less advanced stage such as contemplation or preparation (or even action) may be becoming active for extrinsic reasons such as to lose weight or improve health; a true appreciation of and desire for physical activity for its own sake may not come until individuals have been active for some time and entered the maintenance stage of behaviour change. By definition, the participants in this study have become active only in the 3 months preceding the delivery of the booster intervention and are therefore still in the action stage. Thus, although there is a focus on MI and related interventions that emphasise building intrinsic motivation for physical activity in the field of exercise psychology, it is possible that many people who have only just started to become more active may prefer to be told what they should be doing or participate in an exercise class. It is also possible that other differences aside from motivational style may influence people's preference for a certain delivery approach. Whatever the reason, the implication here is that delivery of physical activity promotion should involve some form of assessment to ascertain each person's preferred approach and then a relevant style of delivery should be selected from a toolkit of approaches.[138,139]

The monitoring and feedback elements of the intervention were identified as important motivators by participants. However, this may be another indicator of the prevalence of extrinsic motivation amongst these participants, and psychological theories of behaviour change suggest that extrinsically (rather than intrinsically) motivated behaviour change might impact negatively on the sustainability of the treatment effect.

The role of a professional has traditionally been seen as one of diagnosis and prescription for both pharmacological and behavioural interventions. In recent years, this has given way to a more inclusive person-centred approach, which challenges the individual, with empathy, to take a more active role in their behaviour change. The focus of more health practitioner sessions, also described as a 'directive approach', can resolve people's resistance to change.[140] However, the process evaluation suggested that some people have concerns about the client centeredness of MI consultations (see *Chapter 4*, *Motivational interviewing: consistency with perspectives or world views*). As in other studies involving low socioeconomic status groups, some of our participants said that they had hoped for more paternalistic and didactic communication approaches.[63] Although autonomy-supported communication is understood to enhance intrinsic motivation (whereas paternalistic approaches diminish it), it has been suggested that MI can be adapted to suit client communication preferences.[63–65] Therefore, if the motivational interviewer becomes aware that the client would prefer a more didactic approach, the consultation can be directed towards that need. This 'way of being' with the client is a key part of skilful MI and a flexible and adaptive approach is an important part of challenging with empathy in a bespoke manner.

The process evaluation also suggested that two key motivators for adherence to physical activity targets are the anticipated shame, when face to face with a professional monitor, if one does not achieve the agreed objectives, and the pleasure of receiving feedback on one's performance (see *Chapter 4*, *The importance of monitoring and feedback*). Different methods of feedback are the subject of the Feedback, Awareness and Behaviour (FAB) study (ISRCTN92551397; funded by the National Institute for Health Research programme).[141] The FAB team aims to randomly allocate 500 people aged 30–55 years to either a control group (no feedback) or one of three types of personalised physical activity feedback ('simple', 'visualised' or 'contextualised') and complete repeat measures of self-rated physical activity and psychosocial correlates.

One concern for physical activity promotion and ongoing patient behaviour change support is that there is no clear pathway for physical activity promotion at the moment in the UK. Current provision is limited to GP advice to individual patients to become active or, at best, referral to a PARS. Although other community-based interventions such as 'green gyms' and walking programmes do exist, these are rarely integrated into the care pathway. The traditional approach to physical activity promotion delivered in health-care settings is one of information exchange, which can often be seen as provision of unsolicited advice. In 2009, the Department of Health launched *Let's Get Moving*[59] to be delivered by health-care professionals and complement the PARS. *Let's Get Moving* is physical activity counselling intervention

based on MI principles and designed to be delivered by health-care professionals within usual care settings. Early research questioned the feasibility of using *Let's Get Moving* in a primary care setting.[82,142] Materials have recently been revised and were relaunched in March 2012. Aside from referral to a PARS and *Let's Get Moving*, there are some nurse practitioners who do deliver diet and exercise counselling within primary care. This provision, however, is variable by nurse and practice.

It is therefore essential that local strategies for physical activity promotion and local commissioning by clinical commissioning groups and local authorities is in future informed by the wider evidence base in relation to the broad range of potential community and individual interventions. As resources are limited and the potential for population benefits large, a systematic approach, prioritising the most cost-effective interventions and targeting the groups with the greatest baseline risk and ability to benefit from supportive interventions, is required.

Implications for future research

The process evaluation suggested that some participants were confused about the initiation and maintenance components and also between data collection and delivery of the intervention. They often seemed to perceive that the data collection sessions were part of the intervention and a source of support and there is therefore a need to be aware of a Hawthorne effect, which will influence participant behaviour and therefore both self-reported and objectively measured primary outcomes. Future research should ensure that clear goals, and the agenda for specific sessions, are discussed and agreed with the participants. When baseline information is required this has a different role (unless part of normative feedback) and should be treated accordingly in the session. Therefore, future interventions should clearly define (and report) the content of the intervention so that aspects such as agenda setting, exploring pros and cons of change and action planning or information exchange are systematic and meaningful.

Because some participants seemed to like the MI approach whereas others seemed to expect or prefer a more didactic approach, future research could investigate the impact of people's intervention style preferences (i.e. didactic information giving vs. MI) on the effectiveness of a physical activity maintenance intervention. A suitable comparison might be to examine preferred style compared with not preferred style (compared with the control).

There is a clear need to ensure that counselling interventions such as MI are delivered as intended and that the content and approach are accurately reported. Recent studies have explored the potential use of integrating MI and cognitive–behavioural therapy to form physical activity interventions and unless a clear description of the components of interventions are clearly stated it is difficult for practitioners to adapt and embed such approaches when they are shown to be efficacious in research settings. Until studies have demonstrated that an intervention is consistently delivered and internal validity is gained, it is not possible to infer accurately its likely efficacy in increasingly varied contexts.

Our research suggests that correlation between activity questionnaires and accelerometer data is poor (see *Chapter 3*, *Effectiveness of the mini booster intervention compared with the full booster intervention at 3 months*, and *Chapter 4*, *The prevalence of optimistic self-assessment*), a phenomenon that has been noted previously in the peer-reviewed literature.[143] This might be an indication of social desirability bias, the tendency to answer questions in a fashion that will be viewed positively by others. Social desirability has been found to bias self-reports of diet and physical activity and some research teams recommend methods to measure and control for social desirability bias when self-report questionnaires are used.[144,145]

In *Chapter 4* (see *The prevalence of optimistic self-assessment*) we reviewed claims of large amounts of moderate to vigorous physical activity when 7-day accelerometry data showed low levels of physical activity across the week. Nicaise and colleagues[143] make the point that, although low-income Latinas often over-report the amount of moderate to vigorous activity carried out (compared with accelerometry results),

they do substantial amounts of light-intensity activity. Healy and colleagues[146] have suggested that light-intensity physical activity is associated with improved glycaemic control that is independent of the amount of moderate and vigorous physical activity carried out. Researchers and policy-makers may need to adjust unreasonable expectations of those who are constrained by motivational, physical, social or environmental factors; for such people, reducing sedentary behaviour and increasing low-intensity activity may be both appropriate and clinically important.

Chapter 9 Conclusions

Although some individuals do find a community-based, brief MI 'booster' intervention supportive, the low levels of recruitment and retention in this trial and the lack of impact on objectively measured physical activity levels in those with adequate outcome data suggest that it is unlikely to represent a clinically effective or cost-effective intervention for the maintenance of recently acquired physical activity increases in deprived, middle-aged, urban populations.

The gap between the size of the sedentary population who could achieve significant long-term health benefits from relatively small but sustained increases in physical activity levels and the numbers taking up the offers of both the initial brief intervention and the subsequent 'booster' interventions suggests that this type of MI-based approach will be appropriate only for a minority of the sedentary population who could, in principle, benefit from being more physically active. Other approaches that require less proactive (and potentially time-consuming) engagement from individuals, including environmental interventions to encourage active travel and recreational activity, may be particularly important for deprived communities and middle-aged populations who are less likely to prioritise their own physical fitness and well-being over other demands on their time and resources.

Many types of physical activity interventions can exacerbate health inequalities because they are more likely to be taken up, and subsequent behaviour change achieved and maintained, by those who are already active and those in better health. The booster study was therefore explicitly designed to target recruitment in communities that were known to have poorer health outcomes. The lessons learnt in undertaking this trial should inform both the design of future physical activity intervention trials and the development of more effective interventions that not only are feasible and affordable but also will have sufficient reach to have an impact in the most deprived and most sedentary populations who could benefit most from sustained increases in their physical activity levels.

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Elizabeth Goyder, **Stephen J Walters**, **Jeff Breckon**, **Helen Crank**, **Robert Copeland** and **Cindy Cooper** made substantial contributions to the conception and design of the main study.

Daniel Hind, **Emma Everson-Hock**, **Elizabeth Goyder**, **Jeff Breckon**, **Helen Crank**, **Robert Copeland** and **Karen Collins** made substantial contributions to the conception and design of the process evaluation (qualitative substudy).

Nicolas Latimer and **Jonathan Minton** made substantial contributions to the conception and design of the health economic analysis.

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Publications

Hind D, Scott EJ, Copeland R, Breckon JD, Crank H, Walters SJ, *et al.* 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. *BMC Public Health* 2010;**10**:3.

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Appendix 1 Protocol

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.

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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.

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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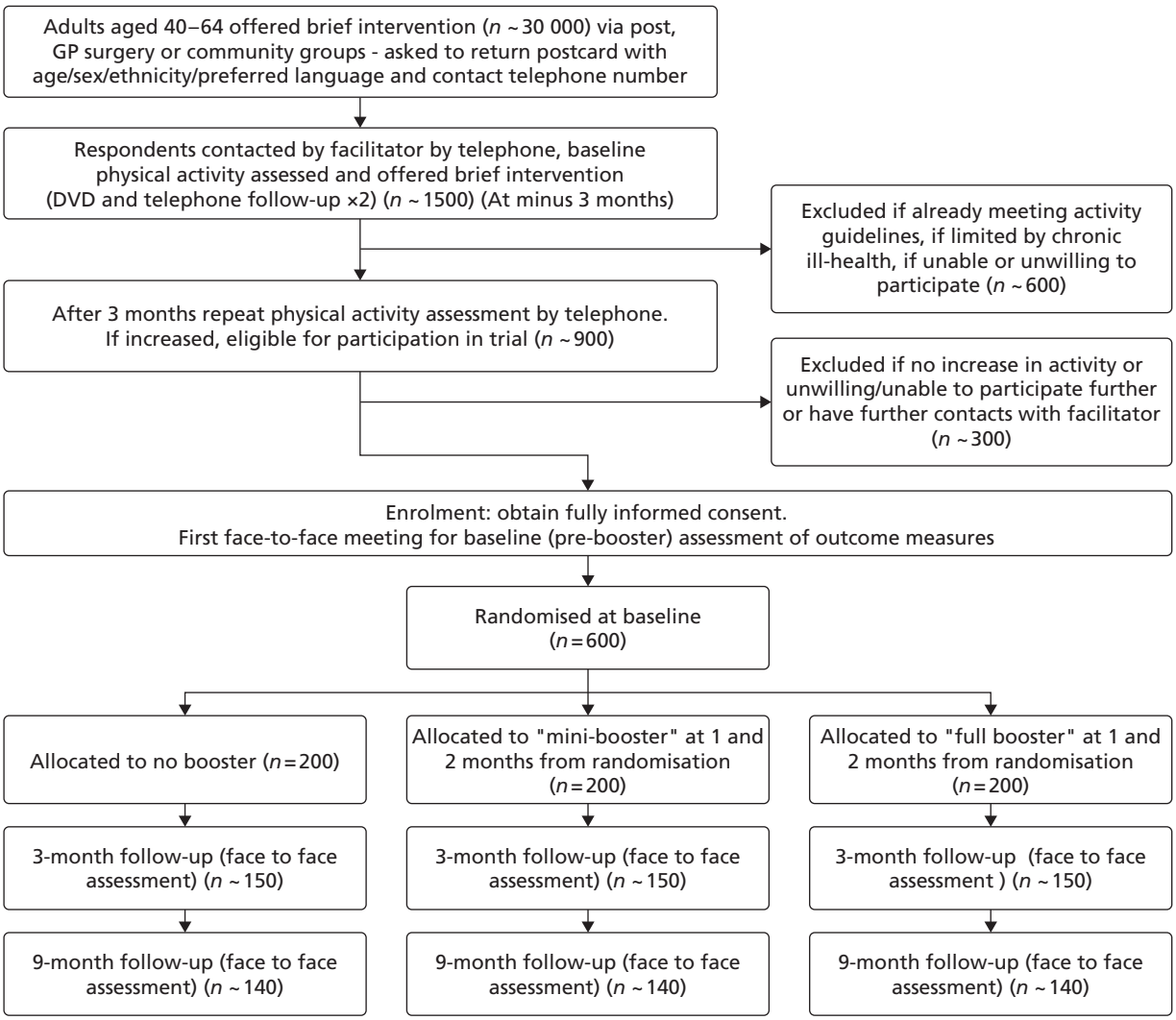
Trial Summary

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.



Introduction

Rationale

There are a number of published systematic reviews of evidence for interventions that increase physical activity.[1–5] More recently the evidence base for brief interventions in primary care has been reviewed.[6] 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.[7,8] 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[9,10] suggest that the transtheoretical model (TTM)[11] 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.[10,12–14] The TTM describes how people modify problem behaviours or acquire positive new ones.[11,15,16] 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).[11] 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.[17] 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.[18] A MI approach has been shown to impact positively on lifestyle and health outcomes including physical activity behaviours in adults.[18–21] MI has been applied in a number of formats including technology-based, such as internet and video,[7,8,22,23] telephone[24] and face-to-face consultations.[19] An example of a technology-based intervention adopting an MI approach is The Drinker's Check-up.[7,8,23] 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,[25–27] positively influence user engagement and self-efficacy and yield health benefits in low-income populations.[28,29] Survey data reveals that at least 80% of adults aged 35–64 own a DVD player.[30] 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, the brief intervention will aim to help middle age adults consider, initiate and maintain physical activity behaviours.[6] 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)[6]

'*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)[31]

'*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[15] and replicate a brief version of motivational interviewing based on a method designed for time limited consultations in medical settings.[32] Such an approach has been successfully employed to change health-related behaviours previously.[33] 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[32] 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,[33] 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.[3,34] A telephone based approach has been effective in increasing physical activity participation at six months compared to no telephone support[35] and has also been shown to increase physical activity participation to a greater extent than standard reading materials in adult populations.[34] 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.[36] This framework provides quality assurance parameters based on the intervention design, training, delivery, receipt and enactment. Further detail of this can be found elsewhere.[36] A recent review has highlighted inconsistent delivery and levels of competence of physical activity interventionists reporting to deliver a physical activity counselling components[37] 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.[38] 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.

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.

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[39,40]. 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-day accelerometry 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:

   – Total Energy Expenditure (TEE), in Kcal per day, from seven-day accelerometry and heart rate monitoring using Actiheart
   – Physical activity counts (PAC) per week;
   – Minutes of moderate/vigorous physical activity per day;
   – 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.[41] Exercise stages of change[42], and self-determination will be assessed using Behavioural Regulation in Exercise Questionnaire[43] and questions used in the HTA-funded Exercise Evaluation Randomised Trial (EXERT).[44] 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)[45]

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.

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[46] and wishing to have support to become more active

Additional inclusion criteria for booster trial:

1. 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
2. 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.

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).

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.

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.[47] 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:
   - Physical activity counts (PAC) per week;
   - Minutes of moderate/vigorous physical activity per day;
   - 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
3. Change in health-related quality of life measured by changes in SF-12v2 plus 4 (converted to SF-6D)
4. Health and social care contacts
5. 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.[48]

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.[49]

SF-12v2 plus 4 data will be converted into health state utility values using the SF-6D preference-based algorithm.[50] 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.[51] 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.

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.

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.

Publication

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

Ethics approval

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

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.

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Appendix 2 Changes to protocol

Change to Protocol	Progress Report	Date	Approved by
Protocol Version 2 (3rd Feb 2009), changes for accuracy, clarification and internal consistency were never approved by the REC	Not reported	–	Sheffield REC
Protocol Version 3 (25 Jun 09) Sheffield Research Ethics Committee approved a protocol amendment on 14 July 2009. The amendment related to the collection of data during the brief intervention (pre-randomisation or screening) phase of the study	01	03 Aug 2009	Sheffield REC
Protocol Version 04 (13 Jan 2011). This change involved the way the primary outcome was collected and analysed. The primary outcome remained an objective measure of physical activity obtained through seven-day accelerometry using Actiheart. However, the chair of the Trial Steering Committee recommended that we change the way this was calculated from the use of physical activity counts to energy expenditure. On the request of the NIHR HTA monitors the rationale for this change was externally peer reviewed and approved by the NIHR HTA (please see 'Letter from HTA 04 Aug 2010.pdf'). The changes to the protocol reflected the decision of the funding body that the method of calculating the primary outcome should change. There was no difference to participants in terms of how data is collected	HTA instructed team to make change (correspondence: 04 Aug 2010); not reported due to an oversight	–	Sheffield REC
Protocol Version 5 (09 Mar 2011), given a favourable opinion by Sheffield REC on 06 Jun 2011, refers to a new piece of study documentation, the study introduction letter. This letter is sent to study candidates before the participant information sheet and delivers key information in simple language	05	01 Aug 2011	Sheffield REC

Appendix 3 Motivational interviewing

Motivational interviewing: principles and key elements

Ground work and typical day

Using key skills in MI including Open ended questions, Affirmations of change talk, Reflective listening and Summarising (OARS) to elicit client attitudes towards adopting lifestyle change. This opening exchange will also ensure client centredness through empathetic listening and respectfulness. The main outcome is a greater understanding (for both the client and therapist) of the client's current situation and their relevant health history and envisaging the impact of changing and not changing. TYPICAL DAY: Exploration (guiding and supporting the client) to understand a typical day and what 'high risk' scenario's exist as well as opportunities for change and adapting current behaviours. Key skills used are again OARS.

Assess importance and readiness

A. How important is the change? (e.g. physical activity) (1–10) ( ) Why X Not Y?

B. How ready are you to change? (1–10) ( ) Why X Not Y?

C. How confident are you to maintain the change? (1–10) ( ) Why X Not Y?

This measure is mapped (conceptually) onto the transtheoretical model (TTM) of behaviour change,[147] although, unlike most other applications, the MI interview integrates more than stages of change and incorporates 'decisional balance', 'self-efficacy/temptation' and 'processes of change'. Many other interventions in health settings wrongly assume that stages of change and TTM are the same thing when stages of change is just one of four dimensions. This measure helps both parties understand the client readiness to change across his or her own selected health behaviour change aspects (i.e. smoking, diet, exercise, alcohol).

Assessing ambivalence

Whenever a client is considering change (from a position of contemplation, for example), ambivalence is a normal consequence. Eliciting all aspects of this position is important and can be done in MI using a four-cell decisional balance grid.

When we think about making changes, most of us don't really consider all 'sides' in a complete way. Instead, we often do what we think we 'should' do, avoid doing things we don't feel like doing, or just feel confused or overwhelmed and give up thinking about it at all.

Thinking through the pros and cons of both changing and not making a change is one way to help us make sure we have fully considered a possible change. This can help us to 'hang on' to our plan in times of stress or temptation. *Below, write in the reasons that you can think of in each of the boxes.*

	Benefits/pros	Costs/cons
Making a change		
Not changing		

Summary

Again, the key counselling skill applied here is reflective listening, in which the therapist draws together the main facets of the conversation and provides a reflective summary for the client. This enables the client to 'listen back' to the points they have raised themself and provides an opportunity to clarify points, adjust the inference or level of importance or merely have it verbalised from an objective source. This is an important phase in preparation for action planning and will include a recapitulation and asking key questions about subsequent stages.

Action plan

When there are clear signs of preparatory change talk,[84] which are Desire, Ability, Reasons, Need (DARN), then greater elicitation and strengthening is required to increase the likelihood of predictor change talk, which is Commitment, Activation, Taking steps (CAT). Use the 'ten strategies for eliciting and strengthening change talk' worksheet to achieve this.

Key sections in the action planning phase:

_____

The most important reasons why I want to change are:

My main goal for myself in making this change are:

I plan to do these things in order to accomplish my goals;

SPECIFIC ACTION WHEN?

Other people could help me with change in these ways;

PERSON POSSIBLE WAYS TO HELP

These are some possible obstacles to change, and how I could handle them;

POSSIBLE OBSTACLE TO CHANGE HOW TO RESPOND

I know that my plan is working when I see these results;

_____

_____

_____

4. Eliciting Commitment

"Is this what you want to do?"

If the response is "I guess so", or "I'll think about it", there is still some work to do.

Explore ambivalence in this case using phase 1 skills.

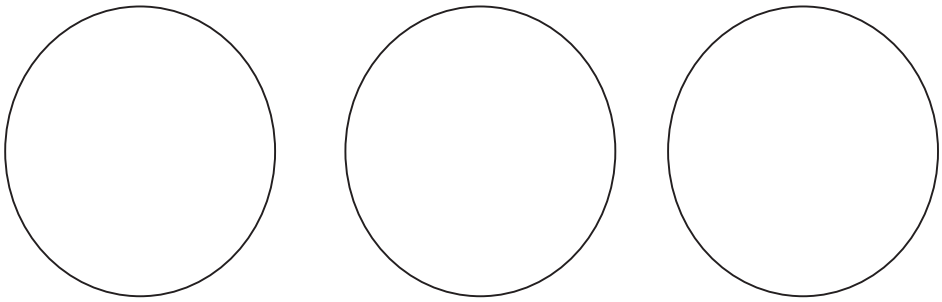
Motivational Interviewing

Practice resources pack

Dr. Jeff Breckon CPsychol.

Motivational Interviewing Network of Trainers (MINT)

Agenda setting (identifying target behaviours)



How important?

Decisional balance

TARGET BEHAVIOUR: _____

	PROS	CONS
CHANGE		
NO CHANGE		

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*How ready are you?

Importance/Readiness/Confidence ruler

On a scale of 0-10 how important is it that you ________________or how confident are you that you_______________

What puts you at a __________ and not a ______? (lower number) What would it take to move you from a _____ to a _____? (higher number)

Readiness/Confidence Ruler

Topic		Not Ready		Unsure		Ready			Trying	
	1	2	3	4	5	6	7	8	9	10
	1	2	3	4	5	6	7	8	9	10
	1	2	3	4	5	6	7	8	9	10
	1	2	3	4	5	6	7	8	9	10
	1	2	3	4	5	6	7	8	9	10
	1	2	3	4	5	6	7	8	9	10
	1	2	3	4	5	6	7	8	9	10

How confident?

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ACTION PLANNING

The change I want to make is:

The most important reasons why I want to make this change are:

I plan to do these things in order to accomplish my goals:

Specific action	When?

Other people could help me with change in these ways:

Person	Possible ways to help

These are some of the obstacles to change, and how I could handle them:

Possible obstacles to change	What I will do

If I lapse I will do the following:

I will know that my plan is working when I see these results:

How confident am I that I can make this change?

0	1	2	3	4	5	6	7	8	9	10
Not at all Confident										**Extremely confident**

OBSERVERS SHEET

SIMPLE REFLECTION (S): Essentially a repetition or slight rewording of what the client said

COMPLEX REFLECTION (C): Paraphrasing meaning, continuing the paragraph, or otherwise reflecting a level of content or feeling beyond that which the client voiced

REFFLECTIVE SUMMARY (RS): Counsellor pulled together two or more client statements into a summary, including material that had not been voiced by the client immediately before

Characteristic		Frequency count
SIMPLE REFLECTION (S)		
COMPLEX REFLECTION (C)		
REFFLECTIVE SUMMARY (RS)		
QUESTION (Q)	CLOSED (CQ)	
	OPEN (OQ)	
AFFIRMATION (A)		
GAVE TIME/SPACE		
OTHER (e.g. ADVICE GIVING)		

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Appendix 4 Questionnaire for participants in the full booster arm

Office Use Only:

Randomisation Number: ☐

Allocation: Full Booster

This survey asks you questions about physical activity you may have taken part in the **last three months**. It also asks you your thoughts about your **one-to-one booster sessions**. Please place the survey into the envelope provided and seal it before you come in for your appointment.

Please try and answer every question as honestly as possible, and do not spend too much time on any one question.

1. Over the last three months have you taken part in any of the following?

☐ Recreational/leisure activities (e.g. gardening, cycling)
please state_____

☐ Competitive sports/exercise
please state_____

☐ Structured exercise (e.g. exercise class)
please state_____

☐ Active commuting (e.g. walking/cycling to work)
please state_____

2. Please specify the places where you have done your chosen activities over the last three months (e.g. home, Ponds Forge)

☐ Home

☐ Local open space (e.g. park)

☐ Facility (e.g. gym, pool, community centre, track) – please state _____

_____

☐ As part of daily activities (e.g. in work, shopping, walking the dog, commuting)

☐ Other – please state _____

3. Why have you chosen to stay physically active? (Please tick one box per reason to indicate how much each reason relates to you personally)

	Not at all	Not really	Neutral	Slightly	Very much
To improve my health					
To get fitter/stay fit					
To lose weight					
To look better					
To encourage my family to be more active					
To make new friends					
To have fun/ enjoyment					
To spend time with my family					
To spend time with my friends					
For competition/to win					
It's part of my job					
It gives me a sense of achievement					
Reduce risks of health problems e.g. diabetes, heart disease					
I haven't stayed active					
A health professional recommended I should – who was that? …….. ……					
Other ……					

4. What influences whether or not you are able to perform your chosen activity? (Please tick one box per reason to indicate how much each reason relates to you personally)

	Not at all	Not really	Neutral	Slightly	Very much
Value for money					
Activity is available when I want					
Childcare available					
Within walking distance/home/work					
Within easy reach on public transport					
If I feel I'm getting something out of it					
Whether there is someone else to do it with					
It's a habit					
Whether I can make time to do it					
My own health					
Other ……					

5. Do you do physical activity with anyone else?

☐ Yes

☐ No

If you answered yes, who do you usually do physical activity with? (Please tick all that apply)

☐ Spouse/partner

☐ Other family member/s

☐ Friend/s

☐ Other adult/s

☐ Child/children under 16 years

☐ As part of a group/class (including walking group)

☐ Other (please state) _____

If you answered yes, how useful do you find this support in helping you to stay active? (please tick one)

Very Useful	Fairly useful	Neither useful nor useless	Fairly useless	Very useless	Not applicable

Questions on the "booster" advice or counselling you received

6. Why did you decide to take part in this project? (Please write in the space below)

7. If you were to receive further physical activity "booster" counselling/advice in the future, how would you prefer it to be delivered?

☐ Over the telephone

☐ In person (face to face)

☐ Written advice

8. Before you received the "booster" physical activity counselling/advice, what did you expect to gain from the two sessions? (Please write in the space below)

9. Did the "booster" counselling/advice sessions meet the expectations you described above?

☐ Yes

☐ No

Questions 10-14 – please indicate your agreement with the following statements.

10. The "booster" counselling/advice sessions fitted easily into my daily schedule (Please tick one)

Strongly disagree	Disagree	Neutral	Agree	Strongly agree

11. The face to face "booster" counselling/advice sessions were conducted at a convenient location (please only tick one)

Strongly disagree	Disagree	Neutral	Agree	Strongly agree

12. Throughout the "booster" counselling/advice sessions I feel I wasn't being judged by the project worker (please tick one)

Strongly disagree	Disagree	Neutral	Agree	Strongly agree

13. The "booster" counselling/advice sessions were non-confrontational in nature (please tick one)

Strongly disagree	Disagree	Neutral	Agree	Strongly agree

14. Throughout the "booster" counselling/advice sessions I thought the project worker understood what I was saying (please tick one)

Strongly disagree	Disagree	Neutral	Agree	Strongly agree

15. How involved did you feel in the "booster" counselling advice sessions? (Please tick one)

☐ I spoke more than the project worker

☐ I spoke less than the project worker

☐ I spoke roughly the same amount as the project worker

16. How do you feel about the amount of contact time that occurred between you and the project worker? (Please tick one)

Too long	Slightly too long	About right	Slightly too short	Too short

17. During the "booster" counselling/advice sessions I was encouraged to set my own goals for physical activity (please tick one)

Not Discussed	Strongly Disagree	Disagree	Neutral	Agree	Strongly agree

18. As a result of the "booster" counselling /advice sessions I feel I have been able to resolve my barriers towards physical activity (please tick one)

Strongly disagree	Disagree	Neutral	Agree	Strongly agree

19. As a result of the "booster" counselling/advice sessions I now know more about the benefits of physical activity (please tick one)

Not Discussed	Strongly Disagree	Disagree	Neutral	Agree	Strongly agree

20. As a result of the "booster" counselling/advice sessions I now know more about the risks associated with living an inactive lifestyle (please tick one)

Not Discussed	Strongly Disagree	Disagree	Neutral	Agree	Strongly agree

21. As a result of the "booster" counselling/advice sessions, I am now more aware of available physical activity facilities and opportunities (please tick one)

Not Discussed	Strongly Disagree	Disagree	Neutral	Agree	Strongly agree

22. As a result of the "booster" counselling/advice sessions my confidence to stay active has increased (please tick one)

Strongly disagree	Disagree	Neutral	Agree	Strongly agree

23. If you are more physically active now than you were before taking part in this study, what helped you? (Please write in the space below)

Finally, would you be happy to discuss some of the things mentioned in this questionnaire further in an interview with a different person to the person you have been in contact with about this study so far, either face-to-face or on the telephone?

☐ Yes – face to face

☐ Yes – over the telephone

☐ No

If you would like us to contact you by telephone, please give a telephone number we can contact you on:

_____

Thank you very much for your help.

Appendix 5 Interview topic guide

Introduction: Just like to talk to you about your experiences of taking part in the telephone/face-to-face 'booster'/advice and whether this influenced you being physically active.

Prompts:

Firstly, how long did your session last?
Where did it take place? Was that convenient for you
What did you think of the advice session?
Can you tell us if you felt the advice session helped in any way to keep you active? How/why do you think that was? (Probe: attitude change, reaffirm message)
What else influenced you in being able to stay active or deterred you from staying active? (e.g. costs, facilities, personal circumstances, people to be active with, priorities, others who support you/discourage you from being active, motivation for being active). How/why?
Can you describe the things that motivate you the most to be physically active? (e.g. external/internal; why feel the need to do or not do something active?)
Can you describe if and how physical activity fits into your lifestyle? (i.e. explore habits/routines)
What type of activity/activities did you participate in and why? (Interviewer refer to survey and follow up answers)

What were you expecting from the study? Was it what you expected?

Prompt: have you received any advice like this before?

What benefits do you feel there are to staying active?

Prompts:

Physical/medical?
Mood/well-being?
Social?
Other behaviours, e.g. eating habits, smoking?
Saving money? (e.g. by walking/cycling as transport)
What disadvantages do you think there are to staying active?

Prompts:

Time
Cost
Planning

Was this a good way to give you advice/help you needed? Why?

Prompts:

What would you have preferred? What, if anything, would you change about the 'booster'/support and advice for keeping active?
If a friend was thinking of becoming/staying active, how would you advise them to go about this?

Appendix 6 Results tables from the main trial

TABLE 16 Mail-out areas

Mail-out	Neighbourhoods	Letters sent, *n*	Replies received, *n* (%)	Randomised, *n* (%)
1	High Green	3300	329 (10.0)	48 (1.5)
2	Southey Green, Longley, New Parsons Cross, Old Parsons Cross, Shirecliffe, Tinsley, Darnall, Flower, Shiregreen, Stubbin, Brushes, Acres Hill, Winn Gardens	15,366	1045 (6.8)	88 (0.6)
3	Gleadless Valley, Hemsworth, Lowedges, Batemoor, Jordanthorpe, Manor, Woodthorpe, Park Hill, Norfolk Park, Arbourthorne, Tinsley, Darnall, Acres Hill	18,784	974 (5.2)	60 (0.3)
4	Broomhall, Sharrow (including the Abbeydale corridor), Highfield, Burngreave, Abbeyfield, Fir Vale, Firshill, Woodside, Netherthorpe, Upperthorpe, Langsett, Wybourn, City Centre	16,072	1185 (7.4)	52 (0.3)
5	Brightside, Firth Park, Fox Hill, Richmond, Wincobank	6862	385 (5.6)	8 (0.1)
6	Base Green, Beighton, Charnock, Gleadless, Halfway, Handsworth, Hollins End, Mosborough, Owlthorpe, Sothall	10,000	836 (8.4)	26 (0.3)

TABLE 17 Baseline characteristics of all randomised study participants (*n* = 282)

Variable	Control (*n* = 96)	Booster (*n* = 186)	Total (*n* = 282)
Gender, *n* (%)			
Male	37 (38.5)	93 (50.0)	130 (46.1)
Female	59 (61.5)	93 (50.0)	152 (53.9)
Employment status, *n* (%)			
Part-time	18 (18.8)	34 (18.3)	52 (18.4)
Full-time	34 (35.4)	59 (31.7)	93 (33.0)
Not employed	44 (45.8)	90 (48.4)	134 (47.5)
Missing	0 (0.0)	3 (1.6)	3 (1.1)
Ethnicity, *n* (%)			
White British	83 (86.5)	163 (87.6)	246 (87.2)
Other	13 (13.5)	20 (10.8)	33 (11.7)
Missing	0 (0.0)	3 (1.6)	3 (1.1)

continued

TABLE 17 Baseline characteristics of all randomised study participants (*n* = 282) (*continued*)

Variable	Control (*n* = 96)	Booster (*n* = 186)	Total (*n* = 282)
Marital status, *n* (%)			
Single	16 (16.7)	29 (15.6)	45 (16.0)
Married	50 (52.1)	101 (54.3)	151 (53.5)
Co-habiting	5 (5.2)	15 (8.1)	20 (7.1)
Divorced/separated	20 (20.8)	35 (18.8)	55 (19.5)
Widowed	5 (5.2)	6 (3.2)	11 (3.9)
Stage of change, *n* (%)			
Contemplation	1 (1.0)	11 (5.9)	12 (4.3)
Preparation	39 (40.6)	86 (46.2)	125 (44.3)
Action	36 (37.5)	55 (29.6)	91 (32.3)
Maintenance	18 (18.8)	32 (17.2)	50 (17.7)
Missing	2 (2.1)	2 (1.1)	4 (1.4)
Age (years)			
n (%)	96 (100.0)	186 (100.0)	282 (100.0)
Mean (SD)	54.5 (6.8)	54.6 (7.6)	54.6 (7.3)
Median (IQR)	54.9 (50.3 to 60.0)	55.6 (48.1 to 61.8)	55.3 (48.8 to 61.4)
Min. to max.	40.5 to 65.5	40.4 to 65.1	40.4 to 65.5
Height (m)			
n (%)	95 (99.0)	186 (100.0)	281 (99.6)
Mean (SD)	1.7 (0.1)	1.7 (0.1)	1.7 (0.1)
Median (IQR)	1.7 (1.6–1.7)	1.7 (1.6–1.8)	1.7 (1.6–1.8)
Min. to max.	1.5 to 1.9	1.5 to 1.9	1.5 to 1.9
Weight (kg)			
n (%)	96 (100.0)	186 (100.0)	282 (100.0)
Mean (SD)	84.5 (19.2)	85.5 (18.5)	85.2 (18.7)
Median (IQR)	82.8 (70.1 to 95.0)	83.0 (73.0 to 96.8)	82.9 (72.5 to 96.6)
Min. to max.	50.8 to 160.0	46.9 to 145.8	46.9 to 160.0
BMI (kg/m^2)			
n (%)	95 (99.0)	186 (100.0)	281 (99.6)
Mean (SD)	30.3 (6.3)	30.3 (5.7)	30.3 (5.9)
Median (IQR)	28.9 (25.7 to 33.0)	29.8 (26.4 to33.2)	29.8 (26.3 to 33.0)
Min. to max.	20.3 to 53.4	17.1 to 49.4	17.1 to 53.4
SPAQ change[a] (3 months post randomisation)			
n (%)	96 (100.0)	186 (100.0)	282 (100.0)
Mean (SD)	199.8 (261.6)	215.3 (416.1)	210.0 (370.4)
Median (IQR)	120.0 (75.0 to 255.0)	120.0 (50.0 to 255.0)	120.0 (60.0 to 255.0)
Min. to max.	−1010.0 to 1240.0	−1840.0 to 3360.0	−1840.0 to 3360.0

TABLE 17 Baseline characteristics of all randomised study participants (*n* = 282) (*continued*)

Variable	Control (*n* = 96)	Booster (*n* = 186)	Total (*n* = 282)
SF-12v2 plus 4 (PCS)			
n (%)	90 (93.8)	180 (96.8)	270 (95.7)
Mean (SD)	46.8 (11.2)	46.2 (10.6)	46.4 (10.8)
Median (IQR)	51.8 (39.9 to 54.8)	49.1 (39.6 to 53.9)	49.9 (39.7 to 54.5)
Min. to max.	13.9 to 60.7	13.0 to 66.7	13.0 to 66.7
SF-12v2 plus 4 (MCS)			
n (%)	90 (93.8)	180 (96.8)	270 (95.7)
Mean (SD)	47.8 (10.2)	49.2 (9.6)	48.7 (9.8)
Median (IQR)	50.4 (41.7 to 54.9)	51.0 (41.9 to 57.1)	50.8 (41.9 to 56.2)
Min. to max.	20.8 to 65.8	15.9 to 68.5	15.9 to 68.5
BREQ-2 (RAI)			
n (%)	93 (96.9)	181 (97.3)	274 (97.2)
Mean (SD)	5.4 (3.7)	5.2 (3.7)	5.3 (3.7)
Median (IQR)	5.8 (3.3 to 7.9)	6.3 (3.3 to 8.0)	6.0 (3.3 to 8.0)
Min. to max.	−3.3 to 12.0	−9.1 to 11.5	−9.1 to 12.0

max., maximum; min., minimum.

a Twenty-eight participants reported an increase in physical activity of < 30 minutes at pretrial screening (23 reported atypical activity either at brief intervention or pretrial screening; five reported typical activity on both occasions and a change in activity less than the required amount of at least 30 minutes).

TABLE 18 Baseline characteristics of ITT study participants (*n* = 160)

Variable	Control (*n* = 61)	Booster (*n* = 99)	Total (*n* = 160)
Gender, *n* (%)			
Male	26 (42.6)	42 (42.4)	68 (42.5)
Female	35 (57.4)	57 (57.6)	92 (57.5)
Employment status, *n* (%)			
Part-time	14 (23.0)	19 (19.2)	33 (20.6)
Not employed	27 (44.3)	55 (55.6)	82 (51.3)
Ethnicity, *n* (%)			
White British	54 (88.5)	89 (89.9)	143 (89.4)
Any other	7 (11.5)	8 (8.1)	15 (19.4)
Missing	0 (0.0)	2 (2.0)	2 (1.3)
Marital status, *n* (%)			
Single	11 (18.0)	13 (13.1)	24 (15.0)
Married	30 (49.2)	55 (55.6)	85 (53.1)
Co-habiting	5 (8.2)	6 (6.1)	11 (6.9)
Divorced/separated	11 (18.0)	20 (20.2)	31 (19.4)
Widowed	4 (6.6)	5 (5.1)	9 (5.6)

continued

TABLE 18 Baseline characteristics of ITT study participants (n = 160) (*continued*)

Variable	Control (n = 61)	Booster (n = 99)	Total (n = 160)
Stage of change, *n* (%)			
Contemplation	0 (0.0)	5 (5.1)	5 (3.1)
Preparation	24 (39.3)	40 (40.4)	64 (40.0)
Action	23 (37.7)	34 (34.3)	57 (35.6)
Maintenance	13 (21.3)	19 (19.2)	32 (20.0)
Missing	1 (1.6)	1 (1.0)	2 (1.3)
Age (years)			
n (%)	61 (100.0)	99 (100.0)	160 (100.0)
Mean (SD)	54.3 (7.0)	55.3 (7.7)	54.9 (7.4)
Median (IQR)	54.0 (50.4 to 60.6)	57.0 (48.5 to 62.3)	56.0 (49.4 to 61.8)
Min. to max.	40.5 to 65.5	40.5 to 65.1	40.5 to 65.5
Height (m)			
n (%)	61 (100.0)	99 (100.0)	160 (100.0)
Mean (SD)	1.7 (0.1)	1.7 (0.1)	1.7 (0.1)
Median (IQR)	1.7 (1.6 to 1.7)	1.6 (1.6 to 1.7)	1.7 (1.6 to 1.7)
Min. to max.	1.5 to 1.9	1.5 to 1.9	1.5 to 1.9
Weight (kg)			
n (%)	61 (100.0)	99 (100.0)	160 (100.0)
Mean (SD)	81.7 (15.1)	82.1 (17.9)	82.0 (16.9)
Median (IQR)	82.0 (70.1 to 92.0)	80.6 (70.1 to 91.1)	80.6 (70.1 to 91.5)
Min. to max.	50.8 to 115.0	47.1 to 142.2	47.1 to 142.2
BMI (kg/m^2)			
n (%)	61 (100.0)	99 (100.0)	160 (100.0)
Mean (SD)	29.2 (5.0)	29.6 (5.7)	29.4 (5.4)
Median (IQR)	27.9 (25.6 to 32.2)	29.2 (25.5 to 32.2)	28.9 (25.6 to 32.2)
Min. to max.	20.3 to 43.7	17.1 to 49.4	17.1 to 49.4
SPAQ change (3 months post randomisation)			
n (%)	61 (100.0)	99 (100.0)	160 (100.0)
Mean (SD)	216.9 (243.1)	188.6 (316.4)	199.4 (290.2)
Median (IQR)	120.0 (90.0 to 255.0)	110.0 (45.0 to 225.0)	120.0 (60.0 to 237.5)
Min. to max.	–210.0 to 1240.0	–480.0 to 1740.0	–480.0 to 1740.0
SF-12v2 plus 4 (PCS)			
n (%)	58 (95.1)	95 (96.0)	153 (95.6)
Mean (SD)	48.4 (9.3)	47.3 (9.8)	47.7 (9.6)
Median (IQR)	52.0 (42.0 to 54.8)	49.9 (42.8 to 54.3)	50.7 (42.6 to 54.5)
Min. to max.	17.5 to 60.6	20.7 to 60.9	17.5 to 60.9

TABLE 18 Baseline characteristics of ITT study participants (*n* = 160) (*continued*)

Variable	Control (*n* = 61)	Booster (*n* = 99)	Total (*n* = 160)
SF-12v2 plus 4 (MCS)			
n (%)	58 (95.1)	95 (96.0)	153 (95.6)
Mean (SD)	47.7 (9.8)	50.0 (8.7)	49.1 (9.2)
Median (IQR)	50.1 (41.1 to 54.9)	51.2 (44.2 to 57.1)	51.0 (43.2 to 56.3)
Min. to max.	20.8 to 63.8	21.7 to 65.5	20.8 to 65.5
BREQ-2 (RAI)			
n (%)	59 (96.7)	96 (97.0)	155 (96.9)
Mean (SD)	5.6 (3.6)	5.6 (3.6)	5.6 (3.6)
Median (IQR)	6.1 (3.4 to 8.0)	6.4 (3.7 to 8.3)	6.3 (3.5 to 8.3)
Min. to max.	–3.3 to 12.0	–9.1 to 11.5	–9.1 to 12.0

max., maximum; min., minimum.
Note: the ITT set is defined as randomised participants with at least 4 complete days on the Actiheart device as measured by lost minutes during the day of not more than 1000 minutes at 3 months of follow-up.

TABLE 19 Comparability of baseline characteristics of completers and non-completers

	Non-completers			Completers		
Variable	Control	Booster	All	Control	Booster	All
Age (years)						
n	35	87	122	61	99	160
Mean (SD)	55.4 (6.6)	54.3 (7.4)	54.6 (7.2)	54.7 (7.0)	55.7 (7.7)	55.3 (7.4)
Median (IQR)	58 (50.5 to 60.3)	52.9 (48.4 to 61.9)	54.6 (48.9 to 60.7)	54.7 (50.7 to 61.0)	57.8 (49.0 to 62.7)	56.4 (49.8 to 62.3)
Height (m)						
n	34	87	121	61	99	160
Mean (SD)	1.7 (0.1)	1.7 (0.1)	1.7 (0.1)	1.7 (0.1)	1.7 (0.1)	1.7 (0.1)
Median (IQR)	1.6 (1.6 to 1.7)	1.7 (1.6 to 1.8)	1.7 (1.6 to 1.8)	1.7 (1.6 to 1.7)	1.6 (1.6 to 1.7)	1.7 (1.6 to 1.7)
Weight (kg)						
n	35	87	122	61	99	160
Mean (SD)	89.4 (24.1)	89.4 (18.4)	89.4 (20.1)	81.7 (15.1)	82.1 (17.9)	82.0 (16.9)
Median (IQR)	82.8 (69.0 to 105.0)	87.7 (76.0 to 99.5)	87.5 (75.9 to 101.9)	82 (70.1 to 92.0)	80.6 (70.1 to 91.1)	80.6 (70.1 to 91.5)
BMI (kg/m^2)						
n	34	87	121	61	99	160
Mean (SD)	32.2 (7.8)	31.2 (5.7)	31.5 (6.4)	29.2 (5.0)	29.6 (5.7)	29.4 (5.4)
Median (IQR)	30 (26.3 to 37.9)	30.9 (26.9 to 34.0)	30.9 (26.9 to 34.4)	27.9 (25.6 to 32.2)	29.2 (25.5 to 32.2)	28.9 (25.6 to 32.2)

continued

TABLE 19 Comparability of baseline characteristics of completers and non-completers (*continued*)

	Non-completers			Completers		
Variable	Control	Booster	All	Control	Booster	All
SPAQ change (3 months post randomisation)						
n	35	87	122	61	99	160
Mean (SD)	170.0 (292.2)	245.7 (506.6)	224.0 (455.6)	216.9 (243.1)	188.6 (316.4)	199.4 (290.2)
Median (IQR)	110 (60.0 to 270.0)	120 (60.0 to 300.0)	120 (60.0 to 275.0)	120 (90.0 to 255.0)	110 (45.0 to 225.0)	120 (60.0 to 237.5)
SF-12v2 plus 4 (PCS)						
n	32	85	117	58	95	153
Mean (SD)	43.9 (13.6)	45.0 (11.4)	44.7 (12.0)	48.4 (9.3)	47.3 (9.8)	47.7 (9.6)
Median (IQR)	51.4 (32.1 to 54.2)	48.0 (37.3 to 53.6)	48.7 (35.8 to 53.9)	52.0 (42.0 to 54.8)	49.9 (42.8 to 54.3)	50.7 (42.6 to 54.5)
SF-12v2 plus 4 (MCS)						
n	32	85	117	58	95	153
Mean (SD)	48.1 (11.1)	48.3 (10.5)	48.3 (10.6)	47.7 (9.8)	50.0 (8.7)	49.1 (9.2)
Median (IQR)	51.2 (43.1 to 55.5)	49.8 (41.2 to 56.2)	49.9 (41.2 to 56.2)	50.1 (41.1 to 54.9)	51.2 (44.2 to 57.1)	51.0 (43.2 to 56.3)
BREQ-2 (RAI)						
n	34	85	119	59	96	155
Mean (SD)	5.0 (3.9)	4.8 (3.9)	4.8 (3.9)	5.6 (3.6)	5.6 (3.6)	5.6 (3.6)
Median (IQR)	5.5 (2.5 to 7.4)	5.5 (2.0 to 7.8)	5.5 (2.2 to 7.8)	6.1 (3.4 to 8.0)	6.4 (3.7 to 8.3)	6.3 (3.5 to 8.3)
Gender						
n	35	87	122	61	99	160
Male, *n* (%)	11 (31.4)	51 (58.6)	62 (50.8)	26 (42.6)	42 (42.4)	68 (42.5)
Female, *n* (%)	24 (68.6)	36 (41.4)	60 (49.2)	35 (57.4)	57 (57.6)	92 (57.5)
Ethnicity, *n* (%)						
White British	29 (82.9)	74 (85.1)	103 (84.4)	54 (88.5)	89 (89.9)	143 (89.4)
Other	6 (17.1)	12 (13.8)	18 (14.8)	7 (11.5)	8 (8.1)	15 (9.4)
Missing	0 (0.0)	1 (1.1)	1 (0.8	0 (0.0)	2 (2.0)	2 (1.3)
Employment status, *n* (%)						
Part-time	4 (11.4)	15 (17.2)	19 (15.6)	14 (23.0)	19 (19.2)	33 (20.6)
Full-time	14 (40.0)	34 (39.1)	48 (39.3)	20 (32.8)	25 (25.3)	45 (28.1)
Not employed	17 (48.6)	35 (40.2)	52 (42.6)	27 (44.3)	55 (55.6)	82 (51.2)
Missing	0 (0.0)	3 (3.4)	3 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)

Note: completers and non-completers are those with and without evaluable data at 3 months for any reason respectively.

TABLE 20 Exploratory analysis of the risk factors (categorical) associated with completing evaluable data at 3 months

Variable	Completers (*n* = 160), *n* (%)	Non-completers (*n* = 122), *n* (%)	OR (95% CI)[a]	*p*-value	Interaction	
					OR (95% CI)[b]	*p*-value
Gender						
Female	92 (57.5)	60 (49.2)	1.40 (0.87 to 2.24)	0.165	0.3 (0.1 to 0.9)	0.034
Male	68 (42.5)	62 (50.8)	1.00			
Treatment group						
Booster	99 (61.9)	87 (71.3)	0.65 (0.39 to 1.08)	0.098		
Control	61 (38.1)	35 (28.7)	1.00		NA	
Treatment group						
Full	52 (33)	42 (34)	0.71 (0.40 to 1.27)	0.249		
Mini	47 (29)	45 (37)	0.60 (0.33 to 1.07)	0.085	NA	
Control	61 (38)	25 (27)	1.00			
Employment status						
Yes	78 (48.8)	70 (57.4)	0.71 (0.44 to 1.14)	0.151	0.5 (0.2 to 1.3)	0.127
No	82 (51.3)	52 (42.3)	1.00			
Ethnicity[c]						
n	158	121				
White British	143 (90.5)	103 (85.1)	1.67 (0.80 to 3.46)	0.171	NA	
Any other	15 (9.5)	18 (14.9)	1.00			

NA, not applicable.

a The odds of completing a 3-months assessment with evaluable data compared with not completing a 3-months assessment with evaluable data for any other reasons using logistic regression.

b Interaction effect between treatment (booster and control) and completers group (completer or non-completer) using logistic regression.

c Excludes three participants with missing ethnicity data at baseline (no interaction test because of small sample within subgroups).

TABLE 21 Exploratory analysis of the risk factors (continuous) associated with completing evaluable data at 3 months

	Non-completers		Completers				Interaction	
Variable	*n*	Mean (SD)	*n*	Mean (SD)	Mean difference (95% CI)[a]	*p*-value[a]	Effect (95% CI)[b]	*p*-value[b]
Age (years)	122	54.6 (7.2)	160	55.3 (7.4)	0.7 (–1.0 to 2.4)	0.426	2.1 (–1.6 to 5.8)	0.267
BMI (kg/m^2)	121	31.5 (6.4)	160	29.4 (5.4)	–2.0 (–3.4 to –0.6)	0.005	1.5 (–1.5 to 4.5)	0.320
Weight (kg)	122	89.4 (20.1)	160	82.0 (16.9)	–7.4 (–11.7 to –3.1)	0.001	0.5 (–8.9 to 9.8)	0.924
SF-12v2 plus 4 (PCS)	117	44.7 (12.0)	153	47.7 (9.6)	3.1 (0.5 to 5.7)	0.019	–2.2 (–7.8 to 3.5)	0.452
SF-12v2 plus 4 (MCS)	117	48.3 (10.6)	153	49.1 (9.2)	0.8 (–1.6 to 3.2)	0.508	2.1 (–3.1 to 7.2)	0.430
Height (m)	121	1.7 (0.1)	160	1.7 (0.1)	–0.0 (–0.0 to 0.0)	1.000	–0.0 (–0.1 to 0.0)	0.080
SPAQ change[c]	122	199.8 (261.6)	160	215.3 (416.1)	–15.5 (–95.3 to 64.3)	0.703	–104.0 (–292.6 to 84.6)	0.279
BREQ-2 (RAI)	119	4.8 (3.9)	155	5.6 (3.6)	0.8 (–0.1 to 1.7)	0.077	0.2 (–1.7 to 2.1)	0.843

a Using a two independent sample *t*-test.
b Interaction effect between treatment (control or booster) and completers group (completer or non-completer) using logistic regression.
c Using independent two-sample *t*-test with unequal variances.

TABLE 22 Difference in mean TEE per day between the booster intervention group (mini plus full) and the control group at 3 months ($n = 160$)

Outcome	Control ($n = 61$), mean (SD)	Booster ($n = 99$), mean (SD)	Mean difference (95% CI)[a]	*p*-value[a]	Adjusted mean difference (95% CI)[b]	*p*-value[c]
Mean TEE per day (kcal)	2265.9 (410.8)	2226.9 (422.6)	–39.0 (–173.4 to 95.4)	0.567	–40.3 (–117.2 to 36.6)	0.302

a Using a two independent sample *t*-test.
b Adjusted for age, gender, BMI, total minutes of physical activity at 3 months and 1 week before randomisation, and HRQoL (SF-12v2 plus 4 total score).
c Using multiple regression.
Note: a negative mean difference favours the control over the booster interventions and indicates decreased physical activity in the booster intervention group compared with the control group.

TABLE 23 Sensitivity analysis: difference in mean TEE per day between the booster intervention group (mini plus full) and the control group at 3 months

Mean TEE per day (kcal)	Control, mean (SD)	Booster, mean (SD)	Mean difference (95% CI)[a]	*p*-value[a]	Adjusted mean difference (95% CI)[b]	*p*-value[c]
Multiple imputation (≥ 4 days)	($n = 61$)	($n = 99$)				
	2252.3 (393.6)	2215.1 (366.0)	–37.2 (–174.9 to 100.6)	0.595	–34.5 (–118.1 to 49.0)	0.415
Regression imputation (≥ 4 days)	($n = 58$)	($n = 95$)				
	2263.1 (398.6)	2245.2 (409.4)	–18.0 (–151.5 to 115.5)	0.790	–27.0 (–97.3 to 43.3)	0.449
Complete cases (7 complete days)	($n = 44$)	($n = 68$)				
	2241.7 (393.6)	2222.5 (366.0)	–19.2 (–163.8 to 125.4)	0.793	–31.2 (–114.3 to 51.9)	0.458
Per protocol[d]	($n = 61$)	($n = 96$)				
	2265.9 (410.8)	2231.3 (426.6)	–34.6 (–170.6 to 101.4)	0.616	–35.6 (–112.5 to 41.3)	0.362
Multiple imputation (≥ 1 day)	($n = 70$)	($n = 113$)				
	2194.0 (393.6)	2215.3 (366.0)	21.3 (–133.1 to 175.7)	0.786	9.9 (–111.3 to 131.1)	0.872
Mean TEE per day (kcal)[e]	($n = 61$)	($n = 98$)				
	2265.9 (410.8)	2211.4 (395.5)	–54.5 (–183.8 to 74.8)	0.406	–43.6 (–119.9 to 32.7)	0.260

a Using a two independent sample *t*-test.
b Adjusted for age, gender, BMI, total minutes of physical activity at 3 months and 1 week before randomisation, and HRQoL (SF-12v2 plus 4 total score).
c Using multiple regression.
d 'Per protocol' defined as received intended intervention at 1 and 2 months post brief intervention.
e Excluding an outlier (only for sensitivity analysis).
Note: a positive mean difference favours the booster interventions over the control and indicates increased physical activity in the booster intervention group compared with the control group.

TABLE 24 Difference in mean TEE per day between the full booster intervention group and the control group at 3 months

Outcome	Control ($n = 61$), mean (SD)	Full booster ($n = 52$), mean (SD)	Mean difference (95% CI)[a]	*p*-value[a]	Adjusted mean difference (95% CI)[b]	*p*-value[c]
Mean TEE per day (kcal)	2265.9 (410.8)	2279.9 (425.6)	14.0 (–142.2 to 170.2)	0.859	–6.7 (–96.6 to 83.2)	0.883

a Using a two independent sample *t*-test.
b Adjusted for age, gender, BMI, total minutes of physical activity at 3 months and 1 week before randomisation, and HRQoL (SF-12v2 plus 4 total score).
c Using multiple regression.
Note: a positive mean difference favours the full booster intervention over the control and indicates increased physical activity in the full booster intervention group compared with the control group.

TABLE 25 Difference in mean TEE per day between the mini booster intervention group and the control group at 3 months

Outcome	Control ($n = 61$), mean (SD)	Mini booster ($n = 47$), mean (SD)	Mean difference (95% CI)[a]	*p*-value[a]	Adjusted mean difference (95% CI)[b]	*p*-value[c]
Mean TEE per day (kcal)	2265.9 (410.8)	2168.2 (415.8)	–97.7 (–256.6 to 61.2)	0.226	–69.6 (–165.4 to 26.2)	0.153

a Using a two independent sample *t*-test.
b Adjusted for age, gender, BMI, total minutes of physical activity at 3 months and 1 week before randomisation, and HRQoL (SF-12v2 plus 4 total score).
c Using multiple regression.
Note: a negative mean difference favours the control over the mini booster intervention and indicates decreased physical activity in the mini booster intervention group compared with the control group.

TABLE 26 Subgroup evaluation: difference in mean TEE per day between the mini booster intervention group and the full booster intervention group at 3 months

Outcome	Mini booster, mean (SD)	Full booster, mean (SD)	Mean difference (95% CI)[a]	*p*-value[a]	Adjusted mean difference (95% CI)[b]	*p*-value[c]
Mean TEE per day (kcal)	(*n* = 47)	(*n* = 52)				
	2168.2 (415.8)	2279.9 (425.6)	111.7 (–56.5 to 279.9)	0.190	55.5 (–38.2 to 149.2)	0.242
Mean TEE per day (kcal)[d]	(*n* = 47)	(*n* = 51)				
	2168.2 (415.8)	2251.2 (375.6)	82.9 (–75.8 to 241.6)	0.302	47.0 (–45.2 to 139.2)	0.314

a Using a two independent sample *t*-test.
b Adjusted for age, gender, BMI, total minutes of physical activity at 3 months and 1 week before randomisation, and HRQoL (SF-12v2 plus 4 total score).
c Using multiple regression.
d Sensitivity analysis excluding an outlying participant.
Note: a positive mean difference favours the full booster intervention over the mini booster intervention and indicates increased physical activity in the full booster intervention group compared with the mini booster intervention group.

TABLE 27 Difference in mean TEE per day between the booster intervention group (mini plus full) and the control group at 9 months

Outcome	Control, mean (SD)	Booster, mean (SD)	Mean difference (95% CI)[a]	*p*-value[a]	Adjusted mean difference (95% CI)[b]	*p*-value[c]
Mean TEE per day (kcal)	(*n* = 36)	(*n* = 55)				
	2177.2 (390.7)	2308.2 (646.3)	131.0 (–107.5 to 369.5)	0.278	51.5 (–137.2 to 240.2)	0.589
Mean TEE per day (kcal)[d]	(*n* = 36)	(*n* = 54)				
	2177.2 (390.7)	2239.1 (397.1)	61.9 (–106.8 to 230.6)	0.468	–7.1 (–115.8 to 101.6)	0.897

a Using a two independent sample *t*-test.
b Adjusted for age, gender, BMI, total minutes of physical activity at 3 months and 1 week before randomisation, and HRQoL (SF-12v2 plus 4 total score).
c Using multiple regression.
d Sensitivity analysis excluding one participant with extreme mean TEE per day of 6041.6 kcal (see *Figure 16*) (data were queried but record assumed to be correct).
Note: a positive mean difference favours the booster interventions over the control and indicates increased physical activity in the booster intervention group compared with the control group.

TABLE 28 Sensitivity analysis: difference in mean TEE per day between the booster intervention group (mini plus full) and the control group at 9 months

Mean TEE per day (kcal)	Control, mean (SD)	Booster, mean (SD)	Mean difference (95% CI)[a]	*p*-value[a]	Adjusted mean difference (95% CI)[b]	*p*-value[c]
Multiple imputation (≥ 4 days)	(*n* = 36)	(*n* = 55)				
	2163.0 (298.9)	2235.2 (395.5)	72.3 (–101.8 to 246.3)	0.411	18.1 (–102.9 to 139.1)	0.766
Regression imputation (≥ 4 days)	(*n* = 34)	(*n* = 52)				
	2202.0 (371.3)	2281.7 (379.8)	79.6 (–85.5 to 244.7)	0.341	13.9 (–80.1 to 107.9)	0.769
Complete cases	(*n* = 21)	(*n* = 39)				
	2118.1 (298.9)	2315.5 (726.2)	197.5 (–134.8 to 529.8)	0.239	118.6 (–152.7 to 389.9)	0.384
Complete cases[d]	(*n* = 21)	(*n* = 38)				
	2118.1 (298.9)	2217.5 (395.5)	99.4 (–99.1 to 297.9)	0.320	31.7 (–88.7 to 152.1)	0.599
Multiple imputation (≥ 1 days)	(*n* = 37)	(*n* = 61)				
	2168.4 (298.9)	2215.9 (395.5)	47.5 (–122.5 to 217.5)	0.581	14.5 (–105.6 to 134.6)	0.811
Per protocol	(*n* = 36)	(*n* = 55)				
	2177.2 (390.7)	2308.2 (646.3)	131.0 (–107.5 to 369.5)	0.278	51.5 (–137.2 to 240.2)	0.589
Per protocol[d]	(*n* = 36)	(*n* = 54)				
	2177.2 (390.7)	2239.1 (397.1)	61.9 (–106.8 to 230.6)	0.468	–7.1 (–115.8 to 101.6)	0.897

a Using a two independent sample *t*-test.
b Adjusted for age, gender, BMI, total minutes of physical activity at 3 months and 1 week before randomisation, and HRQoL (SF-12v2 plus 4 total score).
c Using multiple regression.
d Sensitivity analysis excluding one participant with extreme mean TEE per day of 6041.6 kcal (see *Figure 16*) (data were queried but record assumed to be correct).
Note: a positive mean difference favours the booster interventions over the control and indicates increased physical activity in the booster intervention group compared with the control group.

TABLE 29 Subgroup evaluation: difference in mean TEE per day between the mini booster intervention group and the full booster intervention group at 9 months

Outcome	Mini booster, mean (SD)	Full booster, mean (SD)	Mean difference (95% CI)[a]	*p*-value[a]	Adjusted mean difference (95% CI)[b]	*p*-value[c]
Mean TEE per day (kcal)	(*n* = 25)	(*n* = 30)				
	2204.0 (415.9)	2395.1 (785.7)	191.1 (–159.3 to 541.5)	0.279	100.9 (–203.8 to 405.6)	0.508
Mean TEE per day (kcal)[d]	(*n* = 25)	(*n* = 29)				
	2204.0 (415.9)	2269.4 (384.9)	65.4 (–153.4 to 284.2)	0.551	–9.3 (–175.2 to 156.6)	0.911

a Using a two independent sample *t*-test.
b Adjusted for age, gender, BMI, total minutes of physical activity at 3 months and 1 week before randomisation, and HRQoL (SF-12v2 plus 4 total score).
c Using multiple regression.
d Sensitivity analysis excluding one participant with extreme mean TEE per day of 6041.6 kcal (see *Figure 16*) (data were queried but record assumed to be correct).
Note: a positive mean difference favours the full booster intervention over the mini booster intervention and indicates increased physical activity in the full booster intervention group compared with the mini booster intervention group.

TABLE 30 Difference in PACs per week between the booster intervention group (mini plus full) and the control group at 3 months

Outcome	Control, mean (SD)	Booster, mean (SD)	Mean difference (95% CI)[a]	*p*-value[a]	Adjusted mean difference (95% CI)[b]	*p*-value[c]
PACs per week (×1000)	(*n* = 61)	(*n* = 99)				
	339.0 (146.0)	331.7 (169.4)	–7.2 (–59.0 to 44.5)	0.783	0.4 (–49.9 to 50.6)	0.988
PACs per week (×1000)[d]	(*n* = 61)	(*n* = 98)				
	339.0 (146.0)	324.4 (154.0)	–14.5 (–63.1 to 34.1)	0.556	–7.1 (–53.3 to 39.2)	0.763

a Using a two independent sample *t*-test.
b Adjusted for age, gender, BMI, total minutes of physical activity at 3 months and 1 week before randomisation, and HRQoL (SF-12v2 plus 4 total score).
c Using multiple regression.
d Sensitivity analysis excluding one participant with extreme PACs per week.
Note: a positive mean difference favours the booster interventions over the control and indicates increased physical activity in the booster intervention group compared with the control group; a negative difference favours the control over the booster interventions.

TABLE 31 Sensitivity analysis: difference in PACs per week between the booster intervention group (mini plus full) and the control group at 3 months

PACs per week (×1000)	Control, mean (SD)	Booster, mean (SD)	Mean difference (95% CI)[a]	*p*-value[a]	Adjusted mean difference (95% CI)[b]	*p*-value[c]
Multiple imputation (≥ 4 days)	(*n* = 61)	(*n* = 99)				
	379.4 (135.0)	368.5 (155.6)	–10.9 (–77.6 to 55.8)	0.747	–2.7 (–67.1 to 61.8)	0.935
Regression imputation (≥ 4 days)	(*n* = 58)	(*n* = 95)				
	332.5 (133.8)	328.1 (157.1)	–4.4 (–53.4 to 44.6)	0.859	–1.6 (–48.0 to 44.9)	0.946
Complete cases (7 complete days)	(*n* = 44)	(*n* = 68)				
	325.1 (134.9)	322.6 (155.6)	–2.6 (–59.3 to 54.1)	0.929	–12.3 (–65.1 to 40.4)	0.644
Per protocol	(*n* = 61)	(*n* = 96)				
	339.0 (146.0)	335.6 (170.5)	–3.3 (–55.6 to 48.9)	0.900	2.9 (–47.8 to 53.6)	0.910
Per protocol[d]	(*n* = 61)	(*n* = 95)				
	339.0 (146.0)	328.2 (154.9)	–10.8 (–59.9 to 38.3)	0.665	–4.9 (–51.6 to 41.8)	0.836

a Using a two independent sample *t*-test.
b Adjusted for age, gender, BMI, total minutes of physical activity at 3 months and 1 week before randomisation, and HRQoL (SF-12v2 plus 4 total score).
c Using multiple regression.
d Sensitivity analysis excluding one participant with extreme PACs per week.
Note: a positive mean difference favours the booster interventions over the control and indicates increased physical activity in the booster intervention group compared with the control group.

TABLE 32 Difference in PACs per week between the booster intervention group (mini plus full) and the control group at 9 months

Outcome	Control, mean (SD)	Booster, mean (SD)	Mean difference (95% CI)[a]	*p*-value[a]	Adjusted mean difference (95% CI)[b]	*p*-value[c]
PACs per week (×1000)	(*n* = 36)	(*n* = 55)				
	319.0 (158.9)	315.4 (202.1)	–3.6 (–83.0 to 75.7)	0.928	–14.5 (–90.8 to 61.7)	0.705
PACs per week (×1000)[d]	(*n* = 36)	(*n* = 54)				
	319.0 (158.9)	302.5 (179.6)	–16.6 (–90.0 to 56.8)	0.655	–29.4 (–100.0 to 41.4)	0.411

a Using a two independent sample *t*-test.
b Adjusted for age, gender, BMI, total minutes of physical activity at 3 months and 1 week before randomisation, and HRQoL (SF-12v2 plus 4 total score).
c Using multiple regression.
d Sensitivity analysis excluding one participant with extreme PACs per week.
Note: a positive mean difference favours the booster interventions over the control and indicates increased physical activity in the booster intervention group compared with the control group.

TABLE 33 Sensitivity analysis: difference in PACs per week between the booster intervention group (mini plus full) and the control group at 9 months

PACs per week (×1000)	Control, mean (SD)	Booster, mean (SD)	Mean difference (95% CI)[a]	*p*-value[a]	Adjusted mean difference (95% CI)[b]	*p*-value[c]
Multiple imputation (≥ 4 days)	(*n* = 36)	(*n* = 55)				
	351.2 (102.0)	353.2 (176.0)	19.8 (–120.0 to 123.8)	0.974	–1.3 (–120.0 to 117.5)	0.982
Regression imputation (≥ 4 days)	(*n* = 34)	(*n* = 52)				
	323.0 (151.6)	319.8 (188.2)	–3.3 (–79.9 to 73.4)	0.933	–13.5 (–83.3 to 56.3)	0.702
Complete cases (7 complete days)	(*n* = 21)	(*n* = 39)				
	299.4 (102.0)	295.0 (176.0)	–4.4 (–88.1 to 79.3)	0.916	–15.2 (–110.0 to 74.9)	0.735
Complete cases (7 complete days)[d]	(*n* = 21)	(*n* = 37)				
	299.4 (102.0)	265.8 (123.7)	–33.7 (–97.4 to 30.0)	0.294	–37.3 (–110.0 to 31.6)	0.282
Per protocol	(*n* = 36)	(*n* = 55)				
	319.0 (158.9)	315.4 (202.1)	–3.6 (–83.0 to 75.7)	0.928	–14.5 (–90.8 to 61.7)	0.705
Per protocol[d]	(*n* = 36)	(*n* = 54)				
	319.0 (158.9)	302.5 (179.6)	–16.6 (–90.0 to 56.8)	0.655	–29.4 (–100.0 to 41.4)	0.411

a Using a two independent sample *t*-test.
b Adjusted for age, gender, BMI, total minutes of physical activity at 3 months and 1 week before randomisation, and HRQoL (SF-12v2 plus 4 total score).
c Using multiple regression.
d Sensitivity analysis excluding one participant with extreme PACs per week.
Note: a positive mean difference favours the booster interventions over the control and indicates increased physical activity in the booster intervention group compared with the control group.

TABLE 34 Difference in SF-12v2 plus 4 dimension scores between the booster intervention group (mini plus full) and the control group at 3 and 9 months (ITT set)

		Control		Booster					
Follow-up (months)	Outcome	*n*	Mean (SD)	*n*	Mean (SD)	Mean difference (95% CI)[a]	*p*-value[a]	Adjusted mean difference (95% CI)[b]	*p*-value[c]
3	PCS score	57	49.3 (8.9)	89	48.8 (9.9)	0.7 (–1.4 to 2.7)	0.509	0.9 (–1.2 to 2.9)	0.394
	MCS score	57	47.2 (9.5)	89	49.5 (9.1)	0.8 (–1.5 to 3.1)	0.499	0.8 (–1.6 to 3.1)	0.525
	SF-6D utility score	56	0.644 (0.064)	88	0.648 (0.070)	0.002 (–0.017 to 0.021)	0.826	0.005 (–0.014 to 0.024)	0.623
9	PCS score	38	46.1 (9.4)	62	48.3 (10.4)	1.8 (–1.2 to 4.7)	0.244	1.7 (–1.2 to 4.6)	0.260
	MCS score	38	48.3 (10.4)	62	52.3 (8.7)	2.0 (–0.7 to 4.8)	0.149	1.7 (–1.1 to 4.5)	0.237
	SF-6D utility score	38	0.651 (0.083)	62	0.665 (0.080)	–0.000 (–0.028 to 0.028)	0.989	0.001 (–0.027 to 0.030)	0.921

a Adjusted for baseline using the ANCOVA model.
b Adjusted for age, gender, BMI, total minutes of physical activity at –3 months and –1 week before randomisation, HRQoL (SF-12v2 plus 4 total score) and baseline outcome measurement.
c Using multiple regression.
Note: higher PCS and MCS scores indicate a better physical and mental health status respectively; higher SF-6D utility scores indicate a better health status; a positive mean difference indicates improved health status in favour of the booster intervention.

TABLE 35 Difference in SF-12v2 plus 4 dimension scores between the booster intervention group (mini plus full) and the control group at 3 and 9 months (for all available data)

Follow-up (months)	Outcome	Control		Booster		Mean difference (95% CI)[a]	*p*-value[a]	Adjusted mean difference (95% CI)[b]	*p*-value[c]
		n	Mean (SD)	*n*	Mean (SD)				
3	PCS score	70	48.6 (9.7)	118	48.8 (9.6)	0.7 (–1.1 to 2.5)	0.449	0.8 (–0.9 to 2.6)	0.354
	MCS score	70	47.9 (9.4)	118	48.8 (10.2)	–0.2 (–2.4 to 2.0)	0.849	–0.3 (–2.6 to 1.9)	0.770
	SF-6D utility score	71	0.645 (0.071)	117	0.649 (0.075)	–0.001 (–0.017 to 0.016)	0.920	0.001 (–0.016 to 0.018)	0.934
9	PCS score	46	46.2 (9.0)	81	48.6 (10.1)	2.2 (–0.5 to 4.9)	0.102	1.8 (–0.9 to 4.5)	0.191
	MCS score	46	49.1 (10.2)	81	50.4 (9.3)	–0.2 (–3.0 to 2.6)	0.892	–0.4 (–3.3 to 2.6)	0.804
	SF-6D utility score	47	0.651 (0.083)	81	0.655 (0.077)	–0.004 (–0.028 to 0.021)	0.755	–0.005 (–0.030 to 0.020)	0.709

a Adjusted for baseline using the ANCOVA model.
b Adjusted for age, gender, BMI, total minutes of physical activity at 3 months and 1 week before randomisation, HRQoL (SF-12v2 plus 4 total score) and baseline outcome measurement.
c Using multiple regression.
Note: higher PCS and MCS scores indicate a better physical and mental health status respectively; higher SF-6D utility scores indicate a better health status; a positive mean difference indicates improved health status in favour of the booster intervention.

TABLE 36 Difference in the average number of minutes spent on type of activity per day (over a week) between the booster intervention group (mini plus full) and the control group at 3 months based on an objective measure (ITT set; $n = 160$)

Outcome	Control ($n = 61$), mean (SD)	Booster ($n = 99$), mean (SD)	Mean difference (95% CI)[a]	*p*-value[a]	Adjusted mean difference (95% CI)[b]	*p*-value[c]
At least moderate activity (minutes)	48.4 (42.9)	46.8 (39.6)	–1.6 (–14.7 to 11.5)	0.810	–1.9 (–15.1 to 11.3)	0.776
Moderate activity (minutes)	47.1 (42.1)	44.7 (37.9)	–2.3 (–15.0 to 10.4)	0.721	–2.4 (–15.1 to 10.3)	0.710
Vigorous activity (minutes)	1.3 (2.4)	2.0 (4.2)	0.7 (–0.5 to 1.9)	0.236	0.5 (–0.7 to 1.7)	0.409

a Using a two independent sample *t*-test.
b Adjusted for age, gender, BMI, total minutes of physical activity at –3 months and -1 week prior to randomisation, and HRQoL (SF12v2 plus 4 total score).
c Using multiple regression.
Note: at least moderate, moderate and vigorous activity were defined as having at least 3 METs, 3–6 METs and > 6 METs respectively.

TABLE 37 Difference in the average number of minutes spent on type of activity per day (over a week) between the booster intervention group (mini plus full) and the control group at 9 months based on an objective measure (ITT set; *n* = 91)

Outcome	Control, mean (SD)	Booster, mean (SD)	Mean difference (95% CI)[a]	*p*-value[a]	Adjusted mean difference (95% CI)[b]	*p*-value[c]
Main analysis	(*n* = 36)	(*n* = 55)				
At least moderate activity (minutes)	36.6 (22.7)	50.8 (71.9)	14.2 (–10.4 to 38.8)	0.255	17.0 (–7.9 to 41.9)	0.177
Moderate activity (minutes)	35.7 (22.2)	44.9 (47.9)	9.1 (–7.9 to 26.1)	0.289	11.8 (–5.1 to 28.7)	0.168
Vigorous activity (minutes)	0.9 (2.2)	6.0 (29.0)	5.1 (–4.6 to 14.8)	0.297	5.2 (–4.8 to 15.2)	0.306
Sensitivity analysis[d]	(*n* = 36)	(*n* =54)				
At least moderate activity (minutes)	36.6 (22.7)	42.5 (36.7)	5.8 (–7.8 to 19.4)	0.400	8.9 (–5.0 to 22.8)	0.208
Moderate activity (minutes)	35.7 (22.2)	40.3 (34.6)	4.6 (–8.3 to 17.5)	0.482	7.6 (–5.5 to 20.7)	0.252
Vigorous activity (minutes)	0.9 (2.2)	2.1 (4.7)	1.2 (–0.5 to 2.9)	0.159	1.3 (–0.5 to 3.1)	0.150

a Using a two independent sample *t*-test.
b Adjusted for age, gender, BMI, total minutes of physical activity at 3 months and 1 week before randomisation, and HRQoL (SF-12v2 plus 4 total score).
c Using multiple regression.
d Sensitivity analysis excluding a participant with an extreme value.
Note: at least moderate, moderate and vigorous activity were defined as having at least 3 METs, 3–6 METs and > 6 METs respectively.

TABLE 38 Difference in the proportions of participants who maintained or increased physical activity at 3 and 9 months from baseline [based on self-reported measure of physical activity (SPAQ) for ITT participants]

Follow-up (months)	Outcome	Control, *n* (%)	Booster, *n* (%)	Difference in proportion maintaining or increasing physical activity (95% CI) (%)[a]	*p*-value[a]
3	Maintained or increased physical activity	(*n* = 60)	(*n* = 96)		
		30 (50.0)	55 (57.3)	7.3 (–8.8 to 23.3)	0.374
9	Maintained or increased physical activity	(*n* = 44)	(*n* = 66)		
		23 (52.3)	41 (62.1)	9.8 (–9.0 to 28.7)	0.305

a Based on a two independent sample proportion test with continuity correction.
Note: a positive difference in proportion indicates increased self-reported physical activity in the booster intervention group compared with the control group.

TABLE 39 Difference in the proportions of participants who maintained or increased physical activity at 3 and 9 months from baseline [based on self-reported measure of physical activity (SPAQ) for all participants]

Follow-up (months)	Outcome	Control, *n* (%)	Booster, *n* (%)	Difference in proportion maintaining or increasing physical activity (95% CI) (%)[a]	*p*-value[a]
3	Maintained or increased activity	(*n* = 76)	(*n* = 125)		
		41 (53.9)	71 (56.8)	2.9 (–11.0 to 17.1)	0.693
9	Maintained or increased activity	(*n* = 54)	(*n* = 85)		
		25 (46.3)	49 (57.6)	11.4 (–5.6 to 28.3)	0.191

a Based on a two independent sample proportion test with continuity correction.
Note: a positive difference in proportion indicates increased self-reported physical activity in the booster intervention group compared with the control group.

TABLE 40 Differences in change in the BREQ-2 multidimensions between the booster intervention group (mini plus full) and the control group at 3 months (all available data)

	Control		Booster					
Outcome	*n*	Mean (SD)	*n*	Mean (SD)	Mean difference (95% CI)[a]	*p*-value[b]	Adjusted mean difference (95% CI)[c]	*p*-value[d]
Amotivation	75	0.3 (0.5)	123	0.2 (0.5)	–0.0 (–0.2 to 0.1)	0.515	–0.0 (–0.2 to 0.1)	0.762
External regulation	75	0.3 (0.5)	123	0.4 (0.6)	0.1 (–0.1 to 0.2)	0.406	0.1 (–0.1 to 0.2)	0.408
Introjected regulation	76	1.1 (1.0)	123	1.4 (1.2)	0.3 (0.1 to 0.6)	0.018	0.3 (–0.0 to 0.6)	0.053
Identified regulation	75	2.9 (0.7)	123	3.0 (0.6)	0.2 (0.0 to 0.3)	0.047	0.1 (–0.0 to 0.3)	0.092
Intrinsic regulation	73	2.8 (1.0)	120	2.9 (1.0)	0.2 (–0.0 to 0.4)	0.077	0.2 (–0.0 to 0.4)	0.103
RAI	73	6.2 (3.4)	120	6.2 (3.3)	0.3 (–0.5 to 1.0)	0.478	0.2 (–0.5 to 0.9)	0.606

a Adjusted for baseline.
b Using the ANCOVA model.
c Adjusted for age, gender, BMI, total minutes of physical activity at 3 months and 1 week before randomisation, HRQoL (SF-12v2 plus 4 total score) and baseline outcome measurement.
d Using multiple regression.
Note: a higher RAI score indicates higher self-determination and a positive mean difference favours the booster interventions over the control.

TABLE 41 Differences in change in the BREQ 2 multidimensions between the booster intervention group (mini plus full) and the control group at 9 months (all available data)

Outcome	Control		Booster		Mean difference (95% CI)[a]	*p*-value[b]	Adjusted mean difference (95% CI)[c]	*p*-value[d]
	n	Mean (SD)	*n*	Mean (SD)				
Amotivation	54	0.3 (0.6)	84	0.2 (0.5)	−0.0 (−0.2 to 0.1)	0.751	−0.0 (−0.2 to 0.1)	0.785
External regulation	54	0.3 (0.6)	84	0.3 (0.5)	0.0 (−0.2 to 0.2)	0.895	0.0 (−0.2 to 0.2)	0.939
Introjected regulation	54	1.2 (1.1)	84	1.4 (1.1)	0.1 (−0.2 to 0.4)	0.479	0.1 (−0.2 to 0.4)	0.657
Identified regulation	55	2.9 (0.7)	84	3.0 (0.6)	0.1 (−0.1 to 0.3)	0.412	0.1 (−0.1 to 0.3)	0.515
Intrinsic regulation	54	2.8 (1.1)	81	2.8 (1.0)	0.2 (−0.1 to 0.4)	0.239	0.2 (−0.1 to 0.4)	0.210
RAI	53	6.0 (3.8)	81	6.1 (3.5)	0.2 (−0.8 to 1.2)	0.711	0.2 (−0.8 to 1.3)	0.649

a Adjusted for baseline.
b Using the ANCOVA model.
c Adjusted for age, gender, BMI, total minutes of physical activity at 3 months and 1 week before randomisation, HRQoL (SF-12v2 plus 4 total score) and baseline outcome measurement.
d Using multiple regression.
Note: a higher RAI score indicates higher self-determination and a positive mean difference favours the booster interventions over the control.

TABLE 42 Differences in change in the BREQ-2 multidimensions between the booster intervention group (mini plus full) and the control group at 3 months (ITT set)

Outcome	Control		Booster		Mean difference (95% CI)[a]	*p*-value[b]	Adjusted mean difference (95% CI)[c]	*p*-value[d]
	n	Mean (SD)	*n*	Mean (SD)				
Amotivation	59	0.3 (0.5)	95	0.2 (0.5)	−0.1 (−0.2 to 0.1)	0.510	−0.0 (−0.2 to 0.1)	0.735
External regulation	59	0.3 (0.5)	95	0.4 (0.6)	0.0 (−0.1 to 0.2)	0.514	0.0 (−0.1 to 0.2)	0.565
Introjected regulation	60	1.1 (1.1)	95	1.4 (1.2)	0.2 (−0.1 to 0.5)	0.175	0.1 (−0.2 to 0.5)	0.434
Identified regulation	59	2.9 (0.8)	95	3.1 (0.6)	0.2 (0.1 to 0.4)	0.011	0.2 (0.0 to 0.4)	0.020
Intrinsic regulation	57	2.8 (1.0)	92	3.0 (0.9)	0.3 (0.0 to 0.5)	0.028	0.2 (0.0 to 0.5)	0.049
RAI	57	5.8 (3.4)	92	6.4 (3.4)	0.6 (−0.3 to 1.5)	0.168	0.6 (−0.3 to 1.4)	0.192

a Adjusted for baseline.
b Using the ANCOVA model.
c Adjusted for age, gender, BMI, total minutes of physical activity at 3 months and 1 week before randomisation, HRQoL (SF-12v2 plus 4 total score) and baseline outcome measurement.
d Using multiple regression.
Note: a higher RAI score indicates higher self-determination and a positive mean difference favours the booster interventions over the control.

TABLE 43 Differences in change in the BREQ-2 multidimensions between the booster intervention group (mini plus full) and the control group at 9 months (ITT set)

Outcome	Control		Booster		Mean difference (95% CI)[a]	*p*-value[b]	Adjusted mean difference (95% CI)[c]	*p*-value[d]
	n	Mean (SD)	*n*	Mean (SD)				
Amotivation	44	0.3 (0.6)	65	0.2 (0.3)	–0.1 (–0.2 to 0.1)	0.386	–0.1 (–0.2 to 0.1)	0.454
External regulation	44	0.3 (0.6)	65	0.2 (0.4)	–0.1 (–0.2 to 0.1)	0.328	–0.1 (–0.3 to 0.1)	0.340
Introjected regulation	44	1.3 (1.1)	65	1.4 (1.1)	–0.0 (–0.4 to 0.3)	0.894	–0.1 (–0.4 to 0.2)	0.527
Identified regulation	44	2.9 (0.7)	65	3.0 (0.6)	0.1 (–0.1 to 0.3)	0.483	0.1 (–0.2 to 0.3)	0.558
Intrinsic regulation	43	2.8 (1.1)	62	3.0 (0.9)	0.2 (–0.0 to 0.5)	0.072	0.3 (0.0 to 0.6)	0.043
RAI	43	5.9 (3.9)	62	6.8 (2.6)	0.7 (–0.4 to 1.7)	0.218	0.8 (–0.3 to 1.9)	0.169

a Adjusted for baseline.
b Using the ANCOVA model.
c Adjusted for age, gender, BMI, total minutes of physical activity at 3 months and 1 week before randomisation, HRQoL (SF-12v2 plus 4 total score) and baseline outcome measurement.
d Using multiple regression.
Note: a higher RAI score indicates higher self-determination and a positive mean difference favours the booster interventions over the control.

TABLE 44 Difference in BMI between the booster intervention group (mini plus full) and the control group at 3 and 9 months (all available data)

Follow-up (months)	Outcome	Control		Booster		Mean difference (95% CI)[a]	*p*-value[b]	Adjusted mean difference (95% CI)[c]	*p*-value[d]
		n	Mean (SD)	*n*	Mean (SD)				
3	BMI (kg/m^2)	75	29.6 (5.9)	124	30.1 (5.5)	–0.2 (–0.5 to 0.1)	0.194	–0.1 (–0.4 to 0.2)	0.385
9	BMI (kg/m^2)	55	28.4 (5.4)	85	29.1 (5.1)	0.1 (–0.3 to 0.6)	0.601	0.1 (–0.4 to 0.6)	0.594

a Adjusted for baseline BMI.
b Using the ANCOVA model.
c Adjusted for age, gender, total minutes of physical activity at 3 months and 1 week before randomisation, HRQoL (SF-12v2 plus 4 total score) and baseline BMI.
d Using multiple regression.
Note: a negative mean difference in BMI favours the booster interventions over the control.

TABLE 45 Difference in BMI between the booster intervention group (mini plus full) and the control group at 3 and 9 months (ITT set)

Follow-up (months)	Outcome	Control		Booster		Mean difference (95% CI)[a]	*p*-value[b]	Adjusted mean difference (95% CI)[c]	*p*-value[d]
		n	Mean (SD)	*n*	Mean (SD)				
3	BMI (kg/m^2)	59	29.0 (4.5)	95	29.6 (5.5)	−0.2 (−0.6 to 0.1)	0.160	−0.2 (−0.5 to 0.1)	0.300
9	BMI (kg/m^2)	44	28.4 (4.9)	66	28.6 (5.2)	0.1 (−0.5 to 0.6)	0.844	0.1 (−0.5 to 0.6)	0.839

a Adjusted for baseline BMI.
b Using the ANCOVA model.
c Adjusted for age, gender, total minutes of physical activity at 3 months and 1 week before randomisation, HRQoL (SF-12v2 plus 4 total score) and baseline BMI.
d Using multiple regression.
Note: a negative mean difference in BMI favours the booster interventions over the control.

TABLE 46 Difference in total minutes of self-reported physical activity over a week period between the booster intervention group (mini plus full) and the control group at 3 and 9 months (ITT set)

Follow-up (months)	Outcome	Control		Booster		Mean difference (95% CI)[a]	*p*-value[a]	Adjusted mean difference (95% CI)[b]	*p*-value[c]
		n	Mean (SD)	*n*	Mean (SD)				
3	Total minutes of physical activity	60	383.8 (404.5)	96	419.8 (527.9)	49.5 (−109.4 to 206.3)	0.545	32.1 (−131.1 to 195.3)	0.698
9	Total minutes of physical activity	44	461.0 (457.4)	66	535.0 (560.2)	74.0 (−128.2 to 276.2)	0.470	120.0 (−92.1 to 332.1)	0.264

a Adjusted for baseline total minutes of physical activity using the ANCOVA model.
b Adjusted for age, gender, BMI, HRQoL (SF-12v2 plus 4 total score) and total minutes of physical activity.
c Using multiple regression.
Note: a positive mean difference in self-reported total minutes of physical activity favours the booster interventions over the control.

TABLE 47 Difference in total minutes of self-reported physical activity over a week period between the booster intervention group (mini plus full) and the control group at 3 and 9 months (all available data)

Follow-up (months)	Outcome	Control		Booster		Mean difference (95% CI)[a]	*p*-value[a]	Adjusted mean difference (95% CI)[b]	*p*-value[c]
		n	Mean (SD)	*n*	Mean (SD)				
3	Total minutes of physical activity	76	458.0 (681.2)	125	411.2 (498.3)	−35.4 (−200.0 to 129.2)	0.672	−52.5 (−222.6 to 117.6)	0.543
9	Total minutes of physical activity	54	446.1 (472.4)	81	508.6 (597.4)	62.4 (−128.4 to 253.3)	0.519	88.4 (−114.3 to 291.1)	0.390

a Adjusted for baseline total minutes of physical activity using the ANCOVA model.
b Adjusted for age, gender, BMI, HRQoL (SF-12v2 plus 4 total score) and total minutes of physical activity.
c Using multiple regression.
Note: a positive mean difference in self-reported total minutes of physical activity favours the booster interventions over the control.

TABLE 48 Difference in distance walked between the booster intervention group (mini plus full) and the control group at 3 and 9 months (all available data)

Follow-up (months)	Outcome	Control, mean (SD)	Booster, mean (SD)	Mean difference (95% CI)[a]	*p*-value[a]	Adjusted mean difference (95% CI)[b]	*p*-value[c]
3	Distance walked (m) on 12-minute walk test	(*n* = 75)	(*n* = 118)				
		898.9 (257.5)	962.4 (227.5)	63.5 (–6.3 to 133.3)	0.074	80.3 (13.8 to 146.8)	0.018
9	Distance walked (m) on 12-minute walk test	(*n* = 51)	(*n* = 82)				
		992.2 (292.7)	1077.4 (301.0)	85.2 (–19.9 to 190.3)	0.111	80.6 (–26.8 to 188.0)	0.140

a Using a two independent sample *t*-test.
b Adjusted for age, gender, BMI, total minutes of physical activity at 3 months and 1 week before randomisation, and HRQoL (SF-12v2 plus 4 total score).
c Using multiple regression.

TABLE 49 Difference in distance walked between the booster intervention group (mini plus full) and the control group at 3 and 9 months (ITT set)

Follow-up (months)	Outcome	Control, mean (SD)	Booster, mean (SD)	Mean difference (95% CI)[a]	*p*-value[a]	Adjusted mean difference (95% CI)[b]	*p*-value[c]
3	Distance walked (m) on 12-minute walk test	(*n* = 59)	(*n* = 91)				
		917.6 (254.9)	984.2 (226.2)	66.6 (–12.0 to 145.2)	0.096	90.8 (14.5 to 167.1)	0.020
9	Distance walked (m) on 12-minute walk test	(*n* = 42)	(*n* = 64)				
		1000.2 (308.8)	1102.4 (285.4)	102.2 (–13.9 to 218.3)	0.084	115.9 (1.1 to 230.7)	0.048

a Using a two independent sample *t*-test.
b Adjusted for age, gender, BMI, total minutes of physical activity at 3 months and 1 week before randomisation, and HRQoL (SF-12v2 plus 4 total score).
c Using multiple regression.

TABLE 50 Proportions of participants meeting current recommendations of at least 30 minutes of at least moderate physical activity for at least 5 days a week at 3 and 9 months

Follow-up (months)	Outcome	Control, *n* (%)	Mini booster, *n* (%)	Full booster, *n* (%)	Mini + full booster, *n* (%)	Difference in proportion maintaining or increasing physical activity (95% CI) (%)	*p*-value
3	Meeting current physical activity recommendations	(*n* = 73)	(*n* = 57)	(*n* = 59)	(*n* = 116)		
		25 (34.2)	12 (21.1)	27 (45.8)	39 (33.6)	–0.6 (–14.5 to 13.2)	0.929
9	Meeting current physical activity recommendations	(*n* = 39)	(*n* = 27)	(*n* = 35)	(*n* = 62)		
		11 (28.2)	7 (25.9)	12 (34.3)	19 (30.6)	2.4 (–15.7 to 20.6)	0.794

Note: at least moderate physical activity was defined as having at least 3 METs.

TABLE 51 Subgroup evaluation: interaction effect at 3 months between gender and intervention

Outcome measure	Subgroup	Control, mean (SD)	Booster, mean (SD)	Mean difference (95% CI)	*p*-value
Mean TEE per day (kcal)	Male	(*n* = 26)	(*n* = 42)		
		2483.0 (421.8)	2455.2 (416.3)	–27.8 (–236.3 to 180.6)	0.791
	Female	(*n* = 35)	(*n* = 57)		
		2104.6 (322.7)	2058.6 (343.0)	–46.0 (–189.1 to 97.1)	0.525
	All	(*n* = 61)	(*n* = 99)		
		2265.9 (410.8)	2226.9 (422.6)	–39.0 (–173.4 to 95.4)	0.567
	Interaction test	NA	NA	–18.2 (–260.6 to 224.3)[a]	0.882

NA, not applicable.
a Interaction test mean difference is the difference in the mean difference in treatment effect between men and women.
Note: positive and negative mean difference in mean TEE favours the booster group and the control group respectively.

TABLE 52 Subgroup evaluation: interaction effect at 9 months between gender and intervention

Outcome measure	Subgroup	Control, mean (SD)	Booster, mean (SD)	Mean difference (95% CI)	*p*-value
Mean TEE per day (kcal)	Male	(*n* = 13)	(*n* = 27)		
		2425.9 (402.6)	2409.2 (382.1)	–16.8 (–282.4 to 248.9)	0.899
	Female	(*n* = 23)	(*n* = 27)		
		2036.6 (311.9)	2069.1 (339.6)	32.4 (–154.2 to 219.1)	0.728
	All[a]	(*n* = 36)	(*n* = 54)		
		2177.2 (390.7)	2239.1 (397.1)	61.9 (–106.8 to 230.6)	0.468
	Interaction test	NA	NA	49.2 (–262.6 to 361.0)[b]	0.755

NA, not applicable.
a Excluding a participant with an extreme value (mean TEE per day of 6047.6 kcal).
b Interaction mean difference is the difference in the mean difference in treatment effect between men and women.
Note: positive and negative mean difference in mean TEE favours the booster group and the control group respectively.

TABLE 53 Subgroup evaluation: interaction effect at 3 months between use of community facilities in the last month (yes or no) and intervention

Outcome measure	Subgroup	Control, mean (SD)	Booster, mean (SD)	Mean difference (95% CI)	*p*-value
Mean TEE per day (kcal)	Yes	(*n* = 16)	(*n* = 22)		
		2097.5 (244.0)	2181.1 (358.8)	83.6 (–127.0 to 294.2)	0.426
	No	(*n* = 45)	(*n* = 76)		
		2325.8 (442.5)	2249.2 (435.7)	–76.6 (–239.8 to 86.6)	0.355
	All	(*n* = 61)	(*n* = 98)		
		2265.9 (410.8)	2233.9 (418.9)	–32.0 (–166.0 to 101.9)	0.638
	Interaction test	NA	NA	–160.2 (–469.1 to 148.7)[a]	0.307

NA, not applicable.
a Interaction test mean difference is the difference in the mean difference in treatment effect between men and women.
Note: positive and negative mean difference in mean TEE favours the booster group and the control group respectively.

TABLE 54 Subgroup evaluation: interaction effect at 9 months between use of community facilities in the last month (yes or no) and intervention

Outcome measure	Subgroup	Control, mean (SD)	Booster, mean (SD)	Mean difference (95% CI)	*p*-value
Mean TEE per day (kcal)	Yes	(*n* = 11)	(*n* = 14)		
		2084.8 (398.5)	2079.7 (230.0)	–5.1 (–267.2 to 257.1)	0.968
	No	(*n* = 25)	(*n* = 39)		
		2217.9 (388.4)	2313.1 (419.0)	95.2 (–113.4 to 303.9)	0.365
	All[a]	(*n* = 36)	(*n* = 53)		
		2177.2 (390.7)	2251.5 (390.3)	74.2 (–93.4 to 241.9)	0.381
	Interaction test	NA	NA	100.3 (–264.8 to 465.3)[b]	0.586

NA, not applicable.
a Excluding a participant with an extreme value (mean TEE per day of 6047.6 kcal).
b Interaction mean difference is the difference in the mean difference in treatment effect between men and women.
Note: positive and negative mean difference in mean TEE favours the booster group and the control group respectively.

TABLE 55 Subgroup evaluation: interaction effect at 3 months between seasonality (time of initial contact) and intervention (full booster vs. control)

Outcome measure	Subgroup	Control, mean (SD)	Full booster, mean (SD)	Mean difference (95% CI)	*p*-value
Mean TEE per day (kcal)	Summer/ spring	(*n* = 48)	(*n* = 33)		
		2275.8 (417.6)	2315.2 (444.9)	39.4 (–153.7 to 232.4)	0.686
	Winter/ autumn	(*n* = 13)	(*n* = 19)		
		2229.3 (398.3)	2218.6 (394.0)	–10.8 (–301.6 to 280.1)	0.940
	All	(*n* = 61)	(*n* = 52)		
		2265.9 (410.8)	2279.9 (425.6)	14.0 (–142.2 to 170.2)	0.860
	Interaction test	NA	NA	–50.1 (–404.0 to 303.7)[a]	0.779

NA, not applicable.
a Interaction test mean difference is the difference in the mean difference in treatment effect between those approached in summer/spring and those approached in winter/autumn.
Note: positive and negative mean difference in mean TEE favours the full booster group and the control group respectively.

TABLE 56 Subgroup evaluation: interaction effect at 3 months between seasonality (time of initial contact) and intervention (mini booster vs. control)

Outcome measure	Subgroup	Control, mean (SD)	Mini booster, mean (SD)	Mean difference (95% CI)	*p*-value
Mean TEE per day (kcal)	Summer/ spring	(*n* = 48)	(*n* = 35)		
		2275.8 (417.6)	2154.5 (411.9)	–121.4 (–305.0 to 62.3)	0.192
	Winter/ autumn	(*n* = 13)	(*n* = 12)		
		2229.3 (398.3)	2208.4 (442.8)	–20.9 (–368.8 to 327.0)	0.902
	All	(*n* = 61)	(*n* = 47)		
		2265.9 (410.8)	2168.2 (415.8)	–97.7 (–256.6 to 61.2)	0.226
	Interaction test	NA	NA	100.4 (–277.6 to 478.5)[a]	0.599

NA, not applicable.
a Interaction test mean difference is the difference in the mean difference in treatment effect between those approached in summer/spring and those approached in winter/autumn.
Note: positive and negative mean difference in mean TEE favours the full booster group and the control group respectively.

Appendix 7 Results tables from the process evaluation

TABLE 57 Process evaluation survey responders' baseline characteristics

Variable	Non-responders (*n* = 207)	Responders (process evaluation participants)				All participants (*n* = 282)
		All (*n* = 75)	Control (*n* = 26)	Mini booster (*n* = 25)	Full booster (*n* = 24)	
Gender, *n* (%)						
Male	98 (47)	32 (43)	11 (42)	7 (28)	14 (58)	130 (46)
Female	109 (53)	43 (57)	15 (58)	18 (72)	10 (42)	152 (54)
Employment status, *n* (%)						
Part-time	35 (17)	17 (23)	5 (19)	9 (36)	3 (13)	52 (18)
Full-time	69 (33)	24 (32)	12 (46)	6 (24)	6 (25)	93 (33)
Not employed	100 (48)	34 (45)	9 (35)	10 (40)	15 (63)	134 (48)
Missing	3 (1)	0 (0)	0 (0)	0 (0)	0 (0)	3 (1)
Ethnicity, *n* (%)						
White British	179 (87)	67 (89)	23 (88)	22 (88)	22 (92	246 (87)
Any other	25 (13)	8 (11)	3 (12)	3 (12)	2 (8%)	33 (12)
Missing	3 (1)	0 (0)	0 (0)	0 (0)	0 (0)	3 (1)
Stage of change, *n* (%)						
Contemplation	11 (5.3)	1 (1.3)	0 (0)	0 (0.0)	1 (4.2)	12 (4.3)
Preparation	91 (44.0)	34 (45.3)	13 (50.0)	13 (52.0)	8 (33.3)	125 (44.3)
Action	66 (31.9)	25 (33.3)	8 (30.8)	6 (24.0)	11 (45.8)	91 (32.3)
Maintenance	37 (17.9)	13 (17.3)	4 (15.4)	6 (24.0)	3 (12.5)	50 (17.7)
Missing	2 (1.0)	2 (2.7)	1 (3.8)	0 (0.0)	1 (4.2)	4 (1.4)

Variable	Non-responders (*n* = 207)	Responders (process evaluation participants)				All participants (*n* = 282)
		All (*n* = 75)	Control (*n* = 26)	Mini booster (*n* = 25)	Full booster (*n* = 24)	
Marital status, *n* (%)						
Single	33 (16)	12 (16)	5 (19)	6 (24)	1 (4)	45 (16)
Married	112 (54)	39 (52)	12 (46)	10 (40)	17 (71)	151 (54)
Co-habiting	14 (7)	6 (8)	1 (4)	3 (12)	2 (8)	20 (7)
Divorced/separated	40 (19)	15 (20)	7 (27)	5 (20)	3 (13)	55 (20)
Widowed	8 (4)	3 (4)	1 (4)	1 (4)	1 (4)	11 (4)
Age (years)						
n (%)	207 (100)	75 (100)	26 (100)	25 (100)	24 (100)	282 (100)
Mean (SD)	54.1 (7.4)	56.0 (7.0)	54.9 (5.9)	55.6 (8.1)	57.5 (6.8)	54.6 (7.3)
Median (IQR)	54.2 (47.9 to 60.8)	56.0 (50.4 to 62.7)	52.7 (50.5 to 60.9)	59.1 (49.9 to 62.0)	59.5 (51.2 to 63.8)	55.3 (48.8 to 61.4)
Min. to max.	40.5 to 65.5	40.4 to 65.0	46.3 to 64.8	40.4 to 65.0	44.0 to 64.9	40.4 to 65.5
Height (m)						
n (%)	206 (100)	75 (100)	26 (100)	25 (100)	24 (100)	281 (100)
Mean (SD)	1.7 (0.1)	1.7 (0.1)	1.7 (0.1)	1.6 (0.1)	1.7 (0.1)	1.7 (0.1)
Median (IQR)	1.7 (1.6 to 1.7)	1.7 (1.6 to 1.8)	1.7 (1.6 to 1.7)	1.6 (1.6 to 1.7)	1.7 (1.6 to 1.8)	1.7 (1.6 to1.8)
Min. to max.	1.5 to 1.9	1.5 to 1.9	1.5 to 1.9	1.5 to 1.8	1.5 to 1.9	1.5 to 1.9
Weight (kg)						
n (%)	207 (100)	75 (100)	26 (100)	25 (100)	24 (100)	282 (100)
Mean (SD)	84.7 (19.2)	86.5 (17.3)	86.4 (17.1)	82.6 (17.9)	90.7 (16.7)	85.2 (18.7)
Median (IQR)	82.0 (71.7 to 97.3)	84.3 (74.5 to 95.2)	84.4 (72.6 to 92.5)	83.0 (73.0 to 89.8)	87.7 (76.9 to 102.3)	82.9 (72.5 to 96.6)
Min. to max.	46.9 to 160.0	54.7 to 141.0	65.3 to 135.0	54.7 to 141.0	67.7 to 124.0	46.9 to 160.0

continued

TABLE 57 Process evaluation survey responders' baseline characteristics (*continued*)

Variable	Non-responders (*n* = 207)	Responders (process evaluation participants)				All participants (*n* = 282)
		All (*n* = 75)	Control (*n* = 26)	Mini booster (*n* = 25)	Full booster (*n* = 24)	
BMI (kg/m^2)						
n (%)	206 (100)	75 (100)	26 (100)	25 (100)	24 (100)	281 (100)
Mean (SD)	30.2 (6.1)	30.7 (5.5)	31.1 (6.7)	30.3 (5.5)	30.8 (3.9)	30.3 (5.9)
Median (IQR)	29.7 (25.7 to 33.0)	29.8 (27.3 to 33.2)	28.8 (27.2 to 33.1)	29.9 (26.9 to 32.6)	29.9 (28.2 to 34.2)	29.8 (26.3 to 33.0)
Min. to max.	17.1 to 48.3	21.6 to 53.4	21.6 to 53.4	22.5 to 49.4	25.0 to 39.1	17.1 to 53.4
SPAQ change (3 months post randomisation)						
n (%)	207 (100)	75 (100)	26 (100)	25 (100)	24 (100)	282 (100)
Mean (SD)	227.2 (401.0)	162.7 (265.0)	159.8 (191.6)	143.0 (245.6)	186.3 (349.4)	210.0 (370.4)
Median (IQR)	125.0 (70.0 to 260.0)	90.0 (40.0 to 210.0)	117.5 (65.0 to 180.0)	90.0 (40.0 to 260.0)	80.0 (35.0 to 182.5)	120.0 (60.0 to 255.0)
Min. to max.	–1840.0 to 3360.0	–480.0 to 1500.0	–210.0 to 690.0	–480.0 to 795.0	–150.0 to 1500.0	–1840.0 to 3360.0
BREQ-2 (RAI)						
n (%)	201 (97)	73 (97)	24 (92)	25 (100)	24 (100)	274 (97)
Mean (SD)	5.2 (3.6)	5.4 (4.0)	5.8 (3.9)	3.9 (4.5)	6.4 (3.1)	5.3 (3.7)
Median (IQR)	5.8 (3.3 to 7.9)	6.4 (2.9 to 8.3)	6.5 (4.3 to 8.0)	5.8 1.3 to 7.3)	6.9 (3.7 to 9.0)	6.0 (3.3 to 8.0)
Min. to max.	–9.1 to 11.5	–5.3 to 12.0	–2.6 to 12.0	–5.3 to 9.2	–0.2 to 11.0	–9.1 to 12.0

max., maximum; min., minimum.

TABLE 58 Responses to process evaluation closed questions

Survey question	Scoring	Control (*n* = 26), *n* (%)	Mini (*n* = 25), *n* (%)	Full (*n* = 24), *n* (%)	Total (*n* = 75), *n* (%)
Q1: Over the last 3 months have you taken part in any of the following?					
Recreational/leisure activities (e.g. gardening, cycling)	Not ticked	6 (23.1)	2 (8.0)	4 (16.7)	12 (16.0)
	Ticked	20 (76.9)	23 (92.0)	20 (83.3)	63 (84.0)
Competitive sports/exercise	Not ticked	22 (84.6)	22 (88.0)	22 (91.7)	66 (88.0)
	Ticked	4 (15.4)	3 (12.0)	2 (8.3)	9 (12.0)
Structured exercise (e.g. exercise class)	Not ticked	16 (61.5)	18 (72.0)	15 (62.5)	49 (65.3)
	Ticked	10 (38.5)	7 (28.0)	9 (37.5)	26 (34.7)
Active commuting (e.g. walking/cycling to work)	Not ticked	11 (42.3)	7 (28.0)	4 (16.7)	22 (29.3)
	Ticked	15 (57.7)	18 (72.0)	20 (83.3)	53 (70.7)
Q2: Please specify the places where you have done your chosen activities over the last 3 months					
Home	Not ticked	12 (46.2)	12 (48.0)	14 (58.3)	38 (50.7)
	Ticked	14 (53.8)	13 (52.0)	10 (41.7)	37 (49.3)
Local open space (e.g. park)	Not ticked	14 (53.8)	12 (48.0)	8 (33.3)	34 (45.3)
	Ticked	12 (46.2)	13 (52.0)	16 (66.7)	41 (54.7)
Facility (e.g. gym, pool, community centre, track)	Not ticked	16 (61.5)	12 (48.0)	14 (58.3)	42 (56.0)
	Ticked	10 (38.5)	13 (52.0)	10 (41.7)	33 (44.0)
As part of daily activities (e.g. in work, shopping, walking the dog, commuting)	Not ticked	8 (30.8)	8 (32.0)	7 (29.2)	23 (30.7)
	Ticked	18 (69.2)	17 (68.0)	17 (70.8)	52 (69.3)
Other places	Not ticked	23 (88.5)	21 (84.0)	20 (83.3)	64 (85.3)
	Ticked	3 (11.5)	4 (16.0)	4 (16.7)	11 (14.7)
Q3: Why have you chosen to stay physically active?					
To improve my health	Not at all	1 (3.8)	1 (4.0)	0 (0.0)	2 (2.7)
	Neutral	0 (0.0)	2 (8.0)	1 (4.2)	3 (4.0)
	Slightly	4 (15.4)	3 (12.0)	4 (16.7)	11 (14.7)
	Very much	20 (76.9)	19 (76.0)	19 (79.2)	58 (77.3)
To get fitter/stay fit	Not at all	0 (0.0)	1 (4.0)	0 (0.0)	1 (1.3)
	Slightly	6 (23.1)	5 (20.0)	4 (16.7)	15 (20.0)
	Very much	19 (73.1)	19 (76.0)	20 (83.3)	58 (77.3)

continued

TABLE 58 Responses to process evaluation closed questions (*continued*)

Survey question	Scoring	Control (*n* = 26), *n* (%)	Mini (*n* = 25), *n* (%)	Full (*n* = 24), *n* (%)	Total (*n* = 75), *n* (%)
To lose weight	Not at all	4 (15.4)	2 (8.0)	0 (0.0)	6 (8.0)
	Not really	0 (0.0)	0 (0.0)	1 (4.2)	1 (1.3)
	Neutral	1 (3.8)	1 (4.0)	0 (0.0)	2 (2.7)
	Slightly	7 (26.9)	8 (32.0)	10 (41.7)	25 (33.3)
	Very much	14 (53.8)	14 (56.0)	13 (54.2)	41 (54.7)
To look better	Not at all	0 (0.0)	0 (0.0)	1 (4.2)	1 (1.3)
	Not really	3 (11.5)	2 (8.0)	2 (8.3)	7 (9.3)
	Neutral	6 (23.1)	3 (12.0)	2 (8.3)	11 (14.7)
	Slightly	6 (23.1)	12 (48.0)	7 (29.2)	25 (33.3)
	Very much	10 (38.5)	7 (28.0)	12 (50.0)	29 (38.7)
To encourage my family to be more active	Not at all	6 (23.1)	8 (32.0)	6 (25.0)	20 (26.7)
	Not really	6 (23.1)	5 (20.0)	3 (12.5)	14 (18.7)
	Neutral	8 (30.8)	7 (28.0)	4 (16.7)	19 (25.3)
	Slightly	4 (15.4)	2 (8.0)	9 (37.5)	15 (20.0)
	Very much	1 (3.8)	2 (8.0)	2 (8.3)	5 (6.7)
To make new friends	Not at all	6 (23.1)	8 (32.0)	7 (29.2)	21 (28.0)
	Not really	8 (30.8)	10 (40.%)	5 (20.8)	23 (30.7)
	Neutral	7 (26.9)	5 (20.0)	7 (29.2)	19 (25.3)
	Slightly	3 (11.5)	1 (4.0)	4 (16.7)	8 (10.7)
	Very much	2 (7.7)	1 (4.0)	1 (4.2)	4 (5.3)
To have fun/enjoyment	Not at all	2 (7.7)	3 (12.0)	0 (0.0)	5 (6.7)
	Not really	2 (7.7)	2 (8.0)	1 (4.2)	5 (6.7)
	Neutral	6 (23.1)	5 (20.0)	5 (20.8)	16 (21.3)
	Slightly	10 (38.5)	7 (28.0)	13 (54.2)	30 (40.0)
	Very much	5 (19.2)	8 (32.0)	5 (20.8)	18 (24.0)
To spend time with family	Not at all	9 (34.6)	9 (36.0)	7 (29.2)	25 (33.3)
	Not really	8 (30.8)	5 (20.0)	3 (12.5)	16 (21.3)
	Neutral	6 (23.1)	7 (28.0)	5 (20.8)	18 (24.0)
	Slightly	2 (7.7)	2 (8.0)	7 (29.2)	11 (14.7)
	Very much	0 (0.0)	1 (4.0)	1 (4.2)	2 (2.7)

TABLE 58 Responses to process evaluation closed questions (*continued*)

Survey question	Scoring	Control (*n* = 26), *n* (%)	Mini (*n* = 25), *n* (%)	Full (*n* = 24), *n* (%)	Total (*n* = 75), *n* (%)
To spend time with friends	Not at all	6 (23.1)	9 (36.0)	7 (29.2)	22 (29.3)
	Not really	10 (38.5)	8 (32.0)	3 (12.5)	21 (28.0)
	Neutral	8 (30.8)	4 (16.0)	6 (25.0)	18 (24.0)
	Slightly	1 (3.8)	1 (4.0)	5 (20.8)	7 (9.3)
	Very much	0 (0.0)	2 (8.0)	3 (12.5)	5 (6.7)
For competition/to win	Not at all	19 (73.1)	16 (64.0)	17 (70.8)	52 (69.3)
	Not really	4 (15.4)	3 (12.0)	1 (4.2)	8 (10.7)
	Neutral	2 (7.7)	5 (20.0)	4 (16.7)	11 (14.7)
	Very much	0 (0.0)	0 (0.0)	2 (8.3)	2 (2.7)
It's part of my job	Not at all	18 (69.2)	17 (68.0)	16 (66.7)	51 (68.0)
	Not really	2 (7.7)	1 (4.0)	4 (16.7)	7 (9.3)
	Neutral	2 (7.7)	3 (12.0)	2 (8.3)	7 (9.3)
	Slightly	2 (7.7)	2 (8.0)	0 (0.0)	4 (5.3)
	Very much	1 (3.8)	1 (4.0)	1 (4.2)	3 (4.0)
	Missing	1 (3.8)	1 (4.0)	1 (4.2)	3 (4.0)
It gives me a sense of achievement	Not at all	0 (0.0)	1 (4.0)	1 (4.2)	2 (2.7)
	Not really	0 (0.0)	0 (0.0)	1 (4.2)	1 (1.3)
	Neutral	3 (11.5)	4 (16.0)	2 (8.3)	9 (12.0)
	Slightly	9 (34.6)	7 (28.0)	9 (37.5)	25 (33.3)
	Very much	14 (53.8)	13 (52.0)	11 (45.8)	38 (50.7)
To reduce the risks of health problems (e.g. diabetes, heart disease)	Not at all	1 (3.8)	1 (4.0)	0 (0.0)	2 (2.7)
	Not really	2 (7.7)	0 (0.0)	0 (0.0)	2 (2.7)
	Neutral	0 (0.0)	3 (12.0)	1 (4.2)	4 (5.3)
	Slightly	3 (11.5)	3 (12.0)	5 (20.8)	11 (14.7)
	Very much	19 (73.1)	18 (72.0)	18 (75.0)	55 (73.3)
	Missing	1 (3.8)	0 (0.0)	0 (0.0)	1 (1.3)
I haven't stayed active	Not at all	16 (61.5)	11 (44.0)	18 (75.0)	45 (60.0)
	Not really	2 (7.7)	4 (16.0)	1 (4.2)	7 (9.3)
	Neutral	3 (11.5)	4 (16.0)	3 (12.5)	10 (13.3)
	Slightly	3 (11.5)	3 (12.0)	0 (0.0)	6 (8.0)
	Very much	1 (3.8)	1 (4.0)	0 (0.0)	2 (2.7)
	Missing	1 (3.8)	2 (8.0)	2 (8.3)	5 (6.7)

continued

TABLE 58 Responses to process evaluation closed questions (*continued*)

Survey question	Scoring	Control (*n* = 26), *n* (%)	Mini (*n* = 25), *n* (%)	Full (*n* = 24), *n* (%)	Total (*n* = 75), *n* (%)
A health professional recommended that I should	Not at all	11 (42.3)	12 (48.0)	14 (58.3)	37 (49.3)
	Not really	2 (7.7)	1 (4.0)	0 (0.0)	3 (4.0)
	Neutral	0 (0.0)	2 (8.0)	1 (4.2)	3 (4.0)
	Slightly	5 (19.2)	1 (4.0)	3 (12.5)	9 (12.0)
	Very much	1 (3.8)	2 (8.0)	1 (4.2)	4 (5.3)
	Missing	7 (26.9)	7 (28.0)	5 (20.8)	19 (25.3)
Other reasons	Not at all	4 (15.4)	2 (8.0)	2 (8.3)	8 (10.7)
	Neutral	0 (0.0)	0 (0.0)	1 (4.2)	1 (1.3)
	Missing	22 (84.6)	23 (92.0)	21 (87.5)	66 (88.0)
Q4: What influences whether or not you are able to perform your chosen activity?					
Value for money	Not at all	6 (23.1)	4 (16.0)	10 (41.7)	20 (26.7)
	Not really	5 (19.2)	5 (20.0)	3 (12.5)	13 (17.3)
	Neutral	0 (0.0)	6 (24.0)	1 (4.2)	7 (9.3)
	Slightly	8 (30.8)	5 (20.0)	3 (12.5)	16 (21.3)
	Very much	6 (23.1)	4 (16.0)	5 (20.8)	15 (20.0)
	Missing	1 (3.8)	1 (4.0)	2 (8.3)	4 (5.3)
Activity is available when I want	Not at all	0 (0.0)	1 (4.0)	2 (8.3)	3 (4.0)
	Not really	3 (11.5)	1 (4.0)	2 (8.3)	6 (8.0)
	Neutral	3 (11.5)	0 (0.0)	0 (0.0)	3 (4.0)
	Slightly	4 (15.4)	7 (28.0)	6 (25.0)	17 (22.7)
	Very much	16 (61.5)	15 (60.0)	12 (50.0)	43 (57.3)
	Missing	0 (0.0)	1 (4.0)	2 (8.3)	3 (4.0)
Childcare available	Not at all	21 (80.8s)	21 (84.0)	21 (87.5)	63 (84.0)
	Neutral	2 (7.7)	1 (4.0)	0 (0.0)	3 (4.0)
	Very much	0 (0.0)	1 (4.0)	1 (4.2)	2 (2.7)
	Missing	3 (11.5)	2 (8.0)	2 (8.3)	7 (9.3)
Within walking distance of home/work	Not at all	6 (23.1)	5 (20.0)	7 (29.2)	18 (24.0)
	Not really	2 (7.7)	6 (24.0)	5 (20.8)	13 (17.3)
	Neutral	3 (11.5)	3 (12.0)	2 (8.3)	8 (10.7)
	Slightly	6 (23.1)	3 (12.0)	4 (16.7)	13 (17.3)
	Very much	8 (30.8)	7 (28.0)	2 (8.3)	17 (22.7)
	Missing	1 (3.8)	1 (4.0)	4 (16.7)	6 (8.0)

TABLE 58 Responses to process evaluation closed questions (*continued*)

Survey question	Scoring	Control (*n* = 26), *n* (%)	Mini (*n* = 25), *n* (%)	Full (*n* = 24), *n* (%)	Total (*n* = 75), *n* (%)
Within easy reach on public transport	Not at all	7 (26.9)	9 (36.0)	6 (25.0)	22 (29.3)
	Not really	2 (7.7)	6 (24.0)	5 (20.8)	13 (17.3)
	Neutral	1 (3.8)	4 (16.0)	2 (8.3)	7 (9.3)
	Slightly	9 (34.6)	2 (8.0)	5 (20.8)	16 (21.3)
	Very much	5 (19.2)	3 (12.0)	2 (8.3)	10 (13.3)
	Missing	2 (7.7)	1 (4.0)	4 (16.7)	7 (9.3)
If I feel I'm getting something out of it	Not at all	2 (7.7)	0 (0.0)	0 (0.0)	2 (2.7)
	Not really	1 (3.8)	1 (4.0)	1 (4.2)	3 (4.0)
	Neutral	1 (3.8)	1 (4.0)	1 (4.2)	3 (4.0)
	Slightly	7 (26.9)	6 (24.0)	6 (25.0)	19 (25.3)
	Very much	15 (57.7)	16 (64.0)	13 (54.2)	44 (58.7)
	Missing	0 (0.0)	1 (4.0)	3 (12.5)	4 (5.3)
Whether there is someone to do it with	Not at all	11 (42.3)	8 (32.0)	10 (41.7)	29 (38.7)
	Not really	6 (23.1)	7 (28.0)	1 (4.2)	14 (18.7)
	Neutral	3 (11.5)	4 (16.0)	3 (12.5)	10 (13.3)
	Slightly	4 (15.4)	4 (16.0)	6 (25.0)	14 (18.7)
	Very much	1 (3.8)	1 (4.0)	0 (0.0)	2 (2.7)
	Missing	1 (3.8)	1 (4.0)	4 (16.7)	6 (8.0)
It's a habit	Not at all	3 (11.5)	7 (28.0)	8 (33.3)	18 (24.0)
	Not really	5 (19.2)	3 (12.0)	3 (12.5)	11 (14.7)
	Neutral	3 (11.5)	8 (32.0)	6 (25.0)	17 (22.7)
	Slightly	9 (34.6)	4 (16.0)	1 (4.2)	14 (18.7)
	Very much	6 (23.1)	2 (8.0)	2 (8.3)	10 (13.3)
	Missing	0 (0.0)	1 (4.0)	4 (16.0)	5 (6.6)
Whether I can make time to do it	Not at all	1 (3.8)	5 (20.0)	3 (12.5)	9 (12.0)
	Not really	4 (15.4)	4 (16.0)	1 (4.2)	9 (12.0)
	Neutral	4 (15.4)	1 (4.0)	4 (16.7)	9 (12.0)
	Slightly	12 (46.2)	7 (28.0)	7 (29.2)	26 (34.7)
	Very much	4 (15.4)	7 (28.0)	5 (20.8)	16 (21.3)
	Missing	1 (3.8)	1 (4.0)	4 (16.7)	6 (8.0)

continued

TABLE 58 Responses to process evaluation closed questions (*continued*)

Survey question	Scoring	Control (*n* = 26), *n* (%)	Mini (*n* = 25), *n* (%)	Full (*n* = 24), *n* (%)	Total (*n* = 75), *n* (%)
My own health	Not at all	1 (3.8)	1 (4.0)	0 (0.0)	2 (2.7)
	Not really	1 (3.8)	1 (4.0)	0 (0.0)	2 (2.7)
	Neutral	2 (7.7)	1 (4.0)	0 (0.0)	3 (4.0)
	Slightly	2 (7.7)	2 (8.0)	4 (16.7)	8 (10.7)
	Very much	18 (69.2)	19 (76.0)	18 (75.0)	55 (73.3)
	Missing	2 (7.7)	1 (4.0)	2 (8.3)	5 (6.7)
Other influences	Not at all	0 (0.0)	1 (4.0)	1 (4.2)	2 (2.7)
	Very much	0 (0.0)	0 (0.0)	1 (4.2)	1 (1.3)
	Missing	26 (100.0)	24 (96.0)	22 (91.7)	72 (96.0)
Q5: Do you do physical activity with anyone else?					
	No	17 (65.4)	14 (56.0)	8 (33.3)	39 (52.0)
	Yes	9 (34.6)	10 (40.0)	14 (58.3)	33 (44.0)
Q6: If you answered 'yes' to Q5, who do you usually do physical activity with?					
Spouse/partner	Not ticked	4 (15.4)	5 (20.0)	8 (33.3)	17 (22.7)
	Ticked	5 (19.2)	6 (24.0)	8 (33.3)	19 (25.3)
	Not applicable	17 (65.4)	14 (56.0)	8 (33.3)	39 (52.0)
Other family member(s)	Not ticked	6 (23.1)	8 (32.0)	12 (50.0)	26 (34.7)
	Ticked	3 (11.5)	3 (12.0)	4 (16.7)	10 (13.3)
	Not applicable	17 (65.4)	14 (56.0)	8 (33.3)	39 (52.0)
Friend(s)	Not ticked	7 (26.9)	7 (28.0)	8 (33.3)	22 (29.3)
	Ticked	2 (7.7)	4 (16.0)	8 (33.3)	14 (18.7)
	Not applicable	17 (65.4)	14 (56.0)	8 (33.3)	39 (52.0)
Other adult(s)	Not ticked	7 (26.9)	9 (36.0)	12 (50.0)	28 (37.3)
	Ticked	2 (7.7)	2 (8.0)	4 (16.7)	8 (10.7)
	Not applicable	17 (65.4)	14 (56.0)	8 (33.3)	39 (52.0)
Child or children under 16 years	Not ticked	7 (26.9)	7 (28.0)	14 (58.3)	28 (37.3)
	Ticked	2 (7.7)	4 (16.0)	2 (8.3)	8 (10.7)
	Not applicable	17 (65.4)	14 (56.0)	8 (33.3)	39 (52.0)
As part of a group/class (including walking group)	Not ticked	6 (23.1)	9 (36.0)	13 (54.2)	28 (37.3)
	Ticked	3 (11.5)	2 (8.0)	3 (12.5)	8 (10.7)
	Not applicable	17 (65.4)	14 (56.0)	8 (33.3)	39 (52.0)
Other	Not ticked	9 (34.6)	11 (44.0)	15 (62.5)	35 (46.7)
	Ticked	0 (0.0)	0 (0.0)	1 (4.2)	1 (1.3)
	Not applicable	17 (65.4)	14 (56.0)	8 (33.3)	39 (52.0)

TABLE 58 Responses to process evaluation closed questions (*continued*)

Survey question	Scoring	Control (*n* = 26), *n* (%)	Mini (*n* = 25), *n* (%)	Full (*n* = 24), *n* (%)	Total (*n* = 75), *n* (%)
Q7: If you answered 'yes' to Q5, how useful do you find this support in helping you stay active?					
	Not applicable	1 (3.8)	0 (0.0)	0 (0.0)	1 (1.3)
	Very useful	3 (11.5)	1 (4.0)	9 (37.5)	13 (17.3)
	Fairly useful	3 (11.5)	8 (32.0)	4 (16.7)	15 (20.0)
	Neither useful nor useless	1 (3.8)	1 (4.0)	1 (4.2)	3 (4.0)
	Very useless	1 (3.8)	0 (0.0)	0 (0.0)	1 (1.3)
	Doesn't do activity ('no' on Q5)	17 (65.4)	14 (56.0)	8 (33.3)	39 (52.0)
	Missing	0 (0.0)	1 (4.0)	2 (8.3)	3 (4.0)
			(*n* = 25)	(*n* = 25)	(*n* = 50)
Q8: If you were to receive further activity 'booster' counselling/advice in the future, how would you prefer it to be delivered?					
Over the telephone	Not ticked	NA	13 (52.0)	23 (95.8)	36 (73.5)
	Ticked	NA	12 (48.0)	1 (4.2)	13 (26.5)
In person (face to face)	Not ticked	NA	16 (64.0)	5 (20.8)	21 (42.9)
	Ticked	NA	9 (36.0)	19 (79.2)	28 (57.1)
Written advice	Not ticked	NA	17 (68.0)	20 (83.3)	37 (75.5)
	Ticked	NA	8 (32.0)	4 (16.7)	12 (24.5)
Q9: Did the 'booster' physical activity counselling/advice meet the expectations you described above?					
	No	NA	2 (8.0)	0 (0.0)	2 (4.1)
	Yes	NA	19 (76.0)	23 (95.8)	42 (85.7)
	Missing	NA	4 (16.0)	1 (4.2)	5 (10.2)
Q10: The 'booster' counselling/advice sessions fitted easily into my daily schedule					
	Strongly disagree	NA	2 (8.0)	2 (8.3)	4 (8.2)
	Disagree	NA	0 (0.0)	1 (4.2)	1 (2.0)
	Neutral	NA	1 (4.0)	2 (8.3)	3 (6.1)
	Agree	NA	12 (48.0)	10 (41.7)	22 (44.9)
	Strongly agree	NA	7 (28.0)	8 (33.3)	15 (30.6)
	Missing	NA	3 (12.0)	1 (4.2)	4 (8.2)
Q11: The 'booster' counselling/advice sessions were conducted at a convenient location					
	Strongly disagree	NA	0 (0.0)	1 (4.2)	1 (2.0)
	Neutral	NA	0 (0.0)	1 (4.2)	1 (2.0)
	Agree	NA	0 (0.0)	10 (41.7)	10 (20.4)
	Strongly agree	NA	0 (0.0)	10 (41.7)	10 (20.4)
	Missing	NA	25 (100.0)	2 (8.3)	27 (55.1)

continued

TABLE 58 Responses to process evaluation closed questions (*continued*)

Survey question	Scoring	Control (*n* = 26), *n* (%)	Mini (*n* = 25), *n* (%)	Full (*n* = 24), *n* (%)	Total (*n* = 75), *n* (%)
Q12: Throughout the 'booster' counselling/advice sessions I feel I wasn't being judged by the project worker					
	Strongly disagree	NA	1 (4.0)	2 (8.3)	3 (6.1)
	Disagree	NA	1 (4.0)	1 (4.2)	2 (4.1)
	Agree	NA	7 (28.0)	5 (20.8)	12 (24.5)
	Strongly agree	NA	13 (52.0)	15 (62.5)	28 (57.1)
	Missing	NA	3 (12.0)	1 (4.2)	4 (8.2)
Q13: The 'booster' counselling/advice sessions were non-confrontational in nature					
	Strongly disagree	NA	1 (4.0)	2 (8.3)	3 (6.1)
	Disagree	NA	0 (0.0)	1 (4.2)	1 (2.0)
	Neutral	NA	1 (4.0)	0 (0.0)	1 (2.0)
	Agree	NA	6 (24.0)	5 (20.8)	11 (22.4)
	Strongly agree	NA	13 (52.0)	14 (58.3)	27 (55.1)
	Missing	NA	4 (16.0)	2 (8.3)	6 (12.2)
Q14: Throughout the 'booster' counselling/advice sessions I thought the project worker understood what I was saying					
	Strongly disagree	NA	1 (4.0)	1 (4.2)	2 (4.1)
	Agree	NA	9 (36.0)	9 (37.5)	18 (36.7)
	Strongly agree	NA	12 (48.0)	13 (54.2)	25 (51.0)
	Missing	NA	3 (12.0)	1 (4.2)	4 (8.2)
Q15: How Involved did you feel in the 'booster' counselling advice sessions?					
	I spoke more than the project worker	NA	15 (60.0)	7 (29.2)	22 (44.9)
	I spoke less than the project worker	NA	3 (12.0)	0 (0.0)	3 (6.1)
	I spoke roughly the same amount as the project worker	NA	4 (16.0)	16 (66.7)	20 (40.8)
	Missing		3 (12.0)	1 (4.2)	4 (8.2)
Q16: How do you feel about the amount of contact time that occurred between you and the project worker					
	About right	NA	22 (88.0)	22 (91.7)	44 (89.8)
	Slightly too short	NA	0 (0.0)	1 (4.2)	1 (2.0)
	Missing	NA	3 (12.0)	1 (4.2)	4 (8.2)

TABLE 58 Responses to process evaluation closed questions (*continued*)

Survey question	Scoring	Control (*n* = 26), *n* (%)	Mini (*n* = 25), *n* (%)	Full (*n* = 24), *n* (%)	Total (*n* = 75), *n* (%)
Q17: During the 'booster' counselling advice sessions I was encouraged to set my own goals for physical activity					
	Not discussed	NA	1 (4.0)	0 (0.0)	1 (2.0)
	Neutral	NA	2 (8.0)	1 (4.2)	3 (6.1)
	Agree	NA	13 (52.0)	12 (50.0)	25 (51.0)
	Strongly agree	NA	6 (24.0)	10 (41.7)	16 (32.7)
	Missing	NA	3 (12.0)	1 (4.%)	4 (8.2)
Q18: As a result of the 'booster' counselling/advice sessions I feel I have been able to resolve my barriers towards physical activity					
	Disagree	NA	1 (4.0)	0 (0.0)	1 (2.0)
	Neutral	NA	8 (32.0)	5 (20.8)	13 (26.5)
	Agree	NA	10 (40.0)	12 (50.0)	22 (44.9)
	Strongly agree	NA	3 (12.0)	6 (25.0)	9 (18.4)
	Missing	NA	3 (12.0)	1 (4.0)	4 (8.0)
Q19: As a result of the 'booster' counselling/advice sessions I now know more about the benefits of physical activity					
	Neutral	NA	8 (32.0)	5 (20.8)	13 (26.5)
	Agree	NA	11 (44.0)	11 (45.8)	22 (44.9)
	Strongly agree	NA	3 (12.0)	7 (29.2)	10 (20.4)
	Missing	NA	3 (12.0)	1 (4.2)	4 (8.2)
Q20: As a result of the 'booster' counselling/advice sessions I now know more about the risks associated with living an inactive lifestyle					
	Not discussed	NA	1 (4.0)	0 (0.0)	1 (2.0)
	Disagree	NA	1 (4.0)	0 (0.0)	1 (2.0)
	Neutral	NA	7 (28.0)	4 (16.7)	11 (22.4)
	Agree	NA	9 (36.0)	13 (54.2)	22 (44.9)
	Strongly agree	NA	4 (16.0)	6 (25.0)	10 (20.4)
	Missing	NA	3 (12.0)	1 (4.2)	4 (8.2)
Q21: As a result of the 'booster' counselling/advice sessions I am now more aware of available physical activity facilities and opportunities					
	Not discussed	NA	1 (4.0)	0 (0.0)	1 (2.0)
	Neutral	NA	7 (28.0)	5 (20.8)	12 (24.5)
	Agree	NA	9 (36.0)	13 (54.2)	22 (44.9)
	Strongly agree	NA	4 (16.0)	5 (20.8)	9 (18.4)
	Missing	NA	4 (16.0)	1 (4.2)	5 (10.2)

continued

TABLE 58 Responses to process evaluation closed questions (*continued*)

Survey question	Scoring	Control (*n* = 26), *n* (%)	Mini (*n* = 25), *n* (%)	Full (*n* = 24), *n* (%)	Total (*n* = 75), *n* (%)
Q22: As a result of the 'booster' counselling/advice sessions my confidence to stay active has increased					
	Neutral	NA	5 (20.0)	0 (0.0)	5 (10.2)
	Agree	NA	12 (48.0)	13 (54.2)	25 (51.0)
	Strongly agree	NA	5 (20.0)	10 (41.7)	15 (30.6)
	Missing	NA	3 (12.0)	1 (4.2)	4 (8.2)
Finally, would you be happy to discuss some of the things mentioned in this questionnaire further in an interview with a different person from the person you have been in contact with about this study so far, either face to face or over the telephone?					
	No	1 (3.8)	1 (4.0)	2 (8.3)	4 (5.3)
	Yes	25 (96.2)	21 (84.0)	21 (87.5)	67 (89.3)
	Missing	0 (0.0)	3 (12.0)	1 (4.2)	4 (5.3)
Interview method: face to face	No	6 (23.1)	11 (44.0)	7 (29.2)	24 (32.0)
	Yes	20 (76.9)	14 (56.0)	17 (70.8)	51 (68.0)
Interview method: over the telephone	No	12 (46.2)	11 (44.0)	14 (58.3)	37 (49.3)
	Yes	14 (53.8)	14 (56.0)	10 (41.7)	38 (50.7)

NA, not applicable.

TABLE 59 Interview population baseline characteristics

Variable	Not interviewed (*n* = 256)	Interviewed			Total (*n* = 282)
		All (*n* = 26)	Mini booster (*n* = 13)	Full booster (*n* = 13)	
Gender, *n* (%)					
Male	116 (45)	14 (54)	7 (54)	7 (54)	130 (46)
Female	140 (55)	12 (46)	6 (46)	6 (46)	152 (54)
Employment status, *n* (%)					
Part-time	44 (17)	8 (31)	5 (38)	3 (23)	52 (18)
Full-time	89 (35)	4 (15)	2 (15)	2 (15)	93 (33)
Not employed	121 (47)	13 (50)	5 (38)	8 (62)	134 (48)
Missing	2 (1)	1 (4)	1 (8)	0 (0)	3 (1)

TABLE 59 Interview population baseline characteristics (*continued*)

Variable	Not interviewed (*n* = 256)	Interviewed			Total (*n* = 282)
		All (*n* = 26)	Mini booster (*n* = 13)	Full booster (*n* = 13)	
Ethnicity, *n* (%)					
White British	222 (87)	24 (92)	13 (100)	11 (85)	246 (87)
Any other	31 (12)	2 (8)	0 (0)	1 (8)	33 (12)
Missing	3 (1)	0 (0)	0 (0)	1 (8)	3 (1)
Marital status, *n* (%)					
Single	40 (16)	5 (19)	4 (31)	1 (8)	45 (16)
Married	138 (54)	13 (50)	5 (38)	8 (62)	151 (54)
Co-habiting	18 (7)	2 (8)	1 (8)	1 (8)	20 (7)
Divorced/ separated	51 (20)	4 (15)	2 (15)	2 (15)	55 (20)
Widowed	9 (4)	2 (8)	1 (8)	1 (8)	11 (4)
Stage of change, *n* (%)					
Contemplation	12 (4.7)	0 (0.0)	0 (0.0)	0 (0.0)	12 (4.3)
Preparation	114 (44.5)	11 (42.3)	7 (53.8)	4 (30.8)	125 (44.3)
Action	84 (32.8)	7 (26.9)	3 (23.1)	4 (30.8)	91 (32.3)
Maintenance	43 (16.8)	7 (26.9)	3 (23.1)	4 (30.8)	50 (17.7)
Missing	3 (1.2)	1 (3.8)	0 (0.0)	1 (7.7)	4 (1.4)
Age (years)					
n (%)	256 (100)	26 (100)	13 (100)	13 (100)	282 (100)
Mean (SD)	54.3 (7.4)	57.6 (6.1)	57.0 (5.6)	58.2 (6.6)	54.6 (7.3)
Median (IQR)	54.5 (48.3 to 61.0)	58.1 (53.2 to 63.5)	56.7 (53.2 to 61.8)	61.1 (54.3 to 63.9)	55.3 (48.8 to 61.4)
Min. to max.	40.4 to 65.5	45.5 to 65.1	47.9 to 65.1	45.5 to 64.9	40.4 to 65.5
Height (m)					
n (%)	255 (100)	26 (100)	13 (100)	13 (100)	281 (100)
Mean (SD)	1.7 (0.1)	1.7 (0.1)	1.7 (0.1)	1.7 (0.1)	1.7 (0.1)
Median (IQR)	1.7 (1.6 to 1.7)	1.7 (1.6 to 1.8)	1.7 (1.6 to 1.8)	1.7 (1.6 to 1.8)	1.7 (1.6 to 1.8)
Min. to max.	1.5 to 1.9	1.6 to 1.9	1.6 to 1.8	1.6 to 1.9	1.5 to 1.9

continued

TABLE 59 Interview population baseline characteristics (*continued*)

Variable	Not interviewed (*n* = 256)	Interviewed			Total (*n* = 282)
		All (*n* = 26)	Mini booster (*n* = 13)	Full booster (*n* = 13)	
Weight (kg)					
n (%)	256 (100)	26 (100)	13 (100)	13 (100)	282 (100)
Mean (SD)	85.2 (19.1)	84.5 (13.9)	80.3 (13.1)	88.7 (13.9)	85.2 (18.7)
Median (IQR)	83.0 (72.3 to 96.5)	80.8 (74.5 to 96.6)	78.0 (73.5 to 89.3)	88.0 (79.0 to 97.0)	82.9 (72.5 to 96.6)
Min. to max.	46.9 to 160.0	57.0 to 114.0	57.0 to 101.9	70.5 to 114.0	46.9 to 160.0
BMI (kg/m^2)					
n (%)	255 (100)	26 (100)	13 (100)	13 (100)	281 (100)
Mean (SD)	30.4 (6.1)	29.6 (3.9)	27.9 (2.8)	31.3 (4.3)	30.3 (5.9)
Median (IQR)	29.8 (26.0 to 33.2)	29.5 (26.9 to 31.5)	27.7 (26.7 to 30.4)	29.9 (29.0 to 35.1)	29.8 (26.3 to 33.0)
Min. to max.	17.1 to 53.4	22.5 to 39.3	22.5 to 32.0	25.0 to 39.3	17.1 to 53.4
SPAQ change (3 months post randomisation)					
n (%)	256 (100)	26 (100)	13 (100)	13 (100)	282 (100)
Mean (SD)	223.1 (382.3)	81.1 (178.6)	48.1 (187.3)	114.1 (170.4)	210.0 (370.4)
Median (IQR)	120.0 (60.0 to 257.5)	65.0 (0.0 to 200.0)	60.0 (0.0 to 150.0)	75.0 (40.0 to 200.0)	120.0 (60.0 to 255.0)
Min. to max.	–1840.0 to 3360.0	–480.0 to 540.0	–480.0 to 270.0	–150.0 to 540.0	–1840.0 to 3360.0
BREQ-2 (RAI)					
n (%)	248 (97)	26 (100)	13 (100)	13 (100)	274 (97)
Mean (SD)	5.2 (3.7)	5.7 (4.2)	3.8 (4.8)	7.6 (2.5)	5.3 (3.7)
Median (IQR)	5.8 (3.2 to 7.9)	7.2 (4.2 to 8.7)	5.8 (0.3 to 7.5)	8.3 (6.3 to 9.7)	6.0 (3.3 to 8.0)
Min. to max.	–9.1 to 12.0	–4.7 to 11.0	–4.7 to 9.0	2.9 to 11.0	–9.1 to 12.0

max., maximum; min., minimum.

TABLE 60 Objective physical activity levels in the interview population

Participant	Days meeting guidance/ accelerometry days	Median (range) moderate/ vigorous activity (minutes)
1064	0/3	0 (0 to 0)
1087	0/7	0 (0 to 9)
1094	0/7	0 (0 to 3)
1096	0/7	0 (0 to 5)
1152	3/3	576 (280 to 583)
1217	NA	NA
1230	2/7	3 (1 to 91)
1231	1/7	7 (3 to 53)
1232	1/7	15 (4 to 43)
1235	NA	NA
1237	NA	NA
1238	2/7	2 (0 to 47)
1240	0/7	0 (0 to 0)
1243	0/7	0 (0 to 26)
1245	NA	NA
1252	0/7	2 (0 to 23)
1253	NA	NA
1257	1/7	1 (0 to 41)
1258	3/7	28 (2 to 54)
1265	0/7	5 (0 to 14)
1267	0/7	13 (0 to 26)
1272	0/7	3 (0 to 6)
1279	0/7	0 (0 to 0)
1280	NA	NA
1281	0/7	2 (0 to 12)
1282	0/4	0.5 (0 to 3)

NA, not applicable.

TABLE 61 Motivational Interviewing Treatment Integrity interventionist ratings (treatment fidelity)

	Evocation (/5)			Collaboration (/5)			Autonomy/support (/5)			Direction (/5)			Empathy (/5)		
Name	First	Second	Mean	First	Second	Mean	First	Second	Mean	First	Second	Mean	First	Second	Mean
RA1	4	3	3.5	3	4	3.5	4	3	3.5	4	4	4	5	4	4.5
RA2	2	3	2.5	3	4	3.5	3	3	3	5	5	5	3	3	3
RA3	4	4	4	3	4	3.5	3	3	3	5	5	5	3	3	3
RA4	3	3	3	3	4	3.5	4	3	3.5	5	4	4.5	4	3	3.5
RA5	4	–	4	3	–	3	4	–	4	4	–	4	4	–	4
RA6	3	–	3	3	–	3	3	–	3	2	–	2	4	–	4

Note: proficiency = 3.5; competency = 4.0.

Average global rating (/5)			% Complex reflections (%CR)			% Open questions (%OQ)			Reflection to question ratio (R : Q)			% MI adherent (%MIA)		
First	Second	Mean	First	Second	Mean	First	Second	Mean	First	Second	Mean	First	Second	Mean
3.6	3.3	3.5	67	23	45	27	53	40	2.5	2.6	2.6	100	75	88
2.6	3.3	3	24	11	18	36	36	36	0.6	1.8	1.2	0	100	50
3.3	3.6	3.5	20	16	18	38	51	45	1.1	1.2	1.2	100	100	100
3.6	3.3	3.5	45	22	34	28	54	41	0.7	1.6	1.2	100	100	100
3.6	–	3.6	38	–	38	30	–	30	1.8	–	1.8	100	–	–
3	–	3	40	–	40	33	–	33	1.6	–	1.6	100	–	–

TABLE 62 Assumptions and derivations used to produce estimates of the intervention cost

Code	Parameter	Value	Assumptions/source/derivation
A	Sessions per completer	2	Booster trial
B	Average number of completer sessions per RA	35.67	214 completers, six RAs
C	Completers at 3 months in mini booster arm	55	Booster trial
D	Completers at 3 months in full booster arm	52	Booster trial
E	Completers at 9 months in mini booster arm	27	Booster trial
F	Completers at 9 months in full booster arm	35	Booster trial
G	Participants in mini booster	92	Booster trial
H	Participants in full booster	94	Booster trial
I	Fixed costs per RA, high estimate	£1800	Upper estimate of training/monitoring costs from booster MI expert
J	Fixed costs per RA, low estimate	£1000	Lower estimate of training/monitoring costs from booster MI expert
K	Hourly wage per RA	£15.76	Assuming wage of £26,000/year and 1650 hours/year
L	Additional cost per hour, full booster	£10	RA estimate of room hire costs per session
M	Additional cost per hour, mini booster	£4.80	Assuming telephone call costs of 8p/minute
N	Session duration, mini booster	20 minutes	RA estimate
O	Session duration, full booster	30 minutes	RA estimate
P	Participants per completer	1.87	200 participants/107 completers
Q	Variable cost per session, mini booster	£6.85	N × (M + K)
R	Variable cost per session, full booster	£12.88	O × (L + K)
S	Effective sessions per completer, 3 months, mini booster	3.35	A × (G/C)
T	Effective sessions per completer, 3 months, full booster	3.62	A × (H/D)
U	Effective sessions per completer, 9 months, mini booster	6.81	A × (G/E)
V	Effective sessions per completer, 9 months, full booster	5.37	A × (H/F)
W	Variable cost per completer, 3 months, mini booster	£22.92	Q × S
X	Variable cost per completer, 3 months, full booster	£46.56	R × T
Y	Variable cost per completer, 9 months, mini booster	£46.70	Q × U
Z	Variable cost per completer, 9 months, full booster	£49.18	R × V
AA	Fixed cost per completer, 3 months, mini booster, assuming I	£168.84	(I/C) × S
AB	Fixed cost per completer, 3 months, full booster, assuming I	£182.46	(I/C) × T
AC	Fixed cost per completer, 9 months, mini booster, assuming I	£343.93	(I/C) × U

TABLE 62 Assumptions and derivations used to produce estimates of the intervention cost (*continued*)

Code	Parameter	Value	Assumptions/source/derivation
AD	Fixed cost per completer, 9 months, full booster, assuming J	£271.08	(I/C) × V
AE	Fixed cost per completer, 3 months, mini booster, assuming J	£93.80	(J/C) × S
AF	Fixed cost per completer, 3 months, full booster, assuming J	£101.37	(J/C) × T
AG	Fixed cost per completer, 9 months, mini booster, assuming J	£191.07	(J/C) × U
AH	Fixed cost per completer, 9 months, full booster, assuming J	£150.60	(J/C) × V
AI	Total cost per completer, 3 months, mini booster, assuming I	£191.76	W + AA
AJ	Total cost per completer, 3 months, full booster, assuming I	£229.02	X + AB
AK	Total cost per completer, 9 months, mini booster, assuming I	£390.62	Y + AC
AL	Total cost per completer, 9 months, full booster, assuming I	£340.26	Z + AD
AM	Total cost per completer, 3 months, mini booster, assuming J	£116.72	W + AE
AN	Total cost per completer, 3 months, full booster, assuming J	£147.93	X + AF
AO	Total cost per completer, 9 months, mini booster, assuming J	£237.77	Y + AG
AP	Total cost per completer, 9 months, full booster, assuming J	£219.78	Z + AH

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