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]

[1]School of Health and Related Research (ScHARR), University of Sheffield, Sheffield, UK
[2]Sheffield Clinical Trials Research Unit, University of Sheffield, Sheffield, UK
[3]Centre for Sport and Exercise Science, Sheffield Hallam University, Sheffield, UK
[4]Centre for Health and Social Care Research, Sheffield Hallam University, Sheffield, UK

*Corresponding author

Declared competing interests of authors: Jeff Breckon has delivered consultancy and training services on behalf of Sheffield Hallam University relating to motivational interviewing in health care.

Published February 2014
DOI: 10.3310/hta18130

Scientific summary

Evaluation of 'booster' interventions for physical activity in adults

Health Technology Assessment 2014; Vol. 18: No. 13
DOI: 10.3310/hta18130

NIHR Journals Library www.journalslibrary.nihr.ac.uk

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.

Health Technology Assessment

HTA/HTA TAR

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Five-year impact factor: 5.804

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index and is assessed for inclusion in the Database of Abstracts of Reviews of Effects.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: nihredit@southampton.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the *Health Technology Assessment* journal

Reports are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

The HTA programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

For more information about the HTA programme please visit the website: www.hta.ac.uk/

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 07/25/02. The contractual start date was in February 2009. The draft report began editorial review in November 2012 and was accepted for publication in May 2013. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).