A pilot randomised trial to assess the methods and procedures for evaluating the clinical effectiveness and cost-effectiveness of Exercise Assisted Reduction then Stop (EARS) among disadvantaged smokers

Adrian H Taylor,[1]* Tom P Thompson,[2] Colin J Greaves,[3] Rod S Taylor,[3] Colin Green,[3] Fiona C Warren,[3] Rebecca Kandiyali,[3] Paul Aveyard,[4] Richard Ayres,[1] Richard Byng,[1] John L Campbell,[3] Michael H Ussher,[5] Susan Michie[6] and Robert West[7]

[1]Plymouth University Peninsula School of Medicine and Dentistry, Plymouth, UK
[2]Sport and Health Sciences, University of Exeter, Exeter, UK
[3]University of Exeter Medical School, University of Exeter, Exeter, UK
[4]Department of Primary Care Health Services, University of Oxford, Oxford, UK
[5]Division of Population Health Sciences and Education, St George's University of London, London, UK
[6]Research Department of Clinical, Educational and Health Psychology, University College London, London, UK
[7]Health Behaviour Research Centre, Department of Epidemiology and Public Health, University College London, London, UK

*Corresponding author

Declared competing interests of authors: PA has been a consultant and done research for manufacturers of smoking-cessation products. RW has undertaken research and consultancy for companies that develop and manufacture smoking-cessation medications. He is co-director of the National Centre for Smoking Cessation and Training and a trustee of the stop-smoking charity, QUIT. He has a share of a patent on a novel nicotine delivery device. All other authors have declared no competing interests.

Published January 2014
DOI: 10.3310/hta18040

This report should be referenced as follows:

Taylor AH, Thompson TP, Greaves CJ, Taylor RS, Green C, Warren FC, *et al.* A pilot randomised trial to assess the methods and procedures for evaluating the clinical effectiveness and cost-effectiveness of Exercise Assisted Reduction then Stop (EARS) among disadvantaged smokers *Health Technol Assess* 2014;**18**(4).

Health Technology Assessment is indexed and abstracted in *Index Medicus*/MEDLINE, *Excerpta Medica*/EMBASE, *Science Citation Index Expanded* (SciSearch®) and *Current Contents®*/ Clinical Medicine.

Scientific summary

Background

In the UK, only 4% of those who attempt to quit smoking will still be abstinent 1 year later. This rate is nearly quadrupled, to 15% (across the whole population), with NHS specialist Stop Smoking Service (SSS) support. Smoking prevalence is reducing nationally, but at a slower rate among socially disadvantaged groups than in the more affluent groups, which is leading to increasing health inequalities. While the prevalence of quit attempts is similar across all social groups, those with low socioeconomic status are less successful in remaining abstinent. Further research is therefore required to establish better ways to increase the reach of interventions into disadvantaged communities to increase the number of successful quitters.

Abrupt cessation is currently the preferred approach to quitting, rather than reduction (which is thought to make quitting harder as longer gaps between each cigarette make each one more rewarding). Over half of smokers want to reduce (or are reducing) smoking, but do not want to quit in the immediate future. Those who do reduce, with the support of nicotine replacement therapy (NRT), are more likely to quit and remain abstinent. Smoking reduction appeals to heavier smokers and those who are not ready to quit in the near future, yet there is little evidence available on the clinical effectiveness and cost-effectiveness of behavioural support for smoking reduction and cessation induction among such smokers.

There is good evidence that physical activity (PA) can influence smoking behaviour in a number of ways. In the short term a single bout of moderate or vigorous PA can reduce cravings and withdrawal symptoms by about 30% and delay the time until the next cigarette is smoked. Longer-term studies show mixed support for PA as an aid for smoking cessation, but this may reflect poor research design. Those studies that have shown some beneficial effects involved group exercise classes, which may not appeal to many smokers.

The Exercise Assisted Reduction then Stop (EARS) intervention was therefore designed to address the pragmatic question of whether or not a PA and smoking reduction counselling intervention, targeted at disadvantaged smokers, would be feasible and acceptable.

Objectives

1. To develop a multicomponent PA intervention aimed at helping smokers (not intending to quit in the next month) to cut down, and then quit (if they wish), in conjunction with professionals working with the 'hard to reach'.
2. To qualitatively assess the acceptability of such a PA intervention, as an aid to cutting down, among 'hard-to-reach' smokers.
3. To qualitatively assess the acceptability of recruitment, assessment and randomisation procedures within a pilot pragmatic randomised controlled trial (RCT), in order to compare the effects of a PA intervention against brief advice (on SSS support to quit), among 'hard to reach' smokers.
4. To obtain an estimate of the intervention (PA vs. brief advice) effect size and its precision to inform sample size calculations for a fully powered trial, from a pilot randomised trial to assess expired air carbon monoxide (CO)-confirmed abstinence at 4 weeks post quit date.
5. To assess process measures at 4, 8 and 16 weeks post baseline, including self-reported cigarettes smoked; number of quit attempts; self-reported quality of life; mood and physical symptoms; cravings; PA by self-report and accelerometer (in a subsample); pharmacological and behavioural support used; and weight.
6. To estimate the resource use and costs associated with delivery of the intervention, and to pilot methods for determining future cost-effectiveness analyses.

Methods

We carried out an individually randomised, single-centre pilot RCT comparing an integrated smoking reduction and PA promotion intervention in addition to usual care, against usual care (which at the time of writing was to provide information about quitting). The randomisation rate was 1 : 1 and completed via a web-based randomisation sequence and minimised by health trainer (HT) (one of three), age (over/under 30 years), smoking dependence (high/low) and sex.

Participants were recruited through three approaches:

1. mailed invitation (with telephone reminders) via three general practitioner (GP) surgeries in the targeted communities
2. mailed invitation (with telephone reminders) via the local SSS to residents of the targeted communities
3. a wide range of other community-based approaches (e.g. media exposure, networking, attending local community centre events).

Participants were eligible to enter the study if they were over 18 years old, smoked at least 10 cigarettes per day (and had done so for at least 2 years), did not want to quit in the next month, were able to engage in moderate-intensity PA (walk without stopping for at least 15 minutes), were registered with a GP, and did not wish to use NRT to reduce smoking. The study focus was on initially reducing smoking, not on quitting, and so those who expressed an immediate desire to quit were referred directly to the SSS without entering the study. Those wishing to use NRT were excluded to avoid any confounding of the effects of PA on their smoking behaviour. We excluded those with severe mental health problems and ongoing substance misuse who may have put the safety of the research team at risk. Given the exploratory nature of the study, participants were required to be able to converse in English.

The primary outcome was expired air CO-confirmed abstinence 4–8 weeks after quitting, among those who made a quit attempt while involved in the study. Secondary outcomes included those reducing their smoking by at least 50% from baseline, self-reported and objectively measured PA levels, along with several other behavioural, emotional and cognitive variables, at 4, 8 and 16 weeks.

Extensive data on recruitment activity, time invested, response rates and randomisations rates were recorded for all recruitment approaches for comparison.

Comprehensive qualitative work was completed in order to address issues of acceptability and feasibility about the trial and intervention design and methods. This included the following: interviews with the HTs early and late in the trial; fidelity coding of a selection of recorded (and transcribed) intervention sessions against an 11-item fidelity coding framework based on the expected active components of the intervention; the identification of examples of good practice for future training from interviews with 25 completing participants to assess acceptability of the intervention and trial methods; and further identification of the perceived effective intervention components.

Data were collected within trial, via work sampling procedures and trial-level data collection, to inform estimates of the resource use and associated cost for the EARS intervention. Longer-term outcomes associated with estimates of the effectiveness of the EARS intervention and the cost-effectiveness of the intervention compared with brief advice were explored.

The PA intervention was client centred and counselling based, with sessions taking place face to face in a local multiuse NHS building (or by telephone) over 8 weeks, with up to a possible further 6 weeks' support following a quit attempt. A written EARS intervention manual was provided for the HTs, designed to build on existing HT competencies.

Results

A total of 99 participants were randomised from the three recruitment approaches with a 62% follow-up rate at 16 weeks. Sixty-two were recruited through mailed GP practice invitations (plus reminder telephone calls of varying intensity) and 31 through mailed SSS invitation (with reminder telephone calls of varying intensity). Depending on the intensity and time invested in following up those who did not initially respond to the letters, we randomised between 5.1% and 11.1% of those invited, with associated researcher time to recruit one participant varying from 18 to 157 minutes. Despite substantial time and effort, only six participants were recruited through other community-based approaches, with an associated researcher time of 469 minutes to recruit one participant. Participant demographics did not differ as a result of recruitment location or approach. Recruitment targets for a pre-defined disadvantaged population were met, with 91% of the sample in social class C2-E, up to 41% demonstrating mental health problems, and a small sample of single parents being recruited.

At baseline, 49 were randomised to the intervention arm and 50 to the usual care arm. Adherence to the intervention was generally positive, with 88% attending at least one intervention session and 59% attending at least four sessions. The mean number attended was four.

In the intervention and control arms, 22% versus 6%, respectively [relative risk = 3.74; 95% confidence interval (CI) 1.11 to 12.60), made a quit attempt; 14% versus 4% (relative risk = 3.57; 95% CI 0.78 to 16.35) had expired air CO-confirmed abstinence 4–8 weeks post quit; at 16 weeks, 10% versus 4% (relative risk = 2.55; 95% CI 0.52 to 12.53) achieved point-prevalence abstinence; and 39% versus 20% (relative risk = 1.94; 95% CI 1.01 to 3.74) achieved at least a 50% reduction in the number of cigarettes smoked daily. As the study was not powered for hypothesis testing, no inferred statistical significance of these results is reported.

Qualitative data from both recorded sessions and participant interviews showed that the HTs generally delivered the planned intervention as intended following phase 1 developmental work and that it was largely acceptable among interviewed participants. The intervention fidelity analysis identified several areas for improvement (e.g. in exploring social influences and those linked with PA) with associated implications for updating the training course (e.g. HTs should be given more training and supervision to identify opportunities to build motivation to increase PA and to more positively reinforce health-identity shifts). We identified a case study that could be used in future training in which an increase in PA reinforced a stronger positive health identity as smoking was reduced. Interviews with patients and the HTs identified further possible adaptations and refinements for future practice, and effective components of the intervention (e.g. the process of engagement, behavioural strategies for smoking reduction, and to a lesser extent the promotion of PA). Issues surrounding the complexities of integrating PA and smoking reduction were highlighted and will inform refinements to the process model of how people use PA to manage smoking behaviour (and the related intervention processes).

The cost-effectiveness analysis estimated the mean cost of the EARS intervention at £192 per participant. It also provided valuable information on how to assess the cost-effectiveness of a future phase 3 definitive RCT, indicating the required scope of any modelling in the context of the EARS intervention. Exploratory cost-effectiveness analyses suggested that the EARS intervention is likely to be cost-effective where it is confirmed to be low cost and where the intervention effectiveness could be demonstrated.

Conclusions

Implications for future research

A larger, fully powered trial is needed to confirm the effectiveness and cost-effectiveness of the EARS intervention. The present pilot trial provided confidence that from mailed invitations and follow-ups a future trial could recruit about 17% of smokers interested in reduction but not quitting. In terms of

staffing, a dedicated administrator should be used to arrange appointments and issue prior reminders, which will add to the resources available to increase recruitment and retention. Future research should consider the reward of vouchers or other non-monetary incentives for attending assessments to increase study retention. Minor refinements to the intervention and training of HTs may increase acceptability and effectiveness. Further exploratory work, involving focus groups and piloting intervention adaptations is needed (e.g. over 6 months), to assess acceptability for a more ethnically diverse sample. A larger study would add further information about the core effective components of the intervention, and any moderators and mediators of any effects. A follow-up of at least 6 months post intervention is needed to provide evidence of long-term effectiveness.

We are not aware of any research on weight gain associated with smoking reduction (i.e. not cessation). The present study suggests that this should be considered carefully in future research. If indeed reduction is associated with weight gain then this may provide a rationale for more support for smokers to further increase PA to minimise the risk of weight gain.

Implications for health care

It is premature for any guidance for health professionals, policy makers and commissioners to be derived from the present study because the findings provide only preliminary support for the EARS intervention with a relatively short-term follow-up and sample from non-ethnically diverse population. The study is timely in light of the recent National Institute for Health and Care Excellence guidelines on harm reduction for smoking which calls for more evidence on the effects of behavioural support for smoking reduction and cessation induction.

Trial registration

This trial is registered as ISRCTN 13837944.

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. 4. See the NIHR Journals Library website for further project information.

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 07/78/02. The contractual start date was in September 2010. The draft report began editorial review in December 2012 and was accepted for publication in April 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).