Motivational support intervention to reduce smoking and increase physical activity in smokers not ready to quit: the TARS RCT

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Primary conflicts of interest: Paul Aveyard reports a National Institute for Health and Care Research (NIHR) Senior Investigator Award and that he participated in the NIHR Cochrane Tobacco Addiction Group during the conduct of the study. Siobhan Creanor reports that the Peninsula Clinical Trials Unit

received NIHR Clinical Trials Unit support funding for the duration of this trial; she also declares that she is chairperson of the NIHR Research for Patient Benefit South West Advisory Committee outside the submitted work. Tess Harris declares that she was a member of several Health Technology Assessment (HTA) groups: the HTA End of Life Care and Add on Studies groups (September 2015–February 2016), the HTA Primary Care, Community and Preventive Interventions Panel (January 2015–May 2018) and HTA Prioritisation Committee A (Out of Hospital) (January 2015–February 2019). Colin Green declares that he was a member of the HTA General Funding Committee (March 2019–October 2020). Lisa Price reports personal fees from NIHR/University of Plymouth during the conduct of the study. Lisa Price also reports that the University of Exeter, specifically the Physical Activity and Health Across the Lifespan group (within the Sport and Health Sciences department), is part of a collaboration with Activinsights Ltd (Kimbolton, UK), the manufacturer of the GENEActiv accelerometer used in this trial. The collaboration provides data analytics services for human activity research. Lynne Callaghan reports funding from NIHR Applied Research Collaboration South West Peninsula (PenARC) outside the submitted work.

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Scientific summary

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Scientific summary

Background

Behavioural support to aid smoking cessation is an effective and cost-effective intervention for smokers wanting to quit. Motivational support can reduce smoking, with greater reductions leading to successful quitting, but the evidence is fairly weak for those not wanting to immediately quit. Smoking reduction studies may involve two types of smokers: (1) those who want to quit and are willing to reduce first rather than quit abruptly and (2) those who do not want to quit (immediately) but are interested in smoking reduction or harm reduction. At least four studies have investigated the effects of behavioural support for smokers wanting to reduce but not quit, and provide imprecise or no evidence of effects on smoking reduction, quitting and sustained abstinence. Exercise has been shown to aid smoking cessation for those wanting to quit, but there is only exploratory evidence that promoting physical activity (PA) and supporting smoking reduction can facilitate smoking reduction and quitting. A definitive study is needed to determine the effectiveness and cost-effectiveness of behavioural support for smoking reduction and increasing PA, on smoking outcomes, especially prolonged, carbon monoxide-verified smoking abstinence.

Objectives

The overall aim of the Trial of physical Activity-assisted Reduction of Smoking (TARS) was to determine if adding a motivational intervention to reduce smoking and increase PA to usual support was more effective and cost-effective in facilitating carbon monoxide-verified 6-month floating prolonged abstinence.

The specific research questions were as follows.

- Compared with usual support, did the TARS intervention:
    - increase the proportion of participants achieving carbon monoxide-verified 6-month floating prolonged abstinence at 9 months post baseline?
    - increase the proportion of participants reporting a ≥50% reduction in the number of cigarettes smoked (between baseline and 3 months, and baseline and 9 months)?
    - increase the proportion of participants achieving carbon monoxide-verified 12-month floating prolonged abstinence at 15 months post baseline?
    - increase the proportion of participants achieving self-reported and carbon monoxide-verified point prevalence abstinence at 3 and 9 months post baseline?
    - increase self-reported PA at 3 and 9 months post baseline, and accelerometer-assessed PA at 3 months post baseline?
    - improve body mass index, quality of life, sleep, cigarette cravings and other beliefs about smoking and PA at 3 and 9 months post baseline?
- What were the intervention, health-care and social care costs, compared with support as usual, at 9 months post baseline?
- Was the intervention cost-effective, compared with usual support, (1) at 9 months, and (2) over a longer-term/lifetime horizon?
- Were the trial methods and intervention acceptable and feasible, based on an embedded internal pilot phase?
- Did the intervention demonstrate good fidelity (design, training, delivery, receipt and enactment) and acceptability and what were the mechanisms of action of the intervention?

Methods

The study involved a multicentred, parallel, two-group, individually randomised controlled, superiority trial with a mixed-methods embedded process evaluation and economic evaluations. Recruitment took place over 16 months from January 2018, with follow-up assessments ending in October 2020 (with only minimal overlap with COVID-19 restrictions) around four English cities: Plymouth, Nottingham, London and Oxford.

Intervention participants were offered up to eight face-to-face or telephone behavioural support sessions to reduce smoking and increase PA, with up to six additional sessions if a participant wanted support with cessation. Substantial patient and public involvement supported both the development and evaluation of a pilot trial of the intervention, and adaptations for the present intervention. An intervention manual underpinned the training and remote supervision of eight health trainers (HTs) across four sites, and all aspects of intervention fidelity (design, training, receipt, delivery and enactment) were assessed. The client-centred intervention was informed by motivational interviewing and linked to self-determination theory. It aimed to empower participants to decide what support they required, and where, when and for how long, and, if the participant became ready to quit, to provide appropriate support. Control participants received brief advice on smoking cessation.

Participants were recruited from primary and secondary care and community settings. Participants were adult smokers (≥18 years) who smoked ≥10 cigarettes per day (for at least 1 year), who wanted to reduce smoking but not quit immediately. Smokers were ineligible if they were unable to engage in at least 15 minutes of moderate-intensity PA, had any illness or injury that might be exacerbated by exercise, or were unable to engage in the trial and/or the intervention because of a language barrier or for other reasons.

Following screening and consent, participants completed baseline assessments face to face or via telephone. At 3 and 9 months post baseline, participants were posted a questionnaire (and an accelerometer at 3 months for a random sample). Participants reporting having made a quit attempt and not having smoked at follow-up were invited to complete a biochemical verification of abstinence. Most did this with a carbon monoxide expired air test, but a few were posted a saliva cotinine test kit late in the trial as a result of COVID-19 restrictions. Those with carbon monoxide-verified abstinence at 9 months were also followed up at 15 months.

The primary outcome was carbon monoxide-verified 6-month floating prolonged (i.e. with no fixed quit date) abstinence between 3 and 9 months. Other smoking measures were carbon monoxide-verified 12-month floating prolonged abstinence, point prevalence self-reported abstinence and number of cigarettes smoked per day, and carbon monoxide-verified abstinence and number of quit attempts at both 3 and 9 months. Analyses of smoking abstinence outcomes were in line with the Russell Standard, with non-responders assumed to be still smoking. Self-reported (3 and 9 months) and accelerometer-recorded (3 months) PA, body mass index, sleep and quality of life were also assessed at 3 and 9 months.

The embedded mixed-methods process evaluation was split into two phases: (1) an initial evaluation linked to the internal pilot phase and (2) the subsequent main trial phase, with four workstreams as follows – (1) data related to levels of intervention engagement; (2) assessment of intervention delivery, receipt and enactment fidelity, using survey items related to the intervention logic model and recorded intervention sessions; (3) mediation analyses of changes in PA and process measures on outcomes; and (4) an embedded qualitative study with HT and intervention participant interviews.

The health economic evaluation included an estimation of the cost of delivering the intervention from data collected during the trial, supplemented by investigator estimates.

A trial-based economic evaluation was conducted using patient-reported resource use and health-related quality of life (EuroQol-5 Dimensions, five-level version), collected in questionnaire booklets at baseline and at 3 and 9 months post randomisation. Aggregate costs and quality-adjusted life-years (QALYs) over a 9-month time horizon were estimated and regression methods were used to adjust for potential confounders.

A decision-analytic model was developed following a review of the existing literature. Smoking cessation rates were assumed to affect rates of coronary obstructive pulmonary disease, coronary heart disease, stroke and lung cancer, as well as quality of life and other smoking-related causes of mortality. Lifetime costs and QALYs were estimated.

Results

The sample (n = 915) had a mean age of 49.8 [standard deviation (SD) 13.9] years; 55% were female and 85% identified as white. Sixty per cent lived within one of the four highest-ranked deciles for social deprivation. They initially smoked an average of 18.0 cigarettes daily, with 77.68% smoking within 30 minutes of waking, and reported doing a median of 337 minutes of moderate to vigorous physical activity (MVPA) weekly.

Primary analysis

Using the Russell Standard, assuming missing participant data at follow-up implied continued smoking, 0.9% (n = 4) of control and 2.0% (n = 9) of intervention participants achieved carbon monoxide-verified 6-month floating prolonged abstinence between 3 and 9 months. This difference was not statistically significant [fully adjusted estimated odds ratio 2.30, 95% confidence interval (CI) 0.70 to 7.56; p = 0.169]. Including participants who achieved the outcome between 9 and 15 months increased this to 2.2% (n = 10) and 3.1% (n = 14) in the control and intervention groups, respectively, which was also not statistically significantly different (fully adjusted estimated odds ratio 1.43, 95% CI 0.62 to 3.26; p = 0.398).

For the 19 and 20 participants followed up at 15 months, 0.2% (n = 1) and 1.3% (n = 6) of the overall control and intervention groups, respectively, achieved carbon monoxide-verified 12-month floating prolonged abstinence, which was also not statistically significantly different (fully adjusted estimated odds ratio 6.3, 95% CI 0.8 to 53.1; p = 0.089).

Secondary outcomes

The intervention had weak effects on self-reported 7-day point prevalence abstinence at 3 months (5.5% vs. 2.9%, adjusted odds ratio 1.99, 95% CI 1.00 to 3.94; p = 0.049), but there was no evidence of a statistically significant effect on carbon monoxide-verified point prevalence abstinence at 3 months (3.7% vs. 1.8%, adjusted odds ratio 2.19, 95% CI 0.93 to 5.14; p = 0.071). Nor was there an intervention effect at 9 or 15 months, compared with control, for either of these outcomes.

The intervention group reported smoking fewer cigarettes daily than the control group at 3 months (adjusted mean difference −5.62, 95% CI −9.80 to −1.44; p = 0.009), but not at 9 months (adjusted mean difference 0.95, 95% CI −5.37 to 3.46; p = 0.671). A greater proportion of intervention participants reported having reduced their daily number of cigarettes smoked by at least 50%, up to 3 months (18.9% vs. 10.5%, adjusted odds ratio 1.98, 95% CI 1.35 to 2.90; p < 0.001) and 9 months (14.4% vs. 10%, adjusted odds ratio 1.52, 95% CI 1.01 to 2.29; p = 0.04). There was no difference between the groups in the proportions reporting a quit attempt by 3 or 9 months. In exploratory analysis of moderation effects for the number of cigarettes smoked per day, the intervention effects were stronger among participants who lived in more socially deprived areas.

The intervention participants did more self-reported MVPA than the control participants at 3 months (but not at 9 months), with an adjusted weekly mean difference of 81.61 minutes (95% CI 28.75 to 134.47 minutes; p = 0.003), but there were no differences in accelerometer-recorded PA at 3 months.

There was no evidence that change in PA between baseline and 3 months mediated intervention effects on smoking outcomes at 3 or 9 months.

There was no evidence of intervention effects on body mass index, sleep or quality-of-life measures.

Process evaluation

Intervention participants had a mean of 4.8 (SD 3.4) sessions with a HT, lasting a mean of 33.5 (SD 20.3) minutes, with face-to-face sessions lasting over twice as long as telephone sessions. Seventy-six per cent of intervention participants had two or more sessions, but because of the small numbers of participants who achieved prolonged carbon monoxide-verified abstinence, a planned sensitivity analysis to examine the effects of intervention engagement on the primary outcome was not performed.

The intervention was mostly delivered as planned and influenced the key components of the logic model. Seventy-two recorded sessions were coded by two independent coders and involved delivery to 24 different participants (who each did three or more sessions), equally spread across the eight HTs. Across 11 different competencies, the coding mean score of 3.2 (SD 1.4, range 1.7–4.1) on a 0–6 scale suggested generally good intervention delivery fidelity, with 'active participant involvement' and 'managing social influence on PA' being the best and least well delivered, respectively. There were statistically significant intervention effects on 8 out of 11 smoking process survey items, and on all seven PA process survey items at 3 months, with changes in importance of reducing smoking and confidence to reduce smoking, use of action planning, coping planning, availability of support, and self-monitoring of smoking up to 3 months mediating intervention effects on the number of cigarettes smoked per day up to 3 months. Changes in confidence to reduce and to quit, action planning, coping planning, self-monitoring and thoughts about quitting also mediated intervention effects on whether or not participants reduced their smoking by ≥50% up to 3 months. Only changes in urges to smoke up to 3 months mediated smoking reduction at 9 months. Similarly, changes in confidence to be physically active and self-monitoring PA up to 3 months mediated intervention effects on self-reported PA at 3 months.

Thematic analysis of coded interview scripts with 24 participants highlighted the ways that participants approached smoking reduction and increasing PA, multiple behaviour change, progression to quitting, and other effective and less effective intervention components, but, overall, the intervention appeared to be acceptable.

Health economic analysis findings

The intervention was estimated to cost a mean of £239.18 per participant, with the majority of costs attributed to HT time (£92.84), travel time (£53.02) and non-contact time (£71.69). There is some uncertainty in this estimate of the total, and the cost to deliver the intervention could be between £200 and £300 per participant. The trial-based cost-effectiveness analysis revealed that the intervention would lead to a non-statistically significant increase in costs (combining the cost of delivering the intervention with the impact on NHS/Personal Social Services resource use) of £173.50 (95% CI −£353.82 to £513.77) and a non-statistically significant decrease in QALYs of 0.006 (95% CI 0.033 QALY decrease to 0.021 QALY increase). The probability that the intervention is cost-effective over the 9-month time horizon was estimated to be 17% at a threshold of £20,000 per QALY, rising to 20% at a threshold of £30,000 per QALY. The model-based economic evaluation adopted an effect of a 1.1% absolute difference in the probability of a sustained quit to 9 months. We estimated that the intervention would lead to a small gain in lifetime QALYs and a small reduction in lifetime costs from smoking-related diseases, resulting in an incremental cost-effectiveness ratio of £37,100 per QALY, with the probability of the intervention being cost-effective being <50% for a cost-effectiveness threshold of between £20,000 and £30,000 per QALY.

Conclusions

There was no evidence that the intervention increased the likelihood of achieving carbon monoxide-verified prolonged abstinence from smoking, although it did lead to short-term increases in PA and abstinence, and ≥50% reductions in the number of cigarettes smoked per day at up to 3 and 9 months.

The intervention was delivered with good fidelity, and process measures appeared to mediate short-term, but not longer-term, changes in the number of cigarettes smoked daily and PA. Overall, participants found the intervention acceptable. The intervention is not cost-effective by UK standards.

The trial shows that it is possible to engage heavier smokers, many living in areas with high social deprivation, in a smoking reduction and PA intervention, with some positive effects on both behaviours. But further adaptations would be needed to translate early behaviour change into quit attempts and prolonged abstinence, and longer-term PA improvements.

Trial registration

This trial is registered as ISRCTN47776579.

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This report

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