Received: 21 July 2022 | Accepted: 13 December 2022

DOI: 10.1111/add.16129

RESEARCH REPORT

ADDICTION SSA

Effectiveness and cost-effectiveness of behavioural support for prolonged abstinence for smokers wishing to reduce but not quit: Randomised controlled trial of physical activity assisted reduction of smoking (TARS)

Adrian H. Taylor[1] | Tom P. Thompson[1] | Adam Streeter[1,2] | Jade Chynoweth[1] | Tristan Snowsill[3] | Wendy Ingram[1] | Michael Ussher[4,5] | Paul Aveyard[6,7] | Rachael L. Murray[8] | Tess Harris[5] | Lynne Callaghan[1] | Colin Green[3] | Colin J. Greaves[9] | Lisa Price[10] | Siobhan Creanor[3]

[1]Faculty of Health, University of Plymouth, Plymouth, UK

[2]Institut für Epidemiologie und Sozialmedizin, University of Münster, Munster, Germany

[3]University of Exeter Medical School, University of Exeter, Exeter, UK

[4]Institute for Social Marketing and Health, University of Stirling, Stirling, UK

[5]Population Health Research Institute, St. George's University of London, London, UK

[6]Nuffield Department of Primary Care Health Sciences, University of Oxford, Oxford, UK

[7]NIHR Oxford Biomedical Research Centre, Oxford University Hospitals, Oxford, UK

[8]Lifespan and Population Health, Clinical Science Building, School of Medicine, University of Nottingham, Nottingham, UK

[9]School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, Birmingham, UK

[10]Sport and Health Sciences, University of Exeter, Exeter, UK

Correspondence
Adrian H. Taylor, Peninsula Medical School, Faculty of Health, University of Plymouth, ITTC1 Building, N14, Plymouth Science Park, Plymouth, PL6 8BX, UK.
Email: adrian.taylor@plymouth.ac.uk

Abstract

Aims: For smokers unmotivated to quit, we assessed the effectiveness and cost-effectiveness of behavioural support to reduce smoking and increase physical activity on prolonged abstinence and related outcomes.

Design: A multi-centred pragmatic two-arm parallel randomised controlled trial.

Setting: Primary care and the community across four United Kingdom sites.

Participants: Nine hundred and fifteen adult smokers (55% female, 85% White), recruited via primary and secondary care and the community, who wished to reduce their smoking but not quit.

Interventions: Participants were randomised to support as usual (SAU) (n = 458) versus multi-component community-based behavioural support (n = 457), involving up to eight weekly person-centred face-to-face or phone sessions with additional 6-week support for those wishing to quit.

Measurements: Ideally, cessation follows smoking reduction so the primary pre-defined outcome was biochemically verified 6-month prolonged abstinence (from 3–9 months, with a secondary endpoint also considering abstinence between 9 and 15 months). Secondary outcomes included biochemically verified 12-month prolonged abstinence and point prevalent biochemically verified and self-reported abstinence, quit attempts, number of cigarettes smoked, pharmacological aids used, SF12, EQ-5D and moderate-to-vigorous physical activity (MVPA) at 3 and 9 months. Intervention costs were assessed for a cost-effectiveness analysis.

Funding information
We are grateful for funding for the trial from the National Institute for Health Research (NIHR) Health Technology Assessment programme: 15/111/01 and the NHS Clinical Research Networks involved in supporting recruitment. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care. All authors were funded to conduct work as part of the TARS trial, except T.H. The study sponsor and funder had no role in the study design, data collection, analysis, interpretation or writing the report. The corresponding author had full access to all data necessary to write this report and had final responsibility for the decision to submit for publication. P.A. was funded by NIHR Oxford Biomedical Research Centre and the NIHR Applied Research Collaboration. L.C. was funded by the National Institute for Health Research Applied Research Collaboration South West Peninsula.

Findings: Assuming missing data at follow-up implied continued smoking, nine (2.0%) intervention participants and four (0.9%) SAU participants achieved the primary outcome (adjusted odds ratio, 2.30; 95% confidence interval [CI] = 0.70–7.56, $P = 0.169$). At 3 and 9 months, the proportions self-reporting reducing cigarettes smoked from baseline by ≥50%, for intervention versus SAU, were 18.9% versus 10.5% ($P = 0.009$) and 14.4% versus 10% ($P = 0.044$), respectively. Mean difference in weekly MVPA at 3 months was 81.6 minutes in favour of the intervention group (95% CI = 28.75, 134.47: $P = 0.003$), but there was no significant difference at 9 months (23.70, 95% CI = −33.07, 80.47: $P = 0.143$). Changes in MVPA did not mediate changes in smoking outcomes. The intervention cost was £239.18 per person, with no evidence of cost-effectiveness.

Conclusions: For United Kingdom smokers wanting to reduce but not quit smoking, behavioural support to reduce smoking and increase physical activity improved some short-term smoking cessation and reduction outcomes and moderate-to-vigorous physical activity, but had no long-term effects on smoking cessation or physical activity.

KEYWORDS
Behavioural support, biochemical verification, health economic evaluation, motivational interviewing, multiple behaviour change, physical activity, prolonged abstinence, smoking cessation, smoking reduction

INTRODUCTION

For people attempting to stop smoking, a combination of pharmacotherapy and behavioural support maximises the likelihood of cessation [1–3]. Such interventions are highly cost-effective, and, consequently, guidelines recommend that health systems provide such care and people take up the offer [4].

For smokers wishing to reduce but not immediately quit, the effects of tobacco harm reduction interventions on abstinence are less certain, and healthcare professionals and policy makers urgently seek evidence-based guidance. Two systematic reviews show evidence that nicotine replacement therapy (NRT), often with behavioural support, can reduce smoking and increase quit attempts and abstinence for smokers not immediately wishing to quit [5, 6]. However, a significant proportion of smokers do not wish to use pharmacological aids, including e-cigarettes and licenced nicotine-containing products (LNCPs) for several reasons, including the uncertainty of health risks [7].

Before the present study, we identified four randomised controlled trials (RCTs) [8–11] that examined the effects of behavioural support for smoking reduction among smokers wishing to reduce smoking but not quit. Our unpublished meta-analysis of intervention effects on the most rigorous outcomes in these studies provided a pooled relative risk (RR) of abstinence of 1.46 (95% CI = 0.90–2.38), suggesting that such interventions are effective for increasing quit attempts and point prevalence abstinence; however, there was a high risk of bias, with only one study biochemically verifying abstinence [11] and none assessing floating prolonged abstinence [12].

Continued smoking by people with moderate to high tobacco dependence who want to reduce but not quit is usually driven by urges to smoke or cravings [13]. There is strong evidence that the intensity of these urges can be acutely reduced by physical activity [14]. For smokers wishing to quit, a systematic review of exercise interventions provided little evidence for physical activity aiding sustained smoking cessation [15]. However, most trials were of low quality, and comparisons were mostly with existing evidence-based effective treatments, which possibly minimised any effects.

In a pilot RCT, we uniquely examined the acceptability, feasibility, intervention fidelity and exploratory effectiveness of behavioural motivational support to promote smoking reduction and physical activity among smokers who wished to reduce their smoking but not quit [16–18]. Intervention participants were twice as likely to reduce their self-reported smoking by at least 50%, were nearly four times more likely to attempt to quit and were two to three times more likely to be biochemically verified as abstinent in the short term. Participants appreciated the value of physical activity as a diversionary shift to a more positive health identity, for managing mood and weight gain, and the intervention was plausibly cost-effective. The pilot also highlighted the need to embrace a flexible approach to supporting disadvantaged smokers, who wished to reduce in different ways and timescales, and offer evidence-based support when they wished to quit, aligned to a phase-based model [19].

The present study (trial of physical activity assisted reduction of smoking [TARS]) aimed to test the effectiveness and cost-effectiveness of a multi-component intervention for smokers wishing to reduce but not quit, to increase biochemically verified 6-month prolonged abstinence and other smoking and physical activity outcomes, while seeking to understand the role of the respective components.

METHODS

Study design and participants

We conducted a pragmatic, multi-centred, parallel two-arm, community-based, randomised controlled, superiority trial. The published protocol describes the trial procedures in detail [20].

We recruited participants from the United Kingdom (UK) primary and secondary care and community settings using a wide range of methods including general practitioner (GP) letters, text messages and e-mails, community adverts and social media, at four sites: East Midlands; South Central England; Devon and Cornwall; and London. After expressing interest, potential participants were screened by phone. Participants were ages ≥18 years, smoking ≥10 cigarettes per day (for at least 1 year), wishing to reduce smoking, but not quit immediately. They were ineligible if unable to engage in at least 15 minutes of continuous moderate intensity physical activity, had illness or injury that might be exacerbated by exercise or were unable to engage in the study and/or intervention because of language or other reasons. We did not exclude those who also wished to use pharmacological aids, but accounted for this in our analysis plan. Participants gave written informed consent.

The study was approved by the South West Central Bristol Research Ethics Committee (REC reference: 17/SW/0223) and Health Research Authority and registered with the International Standard Randomised Controlled Trial Number register (ISRCTN47776579) before trial commencement. An independent trial steering committee and data monitoring committee oversaw the trial.

Randomisation and masking

Following baseline assessments, participants were randomised by the Peninsula Clinical Trials Unit (CTU) using a web-based system to conceal allocation. Participants were individually randomised to intervention or support as usual (SAU) group (1:1 ratio) using random permuted blocks, with stratification by recruitment site and the Heaviness of Smoking Index (HSI) [21] (low vs high) as a measure of dependence. An independent statistician developed the sequence.

Participant blinding was not possible. Researchers conducting follow-up assessments were masked to participants' allocation, and primary analysis of primary and secondary outcomes was undertaken by trial statisticians blinded to allocation. We also used objective biochemically verified abstinence.

Procedures

Briefly, intervention participants were offered up to eight, usually weekly, behavioural support sessions, face-to-face or by phone, lasting 10 to 60 minutes, to reduce smoking and increase physical activity, as described in detail elsewhere [20]. Up to six additional cessation-support sessions were offered to participants who decided to make a quit attempt. Building on the pilot study [16] and patient and public involvement, an intervention manual underpinned training (see http://hdl.handle.net/10026.1/17035) and supervision of eight health trainers (two per site) with experience of delivering behaviour change interventions and was the basis for the assessment of intervention fidelity. The client-centred intervention, particularly designed to engage with those living in disadvantaged communities, was informed by motivational interviewing and self-determination theory [22]. The TARS intervention aimed to enhance participant's sense of importance and confidence to autonomously change behaviours while connecting with others. The content had some overlap with interventions with a focus on smoking reduction for those smokers unmotivated to quit [8–11]. Participants were encouraged to self-monitor and set goals for both smoking and physical activity, problem-solve to overcome barriers for changing both behaviours, identify links between how physical activity may influence smoking acutely and chronically and vice versa and manage social influences that influenced the two behaviours. For example, with personal experimentation, we encouraged participants to use physical activity to manage cravings and weight gain and shift to a healthier self-identity. For participants wishing to quit, additional health trainer support sessions were provided to help maintain abstinence and to also access support as usual.

SAU participants received brief advice on smoking cessation immediately post-randomisation, reflecting guidelines in the United Kingdom for smokers not wishing to quit (see Supporting information Appendix S1).

Baseline data including demographics and smoking and physical activity history were collected in-person or by telephone. Follow-up data were collected by telephone or mailed survey. At 3 and 9 months, participants who reported making a quit attempt and having not smoked were asked to complete a biochemical verification of abstinence. At 15 months, only those with biochemically verified abstinence at 9 months were followed up to determine 12-month prolonged abstinence (i.e. 3–15 months) and identify any additional participants who achieved 6-month prolonged abstinence from 9 to 15 months.

Outcomes

To extend the evidence for sustained intervention effects the primary outcome was floating (i.e. no fixed quit date) biochemically verified 6-month prolonged smoking abstinence (as recommended by Aveyard *et al.*) [12] between 3 and 9 months, biochemically verified using a CareFusion MicroCO meter (Williams Medical Supplies; www.carefusion.co.uk). Because of coronavirus disease 2019 (COVID-19)-related restrictions introduced on 26 March 2020 in the United Kingdom, two of 48 participants at 9 months, and nine of 21 participants at 15 months, were provided with a mailed saliva cotinine test kit (ABS Laboratories; www.acmgloballab.com). At 3 months, participants who reported making a quit attempt (at least 24 hours without a puff) since joining the study, smoking not a puff since the quit date and providing an exhaled CO < 10 ppm were deemed abstinent. At 9 months, participants who had been confirmed as biochemically verified abstinent at 3 months and who reported

having smoked fewer than five cigarettes since that quit attempt were deemed abstinent with biochemical verification.

Secondary smoking outcomes were floating 12-month prolonged, biochemically verified smoking abstinence (between 3 and 15 months), and point prevalence self-reported abstinence, cigarettes per day, biochemically verified abstinence and quit attempts at both 3 and 9 months. Use of e-cigarettes or LNCPs and urge and strength of urge to smoke [23] were self-reported at 3 and 9 months. The proportion of participants reducing the number of cigarettes smoked by ≥50% between baseline and 3 and 9 months was also determined. For analyses of smoking abstinence outcomes, non-responders were assumed to be smoking [24]. Self-reported 7-day physical activity recall [25] (at 3 and 9 months) and GENEActiv accelerometer (only at 3 months for a sample of participants) recorded moderate-to-vigorous physical activity (MVPA), and self-reported body mass index, sleep and quality of life (SF-12, EQ-5D-5L) [26, 27] (at 3 and 9 months) were assessed.

For the trial-based cost-effectiveness analysis, we estimated the direct cost of delivering the intervention from contact data collected during the study by health trainers and based on assumptions and estimates provided by investigators for cost components not measured during the study. We estimated quality-adjusted life years (QALYs) from participant-reported EQ-5D-5L (mapped to EQ-5D-3L value set) [26] and costs from a health and social care resource use questionnaire, completed at baseline, 3 and 9 months.

Serious adverse events (SAEs), defined as a hospitalisation or sudden death, were recorded during the trial up to 8 weeks after the 9-month follow-up and were assessed for likelihood of relatedness to the trial procedures.

Statistical analysis

We aimed to recruit 900 participants, giving 90% power at the two-sided 5% significance level to assess whether the intervention increased the biochemically verified 6-month prolonged smoking abstinence rate from 5% in the control group to 11%. These estimated abstinence rates were consistent with the pilot study [16] and those in a systematic review of pharmacological interventions [28]. As only participants who were unavoidably lost to follow-up (death or address untraceable) were excluded from the primary analysis (expected to be <5% of recruited participants), the sample size was not inflated for loss to follow-up.

A detailed study protocol (finalised 11 June 2020), statistical analysis plan (finalised 20 September 2020) and health economic evaluation plan (finalised 5 November 2019) were approved by the oversight committees before locking the trial database and are available at https://fundingawards.nihr.ac.uk/award/15/111/01 [29].

Primary analyses of primary and secondary outcomes, and reported SAEs, were by intention-to-treat (ITT). Analyses used Stata 14.0 and R4.0.3; the inferential analyses were pre-specified in the statistical analysis plan, for which the primary analysis was independently programmed by two statisticians.

Fully adjusted models included the stratification variables (site and HSI), as well as the corresponding baseline measure of outcome being modelled, where appropriate. Adjustments for multiple analyses were not made [29]. To check that the intervention effect was not heterogeneous across study centres, we tested the interaction between intervention and study site using a fixed-effect model. There was no evidence for this (P value = 0.8338), and consequently, the inclusion of a random effect term for site was not necessary in our analysis model.

The primary analysis of the primary outcome used a multi-variable logistic regression model to compare the floating biochemically verified 6-month (between 3 and 9 months) prolonged abstinence rate, between groups, with adjustment for stratification factors. Both adjusted and unadjusted ORs and 95% CIs were determined, together with absolute between-group differences. Intervention effectiveness was also presented as an RR, calculated from the estimated OR for the intervention and the baseline rate for the SAU group, along with the corresponding 95% CI. Planned sensitivity analyses of the primary outcome included a 'best-case scenario', where participants with missing primary outcome data were assumed to have quit at 3 and 9 months, and a complier average causal effect (CACE) analysis to determine intervention effects for participants who had received a pre-determined dose of at least two interventions sessions, compared with those who received fewer and SAU participants. Additional planned analyses included adjustment for potential confounding variables at baseline (index of multiple deprivation [IMD], self-reported MVPA, LNCP use, vaping), in addition to the stratification factors, if there were notable group imbalances at baseline. An exploratory analysis of the health trainer effect using a multi-level, mixed-modelling approach to allow for the partially nested data (participants allocated to the intervention group were partially clustered within the HT, in turn nested within sites) was also planned. To test the significance of adding an interaction between allocated group and study centre, the log-likelihood from the interaction model was compared to that from the primary model of the primary outcome fitted to the same data subset (n = 761).

The analyses of secondary outcomes followed a similar approach to that for the primary outcome, using both adjusted and unadjusted multi-variable logistic or linear regression modelling, and pre-planned exploratory analyses as for the primary outcome.

We were unable to test the mediating effects of physical activity on the primary outcome because of sparsity of data, but we did explore if intervention effects on self-reported physical activity at 3 months mediated effects on cigarettes smoked and % achieving ≥50% smoking reduction from baseline to 3 and 9 months (see Figure 1). We used structural equation modelling (SEM) [30] with CI for the mediated path estimated through the bootstrap resampling method, with 1000 replications.

The cost-effectiveness analysis included only complete cases, that is, participants for whom we could calculate a total cost and QALYs over 9 months and for whom we had full baseline data. A generalised linear modelling approach was used, with adjustment for baseline costs and quality of life.

RESULTS

The flow of participants is shown in Figure 2. Between 15 January 2018 and 6 June 2019, 1441 people were screened, of whom 915 (63%) were eligible, consented and randomly assigned to the intervention (n = 457) or SAU (n = 458). Six-hundred and forty-nine (71%) were recruited via primary care, predominantly after a search of medical records and mailed, e-mailed or texted an invitation, with the remainder through secondary care, various community and social media engagement. The last follow-up was on 20 August 2020.

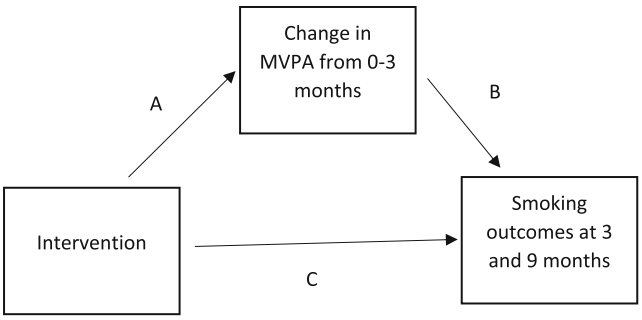

FIGURE 1 Path model for mediating effects of changes in moderate to vigorous physical activity (MVPA) on smoking outcomes.

Participants' baseline characteristics are shown in Table 1 and were balanced across groups. Approximately 60% came from post-codes in the 40% most deprived areas of England, with 17% unemployed and 21.5% having no qualifications. The mean (SD) age was 49.8 (13.9) years, 55.4% were female, and most identified as White (84.9%). Overall, 30.3% reported having a partner who smoked. Participants smoked a mean (SD) of 18.0 (13.4) daily cigarettes with 32.6% smoking within 5 minutes of waking. No participants reported using a pharmacological smoking cessation product, 11% used vaping, and 7% used LNCPs. Participants reported a greater perceived importance of and confidence for reducing rather than quitting smoking. Follow-up of participants is detailed in Figure 2. In summary, 318/457 (69.6%) intervention participants, and 306/458 (66.8%) SAU

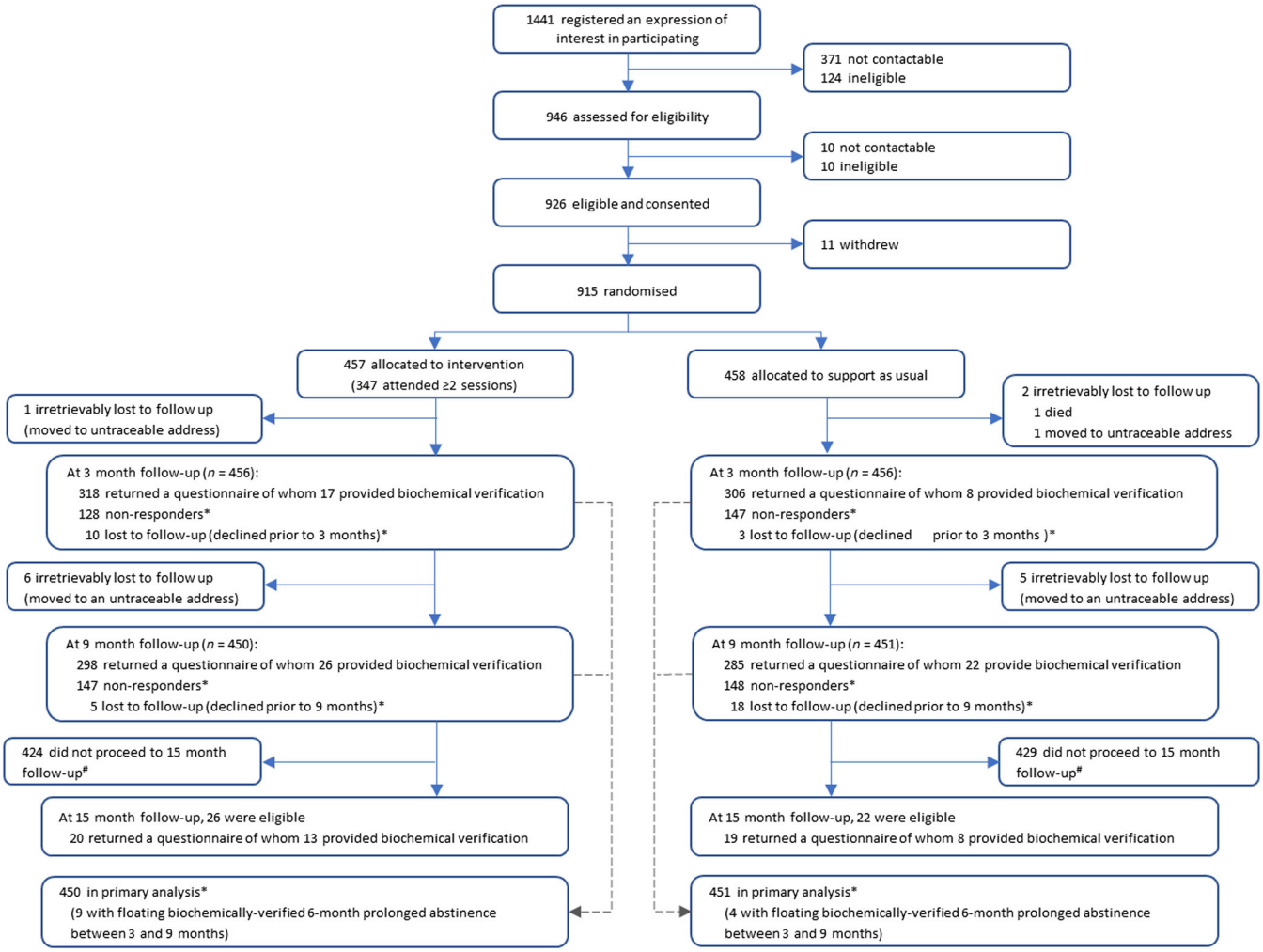

FIGURE 2 Trial profile. *Primary analysis of the primary outcome in line with the Russell Standard (i.e., participants with missing responses were considered to still be smokers with the exception of those unavoidably lost to follow-up, defined as participants who had died or were untraceable). #Only participants with 9 month biochemically-verified abstinence were followed up at 15 months.

TABLE 1 Baseline characteristics, according to study group.

	Intervention	Support as usual
N	457	458
Age (years)—mean (SD)	49.5 (14.1)	50.0 (13.6)
Gender, female	244 (53.4)	263 (57.4)
Ethnicity, White	387 (84.7)	390 (85.2)
Index of multiple deprivation rank[a] (derived from postcode), mean (SD)	14,393.1 (8823.2)	14,467.6 (8655.3)
Relationship status		
Single (never married or civil partnered)	200 (43.8)	190 (41.5)
Married (or common-law partner)	186 (40.7)	197 (43.0)
Divorced or civil partnership dissolved	54 (11.8)	57 (12.4)
Other	16 (3.5)	14 (3.1)
Work situation		
Working full or part time in paid employment	206 (45.1)	212 (46.3)
In full-time education	21 (4.6)	14 (3.1)
Retired	70 (15.3)	76 (16.6)
Unemployed	83 (18.2)	73 (15.9)
Other	77 (16.8)	83 (18.2)
Educational attainment		
No qualifications	102 (22.3)	95 (20.7)
First degree	83 (18.2)	104 (22.7)
Total daily equivalent cigarettes smoked, mean (SD)	18.2 (13.2)	17.4 (9.9)
Smoking more than 20 cigarettes per day	125 (27.4)	127 (27.7)
Smoking within 5 min of waking	149 (32.6)	149 (32.5)
Partner smokes, yes	145 (31.7)	132 (28.8)
Use vaping or licenced nicotine containing products, yes	69 (15.1)	59 (12.9)
Body mass index (kg/m^2), mean (SD)	26.4 (5.8)	26.4 (5.8)
Weight (kg), mean (SD)	76.7 (18.7)	76.4 (19.2)
Self-reported total weekly minutes of moderate-to-vigorous PA, mean (SD)	456.1 (434.0)	462.4 (419.2)
Self-reported daily hours spent sleeping, mean (SD)	6.9 (1.6)	6.7 (1.5)
Important I reduce my smoking[b]	4.7 (0.6)	4.7 (0.5)
Important I quit smoking[b]	4.2 (0.9)	4.2 (1.0)
Confident I can reduce my smoking[b]	3.6 (1.0)	3.6 (1.0)
Confident I can quit smoking[b]	3.0 (1.1)	2.9 (1.1)
Frequency of urges to smoke[c]	3.2 (1.2)	3.3 (1.1)
Strength of urges to smoke[d]	3.2 (1.1)	3.2 (1.1)

Note: Values are numbers (%) unless stated otherwise.
Abbreviation: PA = physical activity
[a]IMD (https://imd-by-postcode.opendatacommunities.org/imd/2019).
[b]Using a 5-point Likert scale from 1 (strongly disagree) to 5 (strongly agree), reported as mean (SD).
[c]Using a 6-point Likert scale from 0 (not at all) to 5 (all the time), reported as mean (SD).
[d]Using a 6-point Likert scale from 0 (no urges) to 5 (extremely strong), reported as mean (SD).

participants completed the 3-month questionnaire, and 298/457 (65.2%) and 285/458 (62.2%) completed the 9-month questionnaire. There was no evidence of differential follow-up rates at either 3-month (95% CI = −3.3%–8.8%; $P = 0.368$) or 9-month (95% CI = −3.2%–9.2%; $P = 0.348$) follow-up. Only participants with biochemically verified abstinence at 9 months were scheduled for 15-month follow-up; 20/26 (76.9%) intervention group and 19/22 (86.4%) SAU group were successfully followed up at 15 months.

Intervention participants had a mean (SD) 4.8 (3.4) sessions with a health trainer, which lasted a mean (SD) of 33.5 (20.3) minutes. Overall, the same proportion of sessions were delivered face-to-face and by phone, with the face-to-face sessions lasting over twice the

duration of phone sessions. A total of 76% of intervention participants had ≥2 sessions.

The primary analysis included 450 (98.5%) intervention and 451 (98.5%) SAU participants as shown in Table 2. There was no significant between-group difference in primary outcome rates (2.0% (*n* = 9) vs 0.9% [*n* = 4]) in intervention and SAU, respectively; adjusted OR for biochemically verified floating 6-month prolonged abstinence between 3 and 9 months, 2.30 (95% CI = 0.70–7.56; *P* = 0.17). Most pre-planned sensitivity analyses were not conducted because of sparseness in data for the primary outcome, but of those able to be completed, none changed the findings of the main analysis. Applying the pre-specified best-case scenario to the primary outcome, the direction of effect switched to favouring the SAU group, with 27.5% of participants (*n* = 124) categorised as being floating biochemically verified 6-month prolonged abstainers in the SAU group compared with 24.2% (*n* = 109) in the intervention group (OR = 0.84, 95% CI = 0.62–1.14; *P* = 0.26).

Seven SAEs were reported, five in the intervention and two in the control arm. None were deemed to be related to the intervention or to taking part in the study as shown in Supporting information Appendix 2.

All nine participants in the intervention group who achieved the primary outcome attended at least two HT sessions. Secondary analysis of the primary outcome (i.e. combining those who achieved prolonged biochemically verified 6-month prolonged abstinence between 3 and 9 months or between 9 and 15 months) showed no significant benefit from the intervention. Analysis of biochemically verified 12-month prolonged abstinence (between 3 and 15 months) also showed no significant between-group differences (see Table 2).

Results of the analysis of the smoking-related secondary outcomes are shown in Table 3. Marginal effects in favour of the intervention were evident at 3 months for both self-reported abstinence and biochemically verified abstinence. There was no significant intervention effect on point prevalent self-reported and biochemically verified abstinence at 9 months or at 15 months (only assessed among participants with verified abstinence at 9 months). On average, the intervention group reported smoking significantly fewer daily cigarettes than the control group at 3 months, but not at 9 months. A significantly greater proportion of intervention participants compared to SAU participants reported reducing daily cigarettes smoked by ≥50%, at both 3 and 9 months. There was no significant between-group difference in the proportions reporting a quit attempt by 3 or 9 months.

At 3 months, the intervention group reported doing significantly more MVPA than the control group by 82 minutes per week, but there was no significant difference in accelerometer-recorded MVPA, for the sub-sample wearing them, as shown in Table 4. There were no significant between-group differences in body mass index or self-reported daily average time spent sleeping in past week, at 3 or 9 months.

TABLE 2 Primary and secondary prolonged abstinence outcomes.

Outcomes	Intervention (*n* = 450)	SAU (*n* = 451)	Adjusted OR[a] (95% CI), *P*-value	Adjusted absolute between-group differences in risk (%)[a] (95% CI), *P*-value	Adjusted relative risk[c] (95% CI), *P*-value
Primary					
Floating biochemically verified 6-month prolonged abstinence between 3 and 9 months	9 (2.0)	4 (0.9)	2.30 (0.70–7.56), 0.17	1.12 (−0.43 to 2.67), 0.16	2.27 (0.71–7.29), 0.17
Secondary					
Floating biochemically verified 6-month prolonged abstinence verified between 3 and 9 months or 9 and 15 months[d]	14 (3.1)	10 (2.2)	1.43 (0.62–3.26), 0.40	0.91 (−1.19 to 3.00), 0.40	1.41 (0.64–3.13), 0.40
Floating biochemically verified 12-month prolonged abstinence between 3 and 15 months[d]	6 (1.3)	1 (0.2)	6.33 (0.76–53.10), 0.089	2.03 (−0.028 to 4.09), 0.053	6.17 (0.75–50.84), 0.091

Note: Values are numbers (%) unless stated otherwise. Analysis adjusted for stratification variables (HSI and site).
Abbreviation: SAU = support as usual.
[a]Odds of confirmed abstinence in intervention group relative to SAU.
[b]The difference in risk of confirmed abstinence subtracting SAU from intervention group.
[c]Relative risk of confirmed abstinence in intervention group relative to SAU.
[d]Only participants with biochemically verified abstinence at 9 months were followed up at 15 months.

TABLE 3 Secondary smoking outcomes.

Outcomes	Intervention (n = 450)	SAU (n = 451)	Adjusted OR[a] (95% CI), P-value	Adjusted absolute between-group differences in risk (%)[b] (95% CI), P-value	Adjusted relative risk[c] (95% CI), P-value
Self-reported point prevalence abstinence					
At 3 months[d]	25 (5.5)	13 (2.9)	1.99 (1.00–3.94), 0.049	2.64 (0.060–5.23), 0.045	1.93 (1.00–3.72), 0.050
At 9 months[d]	38 (8.4)	36 (8.0)	1.07 (0.66–1.72), 0.79	0.48 (−3.10 to 4.06), 0.79	1.06 (0.69–1.64), 0.79
At 15 months[e]	16 (3.6)	14 (3.1)	1.15 (0.56, 2.40), 0.70	0.46 (−1.87 to 2.79), 0.70	1.15 (0.57–2.32), 0.70
Biochemically verified point prevalence abstinence					
At 3 months[d]	17 (3.7)	8 (1.8)	2.19 (0.93–5.14), 0.071	1.99 (−0.12 to 4.11), 0.064	2.14 (0.93–4.90), 0.072
At 9 months[d]	25 (5.6)	21 (4.7)	1.21 (0.66–2.19), 0.54	0.90 (−1.97 to 3.77), 0.54	1.19 (0.68–2.10), 0.54
At 15 months[e]	11 (2.4)	7 (1.6)	1.61 (0.62–4.21), 0.33	0.91 (−0.91 to 2.73), 0.33	1.59 (0.62–4.04), 0.33
Reduced smoking by ≥50% between baseline and 3 months	86 (18.9)	48 (10.5)	1.98 (1.35–2.90), <0.0004	8.35 (3.79–12.91), 0.0003	1.79 (1.29–2.49), 0.0005
Reduced smoking by ≥50% between baseline and 9 months	65 (14.4)	45 (10.0)	1.52 (1.01–2.29), 0.043	4.41 (0.17–8.65), 0.042	1.44 (1.01–2.05), 0.044
Total daily equivalent cigarettes smoked at 3 months—n, mean (SD)	275, 21.1 (23.6)	283, 26.8 (27.0)	Adjusted mean difference[f] (95% CI), P-value: −5.62 (−9.80 to −1.44), 0.0085		
Total daily equivalent cigarettes smoked at 9 months—n, mean (SD)	244, 22.6 (25.8)	240, 24.2 (23.9)	Adjusted mean difference[f] (95% CI), P-value: −0.95 (−5.37 to 3.46), 0.67		
Quit attempt made in first 3 months[g]	54 (11.8)	37 (8.1)	1.53 (0.99, 2.39), 0.058	3.77 (−0.096 to 7.64), 0.056	1.47 (0.99–2.18), 0.058
Quit attempt made between 3 and 9 months[g]	76 (16.9)	68 (15.1)	1.15, (0.80–1.64), 0.45	1.85 (−2.92 to 6.62), 0.45	1.12 (0.83–1.52), 0.45
Vaping or LNCP use at 3 months—n/N (%)	125/296 (42.2)	113/288 (39.2)	1.05 (0.74–1.49), 0.80	0.99 (−6.54 to 8.51), 0.80	1.02 (0.85–1.23), 0.80
Vaping or LNCP use at 9 months—n/N (%)	114/270 (42.2)	96/268 (35.8)	1.27 (0.88–1.83), 0.20	5.24(−2.67 to 13.14), 0.19	1.14 (0.93–1.40), 0.20

Note: Values are numbers of participants (%) unless stated otherwise. Analysis adjusted for stratification variables (HSI and site) and baseline measures of outcome under analysis if applicable.
Abbreviations: SAU = support as usual; LNCP = licenced nicotine-containing products; HSI = Heaviness of Smoking Index
[a]Odds of 'success' in Intervention relative to SAU.
[b]The difference in risk of 'success' subtracting SAU from Intervention.
[c]Relative risk of 'success' in Intervention group relative to SAU.
[d]Not having smoked a puff in the past week.
[e]Only participants with biochemically verified abstinence at 9 months were followed up at 15 months. Not having smoked a puff in the past week.
[f]The mean difference in each outcome subtracting SAU from Intervention.
[g]24 h without smoking even a puff.

TABLE 4 Other secondary outcomes.

Secondary outcomes	Intervention	SAU	Adjusted mean between-group difference[a] (95% CI), *P*-value
Self-reported total weekly minutes MVPA at 3 months	308, 397.7 (389.9)	300, 319.1 (354.9)	81.61 (28.75, 134.47), 0.0025
Self-reported total weekly minutes MVPA at 9 months	273, 352.9 (375.5)	269, 330.7 (360.6)	23.70 (−33.07, 80.47), 0.41
Accelerometer assessed average daily minutes of MVPA at 3 months[b]	42, 95.2 (43.6)	45, 82.4 (53.6)	13.88 (−7.74, 35.50), 0.21
BMI at 3 months (kg/m^2)	301, 26.1 (5.8)	288, 26.7 (6.1)	−0.17(−0.50–0.16), 0.32
BMI at 9 months (kg/m^2)	262, 26.4 (6.1)	265, 26.7 (5.9)	−0.26 (−0.64–0.11), 0.17
Self-reported daily average time spent sleeping over past week at 3 months	287, 7.1 (1.6)	278, 6.9 (1.7)	−0.02 (−0.26–0.22), 0.86
Self-reported daily average time spent sleeping over past week at 9 months	260, 7.0 (1.8)	247, 6.7 (1.6)	0.09 (−0.19–0.36), 0.53
SF-12 (mental component score at 3 months)	240, 44.8 (11.7)	231, 42.9 (11.6)	1.91 (0.15, 3.67), 0.034
SF-12 (physical component score at 3 months)	240, 47.7 (11.1)	231, 46.7 (10.7)	1.33 (−0.13, 2.80), 0.074
EQ-5D-5L utility at 3 months[c]	306, 0.717 (0.249)	298, 0.662 (0.310)	0.022 (−0.012, 0.056), 0.20
EQ-5D-5L utility at 9 months[c]	279, 0.681 (0.272)	267, 0.666 (0.295)	0.006 (−0.030, 0.043), 0.73

Notes: Values are *n* and means (SD) unless stated otherwise. Accelerometer data was not in bouts. Analysis adjusted for stratification variables (HSI and site) and baseline measures of outcome under analysis if applicable

Abbreviations: SAU, support as usual; BMI = body mass index; HSI = Heaviness of Smoking Index; MVPA = moderate-to-vigorous physical activity

[a]The mean difference in each outcome subtracting SAU from Intervention.

[b]Accelerometer data is from participants providing at least 4 days of data including 1 weekend day, with a daily wear-time of at least 16 hours, and adjusted for baseline self-report MVPA.

[c]EQ-5D-5L mapped to EQ-5D-3L utility values using the crosswalk method and mean differences estimated using linear regression [26].

TABLE 5 Mediation analysis of changes in self-report MVPA at 3 months as a mediator of intervention effects on cigarettes smoked at 3 months and ≥50% reduction in self-reported smoking from baseline to 3 and 9 months.

Outcome	N	A path Coefficient (SE)	B path Coefficient (SE)	Mediated effect		C path Coefficient (SE)
				Coefficient (SE)	95% CI	
Cigarettes smoked per day	608	**0.195 (0.064)**	0.841 (1.102)	0.164 (0.265)	(−0.228, 0.943)	**−5.470 (2.162)**
Achieving ≥50% reduction in self-reported smoking at 3 months	608	**0.195 (0.064)**	0.044 (0.102)	0.009 (0.021)	(−0.032, 0.053)	**0.648 (0.205)**
Achieving ≥50% reduction in self-reported smoking at 9 months	608	**0.195 (0.064)**	−0.056 (0.116)	−0.011 (0.024)	(−0.068, 0.033)	0.251 (0.232)

Note: Statistically significant effects at the two-sided 5% level are in bold.

There was no evidence that the intervention effects on secondary outcomes differed by socio-economic status, baseline HSI, confidence in quitting or physical activity or whether participants used medication or vaped during the study, or by centre, but analyses were limited by the number of participants involved.

From a low baseline reported use of vaping and LNCPs, at 3 and 9 months (assuming those who were missing at follow-up were not vaping or using LNCPs), the proportion vaping had approximately doubled at 3 and 9 months, whereas the proportion using LNCPs remained similar at ~13% to 14% at 3 and 9 months, with no statistical differences between the groups. Given the non-significant findings and sparse data for the primary outcome, we did not explore if change in vaping and/or LNCP usage mediated intervention effects on the primary outcome as planned.

As shown in Table 5, there was no evidence from the mediation analysis that intervention effects on self-reported MVPA at 3 months mediated changes in intervention effects on cigarettes smoked at 3 and 9 months or on the percentage of participants who reduced smoking by ≥50% from baseline to 3 or 9 months.

The estimated direct cost of delivering the intervention was £239.18 per participant, with sensitivity analyses ranging between £204 and £292. Four hundred and seventy participants (51.4%) contributed to the trial-based cost-effectiveness analysis, in which we estimated the intervention would lead to a non-statistically significant

increase in costs (combining the cost of delivering TARS with the impact on National Health Service [NHS]/Prescribed Specialised 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), compared with SAU. Using central estimates, the intervention was dominated (more expensive and less effective than) by SAU. Considering sampling uncertainty, the probability that behavioural support was cost-effective over the 9-month trial duration was estimated to be 17% at a threshold of £20 000 per QALY, rising to 20% at a threshold of £30 000 per QALY. Numerous sensitivity analyses were conducted, including a multiple imputation analysis for missing data. These will be presented elsewhere [31].

DISCUSSION

In people wishing to reduce but not immediately quit smoking, there was evidence that behavioural support to reduce smoking and increase physical activity levels can have short-term effects on various smoking outcomes and physical activity, but not increase biochemically verified prolonged abstinence. Overall abstinence rates were much lower than expected, reducing the statistical power to exclude small differences in effectiveness, and too small to conduct analyses of the moderating effects of various baseline measures, or the mediating effects of physical activity on the primary outcome. Cost-effectiveness analysis suggested this intervention was not cost-effective in terms of driving quality of life gains within the trial follow-up window of 9 months.

The present findings add rigorous evidence to the few studies (with a high risk of bias) that have investigated the effectiveness of behavioural support for smokers wishing to reduce but not quit (predominantly without pharmacological support) [8–11]. Our study involved similar delivery approaches to those reported across four identified studies (i.e. phone and face-to-face support for graduated reduction) and behaviour change components, but involved generally greater intensity (i.e. more sessions), a more client-centred motivational interviewing approach (to maximise engagement with participants from disadvantaged communities) and a focus on multiple behaviour change.

Like previous behavioural support studies for smokers unmotivated to quit, the present study showed some encouraging short-term intervention effects on point prevalent self-reported and biochemically verified abstinence, but uniquely did not show that these effects could be sustained as evidenced by our primary outcome measure: floating 6-month prolonged biochemically verified abstinence. Such a measure may be a better predictor of permanent abstinence and hence, health benefits and for assessing cost-effectiveness. The present study, therefore, challenges future studies on the effects of behavioural support (focusing on smoking and/or physical activity) to demonstrate more sustained abstinence for smokers initially unmotivated to quit.

In the present study, the percentage of participants in both arms of the trial using vapes and/or LNCPs doubled or tripled from baseline, depending on assumptions about missing data. At the time of our pilot study [16], use of such products was nowhere near as common, and we were able to exclude smokers from the study who wished to use them and focus on promoting physical activity to support smoking reduction. It may be that an increase in participants' vaping in both arms of the present trial washed out any effects of physical activity that were more evident in our pilot trial. Although the present study showed short-term intervention effects on physical activity, we found no evidence that such effects mediated intervention effects of smoking outcomes, although we were limited by sparseness of data for some analyses.

To isolate the effective intervention components on respective smoking outcomes, the findings from three factorial studies have also been reported [32–35]. Across the three studies, there was only very limited evidence of the beneficial effects of behavioural support and in some cases adding such support to pharmacological components reduced effectiveness, making the overall findings hard to interpret. Factorial studies that assign participants who are unmotivated to quit do not easily compare with the present pragmatic study involving a participant-centred approach with autonomy to use physical activity, vaping or LNCPs to manage cigarette cravings and smoking behaviour.

Our study widens the literature on the effects of physical activity on smoking outcomes. Most studies have examined the effects of structured exercise sessions on smoking cessation [15] for smokers who wish to quit, whereas our focus was on behavioural support for those unmotivated to quit. On average, the TARS participants, like in our pilot trial [16], were fairly active, reflecting a large proportion of participants living in areas with high social deprivation with low car ownership, physically active occupations and limited involvement in physically active leisure. Although the intervention resulted in short-term increases in MVPA, these did not mediate changes in secondary smoking outcomes at 3 or 9 months. Our process evaluation, reported elsewhere, indicated that some interviewed participants embraced the idea of using physical activity to manage cravings, shift to a more positive health identity and manage weight gain because of smoking cessation, but other participants reduced their smoking without being more physically active (see Taylor *et al.*) [31].

Strengths of the present study include the large sample (relative to other studies) [8–11, 16] of moderately heavy smokers initially unmotivated to quit and with low use of pharmacological aids to manage smoking, drawn from multiple sites with high social deprivations. The intervention was evidence-based, participant-centred with good participant engagement. This is the first study to add physical activity promotion as part of behavioural support for reduction, and our extensive process evaluation provided valuable insights into processes of multiple health behaviour change [31]. Further strengths were the use of stratified randomisation, researcher blinding for follow-ups, biochemical verification of abstinence and transparent, planned statistical and health economic analysis.

There were limitations. The low rate of floating prolonged abstinence was unexpected and undermined power to detect the relative difference in quit rates we expected, and planned sensitivity and secondary analyses of the primary outcome, including the moderation

analysis. Despite this, we were able to exclude absolute differences in quit rate of the size we deemed a priori to be of clinical significance. Approximately a third of participants were not available for follow-up at 9 months. However, none of these people were abstinent at 3 months, meaning they could not have achieved the primary outcome. Some participants reported that they would have valued more flexibility, allowing longer intervals between support sessions and a longer time in which to reduce their smoking level, especially with improvements in respiratory function from becoming more physically active [36].

Future studies could explore the role of longer interventions and follow-up periods, especially because abstinence may be the result of multiple quit attempts and more intensive interventions [1]. There is also a need to further examine psychological mediating processes (e.g. perceived importance and confidence to reduce and quit) identified in the TARS's logic model as initially described elsewhere [31].

The health economic analysis showed a low probability that behavioural support for smokers who wished to reduce but not quit was cost-effective over the 9-month time horizon. This analysis included any benefits accruing because of the intervention detectable by a generic health-related quality of life questionnaire and was not restricted to benefits from changes in smoking behaviour, but was limited because of substantial missing data and the short time horizon.

In summary, there was no evidence of intervention effectiveness on sustained abstinence or that the TARS intervention was cost-effective. The TARS intervention achieved high engagement with predominantly socially disadvantaged moderately heavy smokers and its initial goals of supporting smoking reduction and increasing physical activity, but evidence is needed on how to convert these short-term benefits into sustained abstinence.

ACKNOWLEDGEMENTS

We appreciate the support of the study sponsor, University Hospitals Plymouth NHS Trust. The study was led by researchers and managed by the Peninsula Clinical Trials Unit at the University of Plymouth. We are indebted to Dr Helen Hancocks for her contribution to the TARS study as Clinical Trial Manager at Peninsula Clinical Trials Unit; sadly, Helen passed away suddenly on 24 January 2019. We thank Doug Webb (Assistant Trial Manager) for helping to develop the protocol and Jonny Wilks (Clinical Trials Data Manager), Sarah Campbell (Senior Trials Manager) in the Peninsula Clinical Trials Unit, Lucy Cartwright for qualitative data analysis and Dan Preece for input into understanding usual care in Stop Smoking Services and the place of Health Trainers within Community Health Services. Our thanks go to all organisations involved in recruitment, and especially those working in primary and secondary care and in local Stop Smoking Services. We thank James Davies and Will Moyle for preparing the search code for identifying potential participants within primary care. We acknowledge the contribution of the health trainers in delivering the intervention: Alix Covenant, Stephanie Erivo, Gemma Fox, Alex Gude, Sarah Kennedy, Amanda Perry, Lucy Porter and Charlotte Wahlich. We acknowledge the contribution of site researchers in recruitment activities and data collection: Jennie King, Mary George, Louise Hamilton and Kelisha Cheema. We gratefully acknowledge the members of our Trial Steering Committee (TSC) and Data Monitoring Committee (DMC) for their valuable support and guidance. The TSC members consist of: Prof. Marcus Munafo (Chair), Dr Stephanie MacNeill, Prof. Amanda Amos and Dr Michael Callaghan (PPI representative). Sadly, Michael died having made a valuable contribution to the study. The DMC members consist of: Dr Rebecca Playle (Chair), Dr Charlie Foster and Dr Jamie Brown. Our sincerest thanks go to all the participants involved in the trial.

DECLARATION OF INTERESTS

S.C. reports that Peninsula Clinical Trials Unit received National Institute for Health Research (NIHR) CTU support funding for the duration of this trial. S.C. declares that she was Chair of the NIHR Research for Patient Benefit South West Advisory Committee from May 2017 to April 2021, outside the submitted work. T.H. declares membership of the NIHR Health Technology Assessment (HTA) Primary Care and Community Preventive Interventions Prioritisation Committee and subsequently the HTA Prioritisation Committee A from 2016 to 2019. C.G. declares the following committee membership: HTA General Committee 01/03/2019 until 02/10/2020. L.P. received funding from the trial grant as a consultant while at the University of Exeter, as part of the physical activity and health across the lifespan group (within sport and health sciences department), and is part of a collaboration with Activinsights, the manufacturer of the GENEActiv accelerometer used within this trial. The collaboration provides data analytics services for human activity research. All other authors have nothing to disclose.

The trial was registered as ISRCTN47776579.

AUTHOR CONTRIBUTIONS

Adrian H. Taylor: Conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration; resources; software; supervision; validation; visualization; writing - original draft; writing - review and editing. **Tom P. Thompson:** Conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration; resources; software; supervision; validation; visualization; writing - original draft; writing - review and editing. **Adam Streeter:** Formal analysis; software; supervision; validation; visualization; writing - original draft; writing - review and editing. **Jade Chynoweth:** Data curation; formal analysis; software; validation; writing - original draft; writing - review and editing. **Tristan Snowsill:** Data curation; formal analysis; methodology; validation; visualization; writing - original draft; writing - review and editing. **Wendy Ingram:** Data curation; methodology; project administration; resources; validation; writing - original draft; writing - review and editing. **Michael Ussher:** Conceptualization; funding acquisition; investigation; methodology; resources; supervision; writing - original draft; writing - review and editing. **Paul Aveyard:** Conceptualization; funding acquisition; investigation; methodology; project administration; resources; supervision; writing - original draft; writing - review and editing. **Rachael L. Murray:** Conceptualization; funding acquisition; methodology; project administration; resources; supervision; writing - original draft; writing - review and editing. **Tess Harris:**

Data curation; project administration; resources; supervision; writing - original draft; writing - review and editing. **Lynne Callaghan:** Data curation; formal analysis; supervision; validation; visualization; writing - original draft; writing - review and editing. **Colin Green:** Data curation; formal analysis; funding acquisition; methodology; supervision; validation; visualization; writing - original draft; writing - review and editing. **Colin Greaves:** Conceptualization; funding acquisition; investigation; methodology; validation; visualization; writing - original draft; writing - review and editing. **Lisa Price:** Conceptualization; data curation; formal analysis; funding acquisition; methodology; software; validation; visualization; writing - original draft; writing - review and editing. **Siobhan S. Creanor:** Conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; supervision; validation; visualization; writing - original draft; writing - review and editing.

ORCID

Adrian H. Taylor https://orcid.org/0000-0003-2701-9468
Tom P. Thompson https://orcid.org/0000-0002-6366-9743
Adam Streeter https://orcid.org/0000-0001-9921-2369
Jade Chynoweth https://orcid.org/0000-0002-2516-5923
Wendy Ingram https://orcid.org/0000-0003-0182-9462
Michael Ussher https://orcid.org/0000-0002-0995-7955
Paul Aveyard https://orcid.org/0000-0002-1802-4217
Rachael L. Murray https://orcid.org/0000-0001-5477-2557
Tess Harris https://orcid.org/0000-0002-8671-1553
Lynne Callaghan https://orcid.org/0000-0002-0766-645X
Colin J. Greaves https://orcid.org/0000-0003-4425-2691
Siobhan Creanor https://orcid.org/0000-0002-7373-8263

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Taylor AH, Thompson TP, Streeter A, Chynoweth J, Snowsill T, Ingram W, et al. Effectiveness and cost-effectiveness of behavioural support for prolonged abstinence for smokers wishing to reduce but not quit: Randomised controlled trial of physical activity assisted reduction of smoking (TARS). Addiction. 2023;118(6):1140–52. https://doi.org/10.1111/add.16129