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A trial of physical activity assisted reduction of smoking

Submission date 23/10/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/10/2017	**Overall study status** Completed	
Last Edited 12/02/2025	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
It can be very difficult to quit smoking and there are many different methods to try and stop smoking. A recent study showed that providing support to reduce cigarettes and increase physical activity may reduce smoking, and induce more quit attempts and short-term abstinence. By also focusing on increasing healthy behaviours some smokers may want to reduce and ultimately quit altogether. There are recent national guidelines to help smokers who are not ready to quit but until a larger study provides evidence that reducing smoking and increasing physical activity is effective, such an approach will not feature in any future updated guidelines. The overall aim of the this study is to examine if supporting smokers (who do not want to quit immediately) to reduce smoking and increase physical activity results in a reduction in smoking and, most importantly, in more smokers deciding to quit, and remain abstinent for at least 12 months, compared to those receiving usual support.

Who can participate?
Adult smokers aged 18 and older who are wishing to reduce but not quit in the next month.

What does the study involve?
Suitable smokers recruited from primary health care are randomly allocated to one of two groups. Those in the first group receive usual advice on reducing smoking and where to get further support. Those in the second group receive up to eight face-to-face or phone contacts with a health trainer for up to 8 weeks with support to reduce smoking and increase physical activity as decided by the smoker. After completing an initial assessment, all participants are asked to complete various surveys and measures after 3 and 9 months. If participants report that they are no longer smoking at 3 and 9 months will they be asked to confirm their abstinence by attending a face-to-face meeting with a researcher for measurement of carbon monoxide in expired breath (or by completing a postal saliva cotinine test*). Only if after 9 months they are abstinent will they be followed up after 15 months.

*introduced to meet UK Government guidelines on social distancing (infection control measures) during the COVID-19 outbreak.

What are the possible benefits and risks of participating?
Participants receive a shopping voucher for completing and returning the questionnaire booklet at baseline, 3 and 9 months. We are mostly interested in moderate exercise, if participants who report that they would like to try heavy exercise during the intervention with the health trainer will be advised to check first with their GP as heavy exercise may pose a health risk.

Where is the study run from?
1. Plymouth University (Lead Centre) (UK)
2. Oxford University (UK)
3. Nottingham University (UK)
4. St George's University of London (UK)

When is the study starting and how long is it expected to run for?
May 2017 to October 2020

Who is funding the study?
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC) (UK)

Who is the main contact?
Dr Wendy Ingram, tars.team@plymouth.ac.uk

Study website
https://www.plymouth.ac.uk/research/primarycare/

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
33609

Study information

Scientific Title
Trial of physical Activity assisted Reduction of Smoking (TARS): A multi-centred, parallel, two group, randomised controlled clinical trial, with internal pilot, to compare tailored support to reduce smoking and increase physical activity as an aid to smoking reduction with brief advice to reduce or quit smoking

Acronym
TARS

Study objectives
The overall aim of the proposed research is to examine if supporting smokers (who do not want to quit immediately) to reduce smoking and increase physical activity results in a reduction in smoking and, most importantly, in more smokers deciding to quit, and remain abstinent for at least 12 months, compared to those receiving usual support.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West - Central Bristol Research Ethics Committee, 05/10/2017, ref: 17/SW/0223

Study design
Randomised; Interventional; Design type: Prevention, Process of Care, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Physical

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied

Smoking cessation

Interventions

Current intervention as of 31/07/2020:
Participants are individually randomised to either the intervention (health trainer support & support as usual) or control (support as usual) in a 1:1 ratio, using random permuted blocks, with stratification for recruitment site and a dichotomised low/high score derived from the heaviness of smoking index (HSI).

Intervention group: During the intervention participants meet with a health trainer once a week for 8 weeks. Meetings are a combination of face-to-face, at a convenient place for the participant, and telephone. The health trainer helps participants to reduce the amount they smoke in a way that suits the individual participant. The health trainer also helps participants to do more physical activity or exercise, if they want to. This could include help in setting goals, access to exercise classes, and a free step counter. There is no set amount of physical activity in this study; participants can choose to do as little or as much as is comfortable for them. If participants decide to try any hard physical activity, they are advised to talk to their doctor. We aim to look mainly at moderate physical activity. If participants want further help from their local NHS Stop Smoking Service or GP the health trainer may be able to help with that.
If a smoker wishes to quit at any time during the8-week intervention period, they are offered 6 weeks of additional behavioural and motivational support from the health trainer, as well as support to access services as part of usual care to stop smoking (as available at each location) if desired.

Support as usual: Participants allocated to both arms of the trial receive written guidance for smoking reduction and cessation, including web links to what is offered at local level, or paper versions of this information. Typically, there are no formal programmes for use of medication to support reduction (rather than abrupt stopping) and people usually buy their own replacement therapy or e-cigarette product.

All participants are followed up at 3 and 9 months. Only verified quitters are followed up at 15 months.

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Previous intervention:
During the intervention participants meet with a health trainer once a week for 8 weeks. Meetings are a combination of face-to-face, at a convenient place for the participant, and telephone. The health trainer help participants to reduce the amount they smoke in a way that suits the individual participant. The health trainer also helps participants to do more physical activity or exercise, if they want to. This could include help in setting goals, access to exercise classes, and a free step counter. There is no set amount of physical activity in this study; participants can choose to do as little or as much as is comfortable for them. If participants decide to try any hard physical activity, they are advised to talk to their doctor. Hard physical activity can have risks. We aim to look mainly at moderate physical activity. If participants want further help from their local NHS Stop Smoking Service or GP the health trainer may be able to help with that. If a smoker wishes to quit at any time during theeight week intervention period, they are offered 6 weeks of additional behavioural and motivational support from the health trainer, as well as support to access services as part of usual care to stop smoking (as available at each location) if desired.

All participants are followed up at 3 and 9 months. Only those reporting a quit attempt at 9 months will be followed up at 15 months.

Intervention Type
Behavioural

Primary outcome measure
Carbon monoxide (CO) verified prolonged abstinence over 6 months – Participants will be invited to have the carbon monoxide levels in their breath measured at 3 and 9 months, if they report a quit attempt upon completion of the 3 and 9 month questionnaire booklets.

Secondary outcome measures
Current secondary outcome measures as of 31/07/2020:
1. Biochemical verified point prevalence abstinence at 3, 9 and 15 months post-baseline by measurement of carbon monoxide (CO) in expired breath, or by saliva cotinine level as a contingency measure for follow-up during the coronavirus (COVID-19) outbreak. Only those reporting abstinence by mailed survey will be contacted for biochemical verification.
2. Additional prolonged biochemically verified abstinence over 6 months:
2.1 Prolonged biochemically verified abstinence over 6 months between 9 and 15 months post-baseline.
2.2 Prolonged biochemically abstinence over any 6 months (i.e. between 3 and 9 months or between 9 and 15 months post-baseline).
3. Additional prolonged biochemically verified abstinence for at least 12 months, i.e. between 3 and 15 months post-baseline (derived from biochemically confirmed abstinence at all three follow-up time points).
4. At least a 50% reduction in self-reported reported smoking between baseline and (i) 3 months and (ii) 9 months, derived from self-reported smoking status survey administered in postal questionnaires at baseline, 3 and 9 months.
5. Physical activity measures:
5.1 Self-reported physical activity derived from the 7-day physical activity recall survey administered in postal questionnaires at baseline, 3 and 9 months.
5.2 Objective measure of physical activity derived from accelerometer worn for 1 week by a sample of participants at 3 months.
6. Use of licenced nicotine containing products (LNCP), self-reported use in postal questionnaires at baseline, 3, 9 and 15 months.
7. Body Mass Index derived from self-reported height and weight in postal questionnaires at baseline, 3 and 9 months.
8. Economic evaluation:
8.1 Health related quality of life measured using EQ-5D-5L administered in postal questionnaire at baseline, 3 and 9 months.
8.2 Health service utilisation and costs derived from resource use survey administered in postal questionnaires at baseline, 3 and 9 months.
9. Mixed methods process evaluation. Recruitment processes, acceptability of study processes via qualitative interview; intervention engagement processes and intervention delivery fidelity; evaluation of implementation of the intervention process model; mediating effects of physical activity on smoking outcomes (e.g. urge and strength of urge to smoke) measured by a survey administered in postal questionnaires at baseline and 3 months.

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Previous secondary outcome measures:
1. Point prevalence CO verified abstinence at three, nine and 15 months post baseline - Only those reporting abstinence by mailed survey at 3 and 9 months will be contacted for CO verification. Only those abstinent at 9 months will be followed up at 15 months by mailed questionnaires and if abstinent by face-to-face assessment of expired CO.
2. Self-reported smoking and use of aids to reduce/quit smoking is assessed using self-reporting on the number of cigarettes smoked and type of nicotine product, i.e. pipes, cigars and roll your own as well as reporting the use of e-cigarettes and NRT (nicotine replacement therapy) products as part of the questionnaire booklets at baseline, 3, 9 and 15 months.
3. Physical activity is measured using self-reported seven-day physical activity questions at baseline, three and nine months A sub set of all participants in the TARS study will be invited to wear an accelerometer for a 7 day period during the study. The accelerometer, and instructions for use will be mailed to selected participants at the 3 month time point from CTU, along with the 3 month questionnaire booklet.
4. Self-reported height and weight is measured using Body Mass Index (BMI) questions that are part of the questionnaire booklet mailed to participants from CTU at baseline, three and nine months
5. Health related quality of life (EQ-5D-5L & SF-12) questions which are part of the questionnaire booklet at baseline, three and nine months
6. Health economic outcomes are measured using a Health service utilisation and costs, including smoking related costs questions which are part of the questionnaire booklet at baseline, three and nine months
7. Process measures - The following process measures are also assessed as part of the self-report questionnaire booklets issued to all participants by CTU at the baseline and three months:
7.1. Importance and confidence in smoking reduction and cessation
7.2. Importance and confidence in being physically active
7.3. Availability of support to reduce smoking and increase physical activity
7.4. Use of physical activity for smoking regulation
7.5. Planning to change smoking
7.6. Planning to change physical activity
7.7. Self-monitoring of smoking
7.8. Self-monitoring of physical activity
7.9. Urge & strength of urge to smoke

Overall study start date
01/05/2017

Completion date
31/10/2020

Eligibility

Key inclusion criteria
1. Adult smokers wishing to reduce but not quit in the next month
2. Aged ≥18 years
3. ≥10 cigarettes per day (for at least 1 year). Irrespective of use of other nicotine containing products, for example, e-cigarettes and/or NRT products.
4. Able to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 900; UK Sample Size: 900

Total final enrolment
915

Key exclusion criteria
1. Unable to walk unaided for at least 15 minutes
2. Any illness or injury that might be exacerbated by moderate or vigorous Physical activity
3. Unable to engage in the intervention or trial procedures due to language or other reasons (eg, provide an unacceptable level of risk to the research team)

Date of first enrolment
01/01/2018

Date of final enrolment
06/06/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Plymouth University (Lead Centre)
Peninsula Schools of Medicine and Dentistry
ITTC Building 1
Plymouth Science Park
Plymouth
United Kingdom
PL6 8BX

Study participating centre
Oxford University
Nuffield Department of Primary Care Health Sciences

Radcliffe Observatory Quarter
Woodstock Road
Oxford
United Kingdom
OX2 6GG

Study participating centre
Nottingham University
Faculty of Medicine & Health Sciences
Clinical Sciences Building
Nottingham City Hospital
Hucknall Road
Nottingham
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NG5 1PB

Study participating centre
St George’s University of London
Population Health Research Institute
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Cranmer Terrace
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SW17 0RE

Sponsor information

Organisation
University Hospitals Plymouth NHS Trust

Sponsor details
The Research Office
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MSCP
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Sponsor type
Hospital/treatment centre

Website
http://www.plymouthhospitals.nhs.uk/home

ROR
https://ror.org/05x3jck08

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Results and Publications

Publication and dissemination plan
The research team will work with stakeholders at each site, and nationally, to help to interpret the results and the implications for policy and practice. Dissemination may involve presentation at meetings of relevant support groups or other lay audiences, as well as NHS strategy forum at local and national level.

There will be a standing item on the agenda for each Project Management Group meeting on the publication plan and establishing authorship rules. It is expected that the trial protocol will be submitted for publication no later than the end of the 4 month internal pilot phase of the study. Reports will comply with current CONSORT guidelines for publishing randomised trials. The study results will be submitted for publication in relevant international, high impact, peer reviewed journals. Names of key collaborators and groups who have contributed to the trial will be clearly stated in all publications. The study findings will be presented at regional, national and international meetings as appropriate. An invitation will be extended to the PPI group members to comment on the findings at a dissemination event, and work with other key stakeholders (ie, public health and lead professionals, commissioners of SSS and health promotion support) to maximise impact (eg, through policy changes such as revisions to NICE guidelines for smoking harm reduction).

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/12/2020	03/12/2020	Yes	No
Results article	Process evaluation	01/03/2023	11/04/2023	Yes	No
HRA research summary			28/06/2023	No	No
Results article	Primary outcome results	05/03/2023	12/02/2025	Yes	No