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Improving behavioural support for reducing smoking among those who want to cut down

Submission date
05/07/2010

Recruitment status
No longer recruiting

Registration date
06/07/2010

Overall study status
Completed

Last Edited
17/05/2016

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
NHS smoking cessation treatment aims to help people to remain abstinent after a quit attempt, but even with the best available support as few as 22% are abstinent at 12 months. Studies have shown that during smoking abstinence, a short period of physical activity (e.g., a brisk walk, seated exercise) reduces cravings and withdrawal symptoms, and delays the time between smoking cigarettes. Physical activity has the potential to increase cessation rates. In this study we wish to examine whether physical activity enhances quit attempts and successful quitting among 'hard-to-reach' smokers from lower socio-economic groups.

Who can participate?
Heavy smokers (more than 15 cigarettes per day) aged 18 and over who wish to cut down but who have not yet quit.

What does the study involve?
Participants are randomly allocated to one of two groups. One group receives brief advice on cutting down. The other group receives brief advice and also a physical activity intervention (Health Trainer counselling, use of pedometers and guidance into free physical activity options). Both groups are offered support by the Plymouth NHS Stop Smoking Service for up to 6 weeks. The smoking status of all participants is assessed at 8 and 16 weeks after the start of the study, and at 4 weeks after any quit attempt. We also assess the number of quit attempts, quality of life, withdrawal symptoms, cravings, readiness to quit, confidence to quit and stay quit, use of NHS Stop Smoking Service; physical activity and weight. Taped interviews are conducted with GPs, stop smoking advisors and smokers to assess the feasibility and acceptability of the study procedures.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University of Exeter (UK)

When is the study starting and how long is it expected to run for?
September 2010 to November 2012

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Prof Adrian Taylor
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
HTA 07/78/02

Study information

Scientific Title
An exploratory trial to evaluate the effects of a physical activity intervention as a smoking cessation induction and cessation aid among the 'hard to reach'

Acronym
EARS (Exercise Assisted Reduction then Stop)

Study objectives
Primary objective:
To develop a multi-component physical activity (PA) intervention aimed at helping smokers (not intending to quit in the next month), among 'hard to reach' groups, to cut down.

Secondary objectives:
1. To assess via interview the acceptability of such a PA intervention as an aid to cutting down,

among 'hard to reach' smokers
2. To assess via interview the acceptability of recruitment, assessment and randomisation procedures within a pilot pragmatic randomised controlled trial to compare the effects of a PA intervention versus brief advice (usual care) on quitting, among 'hard to reach' smokers
3. To obtain an estimate of the intervention (PA versus brief advice) effect size, relative risk and its precision to inform sample size calculations for a fully powered trial, from a pilot randomised trial to assess carbon monoxide confirmed abstinence at 4 weeks post-quit date
4. To assess process measures at 4, 8 and 16 weeks post-baseline including:
4.1. Self-reported cigarettes smoked
4.2. Number of quit attempts
4.3. Self-reported quality of life
4.4. Mood and physical symptoms
4.5. Cravings
4.6. PA by self-report and accelerometer (in a sub-sample)
4.7. Pharmacological and behavioural support used
4.8. Weight
5. To estimate the resource use and costs associated with delivery of the intervention, and to pilot methods for determining future cost-effectiveness analyses

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/077802
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0018/51921/PRO-07-78-02.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Pilot randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Smoking reduction and cessation

Interventions
Brief advice:
Written and verbal information on NHS Stop Smoking Service (SSS) with information on the benefits of quitting and how to quit provided at baseline. Those expressing a desire to make a quit attempt will subsequently be referred to NHS SSS.

PA intervention:
Written and verbal information on NHS SSS with information on the benefits of quitting and how to quit provided at baseline. Smokers will select one of three strategies for smoking reduction and receive weekly support to attain this. Face to face physical activity support sessions will be

conducted at weeks 1, 4, and 8 along with supportive phone calls in each intermediate week. The communications will involve tailored physical activity counselling, guidance on using a free pedometer to achieve SMART goals, and signposting to local exercise opportunities with subsidised access as required, with the aim of increasing the amount of regular physical activity completed by each participant for both implicit and explicit purposes as an aid to quit. Those expressing a desire to make a quit attempt will subsequently be referred to NHS SSS.

Added 14/07/2010:
Please note that this trial is recruiting only in Plymouth, specifically in Stonehouse and Devonport areas of the city, where smoking prevalence is more than twice the national, regional and citywide average.

Intervention Type
Behavioural

Primary outcome(s)
Prolonged abstinence at 4 weeks post-quit

Key secondary outcome(s)
1. Weight and height (body mass index [BMI]), measured at baseline, 8 weeks and 16 weeks
2. Self reported cigarettes, pipes, and cigars smoked, measured at baseline and weekly thereafter
3. Readiness to quit smoking, measured at baseline
4. Cigarettes smoked in past week, measured at baseline and weekly thereafter
5. Urge to smoke (single item), measured at baseline and weekly thereafter
6. Mood and Physical Symptom Scores (MPSS, 7 items), measured at baseline and weekly thereafter
7. Physical Symptom Scores (PSS), measured at baseline and weekly thereafter
8. Self reported and accelerometer assessed PA, measured at baseline and weekly thereafter
9. Alcohol consumption
10. 36-item short form health survey (SF36), measured at baseline, 8 weeks and 16 weeks
11. Self reported use of nicotene replacement therapy (NRT) products or smoking related aids, measured at baseline and weekly thereafter

Completion date
01/11/2012

Eligibility

Key inclusion criteria
1. Written informed consent
2. People who are currently smoking at least 15 cigarettes a day and have done for a minimum of 3 years
3. Are at least 18 years of age, either sex
4. Are not motivated to quit smoking in the next month but do wish to cut down the number of cigarettes they do smoke

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Contra-indicated for moderate physical activity
2. Have an injury or illness that might be exacerbated by exercise
3. Pregnant

Date of first enrolment
01/09/2010

Date of final enrolment
01/11/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Exeter
Exeter
United Kingdom
EX1 2LU

Sponsor information

Organisation
University of Exeter (UK)

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2014		Yes	No
Results article	results	12/02/2015		Yes	No