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SHARPISH: study of self help and relapse prevention in smoking

Submission date
25/07/2011

Recruitment status
No longer recruiting

Registration date
28/07/2011

Overall study status
Completed

Last Edited
24/03/2017

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Cigarette smoking is one of the biggest causes of illness and death in the UK. Smoking is extremely addictive, and it can be very difficult to give up. There are many systems in place to try and help people to quit smoking, including within the NHS. These can be very successful, as about half of the people who go to NHS Stop Smoking Clinics manage to successfully stop smoking after several weeks. Unfortunately, many people start smoking again within one year of quitting, and so more resources are needed to help people remain smoke-free. Self-help materials, such as education booklets or online resources, have proven to be very effective for people with a range of different problems. Studies have shown that specially designed self-help materials can help to reduce the number of people who start smoking again after quitting. The aim of this study is to find out if a set of eight educational booklets (called Forever Free) could help more people to remain non-smokers after using NHS Stop Smoking Services.

Who can participate?
Adults who have successfully quit smoking for four weeks.

What does the study involve?
Participants are randomly allocated into one of two groups. Participants in the first group (intervention group) are sent a letter and the set of eight “Forever Free” booklets. The first booklet contains a summary of the issues related to quitting smoking, and the remaining seven booklets provide more detailed information about the issues covered in the first booklet. Participants in the second group (control group) are sent a letter and a leaflet that is currently used in the NHS Norfolk Stop Smoking service. All participants are interviewed over the telephone after three months and then again after 11 months to find out whether they are managing to stay smoke-free. After one year, participants are given a breath test to confirm whether they have successfully stopped smoking long-term.

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

Where is the study run from?
Norwich Medical School (UK)

When is the study starting and how long is it expected to run for?
June 2011 to May 2014

Who is funding the study?
National Institute for Health Research – Health Technology Assessment Programme (UK)

Who is the main contact?
Dr Fujian Song

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HTA 09/91/36, v2, 07/04/2011

Study information

Scientific Title
A randomised controlled trial of self-help materials for the prevention of smoking relapse

Acronym
SHARPISH

Study objectives
The study hypothesis is that the intervention, if effective, will improve abstinence rates, reduce repeated use of stop smoking services and might reduce use of other health care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Essex 1 REC, East of England REC Office 1, 20/04/2011, ref: 11/EE/0091

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Smoking addiction

Interventions
The study has two equal groups: one intervention and a control, each with 700 participants. Participants are people who stop smoking after treatment for 4 weeks in an NHS Stop Smoking clinics. Stop smoking advisors will give the Patient Information Sheet to all clients who attend their Stop Smoking Clinics.

The stop smoking advisors will again explain the trial to successful 4week quitters, answer questions, and invite those eligible, and interested, to participate in the trial and then take informed consent. All participants will then complete the baseline questionnaire.

The participants' paperwork will then be sent to the study researchers, at the University of East Anglia, where participants will be randomised (using a computerised allocation system). The intervention group will be sent a letter and the experimental intervention, which is a set of eight booklets designed to help prevent smoking relapse (called Forever Free). Booklet one is a summary of all issues, including an introduction of nicotine dependence, stages of smoking cessation, situations that are high risk for relapse, ways of coping with urges to smoke, and ways to handle an initial slip. The remaining seven booklets provide more extensive information on important issues for relapse prevention.

The control group will be sent a letter and the leaflet currently in use in NHS Norfolk Stop Smoking service (called Learning to Stay Stopped).

At two and eleven months following randomisation, a researcher will telephone all participants to assess the receipt, liking and use of the booklets, and also assess the key skills the manuals are trying to teach. At the final follow-up point, those people who report themselves as smoke-free, will be invited into the University of East Anglia to have this verified by CO-testing (expenses paid and £20 shopping voucher given in thanks).

Intervention Type
Behavioural

Primary outcome(s)
Prolonged abstinence from smoking between 4 -12 months. This will be confirmed by carbon monoxide, which can be considered as an objectively assessed outcome.

Key secondary outcome(s))

1. 7-day self-report point prevalence abstinence at 3 months and
2. 7-day biochemically confirmed point prevalence abstinence at 12 months
3. EQ-5D
4. Use of resources and mediating variables

Completion date
31/05/2014

Eligibility

Key inclusion criteria
1. Carbon monoxide (CO)-verified quitters at 4 weeks in the NHS stop smoking clinic
2. Can read English and sign the consent form to participate in the trial

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Pregnancy
2. From families in which one member has already been included in the study
3. Unable to read the educational material in English

Date of first enrolment
01/06/2011

Date of final enrolment
31/05/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of East Anglia
Norwich

United Kingdom
NR4 7TJ

Sponsor information

Organisation
University of East Anglia (UK)

ROR
https://ror.org/026k5mg93

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	01/07/2015		Yes	No

Results article	secondary analysis results	01/05/2016		Yes	No
Protocol article	protocol	30/05/2012		Yes	No
Other publications	process evaluation	01/03/2018		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes