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Relapse prevention trial

Submission date
27/11/2016

Recruitment status
No longer recruiting

Registration date
29/11/2016

Overall study status
Completed

Last Edited
18/08/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Smoking is the largest preventable cause of illness and premature death and costs the NHS around £5.2 billion per year. In Australia the investment in tobacco control is $71 million. Both the UK and Australia have strong tobacco control policies and continue to show a slow decrease in smoking rates. Most smokers are trying to quit and although many achieve short-term success, around 70% go on to relapse back to smoking. Typically stop smoking services (SSS) use a base medicine for 8-12 weeks complemented by counselling delivered face-to-face or via telephone (usual care), and are effective at helping people stop smoking in the short-term, but after one year 70% of persons quit at 1 month can be expected to have relapsed. Effective strategies to prevent smoking relapse are desperately needed. The study team have analysed the evidence for relapse prevention interventions (RPI). Traditional non-medicinal RPI for smokers (e.g. behavioural support such as teaching smokers to identify risky situations and to develop ways to cope with them) have not shown any benefit. However, there is now evidence from an Australian trial to suggest that a Structured Planning and Prompting Protocol can reduce relapse out to 6 months post-quit. This approach can be delivered online and may be enhanced by mobile phone text messages, which we have found to be acceptable in clients who have quit smoking using SSS. The extended use of stop smoking medicines can also help clients stop smoking while using them, but they need to be willing to continue use over longer periods. Many researchers have tried to encourage continued use of nicotine replacement therapy (NRT), but found uptake to be modest. New products that deliver nicotine in vapour, such as electronic cigarettes (EC), are becoming popular with smokers wanting to quit and may be more attractive for longer-term use, and so they might be effective in preventing relapse. Although EC have not been studied as closely as NRT products, they have a good safety profile. The aim of this study is to test two RPI, one using a web-based behavioural structured planning and prompting intervention and the other providing a choice of nicotine replacement product.

Who can participate?
Users of the Stop Smoking Service in the UK who haven’t smoked for the last two weeks.

What does the study involve?
Participants are randomly allocated to one of four groups. Those in the first group receive normal care. This involves being encouraged to continue use of base medication (e.g. Champix or NRT) until the end of the recommended period of use. They also receive text message support. Those in the second group are offered a smoking replacement product from a choice of up to

three NRT and e-cigarette options to use as a coping strategy if at risk of relapse as well as text message support. Those in the third group receive a personalised plan, and access to the Structured Planning and Prompting Protocol (S3P) designed to focus planning on strategies to deal with temptations to smoke as well as text message support. Those in the fourth group receive the smoking replacement product plus online support. Participants in all groups complete online questionnaires at 3, 6 and 12 months post quit date (approximately 2, 5 and 11 months post-recruitment). In addition, those who report not having smoked for 12 months are given a saliva swab sample kit, along with instructions on how to provide the sample and a stamp addressed envelope to return it in to confirm their non-smoking status.

What are the possible benefits and risks of participating?
Participants may find the programmes helpful in preventing relapse back to smoking. There are no expected risks from using the online support tool or from receiving the text messages. There are also no risks expected from using a smoking replacement product (e.g. EC or NRT). These products do not contain tobacco, and therefore do not deliver the many harmful substances found in normal cigarettes. The most common side effects that people report when using these products are mild mouth/throat irritation, nausea and sleep disturbance.

Where is the study run from?
1. Queen Mary University of London (UK)
2. Cancer Council Victoria (Australia)

When is the study starting and how long is it expected to run for?
April 2016 to September 2019

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Miss Anna Phillips
a.phillips@qmul.ac.uk

Contact information

Type(s)
Scientific

Contact name
Miss Anna Phillips

Contact details
Health and Lifestyle Research Unit
2 Stayner's Road
London
United Kingdom
E1 4AH
+44 (0)207 882 5747
a.phillips@qmul.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
011132

Study information

Scientific Title
Helping people cope with temptations to smoke to reduce relapse: a factorial randomised controlled trial

Acronym
RP Trial

Study objectives
The aim of this study is to determine if providing additional strategies designed to cope with temptations to smoke (behavioural support and/or access to smoking replacement [SR]) reduces relapse rates in short-term ex-smokers over a 12 months follow-up period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Coast - Surrey Research Ethics Committee, 24/10/2016, ref: 16/LO/1771

Study design
Factorial randomised control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Smoking relapse prevention

Interventions

Participants will be randomised (stratified by country [and service within the UK] in permuted blocks of random size) to one of four study arms described in the Schedule of Intervention below. Randomisation will be done automatically via STATA code with the results imported into the web based program (Quest Engage) that directs the study questionnaires, and will occur after all key baseline information has been collected. Apart from the differential offer of help, it will also tailor subsequent questions relevant to those in each condition.

The two key interventions are:

Smoking Replacement (SR): After being given information about the available SR products, participants will be asked to choose one to use as a coping strategy if at risk of relapse. Up to three NRT and EC options will be available to choose from. The selected product will be couriered to the participant so that they have it at hand if needed. Participants will be proactively offered further supply, via a text message sent by the study team, at 8-weeks post-QD. After this, participants who need further supplies will be encouraged to buy/access any further supply themselves. How to use the product as a strategy for coping with present or anticipated temptations to smoke will be explained to participants, and a leaflet which contains this information will be provided.

The S3P intervention (Structured Planning and Prompting Protocol): Participants will be invited to complete a web-based assessment that generates a 3-4 page letter of personalised advice, and in addition, access to two planning tools:
1. A list of priority activities (e.g. remind yourself of the experienced benefits of having quit; practice replacement strategies; develop alternative activities to do while taking breaks; develop a recovery plan for if you do slip-up and smoke etc.) with the prioritisation based on assessment responses, and
2. A structured tool for generating if-then statements for strategies for avoiding smoking when the urge to smoke occurs.
The tools can be used for as long as required.

This results in four experimental conditions. All participants receive all elements of UC (including using UC medication provided by the SSS until the end of UC treatment protocols if they wish) except where explicitly stated.

UC arm: Participants will be given a brief message warning that relapse is common even after succeeding for 1 month and will be encouraged to persist, and offered a version of the text messaging program without the specific strategies focused on in the S3P intervention. They will not be provided with any SR products (although they may be using them as part of their continued UC at the SSS).

Only SR: This group will be offered a SR product. Participants will choose one SR product from up to three NRT and EC options to use as a coping strategy if at risk of relapse.

S3P / No SR arm: Participants will receive an initial personalised, tailored plan, and access to the Structured Planning and Prompting Protocol (S3P) designed to focus planning on strategies to deal with temptations to smoke, reinforced with additional text messages that will remind them to rehearse these self-statements, replacing some of the more general messages used in the UC condition. These resources will be available to them on the internet for future use, with prompts to use when recommended (around the time of stopping base medication or when having additional problems).

S3P plus SR arm: Participants will receive both interventions, with S3P modified to include integrated references to SR as a relapse prevention strategy.

Participants will complete online questionnaires at 3, 6 and 12 months post quit date (approximately 2, 5 and 11 months post-recruitment) for smoking status and other measures. Participants will have the option of being contacted by telephone to complete the questionnaires if they prefer. Those reporting abstinence at 12 months will be sent a saliva swab sample kit, along with instructions on how to provide the sample and a stamp addressed envelope to return it in.

Intervention Type
Behavioural

Primary outcome measure
Abstinence is measured by the follow up survey created for the purpose of the study at 3, 6 and 12 month post quit date, biochemically validated with a saliva sample.

Secondary outcome measures
1. Biochemically validated sustained abstinence is measured using the follow up survey created for the purpose of the study at 3, 6 and 12 month post quit date, biochemically validated with a saliva sample
2. Mechanisms of effect of strategies are measured using the Ecological Momemtary Assessment sub study data (at 8-12 weeks post quit date) and Qualitative sub study interview transcripts at 3, 6 and 12 month post quit date
3. Sustained reduction in cigarette consumption measured using the smoking status questions using the follow up survey created for the purpose of the study at 3, 6 and 12 months post quit date
4. Cost-effectiveness of the different strategies measured using the EuroQol five dimensions questionnaire (EQ5D) and smoking cessation and health service use questionnaires [provide specific questionnaire names/state if designed for this study – these are their names] at baseline, 6 and 12 months
5. Effects of strategies (e.g. on relapse rates, participant ratings etc.) on people from different socioeconomic and ethnic groups, of different gender, with different prior smoking habits, and those who stopped smoking using different forms of medication measured using demographic details from baseline survey created for the purpose of the study and smoking status /intervention ratings on follow up surveys created for the purpose of the study at 3, 6 and 12 months post quit date
6. Use and ratings of the strategies by participants, including reported engagement and negative aspects of the interventions measured using the use and ratings questions on the follow up surveys created for the purpose of the study at 3, 6 and 12 months post quit date

Overall study start date
01/04/2016

Completion date
16/07/2019

Eligibility

Key inclusion criteria

1. Users of the Stop Smoking Service in the UK who are abstinent in the last 2 weeks of treatment (treatment period is typically 4 weeks post quit date, QD)
2. Willing to use a smoking replacement product or online behavioural support tool if allocated to use
3. Aged 18 years and older
4. Own a mobile phone
5. Has Internet access
6. Able to read/write/understand English

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1400

Total final enrolment
235

Key exclusion criteria
1. Enrolled in other smoking cessation/relapse prevention research
2. Currently using an electronic cigarette/oral NRT and planning to use for longer than 3 months

Date of first enrolment
21/03/2018

Date of final enrolment
20/12/2018

Locations

Countries of recruitment
Australia

England

United Kingdom

Study participating centre
Queen Mary University of London
Health and Lifestyle Research Unit

London
United Kingdom
E1 4AH

Study participating centre
Cancer Council Victoria
615 St Kilda Road
Melbourne
Australia
3004

Sponsor information

Organisation
Queen Mary University of London

Sponsor details
Joint Research Management Office
5 Walden Street
London
England
United Kingdom
E1 2EF

Sponsor type
University/education

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The study results will be:
1. Communicated to the NIHR and published in the HTA journal
2. Published in a peer-reviewed medical journal, in Open Access format
3. Presented at international conferences on tobacco control and public health (e.g. Society for Research on Nicotine and Tobacco (SRNT) Annual Conference; European Respiratory Society Annual Congress)
4. Translated for the lay audience in collaboration with our Patient Group and communicated through the QMUL press office and the UK Centre for Tobacco and Alcohol Studies in a range of press and digital formats
5. Communicated in lay format through various electronic cigarette consumer organisations (e.g. the Electronic Cigarettes Consumer Association of the UK)
6. Integrated into national and international guidelines and training programmes for smoking cessation specialists
7. Directly communicated to key government, NHS, and public health stakeholders
8. Communicated over specialist tobacco control networks (e.g. SRNT, Association for the Treatment of Tobacco Use and Dependence)

Intention to publish date
30/11/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from a.phillips@qmul.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2020	26/01/2021	Yes	No
Funder report results	report to funder	01/12/2020	26/02/2021	No	No
Protocol file	version 4.1	08/08/2018	18/08/2022	No	No
Statistical Analysis Plan	version 2.0	25/09/2019	18/08/2022	No	No
HRA research summary			28/06/2023	No	No