

# Relapse prevention trial

<b>Submission date</b> 27/11/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 29/11/2016	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 18/08/2022	<b>Condition category</b> Mental and Behavioural Disorders	<input checked="" type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

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## Additional identifiers

**Protocol serial number**

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

**Study type(s)**

Prevention

**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(s)**

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.

### **Key secondary outcome(s)**

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 Momentary 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

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

England

Australia

**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

## 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

### 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](mailto: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?
<a href="#">Results article</a>	results	01/12/2020	26/01/2021	Yes	No
<a href="#">Funder report results</a>	report to funder	01/12/2020	26/02/2021	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol file</a>	version 4.1	08/08/2018	18/08/2022	No	No

