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Internet Smoking Cessation Intervention trial

Submission date
22/12/2011

Recruitment status
No longer recruiting

Registration date
02/02/2012

Overall study status
Completed

Last Edited
30/09/2014

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Internet-based interventions can help smokers to stop compared with brief written materials or no intervention. However, they are not widely used in most countries, particularly by more disadvantaged smokers, and there is significant variation in their effectiveness. Therefore, there is a need for a generally available internet-based smoking cessation intervention that will be attractive across the social spectrum and of proven effectiveness. To address this need, a new website has been developed based on principles generated from theory, evidence, and the results from engaging disadvantaged smokers in user-testing and piloting. The aim of the current study is to evaluate the effectiveness of this new, interactive website and whether any identified efficacy translates across the social spectrum.

Who can participate?
You need to be:
1. A regular smoker
2. Over 18 years old
3. Prepared to make a serious attempt to quit smoking within the next month.

What does the study involve?
If you decide to take part you will be randomly assigned to receive support from one of two websites designed to help smokers to stop. We ask that you use your website to help you make a serious attempt to stop smoking within the next month.

Before quitting - During the time leading up to your quit attempt, we ask that you:
1. Answer some questions about your background, smoking history, current smoking, mood and craving levels.
2. Receive email reminders to visit the website.
3. Use the website and read the advice it provides to prepare for an attempt to quit smoking.

After quitting - During the month following your attempt to quit, we ask that you:
1. Receive email reminders to visit the website.
2. Use the website and read the advice it provides.
3. Answer questions about your smoking and the website.

We will email to ask questions about the website and your quit attempt, including whether you are still not smoking. If you are not smoking after 7 months we may need to confirm that. If selected, we ask that you provide a small sample of saliva to be analysed for a nicotine by-product. The sample will be destroyed after testing. We would send the kit through the post and you would just return it using a pre-paid envelope. In return for your trouble, you would receive a £20 gift voucher.

What are the possible benefits and risks of participating?
Possible risks or discomfort:
You may experience withdrawal symptoms such as irritability when you abstain from smoking, which you will be familiar with if you have previously attempted to stop.
Possible benefits:
Stopping smoking is the single most beneficial thing that smokers can do to improve their health. We hope that the results of this study will be of benefit to many thousands of other smokers who want to stop.
Financial considerations:
There are no financial costs to you for taking part. If you provide a saliva sample we will compensate you with a £20 gift voucher.

Where is the study run from?
The study is run online and is managed by researchers at University College London.

When is study starting and how long is it expected to run for?
The study started on 06/12/2011 and it is anticipated that recruitment will continue until 01/11/2012.

Who is funding the study?
The UKs National Prevention Research Initiative (NPRI). The NPRI is a national initiative made up of government departments, research councils and major medical charities that are working together to encourage and support research into chronic disease prevention.

Who is the main contact?
Dr Jamie Brown
stopsmoking@ucl.ac.uk

Study website
http://www.quitsmokingstudy.co.uk

Contact information

Type(s)
Scientific

Contact name
Prof Robert West

Contact details
University College London
Health Behaviour Research Centre
Department of Epidemiology and Public Health
1-19 Torrington Place

London
United Kingdom
WC1E 6BT
+44 (0)20 3108 3075
robert.west@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled trial of a theory-based, interactive, internet-based smoking cessation intervention Stop Advisor

Acronym
ISCI

Study objectives
1. There will be an effect size of 3% difference between intervention and control conditions (i.e. 8% vs 5%) on the primary outcome of 6 months sustained and biochemically verified abstinence.
2. This efficacy will translate across the social spectrum.

A new smoking cessation website has been systematically developed based on principles generated from theory, evidence, and the results from engaging disadvantaged smokers in user-testing and piloting. The aim of the current study is to evaluate the effectiveness of this new, interactive website and whether any identified efficacy translates across the social spectrum. The proposed study is a two-arm randomised controlled trial, with participants randomised to the offer of the interactive website (intervention condition) or a non-interactive, static website (control condition) and followed up for up to 7 months post enrolment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University College London Research Ethics Committee, 14 February 2011 ref: 2808/001

Study design
Two-arm randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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 cessation

Interventions
Participants randomised to the intervention or control condition and followed up for up to 7 months post-enrolment.

Content will consist of a set of behaviour change techniques (BCTs) linked together under the umbrella of an overarching theme. The theme will be that of an expert Stop Smoking Advisor who is both a ready source of useful information and a guide to help the smoker through the process of stopping, using a structured quit plan. Based on the success of the National Health Service (NHS) Stop Smoking Services, the website will follow as far as possible the quit plan that would be in operation in a well-run service, including the tailoring of information. The major difference will be that BCTs that are well suited to delivery by internet will be emphasized and those that require personal contact will be simulated as far as possible. Format will consist of a combination of menu items and tunnelled dialogue sessions presented according to a standard template. The information will be presented in the form of text, photographs, graphical images, video and audio clips. Users will follow a programme that takes them from preparation for the target quit date, to the quit date itself and then encourages them to report important information that the programme will use to help them overcome difficulties that they encounter. Prior to their quit date users will have access to a menu appropriate to their pre-quit status and up to five unique tunnelled dialogue sessions. Users can opt to take up to two weeks to get medication and two weeks to set a quit date. The pre-quit dialogue sessions will be tailored on assessing how soon they intend to quit, their intended use of medication, their success in obtaining and using medication, and reasons for quitting. The preparatory guidance they receive will focus on: ensuring that they acquire the appropriate medication and use it optimally, making necessary changes in their routines to minimise difficulties and urges to smoke after the target quit date, developing specific coping strategies for when difficulties arise, and having clear expectations about the natures of those difficulties. After their quit-date users will have access to menus appropriate to their post-quit status, and up to thirteen unique tunnelled dialogue sessions, which will be made available with decreasing frequency over the course of the first month following their quit date. The post quit dialogue sessions will be tailored on participants reports of:
1. Abstinence
2. Urges to smoke
3. Confidence in their ability to remain abstinent
4. Use of medication
5. Anticipated frequency of stressful or social events

The guidance they receive in response to this will involve specific advice on how to address these problems and plan for the future to minimise their occurrence.

The control will be a static website that presents brief and standard advice, with none of the presumed active ingredients of the interactive website. The advice offered on the control site about the timescale for setting a quit-date is equivalent to that on the interactive site: smokers will be encouraged to use medication; obtain medication within a fortnight; and set a quit date within two weeks of obtaining medication or deciding not to use it. By offering equivalent advice on quit dates, the average time since quit date at follow-up will be comparable between smokers from both conditions.

All participants will be followed up for up to 7 months post-enrolment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measures as of 10/01/2013:
Russell Standard 6 months sustained abstinence (RS6), defined as self-report of not smoking more than 5 cigarettes in the previous 6 months and no smoking in the previous week, verified by a saliva cotinine level of <15ng/ml at 7 months follow-up or by a saliva anabasine level of <1ng /ml in those recording a saliva cotinine level >14ng/ml and who also report using nicotine replacement therapy.
The final follow-up at 7 months post-enrolment should ensure that participants are at least 6 months post-quit: both control and intervention websites advise upon quit dates within one month of enrolment. Six months of abstinence is endorsed by both the Cochrane review group and National Institute for Health and Clinical Excellenc (NICE) as a sufficient basis for estimating long-term abstinence. Inclusion will be by intent to treat and participants whose smoking status cannot be determined will be counted as continuing smokers.

Previous primary outcome measures until 10/01/2013:
Russell Standard 6 months sustained abstinence (RS6), defined as self-report of not smoking more than 5 cigarettes in the previous 6 months and no smoking in the previous week, verified by a saliva nicotinine level of <15ng/ml at 7 months follow-up.
The final follow-up at 7 months post-enrolment should ensure that participants are at least 6 months post-quit: both control and intervention websites advise upon quit dates within one month of enrolment. Six months of abstinence is endorsed by both the Cochrane review group and National Institute for Health and Clinical Excellenc (NICE) as a sufficient basis for estimating long-term abstinence. Inclusion will be by intent to treat and participants whose smoking status cannot be determined will be counted as continuing smokers.

Secondary outcome measures
Current secondary outcome measures as of 10/01/2013:
The intervention and control groups will also be compared on a number of secondary measures including:
1. Point-prevalence abstinence, defined as a self-report of not smoking in the previous 7 days at 7 months follow-up, verified by a saliva cotinine level of <15ng/ml or by a saliva anabasine level

of <1ng/ml in those recording a saliva cotinine level >14ng/ml and who also report using nicotine replacement therapy.
2. Self-report of abstinence in the previous 4 weeks at 2 months post-enrolment
3. Self-report of abstinence in the previous 3 months at 4 months post-enrolment
4. Self-report of a serious quit attempt in the previous 7 months at 7 months post-enrolment
5. Satisfaction ratings of the website at 2 and 7 months post-enrolment
6. Quantitative indices of website interaction, such as number of log-ins and page views
Note: by definition, those classified as successes according to RS6 will also be classified as successes according to the secondary outcome measures 1 3.

Previous secondary outcome measures until 10/01/2013:
The intervention and control groups will also be compared on a number of secondary measures including:
1. Point-prevalence abstinence, defined as a self-report of not smoking in the previous 7 days at 7 months follow-up, verified by a saliva cotinine level of <15ng/ml
2. Self-report of abstinence in the previous 4 weeks at 2 months post-enrolment
3. Self-report of abstinence in the previous 3 months at 4 months post-enrolment
4. Self-report of a serious quit attempt in the previous 7 months at 7 months post-enrolment
5. Satisfaction ratings of the website at 2 and 7 months post-enrolment
6. Quantitative indices of website interaction, such as number of log-ins and page views
Note: by definition, those classified as successes according to RS6 will also be classified as successes according to the secondary outcome measures 1 3.

Overall study start date
06/12/2011

Completion date
01/11/2012

Eligibility

Key inclusion criteria
1. Adult smokers from the UK
2. Smoke every day
3. Willing to make a serious quit attempt
4. Willing to use a stop-smoking website which sends email reminders
5. Willing to be followed up at 2, 4 and 7 months
6. Able to provide informed consent
7. Able to be contacted by email and telephone

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

A total sample size of at least 4260 smokers with at least 2130 in each of the two socio-economic subgroups.

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
06/12/2011

Date of final enrolment
01/11/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
London
United Kingdom
WC1E 6BT

Sponsor information

Organisation
University College London (UK)

Sponsor details
Gower Street
London
England
United Kingdom
WC1E 6BT

Sponsor type
University/education

Website
http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK), ref: G0802035

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
National Prevention Research Initiative (NPRI) Phase 3 (UK), ref: 913685

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

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