ISRCTN34254423 https://doi.org/10.1186/ISRCTN34254423

Pilot trial to assess the feasibility and response rates for an RCT evaluating the effectiveness of a computer tailored intervention for smoking cessation in general practice

Submission date
30/09/2004

Recruitment status
No longer recruiting

Registration date
30/09/2004

Overall study status
Completed

Last Edited
01/04/2008

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0530137082

Study information

Scientific Title

Study objectives
The aim of the proposed research is to carry out a pilot study to assess the feasibility of, and response rates to, an intervention for smoking cessation. We have already developed a computer-based system for generating individually tailored feedback reports designed to encourage and help smokers to quit. These self-help materials tailored for each individual mimic the care used in clinical settings, but make this available to the general public. We plan to adapt this system for use in general practice, modifying the questionnaire and the feedback reports to different educational levels. The pilot work will lead to a large RCT evaluating the effectiveness of the intervention. The hypothesis to be tested on smokers identified from general practitioners lists is that: Personalised feedback reports tailored to levels of reading ability and sent to smokers in varying stages of readiness to quit, will increase quitting activity and modify the attitudes of the smokers over and above that found with usual standard care received from the practice.

Please note that this trial was completed on the 30th June 2005. The previous end date for this pilot study was 31/05/2009. The main RCT of this pilot study has been registered under ISRCTN05385712 (see http://www.controlled-trials.com/ISRCTN05385712).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial - pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Smoking addiction

Interventions
Questionnaires; Before-After-Study, Randomised Controlled Trial (RCT) comparison between:
1. Normal treatment
2. Normal treatment plus tailored feedback reports group

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Computer tailored feedback, adapted to reading levels and readiness to quit, is a simple intervention which could be widely replicated and delivered cost effectively to a large proportion of the smoking population. A modest success rate could have a large effect on public health given its recruitment potential and make a valuable contribution to lowering smoking prevalence. The method mimics the guidelines of asking, advising, assessing, assisting and arranging and could be incorporated into GPs standard treatment at less time and cost. These materials, tailored to the requirements of each individual, would offer GPs and practice nurses an efficient way of integrating smoking cessation counselling into a busy primary care practice. The computer programme could also be made available on CD Rom to produce immediate printed feedback for use by primary care professionals.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2004

Completion date
30/06/2005

Eligibility

Key inclusion criteria
1. Smokers
2. Aged between 18 and 65 years, either sex
3. Identified from records in four practices

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
Four General Practices. 200 participants will be selected from each practice = 800 in total.

Key exclusion criteria
Does not comply with above inclusion criteria

Date of first enrolment
01/01/2004

Date of final enrolment
30/06/2005

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
North Central London Research Consortium (UK)

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	01/09/2007		Yes	No