# 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	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li></ul>		
30/09/2004		☐ Protocol		
Registration date 30/09/2004	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 01/04/2008	<b>Condition category</b> Mental and Behavioural Disorders	[] Individual participant data		
01/04/2008	Mental and behavioural Disorders			

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

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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