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A primary care study of tailored advice for stopping smoking

Submission date	Recruitment status	[ ] Prospectively registered
04/01/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/02/2008	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/01/2014	Mental and Behavioural Disorders	

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
BRD/06/022

Study information

Scientific Title
Effectiveness of computer tailored Smoking Cessation Advice in Primary carE: a randomised trial

Acronym
ESCAPE

Study objectives
Personally tailored feedback reports, based on an assessment of individual needs and tailored to levels of reading ability, sent to smokers identified from general practitioner (GP) lists with varying levels of motivation and readiness to quit, will increase quit rates and quitting activity over and above that found with standard self help and usual care received from the practice.

The study objectives are:
1. To compare the effectiveness of sending personalised computer tailored feedback reports to smokers with sending standard self-help materials
2. To explore the effectiveness of tailored feedback reports by socio-economic status to determine their effect in more deprived groups
3. To determine the characteristics of smokers who are prompted to change their behaviour after receiving tailored feedback reports

Please note that the pilot study to this randomised trial was assigned an ISRCTN in 2004. This was assigned to 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 (see http://www.controlled-trials.com/ISRCTN34254423).

As of 15/07/2009 this record was updated to include an extended anticipated end date; the initial end date at the time of registration was 31/12/2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Northern and Yorkshire Multicentre Research Ethics Committee (MREC) approved on the 19th April 2006 (ref: 06/MRE03/10).

Study design
Randomised single centre controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Smoking cessation

Interventions
The control group will receive the usual care plus standard information. Participants will be assessed at baseline and sent standard non-tailored information (NHS Smokefree booklet), as well as receiving the usual care offered by their general practice. The control group receive only one mailing on receipt of their completed baseline questionnaire.

The intervention group will receive usual care plus standard information plus computer-tailored feedback reports based on the information obtained at baseline. The intervention group receives an additional assessment and personal report one month after the baseline.

The follow up is 6 months after baseline.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Prolonged abstinence for 1 month and for 3 months at the 6-month follow-up.

Outcomes will be measured by postal questionnaire. Non-respondents to questionnaires will receive one postal reminder. Non-respondents to the reminder will be contacted by telephone. In order to estimate the accuracy of self-reports, a random sample of 20% of the participants who report abstinence will have their status validated by salivary cotinine sample, obtained by post.

Secondary outcome measures
1. 24 hour and 7 day point-prevalence abstinence
2. Quit attempts
3. Changes in motivation and intention to quit
4. Cognitions measured at baseline
5. Use of Nicotene Replacement Therapy (NRT) or Zyban
6. Any contact with advice services or health professionals (group, clinic, telephone, or face-to-face)
7. Use of NHS resources and other smoking cessation aids for economic analysis

Process measures:
1. Adherence to advice
2. Perceptions of the feedback reports
3. Perceived personal relevance of the feedback reports

Information from General Practices:
Performance against target figures set by PCTs before and after the intervention as indicators of activity

Overall study start date
01/07/2007

Completion date
31/12/2009

Eligibility

Key inclusion criteria
All current cigarette smokers aged 18 to 65, either sex, able to read English will be eligible for inclusion in the study.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
7250

Key exclusion criteria
Exclusion criteria are minimal because the aim is to recruit all smokers. However, any patients selected who are considered by the GP to be unsuitable for the project, e.g., people with severe mental impairment or severely or terminally ill, will be excluded.

Date of first enrolment
01/07/2007

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Primary Care and Population Sciences
London
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Sponsor information

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Sponsor type
University/education

Website
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ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK) (ref: C16265)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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	01/04/2012		Yes	No
Results article	results	01/04/2013		Yes	No