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GP/nurse promotion of e-cigarettes in supporting reduced smoking and cessation in smokers

Submission date
27/11/2017

Recruitment status
No longer recruiting

Registration date
28/11/2017

Overall study status
Completed

Last Edited
09/01/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Smoking remains the leading cause of preventable illness and death in England. Evidence shows that brief advice to stop smoking from a GP together with an immediate offer of support is effective at encouraging smokers to quit. Despite this, many people with smoking-related chronic illnesses continue to do so despite being repeatedly offered help to quit. For these ‘ hardcore’ smokers, alternative brief advice interventions need to be explored. Electronic cigarettes (‘e-cigarettes’) are increasingly used by smokers not seeking treatment, many of whom reduce smoking and stop without initially intending to do so. The aim of this study is to test an alternative approach to smoking management designed to support people who have a smoking-related illness reduce their smoking and quit.

Who can participate?
Adults aged 18 years or older who is a current smoker.

What does the study involve?
GPs and nurses receive online training on how to give a brief advice intervention to smokers who do not want to stop but have a smoking-related illness. Patients who are smokers with a long-term condition attend their usual annual review appointment of their condition, where the GP or nurse discuss their smoking. Those who decline referral to NHS stop smoking services (SSS) and smoking cession medication are randomly allocated to one of two groups. Those in the first group receive nothing beyond the usual care already provided. Those in the second group are given brief advice and an offer to try an e-cigarette with technical support provided from an online help forum and telephone call-back service run by experienced e-cigarette users. Consultations are audio-recorded to see how well GPs and nurses followed the training and which communication strategies worked well. Participants are interviewed after taking part to see how they felt about being assisted in this way by their GP or nurse. The study will look at whether more people stop or halve their smoking in the short-term.

What are the possible benefits and risks of participating?
Participants may benefit from reducing their smoking. There are no direct risks with participating.

Where is the study run from?
1. University of Oxford (UK)
2. University of Nottingham (UK)

When is the study starting and how long is it expected to run for?
November 2016 to October 2019

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Rachna Begh
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
36562

Study information

Scientific Title
Management of Smoking in primary Care: A randomised controlled trial on the effectiveness of GP/nurse promotion of e-cigarettes in supporting reduced smoking and abstinence in hardcore smokers with smoking-related chronic disease

Acronym
MaSC

Study objectives
The aim of this study is to examine the feasibility, acceptability and effectiveness of GP/nurse promotion of e-cigarettes to support smoking reduction and cessation in hardcore smokers with smoking-related chronic diseases.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales Research Ethics Committee 4, 15/11/2017, ref: 17/WA/0352

Study design
Randomised; Interventional; Design type: Treatment, Psychological & Behavioural, Complex Intervention

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
See study outputs table

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

Interventions
Smokers with a smoking-related chronic disease and who have no intention of stopping immediately or seeking cessation support are randomised to one of two groups if they decline referral to NHS stop smoking services (SSS) and smoking cessation medication during a routine annual review appointment with their GP or Practice Nurse: an intervention group offered encouragement by their practitioner to use an e-cigarette, or a standard care control group who will receive nothing beyond the usual care already provided prior to randomisation.

Participants in the intervention group are offered an e-cigarette starter pack and accompanying practical support booklet, containing links to a telephone call back service for technical support and a dedicated study-website. Participants are followed-up at two months and eight months after their annual review appointment.

Intervention Type
Behavioural

Primary outcome measure
1. The first primary outcome is 7-day point-prevalence abstinence from smoked tobacco at two months. Abstinence is defined as complete self-reported abstinence from smoking – not even a puff – in the past seven days, accompanied by a salivary anabasine concentration of <1ng/ml.
2. The second primary outcome is reduction in cigarette consumption at two months. Reduction is defined as a 50% reduction in self-reported cigarettes per day on each of the last seven days at two months compared with baseline consumption, accompanied by evidence of reduced smoke intake indicated by salivary anabasine concentrations lower than baseline.

Secondary outcome measures
Secondary outcome measures for abstinence include 7-day point prevalence abstinence measured at eight months, biochemically confirmed by an exhaled CO of <10 ppm. Six-month prolonged abstinence will be measured using the Russell standard criteria, defined as smoking fewer than five cigarettes between two and eight month follow-ups, confirmed by an anabasine concentration of <1ng/ml at two months and an exhaled CO concentration of <10ppm at eight months.

Overall study start date
01/11/2016

Completion date
29/02/2020

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Aged 18 years or above
3. Current smoker with a value of at least 10 parts per million (ppm) for exhaled carbon monoxide (CO)
4. Diagnosed with one or more of the following chronic conditions: ischaemic heart disease, peripheral vascular disease, hypertension, diabetes mellitus (Type 1 and Type 2), stroke, asthma, COPD, chronic kidney disease, depression, schizophrenia, bipolar disorder or other psychoses

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 320; UK Sample Size: 320

Total final enrolment
325

Key exclusion criteria
1. GP believes that switching to e-cigarettes would not benefit the patient given their current medical condition
2. Currently using e-cigarettes, nicotine replacement therapy or non-nicotine based cessation therapies (e.g. bupropion, nortriptyline or varenicline)
3. Plans to stop smoking before or at the annual review
4. Currently enrolled in another smoking-related study or other study where the aims of the studies are incompatible
5. Cannot consent due to mental incapacity
6. Pregnant, breastfeeding or planning to become pregnant during the course of the study

Date of first enrolment
22/01/2018

Date of final enrolment
31/05/2019

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
University of Oxford
Oxford
United Kingdom
OX2 6GG

Study participating centre
University of Nottingham
Division of Primary Care
Tower Building
University Park
Nottingham
United Kingdom
NG7 2RD

Sponsor information

Organisation
University of Oxford

Sponsor details
Joint Research Office
Block 60
Churchill Hospital
Oxford
England
United Kingdom
OX3 7LE

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/052gg0110

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

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal in 2020. Study protocol to be submitted in a peer reviewed journal in 2018 and will be available online.

Intention to publish date
30/06/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Rachna Begh, rachna.begh@phc.ox.ac.uk.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	28/11/2019	02/12/2019	Yes	No
Statistical Analysis Plan	version V1.0	10/03/2020	30/03/2020	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet			09/01/2024	No	Yes
Participant information sheet			09/01/2024	No	Yes