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Lung age or exhaled CO feedback combined with very brief advice and support for smoking cessation in FYR Macedonia

Submission date
04/09/2018

Recruitment status
No longer recruiting

Registration date
07/09/2018

Overall study status
Completed

Last Edited
02/10/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Smoking is a major problem in Macedonia, with rates of smoking having increased over the last few decades. Smoking increases the risk of developing a number of health conditions, and is the leading cause of chronic disease. The benefits of smoking cessation are well established. However, no organised smoking cessation programmes are available in Macedonia, and pharmacotherapy (drug treatment) is limited in availability and accessibility due to its high costs. Currently, there are a few projects being rolled out in Macedonia which focus on providing smoking cessation support, one of which involves GPs offering very brief advice and support to quit smoking. It is important to understand the methods that can encourage people in Macedonia to quit smoking that are also feasible and cost-effective in this setting. The aim of this study is to compare the effectiveness and cost effectiveness of stand-alone very brief smoking cessation advice and support, to the same support with additional feedback about lung age or exhaled CO measurement.

Who can participate?
Current smokers, smoking at least 10 cigarettes (manufactured or roll up) per day, who are aged 35 or over

What does the study involve?
Participants are randomly allocated to one of the three groups: feedback about lung age with very brief advice and support to quit smoking; feedback about exhaled CO with very brief advice and support to quit smoking; or very brief advice and support to quit smoking. Participants are followed up after 4, 12 and 26 weeks to ask whether they have stopped smoking.

What are the possible benefits and risks of participating?
This research will help to understand what type of smoking cessation support is useful in Macedonia. If the results from the study show that such support is beneficial among smokers in Macedonia, it could influence policy and help improve future outcomes for people in Macedonia. The interventions (microspirometry and exhaled CO) and questionnaires pose limited risk to participants. Furthermore, participants will not be recruited if they should not have spirometry

for medical reasons. In the event that participants are identified as having any clinical issues or needs through the research, they will be managed by their GP based on the standard clinical practice in Macedonia.

Where is the study run from?
Medical Faculty Skopje (Macedonia)

When is the study starting and how long is it expected to run for?
June 2017 to May 2020

Who is funding the study?
National Institute for Health Research (NIHR), using Official Development Assistance (ODA) funding

Who is the main contact?
Radmila Ristovska

Contact information

Type(s)
Scientific

Contact name
Prof Katarina Stavrikj

Contact details
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North Macedonia
-

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol v1.0

Study information

Scientific Title
Effectiveness of combining feedback about lung age or exhaled CO levels with very brief advice (VBA) and support for smoking cessation in primary care compared to giving VBA and support alone

Acronym
Smoking cessation in Macedonia (Breathe Well)

Study objectives
Objectives:
1. Assess the effectiveness of combining feedback about lung age or exhaled CO levels with very brief advice (VBA) and support for smoking cessation compared to giving VBA and support alone
2. Conduct a process evaluation informed by MRC process evaluation guidance to understand:
2.1. Fidelity by GPs in delivery of the intervention
2.2. Acceptability to GPs of delivering the intervention
2.3. Participant understanding, acceptability and responses to the intervention
3. Estimate the cost-effectiveness of both interventions compared with VBA and support alone

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 20/05/2020:
1. Initially approved 21/05/2018, first amendment did not need approval, second amendment approved 10/06/2019, Human Research Ethics Committee at the UKIM medical faculty (University of Ss. Cyril and Methodius, Str. 50 Divizija No.6, 1000, Skopje, Republic of North Macedonia; stambolievas@yahoo.com; +389 70 227 402), ref: 03-223719
2. Initially approved 05/10/2018, first amendment approved 15/05/2019, second amendment 28 /05/2019, University of Birmingham STEM International Trials Sub-committee (University of Birmingham, Birmingham, UK B15 2TT; aer-ethics@contacts.bham.ac.uk; +44 121 414 8825), ref: ERN_18-1240A

Previous ethics approval:
1. Human Research Ethics Committee at the UKIM medical faculty, Skopje, Macedonia, 21/05 /2018
2. University of Birmingham STEM International Trials Sub-committee - approval pending

Study design
Multicentre non-blinded three-armed randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
Participants are individually randomly allocated to one of three study arms: lung age with very brief advice and support to quit smoking; exhaled CO with very brief advice and support to quit smoking; and very brief advice alone and support to quit smoking (control group).

Trial arm 1 - Lung age with very brief advice and support to quit smoking:
GPs assess lung-age using a microspirometer, and provide the reading to participants as a motivational tool to stop smoking. This is combined with very brief advice for smoking cessation with support to quit smoking for those who choose to quit.

Trial arm 2 - Exhaled CO with very brief advice and support to quit smoking:
GPs measure participant exhaled CO levels, and this is fed-back to participants as a motivator to stop smoking. This is combined with very brief advice for smoking cessation with support to quit smoking and repeated exhaled CO measurements for those who choose to quit.

Trial arm 3 - Very brief advice alone and support to quit smoking:
GPs deliver VBA which includes: ‘Asking’ patient’s smoking status; ‘Advising’ current smokers to stop smoking; and ‘Acting’ to set up appropriate support to quit for those who are willing to make a quit attempt.

Support to quit smoking will be provided by the GPs following a protocol adapted from the UK standard treatment programme for smoking cessation with support sessions at quit date, then 1, 2, 4 and 8-12 weeks post-quit date. During these visits, patients will receive advice about medication, how to deal with cravings and withdrawal symptoms and behavioural support.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 13/11/2020:
Proportion of smokers who have quit at 4 weeks (7-day point prevalence, confirmed with salivary cotinine level of: <10 ng/ml; or <100 ng/ml for those who report exposure to second

hand cigarette smoke in the home on a daily basis; or ≥10 ng/ml in those who report using nicotine replacement therapy/e-cigarettes at any timepoint during the study, irrespective of exposure to second hand cigarette smoke)

Previous primary outcome measure:
Proportion of smokers who have quit at 4 weeks (7-day point prevalence, confirmed with salivary cotinine)

Secondary outcome measures

Current secondary outcome measures as of 20/05/2020:
1. Proportion who have attempted to quit smoking, measured at 4, 12, and 26 weeks
2. Proportion who have quit smoking at 4, 12, and 26 weeks (self report only)
3. Proportion who have quit smoking at 12 and 26 weeks (7-day point prevalence, self-reported abstinence, confirmed with salivary cotinine level : (1) [<10ng/ml], or (2) <100ng/ml for those who report exposure to second hand cigarette smoke in the home on a daily basis, or (3) ≥10ng /ml in those who report using Nicotine Replacement Therapy/e-cigarettes at any time point during the study, irrespective of exposure to second hand cigarette smoke).
4. Proportion who have reduced the number of cigarettes they smoke per day at 4, 12, and 26 weeks
5. Motivation to quit (self-reported data, using the Motivation to Stop Smoking Scale) at 4, 12, and 26 weeks
6. Cost-effectiveness
6.1. Cost per additional quitter at 4 weeks (self-report data from EQ5D-5L)
6.2. Cost per quality adjusted life year (QALY) gained at 26 weeks (self-report data from EQ5D-5L)
7. Fidelity, acceptability, feasibility
7.1. Acceptability to the GPs of delivering the intervention (qualitative interviews, following the 1-month recruitment period)
7.2. Acceptability, understanding and response to the intervention of participants (qualitative interviews [after 4 weeks] and trial data [26 weeks])
7.3. Fidelity to the delivery of the intervention, using trial data and qualitative interview (collected over 26 weeks)

Exploratory outcomes:
8. In a sub-sample, proportion who have quit smoking at 4, 12, and 26 weeks confirmed with CO monitor tests (7-day point prevalence self-reported abstinence with an exhaled CO reading of <10ppm) in order to avoid affecting patients' motivation. The results will be concealed from participants unless a reading has already been taken earlier that day.
9. In a sub-sample, proportion who have quit at 4, 12, and 26 weeks (7-day point prevalence self-reported abstinence, confirmed with salivary cotinine level of: (1) <10ng/ml, or (2) <100ng/ml for those who report exposure to second hand cigarette smoke indoors in the last 4 days, or (3) ≥10ng/ml in those who report using nicotine replacement therapy/e-cigarettes in the last 4 days, irrespective of exposure to second hand cigarette smoke)

Previous secondary outcome measures:
Secondary effectiveness outcomes
1. Proportion who have attempted to quit smoking at 4, 12 and 26 weeks (self-reported data from study questionnaires)
2. Proportion who have quit smoking at 12 and 26 weeks (7-day point prevalence, prolonged abstinence with smoking induction period of 3 weeks post randomisation, confirmed with salivary cotinine)
3. Proportion who have reduced the number of cigarettes they smoke per day at 4, 12 and 26

weeks (self-reported data from study questionnaires)
4. Motivation to quit at 4, 12, 26 weeks (self-reported data, using the Motivation to Stop Smoking Scale)

Cost effectiveness outcomes:
1. Cost per additional quitter at 4 weeks (self-report data from EQ5D-5L)
2. Cost per quality adjusted life year (QALY) gained at 26 weeks (self-report data from EQ5D-5L)

Process evaluation measures:
1. Acceptability to the GPs of delivering the intervention (qualitative interviews, following the 1-month recruitment period)
2. Acceptability, understanding and response to the intervention of participants (qualitative interviews [after 4 weeks] and trial data [26 weeks])
3. Fidelity to the delivery of the intervention, using trial data and qualitative interview (collected over 26 weeks)

Overall study start date
01/06/2017

Completion date
25/05/2020

Eligibility

Key inclusion criteria
1. Current smoker, smoking at least 10 cigarettes (manufactured or roll up) per day
2. Age 35+ years

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
35 Years

Sex
Both

Target number of participants
1182 participants

Total final enrolment
1366

Key exclusion criteria
1. Deemed unsuitable to participate in the trial by the GP e.g. cognitive impairment, recent bereavement, terminal illness
2. Standard contraindications for spirometry (coughed blood in last month; recent tuberculosis;

recent myocardial infarction; recent detached retina; recent major surgery to chest/abdomen /brain/ears/eyes; recent severe angina)
3. Previously received VBA to quit smoking
4. Currently attempting to quit smoking
5. Currently using e-cigarettes or NRT

Date of first enrolment
10/09/2018

Date of final enrolment
11/11/2019

Locations

Countries of recruitment
North Macedonia

Study participating centre
Medical Faculty Skopje, Ss. Cyril and Methodius University
Centre for Family Medicine
St. 50 Divizija no.6
Skopje
North Macedonia
1000

Sponsor information

Organisation
Medical Faculty Skopje, Ss. Cyril and Methodius University

Sponsor details
St. 50 Divizija no.6
Skopje
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1000

Sponsor type
University/education

ROR
https://ror.org/02wk2vx54

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research, Official Development Assistance (ODA) funding

Results and Publications

Publication and dissemination plan
The plan is to publish the study protocol in a peer-reviewed journal. The study results will also be published in a peer-reviewed scientific journal and presented at an international conference. Web-links to publications will be provided on the Breathe Well website (https://www.birmingham.ac.uk/breathewell).

Intention to publish date
31/05/2021

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 Rachel Jordan (r.e.jordan@bham.ac.uk
Type of data: individual participant data, quantitative (anonymised)
When the data will become available: December 2020
Access criteria for sharing data:
1. With whom: academics
2. For what types of analyses: observational/meta-analyses
3. By what mechanism: data acquisition forms will be available from the Investigator. Submitted forms will be reviewed by the Programme Directors, before contacting the applicant directly
Participant consent: Participant consent will be obtained to release anonymous data to other researchers
Data anonymization: all identifiable data will be removed prior to sharing data with other researchers

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v3	17/05/2019	20/05/2020	No	No
Statistical Analysis Plan	version v1.0	09/04/2020	18/06/2020	No	No
Results article		29/09/2023	02/10/2023	Yes	No