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The coaching for smokers trial

Submission date
27/09/2017

Recruitment status
No longer recruiting

Registration date
02/10/2017

Overall study status
Completed

Last Edited
18/07/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Tobacco abuse is a frequent issue in primary care, and general practitioners (GPs) play a key role in promoting smoking cessation to their patients who smoke. However, smoking is often accompanied by other harmful behavior patterns, and not all smokers are ready and willing to give up smoking. Thus, a GP focusing on smoking cessation alone might waste the opportunity to improve his patient's health by supporting a change of another adverse habit of higher priority from the patient's view. A "multithematic" and patient-centered coaching strategy based on shared decision making and motivational interviewing should be preferred over a mere smoking cessation approach. The health promoting program "Gesundheitscoaching-KHM" (www.gesundheitscoaching-khm.ch), developed by a group of Swiss family doctors, is based on the above principles with particular emphasis on the patients' freedom of choice with regard to what aspect of their health-related behavior they want to address primarily. The program has already proved its practicability in a study carried out among primary care practitioners and their patients in eastern Switzerland. This present study intends to show that using "Gesundheitcoaching-KHM" with smokers among general practitioners' patients will lead to higher overall health benefits without resulting in a reduced rate of successful smoking cessation, compared to a "monothematic" state of the art smoking cessation scheme.

Who can participate?
Primary care providers in the German-speaking part of Switzerland without any previous training in "Gesundheitscoaching-KHM", and their cigarette smoking adult patients

What does the study involve?
The general practitioners are randomly allocated to either the intervention or the control group. The general practitioners in the intervention group then undergo a standardized teaching session involving role play with actors posing as patients (standardized patients) and covering communication skills and the use of various structured counseling tools. The control group is instructed in smoking cessation counseling and the use of smoking cessation tools only. After training, the participating general practitioners recruit cigarette smokers from their patients. The included patients undergo a variable number of individual coaching or counseling sessions with their doctors. Coaching of patients in the intervention group is conducted according to "Gesundheitscoaching-KHM" and patients in the control group receive state of the art smoking

cessation counseling. Data from the patients is collected over a period of 12 months after the first session (follow up). Self-reported smoking cessation is confirmed by means of saliva cotinine tests.

What are the possible benefits and risks of participating?
The patients profit from the beneficial effects of either “Gesundheitscoachig-KHM” or of smoking cessation counseling. General practitioners receive a financial incentive. No new or untested treatment or therapy will be tried on the patients and no invasive procedures performed. Therefore, the risk for all study participants is minimal and not higher than the risk associated with established smoke cessation or other counseling-based health promoting programs.

Where is the study conducted?
Institute of Primary Care of the University of Zurich (Switzerland)

When is the study starting and how long is it expected to run for?
January 2017 to December 2021

Who is funding the study?
1. Tobacco-prevention fund TPF, c/o Federal Office of Public Health FOPH (Switzerland)
2. Institute of Primary Care, University Hospital Zurich (Switzerland)

Who is the main contact?
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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Efficacy of motivating short interventions for smokers in primary care: a cluster randomized controlled trial

Acronym
COSMOS

Study objectives
Activating and coaching of cigarette smoking patients in general practitioners' offices following the principles of the health-promoting program "Gesundheitscoaching-KHM" leads to improved health-related behavior with better overall health benefits than subjecting all smoking patients to a monothematic state of the art smoke cessation scheme, without resulting in a reduced rate of successful smoke stops.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Canton of Zurich, 23/01/2018, request no. 2017-02043

Study design
Single-center double-blind cluster-randomized parallel-controlled clinical trial

Primary study design
Interventional

Secondary study design
Cluster randomised 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
Tobacco abuse and other modifiable health risk factors of smokers

Interventions
The general practitioners are randomly allocated to either the intervention or the control arm of the trial. Randomization on the level of physicians (= clusters) with stratification by type of doctor's office (i.e. single and group practice being the strata) will be done using a software random number generator.

The general practitioners in the intervention group will be trained in coaching according to the principles of “Gesundheitscoaching-KHM”. In group training sessions of four hours involving standardized patients they will be taught how to use motivational interview techniques and validated coaching tools to explore, promote and build on their patients’ motivation and confidence to achieve a change of their modifiable health risk factors.

The general practitioners in the control group will be trained in the use of a smoke cessation counseling-algorithm based on the motivation of the patient. The training will correspond in duration and structure to the training of the physicians in the intervention arm but will be different with regard to content.

After training, the participating general practitioners will recruit cigarette smokers successively from their patients. The included patients will undergo a variable number of individual coaching or counseling sessions with their doctors (usually up to three). Coaching of patients in the intervention arm will be conducted according to “Gesundheitscoaching-KHM” and patients in the control arm will receive state of the art smoke cessation counseling. Data from the patients will be collected over a period of 12 months after the first session (follow up). Self-reported smoke stops will be confirmed by means of saliva cotinine tests.

Intervention Type
Behavioural

Primary outcome measure

Proportion of participants with any relevant health-promoting change in either smoking behavior, body weight, physical activity, alcohol consumption, stress level, eating habits or another self-chosen health related behavioral dimension (self-declaration questionnaires; additional confirmatory saliva cotinine test after 12 months) after 1, 6 and 12 months

Secondary outcome measures
1. Smoking cessation rates among patients with high intrinsic motivation to stop smoking after 1, 6, and 12 months based on self-declaration (questionnaires) and after 12 months using saliva cotinine-testing
2. Smoking cessation rates among all participants after 1, 6, and 12 months based on self-declaration (questionnaires) and after 12 months using saliva cotinine-testing
3. Reduction in number of cigarettes per day (self-declaration questionnaires) after 1, 6, and 12 months compared to baseline
4. Weight loss in units of 1 kg (self-declaration questionnaires) after 1, 6, and 12 months, compared to baseline
5. Increase in physical activity time per week in units of 5 minutes (self-declaration questionnaires) after 1, 6, and 12 months, compared to baseline
6. Reduction in number of standard drinks per week (self-declaration questionnaires) after 1, 6, and 12 months, compared to baseline, and number of alcohol-free days per week (self-declaration questionnaires) at 1, 6, and 12 months
7. Reduction in score of the 10-item Perceived Stress Scale (PSS-10, German version) after 1, 6, and 12 months, compared to baseline
8. Increase in score of translated “MedDietScore” questionnaire after 1, 6, and 12 months, compared to baseline
9. Participant’s degree of motivation and – if applicable – confidence to achieve and maintain a change in behavior (self-efficacy) (self-declaration questionnaires after each coaching /counseling session)
10. If applicable: Availability of a plan on when and how to take action (action planning) and existence of a relapse plan (coping planning) (self-declaration questionnaires after each coaching /counseling session)

Parameters describing setting (e.g. characteristics of GPs’ clientele and infrastructure), process quality (e.g. training course quality), structure quality (e.g. refusal or dropout rates), and other data will be collected as covariates using questionnaires after recruitment of GPs, GP training, and the GPs’ individually last patient coachings/counselings).

Overall study start date
01/01/2017

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Current cigarette smoker
2. Male or female of at least 18 years of age
3. Registered as patient in the recruiting physician’s patient base
4. Capable of judgement with regard to participation in the study
5. Signed informed consent after being informed

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
60 general practitioners (clusters) and 200 patients (target cluster size about 4)

Total final enrolment
239

Key exclusion criteria
1. Severe general or psychiatric illness (e.g. malignancy, major depressive episode, dementia etc)
2. Inability of the participant to follow the procedures of the study due to other reasons (e.g. language problems)
3. Foreseeable change of general practitioner within one year (e.g. due to planned relocation)

On the level of general practitioners previous training in “Gesundheitscoaching-KHM” disqualifies from participation in the study.

Date of first enrolment
01/01/2018

Date of final enrolment
30/06/2020

Locations

Countries of recruitment
Switzerland

Study participating centre
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Sponsor information

Organisation
Institute of Primary Care

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Sponsor type
University/education

Website
http://www.hausarztmedizin.uzh.ch/de.html

ROR
https://ror.org/029ma5383

Funder(s)

Funder type
Government

Funder Name
Tobacco-prevention fund TPF of the Swiss Federal Office of Public Health FOPH

Funder Name
Universität Zürich

Alternative Name(s)
University of Zurich, Switzerland, University of Zurich, UZH

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Switzerland

Results and Publications

Publication and dissemination plan
The study protocol will be submitted for publication before completion of patient recruitment. Full study results are intended to be published in an international scientific journal from October 2019 to December 2020.

Intention to publish date
31/03/2022

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 09/12/2021:
Deidentified individual participant data, informed consent forms, and/or case report forms generated and/or analysed during the current study will be available for research purposes related to the trial from the sponsor-investigator Dr. med. Stefan Neuner-Jehle MPH (stefan.neuner-jehle@usz.ch) after the publication of the study results. All proposals requesting data access will need to specify an analysis plan and have approval from the Hospital Discharge Study research group before data release.

Previous IPD sharing statement:
The data-sharing plans for the current study are currently unknown and will be made available at a later date. All study data will be archived at the study center (Institute of Primary Care, University Hospital Zurich) for a minimum of 10 years after study completion or premature termination of the clinical trial.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	25/01/2019		Yes	No
Results article		27/06/2022	18/07/2022	Yes	No