ISRCTN50627997 https://doi.org/10.1186/ISRCTN50627997

Evaluation of the effectiveness of brief counseling for tobacco cessation during dental care in Sweden

Submission date
23/07/2012

Recruitment status
No longer recruiting

Registration date
28/08/2012

Overall study status
Completed

Last Edited
25/07/2017

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Dental professionals in Sweden are in a unique position to give advice on quitting smoking, since a high proportion of the adult population (about 84%) visit a dental clinic at least every other year, most of the visits having a preventive scope. However, there are no Swedish studies on the effectiveness of brief advice for quitting smoking delivered in dental clinics, and its feasibility on a systematic basis is not known. This study aims to fill this gap by evaluating the feasibility and effectiveness of a brief structured counseling to help tobacco users to quit the habit .

Who can participate?
Patients in dental clinics of both sexes, age 18-75 years, who have smoked tobacco daily for at least 1 year and are not currently treated for tobacco dependence.

What does the study involve?
About 30 dental clinics (both publicly and privately run) in two regions of Central Sweden are randomly allocated to one of two groups: either the intervention group or the control group. At the intervention group clinics trained dental care professionals deliver a brief and structured motivational counseling to quit smoking. At the control group clinics patients receive usual care.

What are the possible benefits and risks of participating?
The health advantages of quitting smoking are widely known. There are no risks connected to the intervention, which is based on behavioral counseling.

Where is the study run from?
Department of Public Health Sciences at Karolinska Institutet (Sweden)

When is the study starting and how long is it expected to run for?
October 2012 to September 2013

Who is funding the study?
Swedish Government - National Board of Health and Welfare

Who is the main contact?
Associate Professor Maria Rosaria Galanti
rosaria.galanti@ki.se

Contact information

Type(s)
Scientific

Contact name
Dr Maria Rosaria Galanti

Contact details
Department of Public Health Sciences
Karolinska Institutet
Stockholm
Sweden
17176
+46 (0)812 337 165
rosaria.galanti@ki.se

Additional identifiers

Protocol serial number
2.4-43860/2011

Study information

Scientific Title
A cluster randomized controlled trial for the evaluation of brief motivational counseling for tobacco cessation among patients attending dental clinics in Central Sweden

Acronym
FRITT (Free from Tobacco in Dental Care)

Study objectives
The point prevalence of abstinence from tobacco after 6 months will be at least 100% higher among patients undergoing the brief intervention under evaluation compared to controls in usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Review Board of Stockholm Region, 15/03/2102, ref: 2012/237-31/5

Primary study design
Interventional

Study design
Single-center interventional randomized study

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Smoking and smokeless tobacco cessation

Interventions
Randomized 1:1 allocation of 30 dental clinics and 460 patients thereof to intervention (brief motivational advice) or control (usual care).

The intervention consists of a manualized brief motivational counseling developed by a chartered psychologist on behalf of the Swedish National Institute for Public Health, including referral to second-level tobacco cessation services. The brief counseling is based on a modified version of the 5 A (ask, advise, assess motivation, assist, arrange). The counseling will be delivered by either a dentist or a dental hygienist to consenting consecutive patients in the intervention group during an ordinary visit. The approximate duration of the counseling will be about 5 minutes and will end with the offer of referral to a second-level cessation service, such as specialized cessation counseling at the health care district or telephone Quit-Line.

The control condition consists of 'usual care', i.e. the praxis followed in the corresponding clinic to advise patients to quit tobacco, if any. No effort will be made to standardize this condition. An investigation carried out among the clinics prior to inclusion in the trial showed a low proportion of clinics with guidelines and training of personnel on tobacco cessation.

Patients in both groups will answer a structured questionnaire at time 0 (recruitment) and 6 months after (follow-up), encompassing information on own tobacco use as well as on selected psycho-social predictors of tobacco use.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Point prevalence of total abstinence from tobacco (no use of tobacco in the 7 days preceding the follow-up survey) 6 months after recruitment

Key secondary outcome(s)
1. Prevalence of sustained abstinence from tobacco during the 3 months preceding the survey
2. Proportion of patients reporting cutting tobacco consumption by at least 50% at follow-up compared to baseline
3. Proportion of patients reporting quit attempts (at least 24 hours abstinence from tobacco) during the past 6 months
4. Number of quit attempts

Completion date
30/09/2013

Eligibility

Key inclusion criteria
1. Attend dental care during the study period
2. Age between 18 and 75
3. Daily smokers and/or smokeless tobacco users (used tobacco in all of the preceding 30 days)
4. Continued tobacco use for at least 1 year
5. Provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Unable to speak and read basic conversational Swedish
2. Serious psychiatric co-morbidity, alcohol problems, or regular use of addictive substances other than tobacco
3. Currently in treatment (behavioral or pharmacologic) for tobacco cessation
4. Seeking treatment for acute dental illness

Date of first enrolment
01/10/2012

Date of final enrolment
30/09/2013

Locations

Countries of recruitment
Sweden

Study participating centre
Karolinska Institutet
Stockholm
Sweden
17176

Sponsor information

Organisation
National Board of Health and Welfare (Sweden)

ROR
https://ror.org/01v4pc162

Funder(s)

Funder type
Government

Funder Name
National Board of Health and Welfare (Socialstyrelsen) (Sweden)

Results and Publications

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	20/07/2017		Yes	No