APPENDIX 2 Research Plan

Project "Free from Tobacco in Dentistry" (Fri från Tobak i Tandvården - FRITT)

Title: Effectiveness of a brief counselling for tobacco cessation among smokers and snus users in dental care.

Aim and research questions

In accordance with the Ministry of Social Affair's assignment to the National Board of Health and Welfare (Government’s decision 11:18, 2011-06-16) this evaluation plan is primarily aimed to answer the question whether a brief patient-centred intervention delivered as part of the routine care in a dentistry is effective for promoting behavioural change in tobacco use, on individual level. If the intervention proved effective, a further aim is to deem the applicability of the intervention in the frame of routine dental care. Additional secondary research questions that the evaluation plan aims to answer are: whether counselling affects intermediary behavioural factors, for instance support seeking at different care givers; costing of diverse intervention components (e.g. training of the personnel, information materials, etc.).

2. Method

2.1 Intervention

The counselling model to be evaluated is developed by the National Institute of Public Health. The main characteristics of the model are:

1. Increasing motivation, if it is taken that high level of motivation, associated with information on available support, is the most important factor for achieving permanent abstinence. The patient can thereafter decide which support is needed and follow the active advice given by the dental care professionals.

2. Includes referral to primary care or other professional counselling as described above

3. Brief counselling (duration of conversation approximately 5 minutes), which is a requirement to be able to carry out the
intervention without impact the effectivity of the prevailing clinical care.

4. Brief training for the counsellors, which has a positive impact on resource use in the eventual later implementation stage.

2.2 Population
The target group for evaluation of the intervention are patients with established tobacco use (smoking and/or snus) seeking care during the study period at the selected dental care clinics in the counties of Södermanland and Örebro. The choice of the counties was based on:

a. Geographic location in central Sweden, to assure logistical viability
b. Possibility to adopt referral system between dental care and primary care centres
c. The proportion of dental professionals in private sector, where one county with high (Södermanland) and one with low (Örebro) proportion will be included in the evaluation.

2.3 Design
The evaluation will be conducted as a randomized controlled study, in which the dental care clinics will be the entities randomly chosen to either apply the novel counselling model (intervention condition) or to follow the usual counselling according the clinic’s practice (control condition). Dentists and/or dental hygienists in the intervention condition will be trained in and to deliver the new counselling to smoking or snus using patients during the project period. The affected dental care professionals in both the intervention and the control conditions will document treatment of their patients tobacco use. The procedure for data collection and follow-up will be identical in both groups. The follow-up period for each patient is six months.

2.4 Study protocol
We aim to include approximately 30 dental care clinics, 30 dental care professionals and at least 460 patients in the evaluation.

2.4.1 Selection and randomization of the dental care clinics
Step 1. A county’s stratified sample of approximately 70 dental care clinics - no specialized clinics – is drawn from the most updated registry from The Dental and
Pharmaceutical Benefits Agency, accessible through each county council.

**Step 2.** The manager/responsible for each clinic is invited to a meeting held on regional level, where the evaluation team will explain the background and setup of the project. For each clinic information of structural character is collected (Appendix 1).

**Step 3.** Preliminary consent for cooperation and randomization is given by the operations manager.

**Step 4:** The dental professionals (dentists or dental hygienists, depending on who meets the patients at first hand) in the affected clinics are contacted by the managers and asked for cooperation, including following obligatory components: participation in a training on counselling skills, implementing of the counselling with the intended number of smoking or snus using patients, registration of information about the intervention and its evaluation (Appendix 2). For each clinic two staff members are selected (one regular and one deputy) to recruit patients for the project, but other staff can choose to participate in the training. Clinics where no personnel are willing to cooperate are considered dropouts, irrespective of earlier position of the manager. Apart from what is needed for implementing the intervention, the clinics are advised against changing their organizational routines in order to enable participation in the study.

**Step 5:** The cooperating clinics are assigned a minimum number of patients to be recruited for the study, based on an estimation of the patient turnover (average: 15 patients). For the purpose of the study, a unique code will identify each clinic. Thereafter, based on a computer-generated random sequence, the clinics are randomized to intervention or control conditions, with as many clinics in each condition. The key for the group identity is kept at the study secretariat,
separated from the database in which other relevant data for the study will be registered eventually. This is done to avoid that knowledge about the group identity could influence the interpretation or registering of data.

**Step 6:** The managers and other cooperating staff at the clinics are informed about the outcome of the randomization and are invited to participate respective training days.

**Step 7:** Training of the dental care professionals in the intervention condition is provided by the National Institute of Public Health with methods described in the chapter on the intervention. The training day for the control condition is held by Karolinska Institute, and will include general information about the project and its evaluation. During the training, a detailed demonstration on the procedures in the evaluation protocol are given to both groups. The training is obligatory in order to participate in the study. Two opportunities to participate in the training are offered for each clinic, thereafter absence is considered dropout in the study.

Declined participation at steps 1-4 represents pre-randomization dropout, at steps 6-7 post-randomization. We expect a total dropout rate at approximately 50 % on the clinic level.

2.4.2 Recruitment of patients
Patients seeking care at the chosen dental care clinics during the study recruitment period (see section 2.6) can be included in the evaluation if they fulfil the following criteria:

a. Adequate understanding of Swedish, both oral and written or access to interpret
b. Age between 18 and 75 years
c. Uses tobacco daily (each of the previous 30 days) as cigarettes, other smoked tobacco and/or snus, since at least one year back

Patients are excluded if:

a. Seeking acute care
b. Current use of medicines for tobacco cessation (nicotine replacement therapy, bupropion, vareniklin, etc.)
c. Abuse of drugs or other mental illness which can affect the voluntariness of participation in the study or the reliability of the reported information

The choice to recruit to the study also patients with chronic oral harm is made for two reasons: partly because these patients are interesting as they represent the target group for indicated prevention [2]; party to hasten the recruitment of the desired number of patients.

The recruitment will be done according the following schedule.

**Step 1:** The patients who have booked visit to the clinic is asked to fill out a form (Appendix 3) where background information is asked about, prerequisites for recruitment is assessed, and short information about the study is given.

**Step 2:** A dental hygienist or a secretariat controls the information and refers patients not fulfilling the criteria to their appointment. The remaining patients are asked to read detailed information about the study (Appendix 4), to sign an informed consent (Appendix 5), and to provide additional baseline information (Appendix 6). The signed consent is given directly to the dental care personnel at the appointment, and thus they can deliver the intervention (in the intervention condition) or the customary information (in the control condition).
Step 3: Before the patient leaves the clinic, a new appointment is booked for oral health control after 6 months. The appointment is voluntary and free of charge for the patient. The aim of the visit is to promote adherence to the follow-up questionnaire. Patients who have not been booked for a follow-up visit will be mailed the questionnaire according to the procedure described under 2.4.5.

Step 4: A note on the patients included in the evaluation is made in their medical record, while other information from the form are transferred to the study secretariat for central registration in a specifically designed database, in which the patients are identified with the clinic’s code and the id number of their record.

Step 5: Basic information (gender, age, tobacco use habits) on the patients excluded from or declining to participate in the study are registered anonymously and without a code key in a separate database.

The procedure is repeated for each consecutive patient until the clinic has achieved the quota of number of patients to be recruited. The duration of the recruitment is estimated to be approximately three months. We expect a dropout rate of approximately 30% among eligible patients.

2.4.3 Implementation of the intervention
The affected dental care staff in the respective groups implements the intended counselling during the appointment following recruitment, at an appropriate time. Information on the counselling (especially duration) is registered locally in an electronic document (template shown in Appendix 7).

2.4.4 Monitoring of the control group
In an intervention with a control condition, it is particularly important to document any treatment or
other actions provided to the control group. The reason for this is to be able to draw correct conclusions on the effectiveness of the novel intervention, especially if only a moderate or no effect is reported. In a naturalistic experiment, the control group’s exposure is not manipulated, and therefore it can be assumed that more or less intensive actions with previously unknown effects reach also these individuals. Besides, the use of motivational interviewing, MI, is rather prevalent in the Swedish healthcare, according to recommendations issued by, among others, the National Institute for Public Health (http://www.fhi.se/Metoder/Halsoframjande-och-forebyggande-metoder/Motiverande-samtal/).

The dentists or dental hygienists at the control clinics commit to document the same information as the intervention group on any tobacco counselling with recruited patients, according to the protocol (Appendix 7).

2.4.5 Follow-up and measuring of the outcome
A measurement on the patient level is intended six months after the first visit (recruitment). The primary outcome will be the so called point prevalence of abstinent patients (have not used tobacco during the past seven days.) The following will be considered as secondary outcomes:

a. Continuous abstinence during the past three months
b. Reduction with at least 50 % of the daily tobacco use in the last month (number of cigarettes/day and/or snusboxes/week) compared with the baseline

Information on the outcome is collected by a questionnaire (Appendix 8), in connection with the revisit, which is booked at the time of recruitment (see section 2.4.2) or sent home to the affected patients.
At follow-up, the following reminder is sent to the absent or non-responding patients:

**Reminder 1**: text message and a printed or electronic version of the questionnaire are sent at latest one week after the missed appointment or two weeks after the mailed questionnaire. Patients are given opportunity to book a new free visit at latest one week after the reminder.

**Reminder 2**: text message urging to fill out the questionnaire - without an offer to book visit – is sent at latest two weeks after the first reminder if previous answer to the questionnaire is not received.

**Reminder 3**: this last reminder is done by telephone, with offer to answer the questionnaire directly via phone interview, at latest one month after the first reminder.

We expect a dropout rate of 10-12% at 6-month follow-up.

In the Appendix 9, there is a summary of the steps and time plan for the follow-up of the patients.

### 2.4.6 Data management and privacy

The data collected during the project is registered in electronic databases according to following:

1. Data on patients asked to participate and information on consent is manually entered at each clinic. The resulting databases, with no identification information, are transferred in a safe way to the study secretariat.

2. Data from the baseline questionnaire is registered centrally with optical scanning

3. Data on the counselling and patient data from the follow-up in paper format (identified only with the patient’s record number) is sent monthly by the dental clinics to the study secretariat (see below), for optic scanning. Only one contact person is appointed between each dental clinic and the study secretariat
The computerized registry, which is thereby set up, will have KI as principal and will thereafter be reported to KI’s Personal Data Act ombudsman. The set up registry will not be based on identification information (such as personal identity number, name, address, etc.).

Patient related documentation related to the study that is found in supporting documents in paper form (e.g. the signed informed consent), is handled in accordance with record keeping at the original clinic.

2.5 Statistical considerations and data analysis methods

2.5.1 Sample size and statistical power
With a recruited sample of a total of 460 patients (230 in each group), distributed on approximately 30 clinics, the study has 80% power to find as statistically significant on a 5% level (double sided test) a relative risk of 6-months point estimated abstinence of 2.0 assuming that the prevalence of the outcome in the control condition is approximately 10%. This statistical power is calculated considering the study design, which is based on cluster selection, and attrition.

The advantage in recruiting more clinics, each with fewer patients rather than fewer clinics with more patients is that the cluster size has a big impact on how big the final sample size needs to be for achieving the same statistical power [3]. For instance, if the aim was to recruit in average 30 patients per clinic, 520 patients distributed on 17 clinics would be needed. The study on the applicability of the intervention is of descriptive character and is not included in the power calculation.

2.5.2 Data analysis
The results will be analysed according to “intention to treat” principle, i.e. each patient is treated according to the initial randomization irrespective of the counselling actually received [4]. The reporting will be based primarily on the primary outcome.
In the secondary analysis several outcomes can be considered (see section 1) as well as “per protocol” analyses, in which the patients’ outcomes are analysed according to the actual exposure to counselling, with regard to underlying factors (see section 2.4.4).
Because the primary outcome is dichotomy, multilevel logistic regression will be mainly used as analytical method [5], considering the cluster based design.

2.5.3 Validity of self-reported data
For the outcome measure, self-reported data on tobacco use at baseline and follow-up will be used. For financial reasons a biochemical validation is not feasible for this evaluation. In randomized controlled trials on tobacco cessation which have validated the self-reported behaviour against a biological marker, an underreporting of daily smoking has been noted among 15% of study participants in average [6].

2.6 Time plan

During the first six months from the project initiation (120101) the necessary administration for the study will be set up (management team, secretariat, logistics) and preparatory work for recruitment of dental clinics and dental personnel will be done. We intend to begin recruiting patients starting in October 2012.
The recruitment period is estimated to be approximately three months. Accordingly, the follow-up period for the last recruited patients will extend to early autumn 2013.
The following table shows the outline of the time schedule for the evaluation:

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<tr>
<th>2012</th>
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<th>2014</th>
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<td><strong>Jan-Apr</strong></td>
<td><strong>May-Aug</strong></td>
<td><strong>Sept-Dec</strong></td>
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<tr>
<td>Recruitment of personnel, set up of secretariat and managerial team</td>
<td>Recruitm ent of the clinics</td>
<td>Training of dentists</td>
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<td>Protocol review and approval</td>
<td>Data collection at clinic level</td>
<td>Recruitment of patients</td>
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<tr>
<td>Selection of dental clinics</td>
<td>Delivery of intervention</td>
<td>Data collection at patient level</td>
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In house and organization

Intervention and data collection

Analysis and summarizing

2.7 Organization and coordination
The protocol for a randomized controlled trial is complex, and requires a strict monitoring of the different stages to avoid sources of error and thus incorrect conclusions. For this purpose, three organizational bodies are considered necessary:

a. **A study secretariat** with following tasks:
   i. Archiving of administrative data
   ii. Randomization procedures and keeping of code keys
   iii. Contacts with the public and patient requests
   iv. Contacts with the clinics (e.g. reminder)
   v. Focal point for data collection
   vi. Assistance for vid reporting, etc.
   vii. Economic issues

The study secretariat consists of a fulltime research officer/research assistant during first and second years of the project.

b. **A steering group** with following tasks:
   i. Monitoring of the protocol integrity
   ii. Affiliating necessary additional expertise
   iii. Contacts with authorities and orderers
   iv. Assessment of critical incidents of value for the validity of the study results
   v. Disposition of resources
   vi. Contacts with media

The steering group consists of: a project manager and secretariat; a representative from the National Board of Health and Welfare; an expert in tobacco cessation (not the same who developed the intervention); one/two representatives of dental care; a statistician; a researcher from the same or another institution with expertise in randomized controlled trials. The project manager is the president of the steering group.

c. **An operative group** with following functions:
   i. Monitoring of data collection and quality
   ii. Proposals to agenda and supporting information for the steering group
   iii. Execution of the steering group’s decisions
iv. Preliminary analysis of the material

The operative group consists of: the project manager; study secretariat; statistician/data manager (part-time).

3 Ethical questions

The evaluation study will be ethically reviewed before the initiation. The project implies however no physical infringement of risk for the participants. Besides the usual issues with privacy and handling of sensitive personal information, the only ethical consideration is about the usefulness of the novel counselling in contrast with other proven tobacco cessation methods. It is evidently shown in literature reviews, conducted among others by Cochrane Collaboration, that individual qualified counselling is more effective than brief counselling for quitting smoking [7]. The guidelines for disease prevention in health care by the National Board for Health and Welfare [8] recommends that daily smokers and pregnant snus users should be offered qualified individual counselling or proactive telephone counselling, which are much more comprehensive interventions than the brief counselling that will be evaluated in this study.

Intensive tobacco cessation methods are however not applicable in a context, such as dental care clinics, where the time with individual patients is limited, which is why trying a novel approach is warranted. Besides, the proposed intervention is not intended to substitute more intensive tobacco cessation, but rather to increase patients’ motivation and hasten the transition to action (e.g. referral to primary care).

4 Bibliography


