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Evaluation of a brief counseling for tobacco cessation in dental clinics among Swedish smokers and snus users. A cluster randomized controlled trial (the FRITT study)

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ABSTRACT

Objective. The aim of this study is to assess the effectiveness of a very brief structured counseling for tobacco cessation in dentistry clinics.

Method. A cluster randomized trial was conducted in Sweden in 2012–2013.
Twenty-seven dentistry clinics in two Swedish counties were randomized to provide either a structured brief advice based on the 5 A's model or usual care. Participants were 467 patients currently using tobacco daily (225 in the intervention group and 242 in usual care), of which 97% were retained at follow-up, six months after enrolment. Study outcomes were: 7-day abstinence (primary outcome); 3-month sustained abstinence; 50% reduction of the amount tobacco used; quit attempts lasting at least 24 h.

Results. Compared to usual care, brief counseling was not associated to statistically significant increase in the proportion abstinent from tobacco use after 6 months. However, there was a statistically significant association with reduction of tobacco consumption (OR = 2.07 95% CI 1.28–3.35). Changes in the expected direction for all outcomes were more frequent in the intervention than in the usual care group, and larger among exclusive *snus* users than among smokers.

Conclusions. Very brief and structured counseling in dentistry may achieve positive behavioral modifications among tobacco users, with significant reduction of tobacco consumption, particularly among smokeless tobacco users.

Introduction

Helping cigarette smokers to quit is one of the most cost-effective and egalitarian investments a health-care system can set on its agenda (Gollust et al., 2008). Most tobacco users are motivated to quit. For instance, in Sweden about 8 out of 10 of current cigarette smokers have made a serious attempt in this direction (Fagerstrom et al., 2001). Not much is known on trajectories of behavioral changes among smokeless tobacco users, but studies indicate that the proportion attempting to quit may be lower (Agaku et al., 2013; Panda et al., 2014). In a Swedish national survey in 2013 about 42% of the users of the smokeless tobacco *snus* reported willing to quit, in contrast to 73% of the cigarette smokers (Public Health Agency of Sweden, 2014). Irrespective of motivation and intentions, the proportion achieving a sustained abstinence among tobacco users trying to quit on their own is low. In observational studies, it has been estimated that the likelihood of protracted abstinence from smoking following an unassisted quit attempt is about 12% (Zhou et al., 2009). A number of treatments—both pharmacologic and based on behavioral modification have proven to be highly effective in increasing smoking cessation rates by a factor of two, representing some of the most cost-effective clinical interventions available today (Stead and Lancaster, 2012).

Non-pharmacologic interventions typically include support to behavioral modification resting on different theoretical assumptions, methods and intensities (Fiore et al., 2008; The Swedish National Institute of Public Health, 2009). Higher treatment intensity, longer

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counseling time or higher numbers of contacts are likely to increase abstinence rates in a dose-response fashion (Fiore et al., 2008). In the newly released guidelines to lifestyle modification in health care services the Swedish National Board of Health and Welfare (2011a) establishes a gradient of increasing effectiveness from the simple medical advice to quit to high-intensity counseling, including proactive telephone counseling. Similar guidelines have been issued for dental health care (The National Board of Health and Welfare, 2011b). These recommendations are similar to the guidelines by the U.S. Department of Health and Human services that advocate the combined use of counseling and medications, as well as the use of telephone quit-lines (Fiore et al, 2008). However, a Cochrane review indicates that even a one-time individual counseling of at least 10 min may be sufficient to increase the proportion abstinent compared to minimal intervention, i.e. counseling or advice of shorter duration (Lancaster and Stead, 2005). Earlier studies showed favorable effects of counseling of even shorter duration (Slama et al., 1995). Questions of effectiveness linked to the intensity of tobacco cessation counseling have a direct bearing on what represents an optimal provision of this type of treatment in health care systems. High accession facilities certainly represent an optimal setting for tobacco cessation interventions, because of their large population reach.

In Sweden this is the case for dental care. Due to the extensive state-wide subsidies and the emphasis on oral health promotion 84–90% of the adult population visits dentistry clinics during two years (Clevenpalm and Karlsson, 2009; Hjern et al., 2001; The National Board of Health Welfare, 2010). Also, the negative consequences of tobacco use for oral health, such as oral cancer and poor periodontal health in smokers and local lesions in *snus* users, give high legitimacy to dental professionals to provide tobacco cessation support to their patients (Cnattingius et al., 2005; Scientific Committee on Emerging and Newly Identified Health Risks, 2008; Swedish Council on Health Technology Assessment, 2002; U.S. Department of Health and Human Services, 2004). In fact, both a recent Cochrane review and a report by Swedish Council on Health Technology Assessment concluded that tobacco cessation interventions in dental care clinics are effective in increasing the abstinence rates among tobacco users (Carr and Ebbert, 2012; Swedish Council on Health Technology Assessment, 2002).

Despite this encouraging evidence tobacco cessation activities are not widely implemented in dental care (Amemori et al., 2013; Axelsson et al., 2006; Halling et al., 1995; Prakash et al., 2013). Lacks of time, of financial resources, and of professional skills were reported by dental care professionals as major obstacles to provide tobacco cessation support (Helgason et al., 2003; Nasser, 2011; Prakash et al., 2013; Preber and Åkerberg, 2000). Therefore, effective low-intensity interventions in this setting would be very valuable. To our knowledge there are no Swedish studies evaluating the effectiveness of very brief tobacco cessation counseling in dental care. In fact, the only Swedish trial conducted in dentistry clinics compared an intensive counseling including eight 40-minute sessions with a shorter version of the same intervention (Nohlert et al., 2009).

To fill this gap, a cluster randomized trial (The FRITT study—Swedish acronym for "Free from Tobacco in Dentistry") was designed to evaluate the effectiveness of a very brief and structured tobacco cessation counseling conducted in dental clinics compared to usual care. The study was promoted by the National Board of Health and Welfare on behalf of the Swedish government.

Methods

The study was approved by the Ethical Review Board of Stockholm Region, March 15, 2012 (nr. 2012/237-31/5).

The trial was registered in the ISRCTN Register of controlled trials with identification number ISRCTN50627997.

Evaluation design

A cluster randomized design was chosen to evaluate the effectiveness of the intervention with dental clinics allocated to either of the trial conditions. Cluster randomization was employed, despite the intervention was delivered at individual level, in order to avoid contamination of the trial conditions and because of feasibility reasons.

Intervention

The intervention was developed by two chartered psychologists employed by the Swedish National Institute of Public Health, to be delivered individually to patients visiting dental clinics by a dentist or by a dental hygienist. It consisted of a structured very brief advice (planned duration of maximum 5 min) based on the 5 A's. This latter is a 5-step model developed to promote behavioral changes in brief interventions, here described with reference to tobacco use: 1) Asking about tobacco use, 2) Advising to quit, 3) Assessing willingness to quit, 4) Assisting the tobacco user in quitting, for instance by providing information on available counseling and medications and 5) Arranging follow-up contacts (Fiore et al., 2008). The use of the 5 A's approach is advocated for routine tobacco cessation in dental care settings as well as in other health care settings (Fiore et al., 2008; Ramseier and Fundak, 2009).

In the proposed intervention: 1. asking about tobacco use followed a structured path, especially inquiring on recent and habitual amount. 2. in advising to quit, the dental health care professionals were instructed to specifically refer to patients' oral health. 3. motivation to quit was assessed with questions prompting the patient's thoughts and possible interest to proceed to a quit attempt 4. standardized information was provided on pharmacotherapy and other available support to quit, e.g. more intensive counseling available at primary care clinics and via the Swedish national telephone quit-line (Sluta röka-linjen). The availability of this external counseling was not manipulated in the study. A leaflet about the quitting process was also offered. 5. lastly, the advisor informed the patient that a follow-up visit was planned after six months.

Dentistry staff was trained to deliver the intervention during a one-day workshop conducted by the two developers. Information was provided about tobacco harms, dependence and cessation. The counseling technique was demonstrated with the use of interactive teaching techniques such as role playing, films, simulations and group discussions. Study protocol and data collection procedures were illustrated at this stage.

Control condition

Patients in the control condition received assistance to tobacco cessation according to the usual praxis established at the clinic (if any). No attempts were made to standardize this condition, but a record was kept of the type and duration of advice provided to each patient.

These records indicated that no advice was given to about 28% of the participants in the control condition. When given, it mainly consisted of information about consequence of tobacco use for oral health. The staff at control clinics participated in a half-day workshop on the study protocol and data collection procedures, similar to staff in the intervention condition (see above).

Outcome definition

The primary outcome was defined as total abstinence from tobacco (both cigarettes and *snus*) during the seven days preceding the follow-up survey. Secondary outcomes were: a. sustained abstinence from all tobacco during the three months preceding the survey; b. reduction by half of the number of cigarettes smoked or *snus* portions used daily compared to baseline and c. quit attempts lasting at least 24 h in the course of follow-up. All outcomes were based on patients' self-reports.

Sample size

The desired sample size was calculated with reference to the primary outcome, assuming a proportion of patients abstinent at follow-up of 10% in the control group, an attrition of 13% and 80% power to detect as statistically significant a relative risk (RR) of abstinence of 2.0 in the intervention vs. control group at 6-month follow-up, with alpha error of 5% (double tailed).

In order to accommodate for the cluster design, the estimated sample size was augmented by an inflation factor calculated according to: $1 + (m - 1)\rho$, where m represents the mean number of patients in each cluster (estimated