A cluster randomized trial in general practice with referral to a group-based or an internet-based smoking cessation programme

Charlotta Pisinger1, Michael Milo Jørgensen1, Niels Erik Møller2, Martin Døssing3, Torben Jørgensen1

1Research Centre for Prevention and Health, Ndr. Ringvej, Glostrup University Hospital, DK-2600 Glostrup, Denmark
2Holte Stationsvej 8-9, 2840, Holte, Denmark
3Medicinsk Afdeling, Frederikssund sygehus, 3600 Frederikssund, Denmark
Address correspondence to Charlotta Pisinger, E-mail: chpi@glo.regionh.dk

ABSTRACT

Background Reviews state that there is a room for improvements of smoking cessation (SC) intervention in general practice.

Methods In 2005, all 61 general practitioners (GPs) in four municipalities in Copenhagen, Denmark, were invited to participate. Twenty-four GPs accepted and were cluster randomized to one of three groups: Group A, referral to group-based SC counselling (national model), n = 10; Group B, referral to internet-based SC programme (newly developed), n = 8; or Group C, no referral (‘do as usual’), n = 6. A total of 1518/1914 smokers were included, and 760 returned a questionnaire at 1-year follow-up.

Results The participating GPs reported significantly more SC counselling than GPs who refused participation (P = 0.04). Self-reported point abstinence was 6.7% (40/600), 5.9% (28/476) and 5.7% (25/442) in Groups A, B and C, respectively. Only 40 smokers attended group-based SC counselling, and 75 logged in at the internet-based SC programme. In cluster analyses, we found no significant additional effect of referral to group-based (OR: 1.05; 95% CI: 0.6–1.8) or internet-based SC programmes (OR: 0.91; 95% CI: 0.6–1.4).

Conclusions We found no additional effect on cessation rates of GPs’ referring to group-based SC counselling or internet-based SC programme. This finding might, to some degree, be explained by the short time used by the GPs on SC counselling and the selection of the participating doctors.

Keywords family practice, group-based, internet, referral and consultation, self-efficacy, smoking, smoking cessation

Introduction

General practitioners (GPs) have repeated contact with the majority of the population. There is evidence that short smoking cessation (SC) advice given by a doctor is an efficient way to help smokers to quit and a more intensive SC intervention in a general practice increases the quit rates.1 The GPs have a relationship of confidence with their patients, and knowledge of the smoker’s health that might be a motivational factor for the patient to quit. Therefore, in the clinical guidelines from the Danish National Board of Health, it is implemented that GPs shall identify systematically all smokers in their practice and give relevant SC assistance to all smokers motivated to quit. However, only 38% of the smokers in the Capital Region of Denmark2 stated that they have been advised, within the last year, by their GP to quit smoking, which is comparable with other countries.1,3,4 Several reviews state that even though some GPs work hard to assist their patients to quit, there are large variations in counselling and room for improvements of SC intervention in general practice.5–8
A recent study showed that GPs referring smokers to an evidence-based quit-line service results in increased cessation.\(^9\) Also, it is well-documented that group-based SC counselling is efficient in helping people to quit.\(^10\) The Danish national model for group-based SC counselling has showed stable quit rates \(\sim 16\%\) after 1 year and has proved to be very cost-effective.\(^11,12\) However, about one in three Danish GPs state that possibilities for referral to other SC activities are insufficient.\(^13\)

Studies suggest that education and knowledge-sharing benefits can be achieved through computer-based education methodologies,\(^14\) but there is still limited evidence of the outcome.\(^15,16\) Thus, routinely referring to group-based SC counselling or internet-based SC programmes could be an effective and acceptable way of intensifying SC intervention in general practice and of relevance for public health.\(^17\) However, little is known about acceptance and effectiveness of referral to these SC alternatives.

The objective of this study was to test if GPs routinely refer to either group-based SC counselling or an internet-based SC programme, would this practice result in higher SC rates after 1 year than usual in-clinic SC advice given by GPs.

Primary outcome was self-reported point abstinence at 1-year follow-up. Secondary outcomes were: validated abstinence and smokers’ and GPs’ attitude to SC in general practice. The target subjects were all daily smokers attending general practice.

Methods

In Denmark, every citizen is offered a personal GP close to his/her home and the GPs are regarded as gate-keepers. It is free for all citizens to consult a GP (national health insurance paid by taxes). Since 2006, GPs have been paid for life-style consultations (individual counselling on, for example, SC, healthier diet and/or increased physical activity).

The study was designed by the request of general practice and designed to reflect ‘real life’ as much as possible. It was a demand from general practice that the intervention should be very easy to implement in a daily routine and not put the GPs under obligation of time-consuming registration or SC activities.

In the spring of 2005, all GPs \(n = 61\) in four municipalities in the suburb of Copenhagen, Denmark, were requested by mail to participate. The Local Medical Society and the Committee of Multi Practice Studies strongly recommended participation. The four municipalities were chosen because they were geographically close to the Research Centre for Prevention and Health, where the group-based SC counselling (see below) took place. The doctors were informed that the extra workload during the study would be low. The extra workload for the nurse or secretary was: registering all patients (smokers and non-smokers) at daily basis, asking about smoking status and registering all daily smokers, asking smokers to participate in the study and to complete a questionnaire. For the doctors in the referral groups, the extra work was: completing questionnaires (see below) and having a brief talk with every smoker. The doctors in the control group should do the same, except that they did not have to talk about smoking with all smokers.

The study was approved by the Copenhagen County Ethical Committee. Unwritten informed consent was sought for every smoker.

Baseline intervention

The GPs were pre-randomized at the Research Centre by a computer generated list to one of the three groups: A \((n = 21)\), B \((n = 20)\) or C \((n = 20)\). Thus, the doctors could not choose a certain group, and they knew which group they were randomized to, before accepting participation. Doctors sharing the same address \((n = 15)\) were randomized by the investigators to the same group as the first drawn doctor. The GPs were repeatedly requested by mail and phone to take part in the project and to complete a baseline questionnaire. The investigator was in close and continuous contact with the GPs.

Group A

GPs allocated to this group should, for a period of 8 weeks, briefly and freely talk about smoking (no standard text) with all smokers and refer all smokers with motivation to quit to a group-based SC counselling. The doctor should briefly ask about smoking, inform that smoking was very unhealthy, ask whether the smoker was motivated to quit, encourage the smoker to try to quit and give the smoker a little card with name and phone number of the SC counsellor at the Research Centre. The smokers were requested to arrange a date on his/her own.

The group-based SC counselling was based on a validated Danish national model (www.cancer.dk/tobak).\(^11\) The SC counsellors receive 3 days of standard education. There were five sessions of 2 h. An intensive non-pharmacological (behavioural) approach was combined with a pharmacological approach (recommending nicotine replacement therapy as first choice).

Group B

GPs allocated to this group should, for a period of 8 weeks, briefly and freely talk about smoking (no standard text) with
all smokers (as in Group A) and refer all smokers motivated to quit to an internet-based SC programme (interactive, individual advice, newly developed by the Research Centre). The GP gave the smokers a card with the website and requested the smoker to login on his/her own. The general public could not login but the smokers in the study could potentially share the website with family/friends. The internet-based programme was basically based on the national model for SC in the groups but there were 13 ‘sessions’ during 6 months.

Group C
GP s allocated to the control group should continue to give SC advice and assistance to quit as they used to (not necessarily to all smokers). The control group did not have any special programme, beyond what is known from a national survey on Danish GPs ultimo 2004. In our study, the control group only registered whether they discussed smoking with the patient or not, and the time consumed by counselling, as further registration was regarded as too time-consuming by the GPs.

Questionnaires
Eight-week registration form: during the inclusion period, all patients attending their GP were registered and asked if they smoked.

All 61 GPs were requested to complete a one-page questionnaire giving a baseline characteristic of the participating and non-participating doctors in the study. Furthermore, the 24 participating doctors completed two questions on every smoker’s baseline questionnaire estimating the smoker’s interest for referral to an SC activity and the time spent on the conversation about smoking.

All smokers were asked to complete a one-page baseline questionnaire. After 1 year, a questionnaire was sent by mail to all baseline smokers, asking about smoking status. Nicotine dependence was measured by Fagerström score (FTND). Socio-economic status was measured by two simple questions: ‘Do you have a vocational training?’ (No/Yes <1 year/Yes ≥1 year) combined with ‘Are you employed?’ (Yes/No).

Participation
One GP died shortly after randomization and was excluded before starting the study. Twenty-four GPs (40.0%) accepted to participate in the study; 10 in Group A, 8 in Group B and 6 in Group C. The difference in participation was not significant (P = 0.39).

Fifty-five doctors (90.2%) returned the baseline questionnaire. The most important reasons for refusal were high workload (41.8%), practical reasons (holiday in the inclusion period, lack of nurse/secretary etc. 21.8%) and lack of fee for participation (10.9%). Only one of the GPs stated that SC intervention in general practice was in no need of changes.

Twenty-three of 24 included doctors (95.8%) returned the 8-week registration form.

In total, the GPs registered 16 867 patients during the 8-week period, e.g. almost 20 patients per day (Fig. 1). In total, 1914 smokers were registered (target group) and 1518 included and completed questionnaires (study population). Participation rate at baseline was high, 79.3%. After 1 year, 760 of the baseline smokers (50.1%) returned the questionnaire (Fig. 1). Sixty-four of 93 (68.8%) self-reported smoke-free participants returned the urine sample for validation.

Quit rates
We measured self-reported point abstinence at 1-year follow-up. The question was: do you smoke now (yes daily/yes occasionally/no). This reflects the actual situation (no minimum of days/weeks of abstinence of smoking), not continuous abstinence. Participants who reported to be
smoke-free at 1 year were contacted by mail and requested to return a urine sample for validation of abstinence. We used the IMMULITE 2000 Nicotine Metabolite Analyzer to measure urine-cotinine levels. The cut-off limit was set to <200 ng/ml for validated non-smokers with self-reported abstinence.18,19

Statistics
Power calculations were done before start of the study. To achieve a power of 80%, we needed 475 smokers in each group (comparing two groups). We expected that 10% of the smokers in the referral groups had quit smoking at 1 year and compared with expected 5% in the non-referral group.

All data processing was done with the SPSS 14.0 software at baseline and 15.0 at 1-year follow-up (SPSS Inc., Chicago, IL, USA). Categorical data were tested by Pearson’s chi-square test. Continuous data and ordinal data were tested by the explore and independent-samples t-test. Daily number of SC counselling was tested by the Mann–Whitney test. Tobacco consumption was right skewed, so it was logarithmically transformed. One-way ANOVA was used to test difference between groups.

To test for efficacy of the intervention, we used intention-to-treat analyses, including all smokers from baseline, assuming that all participants who did not return the 1-year questionnaire were still smokers. These analyses were used both when we calculated the self-reported and the validated abstinence rates at 1 year.

We tested the effect of the study in general linear models (generalized estimating equations, GEE) with (i) self-reported point abstinence and (ii) validated point abstinence as dependent variable and group as independent variable, adjusted for age, sex, socio-economic status, tobacco consumption and self-reported motivation to quit at baseline. The GPs were clusters.

Level of significance was set to 5% in all analyses.

Results
The participating GPs were significantly more often women and reported significantly more SC counselling (Table 1). Less than 10% of the GPs were smokers, and less than 10% had a high self-efficacy in SC counselling (Table 1).

Time spent on SC counselling was registered in 78.8% of the office visits with smokers. Thirty-eight per cent of the doctors spent less than 1 min on SC counselling. Median time spent, when >1 min, on SC counselling in Group A: 2 min (range: 1–60), Group B: 4 min (range: 1–15) and Group C: 3 min (range: 1–37). Doctors in Group A,

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Baseline characteristics of the participating and non-participating GPs (n = 55) (Denmark, 2005)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Participating GPs (Groups A, B and C (n = 24))</td>
</tr>
<tr>
<td>Sex = female (%)</td>
<td>54.2</td>
</tr>
<tr>
<td>Practice = solo (%)</td>
<td>62.5</td>
</tr>
<tr>
<td>Smoker = yes (%)</td>
<td>9.5</td>
</tr>
<tr>
<td>Daily number of SC counselling [median (range)]</td>
<td>2.0 (1–10)</td>
</tr>
<tr>
<td>Priority of SC counselling (0, lowest; 10, highest) [mean (SD)]</td>
<td>7.1 (+2.0)</td>
</tr>
<tr>
<td>Self-efficacy in SC counselling</td>
<td></td>
</tr>
<tr>
<td>High (%)</td>
<td>9.5</td>
</tr>
<tr>
<td>Acceptable (%)</td>
<td>57.1</td>
</tr>
<tr>
<td>Low (%)</td>
<td>33.3</td>
</tr>
<tr>
<td>Usually refers to SC assistance elsewhere</td>
<td></td>
</tr>
<tr>
<td>Yes, often (%)</td>
<td>22.7</td>
</tr>
<tr>
<td>Yes, sometimes (%)</td>
<td>63.6</td>
</tr>
<tr>
<td>No (%)</td>
<td>13.6</td>
</tr>
<tr>
<td>Would routinely refer smokers to free SC groups if this was an option</td>
<td></td>
</tr>
<tr>
<td>Yes, most of them (%)</td>
<td>72.7</td>
</tr>
<tr>
<td>Yes, some of them (%)</td>
<td>27.3</td>
</tr>
<tr>
<td>No (%)</td>
<td>0.0</td>
</tr>
</tbody>
</table>

SC, smoking cessation.
*P < 0.05.
referring to group-based SC counselling, spent significantly less time discussing smoking than doctors in Groups B and C \((P < 0.001)\). The GPs in Group C discussed smoking with 47.1% (208/442) of the smokers, whereas the GPs in Groups A and B were randomized to discuss smoking with all smokers.

There were no significant differences between the groups in terms of the number of patients seen or smokers included. Six hundred smokers were included in Group A, 476 in Group B and 442 in Group C (Fig. 2).

The mean registered smoking prevalence was 16.9% (1914/11 331 eligible patients) with a great variation between practices (3.8% to 22.9%).

Thirty-two per cent of the smokers were very addicted to nicotine (Fagerström = six or more). Smokers in Group C were younger, had lower tobacco consumption and were less motivated to quit (Table 2). There was no difference between the groups in wish to quit and only one of seven smokers had no wish to quit at all (Table 2).

The GPs in Group A registered that one of three smokers was interested in attending a group-based SC counselling (Fig. 2) and that an additional one-third of the smokers was ‘possibly interested’, which was in accordance with the smokers’ self-reported wish to quit. However, less than 1 of 10 actually contacted the SC counsellor and registered for an SC group and even fewer attended the first visit (Fig. 2).

The GPs in Group B registered that almost 60% of the smokers expressed interest in trying the internet-based SC programme (Fig. 2). In a period of 3 months after the consultation, only about one out of six of all smokers had logged in the internet-based programme (Fig. 2). Some of these might have been smokers who were not referred by the GP (family members, friends or colleges).

In total, 93 (12.2%) out of the 760 baseline smokers who completed the 1-year questionnaires reported to have quit. All 64 returned urine-cotinine measurements confirmed non-smoking status. In intention-to-treat analyses, the point

Fig. 2 Flowchart of the smokers in the three randomized groups (Denmark, 2005). Asterisk, number of smokers estimated by the GPs. Star, the doctors estimated that additional 199 (33.2%) of the patients were possibly interested in participation in group-based SC. Double asterisk, point abstinence at 1-year follow-up; all smokers from baseline are included in analyses (intention-to-treat). Hash, validated point abstinence at 1-year follow-up; all smokers from baseline are included in analyses (intention-to-treat).
abstinence rates at 1 year were a little higher in Group A (6.7%) than in Groups B (5.9%) and C (5.7%) (Fig. 2). The validated point abstinence rates were lower, but showed the same pattern: 3.5%, 2.5% and 2.7% in Groups A, B and C, respectively. Nine out of 40 participants (22.5%) attending the group-based SC counselling reported to be abstinent at 1-year follow-up.

In cluster analyses, we found no additional effect on self-reported 1-year abstinence rates of either referral to group-based SC counselling (OR = 1.05; 95% CI = 0.6–1.8) or to an internet-based SC programme (OR = 0.91; 95% CI = 0.6–1.4). Neither did we find significant difference in validated abstinence rates (P = 0.58 and 0.53).

**Discussion**

**Main findings of this study**

No additional effect on SC rates was seen after routinely referring to two different SC programmes. Fewer smokers than expected were identified in the general practices, and there was a great discrepancy between the high numbers of patients registered as interested in external referral and the low number who actually signed up for a group-based SC counselling or logged in at the internet-based SC programme.

The GPs included in the study were a selected group, who at baseline reported to be very active in SC counselling.

**What is already known on this topic**

Many reasons have been identified to explain the low intensity of SC intervention in general practice. Lack of time, lack of economical reimbursement, patients’ low motivation to quit, patients’ resistance to speak about smoking, patients’ low compliance, consideration to smokers’ other problems, an uneasy feeling when talking about SC, respect of privacy, lack of skills and low self-efficacy have been identified as barriers.

A Canadian study found that the most important factor predicting SC counselling was GPs’ high self-efficacy. In our study only 1 out of 10 GPs had a high self-efficacy in SC counselling. A previous study, as ours, showed that GPs participating in surveys are more active in SC counselling, have higher self-efficacy and experience greater success with SC counselling than doctors who did not participate.
The smoking prevalence in this trial was 17%, compared with 25% in a national sample the same year, and much lower than the smoking prevalence, 36%, found at the same time in a local large population-based study. There might be several reasons for these findings. First, this might be a registration problem, e.g. the doctor/nurse has forgotten to ask about smoking status. Second, it might be a selection problem, e.g. the GPs have been giving sufficient SC counselling for years and their patients had already quit smoking, or the reluctant smokers had chosen another, less ‘SC aggressive’ GP. Finally, it could be due to under-reporting. Some of the smokers might want to conceal their smoking for their doctor.

In Group A, the GPs estimated that ~3 out of 10 expressed interest in participation in the group-based SC programme and additionally 1 out of 3 showed possible interest. The GPs in Group B registered that ~6 out of 10 smokers expressed interest in trying the internet-based SC. However, only about one out of four of the smokers who expressed interest to take advantage of the assistance to quit signed for an SC group or logged in at the internet programme. A possible explanation could be that the smokers wanted to leave an impression of motivation to quit, avoiding a confrontation with their GP. This is not very probable, as more than half of the smokers also reported high wish to quit in the questionnaires. Alternatively, the smokers never managed to contact the SC counsellor or login on the internet. If the reason is forgetfulness or busyness, it might help if a nurse/secretary routinely signed the smoker in for a cessation group before he/she left the practice. In the Danish nationwide survey, one out of three GPs stated that they had their nurse/secretary involved in SC activities. Another explanation might be that motivation to quit is not a stable condition. One day the smoker may be worried about the damage on health and seriously consider quitting, and on the next day he/she may be partying with smoking friends and has forgotten all about quitting.

A recent Australian study provided evidence that GPs referring smokers to an evidence-based quit-line service resulted in increased cessation. The benefit was largely due to patients in the referral condition receiving more external help than those in the in-practice condition. In our study, baseline smokers who accepted external help and attended the SC groups had high abstinence rates at 1 year, 23%. Also, abstinence rates were a little higher in the group referred to group-based SC counselling. However, the low number of patients who accepted the offer given resulted in no significant additional effect of referral to group-based SC counselling.

The GPs were instructed to talk freely and briefly. It can be argued that the variation in the length and content of the conversations makes the ‘quit smoking message’ too diverse. It was not a part of the study to educate the doctors in how to talk about smoking, but this is of course important. Most GPs, including those in the control group, spent only a few minutes talking about smoking with their patients and had, on average, only two consultations a day with smokers, so there seems to be potential for improvement.

A recent English study found that a brief training session can significantly increase GPs referral to SC services. Another randomized study found that proactively identifying smokers, and referring them to a cessation service, significantly increased contacts with cessation services and the number of quit attempts. A significant effect on long-term cessation rates was not detected, but the study was not powered to detect the difference.

**What this study adds**

This study underlines how difficult it is to achieve good SC results in general practice and how difficult it is to implement interventions and methods that are effective, even in practices with very motivated doctors. Probably, the few minutes spent on SC counselling were not sufficient to achieve significant results.

The strengths of the study are the validation of abstinence, the high participation rate of smokers and high completion rate in questionnaires/register forms and the randomized cluster design with relevant analyses. An important strength is the real-life setting.

**Limitations of this study**

There are several limitations of the study. Participation rate of the GPs was low, despite intensive reminders, low workload and recommended participation. The participating doctors selected were very active in SC counselling, and more than 3 in 10 doctors frequently referred to other SC activities before the start of the study. This could explain why a systematic offer of referral did not have an additional effect.

Using intention-to-treat analyses is a very conservative approach to test the efficacy of the intervention. Also, it is probable that we underestimate the number of ex-smokers due to the low follow-up rate. However, this is due for all three groups and should not affect the result.

According to power calculations, the number of smokers included in Group C was a little low, which may slightly have reduced the study’s ability to detect a significant difference between the referral and the non-referral groups.
Contributors
C.P., M.E.M., M.M.J. and T.J. contributed to the design of the study, collection and assembly of the data, analysis and interpretation of data and drafting the article. M.D. took part in the interpretation of data and drafting of the article. All authors approved the final manuscript. C.P. is the guarantor. The guarantor accepts full responsibility for conducting the study, had access to the data and controlled the decision to publish.

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