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Oystein Bakkevig, Siri Steine, Kari von Hafenbrädl & Even Lærum

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Smoking cessation

A comparative, randomised study between management in general practice and the behavioural programme SmokEnders

Øystein Bakkevig[1], Siri Steine[1], Kari von Hafenbrädl[2] and Even Lærum[1]

[1]Institute of General Practice and Community Medicine, University of Oslo, [2]Country Manager SmokEnders Norway.

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***Objective* – To compare the effectiveness of two different stop smoking interventions.**
***Design* – A randomised, controlled trial. Results based on intention to treat.**
***Setting* – Three towns in the south-eastern part of Norway.**
***Interventions* – Visits to GP for "practice as usual" (GP group) or participation in the behavioural programme SmokEnders (SE group) with follow-up 2 weeks, 2 months and 1 year after an agreed stopping date.**
***Subjects* – 139 smokers recruited through open invitation.**
***Main outcome measure* – Self-reported smoking stop rate 2 weeks, 2 months and 1 year after an agreed stopping date, completed with biochemical indicators by the 1-year registration.**

***Results* – Two weeks after the agreed cessation date, 10/70 (14%) of the GP group and 46/69 (67%) of the SE group had stopped smoking. After 2 months, 9/70 (13%) in the GP group and 37/69 (54%) in the SE group were non-smokers. One year after cessation 5/70 (7%) in the GP group and 21/69 (30%) in the SE group were non-smokers.**
***Conclusions* – Both interventions were effective as measured by the smoking cessation rate. However, the intervention in the SE group was considerably more effective than in the GP group, which suffered from a sizeable number of drop-outs.**

***Key words:* smoking cessation, general practice, behavioural programme, intervention.**

Øystein Bakkevig, Institute of General Practice and Community Medicine, University of Oslo, NO-0318 Oslo, Norway.

Smoking is a major health problem throughout the world regarding both morbidity and mortality. To reduce smoking is therefore a crucial factor in preventing disease and promoting health (1,2). The number of smokers in most countries in the western world is decreasing or constant. In Norway, the total intake of tobacco has been relatively constant over the last 3 years, although the number of smokers has decreased (3).

In 1995, 33% of the Norwegian population between 16 and 74 years of age were smokers (33% men and 32% women). The total number of smokers born before 1940 is decreasing and approximately one in four has seriously attempted to stop smoking at least once over the last 12 months (4).

Seventy percent of the smokers visit a general practitioner (GP) during a year and GPs are encouraged to help their patients to stop smoking (5). The success rates in smoking cessation range from 2% to 11%, depending among other things on the GP's level of training (6).

Smoking cessation programmes based on different theories and methods from behavioural psychology have been presented as aids for smokers who want to stop. Raaheim (7), who assessed such programmes, found an overall success rate of 20–30% after 6–12 months.

SmokEnders (SE) was developed by the American psychologist Jacquelyn Rogers in 1969. This original programme includes the elements used in different behavioural programmes in an interactive and integrated way, and has been translated, modified and revised for use in Norway by one of the authors of this study (KvH).

The aim of the present work, as part of a more comprehensive smoking cessation study, was to compare the effectiveness on smoking cessation of smokers attending this specific programme versus smokers being followed up as usual by their own GP in a randomised, controlled trial.

SUBJECTS AND METHODS

The study was carried out in Oslo and in two other towns in Norway in 1994–96. Through local newspapers we invited smokers to open information meetings about the study and the behavioural programme. Smokers who wanted to be included in the study completed a questionnaire about background characteristics and smoking habits before they were randomly allocated to one of two different groups: to be followed up by their own GP or to participate in the behavioural programme.

Participants who reported severe mental or physical illness or disorder, or individuals who for other reasons were unable to follow the programme or visit their GP, were not included in the intervention and are classified as non-quitters in the study.

Participants in the GP group were encouraged to contact their GP and ask for help to stop smoking. The 27 doctors who became engaged in the trial through their patients received written and oral (ÖB) information about the study. They were asked to follow their usual practice, to obtain mutual agreement with their patients on a specific stop-smoking date (including the stop of nicotine patches and chewing gum), and to perform a follow-up consultation 2 weeks after this date. During that visit a questionnaire about smoking habits was to be completed. The GPs were asked to report their intervention and non-responding doctors were sent a reminder.

Participants randomised to the SE group were encouraged to come for the first session 2 weeks after the information meeting. The programme, which is conducted by earlier smokers trained as moderators, included seven weekly sessions (five before and two after stopping) and one follow-up meeting 4 weeks later.

SE is based on the theory that smoking cessation is a learning process, and participants continue smoking through the first 5 weeks while step-by-step they prepare themselves and learn to stop through a strictly defined multifaceted approach. This includes elements of cognitive theories, conceptual matters leading to attitudinal changes, self-awareness and self-image, motivation building, behavioural modification, nicotine reduction and reinforcement techniques. Another questionnaire about smoking habits was completed 2 weeks after the agreed stopping date.

In the follow-up sessions for both groups 2 months after the agreed stopping date, the participants answered yet another questionnaire. Non-attenders were sent a questionnaire for postal return. Participants who did not respond after one questionnaire had been sent to them were assumed to have relapsed and were categorised as non-quitters.

Smoking cessation was defined as self-reported non-smoking at registration after 2 months. In the follow-up sessions 1 year after cessation, objective measures (s-cotinin and s-thiocyanat) completed the self-reports. Non-smokers were defined as participants who reported non-smoking status and had serum values below 83 μmol/l thiocyanat and/or below 75 ng/ml cotinin (8,9).

Analysis and statistics

The study was planned with a power of 0.90 to detect a 20% difference between the absolute rates of smoking cessation and a significance level of 0.05. To achieve this, 27 participants were required in each group. The efficacy data were analysed on an intention-to-treat basis. In the statistical analysis, two-tailed t-tests and chi-squared tests were applied.

Ethics

The study was carried out in accordance with the Helsinki declaration and was approved by the Regional Committee for Medical Research Ethics.

RESULTS

One-hundred-and-sixty smokers attended the information meetings; 139 wanted to be included and were randomly allocated to the GP (70) and SE (69) groups. After randomisation, 17 (25%) in the GP group and 3 (4%) in the SE group withdrew from the study due to reluctance to accept their allocation. They are treated as non-quitters.

There was no significant difference between the groups with respect to the sociodemographic data, smoking status or lifestyle variables. Baseline characteristics are given in Table I and a flow-chart of the study population is shown in Fig. 1.

In the GP group, 25/70 (36%) consulted their GP in an attempt to stop smoking, and 14/70 (20%) completed the intervention. In the SE group, 52/69 (75%) attended and 48/69 (70%) completed the programme. Two months after the agreed stopping date, 14/70 (20%) in the GP group and 45/69 (65%) in the SE group completed the questionnaire. After 1 year 7/70 (10%) in the GP group and 24/69 (35%) in the SE group came for the follow-up.

Table I. Characteristics of subjects before intervention (n = 139).

	GP group		SE group	
	n = 70	100%	n = 69	100%
Women	47	67.2	46	66.8
Living alone	26	37.2	18	26.1
Basic education only	9	12.9	7	10.2
High school or similar	25	35.7	31	44.9
University or similar	36	51.4	31	44.9
Employed	51	72.6	50	72.5
Living with a smoker	22	31.4	22	31.4
	Mean	SD	Mean	SD
Cigarettes/day	18.4	5.7	20.6	8.1
Smoking years	26.0	10.0	26.5	10.6
Age	44.0	11.5	44.8	12.5

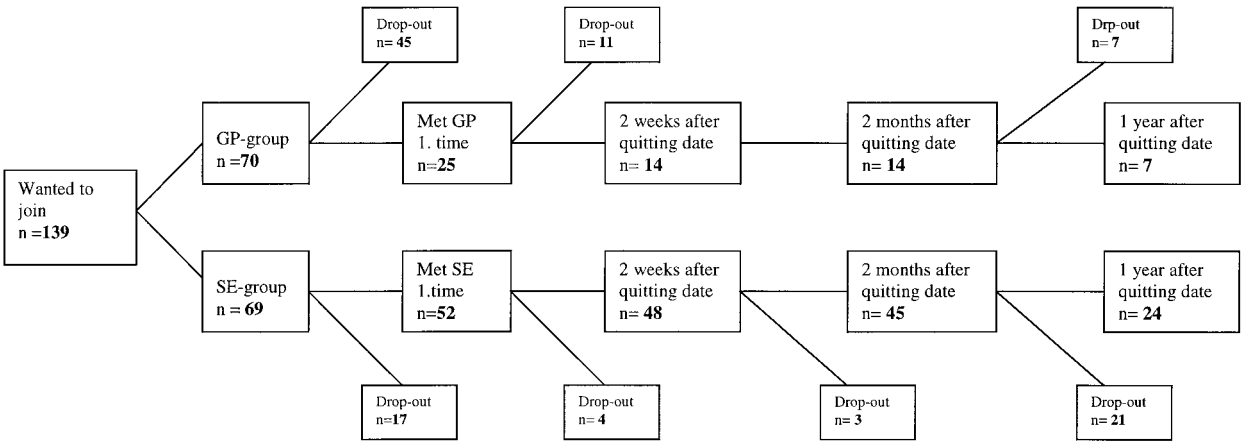

Fig. 1. Flow chart of the study population (n = 139)

Table II gives the stop-smoking rates 2 weeks, 2 months and 1 year after the stopping date. In the GP group 10/70 (14%) managed to stop and were still non-smokers after 2 weeks, compared with 46/69 (67%) in the SE group. Two months later, 9/70 (13%) in the GP group and 37/69 (54%) in the SE group were still non-smokers. After 1 year 5/70 (7%) in the GP group and 21/69 (30%) in the SE group reported a non-smoking status, verified with serum concentrations below 83 μmol/l of thiocyanate and/or 75 μmol/l of cotinin. There were no discrepancies between the self-reports and the serum levels.

Among participants who actually contacted their GP or came for the first session in the SE group (Table III), 10/25 (40%) in the GP group and 46/52 (88.5%) in the SE group reported non-smoking 2 weeks after the stopping date. Two months later, 9/25 (36%) in the GP group and 37/52 (71%) in the SE group were non-smokers. After 1 year, 5/25 (20%) and 21/52 (40%) were non-smokers due to our non-smoker criteria.

Those who stopped smoking had a significantly higher level of education than those who continued ($p = 0.02$). No significant differences regarding the other basic characteristics described in Table I were found.

Eighteen of the 27 GPs originally included were consulted by the participants. They saw their patients between two and seven times during the intervention period and their interventions were in general of a supportive nature. Seven GPs prescribed nicotine patches.

DISCUSSION

The stop-smoking rate was relatively high in both groups, but considerably higher following the Smok-Enders programme. The main explanation for the success of the SE programme is probably the purposeful integration of different approaches addressing the complexity of the tobacco dependency, combined with sufficient time to reduce the physical addiction. The unity and positive strength in a group with the shared interest of smoking cessation may also have contributed to the good results in the SE group.

Although the immediate stopping rate in the GP group was encouragingly high, the long-term outcome did not surpass quitting rates reported previously. In a Canadian study, setting a stopping date, as in the present one, was seen as an important element in a successful cessation programme (10). The use of nicotine patches may contribute to a high quitting rate (11), but from the present study we cannot conclude whether it had any supplementary effect.

There were many dropouts, including those who refused to enter the GP group, and more than 40% of those who met their GP did not complete the GP intervention. Practical inconveniences attached to a GP visit, such as difficulties in getting an appointment, waiting time, and lost time at work, may have been a hindrance to a continuous contact or to complete the GP consultations. Smoking has been held as the most important health risk by physicians (12). Still, the GP setting, with its limited time for each patient and a strong association between en-

Table II. Success rates 2 weeks, 2 months and 1 year after agreed stopping date for the total study population (n = 139).

	2 weeks	2 months	1 year
SE group	46/69 (67%)	37/69 (54%)	21/69 (30%)
GP group	10/70 (14%)	9/70 (13%)	5/70 (7%)
	56/139 (40%)	46/139 (33%)	26/139 (19%)

Table III. Success rates 2 weeks, 2 months and 1 year after agreed stopping date for the subjects enrolled in the study (n = 77).

	2 weeks	2 months	1 year
SE group	46/52 (88%)	37/52 (71%)	21/52 (40%)
GP group	10/25 (40%)	9/25 (36%)	5/25 (20%)

counter and disease, may be unsuitable for long-term preventive intervention which aims at profound behavioural changes such as smoking cessation. The GP in general has not the same possibility to follow a smoker who wants to stop as intensively as someone engaged in a behavioural programme. Many smokers know the strength of their addiction (13) and may regard even a 15–20 min consultation once every week as insufficient. The physician's role in smoking cessation has often been to initiate behavioural change through information, often in correlation with a smoke-related disease, thus activating the patient's negative feelings of guilt towards his own smoking habits.

Bearing in mind the low success rate in several smoking cessation studies from general practice, a low priority for and trust in smoking cessation intervention is understandable (14). We also registered reluctance from some of the GPs who felt that the intervention initiated by their patients was an unreasonable demand.

The present study design resulted in two comparable groups with a sufficient number of smokers to achieve our aim. The participants probably had a high level of motivation for stopping and the decision to join this study might have brought them from the stage of contemplation to the stage of action to change an untoward behaviour (15).

Hence, the participants were not representative of the total population of smokers in Norway. They were older than the average smoking population, but still comparable with similar studies (16).

Objective measurements of smoking cessation were only used at the 1-year registration. This is not usual in general practice and would have disturbed the first part of the study if it had been used more extensively during the study. Our study confirmed the high validity of self-reported smoking habits in questionnaires (17).

This study was based on intention to treat and had a strict design. It implies that the SE programme is capable of tackling nicotine addiction with a higher rate of success than other studies of smoking cessation programmes. The GPs have their strength in their knowledge of and relation to their patients and thus are in a position to motivate smokers to stop. Even greater success might be achieved if GPs could refer patients to SE groups or similar programmes in their area, based on an evaluation of the stage of change in which their smokers find themselves.

In conclusion, management in general practice and attending the behavioural programme SmokEnders were both effective ways to stop smoking. However, the SE group intervention was considerably more effective than that of the GP group.

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