

Smoking cessation intervention in a large randomised population-based study. The Inter99 study.

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Abstract

Background. Several large and well-conducted community interventions have failed to detect an effect on prevalence of smoking.

Methods. Two thousand four hundred eight daily smokers in all motivational stages were actively recruited and included in a randomised population-based intervention study in Copenhagen, Denmark. All smokers completed a questionnaire and underwent a health examination and a lifestyle consultation. Daily smokers in the high intensity intervention group were offered assistance to quit in smoking cessation groups.

Results. The validated abstinence rate at 1-year follow-up was 16.3% in the high intensity group and 12.7% in the low intensity group compared with a self-reported abstinence rate of 7.3% in the background population. The adjusted odds ratio of abstinence in the high intervention group was significantly higher, OR = 2.2 (1.6–3.0) than in the background population, also in the ‘intention-to-treat’ analyses, OR = 1.5 (1.1–2.0). Higher socioeconomic status, higher age at onset of daily smoking, and a higher wish to quit were predictors of success.

Conclusion. In a population-based setting, using active recruitment and offering assistance to quit, it was possible to include many smokers and to achieve a significantly higher validated abstinence in the high intensity intervention than in the background population, even when using ‘intention-to-treat’ analyses.

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Introduction

Smoking cessation interventions can be classified by their recruitment strategies. In the reactive recruitment strategy, the smokers must actively contact the programme or smoking cessation clinic to receive assistance to quit. This strategy appeals to the highly motivated and well-educated smokers, and results in low participation rates [1], but can achieve high abstinence rates [2,3]. The proactive recruitment strategy recruits smokers in an active way by offering assistance to quit, for example, self-help manuals or physicians’ advice to quit. These programmes can reach a

large percentage of the population, but the abstinence rates are low [4,5]. The challenge is to draw on the experience of both strategies, combining the high participation rates of the proactive strategies with the high abstinence rates of the reactive strategies.

Many large and well-conducted community interventions studies have failed to detect an effect on prevalence of smoking [6]. Interpersonal communication appears to be an important catalyst of community programs [7], and its inclusion should be emphasised to obtain a higher impact.

Inter99 (abbreviation of Intervention 1999) is a large population-based intervention study. The smoking intervention tries to combine the proactive recruitment strategy by sending a personal invitation with a prearranged date and time, with the reactive strategy, by offering an intensive smoking intervention to achieve a high impact. In previous papers, we have described a high recruitment rate of smokers

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in all stages of motivation, high acceptance of the smoking cessation groups, and high abstinence rates after the smoking cessation groups [8,9].

The aim of this paper was to report the abstinence rates after 1 year and compare them with abstinence rates in the background population and to compare the high intensity intervention with the low intensity intervention. We also wanted to investigate predictors of abstinence in the study population.

Methods

Inter99 is an ongoing population-based intervention study, which started in March 1999. The study is at Research Centre for Prevention and Health, Glostrup University Hospital, Copenhagen. The Copenhagen County Ethical Committee and the Danish Health Board have approved the study. The aim of the study is to prevent cardiovascular disease and type 2 diabetes by nonpharmacological intervention, that is, through change of lifestyle. We focused on changes in smoking, diet, and physical activity. The study population was randomly selected within age strata (30–60 years) from a defined area of the suburb of Copenhagen. The individuals were drawn from the Civil Registration System in which a unique 10-digit number registers all inhabitants in Denmark, making linkage across time and registers very accurate. The subjects were prerandomised into one of three groups: a high intensity intervention group A ($n = 11,708$), a low intensity intervention group B ($n = 1,308$), and a nonintervention group C ($n = 48,285$). Group A was almost 10 times larger than group B, as we wanted mainly to test the effect of a high intensity intervention on long-term endpoints, such as cardiovascular disease. Group B was invited to test the intensity of the intervention on intermediate endpoints, such as change in smoking habits. More 40- to 50-year-old persons were invited in study groups A and B as the highest impact of the intervention was expected among the middle-aged. A random sample of 5,264 persons in group C, equally distributed within the age strata, served as control group and received questionnaires at baseline and after 1, 3, and 5 years to register spontaneous lifestyle changes in the background population. The study design is described in detail elsewhere [10].

Eighty-two of the persons in group AB were noneligible. The remaining 12,934 individuals in groups A and B received a personal invitation with a prearranged date and time of a consultation. Those who did not answer the first letter received a new invitation and those who still did not answer or said that they would not participate were sent a two-page nonresponder questionnaire. A total of 6,906 (53.4%) turned up for the investigation. Of these, 122 were excluded either due to alcoholism or drug abuse ($n = 23$) or because of linguistic problems ($n = 99$), leaving 6,784 (52.5%) for analyses. In general, the participation

rate was higher in younger women than in younger men, and it increased with increasing age until 55 years of age after which it declined. Participation rate in groups A and B was identical. In group C, the participation rate was 63.1% ($n = 3,324$) with the same trend in age and sex difference as in groups A and B.

On the day of attendance in the clinic, all participants completed questionnaires, underwent a medical health examination, and were given an individual cardiovascular risk assessment with a computerised programme PRE-CARD® [11] and a lifestyle consultation. The criteria for identifying persons at high risk of cardiovascular disease were a high total risk and isolated risk factors (high cholesterol, high systolic blood pressure, high body mass index, and daily smoking). This is described in detail in a previous article [10].

The smokers in the study

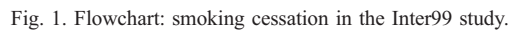
A total of 2,408 daily smokers were included at baseline: 2,168 in group A and 240 in group B (Fig. 1). All daily smokers were offered follow-up after 1, 3, and 5 years. The interventions after 1 and 3 years were identical with the intervention at baseline. Sixteen smokers had died or emigrated at 1-year follow-up, and 1,387 (57.6%) showed up. In the background population, 16 of the 1,276 daily smokers at baseline had died or emigrated, and 1,005 (78.8%) returned questionnaires at 1-year follow-up (Fig. 1).

The baseline questionnaire

Before the baseline visit, all participants completed a detailed questionnaire. The participants in groups A and B received the same questionnaires, whereas the persons in group C received a shorter version. The questionnaires included age, sex, marital status, educational level, occupational status, self-reported health, physical activity, eating habits, alcohol use, personal psychological and physical well-being, health knowledge, previous contact with the health care system, and a battery of smoking-related measures. Smokers were categorised in motivational stages using a simplified typology of Prochaska and Di Clemente [12,13]. Preparation stage was defined as ‘planning to quit within 1 month’. Contemplation stage was defined as ‘planning to quit within the next 6 months’. Precontemplation stage was defined as ‘not planning to quit’. Another measure of motivation to quit was the simple question ‘wish to quit’ (very much, much, only a little, not at all).

The likelihood of abstinence in the near future was measured by the variable ‘how likely is it that you would achieve abstinence if you tried to quit in the near future?’ (almost certain, likely, not so likely, not at all likely).

The knowledge of harm of smoking was defined by the variable ‘does smoking cause...?’: asthma, chronic bronchitis, lung cancer, other cancers (mouth, throat, bladder), headache, thrombosis, circulatory disease, high blood pres-



We measured point abstinence at 1-year follow-up. Daily smokers at baseline reporting to be nonsmokers at the time of the 1-year visit were registered as ‘self-reported abstinence’. IMMULITE 2000 Nicotine Metabolite kit, a solid-phase competitive chemiluminescent immunoassay, was used for the quantitative measurement of serum cotinine. Smokers with validated serum cotinine < 20 ng/mL were registered as ‘validated abstinence’. Users of nicotine replacement therapy at time of cotinine measurement were validated as abstinent if cotinine was < 100 ng/mL. The abstinence rates in group C were self-reported.

Intention-to-treat

To describe the impact of the trial, we chose to do two types of intention-to-treat analyses (see Fig. 2).

Model I. When calculating the mean abstinence rate in the study population, we assumed that those who did not attend the 1-year follow-up visit or did not return the questionnaires were continuous smokers.

Model II. To demonstrate any effect of the intervention on the entire invited population, including nonrespondents, we assumed that the entire invited group A/B was equal to the entire invited group C with respect to sex- and age-related smoking prevalence at baseline. We calculated an assumed smoking prevalence for the entire invited populations A, B, and C at baseline and after 1 year and adjusted for differences in sex and age for direct comparison.

Statistical analyses

Categorical data were tested by Pearson chi-square test. Continuous data and ordinal data were tested by independent samples *t* test. The variable ‘number of previous quit attempts’ was not normally distributed but skewed towards higher values; therefore, the Mann–Whitney test was used.

With an expected participation rate of 70%, it was calculated that a difference in smoking cessation on 10% after 1 year between groups A and B could be detected with an $\alpha = 0.05$ and $\beta = 0.20$.

In a logistic regression analyses, we tested the following variables as determinants for abstinence: ‘sex’, ‘socioeconomic status’, ‘years smoked’, ‘daily tobacco consumption’, ‘age at onset of daily smoking’, ‘smoking status of the spouse’, ‘change in smoking habits within the previous year’ (before baseline), ‘smokers knowledge of harm of smoking’, ‘previous quit experiences’, ‘likelihood of absti-

nence in the near future’, and measures of motivation to quit. Logistic regression analysis was used to analyse the likelihood of cessation among smokers in the high intensity intervention group A, who accepted or rejected participation in a smoking cessation group; adjusted for sex, age, socioeconomic status, and motivational level at baseline. Logistic regression analysis was used to analyse the likelihood of cessation in the high intensity intervention group A compared with low intensity population group B and background population group C, adjusted for sex, age, socioeconomic status, and motivational level at baseline. Level of significance was set to 5% in all analyses. The models were controlled by the Hosmer-Lemeshow goodness-of-fit test. All data processing was done with the SPSS 10.0 software (SPSS Inc., Chicago, IL, USA).

Results

Characteristics of the smokers in the study

See Table 1. The mean age of the smokers was 46 years for both group A/B and C. The mean daily tobacco consumption in group A/B was 17 g which was equal to group C’s. The differences in socioeconomic status and ‘wish to quit’ were equalised when adjusted for age. More smokers in the study population were planning to quit within 6 months compared with the background population.

Smoking cessation rates after 1 year

At 1-year follow-up, 263 participants stated to have quit smoking (Table 2), and 221 were biochemically verified nonsmokers for analyses (classification error = 16.0%). The self-reported abstinence rate in group A was 19.3% compared

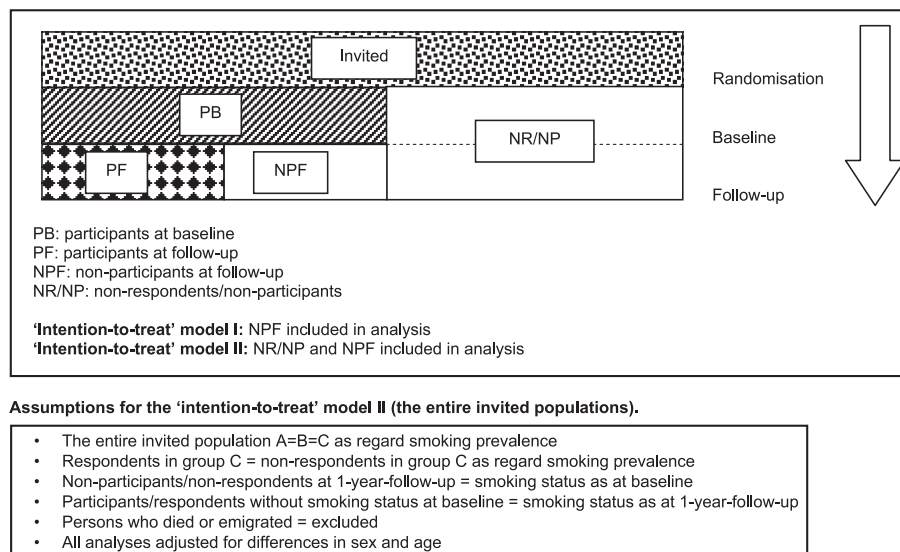


Fig. 2. The two 'intention-to-treat' models.

Table 1

Characteristics of the daily smokers included in the study population compared with the background population

	Group A + B, N = 2,408	Group C, N = 1,276	Significance level, <i>P</i>	Significance level- adjusted for age ^a , <i>P</i>
Sex = male	50.3%	50.4%	0.973	
Age			<0.001	
30	5.0%	11.0%		
35	9.6%	12.3%		
40	18.7%	13.9%		
45	23.1%	17.0%		
50	21.2%	14.8%		
55	15.4%	15.0%		
60	7.0%	16.1%		
Socioeconomic status			0.002	0.234
Unemployed, no vocational training	6.8%	6.6%		
Unemployed, ≥1 year of vocational training	9.4%	13.6%		
Employed, no vocational training	15.9%	16.3%		
Employed, ≥1 year of vocational training	67.9%	63.5%		
Age at onset of daily smoking (mean)	17.1 (± 4.5)	17.1 (± 4.5)	0.839	0.282
Daily tobacco consumption (g, mean)	17.7 (± 8.4)	17.4 (± 8.5)	0.299	0.780
Number of previous quit attempts (median, range)	2.0 (99)	2.0 (99)	0.181 ^b	0.964 ^b
Ever tried to quit = yes	73.3%	71.9%	0.391	0.491
Changes within the previous year			0.236	0.397
‘Did not try to change smoking habits’	53.2%	49.8%		
‘Tried to reduce tobacco consumption’	24.7%	26.8%		
‘Tried to quit smoking’	22.1%	23.4%		
Stages of change			<0.001	<0.001
Preparation stage	10.8%	7.2%		
Contemplation stage	32.2%	29.8%		
Precontemplation stage	57.0%	62.9%		
Wish to quit			0.024	0.085
‘Only a little’ or ‘not at all’	51.8%	56.3%		

Results expressed as percent or mean (± SD).

^a More middle-aged persons than young and old persons were invited to the intervention groups A/B compared with group C where the age distribution was equal.^b As the number of quit attempts was skewed, we used the Mann–Whitney test.

with 16.2% in group B and 7.3% in the background population. High intensity group, but not low intensity group, had significantly higher validated abstinence compared with the

self-reported abstinence in the background population. Participation in the intervention more than doubled the probability of abstinence. Validated abstinence in the high intensity

Table 2

Point abstinence after 1 year

	Smokers at baseline <i>N</i> , all	Self-reported abstinence <i>N</i>	%	Validated abstinence <i>N</i>	%	Group as predictor of abstinence ^a group C = reference	
						OR	95% CI
<i>Study population group A</i>							
Smokers attending baseline + 1-year visit	1245	240	19.28	203	16.31	2.2	(1.6–3.0)
Smokers at baseline ^b	2155		11.14		9.42	1.5	(1.1–2.0)
<i>Study population group B</i>							
Smokers attending baseline + 1-year visit	142	23	16.20	18	12.68	1.6	(0.9–2.9)
Smokers at baseline ^b	237		9.70		7.59	1.1	(0.6–2.0)
<i>Study population group A + B</i>							
Smokers attending baseline + 1-year visit	1378	263	19.09	221	16.04	2.1	(1.5–2.8)
Smokers at baseline ^b	2392		10.99		9.24	1.4	(1.1–2.0)
<i>Background population group C</i>							
Smokers with baseline + 1-year data	1005	73	7.26				
Smokers at baseline ^b	1260		5.84				

^a Adjusted for sex, age, socioeconomic status, and motivational level at baseline. Validated abstinence used in group AB. Self-reported abstinence used in group C.^b Smokers who emigrated or died or smoke occasionally were excluded. Smokers not attending the 1-year visit or not returning the 1-year questionnaire were classified as smokers.

group A was not significantly higher than in the low intensity group B, OR = 1.4 (0.8–2.3). The ‘intention-to-treat’ model I, including nonparticipants, showed a significantly higher likelihood of abstinence in group A but not in group B compared with the background population (Table 2).

In the ‘intention-to-treat’ model II (see Fig. 2 for definition), the smoking prevalence at baseline for the entire invited groups A, B, and C was assumed to be 40%. After 1 year, the sex- and age-adjusted smoking prevalence in the entire group A was calculated to be 39%. In group B, it was calculated to be 40% and in group C to be 40%. Because of the assumptions and adjustments, no significance test was performed.

Acceptance of participation in a smoking cessation group (adjusted for sex, age, socioeconomic status and motivation to quit before the lifestyle consultation) increased the likelihood of abstinence at 1 year more than fourfold, OR = 4.6 (3.2–6.7), compared with the smokers in group A who did not accept to participate in the smoking cessation groups.

Predictors of cessation

See Table 3. Higher socioeconomic status was a predictor of success, but there was no difference between the unemployed with and without education. Also, the older the smoker was at onset of daily smoking and the higher the wish to quit he/she had at baseline, the more probable it was that he/she had quit after 1 year. The motivational level (stage of change) was not significant in the model but showed that smokers in the contemplation stage (planning to quit within 6 months) had a significantly higher probability to quit than smokers in the precontemplation stage (without plans to quit).

Discussion

The study and the background populations were comparable except for higher motivation to quit in the study

population. The 1-year validated abstinence rate among those who attended 1-year follow-up tended to be higher in high intensity intervention group A than in low intensity group B, but the difference was not significant. The adjusted odds ratio for abstinence, when using the worst-case ‘intention-to-treat’ analyses, was significantly higher in the intervention group A but not in group B compared with the background population C. The difference seems clinically relevant. Higher socioeconomic status, higher age at onset of daily smoking, and a higher wish to quit were predictors of success.

Participation in smoking cessation groups increased the likelihood of long-term abstinence more than four times, but there was no statistically significant difference between the quit rates in groups A and B. However, a trend was seen, indicating higher quit rates in high intensity group A. The participation rates at baseline and 1-year follow-up were lower than we expected in our power calculations, which resulted in low power and difficulties to detect a difference between groups A and B. Therefore, after 1 year of intervention, we were not able to make conclusions on the optimal intensity of a smoking cessation program. It is important to answer the question of intensity of a smoking cessation program. If a minimal intervention can result in even a small increase in cessation rates, this would have a large public health impact.

In a previous article, being a man, having a higher age, and higher socioeconomic status were predictors of 17-week continuous abstinence after participation in a smoking cessation group, whereas living with a smoking spouse and having a high nicotine dependence predicted failure [8]. In this paper, we present point abstinence at 1 year among all smokers irrespective of their participation in smoking cessation groups or not. The only variable that significantly predicted abstinence both after a smoking cessation group (short-term) and at 1-year visit (long-term) was a high socioeconomic status. More than 1 year of vocational training and having a job increased the probability of abstinence five times after 1 year. This is in accordance with other studies [18,19]. Smokers with the lowest socioeconomic status accepted the smoking cessation groups [9], but the intervention could not obliterate the social differences in ability to achieve abstinence. A simple wish to quit was a stronger predictor of abstinence than the ‘stage of change’ [12]. This indicates that the smoking counsellor was able to give some of the smokers in early motivational stages inspiration and tools for quitting. It is interesting and conflicting with the ‘Health Belief Model’ [16] that a high PRECARD® risk score, the calculated cardiovascular risk of each individual, did not predict participation in smoking cessation groups. This might indicate that a threat alone is not enough for a person to try to quit smoking. It might also be due to the fact that this variable does not reflect the subject’s idea of the personal risk but only the calculated ‘theoretical risk’.

Table 3
Multivariate model: predictors of validated abstinence at 1-year follow-up. (1,264 subjects included).

	Validated abstinence		
	OR	95% CI	P
Wish to quit			<0.001
Not at all	1		
Only a little	4.5	1.8–11.4	
Much	9.2	3.6–23.2	
Very much	9.7	3.7–25.0	
Socioeconomic status			0.002
Unemployed, no vocational training	1		
Unemployed, ≥1 year of vocational training	2.0	0.5–7.7	
Employed, no vocational training	3.6	1.0–12.7	
Employed, ≥1 year of vocational training	5.0	1.5–16.5	
Age at onset of daily smoking	1.1	1.0–1.1	0.006

Potentially misclassified nonsmokers are found to deviate strongly from other nonsmokers with respect to mortality and morbidity, so validation of smoking status is essential [20]. A metaanalysis concluded that self-reports of smoking are accurate in most studies, but biochemical assessment should be considered in intervention studies [21]. In the Lung Health Study (LHS) including almost 4,000 smokers, the error in self-report was very low, between 3% and 5% in the first year of follow-up [22]. The frequent carbon monoxide measurements in the LHS have probably reduced the error in self-report at 1-year visit. In our study, the misclassification rate was much higher—16.0%—but low compared with a controlled antismoking trial in general practice of same size as our study, with misclassification rates between 24% and 40% [23].

At end of the smoking cessation groups, we reported a sustained abstinence rate of 35% [8]. In this paper, we present point abstinence rates between 19% and 9% and an assumed decrease in smoking prevalence by about 1% point. The decreasing rates are an expression of inclusion of a more unselected smoking population and represent a more ‘true’ picture if we look at smoking cessation from a population-based perspective. Population-based or community-based interventions include smokers in all stages of motivation and reflect ‘real life’ in a population. The quit rates in the large population-based smoking cessation interventions from the 1990s were typically of 10% or less [24,25] and were most often self-reported and not adjusted for those lost or not willing to participate at follow-up. In our study, the self-reported nonvalidated quit rate was 19% in group A and 16% in group B. When diluting the analyses with all nonattending persons and nonmotivated smokers and presenting ‘intention-to-treat’ results—assuming that nonparticipants do not change their smoking habit—a much more limited effect must be expected. ‘Intention-to-treat’ results should be presented in all studies to show not only the efficacy, but also the efficiency of a trial, but only few of the large smoking cessation studies have reported these results. In some of the studies, the abstinence rates remained significant after inclusion of nonparticipants at follow-up [26,27], but not in all [28]. In the OXCHECK study, the quit rates were not significant, and when efficiency analyses were used, the abstinence rates were even lower than in the control group. This illustrates that we probably make an overadjustment when we assume that all nonparticipants remain smokers, and thereby present the ‘worst case’ results. No trials, as far as we know, have tried to compare the entire invited populations. Our study showed a little positive effect, but significance tests were not performed, and the results must be interpreted cautiously. More calculations will be done at the 5-year follow-up.

Acceptance of and participation in a smoking cessation group increased the likelihood of abstinence at 1 year, even when we adjusted for motivation to quit at baseline. The study was not designed to answer which component of the smoking cessation groups was the most effective. The

intensive use of nicotine replacement therapy probably increased the quit rates, but the behavioural therapy and the setting in the group of smokers have presumably contributed to this increase.

It seems that the higher the intensity of the intervention, the higher the cessation rates. Intensive smoking cessation programmes of this character are expensive. Therefore, it is of great importance to discuss the costs–benefit and feasibility of a program like this. The Inter99 study is a 5-year multifactorial intervention on smoking, diet, and exercise. The smoking intervention is only one part of the study. The cost-effectiveness, feasibility, and impact of the whole study will be described thoroughly at end of the trial.

Conclusion

Most smokers in the population have no plans to quit in the near future. In this study, it was possible to recruit a large number of smokers in all motivational stages, by sending a personal letter with prearranged date and time of a consultation. Participation in a smoking cessation group significantly increased the likelihood of abstinence at 1 year. The point abstinence rates after 1 year were significantly higher in the high intensity study population, who received a lifestyle consultation and were offered participation in smoking cessation groups, than in the background population. These results were significant even when using ‘intention-to-treat’ analyses and seem clinically relevant. A proactive recruitment strategy aimed at smokers in all stages of motivation combined with assistance to quit seems as a promising approach in smoking cessation intervention in a population.

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