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Impact of compliance on quit rates in a smoking cessation intervention: population study in Denmark

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Abstract

Objectives Primary objective was to evaluate whether patients completing at least 75% of the smoking cessation program had a higher quit rate after 6 months than patients participating in less than 75% of the program. Secondary objective was to evaluate whether there might be a more appropriate compliance level than 75% .

Methods The study included all patients (17,439) who participated in the National Gold Standard Smoking Cessation Program in Denmark (GSP) with planned follow-up for smoking cessation at 6 months. Patients were randomly divided into two groups (datasets) in order to investigate and re-validate the objectives on two separated groups of smokers. Sensitivity analyses were undertaken for non-responders.

Results Patients who completed at least 75% of the program sessions had higher quit rates in comparison to patients who completed less than 75% of the program (OR = 0.27; 95% CI 0.24 - 0.31 and 0.31; 0.27 - 0.35) for the first and second dataset, respectively. However patients who completed the whole program had higher quit rates compared to patients completing only 75% (0.49; 0.43 - 0.56, and 0.54; 0.47 - 0.62, respectively). The sensitivity analysis showed that baseline characteristics were similar between patients with missing and available follow-up data.

Conclusion Compliance to 75% of the national smoking cessation program (GSP) is shown to be effective; however, 100% compliance leads to even higher quit rates.

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Introduction

According to the Danish Cancer Society, around 20% of Danes aged 15 years and older were daily smokers in 2010 (1). Moreover, it is estimated that over 800,000 Danes are daily smokers, and around 14,000 Danes die annually due to smoking, while 4,500 die of cancer, where smoking is one of the main contributing risk factors. Consequently, Danish public health and tobacco control strategies include nationwide smoking cessation interventions. A national smoking cessation database (SCDB) was established to monitor and improve the clinical quality of smoking cessation programs (2). The leading and dominant intervention on smoking cessation in Denmark is a comprehensive evidence based intervention called the Gold Standard Program (GSP) (3). This program combines pharmacotherapy and psychological interventions in an intensive 6 week manual-based program; such an approach has been shown to be more effective than less intense interventions (4;5). For instance, such intensive programs on smoking cessation are the ones considered most relevant for hospitalised patients (6).

The program is delivered as a group or individual intervention by trained counsellors to patients who are referred by their doctors, other health professionals, or enter on their own initiative. The program is delivered at diverse settings including hospitals, municipality clinics, general practices, pharmacies, and companies. It consists of five manual-based face-to-face sessions along with supportive medications over six weeks.

As a general principle, a patient is often considered as having completed a treatment program, if patient compliance/adherence to the program is at least 75%. This compliance level has been used for our smoking cessation program GSP, and for evaluating the program effectiveness at the national level in a previous study (7). However, the appropriateness of this compliance level has never been evaluat-

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ed before. Therefore, the main aim of this study is to evaluate the evidence for this compliance level. Counselling compliance is one of the specified predictors for smoking cessation in the literature (8). In a meta-analysis of 45 studies, smoking cessation rates increased with the increase in the number of counselling sessions attended (8). The literature therefore indicates an established relationship between intensity in terms of program duration and/or number of sessions and effectiveness of the smoking cessation interventions (7-10). Nevertheless, there is little evidence on typical number and duration of smoking cessation interventions (9;10).

Objectives

- The primary objective was to investigate whether smokers completing at least 75% of the smoking cessation intervention had higher quit rates after 6 months than smokers participating in less than 75% of the program.

- The secondary objective was to investigate whether there might be a more appropriate compliance level than the 75% compliance level.

Methods

The Gold Standard Program

This is a standardised program in terms of setting a standard orientation and training program for all smoking cessation counsellors who are responsible for delivering the Standard Smoking Cessation Program, standardised delivery of the program aided with a manual and standardised data collection procedure (3).

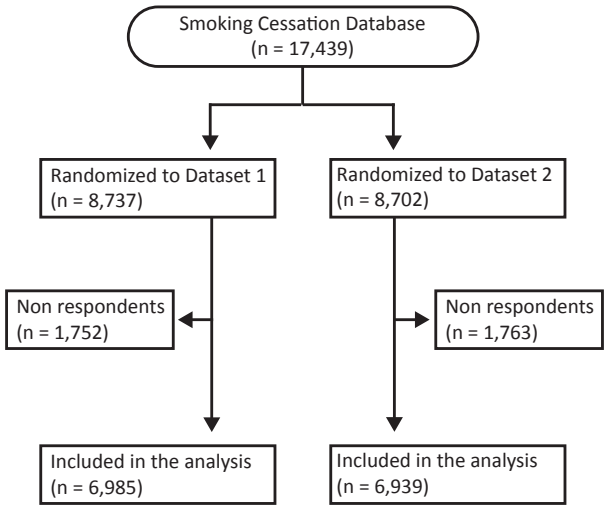
Patients

In total, 299 smoking cessation units provided patient data to the Smoking Cessation Database (SCDB) in Denmark. While 23,775 daily smokers who had enrolled in the GSP from 2006-2009, 6,336 (26%) were not included in this study, because some smoking cessation clinics had a priori decided not to follow-up on any of their patients. After 6 months, the included patients were contacted by phone and asked about their quitting status; at least four attempts including one in the evening were initiated to contact the patient. Only if all of the attempts failed was the patients' quitting outcome considered as missing (approximately 15 % of patients) (Figure 1).

Main independent variable

The main exposure is the different compliance levels expressed as the number of sessions attended; data on attendance was entered into the SCDB for almost all patients since 2006.

Figure 1 Trial Profile



Quitting outcome measure

Patients were grouped according to the availability of 6-month follow up data on quitting outcomes into two "follow-up outcome" groups:

a) Patients with existing data on quitting outcomes at 6-months of follow up (base case scenario).
b) Patients with missing quitting outcome data due to failed follow-up attempts (non-responders). This group has been used in sensitivity analyses as worst and best case scenarios.

Design

We undertook a national population study using prospectively recorded data on patients and GSP characteristics. Patients' data was stratified by gender, age, and calendar year, and then randomly split into two datasets by a colleague not otherwise involved in the project. It is worth mentioning that population studies often generate many significant results, which requires further evaluation in new studies for confirmation. To overcome this methodological problem, we decided a priori to generate two datasets (dataset 1 and dataset 2) through random splitting of the original data in the SCDB; the second dataset was concealed from the researchers until the analysis of the first dataset had been finalised (Figure 1).

Statistical methods

The following analyses were performed and finalised for the first dataset "dataset 1", then repeated for the second dataset "dataset 2". Initially, logistic regression (LR) models were constructed, and two analyses compared the quit rates between different levels of compliance. The first analysis tested the primary objective and compared patients who completed less than 75% of the

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program (i.e. one, or two, or three sessions) and who attended at least 75% of the program (four or five sessions); using patients who attended less than 75% of sessions as the reference group. The second analysis tested the secondary objective and compared the quit rates for patients who attended one, two, three, four, or five sessions; using the last group as the reference group. The set of predictors used in the LR models along with level of compliance were; smoking cessation unit setting, calendar year, intervention type, setting, if relapse prevention strategy offered for the patient, if nicotine replacement therapy offered to the patient, age, gender, overall Fagerström score, smoking years, living with smoker, living with adult, living with child, previous attempts to stop smoking, employment status, level of education, and housing type. It is worth mentioning that predictors have been chosen after screening of relevant literature (6;11-13).

Two sensitivity analyses (worst- and best-case scenarios) were performed on both datasets by including the data on non-respondents. The worst-case scenario considered non-responding patients as smokers, while the best-case scenario considered them as quitters. Statistical analysis was undertaken using SPSS 19.

Ethical considerations

Written informed consent in the national language was obtained from all patients who participated in the smoking cessation interventions. SCDB is registered at the Scientific Ethical Committee (Prot.-Nr. H-C-FSP-2010-049). All data were analysed anonymously. The whole procedure on obtaining, storing, and utilising patients' information by the National Clinical Smoking Cessation Database Secretariat was approved by the Danish Data Protection Agency (J.-Nr. 2010-41-5463).

Results

Statistics on comparability of groups

Comparison of the different patient groups in terms of follow-up (base case and non-respondents) showed that the groups were similar for patient and program related characteristics, and for the two datasets (Table 1).

Quitting outcomes data

Table 2 shows quit rates at 6-months follow up in relation to different levels of compliance for the base case, and non-respondents (worst and best cases).

Main Results

Table 3 shows the main results along with results of the sensitivity analyses. Table 4 shows predictors of the relationship between compliance and quit rates on the two study objectives and for the two datasets.

Primary objective

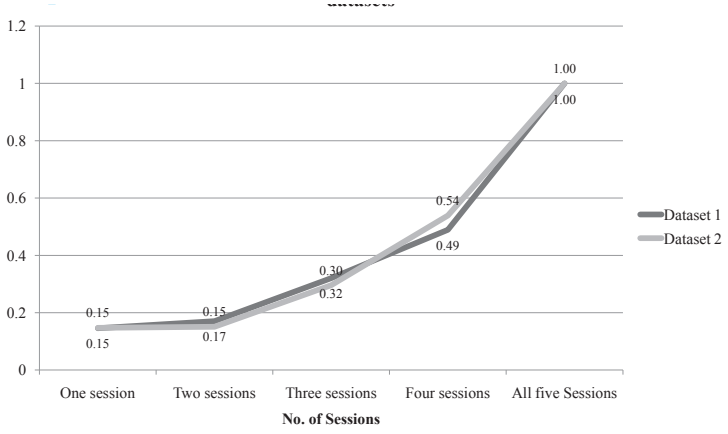
Considering the base case scenario in both datasets 1 and 2, patients who completed at least 75% of the pre-planned sessions (attended four or five sessions) had almost triple the quit rates in comparison to patients who attended less than 75% of pre-planned sessions (OR = 0.31; 95% CI 0.27 - 0.35, and 0.27 ; 0.24 - 0.31, for the first and second datasets) (See Table 3).

Secondary objective

Considering the base case scenario in both datasets 1 and 2, patients who attended one, two, three, or four sessions had a lower probability of quitting compared to patients who completed the whole program. For instance, patients who completed only 75% of the program (four sessions) had a lower probability of quitting (almost half) compared to patients who completed 100% of the program by attending all the five sessions (0.49; 0.43 - 0.56, and 0.54; 0.47 - 0.62, for the first and second datasets) (Table 3).

These results indicated an association between higher compliance levels and higher quit rates (Figure 2).

Figure 2 Adjusted ORs estimates on the secondary objective for both datasets*



*Reference group: patients who completed the whole programme (OR= 1)

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Table 1 Population cohort main characteristics in the two datasets, given in numbers (%) or median (range)

Dataset	Dataset 1 (N = 8,737)		Dataset 2 (N = 8,702)	
Patient group	**Base Case**	**Non-respondents**	**Base Case**	**Non-respondents**
Count	6985	1752	6939	1763
Percent of the total count %	58.6	14.7	58.5	14.8
Characteristics				
Unit Type %				
Pharmacy	24.9	23.2	24.7	25.4
Hospital Clinic incl. Midwives	10.8	10.4	10.9	9.8
Municipality and other practices	59.3	63.7	59.0	61.5
County coordinator	5.0	2.7	5.4	3.3
Year %				
2006	23.9	20.0	23.7	21.2
2007	28.1	28.5	27.8	27.0
2008	24.1	26.7	24.6	26.3
2009	24.0	24.8	23.9	25.6
Intervention type %				
Individual	8.0	8.2	8.1	9.9
Group and other interventions	92.0	91.8	91.9	90.1
Relapse Prevention %				
No	51.1	57.7	51.3	60.1
Yes	48.9	42.3	48.7	39.9
Nicotine Replacement %				
No	51.3	46.5	51.8	49.1
Yes	48.7	53.5	48.2	50.9
Age %				
Less than 35	14.2	21.4	13.6	22.1
From 35 to 54	43.7	44.2	45.1	44.8
More than 55	37.8	29.9	36.6	29.8
Missing Data	4.3	4.6	4.6	3.3
Gender %				
Women	61.7	60.9	62.3	61.7
Men	38.3	39.1	37.7	38.3
Fagerström Score %				
From 0 to 4	38.4	38.0	37.6	35.0
From 5 to 10	61.6	62.0	62.4	65.0
Living with smoker %				
No	64.8	67.6	64.7	64.8
Yes	34.5	31.5	34.6	34.7
Missing	.7	.9	.7	.5
Living with adult %				
No	43.2	48.0	44.4	47.2
Yes	55.7	50.8	54.6	51.8
Missing Data	1.1	1.2	1.0	1.0

Table 1 continues on the following page.

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Living with child %				
No	66.5	69.1	66.9	66.8
Yes	32.3	29.6	32.1	32.3
Missing Data	1.2	1.4		1.0
Previous quitting attempts %				
Non	38.9	40.5	39.2	39.1
1-3 times	49.4	48.1	49.9	49.1
more than 3 times	9.9	9.0	9.2	9.0
Missing Data	1.8	2.3	1.6	2.8
Employment status %				
with job	63.2	63.0	63.1	60.6
without job	34.6	34.0	34.4	36.6
Missing Data	2.2	3.1	2.5	2.8
Education %				
lower education = less than 11 years	59.8	58.4	60.2	63.0
higher and other education	37.2	38.0	36.7	33.5
Missing Data	3.0	3.6	3.1	3.6
Housing Type %				
Residential property+ other housing	51.9	42.5	52.2	39.0
Co-operative dwelling	9.0	11.4	8.9	10.4
Rented accommodation	37.3	44.5	37.3	48.4
Missing Data	1.7	1.6	1.6	2.2
Smoking (years)	32 (0-74)	29 (0-66)	32 (0-99)	30 (0-67)
Compliance/attendance (meetings)	4 (1-5)	3 (1-5)	4 (1-5)	3 (1-5)

Table 2 Quit rates in the two datasets

	Dataset 1			Dataset 2		
Total count	**Base Case**	**Worst Case**	**Best Case**	**Base Case**	**Worst Case**	**Best Case**
	n = 9,251	n = 11,003	n = 12,755	n = 9,157	n = 10,920	n = 12,683
Quitters	2266	2266	4018	2218	2218	3981
Percentage %	32.4	25.9	46.0	32.0	25.5	45.7
Compliance /Attendance						
1 Session	0.8	0.6	4.1	0.8	0.6	4.1
2 sessions	1.5	1.2	4.3	1.4	1.1	4.4
3 sessions	3.7	2.9	6.7	3.4	2.7	6.4
4 sessions	7.9	6.3	10.8	8.2	6.5	10.9
5 sessions	18.5	14.8	20.1	18.2	14.5	19.9
Less than 75%	6.0	4.8	15.1	5.6	4.5	14.9
At least 75%	26.5	21.2	30.9	26.3	21.0	30.9

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Table 3 Main results along with the two sensitivity analyses; evaluating whether smokers completing at least 75% of the smoking cessation intervention had higher quit rates after 6 months than smokers participating in less than 75% of the program; and investigating whether there might be a more appropriate compliance level than the 75% compliance level (Please, observe that all results were significant). The value 1 was the reference.

	Dataset 1			Dataset 2		
Scenario	**Base Case**	**Worst Case**	**Best Case**	**Base Case**	**Worst Case**	**Best Case**
	OR (95% CI)	**OR (95% CI)**	**OR (95% CI)**	**OR (95% CI)**	**OR (95% CI)**	**OR (95% CI)**
> 75% Attendance	1	1	1	1	1	1
< 75% Attendance	0.31 (0.27-0.35)	0.29 (0.25-0.33)	0.64 (0.58-0.71)	0.27 (0.24-0.31)	0.27 (0.24-0.31)	0.57 (0.52-0.63)
All 5 sessions	1	1	1	1	1	1
4 sessions	0.49 (0.43-0.56)	0.49 (0.43-0.56)	0.61 (0.54-0.69)	0.54 (0.47-0.62)	0.54 (0.48-0.62)	0.66 (0.58-0.74)
3 sessions	0.32 (0.27-0.38)	0.32 (0.27-0.37)	0.52 (0.45-0.59)	0.30 (0.25-0.35)	0.31 (0.26-0.37)	0.46 (0.40-0.53)
2 sessions	0.17 (0.14-0.22)	0.17 (0.13-0.21)	0.43 (0.37-0.50)	0.15 (0.12-0.19)	0.15 (0.12-0.19)	0.42 (0.36-0.49)
1 session	0.15 (0.11-0.20)	0.11 (0.08-0.16)	0.69 (0.58-0.83)	0.15 (0.11-0.20)	0.12 (0.09-0.17)	0.64 (0.54-0.76)

Table 4 Predictors on the association between attendance and quitting rates for smokers completing at least 75% of the smoking cessation intervention and for smokers attending all sessions. The value 1 was the reference.

	Attendance and quitting rates for smokers completing at least 75% of the smoking cessation intervention				Smokers attending all sessions			
	Dataset 1		Dataset 2		Dataset 1		Dataset 2	
	Sign	OR 95% CI	Sign	OR 95% CI	OR 95% CI	Sign	OR 95% CI	
Unit Type								
County coordinator	-	1	-	1		1		1
Pharmacy	0,090	1.27 (0.93-1.73)	0.034	1.39 (1.03-1.89)	0,104	1.26 (0.92-1.72)	0.049	1.36 (1.00-1.85)
Hospital Clinic incl. Midwives	0,079	1.31 (0.94-1.84)	0.009	1.57 (1.12-2.20)	0.087	1.35 (0.96-1.90)	0.006	1.61 (1.14-2.26)
Municipality and other practices	0,120	1.23 (0.91-1.67)	0.006	1.52 (1.13-2.05)	0,110	1.25 (0.92-1.69)	0.012	1.47 (1.09-1.99)
Year								
2009	-	1	-	1	-	1	-	1
2006	0.016	0.80 (0.67-0.96)	0,635	1.01 (0.84-1.22)	0.017	0.80 (0.66-0.96)	0,685	1.00 (0.83-1.20)
2007	0.070	0.87 (0.74-1.01)	0,097	0.89 (0.76-1.04)	0.085	0.87 (0.74-1.02)	0.092	0.87 (0.74-1.02)
2008	0.000	0.71 (0.61-0.84)	0.063	0.86 (0.73-)1.01	0.000	0.72 (0.61-0.85)	0.059	0.85 (0.72-1.01)
Intervention type								
Group and others	-	1	-	1	-	1	-	1
Individual	0.017	1.29 (1.05-1.60)	0,094	1.18 (0.95-1.46)	0,0875	1.18 (0.95-1.47)	0,285	1.10 (0.88-1.36)
Relapse Prevention								
Yes		1		1	-	1	-	1
No	0.070	0.90 (0.79-1.01)	0.072	0.89 (0.79-1.01)	0,089	0.91 (0.81-1.03)	0,0909	0.91 (0.81-1.03)
Nicotine Replacement								
Yes	-	1	-	1	-	1	-	1
No	0,321	0.95 (0.84-1.09)	0,658	1.00 (0.88-1.15)	0,282	0.95 (0.83-1.08)	0,6139	1.01 (0.88-1.15)
Age								
> 55 years	-	1	-	1	-	1	-	1
35 - 54	0.025	0.82 (0.69-0.98)	0,069	0.86 (0.72-1.03)	0.011	0.71 (0.55-0.92)	0.064	0.77 (0.59-1.02)
< 35	0.004	0.68 (0.53-0.88)	0.036	0.75 (0.57-0.98)	0.045	0.84 (0.70-1.00)	0,143	0.89 (0.75-1.06)

Table 4 continues on the following page.

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Gender								
Men	-	1	-	1	-	1	-	1
Women	0.000	0.76 (0.68-0.86)	0.000	0.81 (0.72-0.91)	0.000	0.78 (0.69-0.88)	0.000	0.81 (0.71-0.91)
Fagerström Score								
High (5-10 points)	-	1	-	1	-	1	-	1
Low (0-4 points)	0.000	1.38 (1.23-1.55)	0.000	1.49 (1.32-1.67)	0.000	1.38 (1.23-1.55)	0.000	1.49 (1.32-1.68)
Smoking Years	0.000	0.99 (0.98-0.99)	0.003	0.99 (0.98-1.00)	0.000	0.99 (0.98-0.99)	0.002	0.99 (0.98-1.00)
Living with smoker								
Yes	-	1	-	1	-	1	-	1
No	0.006	1.19 (1.05-1.36)	0,123	1.09 (0.96-1.24)	0.010	1.18 (1.04-1.35)	0,101	1.10 (0.97-1.25)
Living with adult								
Yes	-	1	-	1	-	1	-	1
No	0.052	0.88 (0.78-1.00)	0.043	0.88 (0.77-1.00)	0.094	0.90 (0.79-1.02)	0.041	0.87 (0.77-0.99)
Living with child								
Yes		1		1	-	1	-	1
No	0,430	1.04 (0.90-1.19)	0,312	0.95 (0.82-1.09)	0,547	1.02 (0.88-1.18)	0,272	0.94 (0.81-1.08)
Previous attempts to stop smoking								
More than 3 times	-	1	-	1	-	1	-	1
Non	0,140	0.88 (0.72-1.07)	0,693	1.00 (0.82-1.23)	0,138	0.88 (0.72-1.07)	0,659	0.99 (0.81-1.22)
1-3 times	0.031	0.81 (0.67-0.98)	0,383	0.94 (0.77-1.15)	0.029	0.81 (0.67-0.98)	0,351	0.93 (0.77-1.14)
Employment status								
Non-Employed	-	1	-					
Employed	0.039	01.16 (1.01-1.34)	0,331	01.05 (0.91-1.22)	0.050	1.15 (1.00-1.33)	0,264	1.07 (0.92-1.24)
Education								
Higher	-	1	-	1	-	1	-	1
Lower (< 11 years)	0.059	0.89 (0.79-1.00)	0.000	0.81 (0.72-0.91)	0.047	0.89 (0.79-1.00)	0.000	0.80 (0.71-0.90)
Housing Type								
Rented accommodation	-	1	-	1	-	1	-	1
Residential property and others	0.000	1.28 (1.12-1.45)	0.000	1.36 (1.19-1.55)	0.000	1.28 (1.13-1.46)	0.000	1.34 (1.18-1.53)
Co-operative dwelling	0,249	1.10 (0.89-1.36)	0,584	1.02 (0.82-1.28)	0,268	1.10 (0.89-1.36)	0,511	1.04 (0.83-1.30)

Sensitivity analyses

Primary objective: In both datasets 1 and 2, the best and worst-case scenarios showed similar results to the base case scenario. Results showed that attending less than 75% of the pre-planned sessions was associated with a lower probability of quitting compared with attending at least 75% (at least four) sessions (Table 3).

Secondary objective: In both datasets 1 and 2, the worst-case scenario had similar results to the base-case scenario results. The best-case was quite different on the first session. Nevertheless, the results from the best-case scenario were reflecting the same findings as the base-case and worst-case scenarios; attending less than five sessions (from one to four sessions) was associated with a lower probability of quitting compared with attending all the pre-planned five sessions (Table 3).

Discussion

We found that the results supported the principle of defining completion of the smoking cessation intervention as completion of at least 75% of sessions, while completing the whole intervention (all sessions) was associated with even better outcomes. The obtained results were robust to sensitivity analyses. The total quit rate was 32% (base-case scenario), originating from 26% of those with at least 75% compliance and 6% from those attending less than 75% of the meetings.

Considering our base-case scenario for both datasets, the observed quit rates were relatively comparable to results reported in similar studies conducted in Canada and the USA (32% quit rate for 8 sessions program, and 21% for 4-8 sessions' programs, respectively) (14-

16). The 'dose-response relation' shown in figure 2 between higher completion of the programme and better quit-rate could be a direct consequence of that those, who spent more time on smoking cessation intervention received a higher dosage of effective intervention and thereby got a better outcome. Another part of the explanation on the 'dose-response relation' could be that participants, who continued to smoke or relapsed after a short quitting would to a higher degree stay away from the following sessions, while only the quitters would take part of the programme. This study can not give the answer, and further studies on attitudes and experiences would be required.

We did not validate quit rates using the carbon monoxide "CO" test. However, in two studies from the UK and USA, the difference between self-reported and "CO" validated quit rates were minor (15;17-18). Moreover, evaluating UK NHS short and long term smoking quit rates showed that there was only a very minor increase in non-quit rates when including participants whose self-reported quitting was disproved by CO test (0.5% and 0.2% for short and long term quit rates, consecutively).(15;18) In a systematic review on the effectiveness of the UK NHS smoking cessation services reported cessation rates of around 60% for self-reporters and 53% for "CO" validated rates over four weeks (short term outcome), and around 17% for self-reporters and 15% for "CO" validated rates over one year (long term outcome)(11). It is worth noting that the study on long term (one year outcome) effectiveness of NHS smoking services included only self-reported quitters who quit in the short term (four weeks) (11), while our study included all patients' outcomes at six months, irrespective of short term outcomes. Indeed, the total quit rate (32%) in our study was high compared to previous literature (9), even when compared with the above studies from the UK where the long term follow up only included short term quitters (11).

In a US study on short-and long-term smoking cessation for different levels of intensity of behavioural treatment, biochemically confirmed quit rates at 26 weeks follow-up were higher for the high intensity program compared with less intense interventions (12). In a large systematic review concerning setting guidelines on "Treating Tobacco Use and Dependence in the USA", it was concluded from included meta-analyses that provision of at least four sessions enhances quit rates compared with provision of fewer sessions (9). Another study from the USA found that comprehensive prolonged smoking treatment programs that combine medications and psychological approaches are able to produce higher quit rates than those reported in the literature (4). Indeed, the significant increase in quit rates associated with different degrees of program completeness in our study could partly be explained by the structure of the GSP itself. It is manual-based and includes most of the prognostic factors that influence the success of quitting attempts, such as qualified counselling, nicotine replacement therapy, and relaps prevention strategies. Hence, the longer a participant remains in the GSP, the more prognostic factors are addressed. Another possible explanation for the association is that some of the patients who did not quit may have stopped participating in the GSP before those who managed to quit. On the other hand, some of the early quitters may not feel they need to complete the treatment program. A further strength of the study is that all relevant aspects of the GSP were standardised across all smoking cessation treatment centres.

It is worth considering that this study is a large nationwide population study and thereby results can be generalised to the country as a whole. However, our results should be interpreted with caution when generalising the results to other countries with different smokers, settings, and intervention programs. It is also worth noting that this is not a randomised controlled trial. Other strengths are that the study includes both genders, all age groups, wide geographic coverage, smokers from different socio-economic groups, cover long-term follow-up period (6 months), and data was prospectively collected.

Regarding the study design, predictive models were developed on data simulated from the population included in the database. The utilisation of a validation cohort "dataset 2" was helpful to avoid relying on what could be optimistic or underestimated OR estimates from "dataset 1" on the association between compliance levels and quit rates. Yet, statistical modelling used for data analysis represents a simplified illustration of reality; consequently, many unforeseen variables that represent predictors and confounders related to the quit rates, could exist and not be included in the model (13). Thus, there is still a possibility that this study finding could be either overestimating or underestimating the real results. Nevertheless, the LR models have been validated (goodness of fit) by using the second dataset "dataset 2" which showed similar results to the first dataset "dataset 1"(13).

Concerning the clinical population cohort, this study used only data from a four-year period, as data on compliance/attendance was not routinely collected prior to

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this. Missing data on quitting outcomes was considered in the data analysis strategy according to the reason for the missing data. Another group of patients without planned follow-up due to lack of resources by the smoking cessation unit was not evaluated. The fact that some patients were not routinely followed up represents a potential weakness in the study. However, the results on the two tested objectives from the two sensitivity analyses showed similar findings to the base case scenario. Moreover, patient data on different predictors for quitting has been collected and recorded for almost all included patients, which represents strength. In future studies, the generalisability of study findings may be enhanced by research cooperation with similar programs that have similar interventions and databases in other countries.

Implications

From a clinical perspective, it is important to reinforce the advice to adhere to at least 75% of the pre-planned sessions. However, to maximize the benefit from attending this program, patients should be encouraged to attend the whole program. Crucially, in terms of achieving the highest quit rates, there is a need for changes in tobacco control strategies implied by healthcare personnel and policy makers, where more attention should be given to maintain patients in smoking treatment programs instead of only recruiting them into such programs. Smoking cessation units that have chosen not to follow up on their patients should be supported in increasing their follow-up to improve the quality of further studies. The high participation rate in data collection by smoking cessation counsellors from a wide range of diverse units in Denmark enhances the generalisability of the results, and the ownership of this research study, which may encourage uptake of the results into practice.

From a research point of view further qualitative and quantitative research is needed to investigate predictors on different compliance levels and what triggers higher and lower compliance by patients who are participating in the GSP. Additionally, missing data on quit rates could be addressed through a separate study, specifically analysing missing quitting outcomes (14). It is also important to evaluate different contextual factors and social phenomena involved with the GSP. Integrating such quantitative and qualitative research findings could contribute to the amount of available evidence on compliance as a key predictor of smoking cessation. In addition, such research may be used to identify possible mechanisms to establish a long-term relationship with patients to reinforce important messages concerning smoking cessation and sustained quitting (15).

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