



Come & Quit: A new flexible, Intensive Smoking Cessation Intervention Programme

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Abstract

Aim Smoking cessation is a major challenge for many smokers, and it is necessary to develop and evaluate new programmes. The aim was to compare the effectiveness of 'Come & Quit', a flexible, intensive smoking cessation intervention (SCI) with the Danish gold standard programme (GSP). Second, we aimed to identify whether gender was important among disadvantaged and heavy smokers.

Methods This was a prospective cohort study based on the Danish National Smoking Cessation Database. From 2011-2016, we included 24,930 smokers from smoking cessation units throughout Denmark; 5,750 received 'Come & Quit', and 19,180 received the GSP.

Results A total of 16,348 respondents were included in the outcome analyses on continuous abstinence after six months. Thirty-five percent remained successful quitters. Under the Russell criterion, the crude quit rate was 23.0%. The most important predictor was compliance. Overall, men had 3.0-3.1% higher quit rates than women for both programmes. The fully adjusted model confirmed the significantly higher success among men (OR=1.15, 95% CI: 1.07-1.23). Two multivariable logistic regression analyses for men and women showed no statistically significant differences between 'Come & Quit' and the GSP for men (OR=1.06, 0.92-1.23) or women (OR=0.94, 0.82-1.08). Across gender, compliance with the programmes was the most important predictor of successful quitting. Minor predictors were calendar year, lack of social disadvantage and heavy smoking.

Conclusion The effectiveness of the intensive interventions compared in this study was similar across genders. However, overall, men had a significantly higher quit rate than women.

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Introduction

Smoking is a major risk factor for the global disease burden. Approximately 80% of all smoking takes place in low- and middle-income countries, but smoking is still the leading risk factor in high-income countries. Worldwide, smoking killed 7.10 million persons in 2017 and was responsible for 182 million disability-adjusted life years (DALYs), understood as the number of years of healthy life lost (1).

Smoking cessation is on the agenda worldwide, and many actions are taken to reduce the smoking rate at national and local levels, aiming at preventing new smokers from starting and supporting smokers to quit – as recommended by

the Framework Convention of Tobacco Control from the World Health Organization (2). Nevertheless, successfully quitting is still a major challenge for many smokers. Therefore, it is necessary to develop and evaluate new programmes to ensure success in quitting. Today, intensive smoking cessation intervention (SCI) programmes are recommended for vulnerable groups and hospital patients or is simply the standard programme for the general public (3).

Intensive SCI is defined by having at least four structured face-to-face meetings lasting more than 10 minutes per session and including elements of patient education (4). It is recommended but not mandatory to include pharmaceutical support



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(4). Many programmes contain a patient education part, relapse prevention and follow-up, which is also the case for the national gold standard programme (GSP) in Denmark (5-8) (table 1). We have previously shown that women and smokers with high or medium-high levels of were overrepresented in the Danish SCI (9).

Some groups of smokers may not have the opportunity to take part in a programme with a fixed time schedule such as the GSP but could benefit from a more flexible intervention allowing participation when it fits into the smokers' life conditions in combination with adjusted content and increased support between meetings. The intention was also to attract groups of smokers other than those using the GSP to participate in SCI, especially men and smokers with little or no education. Thus, a more flexible but still intensive SCI called 'Come & Quit' was developed (10) (table 1).

The aim of this study was to compare the effectiveness of the new flexible 'Come & Quit' programme and the GSP in Denmark, measured as successful quitting after 6 months. Second, we wanted to investigate whether gender influenced the outcome among disadvantaged or heavy smokers among the users of the two programmes.

Methods

Participants

A total of 24,930 smokers participated in this study: 5,750 received 'Come & Quit', and 19,180 received the GSP. They originated from 136 SCI units throughout Denmark offering intensive face-to-face SCI in the period from January 2011 to December 2016, with a 6-month follow up through May 2017.

The inclusion criterion was being a smoker with completed or attempted follow-up after 6 months in the study period (n=33,487). The exclusion criteria were

being smokers who did not want to be followed up (n=763), those below 15 years of age (n=39) and those not receiving the GSP or Come & Quit (n=7,755).

Data collection

The SCI units reported their activities in the national Danish Smoking Cessation Database. The database was established in 2001 with the purpose of monitoring, evaluating and improving the quality of face-to-face SCI in Denmark. To date, more than 130,000 smokers undertaking an SCI have been registered in the database after providing informed consent. The Smoking Cessation Database has been described in detail elsewhere (8).

The data reported in the SCDB used in this study included an individual smoking history and socio-demographic profile of each smoker as well as a description of the programme delivered and the smoking status at the 6-month follow-up (see table 2) (8).

Education was categorized into three levels: no education or short courses, less than three years of education, and three or more years of education. Compliance was measured as meeting attendance, and a smoker was defined as being compliant with the programme when participating in at least 75% of the planned sessions in the GSP (11) and at least four sessions in the 'Come & Quit' programme (8). Disadvantaged smokers were defined as having no education or short courses only and/or as having no employment (12). Heavy smokers were defined by at least one of the following characteristics: ≥ 20 pack years, ≥ 20 gram of tobacco per day and/or ≥ 7 points for the Fagerström score of nicotine dependency (13).

Interventions

The Gold Standard Program (GSP) (5-8) has been recommended as the standard intervention in Denmark since 1995 (14), and it includes 5 sessions over

Table 1. Characteristics of the two intensive programmes for smoking cessation intervention

	'Come & Quit'	Gold Standard Programme
Meetings (number)	Up to 8 ^A	5
Fixed order of meetings	No	Yes
Groups or individual sessions	Groups only	Groups or individuals
Duration per meeting (minutes)	90 ^A	120 for groups; 20 for individuals ^B
Pharmaceutical support recommended	Yes	Yes
Patient education in each session	Yes	Yes

^A In addition to an individual introduction meeting of 60 min

^B Longer first meeting of 40 minutes for the individual sessions



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six weeks. A few participants attended extra meetings. The programme was manual based and was based on motivational counselling, individualised pharmaceutical support and structured patient education to increase the individual health literacy regarding smoking cessation and strategies for handling situations with relapse risk. Homework between sessions supported smoking cessation. The large majority of the GSP took place in groups, but an individual GSP was also possible (details in table 1). The Smoking Cessation Database began registration for the GSP in 2001 when the database was established (8).

'Come & Quit' (8;10) was developed later, aiming to be a more flexible programme to attract more smokers with little or no education and more male smokers. All

smokers began with an individual counselling session. Despite the intensive intervention structure and pharmacological support, the programme was very flexible and took place in running groups where each smoker had the opportunity to jump in and out of eight different manual-based sessions on eight themes. This intervention aimed to increase the support between meetings by offering text messages, e-mails or phone calls. In addition, the quit date was made flexible to adapt to the individual needs of the participants, and the educational material that was developed contained only small amounts of text. Furthermore, each meeting was shortened (1.5 hours compared to 2 hours in the GSP). The Smoking Cessation Database began registration for 'Come & Quit' in 2011.

Table 2. Characteristics of the 24,930 included smokers categorized according to their SCI programme

	GSP n (%)	Come & Quit n (%)	Total n (%)
Total ^a	19,180 (100)	5,750 (100)	24,930 (100)
Year of onset of intervention			
2011	3,241 (16.9)	270 (4.7)	3,511 (14.1)
2012	2,925 (15.3)	887 (15.4)	3,812 (15.3)
2013	2,192 (11.4)	898 (15.6)	3,090 (12.4)
2014	2,230 (11.6)	1,022 (17.8)	3,252 (13.0)
2015	4,269 (22.3)	1,458 (25.4)	5,727 (23.0)
2016	4,323 (22.5)	1,215 (21.1)	5,538 (22.2)
Participants			
Sex			
Men	8,232 (42.9)	2,407 (41.9)	10,639 (42.7)
Women	10,948 (57.1)	3,343 (58.1)	14,291 (57.3)
Age (years)			
15–24 years of age	1,018 (5.4)	275 (4.8)	1,293 (5.2)
25–34 years of age	1,957 (10.2)	462 (8.0)	2,419 (9.7)
35–44 years of age	3,124 (16.3)	812 (14.1)	3,936 (15.8)
45–54 years of age	4,793 (25.0)	1,490 (25.9)	6,283 (25.2)
55+ years of age	8,287 (43.2)	2,711 (47.2)	10,998 (44.1)
Education			
No education	5,730 (29.9)	1,717 (29.9)	7,447 (29.9)
Less education	3,921 (20.4)	1,228 (21.4)	5,149 (20.7)
More education	8,775 (45.7)	2,676 (46.5)	11,451 (45.9)
Employment			
No employment	4,935 (25.7)	1,838 (32.0)	6,773 (27.2)
Employment	8,551 (44.6)	2,171 (37.8)	10,722 (43.0)
Retired (due to age)	4,049 (21.1)	1,379 (24.0)	5,428 (21.8)
Students	1,075 (5.6)	272 (4.7)	1,347 (5.4)
Disadvantaged smokers			
Not disadvantaged	9,480 (49.4)	2,702 (47.0)	12,182 (48.8)
Disadvantaged	9,001 (46.9)	2,935 (51.0)	11,936 (47.9)
Smoking			
<20 pack years	6,025 (31.4)	1,644 (28.6)	7,669 (30.8)
≥20 pack years	13,155 (68.6)	4,106 (71.4)	17,261 (69.3)
Fagerström 1–6 points	13,556 (70.7)	3,982 (69.3)	17,538 (70.4)
Fagerström 7–10 points	5,624 (29.3)	1,768 (30.8)	7,392 (29.7)
<20 grams of tobacco/day	8,115 (42.3)	2,419 (42.1)	10,534 (42.3)
≥20 grams of tobacco/day	11,065 (57.7)	3,331 (57.9)	14,396 (57.8)



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	GSP n (%)	Come & Quit n (%)	Total n (%)
Heavy smokers			
Not heavy smokers	4,075 (21.3)	1,070 (18.6)	5,145 (20.6)
Heavy smokers	15,072 (78.6)	4,672 (81.3)	19,744 (79.2)
Compliance			
Not compliant	7,094 (37.0)	1,943 (33.8)	9,037 (36.3)
Compliant	11,980 (62.5)	3,716 (64.6)	15,696 (63.0)
Living with smoker			
Not living with smoker	13,221 (68.9)	4,026 (70.0)	17,247 (69.2)
Living with smoker	5,749 (30.0)	1,679 (29.2)	7,428 (29.8)
Living alone or with others			
Living alone	7,327 (38.2)	2,357 (41.0)	9,684 (38.8)
Living with children (+/- adults)	5,001 (26.1)	1,300 (22.6)	6,301 (25.3)
Living with adults (no children)	6,655 (34.7)	2,047 (35.6)	8,702 (34.9)
Housing situation			
Residential property	7,464 (38.9)	2,236 (38.9)	9,700 (38.9)
Cooperative dwelling	1,699 (8.9)	335 (5.8)	2,034 (8.2)
Rented accommodation	9,251 (48.2)	2,976 (51.8)	12,227 (49.1)
Other housing	337 (1.8)	100 (1.7)	437 (1.8)
Referral			
No referral	6,077 (31.7)	1,698 (29.5)	7,775 (31.2)
Yes, from healthcare staff	12,329 (64.3)	3,891 (67.7)	16,220 (65.1)
Earliest quit attempts			
None	6,990 (36.4)	2,139 (37.2)	9,129 (36.6)
1–3 attempts	9,615 (50.1)	2,938 (51.1)	12,553 (50.4)
> 3 attempts	2,141 (11.2)	594 (10.3)	2,735 (11.0)
Smoking cessation clinics			
Setting			
Municipal	17,177 (89.6)	5,619 (97.7)	22,796 (91.4)
Other setting	2,003 (10.4)	131 (2.3)	2,134 (8.6)
Geographic area			
Capital Region of Denmark	7,074 (36.9)	1,109 (19.3)	8,183 (32.8)
Region Zealand	2,749 (14.3)	254 (4.4)	3,003 (12.1)
Region of Southern Denmark	4,195 (21.9)	1,211 (21.1)	5,406 (21.7)
Central Denmark Region	4,159 (21.7)	2,004 (34.9)	6,163 (24.7)
North Denmark Region	1,003 (5.2)	1,172 (20.4)	2,175 (8.7)
Smoking cessation intervention			
Programme format			
Individual	5,591 (29.2)	0	5,591 (22.4)
Group	13,589 (70.9)	5,670 (98.6)	19,259 (77.3)
Target audience			
Patients and relations	546 (2.9)	85 (1.5)	631 (2.5)
Employees (workplace courses)	2,064 (10.8)	338 (5.9)	2,402 (9.6)
Ordinary citizens	14,610 (76.2)	4,634 (80.6)	19,244 (77.2)
Mixed	693 (3.6)	257 (4.5)	950 (3.8)
Pregnant women (and partners)	148 (0.8)	16 (0.3)	164 (0.7)
Other	1,119 (5.8)	420 (7.3)	1,539 (6.2)
Medication offered for free			
No free medication	9,725 (50.7)	3,311 (57.6)	13,036 (52.3)
Free medication	9,146 (47.7)	2,365 (41.1)	11,511 (46.2)
Unknown	309 (1.6)	74 (1.3)	383 (1.5)
Counselling free of charge			
No	30 (0.2)	0	30 (0.1)
Yes	18,894 (98.5)	5,698 (99.1)	24,592 (98.6)
Planned relapse prevention			
No	11,696 (61.0)	3,266 (56.8)	14,962 (60.0)
Yes	7,484 (39.0)	2,484 (43.2)	9,968 (40.0)

^a The categories did not sum to the total number of participants (or 100%) for all variables. This is due to missing values, which are not shown in the table



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Statistics

The two programmes were compared by means of chi2 tests regarding participant characteristics. The quit rates were compared using a mixed-effect regression model by adjusting for selected predictors and hierarchical clustering. The final model was fitted based on initial logistic regressions adjusting for sex and age and based on established knowledge. These results were described as odds ratios (ORs) with 95% confidence intervals (CIs). The details of the analyses have been described previously (9). A result was considered statistically significant if the p-value was ≤ 0.05 .

Results

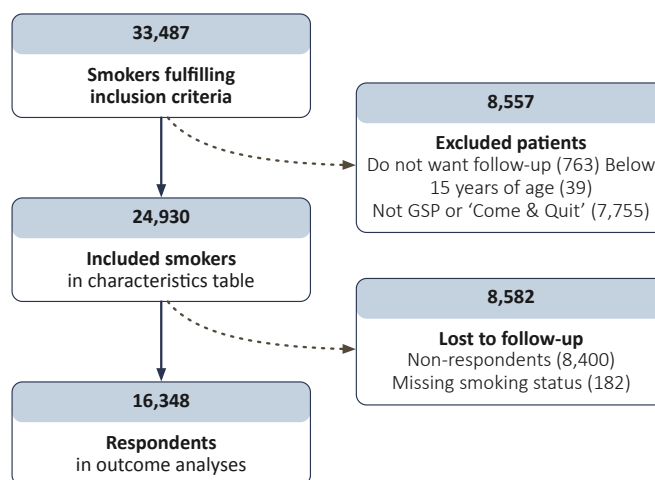
The characteristics of all 24,930 included smokers are presented in table 2. The large majority of smokers participated in the GSP (19,180; 76.9%), whereas 5,750 (23.1%) undertook the 'Come & Quit' programme.

Most of the participants in the GSP completed 4 and 5 meetings (corresponding to a meeting adherence above 75%) and experienced high quit-rates. The 'Come & Quit' was characterised by a more spread out meeting adherence. This group showed an increasing quit-rate closely related to number of meetings (figure 2 + 3).

The successful follow-up rate was 66% (trial profile in figure 1). The proportion of smokers not wanting the follow-up was slightly higher in the 'Come & Quit' programme than in the GSP (2.8% versus 2.4%, respectively, $p = 0.04$). There was no difference regarding the other exclusion criteria.

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Figure 1. Trial profile



adherence. This group showed an increasing quit rate closely related to the number of meetings attended (figure 2 and 3).

Successful quitting rates are presented in table 3 as crude rates according to the programme, sex, level of education and calendar year at the onset of the intervention. Overall, 35.0% (5,752) of the 16,348 respondents included in the outcome analyses reported continuously being successful in smoking cessation after six months. When considering the 8,400 non-respondents as smokers, the crude quit rate was 23.0% (table 3). Men had a higher quit rate than women for both programmes: 3.0% and 3.1% higher in the base case for 'Come & Quit' and the GSP, respectively. The fully adjusted model confirmed a significantly higher quit rate among men (OR=1.15, 95% CI: 1.07-1.23; $p < 0.001$).

Furthermore, from the gender perspective for 'Come & Quit' and GSP, the two separate multivariable logistic regression analyses for men and women, respectively,

Figure 2. Participants in terms of the number of meetings in the GSP (5 planned meetings) and 'Come & Quit' (8 sessions allowing flexible order and number)

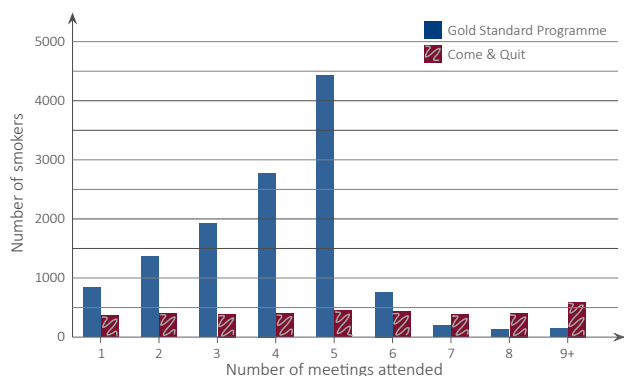
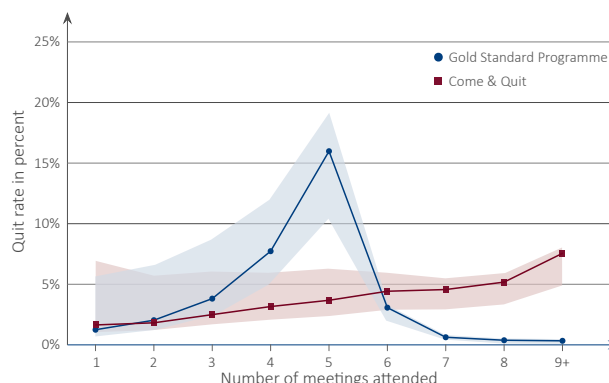


Figure 3. Successful quit rates after 6 months for each number of meetings





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Table 3. Proportion of continuously successful quitters. Crude quit rates according to smoking cessation intervention. The worst case assumed non-respondents to having relapsed

	Base case (RECORD criteria (14))		Worst case (RUSSEL criteria (15))	
	All		All	
	n	(%)	n	(%)
Come & Quit	3,787	34.7	5,750	22.9
Sex				
Men	1,620	36.4	2,407	24.5
Women	2,167	33.4	3,343	21.8
Education				
No education	1,067	30.5	1,717	19.0
Less education	826	32.0	1,228	21.6
More education	1,810	38.3	2,676	26.0
Year of onset of intervention				
2011	191	29.8	270	21.1
2012	597	31.7	887	21.3
2013	592	30.1	898	19.9
2014	661	33.3	1,022	21.5
2015	966	39.0	1,458	25.9
2016	780	37.4	1,215	24.3
GSP (standard intervention)	12,561	35.3	19,180	23.2
Sex				
Men	5,548	37.1	8,232	25.0
Women	7,013	34.0	10,948	21.8
Education				
No education	3,598	33.6	5,730	21.2
Less education	2,582	34.3	3,921	22.6
More education	5,908	36.9	8,775	24.8
Year of onset of intervention				
2011	2,368	31.6	3,241	23.1
2012	1,976	34.5	2,925	23.3
2013	1,444	34.1	2,192	22.4
2014	1,461	35.0	2,230	23.0
2015	2,655	36.0	4,269	22.4
2016	2,657	39.5	4,323	24.3

showed no statistically significant differences between the programmes, either for men (OR=1.06, 0.92-1.23) or for women (OR=0.94, 0.82-1.08); see table 4. For both men and women, being compliant with the programme was the most important predictor of successful quitting. Other minor predictors across genders were calendar year, lack of social disadvantage or heavy smoking (table 4).

Analysis of non-responders

The analysis of non-respondents compared with respondents showed no differences regarding SCI programme, amount of tobacco per day or format (group or individual counselling). All other factors, including age, employment, social disadvantage, pack year and living condition, differed up to 5 percentage points, except for compliance with the programme, which differed by 14.5 percentage points.

Overall, the non-respondents tended to be individuals from a more disadvantaged group.

Discussion

This study showed that both 'Come & Quit' and GSP were followed by similarly high quit rates of 35% after 6 months among those followed up or 23% if the third group not responding to follow-up were considered to be still smoking. Overall, men had a significantly higher quit rate than women. The most important predictor was the compliance measure of attendance.

Overall, the intensive SCI is more effective than shorter interventions (4) and represents the standard for SCIs in Denmark (5-8). The proportion of successful quitting found in this study is similar to that in previous studies on the effect of a GSP (11-13;17;18) but high compared to that in other studies of intensive SCIs



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Table 4. Predictors included in the two separate multivariable logistic regression analyses. Statistical significance is marked in **bold**

	Multivariable analysis ^a OR (95 % CI)	Multivariable analysis ^a OR (95 % CI)	Interaction with sex p
	Men n=7,168 (6,841 in the analysis)	Women n=9,180 (8,716 in the analysis)	
Intervention programme			
Standard intervention (GSP)	1	1	
Come & Quit	1.10 (0.94-1.23)	0.94 (0.83-1.08)	0.613
Year of onset of intervention			
2011	1	1	
2012	1.08 (0.89-1.31)	1.10 (0.93-1.30)	0.959
2013	1.10 (0.89-1.36)	1.11 (0.93-1.33)	0.805
2014	1.06 (0.86-1.31)	1.18 (0.98-1.40)	0.697
2015	1.10 (0.91-1.33)	1.27 (1.07-1.50)	0.877
2016	1.31 (1.09-1.59)	1.27 (1.07-1.50)	0.186
Participants			
Age (years)			
15–24 years of age	1	1	
25–34 years of age	1.13 (0.80-1.59)	1.44 (1.08-1.93)	0.346
35–44 years of age	1.16 (0.84-1.61)	1.26 (0.96-1.65)	0.893
45–54 years of age	1.24 (0.91-1.71)	1.30 (1.00-1.69)	0.909
55+ years of age	1.15 (0.84-1.57)	1.28 (0.99-1.66)	0.886
Disadvantaged smokers			
Not disadvantaged	1	1	
Disadvantaged	0.74 (0.67-0.83)	0.77 (0.70-0.84)	0.790
Heavy smokers			
Not heavy smokers	1	1	
Heavy smokers	0.78 (0.67-0.91)	0.71 (0.63-0.80)	0.183
Compliance			
Not compliant	1	1	
Compliant	2.82 (2.49-3.19)	2.60 (2.33-2.89)	0.203
Living with smoker			
Not living with smoker	1	1	
Living with smoker	0.85 (0.76-0.96)	0.91 (0.82-1.00)	0.475
Smoking cessation clinics			
Setting			
Municipal	1	1	
Other setting	1.04 (0.83-1.29)	1.06 (0.86-1.29)	0.969
Geographic area			
Capital Region of Denmark	1	1	
Region Zealand	1.19 (0.94-1.52)	1.45 (1.16-1.83)	0.142
Region of Southern Denmark	1.05 (0.85-1.31)	1.27 (1.03-1.58)	0.146
Central Denmark Region	0.88 (0.71-1.09)	1.05 (0.85-1.30)	0.202
North Denmark Region	1.16 (0.85-1.57)	1.36 (0.99-1.87)	0.477
Smoking cessation intervention			
Programme format			
Individual	1	1	
Group	0.74 (0.64-0.86)	0.92 (0.81-1.06)	0.215
Medication offered for free			
No free medication	1	1	
Free medication	1.11 (0.97-1.25)	1.02 (0.90-1.14)	0.041
Unknown	1.22 (0.79-1.89)	1.44 (1.00-2.08)	0.582
Hierarchical cluster			
	Variance (95% CI)	Variance (95% CI)	
Smoking cessation clinic			
	Variance of random intercepts	0.05 (0.02-0.11)	



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(19-24). The difference may be due to differences in the programme details but also to the settings, the smokers included and the use of validation as described below. It is important to evaluate new intensive interventions such as 'Come & Quit', as they are generally recommended for vulnerable and disadvantaged groups (3).

'Come & Quit' has involved considerations related to health literacy. On a practical and individual-oriented level, 'Come & Quit' heeds the call of international policies, such as the World Health Organization's (WHO) 2016 Shanghai Declaration, concerning the improvement of health literacy (25) of people – namely, the knowledge and skills needed to make healthy choices in life (26). Health literacy is defined as the skills, knowledge and confidence that determine the motivation and ability of individuals to gain access to, understand and use information in ways that promote and maintain good health, such as by quitting smoking (25;27). On the level of individual/groups, such health promotion actions that include elements of education, counselling, support and empowerment in terms of health literacy can contribute considerably to population health as valuable complimentary strategies to the more structural health promotion actions and strategies such as governance-level initiatives. Interestingly, this was not reflected in the results, as both programmes attracted similar groups of smokers.

From the clinical perspective, health care professionals need to become familiar with the new 'Come & Quit' programme to be able to offer it to smokers. From the smokers' perspective, it is beneficial to have more intensive programmes with a similarly large effect to choose between, as preferences may differ from one smoker to another. At the healthcare and societal level, the results support the recommendation for using an intensive SCI. An existing challenge to be addressed in further research is that even though 'Come & Quit' was developed to attract smokers with little or no education and male smokers, no difference was observed regarding these characteristics.

Bias and limitations

The increasing use of 'Come & Quit' over the study period could introduce a bias from a learning curve, where people show increasingly better outcomes over time. The follow-up interviews were performed by the Danish Quit-line but not validated otherwise by, e.g., CO or nicotine measurement. The lack of validation may have resulted in over-estimating the quit rate. Another bias originates from the one-third of individuals not responding to follow-up. They were considered to be still smoking, but the quit rate may differ between individuals in the two programmes and among the individual smokers. The non-respondent analysis is, however, a strength of this study. The study also has limitations, as the intervention tool was situated in a Danish context with a widespread cluster of SCI units all over the country, and the results may therefore not be transferable to other settings.

Conclusion

In conclusion, the two intensive interventions 'Come & Quit' and the Danish GSP were both effective with similar quit rates of 35%; however, in both programmes, men had a higher quit rate than women, though the difference was small. The most important predictor was the compliance measure of attendance.

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All authors participated in the development of the research project. Mette Rasmussen performed the analyses. All authors took part in the interpretation. Hanne Tønnesen wrote the manuscript. All authors edited and approved the final version.



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