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Are financial incentives more effective than health campaigns to quit smoking? A community-randomised smoking cessation trial in Denmark

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ABSTRACT

The aim of this community-randomised smoking cessation (SC) trial was to investigate both recruitment and SCrates in three municipalities offering financial incentives (FIM) to smokers who stop smoking when attending a municipal SC-program and compare these with three municipalities investing in a campaign (CAM) that should encourage smokers to use the SC-program. Furthermore, in a non-randomised matched control design we investigated whether there was a difference in recruitment and SC-rates in the three FIM and the three CAM, comparing each with three matched control municipalities (MCM).

Each municipality received approx. \$16,000. The FIM rewarded persons who were abstinent when attending the municipal SC-program. The CAM spent the money on a campaign recruiting smokers to the SC-program. Two of three FIM were only partly active in recruiting smokers in the intervention year 2018. An intention-to-treat (ITT) approach was used in analyses. Complete case analyses and multiple imputation were used to address loss to follow-up.

No difference in recruitment was found between the CAM and the FIM (p = 0.954), in adjusted analyses. In ITT analyses, FIM achieved significantly higher odds of validated abstinence from smoking at one-year follow-up (OR (95%CI): 1.63(1.1–2.4)), but not of self-reported continuous abstinence after six months than CAM. Compared with no intervention, campaigns increased the recruitment of smokers to the SC-program while financial incentives increased six months abstinence rates.

In a randomised trial, no difference was demonstrated in the effect of financial incentives and campaigns to recruit smokers to a SC-program and financial incentives seemed superior to help smokers staying smoke-free for a year.

Trial registration: ClinicalTrials.Gov ID: NCT03849092.

1. Introduction

Smoking continues to be one of the greatest public health challenges and is a heavy burden on most countries' economy (Drope and Schluger, 2018). High tobacco taxes, smoke-free policies, prohibition of tobacco product advertising, graphic health warnings and free smoking cessation (SC)-services are key tobacco control measures at the population level (Chung-Hall et al., 2019). However, even when smokers are offered the best evidence-based SC treatment, long-term abstinence rates are often disappointing (European Smoking Cessation Guidelines, 2012). Therefore, new effective interventions are called for.

In Denmark, before start of this study, daily smoking rates had stagnated around 17%, after a steady decline for six decades (Pisinger et al., 2018). Smoking prevention initiatives had been weak in the recent

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Abbrevations: FIM, financial incentive intervention municipalities; FIM-MCM, financial incentive matched control municipalities; CAM, campaign municipalities; CAM-MCM, campaign matched control municipalities.

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years; Denmark ranked number 15 on the Tobacco Control Scale in Europe in 2013 and fell to number 29 in 2019 (Joossens et al., 2020).

Since 2007, municipalities in Denmark have been responsible for offering free smoking cessation services to all citizens. A free-of-cost national Smoking Cessation Gold Standard Program (SC-GSP) has proven to be highly effective and cost-effective (Rasmussen and Tønnesen, 2016; Kjaer et al., 2007; Olsen et al., 2006), even across subgroups (Neumann et al., 2013a; Neumann et al., 2013b; Kehlet et al., 2015; Rasmussen et al., 2018; Rasmussen et al., 2013). It is a comprehensive mostly group-based intervention, which has been continuously updated and comprises six meetings over 6-8 weeks, fulfilling intensive clinical intervention requirements (Jorenby and Fiore, 1999). Smokers are offered repeated counseling and recommended pharmacotherapy (usually not reimbursed) by specially trained counselors. However, many municipalities find it difficult to recruit smokers and only approx. 2% of the smokers use the SC-services when they try to quit (Grønbæk et al., 2020), even though 35% of the smokers had tried to quit within the last year (Rygevaner, 2020; Lau et al., 2018). Each municipality has their own recruitment strategy and mostly there is no, or little money ear marked for recruitment.

In 2016, the Minister of Health in Denmark stated that anti-smoking campaigns and information, not legislation, regulation and tax increases, should be the weapon against smoking (Pedersen, 2016), and this opinion is very widespread. A Cochrane review from 2017, based on 11 studies, concluded that there is some evidence that mass media campaigns can be effective in changing smoking behavior in adults, but the quality of evidence was very low (Bala et al., 2017).

In recent years, many studies have investigated the effect of financially rewarded SC and in 2019, a Cochrane review, based on 33 randomised studies, concluded that there is high-certainty evidence that financial incentives improve SC-rates at the long-term follow-up (Notley et al., 2019). Few of the studies reported on costs, but those who did rated the intervention as being highly cost-effective (Halpern et al., 2018; White et al., 2013; Fraser et al., 2017). Many studies have focused on subgroups such as substance users, mentally ill persons or pregnant women (Notley et al., 2019). Few studies were run outside of the United States and most studies were set in worksites or clinics, not in community settings (Notley et al., 2019).

Therefore, we decided to perform a community trial comparing the effect of campaigns with financial incentives.

The aim of this randomised community trial was to compare recruitment-rates and short-term and long-term SC-rates in three municipalities offering financial incentives to smokers who stopped smoking when attending a SC-program with three other municipalities investing in a campaign that should encourage smokers to use local SCservices.

Furthermore, in a non-randomised matched control design we investigated whether there was a difference in recruitment-rates and short and long-term SC-rates in the three financial incentive intervention municipalities (FIM) compared with three matched control municipalities (FIM-MCM), and in the three campaign municipalities (CAM) compared with three matched control municipalities (CAM-MCM).

2. Methods

2.1. Study design

In a randomised community trial (Fig. 1) called "Rigere uden røg" (Richer without smoking) three Danish municipalities were randomised to be FIM and three were randomised to be CAM. Throughout the trial, we wanted the influence of researchers to be as small as possible, so that it showed a real-world implementation.

Inclusion of the intervention municipalities: The principal investigator invited all 29 municipalities in the Capital Region of Denmark to



Fig. 1. A modified CONSORT Flow Diagram of the "Rigere uden røg" (Richer without smoking) study, 2018, Denmark.

take part in the research project and six agreed (Fig. 1). One municipality withdrew before randomisation, but a municipality outside of the Capital Region was interested in the study and was included instead. One of the municipalities was large, situated on the island of Fyn, the Region of South Denmark (Table 1). The others were small and situated on the island of Zealand, the Capital Region. None of the municipalities were neighbours (low risk of contamination).

The local ethics committee decided that there was no need for approval (Journal-nr.: 18024988). The Danish Data Protection Agency also decided that there was no need, as the national Smoking Cessation Database (SC-DB) (Rasmussen and Tønnesen, 2016) (registered and analysed data) and the national quit line (performed follow-up on longterm abstinence) already had existing data processor agreements. The ClinicalTrials.Gov ID is NCT03849092. The researchers (CP and CGT) did not have access to personal data at any time during the intervention.

2.2. Participants

There were no eligibility criteria for smokers as the intervention was implemented in the existing SC-services. All smokers who wanted assistance to quit and attended the municipal SC-GSP were included, but the SC-counselors tried to recruit as many smokers with low socio economy as possible (based on low income and/or unemployment and/ or short education).

2.3. Randomisation and blinding

Randomisation of the intervention municipalities: At a start-up meeting (May 2017) with the SC-counselors from all six intervention municipalities, the municipalities were randomised by flipping a coin. We paired municipality representatives two and two and they decided who should flip the coin. Heads meant that the municipality was randomised to the FIM, tails to the CAM (Fig. 1). It was not possible to blind the municipalities for the researchers (CGT and CP) or for the statistician performing the analyses. Only the statistician had access to data.

2.4. Matching of non-randomised control municipalities

Increased activity in SC-services can occur in all municipalities for different reasons (local priorities, more resources, increased taxes on tobacco etc.), so we wanted also to compare the results with those from municipalities continuing "as usual". Therefore, we supplemented the randomised trial with a trial using a non-randomised matched control design (Fig. 1, Table 1). An employee at the SC-DB matched the three FIM with three FIM-MCM and the three CAM with three CAM-MCM. The municipalities were matched in pairs, so the number of smokers attending the municipalities' SC-services in 2017 was as comparable as possible. The non-randomised matched control municipalities were not informed about their assignment to the control group. The control municipalities and data were blinded for the two researchers (CGT and CP).

2.5. Interventions in the randomised trial

2.5.1. Intervention in FIM

Each of the three FIM received 100,000 Danish kroner (approx. \$16,000) to reward smokers who were abstinent when attending the SC-GSP. The maximum reward was 1200 Danish kroner (approx. \$190) per ex-smoker, and the amount was given as a voucher to be used in a local shopping mall (which also had a grocery store). Abstinent smokers received a voucher worth 200 Danish kroner (approx. \$32) at the third, fourth and fifth session and a voucher worth 600 Danish kroner (approx. \$95) when they attended the last session, having been abstinent for 4–6 weeks. Smokers who did not know about the financial incentives when they signed up for the SC-group also received incentives when being abstinent. Abstinence from smoking was confirmed by carbon-monoxide levels <10 ppm (Goldstein et al., 2018), measured by the SC-counselor.

The FIM did not receive any money for recruitment of smokers. The municipalities had different recruitment methods before study start and little money ear-marked for recruitment; all advertised for their SC-services on their home page and most of them had some collaboration with pharmacies and/or general practitioners. We gave very simple examples of how/where they might recruit but no assistance to recruit smokers. The SC-counselors advertised on their webpage, informed general practitioners and pharmacies about the project and provided them with flyers, and hung up homemade photocopied A4/A3 posters (Appendix A) e.g. in a vocational school or in residential areas with many persons with low socio economy.

Intervention was fully delivered in only one out of three municipalities. In one municipality, one of the two SC-counselors was on sick leave for half of the intervention year, and all SC-activities were stopped in another municipality after approx. Eight months due to a local political decision.

2.5.2. Intervention in CAM

Each of the three CAM received 100,000 Danish kroner to use on campaigns aimed at smokers with low socio economy. The aim of the campaign was not to inform about the negative health effects of smoking or the benefits of smoking cessation, but to encourage smokers to use the municipal SC-GSP. The three CAM contacted several advertising agencies and ended up with one that offered a combination of big posters, small posters, postcards and online and social media solutions. Photos depicted e.g. a dog begging to be aired or an elderly couple hugging and each had a short humoristic rhyme (Supplement 1). There was information that participation in a SC-group increased the chance of abstinence from smoking by approx. five times (based on Danish data)

Table 1

The number of citizens and the daily smoking prevalence rates before study start in the municipalities included in the "Rigere uden røg" (Richer without smoking) study, 2018, Denmark.

		Municipality	Number of citizens in 2017 (Lau et al., 2018; Danmarks Statistik, 2021)	Daily smoking prevalence in 2017(Lau et al., 2018; Rosendahl-Jensen et al., 2018; Larsen et al., 2018; Kyed et al., 2018)
Randomised	Financial incentives municipalities	А	51,500	20%
	(FIM)	В	88,200	13%
		С	26,100	20%
	Campaign municipalities (CAM)	D	31,200	18%
		E	25,200	16%
		F	27,300	16%
Non-randomised,	Matched financial incentives control	G	82,500	17%
matched	municipalities (FIM-MCM)	Н	41,400	21%
		I	46,500	17%
	Matched campaign control municipalities (CAM-MCM)	J	57,000	17%
		K	43,800	17%
		L	34,000	21%

compared with an unassisted attempt to quit. Smokers could text 1231, and they would be contacted by a SC-counselor. Large posters and banners were placed strategically e.g. at main roads, near malls, on busses and at buss-stops. Digital advertising was shown in busses, on main roads, and on Facebook, etc. post-cards/leaflets were placed in public offices and distributed to selected workplaces and private mailboxes in deprived areas. Smokers attending the municipal SC-GSP did not receive any financial reward for being abstinent.

2.6. Outcomes

Recruitment was registered in 2018, the year of the intervention, and in 2017. The primary recruitment outcome was "Number of participants attending the SC-GSP" (starting with 1 January and ending with 31 December 2018).

Abstinence from smoking was registered multiple times: 1) "COvalidated continuous abstinence after 4–6 weeks" (at the last SC-GPS session); 2) "Self-reported 6-months continuous abstinence (not smoking at all after the quit date)" and 3) "Self-reported 6-months point prevalence (smoke-free for at least the last 14 days). Six months information was obtained by the national quit line. After one year or more, persons living in municipalities included in the randomised trial were contacted by the national quit line again. If citizens were self-reported abstinent, they were contacted by a SC-counselor in their municipalities and abstinence was confirmed by a CO-measurement. Therefore, in the randomised trial we also have information on 4) "CO-validated point prevalence at 12+ months".

Continuous abstinence rates at 6 months were the primary outcome. Secondary outcomes were short-term abstinence rates, and 6 months and 12+ month point prevalence.

2.7. Sample size

Six municipalities were included in the randomised trial and further six in the non-randomised matched trial. Traditional sample size calculations were not performed as this was a community trial, not a clinical research study, and we had no influence on how many individuals would be included by the municipalities. A post hoc power analysis was considered, but rejected, as previous research suggests that post doc power analyses do not provide sensible results (Zhang et al., 2019).

2.8. Statistics

Results were reported as absolute numbers and percentages. Baseline characteristics were compared using a Chi² test.

Recruitment: We calculated the change in number of participants between 2017 and 2018 (Table 2). The differences were analysed using a linear regression model. The randomised groups were tested with no account for clustering, but within the matched design we used a multilevel mixed-effects linear regression model using matching (random effect) as the first level cluster allowing the intercepts to vary between the matched groups while all other predictors were modelled as fixed effects. Both designs (randomised and matched) were adjusting for free/subsidised nicotine replacement therapy (NRT; not provided by all municipalities) and number of participants in 2017, as these differed significantly across municipalities.

Abstinence from smoking (Table 3): Data were analysed using the intention-to-treat (ITT) approach whereby all non-respondents were presumed to have relapsed and secondarily using an as-observed approach, including only participants with a valid follow-up. Odds ratios (ORs) were estimated using mixed-effect logistic regression analyses. Analyses testing the randomised design were performed using municipality (random effect) as the first level cluster, while tests within the matched design used matching (random effect) to account for clustered data. All other predictors were modelled as fixed effects. Initially, univariate analyses were performed, and hereafter the multivariable model was fitted. In a fully adjusted model, we included both individual factors that are already proven in the literature to be related to the outcome and municipality level factors, to take into account difference between municipalities. The final analyses were adjusted for: Sex (male/ female), Age (15-24, 25-34, 35-44, 45-54, 55-66, 67+ (retirement age)) and Fagerström Test for Nicotine Dependence (FTND) (Heatherton et al., 1991) (low: 0-6 points/high: 7-10 points). Furthermore, Disadvantaged (yes (no education except school up to 12 years, or only short work-related courses) and unemployment (being of working age and receiving welfare payments, "housewives" and students were not included in this group)/no) was also used (Neumann et al., 2013b). We also included "Number of smokers attending the (first session of the) SC-GSP" and quit rate, both in year 2017. The last variable was proportion of smokers receiving free/subsidised NRT. All predictors were entered together and participants with missing values were excluded from the analyses (listwise deletion).

We conducted a sensitivity analysis, where we adjusted only for factors that significantly differed between municipalities. We ran the mixed-effect model using the same outcomes and level of clusters

Table 2

Number of smokers attending the smoking cessation program (SC-GSP) in the municipalities in the intervention year 2018 and the year before, and the change in number of participants between 2017 and 2018 between study groups. The "Rigere uden røg" (Richer without smoking) study, Denmark.

Municipality group (number of smokers included in the SC-GSP in year 2017/year 2018 = intervention	Real-world recruitment r	ates	Recruitment rates adjusted for lower intervention intensity in two of three FIM		
year)	Differences in recruitment (Chi ² , <i>p</i> - value)	Differences in recruitment (linear regression analyses, Coef, 95% CI)	Differences in recruitment (Chi ² , <i>p</i> - value)	Differences in recruitment (linear regression analyses, Coef, 95% CI)	
Financial incentive municipalities (FIM; N = 196/295) vs. campaign municipalities (CAM; N = $311/580$) ^a	Pearson $Chi^2 = 34.2; p = 0.064$	-1.6 [-106.1, 102.9]; <i>p</i> = 0.954	Pearson $\text{Chi}^2 = 0.1; p$ = 0.821	-20.0 [-120.2, 80.2]; <i>p</i> = 0.482	
Financial incentive municipalities (FIM) vs. financial incentive control municipalities (FIM- MCM; N = 210/342) ^b	Pearson $Chi^2 = 0.4$; $p = 0.535$	-0.6 [-36.4, 35.1]; <i>p</i> = 0.972	Pearson $\text{Chi}^2 = 1.7; p$ = 0.195	19.8 [-10.3, 49.9]; <i>p</i> = 0.195	
Campaign municipalities (CAM) vs. matched campaign control municipalities (CAM-MCM; N $= 315/210)^{\circ}$	Pearson Chi ² = 84.4; <i>p</i> < 0.001	87.4 [25.6, 149.2]; p = 0.006	-	-	

Randomised and matched groups: adjusted for free/subsidised nicotine replacement therapy (NRT) and number of participants in 2017, as these differed significantly across municipalities.

Bold = significant = p < 0.05

^a The randomised groups: Tested with no account for clustering.

^b The matched groups: A multilevel mixed-effects linear regression model using matching as the first level cluster.

Table 3

Baseline characteristics of smokers attending the smoking cessation program (SC-GSP) in the municipalities in the intervention year 2018 in the "Rigere uden røg" (Richer without smoking) study, 2018, Denmark.

	Randomised		Non-randomised, matched	Total	p-value	
	Financial incentive municipalities (FIM), N (%)	Campaign municipalities (CAM), N (%)	Financial incentive control municipalities (FIM-MCM), N (%)	Campaign control municipalities (CAM-MCM), N (%)		
Sex						0.190
Men	123 (41.7%)	239(41.2%)	151 (44.1%)	104 (49.5%)	617	
Women	172 (58.3%)	341 (58.8%)	191 (55.8%)	106 (50.5%)	(43.2%) 810	
Age (years)					(30.8%)	0.063
Up to 24	8 (2.7%)	43 (7.4%)	14 (4.1%)	17 (8.1%)	82 (5.7%)	
25-34	24 (8.1%)	70 (12.1%)	32 (9.4%)	22 (10.5%)	148	
					(10.4%)	
35–44	45 (15.3%)	83 (14.3%)	39 (11.4%)	24 (11.4%)	191	
		100 (00 10)			(13.4%)	
45–54	71 (24.1%)	128 (22.1%)	84 (24.6%)	52 (24.8%)	335	
55 66	03 (31 5%)	160 (20 1%)	120 (35 1%)	70 (33 3%)	(23.5%)	
33-00	95 (31.3%)	109 (29.1%)	120 (33.1%)	70 (33.3%)	(31.7%)	
67+	54 (18.3%)	87 (15.0%)	53 (15.4%)	25 (11.9%)	219	
					(15.3%)	
Disadvantaged						0.539
No	148 (50.2%)	292 (50.3%)	159 (46.5%)	98 (46.7%)	697	
					(48.8%)	
Yes	137 (46.4%)	274 (47.2%)	167 (48.8%)	106 (50.5%)	684	
					(47.9%)	
Missing	10 (3.4%)	14 (2.4%)	16 (4.7%)	6 (2.9%)	46 (3.2%)	0.002
No (1 14	53 (18 0%)	162 (27.0%)	78 (22.8%)	63 (30,0%)	356	0.003
cigarettes/day)	33 (18.0%)	102 (27.9%)	78 (22.8%)	03 (30.0%)	(24.9%)	
Yes (15+	242 (82.0%)	418 (72.1%)	264 (77.2%)	147 (70.0%)	1071	
cigarettes/day)					(75.1%)	
Fagerström score						0.754
Low (0–6)	200 (67.8%)	411 (70.9%)	244 (71.3%)	149 (71.0%)	1004	
					(70.4%)	
High (7–10)	95 (32.2%)	169 (29.1%)	98 (28.7%)	61 (29.0%)	423	
					(29.6%)	
Free/subsidised						< 0.001
No	133 (45.1%)	189 (32.6%)	132 (38.6%)	154 (73.3%)	608	
		001 ((7.4%))		56 (06 50)	(42.6%)	
Yes	162 (54.9%)	391 (67.4%)	210 (61.4%)	56 (26.7%)	819	
Total	205	580	342	210	(37.4%) 1497	
TOIDI	473	300	374	210	142/	

^a NRT = nicotine replacement therapy.

(random effects), as described above, but only including heavy smoking, free NRT, and quit-rate in 2017 as fixed effects (Appendix B). Furthermore, a sensitivity analysis was performed using a chained multiple imputation model to estimate differences in smoking abstinence between groups. The multiple imputed data were analysed using the fully adjusted model described above (Appendix C).

A two-sided *p* value of <0.05 was considered statistically significant. All statistical calculations were performed using Stata/IC 16.1 (Stata-Corp LP; Stata, 2021)

3. Results

3.1. Attrition and loss to follow-up

There was an increase from 2017 in the number of smokers recruited to the SC-GSP in all groups, except for the CAM-MCM. In 2018, a total of 295 smokers attended the SC-GSP in the FIM, 580 in the CAM, 342 in the FIM-MCM and 210 in the CAM-MCM (Table 2). Lost to follow-up rates were much lower after 6 and 12+ months in the FIM than in the other groups (Fig. 1).

3.2. Baseline characteristics of smokers

Most of those who attended the SC-GSP were between 45 and 66 years and women were slightly over-represented (Table 3). Approximately three in ten smokers were highly addicted, and about half of the smokers were disadvantaged. Significantly fewer smokers in the CAM-MCM received free/subsidised NRT when attending the SC-GSP compared with all other groups (p < 0.001), and significantly more citizens were heavy smokers in the CAM-MCM than in the FIM and FIM-MCM (p = 0.003). The median number of cigarettes per day was approx. 20 across the municipality groups.

3.3. Recruitment

In the randomised trial: In adjusted regression analyses, we found no significant difference between the CAM and the FIM. Sensitivity analyses that took into account the reduced intensity of the intervention in two of three municipalities in the FIM reached the same conclusion.

In the non-randomised trial: We found significantly higher recruitment in 2018 in the CAM than in the matched CAM-MCM (p = 0.006), but no difference between the FIM and the matched FIM-MCM.

3.4. Abstinence

The highest abstinence rates were achieved in the FIM, both at the end of the SC-GSP, after 6 months and after 12+ months (Fig. 2). The abstinence rates achieved in the CAM at the end of the SC-GSP and after 6 months reminded of those achieved in the MCM.

ITT analyses in the randomised trial (Table 4): We found significantly higher rates of validated continuous abstinence at the last SC-GSP session in the FIM than in the CAM in unadjusted, but not in adjusted, analyses. Odds of six-months self-reported continuous abstinence were higher in the FIM than in the CAM, but not significantly different. Odds of validated 12+ months point prevalence were significantly higher in the FIM than in the CAM in all analyses.

ITT analyses in the non-randomised trial (Table 4): We found significantly higher odds of continuous abstinence both at end of the SC-GSP and after six months in the FIM than in the FIM-MCM in unadjusted analyses, and after 6 months in the adjusted analyses. There was no significant difference in continuous abstinence between the CAM and the matched CAM-MCM.

Complete case analyses (Table 4): The FIM achieved significantly higher validated continuous abstinence rates after 4–6 weeks than the CAM, in adjusted analyses. Analyses showed the same tendency of higher odds of abstinence rates in the FIM than in the CAM after 6 and 12 months, as in the ITT analyses, but they were not significant. In the non-randomised trial both FIM and CAM showed a little higher odds of abstinence than their respective MCM, but this was not significant.

Sensitivity analyses, multiple imputation of data: Adjusted analyses showed significantly higher odds at last SC-session in the FIM than in the CAM and the FIM-MCM. There was no significant difference in abstinence between the FIM and the CAM after 6 months (Appendix C).

Partly and fully adjusted analyses gave (more or less) the same results, and there was no difference between continuous and point prevalence abstinence at 6 months follow-up in adjusted analyses (Appendix B).

4. Discussion

In this randomised community trial, we found no significant difference in the recruitment of smokers between municipalities offering financial incentives to abstinent smokers and municipalities spending the same amount of money on SC campaigns. In ITT analyses, municipalities offering financial incentives achieved significantly higher odds of validated abstinence from smoking at one-year follow-up, but not of self-reported continuous abstinence after 6 months, than campaign municipalities. Compared with no intervention, campaigns increased the recruitment of smokers to a municipal smoking cessation program while financial incentives increased six months abstinence rates.

Non-response is a major challenge in many trials. The standard procedure in the smoking cessation literature is to assume that all nonrespondents have resumed smoking (West et al., 2005). As there were more missing data after 6 and 12 months in the CAM than in the FIM and the MCM, the missing = smoking assumption yields a test that favors the FIM. The complete case and multiple imputation analyses confirmed significantly higher odds of short-term, but not long-term, abstinence in the FIM than in the CAM. The ITT analyses have probably overestimated the long-term effect of financial incentives, so the results should be interpreted with caution. However, complete case analyses over-estimate the effect and multiple imputation analyses also result in some degree of bias, which increases with the amount of missing data (Barnes et al., 2010)

No previous trial has compared financial incentives with campaigns. Campaigns can reach large numbers of people, but only half of the randomised studies (RCTs) testing campaigns have shown positive effects on quit rates (Bala et al., 2017). Offering financial incentives can increase the quit-rates (Notley et al., 2019) but can also be an effective way to increase the number of participants recruited into SC-programs (Marcano Belisario et al., 2012). The two interventions had an expected impact at different levels. We hypothesised that campaigns would primarily promote motivation to quit/recruitment to a SC-program while financial incentives would primarily increase self-efficacy (van den Brand et al., 2021) and abstinence rates. Our trial confirmed this, when compared with control groups. A little surprising was, however, that campaigns were not superior to financial incentives in the recruitment of smokers, especially as two of three municipalities did not recruit with full intensity.

Previous RCTs have shown that financial incentives improve SC-rates at the long-term follow-up (Notley et al., 2019). A meta-analysis of previous community trials found that the odds ratio of long-term abstinence was 1.49 in communities offering financial incentives compared with control groups (Notley et al., 2019) (significant). In our study, the odds ratio after six months was 1.50 in the FIM compared with



Fig. 2. Flow-chart showing the number of smoke-free persons (N) and the abstinence rates (%; intention-to-treat analyses (all smokers who attended at least the first session are included)) in the 12 municipalities included in the "Rigere uden røg" (Richer without smoking) study, Denmark, 2018.

Table 4

Odds of abstinence from smoking at end of the group-based municipal smoking cessation program (SC-GSP), after six months, and after 12 months. The "Rigere uden røg" (Richer without smoking) study, 2018, Denmark.

	Intention-to-treat analysesa					Complete case analyses			
	Validated continuous abstinence at 4–6 weeks		Self-reported 6 months continuous abstinence		Validated 12+ months point prevalence		Validated continuous abstinence at 4–6 weeks	Self-reported 6 months continuous abstinence	Validated 12+ months point prevalence
	Unadjusted, OR (95% CI)	Fully adjusted, OR (95% CI)	Unadjusted, OR (95%CI)	Fully adjusted, OR (95% CI)	Unadjusted, OR (95% CI)	Fully adjusted, OR (95% CI)	Fully adjusted, OR (95% CI)	Fully adjusted, OR (95% CI)	Fully adjusted, OR (95% CI)
Campaign municipalities (CAM)	1	1	1	1	1	1	1	1	1
Financial incentives municipalities (FIM)	1.91 (1.1–3.4)	1.31 (0.6–2.8)	1.80 (0.8–4.0)	1.33 (0.8–2.1)	1.96 (1.0–3.7)	1.63 (1.1–2.4)	3.71 (1.5–9.0)	1.27 (0.9–1.9)	1.13 (0.7–1.7)
Number in analyses	875	851	875	851	875	851	742	521	435
Matched financial incentives control municipalities (FIM-MCM)	1	1	1	1			1	1	
Financial incentives municipalities (FIM)	1.81 (1.3–2.5)	1.11 (0.7–1.7)	1.61 (1.1–2.3)	1.50 (1.0–2.2)			1.31 (0.7–2.4)	1.28 (0.8–2.1)	
Number in analyses	637	611	637	611			522	382	
Matched campaign control municipalities (CAM-MCM)	1	1	1	1			1	1	
Campaign municipalities (CAM)	1.12 (0.8–1.5)	0.95 (0.7–1.4)	1.28 (0.9–1.9)	1.11 (0.6–2.1)			1.06 (0.7–1.7)	1.31 (0.8–2.3)	
Number in analyses	790	770	790	770			670	442	

Analyses were adjusted for age, sex, disadvantage status, abstinence rate (ITT) in 2017, free/subsidised NRT, Fagerström score.

Bold = significant = p < 0.05

^a Intention-to-treat: All participants who attended the first session in the SC-GSP were included. Analyses testing the randomised design were performed using municipality as the first level cluster, while tests within the matched design used matching to account for clustered data.

the FIM-MCM, which is very similar.

Many different types of incentives have been tested: e.g. cash (Ghosh et al., 2016; Baker et al., 2018), vouchers (Secades-Villa et al., 2014), self-deposited money (Dallery et al., 2017), or a combination of incentives (Halpern et al., 2015). The financial amounts of incentives in previous studies varied from zero (self-deposited money) to \$1185 per person, and the Cochrane review found no significant difference in SC-effect between trials paying smaller amounts and those paying larger amounts (Notley et al., 2019). In our trial, we offered approx. \$190 per ex-smoker, given as vouchers.

Few studies have investigated the costs of incentives, but those who have indicate that financial incentives for smoking cessation might be highly cost-effective. A recent study suggests that financial incentives in the amount of \$20 per call for the first four quit line SC-counseling calls maximize return on investment to engage low-income smokers in evidence-based SC (Mundt et al., 2020) SC-studies with pregnant women have found that the incremental cost per quitter was £1127 (Boyd et al., 2016) and an incremental cost per quitty-adjusted life years was between £482 (Boyd et al., 2016) and \$734 (Tappin et al., 2015) This is well below National Health Institutes recommended decision thresholds (£20-30,000) (McCabe et al., 2008)

There is evidence that the effect of incentives continues beyond when the incentives had ended (Notley et al., 2019; Halpern et al., 2018; Secades-Villa et al., 2014; Dallery et al., 2017; Cheung et al., 2017a; Glasgow et al., 1993; Cooney et al., 2017). After 6 months we did not see significantly higher odds of abstinence in the FIM than in the CAM, but after 12 months abstinence rates were significantly higher in the FIM, in the ITT (but not in the complete case) analyses, indicating that the effect of incentives might actually increase over time. Public opinion regarding incentives is often negative as many will argue that smokers should not be financially rewarded (Volpp and Galvin, 2014). Three overarching themes expressing opposition to financial incentives for smokers have been detected: smokers' individual responsibility for quitting, concerns about abuse of the incentive program and financial incentives being seen as unfair (Robertson et al., 2018). These concerns will also exist in the political system and be a barrier for implementation (Values of Liberalism, 2020). The National Health Institute in UK has been offering incentives (prize draws, iPods, hotel breaks and helicopter trips) to people with unhealthy lifestyles for some time (Macaskill and Waite, 2009).

4.1. Strengths

A community-randomised trial can investigate a multichannel community-based approach to lifestyle modification (yet it can incorporate individual-level covariates), thus providing generalizability coupled with a rigorous evaluation of the intervention. The strength of a *community* intervention study is that it can evaluate a public health intervention in natural field circumstances. As the trial was performed in and driven by the municipalities it tested not only the effect but also the feasibility of the implementation in the municipalities. It is also a strength that we have several measures of abstinence (Cheung et al., 2017b), that we have validated the long-term abstinence in the RCT, performed both ITT and complete case analyses, supplemented with multiple imputation of data and adjusted for many relevant confounders, both at individual and municipality level.

4.2. Limitations

Evaluation of community interventions in the real world is challenging and divergent from RCTs which are rigorously evaluated within a more tightly-controlled clinical research setting (Moores et al., 2017). In this trial intervention intensity was not delivered as planned in two of the three FIM.

If we were to design the study again today, we would include all municipalities in a randomised trial instead of matching them. Hopefully, the matching and the adjusted analyses at municipal and individual level outweighed this limitation.

We might also have matched the municipalities based on the municipalities' number of citizens and social determinants of health since this may influence recruitment of smokers and SC outcomes. There was, however, no difference across municipalities in the share of socially deprived persons included in the SC-GSP and the number of smokers attending the municipalities' SC-services indirectly reflects not only the size of the municipality but also the socio-economy in the municipality. Also, it would have been optimal to measure smoking rates before and after the intervention across the whole municipality. In particular, the campaign might have encouraged smokers to quit on their own. However, the campaign prompted the smokers to sign up for a SC-GSP, rather than to quit smoking without assistance.

The low follow-up rate, especially after 12 months, is also a major weakness. All those who attended the SC-GSP at least at baseline were called four times by the national quit line; it is an increasing problem that people do not answer their phone when called by an unknown number. If we had known how few participants could be reached after 12 months, we would have validated abstinence at six months instead. Also, it is weakness that power analyses were not performed.

Further, the one-year follow-up was delayed, as we had to get approval by the Danish Data Protection Agency, which took a long time. Also, as there are up to four follow-up calls, it could take a month before the participants' smoking status was registered, so some of the participants' "12-month follow-up" was performed after 14 months or more. Then, we had to wait until the SC-counselor received monthly information on abstinent participants from the quit line and could arrange for CO measurements in the municipality; therefore, measurements of validated abstinence were further delayed.

All smokers in the FIM had to be informed that they had to pay tax on the vouchers, and that it was their own responsibility to inform the tax authorities. This might have weakened the effect of the intervention.

In the beginning of March 2020, Denmark entered lockdown due to the coronavirus pandemic. In June 2020, after data collection was completed, we were informed that there were still a few smokers (<10) in the municipalities that should have been validated but had not been due to the lockdown.

We performed a simple randomisation by flipping a coin. However, it would have been better if we had used a computer-generated random number sequence, so we could have saved the seed and replicated the randomisation. Further, an economic analysis could answer whether the impact of the intervention outweighed its costs. We intend to find resources to perform these analyses.

The generalizability of the trial is estimated to be moderate, as realworld settings influence the outcome.

4.3. Future research

The Cochrane review points out (Notley et al., 2019), that we should keep exploring the lasting effect of incentives and incentive size, as well as the possible harm for those who fail to quit and do not receive the expected financial reward. An economic evaluation should be part of all future trials offering incentives for SC.

4.4. Policy implications

Even though the financial incentive intervention was only partly implemented in two of three municipalities it turned out to be as effective to recruit smokers as CAM encouraging smokers to use the municipal SC-services, and a further benefit was that smokers in the FIM achieved higher long-term quit-rates, for the same amount. This supports existing evidence, that rewarding financial incentives to smokers is a highly effective strategy. A study found that a Government-funded reward-only scheme was seen as the most acceptable option (Robertson et al., 2018), and therefore, health authorities should consider that there is high-certainty evidence that incentives improve SC-rates at the long-term follow-up, when designing future SC-services.

5. Conclusion

In a randomised trial, no difference was demonstrated in the effect of financial incentives and campaigns to recruit smokers to a municipal SC-program. Financial incentives were superior to campaigns to help smokers staying smoke-free for a year, in ITT analyses. The SC-results should be interpreted with caution due to high lost-to-follow-up rates. In a non-randomised trial, compared with no intervention, campaigns were better to recruit smokers to existing SC-services and financial incentives increased 6 months SC-rates. This supports existing evidence, that rewarding financial incentives to smokers is a highly effective strategy.

CONSORT check list

See Appendix D.

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Contribution

CP: Conceptualization; Funding acquisition; Investigation; Methodology; Project administration; Resources; Supervision; Visualization; Writing - original draft; Writing - review & editing. CGT: Investigation; Methodology; Project administration; Supervision; Writing - review & editing. MR: Data curation; Formal analysis; Methodology; Software; Writing - original draft; Writing - review & editing.

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Transparency declaration

The lead author (CP) affirms that this manuscript is an honest,

accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Patient and public Involvement

The municipal smoking cessation counselors were involved after research questions were developed. They had no influence on the design of the study or choice of outcome measures but a high influence on recruitment and conduct of the study from start. In the CAM they chose the advertising agency and type of advertisements. In the FIM they recruited the smokers and decided how to advertise for the project. All smoking cessation counseling was performed by the municipal smoking cessation counselors, not researchers. The smoking cessation counselors have presented their experiences at a national conference and will help with dissemination of the study results to Danish communities.

Dissemination declaration

We have a plan to disseminate the results to all Danish municipalities, the Healthy City Network and the Danish Health Authorities.

Ethical compliance

- Authorship of the paper: contributions of authors are described above
- Originality and plagiarism: this is entirely original work, and when we have used the work and/or words of others, this has been appropriately cited.
- Data access and retention: data sharing is described above
- Multiple, redundant or concurrent publication: results of this study have not been published previously
- Acknowledgement of sources: We thank the smoking cessation counselors in the intervention municipalities above
- Disclosure and conflicts of interest: none of the authors have a conflict of interest
- Fundamental errors in published works: if we should discover an error after publication, we promise to promptly notify the journal editor or publisher and cooperate with the editor to retract or correct the paper.
- Reporting standards: we present an accurate account of the work performed as well as an objective discussion of its significance.
- Hazards and human or animal subjects: chemicals, procedures or equipment that have any unusual hazards inherent in their use have not been used in this study.
- Use of patient images or case details: neither patient images nor case details have been presented.

Declaration of Competing Interest

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.

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C. Pisinger et al.

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