Combination of brief advice, nicotine replacement therapy sampling, and active referral for smoking expectant fathers: abridged secondary publication

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KEY MESSAGES

1. The effectiveness of a combination of brief advice, 1-week nicotine replacement therapy sampling, and active referral for smoking cessation was assessed in 1053 smoking expectant fathers recruited from prenatal clinics of seven public hospitals in Hong Kong.
2. Biochemically validated abstinence was significantly higher in smoking expectant fathers who received a combination of smoking cessation intervention than those who received brief advice alone (6.8% vs 3.6%, P=0.02).
3. Provision of brief smoking cessation intervention to expectant fathers should be a part of routine practice in prenatal care.

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Introduction

The World Health Organization recommends interventions to help expectant fathers quit smoking to protect mothers and children from second-hand smoke exposure.[1] Nonetheless, only one randomised controlled trial of smoking cessation intervention was identified to target expectant fathers with non-smoking partners.[2] In our previous community-based trial, brief advice with active referral to a smoking cessation service was effective in increasing service uptake and smoking abstinence in smokers.[3] Provision of free sampling of 1 to 2 weeks of nicotine replacement therapy (NRT) is a low-cost intervention for promoting quitting.[4] We aim to evaluate the effect of a combination of brief advice, 1-week NRT sampling, and active referral on smoking cessation in expectant fathers.

Methods

Daily smoking expectant fathers of their pregnant partners who presented in prenatal clinics of seven public hospitals in Hong Kong were invited to participate. The expectant couples needed to be Hong Kong residents, living together in the past 7 days, and able to communicate in Cantonese or Mandarin. Expectant fathers were daily cigarette smokers whose partners were pregnant and non-smoking in the past 30 days. Those with contraindications to NRT (severe angina, arrhythmia, myocardial infarction), psychiatric diseases or on psychotropic drugs, or who had attended smoking cessation aids or programmes in the past 3 months were excluded.

Participants were randomly assigned in a 1:1 ratio to receive either a combination of brief advice, 1-week NRT sampling, and active referral as guided by the AWARD (ask, warn, advice, refer, do it again) model (intervention) or brief advice to quit on a leaflet by the Department of Health on the hazards of tobacco smoke exposure during pregnancy (control). Pregnant women were not actively intervened; they only received general advice on preventing second-hand smoke exposure.

For the intervention, participants were asked about their smoking behaviours (ask) and then warned about the harms of second-hand smoke

TABLE 1. Baseline characteristics of participants*

Characteristics	Intervention (n=527)	Control (n=526)
Age, y		
18-25	59 (11.3)	42 (8.1)
26-35	272 (51.8)	280 (53.7)
36-45	168 (32.0)	183 (35.1)
46-55	25 (4.8)	16 (3.0)
56-65	1 (0.2)	0
Education level		
Junior secondary or below	155 (30.3)	156 (30.5)
Senior secondary	243 (47.5)	224 (43.8)
Tertiary	114 (22.3)	132 (25.8)
Daily cigarette consumption		
1-10	365 (69.3)	362 (68.8)
11-20	153 (29.0)	158 (30.0)
≥21	9 (1.7)	6 (1.1)
Time to first cigarette of the day, min		
>60	237 (45.0)	240 (45.6)
31-60	77 (14.6)	76 (14.4)
5-30	72 (13.7)	88 (16.7)
<5	141 (26.8)	122 (23.2)
Heaviness of smoking		
Light	355 (67.4)	370 (70.3)
Moderate	165 (31.3)	150 (28.5)
Heavy	7 (1.3)	6 (1.1)
Exhaled carbon monoxide level, ppm	14 (8-23)	14 (8-22)
Past quit attempt		
Never	206 (39.1)	198 (37.7)
Over 12 months ago	260 (49.3)	283 (53.9)
Within 12 months	61 (11.6)	44 (8.4)
Readiness to quit		
Undecided	403 (76.5)	397 (75.5)
Within 60 days	21 (4.0)	19 (3.6)
Within 30 days	47 (8.9)	50 (9.5)
Within 7 days	56 (10.6)	60 (11.4)
Perception of quitting, 0-10		
Importance	9 (7-10)	8 (7-10)
Difficulty	8 (5-10)	8 (5-10)
Confidence	5 (5-8)	5 (5-8)
Stage of pregnancy of the pregnant women		
1st trimester	108 (21.1)	105 (20.5)
2nd trimester	290 (56.8)	288 (56.3)
3rd trimester	113 (22.1)	119 (23.2)
Smoking status of pregnant women		
Never	272 (52.1)	308 (59.5)
Just tried	73 (14.0)	62 (12.0)
Quit before pregnancy	48 (9.2)	45 (8.7)
Quit after pregnancy	129 (24.7)	103 (19.9)
Living with another smoker		
No	411 (79.5)	406 (78.7)
Yes	106 (20.5)	110 (21.3)

* Data are presented as No. (%) of participants or median (interquartile range), with missing data in some variables

exposure to pregnant women, fetus, and children (warn) using a leaflet. Then, participants were advised to quit smoking as soon as possible (advise) and offered referral to a local smoking cessation service (refer). Researchers used the leaflet to introduce the service and encouraged participants to select a service (counselling and pharmacotherapy). Contacts of those who were willing to be referred were sent to their selected service provider for smoking cessation treatment. Participants received two telephone boosters within a month after baseline assessment by a research nurse. The nurse repeated the AWARD advice during the boosters (do-it-again) and monitored and addressed any issue related to the use of NRT sample. Participants were offered a 1-week sample of NRT patch or gum. The dosing and forms of the NRT were based on the participants' daily cigarette consumption. Those who smoked <10, 10-20 and ≥20 cigarettes per day were offered 2 mg gum, 14 mg patch, and 21 mg patch, respectively. Brief instructions on how to use the NRT products and handle potential adverse effects were provided. Participants could obtain free NRT from smoking cessation services to which they were referred.

Data were collected at baseline using face-to-face questionnaire and at 3 months and 6 months via telephone interview. The primary outcome was biochemically validated tobacco abstinence at 6 months as measured by an exhaled carbon monoxide level of ≤3 parts per million using a Smokerlyzer. Participants who self-reported to have quit smoking for ≥7 days were invited for the test with a small cash incentive of HK$300. Secondary outcomes included self-reported 24-week continuous abstinence at 6 months, 7-day point-prevalence abstinence, 24-hour quit attempt, use of any NRT product, and use of smoking cessation service at 3 and 6 months. Other outcomes in continuing smokers included smoking reduction (defined by at least 50% reduction in cigarette consumption from baseline), change in cigarette dependence (assessed by the Heaviness of Smoking Index), and change in readiness to quit.

The sample size was calculated based on our previous randomised controlled trial of brief advice and active referral,[3] which reported an intervention effect of 1.85 and a validated quit rate of 5.0% in the control group by intention-to-treat analysis. With 80% power and allocation ratio of 1:1, 1148 (574 per group) participants were needed to detect an intervention effect at 2-sided 5% level of significance. Analyses were conducted in Stata/MP version 15.1. Participants with missing outcomes were assumed to have no change in smoking behaviours after baseline. Logistic regressions were used to determine the odds ratio (OR) of the intervention effect on outcomes. Multivariable regressions, multiply-imputed data analyses, and complete case analyses were conducted for the abstinence outcomes.

TABLE 2. Primary and secondary outcomes in the intervention and control groups

Outcome	Intervention (n=527)	Control (n=526)	Odds ratio (95% confidence interval)	P value
	No. (%) of participants			
Biochemically validated abstinence at 6 months	36 (6.8)	19 (3.6)	1.96 (1.11–3.46)	0.02
Self-reported 24-week continuous abstinence at 6 months	38 (7.2)	21 (4.0)	1.87 (1.08–3.23)	0.03
Self-reported 7-day point-prevalence abstinence at 3 months	91 (17.3)	65 (12.4)	1.48 (1.05–2.09)	0.03
Self-reported 7-day point-prevalence abstinence at 6 months	139 (26.4)	90 (17.1)	1.74 (1.29–2.34)	<0.001
24-hour quit attempt at 3 months	213 (40.4)	171 (32.5)	1.41 (1.08–1.80)	0.008
24-hour quit attempt at 6 months (cumulative)	314 (59.6)	259 (49.2)	1.52 (1.19–1.94)	<0.001
Use of any nicotine replacement therapy product at 3 months	150 (28.5)	9 (1.7)	22.6 (11.4–45.0)	<0.001
Use of any nicotine replacement therapy product at 6 months (cumulative)	184 (34.9)	10 (1.9)	27.7 (14.4–53.1)	<0.001
Use of smoking cessation service at 3 months	15 (2.8)	7 (1.3)	2.17 (0.88–5.37)	0.09
Use of smoking cessation service at 6 months (cumulative)	25 (4.7)	15 (2.9)	1.70 (0.88–3.26)	0.11

Results

From 10 October 2018 to 8 February 2020, we approached 11 958 expectant fathers in the prenatal clinics and received 15 online registrations. Of 1415 eligible participants, 1053 (74.4%) consented to participate and were randomised to the intervention (n=527) or control group (n=526). Recruitment was ended early for superiority of the intervention.

Baseline characteristics of the two groups were similar (Table 1). 85.8% of the participants were aged 26 to 45 years; 31.1% had moderate to high heaviness of smoking; 38.4% had never tried to quit; and 79.8% were not ready to quit in 30 days. The smoking profile between participants and eligible smokers who refused to participate were similar (data not shown).

The retention rates were similar between the two groups at 3 months (75.3% vs 76.1%, P=0.79) and at 6 months (81.6% vs 79.8%, P=0.47). Biochemically validated abstinence at 6 months was significantly higher in the intervention than control group (6.8% vs 3.6%, OR=1.96, P=0.02, Table 2), as were self-reported 24-week continuous abstinence at 6 months, self-reported 7-day point-prevalence abstinence, 24-hour quit attempt, and use of any NRT product, but not use smoking cessation service.

In self-reported continuing smokers, intervention resulted in a greater reduction in cigarette dependence at 6 months (-0.37 vs -0.15, P=0.003). The abstinence results were robust, with ORs being 2.04 (1.13-3.67) [P=0.02] after adjusting for baseline characteristics, 2.15 (1.24-3.73) [P=0.007] in multiply-imputed data analysis, and 1.93 (1.09-3.42) [P-0.02] in complete case analysis.

Discussion

A combination of brief advice, 1-week NRT sample, and referral to a smoking cessation service nearly doubled the odds of validated abstinence in smoking expectant fathers, compared with brief advice alone. The real-world effect might be underestimated because expectant fathers typically do not receive any treatment during prenatal visits, and our control group received brief advice. Our biochemically validated abstinence result (OR=1.96) appeared to be greater than the self-reported abstinence result (OR=1.5) reported in previous trials of NRT sampling in primary care clinics[4] and the validated abstinence result (OR=1.85) after active referral in community-based smokers.[3]

Strengths of the present study included the large sample size (n=1053) in an understudied population (expectant fathers), high retention rate (>80%), and the use of biochemical validation (vs self-reported) abstinence as the primary outcome. The similar smoking profile between participants and eligible subjects who refused to participate indicates the representativeness of our sample to the target population. However, there are some limitations. First, attrition bias could not be excluded despite the high retention rate. The use of intention-to-treat analyses preserved randomisation but underestimated the quit rates. Nevertheless, sensitivity analyses using multiply-imputed and complete data showed that the results were robust to missing data. Second, only a fraction of participants who self-reported quitting participated in the biochemical validation, but the effect sizes of validated and self-reported abstinence were similar. Third, the trial targeted smoking expectant fathers; the generalisability of the findings to other populations were uncertain.

In Hong Kong, about 29% of mothers with a newborn reported that their partners were smokers.[5]

Pregnancy presents an opportune time to engage expectant fathers in smoking cessation to protect their partners and children and themselves. Our findings support provision of brief cessation interventions to all expectant fathers visiting prenatal clinics. Further research is warranted to translate the results into practice and test the intervention in other settings to increase the reach of effective smoking cessation treatment.

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Disclosure

The results of this research have been previously published in:

1. Luk TT, Lam TH, Leung WC, et al. Brief advice, nicotine replacement therapy sampling, and active referral for expectant fathers who smoked cigarettes: a randomized clinical trial. JAMA Intern Med 2021;181:1081-9.

2. Luk TT, Hsieh CJ, Leung WC, et al. Brief cessation advice, nicotine replacement therapy sampling and active referral (BANSAR) for smoking expectant fathers: study protocol for a multicentre, pragmatic randomised controlled trial. Contemp Clin Trials 2020;93:106006.

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