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Smoking reduction intervention for smokers not willing to quit smoking: a randomised controlled trial

Key Messages

1. This smoking reduction study examined the effectiveness of smoking reduction counselling together with free nicotine replacement therapy (NRT) for smoking cessation and tested the effectiveness of brief counselling on adherence to NRT among Chinese smokers who were not willing to quit but intended to reduce cigarette consumption.
2. The smoking reduction intervention was effective in helping the unmotivated smokers in quitting (intervention: 17.0% vs control: 10.2%, P=0.012) and in reducing their daily cigarette consumption by 50% or more (intervention: 50.9% vs control: 25.7%, P<0.001) at 6-month follow-up.
3. Our results provided evidence for the effectiveness of smoking reduction intervention, which is important for planning smoking cessation services.
4. Free NRT was widely accepted by participants (8-week NRT adherence rate: 54.5%). Free NRT together with smoking reduction counselling was a feasible and cost-effective approach to help unmotivated smokers to reduce and quit smoking, especially in developing countries like China where NRT is expensive and not used extensively.
5. The motivation to quit smoking was not undermined by smoking reduction intervention. To the contrary, offering assistance to reduce smoking could attract smokers who were not willing or ready to quit.

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Introduction

China has the largest smoking population in the world, but most smokers are not willing to quit smoking. In Hong Kong, the prevalence of smoking was 11.8% in 2008, according to a household survey.[1] Although smoking cessation decreases the health risks associated with tobacco use, many smokers were unmotivated to quit, and 67% of Hong Kong Chinese smokers had never tried to give up smoking.[1] Smoking reduction may provide an intermediate step for complete cessation, especially for those who are unready or unwilling to quit. Although nicotine replacement therapy (NRT) increases the quit rate, few smokers undergoing NRT adhere to the recommended regimen.[2]

There has been no randomised controlled trial on intervention to increase NRT adherence. The present study aimed to evaluate the effectiveness of smoking reduction therapy and adherence intervention for 6 months among Chinese smokers in Hong Kong who were unmotivated to quit smoking. We hypothesised that the smoking reduction and adherence counselling would lead to a higher rate of abstinence, reduction, and adherence to NRT, compared to controls.

Methods

A single-blinded randomised controlled trial was conducted from October 2004 to April 2007. Subjects were eligible for inclusion if they were ethnic Chinese, aged 18 years or above, smoked at least two cigarettes daily, had no intention to quit in the near future or had failed in previous attempts to quit using NRT, intended to reduce smoking within the next 7 days using NRT, had no contraindication to NRT, and were not following other smoking cessation or reduction interventions. People who were psychologically or physically unable to communicate, pregnant or intending to become pregnant within the next 6 months, on regular psychotropic medications, or with any serious health problems such as stroke, palpitations or other life-threatening conditions were excluded.

After informed consent, the subjects were randomised into the control group or one of the two intervention groups. In the control group, subjects received simple advice on smoking cessation and a self-help quitting pamphlet only. In the reduction and adherence intervention group, subjects received 15-minute face-to-face smoking reduction counselling and 3-minute adherence counselling for NRT by a trained smoking cessation counsellor. Information on health consequences of smoking and benefits of quitting was provided. Smokers were encouraged to reduce consumption before quitting. Using the '5R' approach (relevance, risk, rewards, roadblocks, and repetition), the counselling focused on the importance and function of smoking reduction when complete cessation is difficult. In addition, the importance of adherence to the prescribed NRT dosage and the advantages of adherence were emphasised. Ways to overcome barriers were discussed. Problem-orientated interventions to improve adherence were delivered. Strict adherence to the prescribed dosage for at least 4 weeks was advised. In the reduction intervention group, subjects received smoking reduction counselling only.

For both intervention groups, 1 week of NRT was provided at the first contact. Further smoking reduction counselling and free NRT were provided at the 1-week and 4-week follow-ups. For the reduction and adherence intervention group, NRT usage was checked by counting the amount of NRT left, and additional adherence counselling was provided. At month 3, information on NRT use in the intervention groups up to 4 and 8 weeks was collected. At month 6, all subjects (including controls) were interviewed via telephone using a standard questionnaire. All self-reported quitters (with 7-day abstinence) and reducers (reducing daily consumption by ≥50%) were invited for biochemical validation of exhaled carbon monoxide and urinary cotinine levels.

The primary outcome measures were: (1) self-reported 7-day point-prevalence tobacco abstinence at month 6, (2) self-reported reduction rate (≥50%) of cigarette consumption at month 6 between the intervention and control groups, and (3) rate of continuous NRT use for 4 weeks (4-week adherence rate) at month 3 between the two intervention groups. Secondary outcome measures were: (1) validated quit rate at month 6, (2) self-reported quit rate at month 1, (3) self-reported continuous use of NRT for at least 8 weeks, and (4) the number of quit attempts up to month 6.

The required sample size was calculated based on primary outcome measures to provide at least 90% power with a significance level of 5%. We estimated that there would be (1) a 4% difference in the self-reported quit rate between the intervention and control groups, (2) a 12% difference in the self-reported reduction rate between the intervention and control groups, and (3) a 10% difference in the adherence rate between the intervention groups. Thus, 3246 subjects (1229 in the reduction and adherence intervention group, 1229 in the reduction intervention group, and 788 in the control group) were needed.

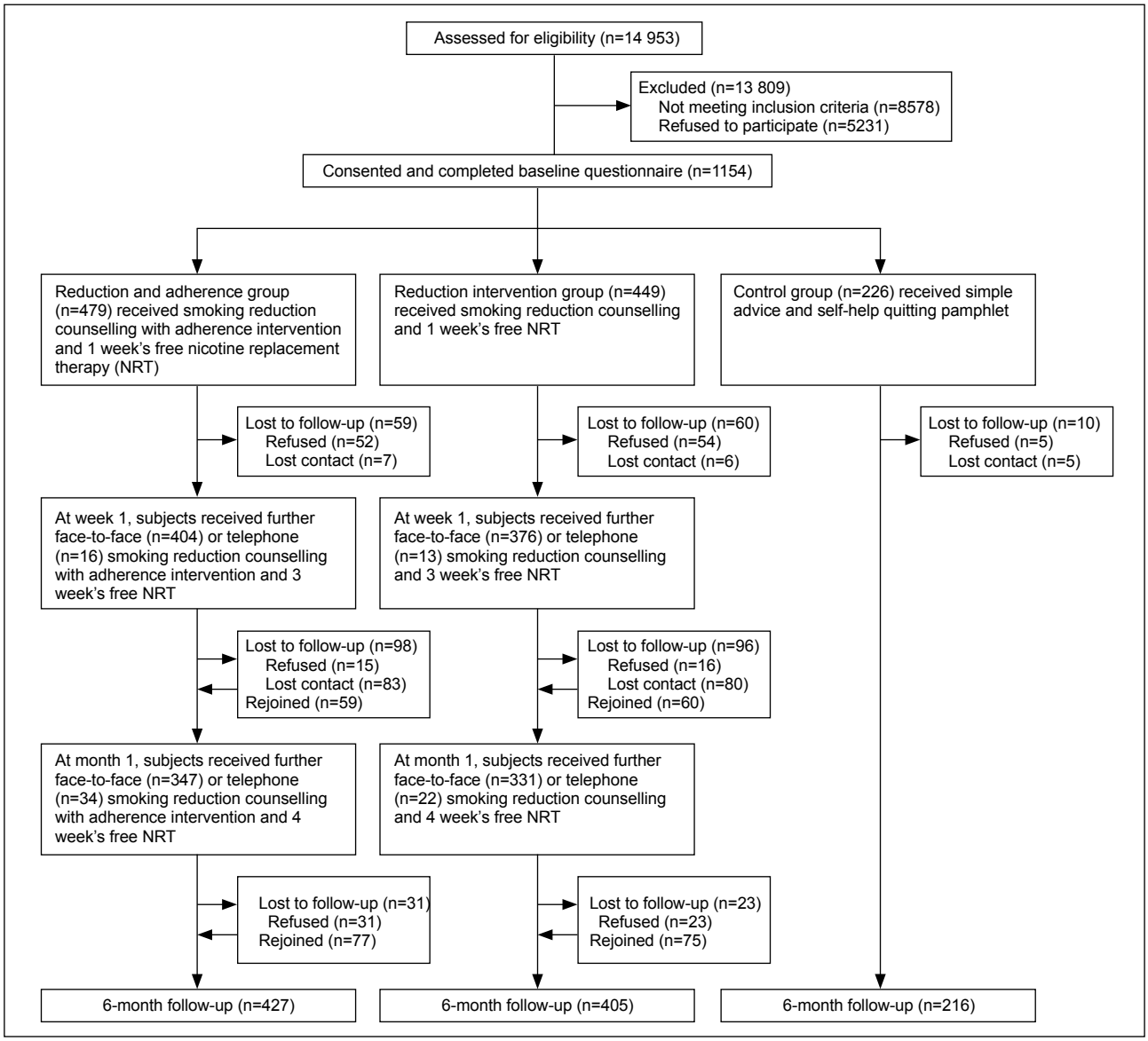

Fig. Consolidated standards of reporting trials flow chart of the study

All analyses were based on the intention-to-treat principle. To test the effectiveness of the smoking reduction counselling and NRT, the two intervention groups were combined and compared with the control group. To test the effectiveness of the adherence intervention to NRT, the two intervention groups were compared. Recruitment of subjects was stopped upon advice from the Independent Data Monitoring Committee after the interim analysis showed that the self-reported quit rate at month 6 was significantly different between the intervention and control groups, and that the adherence rates to NRT between the two intervention groups were almost identical. Tobacco abstinence rates, reduction rates, and the adherence rates between groups were compared using the Pearson Chi-squared test, odds ratios, and 95% confidence intervals.

Results

From October 2004 to April 2007, 1154 participants were randomised into the smoking reduction and NRT adherence intervention group (n=479), the smoking reduction group (n=449), and the control group (n=226). A consolidated standards of reporting trials flow chart detailing the enrolment, allocation and follow-up of participants is shown in the Figure. Table 1 outlines characteristics of participants and results of baseline measurements. No significant difference was noted in baseline variables across the three groups, except that there were more females in the reduction and adherence intervention group (22.1% vs 16.5% vs 12.4% respectively, Table 1). The follow-up rates of the combined intervention group at the 1-week, 1-month, and 3-month follow-up were 87.2%, 79.1%, and 85.9%, respectively. At 6 months, 89.7% of the combined intervention group and 95.6% of the control group were followed up.

Cigarette consumption and abstinence

Smoking status of all subjects was assessed by research assistants at the 6-month follow-up by telephone interview. The mean daily cigarette consumption of the intervention groups was significantly lower than that of the controls (9.5 vs 13.1 cigarettes, P<0.001, Table 2). The quit rate was significantly higher in the intervention groups than the controls (17.0% vs 10.2%, P=0.012, Table 2). Subjects who reported complete abstinence were invited for biochemical validation, and the participation rate was 56.4% (102/181); 74 (quit rate of 8.0%) of the intervention group subjects passed the validation test, with urinary cotinine concentrations of <115 ng/ml and expired carbon monoxide levels of <9 ppm, compared to 10 (quit rate of 4.4%) of the controls (P=0.066).

Smoking reduction and quit attempts

Successful smoking reduction was defined as a self-reported reduction in daily cigarettes by ≥50% at the 6-month follow-up. The smoking reduction rates were significantly

Table 1. Patients' demographics, smoking profiles, quitting history, and self-efficacy to resist smoking at baseline*

Parameter	Reduction and adherence intervention (n=479)	Reduction intervention (n=449)	Control (n=226)
Male	373 (77.9)	375 (83.5)	198 (87.6)
Female	106 (22.1)	74 (16.5)	28 (12.4)
Patient age (years)	41.5±10.3	42.4±10.3	42.5±11.2
Marital status			
Married/cohabiting	323 (67.4)	335 (74.8)	153 (67.7)
Others	156 (32.6)	113 (25.2)	73 (32.3)
Education level			
Primary or below	53 (11.1)	48 (10.7)	27 (11.9)
Secondary	331 (69.1)	329 (73.4)	156 (69.1)
Tertiary or above	95 (19.8)	71 (15.8)	43 (19.0)
Smoking profiles			
Age started smoking (years)	18.0±4.6	17.5±4.8	17.8±4.8
Years of regular smoking	23.5±10.8	24.8±9.9	24.5±11.1
Daily cigarette consumption	19.8±9.4	20.1±10.1	19.2±8.9
Fagerstrom test			
Mild	102 (21.3)	109 (24.3)	56 (24.8)
Moderate	151 (31.5)	134 (29.9)	76 (33.6)
Severe	226 (47.2)	205 (45.8)	94 (41.6)
Quit attempt			
0	104 (21.8)	100 (22.4)	43 (19.1)
1	144 (30.1)	122 (27.4)	55 (24.4)
2-5	178 (37.2)	192 (43.0)	109 (48.4)
6-10	21 (4.4)	11 (2.5)	8 (3.6)
>10	31 (6.5)	21 (4.7)	10 (4.4)
Previous use of nicotine replacement therapy	193 (40.3)	166 (37.1)	84 (37.2)
Self-efficacy to resist smoking†			
Importance of reducing smoking	82.8±17.3	82.5±17.2	79.7±18.8
Difficulty in reducing smoking	69.0±22.7	69.8±21.7	68.1±22.1
Confidence in reducing smoking	64.9±20.1	63.3±20.5	61.6±20.2
Confidence in quitting smoking (years)	76.3±21.0	75.0±21.7	76.4±20.3

* Data are presented as No. (%) or mean±SD

† Range from 0 indicating not important, not difficult, or not confident at all to 100 indicating very important, very difficult, or very confident

Table 2. Abstinence, reduction, quit attempts and adherence rates of the intervention and control groups

Abstinence and reduction rate	No. (%) of subjects		P value	Odds ratio (95% CI)
	Combined intervention (n=928)	Control (n=226)		
Self-reported 7-day point prevalence quit rate	158 (17.0)	23 (10.2)	0.012	1.81 (1.14-2.88)
Biochemical validated quit rate*	74 (8.0)	10 (4.4)	0.066	1.87 (0.95-3.70)
Self-reported reduction in daily cigarette consumption by ≥50%	472 (50.9)	58 (25.7)	<0.001	3.0 (2.16-4.15)
Tried to quit smoking for at least 24 hours within last 30 days (excluding the quitters)	172 (22.9) of 770	42 (20.7) of 203	0.05	0.88 (0.6-1.3)
	Reduction and adherence intervention (n=479)	Reduction intervention (n=449)		
Self-reported 7-day point prevalence quit rate at month 3	67 (14.0)	58 (12.9)	0.91	1.1 (0.75-1.60)
Self-reported 7-day point prevalence quit rate at month 6	100 (20.9)	58 (12.9)	0.001	1.78 (1.25-2.53)
Biochemical validated quit rate*	48 (10.0)	26 (5.8)	0.02	1.81 (1.10-2.98)
4-week adherence rate to nicotine replacement therapy at month 3	334 (69.7)	304 (67.7)	0.51	1.1 (0.83-1.45)
8-week adherence rate to nicotine replacement therapy at month 3	270 (56.4)	236 (52.6)	0.25	1.2 (0.90-1.51)

* Quitting is confirmed by an expired carbon monoxide level of <9 ppm and a urinary cotinine level of <115 ng/ml

higher in the intervention groups than in the control group, including and excluding the quitters (50.9% vs 25.7%, P<0.001; 41.2% vs 17.2%, P<0.001, respectively). Those who had an expired carbon monoxide level reduced by ≥1 ppm were classified as validated reducers. The participation rate was 48.9% (171/350). There were more validated reducers in the intervention groups than the control group (11.2% [104/928] vs 5.3% [12/226], P=0.008). Excluding the quitters, more smokers in the intervention groups tried to stop smoking for at least 24 hours within the previous 30 days than controls did (22.9% vs 20.7%, P>0.05).

Adherence to nicotine replacement therapy

Comparing the two intervention groups, there was no significant difference in the adherence rates to NRT at week 4 (69.7% vs 67.7%, P=0.51) and week 8 (56.4% vs 52.6%, P=0.25), as well as the self-reported 7-day quit rate (14.0% vs 12.9%, P=0.91) at month 3. Nonetheless, the quit rate was significantly higher in the reduction and adherence intervention group (20.9% vs 12.9%, P=0.001).

Discussion

Smoking reduction counselling, with or without NRT adherence counselling, was effective in helping 'pre-contemplators' to quit or reduce their daily cigarette consumption by ≥50%. This is important for planning local smoking cessation services (when most smokers are unmotivated to quit) and making smoking reduction an intermediate step toward complete cessation.

In our study, the effectiveness of the 3-minute adherence counselling on NRT was examined. Although there was no significant difference in the 4-week and 8-week adherence rates between the two intervention groups at the 3-month follow up, NRT was widely accepted (54.5%), compared to previous studies that have reported rates of 16 to 46%.[2-4] This was likely to be due to provision of free NRT. Cost is the main reason for NRT discontinuation; offering free NRT with smoking reduction counselling is feasible and cost-effective in helping unmotivated smokers to reduce and quit smoking, especially for those in developing countries like China where NRT is expensive and not widely used.

Reduction counselling may undermine smoking cessation and smokers' motivation to quit, as smokers may rationalise that reducing consumption is what they can accomplish and perceive reduction as an alternative to complete cessation.[5] Our study does not support this notion. Compared with the controls at month 6, smoking reduction intervention plus nicotine treatment achieved significantly higher abstinence rates, reduction rates, and quit attempts. No evidence of undermined motivation for quitting smoking was noted. To the contrary, offering assistance to reduce smoking may attract the smokers who are unwilling or unready to quit.

The main limitation of our study was the difficulty in subject recruitment despite vigorous promotional campaigns, and thus stopping recruitment before reaching our planned number of participants. From our previous experience, 60% of the current smokers were not intending to quit or join a cessation programme. This percentage was much lower when the smokers were sought from our database. Further studies on new adherence intervention are needed. Our study provided multi-session counselling (baseline, 1-week and 1-month) with telephone follow-up, but 20% of the participants were lost to follow-up and hence did not receive the complete intervention, possibly weakening effectiveness.

Conclusion

Smoking reduction counselling together with NRT was effective in achieving smoking reduction and complete cessation for smokers who were not ready to quit. Although there was no significant difference in the 4-week and 8-week adherence rates to NRT between the two intervention groups, the group receiving the adherence intervention achieved a significantly higher quit rate.

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