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A randomized controlled trial of stage-matched intervention for smoking cessation in cardiac out-patients

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ABSTRACT

Aim To examine the effectiveness of a stage-matched smoking cessation counselling intervention for smokers who had cardiac diseases. **Methods** A total of 1860 Chinese cardiac patients who smoked at least one cigarette in the past 7 days and aged 18 years or above recruited from cardiac out-patient clinics in Hong Kong hospitals were allocated randomly to an intervention group or control group. The intervention group ($n = 938$) received counselling matched with their stage of readiness to quit by trained counsellors at baseline, 1 week and 1 month. The control group ($n = 922$) received brief counselling on healthy diet at baseline. The primary outcomes were self-reported 7-day and 30-day point prevalence (PP) of tobacco abstinence at 12 months after baseline. The secondary outcome measures included biochemically validated abstinence at 12-month follow-up, self-reported 7-day and 30-day PP abstinence and reduction of cigarette consumption by 50% at 3 and 6 months. **Results** By intention-to-treat analysis, the intervention and control groups showed no significant difference in self-reported 7-day PP abstinence (intervention: 26.5% versus control: 25.5%; P = 0.60) and 30-day PP (intervention: 25.4% versus control: 24.2%; P = 0.55), biochemically validated abstinence (intervention: 6.6% versus control: 4.9%; P = 0.14) and overall quit attempts of least 24 hours (intervention: 40.3% versus control: 34.3%; P = 0.007) at the 12-month follow-up, adjusted for the baseline stage of readiness to quit smoking. **Conclusions** An intervention, based on the Stages of Change model, to promote smoking cessation in cardiac patients in China failed to find any long-term benefit.

Keywords behavioural counselling, cardiac out-patients, Chinese population, randomized controlled trial, tobacco abstinence, transtheoretical model of change.

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INTRODUCTION

Smoking is a major cause of recurrent events in patients with coronary heart disease (CHD). Smoking cessation after a coronary event reduces cardiovascular mortality by 35–45% after 5 years [1], and non-fatal myocardial infarction occurs less often in smokers who quit after their first cardiac event [2]. Smoking cessation treatment is highly cost-effective and hence is recommended by clinical guidelines for secondary cardiovascular disease prevention [3].

Behavioural interventions to treat tobacco use are recommended for cardiac patients in general [3–5]. Studies of smoking cessation interventions for CHD patients have provided mixed results. Meta-analyses of randomized controlled trials showed that behavioural smoking cessation interventions, including those targeting to increase self-efficacy, developing risk perception and coping skills, appeared to be effective [6,7], while a meta-analysis of 12 studies concluded that there were very limited effects in promoting tobacco abstinence among CHD patients [8]. However, studies included in these reviews had mixed participant populations and used diverse intervention methods.

Good evidence is needed to promote interventions for secondary prevention in CHD patients. Only a few studies

have targeted out-patients, but with disappointing results. Wiggers *et al*. reported that adding a minimal behavioural smoking cessation intervention to nicotine replacement therapy (NRT) did not provide any additional effect on quitting at 12 months [9], while Harting *et al*. tested a health counselling intervention on multiple behavioural risk factors and reported significant reduction in fat consumption but no significant change in the proportion of smokers at 4 months [10].

Having a cardiac event and requiring medical attention is often regarded as a 'teachable moment' and an excellent opportunity for initiating smoking cessation in patients, as they will be motivated to make changes to improve their health condition. Nevertheless, smoking behaviours of patients receive only limited attention from health-care professionals, and smoking cessation interventions with proper follow-ups are rarely part of routine clinical care in Hong Kong, Mainland China and other countries. The frequently reported reasons include lack of time and counselling skills [11,12].

Although stage-matched cessation counselling has not been used routinely on cardiac patients for treatment of nicotine dependency, it is a widely used method to help smokers in the general public to quit smoking. A recent meta-analysis of 14 randomized trials on smoking cessation showed that psychosocial interventions, in general, was effective compared to brief or usual advice when delivered by general practitioners and trained counsellors [7]. We conducted a randomized controlled trial to test the effectiveness of a nurse-delivered stage-matched smoking intervention on Chinese cardiac outpatients in Hong Kong. The specific aims of this study were to examine (i) the effectiveness of a stage-matched smoking cessation counselling intervention on tobacco abstinence and reduction in cigarette consumption by at least half compared to a control group, and (ii) whether the stage-matched counselling intervention would enhance making quit attempts in the clinical setting in cardiac patients.

METHODS

Participants and settings

Chinese cigarette smokers who attended the cardiac out-patient clinic of 10 major hospitals in Hong Kong for routine follow-up visits were recruited during March 2002 to December 2004. Patients who were aged 18 years old or above and smoked at least one cigarette daily in the past 7 days were eligible for participation. Patients were excluded if they were clinically too ill and not suitable to complete the questionnaire and/or receive intervention, or could not communicate in Chinese.

Study design and procedures

This was a single-blinded multi-centre randomized controlled trial, approved by the ethics committees at each study site, and the Li Ka Shing Faculty of Medicine, the University of Hong Kong, and all patients provided written consent prior to randomization. All cardiac patients who smoked were referred by their physicians after regular consultation to meet our nurse smoking cessation counsellor in a specified room in the clinic for screening, and eligible patients were invited to join the trial.

Baseline data, including demographics, health status, smoking and quitting history, were obtained from each patient using a structured questionnaire, administered in face-to-face interviews by the nurse counsellor prior to randomization. Nicotine dependency was assessed by the Fagerström test [13], and the stage of readiness to quit (pre-contemplation, contemplation, preparation, action) was assessed according to an algorithm adapted from DiClemente *et al*. (1991) based on the quit attempt in the past year and intention to quit in the near future [14]. Appendix S1 shows the staging algorithm for readiness to quit used in this study. After the baseline interview and assessment by the nurse counsellor, patients were assigned into intervention or control groups by opening a serially numbered sealed and opaque envelope containing printed instructions on the specified group. The allocation sequence (intervention or control) was generated sequentially by the project coordinator based on simple random sampling procedure (without replacement) using MS Excel®.

Intervention

Patients assigned to the intervention group received a 30-minute individualized face-to-face smoking cessation counselling matched with their stage of readiness to quit at baseline visit. They also received telephone calls from the nurse counsellor at 1 week and 1 month after the baseline visit to reassess their stage of readiness to quit, and additional counselling for smoking cessation that matched with their updated stage was given at each phone call. Each telephone counselling session lasted about 15 minutes.

The individualized stage-matched smoking cessation counselling was developed based on the Transtheoretical Model of Change [14]. A standard stage-matched protocol was used to provide an appropriate intervention that matched the patient's stage of readiness to quit (pre-contemplation, contemplation, preparation, action, maintenance). In particular, for smokers in the pre-contemplation stage who were not ready to quit, the goal for intervention was to help the patient to think seriously about quitting in the next 6 months. The nurse

counsellor would further assess the smoker's knowledge and misconception. Based on knowledge gaps and misconception, the nurse counsellor would increase the smoker's perceptions of risks and problems of smoking by offering information and resources; and finally discuss the possibility of change in behaviour. For smokers in the contemplation stage who were thinking about quitting, the goal was to tip the balance so that pros for quitting outweighed cons, and to express confidence in the patients' ability to quit. In order to achieve these goals, the nurse counsellor would give advice on reasons for change by clarifying misconception and provide support by identifying barriers and offering potential solutions. In addition, the nurse counsellor would encourage small steps towards quitting action, i.e. delaying first cigarette, cutting down the number of cigarettes. For smokers in the preparation stage who were ready to make a change, the goal for intervention was to help the patient to plan the quit attempt. The nurse counsellor would strengthen the smokers' commitment and motivation to quit by helping the smokers to set a quit date and develop action plans. For smokers in the action stage who were making the change, the goal for intervention was to provide support. The nurse counsellor would discuss with the smokers on removal of cues for relapse, developing coping skills and referral to smoking cessation programme or support group. Details of the counselling provided to the patients in the intervention group are given in Appendix S2.

The control group received only a 15-minute face-to-face counselling on healthy diet by the nurse counsellor at baseline visit, and a one-page A4-sized leaflet which highlighted the importance of a healthy diet for cardiac patients was given to the patients. No telephone counselling was given thereafter.

All patients from both arms also received standard care that was provided routinely by the respective hospital. No drug such as nicotine replacement therapy (NRT) in the form of gum or patch was provided, due to lack of resources. However, stage-matched medication counselling on NRT was discussed with patients in the contemplation or action stages in the intervention group if deemed appropriate.

Fidelity of the intervention delivery

The intervention was conducted by five registered nurses who had completed a 2-day training workshop in smoking cessation counselling and passed a written and practical test. Training included health hazards of smoking, tobacco epidemic, stage of readiness to quit smoking and stage-matched smoking cessation treatment and counselling techniques. Nurse counsellors used a decisional balance review tool and intervention component checklists to ensure treatment fidelity and to document delivery of the intervention components. Total time spent in each counselling session was also recorded. The quality of the counselling intervention was monitored through a quality assurance mechanism. Regular meetings with the counsellors were held every 2 months for case-sharing and evaluation. Each counsellor audiotaped one counselling session per month and tapes were audited by an experienced nurse supervisor for performance assessment; feedback for improvement was provided to individual counsellors and shared in the regular meetings. All trained nurse counsellors followed the random allocation procedures strictly and provided intervention or otherwise to the patients following the instructions in the sealed opaque envelopes. No contamination in the intervention was observed.

Follow-up and outcome measures

All patients were telephoned at 3, 6 and 12 months after initial contact by trained interviewers who were blinded to the group assignment. At each follow-up, the patients were asked about the use of cigarettes or other tobacco products since the last contact and during the past 7 days and 30 days. At least five attempts were made before we considered the patient was lost to follow-up.

The primary outcome measures were self-reported 7-day and 30-day point prevalence (PP) tobacco abstinence at 12 months after initial contact. At 12-month follow-up, patients who reported total abstinence from smoking (not even one puff) in the past 7 days and/or 30 days were considered as self-reported quitters. Secondary outcomes included self-reported 7-day and 30-day PP tobacco abstinence at 3 and 6 months, biochemically validated tobacco abstinence at 12 months [exhaled carbon monoxide level $\leq$8 parts per million (ppm)] measured by smokerlyzer and urine cotinine level <100 ng/ml, measured by NicAlert® strips [15]), had at least one quit attempt of stopping smoking lasting at least 24 hours during the course of 12 months (quit attempt rate), and reduction in cigarette consumption by at least 50% compared to baseline at each follow-up (reduction rates). Except for biochemically validated tobacco abstinence at 12 months, all the outcomes were measured based on self-reports. Patients who reported that they had stopped smoking for at least 7 days at 12 months were invited to attend the Centre of Health Promotion, the University of Hong Kong, for biochemical validation. A travel allowance of HKD$50 (US$1 = HK$7.8), which was increased later to HKD$100 and then HKD$200, was offered to patients who presented for validation. Those who were lost to follow-up or refused to participate in validation tests were treated as smokers.

Sample size calculation

Based on a previous study, the 12-month tobacco abstinence of in-patients who received nurse-delivered behavioural-orientated counselling (baseline plus four post-discharge telephone follow-ups) was 27% versus 20% in the control group, who received usual care [16]. To detect a difference of 7% between the two groups based on primary outcome with a two-sided 5% significance level and a power of 90%, 1550 patients were required. Accounting for a possible loss of 15% of patients at 12-month follow-up, a total of 1824 patients were needed.

Statistical analysis

Data analysis was performed using the Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, USA) version 14.0 for Windows. We compared the baseline characteristics of the patients by χ^2 test for categorical variables and *t*-test for continuous variables between the intervention and control groups. We used the χ^2 test to assess the effect of intervention and calculated crude odds ratio (OR) with 95% confidence interval (CI) for the primary and secondary outcomes. Logistic regression was performed with adjustment for the baseline stage of readiness to quit smoking. All the 1860 patients were included in the analysis by intention-to-treat when applicable, i.e. we considered all non-responded follow-up patients as current smokers, who did not made a quit attempt during the follow-up period and did not change their smoking behaviour compared to baseline. A 5% level of significance was set in all analyses.

RESULTS

Patient enrolment

From March 2002 to December 2004, 60 588 patients with cardiac diseases were screened and 58 479 (96.5%) were non-smokers. The much lower smoking rate of 3.5% in cardiac patients in the current study compared to the population daily smoking prevalence of 11% in 2007 was unexpected [17], probably because most cardiac patients had already quit smoking after having the disease, or other cardiac patients who smoked might have died. Among the 2109 eligible patients, 1860 (88.2%) consented to participate and were assigned randomly either to the intervention ($n = 938$) or control groups ($n = 922$). In general, the intervention and control groups had similar demographic characteristics, smoking and cessation history and clinical history of heart disease (*P* ranged from 0.21 to 0.71). However, patients in the intervention group had a higher stage of readiness to quit smoking than the control group (contemplation/preparation stage: 37% versus 27%, $P < 0.001$) (Table 1).

Intervention, study completion and loss to follow-up

Figure 1 shows the Consolidated Standards of Reporting Trials (CONSORT) chart. Among the 938 patients in the intervention group who received baseline face-to-face stage-matched smoking cessation counselling, 54.4% (510 of 938) received both 1-week and 1-month telephone follow-up counselling; 35.4% (332 of 938) received either 1-week or 1-month telephone counselling; and 10.2% (96 of 938) did not receive any telephone counselling after the initial counselling session. All patients in the control group received face-to-face 15-minute healthy diet counselling and a leaflet on healthy diet at baseline.

At the 3-month telephone follow-up, 87.4% (820 of 938) of the intervention and 87.7% (809 of 922) of the control groups were contacted; and 86.5% (811 of 938) of the intervention and 86.1% (794 of 922) of the control groups were retained at 6 months. At 12-month follow-up, 85.5% (802 of 938) of the intervention and 84.3% (777 of 922) of the control groups provided data. No statistically significant difference in retention rates was found between the two groups. A total of 25 patients (intervention: 16 versus control: 9, $P = 0.23$) died during the study period. Excluding the deceased cases, the baseline characteristics were similar between those who did ($n = 1579$ of 1835) and those who did not respond at 12 months (lost to follow-up, $n = 256$ of 1835), except that there were more patients who were single or widowed at baseline in those lost to follow-up in the control group.

Primary and secondary outcomes

For the primary outcomes, the intervention group and the control group had similar self-reported 7-day PP tobacco abstinence (intervention: 26.5% versus control: 25.5%, $P = 0.60$) and self-reported 30-day PP abstinence (intervention: 25.4% versus control: 24.2%, $P = 0.55$) at 12-month follow-up.

For the secondary outcomes, the intervention group had a higher self-reported 7-day PP of abstinence at 3 months (intervention: 22.9% versus control: 17.8%; $P = 0.006$) and at 6 months (intervention: 27.8% versus control: 21.7%; $P = 0.002$). Similarly, the intervention group had a higher self-reported 30-day abstinence at 3 months (intervention: 19.6% versus control: 15.3%; $P = 0.01$) and at 6 months (intervention: 25.8% versus control: 20.3%; $P = 0.005$) telephone follow-up. However, no statistically significant difference was found in the biochemically validated quit rates at 12 months between the intervention (6.6%) and control (4.9%)

Table 1 Baseline characteristics of the participants.

	Intervention[c] *(n = 938)*	*Control*[d] *(n = 922)*	*P-value*
Sex, *n* (%)			0.22
Male	859 (91.6)	834 (90.5)	
Female	79 (8.4)	88 (9.5)	
Age, mean ± SD, years	58.0 ± 14.1	58.6 ± 14.1	0.38
Education level[a], *n* (%)			0.40
Primary or below	445 (48.0)	460 (50.1)	
Secondary	396 (42.7)	365 (39.7)	
Tertiary or above	86 (9.3)	94 (10.2)	
Marital status, *n* (%)			0.45
Single	103 (11.0)	84 (9.1)	
Married/cohabitating	710 (75.7)	699 (75.8)	
Divorced	54 (5.8)	61 (6.6)	
Widowed	71 (7.6)	78 (8.8)	
Fagerström Nicotine Dependence Score, mean ± SD	2.62 ± 2.1	2.51 ± 2.1	0.21
Years of regular smoking, mean ± SD	38.9 ± 15.5	39.8 ± 15.4	0.25
Daily cigarette consumption, mean ± SD	12.0 ± 8.3	11.6 ± 8.1	0.26
Previous serious quit attempts, *n* (%)			
0	214 (22.8)	224 (24.3)	0.24
≥1	724 (77.2)	698 (75.7)	
Stage of readiness to quit, *n* (%)			<0.001
Pre-contemplation stage	591 (63.0)	673 (73.0)	
Contemplation stage	232 (24.7)	179 (19.4)	
Preparation stage	115 (12.3)	70 (7.6)	
Type of heart disease[a], *n* (%)			0.71
Coronary heart disease	459 (51.5)	460 (52.0)	
Others[b]	441 (48.5)	425 (48.0)	
Duration of cardiac disease[a], *n* (%)			0.26
Less than 1 year	238 (26.3)	227 (25.5)	
1 year to less than 3 years	299 (33.1)	263 (29.5)	
3 years to less than 6 years	207 (22.9)	228 (25.6)	
At least 6 years	160 (17.7)	173 (19.4)	

[a]Missing data are excluded. [b]Included congenital heart diseases, arrhythmia, other cardiovascular diseases. [c]Stage-matched smoking cessation counselling. [d]Healthy Diet Education Programme. SD: standard deviation.

groups ($P = 0.14$) (Table 2). Among the 484 who reported abstinence for at least 7 days at 12 months, 130 (26.9%) participated in the biochemical validation, and the participation rates did not differ between the intervention (28.5%; 71 of 249) and the control group (24.7%; 58 of 235) ($P = 0.34$) (Fig. 1). The misreported rate was slightly, but not significantly, lower in the intervention group (intervention: 12.7%, nine of 71 versus control: 22.4%, 13 of 58; $P = 0.14$).

Including the self-reported quitters, 37.1% (348 of 938) in the intervention group reported reduction in cigarette consumption by at least 50% from baseline at 3 months compared to 26.9% (248 of 922) in the control group ($P < 0.001$). The significant difference in smoking reduction rate was sustained at 6 months (intervention: 41.3% versus control: 33.1%; $P < 0.001$), but not at 12 months (intervention: 40.7% versus control: 37.6%; $P = 0.17$). In addition, the intervention group had a higher proportion with quit attempt(s) (tobacco abstinence for at least 24 hours) during the 12-month study period compared to the control group (intervention: 40.3% versus control: 34.3%; $P = 0.007$) (Table 2).

After adjusting for the baseline group differences on the stage of readiness to quit smoking, the intervention effect diminished in most of the secondary outcomes. The two exceptions were the 7-day PP tobacco abstinence at 6 months (adjusted OR = 1.28, 95% CI: 1.03, 1.59, $P = 0.03$) and the smoking reduction rate at 3 months (adjusted OR = 1.62, 95% CI: 1.22, 2.17, $P < 0.001$) (Table 2).

DISCUSSION

Although there were some effects on quitting and smoking reduction at 3 and 6 months, the differences were not sustained at 12 months. After adjusting for the baseline stage of readiness to quit of cardiac patients,

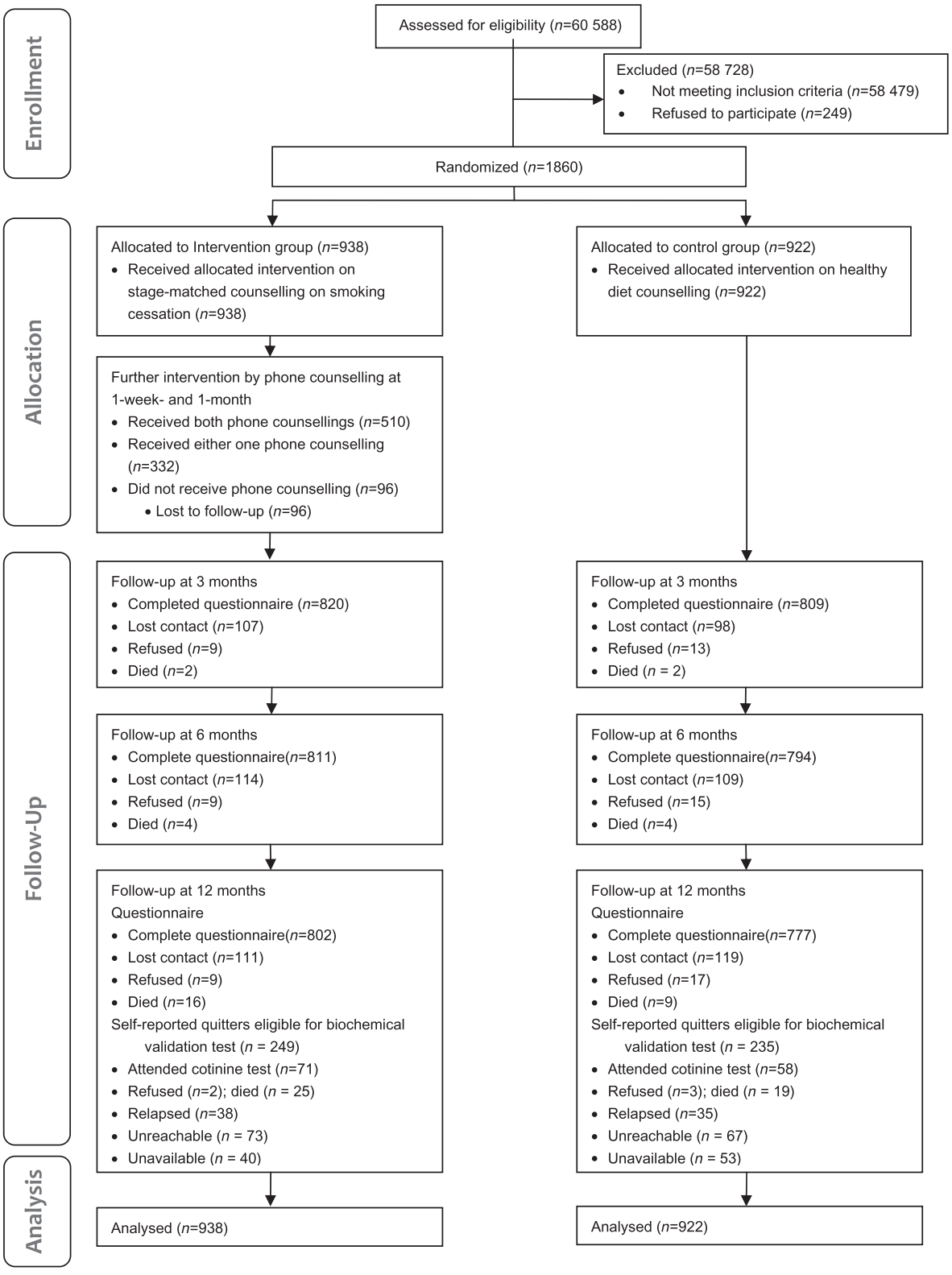

Figure 1 Consort chart of the study

Table 2 Abstinence of tobacco, reduction in smoking at 3-, 6- and 12-month follow-up, and quit attempt(s) within the 12-month period[a].

n (%)	*Intervention*[b] *(n = 938)*	*Control*[c] *(n = 922)*	*Absolute difference in %pt (95% CI)*	*OR (95% CI)*	*Adjusted OR*[d] *(95% CI)*
Primary outcome at 12 months					
Self-reported 7-day PP quit rate	249 (26.5)	235 (25.5)	1.06 (–2.93, 5.05)	1.06 (0.86–1.30)	0.95 (0.77–1.18)
Self-reported 30-day PP quit rate	238 (25.4)	223 (24.2)	1.19 (–2.74, 5.11)	1.07 (0.86–1.32)	0.96 (0.77–1.19)
Secondary outcome					
Self-reported 7-day PP quit rate					
3 months	215 (22.9)	164 (17.8)	5.13 (1.47, 8.80)	1.37 (1.09–1.73)**	1.22 (0.97–1.55)
6 months	261 (27.8)	200 (21.7)	6.13 (2.21, 10.06)	1.39 (1.13–1.72)**	1.28 (1.03–1.59)*
Self-reported 30-day PP quit rate					
3 months	184 (19.6)	141 (15.3)	4.32 (0.87, 7.78)	1.35 (1.06–1.72)**	1.19 (0.93–1.53)
6 months	242 (25.8)	187 (20.3)	5.52 (1.69, 9.35)	1.37 (1.10–1.70)**	0.87 (0.70–1.07)
Biochemically validated quit rate					
12 months	62 (6.6)	45 (4.9)	1.73 (–0.39, 3.85)	1.35 (0.91–2.00)	1.26 (0.85–1.87)
Self-reported reduction in daily cigarette consumption ≥50%					
3 months	348 (37.1)	248 (26.9)	10.2 (5.96, 14.44)	1.60 (1.32–1.95)***	1.62 (1.22–2.17)***
6 months	387 (41.3)	305 (33.1)	8.18 (3.78, 12.57)	1.42 (1.18–1.72)***	1.21 (0.92–1.60)
12 months	382 (40.7)	347 (37.6)	3.09 (–1.35, 7.53)	1.14 (0.95–1.37)	1.20 (0.91–1.57)
Had quit attempt(s) for at least 24 hours within the 12-month period	378 (40.3)	316 (34.4)	6.03 (1.63, 10.42)	1.29 (1.07–1.56)**	1.18 (0.97–1.43)

*P-value < 0.05; **P-value < 0.01; ***P-value < 0.001. [a]By intention-to-treat analysis: assumed all non-responded follow-up patients as current smokers, who did not made a quit attempt over the period, and did not change their smoking behaviour compared to baseline. [b]Stage-matched smoking cessation counselling. [c]Healthy Diet Education Programme. [d]Odds ratio (OR) adjusted for the baseline stage of readiness to quit smoking. CI: confidence interval; PP: point prevalence.

nearly all the short-term effects diminished, except that the intervention group seemed more likely to quit smoking at 6-month follow-up and reduce smoking consumption at 3-month follow-up.

There are a few possible explanations for the lack of long-term effectiveness of the stage-matched counselling intervention in the study. First, only 54.4% (510 of 938) patients in the intervention group had completed both the 1-week and 1-month telephone reminder sessions, which might have weakened the effectiveness of the intervention. Secondly, the overall abstinence rates were overestimated. The biochemically validated abstinence rates at 12 months were very low compared to the self-reported measures. The major reason for the large discrepancy was the low participation rate in the validation tests (<30%). The misreported rates in our study were substantial, and hence the overall abstinence rates were overreported. Furthermore, the inflation in the abstinence rate was higher in the control group, which would have reduced our effect size.

Our findings deviate from some recent systematic review studies, which that suggested behavioural or psychoeducational therapy has a positive effect on helping smokers with heart disease to stop smoking [7,16,18–20]. However, these reviews combined studies with mixed behavioural intervention approaches with and without pharmacotherapy, and the intensity of the behavioural support varied. Huttunen-Lenz and colleagues reviewed randomized controlled trials (RCTs) of smoking cessation interventions on cardiac patients [7] and identified two RCTs which applied the stage-of-change theory in the experimental group (versus usual care) [21,22]. Neither study found that such counselling increased the rate of abstinence in cardiac patients. Additional intervention approaches may be necessary for smokers with heart disease. One possible direction is to add a complementary pharmacotherapy to the behavioural intervention [7,18–20]. Some previous studies demonstrated that smoking cessation intervention based on behavioural therapy with pharmacotherapy using NRT, bupropion or varenicline were associated with higher rates of smoking abstinence in cardiac patients compared with placebo or usual care [19,23,24]. However, medical advice should be sought for use of NRT and other pharmacological products such as buproprion for patients with severe cardiovascular diseases, including heart failure, stable angina or occlusive peripheral artery disease. In rare cases, NRT may cause serious adverse events, including heart palpitations and chest pains [25], while bupropion may increase the rate of ischaemic heart disease [26]. Another potential option would be smoking reduction programmes with the ultimate goal of complete

cessation, which was shown to be effective for smokers not willing to quit [27].

Our study had some limitations. First, some cardiac out-patient clinics provided rehabilitation programmes which included health talks or brief advice on smoking cessation as their usual or standard care (but no stage-matched counselling). It is plausible that our intervention might overlap with the usual standard care which patients from the control group received. As brief intervention in an out-patient setting is effective [28], the usual care might have biased the effect towards null. However, the timing of usual care varied from hospital to hospital, and advice was not specific and brief. This might partly explain the higher 7-day PP quit rates and reduction rates observed in the intervention group at interval follow-ups, and the insignificant differences at the 12-month follow-up, as the proportion of patients with positive outcomes in the control group caught up with the intervention group. Secondly, despite our multiple attempts and financial incentives, we could only manage to encourage just over one-quarter of the self-reported quitters to attend the biochemical validation. Rigotti *et al*. also reported a low participation rate in hospital patients even when a financial incentive was offered, and sample collection was made as easy as possible for the participants [29]. In our study, the two major reasons for quitters not attending the validation were 'unreachable' (39.4%, 140 of 355) and 'unavailable' (26.2%, 93 of 355). Because it is well known that smoking causes heart diseases, it would be more likely for cardiac patients to hide their smoking status compared to other smokers without smoking-related diseases [27].

In conclusion, given a relatively large sample size compared to other relevant studies, stage-matched counselling intervention resulted in earlier cessation and reduction of smoking compared to the control group at 3- and 6-month follow-up, but the benefits were not sustained at 12 months. Further studies on other smoking cessation interventions and relapse prevention for cardiac patients are warranted.

Clinical trial registration

Clinical trial registration number: (http://www.controlled-trials.com number, ISRCTN32840413).

Declarations of interest

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Supporting information

Additional Supporting Information may be found in the online version of this article:

Appendix S1 Staging algorithm for assessing stage of readiness to quit.
Appendix S2 The study protocol for providing stage-matched smoking cessation counselling.

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