

Smoking-Cessation and Adherence Intervention Among Chinese Patients with Erectile Dysfunction

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Background: Whether the association between smoking and erectile dysfunction is causal is uncertain. No RCTs have been previously conducted on cessation counseling and additional nicotine replacement therapy (NRT) adherence counseling among smokers with erectile dysfunction.

Purpose: The aim of the study was to determine if smoking-cessation counseling in conjunction with NRT increases quitting and NRT adherence compared to usual care, and if stopping smoking would improve erectile function among Chinese erectile dysfunction patients who smoke.

Design: An RCT was conducted. Data were collected in 2004–2007 and analyzed in 2008.

Setting/participants: The sample included 719 Chinese adult erectile dysfunction patients who smoked at least 1 cigarette per day, intended to quit smoking within the next 7 days, and would use NRT.

Interventions: Group A1 received 15-minute smoking-cessation and 3-minute NRT adherence counseling at baseline, 1 week, and 4 weeks with free NRT for 2 weeks. Group A2 received the same treatment, except for the adherence counseling. Group B received 10 minutes of quitting advice. All subjects received a self-help quitting booklet at first contact.

Main outcome measures: Self-reported 7-day tobacco abstinence at 6 months, 4-week NRT adherence at 1 month, and improvement in erectile dysfunction condition at 6 months.

Results: The intervention groups (A1 + A2) achieved higher rates of abstinence, both self-reported (23% vs 12.8%, RR=1.79, 95% CI=1.22, 2.62) and biochemically validated (11.4% vs 5.5%, RR=2.07, 95% CI=1.13, 3.77), than the control group. The NRT adherence rate did not differ between Groups A1 and A2 (13.7% vs 12.7%, RR=1.08, 95% CI=0.69, 1.69). An improvement in erectile dysfunction status from baseline to 6 months was associated with self-reported quitting at 6 months but not with intervention status.

Conclusions: Although quitting smoking was associated with improvement in erectile dysfunction, this study found significant outcome differences among the means used to achieve smoking cessation.

Trial registration: ISRCTN13070778.

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Introduction

Cigarette smoking is a leading public health challenge globally. The prevalence of smoking is greater among men than women and is increasing among adolescents and young adults.¹ Erectile dysfunction is a prevalent health problem that has considerable impact on the quality of life of middle-aged men.^{2–4} Recent data^{5–9} suggest an independent and dose-response relationship between smoking and the risk of erectile dysfunction. A cross-sectional study⁵ showed

that Chinese men in Hong Kong who smoked ≥ 20 cigarettes daily had a 50% higher risk of having erectile dysfunction; and ex-smokers had a 30% lower risk of having erectile dysfunction than those who smoked ≥ 20 cigarettes daily. Another cross-sectional study⁷ in China further showed an increasing trend in the risk of erectile dysfunction with cigarette smoking. Improvement in erectile dysfunction in smokers after they stopped smoking was observed in a prospective study¹⁰ in Iran.

Motivating male smokers to stop smoking is an important public health challenge in most Asian countries, as men make up the majority of the smoking population. China has the largest smoking population in the world, and cardiovascular disease is the number one killer, accounting for 22.5% of all deaths in 2000.¹¹ In China, the prevalence of smoking in men was 57% in 2002,¹² and 11.8 million erectile dysfunction cases were attributable to smoking if the association is causal.⁷

Patients with erectile dysfunction have a high risk of coronary heart disease.¹³ Although there is still disagreement about whether the relationship between smoking and erectile dysfunction is causal,^{14,15} erectile dysfunction is an important smoking-related health problem that has the potential to command more attention and create stronger motivation to quit among young people than do other diseases. Many governments have introduced health warnings about smoking and erectile dysfunction on cigarette packs; some state that “smoking *causes* erectile dysfunction”¹⁶ whereas others state that “smoking *may cause* erectile dysfunction.”¹⁷

Nicotine replacement therapy (NRT) can double the quit rate, but few smokers using NRT adhere to the recommended treatment regimens.^{18–20} Many studies^{18,21} reported a positive relationship between NRT adherence and cessation. One study²² examined the reasons for nonadherence in smokers attempting to quit, but there have been no reported interventions designed to increase NRT adherence.

An RCT was conducted to study the effectiveness of a smoking-cessation intervention, test the efficacy of brief counseling on adherence to NRT use, and examine the positive effects of quitting smoking on erectile dysfunction in Chinese patients. It was hypothesized that (1) the percentage of those who quit would be higher in the intervention groups than in the usual or minimal care group; (2) adherence to NRT would be greater in the group receiving both smoking-cessation and NRT adherence counseling than in the group receiving only smoking-cessation counseling; and (3) smoking cessation would improve erectile function.

Methods

Participants

Male subjects were recruited via mass media publicity and referrals from hospitals/clinics and physicians from January 2004 to April 2007 in Hong Kong. Subjects were eligible for inclusion if they were Chinese, male, aged ≥ 18 years, had self-reported erectile dysfunction, smoked at least 1 cigarette per day, intended to quit smoking within 7 days of the first contact, would use NRT, had no contraindication to NRT, and were not following other smoking-cessation regimens. Subjects who did not meet these criteria; were psychologically or physically unable to communicate; were taking regular psychotropic medications; or had any serious health problems that rendered them unsuitable for using NRT, such as recent stroke, palpitation, or other life-threatening conditions, were excluded. The five-item International Index of Erectile Function (IIEF-5) measurement tool was not used for screening because there is usually no objective test to confirm erectile dysfunction, and doctors always accept self-report of erectile dysfunction in order to establish cases in a clinical setting. In addition, the authors believed that men would not report having erectile dysfunction if they have no symptoms.

Study Design

This was a single-blinded RCT, approved by the ethical committees of the University of Hong Kong on February 19, 2003, and each participating clinic and hospital. All subjects provided written informed consent prior to randomization. Subjects were randomly assigned to either the intervention group (A1 and A2) or the control group (B). Members of intervention groups were further randomly assigned to Groups A1 and A2.

Intervention

Intervention Group A1 received a 15-minute face-to-face smoking-cessation counseling session and a 3-minute NRT adherence counseling session with a trained male counselor, in addition to 1 week of free NRT (either nicotine gum or patch) at the first contact. Intervention Group A2 received the same intervention as Group A1, except for the 3-minute NRT adherence counseling. A patient-centered approach was used that utilized motivational interviewing techniques²³ and the recommended AHCPR clinical practice guidelines for smoking cessation.²⁴ The smoking-cessation counseling used the 4R approach²⁴ to boost motivation to quit; included information on the health consequences of smoking; emphasized benefits of quitting; encouraged smokers to quit; and identified barriers and provided suggestions for overcoming them, with specific counseling on the relationship between smoking/quitting smoking and erectile dysfunction. The NRT adherence intervention was developed from the WHO guidelines²⁵ on adherence interventions, which emphasize the importance of adhering to the prescribed NRT dosage, and assessed and discussed ways to overcome barriers, and delivered problem-oriented interventions to improve adherence. Control Group B received a 10-minute face-to-face counseling session, with simple advice to quit smoking. Subjects in all groups were tested for exhaled carbon monoxide (CO) level and received a self-help quitting pamphlet titled “Easy Steps to Quitting” produced by the Hong Kong Council on Smoking and Health.²⁶ Subjects in Groups A1 and A2 also received a telephone hotline number of the counselor to use as needed.

Further counseling and testing for exhaled CO were provided at 1 week and 4 weeks in the two intervention groups. At Week 1, a total of 3 weeks of additional free NRT was planned, but only 1 week of free NRT was offered because further NRT sponsorship could not be obtained. Thus, a total of 2 weeks (at first contact and at the 1-week follow-up) of free NRT was provided; only nicotine patches and nicotine gum were offered, with participants allowed to choose according to their preference. Group A1, but not Group A2, was checked for NRT usage and received additional adherence counseling. At 4 weeks, both groups were checked for use of NRT and received smoking-cessation counseling as needed. Checking of NRT usage included checking the use of the patch on the body and levels of used and unused NRT. Self-reported quitters who reported stopping smoking in the past 7 days were invited for a biochemical validation of urinary cotinine and exhaled CO levels at 1 and 4 weeks. The counseling intervention was completed on May 13, 2007.

Subjects in Groups A1 and A2 at 3 months and all subjects (including Group B) at 6 months received follow-up telephone contact by trained interviewers who were blinded to the intervention assignment. At least seven attempts were made at different time periods before the subjects were categorized as lost to follow-up. At 3 months, detailed information on NRT use up to 8 weeks was collected for the two intervention groups. At 6 months, information on smoking status; nicotine dependency measured by the Fagerström Test of Nicotine Dependency (FTND);²⁷ quit attempts; cessation methods used; psychosocial factors; and erectile function as measured by the IIEF-5²⁸ was obtained via a standardized questionnaire. All self-reported quitters were invited for biochemical validation of urinary cotinine and exhaled CO levels, and a travel allowance (HK\$200; US\$1=HK\$7.8) was offered to subjects who presented for validation.

Outcome Measures

The two primary outcome measures were (1) self-reported 7-day point-prevalence tobacco abstinence at 6 months and (2) continuous use of NRT for 4 weeks (4-week adherence rate) at 1 month. Self-reported quitting was validated by exhaled CO and urinary cotinine levels. Subjects were considered current smokers if they were lost to follow-up or had an exhaled CO level >8 ppm or urinary cotinine concentration >115 ng/mL.²⁹ The main secondary outcome was the change in IIEF-5 scores from baseline to 6 months. Other secondary outcomes included validated quit rate and self-reported reduction ($\geq 50\%$) in cigarette consumption at 6 months and 8-week NRT adherence rate at 3 months.

Statistical Analysis

The required sample size was calculated based on both primary outcomes in order to provide, conservatively, at least 90% power with a 5% significance level. A total of 1210 subjects (422 in A1, 422 in A2, and 366 in B) were needed to detect a 10% difference simultaneously in (1) self-reported 7-day point-prevalence quit rate between intervention groups (A1 + A2) and control group B (26% vs 16%); (2) 4-week adherence rate (29% vs 19%); and (3) self-reported quit rate (31% vs 21%) between Groups A1 and A2. Further, assuming 70% participation, a goal was set of recruiting 1729 subjects.

To test the effectiveness of the smoking-cessation intervention with counseling and NRT, the two intervention groups (A1 and A2) were combined and compared to the control group (B). To test the effectiveness of the NRT adherence intervention, the two inter-

vention groups were compared. Tobacco abstinence and reduction and NRT adherence between groups were compared using Pearson's chi-square tests. Exploratory analysis was conducted on the IIEF-5 score by group smoking status at 6 months. Generalized linear regression (binomial distribution and a log link function) was used to examine the effects of the intervention and smoking status on improvement in at least one stage on IIEF-5 score at 6 months (Table 1). Those who were missing IIEF-5 scores were excluded from the analysis. Relative risk (RR) and 95% CI were reported whenever applicable. Baseline group differences were tested by chi-square tests for categorical variables and ANOVA for normally distributed continuous variables. All analyses were performed with SPSS, version 16.0, in 2008.

Results

Enrollment

A total of 1469 male smokers were screened for study eligibility (Figure 1). Among the 438 subjects who did not meet the inclusion criteria, 66% did not have erectile dysfunction and 24.9% were nonsmokers. Of 999 eligible subjects, 719 (72%) agreed to participate and underwent randomization, resulting in 249 in the smoking-cessation and NRT adherence group (A1), 252 in the smoking-cessation group (A2), and 218 in the control group (B). In all, 345 of the subjects (48%) were recruited via publicity through mass media; 242 (33.7%) from the Men's Health Clinic of the Family Planning Association; 107 (14.9%) from Kwong Wah Hospital (an erectile dysfunction clinic); and 25 (3.5%) from physician referrals.

There was no significant difference between Groups A1 and A2 in retention rate at the three time points (at 1 week: 84.3% vs 80.2%, $p=0.29$; at 1 month: 66.3% vs 63.9%, $p=0.64$; at 3 months: 77.9% vs 72.6%, $p=1.00$) or at 6 months across the three groups (A1: 76.3%, A2: 70.2%, B: 71.5%, $p=0.28$). All the subjects (719) were included in the analyses using intention-to-treat, and 523 subjects (73%) completed the 6-month follow-up. At 6 months, noncompleters were younger than completers (aged 47 vs 49 years, $p=0.02$) but did not differ significantly in the age of starting smoking, years of smoking, number of cigarettes smoked daily, nicotine dependency, or severity of erectile dysfunction. Baseline demographic characteristics, history of smoking and quitting, and erectile dysfunction condition were similar in all three groups, except that more subjects in Group A1 and fewer subjects in Group A2 had taken erectile dysfunction medication in the past month than in the control group (Table 1).

Tobacco Abstinence and Reduction in Cigarette Consumption

Subjects who received smoking-cessation counseling and NRT were more likely to quit (23%) than those in the control group (12.8%) at 6 months (primary outcome: self-reported

7-day point-prevalence quit rate $RR=1.79$, 95% $CI=1.22, 2.62$, $p=0.003$). For secondary outcomes, the biochemically confirmed quit rates were also significantly different ($RR=2.07$, 95% $CI=1.13, 3.77$, $p=0.02$). The overall level of participation for validation was 60.1% (86/143), with 62.6% (72/115) in the intervention groups and 50.0% (14/28) in the control group, respectively ($RR=1.25$, 95% $CI=0.84, 1.86$, $p=0.27$). Of the 72 subjects who participated in the validation test in the intervention groups, 57 (79.2%) had a urinary nicotine level <115 ng/mL and expired CO level <9 ppm, as compared with 12 (85.7%) of 14 subjects in the control group ($RR=0.92$, 95% $CI=0.72, 1.19$, $p=0.52$). Including quitters, more subjects in the intervention groups than in the control group had reduced their daily cigarette consumption by at least 50% from baseline to 6 months ($RR=1.52$, 95% $CI=1.20, 1.92$, $p=0.001$). The results were similar and remained significant when the self-reported quitters were excluded from the analysis ($RR=1.46$, 95% $CI=1.03, 2.08$, $p=0.04$).

Adherence to Nicotine Replacement Therapy

The two intervention groups did not differ significantly in their adherence to NRT for 4 weeks (13.7% vs 12.7%,

Table 1. Baseline characteristics of patients who smoked and had erectile dysfunction, M (SD) unless otherwise indicated

| Characteristics | Smoking-cessation and NRT adherence counseling (A1) (n=249) | Smoking-cessation counseling (A2) (n=252) | Self-help material (B) (n=218) |
|---|---|---|--------------------------------|
| Age (years) | 48.9 (11.8) | 48.7 (11.2) | 49.2 (11.4) |
| Marital status (n [%]) | | | |
| Married/cohabiting | 200 (80.6) | 194 (77.0) | 180 (82.6) |
| Others | 48 (19.4) | 58 (23.0) | 38 (17.4) |
| Education level (n [%]) | | | |
| Primary or below | 54 (21.7) | 49 (19.4) | 45 (20.6) |
| Secondary | 162 (65.1) | 162 (64.3) | 150 (68.8) |
| Tertiary or above | 33 (13.3) | 41 (16.3) | 23 (10.6) |
| Age started smoking (years) | 18.3 (4.6) | 18.6 (5.2) | 18.7 (5.0) |
| Years of smoking | 30.4 (12.1) | 30.1 (11.5) | 30.5 (11.5) |
| Cigarettes smoked per day in the past 30 days | 20.4 (10.0) | 21.1 (12.3) | 20.1 (9.7) |
| FTND score^a | 4.6 (2.5) | 4.6 (2.4) | 4.4 (2.5) |
| Quit attempts (n [%]) | | | |
| None | 70 (28.5) | 76 (30.3) | 53 (24.8) |
| 1 | 51 (20.7) | 46 (18.3) | 56 (26.2) |
| 2–5 | 95 (38.6) | 109 (43.4) | 85 (39.7) |
| 6–10 | 12 (4.9) | 11 (4.4) | 9 (4.2) |
| >10 | 18 (7.3) | 9 (3.6) | 11 (5.1) |
| Taking medicine for erectile dysfunction in the last month (n [%]) | 74 (29.7) | 50 (19.8) | 56 (25.7) |
| IIEF-5 score by stage (n [%])^b | | | |
| Severe (0–7) | 77 (35.6) | 90 (38.8) | 72 (37.5) |
| Moderate (8–11) | 32 (14.8) | 31 (13.4) | 28 (14.6) |
| Mild to moderate (12–16) | 58 (26.9) | 68 (29.3) | 47 (24.5) |
| Mild (17–21) | 39 (18.1) | 32 (13.8) | 35 (18.2) |
| No erectile dysfunction (22–25) | 10 (4.6) | 11 (4.7) | 10 (5.2) |

^aPossible range from 1 to 10, with higher scores indicating greater dependency on nicotine

^b33 subjects from Group A1, 20 from Group A2, and 26 from Group B were excluded from analysis because of missing data.

FTND, Fagerström Test for Nicotine Dependence; IIEF-5, International Index of Erectile Function (five-item version); NRT, nicotine replacement therapy

$RR=1.08$, 95% $CI=0.69, 1.69$, $p=0.75$) at 1 month as a primary outcome, and for at least 8 weeks at 3 months, as a secondary outcome (7.2% vs 3.6%, $RR=2.02$, 95% $CI=0.93, 4.42$, $p=0.08$; Table 2). Further analysis showed that the self-reported 7-day abstinence rate in Group A1 (26.1%) was higher than in Group A2 (21.0%) at 3 months, although the difference was nonsignificant ($RR=1.24$, 95% $CI=0.90, 1.71$, $p=0.18$).

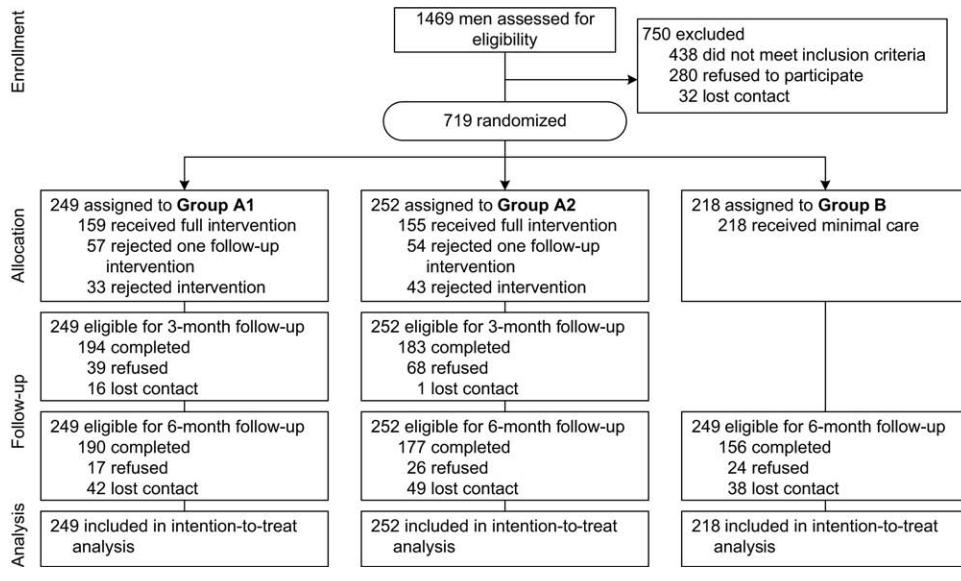


Figure 1. CONSORT chart

Erectile Function Score

At 6 months, 77 of the 143 quitters (53.8%) reported improvement in their erectile dysfunction, as compared with 162 of the 576 nonquitters (28.1%; $RR=2.10$, 95% $CI=1.64$, 2.70 , $p<0.001$). Using a generalized linear model with two predictors, self-reported smoking status at 6 months, and intervention group status at baseline, quitting smoking was a significant predictor of improvement in erectile dysfunction ($RR=2.07$, 95% $CI=1.61$, 2.67 , $p<0.001$), but no intervention effect was observed ($RR=1.10$, 95% $CI=0.82$, 1.47 , $p=0.53$).

Discussion

To the authors' knowledge, this is the first RCT to evaluate whether patient-centered counseling in conjunction with NRT can lead to improved outcomes in smoking cessation and erectile dysfunction. In all subjects, quitting smoking was a predictor of improvement in erectile dysfunction. The current RCT results showing that the risk or severity of erectile dysfunction is reduced after quitting smoking provide further evidence for a potential causal relationship between smoking and erectile dysfunction, and no differences were seen by intervention type. The findings should have a strong impact on Chinese and other Asian populations, as erectile dysfunction is more prevalent in Asian than Western populations.^{4,5,30} Erectile dysfunction patients who smoke can expect some concrete benefits that are more readily appreciated because of their immediate, noticeable effect on patients' personal lives than the more abstract and delayed benefits of reducing the risk of heart disease and cancer, which may not come

into play for many months or years after quitting smoking.

Although not directly comparable to other local studies with nurse-delivered interventions, the current intervention achieved a quit rate (23%) slightly lower than that of a smoking-cessation clinic (27%) using counseling along with 1 week of free NRT,¹⁸ but higher than that of a quitline (12%) without NRT.³¹ The fact that the quit rates in the two studies above, which used face-to-face counseling in addition to free NRT, were higher than

those resulting from telephone counseling, is consistent with previous findings that the quit rate increases with the intensity of an intervention.³² Results from the present RCT and previous studies have provided a strong evidence base for the planning and launching of similar smoking-cessation services in China and Asia. In men's health clinics and erectile dysfunction clinics, smoking cessation should be an integral part of the treatment for those clients who both smoke and have erectile dysfunction.

The second goal of the trial was to assess the efficacy of a brief counseling session on NRT adherence. No significant difference was found in NRT adherence rate between Groups A1 and A2 at 1 and 3 months. Difficulties in subject recruitment were encountered despite aggressive outreach efforts and publicity campaigns. Subject recruitment was discontinued in April 2007 per the advice of an independent data monitoring committee after the second interim meeting. This advice was based on the interim analysis, which showed a significant difference in the self-reported quit rate at 6 months between subjects receiving smoking-cessation interventions (Groups A1 and A2) and the controls, but no effect of the NRT adherence intervention at 6 months.

Stopping recruitment into the study should not have introduced any harm to subjects with erectile dysfunction who smoke, as they would receive simple cessation advice in the course of regular clinical care. Many Chinese men with erectile dysfunction do not seek medical help, as erectile dysfunction is a stigma in the conservative Chinese culture. Calculations completed after the study showed that a total of 1762 subjects were required in

order to achieve the desired power of 90% to detect the observed difference in the secondary outcome of adherence rates (8-week adherence rate at 3 months: 7.2% vs 3.6%). Such low adherence rates and small absolute difference confirm that recruiting more subjects (about three times as many) would not be cost effective. In addition, unlike in an earlier study,²² cost was reported as the main reason for discontinuation of NRT at 4 weeks in the trial³³; further studies on adherence intervention using other methods and provision of a full course of NRT are needed.

The finding of a substantial discrepancy between the self-reported and biochemically validated quit rate at 6 months is noteworthy and is likely due to the modest level of participation (60%) in biochemical validation among self-reported quitters at 6 months, as evidenced by the fact that there was about 20% misreported quitting. The self-reported quit rates might thus have been inflated for both groups by incorrect reports of quitting. However, this level of participation was already higher than that in other local studies (10%) and is comparable to that in studies conducted elsewhere (50%).^{34–36} The need for validation was the major reason for refusal to participate, and relapse was the major reason for misreporting in validation tests. Clearly, additional investigation on alternative methods for encouraging participation in validation testing in smoking-cessation research is needed.

Strengths and Limitations

There are two major strengths of the study. First, 72% of eligible patients were enrolled; they were referred by various sources within the community and represent the range of diversity of the population under study, which

Table 2. Abstinence, reduction, and adherence rates by study group, *n* (%) unless otherwise indicated

| Rates | Intervention (A1 + A2) (<i>n</i> =501) | Control (B) (<i>n</i> =218) | Relative risk (95% CI) |
|---|--|--|---------------------------|
| Abstinence rate at 6 months | | | |
| Self-reported 7-day point-prevalence quit rate | 115 (23.0) | 28 (12.8) | 1.79 (1.22, 2.62) |
| Biochemically validated quit rate ^a | 57 (11.4) | 12 (5.5) | 2.07 (1.13, 3.77) |
| Reduction rate at 6 months | | | |
| Reduction in daily cigarette consumption by at least 50% including all subjects | 213 (42.5) | 61 (28.0) | 1.52 (1.20, 1.92) |
| Reduction in daily cigarette consumption by at least 50% excluding self-reported quitters, <i>n</i> /total <i>n</i> | 98/386 (25.4) | 33/190 (17.4) | 1.46 (1.03, 2.08) |
| Adherence rate | | | |
| | Smoking-cessation and NRT adherence counseling (<i>n</i> =249) | Smoking-cessation counseling (<i>n</i> =252) | |
| 4-week adherence rate to NRT at 1 month | 34 (13.7) | 32 (12.7) | 1.08 (0.69, 1.69) |
| 8-week adherence rate to NRT at 3 months | 18 (7.2) | 9 (3.6) | 2.02 (0.93, 4.42) |

^aQuitting was confirmed by a carbon monoxide level in expired air <9 ppm and urinary cotinine level <115 ng/mL.

NRT, nicotine replacement therapy

adds generalizability to the current findings. Second, 64% in intervention Group A1 and 62% in intervention Group A2 complied with the intervention (counseling at baseline, 1 week, and 1 month), whereas only 13% in Group A1 and 17% in Group A2 did not receive further counseling at either 1 week or 1 month. Such compliance rates were considered high for a study conducted in a nonclinical setting with clinical erectile dysfunction patients.

The study has three limitations. First, 24%–28% of subjects were lost to follow-up at 6 months, even after multiple calls. This attrition level resembled the 20%–25% loss in trials of counseling for hospitalized smokers^{37,38} but exceeded the 15% lost to follow-up at 12 months in the RCT of a stage-matched intervention for cardiac patients in Hong Kong.³⁹ The percentage lost to follow-up is unlikely to introduce substantial bias because the percentages were similar in the study arms, and completers largely resembled noncompleters. The cessation rates in this study could have been underestimated because subjects who were lost to follow-up were counted as continuing smokers. Second, following the guidelines, NRT can only be prescribed if a quit date is set.⁴⁰ Hence, the current study was restricted to erectile dysfunction

patients who were ready to quit within 7 days, which may have explained the high cessation rate but also limited the eligibility of subject recruitment. This inclusion criterion means the findings can be generalized to motivated smokers with erectile dysfunction but not to the general smoking population in Hong Kong, where the majority of smokers (51%) were not ready to quit smoking.⁴¹

Third, 31 subjects (4%) were classified as having no erectile dysfunction by the IIEF-5 scores. The small percentages were similar in the study arms and it is possible that some of these subjects do have erectile dysfunction; in particular, those referred by physicians may not have responded honestly to the questionnaire or may have had very mild symptoms that the IIEF-5 was not sensitive enough to detect. Last, NRT use at 6 months was not checked for all subjects, which might affect the validation results of self-reported quitters if some were using NRT at the time they were tested (this could affect urinary cotinine but not exhaled CO). This possibility, however, is unlikely, as usage was already very low early on and prolonged usage was quite costly. Few smokers believed in the effectiveness of NRT, and its usage among smokers in Hong Kong was very low, even when it was provided at no cost.¹⁸

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References

- Warren CW, Jones NR, Eriksen MP, Asma S. Patterns of global tobacco use in young people and implication for future chronic disease burden in adults. *Lancet* 2006;367:749–53.
- Laumann EO, Paik A, Rosen RC. Sexual dysfunction in the U.S.: prevalence and predictors. *JAMA* 1999;281:537–44.
- Parish WL, Laumann EO, Pan S, Hao Y. Sexual dysfunctions in urban China: a population-based national survey of men and women. *J Sex Med* 2007;4:1559–74.
- Laumann EO, Nicolosi A, Flisser DB, et al. Sexual problems among women and men aged 40–80 y: prevalence and correlates identified in the Global Study of Sexual Attitudes and Behaviors. *Int J Impot Res* 2005;17:39–57.
- Lam TH, Abdullah ASM, Ho LM, Yip AWC, Fan S. Smoking and sexual dysfunction in Chinese males: findings from men's health survey. *Int J Impot Res* 2006;18:364–9.
- Fung MM, Bettencourt R, Barrett-Connor E. Heart disease risk factors predict erectile dysfunction 25 years later. *J Am Coll Cardiol* 2004;43:1405–11.
- He J, Reynolds K, Chen J, et al. Cigarette smoking and erectile dysfunction among Chinese men without clinical vascular disease. *Am J Epidemiol* 2007;166:803–9.
- Millett C, Wen LM, Rissel C, et al. Smoking and erectile dysfunction: findings from a representative sample of Australian men. *Tob Control* 2006;15:136–9.
- Gades NM, Nehra A, Jacobson DJ, et al. Association between smoking and erectile dysfunction: a population-based study. *Am J Epidemiol* 2005;161:346–51.
- Pourmand G, Alidaee MR, Rasili S, Makeki A, Mehra A. Do cigarette smokers with erectile dysfunction benefit from stopping? A prospective study. *BJU Int* 2004;94:1310–3.
- He J, Gu D, Wu X, et al. Major causes of death among men and women in China. *N Engl J Med* 2005;353:1124–34.
- Yang G, Ma J, Lin N, Zhou L. Smoking and passive smoking in Chinese. *Chin J Epidemiol* 2005;26:78–83.
- Kirby M, Jackson G, Betteridge J, Friedli K. Is erectile dysfunction a marker for cardiovascular disease? *Int J Clin Pract* 2001;55(9):614–8.
- British Medical Association. Smoking and reproductive life: the impact of smoking on sexual, reproductive and child health. www.bma.org.uk/images/smoking_tcm41-21289.pdf.
- USDHHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. The health consequences of smoking: a report of the Surgeon General. Atlanta GA: USDHHS.
- Health Canada. Graphic Health Warnings. www.hc-sc.gc.ca/hl-vs/tobac-tabac/legislation/label-etiquette/graph/impotent-impuissant4-eng.phpCanada.
- Tobacco Control Office, Department of Health, HKSAR Government. Smoking (Public Health) (Amendment) Bill 2005 guidelines on health warning on packet or retail container of tobacco products. www.tco.gov.hk/english/downloads/files/Pictorial_Health_Warning_bklet_Eng.pdf.
- Lam TH, Abdullah ASM, Chan SSC, Hedley AJ, Hong Kong Council on Smoking and Health Smoking Cessation Health Centre (SCHC) Steering Group. Adherence to nicotine replacement therapy versus quitting smoking among Chinese smokers: a preliminary investigation. *Psychopharmacology (Berl)* 2005;177:400–8.
- Shiffman S, Hughes JR, di Marino ME, Sweeney CT. Patterns of over-the-counter nicotine gum use: persistent use and concurrent smoking. *Addiction* 2003;98:1747–53.
- Johnstone E, Brown K, Saunders C, et al. Level of nicotine replacement during a quit-smoking attempt. *Nicotine Tob Res* 2004;6:377–9.
- Killen JD, Fortmann SP, Davis L, Strausberg L, Varady A. Do heavy smokers benefit from higher dose nicotine patch therapy? *Exp Clin Psychopharmacol* 1999;7:226–33.
- Burns EK, Levinson AH. Discontinuation of nicotine replacement therapy among smoking-cessation attempters. *Am J Prev Med* 2008;34(3):212–5.
- Emmons KM, Rollnick S. Motivational interviewing in healthcare settings: opportunities and limitations. *Am J Prev Med* 2001;20:68–74.
- Fiore MC, Bailey WC, Cohen SJ, et al. Clinical practice guideline: treating tobacco use and dependence. Washington DC: USDHHS, 2000.
- WHO. Adherence to long-term therapies: evidence for action. Geneva: WHO, 2003.
- Hong Kong Council on Smoking and Health. Good reasons for quitting. www.smokefree.hk/cosh/ccs/detail.xml?lang=en&fldrid=221.

27. Heatherington TF, Kozlowski LT, Frecker RC, Fagerström KO. The Fagerström Test for Nicotine Dependence: a revision of the Fagerström tolerance questionnaire. *Br J Addict* 1999;6:1119–27.
28. Rosen RC, Cappelleri JC, Smith MD, Lipsky J, Pena BM. Development and evaluation of an abridged, 5-item version of the International Index of Erectile Function (IIEF-5) as a diagnostic tool for erectile dysfunction. *Int J Impot Res* 1999;11:319–26.
29. Jarvis MJ, Tunstall-Pedoe H, Feyerabend C, Vesey C, Saloojee Y. Comparison of tests used to distinguish smokers from non-smokers. *Am J Public Health* 1987;77:1435–8.
30. Ng EML, Cheng JYW. Prevalence and biopsychosocial correlates of erectile dysfunction in Hong Kong: a population-based study. *Urology* 2007;70:131–6.
31. Abdullah ASM, Lam TH, Chan SSC, Hedley A. Which smokers use the smoking cessation quitline in Hong Kong, and how effective is the quitline? *Tob Control* 2004;13:415–21.
32. Fiore MC, Jaén CR, Baker TB, et al. Treating tobacco use and dependence: 2008 update. Rockville MD: USDHHS, 2008. www.ahrq.gov/path/tobacco.htm#Clinic.
33. Chan SSC, Leung DYP, Abdullah ASM, et al. Reasons for non-compliance to nicotine replacement therapy among Chinese smoking patients with erectile dysfunction. Presented at the 7th annual conference of the International Society for the Prevention of Tobacco Induced Disease (ISPTID)—A tobacco free future: the way forward; 2008 Sept 26–28; Kyoto, Japan.
34. Smith PM, Burgess E. Smoking cessation initiated during hospital stay for patients with coronary artery disease: a randomized controlled trial. *Can Med Assoc J* 2009;180(13):1297–303.
35. Rigotti NA, Arnsten JH, McKool KM, Wood-Reid KM, Pasternak RC, Singer DE. Efficacy of a smoking cessation program for hospital patients. *Arch Intern Med* 1997;157(22):2653–60.
36. Prokhorov AV, Yost T, Mullin-Jones M, et al. The “Look At Your Health”: Outcomes associated with a computer-assisted smoking cessation counseling intervention for community college students. *Addict Behav* 2008;33:757–71.
37. Hennrikus DJ, Lando HA, McCarty MC, et al. The TEAM project: the effectiveness of smoking cessation intervention with hospital patients. *Prev Med* 2005;40:249–58.
38. Quist-Paulsen P, Gallefoss F. Randomised controlled trial of smoking cessation intervention after admission for coronary heart disease. *BMJ* 2003;327:1254–7.
39. Chan SSC, Chan SC, Lau CP, Lam TH. The effectiveness of a stage-matched smoking cessation intervention for cardiac patients: a randomized controlled trial. Poster presented at the 13th World Conference on Tobacco or Health; 2006 July 12–15; Washington DC. 2006.confex.com/uicc/wctoh/techprogram/P8926.HTM.
40. National Institute for Clinical Excellence. Guidance on the use of nicotine replacement therapy (NRT) and bupropion for smoking cessation. Technology Appraisal Guidance, No. 39. London: National Institute for Clinical Excellence, 2005.
41. Social Surveys Section. Thematic Household Survey Report No. 26: Pattern of smoking. Hong Kong: Census and Statistics Department, June 2006. www.censtatd.gov.hk/products_and_services/products/publications/statistical_report/social_data/index_cd_B1130226_dt_latest.jsp.

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