The effect of physician’s 30 s smoking cessation intervention for male medical outpatients: a pilot randomized controlled trial

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ABSTRACT

Objective To study the effectiveness of a very brief advice (<30 s) on smoking cessation.

Design A ‘proof-of-principle’ single-blind, randomized controlled trial (RCT).

Setting Medical outpatient clinics of a general hospital in Guangzhou, China.

Participants One hundred and twenty-six male current smokers randomly allocated into an intervention (n = 74) and a control group (n = 52).

Intervention A health warning by physicians that half of all smokers would be killed by smoking, an advice to quit immediately and referral to a cessation clinic. The control group received none.

Outcomes Primary: seven-day quitting point prevalence at 6 months. Secondary: 7-day point prevalence at 1, 3 and 12 months, sustained abstinence at 3, 6 and 12 months, smoking reduction by half and cessation clinic attendance.

Results By intention-to-treat analysis, 7-day quitting point prevalence rates at four follow-ups were 27.0, 23.0, 21.6 and 18.9% in the intervention group, compared with 5.8, 3.8, 5.8 and 5.8% in the control group (first three P < 0.05). At 3, 6 and 12 months, sustained abstinence prevalence rates were 18.9, 17.6 and 14.9% versus 3.8, 3.8 and 3.8% (P = 0.035, 0.046, 0.074). More smokers in the intervention group had reduced smoking. Almost no participants attended the cessation clinic.

Conclusion Our findings support the need for large RCTs on minimal interventions with the ‘one in two’ warning.

Keyword smoking

Introduction

China is the largest consumer of tobacco and has the largest number of smokers (>300 million) and deaths due to smoking (~1.2 million in 2005) in the world.¹ The smoking prevalence in men was 52.9%. Among all current smokers, 5.8% intended to quit in the coming month and 10.3% thought of quitting within 12 months, whereas 49.2% had no interest to quit.² A study on six Chinese cities, including Guangzhou, showed that 45.6% of smokers did not intend to quit, and 52.7% had tried to quit. Only 48.2% of those who had consulted a doctor had received advice to quit.³ Specialized smoking cessation services are scarce and unpopular. Despite strong evidence of cost-effectiveness, brief interventions on quitting by physicians as a routine clinical practice are lacking,³–⁵ which is similar around the world.⁶
In busy clinical settings, most if not all physicians cannot find the extra few minutes to advise each smoker to quit. Smoking cessation interventions often include information on the serious diseases caused by smoking and relative risks compared with non-smokers. Although it is known that tobacco kills up to one in every two users, most smokers grossly underestimated their own risk. The absolute risk of half of the deaths could be used as a simple, direct, strong and evidence-based warning for a minimal intervention.  

We found no randomized controlled trial (RCT) on the effectiveness of a minimal smoking cessation intervention of 1 min based on the absolute risk warning of half of the deaths. In this paper, we report a study on whether a very brief advice (30 s and based on the absolute risk warning of half of the deaths) given by physicians to smoking medical outpatients would increase quit rates and/or reduce smoking than no advice in the ‘real world’ practice in Guangzhou, China. The study formed part of a Master of Public Health dissertation of the first author. The originally planned sample size was not attained, but we present the results here as a ‘proof-of-principle’ report.

Methods

Setting
Medical outpatient clinics in the First Municipal People’s Affiliated Hospital of Guangzhou Medical College, which is a large modern general hospital with 1407 beds.

Study design
A single-blind, RCT following the CONSORT statement.10

Inclusion and exclusion criteria
The inclusion criteria were male outpatients who were current smokers attending the clinics. The physician would ask the male patient a question ‘Do you smoke cigarettes?’ All male patients who answered ‘yes’ were eligible. If the patient asked for information about smoking cessation before randomization, he would be excluded. If the patient had some diseases that let the physician think that it would be unethical not to advise him to quit smoking urgently, he would also be excluded.

Physician recruitment
Physicians in the outpatient clinics of internal medicine in the hospital were asked if they could participate in the trial. Those who agreed to participate were recruited and trained for <1 h. Before the trial started, the recruited physicians were briefed by the researchers verbally and were given written instructions, flowcharts, questionnaires and intervention materials to make sure that they understand their role, the standardized intervention and the procedures. The briefing was designed to be short and took less than an hour. During the trial, the researchers regularly communicated with the physicians to ensure that they had followed the procedures.

Randomization and subject allocation
Randomization was based on the serially numbered opaque sealed envelope method. One thousand opaque envelopes with a paper inside either labelled A indicating intervention or B for control were labeled with serial numbers according to the randomized sequence by SPSS. The envelopes were sealed and nailed together with the baseline questionnaires carrying the same number as that on the envelope. The questionnaires nailed with the envelope were given to the physicians, which ensured that they would not know the allocation before opening the envelopes. The physicians were encouraged to ask the smoking status of all patients and enroll as many as practicable. Allocation was done after opening the envelopes sequentially: A for intervention and B for control.

Intervention content
Smoking information including the number of cigarettes smoked per day, the age started smoking and past attempts to quit smoking was asked from all subjects. These questions, which should be asked routinely in clinical history taking, would take about 10–15 s, including the answering time. For the intervention group, the physician said the following in a standardized manner: ‘From medical research, one out of two smokers will be killed by smoking. Smoking is harmful to your health, so you must quit immediately for your health. The smoking cessation clinic is open every Friday afternoon. Please attend the clinic as soon as possible.’ This intervention ‘WAR’: Warn about 1/2 deaths, Advise to quit and Refer took <30 s (and could be done quickly in about 20 s. The control group did not have any intervention, which was the usual practice. No intervention was given at follow-up, which resembled the real world practice.

Follow-up
The follow-up time was 1 month (for the MPH dissertation), 3 months, 6 months and 1 year after randomization with no further intervention. The trained interviewers, who were blinded to intervention/control status, collected the
follow-up data using a standardized questionnaire via telephone (including some demographic data at 1 month, smoking status and quitting). The additional data, such as demographic data, could not be collected by the physicians at baseline at the clinics because they were too busy. Also, collecting too much data at the clinic would make the situation deviating from real world practice.

**Outcomes**
The primary outcome was self-reported, 7-day quitting point prevalence, defined as no smoking at all in the previous 7 days at 6-month follow-up, as in the US Guideline. The secondary outcomes were (i) 7-day point prevalence at 1 month, 3 months and 1 year. (ii) Sustained abstinence at 3 months, 6 months and 1 year defined as no smoking in the previous 7 days at 3-month, 6-month and 1-year follow-up and had not smoked continuously since previous follow-up time points. (iii) Reduction of smoking, defined as the number of cigarettes smoked per day at each of four follow-up time points had reduced by at least half, compared with that at baseline. (iv) Whether or not the enrolled patients attended the smoking cessation clinic after baseline.

**Intention to treat**
Our main results were based on the analysis by intention to treat. All enrolled patients allocated to either arm of the two groups were analysed as allocated, regardless of whether or not they agreed or completed the follow-up. Those without follow-up data were assumed to have not changed their smoking status or amount. We then repeated the analysis on those who were present at follow-up assessment, as intention-to-treat analyses might result in an over-estimated effect size due to a higher follow-up rate in the intervention than in the control group.

**Sample size**
Following Russell’s study, we assumed that the quit rate was 1% in the control group and 4% in the intervention group. With \( \alpha = 0.05 \) and \( \beta = 0.2 \) (power = 80%), the sample size was estimated to be 668 in total. We needed to include 1000 in total to take into account dropouts. However for this pilot, we had only 126 patients successfully included from 1 April till 30 June 2009 and had to stop recruitment to allow a few months for follow-up, writing up and submission of the MPH dissertation. In the event, the baseline quit rates were considerably higher than the 1% we anticipated and as a result, a much smaller sample was needed.

**Statistical analysis**
We calculated the prevalence rate ratio or relative risk (RR) and 95% confidence interval (95% CI) as the quit rate in the control group was not high (<1%). The RRs with 95% CIs at 1 month, 3 months, 6 months and 1 year after randomization were estimated with Cox regression models.

**Ethical consideration**
No informed consent form was needed so that our results could be applicable to the ‘real world’ practices in outpatient clinics. Participants only were asked whether they agreed to follow-up via telephone. This trial was approved by the Ethical Committee of the First Municipal People’s Affiliated Hospital of Guangzhou Medical College.

**Results**
Of 22 physicians in the outpatient clinics of internal medicine in the hospital, 10 (four respiratory, three general medicine, one cardiologist, one endocrinologist and one gastroenterologist) participated voluntarily, including three female and seven male physicians (only two male physicians were smokers). The 12 physicians refused because they were too busy. 67.5% of the completed baseline questionnaires were from the three female physicians. The average number of participants enrolled was 28.3 and 5.8 per female and male physician, respectively. 81.7% of the completed baseline questionnaires were from four respiratory physicians. Not all the physicians asked every patient the smoking status, as they only asked when they were not busy. This was expected and was allowed, given that the clinics were always busy. One hundred and forty-five smoking patients attending the 10 recruited physicians’ clinics meeting the inclusion criteria initially were asked about their smoking history. As the physicians did not (and were not asked to, because we wished to avoid adding extra burden) record how many patients they had not asked about the smoking history, it was not possible to determine how many subjects were eligible for the trial during the subject recruitment period.

Among the 145 patients who were current smokers, 19 met the exclusion criteria. Details of recruitment and follow-up are shown in a CONSORT Flow Chart (Fig. 1). One hundred and twenty-six eligible current smokers were randomly assigned to the intervention group \( (n = 74) \) and the control group \( (n = 52) \), and 4 and 7 refused to be contacted again. Of the 70 and 45 who agreed, the follow-up rates at 1 month, 3 months, 6 months and 1 year were quite similar between the two groups (intervention: 100, 95.7, 90.0 and 82.9%; control: 86.7, 84.4, 80.0 and 75.6%) respectively.
Assessed for inclusion criteria (n = 145)

Excluded (n = 19)
- Consulted for smoking cessation before randomization (n = 2)
- Had some diseases and were asked to quit urgently (n = 17):
  - Acute onset of asthma (n = 5)
  - Acute onset of COPD (n = 10)
  - Lung cancer (n = 2)

Allocated to intervention group (n = 74)

1 month: completed (n = 70), not agreed to follow-up at baseline (n = 4)
- 3 months: completed (n = 67), lost (wrong phone number 1, away on business 2) (n = 3), not agreed to follow-up next time (n = 3)
- 6 months: completed (n = 63), lost (wrong phone number) (n = 1), not agreed to follow-up next time (n = 5)
- 1 year: completed (n = 58), lost (n = 0)

Allocated to control group (n = 52)

1 month: completed (n = 39), lost (wrong phone number 4, away on business 2) (n = 6), not agreed to follow-up at baseline (n = 7)
- 3 months: completed (n = 38), lost (not answer phone call) (n = 1), not agreed to follow-up next time (n = 2)
- 6 months: completed (n = 36), not agreed to follow-up next time (n = 2)
- 1 year: completed (n = 34), lost (n = 0)

Analyzed at baseline (n = 74)
Analyzed at 1, 3, 6 months, 1 year follow-up:
- Present at assessment (n = 70, n = 67, n = 63, n = 58)
- Intention to treat (n = 74, n = 74, n = 74, n = 74)

Analysis

Fig. 1 CONSORT flow chart.
Table 1 shows that the demographic variables at baseline and 1-month follow-up were similar between the two groups. Most participants were new patients. For diagnoses, most were respiratory diseases including relatively stable chronic obstructive pulmonary disease, upper airway infection, pneumonia and cough. The mean age was about 48 years. Most were working, married, above junior education level, from the middle income group, with monthly income
from 2500 RMB to 4999 RMB (US$1 = RMB¥6.3). There were also no significant differences between the two groups in smoking variables at baseline.

Table 2 shows that by intention to treat including all allocated participants, the 7-day quitting point prevalence were 27.0, 23.0, 21.6 and 18.9% in the intervention group, when compared with 5.8, 3.8, 5.8 and 5.8% in the control group (the first three \( P < 0.05 \), the last \( P = 0.062 \)). After excluding participants who did not agree to follow-up, the 7-day quitting point prevalence at 1 month, 3 months and 6 months were greater in the intervention group (all \( P < 0.05 \)), but the difference at 1-year follow-up was of borderline significance (\( P = 0.088 \)). Analysis of those present at assessment showed similar results but with a reduced effect size. Note that although the follow-up contacts could influence the outcomes, there was no increase in quitting at the four follow-up time points (20, 17, 16, 14 quitters in the intervention group and 3, 2, 3, 3 in the control group). Table 3 shows that by intention to treat, the prevalence of sustained abstinence at 3 months, 6 months and 1 year were 18.9, 17.6 and 14.9% in the intervention group, when compared with 3.8, 3.8 and 3.8% in the control group (the first two \( P < 0.05 \), the last \( P = 0.079 \)). Other results were similar but most of the differences were of borderline significance.

Table 4 shows that analysis by intention to treat including quitters, the proportion of smoking reduction in the intervention group was much higher than that in the control group at all follow-up time points (the first three \( P < 0.05 \), the last \( P = 0.067 \)). Analysis by intention to treat excluding quitters showed that the proportion of smoking reduction in the intervention group was greater than that in the control group at 1-month and 6-month follow-up (\( P < 0.05 \)). Other analysis showed similar but mostly nonsignificant results. Because only a few participants attended the smoking cessation clinic (1, 3, 2 and 3 at four time points in the intervention group, compared with 0, 1, 0 and 0 in the control group), no further analysis was done.

Table 5 shows the proportion of quitters with weight increase at four follow-up time points were 57.1, 68.4, 63.2 and 58.8%, compared with 42.9, 40.7, 40.0 and 37.3% in the smokers (\( P > 0.05 \)). Because weight increase is a common consequence of quitting, our results that more quitters reported weight increase, which although not significant, suggested some validity of self-reported quitting.

**Discussion**

**Main finding of this study**

Results from this ‘proof of principle’ study suggest that a very brief intervention by physicians on smoking cessation to smokers is better than no advice in the ‘real world’ practice in the medicine outpatient clinics. Based on the analysis by intention to treat including all randomized subjects, the primary outcome of 7-day quitting point prevalence at 6 months (which was the main outcome in the US Guideline) was greater in the intervention group than in the control group (21.6 versus 5.8%; prevalence rate ratio or
Results on secondary outcomes of quitting were similar. The sustained abstinence at 1 year was 14.9 versus 3.8% (RR = 3.86, P = 0.079). Furthermore, the prevalence of reduced smoking in the intervention group (including or excluding quitters) at four time points were also higher than in the control group. No effect was found on smoking cessation clinic attendance. This was not unexpected as clinic attendance was inconvenient, involving additional costs and
hence unacceptable. We had added this simple oral referral to the intervention, so that the busy physicians did not need to spend extra time to answer queries and would be more willing to provide the brief warning and advice.

Lack of knowledge on how to help smokers to quit was a significant predictor of not asking and advising patients to quit. Our study involved only simple training which could be practiced easily by the doctors. Female physicians were more active in enrolling the participants, which is consistent with our previous finding.

We had not asked whether our subjects intended to quit, as our brief intervention was designed for all smokers, regardless of their intention. Although few smokers wished to quit in China, we expected more intention among patients, especially respiratory patients, than those in the general population. There are no data on the natural quitting rate in China to compare with the quit rate (5.8% for 7-day point prevalence at 6 months) in our control group. Given that 61.5% of our control subjects had past quit attempts, 76.9% had respiratory diseases (and most likely also respiratory symptoms) and all had been asked about smoking by their physicians, having 2 to 3 of 52 smokers reported quitting seemed reasonable.

What is already known on this topic
The Cochrane review on RCTs concluded that simple physician’s advice can increase quitting. Minimal intervention was defined as advice of one to <20 min done once plus up to one follow-up, and the RR of quitting after at least 6 months of follow-up was 1.66 (95% CI 1.42–1.94). The US guideline states that brief interventions are effective and clinicians should use these at every opportunity. The UK NICE guidance on brief intervention suggests 5–10 min. Although more intensive interventions are recommended that ‘more is more’ effective is not supported by the evidence and the biggest effect is probably between no intervention and some form of brief advice and support.

What this study adds
To our best knowledge, our trial is the first which (i) tested an intervention of <30 s, (ii) used the absolute risk warning that one in two smokers will be killed by smoking and (iii) based on ‘real world’ practice with no signed informed consent form, no lengthy questionnaire and no follow-up intervention. It should be noted that the warning of one-half deaths is not found in many websites on smoking and quitting (such as US CDC; http://www.cdc.gov/Features/Smokingcessation), and on pictorial or other health warnings on cigarette packs (http://www.smoke-free.ca/warnings).

Limitations of this study
Our RR of >3 is greater than that in previous reviews. Social desirability could lead to greater reporting of quitting in the intervention group. Because our intervention was very brief with no follow-up intervention, social desirability bias should not be substantial. We did not have biochemical validation of abstinence. The Cochrane review shows that only a minority of trials had such but there is no strong evidence that it will lead to bias in the estimates of relative effect. Previous studies have found good reliability of self-reported data, compared with biochemical assessment. Following Aveyard’s review that ~72% achieving 7-day point prevalence at 6 months will have achieved prolonged abstinence, and 30% of those claiming abstinence did not provide samples or failed validation, our 7-day point prevalence quit rate at 6 months of 21.6 versus 5.8% (number needed to treat, NNT = 6.3) would become 10.9% versus 2.9% (NNT = 12.5). Our NNT probably lying between 6 and 13 is consistent with that of 10 from Aveyard. Other limitations of our trial were as follows: first, our hospital is rated as a grade A hospital and our patients might not represent those in the population because some patients with low income might go to community hospitals or private clinics. Second, our results might not be applicable to female smokers. Third, most of the physicians did not ask each male patient whether he smoked. Because they asked only when they were not busy, we did not know how many eligible patients were missed. However, this could reflect the real situation when our intervention is to be implemented in busy clinics. Fourth, the sample size achieved in our trial had not reached what we had aimed at, leading to no significance in some results, and the number in the intervention group was reached what we had aimed at, leading to no significance in some results, and the number in the intervention group was not similar to that in the control group. We did not have enough sample size to do stratified analysis by potential confounders, such as physicians’ smoking status which could be a critical determinant of both participation and smoking.

Table 5 Self-reported body weight increase among quitters and continuing smokers

<table>
<thead>
<tr>
<th>Weight increase</th>
<th>Quitters n (%)</th>
<th>Smokers n (%)</th>
<th>P-value</th>
<th>Prevalence rate ratio [95% CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 month</td>
<td>13 (57.1)</td>
<td>37 (42.9)</td>
<td>0.40</td>
<td>1.31 (0.70–2.47)</td>
</tr>
<tr>
<td>3 months</td>
<td>13 (68.4)</td>
<td>35 (40.7)</td>
<td>0.110</td>
<td>1.68 (0.89–3.18)</td>
</tr>
<tr>
<td>6 months</td>
<td>12 (63.2)</td>
<td>32 (40.0)</td>
<td>0.18</td>
<td>1.58 (0.81–3.07)</td>
</tr>
<tr>
<td>1 year</td>
<td>10 (58.8)</td>
<td>28 (37.3)</td>
<td>0.22</td>
<td>1.58 (0.77–3.24)</td>
</tr>
</tbody>
</table>
cession. Fifth, the strong effect could be due to the absolute risk warning of half of the deaths. Warning smokers that they are betting their lives by the toss of a coin (50% chance of being killed by smoking) should have stronger impacts than telling them relative risks of specific diseases or that other smokers have died of smoking. But we did not compare the intervention using one-half deaths with other warnings, and further research is needed. Unfortunately, and for unknown reasons, such warning is absent in most, if not all, websites and sources of information on smoking and quitting, and is not shown in pictorial health warnings in cigarette packages worldwide.\(^9\) Finally, our study could have been strengthened with some focus group or in-depth interviews among physicians and smokers. Future research should include qualitative studies on how providers could be motivated to intervene and how patients be motivated to quit or seek further assistance. Although medications were available, none of our physicians prescribed any, which is still the common situation in China and other low and middle countries. Further trials on minimal advice plus medications are warranted.

**Conclusion**

This study shows that a very brief intervention of \(<30\) s by physicians to medical outpatients including a warning of the absolute risk of 1/2 deaths plus brief advice to quit immediately and simple referral to a smoking cessation clinic could be an effective means to encourage cessation. On the basis of these ‘proof-of-principle’ findings, large phase III RCTs using very brief or minimal interventions that are acceptable to very busy health care professionals at different clinical settings testing the effectiveness of the absolute risk warning of one-half deaths due to smoking are warranted to assess long-term sustained abstinence.

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**References**