The Study Protocol of Women's Education to Create Smoke-free Home on the Basis of Family Ties in Isfahan, Iran

Ahmadreza Zamani, Parastou Golshiri, Babak Moqtader

Department of Community Medicine, Isfahan University of Medical Sciences, Isfahan, Iran

Correspondence to:
Dr. Babak Moqtader,
Department of Community Medicine,
Isfahan University of Medical Sciences,
Hezar Jerib St., Isfahan, Iran.
E-mail: dr.b_moqtader@yahoo.com

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Original Article

ABSTRACT

Background: Tobacco smoke is the leading cause of preventable death world-wide. Unfortunately, the risk is not limited to smokers. It is dangerous for non-smokers particularly women, kids and elderly. Despite the remarkable reduction of tobacco exposure in public places, it is still continuing at homes as the most common places. Interventions to create a smoke-free home are needed, but little is known about them. The aim of this study is to explain the field randomized controlled trial that is designed to examine the role of non-smoker women to create a smoke-free home through establishing complete agreement on ban smoking at home.

Methods: In this field randomized controlled trial, the effectiveness of women's education will be evaluated in primary health-care centers. A total of 136 non-smoker women who exposed to second-hand smoke by their husbands at home will be included (68 intervention/non-intervention group). The intervention arm will receive an educational package including a consultation visit individually, a peer group session, a booklet, a "no smoking" sign. The primary outcome is the frequency of smoke-free home (no exposure to second-hand smoke at home). Mediator outcomes include a complete agreement to ban smoking at home, second-hand smoke exposure rate and self-assertiveness rate. All measurements will be conducted on baseline, 1 and 3 months after intervention.

Conclusions: Outcomes will present the effects of implementing multi-component women's education intervention program to ban smoking at home. If the effectiveness of the trial is confirmed, it will be suggested to merge this package to routine care in primary health-care centers.

Keywords: Agreement, environmental tobacco smoke exposure, home smoking ban, intervention, second-hand smoke exposure, self-assertiveness, women's role

INTRODUCTION

Second-hand smoke is a diluted mixture of "mainstream" smoke exhaled by smokers and "side-stream" smoke from the burning end of a cigarette or other tobacco products. It is

chemically similar to the smoke inhaled by smokers and contains a complex mixture of more than 4000 chemicals, including more than 50 cancer-causing chemicals and other toxic substances.[1,2]

In 2004, Eastern Mediterranean Regional Office of World Health Organization (WHO-EMRO) reported the prevalence of second-hand smoke exposure in children, women and men 38-33%, 35-25% and 24-21%, respectively. Mortality among women were more than men.[3] Isfahan Healthy Heart Program showed that second-hand smoke exposure at home is more than 36% on average in rural and urban population in 2001.[4]

Previous studies revealed major obstacles and promoters to ban smoking at home. The obstacles are unawareness about the dangers of second-hand smoke for non-smokers, myths, superiority of men, social norms, smoker relatives, heavy smoking, low socio-economic status, low educational level, tobacco smoking as entertainment and the promoters are ban smoking in public places, an agreement to ban smoking at home, having children or patient at home.[5-10] In previous studies, the positive effect of consultation of smokers was detected but second-hand smoke exposure was not reduced significantly.[11,12]

A field randomized trial study in Iran, Tehran, on Iranian women visiting public health centers showed that increasing perceived susceptibility and severity of second-hand smoke hazards could reduce the exposure, but there was no significant difference between groups in terms of ban smoking at home.[11] Another field randomized trial study in Iran, Tehran, showed that the consultation of smoker women could be effective in reducing smoking at home. In this study, fathers just received phone consultation. Frequency of ban smoking at home was significantly different.[13] A qualitative study in China, Shanghai, showed that parents tended to protect their children against second-hand smoke hazards at home. They had no agreement to ban smoking at home. Most family members did not discuss about second-hand smoke hazards at home too. The superiority of men was one of the obstacles.[5] Studies pointed that the most effective way to prevent second-hand smoke hazards is no smoking indoors.[14-16]

As noted above, the effectiveness of interventions implicated on smokers have been investigated whereas there is insufficient evidence about appropriateness and effectiveness of interventions to aid non-smokers, which are innocent victims.

We will design an intervention to educate non-smoker women to create a smoke-free home as the main outcome. The complete ban smoking at home is the cornerstone of creating a smoke-free home. In order to reach the better outcome, we will implement the intervention program based on self-assertiveness skill. The present paper reports the methodological design of the women's education study as well as the content of the intervention program.

METHODS

Study design

This trial is a multi-center, single-blind, field randomized, controlled trial, designed to investigate the effectiveness of women's education intervention program in reaching a complete agreement to ban smoking at home in order to create a smoke-free home in short-and long-term follows-up. The Medical Ethics Committee of Isfahan University of Medical Sciences has approved the study design, protocols and informed consent procedure (Ethical Number: 391319).

This trial will be carried out in four health-care centers in Isfahan, Iran. The health-care centers will be assigned randomly (two centers as the intervention arms and two as the non-intervention arms).

A total of 136 participants (68/group) will be enrolled in the study after being selected according to inclusion and exclusion criteria.

Inclusion criteria

non-smoker women exposed to second-hand smoke at home by their husbands, able to read, write and speak persian.

Exclusion criteria

Another smoker member except her husband in the family, not interested in participating or not completes the study for any reason.

Written consent will be obtained from all of the participants.

Demographic data, second-hand smoke exposure rate, agreement to ban smoking at home will be obtained through the checklist and self-assertiveness rate will be obtained through

the self-assertiveness questionnaire at baseline assessment.

Intervention program with main focus on creating a smoke-free home will be held on defined structures by trained health-care providers.

The intervention group will receive an educational package consists of a face-to-face consultation session, a peer group session, a booklet, a "no smoking" sign.

The face-to-face consultation session will be held for women attending primary health-care centers to receive routine care simultaneously, which described in detail at intervention program part. 2 weeks post baseline, health-care providers will call the participants to follow the implementation of the program at home.

Women will be invited to participate in a peer group session 1 month post baseline.

We will try to test the effect of mobile phone text messages on the participants' adherence to intervention program too.

The final assessment will be performed 3 months post baseline for long-term follow-up.

Non-intervention arm will not receive educational package and will be evaluated in the same way.

Setting

This trial will be carried out in Isfahan, the capital of Isfahan Province and Iran's third largest city after Tehran and Mashhad, located about 340 km South of Tehran, with a population of 1,583,609 in the 2006 Census. A list of all urban public health-care centers will be extracted from the Isfahan province health center. In order to distinguish the effects of socio-economic status on intervention's results, we decided to implement intervention in two different socio-economic areas. We will select them randomly. In order to prevent contamination, we will assign the intervention/non-intervention groups at different centers. With regard to socioeconomic status as a confounder in the statistical analysis, these centers will be selected at the same city area.

To accomplish the study, we will send a letter to the principals of health-care centers for collaboration.

Selection of health providers

Because of a regular visit of women to the family health unit, we decide to engage health-care providers as a counselor and supervisor of participants. We will request them to collaborate in the study.

In each public health-care center, one health-care provider will be engaged voluntarily.

In each health-care center, one hour workshop will be held on for health-care provider to explain the study protocol and contents of intervention program. No data exchange will be occurred between researchers and health-care providers during the study. Their performance will be evaluated by a checklist.

Selection of participants

Participants are women who are attending to the family health-care unit. Subjects are selected randomly based on the inclusion/exclusion criteria.

At first, health-care providers will explain about the contents and confidentiality of study for eligible women and ask them if they want to participate in the study (participation in the study will be voluntary). The informed consent will be taken if they want to participate in the study.

Women will be able to opt out of study at any time they wish.

Sample size

The sample size estimated based on the self-assertiveness questionnaire (33 items) are 124 (standard deviation [SD] =16). The power of the study (1-β) is 0.80 with α =0.05 (two-sided). With regard to 10% attrition rate, total sample size was estimated 136 (68/group).

Blinding

All assessments will be self-reported (by filling out the checklist and the questionnaire by participants). Participants and observers (as examiners) cannot be blinded to the intervention but the key of coding concerning group assignment is unknown to the researchers.

Baseline assessment

Demographic data, second-hand smoke exposure rate and agreement to ban smoking at home (complete or partial) will be obtained through the checklist (21 items) and self-assertiveness rate will be obtained through the self-assertiveness questionnaire (33 items) at baseline assessment just before the face-to-face consultation. Participants will fill out the checklist and the questionnaire by themselves.

Questionnaire

Self-assertiveness rate is measured by the self-assertiveness questionnaire, which was established by Lee *et al*. in 1985.[17] This questionnaire has 33 items, which was translated to Persian by Shahny and Mansour (Cronbach's alpha = 0.69, content validity index = 0.62).[18]

Each item describes an interpersonal situation. Every situation has three options to answer, but only one of them represents the self-assertiveness, which gets score 1 (the rest of them get score zero).

The sum of scores provides the self-assertiveness skill rate. It can range from 0 to 33 (the higher score, the greater self-assertiveness skill).

Checklist

It is designed to collect demographic data (nine items such as age, number of family, job, level of education, having children and patient), husband's smoking habits (four items to determine the pattern of tobacco use), exposure to second-hand smoke at home, second-hand smoke exposure rate at home (one item to determine how many days are woman exposed weekly and how many minutes/day to estimate exposure rate on minutes/week) and one item to determine if there is an any agreement to ban smoking at home if the answer is positive so she will fill out the rest of the questions (six questions) to distinguish complete agreement (an agreement to ban smoking at home in any way) or partial agreement (an agreement to ban smoking just in some situations). The participants will fill out this checklist by themselves.

Intervention program

The intervention arm will receive an educational package including a consultation visit individually, a peer group session, a booklet, a "No smoking" sign. Furthermore, we will try to test the effect of mobile phone text messages on the participant's adherence to the intervention program.

A face-to-face consultation visit will be held on by health-care providers after explaining the study and obtaining written consent from participants. Through this session, the health-care providers will educate the participants based on the booklet guide and require them to implement these items to reach a complete agreement in ban smoking at home. This booklet is provided based on the WHO and the Center of Disease Control and Prevention guidelines practically,[19,20] includes three units: The first unit describes the information about the second-hand smoke exposure hazards for non-smokers. The second unit describes strategies to combat with second-hand smoke at home based on communication skill for better outcomes. The third unit explains the wrong beliefs and strategies.

Health-care providers will require the participants to visit primary health-care center two weeks later to assess how intervention program is going on at home. This session will take around 30 min.

A week later, first short message service (SMS) will be sent to the participant cell phone from the Isfahan province health center as a reminder to action. The message is "smoking at home is dangerous for non-smokers at any way." We hope that it would persuade the participants to do the instructions at home.

At the end of 2nd week from baseline, the health-care providers will ask participants (by a two-question checklist) if they have implemented a program at home according to instruction or not, did they put the "no smoking" sign on the appropriate place or not then they will emphasize to continue the intervention program. They will call them if the participants do not visit the health center.

At the end of the 1st month, a peer group session will be held on by the trained health-care providers in health-care centers for 2 h. Participants will be invited by phone calling and sending SMS from Isfahan province health center 2 days before the session. At first, participants will fill out the checklist and the self-assertiveness questionnaire themselves. In this session, participants will be encouraged to discuss about the benefits and barriers encountered during implementing the intervention program at home. It will be an opportunity to share new experiences among participants.

At the 2nd month, the second SMS will be sent as a reminder. The message is "you have an important role in maintaining and promoting family health."

The non-intervention arm will not receive the educational package.

Follow-up protocol

The follow-up assessment will take place 3 months after baseline and includes the same

assessment as those performed at baseline. The follow-up protocol for the non-intervention group is the same.

Statistical analysis

Data will be gathered by the self-reported checklist and questionnaire then insert to the mother sheets by researcher. Analyses will be performed to estimate the effect of the intervention program on four domains: (1) frequency of smoke-free home after intervention and follow-up period (2) frequency of an agreement to ban smoking at home (complete and partial) (3) second-hand smoke exposure rate (4) self-assertiveness rate; as dependents variable, women's education based on family ties as an independent variable. Primary analysis will be performed according to the intent-to-treat method. Findings will be displayed as frequencies, percentages, means and SD, using tables and plots.

Statistical comparison of continuous (numerical) variables (second-hand smoke exposure rate and self-assertiveness rate) in each group will be carried out by using paired *t*-test before and after the intervention and for the follow-up period by repeated measure ANOVA and comparison of (nominal) variables (agreement to ban smoking at home and smoke-free home frequency) by Chi-square test. Statistical analysis between intervention and non-intervention group will be performed by mixed model ANOVA and Chi-square test.

We will use logistic regression analysis for dichotomous outcomes (smoke-free home and agreement on banning smoking at home frequency) and linear regression analyses for all other outcomes. Data will be analyzed based on intention-to-treat principle and if the attrition rate become more than 20%, the drop out will be substituted during the study process.

We note the participants age, number of a family member, having children and patient, level of education and being heavy smoking are confounders therefore we will control the effects of them with analysis of covariance model. As the interventions will be conducted in two separate health-care centers by different health-care providers, we also compare two sets of results by *t*-test analysis. All analyses are performed using SPSS 20.0 statistical package (SPSS, Inc., Chicago, Ill., USA).

RESULTS

This is a protocol study which has no result now.

DISCUSSION

As we mentioned above, according to the WHO-EMRO report, the mortality rate among women are at the second rank therefore designing programs appropriate to protect them is a critic.[3] With respect to empowering family members for health promotion, we consider susceptibility and responsibility of women in terms of family health promotion as an opportunity for health-care providers in this battle to improve our nation's health. We should note that prevention is always better than the treatment.

This intervention program is designed to fill the gaps that currently exist for primary health-care settings in order to provide appropriate guidance for non-smokers to combat second-hand smoke exposure. We will also present a helpful, simple and cheap way for empowering of women. Furthermore, our package contains practical recommendations to exercise at home in order to delegate family health promotion by themselves. We will try to test the effect of mobile phone text messages on the participants' adherence to intervention program. We could use the urine cotinine as a precise method, but our funding is limited. Furthermore, we need the longer period to follow-up to reach the better outcomes, but our study time is limited too.

CONCLUSIONS

The main outcome of our study is creating smoke-free home by reaching a complete agreement to ban smoking at home as a mediator outcome. In order to reach the better outcome, we will implement the intervention program based on self-assertiveness skill.

In brief, the results of this trial will provide the scientific rationale for implementing multi-component intervention program designed to ban smoking at home and ultimately prevent second-hand smoke exposure hazards.

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