A Randomized Controlled Trial Exploring Mindfulness-based Smoking Cessation Intervention Using Mobile Technology in Vietnam

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Georgia State University

Informed Consent

A randomized controlled trial of the cultural adaptation of mobile health intervention on smoking cessation for Vietnam.

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Sponsor: U. S National Institute of Health/Fogarty International Center

Introduction and Key Information

You are invited to take part in this study. It is up to you to decide if you would like to take part in the study.

The purpose of this study is to test mobile health-based intervention developed for Vietnamese smokers.

Your role in the study will last for about 1,5 hours to complete all assessments and 12 weeks receiving text messages over a 9-month period of the study.

You will be asked to do the following:

- Complete the baseline assessment about your demographic information, mobile phone usage, smoking habit, knowledge related to smoking harms, nicotine dependence levels, self-assessment of your health, etc.,
- You will be assigned randomly to one of three groups to receive text messages every day. If any interactive messages send to you, we encourage you to reply to the system to get more information.
- You will be asked to complete three assessment surveys via phone-calls after the text-messaging program, including assessment right after the text-messaging program end, a 1-month follow-up, and a 6-month follow-up.

The risks of being in this study may include:

- It may cost you a minimal amount of money when you reply to the SMS system.
- If you decide to quit smoking, you may suffer some nicotine withdrawal symptoms as you addicted to it. The symptoms include: mood changes, anxiety, anger, trouble concentrating, sleep changes, and less common symptoms of headache, constipation, increased hunger, and heart palpitations.
- Providing contact information of your wife or relatives for the purpose of contacting you may cause them to find out about your participation in this study. If they are not aware of this already, this may cause distress or concern.

- Emotional discomfort associated with answering questions in the assessment surveys.

This study is designed to benefit you and many other Vietnamese smokers in the future. You would receive useful information related to either smoking cessation or healthy lifestyles.

Purpose:

The purpose of this study is to design an effective intervention via text messages to help millions of smokers in Vietnam to quit smoking. You are invited to this study because you are a male smoker aged 18-65 and currently living in Chi Linh, Hai Duong province. About 1200 people are invited to take part in this study.

Procedures:

If you agree to take part in this study, you will be asked to complete a questionnaire now, and it will take you about 20-30 minutes. We will ask information about your age, education, marital status, occupation, economic status, mobile phone use, tobacco use status and history, knowledge related to smoking harms, your nicotine dependence level, and self-assessment of your health. After the baseline assessment, you will be assigned randomly to one of the three intervention groups receiving text messages. Text messages will be sent to you every day for about 12 weeks. The frequency of receiving messages and the content that you receive will depend on the group that you will be randomly assigned to. For example, you may receive 1-2 messages per day or 1 message per day for 12 weeks depending on the group you were assigned to.

Right after the text-messaging intervention, 1 month and 6 months after the intervention, you will be asked to complete short survey assessments via phone-calls. The questions in assessment surveys aim to re-evaluate your smoking status and history, knowledge about health risks of smoking and secondhand smoking, and self-assessment of your health. Each survey will take you about 15 to 20 minutes to complete.

Future research:

Researchers will remove information that may identify you and may use your data for future research. If we do this, we will not ask for any additional consent from you.

Risks:

- It may cost you money when you reply to the SMS system. However, this cost is minimal as you text to your friends or relatives (i.e., 450 VND per message). We encourage you to reply to get extra information, but it is totally up to you.

- If you decide to quit smoking, you may suffer some nicotine withdrawal symptoms as you addicted to it. The symptoms include: mood changes, anxiety, anger, trouble concentrating, sleep changes, and less common symptoms of headache, constipation, increased hunger, and heart palpitations. However, these feelings usually only last for around 1-2 weeks after quitting and don't affect health long-term.
- Providing contact information of your wife or relatives for the purpose of contacting you may cause them to find out about your participation in this study. If they are not aware of this already, this may cause distress or concern. Nevertheless, you do not have to provide this information if you do not want to.
- Emotional discomfort associated with answering questions in the assessment surveys, but you can skip any questions that you do not want to answer.

Benefits:

This study is designed to benefit you and many other Vietnamese smokers in the future. You would receive useful information related to either smoking cessation or healthy lifestyles. The study can help to provide evidence for the development of an effective smoking cessation program via text messages to help millions of smokers in Vietnam to quit smoking.

Alternative:

The alternative to taking part in this study is to not take part in the study.

Compensation:

If you complete the interview, you will receive about US$25 (550.000 VND) at the end of the study.

Voluntary participation and withdrawal:

Participation in this study is totally voluntary. You do not have to participate in this study if you do not want. If you agree to take part in this study and then you change your mind, you can withdraw from the study any time. You can also skip any question that you do not want to answer or stop the interview at any time. Whatever decision you made related to your participation, you will not lose any other benefits that you are entitled.

Confidentiality:

We will keep your records private to the extent allowed by law. The following people and entities will have access to the information you provide:

- Principal Investigator Dr. Hoang Van Minh and his research team at GSU
- GSU Institutional Review Board, Hanoi University of Public Health IRB
- Fogarty International Center/National Institute of Health

We will use a participant ID number rather than your name on study records. All records will be kept in locked files or password-protected computer files. These records will only be available to the research staff who know about keeping your information private and safe.

Although the text messages that you receive will include your first name, your text message responses will not be connected to your name. Only phone numbers and random ID numbers will be used, and for the purpose of this project only. Your phone number will not be used by any other parties else HUPH and IT company for other purposes, such as sending advertisements or spam messages.

When we present or publish the results of this study, we will not use your name or other information that may identify you.

Contact information:

Please contact Dr. Hoang Van Minh at (844) 62662390 or hvm@huph.edu.vn

- If you have questions about the study or your part in it
- If you have questions, concerns, or complaints about the study

The IRB at Georgia State University reviews all research that involves human participants. You can contact the IRB if you would like to speak to someone who is not involved directly with the study. You can contact the IRB for questions, concerns, problems, information, input, or questions about your rights as a research participant. Contact the IRB at 404-413-3500 or irb@gsu.edu.

A description of this clinical trial will be available on http:/www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Consent:

We will give you a copy of this consent form to keep.

If you are willing to volunteer for this research, please sign below.

_____

Full name of participant

_____ _____

Signature of participant date

_____ _____

Principal investigator or researcher obtaining the consent form date