RESEARCH CONSENT FORM

Basic Information

Title of Project: Quit For Life (QFL): Smoking Cessation Among Chinese Smokers Living with HIV

IRB Number: H-41807 **NCT05020899**

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Overview

We are asking you to be in a research study. A research study is an organized way of collecting information about scientific questions. This form will tell you what you should expect if you agree to be in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form.

It is your decision whether or not to join the study. We are asking you to be in this study because you are someone who smokes cigarettes and wants to quit smoking. We are doing the research to evaluate if a smoking cessation program that involves texting and counseling would be helpful for patients in China who have HIV and smoke. If you agree, you will have the chance to receive smoking cessation guidance, helpful tips, and nicotine replacement therapy in order to help you quit smoking. You will be in the study for 12 weeks if you decide to stay for the whole study. You will find more information about what will happen in this study later in this form.

The main risks of being in the study is the potential breach of confidentiality. You will find more information about risks later in this form.

You might benefit from being in the study because your smoking behaviors might change as a result of the program. You will find more information about benefits later in this form.

You could get these benefits without being in the study by consulting your doctor about available smoking cessation resources or by calling the smoking cessation hotline at 4008885531. You will find more information about alternatives later in this form.

Purpose

The purpose of this study is to develop and test if a smoking cessation program called Quit for Life is effective for patients in China with HIV who smoke. This program is designed to suit the needs of people with HIV who smoke in China. We are asking if you would like to participate in this study so we can understand whether our program works.

What Will Happen in This Research Study

The study involves participating in a program to help you quit smoking. After you agree to participate in the study and sign this consent document, we will randomly assign you to one of two groups. Random assignment means that the choice of group is made at random, like the flip of a coin. The two groups are described below.

Quit smoking program:
In this study, there are two groups:

The Quit for Life group: In this group, you will receive a quit smoking program that lasts for 8 weeks. The program has two parts:

1) 4 sessions with a trained counselor who will discuss your smoking habits with you and strategies to help you quit. The first session is in-person, lasts for 20 minutes, and typically happens when you come to the HIV clinic to pick up your medication. Sessions 2 through 4 are over the telephone or in-person and last for 15 minutes each. These occur 1-2 week, 4 weeks, and 8 weeks after your first session.
2) Messages sent to your cell phone using WeChat/text. These brief messages give tipsto help you quit smoking. You will get approximately 1-2 messages per day.

The Control group: In this group, you will not get sessions with a trained counselor or messages sent to your cell phone.

- In both the Quit for Life group and the Control group, you will be offered nicotine replacement therapy (gum or patch, depending on which one is available) and a self-help guide with information about quitting smoking.

Measurements for the study:
Because this is research, we will also collect some measurements about you through face-to-face method. If face-to-face does not work, we will ask you to complete these surveys through phone or WeChat. This is so we can understand how effective the smoking cessation program is. No matter which group you are assigned to, you will be asked to complete all study measurements described below.

Before the start of the program, we will ask you to complete a survey to report information about yourself, your smoking habits, your alcohol and substance use, and perceptions of your HIV diagnosis. In total, these activities will take about 25 minutes and will be completed in your first visit.

8 weeks after you enroll in the study, you will be asked to complete another survey about your health status, smoking patterns, and whether you have quit smoking. These activities will take about 20 minutes.

12 weeks after you enroll in the study, you will be asked to complete a final survey about your health status, smoking patterns, and whether you have quit smoking. If you report that you have quit smoking, we will ask you to blow into a small machine. That machine will measure whether your breath indicates if you have been smoking or not. This concludes your participation in the study. These activities will also take about 20 minutes.

The ways we will protect your privacy and confidentiality are described in a separate section later in this form.

We will make audio recordings of your in-person and/or telephone sessions with your trained counselor. We use this to make sure that we understand what your counselor is doing. We don't save or use the recording beyond that. We will write down what is said in the recording and then erase the recording by the time the study ends.

You will be one of approximately 100 people asked to participate in the study.

Risks and Discomforts

Some of the questions we ask you about your personal health habits may make you feel uncomfortable. You may skip questions on the survey if you want to.

Participants who say they have stopped smoking will be asked to provide samples of their breath to confirm that there is no more tobacco in their bodies. These samples will never be tested for anything besides the presence or type of tobacco in your body.

Potential Benefits

The benefits of being in this study may be: If you stop smoking as a result of this program, particularly if you stay quit, there may be long-term benefits to your health. However, you may not receive any benefit. The primary goal of this research is to collect information about the scientific questions asked in this study. Your being in the study will help the research team learn how to improve the program to help people living in China, who have HIV and smoke, quit smoking.

Alternatives

The following alternative procedures or treatments are available if you choose not to be in this study:

- Call a smoking cessation hotline at 4008885531
- Consult with your doctor about available smoking cessation services offered at the hospital

Costs

If you are in this study, you will be responsible for any fees that your wireless provider normally charges you to receive phone calls on your cell phone.

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Payment

You will receive ¥50 (Chinese Yuan) with the completion of all baseline assessment activities; ¥50 at the completion of all 8-week assessment activities; and ¥100 at the completion of all 12-week assessment activities. Therefore, you will receive ¥200 if you complete assessments at all three time points.

Confidentiality

We must use information that shows your identity to do this research. Information already collected about you will remain in the study record even if you later withdraw.

We will store your information in ways we think are secure. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection. Only the people on the research team will be given access to your information. However, we cannot guarantee complete confidentiality.

Messaging through WeChat: This is not a confidential method of communication and may be insecure. And because of this, there is a risk that texting might be intercepted and read by a third party, which may include your wireless provider.

This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information are covered by a CoC. The CoC provides how we can share research information. Because we have a CoC, we cannot give out research information that may identify you to anyone that is not involved in the research except as we describe below. Even if someone tries to get your information in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information.

If you agree to be in the study and sign this form, we will share information that may show your identity with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.
- People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
- Any people who you give us separate permission to share your information.

We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

- Publishing results in a medical book or journal.
- Adding results to a Federal government database.
- Using research data in future studies, done by us or by other scientists.

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.

Subject's Rights

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study. You will be given a copy of this form to keep.

If you do not agree to be in this study or if at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you. Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get. You will only be paid for the study activities that you complete before withdrawing.

We may decide to have you stop being in the study even if you want to stay. Some reasons this could happen are if staying in the study may be bad for you, or if the study is stopped.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact Professor Jiegang Huang at (0771)5334215. You may also contact the researchers in the United States. Dr. Lisa Quintiliani (E-mail: lisa.quintiliani@bmc.org) and Shanyin Yang (E-mail: shanyin.yang@bmc.org). Also call if you need to report an injury while being in this research.

You may also call 617-358-5372 or email medirb@bu.edu. You will be talking to someone at the Boston Medical Center and Boston University Medical Campus IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

You may also contact the Office of the Institutional Review Board of Guangxi Medical University at (0771) 5323713.

Subject: _____
Printed name of subject

By signing this consent form, you are indicating that

- you have read this form
- your questions have been answered to your satisfaction
- you voluntarily agree to participate in this research study
- you permit the use and sharing of information that may identify you as described, including HIV-positive diagnosis and smoker status

_____ _____
Signature of subject Date

Researcher: _____
Printed name of person conducting consent discussion

I have personally explained the research to the above-named subject (who has read this consent form) and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

_____ _____
Signature of person conducting consent discussion Date

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