Study Title: Storytelling Narrative Communication Intervention for Smoking Cessation in Women Living with HIV

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Consent Form for Storytelling Narrative Communication Intervention for Smoking Cessation in Women Living with HIV

Principal Investigator: Sun S Kim, PhD, APRN

Introduction and Contact Information

You are being asked to take part in a **research** study. The purpose of this research is to study whether women living with HIV would like to watch a video of women who also live with HIV talking about their success in quitting smoking. We are also studying whether the women would more like to quit smoking if they watch the video of quitting smoking compared to the video of talking about HIV infection. The researcher is Sun Kim, PhD, Associate Professor in the Department of Nursing at the University of Massachusetts Boston. Please kindly read this form and feel free to ask questions. If you have more questions later, you can ask Dr. Kim at 617-287-6831.

Description of the Project

Your participation in the study will take about 4 months from enrollment into the study. About 50 people will participate in this study. During the study, you will have telephone-video calls, smoking cessation counseling, nicotine patches and gums, watching videos, and a spit test. All these procedures will be conducted remotely.

Once you agree to participate in the study, you will have a telephone-video call to complete initial research questionnaires. During the call, you will be asked about your age, schooling, questions related to living with HIV, illegal drug and alcohol use, smoking history, nicotine addiction, your confidence in quitting smoking, and bad moods. Your answers to these questions will help counselors identify your personal needs for counseling and provide the right advice.

You will have a counseling session by telephone video-call and a trained personnel will provide the counseling once a week for 8 weeks, and each session will last about 30 minutes. The approximate duration of the total counseling sessions is 240 minutes. Each of your counseling sessions will be audiotaped. All counseling will be the same for everybody. The counseling is given to help you quit. After you quit, you will be counseled on how to manage withdrawal symptoms of smoking. Right after the first session, you will be told to which video you are going to watch.

The video that you are to watch will be decided by chance, like flipping a coin. Half of you will watch a video of women who also live with HIV talking about their success in quitting smoking, and the other half will watch a video of women who talk about living with HIV. You will have an equal chance of getting the video about quitting smoking or the video about living with HIV. You will receive the link to the video by a text message, and then you will be asked to watch it between and after counseling sessions. You will receive weekly video calls from your counselor for the sessions and receive nicotine patches by mail. Those who are assigned to the video about living with HIV will receive the other video about quitting smoking at the end of the study after 3-month follow-up assessment. You will also receive nicotine gums if you report difficulty using nicotine patches or you have a high level of nicotine addiction.

Research staff will contact you monthly at 1-, 2-, and 3-month(s) over 3 months from the first day of your quitting. You will be asked to participate in all follow-ups even if you are not able to quit smoking. If you report no smoking for the past 7 days and no use of nicotine products at 3-month follow-up, you will be asked to perform a spit test. Research staff will help you do the test while watching you via telephone-video call. Follow-up assessments at post-quit 1 and 2 months each will usually take 10 minutes, and follow-up at post-quit 3 months will take 30 minutes.

Your participation in this study will take the following schedule.

Timeline of the Study

Week 1st	**Week 1 – 4** **1st Month**	**Week 4 - 8** **2nd Month**	**Week 12** **3rd Month**	**Week 16** **4th Month**
Baseline Data Collection and Random Assignment	4 Counseling Sessions before the Quit Date Watch Video	4 Counseling Sessions and Nicotine Patches/Gums for 8 weeks & Post-quit 1-Month Follow-up Watch Video	Post-quit 2-Month Follow-up Watch Video	Post-quit 3-Month Follow-up & Saliva Cotinine Test

There will be no in person visit related to this study. You will receive a gift card of $25 by mail at each data collection (baseline and three follow-ups: post-quit 1-, 2-, and 3-month[s]). If you perform a spit test at 3-month follow-up, you will receive an additional gift card worth $25 (a total of $50). You will receive a gift card of $100 if you have participated in all three follow-up assessments, including the spit test if you are asked to perform the test. To receive the gift card, you will be asked to provide your home address to us.

If you take part in the research, it is important for your safety that you follow the directions of the researcher. Call the researcher if you have any questions.

Risks or Discomforts

You may experience uncomfortable feelings when you quit smoking. If you have a thought of hurting yourself, please call a local toll-free suicidal hotline such as 1-800-784-2433 in Boston, MA and 1-800-273-8255 in New York, NY or 911.

You may experience some side effects of nicotine patches and gums such as rashes, upset stomach, headache, dizziness, fast heart beats and weird dreams. All these things occur in 10% of people, and most of the symptoms are mild. They will disappear once you stop using patches or gums. If you have a severe headache, dizziness, upset stomach or blister on the area where you have applied the patch, you should immediately take off the patch and call the researcher at (617) 287-6831. If you become pregnant during the study, nicotine patches and gums may hurt your baby. So, you must agree to use an effective birth control during the study. If you become pregnant, you will be advised not to use patches and gums. However, you will be allowed to stay in the study and continue to get advice and do follow-up assessments.

Another risk of being in the study is the emergence of negative or distressful feelings in completing the research materials. The spit test may make you feel uncomfortable.

Another risk of being in this study is potential breach of confidentiality. This is very unlikely to happen, and we will do everything we can to make sure that your information is protected. However, if we learn that you plan to hurt yourself or others, we will break confidentiality to help you.

Benefits
Being in this study may or may not help you quit smoking successfully. The results of the study may help others in the future.

Costs
There are no costs to you to be in this study. The counseling and nicotine patches (and gums) that you will receive in the study are at no cost to you.

Research Related Injury
If you become ill or injured as a result of participating in this research study, seek treatment and contact the researcher as soon as you are able. The University of Massachusetts Boston does not provide funds for the treatment of research-related injury. No additional financial compensation for injury or lost wages is available. You do not give up any of your legal rights by signing this form.

Confidentiality
Your part in this research is **confidential**. That is, the information gathered for this project will not be published or presented in a way that would allow anyone to identify you. Information gathered for this project will be stored in a locked file cabinet and password-protected electronic files, and only the research team will have access to the data. The UMB Institutional Review Board (the committee that reviews, approves, and monitors human research studies) and its representatives may want to see your information; however, they are required not to reveal your identity with others. The sponsor of the study may also access your information.

Your name or any other information linking you to the study will be stored separately from data files. The tapes will be erased once they are checked for accuracy. Neither your name nor any other identifying information will be used in presentations or in written products resulting from the study. Personal identifying information will be destroyed upon the completion of 3-month follow-up assessment.

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.

Alternatives
You can get smoking cessation counseling and strategies without being in this research study.

Voluntary Participation
Your decision whether or not to take part in this research study is **voluntary**. You have the right to choose not to participate. You may choose not to participate or stop at any time without any problems. If you wish to stop, you should call the researcher at617-287-6831. Whatever you decide will in no way penalize you. You can ask us to destroy any information that identifies you if you leave the study. After counseling, you will be given a chance to have the tape erased if you wish to withdraw your consent to taping or participation in this study.

The person in charge of the research study or the sponsor can take you out of the study even if you do not want to leave. This may happen if the study is stopped by the sponsor, IRB, or for administrative reasons. You can be taken out of the study if we find out later that you are not qualified for the study such as having stopped smoking before your enrollment or do not have HIV infection.

New Findings
You will be told about any new information or changes in the study that could affect you.

Who to Contact
You have the right to ask questions about this study before you agree to participate and at any time during the study. You can reach the researcher, Sun Kim, PhD, APRN at 617-287-6831. If you have any questions or concerns about your rights as a research participant, please contact a representative of the Institutional Review Board (IRB) at the University of Massachusetts Boston. The IRB may be reached at: IRB, Quinn Administration Building 2-080, University of Massachusetts Boston, 100 Morrissey Boulevard, Boston, MA 02125-3393. You can also contact the IRB by telephone or e-mail at (617) 287-5374 or at human.subjects@umb.edu.

I HAVE READ THE CONSENT FORM. MY QUESTIONS HAVE BEEN ANSWERED. MY TEXT MESSAGE WITH MY NAME AND DATE INDICATES THAT I CONSENT TO PARTICIPATE IN THIS STUDY.