Determining the Feasibility and Acceptability of a Novel Stigma Resistance Text Message Intervention for People who Use Drugs

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University of North Carolina-Chapel Hill Consent to Participate in Research

Study Title:	Determining the Feasibility and Acceptability of a Novel Stigma Resistance Text Message Intervention for People who Use Drugs
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This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate.

Concise Summary

You are being asked to take part in a research study. This study is sponsored by the National Institute on Drug Abuse and is being carried out by investigators from the University of North Carolina at Chapel Hill.

The purpose of this study is to understand whether a new program we have developed is acceptable and appropriate for people who use drugs. The information we learn by doing this study may help us improve services for people who use drugs in the future.

Participants in this study will be asked to complete a survey about stigma, hope, and self-esteem that is expected to last about 1 hour. Participants will then enroll in a program in which they receive automated text messages to their phone for 4 weeks. These text messages contain information, positive affirmations, and suggestions for coping with difficult feelings around one's drug use. Once per week (4 times total), participants will be able to rate the effectiveness of these messages in a brief electronic survey. At the end of the 4-week period, participants will be asked to complete another survey, also lasting about 1 hour. This survey will ask the same questions, along with participants' opinions of the program. Some participants may also be asked to participate in a telephone interview to discuss their opinions of the program in more detail. Participants may choose not to answer any survey or interview questions or to withdraw their consent to be in the study at any time, for any reason, without penalty. Deciding not to be in the study or leaving the study before it is done will not affect participants' relationship with the researcher, the University of North Carolina-Chapel Hill, or any harm reduction or treatment organizations that they use.

While some participants may feel benefits from this program, like improved self-esteem, there may be no direct benefits to participants for participating in this study. There may also be risks associated with participating, such as feeling embarrassed or emotionally distressed. There is also a small risk of breach of confidentiality.

Details about this study are discussed below. Please consider the information carefully and remember that your decision to participate is voluntary. Feel free to ask questions before making your decision whether or not to participate. If you decide to participate, you will be asked to sign this form and will receive a copy of the form.

What is the purpose of this study? As you may know, people who use drugs are sometimes judged or treated unfairly for their drug use. Our research team is interested in developing programs to help people who use drugs deal with judgment and unfair treatment. The purpose of the overall study is to gain a better understanding of whether a new automated text messaging program is acceptable and appropriate for people who use drugs. In order to inform overall study goals, we are asking people who use drugs to participate in a trial of this program and share their experiences with and opinions of the program. You are being asked to participate because you told us you've recently used drugs and have a cell phone that can receive text messages.

How many people will take part in this study? Approximately 30 people who use drugs will take part in this study. Up to 12 of these participants may be asked to participate in a follow-up telephone interview.

Are there any reasons you should not be in this study? You should not be in this study if you have not used drugs in the last 30 days, if you do not currently reside in Scioto County, if you are younger than 18 years of age, if you are currently incarcerated, or if you plan to move out of the area in the next month. If you are unable or unwilling to provide locator information (a family member or friend we can contact in case we cannot reach you), you should also not participate in this study.

How long will your part in this study last? If you agree to participate, then you will be in the research for up to one month overall.

What will happen if you take part in the study? If you agree to participate in this study, you will be asked to sign this consent form. Your participation will include 2 study visits – a baseline visit and a follow-up visit. You will also be asked to complete one brief survey per week on your phone (4 surveys total) about your opinions of the program's text messages. You may also be asked to participate in a telephone interview after your follow-up visit. These procedures are described below.

Baseline visit. Your first study visit will be your baseline visit. During the baseline visit, you will take a baseline survey about stigma (in other words, your feelings and experiences of judgment and discrimination), hope, and self-esteem. This survey will take about 1 hour to complete. You will take this survey at your own pace on a study computer. After the survey, you will be provided a brief orientation to the program, including setting up your cell phone to receive the text messages, securing your phone so others don't accidentally read these messages, and introducing you to the program in more detail.

Text message program. Starting the day after the baseline visit, you will begin to receive 2 text messages a day for a total of 4 weeks, one in the morning and one in the evening. These text messages contain information, positive affirmations, and suggestions for coping

with difficult feelings around one's drug use. These messages will be sent to you automatically, and any responses you provide will not be monitored.

Phone-based opinion survey. Once per week during the program, you will receive a link to a survey you can complete on your phone. The survey will ask you to rate the previous week's text messages on how effective you thought they were. You will receive 4 of these surveys during the program.

Follow-up visit. You will be recontacted a few days before the end of the program to schedule your in-person follow-up visit. During the follow-up visit, you will complete a survey about stigma, hope, and self-esteem as you did at your baseline visit. The survey will also include questions about your thoughts and opinions of the program. This survey will take about 1 hour to complete. You will take this survey at your own pace on a study computer.

Telephone interview. Up to 12 participants may be asked to participate in a follow-up telephone interview, which will take place within the 2 weeks following their follow-up visit. The purpose of the interview is to understand participants' thoughts and opinions of the program in more detail. The interview will be audio recorded, and notes may also be taken in a notebook. The interview is expected to last 30 minutes on average. **Please indicate at the end of this consent form whether you agree or not to be considered to take part in the telephone interview.**

For all study procedures. During all surveys and interviews, you may choose not to answer any question for any reason. You may also choose to pause or end any survey or interview at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will **not affect** your future relationship with the University of North Carolina-Chapel Hill or any harm reduction or treatment programs you may participate in.

What are the possible benefits from being in the study? Research is designed to benefit society by gaining new knowledge. You may benefit from participating in the text message program by improving your knowledge and skills to cope with stigma. You will not receive any direct benefit from completing the surveys and interview. However, your data may help researcher design more effective programs to help others in the future.

What are the possible risks or discomforts involved from being in this study? There is a small risk that questions asked during the surveys and interview, such as about drug use and experiences with discrimination or unfair treatment, could cause some people to become upset or uncomfortable. However, you do not have to answer any questions that you do not want to and can stop the surveys or interview at any time.

There is also a small risk of possible breach of confidentiality, which could reveal information you share about illegal activities like illicit drug use. However, the research staff will take precautions to prevent this from happening.

- We will keep your information private by storing it on a password-protected server at UNC-Chapel Hill.
- Your name and other identifying information will not be linked to your survey responses.

- If you are selected to participate in the telephone interview, we will delete your name and other identifying information from the interview transcript.
- We will never identify you in any report or publication.

There may be uncommon or previously unknown risks. You should report any problems to the researcher listed on this form or to our study staff.

What if we learn about new findings or information during the study? There may be new information learned during the course of the study that may affect your willingness to continue participating. If we learn about findings that might impact your willingness to participate, we will share these findings with you.

How will information about you be protected? Every effort will be made to keep your study-related information confidential. There may be circumstances where information about your participation must be released, for example, if required by law. For instance, under Ohio law, confidentiality does not extend to information about abuse or neglect of a child or disabled adult. If the researchers become aware of such information, they are required to report it to state authorities. Your records may also be reviewed by:

- The University of North Carolina Institutional Review Board;
- The Office for Human Research Protections or other federal, state, or international regulatory agencies; and
- The sponsor supporting the study, their agents, or study monitors.

All study procedures will be administered by trained study staff in a private room. If names and identifying information (like phone numbers) are collected, a logbook will be used to link a participant's identifying information with a study identification number (PID); personal identifiers will never be stored with the data set. The logbook will be kept in a locked cabinet, separate from other study file cabinets, in a locked project office room; an electronic copy will be saved to a secure server on a password-protected, encrypted computer. All data, notes, and audio-recordings will also be kept on the secure server. Access to the locked files and passwords will only be given to trained members of the research team. The logbook will be destroyed and the electronic copy deleted 4 weeks after the end of data collection. For telephone interview participants, audio recordings will be uploaded to the secure server within 24 hours of the interview then immediately deleted from the recording device. Within one week, the audio will be transcribed to text, identifiers will be removed, and the audio file will be immediately and permanently deleted from the server.

You will not be identified, and no information will be used that would make it possible for anyone to identify you in any presentation or written report about this study. We may use de-identified data from this study in future research without additional consent.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

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

Certificate of Confidentiality. This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What if you want to stop before your part in the study is complete? You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. If you withdraw or are withdrawn from the interview, all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal. You may be removed from the study without your consent if the study is stopped or cancelled, or if you are not able to attend study visits or complete study procedures.

Will you receive anything for being in the study? You will receive a $30 gift card at the end of each study visit. If you are selected to participate in the telephone interview, you will receive an additional $15 gift card.

Will it cost you anything to be in the study? There are no costs to you for participating.

Who is sponsoring this study? This research is funded by the National Institute on Drug Abuse. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study? You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant? All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at **919-966-3113** or by email to **IRB_subjects@unc.edu**.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I understand the information and I voluntarily agree to participate in this study. I know the interview will be audio recorded.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of subject	**Signature of subject**
	_____ **AM/PM**
	Date and time

Please indicate below by writing your initials if you agree or not to take part in the follow-up telephone interview, if selected.

I agree _____

I do not agree _____

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	_____ **AM/PM**
	Date and time