Evaluating a Mobile Intervention for Individuals in Methadone Maintenance Treatment – Clinical Trial

Informed Consent Form

Introduction

You are invited to participate in a research study to evaluate a mobile phone-delivered psychosocial intervention for opioid-dependent individuals in methadone maintenance treatment. Opioid dependence refers to the chronic use of opioids (e.g., heroin, morphine, dilaudid, etc.) such that stopping of opioid use will result in withdrawal symptoms such as sweating, runny nose, muscle ache, diarrhea, etc. This study is designed to evaluate if a mobile phone-delivered psychosocial intervention may be useful as part of methadone maintenance treatment.

This study is being conducted by XXXXX and is funded by XXXXX. XXXXX has been contracted as a study site and will be paid for its participation. The Principal Investigator is XXXXX. You are eligible to participate in this study because you are a new client entering methadone maintenance treatment at XXXXX.

Participation in the Study

If you agree to participate in this study, you will be randomly assigned (like by the flip of a coin) to **one** of three conditions, Condition 1, Condition 2, or Condition 3. If your significant other or roommate (family member or friend) is participating in the study, you will be assigned to the same condition as your significant other or roommate. Each condition is described below.

Condition 1: Standard Methadone Counseling

If you agree to participate in this study, you will receive the regular drug counseling offered as part of treatment at XXXXX. (This is the treatment you would normally get at this program if you were not a part of the research study.) As part of this treatment, you may be asked to meet with a substance abuse counselor at the program for one hour-long individual sessions. You may be asked to meet with your counselor at least once a week during your first month of treatment and twice a month in your second through twelfth months of treatment. Your counselor may help you understand and comply with program rules, talk with you about your progress in treatment and any problems you may be experiencing, and refer you to outside services if necessary. You should understand that you will be asked to participate in standard drug counseling at XXXXX if you choose not to participate in this study.

Condition 2: Standard Methadone Counseling Plus Mobile Phone Intervention A

You will receive the same standard drug counseling that is offered as part of treatment at (described above). You also will receive mobile phone intervention A for the first 3 months of your treatment. This mobile phone intervention includes information and interactive exercises focusing on goal setting, identifying patterns of drug use, making plans to avoid drug use, drug refusal skills, problem solving, and increasing healthy activities. In addition, you will receive daily text messages reminding you to use the intervention.

You will be given a mobile phone with the intervention on it. Your mobile phone will come with a plan that will pay for minutes and text messaging for you to use as you like. The study will cover the cost of the talk and text plan on your study mobile phone. You do not need to have had any previous experience with mobile phones in order to participate in this study; (someone will show you how to use the mobile phone.) You will be shown how to use the intervention on the mobile

phone, and encouraged to use the mobile intervention between counseling sessions or whenever you feel you need it. There is no minimum or maximum amount of time you will be required to use the mobile intervention.

Condition 3: Standard Methadone Counseling Plus Mobile Phone Intervention B
You will receive the same standard drug counseling that is offered as part of treatment at XXXXX (described above). You also will receive mobile phone intervention B for the first 3 months of your treatment. This mobile phone intervention includes information on different drugs of abuse and effective treatments for drug abuse. In addition, you will receive daily text messages reminding you to use the intervention.

You will be given a mobile phone with the intervention on it. Your mobile phone will come with a plan that will pay for minutes and text messaging for you to use as you like. The study will cover the cost of the talk and text plan on your study mobile phone. You do not need to have had any previous experience with mobile phones in order to participate in this study; (someone will show you how to use the mobile phone.) You will be shown how to use the intervention on the mobile phone, and encouraged to use the mobile intervention between counseling sessions or whenever you feel you need it. There is no minimum or maximum amount of time you will be required to use the mobile intervention.

Semi-structured Interview:
If you participate in Conditions 2 or 3, we may also ask you to participate in one semi-structured interview during the time you are using the mobile phone intervention. This interview will be digitally audio-recorded and will last about 30-60 minutes. In this interview, you will be asked about your experiences using the mobile phone intervention and your opinion of the intervention.

In addition to participating in Condition 1, Condition 2, or Condition 3, you will be asked to complete monthly questionnaires and to provide weekly urine samples while you are a participant in this study.

Questionnaires:
You will be asked to complete several questionnaires before you begin the study, once per month during the 3 months you are in the study and again at 1 and 3 months after you finish the study, while you are in methadone maintenance treatment at XXXXX. You will be asked to meet with a research staff member at XXXXX to complete these questionnaires.

These questionnaires will ask you about a variety of topics, including your recent heroin/opiate and other drug use; recent criminal activity; your health and health-related behaviors (including any drug or sex-related behaviors that may place you at risk for hepatitis or HIV infection); and your employment status. You will also be asked to complete questionnaires about how motivated you are for treatment and how satisfied you are with your treatment status. It should take about 1½ - 2 hours to complete these questionnaires each month.

Optional Additional Questionnaires:
You also will be offered the option to complete an additional set of questionnaires two times during the study – once before you are assigned to your study condition and again 3 months later. The purpose of this questionnaire is to compare peoples' experiences across different interventions and the possible impact of the interventions on behavior. You will be given the option to complete these additional questionnaires when you meet with a research staff member

(no separate visit is necessary to complete the optional questionnaire). It will take about 30 minutes to complete these optional questionnaires each time.

Urine Tests: You will also be asked to provide a urine sample that will be screened for drugs of abuse (including opioids, cocaine, benzodiazepines, amphetamines and marijuana) before starting the study, one time per week during the 3 months (12 weeks) of the study, and then at 1 month and 3 months after the study. A research staff member of the same sex as you may observe you provide a urine sample each week.

The total time you are being asked to participate in this study is 6 months. You can choose to withdraw from this study at any time before completing it. **You will be discharged from the intervention portion of the study if you leave or are discharged from methadone maintenance treatment at XXXXX.** However, even if you are discharged from treatment at XXXXX, we may contact you to complete research questionnaires and/or interviews.

Compensation

If you agree to be in the study, you will receive $XX in cash for each set of questionnaires that you complete at the end of the interview. As a result, if you complete questionnaires at the time you enter the study, once a month for the 3 months of the study, and once at 1 and 3 months after the study, you can earn a total of $XX in cash. In addition, if you choose to complete the optional additional questionnaires, you will receive $XX in compensation each time you complete them ($XX at your initial visit and $XX at your 3-month follow-up visit). Thus, if you complete all regular study questionnaires, plus the optional questionnaires, you can earn a total of $XX for completing questionnaires in the study.

You also will receive $XX in cash for each urine sample that you provide immediately after you provide the urine sample. This money is in addition to money earned for completing questionnaires. As a result, if you provide urine samples at the time you enter the study, once a week for 12 weeks while in the study, and once at 1 and 3 months after the study, you will earn $XX.

Thus, if you complete all scheduled questionnaires (including the optional questionnaires) and provide all requested urine samples in this study, you will earn a total of $XX.

If you are participating in Condition 2, you may also be asked to participate in one 30-60-minute semi-structured interview, as described above. If you are asked and agree to participate in this interview, you will receive an additional $XX in cash as compensation.

If you are in Condition 2 or Condition 3, you also will be given a mobile phone for the 3 months of the study. The phone will come with a talk and text plan paid for by the study. You will receive $XX if you return the study mobile phone unbroken at the end of the 12 week study.

Your participation in this study is voluntary. Refusal to participate will result in no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without loss of benefits to which you would otherwise be entitled.

Potential Benefits of the Research

The possible benefit of being in this study is that you may receive free access to counseling and educational information that may help you become and remain drug-free. In addition, your participation may help us better understand how a mobile phone intervention may benefit opioid-dependent individuals in methadone treatment.

Potential Risks and Safeguards

A risk of the study is that you may feel uncomfortable participating in counseling sessions or answering study questionnaires asking you about your behavior. You may also feel uncomfortable being observed when providing a urine sample. Another risk is that you may be asked to disclose sensitive information (e.g., regarding your HIV status, drug use, etc.).

Please understand that if you do not want to answer a certain question, you may choose to not answer the question. If you choose to not answer a question, you can continue in the rest of the study without any penalty.

You will not have to pay any money in order to participate in this study. However, the costs to you for participating in this study include your time spent participating in this study and the cost of transportation to and from XXXXX where the study will be conducted.

Please understand that all the information that you provide in this study, including your answers to the questionnaires, the results of your urine tests and, if applicable, the digital audio-recording of your semi-structured interview, will be kept confidential. This means that all of your responses and test results will be coded by a study identification number and not by your name. The only place we will store your name is on the consent form, locator form and master tracking log. All study information will be kept in locked files and computer networks accessible only to research staff. Research staff are carefully trained to maintain the confidentiality of the information collected. Any publications that may result from this study will not mention your name or anything about you that someone could recognize. Audio recordings of semi-structured interviews will be stored in a secure computer network at XXXXX and will be destroyed within 3 years after this study is completed.

Authorization to Use or Disclose Protected Health Information for Research

By signing this form, you are allowing the investigator and the study staff to use and disclose your personal health information to those agents that are monitoring the study and auditing results.

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.

Certificate of Confidentiality

To help us protect your privacy, we have received a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to give information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

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

The Certificate of Confidentiality does not prevent the researchers from voluntarily disclosing information that would identify you as a participant in the research project, but it would only be released according to both the strict confidentiality procedures of XXXXX and XXXXX and the rules of ethical research practice under the following circumstances:

- If you tell the researcher that you are planning to harm yourself or someone else (such as serious thoughts of suicide, current or future child abuse, intended assault or similar crimes), we would have to tell the staff at XXXXX or the appropriate agencies without your permission.
- If you tell the researcher something that could help with your treatment at XXXXX , we will ask for your permission to share this information with the staff at XXXXX .

The Certificate of Confidentiality does not guarantee absolute confidentiality. However, disclosing information that would identify you as a participant in the research project would only be released according to both the strict confidentiality procedures of XXXXX and XXXXX and the rules of ethical research practice under the following circumstances:

- If necessary to protect your rights or welfare (for example, if you are injured and need emergency care).
- If required by XXXXX State law, such as cases of child or elder abuse or neglect.
- If you are found to have a communicable disease, and the laws of XXXXX State require that we report it to the state of XXXXX.
- If we suspect that you are a danger to yourself or others, we may also give this information to medical personnel or other proper authorities. In addition, we may report certain cases of domestic violence.

Additional Information

If you have any questions about the study or to report any possible injury that might occur as a result of your participation in this study, please contact the Principal Investigator, XXXXX (xxx-xxx-xxxx) or the Principal Investigator, XXXXX, at XXXXX (xxx-xxx-xxxx). You may also contact XXXXX (xxx-xxx-xxxx) to answer any questions you may have about your rights as a research subject.

For further information about your rights as a research participant or if you are not satisfied with the manner in which this study is being conducted or you believe that the privacy of your protected health information has been violated and would like to discuss your participation with an independent person who is not part of this study, please contact at (xxx) xxx-xxxx.

No provision has been made to pay any subject for harm which may result from participation, but nothing in this consent limits your right to seek payment for any harm resulting from your participation.

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I have read all the items on the information sheet, and all questions about the study have been answered to my satisfaction.

I understand the following:

- My participation is voluntary;
- I can discontinue participation at any time without penalty;
- I can receive up to $XXX for my time/participation if I complete all questionnaires and tests;
- If I am asked to participate in a semi-structured interview, I will receive an additional $XX for my time participating in this interview;
- My name will not appear on questionnaires, audio recordings of interviews, or other data collection forms: only a code number will be used;
- All information will be kept in locked files accessible only to professional research staff;
- A Certificate of Confidentiality has been obtained to protect my privacy;
- All written and published information will be reported as group data, with no reference to individuals.

_____ _____

Participant Signature Date

_____ _____

Interviewer Signature Date