AN EVALUATION OF A COMPUTER-DELIVERED PSYCHOSOCIAL INTERVENTION FOR INDIVIDUALS IN METHADONE MAINTENANCE TREATMENT

Informed Consent Form for Counselors

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. 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. You are eligible to participate in this study because you are a new client entering methadone maintenance treatment at XXXXX.

Study Participation for MMT Clients:

New clients entering methadone treatment at XXXXX will be offered the opportunity to participate in this research study. Clients who agree to participate in this study will be randomly assigned to one of three conditions, Condition 1, Condition 2, or Condition 3.

Clients assigned to Condition 1 will receive the standard drug counseling offered as part of treatment at XXXXX. They may be asked to meet with their substance abuse counselor at the program for one hour-long individual sessions according to the following schedule: at least once a week during their first month of treatment and twice a month in their second through twelfth months of treatment.

Clients assigned to Conditions 2 and 3 will receive the same standard drug counseling that is offered as part of treatment at the XXXXX. Clients also will receive one of two mobile phone interventions for the first 3 months of treatment. Clients will be encouraged to use the mobile intervention between counseling sessions or whenever they feel they need it. There is no minimum or maximum amount of time clients will be required to use the mobile intervention.

Clients in Conditions 2 and 3 will be given a mobile phone with one of two interventions on it for the first 3 months of treatment. The mobile phone will come with a paid talk and text plan. Clients will be asked to return the mobile phones to the study staff at the end of the 3 months.

All participants will be asked to participate in the study for 3 months. Study participants will be asked to complete a set of questionnaires before beginning the study, once per month during the 3 months they are in the study, and again at 1 and 3 months after the study. In addition, they will also be asked to provide a urine sample that will be screened for drugs of abuse before starting the study, one time per week during the 3 months (12 weeks) of the study, and once at 1 month and 3 months after the study. A research staff member of the same sex may observe clients providing a urine sample each week.

The total time clients are being asked to participate in this study is 6 months. However, they can choose to withdraw from this study at any time before completing it. Clients will be discharged from the

study if they leave, or are discharged from, methadone maintenance treatment at XXXXX.

Clients who participate in the study will receive $XX in cash for each set of questionnaires they complete (which will take about 1 ½ - 2 hours to complete) and $XX in cash for each urine sample they provide. As a result, participants who complete all questionnaires and provide all urine samples for the 6-month duration of their study participation will earn a total of $XXX.

Study Participation for Substance Abuse Counselors:
If one or more of the clients on your caseload is participating in the study, you will be asked to complete one or two brief feedback surveys each month. In these surveys you will be asked to provide feedback on how useful you thought your clients found the mobile intervention to be and the extent to which clients discussed information from the mobile intervention in your counseling sessions. It should take about 10-15 minutes to complete these surveys each month.

In addition, each month you will be asked to complete a brief questionnaire for each of your clients who is a participant in the study. This questionnaire asks you to rate the therapeutic alliance, or degree of helping relationship, that has developed between you and the client. It should take about 20 minutes for you to complete this set of questionnaires each month.

In total, then, it should take you about 30-35 minutes to complete the feedback survey and set of questionnaires each month.

Compensation:
You will receive $XX in cash for each monthly feedback survey and set of questionnaires you complete immediately after you complete them. You will be asked to complete one set of questionnaires for each client you have that is currently participating in the study. Therefore, the amount of money you can earn in the study depends on how many clients you have that choose to participate in the study and how many sets of surveys/questionnaires you choose to complete.

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 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 participating in the study is that you may feel frustrated or bored answering feedback surveys and questionnaires about your use and opinions of the mobile phone reporting system and your therapeutic alliance with your clients.

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. Additionally, your responses on the monthly feedback surveys and questionnaires will not impact your employment in any way.

The primary cost to you for participating in this study is the time you spend completing feedback surveys and questionnaires and reviewing summary reports of your clients' use of the mobile intervention.

Please understand that all the information that you provide in this study will be kept confidential. This means that all of your responses will be coded by a study identification number and not by your name. The only place we will store your name is on the Informed Consent Form for Counselors and the 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.

Certificate of Confidentiality

To help us protect your privacy and the privacy of the clients who participate in this study, 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 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 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.

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, at XXXXX (xxx-xxx-xxxx). You may contact XXXXX at XXXXX (xxx-xxx-xxxx) to answer any questions you may have about your rights as a research subject.

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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Informed Consent Form for Counselors Signature Form

I have read all the items on the informed consent form, 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 $xx for each monthly set of questionnaires I complete;
- My name will not appear on interview 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;
- All written and published information will be reported as group data, with no reference to individuals.

_____ _____

Participant Signature Date

_____ _____

Interviewer Signature Date