Women's Treatment and Early Recovery (MBRP-W)

NCT02977988

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University of Southern California
School of Social Work
669 W 34th St, Rm 220
LA, CA 90089

INFORMED CONSENT FOR NON-MEDICAL RESEARCH

Women's Health Study

You are invited to participate in a research study conducted by Dr. Hortensia Amaro at the University of Southern California, because you have almost completed the orientation phase of your treatment program at Prototypes, are a female aged 18-65, speak fluent English, and if you are pregnant are no more than six months along in your pregnancy.

This study is funded by the National Institutes of Health**.** Your participation is voluntary. The research interviewer will explain the study to you. We are also providing you with this written explanation of the study so that you can read the information. Feel free to ask questions about anything you do not understand, before deciding whether to participate. Please take as much time as you need to read the consent form. You may also decide to discuss participation with your family or friends. If you decide to participate, you will be asked to sign this form. You will be given a copy of this form.

PURPOSE OF THE STUDY

The purpose of the study is to learn about how helpful two new education groups may be for women in substance abuse treatment. We are doing this research because we want to learn if one or both of these two new education groups that we are offering at Prototypes are helpful for women who are in residential treatment.

Women who are in treatment for substance use problems can experience challenges with relapse and staying in treatment. This is important because drug use relapse and not completing treatment can have serious consequences for women. In order to learn if these education groups are helpful, each woman in this study will be asked to participate in one of two different groups. These groups are in addition to the usual services you will receive at Prototypes. These groups are not required as part of the services you receive as part of your regular treatment at Prototypes. The groups are new and additional services that we are offering.

STUDY PROCEDURES

If you volunteer to participate in this study, you will be asked to participate for about ten months. In the event you relapse during your participation in the study, you can continue to

participate in the study. If you leave the residential facility, you will no longer be able to participate in the group sessions, but you will be able to participate in the remaining interviews and receive compensation for completing the interviews. You will be randomly assigned to one of two groups, and will have a 50:50 chance of being assigned to either Group A or B; the assignment is much like the toss of a coin. Education Group A will be on how alcohol and drug use affect the brain. Education Group B will be on how stress affects recovery. The groups will take place on site at Prototypes. These groups will provide information about addiction and recovery that you are not getting now as part of your treatment. The group will meet 2 times per week for 1 hour and 20 minutes each time for a total of 12 group sessions. You will be attending the group for 6 weeks.

If you are assigned to group A: Brain and Recovery, you will be asked to attend education sessions that involve: presentations by the group facilitators, discussions, viewing videos and activities to help you understand the material and learn about how the brain is affected by substance use and recovery.

If you are assigned to group B: Recovery and Stress, you will be asked to attend education sessions that involve: presentations by the group facilitators, discussions, and activities to help you understand the material and learn how to use strategies for coping with stress.

You will be asked to complete short questionnaires at the end of the sessions that will ask about your satisfaction with the sessions and about your understanding of the material.

If you drop out of treatment before you attend the first group session or if you are still in treatment but do not attend the first group session, we will not be able to follow-up with you and you will be terminated from the study. If after attending the first group session, you drop out of treatment and can't attend the remaining groups, we will still follow up with you to conduct interviews and you will continue to be part of the study.

In addition to the group, you will also be asked to complete three interviews of about 1 ½ hours each. The first interview will be before the first education group meeting. The second interview will be after the last education group meeting. The last interview will be eight months after the last group session. The interviews will be conducted by a USC research interviewer they are not employees of Prototypes. The interviewer will ask you questions about substance use, desire to use drugs, mental health, stress, trauma, coping strategies and things you may do to help you in recovery. The interviewer will also ask you for information that will help us contact you for your 2nd and 3rd interviews. This includes information like where you may expect to live after leaving Prototypes and contact information for people who you may be in contact with after you leave treatment. We ask for this information because it is very important that we are able to complete all the interviews with you even if you are no longer at Prototypes. We will only

contact people you have given us permission to contact and we will not talk to them about the nature of the study or give them any information about you.
At the first interview, you will be asked to allow the interviewer to take your photograph to help us identify you at the later interviews. The photographs will be destroyed upon completion of the study and will be confidential.

At each of the interviews, you will also be asked to provide a urine sample and a Breathalyzer test to test for substances.

The interviews will be audio recorded to make sure that the interviewer is doing a good job conducting the interviews. These recording will only be available to the USC research team and not to Prototypes staff. If you do not want to be audio-taped, you cannot participate in this study.

If you are incarcerated at the 2nd and or 3rd interview, we will conduct the interview in an attorney room while you are in jail to ensure your privacy. Only the research staff interviewer will be in the room with you for the interview. We will not ask you to provide a urine sample nor complete the Breathalyzer test. Interviews conducted in jail will not be audio-recorded. The staff at the jail will not have access or be given any information from your interviews. We will not inform the parole board or any other entity not connected to the study of your participation in the study.

If your place of residence at the 2nd and or 3rd interview is more than 1.5 hours or more than 90 miles one-way from our project office (Los Angeles) and you are not able to meet us at our project office, we will conduct the interview over the telephone. We will not ask you to provide a urine sample or complete the Breathalyzer test.

The education groups will be audio-taped to make sure that the group facilitator is doing a good job conducting the groups. The audio recordings will only be available to the USC research staff and not to the Prototypes staff. If you do not want to be audio-taped, you cannot participate in this study.

You will be asked to allow us to get information from your Prototypes records on things like your date of Prototypes treatment entry and completion, types of services you received while at Prototypes and updates on your contact information so that we can reach you for the follow-up interviews. Getting this information from your records will help us to not have to ask you about these things. In order to receive access to the records, you are asked to review and sign the HIPAA Form.

The interviewer may contact you after the 3rd interview to let you know about the possibility of participating in other studies. At that time, information will be provided to you about other studies and you can decide if you want to participate or not.

POTENTIAL RISKS AND DISCOMFORTS

We do not anticipate any risks to you from participating in the study. However, we cannot be sure how you will respond to the education groups or the research interviews. The following are possible difficulties you may experience:

- There is the risk that what you say in the group will not be kept confidential. This is a risk that is common to any group. To reduce this risk, the group facilitator will emphasize to the group the importance of confidentiality among group members, and that members should not mention anything said in the group to anyone outside the group. Also, during your participation in the groups, you are free to choose what you share and what you don't want to share.

- Another risk is the possibility that some questions in the research interview may make you uncomfortable. If this happens, women usually feel they can manage the discomfort themselves or they talk with other supportive people. If you feel uncomfortable during an interview, you can choose not to answer certain questions, take a break and continue later, or you can stop the interview. If you choose, the interviewer can call a staff member of your choice at Prototypes, or some other concerned person, to make sure you have someone to talk with about the interview.

- There is a risk that information you provide as part of the study may not remain confidential. We have taken several steps to protect your privacy so that this risk is very small (see the section on Confidentiality below).

POTENTIAL BENEFITS TO PARTICIPANTS AND/OR TO SOCIETY

We don't yet know if you will benefit from participating in the study. However, in the group education sessions, you may learn things about addiction and recovery that you don't know about and/or that are not covered in other services at Prototypes. Your participation may help us to develop better services for women in recovery**.** The feedback you provide us on the groups may help to improve services for women in treatment. Your participation in the interviews will help us to find out if the groups help women in treatment and how to make them more effective.

PAYMENT/COMPENSATION FOR PARTICIPATION

You will be paid for participation in this study. You can earn a maximum of $140 for participating:

$40 total for the 1st interview: $30 for the interview plus $5 for urine sample and $5 for Breathalyzer test
$40 total for the 2nd interview: $30 plus $5 for urine sample and $5 for Breathalyzer test
$60 total for the 3rd interview: $50, plus $5 for urine sample and $5 for Breathalyzer test

In addition, if at the time of your 2nd or 3rd interviews, you are no longer at Prototypes, you will receive an additional $20 at each interview to reimburse you for childcare and transportation costs for getting to the interview location.
You will receive payment at the end of each interview. Payment for interviews and samples will be in the form of gift cards to a local store. Payment for childcare and transportation will be in cash.

If you complete your 2nd and/or 3rd interview while you are in jail, we will deposit a cash payment for the interview to your inmate money account on the same day as the interview. If you are incarcerated at the 2nd or 3rd interview, we will not ask you to provide a urine sample or complete the Breathalyzer test, which means that you will not receive $5 for the urine sample nor the $5 for the breathalyzer test. If you complete your 2nd and/or 3rd interviews in jail, you will not receive the additional $20 in cash to reimburse you for childcare and transportation costs for getting to the interview location

If you complete your 2nd and/or 3rd interview over the telephone, we will not ask you to provide a urine sample or complete the Breathalyzer test, which means that you will not receive $5 for the urine sample nor the $5 for the breathalyzer test. If you complete your 2nd and/or 3rd interviews by telephone, you will not receive the additional $20 in cash to reimburse you for childcare and transportation costs for getting to the interview location

CONFIDENTIALITY

We will keep your records for this study confidential as far as permitted by law. However, if we are required to do so by law, we will disclose confidential information about you. The members of the research team, the funding agency and the University of Southern California's Human Subjects Protection Program (HSPP) may access the data. The HSPP reviews and monitors research studies to protect the rights and welfare of research subjects.

The data will be stored at the USC School of Social Work Project Office, which is a locked office with access only to the study staff. Files will be kept in locked file cabinets in that locked office

with access only to research staff. All data collection forms including the interviews will not have your name. Instead, we will use an identification number without your name. A list will be kept in a separate locked cabinet by the Principal Investigator and Project Coordinator with your name and participant identification code. The list and photographs, will be destroyed three years after completion of the research study. The remaining data will be stored indefinitely and may be used in future research studies. If you do not want your data used in future studies, you cannot participate in this study.

Audio recordings of the interviews will be used to determine if the interviewers adhere to the interview protocol. Audio recordings of education sessions will be used to determine if the group leader adheres to the group curriculum protocol. These will be viewed only by the USC research team members. Recordings will be destroyed within four years of the study's completion.

Staff at Prototypes will not have access or be given any information from your interviews, group audio recordings or the results of urine or breathalyzer for the study. Prototypes staff will only know if you agree to participate in the study.

At no time will data be reported in a way that links your name or identity to the study data or findings. Data will be collected by a secure, web-based data capture system maintained by USC.

CERTIFICATE OF CONFIDENTIALITY

Any identifiable information obtained in connection with this study will remain confidential, except if necessary to protect your rights or welfare (for example, if you are injured and need emergency care). A Certificate of Confidentiality has been obtained from the Federal Government for this study to help ensure your privacy. This certificate means that the researchers cannot be forced to tell people who are not connected with the study, including courts, about your participation. If you ask us to disclose information, we will do it. This protection does not prevent the investigators from voluntarily reporting, without your consent, information about suspected or known sexual or physical abuse of a child or a threatened violence to yourself or others. We will not ask you any questions about sexual or physical abuse of a child, or threatened violence to yourself or others, but if you volunteer this type of information we are required by law to report it to the proper authorities.

When the results of the research are published or discussed in conferences, no identifiable information such as your name or photos will be used.

PARTICIPATION AND WITHDRAWAL

Your participation is voluntary. Your refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or

remedies because of your participation in this research study. The investigator may withdraw you from this research if circumstances arise which warrant doing so.

If you do not attend the first group session either because you have left Prototypes or for any other reason, we will withdrawal you from the study and you will not be able to continue participating in the study. If drop out of Prototypes after attending the first group, you will continue to be in the study and we will contact you for follow-up interviews.

ALTERNATIVES TO PARTICIPATION

If you choose to not participate in this study, you will still have access to all standard services at Prototypes. Once the study is completed, the Prototypes staff may choose to provide the group interventions to all clients.

EMERGENCY CARE AND COMPENSATION FOR INJURY

If you are injured as a direct result of research procedures you will receive medical treatment; however, you or your insurance will be responsible for the cost. The University of Southern California does not provide any monetary compensation for injury.

INVESTIGATOR'S CONTACT INFORMATION

If you have any questions or concerns about the research, please feel free to contact the Principal Investigator, Dr. Hortensia Amaro via phone at 617 799-7280 or email at hamaro@usc.edu

RIGHTS OF RESEARCH PARTICIPANT – IRB CONTACT INFORMATION

If you have questions, concerns, or complaints about your rights as a research participant or the research in general and are unable to contact the research team, or if you want to talk to someone independent of the research team, please contact the University Park Institutional Review Board (UPIRB), 3720 South Flower Street #301, Los Angeles, CA 90089-0702, (213) 821-5272 or upirb@usc.edu

SIGNATURE OF RESEARCH PARTICIPANT

I have read the information provided above. I have been given a chance to ask questions. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

□ *I agree to be photographed*

□ *I do not want to be photographed*

_____
Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF INVESTIGATOR

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

_____
Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date