Evaluation of EBT with Young, Substance Abusing Homeless Mothers

NCT02577666

Informed Consent, 4/25/18

The Ohio State University Consent to Participate in Research

Study Title: Evaluation of EBT with Young, Substance Abusing Homeless Mothers

Researcher: Natasha Slesnick, Ph.D.

Sponsor: National Institute on Drug Abuse

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate.

Your participation is voluntary. Please consider the information carefully. 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.

Purpose:

Little guidance is available on how best to meet the needs of young homeless mothers and their children. The purpose of this study is to address that gap through testing a comprehensive intervention that offers housing and support services to meet the multiple needs of homeless mothers with a child 6 years or younger in their care. You are being asked to participate in this study because you are homeless, between the ages of 18 to 24 years, report substance use and because you have a child under 6 years of age in your care.

Procedures/Tasks:

This study will evaluate a comprehensive housing and substance use/mental health intervention for young homeless mothers. Women, 18-24 years, who have a child 6 years or younger in their care, report alcohol and/or drug use and are homeless will meet with a project research assistant (RA), and will be asked basic questions regarding their eligibility for participation in the study. If the mother is interested and eligible, she will continue with the formal study assessment. Those not meeting the inclusion criteria during the formal assessment will be provided a care package, estimated value $15, that includes toiletries and food items, and informed that even though they are not eligible for the current research, they can continue with the treatment as usual through the drop-in center. Two hundred and forty women will be invited to participate in this study.

Instruments will be administered by a research assistant. The format includes both interview, observation and client self-report. Observation entails observing the mother and child in normal activity setting for 30 minutes at each assessment point. Upon completion of the assessment interview, women will be assigned to either 1) the comprehensive intervention that includes housing and support services, 2) housing only, or 2) treatment as usual through

the drop-in center. The condition to which women are assigned is chosen by chance. Participants assigned to the comprehensive intervention will receive housing vouchers (3 months) and 20 50-minute substance use/mental health counseling sessions which will be digitally (audio) recorded for research and supervisory purposes. These women will also receive 26 case management sessions. Treatment sessions and case management can be offered in the home or at the drop-in center. The goal is to complete the therapy sessions within 3 months, but all therapy must be completed within 6 months of the first assessment interview. Women who drop-out or refuse to attend treatment will continue to be assessed at follow-up. Mothers that do not receive a housing intervention may not live with or stay with those mothers who received housing, and are asked to honor the intervention group that they are assigned. In most cases, lease agreements restrict who may stay in the apartment. All women will be evaluated at 3, 6, 9 and 12 months after the baseline assessment. At each assessment interview, an onsite urine toxicology screen will be collected to confirm self-reported drug use. These data are used solely for research purposes. Contact information provided by women of family, friends or others may be used to help research staff track women for their follow-up assessments. Follow-up assessment interviews can be conducted in the participant's home or at The Ohio State University research office/drop-in center.

Nutrition questionnaires for a cross-sectional study may also need to be completed by you at either your baseline assessment or at one of your follow up assessments. These Nutrition questionnaires expands on the research goal by identifying nutritional susceptibilities that contribute to the etiology of substance abuse and/or aggravates the health consequences associated with it. Identifying the nutritional challenges unique to this population is the first step towards identifying solutions.

One of the Nutrition questionnaires will include the use and recording of body measures, including: weight, height, waist and hip circumference.

Duration:

- Each of the five assessment interviews (the first assessment, or baseline assessment, and the 3, 6, 9 and 12 months post-baseline assessment) is expected to require approximately 3.0 hours to complete. Participants will be given the option of completing the interview in one session or in two shorter sessions on separate days. Follow-up assessment interviews that are missed will not be made up if the next follow-up is currently due. For example, the 6 month follow-up assessment interview will not be done if the due date for the 9 month assessment interview has passed.

If the Nutrition questionnaires need to be completed they will take approximately 30 additional minutes. They will only need to be completed once, either at your baseline assessment or at one of your follow up assessments.

For those women assigned to the housing + supportive services intervention:

-Approximately 46 hours of therapy and case management will be offered across 3 to 6 months. All therapy and case management will end 6 months after the baseline interview. Sessions that are missed for any reason will not be made up after that point.

For those women assigned to housing only: Up to 10 hours will be needed for you to work with the project staff member to find your apartment.

You may leave the study 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 Ohio State University.

Risks and Benefits:

If we suspect child abuse, neglect or abandonment we may report this to protective services which could lead to possible long-term consequences for parental rights and legal prosecution. Sensitive information will be collected, and although many protections are in place to maintain participant confidentiality and security of records, there is always a risk associated with breaches in confidentiality of research data, such as through break-ins to confidential folders or thefts. However, this is unlikely as the PI has separately keyed storage rooms within her offices on campus for data storage that include separately keyed file cabinets. The assessment might create boredom. You may recall unpleasant events from your life which can cause distress.

There may be no benefit to you from participating in this research. However, we expect the experience will be positive for both you and your child. You may benefit from being offered housing and support services. Support services can include assistance obtaining employment and other needed services through the community. Therefore, it is possible that the project intervention will increase your level of support and future success. Also, the information that you provide through the assessments will help us know whether the treatment is effective. Such information can improve our understanding and our ability to stabilize other homeless mothers and their children.

Confidentiality:

Efforts will be made to keep your study-related information confidential. However, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor, if any, or agency (including the Food and Drug Administration for FDA-regulated research) supporting the study.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, it has been reported to us by the National Institutes of

Health that the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

Exceptions: A Certificate of Confidentiality does not prevent researchers from voluntarily disclosing information about you, without your consent. For example, we may voluntarily disclose information about incidents such as child abuse (e.g. of your child) and intent to hurt yourself or others. In addition, a Certificate of Confidentiality does not prevent you or a member of your family 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. Finally, the Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

Incentives:

You will be offered a $40 gift card for completing the baseline assessment interview (the first assessment) and $50 for the 3, 6, 9 and 12 month interviews. You will receive half of the gift card amount for completing up to half of the assessment. You will receive the full gift card amount if you complete at least half of the assessment. If you are assigned to the housing + supportive services intervention, you will receive a $5 gift card for attending each of the 20 substance use/mental health treatment sessions, and $3000 total in housing and utility vouchers for 3 months. You will also receive $10 for completing a questionnaire once/month about your treatment experience. If you are assigned to housing only, you will received $3000 total in housing and utility vouchers for 3 months. If you withdraw from the study and are in a housing condition, we will continue to offer rental assistance for the 3 month duration. Monthly bus passes (6 months @ $62/mo) will be provided to all mothers so that they can travel to work and other appointments as needed. Mother's that have vehicles will be offered a gas card instead of a bus pass (6 months@ $62/mo).

When you complete the one time Nutrition questionnaires you will receive an additional $30 gift card.

Participant Rights:

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

Contacts and Questions:

For questions, concerns, or complaints about the study you may contact Dr. Natasha Slesnick, Principal Investigator at (614) 247-8469.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. Natasha Slesnick, Principal Investigator at (614) 247-8469**.**

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 voluntarily agree to participate in this study.

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
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
	AM/PM
Relationship to the subject	**Date and time**

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