

HUMAN SUBJECTS

Risks to the Subjects

a. Human Subjects Involvement and Characteristics

The proposed study will include 240 homeless mothers with a biological child under the age of 6 years. All mothers will be recruited from outreach efforts and our drop-in center. The rationale for involvement of this vulnerable population in the project is to identify treatments that will intervene in homelessness and its related problems, and to identify an intervention that will work even in communities that do not have access to homeless families shelters. Mothers will range in age from 18 to 24. Ethnic and racial characteristics of Columbus homeless youth are: 67% Black/African American, 20% are White, non-Hispanic, 4% Hispanic or Latino, 1% Native American, and 8% "other" or mixed ethnicity/race.

Inclusion criteria for participating mothers are:

1. Mother meets criteria for homelessness as defined by the McKinney-Vento Act as those who lack a fixed, regular, and adequate nighttime residence; lives in a welfare hotel, or place without regular sleeping accommodations; or lives in a shared residence with other persons due to the loss of one's housing or economic hardship. This definition of homelessness is inclusive and is meant to capture the multiple locations where homeless youths seek refuge.
2. Mother is between the ages of 18-24 years. Homeless youth is a term commonly used to describe homeless young adults up to the age of 24 (Robertson & Toro, 1998). This age range represents a relatively homogeneous group of late adolescents and early adults whose development is considered separate from early and mid-adolescents ranging from 12 to 17 years (McGivern et al., 2002).
3. Mother meets DSM-5 diagnostic criteria for Psychoactive Substance Use or Alcohol Use disorder, as assessed by the computerized diagnostic interview schedule (CDIS, Shaffer, 1992). If the mother has more than one child in this age range, a coin will be flipped to determine which child the mother will refer to when completing the Child Behavior Checklist.
4. The mother has physical custody of a biological child under the age of 6 years.

Exclusion criteria will be:

5. Evidence of unremitted psychosis or other condition which would impair youth's ability to understand and participate in the research (as determined by CDIS).

b. Sources of Material

The sources of research material will be structured clinical interviews, self-report questionnaires, urine screen results and digital recordings of therapy sessions. Audio computer assisted interview will be used to collect questionnaire data. Urine screens will be completed onsite with one-step Toxcups, which provide instant readings for the detection of marijuana, cocaine, methamphetamine, opiates, and PCP. The material will be used only for research purposes. Research material will not be shared with anyone outside the research project, or used for any other purpose than research, without written consent from the client.

c. Potential Risks

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 project's Human Ecology House has separately keyed rooms, with separately keyed file cabinets, and is protected by ADT alarm company. The assessment might create boredom. However, the assessment can be broken up over two days, and frequent breaks will be provided. It will be incumbent upon project staff to ensure that the client understands the voluntary nature of participation. Characteristic of therapy in general, clients may discover unpleasant information about themselves which can cause distress.

Risk for the children is that if child abuse or neglect is suspected, project personnel will be required to make a report to Child Protective Services, and the investigation may result in the child being removed from mother's care. The mandatory reporting requirement is meant to protect the child against risk of harm, though if this were to happen, the child may not understand being removed from the mother as protection. Children are not directly involved in any research tasks. However, the artificial situation and contact with unfamiliar people (the researchers) might be stressful to the child, especially when the child is watching a movie or playing with project personnel while the mother is engaging in research activities. However, it is expected that the child will enjoy the play time but if they become distressed, they will be reunited immediately with their mother.

Adequacy of Protection Against Risks

a. Recruitment and Informed Consent

As noted, mothers will be recruited from the drop-in center. The drop-in center serves about 20-30 youth per day, and we engage new youth through outreach to sandwich lines, soup kitchens and the library. Mothers interested in participating in this project will be interviewed by a research assistant using the basic eligibility criteria as a guide. Those found to be ineligible will continue to receive basic services through the drop-in center which include food, showers, washer/dryers, case management, access to other programs that serve homeless individuals onsite such as Healthcare for the Homeless and Columbus AIDS Task Force. Those meeting eligibility criteria will be scheduled for a baseline evaluation as soon as possible, ideally within 24 hours of contact. The evaluation will be conducted by the research assistants at the Project House (drop-in center) and will begin with a review of the nature of the study, participation requirements, a formal review of the elements of informed consent, and signing of the research consent statement. The interviewer will proceed to administer the CDIS sections on alcohol, drugs, and psychosis to determine formal eligibility. Choosing not to participate in the study will not influence the services that the mother could receive at any other community service agency. Mothers who are screened (requiring approximately 30 minutes) and do not meet criteria for participation will receive a care package including toiletries and food items. Upon completing the full assessment battery they will be randomly assigned to EBT (housing and supportive services) +TAU (n = 80), Housing only (HO) + TAU (n = 80) or TAU alone (n = 80).

The Mother's baseline and follow-up interviews will take approximately 2 hours to complete. This assessment burden was found to be reasonable in our other projects. Mothers will be offered frequent breaks, and will be offered food and beverages to increase comfort. All participants will be assessed monthly during treatment on the Working Alliance and will receive a full battery at baseline, 3, 6, 9 and 12 months post-baseline. The mother will receive a \$40 gift card at baseline, \$10 gift cards for each of the shorter monthly assessments, and will receive a \$50 gift card for completing each follow-up assessment. To increase treatment participation, mothers will receive a \$5 McDonald's, Burger King or Wendy's gift card for every CRA session that they attend.

b. Protection Against Risk

Federal guidelines will be followed regarding the protection of subjects in alcohol/drug studies. As in our other projects, we will obtain a Certificate of Confidentiality. Subjects will be informed that project records will be kept in a locked and secure records area in the Project House. Anonymity will be maintained on questionnaires by labeling materials with identification numbers instead of names. Project staff who have access to records are trained in procedures to maintain strict confidentiality, which includes a prohibition against removing records from the project area, and prohibition to divulge any information or revealing the identity of participants without written consent. Urine screens are not sent to the lab but are read on-the-spot further reducing risk to breaches of confidentiality.

Participants will be fully informed before the study begins as to the risk that they may discover information about themselves that they find unpleasant. Unpleasant emotions that may occur in the therapy context may be processed with a trained therapist. Participants will also be assured that they may withdraw from the study at any time even after agreeing to participate, so that if they experience

discomfort during the procedures they may terminate participation or refuse to answer any particular item without penalty.

During the intake, mothers will be assessed for suicide and homicide. They will be told, and sign a consent statement, informing them of the limits to confidentiality, including child abuse. If it is suggested at that time or at any later time, that child abuse or neglect, including sexual or physical abuse (leaving marks, bruises or burns) or abandonment has occurred or currently takes place, Public Children's Services Agency (PCSA) of the State of Ohio will be notified immediately by phone and may instigate an investigation. It is our policy to report alleged abuse with the participant in the room, if possible, during the call to PCSA by the interviewer or therapist. In order to mitigate potential negative effects on the mother (e.g., breakdown of trust) the staff member will discuss with them the purpose, legal and clinical, of reporting and answer concerns and fears that the participant may have. In the case of homicide, we are mandated to report the information to both the police and the intended victim. In the case of suicide, if the client is acutely suicidal we are required to secure them a bed in a psychiatric hospital if necessary – otherwise, if the client is not deemed acutely suicidal, we are required to provide treatment and/or referrals.

There is no deception involved at any time in the study. In fact, great lengths are taken to explain what participation involves since that provides a greater likelihood of study completion. Risk may include boredom. Some questions on the assessment may make youth uncomfortable as the questions involve sensitive information about behaviors in which they may have engaged. These questionnaires will be described to mother prior to their administration by the interviewer, and mothers will be told that if they feel discomfort at any point, that they may let the interviewer know and cease answering the questions without penalty. As these forms and others are identified only by a number, confidentiality is maintained.

Potential Benefits of the Proposed Research to the Subjects

There may be no benefit to the mother or child from participating in this research. It is more likely however, that the mother will receive assistance through the interventions which are free of charge. We expect the interventions to be beneficial to the mothers and their children and that the experience will be positive.

Importance of the Knowledge to Be Gained

The knowledge generated by this research is expected of be of great value in making policy recommendations and in designing interventions and treatments for homeless substance abusing mothers and their young children. The potential benefits for helping those in the program and for providing an empirical and theoretical basis for understanding and intervening in homelessness seem sufficiently advantageous to justify the project.

Data and Safety Monitoring Plan

Safety. The population with which we propose to recruit often have a history of abuse, have high levels of alcohol and drug use, and many experience depressive symptoms. Those requiring hospitalization will be taken directly to the hospital by police or ambulance. Natasha Slesnick, Ph.D., Professor, and licensed clinical psychologist (Ohio license #6081) is responsible for monitoring the clinical management of serious adverse events. *If any intervention is found to cause harm to participants, the trial will be stopped.* Required data reports on adverse event cases will be submitted.

There is no deception involved at any time in the study. In fact, great lengths are taken to explain what participation involves, since that provides a greater likelihood of completion of the course of treatment and follow-ups. As explained above, risk to the subjects is minimal. Nevertheless, subjects are assured that they can decline to participate at any point in the study if they so choose. Confidentiality of subject information is provided according to the requirements of 42 CFR, Part 2, and we will apply for a certificate of confidentiality. Only numbers are used for identifiers on assessment data and tapes. All paper records and tapes are kept in locked cabinets in a locked room, with access only by appropriate project personnel. All data entry is password protected and OSU's network is firewall protected from unauthorized outsiders.

Specific emergency procedures for expression of intent to commit suicide or harm others.

Emergency procedures have been set up for addressing these issues since the PI began working with runaway and homeless youths in 1998. All staff are trained in these emergency procedures. In summary, all participants are interviewed at baseline for harm to self and others. If a youth answers yes to any of the screening questions during the intake interview, the staff member pulls out the "Harm to Self or Others" assessment, and does a full suicide/homicide assessment interview. In essence, if any of the screening questions on the demographic form are answered in the affirmative, a full assessment of imminent risk is conducted that includes 1) whether a plan is in place, 2) whether the means to carry out the plan are available, 3) intent to carry out the plan and reasons for wanting to harm self. The RA or therapist then calls the PI and reviews the information with the PI. Upon this review, next steps are discussed. If imminent risk is determined, the client is asked to accompany the staff member to Netcare. Netcare Access provides twenty-four hour mental health and substance abuse crisis intervention, stabilization and assessment for Franklin County, Ohio residents. These services are provided for children, adolescents and adults who evidence a mental health or substance abuse disorder. If necessary, Netcare coordinates treatment, such as hospitalization, through local agencies. Netcare is staffed with skilled physicians, nurses, psychologists, social workers, counselors and technicians. Services are available to anyone, regardless of the ability to pay. No one in need is turned away. If the client refuses to accompany the staff to Netcare and imminent risk of suicide/harm to self is determined, then we will call the police to accompany the youth. Also, in the fifteen years of working with runaway and homeless youth, we have only had to make one homicide report in which both the police and intended victim were notified, as per Tarasoff. However, the procedure is essentially the same as described above.

Data protection. OSU's College of Education and Human Ecology employs a Cisco PIX Security Appliance as its firewall. Cisco's Adaptive Security Algorithm provides stateful packet inspection firewall services. Authorized network communications are tracked and unauthorized attempts are blocked. The PIX uses the Syslog service to log both inbound and outbound traffic to a Syslog server. Daily logs are monitored daily and stored monthly. All users have passwords that are re-generated and changed every 90 days. Individual files are further protected by user/owner set protection. Only certain users have write privileges on these databases. Backups are run daily on volatile datasets. System-wide weekly and monthly backups are performed. Paper records including consent forms and therapy files will be maintained in a locked and secured data storage area within the Drop-in Center.