

“Prevention of OUD: The HOME (Housing, Opportunities, Motivation and Engagement) Randomized Trial”

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Study Protocol

Overview of Design

240 homeless youths between the ages of 18 to 24 years recruited from the streets and drop-in center/shelters will be randomly assigned to 1) 6-months of housing + opioid and related risk prevention services (n = 120), or to 2) opioid and related risk prevention services alone (n = 120). Using an intent to treat design, follow-up assessments will be completed at 3, 6, 9 and 12 months post-baseline. Upon completion of the baseline assessment interview, youths will be randomly assigned to the intervention conditions using a computerized urn randomization program. Four advocates will provide services so that advocate effects can be examined (Baldwin et al., 2011), and each advocate will provide all opioid and related risk prevention services to the youth on their caseload. Advocates will be crossed by condition to “equate” conditions on advocate characteristics.

Sample Inclusion Criteria.

1. Youth were between the ages of 18 to 24 years. Our experience is that landlords will not accept leases signed by youth ages 16-17 years. “Homeless youth” commonly refers to those up to the age of 24 years (Robertson & Toro, 1999; USICH, 2010), thus, this age range generally reflects the age range of the homeless youth population served by providers across the country.
2. Youth met the criteria for homelessness as defined by the federal McKinney-Vento Act (2002) as “lacking a fixed, regular, stable, and adequate nighttime residence” and includes “living in a publicly or privately operated shelter designed to provide temporary living accommodations, or a public or private place not designed for, or ordinarily used as, regular sleeping accommodations for human beings.”
3. Youth failed to meet DSM 5 criteria for Opioid Use Disorder as assessed by the SCID (First et al., 2015).

Screening and intake. Project staff maintain offices within the drop-in center. An RA engaged and screened youth to determine basic eligibility for the study. After the brief screening and stated interest in the project, written consent was obtained and the Structured Clinical Interview for DSM-5 Disorders (SCID) (First, Williams, Karg, & Spitzer, 2015) section on Opioid Use Disorder, was administered to determine formal eligibility.

Project Intervention: Opioid and Related Risk Prevention Services

Housing + Opioid and Related Risk Prevention Services integrates independent housing, Strengths-Based Outreach and Advocacy (SBOA), HIV prevention and MI (Miller & Rollnick, 2012). In the housing + opioid and related risk prevention services condition, youth will be housed in an apartment of their choosing and receive six months of utility and rental assistance of up to \$600 per month. The independent housing is not contingent on the youth’s substance use or attendance in prevention services. SBOA, MI and HIV risk prevention occur simultaneously in this approach. Addressing basic needs but not opioid and other drug use, through MI and service linkage, may lead to difficulty in maintaining basic needs and vice versa. During the intervention, advocates assist youth in accessing community supports so that if more assistance is needed at the end of the intervention period, youth will have been linked to those additional supports. Findings from the pilot study with non-service connected youth indicated that up to 26 advocacy sessions should be offered. Each component of the intervention is described below.

Strengths-Based Outreach and Advocacy (SBOA). Those individuals experiencing homelessness with access to a social service worker, or who utilize community services, are more likely to exit homelessness (Dworsky & Piliavin, 2000; Raleigh-DuRoff, 2004; Zlotnick et al., 2003). In general, the range and severity of adverse outcomes increases over time; the longer a young person experiences homelessness, the more likely they are to experience opioid and other substance use, victimization and mortality, and the harder it becomes to exit street life (Ferguson et al., 2011; Milburn et al., 2006; Scutella et al., 2013), highlighting the importance of engaging disconnected youth to services. SBOA focuses on identifying and engaging youth from the streets and drop-ins/shelters etc. and assisting these youth to meet their basic needs (i.e., referrals to food pantries), obtain government entitlements (i.e., SSDI/SSI, cash assistance, food stamps), and connect to other needed supports (education, job training). The advocates provide referrals and/or transport youth to appointments as needed. The initial meeting provides an opportunity to gather information. The advocate will review each of six general areas with the youth to gather a history and picture of the current situation: (1) housing needs; (2) health care; (3) food; (4) legal issues, (5) employment and (6) education. The advocate will assist youth assigned to the opioid and related risk prevention services only comparison

condition to obtain housing within the community, as is usually provided with SBOA, but unlike the youth in the housing intervention, they are not provided housing by the project. Once this review is complete, an initial intervention plan is developed with specific goals and objectives. Advocates are available 24 hours for crises.

HIV prevention. Some have argued that HIV prevention should be offered to all individuals seeking therapy for drug problems (Roehrich et al., 1994). Every youth will receive the 2-session intervention which uses cognitive-behavioral techniques with a focus on skills building/behaviors (role plays with condom application, cleaning needles, communication/negotiation and problem solving), used in prior projects with homeless youth with success reducing risk behaviors (e.g., Carmona et al., 2014; Slesnick & Kang, 2008). Successful practice of skills is expected to increase confidence and self-efficacy which is expected to increase the youth's use of skills including condom use and negotiation in other micro-system interactions. The first session is devoted to AIDS education, assessment of risk, risk reduction and skills practice. Session 2 focuses on sexual assertiveness and practicing negotiation. Role plays are incorporated to allow the youth to practice social competency skills relevant to their life situations.

Motivational Interviewing (MI). Typically offered as a brief intervention of 1-2 sessions, Motivational Interviewing (MI, Miller & Rollnick, 2012) has a strong record of efficacy in the prevention and treatment of alcohol and other drug use disorders (Copeland et al., 2015; Miller & Rollnick, 2012). MI assumes that the responsibility and capability for change lie within the client and needs to be evoked (rather than created or installed). Baer, Peterson and Wells (2004) provide some rationale for utilizing brief feedback and motivational intervention with street living youth - the intervention is less costly and demands much less of a hard-to-reach population than more intensive interventions. Utilizing a sample of runaway adolescents recruited from a runaway shelter, Slesnick et al. (2013) found that substance use reductions were significant for those assigned to MI even to two years post-treatment. The advocate will administer MI. Four principles guide the practice of MI: express accurate empathy, develop discrepancy, roll with resistance and support self-efficacy. The Project Match manual was adapted for homeless/runaway youth in prior trials in consultation with William R. Miller and Bo Miller (NIAAA grant no. R01AA12173 and NIDA grant R29DA11590). Adaptation of the manual included attention to the unique life situation of homeless youth in understanding motivations and challenges to recovery while homeless. Session 1 begins with a period of open-ended MI, to establish therapeutic rapport and elicit client change talk. In session 2 the advocate continues to focus on enhancing intrinsic motivation for change, developing discrepancy, transitioning as appropriate into the negotiation of a change plan and evoking commitment to the plan.

Housing + Opioid and Related Risk Prevention Services. Those randomized to receive housing + opioid and related risk prevention services will receive all the above and also receive 6-months of rental and utility supports in an apartment of their choosing.

All youth completed a **baseline and follow-up assessment** which included self-report, interview, and physiological measures, with the following outcomes.

Primary Outcomes: **1)** time to OUD (SCID) (UH3) **2)** % days opioid use (Form 90) (UG3, UH3).

Secondary Outcomes: **1)** % days other alcohol/drug use (Form 90), **2)** drug use consequences (SIP) **3)** HIV risk score (0-7) **4)** % days housed (Form 90), **5)** BDI-II depression score, **6)** Physical health score (SF-6), **7)** % days employed and % days in school/training (Form 90), **8)** resilience score (BRS), **9)** coping (task, emotion and avoidance) scores (CISS) **10)** cognitive distortions score (CD-QUEST), and **11)** self-regulation score (SSRS).

Mediators: **Primary:** **1)** # of service contacts (service log), **2)** working alliance score (WAI), **3)** social support (SNI): number and satisfaction of support persons, and **4)** # of violence/victimization exposures (HEQ).

Secondary: **1)** Stress (2 dv's) self-reported stress score (Cohen's PSS), and physiological hair cortisol level, and **2)** Self-efficacy (3 dv's): HIV, substance use, and perceived personal control scores.

Study Aims were as follows:

Specific Aim 1. Evaluate the relative efficacy of housing + opioid and related risk prevention services compared to prevention services alone (N = 240). **Hypothesis.** Youth receiving the 6-month housing + prevention services will show better 3, 6, 9 and 12 month outcomes than those receiving prevention services alone. Fewer Housing First youth will progress to OUD and will be more likely to remain housed at one year.

Specific Aim 2. Test the effects of the primary and secondary mediators on the primary outcome (opioid use/time to OUD) and secondary outcomes. **Hypothesis.** Inasmuch as the intervention triggers

successful social micro and meso-system interactions or social resources (e.g., advocate and social service meetings), individual resources will be activated – e.g., stress will decrease and self-efficacy will increase, leading to multiple positive outcomes.

Specific Aim 3. Explore how moderators affect individual's response to housing + opioid and related risk prevention services.

Statistical Analysis Plan

Missing Data. The patterns of missing data will be first examined before each analysis. If data are missing at random, they will be estimated using full information maximum likelihood (FIML) or multiple imputations (MI) method. When data are missing completely at random (MCAR) or are missing at random (MAR), both FIML and ML produce unbiased results (Enders, 2010). The main statistical program used for this study, MPlus, can handle missing data by providing FIML estimation. If the missingness cannot be explained by observed data, that is, data are Missing Not at Random (MNAR), data analysis will be conducted using the pattern mixture model (Roy, 2003) framework.

Study Aim 1. The impact of the two intervention conditions (i.e., 6-months housing + opioid and related risk preventive services, and opioid and related risk preventive services alone) on the primary and secondary outcomes will be tested in Aim 1. Specifically, the primary outcome, time to the onset of OUD, will be analyzed using the discrete-time survival analysis. In this analysis, whether the onset of OUD has occurred at a specific time point is included as the indicator of a latent factor, the proportional odds for the hazard of OUD, which is predicted by the contrasts between conditions. It is expected that youth assigned to the housing + preventive services condition will have longer delay in the onset of OUD than those in the preventive services alone condition. For the primary outcome, % days opioid use, and secondary outcomes that are continuous variables, latent growth models (LGM) will be conducted to estimate the trajectories of change across five time points (baseline, 3, 6, 9 and 12 months follow-up) to estimate the trajectories of change over time. Differences between treatment conditions on estimated growth parameters, including intercepts (i.e., initial status) and slopes (i.e., the rates of change), will be tested. It is expected that those assigned to the 6-month housing + opioid and related risk prevention services group will show greater decreases in opioid use (for those using opioids), as well as greater improvement in secondary outcomes, and that these improvements will maintain for a longer period of time, compared to those assigned to prevention services alone. To increase validity of the conclusions drawn from the analysis, the number of intervention sessions and contacts with other service providers will be covariates in the LGM analyses.

Study Aim 2. To test the proposed behavioral change mechanisms (i.e., social and individual resources), a series of path analysis will be conducted. Specifically, we will first test whether the primary mediator (e.g., service connections, social support) or secondary mediator (e.g., self-efficacy, stress) assessed at the 3- or 6-month follow-up mediates the association between intervention and outcome at 6-month and 9-/12-month follow-up, respectively. We expect that the intervention condition with the housing component will produce greater improvement in social/individual resources, which in turn will predict better outcomes. We will also estimate serial mediation models, in which both primary and secondary mediators are included (Figure 1), to test whether intervention first affects social resources, which then lead to changes in individual resources and subsequent outcomes. In these models, the baseline assessment of the mediators and outcomes will be controlled for in the analysis. Following MacKinnon and colleagues (MacKinnon et al., 2007), the product of the coefficient of the path from the independent variable to the mediator(s) and the coefficient of the path from the mediator(s) to the outcomes will be computed as the indirect (mediation) effect between the intervention and outcomes. The strength and significance of the mediation will be estimated using a bootstrap sampling method (Shrout & Bolger, 2002).

Study Aim 3. The effect of the moderating variables (age, sex, race/ethnicity, sexual orientation, childhood abuse history, and baseline substance use and service connection) will be tested by examining the interaction between intervention type and each moderator in predicting outcome slopes in the growth models and survival analysis. The contrast between intervention conditions will be multiplied by each moderator variable to form an interaction term. Next, the interaction terms will be included in the analyses for Aim 1 for the primary/secondary outcomes, one at a time, and their strength of association with the outcome slope will be assessed while controlling the direct effects of the predictors on outcome and the direct effect of moderator variables on outcome. If the interaction term is significant, this suggests moderation.

Statistical Power Analysis. The power analyses were conducted using the Monte Carlo simulation method. The MPI's ongoing study testing the effect of housing support on homeless mothers reveals medium effect sizes in reducing substance use ($d = .49$) and depressive symptoms ($d = .59$), and a large effect ($d = 1.26$) in improving housing stability, favoring the housing intervention over TAU/assessment only. Given that the proposed study tests housing support against an active intervention, and the differences between the two conditions may be smaller than that between housing support and TAU, we assumed small-to-medium effect sizes when conducting the power analysis. For the latent growth analyses, with dichotomous predictors (contrasts between intervention conditions) that have regression coefficients of .15 (small-to-medium effect size) for the slopes of growth factors (Muthén & Muthén, 2002), a sample size of 240, with an overall attrition rate of 15%, can produce a power of .86 to detect the intervention effect on the growth rate of outcomes. For Aim 2, in the simulated mediation analysis, we again assumed a small-to-medium effect size for the intervention effect. Data from the MPI's ongoing clinical trial shows that the associations between social/individual resources and outcomes are of medium effect size or larger (e.g., personal control is associated with depressive symptoms at $r = -.46$ and with general mental health at $r = .43$). Thus we assumed medium effect sizes for the mediator to outcome pathways. Following the model specification suggested by Thoemmes et al., (2010), the proposed sample size could provide a power of .93 to detect mediating effects for the one mediator model and a power of .82 for the serial mediation model with two mediators.