An Enhanced Housing Placement Assistance (EHPA) Program for Homeless Persons Living With HIV/AIDS in New York City

NCT03334825

Study Protocol and Statistical Analysis Plan

April 1, 2012

EHPA Study Protocol

1. **Background:** Homelessness, drug use, and HIV/AIDS are significant, interrelated public health problems. Evidence indicates that providing stable housing to drug-using persons living with HIV/AIDS (PLWHA) can help to reduce drug use and HIV sexual risk behavior, as well as improve outcomes related to health and well-being. Maintaining stable housing is often a challenge for drug-using PLWHAs. The proposed study targets clients of New York City's (NYC) HIV/AIDS Services Administration (HASA) housing program, which provides emergency and permanent housing to nearly 35,000 low-income PLWHAs per year. About half of HASA's homeless clients who reside in emergency single room occupancy (SRO) hotels, cycle through these hotels for long periods with little success at maintaining permanent housing. A recent formative study conducted by DOHMH indicated that SRO hotel environments support drug abuse through drug-abusing networks. Though permanent housing placement is available through organizations that provide direct services on location at SRO hotels, some PLWHA do not use these services. We hypothesize that drug abuse is a primary reason for failure to achieve and maintain permanent housing, and that this is strongly impacted by drug-abusing social networks. The proposed study is an evaluation of a pilot Enhanced Housing Placement Assistance (EHPA) program funded by NYC's Housing Opportunities for Persons With AIDS (HOPWA), intended to transition homeless PLWHA from emergency SRO hotels into permanent housing, with focused support services provided over 12 months including a social network intervention. A randomized controlled trial design will be implemented to evaluate program effectiveness of EHPA at improving housing and health outcomes, compared to the usual care (UC), or the usual process of referral and connection to housing services for homeless PLWHA in NYC. In addition, the study will help to describe NYC's population of homeless PLWHA residing in emergency SROs, in terms of their support service needs, barriers to housing, and behavioral and social contributors to homelessness.
2. **Aims and Objectives:** Specific Aim 1: To determine the impact of the EHPA program compared to UC on housing placement status at 6 and 12 months post-enrollment. Specific Aim 2: To determine the impact of the EHPA program compared to UC on housing status at 6 and 12 months post-enrollment. Specific Aim 3: To determine the impact of the EHPA program compared to UC on acute medical care utilization at 6 and 12 months post-enrollment. Specific Aim 4: To determine the impact of the EHPA program compared to UC on HIV clinical outcomes (CD4 counts and viral loads) at 6 and 12 months post-enrollment.
3. **Study Design**: The proposed program evaluation is a two-year, two-arm randomized controlled trial with the following arms: 1) EHPA: Assistance in transition to permanent housing, with specific support services including a social network intervention, focused on increasing clients' capacity to live independently and maintain stable housing. 2) Usual care (UC): Referrals to usual support and housing services provided to homeless PLWHA in NYC. The primary difference between these two study arms is that EHPA clients will receive 12 months of support services post-placement as well as a social network intervention designed to help clients improve and strengthen their social networks. UC clients may be connected to similar housing and support services, but in standard practice less than one-third of clients continue to receive supportive services after housing placement; additionally, UC clients will not receive the EHPA social network intervention. All study participants will provide baseline interviews as well as 6- and 12-month follow-up interviews.
4. **Target Population**: Homeless HIV-positive individuals who are at least 18 years of age and currently residing in a HASA single adult emergency SRO hotel.
5. **Sample Size**: Based on estimated housing placement success rates, it is expected that 280 participants (140 each year) will be enrolled in each study arm, for a total N = 560, with 140 in each arm ultimately being successfully placed in housing. This adequately powers the study to detect differences in outcomes across the study arms.
6. **Risk and Benefits to the Subjects**: Risks to study subjects are considered minimal. All information collected will be kept secure and private. Minimal risks include discomfort from the personal nature of some of the questions. Benefits to being in the study include potential streamlined acquisition of housing for individuals in the EHPA arm.
7. **Data Analysis**: Data analysis will begin with ensuring the randomization is successful in creating equivalent groups of participants across study conditions at baseline, by using significance tests (Z-tests for means and chi-square tests for proportions). Primary analysis will follow an intent-to-treat approach, examining impact of randomization to treatment arm, with secondary analysis assessing impact of actual housing status. Generalized Estimating Equations (GEE) will be used to model trends across time points, stratified by condition, for non-normally distributed dependent variables. Mixed-model regression with robust standard errors will be used to model trends across time points for continuous, normally distributed dependent variables.
8. **Expected Results**: Hypothesis 1: A higher proportion of EHPA participants will have been placed in permanent housing at 6 and 12 months compared to UC participants. Hypothesis 2: A higher proportion of EHPA participants will remain in permanent housing after placement at 6 and 12 months post-enrollment compared to UC participants. EHPA participants will spend, on average, fewer nights sleeping in a shelter, on the street or in an SRO hotel, at 6 and 12 months post-enrollment compared to UC participants. Hypothesis 3: EHPA participants will have, on average, fewer emergency department (ED) visits at 6- and 12-months post enrollment compared to UC participants. EHPA participants will have, on average, fewer overnight hospitalizations at 6 and 12 months post-enrollment compared to UC participants. EHPA participants will have, on average, lower non-prescription Medicaid costs at 6 and 12 months post-enrollment compared to UC participants. Hypothesis 4: A higher proportion of EHPA participants will have achieved 1) viral suppression and 2) stable or improved CD4 counts at 6 and 12 months post-enrollment compared to UC participants. Hypothesis 5: A higher proportion of EHPA participants will report decreased sexual risks (i.e. increased self-reported condom use) and increased self-reported use of harm reduction techniques associated with drug use.