Study Protocol and Statistical Analysis Plan

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Study Title: A Social Network AOD Intervention for Homeless Youth Transitioning to Housing

SIGNATURE PAGE

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Abbreviations

MNI	Motivational Network Intervention
TAY	Transitional Age Youth
YEH	Youth Experiencing Homelessness
GAIN-SS	Global Appraisal of Individual Needs - Short Screener

Study Protocol

Objectives

The objective of this study is to conduct a pilot evaluation of a motivational network intervention (MNI) to reduce substance use and strengthen supportive connections for recently homeless 18-25 year-olds who have transitioned to a housing program. The pilot study evaluates, through a small randomized controlled trial (Stage 1b), the added benefit of incorporating the MNI into case management for transitional age youth (TAY) residents of housing programs. We hypothesized that residents receiving the MNI as part of case management would show more positive changes in their substance use behaviors and the composition and structure of their personal networks (i.e., greater proportion of network members who are low-risk) over a 3-month follow-up period compared to residents receiving usual case management only.

Design

The study is a 2 arm, parallel assignment, single blind, phase 1 randomized intervention study. The intervention will consist of four sessions spaced two weeks apart that will last approximately 30 minutes each and consist of two parts: a network interview to capture network data about the time period since their last interview and a discussion of a resulting network visualization conducted in a motivational interviewing style. Participants will receive the intervention as part of existing case management. The control arm will receive regular case management meetings as provided with their residency.

Methods

Individuals will be recruited through a nonprofit organization in Los Angeles County that provides a comprehensive continuum of care to youth experiencing homelessness (YEH) that includes free emergency resources such as food and clothing in combination with case management, health, vocational, educational, therapeutic, and housing services. Individuals will be eligible for the study if they: (1) are age 18 to 25; (2) are in a housing program serving YEH; (3) screen positive for past-year harmful substance use using the Global Appraisal of Individual Needs - Short Screener (GAIN-SS;53 score of 3 or higher); (4) have used alcohol or drugs in the past 30 days; and (5) are willing to provide contact information for themselves and others who will know how to reach them so the resident can be contacted to complete a follow-up survey 3 months later. Individuals will be ineligible if they: (1) are not able to speak and understand English; and (2) have been in the housing program for longer than one year. All participants, regardless of condition, will be eligible for all services provided by the housing program.

The MNI is designed to be delivered by a trained case manager as part of their regular case management meetings with residents. Case managers are provided with a handbook that provides step-by-step instructions for using the MNI and watch a 30-minute video demonstration of an MNI session. They also receive a half-day in-person training on Motivational Interviewing (MI) techniques and a half-day “hands on” training on using the EgoWeb 2.0 platform (see egoweb.info) to deliver the MNI. Prior to using the tool with residents, additional training is provided on a case-by-case basis (if needed) until the case manager demonstrates proficiency in conducting an MNI session.

The MNI consists of four sessions that build on each other and can be delivered face-to-face or virtually. Similar to the baseline and follow-up assessments, MNI session responses will be entered into the same secure EgoWeb 2.0 application along with the same participant ID. Each MNI session lasts approximately 30 minutes and consists of three parts: (1) identifying two goals that are most important for the resident over the next year (e.g., get or keep a job, finish or stay in school, have own place to live, reduce substance use,

strengthen relationships); (2) a network interview with the resident to capture network data pertaining to their interactions in the past two weeks; and (3) a discussion between the case manager and the resident of the resulting network visualizations, conducted in a MI style, and what role the resident's network may play in reaching their most important goals over the next year. We discuss the latter two parts of the session in more detail below.

Network interview. Case managers read the network questions from EgoWeb 2.0 verbatim. Answers to these questions provide raw data to generate network visualizations. These structured network interview questions are an abbreviated set of the questions asked at baseline (described below), cover the timeframe between the baseline and first session (or between visits in subsequent sessions), and consist of three components. The interview is best conducted when the participant can also see the EgoWeb 2.0 screen to facilitate easier responding. The first component is a network name generator (e.g., "Please name 15 people, who are at least 18 years old, who you have talked to the most over the past 2 weeks, either in person or over the phone, or by texting, emailing, etc."). The second component is network composition questions focusing on support receipt (e.g., Consider who could help you reach your goals in the next year. Pick the option that best describes each person: (a) I could go to them if I needed support reaching my goals in the next year; (b) I could go to them now for support, but not sure I can count on them in the future; (c) I would not go to them for support in reaching my goals – either now or in the future) and substance use (e.g., Pick the option that best describes each person's alcohol and drug use; if you're not sure, give you best guess: (a) They will probably not use in the next 2 weeks; (b) They will probably use in the next 2 weeks, but not with me; (c) They will probably use in the next 2 weeks, and I would probably use my regular amount with them; and (d) they will probably use in the next 2 weeks, and I would probably use more than usual with them). The third component is network structure items (e.g., Let's talk about who in your network knows each other. For each pair of people, pick the best option: (a) they don't know each other; (b) they know each other but did not connect recently; and (c) they know each other and connected recently).

Network discussion. Once all network questions have been asked and answered, case managers will transition to discussing the network visualizations generated by EgoWeb 2.0. They will show the resident a series of three network diagrams customized for the resident based on the responses they provided in the network interview and use a MI style to discuss the resident's reactions. Each diagram will focus on a particular aspect of the network and will highlight key network members ("alters" in social network terminology) and subgroups by varying colors, node sizes, thickness of lines, etc. The initial diagram will present the network structure (drawing visual attention to subgroups, highly central members, isolated members, etc.) and subsequent diagrams will highlight social support (consistent sources of support for achieving their goals) and substance use (who is likely to use substances, who is a negative influence on the resident's substance use) in the network. Case managers will explore the pros and cons of residents' current social network composition and structure, discuss their willingness to make changes to their substance use and what steps they can make in the next two weeks, and changes they want to make in their social networks in the next two weeks (e.g., spending more or less time with certain network members; making new connections). Case managers can use the MNI to record notes on the statements the resident makes regarding their goals and the steps they are willing to take towards modifying their substance use and social network relationships over the next two weeks.

The three subsequent sessions cover the time periods between sessions and repeat the network interview and discussion. The MNI displays the names of network members mentioned in previous sessions, but participants are able to name new network members. These sessions begin with a discussion of the residents' stated goals from the previous session. Discussions of the visualizations focus on the ways in which the network changed between sessions, including discussing alters they either started or stopped interacting with since the previous MNI session and discussing what has not changed since the last interview. Case managers

review notes from previous interviews and ask follow-up questions about attempts at change and encourage steps that residents are taking toward meeting their goals.

The in-depth discussions of the social environment of the resident and the documentation of the network composition/structure and stated goals about change are designed to enhance the supportive relationship between the case manager and resident beyond the individual MNI sessions. The network visualizations resulting from the network interviews provide both case managers and residents with a tangible output on which to focus discussions and make abstract discussions of social life, relationships, and social change more concrete. They also provide documentation of the personal goals and aspirations of the residents across sessions and facilitate discussions of successful attempts at change to allow for reinforcement during MNI sessions and other interactions.

Description of usual care condition

Since we are interested in evaluating the added benefit of the MNI over usual case management, residents in the control condition will be asked to meet with their case manager four times (once every two weeks) during their participation in the study. These meetings are anticipated to last approximately 30-60 minutes and will be customized to the residents' needs.

Measures

Demographics— Demographic characteristics captured at baseline will include age, gender (male, female, non- binary, other), and race and ethnicity (non-Hispanic Black, non-Hispanic White, Hispanic, and Multiracial/other).

Substance use. Registered outcomes for the study include the number of days in the past month (0-30) that participants report engaging in any alcohol use, heavy alcohol use (5 or more drinks for men and four or more drinks for women on a single occasion), cannabis use, or other drug use (e.g., crack, cocaine). Participants will also report on the typical number of drinks they consumed on drinking days in the past month. We will use a Quantity-Frequency Index (QFI) by multiplying number of days drinking with average number of drinks per day.

Network characteristics. Network composition will be assessed by asking participants to "think about people you have connected with the most over the past four weeks, either in person or over the phone, or by texting, emailing… things like that." The participant will name up to 15 people who are at least 18 years old and then answer a series of questions about each person. These questions include how often they used alcohol or drugs with this person in the past four weeks (1 = never, 2 = sometimes, 3 = often); if applicable, whether they tended to engage in more (= 3) , less (= 1), or about the same (= 2) substance use as usual when they were with this person; and whether they would go to this person for support in meeting the goals they have set for themselves, for emotional support or encouragement, and for money, transportation, food, or other items that they need (separate items; 1 = yes, 2 = maybe, 3 = no). From this information we will derive network composition measures including the proportion of supportive ties in the network and the proportion of risky ties in terms of substance use. Finally, participants will be asked whether each pair of network members knew each other and if they connected recently. Based on this information we will derive network structure measures that include the centrality of supportive and risky network members using standard social network centrality measures.

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Statistical Analysis Plan (SAP)

Introduction

The major goals of the study are to assess intervention feasibility, acceptability and promise; estimate the variability of measures in the study population; and obtain preliminary estimates of intervention effect sizes. The analyses will be primarily descriptive given the anticipated small sample size; sophisticated modeling and adjustments for non-response will not be possible. We will estimate the outcomes' variability in this population and more generally assess the hypothesized trends to determine the intervention's promise.

Analyses will use the standard intent-to-treat (ITT) approach such that residents will be analyzed as belonging to the group they will be randomized to, regardless of their compliance, because excluding those who do not complete the MNI would bias results in favor of MNI, increasing type I errors.

We will examine variable distributions from both time points to assess missing data patterns, and will use a model-based multiple imputation approach for these missing data where appropriate. Although participants will be randomly assigned to condition, imbalance between the two groups on some baseline characteristics may occur. Such differences can contribute to the variability in estimates of intervention effects, weakening the power of the tests. In all relevant analyses we will control for those variables that exhibit baseline imbalance between the two groups by including them in the models.

Detailed study design

Procedures. Case managers first will ask residents if they are willing to be contacted by the research team about the study. Residents who consent will complete an eligibility screener and provide contact information and informed consent if eligible and willing to participate. Baseline survey data will be gathered by phone interview and entered directly into EgoWeb 2.0, a social network data- collection/visualization software (see egoweb.info).

After completing the baseline survey, residents will be initially randomized to four sessions of usual case manager or case manager plus MNI using a stratified [by time since entering housing program (past two weeks vs. longer)] permuted block randomization strategy. Given the small sample size of the pilot study, a stratified randomization approach will be used to prevent an unbalanced assignment with respect to length of residence. During the final year of the project, the project team will end randomization and assign all study participants to the CONNECT arm to adjust for recruitment/session delivery shortfalls. The outcome assessor will be blinded to the participant's study condition. Participants in both conditions will receive $5 for each of the four case management sessions attended, $30 for the baseline interview, and $40 for the follow-up interview.

CONNECT motivational network intervention. CONNECT will be delivered by a trained case manager as part of their regular case management meetings with residents. Case managers will watch a demonstration video, receive a training manual, a half-day in-person training on MI techniques, and a two-hour training on using the EgoWeb 2.0 platform to deliver the MNI. Prior to using the tool with residents, case managers will participate in supervised role-plays, conduct the intervention a minimum of three times, and receive additional coaching until the case manager can demonstrate proficiency in conducting an MNI session. CONNECT consists of four sessions that build on each other and can be delivered face-to-face or virtually. Each session consists of three parts: (1) identifying two goals that are most important for the resident over

the next year (e.g., get or keep a job); (2) a resident network elicitation about interactions in the past two weeks; and (3) an MI-style discussion of the resulting network visualizations and what role the residents use MI techniques to explore the pros and cons of residents' current social network composition and structure and discuss their willingness to make changes to their substance use and social networks in the next two weeks. The three subsequent sessions cover the time periods between sessions and repeat the network interview and discussion, including a discussion of the previous session goals and the ways in which the network changed between sessions.

Primary analysis

The treatment and control groups will be compared at baseline on demographic characteristics and the outcomes of interest using t-tests for continuous variables and chi-squared tests for categorical variables.

For each outcome, we will compare means for treatment and control arms at baseline and follow-up. We also will conduct difference in differences (DID) analysis by first constructing measures of difference between follow-up and baseline for each participant for each measure and then compare the means of these difference measures for each arm.