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Title: Cognitive Behavioral Suicide Prevention for Psychosis: Aim 2

Contents: Aim 2 Statistical Analysis Plan (Approved for use by IRB on 3/22/2024)

Note: Any mention of Aim 1 stakeholder phase or Aim 1 is informational and pertains to NCT04689867

B.6 Statistical Design and Analysis

B.6.a Aim 2 qualitative data analysis. All interviews will be transcribed and coded using Atlas.ti qualitative analysis software program,[58] which aids in management, retrieval, and interpretation of textual data, and facilitates analytic steps, including coding, memos, and diagramming. Random quality assurance checks will be done wherein sections of audiotapes will be compared to their transcripts. The data will be analyzed inductively and iteratively using thematic analysis and the constant comparative approach[144,145] to identify emergent themes regarding potential modifications of CBSPp content and protocol (e.g. treatment manual including treatment duration, session content), training protocol and its delivery, and implementation CBSPp (e.g. feasibility, acceptability, and usability). Three RS will independently analyze a subset of transcripts to iteratively develop codes until a final codebook is agreed upon by the research team and intercoder reliability is achieved; codes will then be applied to transcripts.[152,153] To further ensure the rigor of data analysis, the following strategies will be used:[64,65] 1) findings will be presented to participants, when possible for comments and additional avenues of investigation (member checking) and 2) an audit trail of the data and team meeting minutes will be maintained.

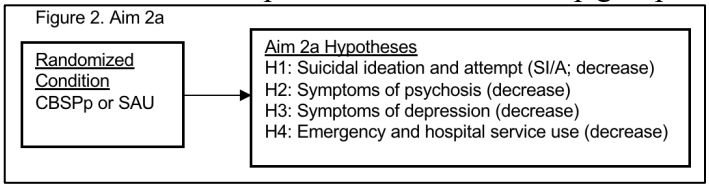
B.6.b Aim 2 quantitative data analysis

Analysis Strategy. The focus of Aim 2 is to examine differences between the treatment (CPSPp) and comparison (SAU) groups over time and the strategy will be the same for the open pilot in Aim 1. For H1-H12 (*see hypotheses in C.3.b.16.a),* we will use linear mixed models (LMM) for continuous outcomes (e.g. suicidal ideation and attempt scale scores, depression, psychosis) and generalized linear mixed models (GLMM) for dichotomous outcomes (e.g. incidence of ideation and attempt, emergency/hospital service use; see Figures 2 and 3). LMM provide greater flexibility than repeated measures ANOVA. For example, if a subject is missing data at any time point, they will be eliminated from the analysis in ANOVA, but can be retained in a mixed model so all participant data are used, even if data is missing at one or more time points.[170] LMM also allows for testing different assumptions about the structure of the variance-covariance matrix, thus increasing model fit to the data. Parameter estimates for the interaction between group membership and time will determine if the treatment group has significantly different changes over time than the comparison. Between-group differences in the characteristics of the two groups will be examined using Chi-Square analysis (categorical variables) or an analysis of variance (ANOVA; scaled variables). Variables with significant between-group differences will be used as covariates in all subsequent analyses. Measures of dispersion (mean, standard deviation, variance, range) and distribution (kurtosis, skewness) will be computed. Scatterplots will be generated to examine linearity and outliers for bivariate relationships. Analyses will be intent-to-treat (ITT) as all clients undergoing randomization will be included. We use multiple imputation methods[171] and pattern mixture modeling[172] to handle missing data after T1, in addition to sensitivity analyses to examine potential influence of missingness on findings.

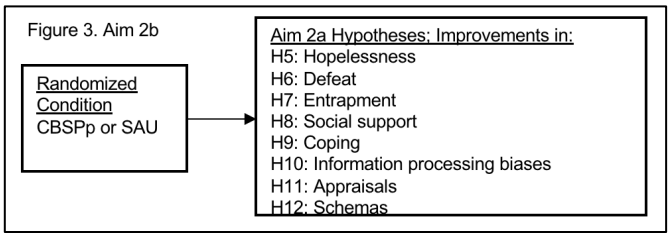
Study Hypothesis (H) and Analytic Approaches:

Aim 2a (Figure 2): To assess whether modified CBSPp is associated with reductions in SI/A (primary outcome), symptoms of psychosis, depression, and emergency/hospital service use over time. Compared to SAU, the CBSPp group will experience reductions in suicidal ideation and attempt (**H1**), psychosis (**H2**), depression (**H3**), and emergency/hospital service use (H4).

Figure 2. Aim 2a



Aim 2b (Figure 3): To assess whether modified CBSPp is associated with clinical (hopelessness, defeat, entrapment) and cognitive improvements (information processing biases, appraisals, and schemas) over time. Compared to SAU, the CBSPp group will experience improvements in hopelessness (**H5**), defeat (**H6**), entrapment (**H7**), suicide-related information processing biases (**H8**), appraisals (**H9**), and schemas (**H10**).



Exploratory Quantitative and Qualitative Aims (Figure 4): First, we will explore potential mechanisms of CBSPp effectiveness (i.e., decreased SI/A, psychosis, depression, and service use), by analyzing potential mediators (i.e., hopelessness, defeat, entrapment, and suicide-related information processing biases, appraisals, and schemas) and moderators (e.g., illness duration, history of suicidal ideation and behavior, psychosis symptom profile). To test mediation, we will run separate mixed models with and without the potential mediators and examine whether the effect of group membership is decreased by the addition of the mediator. To test moderation, we will include interaction terms between the possible moderator and group membership in the mixed model. Second, we will explore other potential mechanisms for lack of improvements in suicidal ideation and behavior, psychosis, depression, and service use by examining group differences and associations with symptoms of psychosis between groups with good outcomes and groups with poor outcomes. Third, we will collect exploratory qualitative implementation data by interviewing providers about: 1) their experience in training and delivery of CBSPp; 2) potential barriers and facilitators for CBSPp implementation; and, 3) scalability. We will use qualitative methods and analyses described above in *C.3.a.3 Aim 1 Qualitative Data analysis.* Lastly, a random sample of clients (n=12) from the CBSPp group will provide quantitative and qualitative data on the acceptability and feasibility of CBSPp (analyzed using the same methods above; *C.3.a.3*). We will report descriptive statistics for the quantitative treatment and satisfaction scale and expand on the following topics related to treatment experience: engagement, helpfulness, and instilling hope. To assess study feasibility, summary values will be calculated for the number of participants: 1) screened for the study, 2) eligible based on the screening instrument, 3) commencing treatment (i.e. attended session 1), completing each timepoint assessment, and 3) completing all aspects of the study. CBSPp drop-outs (complete T1 but not T2, T3, or T4) will be compared to those who complete the study. Participant characteristics will be evaluated as predictors of dropout using regression.