Study Protocol and Statistical Analysis Plan

Official Title: Member Engagement Application for Personalized Arts-Based Social Prescriptions

NCT Number: Pending

Document Date: May 13, 2026

Study Protocol

Study Title: Member Engagement Application for Personalized Arts-Based Social Prescriptions

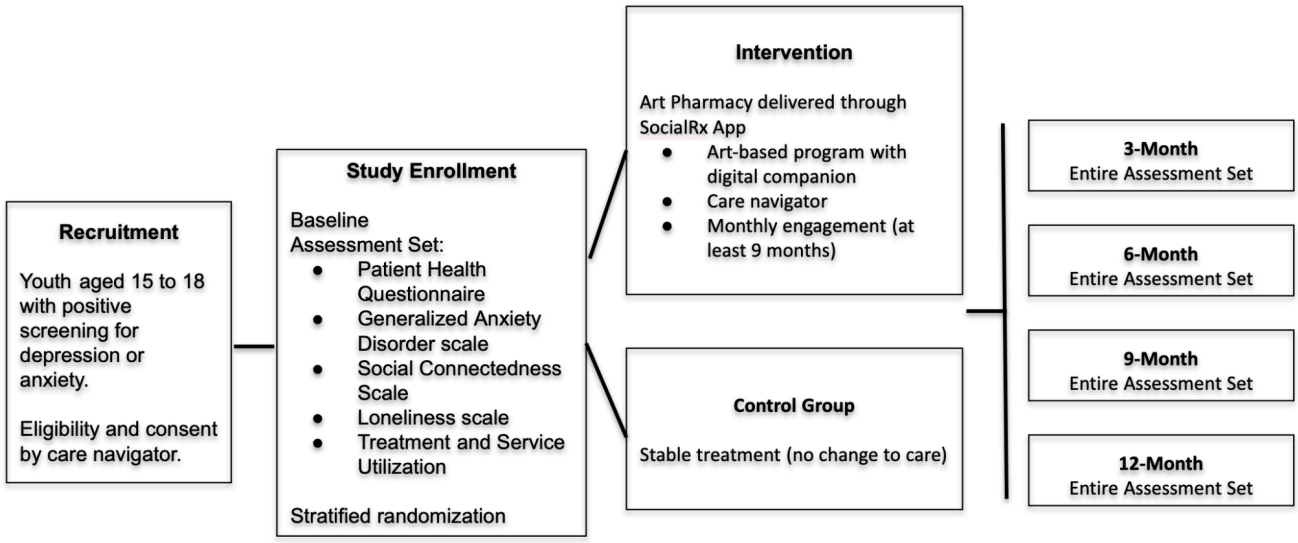
Background and Rationale: Adolescents in Medicaid systems experience high rates of depression, anxiety, loneliness, and social isolation. Arts-based social prescribing has emerged as a promising approach to improve mental health and social connectedness. Digital companion applications may enhance engagement, personalization, and adherence to such interventions.

The goal of this clinical trial is to learn if a personalized arts-based social prescribing program, Art Pharmacy, delivered through a mobile app (SocialRx App) can improve mental health and social connectedness in adolescents aged 15–18 with depression or anxiety enrolled in Medicaid managed care.

Objectives: To conduct a randomized controlled trial (RCT) to evaluate efficacy of Art Pharmacy delivered through a mobile app (SocialRx App) on mental health and social connectedness, compared to a stable treatment control group.

Study Design: This is a randomized controlled trial with two parallel arms: (1) Art Pharmacy intervention delivered through the SocialRx App and (2) control group receiving stable treatment (no change to existing care) (see Figure 1).

Figure 1. Study Design



Sample Size and Power Considerations: A total of 200 evaluable participants (100 per group) is planned, with participants randomized in a 1:1 ratio to the intervention and control groups using stratified randomization.

This sample size is based on a power analysis assuming a small standardized effect size (Cohen's d = 0.20), consistent with expected effects in similar mental health interventions. Assuming a standard deviation of 20 and a mean difference of 4 points on the WHO-5 Well-Being Index between groups, a simulation-based power analysis using a generalized estimating equations framework indicated that 126 participants (63 per group) would provide 80% power to detect group differences at a two-sided alpha level of 0.05, and 170 participants (85 per group) would provide 90% power.

To ensure adequate power to detect clinically meaningful effects and to support secondary and subgroup analyses, the study will enroll up to 230 participants (115 per group) to account for potential attrition, assuming an engagement rate of approximately 86%. This approach ensures that approximately 200 participants will be retained for the primary analysis.

Study Population: Adolescents aged 15–18 years enrolled in Medicaid managed care with a diagnosis of depression or anxiety.

Inclusion Criteria:
Participants must meet the following criteria:

- Aged 15–18 years enrolled in Medicaid managed care
- Positive screen for depression and/or anxiety (e.g., PHQ-2 or GAD-2 ≥ 3)
- Currently own and easily operate a smartphone
- Have a valid e-mail address checked regularly
- English fluency, and
- Have a stable treatment regimen for at least 30 days prior to baseline with no planned treatment changes.

Exclusion Criteria:
Participants will be excluded if they:

- Endorse current suicidal ideation at study screening, defined as a response ≥ 1 ("several days") on Item 9 of the PHQ-9A
- Initiate a new treatment regimen or plan on initiating a new treatment regimen (i.e., medication, psychotherapy, or mind-body interventions) at the time of enrollment.

Intervention: Participants in the Art Pharmacy intervention group will receive personalized arts and cultural activity recommendations and interact with a Care Navigator through the SocialRx App. They will be encouraged to attend activities on a monthly basis for a 12-month period.

Control Condition: Participants in the control group will continue stable treatment without additional arts-based programming.

Study Procedures
Participants will:

- Be randomized to intervention or control group
- Complete surveys at baseline, 3, 6, 9, and 12 months
- Engage with the intervention if assigned to that group

Outcome Measures

Primary Outcomes:

- **Anxiety - Generalized Anxiety Disorder-7 (GAD-7):** The GAD-7 is a 7-item self-report measure of anxiety symptoms. Scores range from 0 to 21, with higher scores indicating greater anxiety severity. **Time Frame:** At baseline, and 3-, 6-, 9-, and 12-month follow-up.
- **Depression** - **Patient Health Questionnaire-9 Adolescent Version (PHQ-9A):** The PHQ-9A is a 9-item self-report measure of depressive symptoms in adolescents. Scores range from 0 to 27, with higher scores indicating greater depression severity. **Time Frame:** At baseline, and 3-, 6-, 9-, and 12-month follow-up.
- **Loneliness - UCLA Loneliness Scale:** The UCLA Loneliness Scale assesses subjective feelings of loneliness and social isolation. Scores range from 20 - 80, with higher scores indicating a higher degree of loneliness. **Time Frame:** At baseline, and 3-, 6-, 9-, and 12-month follow-up.
- **Social Connectedness - Social Connectedness Scale–Revised (SCS-R)** The SCS-R measures feelings of interpersonal closeness and connectedness. Scores range from 20 to 120, with higher scores indicating greater social connectedness. **Time Frame:** At baseline, and 3-, 6-, 9-, and 12-month follow-up.

Secondary Outcomes:

- **Treatment Utilization - Treatment and Arts/Cultural Engagement Utilization Questionnaire** - A study-developed questionnaire assessing participant engagement with behavioral health treatment and arts/cultural activities. Higher scores/frequencies indicate greater utilization and engagement. **Time Frame:** At baseline, and 3-, 6-, 9-, and 12-month follow-up.

Ethical Considerations

This study received IRB approval from Boston College on February 16, 2026. Informed consent/assent will be obtained from all participants. Participant confidentiality will be maintained.

Statistical Analysis Plan

Comparisons between groups will be conducted to assess differences in outcomes over time. We will use SAS to conduct analyses on private BC servers. The analytic strategy uses generalized estimating equation (GEE) models to examine treatment effects across time while accounting for repeated measures. The primary analysis includes only those participants whose mental health treatment regimens remained stable throughout the study, allowing for clearer interpretation of the digital companion's effects. Secondary analyses follow an intent-to-treat framework, incorporating all available data regardless of adherence, engagement, or treatment changes. Missing data will be examined for patterns, and multiple imputation will be used when data are missing at random. Sensitivity analyses—including complete-case analyses and trimmed-mean approaches—will be conducted if dropout differs by study arm.