STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

Title: mHealth for Psychosis Help-Seeking
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OVERVIEW

Study Objectives. A long duration of untreated illness is linked with poorer outcomes among youth experiencing early psychosis. While this population faces numerous barriers to in-person services (e.g. long travel distances, a lack of symptom recognition, stigmatizing attitudes toward help-seeking) most young people express interest in digital technologies to support their mental health. While multiple digital mental health interventions have demonstrated value in supporting self-management of individuals experiencing symptoms of psychosis, there is a need for new interventions designed for delivery to those who are not engaged with services but are seeking resources to learn more about their experiences online. The present study examines the acceptability, usability, and preliminary efficacy of the NORTH mHealth intervention, a mobile app designed to remotely and scalably provide support to young adults in need of evaluation or treatment for symptoms of early psychosis. This intervention, which was developed in a multi-phase user-centered design process, offers multimedia interactive content based on the principles of cognitive behavior therapy and motivational enhancement. Following an experimental therapeutics paradigm, this study examines two versions of the NORTH mHealth intervention: (1) NORTH “lite” – a version of NORTH that provides only self-management components, and (2) NORTH “full” – a version of NORTH that offers components designed to increase treatment motivation, including interactive psychoeducational information about diagnoses, treatments, and the treatment-seeking process. This study aims to examine whether the promise of mHealth can be leveraged to improve treatment-seeking attitudes and actions among this at-risk population.

Design. This is a parallel group randomized controlled trial design. Participants are randomized 1:1 to either NORTH “lite” or NORTH “full.” Randomization is stratified based on whether the individual had engaged in mental health treatment (per inclusion criterion i.e. either regular psychotherapy or antipsychotic medication) within the past year vs. longer than one year ago (or not at all). Primary outcome assessments are collected at (1) baseline, (2) 6 weeks after app installation, and (3) 12 weeks after app installation.

METHODS

Participants. Participants are 60 treatment-unengaged young adults experiencing psychosis symptoms indicating need for evaluation and/or treatment who meet the following criteria: (1) age 18-30, (2) living in the US, (3) owning an iPhone, (4) symptoms of psychosis as measured by both (4a) a score >= 20 on the Prodromal Questionnaire, Brief (PQB), (4b) a positive frequency average score >= 1.47 on the Community Assessment of Psychic Experiences (CAPE-P15), and (4c) a score =< 8 on the Moritz CAPE lie scale designed for online data collection, (5) less than five years since a first episode of psychosis or awareness of symptom onset, and (6) unengaged in specialty mental health services in the previous three months as defined either (6a) having taken a prescribed antipsychotic medication, (6b) or having attended regular psychotherapy. Exclusion criteria included (1) failure to accurately complete consent comprehension questions or (2) being unengaged in mental health services because of having completed or "graduated" from a specialty mental health program.

Recruitment. Participants are recruited through online study ads (i.e. Google, Instagram, and YouTube) as well as distribution through mental health advocacy organization and treatment websites and listservs.

Procedures. All screeners and study questionnaires are completed through online data capture (i.e. REDCap). Once participants click a link to the study landing page from a recruitment ad or posting, they are required to demonstrate understanding of study details through a comprehension questionnaire, provide informed consent and are subject to a series of steps to ensure eligibility for the study and identity verification. Study team members evaluate screening data and conduct

confirmatory synchronous screening by phone. The invitation to complete the baseline assessment is sent to participants after eligibility confirmation via text message. After baseline is complete, participants are invited to asked to complete an installation session wherein they are introduced to their intervention, and oriented to study details. Participants are randomized to condition (via a pre-set stratified randomization algorithm, see above) at the time of the installation session.

Once participants have installed and been oriented to their study app, members of the study team are available to answer questions about study interventions or respond to concerns about the study. Up to three times during the study period, participants receive outreach via text message and phone call if they stopped using the app for five consecutive days (confirmed via app usage logs). This outreach assesses for technical issues or concerns from participants about app use. Subsequent assessments are sent to participants via text messages 6 and 12 weeks after they installed the NORTH app, and participants are also invited to complete weekly questionnaires to report actual treatment engagement frequency. Participants are compensated with $60 gift cards for completing each assessment battery (or, in the case of baseline, baseline and installation session both).

Interventions. NORTH (Normalizing ORientation to Treatment and Help-Seeking) is a self-guided iOS mobile app designed to provide self-guided coping support to individuals experiencing early psychosis. It combines video, audio, and written text, and draws on principles of cognitive behavior therapy and motivational enhancement. While both NORTH “full” and NORTH “lite” contain lessons (i.e. introductory modules to new skills), practices (i.e. opportunities to practice skills through video coaching or written prompts), and tracking (i.e. rating changes in a well-being score over time), only participants with NORTH “full” receive in-app treatment-seeking and psychoeducational content. Note that all participants regardless of condition receive thorough materials about mental health symptoms, treatment options, and crisis resources. For participants in the NORTH “full” condition, treatment-seeking and in-depth psychoeducation is a focus of interactive mHealth content, whereas in the “lite” arm, only the self-management components can be found in-app.

Outcome Measures. Primary and secondary registered measures are listed below.

Measure	Construct	Description	Time Frame
Measure to Assess Steps to Service (MASS)	Change in Treatment Seeking Steps	Treatment seeking will be measured using the Measure to Assess Steps to Service (MASS). The MASS is a 17-item self-report assessment of steps taken towards the attainment of mental health treatment, including research, social support, and engagement with service provider steps. Each item is endorsed on a three-point Likert scale (0 = No, I have not done this, 1 = I have done this once or twice, 2 = I have done this multiple times). The MASS is scored by summing individual items with higher scores indicating greater levels of treatment-seeking actions.	Baseline, 6 weeks, 12 weeks
Endorsed and Anticipated Stigma Inventory (EASI) – Beliefs about Treatment / Beliefs about Treatment-Seeking subscales	Change in Treatment-related Attitudes / Beliefs	Help-Seeking Attitudes and Stigma will be measured primarily using the Endorsed and Anticipated Stigma Inventory (EASI). The full EASI is a 40-item self-reported questionnaire with subscales measuring beliefs about mental illness, beliefs about mental health treatment, beliefs about mental health treatment seeking,	Baseline, 6 weeks, 12 weeks

		concerns about stigma from loved ones, and concerns about stigma from the workplace. The subscales are scored by summing the ratings from the eight individual items in each subscale (5-point scale with 1 = Strongly disagree, 5 = Strongly agree), with lower scores indicating less stigma, and more positive attitudes towards treatment and treatment-seeking. The Beliefs About Treatment scale assesses individuals' beliefs about the efficacy and usefulness of mental health treatments. It is totaled as a sum, with higher scores indicating more stigmatizing attitudes toward treatment. The Beliefs About Treatment Seeking scale assesses individuals' attitudes toward seeking mental health treatments. It is totaled as a sum, with higher scores indicating more stigmatizing attitudes toward treatment seeking.	
Internalized Stigma of Mental Illness Inventory (ISMI-9)	Change in Internalized Stigma	The Internalized Stigma of Mental Health Inventory, Brief (ISMI-9) will provide additional insight into the strength of participants' internalized stigma of mental illness. The ISMI-9 is a nine-item self-report short form, where each item is rated on a four-point Likert scale (1 = Strongly disagree, 4 = Strongly agree) and totaled as a mean score. Thus scores range from 1 to 4 with higher scores indicating more severe internalization of mental illness stigma.	Baseline, 6 weeks, 12 weeks
Perceived Stress Questionnaire (PSQ)	Change in Perceived Stress	Perceived stress will be measured using the Perceived Stress Questionnaire (PSQ), which is a 30-item, self-report questionnaire that examines the experience of stress independent of a specific and objective occasion. Items are endorsed on a four-point scale (1 = Almost never, 4 = Usually), and are summed for a total score (ranging from 30 to 120), with higher scores indicating higher levels of perceived stress.	Baseline, 6 weeks, 12 weeks
Brief Resilience Scale (BRS)	Change in Resilience / Coping	The Brief Resilience Scale (BRS) will be used to assess resiliency. The BRS is a self-report form that consists of six resiliency statements that participants agree or disagree with on a five-point scale (1 = Strongly disagree, 5 = Strongly agree). Scores are totaled as a mean, and thus range from 1 to 5, with higher scores indicating greater resilience.	Baseline, 6 weeks, 12 weeks

Community Assessment of Psychic Experiences	Change in Symptoms	The Community Assessment of Psychic Experiences (CAPE-42) will be used to assess positive, negative and depressive symptoms of psychosis. The CAPE-42 is a self-report, 42 two-part item assessment that measures both the frequency of experiencing symptoms (four-point scale, 1 = Never, 4 = Almost Always) as well as the distress level (four-point scale, 1 = Not Distressed, 4 = Very Distressed) associated with each endorsed symptom. The CAPE weighted score can be calculated by summing the frequency and distress item responses. The positive subscale is 20 items and is totaled as a mean response ranging from 2 to 8, with higher scores indicating more frequent and distressing positive symptoms. The negative subscale is 14 items and is totaled as a mean response ranging from 2 to 8, with higher scores indicating more frequent and distressing negative symptoms. The depressive subscale is 8 items and is totaled as a mean response ranging from 2 to 8, with higher scores indicating more frequent and distressing depressive symptoms.	Baseline, 6 weeks, 12 weeks
Choice of Outcome in CBT for Psychoses, Short-Form (CHOICE-SF)	Change in Recovery	Recovery will be assessed using the Choice of Outcome in CBT for Psychoses, Short Form (CHOICE-SF). The CHOICE-SF is an 11-item self-report form developed to assess recovery-related goals for therapy. Participants rate themselves in different therapy-focused areas such as "self-confidence" or "ways of dealing with everyday stress" on a scale (0 = Worst, 10 = Best). Scores on the CHOICE-SF are totaled as mean score across all standard items, and thus range from 0 to 10 with higher scores reflecting improved recovery.	Baseline, 6 weeks, 12 weeks
Sheehan Disability Scale	Change in Functioning	Functioning will be measured using the Sheehan Disability Scale (SDS). The SDS is a short, five-item self-report form that assesses disability and functional impairment. The total score is the sum of three items measure to what extent symptoms have disrupted different aspects of daily life on a scale (0 = Not at all, 10 = Severely), thus the scale ranges	Baseline, 6 weeks, 12 weeks

		from 0 to 30 with higher scores indicating greater functional impairment.	
Modified Usability Scale	Intervention Acceptability / Usability	Usability/Acceptability will be assessed with a modified version of the System Usability Scale derived from our group's previous work developing mHealth interventions. This composite measure, which comprises 26 items based on four measures - the System Usability Scale, Post Study System Usability Scale, Technology Assessment Model Measurement Scales, and Usefulness, Satisfaction and Ease Questionnaire - assesses participants' experiences with the intervention during the study period (1 = Disagree, 2 = Neutral, 3 = Agree). While this measure is often interpreted qualitatively by item, we will also compare the overall score, which will comprise an average and thus range from 1 to 3, with higher scores reflecting higher acceptability and usability.	6 weeks

DATA ANALYTIC PLAN

Clinical-trial data analyses. Linear regression will be used for continuous outcomes wherein participant and treatment condition are clustered as independent variables (i.e. adjusting for the baseline value of the outcome measure relevant to each model). We will separately model outcomes at 6 weeks and 12 weeks respectively. Within-condition changes will also be modeled using linear regression with assessment and value at baseline as independent variables. Effect sizes will be estimated using Cohen’s d and 95% confidence intervals. Mean imputation is used to generate total scale scores consistent with measure convention (i.e. totaling sums or means) in instances when participants complete fewer than 50% of scale items. Descriptive outcome measures (i.e. measures of usability and acceptability) will be described qualitatively as well as compared with independent-samples t-tests. As this is a pilot trial with limited statistical power, we will model and interpret direction and size of effects for primary outcomes.