STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

Title: Bolster: Caregiver App to Reduce Duration of Untreated Psychosis
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OVERVIEW

Study Objectives. Caregivers play a critical role in the recovery of young adults with early psychosis. The involvement of a supportive caregiver is associated with more rapid and sustained treatment engagement, reduced relapse risk, and improved functional outcomes. Family-focused interventions reduce caregiver burden and reduce risk of patient relapse, but many caregivers face barriers to access. mHealth interventions have shown promise in providing self-guided interventions to individuals that face barriers to services. Our team conducted a multi-phase user-centered design and development process to build Bolster, an mHealth intervention for caregivers to young people experiencing early psychosis. Bolster is designed to provide psychoeducation, communication coaching, and self-care support consistent with principles of family psychoeducation, cognitive behavior therapy, and motivational enhancement. The objective of this project is to evaluate the acceptability and preliminary effectiveness of Bolster, as well as examine the feasibility of our proposed study methods should results warrant future testing in a fully-powered trial. Participants will be sixty (N = 60) caregivers randomized (2:1) to either receive a collection of resources on psychosis and caregiving from scientific and advocacy organizations (control arm) or the same resources and the Bolster app (active intervention or Bolster arm). Participants will complete assessments of outcomes at baseline as well as 6- and 12-weeks after beginning the intervention. This study aims to evaluate whether Bolster improves caregiver knowledge and illness appraisals, reduces distress, improves coping, family communication, and results in increased treatment facilitation and treatment received by the affected young adult.

Design. This is a parallel group randomized controlled trial design. Participants are randomized 2:1 to receive either Bolster (Bolster arm) or control exemplar resources gathered from multiple scientific and advocacy organizations. Randomization is stratified based on whether the identified patient had engaged in specialty mental health within the past year. Primary outcome assessments are collected remotely with electronic data capture at (1) baseline, (2) 6 weeks after app installation, and (3) 12 weeks after app installation. Treatment engagement outcomes are reported remotely weekly during the study period.

METHODS

Participants. Participants are 60 individuals (1) aged 18 years or older, who (2) live in the United States, and (3) identify as a caregivers to a youth or young adult experiencing early psychosis, wherein this is defined as (3a) being between the ages of 15 and 35, who (3b) within the last five years started experiencing symptoms meeting the following criteria: (3c) A positive screen according to the Caregiver Prime Screen - Revised (endorsed two or more responses of five or six ("somewhat"/"definitely" agree), as well as (3d) “hallmark symptoms” including (3d.1) the presence of psychotic symptoms represented by one or more of hallucinations, delusions, marked thought disorder, psychomotor disorder or bizarre behavior, as well as (3d.2) definite change of personality or behavior manifesting as two or more of the following: serious deterioration of function, marked social withdrawal, persistent self-neglect, episodic marked anxiety. The affected person must also be (4) not enrolled in specialty mental health services (i.e. a program wherein the affected person can access both psychiatry and counseling/therapy services) and has not been enrolled in such services for at least three months prior to screening. If an affected person is receiving one of these services, the caregiver reports that this is an inadequate level of care. Participants are also required to (5) own an Apple iPhone. Participants are excluded they or their loved one is (1) incarcerated or living in a long-term care setting, (2) they failed to demonstrate understanding of study details in comprehension screening, or (3) the loved one is not enrolled in services only because they previously completed or “graduated” from a specialty treatment program for psychosis.

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. 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 either the study app and online resources or online resources only, 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 in the Bolster arm 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. To match this outreach in the Bolster arm, all participants in the control arm receive two phone calls during their time in the study, once in the third week and once in the ninth week. Subsequent assessments are sent to participants via text messages 6 and 12 weeks after their installation session. Participants are compensated with $60 gift cards for completing each assessment battery (or, in the case of baseline, baseline and installation session both).

Interventions. Bolster is a self-guided iOS mobile app designed to provide self-guided support to caregivers to youth and young people experiencing early psychosis. It combines video, audio, and written text, and draws on principles of family psychoeducation, cognitive behavior therapy and motivational enhancement. Participants in both arms will be provided support resources from mental health advocacy organizations representing currently available resources for caregivers (including a selection from the National Alliance on Mental Illness and Mental Health America). They will also have access to the research team by phone for technical troubleshooting and support as necessary.

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

Measure	Construct	Description	Time Frame
Family Questionnaire (FQ)	Change in Family Communication	Family communication will be assessed with the Family Questionnaire (FQ). The FQ is a 20-item self-report assessment of criticism and emotional expression in interactions with family members toward patients with mental illness. Each item is rated on a 4-point scale (1 = never/very rarely; 4 = very often). The FQ is scored by summing individual items with higher scores indicating greater levels of expressed emotion. As a primary outcome, we will examine the combined total of emotional overinvolvement and critical comments; scores range from 20 to 80 with higher scores indicating greater expressed emotion.	Baseline, 6 weeks, 12 weeks
Measure to Assess Steps to Services, Caregivers Edition (MASS-CG)	Change in Treatment Facilitation	Treatment seeking will be measured using the Measure to Assess Steps to Service-Caregivers (MASS-CG). The MASS-CG is a 23-item self-report assessment of steps taken by the caregiver towards the attainment of mental health treatment for their loved one, including research, social support, encouragement or support of the loved one's help-seeking actions, 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	Baseline, 6 weeks, 12 weeks

		MASS-CG is scored by summing individual items with higher scores indicating greater levels of treatment facilitation activities.	
Report of Treatment Engagement, Medication Provider	Change in Treatment Engagement, Medication Provider	Treatment facilitation / duration of untreated psychosis will be assessed according to participants' report of appointments attended by their relative in the past during the treatment period. This first category includes meeting with a clinician providing psychiatric medications. At screening, participants report treatment engagement over the previous three months and during the study period, participants are asked to report on this weekly.	Baseline, 12 weeks
Report of Treatment Engagement, Therapy or Counseling	Change in Treatment Engagement, Therapy or Counseling	Treatment facilitation / duration of untreated psychosis will be assessed according to participants' report of appointments attended by their relative in the past during the treatment period. This first category includes meeting with a clinician providing mental health therapy or counseling. At screening, participants report treatment engagement over the previous three months and during the study period, participants are asked to report on this weekly.	Baseline, 12 weeks
Knowledge About Schizophrenia Test (KAST)	Change in Illness Knowledge, Factual Knowledge	This is assessed with the Knowledge About Schizophrenia (KAST), an 18-item multiple-choice assessment examining individuals' knowledge of the etiology, symptoms, and prognosis of schizophrenia. Total scores indicate the number of correct responses and thus range from 0 to 18.	Baseline, 6 weeks, 12 weeks
Illness Perception Questionnaire for Schizophrenia Relatives (IPQSR), Coherence	Change in Illness Knowledge, Caregiver Self-rated	Illness appraisals will be assessed with the Illness Perception Questionnaire for Schizophrenia Relatives (IPQSR), a self-report scale of caregivers' beliefs about the severity, prognosis, and responsiveness to treatment of mental illnesses. Each item is rated on a 5-point scale (1 = strongly disagree; 5 = strongly agree), and totals are scored by summing individual items. For the coherence total, we are totaling the 5 items related to the caregiver’s report of how much they understand or know about their loved one’s illness. Scores range from 5 to 25 with lower scores indicating better self-rated understanding or coherence.	Baseline, 6 weeks, 12 weeks
Illness Perception Questionnaire for Schizophrenia Relatives	Change in Illness Appraisals, Consequences	Illness appraisals will be assessed with the Illness Perception Questionnaire for Schizophrenia Relatives (IPQSR), a self-report scale of caregivers' beliefs about	Baseline, 6 weeks, 12 weeks

(IPQSR), Consequences		the severity, prognosis, and responsiveness to treatment of mental illnesses. Each item is rated on a 5-point scale (1 = strongly disagree; 5 = strongly agree), and totals are scored by summing individual items. For the consequences total, we are totaling the 20 items related to consequences affecting the caregiver and the affected person. Scores range from 20 to 100 with higher scores indicating greater perceptions of negative consequences.	
Illness Perception Questionnaire for Schizophrenia Relatives (IPQSR), Control	Change in Illness Appraisals, Control	Illness appraisals will be assessed with the Illness Perception Questionnaire for Schizophrenia Relatives (IPQSR), a self-report scale of caregivers' beliefs about the severity, prognosis, and responsiveness to treatment of mental illnesses. Each item is rated on a 5-point scale (1 = strongly disagree; 5 = strongly agree), and totals are scored by summing individual items. For the control total, we are totaling the 8 items related to caregiver, affected person, and treatment control over illness course. Scores range from 8 to 40 with higher scores indicating greater perceptions of possibilities for actions that affect the course of illness.	Baseline, 6 weeks, 12 weeks
Illness Perception Questionnaire for Schizophrenia Relatives (IPQSR), Emotional Distress About Illness	Change in Illness Appraisals, Emotional Distress About Illness	Illness appraisals will be assessed with the Illness Perception Questionnaire for Schizophrenia Relatives (IPQSR), a self-report scale of caregivers' beliefs about the severity, prognosis, and responsiveness to treatment of mental illnesses. Each item is rated on a 5-point scale (1 = strongly disagree; 5 = strongly agree), and totals are scored by summing individual items. For the emotional distress score, we are examining the emotional representation scale, a 9-item scale with scores ranging from 9 to 45, with higher scores indicating greater emotional distress.	Baseline, 6 weeks, 12 weeks
Brief Experience of Caregiving Inventory (BECI)	Change in Appraisal of Caregiving Experiences	Appraisals of caregiving experiences will be assessed with the Brief Experience of Caregiving Inventory (BECI). The BECI is a 19-item assessment of the impact of caregiving on the individual's life, both in negative and positive ways. The items are rated on a 5-point Likert scale (never to nearly always), and scores range from 0 to 76, with a higher score denoting more negative appraisals of one’s caregiving experience.	Baseline, 6 weeks, 12 weeks
Brief COPE Inventory	Change in Caregiver Coping, Activities	Caregiver coping will be assessed with the Brief COPE Inventory, a 28-item self-	Baseline, 6 weeks, 12 weeks

		report scale of coping skills in response to stressors, based on the full COPE inventory; items generate a range of subscale scores related to specific coping areas. The instrument consists of 28 items which will be scored on a 1 to 4 Likert scale (I haven't been doing this at all to I've been doing this a lot), with higher values representing a greater frequency of engaging in each coping strategy. For this outcome, we will examine total frequency sum of items (14) assessing variables a priori selected to represent adaptive coping. Scores on this scale range from 14 to 56.	
Coping Self-Efficacy Scale (CSES)	Change in Caregiver Coping, Self-efficacy	Caregiver coping self-efficacy will be assessed with the Coping Self-Efficacy Scale, a 26-item self-report questionnaire measuring the perceived ability of coping with various life challenges. Responses are rated on a 0 to 10 scale, and scores range from 0 to 260, with higher scores denoting a greater sense of self-efficacy in coping.	Baseline, 6 weeks, 12 weeks
General Health Questionnaire, 12 Item Version (GHQ-12)	Change in Caregiver Distress	Caregiver distress (secondary mediator) will be assessed with General Health Questionnaire (GHQ), a 12-item questionnaire assessing general psychological morbidity. Respondents indicate agreement on a four-point scale (0 = Not at all; 3 = More than usual) and total scores ranging from 0 to 36 with higher scores indicating more severe psychological morbidity.	Baseline, 6 weeks, 12 weeks

DATA ANALYTIC PLAN

Clinical-trial data analyses. Linear regression will be used for continuous outcomes with treatment condition and baseline values entered as covariates. We will separately model outcomes at 6 weeks and 12 weeks respectively. Participants with missing follow-up data will be included using multiple imputation to reduce bias in effect estimates. Within-condition changes will be modeled using linear regression with assessment and value at baseline as independent variables. For zero-inflated count outcomes, hurdle models will be used to compare treatment conditions on (1) the probability of having such encounters during the 12-week follow-up period (binary model, fit using modified Poisson regression to obtain aRR estimates) and the number of weeks with such encounters among those with one or more encounters (count model, fit using negative-binomial regression to obtain adjusted incidence rate ratio [aIRR] estimates), with offset terms for the natural logarithm of the number of weeks surveys were completed. Models will use a two-tailed alpha level of 0.05 to detect significant differences between Bolster and control, with patterns of effect sizes and 95% confidence intervals (CIs) examined for all outcomes to inform future trials. As this is a pilot trial, conclusions will involve interpretations of overall effect sizes.