Altitudes for Caregivers: A Pilot Study

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ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviation	Definition
A-HCCQ	Altitudes Health Care Climate Questionnaire
A-PCS	Altitudes Perceived Competence Scale
AUQ	Altitudes Usability Questionnaire
CBT	Cognitive Behavioral Therapy
CSC	Coordinated Specialty Care
FEP	First Episode Psychosis
FFMQ	Five Facet Mindfulness Questionnaire
GHQ	General Health Questionnaire
NC	North Carolina
NSR	Non-significant Risk
OASIS	Outreach and Support Intervention Services
PAS	Psychosis Attitude Survey
PI	Principal Investigator
PSS	Peer Support Specialist
PTGI	Post-Traumatic Growth Inventory
PTSD	Post-Traumatic Stress Disorder
SCS-SF	Self Compassion Scale – Short Form
SHORE	Supporting Hope, Opportunities, Recovery and Empowerment
UCLA	University of California, Los Angeles
UNC-CH	University of North Carolina at Chapel Hill
WAI-I	Working Alliance Inventory – guided Internet interventions

PROTOCOL SYNOPSIS

Title

Altitudes for caregivers: A pilot study

Funding

This trial is funded by North Carolina Department of Health and Human Services & University of North Carolina at Chapel Hill

Clinical Phase

Pilot

Study Rationale

The purpose of the present study is to investigate the acceptability and feasibility of implementing a moderated online social media platform with therapeutic content, Altitudes, as a part of an adjunct services offered at first-episode psychosis (FEP) clinics across North Carolina, also known as coordinated specialty care (CSC) programs. Additionally, to further assess the secondary aim of impact on well-being, we will recruit a control group of caregivers.

Study Objective(s)

Examine the acceptability and feasibility of Altitudes at North Carolina (NC) FEP clinics as part of an adjunct clinical service through the following objectives:

1) Assessment of any changes in psychological measures across the six-month intervention
2) Ability to meet our recruitment targets
3) Evaluation of the safety and privacy protocol
4) Evaluation of the frequency and types of engagement on Altitudes

Study Design

This is a quasi-experimental open trial enrolling parents and caregivers of individuals with first episode psychosis (FEP) receiving care from CSC clinics across North Carolina. Parents and caregivers in the Altitudes condition, which will be drawn from 2 CSC clinics (OASIS, SHORE), will participate in the use of Altitudes, a novel digital intervention, which has previously demonstrated benefits to this population in an Australian pilot trial. They will also complete psychological measures as part of the study. Participants in the control condition from 3 other CSC clinics in North Carolina (Eagle, Encompass, AEGIS) will not have access to the digital intervention but may engage with standard clinical services at the CSC clinics. The control participants will complete measures at the same time points as the open trial participants at OASIS and SHORE clinics.

Subject Population Key Criteria for Inclusion and Exclusion:

Inclusion criteria:

1) Parent or caregiver of a young person who is currently receiving treatment from a CSC program for FEP, or who have recently graduated from a CSC program
2) Parent or caregiver must be at least 18 years of age

3) Participants recruited from Outreach and Support Intervention Services (OASIS) & SHORE (Supporting Hope, Opportunities, Recovery and Empowerment; i.e., two CSC programs in NC), as this is a pilot study, or Eagle, Encompass, and AEGIS clinics for participants part of the control group
4) Parent or caregiver must have access to internet through a mobile phone, tablet, or computer

Exclusion criteria:

1) Parent or caregiver is currently engaged in legal action against the loved one receiving services from the CSC program
2) Parent or caregiver does not speak English
3) Parent or caregiver is under 18 years of age

Number of Subjects

Thirty parent or caregiver participants from OASIS and SHORE CSC clinics and 30 parent or caregiver participants from Eagle, Encompass, and AEGIS.

Study Duration

Each subject's participation will last approximately 6 months from baseline to post-treatment. The entire study is expected to last approximately 12 months (including a 6-month recruitment period).

Study Phases

Screening: Completed prior to the first virtual appointment via a telephone screen to confirm study eligibility.

Baseline: Parents or caregivers who are deemed eligible schedule a virtual appointment with the study coordinator to obtain informed consent and complete the baseline assessments (Demographics & psychological measures). Specifically, all participants will be asked to complete the Experience of Caregiving Inventory (ECI; Szmukler), the Family Questionnaire of Expressed Emotion (Wiedemann et al., 2002), Brief COPE (Carver, 1997), UCLA Loneliness Scale (Russell, 1996), Multidimensional Scale of Perceived Social Support (For control and Alternative form for Altitudes condition; Zimet et al., 1990), Modified Psychosis Attitudes Survey (PAS; Kopelovich et al., 2022), PTSD Checklist for DSM-5 (PCL-5, Weathers et al., 2013), Post Traumatic Growth Inventory (PTGI, Tedeschi & Calhoun, 1996), General Health Questionnaire-12 (GHQ-12; Goldberg, 1972), Self-Compassion Scale – Short Form (SCS-SF; Raes et al., 2011), and Five Facet Mindfulness Scale (FFMQ; Bohlmeijer et al., 2011). Additionally, all participants will complete a brief survey on engagement with services within the CSC program and outside the program (e.g., individual therapy, family groups outside of CSC, etc.). Altitudes condition participants are then oriented to the Altitudes platform if part of the open trial enrollment.

Study Treatment: Participants in the Altitudes condition will be given access to the digital platform Altitudes for approximately 6 months. Weekly engagement is decided by the participant. Digital access is available daily and digital access to family peer worker and online therapists is made available during their engagement with the platform. Control participants will have not interaction with the platform but may engage in routine clinical

care for parents and caregivers at CSC clinics, such as multifamily group and treatment planning sessions

Mid-treatment: Participants will be asked to complete a battery of measures assessing psychological domains such as social support, loneliness, and mood symptoms at the approximately 3-month timepoint (+/- 2 weeks). Specifically, participants will be asked to complete the Experience of Caregiving Inventory (ECI; Szmukler), the Family Questionnaire of Expressed Emotion (Wiedemann et al., 2002), Brief COPE (Carver, 1997), UCLA Loneliness Scale (Russell, 1996), Multidimensional Scale of Perceived Social Support (For control and Alternative form for Altitudes condition; Zimet et al., 1990), Modified Psychosis Attitudes Survey (PAS; Kopelovich et al., 2022), PTSD Checklist for DSM-5 (PCL-5, Weathers et al., 2013), Post Traumatic Growth Inventory (PTGI, Tedeschi & Calhoun, 1996), General Health Questionnaire-12 (GHQ-12; Goldberg, 1972), Self-Compassion Scale – Short Form (SCS-SF; Raes et al., 2011), and Five Facet Mindfulness Scale (FFMQ; Bohlmeijer et al., 2011). Additionally, all participants will complete a brief survey on engagement with services within the CSC program and outside the program (e.g., individual therapy, family groups outside of CSC, etc.). Altitudes condition participants will also be asked to provide their perceptions of the Altitudes platform and clinical moderators via four brief questionnaires: the Altitudes Health Care Climate Questionnaire (A-HCCQ), Altitudes Usability Questionnaire (AUQ), and Altitudes Perceived Competence Scale (A-PCS), and Working Alliance Inventory for guided Internet interventions (WAI-I, Gomez Penedo et al., 2019). Participants in the control condition will be asked to complete all of the aforementioned measures except for the A-HCCQ, AUQ, A-PCS, and WAI-I.

Post-treatment: Participants in the Altitudes condition will be asked to complete the battery of measures examining psychosocial constructs at the approximately 6-month timepoint (+/- 2 weeks). Specifically, Altitudes participants will be asked to complete the Experience of Caregiving Inventory (ECI; Szmukler), the Family Questionnaire of Expressed Emotion (Wiedemann et al., 2002), Brief COPE (Carver, 1997), UCLA Loneliness Scale (Russell, 1996), Multidimensional Scale of Perceived Social Support (For control and Alternative form for Altitudes condition; Zimet et al., 1990), Modified Psychosis Attitudes Survey (PAS; Kopelovich et al., 2022), PTSD Checklist for DSM-5 (PCL-5, Weathers et al., 2013), Post Traumatic Growth Inventory (PTGI, Tedeschi & Calhoun, 1996), General Health Questionnaire-12 (GHQ-12; Goldberg, 1972), Self-Compassion Scale – Short Form (SCS-SF; Raes et al., 2011), Five Facet Mindfulness Scale (FFMQ; Bohlmeijer et al., 2011) and aforementioned Altitudes platform brief questionnaires: the Altitudes Health Care Climate Questionnaire (A-HCCQ), Altitudes Usability Questionnaire (AUQ), and Altitudes Perceived Competence Scale (A-PCS), and Working Alliance Inventory for guided Internet interventions (WAI-I, Gomez Penedo et al., 2019). Participants will complete a brief survey on engagement with services within the CSC program and outside the program (e.g., individual therapy, family groups outside of CSC, etc.). They will also be asked to participate in a qualitative interview focusing on the experience of Altitudes and deeper understanding of acceptability and feasibility of the platform. Participants in the control condition will complete all the aforementioned measures except for the four brief Altitudes questionnaires and the qualitative interview.

Evaluations

Primary outcomes: Our primary objective is to examine the feasibility and acceptability of implementing Altitudes as a part of coordinated specialty care services provided by first-episode psychosis clinics across the state of North Carolina. We will examine site usage information as well as collect data on carers' perceptions of the platform to assess this outcome (e.g., its utility, approachability, and helpfulness).

Secondary outcomes: Our second aim is to assess the extent to which carers engage with the platform (i.e., site usage information) is associated with improvements in expressed emotion, perceptions of caregiving, coping strategies, loneliness, social support, self compassion, mindfulness, and mood symptoms. We also plan to examine the associations between carers' involvement in Altitudes and their loved one with FEP's use of emergency services (e.g., ED visits). We will compare outcomes from the Altitudes and control groups to examine any improvements experienced by participants who engaged with the platform compared to routine clinical care.

Exploratory outcomes: We would like to explore rates of trauma symptoms related to experiencing and providing support for a loved one who experienced an initial psychotic episode. One of the exploratory aims is to examine the extent to which their loved one's initial psychotic episode and related experiences (e.g., psychiatric hospitalizations, changes in work/school engagement, etc.) might be associated with trauma-related symptoms. We are also interested in the extent to which engagement in Altitudes might promote post traumatic growth among caregivers of a young person with FEP. Trauma and post traumatic growth from caregivers in the treatment group will be compared to controls to assess the extent of impact of Altitudes on these outcomes.

Safety Evaluations

A safety plan for Altitudes was developed before participants joined the digital platform by research staff based on previous experience with digital interventions. All safety measures were approved by the director of each participating NC FEP clinic.

Statistical and Analytic Plan

Primary Outcomes: For Aim 1, we will use descriptive statistics to examine carers' perceptions of the Altitudes platform and clinical moderators via four brief questionnaires: the Altitudes Health Care Climate Questionnaire (A-HCCQ), Altitudes Usability Questionnaire (AUQ), Altitudes Perceived Competence Scale (A-PCS), and Working Alliance Inventory for Guided Internet interventions (WAI-I, Gomez Penedo et al., 2019). Additionally, descriptive statistics will assess interactions with the platform to evaluate acceptability and engagement (e.g., logins, posts, reactions, completed activities, etc.) with the platform (i.e., acceptability and usability).

Information gathered in the post-treatment qualitative interview will be analyzed to identify participants' thoughts about the usefulness of Altitudes as well as feedback to improve the intervention for others. Qualitative analysis will be conducted on the feedback interviews using grounded theory. As with qualitative analysis, a codebook will be developed by the research team in which thematic analysis of all interviews will conducted. The codebook will include themes and subthemes with a focus on the different perceived strengths of the intervention as well as areas that need improvement.

Secondary Outcomes: The platform will collect information about frequency of engagement with Altitudes (i.e., site usage). Psychosocial outcomes will be summarized within and between conditions using univariate statistics (e.g., means, standard deviations). To evaluate change over time on psychosocial outcomes, we will utilize linear mixed models (LMM) including fixed effects of time, group, and group x time interactions and random effects at the participant level. We will calculate changes from baseline at each time point using least-squares means and standardized least-squares mean differences to estimate within- and between-group changes, respectively. To estimate magnitude of change from baseline, we will calculate effect sizes. We will explore the relationship between baseline characteristics (e.g., age, gender) and engagement data (i.e., site usage information) on any changes in psychosocial outcome measures from baseline to midpoint and posttreatment using multiple linear regression. We will use Pearsons correlation coefficients to examine associations between carers' involvement in Altitudes and their loved one with FEP's use of emergency services (e.g., ED visits). If possible based on sample size, we will dichotomize engagement data (site usage) between low engagement and high engagement before comparing site usage with emergency service utilization.

Exploratory Outcomes: We will use descriptive statistics (M, SD) to examine self-reported trauma symptoms among carers of individuals with FEP. Descriptive statistics (M, SD, & effect sizes) will also be used to examine any changes in posttraumatic growth from baseline to midpoint and baseline to post-treatment. We will evaluate change over time in trauma-related symptoms and post-traumatic growth both within- and between-groups using LMMs in the same manner as specified in our analysis of secondary outcomes. We will explore the relationship between baseline characteristics (e.g., age, gender) and engagement data (i.e., site usage information) on any changes in trauma-related symptoms and posttraumatic growth orientation over time.

Data and Safety Monitoring Plan

Privacy and online safety will be managed in accordance with the 'Online social networking' guidelines published by 'Cybersmart', a national cybersafety and cybersecurity education program managed by the Australian Communications and Media Authority (ACMA). Online safety will be monitored by Altitudes moderators (clinicians involved in the project, family peer support workers, graduate students in the Department of Psychology and Neuroscience) with supervision from licensed clinical psychologists Drs. David Penn and Kelsey Ludwig. Dr. Diana Perkins will function as the Project Medical Officer.

INTRODUCTION

Background and Rationale

Psychosis is one of the most debilitating health conditions, both mental or physical disorders, with significant impact on the individual as well as their family and supports. In response to these psychiatric disorders, known as schizophrenia-spectrum disorders, and to circumvent poor outcomes, early intervention services for first episode psychosis

(FEP) were established to assist these individuals and their families and supports. These services for FEP, called Coordinated Specialty Care (CSC) in the United States, have been evaluated to improve symptoms, social functioning, and quality of life for the individual [1]. Further, as the onset of psychosis typically occurs in late adolescence and early adulthood, CSC programs additionally provide support to family and supports through psychoeducation offered by a family therapist. Even with this additional support, family members often experience issues related to their health and wellbeing, including stress, anxiety, depression, and social isolation or lack of support. Further, CSC programs have limited office hours that often do not work into the schedule of families who are caregiving in addition to working.

Family members and supports are often the young person's caregiver and support during this initial onset. Research into the impact of this care for a loved one experiencing FEP has been assessed cross-sectionally and longitudinally via qualitative and quantitative data (i.e., interviews and questionnaires, respectively). Findings from these studies have discerned that family and supports are significantly involved in the life, care, and help-seeking for their loved one [2,3,4]. Up to 90% of young people reside with family during the initial episode of psychosis [5]. At the onset of FEP, it is a period that is often overwhelming for both the individual and family. Families have compared this time as bereavement and losing their loved one to the illness or the future the family thought the individual would have [6]. In addition to the stress of coordinating care for their loved one, families experience moderate stress with twenty-six percent were assessed to experience severe stress in this stage [7]. Further, nearly two thirds of family caregivers experience at least mild depression [8]. During this period, the responsibilities of caring for a loved one have also shown to deplete social connection and network, which have shown to buffer stress [9].

Previously, it has been observed that caregiver re-appraisals promote caregiver coping with the situation and reduce stress [10]. Caregivers' appraisals of their loved one's disorder are also known to influence how they communicate with their loved one. For example, if a family member blames themselves for their loved one's diagnosis, they are significantly more likely to become emotionally over-involved with their loved one [11]. Research has shown this to be an important issue to address as family communication patterns and dynamics influence the course of psychosis, in particular criticism and expressed emotion have been found to significantly increase their loved one's risk of relapse in symptoms of psychosis [12]. Therefore, for the mental health of all family members, it is critical to identify ways to support them and reduce their stress by encouraging positive re-appraisal and by increasing the family members' ability to appropriately respond to their loved one.

Despite the abundance of research on the significant impact of psychosis on the lives of family members and their care for their loved one experiencing psychosis, there is a paucity and gaps in the existing scientific knowledge. There is little known about how caregivers' self-efficacy, coping, and social supports influence and shield caregivers from the stress of their situation. The key construct of caregiver self-efficacy (i.e., a caregiver's belief in their ability to complete tasks and reach goals associated with the caregiving role) is absent from psychosis research with the exception of a pilot from Australia. However, additional research is needed to assess whether this is an important target to intervene and improve outcomes for both family members and their loved ones [13].

Social support is typically provided to caregivers via peer support programs but its impact upon caregiver stress in psychosis is poorly understood.

Further, meta-analyses of randomized controlled trials (RCTs) of caregiver interventions in chronic psychosis has shown robust beneficial treatment effects leading to reduced rates of relapse in patients diagnosed with psychosis [14] and the individual trials have evaluated it to beneficial to caregivers [15] and such interventions have proven to be cost effective [16]. Such interventions are typically based on cognitive behavioral therapy principles with a particular focus on psychoeducation, training in structured problem solving and communication skills. In addition to individual family sessions, family interventions have also been structured as multi-family sessions (i.e., multifamily therapy) with the added component of encouraging support between families [17]. Correctly targeted family intervention in the early stages of FEP may alter the long-term trajectory of family stress [18] and may improve long-term outcomes for the individual experiencing FEP [5]. However, the considerably less evidence for the effectiveness of interventions in FEP than for chronic psychosis (i.e., chronic schizophrenia) [5].

Previously, a group in Australia, a partnership between Australian Catholic University and the University of Melbourne, implemented and published on their RCTs that evaluated a family intervention specifically developed for families with loved ones experiencing FEP and currently receiving treatment within their FEP programs [18]. Their 30-month follow-up study included cognitive behavioral therapy (CBT) sessions for families. These sessions were provided over a 7-month period and were compared to the gold standard specialist treatment as usual (STAU) provided within an FEP program, and not typical “usual care”. In this study, perceived stress related to caregiving was significantly improved in the CBT family condition compared to STAU at the 30-month follow up. To the best of our knowledge, this is the only published RCT to show such a treatment effect in FEP families.

Despite the results from this study, similar interventions for families and supports have not been routinely implemented, particularly outside of Australia. One such concern for these interventions is the wide disparity between evidence of efficacy of family treatments in chronic psychosis and the low rate at which families actually receive evidence-based interventions [19,20]. A large reason for the low rate of families receiving evidence-based interventions is their lack of time and access. Therefore, similar to this aforementioned study and in partnership with the original developers, we are proposing to adapt the intervention into a novel online platform to optimize its usability and accessibility. To the best of our knowledge, this will be the first implementation of an online digital intervention for families with loved ones experiencing psychosis and engaging in the CSC family psychoeducation program in the United States.

With the emergence of websites and apps that allow for interaction and collaboration (i.e., social media websites via Web 2.0) and the accessibility and availability of the internet via smart technology, there is the opportunity to deliver and evaluate an accessible intervention for families with loved ones in CSC programs. Implementing such a platform has the potential to be cost effective, easily disseminated and highly accessible due to 1) the number of caregivers the content can reach without the need of one-on-one support (i.e., family therapist visits); 2) communication can be shared asynchronously between a large population of caregivers by a small team of online therapists and family

peers; and 3) the ability to access the content, including psychoeducation, outside traditional office hours and in convenient spaces for caregivers, compared to typical office hours at CSC programs. Further, this platform captures data (e.g., patterns of system use and engagement) that offers a distinct opportunity to research determinants of any treatment effects. To the best of our knowledge, outside of the platform being implemented in Australia in which we are partnered, no other platform has been developed to study and address the specific needs of families and caregivers with loved ones in CSC programs. Outside of the Australian pilot, previous studies have demonstrated the acceptability of online interventions for caregivers of individuals with chronic schizophrenia but have not provided evidence that the effectiveness of face-to-face interventions, relative to treatments as usual, and how they can be translated to an online platform.

Previously the group in Australia as well as our group have successfully developed and piloted Moderated Online Social Therapy (MOST; known as Horyzons in North Carolina) model for young people recovering from psychosis. MOST integrates purpose-built online social networking, expert and peer moderation, and evidence-based psychoeducation within a single platform. The group in Australia adapted the platform for caregivers called "Altitudes". The platform is based on Horyzons, which was originally built for individuals experiencing FEP. The MOST model [21] provides unique opportunity for caregivers to share information and resources with the support of trained experts and peer moderators. Altitudes will be further adapted for caregivers in the United States and further provide a unique opportunity to extend the availability of evidence-based family intervention for FEP families in North Carolina.

The efficacy of the Altitudes platform for North Carolinian caregivers will be assessed as an open trial with a quasi-experimental design. The primary aim of this trial is to examine the acceptability and feasibility of the platform as an adjunct to standard of care in CSC programs for families with loved ones experiencing FEP. The secondary aim is to evaluate the platform's effect on caregiver stress, mental and physical health over a 6-month intervention period in comparison to a matched control group of caregivers..

Objectives

This program is for families and caregivers of young people diagnosed with a first episode of psychosis. The purpose of the study is to assess the feasibility, acceptability, and efficacy of implementing Altitudes as part of routine care received by families in first episode psychosis clinics in North Carolina. Altitudes is an online platform that integrates: 1) peer-to-peer family online social networking; 2) tailored interactive psychoeducation and psychosocial intervention; and 3) trained moderation. Altitudes was developed and first tested in Australia but has yet to be adapted and evaluated as part of care in family and supports in the United States. Further, efficacy will be more rigorously evaluated with a control group of caregivers who are receiving clinical services but will not have access to the platform over the course of the six months.

RESEARCH DESIGN & METHODS

Participants, interventions, and outcomes

Overview

Participants in the Altitudes condition (parents and caregivers) will be given access to the Altitudes platform (which is considered a "non-significant risk" medical device and is described below) from their date of enrollment up to 6 months. Altitudes will be monitored daily (one hour per day) by trained family peer support specialists, master's level clinicians, Drs. David Penn and Kelsey Ludwig, and/or graduate students in the Department of Psychology and Neuroscience at UNC. To facilitate and monitor engagement, a protocol is in place that directs moderators to contact participants via text message and/or email if he/she/they have not logged onto the platform for two weeks at the beginning of the service, primarily to assess for and troubleshoot logging into Altitudes or navigating the site. If a participant remains inactive for an additional two weeks, moderators will contact participants by phone to check in about any issues and discuss participants' goals for engaging in Altitudes. From that point forward, participants will be encouraged to contact moderators as needed with questions or help-seeking. Moderators will check in with participants monthly throughout the study to ensure Altitudes is meeting their treatment needs and to tailor content to the carers' interests. Caregiver participants may opt out of receiving monthly check-ins. Licensed clinical psychologists, Drs. David Penn and/or Kelsey Ludwig, will lead weekly supervision calls to ensure appropriate care and support of participants involved in this project, to discuss case conceptualization and suggestions for engaging individuals on the platform, as well as to monitor any potential safety concerns.

Overview of Altitudes. Altitudes is an online social media platform that integrates: 1) peer-to-peer online social networking; 2) tailored interactive psychoeducation and psychosocial interventions; and 3) expert moderation.

Peer-to-peer online social networking (the "Community"). The 'community' page includes a web feed where participants can post comments, information, upload pictures and videos, and react to different content. Moreover, the system includes a 'wall' function displaying the activity of individual users, and a 'network' (similar to a 'friends' function). The open trial also incorporates the participation of family peer support workers. Family peer supports are individuals with loved ones who have lived experience of severe mental illness who are familiar with the Altitudes platform. These individuals are part of the investigational staff who will be interacting with participants for research purposes. Their primary function will be to induct individuals to the platform, reach out to inactive participants, answer any questions parents or caregivers may have about the site, and help facilitate discussion in the 'Community' and other sharing areas of the platform. Research staff at the university will train and supervise all Altitudes family peer support workers.

Interactive Psychoeducation and Psychosocial Interventions. Altitudes includes a range of tailored interactive psychoeducation pathways divided into separate steps. These pathways target key educational information in early psychosis including: (a) introduction to psychosis, (b) different phases of psychosis (and what to expect), (c) causes of psychosis and potential relapse, as well as d) strategies to cope with increased demands of caregiving and other stressors. The platform is self-directed and individuals are able to select which pathways they would like to utilize based on their treatment goals. All pathways are available to Altitudes participants in this study.

Expert Moderation. Family peer support workers, providers with significant experience in the psychosocial treatment, as well as graduate students with relevant clinical/research experience with FEP will serve as expert moderators. Their role is to provide guidance, monitor participants' status and ensure the safety of the social networking environment. The moderator reviews interactivity in the social networking space and information from individual participants' modules to monitor risk. The Altitudes Moderation Checklist will be completed by each moderator every time he/she/they moderates the platform. The checklist is designed to ensure moderators complete the appropriate safety checks during the moderation session, and to give moderators ideas as to how to engage users.

Treatment period. At the mid-treatment assessment period (approximately 10-14 weeks after an Altitudes participant is onboarded to the platform), clients will meet with the study coordinator over secure video conferencing. The study coordinator will use screen sharing to complete all assessment measures with the individual. Control participants will also meet via secure video conferencing with research staff approximately 10-14 weeks after their initial battery assessment.

After Altitudes participants have engaged with the platform for 24 weeks, they will be provided with an optional feedback form as a way of better understanding their experience with the platform and collecting suggestions for improving the site. Additionally, we will conduct individual feedback interviews (lasting approximately 45 minutes) with parents and caregivers. These interviews will address participants' social relationships, experiences with loneliness, and thoughts about connecting with others through Altitudes. Control participants will also complete the same measure battery via video conferencing at approximately 24 weeks after their initial survey visit.

To evaluate the extent to which engagement in Altitudes may have impacted treatment participants' psychological health and perceptions of their social environment in comparison to the control group, all individuals will be asked to complete a battery of psychological measures at baseline, mid-treatment, and post-treatment visits. All measures will be administered by a member of the study team via secure Zoom. They will additionally complete a brief engagement measures on services they are accessing (e.g., services through the CSC program, individual therapy, group therapy at an outside organization, etc.).

At each of the three timepoints, all participants will be asked to complete the Experience of Caregiving Inventory (ECI; Szmukler), the Family Questionnaire of Expressed Emotion (Wiedemann et al., 2002), Brief COPE (Carver, 1997), UCLA Loneliness Scale (Russell, 1996), Multidimensional Scale of Perceived Social Support (For control and Alternative form for Altitudes condition; Zimet et al., 1990), Modified Psychosis Attitudes Survey (PAS; Kopelovich et al., 2022), PTSD Checklist for DSM-5 (PCL-5, Weathers et al., 2013), Post Traumatic Growth Inventory (PTGI, Tedeschi & Calhoun, 1996), General Health Questionnaire-12 (GHQ-12; Goldberg, 1972), Self-Compassion Scale – Short Form (SCS-SF; Raes et al., 2011), and Five Facet Mindfulness Scale (FFMQ; Bohlmeijer et al., 2011).

At baseline, all participants will be asked to complete a brief demographic questionnaire and answer a small number of clinical questions about their loved one (e.g., "Of the options provided below, what stage of recovery best describes your loved one?").

At midpoint, Altitudes condition participants will also be asked to provide their perceptions of the Altitudes platform and clinical moderators via four brief questionnaires: the Altitudes Health Care Climate Questionnaire (A-HCCQ), Altitudes Usability Questionnaire (AUQ), and Altitudes Perceived Competence Scale (A-PCS) and Working Alliance Inventory for guided Internet interventions (WAI-I, Gomez Penedo et al., 2019).

At posttreatment, Altitudes condition participants will be asked to participate in a qualitative interview focusing on the experience of Altitudes and deeper understanding of acceptability and feasibility of the platform.

As this platform will be provided as an adjunct to CSC clinical care, pertinent clinical impressions and other relevant clinical information will be shared with the individual's clinical team at their respective FEP clinic.

All individual interviews will be conducted virtually via secure Zoom and will be led by the Altitudes study coordinator and/or a graduate student in clinical psychology at UNC-Chapel Hill. All feedback sessions will be digitally recorded, and will be de-identified and transcribed by a member of the research team or a transcription service. The purpose of these recordings and transcriptions is to allow the research team to examine the feedback provided in the interviews for the purposes of improving the platform to better support families and caregivers in supporting their loved ones experiencing psychosis via psychoeducation and skills such as healthy coping mechanisms.

Subjects

Up to 30 total Altitudes participants will be recruited from two of the FEP clinics in North Carolina (OASIS & SHORE) as it is a pilot study, specifically family members of individuals experiencing FEP. An additional 30 control participants will be recruited from three other FEP clinics in North Carolina (Eagle, Encompass, and AEGIS). All participants will have a loved one currently enrolled in or recently graduated from a CSC program. Demographic and clinical information that will be collected as self-report for possible use as covariates includes: 1) participant demographics: age, sex/gender identity, race/ethnicity, level of education, current zip code, relationship to loved one, employment status, proximity to the loved one with psychosis (e.g., cohabitating, living in different states), hours of contact with loved one per week on average, number and ages of any other children; and 2) young person with psychosis' demographics and relevant clinical information: age, sex/gender identity, level of education, stage of recovery, and level of education.

Eligibility Criteria

Inclusion criteria for the study will be family (i.e., parent or other loved one in a caregiving role such as a grandparent, godparent, etc.) of a young person who is currently receiving treatment from a CSC program for first episode psychosis, or who have recently graduated from a CSC program. For the parent or caregiver to be eligible, the parent or caregiver must be at least 18 years of age. More than one family member will be eligible to participate from each family. Altitudes participants will be recruited from only two North Carolina CSC programs (OASIS & SHORE), as this is a pilot study, while the control participants will be recruited from three other CSC programs (Eagle, Encompass, and

AEGIS). Additionally, the parent/caregiver must have access to the internet through a mobile phone, tablet, or computer.

Exclusion criteria: Family who are currently engaged in legal action against the identified individual, do not speak English, or under 18 years of age.

ASSESSMENT OF DATA

At this stage of treatment development, specific outcomes include examining the feasibility and acceptability of implementing Altitudes at NC FEP clinics for parents and caregivers through the following objectives:

1) Ability to meet our recruitment targets
2) Evaluation of the safety and privacy protocol
3) Evaluation of the frequency and types of engagement on Altitudes
4) Examination of carers' perceptions of the platform (e.g., its utility, approachability, and helpfulness)
5) Assessment of any changes in psychological measures across the six-month intervention

Outcomes

We hypothesize that caregivers of individuals with psychosis will utilize the Altitudes platform and perceive it to be useful and beneficial for their understanding of their loved one's mental health issues. We also hypothesize that engagement in Altitudes will contribute to increased utilization of adaptive coping strategies, reduced expressed emotion in the familial milieu, and improved understanding of psychosis in comparison to the control participants.

STUDY PROCEDURES

Screening Procedures

The research study coordinator will communicate with clinicians and other members of the treatment team to explain the project and discuss eligibility criteria for the study. If agreed to by the clinical team at each site, the research team will attend the beginning or end of multifamily group (MFG) sessions at OASIS & SHORE to provide an overview of Altitudes and answer any questions that potential participants might have about the study. Research staff will additionally contact the other three clinics (Eagle, Encompass,, AEGIS, and We2Care) about control participants and attend their MFG to provide information to prospective participants. Clinical team members will be asked to review their current caseloads to identify potentially eligible participants (i.e., parents and caregivers of patients who are currently receiving services or recently graduated from one of the programs). The study coordinator and/or research assistant (RA) will engage in discussion with the treatment team to help identify appropriate individuals for inclusion in the project. When participants have been identified and expressed interest in participation to their clinician or other treatment provider, the research study coordinator or RA will reach out to the individual in their preferred method of contact (i.e., in person at the clinic or via phone/email) to discuss the project and complete an initial screen to confirm the inclusion and exclusion criteria. Participants will then be

given the highlights of the study and their participation via phone after their screening. Highlights will include the study, its aims, what they will be asked to do, the timeframe of their participation, and that it is completely voluntary and they can withdraw consent at any time, for any reason, without penalty. Additionally, in the email to review the document and at the top of the consent forms in DocuSign there will be a phone number for them to contact and explicitly state to call the number if they have any questions prior to signing the documents.

With approval from the IRB & clinic directors, the research time will post flyers with a description of the study and eligibility criteria in the clinic waiting rooms to allow for caregivers to self-refer and/or to enable clients with FEP to share information about the study with their loved ones. If individuals self-refer (in response to flyers), the RA and PI will consult with the treatment team first before screening the individual (i.e., to confirm their loved one is currently receiving or recently graduated from the CSC program).

Baseline Procedures

The study coordinator will meet virtually with prospective participants for about 1 hour to complete all baseline measures. The demographic form will be completed first, which collects basic information about sex, age, ancestry, education, current zip code, and basic information on their loved one, including their loved one age, duration of illness, and length of time in the CSC program. After completing these documents, the study coordinator will guide participants through virtual copies of the demographic questions and psychological measures , including the Experience of Caregiving Inventory (ECI; Szmukler), the Family Questionnaire of Expressed Emotion (Wiedemann et al., 2002), Brief COPE (Carver, 1997), UCLA Loneliness Scale (Russell, 1996), Multidimensional Scale of Perceived Social Support (For control and Alternative form for Altitudes condition; Zimet et al., 1990), Modified Psychosis Attitudes Survey (PAS; Kopelovich et al., 2022), PTSD Checklist for DSM-5 (PCL-5, Weathers et al., 2013), Post Traumatic Growth Inventory (PTGI, Tedeschi & Calhoun, 1996), General Health Questionnaire-12 (GHQ-12; Goldberg, 1972), Self-Compassion Scale – Short Form (SCS-SF; Raes et al., 2011), and Five Facet Mindfulness Scale (FFMQ; Bohlmeijer et al., 2011). Additionally, all participants will complete a brief survey on engagement with services within the CSC program and outside the program (e.g., individual therapy, family groups outside of CSC, etc.).

For Altitudes participants only, once all baseline study measures are complete, the study coordinator will conduct a 20- to 30-minute orientation of the Altitudes platform, including creation of an Altitudes profile and orientation to the features of the site. All participants will be compensated $20.00/hour prorated to the nearest half hour for completion of this visit and their time.

Intervention Period Procedures

Mid-Treatment Procedures

The study coordinator will meet virtually with all participants for approximately 30 minutes to complete the mid-treatment measures. All participants will complete virtual copies of the Experience of Caregiving Inventory (ECI; Szmukler), the Family Questionnaire of Expressed Emotion (Wiedemann et al., 2002), Brief COPE (Carver, 1997), UCLA Loneliness Scale (Russell, 1996), Multidimensional Scale of Perceived Social

Support (For control and Alternative form for Altitudes condition; Zimet et al., 1990), Modified Psychosis Attitudes Survey (PAS; Kopelovich et al., 2022), PTSD Checklist for DSM-5 (PCL-5, Weathers et al., 2013), Post Traumatic Growth Inventory (PTGI, Tedeschi & Calhoun, 1996), General Health Questionnaire-12 (GHQ-12; Goldberg, 1972), Self-Compassion Scale – Short Form (SCS-SF; Raes et al., 2011), and Five Facet Mindfulness Scale (FFMQ; Bohlmeijer et al., 2011). Additionally, all participants will complete a brief survey on engagement with services within the CSC program and outside the program (e.g., individual therapy, family groups outside of CSC, etc.). At midpoint, Altitudes participants will also be asked to provide their perceptions of the Altitudes platform and clinical moderators via four brief questionnaires: the Altitudes Health Care Climate Questionnaire (A-HCCQ), Altitudes Usability Questionnaire (AUQ), and Altitudes Perceived Competence Scale (A-PCS) and Working Alliance Inventory for guided Internet interventions (WAI-I, Gomez Penedo et al., 2019). All participants will be compensated $20.00/hour prorated to the nearest half hour for completion of this visit and their time.

Post-Treatment Procedures

The study coordinator will meet virtually with family and support participants for approximately 1-1.5 hours to complete the post-treatment measures; however, visits for control participants is likely to be closer to a half hour. All participants will complete virtual copies of the Experience of Caregiving Inventory (ECI; Szmukler), the Family Questionnaire of Expressed Emotion (Wiedemann et al., 2002), Brief COPE (Carver, 1997), UCLA Loneliness Scale (Russell, 1996), Multidimensional Scale of Perceived Social Support (For control and Alternative form for Altitudes condition; Zimet et al., 1990), Modified Psychosis Attitudes Survey (PAS; Kopelovich et al., 2022), PTSD Checklist for DSM-5 (PCL-5, Weathers et al., 2013), Post Traumatic Growth Inventory (PTGI, Tedeschi & Calhoun, 1996), General Health Questionnaire-12 (GHQ-12; Goldberg, 1972), Self-Compassion Scale – Short Form (SCS-SF; Raes et al., 2011), and Five Facet Mindfulness Scale (FFMQ; Bohlmeijer et al., 2011). Additionally, all participants will complete a brief survey on engagement with services within the CSC program and outside the program (e.g., individual therapy, family groups outside of CSC, etc.). After completing these virtual measures, the study coordinator will lead Altitudes participants only through a feedback survey and individual feedback interview regarding the Altitudes platform, their online therapist, the Family PSS, and the community newsfeed. Altitudes participants will be welcomed to share their opinions regarding their experience, including suggestions for how to improve Altitudes in the future. All participants will be compensated $20.00/hour prorated to the nearest half hour for completion of this visit and their time.

DATA ANALYTIC PLAN

Primary Outcome Measures*

*Primary outcomes solely apply to those in the Altitudes condition

1. Qualitative Summaries of Participant Experience in Post-Treatment Feedback [Time Frame: up to 6 months]

   This qualitative data will be collected post-treatment from Altitudes participants. Individual interviews will discuss usage of the platform and any feedback participants may have. Feedback from participants will be summarized to include

common themes regarding likes and dislikes of the platform, implementation within the clinical setting, and participant ideas for future directions.

2. Quantitative Summaries of Participant Experience in Post-Treatment Feedback [Time Frame: up to 6 months]

   This quantitative data will be collected post-treatment from Altitudes participants. Feedback forms will prompt participants to answer questions regarding their experience with the platform on a scale of 1 to 5, with higher scores reflecting a more positive experience. Frequency counts will be included here.

3. Mean change in Working Alliance Inventory for Guided Internet Interventions (WAI-I) – Total Score [Time Frame: Mid-treatment, post-treatment, up to 6 weeks]

   The Working Alliance Inventory for Guided Internet Interventions (WAI-I) is a 12-item scale. Answers are on a 5-point scale with options "seldom", "sometimes", "fairly often", "very often", and "always". Possible scores are averaged across items and range from 1 to 5. Higher scores indicate greater therapeutic alliance.

4. Mean change in Working Alliance Inventory for Guided Internet Interventions (WAI-I) – Task and goals subscale [Time Frame: Mid-treatment, post-treatment, up to 6 weeks]

   The Working Alliance Inventory for Guided Internet Interventions (WAI-I) task and goals subscale is an 8-item scale. Answers are on a 5-point scale with options "seldom", "sometimes", "fairly often", "very often", and "always". Possible scores are averaged across items and range from 1 to 5. Higher scores indicate greater agreement between the therapist and client on tasks and goals.

5. Mean change in Working Alliance Inventory for Guided Internet Interventions (WAI-I) – Bond subscale [Time Frame: Mid-treatment, post-treatment, up to 6 weeks]

   The Working Alliance Inventory for Guided Internet Interventions (WAI-I) is a 4-item scale. Answers are on a 5-point scale with options "seldom", "sometimes", "fairly often", "very often", and "always". Possible scores are averaged across items and range from 1 to 5. Higher scores indicate stronger bond with the supporting therapist

6. Mean change in Perceived Autonomy Support Scale – Total Score [Time Frame: Mid-treatment, post-treatment, up to 6 weeks]

   The Perceived Autonomy Support Scale is a 6-item scale. Answers are on a 7-point scale ranging from "strongly disagree", "moderately disagree", "slightly disagree", "neutral", "slightly agree", "moderately agree", and "strongly agree". Possible scores are averaged across all 6 items. Higher scores indicate greater global support of client autonomy from the treatment provider or team.

Secondary Outcome Measures

1. Descriptive statistics examining Site Usage Information [Time Frame: Duration of the trial, from onboarding at baseline through post-treatment]

   The Altitudes platform passively collects engagement data, including the number of therapeutic pathways started and completed as well as any posts or comments made on the platform. We will provide mean and standard deviation scores for each site usage category, as well as a range, for the Altitudes group only. Depending on sample size, we will categorize users in low or high engagement groups.

2. Mean Change in UCLA Loneliness Scale Score [Time Frame: Baseline, Post-treatment, up to 14 weeks]

   The UCLA Loneliness scale is a 20-item scale. Answers are on a 4-point scale with options "I often feel this way," "I sometimes feel this way," "I rarely feel this way," and "I never feel this way." Possible scores range from 20 to 80. Higher scores reflect worse outcomes (greater feelings of loneliness). The UCLA Loneliness Scale is a part of the PhenX Toolkit.

3. Mean Change in Multidimensional Scale of Perceived Social Support - total score [Time Frame: Baseline, Post-treatment, up to 14 weeks]; Alternative form for Altitudes participants, original form for control group.

   The MOS Social Support Survey is a 16-item scale. Answers are on a 7-point scale with options ranging from “very strongly disagree” to “very strongly agree”. Possible scores range from 16 to 112. Higher scores reflect higher feelings of social support (more perceived social support).

4. Mean Change in the Experience of Caregiving (ECI) Score [Time Frame: Baseline, Post-treatment, up to 14 weeks]

   The Experience of Caregiving (ECI) Scale is a 66-item scale. Answers are on a 5-point scale starting at 0 with options "never,” “rarely,” “sometimes,” “often,” and “nearly always”. Possible scores range from 0 to 264. Higher scores indicate greater feelings of preparedness for caregiving whereas lower scores reflect feeling less prepared to provide caregiving.

5. Mean Change in Family Questionnaire of Expressed Emotion - Total Score [Time Frame: Baseline, Post-treatment, up to 14 weeks]. The Family Questionnaire of Expressed Emotion is a part of the PhenX Toolkit.

   The Family Questionnaire (FQ) is a 20-item, self-administered questionnaire that measures expressed emotion status (criticism and emotional over involvement [EOI]) of family members toward patients with mental illness. The FQ has two subscales: critical comments, and EOI. Each item is rated on a 4-point scale (1 = never/very rarely; 4 = very often). The FQ is scored by adding together the ratings

from the individual items, with higher scores indicating greater levels of expressed emotion.

6. Mean Change in General Health Questionnaire-12 Score [Time Frame: Baseline, Post-treatment, up to 14 weeks]

   The GHQ-12 is a 12-item scale. Answers are on a 4-point scale ranging from 0 "not at all" to 3 "much more than usual." Possible scores range from 0 to 36. Higher scores reflect worse outcomes (more frequent depressive symptoms).

7. Mean Change in the Brief COPE scale [Time Frame: Baseline, Post-treatment, up to 14 weeks]

   The Brief-COPE is a 28-item self-report questionnaire designed to measure effective and ineffective ways to cope with a stressful life event. It can be divided into three subscales: problem-focused (8 items), emotion-focused (12-items), and avoidant (8-items) coping styles. Answers are on a 4-point scale ranging from 1 "I haven't been doing this at all" to 4 "I have been doing this a lot." Higher scores on each reflect more frequent use of that style of coping.

Tertiary/Exploratory Outcome Measures

1. Mean Change in the PTSD Checklist for DSM-5 [Time Frame: Baseline, Post-treatment, up to 14 weeks]

   The PCL-5 is a 20-item self-report measure of the 20 DSM-5 symptoms of Post Traumatic Stress Disorder (PTSD). Included in the scale are four domains consistent with the four criteria of PTSD in DSM-5: Re-experiencing (criterion B), Avoidance (criterion C), Negative alterations in cognition and mood (criterion D), and Hyper-arousal (criterion E). Answers are on a 5-point scale including "Not at all," "A little bit," "Moderately," "Quite a bit," and "Extremely" and with total scores ranging from 0 to 80. Higher scores on the PCL-5 reflect more severe trauma-related symptoms.

2. Mean Change in the Posttraumatic Growth Inventory Score [Time Frame: Baseline, Post-treatment, up to 14 weeks]

   The PTGI is a 21-item self-report measure that assesses five domains of personal growth that may follow a stressful encounter. Answers are on a 6-point scale ranging from 0 "I did not experience this" to 5 "I experienced this change to a very great degree." Total scores on this scale range from 0 to 105. Higher scores reflect more positive changes in an individual's life following a stressful experience.

Power Analysis

We did not conduct *a priori* power calculations to determine a sample size with 80% power because this is an exploratory pilot study and will inform future well-powered trials of Altitudes in the United States.

Data Management

We will use the Research Electronic Data Capture (REDCap) system to facilitate data entry and management. We will leverage features in REDCap such as real-time data validation, built-in integrity checks, and other mechanisms for ensuring data quality (i.e., double data entry). Our team will use the Atlas.ti program for qualitative analysis. All analyses will be conducted by the study research coordinator (Elizabeth Fraser) and graduate student (Bryan Stiles).

RISKS AND BENEFITS

Risks for all participants. Identifying research subjects by a study number on all research documents minimizes risk of breach of confidentiality. Study documents that must contain personal information, such as the document that links study ID number to personal identifying information (necessary due to the longitudinal nature of this study) are kept in locked filing cabinets in locked rooms and/or are on password protected servers that only research staff have access to. Research data is kept on password-protected drives, and our computer systems are HIPAA compliant. All study staff participate in annual human subjects training that includes education about responsibilities to minimize risk that confidentiality may be breached.

Risks for parent and caregivers only. Risk of anxiety, shame, and/or embarrassment due to experiences using this online platform is minimized by completion of an Altitudes induction procedure. This will also be mitigated through the use of consistent moderating of the site as well as moderators' use of a nonjudgmental clinical attitude. The informed consent process will be completed in private spaces within the clinic/research setting or via video conferencing will be done in secure locations and on secure servers. The participant will be instructed via email or phone call before the interview to find a private location to complete the induction to the platform. All documents such as consent and questionnaires will be sent to the participant using a secure UNC email account. Documents will not contain confidential information.

Monitoring Risks

To address subject anxiety or embarrassment due to revealing personal information, we have trained research staff who are experienced in working with individuals with schizophrenia spectrum disorders and their families or supports. They have been trained to put subjects at ease, let them take their time, and to conduct interviews in private rooms.

To address the issue of accidental disclosure of personal information to others outside of the research staff, we will identify research subjects by study number on all research documents to minimize the risk of breach of confidentiality. Study documents that must contain personal information, including the informed consent document, and the

document that links study ID number to personal identifying information are kept in locked filing cabinets in locked rooms or on password-protected drives. Research data will be kept on password-protected drives, and our computer systems are HIPAA compliant. All study staff participate in annual human subject training that includes education about responsibilities to minimize risk that confidentiality may be breached.

Altitudes safety protocol

A rigorous safety protocol has been developed by the researchers in conjunction with experts from the computing and information systems discipline. The safety protocol is comprised of 3 levels of security including: 1) *system and privacy protection*, 2) *online safety*, and 3) *clinical safety*.

System and privacy protection. A range of measures are in place to help ensure the security of the website. The platform is hosted on the State of North Carolina's AWS server. The State has significant measures in place to prevent unauthorized access to the server. In addition, the web application includes measures to secure the application and database against unauthorized access. These measures conform to industry best practice as defined by the Open Web Application Security Project (www.OWASP.org).

Online safety. Privacy and online safety will be managed in accordance with the 'Online social networking' guidelines published by 'Cybersmart', a national cybersafety and cybersecurity education program managed by the Australian Communications and Media Authority (ACMA). Cybersmart is designed to meet the needs of its target audiences of young people, parents, teachers and library staff. Information about Cybersmart can be found at https://www.esafety.gov.au/, while the guidelines are available at https://www.acma.gov.au/.

Safe and informed orientation to the system will be a priority for the research team. A family peer support specialist, online moderator, and/or research staff from UNC Chapel Hill will meet with each Altitudes participant to provide them with login details, help set up their account, and orient them to the Altitudes system, including details of the terms of use. Hard copies of *'Altitudes Terms of Use'* will be provided to users, which will be made available online and in printed form. Participants will be required to sign the hard copy as well as accepting the terms of use on entry into the system. The system also includes a "report function" which enables users at any time to indicate to the moderator a concern about any material posted by a user, including concern about potential abuse. The moderator will assess the basis of the report and respond accordingly, which can include the removal of the material and in some cases the deactivating or restriction of the user's account.

In addition, users will be able to "switch off" their profile and hide all of their existing comments on the system should they become concerned about their privacy during their course of participation. The limits of the moderator to respond (e.g., in a timely manner to emergencies) will also be fully explained. In order to protect the privacy of users who discontinue using the system, any accounts that have not been activated for one month may be deactivated following a follow-up telephone call from a moderator. Specifically, our disengagement protocol states that a participant will receive an email/call/text message if they have not logged onto the platform for two weeks. If another two weeks pass, we will call this person to check in about any potential issues or concerns. As noted

above, the moderation team will check in with participants on a monthly basis to ensure they are able to navigate the site with ease and to answer any questions they might have about the platform and any of its components/capabilities. Participants can opt out of these regular check ins from moderators at any time. If participants do not comply with the guidelines for safe use of Altitudes (e.g., discriminatory comments towards other users; disclosing identifying details of the identified patient) they will be excluded from the system.

Clinical safety: Although highly unlikely for the parent or caregiver, it is possible that participants may post information indicative of a clinical risk in their loved one, although participants will be advised that the service cannot respond to emergencies. Nonetheless, clinical risk will be monitored through manual and automated procedures. Information related to clinical risk will be screened daily by moderators and/or research staff . This information can include: 1) posts made by participants, which disclose evidence of deterioration in mental state of the young person in the care of participants; 2) participants reports or complaints on posts made by other users; and 3) automatically detected and blocked words posted by participants in the system. Additionally, clinical and family peer moderators will analyze the 'Community' feed to ensure that misinformation and falsehoods are not being spread by users of the platform.

Any detected increased risk will activate the Altitudes safety protocol which includes a number of potential actions. Initially, the moderator will conduct a risk assessment based upon available information, inform the research team, and advise the participant on appropriate action, such as emergency services when necessary. In addition, the system incorporates visible emergency guidelines and contact information (i.e., on every webpage). Telephone numbers and contact details will be provided on each page of the website.

An automated keyword system has also been built in Altitudes which will be activated each time a participant posts a contribution containing potentially offensive words. When these words are detected the contribution will be blocked and the participant will be sent an automated email explaining that the message has been blocked and if they are facing distress then they should contact the emergency contact number as soon possible or if they are not facing distress they may like to consider rephrasing their post. An automated email will also be sent to the Altitudes moderator containing the attempted post.

In addition, a message will be available on each page providing a mobile telephone number carried by a member of the research team for any emergencies that are related specifically to the use of the Altitudes' system (e.g., highly inappropriate use of the system). Further, each page includes an "In Case of Emergency" link that provides about way to contact emergency services (911), the UNC crisis line (984-974-3950), and crisis services (http://crisissolutionsnc.orge/ ; [988]).

Withdrawal criteria. Temporary or permanent withdrawal from Altitudes will be triggered by repeated inappropriate use of the system. This can include either suspension of a users' Altitudes account or restrictions regarding participation and use of Altitudes (i.e., the user is able to access therapeutic content and support from moderators but cannot post comments or participate in existing threads within the social network).

Non-Significant Risk Documentation

The present study has been deemed of non-significant risk (NSR) to participants.

Potential Benefits of the Research to Subjects and Others

While the field is still in its infancy, there is preliminary evidence that online interventions combining therapy, social networking opportunities, and expert and peer moderation may be well received by individuals whose loved ones are experiencing FEP, as it develops skills and offers a support network of people with similar experiences. Further, it increases accessibility and availability of evidence-based resources for parents and caregivers whose schedules are already overextended and are unable (or have to take time off work) to attend family therapy appointments at the CSC outpatient clinics. The proposed study will expand this growing body of work by testing the clinical utility of this intervention when implemented as an adjunct service of CSC clinics in North Carolina.

Benefits to treatment participants. The proposed study may increase the family and supports' sense of belonging and social support. Additionally, if they engage with the educational material, they may learn effective strategies to reduce stress and improve mood, better understand their loved one and their experience, as well as identify ways to support their loved one in their recovery from psychosis.

Benefits to control participants. While control participants may not receive direct benefits from this study, they will contribute to the scientific knowledge underlying Altitudes with the hopes of expanding this novel digital intervention to all families receiving services in CSC programs.

Confidentiality of Data

Names and associated contact information for potential subjects during the recruitment phase will be stored in a manner similar to that used to store study data. This information will be kept in a locked file cabinet in a locked office at UNC or within the administrative or secure storage areas of the FEP clinics involved in this project. Contact information will be destroyed immediately after it is ascertained that an individual does not want to participate in the study. Individuals who decline to participate will have their names retained on a secure password protected network to ensure that they are not contacted more than once regarding participation.

A member of the research team will meet individually with the parent or caregiver to explain the components of the Altitudes platform (or the study in general in the case of participants in the control group), elicit and answer any questions the potential participant may have after the screening then informed consent will be obtained via the DocuSign system. Altitudes participants will also create a profile on the platform and answer questions about their caregiving experience (e.g., their loved one's stage of recovery), which are introduced to each participant during the onboarding to the Altitudes platform. This data will be linked to other sources of information, including the record of their interactions within the Altitudes system (e.g., number of posts/comments in the 'Community').

The Altitudes system and data generated by users of Altitudes will be hosted on a secure web server. A range of measures are in place to ensure the security of the Altitudes website and the data generated by users. In addition, the team who developed the web application has placed measures within the application to secure the application and database against unauthorized access. These measures conform to industry best practice as defined by the Open Web Application Security Project (www.OWASP.org). All data collection visits will be conducted via secure Zoom. All interviews will also be conducted via secure Zoom and will be digitally recorded (via Zoom or using audio recorders) for the purposes of transcription. These recordings and transcripts will be immediately uploaded to a secure, password-protected server and deleted from local devices. The project electronic database (including all transcripts from interviews) will be password protected and stored securely, and will only be directly accessible by the research staff, clinicians and family peer support workers, involved in this project, or the principal investigator.

As this research program is being implemented in clinical settings, it is possible that FEP clinicians will create notes that indicate the participant is involved in the project, describe any issues that may arise, etc. that will be connected to their medical record. These documents will be stored in approved medical record systems on HIPAA-compliant computers.

If researchers complete inductions or introductions to the site via video conference, the video or audio from these interviews will not be saved or recorded. Audio from qualitative interviews will be stored on a secure, password-protected server.

Identifiable data will only be shared with the clinicians of participants in the study with the permission of the participants (obtained during informed consent). Clinicians will be contacted if issues arise related to safety during the trial. As part of the informed consent process, all participants will be asked to provide the name and contact info of an emergency contact that we may contact if we become concerned about their safety or the safety of their loved one (e.g., physical and/or mental health) during the trial. Any limitations to privacy and confidentiality, including any indication of neglect or abuse of a minor, elder, or other vulnerable group, will be explicitly discussed with all participants during the informed consent process. We will not be sharing any confidential information with anybody outside of these clinicians.

Identifiable data will be maintained for 5 years following study completion. At that point, hard copies of identifiable data including consent forms and contact information will be shredded. Electronic data will be de-identified upon entry, with the exception of the subjects' birth dates for the purposes of calculating their exact age.

Safety Management

Adverse Events

System and privacy protection will be monitored by the study staff. Online safety will be monitored by the clinical and family peer moderators with supervision from the senior researcher staff (Drs. David Penn and Kelsey Ludwig). The moderators will have the authority to respond to online reports (e.g., remove offending material from the system)

and automated emails.

Clinical safety will be monitored proactively by the moderators through daily monitoring of the activity on Altitudes (i.e., twice a day during the weekdays and once a week on weekend days). In addition, information related to the well-being of participants could be brought to the attention of the research team from two potential sources: a) the online moderators via daily monitoring of the site; and b) the research coordinator at an interview.

The research team will respond according to a ***risk management algorithm***, which outlines the required response to potential indicators of clinical risk in terms of the source of the information. If the online moderator becomes aware of potential indicators of risk in the online application they will conduct an initial risk assessment, make the appropriate clinical response and inform the supervisor. If the study research coordinator becomes aware of an indicator of clinical risk they will inform their supervisor who will again respond clinically. The principal investigator will assess the criteria for withdrawal and potential suspension of usage restriction to a user's Altitudes account. The principal investigator will have ultimate responsibility for withdrawing participants from the study or restricting their Altitudes account.

Reporting of adverse events

Any adverse outcomes for participants, such as exposure to potentially harmful interactions through social networking, will be reported to University of North Carolina at Chapel Hill's (UNC-CH) Institutional Review Board (IRB). If a participant informs the moderators of an adverse event relating to the young person in their care or of any signs of deterioration in their mental health, the Altitudes moderators will communicate with the relevant clinicians where indicated.

RECRUITMENT STRATEGY

For recruitment, research staff have partnered with CSC clinics in previous studies and consultation. For this reason, research staff have extensive knowledge regarding recruiting from this target population. Research staff will inform the CSC providers and PSS about the study and its eligibility criteria to allow the treatment team the ability to identify potentially eligible participants. The treatment team will then approach potential parent and caregiver participants to gauge their interest in participating on the digital platform. If the person expresses interest or would like to know more about the study, the provider or PSS will pass along their information to research staff via referral forms to contact them to further discuss specifics about the study (e.g., describe the social networking and educational aspects of the platform). If the individual is still interested in participating, the client will be screened for eligibility. Upon meeting eligibility criteria, the individual will be scheduled for a baseline visit.

CONSENT PROCESS

As screening will occur prior to informed consent, participants will be given a brief overview of the study (see participant screening document). Prior to administering eligibility screening questions, participants will be asked if they are still interested and give verbal consent to complete the screening form. If the participant verbally consents to screening this will be documented prior to administering the screening questions. Upon verification of eligibility, participants will be given the highlights of the study and

their participation via phone after their screening. Highlights will include the study, its aims, what they will be asked to do, the timeframe of their participation, and that it is completely voluntary and they can withdraw consent at any time, for any reason, without penalty. Additionally, in the email to review the document and at the top of the consent forms in DocuSign there will be a phone number for them to contact and explicitly state to call the number if they have any questions prior to signing the documents. The participant will then be scheduled for a baseline visit (see below). If the individual is not eligible, they will be thanked for their time and notified that they are not currently eligible for the study.

A member of the research team will meet individually with the client in order to explain the components of the study (including the Altitudes platform), elicit and answer any questions the participant may have during the screening phone call. Participants will then provide informed consent via the DocuSign platform. For Altitudes participants, it will be explained that their data will be linked to other sources of information, including the record of their interactions within the Altitudes system (e.g., number of posts/comments on the 'Community'), but the data exported from the site will be de-identified before storage on password protected drives located on secure servers. All participants will be provided with a copy of the consent form and research staff will encourage each participant to contact the principal investigator or IRB for any questions they may have related to the study or their rights as a research participant. There are also several procedures in place to ensure that prospective participants fully understand the procedures, risks, and protections of the study. First, the consent form is written in easy-to-understand language. Second, participants will know the number and email of the person to call if they have any questions prior to signing the document. Participants will have the option to provide electronic consent via DocuSign's Part 11 compliant electronic consent platform (i.e., electronic signature and verification) or in person on paper with wet ink signatures if preferred.

ETHICS

Research Ethics Approval

Research ethics approval for the Altitudes Pilot will be sought from University of North Carolina at Chapel Hill's IRB.

Protocol Amendments

Any modifications to the research protocol and conduct of the study will be notified to UNC's IRB prior to their enactment. Approval from UNC's IRB will be sought for any proposed protocol amendment including changes to eligibility criteria, outcomes, analysis and changes to research personnel.

Declaration of interests

The researchers report no financial or competing interests for the conduct of the trial.

Access to Data

Personnel who will have access to one or more sources of information collected through

the course of this study include all of the listed research staff in the IRB application (all data) and the study moderators (the online data captured within the Altitudes system).

Ancillary and Post-Trial Care

At the completion of the study, identifiable and deidentified data will be stored securely (i.e., hard copies will be stored in locked cabinets within locked offices and electronic will be in secure databases on secure computers). Three years after completion of the study, identifiable data will be properly and confidentially destroyed. Five years after the final publication arising from the deidentified data will be properly disposed and destroyed (i.e., electronic data will be deleted and paper data will be confidentially disposed).

Future Projects

We will seek permission from participants to use the data we collect for this study for projects that are not described here but that are closely related. Any future projects using the data will have been approved by UNC's IRB. The deidentified data will only be used and researchers will not have access to participant's identifiable data.

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