Horyzons: Implementation and Integration in Clinical Practice

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Clinical Protocol & Data Analytic Plan

Horyzons: Implementation and Integration in Clinical Practice

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Abbreviations and Definitions of Terms

Abbreviation	Definition
CBT	Cognitive-Behavioral Therapy
CSC	Coordinated Specialty Care
DUP	Duration of Untreated Psychosis
FEP	First Episode Psychosis
LAR	Legally Authorized Representative
NC	North Carolina
NIMH	National Institutes of Mental Health
NSR	Non-significant Risk
OASIS	Outreach and Support Intervention Services
PI	Primary Investigator
PSS	Peer Support Specialist
SSD	Schizophrenia Spectrum Disorder

Protocol Synopsis

Study Title	Horyzons: Implementation and Integration in Clinical Practice
Funder	North Carolina Department of Health and Human Services, University of North Carolina at Chapel Hill
Clinical Phase	Phase I
Study Rationale	The purpose of the present study is to investigate the barriers and facilitators to implementing a moderated online social media platform with therapeutic content, Horyzons, as a part of routine care received at first-episode psychosis (FEP) clinics across North Carolina.
Study Objective(s)	Examine the implementation and integration Horyzons at NC FEP clinics as part of routine clinical care through the following objectives: 1. Identifying the unique barriers and facilitators in implementing Horyzons at each FEP clinic as part of standard care and distinct implementation strategies 2. Evaluate client engagement with Horyzons and attrition as part of clinical care across 12 months 3. Assess change in clients' psychological measures across 12 months and use of emergency and social services across 12 months prior and during engagement with Horyzons platform
Test Article(s) *(If Applicable)*	Horyzons is a private digital platform that includes curated therapeutic content surrounding issues such as generalized anxiety, social anxiety, social functioning, depression, and distress tolerance. The site also includes a social media function, in which participants and peer support specialists (PSS) can post text, images, and videos. The site is moderated by graduate students and trained fs.
Study Design	This is an open trial enrolling both clients from NC FEP clinics and clinicians and PSSs. FEP clients will participate in the use of Horyzons, a novel digital intervention, which has previously demonstrated benefits to this population and complete psychological measures. FEP clinicians and PSSs will take part in qualitative interviews and surveys to identify unique barriers and enablers in integrating Horyzons as a clinical service within FEP clinics.
Client Participants *Key Criteria for Inclusion and Exclusion:*	<u>Inclusion Criteria</u> 1. Clients must be between the ages of 16 and 35 2. Clients must have a diagnosis of schizophrenia, schizoaffective disorder, schizophreniform disorder, or Unspecified Schizophrenia Spectrum or Other Psychotic disorder 3. Clients must be receiving services at one of the five FEP clinics in North Carolina (OASIS, Encompass, Eagle, SHORE, or AEGIS) or one of their stepdown outpatient clinics (STEP and TIDES) 4. Clients must not have had thoughts of harming themselves in the month before enrollment

	5. Clients must not have been hospitalized for psychiatric reasons in the three months before enrollment 6. Clients must actively be engaging with medication management via their clinic or another provider 7. Clients must have access to the internet through a phone, tablet, or computer Exclusion Criteria 1. Clients who do not speak English will not be considered for enrollment 2. Clients with legal guardians (LARs) will not be considered for the study
Provider &/or PSS Participants *Key Criteria for Inclusion and Exclusion:*	Inclusion Criteria 1. Provider &/or PSS must be 18 years or older 2. Provider &/or PSS must be currently serving clients within their FEP clinic 3. Provider &/or PSS must be able to speak and read English
Number of Subjects	50 client participants with SSDs, 20 provider &/or PSS participants from NC FEP clinics
Study Duration	Each subject's participation will last approximately 12 months from baseline to post-treatment. The entire study is expected to last approximately 24 months (including a 12-month recruitment period).
Study Phases *Screening* *Study Treatment* *Qualitative Interviews*	Screening- Completed prior to the first virtual appointment via a telephone screen to confirm study eligibility. Baseline- Client participants who are deemed eligible schedule a virtual appointment with the study coordinator to obtain consent, HIPAA authorization, and complete the baseline assessments (Demographics, Clinical Characteristics, & psychological measures). Client participants are then oriented to the Horyzons platform. Provider &/or PSS participants will complete consent, demographics and characteristics, and baseline survey, the adapted CPCRN Federally Qualified Health Centers Survey. Study Treatment- Client participants will be given access to the digital platform Horyzons for approximately 12 months. Weekly engagement is decided by the participant. Digital access is available daily, digital access to PSS and online therapists is made available daily, and virtual "Horyzons Hangs" are hosted over Zoom by PSS approximately twice each month. Provider &/or PSS participants will have the option to engage with the Horyzons platform to track their caseload's interaction with the platform, along with other ways in order to integrate the platform within their care. Mid-treatment – Client participants will be asked to complete a short battery of measures (UCLA Loneliness Scale, MOS Social Support Survey, and Horyzons Feedback Survey) at the approximately 6-month

	timepoint. Provider &/or PSS participants will be asked to complete CPCRN Federally Qualified Health Centers Survey at approximately 6-month timepoint. Post-treatment – Client participants will be asked to complete the short battery of measures (UCLA Loneliness Scale, MOS Social Support Survey, and Horyzons Feedback Survey) at the approximately 12-month timepoint. There will be an additional follow-up visit to complete the brief surveys. Provider &/or PSS participants will be asked to participate in a qualitative interview focusing on the perceived barriers and facilitators to integrating Horyzons within their clinical practice as well as the CPCRN Federally Qualified Health Centers Survey at the approximately 12-month timepoint.
Evaluation	Primary outcomes – Identification of barriers and enablers to implementing Horyzons to assess each clinic's unique circumstances to integrate Horyzons as part of routine clinical care. Secondary outcomes – Client engagement with the Horyzons platform and attrition in the study to assess Horyzons as part of routine clinical care. Tertiary outcomes – The UCLA Loneliness Scale and MOS Social Support Survey (total score) will be used to assess subjective feelings of loneliness and social support. Further, clients' use of emergency and social services to further evaluate Horyzons benefit in clinical outcomes.
Safety Evaluations	A safety plan for Horyzons was developed before participants joined the Horyzons digital platform by Dr. David Penn and study coordinator Elizabeth Fraser. All safety measures were approved by the director of each NC FEP clinic.
Statistical and Analytic Plan	Analyses will primarily be thematic qualitative analysis in nature, along with quantitative measure of barriers and enablers. Semi-structured interviews will be coded to identify each clinic's unique situation to integrate Horyzons as part of a clinical offering within their FEP clinic. Secondary analyses will include an examination of client participation rates and utilization of the platform across sites and their attrition. We will also evaluate changes in mean loneliness and social support across 12 months.
Data and Safety Management	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 Horyzons moderators (clinicians involved in the project, peer support specialists, graduate students in the Department of Psychology and Neuroscience) with supervision from the Principal Investigator, Dr. David Penn, or Licensed Clinical Psychologist and research collaborator, Dr. Kelsey Ludwig. Dr. Diana Perkins will function as the Project Medical Officer.

1 BACKGROUND AND RATIONALE

Schizophrenia is one of the most devastating and costly of medical/psychiatric disorders. In the last 25 years, first episode psychosis (FEP) services have emerged to thwart the high relapse rates associated with this disorder and increase client treatment engagement. Increasing evidence shows that such services lead to improvements in symptoms, social functioning, quality of life and treatment satisfaction (1). In the United States, these services have come to be known as Coordinated Specialty Care (CSC).

There are a number of North Carolina based CSC programs that provide early psychosis treatment to adolescents and young adults who have recently experienced the onset of psychosis. Specifically, there are 5 CSC programs in operation in North Carolina, including the Outreach and Support Intervention Services (OASIS) clinic in Chapel Hill, the Eagle Program for First Episode Psychosis in Charlotte, the Wake Encompass Program in Raleigh, the SHORE program in Wilmington, and AEGIS in Asheville. Each CSC clinic employs a multidisciplinary team of providers and PSSs that promotes recovery, person-centered and culturally competent evidence-based interventions with the goal of decreasing illness severity and reducing or preventing disability by intervening early in the course of illness. The goal of these programs is to help individuals get back "on track" in order to achieve school, work, relationship and other life goals. Evidence-based services including CBT-based individual psychotherapy, evidence-based pharmacology, supports for wellness and primary health coordination, family education and support, case management, supported employment and education, and/or peer support with an emphasis on shared decision-making, values, and recovery.

Young people receiving services from CSC programs typically attain significant positive outcomes including decreased rates of hospitalization and improved social and occupational functioning within an average of two years of treatment (2). However, treatment benefits are usually not maintained over time (3-4) in particular when clients are less engaged in treatment or have recently experienced discharge from the program. For instance, the benefits of early intervention seen at the end of 2 years may not persist at 5 years (5). There is a need, therefore, to explore ways to provide ongoing support for individuals experiencing first episode psychosis. This support should address especially what some have called "social network crisis" experienced by the FEP population. This refers to the limited social networks and community support that individuals with psychosis generally have. Innovative approaches through internet-based interventions may shed valuable light on the issue of maintaining treatment effects derived from FEP services and offer additional social support to those enrolled in such services.

Additionally, the proposed research is aligned with the NIMH strategic objective of striving for prevention and cures through the study of mechanisms of therapeutic action. Specifically, it aligns with the goals of developing new treatments based on discoveries in the behavioral sciences and testing interventions for effectiveness in community practice settings. This project in essence builds and extends the findings of research on the effectiveness of CSC and looks to determine whether these benefits can be extended beyond CSC in a web-based platform delivered to individuals in the community.

We suggest that internet-based interventions have the potential to provide cost-effective, non-stigmatizing, constantly available support to FEP people. These interventions, especially those aimed to strengthen social networks, can be used to counteract social isolation and disadvantage; increase functional outcomes and engagements (6); reduce symptomatology; and improve uptake and acquisition of therapeutic strategies. These also provide an entirely new approach in which participants can safely self-disclosure, take positive interpersonal risks, gain perspective, broaden and rehearse coping skills, obtain encouragement and validation, and learn how to solve problems (7).

The aims of this study are to assess barriers and facilitators to the implementation of Horyzons as a part of routine clinical care received at first-episode psychosis clinics across North Carolina and to evaluate how best the digital intervention can be integrated in treatment. Horyzons is an online platform that integrates: i) peer-to-peer on-line

social networking; ii) individually tailored interactive psychosocial interventions; and iii) trained moderation. First tested in Australia, this type of intervention has been evaluated for individuals with first episode psychosis (FEP) in Australia and abroad, including the US and Canada, and has found to be effective impacting various outcomes.

Of note, a pilot study was completed at the Outreach and Support Intervention Services (OASIS) clinic incorporated Horyzons as an adjunct to care rather than part of routine services to assess acceptability and effectiveness as well as a follow-up study to further access effectiveness and provider and PSSs' view of Horyzons as part of clinical care. While clients will receive compensation for completion of psychological surveys at 3 timepoints, clients will not be incentivized for engagement (or lack thereof) in Horyzons to examine the process by which clients are referred to and attrition across 12 months. As such, we seek to evaluate the extent to which Horyzons can be integrated into typical treatment at five FEP clinics across North Carolina and their step-down outpatient care clinics (e.g., STEP and TIDES).

2 RESEARCH DESIGN AND METHODS

2.1 OVERVIEW

Client participants will be given access to Horyzons (which is considered a "non-significant risk" medical device and is described below) from their date of enrollment through an intervention period of approximately 12 months. Horyzons will be monitored daily (two hours per weekday & one hour per weekend day) by trained peer support specialists, master's level clinicians, licensed clinical psychologists, and/or graduate students in the Department of Psychology and Neuroscience or Social Work 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, and via telephone if a participant remains inactive for an additional two weeks. Licensed Clinical Psychologists, Dr. David Penn and/or Dr. Kelsey Ludwig will lead weekly supervision calls to ensure appropriate care and support of clients involved in this project, to discuss case conceptualization and suggestions for engaging clients in the platform, as well as to monitor any potential safety concerns.

Overview of Horyzons. Horyzons is an online social media platform that integrates: i) peer-to-peer on-line social networking; ii) individually tailored interactive psychosocial interventions; and (iii) expert moderation.

Peer-to-peer online social networking (the "Community"). The 'community' page includes a web feed where clients and moderators can post comments, information, upload pictures and videos, and 'like' 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 peer support specialists. Peer supports are individuals with lived experience of severe mental illness who are familiar with the Horyzons platform and affiliated with one of the first episode clinics in North Carolina at which this study will be implemented. These individuals are part of the investigational staff who will be interacting with participants for research purposes and will also provide feedback (via study questionnaires and interviews). Their primary function will be to induct clients to the platform, reach out to inactive participants, answer any questions clients may have about the site, and help facilitate discussion in the community and other sharing areas of the platform. Research staff at the university and/or providers at the FEP clinics in North Carolina will train and supervise all Horyzons peer support specialists, who will also be asked to provide feedback through participation in qualitative interviews.

Interactive psychosocial interventions. Horyzons includes a range of tailored interactive psychoeducation pathways divided into separate steps. These pathways target key risk factors and salient domains in the early recovery process including: (a) managing symptoms of (social) anxiety, (b) developing strategies to cope with depressive symptoms, and (c) improve social skills and functioning. Individuals are able to select which pathways they would like to utilize based on their treatment goals. All pathways are available to all participants in this study.

Expert Moderation. Peer support specialists, clinicians with significant experience in the psychosocial treatment of FEP clients, as well as graduate students with relevant clinical/research with individuals experiencing psychosis will serve as expert moderators. Their role is to provide guidance, monitor participants' clinical 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 clinical risk. The Horyzons Moderation Checklist will be completed by each moderator every time he/she/they moderate 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 study midpoint (approximately 6-months) both client and provider/PSS participants will be asked to complete surveys. Client participants will complete a battery of measures evaluating loneliness, social supports, and feedback on the Horyzons platform (UCLA Loneliness Scale, Medical Outcomes Study [MOS] Social Support Survey, and Feedback Questionnaire, respectively). Provider and PSS participants will complete the adapted CPCRN Federally Qualified Health Centers Survey assessing outer-, inner-, and individual-settings in ability to integrate Horyzons. After clients have engaged with the platform for 52 weeks (about 12 months), clients will meet with research staff via HIPAA-compliant Zoom to complete the measure battery (UCLA Loneliness Scale, MOS Social Support Survey, and Feedback Questionnaire). Additionally at the post-treatment timepoint, provider and PSS participants will be asked to participate in feedback about the integration of the Horyzons platform within clinical care through qualitative interviews in addition to the CPCRN Federally Qualified Health Centers Survey. Both qualitative interviews and quantifiable data about their experience with barriers and enablers to the integration of Horyzons within their clinical care. Interviews with providers and PSSs will focus on their perceptions of capability, opportunity and motivation to integrate Horyzons, along with individual, provider, inner, and outer settings that impacted their ability to implement Horyzons within routine clinical care. As this platform will be provided as part of clients' routine clinical care, we will also share clinical impressions and other relevant clinical information to the clinical team at the client's respective FEP clinic.

2.2 SUBJECTS

Up to 70 total study subjects will be recruited from the five FEP clinics in North Carolina (OASIS, Encompass, Eagle, SHORE, and AEGIS) and their stepdown outpatient clinics (STEP and TIDES), including up to 50 FEP clients and 20 FEP providers (clinicians and PSS). All subjects will have a primary diagnosis of schizophrenia spectrum disorder. Demographic and clinical information that will be collected as self-report for possible use as covariates includes: 1) demographics: age, sex & gender identity, race & ethnicity, education, parent education; 2) health: smoking, substance use, current medications, and DUP.

2.2.1 INCLUSION CRITERIA

1. Clients must be between the ages of 16 and 35
2. Clients must have a primary diagnosis of schizophrenia, schizoaffective disorder, schizophreniform disorder, or Unspecified Schizophrenia Spectrum or Other Psychotic disorder
3. Clients must be receiving services at one of the five FEP clinics in North Carolina (OASIS, Encompass, Eagle, SHORE, AEGIS) or FEP clinics stepdown care clinics (STEP and TIDES)
4. Clients must not have had thoughts of harming themselves in the month before enrollment
5. Clients must not have been hospitalized for psychiatric reasons in the three months before enrollment
6. Clients must have been actively engaging in psychiatric medication management in the prior month
7. Clients must have access to the internet through a phone, tablet, or computer

2.2.2 EXCLUSION CRITERIA

1. Clients who do not speak English will not be considered for enrollment
2. Clients with legal guardians (LARs) will not be considered for the study

3 ASSESSMENT OF DATA

At this stage of treatment development, specific outcomes include:

1. Identifying barriers and facilitators of implementing Horyzons at NC FEP clinics through the following:
   - Conducting qualitative interviews following the CFIR framework to identify individual-, inner-, and outer-setting climate and implementation of evidence-based practices within each clinic
   - Administration of quantitative measures pre-, mid-, and post-intervention to further assess barriers and facilitators experienced by providers and PSSs in the integration and implementation of Horyzons
2. Evaluation of engagement of the platform and attrition of client participants across 12 months to assess acceptability of Horyzons as a routine clinical intervention within NC FEP clinics.
3. Evaluation of psychological outcomes (loneliness and social support) in addition to use of services (e.g., emergency department, hospitalization, outpatient services) to assess potential benefits (e.g., stability in symptoms) as a result of engagement with Horyzons.

3.1 OUTCOMES

Based on previous interviews with providers and peer support specialists, we hypothesize providers and/or PSS will report barriers that may be unique to each clinic as each experiences different outer-, inner, and individual-setting circumstances. Previous barriers, which will likely be reiterated and further described include time constraints, workload, staffing turnover, and perception of the implementation of a new intervention within care. Facilitators are also likely to be distinctive to each clinic, including the support of the team lead in the implementation of Horyzons and time dedicated to Horyzons within care, perception and desire to incorporate evidence-based interventions into clinical treatment to improve client outcomes, and goals and aims of Horyzons aligning with their role.

4 STUDY PROCEDURES

4.1 SCREENING & BASELINE PROCEDURES

4.1.1 SCREENING PROCEDURES

For recruitment of client participants, the research study coordinator will communicate with providers 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 review the clinical census at each clinic and/or identify potential participants (clients) via the EPIC system. Clinical team members will be asked to review their current caseloads to identify potentially eligible participants (i.e., patients who are currently receiving services at OASIS, SHORE, Encompass, Eagle, AEGIS, STEP and TIDES and are considered clinically stable without current active suicidal ideation). The study coordinator and research assistant will engage in discussion with the treatment team to help identify appropriate clients 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 client 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.

If clients self-refer (in response to flyers and/or website form), the research coordinator and PI will consult with their treatment team first before screening the client (i.e., to make sure there are no issues that prevent them from safely participating in the study).

Clinicians will be consulted prior to each contact with a prospective participant and asked to advise the research team if any prospective participant should not be contacted.

For provider and PSS participation, research staff will reach out to the five FEP clinics (OASIS, SHORE, Encompass, Eagle, and AEGIS) through the program directors. Due to the long-standing relationship and close working partnership of the PI with programs, research staff are connected to program directors. After an explanation of the study is given to the program directors, program directors will be asked to discuss the study with their team prior to research staff reaching out to each team member individually. Providers and/or PSS will then be contacted by research staff to determine if they would like to participate and be screened to determine eligibility.

4.1.2 BASELINE PROCEDURES

The study coordinator will meet virtually with client participants for approximately 45 minutes to complete all baseline measures. Informed consent and HIPAA authorization will be completed first via DocuSign's electronic consent platform, followed by a demographic and characteristic form collecting basic information about sex, age, ancestry, education (including parent education levels and zip code), cigarette/alcohol use, and basic history of medication/psychosis (including DUP). This will be followed by two psychological measures: the UCLA Loneliness Scale and MOS Social Supports Survey. Once the baseline study measures are complete, the study coordinator will guide clients through a 10-minute orientation to the Horyzons platform, including creating their personal profile and learning the features of the site. Client participants will be paid $20.00 via Visa gift card for their time and completion of the visit.

The study coordinator will verbally highlight over the phone the study aims, what will be asked of the provider, the timeline of their participation, and that their participation is voluntary for each provider participant at the end of the screening. The provider participants will then be sent the consent forms via DocuSign to sign. In the email and at the top of the consent form in DocuSign there will be a number to call if they have questions. The language will explicitly indicate to call the number prior to consenting and signing the document if they have questions. The provider participants will then be sent the baseline surveys (demographics and CPCRN FQHC Survey) to complete on their own. Providers and PSS will be compensated $30 for completing the consent and baseline measures.

4.2 INTERVENTION PERIOD PROCEDURES

4.2.1 MID-TREATMENT PROCEDURES

Research staff will meet with client participants virtually to complete the measure battery (UCLA Loneliness Scale, MOS Social Support Survey and Feedback Survey) for the mid-treatment measures at approximately 6-month mark (+/- 4 weeks). Client participants will be compensated $10 via Visa gift cards or Tango e-gift card for the approximate 30-minute visit. The study coordinator will send the electronic survey to the provider participants for the mid-treatment measures at the 6-month mark (+/- 4 weeks). Provider and/or PSS participants will complete electronic copies of the CPCRN Federally Qualified Health Centers Survey. Provider and/or PSS participants will be paid $20.00 via Visa gift card or Tango e-gift card for these 40 minutes of their time.

4.2.2 POST-TREATMENT PROCEDURES

Research staff will meet virtually with client participants to complete the finally set of aforementioned measure battery for the post-treatment visit at approximately 12-month timepoint (+/- 4 weeks). Client participants will be compensated $10 via Visa gift cards or Tango e-gift card for the approximately 30-minute visit. There will be an additional follow-up survey 3-months post-intervention to complete the brief surveys. Clients will additionally be compensated $10 for this completion of this visit. The study coordinator will send the electronic survey to the provider participants for the post-treatment measures at the 12-month mark (+/- 4 weeks). Provider and/or PSS participants

will complete electronic copies of the CPCRN Federally Qualified Health Centers Survey. After completing the electronic measure, the study coordinator will contact the provider participant to determine if they are willing to participate in the qualitative interview. If they are willing, the study coordinator will meet with them via videoconferencing and lead provider and PSS participants through a semi-structured qualitative interview regarding the Horyzons and various barriers and facilitators to its implementation within their clinic. Provider and PSS participants will be compensated $20 for completing the post-treatment survey as well as an additional $30/hr prorated to the nearest half hour if they complete the qualitative interview.

4.3 Client Procedures

Upon completion of the 12-month intervention period, research staff will collect and amalgamate the passive engagement information of each participant on the platform to assess acceptability and feasibility of Horyzons as part of clinical care. Additionally, client participants' medical records will be examined for service use (e.g., emergency room visits, hospitalizations, outpatient care, etc.) as a result of their mental health.

5 DATA ANALYTIC PLAN

5.1 PRIMARY OUTCOME MEASURES

1. Qualitative Summaries of Provider and PSS Participant Feedback in Post-Treatment Interview [Time Frame: up to 12 months]

   This qualitative data will be collected post-treatment from providers and PSSs. Individual interviews will discuss the utility and usage of Horyzons within their clinical care in addition to barriers and facilitators on numerous levels (individual, inner setting, and outer setting) of its implementation within their clinic. Feedback from participants will be summarized to include common themes regarding implementation, barriers, and enablers within the clinical setting and ideas for future implementation.

2. Quantitative Summaries of Provider and PSS Participant Experience in Post-Treatment Feedback [Time Frame: up to 12 months]

   This quantitative data will be collected pre-, mid-, and post-intervention from providers and PSSs. Feedback forms will prompt participants to answer questions regarding their experience with barriers and facilitators in implementing an evidence-based practice (in this case Horyzons) in various settings (outer, inner, and individual). The survey will be analyzed regarding changes or lack thereof in the various settings and climate.

5.2 SECONDARY OUTCOME MEASURES

1. Mean Change in UCLA Loneliness Scale Score [Time Frame: Baseline, Post-treatment, up to 12 months]

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.

1. Mean Change in Medical Outcomes Study (MOS) Social Support Survey - total score [Time Frame: Baseline, Post-treatment, up to 12 months]

The MOS Social Support Survey is a 19-item scale. Answers are on a 5-point scale with options "none of the time", "a little of the time", "some of the time", "most of the time", and "all of the time". Possible scores range from 19 to 95. Higher scores reflect higher feelings of social support (more perceived social support). The MOS Social Support Survey is a part of the PhenX Toolkit.

2. Quantitative Summaries of Participant Experience in Post-Treatment Feedback [Time Frame: up to 12 months]

This quantitative data will be collected post-treatment from clients and clinicians. 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.

5.3 TERTIARY OUTCOME MEASURES

1. Change in Engagement with the Horyzons Platform and Attrition over time [Time Frame: up to 12 months]

   Changes in engagement with Horyzons will be passively collected for client participants via the platform. Data evaluated will include number of logins, number of journeys, tracks, and activities completed, and number engagements on the community page.

2. Change in use of emergency and social services [Time Frame: Pre- and Post-intervention, up to 12 months]

Collection of use of emergency and social services pre-initiation and post-initiation of Horyzons will be assessed to determine change in use of such services.

5.4 POWER ANALYSIS

We did not conduct a priori power calculations to determine a sample size with 80% power because this is an exploratory study and will inform future implementation of Horyzons in North Carolina as part of clinical services.

5.5 DATA MANAGEMENT

We will use the REDCap system to facilitate data entry and management, including informed consent. 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 NVivo program for qualitative analysis. DocuSign's HIPAA compliant informed consent system will be used to obtain informed consent and electronic signature from participants.

6 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. 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 clients only. Risk of anxiety, paranoia, and/or shame/embarrassment due to experiences using this online platform is minimized by completion of a Horyzons 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. Additionally, consent forms will be sent to the participant using a secure UNC email account. Documents will not contain confidential information.

Risks for providers only. 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. Providers and/or PSS will be instructed via email or phone call before the interview to identify an appropriate location (i.e., private space) if held virtually rather than in person. All documents such as consent documents and surveys will be sent to providers and/or PSS using a secure UNC email account. Documents will not contain confidential information.

6.1 Monitoring Risks

To address subject anxiety or embarrassment due to revealing person information, we have trained research staff who are experienced in working with individuals with schizophrenia spectrum disorders. 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. 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.

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' young people, parents, teachers and library staff. Information about Cybersmart can be found at http://www.cybersmart.gov.au/, while the guidelines are available at http://www.acma.gov.au/.

Safe and informed orientation to the system will be a priority for the research team. Peer support specialists, clinicians, research coordinator, and/or a graduate student in the Department of Psychology and Neuroscience at UNC-CH will meet with each participant to provide them with login information, help set up their account and orient them to the Horyzons system, including details of the terms of use. All users of Horyzons will be asked to nominate an emergency contact person, such as a close family member. The terms of use explain to users that information passed onto moderators or communicated within the system that may indicate concerns regarding their wellbeing may be communicated with their treating team or private practitioner. Hard copies of 'Horyzons 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 or concerns about the wellbeing of another participant. The moderator will assess the basis of the report and respond accordingly, which can include the removal of the material or deactivation of an 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's ability 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 the moderator. Specifically, our disengagement protocol is such 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. If participants do not comply with the guidelines for safe use of Horyzons (e.g., discriminatory comments towards other users) they will be excluded from the system.

Clinical safety. Clinical risk will be managed through manual and automated procedures. Information related to clinical risk will be screened twice daily by moderators (in the morning and late afternoon/evening). This information can include: 1) post made by participants, which disclose evidence of psychotic, depressive or suicidal symptoms; 2) participants reports or complaints of posts made by other users; 3) risk or self-harm related words automatically detected and blocked by the system; and 4) presence of Early Warning Signs of relapse detected by the regular monitoring of psychotic symptoms implemented within Horyzons.

Any detected increased risk will activate the Horyzons crisis 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 emergency contact nominated by the participant, and liaise with suitable emergency services where necessary. In addition, the system incorporates visible emergency guidelines and contact information (i.e., on every webpage).

An automated keyword system has also been built in Horyzons which will be activated each time a participant posts a contribution containing the words or phrases: suicide, die, kill myself/you/him/her/them, hang myself/you/him/her/them, harm myself/you/him/her/them, snort, shoot up, burn myself/you/him/her/them, cut myself, drown myself/you/him/her/them, stab myself/you/him/her/them, slit, slice, electrocute, shoot myself/you/him/her/them, top myself, jump in front of, jump off, end it all, sleep and never wake up, death, die, asphyxiate, or gas. When these words are detected, the contribution will be blocked and the participant will be sent an automated message explaining that the content 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 message will also be sent to the Horyzons moderator containing the attempted post.

In addition, a message will be available on each page providing a cell phone number carried by a member of the research team for any emergencies that are related specifically to the use of the Horyzons system (e.g., highly inappropriate use of the system). Further, each page includes an "In case of emergency" link that provides information about ways to contact emergency services (911), the UNC crisis line (984-974-3950), and crisis services (988; http://crisissolutionsnc.org/).

6.2 NON-SIGNIFICANT RISK DOCUMENTATION

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

6.3 POTENTIAL BENEFITS OF THE RESEARCH TO SUBJECTS AND OTHERS

While the field is still in its infancy, there is preliminary evidence that online interventions that combine therapy, social networking opportunities and expert and peer moderation may be better received by individuals with first episode psychosis than less integrated approaches. The proposed study will expand this growing body of work by testing the clinical utility and ability to implement the intervention as part of mental health care at first episode clinics in North Carolina.

Benefits to clients. The proposed study may increase clients' sense of belonging and social support. Also, if they engage in therapeutic pathways within the Horyzons platform, they might develop cognitive behavioral and mindfulness-based skills.

Benefits to providers. Clinicians and peer support specialists may gain insight into clients' experiences using the platform, including possible barriers to engagement and challenges to disseminating the Horyzons platform within the clinic. This information may prove useful to clinicians and PSSs as they consider ways to incorporate online interventions and other adjunct services into their existing treatment approaches in the future.

6.4 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 in the Department of Psychology and Neuroscience 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. Declining participants' names will be retained on a secure password protected network to ensure that the same participant is not contacted more than once regarding participation.

A member of the research team will meet individually with the client in order to explain the components of the Horyzons platform, elicit and answer any questions the client may have, and obtain informed consent. We will also collect information about current suicidal ideation and stability (e.g., recent hospitalizations) to assess eligibility for participation. Persons will also be creating a Horyzons profile and answering questions about character strengths (e.g., curiosity, love of learning), which are embedded in the Horyzons platform. These data will be linked to other sources of information, including the record of their interactions within the Horyzons system (e.g., number of posts/comments on the community page).

The Horyzons system and data generated by users of Horyzons will be hosted on a secure web server. A range of measures are in place to ensure the security of the Horyzons 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). Qualitative interviews will 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 study coordinators, clinicians and peer support specialists, and collaborators involved in this project, or PI (Dr. Penn).

As this research program is being implemented in clinical settings, it is possible that FEP clinicians or PSSs will create notes that indicate the participant is involved in the project, describe any issues 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 providers and PSSs of subjects in the study with the permission of the subjects (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 subjects will provide the name and contact info of a clinician that

we may contact if we become concerned about their safety (e.g., physical and/or mental health) during the course of the trial. We will not be sharing any confidential information with anybody outside of these providers and PSSs.

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.

7 SAFETY MANAGEMENT

7.1 ADVERSE EVENTS

Client activity on the platform will be monitored daily by the online moderators and PSS. Signs of potential clinical deterioration will be reported to the client's treatment team. It is highly unlikely that clinical deterioration will be attributable to the Horyzons system. However, in the event that this becomes evident (e.g., a participant has clearly communicated that they have incorporated aspects of the Horyzons system into their delusional beliefs) the moderator will communicate this information to the clinical treatment team and/or the principal investigator. The principal investigator will inform the IRB of any concerns regarding adverse events associated with involvement in Horyzons.

7.2 SERIOUS ADVERSE EVENTS

Adverse events (AE) will be assessed to determine if they meet criteria for a serious adverse event (SAE). SAE, as defined by the FDA, will be systematically evaluated at each clinic visit. The trial period is defined from the time that the informed consent document is signed until 30 days after the last study visit. All SAE occurring during the trial period (including death due to any cause) or within 30 days after the last study visit will be communicated within 1 day of the investigator becoming aware of the event to designated personnel, using the telephone or fax numbers provided in the Study Reference Manual. Any fatal or life-threatening AE will be reported immediately, but no longer than 1 day from the time the investigator becomes aware of the event. A causality assessment will be provided for all SAEs. Critical follow-up information on SAEs will be provided as soon as it is available, but no longer than 1 day from the time the investigator became aware of the information. Other essential, but not critical, information may be reported within the following 5 days. An SAE, as defined by the FDA for use in clinical trials https://www.fda.gov/safety/medwatch/howtoreport/ucm053087.htm), is an adverse event that satisfies any of the following criteria:

- Results in death.
- Is immediately life-threatening, including potentially life-threatening suicidal behavior or suicidal behavior that results in hospitalization.
- Requires inpatient hospitalization or prolongation of existing hospitalization.
- Results in persistent or significant disability or incapacity.
- Is a congenital abnormality or birth defect.
- Is an important medical event that may jeopardize the subject or may require medical intervention to prevent one of the outcomes listed above. Examples would include allergic bronchospasm that requires treatment in an emergency department, or a seizure that does not result in hospitalization.

The causality of SAEs (i.e., their degree of relatedness to study treatment) will be assessed by the investigators.

7.3 DEATH

All deaths occurring within the trial period or within 30 days after the last day that the study intervention is administered will be reported within 1 day of the investigator becoming aware of the event. If an autopsy has been performed, results of the autopsy will be obtained and forwarded along with any available toxicology reports.

8 RECRUITMENT STRATEGY

Client study subjects will be drawn from the five first episode psychosis clinics in North Carolina (OASIS, Encompass, SHORE, Eagle, and AEGIS). The OASIS clinic was co-developed by Dr. Penn for the treatment of people with first episode schizophrenia. Currently, each clinic has a census of approximately 100-150 people and admits approximately 3-5 people per month. Approximately 40 client participants will be recruited from the five clinics, or around 6-8 client participants per clinic. Additionally, all providers have been self-identified as clinicians or PSS providing services to clients at one of the five participating clinics; therefore, we expect approximately 20 providers and/or PSS to participate in this project. As such, we expect that we will be able to recruit the number of participants we would like to involve in this project.

Once a client is referred to the study (or self refers), a study clinician or research assistant will speak with the individual (and any other individuals that she/he indicates, such as a family member) to describe the study protocol, expectations of study participation and potential study risks and benefits. If a client contacts a member of the research project to indicate interest in the study, a member of the research team will explain the study over the phone and use the screening questions to assess potential eligibility. Providers and PSSs will be contacted by phone and/or email in order to obtain consent and schedule focus groups.

Recruitment will be completed by the study coordinator, research assistant, and/or clinical providers involved in this project. The latter includes peer support specialists and providers at the local FEP clinics.

9 CONSENT PROCESS

Research staff will obtain informed consent directly from each subject. Staff obtaining the consent will provide the subject with a written document explaining the testing procedures and risks, and will answer any questions. We have 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, the researcher reads the form to and with the potential subject and invites questions after each section of the form. Third, the researcher asks the subject a series of questions about the study, such as what they are to do if they no longer want to participate, or what they would do if they experience any stress during the protocol (this is to be used as comprehension check before consenting). As Horyzons is a fully virtual research study, participants will provide electronic consent via DocuSign's HIPAA compliant electronic consent platform.

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