Horyzons:

Implementation in Clinical Practice

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Clinical Protocol & Data Analytic Plan

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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
MOS	Medical Outcomes Study
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
PWS	Psychological Wellbeing Survey
SIAS	Social Interaction Anxiety Scale
SSD	Schizophrenia Spectrum Disorder
UCLA	University of California, Los Angeles
WAI-I	Working Alliance Inventory – guided Internet interventions

PROTOCOL SYNOPSIS

Study Title	Horyzons: Implementation 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 feasibility and acceptability of implementing a moderated online social media platform with therapeutic content, Horyzons, as a part of care received at first-episode psychosis (FEP) clinics across North Carolina.
Study Objective(s)	Examine the feasibility and acceptability of implementing Horyzons at NC FEP clinics through the following objectives: 1. Assess change in psychological measures across the three-month (cohort 1) and six-month (cohort 2) study period (primary) 2. Ability to meet our recruitment targets 3. Evaluation of the safety and privacy protocol 4. Evaluate frequency and types of engagement on Horyzons 5. Identify barriers/facilitators to implementing Horyzons
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 clinicians.
Study Design	This is an open trial enrolling both clients from NC FEP clinics. FEP clients will participate in the experimental arm of the trial (access to Horyzons), and FEP clinicians will not. We will also ask clients and clinicians to complete qualitative feedback about Horyzons.
Subject Population **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 four FEP clinics in North Carolina (OASIS, Encompass, Eagle, or SHORE) or one of the three UNC STEP-affiliated clinics (Carr Mill Mall, Vilcom Center, Main Wake Clinic) 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 not have had a psychiatric medication change in the month before enrollment 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. Adult clients (18+ years old) with legal guardians (LARs) will not be considered for the study
Number Of Subjects	Cohort 1: 25 client participants with SSDs, 12 clinician participants from NC FEP clinics; Cohort 2: 37 client participants with SSDs, 11 clinician participants from NC FEP clinics.
Study Duration	For Cohort 1, each subject's participation will last 3 months from baseline to post-treatment; the entire study for this group is expected to last approximately 3-4 months. For Cohort 2, each subject's participation will last 6 months from baseline to post-treatment; the entire study for this group is expected to last approximately 6-7 months.
Study Phases **Screening** **Study Treatment** **Focus Groups**	Screening- Completed prior to the first virtual appointment via a telephone screen to confirm study eligibility. Baseline- Participants in both cohorts who are deemed eligible schedule a virtual appointment with the study coordinator to obtain consent, HIPAA authorization, and complete the baseline assessments (Demographics, UCLA Loneliness Scale, MOS Social Support Survey, SIAS, short-form PWS). Client participants are then oriented to the Horyzons site. Participants in the second cohort only also complete other assessments (Questionnaire about the Process of Recovery, Social Anxiety Scale for Social Media Users, Modified Colorado Symptom Index, and Twente Engagement with eHealth Technologies Scale). Study Treatment- Client participants will be given access to the digital platform Horyzons for three 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 biweekly. Mid-treatment- Participants in both cohorts will complete assessments (UCLA Loneliness Scale, MOS Social Support Survey, SIAS, short-form PWS, WAI-I, and Perceived Autonomy Support Scale). Participants in the second cohort only also complete other assessments (Questionnaire about the Process of Recovery, Social Anxiety Scale for Social Media Users, Modified Colorado Symptom Index, and Twente Engagement with eHealth Technologies Scale). Post-treatment – Participants in both cohorts will complete assessments (UCLA Loneliness Scale, MOS Social Support Survey, SIAS, short-form PWS, WAI-I, and Perceived Autonomy Support Scale). Participants in the second cohort only also complete other assessments (Questionnaire about the Process of Recovery, Social Anxiety Scale for Social Media Users, Modified Colorado Symptom Index, and Twente Engagement with eHealth Technologies Scale). An additional feedback survey and qualitative interview are completed. Additional assessment timepoints for the second cohort: Participants in the second cohort will complete the following assessments at 1.5 months and 4.5 months following baseline (WAI-I, Perceived Autonomy Support Scale, Twente Engagement with eHealth Technologies Scale). Focus Groups- Participating clinicians and PSS take part in small focus groups to discuss feasibility, acceptability, and implementation of Horyzons at their NC FEP clinics.
Efficacy Evaluations	Primary outcomes (both cohorts) - The UCLA Loneliness Scale and MOS Social Support Survey (total score) will be used to assess subjective feelings of loneliness and social support. Secondary outcomes (both cohorts) - The SIAS and short-form PWS will be used to assess subjective feelings of social anxiety and psychological wellbeing. Tertiary/Exploratory Outcomes (both cohorts) - Quantitative and qualitative feedback collected at post-treatment and in focus groups will be used to explore feasibility and acceptability of Horyzons as a support tool in NC FEP clinics. Subscales from the MOS Social Support Survey and the short-form PWS as well as total scores from the WAI-I and Perceived Autonomy Support Scale may be explored in data analysis. Among the second cohort only, other scales/subscales such as the Questionnaire about the Process of Recovery, Social Anxiety Scale for Social Media Users, Modified

	Colorado Symptom Index, and Twente Engagement with eHealth Technologies Scale may be explored in data analysis.
Safety Evaluations	A safety plan for Horyzons was developed before participants joined the Horyzons digital platform by PI Dr. David Penn and study coordinator Elena Pokowitz. All safety measures were approved by the director of each NC FEP clinic.
Statistical And Analytic Plan	Analyses will primarily be descriptive in nature. We will calculate means, standard deviations, and effect sizes of the primary outcomes (loneliness, social support) and secondary outcomes (social anxiety, psychological wellbeing).
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 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. Perkins will function as the Project Medical Officer.

1 BACKGROUND AND RATIONALE

Schizophrenia is one of the most devastating and costly of the 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 4 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, as well as the SHORE program in Wilmington. Each CSC clinic employs a multidisciplinary team of providers 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 specially 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 purpose of this study is to examine the feasibility and acceptability of implementing Horyzons across two cohorts of clients receiving routine care at clinics across North Carolina that provide services to individuals experiencing schizophrenia spectrum and other unspecified psychotic disorders, including those in their first episode of psychosis (FEP). 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 not been evaluated as part of standard service provision to individuals with psychosis in the US.

Of note, the pilot study that was completed at the Outreach and Support Intervention Services (OASIS) clinic incorporated Horyzons as an adjunct to care rather than part of routine services. Also, there will be no incentives provided for engagement in Horyzons during the proposed implementation as our goal is to see examine the process by which clients are referred and maintained in the program. As such, we seek to evaluate the extent to which Horyzons can be integrated into typical treatment at four FEP clinics across North Carolina.

2 RESEARCH DESIGN AND METHODS

2.1 OVERVIEW

Participants (clients) will be given access to Horyzons (which is considered a "non significant risk" medical device and is described below) from their date of enrollment up to 3 months in the first cohort (enrolling January 2021) and up to 6 months in the second cohort (enrolling February 2022). Horyzons will be monitored daily (two hours per weekday & one hour per weekend day) by trained peer support specialists, master's level clinicians, Dr. David Penn (PI), and/or graduate students in the Department of Psychology and Neuroscience at UNC. In an effort to facilitate and monitor engagement, a protocol is in place that directs moderators to contact participants via text message and/or email if an 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. The principal investigator, David Penn, 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 focus groups with clinicians) upon completion of the study. 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 cafe and other sharing areas of the platform. Research staff at the university and/or clinicians at the FEP clinics in North Carolina will train and supervise all Horyzons peer support specialists, and will also be asked to provide feedback through participation in focus groups.

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 experience with individuals with 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 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. Participants in both cohorts will complete study assessments at baseline, mid-treatment, and post-treatment. Participants in the second cohort will complete two additional assessments before and after mid-treatment assessment at 1.5 months and 4.5 months following baseline, respectively.

For all administration of assessments/interviews, the study coordinator will use screen sharing via secure videoconferencing to complete measures with the participant. Baseline assessment will be completed alongside the review and completion of informed consent and onboarding of participants onto the Horyzons platform. Participants will complete a mid-treatment assessment with the study coordinator or other trained research assistant, which corresponds to approximately 6-8 weeks after onboarding in the first cohort and approximately 12 weeks after onboarding in the second cohort. Participants will also meet with the study coordinator or other trained research assistant for a post-treatment assessment after clients have engaged with the platform for 12 weeks in the first cohort and 26 weeks in the second cohort. At post-treatment, both clients and clinicians (procedures described below) 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. Individual feedback interviews with clients will also be completed at post-treatment, lasting 60 minutes. These interviews will address participants' social relationships, experiences with loneliness, and thoughts about connecting with others through Horyzons.

In order to evaluate the extent to which engagement in Horyzons may have impacted participants' perceptions of their social environment, participants will be asked to complete brief psychological measures. In the first cohort at baseline, mid-treatment (6-8 weeks), and post-treatment (12 weeks), participants will complete measures of loneliness (UCLA Loneliness Scale), social support (MOS Social Support Survey), social anxiety (Social Interaction Anxiety Scale), recovery (short form PWS - Psychological Wellbeing Scale), and therapeutic alliance (WAI-I and Perceived Autonomy Support Scale).

The second cohort will complete all aforementioned measures at baseline, mid-treatment (12 weeks), and post-treatment (26 weeks) alongside additional measures of personal recovery (Questionnaire about the Process of Recovery), social anxiety related to use of social media (Social Anxiety Scale for Social Media Users), and self-report psychological symptomatology (Modified Colorado Symptom Index). A self-report measure of engagement (Twente Engagement with Ehealth Technologies Scale) will be completed at baseline, mid-treatment, and post-treatment as well as at two additional timepoints: 1.5 months and 4.5 months following baseline. Measures of therapeutic alliance (WAI-I and Perceived Autonomy Support Scale) will be administered at 1.5 months, mid-treatment, 4.5 months, and post-treatment only. 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.

Feedback from providers or staff (i.e., program directors, clinicians, peer specialists) will be collected through focus groups (lasting 60-75 minutes). Prior to initiating the focus groups, providers will complete a brief survey which will include (a) general feedback questionnaire about Horyzons and (b) service mapping questions; regarding the latter, program directors and clinicians/peer specialists will complete separate service mapping questionnaire specific their roles. In the qualitative focus groups, all providers will be asked to provide feedback about their perceptions of their clients' experiences using the platform, and will also be asked to provide opinions about facilitators/barriers to engagement and challenges to implementing and disseminating the Horyzons platform within the clinic. All individual interviews and focus group feedback sessions will be conducted virtually via secure videoconferencing and will be led by the Horyzons 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 by a transcription service. The purpose of these recordings and transcriptions is to allow the research team to examine the feedback provided in the focus groups for the purposes of improving the process of integrating this type of treatment in clinics that provide mental health care to individuals with first episode psychosis.

2.2 SUBJECTS

For the first cohort of participants, up to 50 total study subjects will be recruited from the four FEP clinics in North Carolina (OASIS, Encompass, Eagle, and SHORE), including up to 30 FEP clients and 20 FEP providers (clinicians and PSS). For the second cohort of participants, up to 80 total study subjects will be recruited from the four FEP clinics in North Carolina as well as the UNC-affiliated STEP clinics, including up to 60 FEP clients and 20 FEP providers (clinicians and PSS). All clients who enroll in the study will have a primary diagnosis of a schizophrenia spectrum disorder. Demographic and clinical information that will be

collected as self-report for possible use as covariates includes: 1) demographics: age, sex, ancestry, 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 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 four FEP clinics in North Carolina (OASIS, Encompass, Eagle, or SHORE) or one of the three UNC STEP-affiliated clinics (Carr Mill Mall, Vilcom Center, Main Wake Clinic)
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 not have had a psychiatric medication change in the month before enrollment
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. Adult clients (18+ years old) 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. Examining the feasibility and acceptability of implementing Horyzons at NC FEP clinics through the following objectives:
   - Assessing change in psychological measures across the three-month (cohort 1) and six-month (cohort 2) study period (primary)
   - Ability to meet our recruitment targets
   - Evaluation of the safety and privacy protocol
   - Evaluating frequency and types of engagement on Horyzons
   - Identifying barriers/facilitators to implementing Horyzons

3.1 OUTCOMES

There are no specific hypotheses associated with this study, as it is an exploratory implementation trial that will test the feasibility and acceptability of Horyzons as a supplementary intervention for individuals in FEP programs.

4 STUDY PROCEDURES

4.1 SCREENING/BASELINE PROCEDURES

4.1.1 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 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, or STEP clinics 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), the RA 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.

4.1.2 BASELINE PROCEDURES

The study coordinator will meet virtually with client participants for approximately 1 hour to complete all baseline measures. Informed consent and HIPAA authorization will be completed first, followed by a demographic form collecting basic information about sex, age, ancestry, education (including parent education levels), cigarette/alcohol use, and basic history of medication/psychosis (including DUP). After completing these documents, the study coordinator will guide participants through virtual copies of the UCLA Loneliness Scale, MOS Social Support Survey, SIAS, and short form PWS. Participants in the second cohort only will complete additional baseline measures (e.g., Questionnaire about the Process of Recovery, Modified Colorado Symptom Index, Social Anxiety Scale for Social Media Users, Twente Engagement Questionnaire). Once all baseline study measures are complete, the study coordinator will guide clients through a 20-30 minute orientation to the Horyzons platform, including creating their personal profile and learning the features of the site. Client participants will be paid $15.00 via Visa gift card for this hour of their time.

4.2 INTERVENTION PERIOD PROCEDURES

4.2.1 MID-TREATMENT PROCEDURES

The study coordinator will meet virtually with client participants for approximately 30 minutes to complete the mid-treatment measures. Client participants will complete virtual copies of the UCLA Loneliness Scale, MOS Social Support Survey, SIAS, short form PWS, WAI-I, and Perceived Autonomy Support Scale. Participants in the second cohort only will complete additional measures at mid-treatment (e.g., Questionnaire about the Process of Recovery, Modified Colorado Symptom Index, Social Anxiety Scale for Social Media Users, Twente Engagement Questionnaire). Client participants will be paid $7.50 via Visa gift card for this 30 minutes of their time.

4.2.2 POST-TREATMENT PROCEDURES

The study coordinator will meet virtually with client participants for approximately 1-1.5 hours to complete the post-treatment measures. Client participants will complete virtual copies of the UCLA Loneliness Scale, MOS Social Support Survey, SIAS, short form PWS, WAI-I, and Perceived Autonomy Support Scale. Participants in the second cohort only will complete additional measures at post-treatment (e.g., Questionnaire about the Process of Recovery, Modified Colorado Symptom Index, Social Anxiety Scale for Social Media Users, Twente Engagement Questionnaire). After completing these virtual measures, the study coordinator will lead client participants through a feedback survey and individual feedback interview regarding the Horyzons platform, their online therapist, the PSS, and the community newsfeed. Client participants will be welcomed to share their opinions regarding their experience, including suggestions for how to improve Horyzons in the future.

4.2.3 ADDITIONAL ASSESSMENT PROCEDURES

For participants in the second cohort only, the study coordinator will meet virtually with client participants for approximately .5 hours to complete the measures at 1.5 months following baseline (i.e., between baseline and mid-treatment visits) and 4.5 months following baseline (i.e., between mid-treatment and post-treatment visits). Participants in the second cohort only will complete virtual copies of the WAI-I, Perceived Autonomy Support Scale, and Twente Engagement Questionnaire. Client participants will be paid $7.50 via Visa gift card for this 30 minutes of their time.

4.3 FOCUS GROUPS

Clinicians and PSS from the four FEP clinics in North Carolina will take part in small focus groups to discuss the feasibility and acceptability of Horyzons as a supplementary intervention at NC FEP clinics. Providers will complete informed consent and a demographic form collecting basic information about their age, sex, race, current position at the clinic, and years of experience in the mental health field over secure Zoom with the study coordinator before being assigned to a focus group. Focus groups will begin with a short feedback survey followed by a group interview led by the

study coordinator. Each group should take approximately 1 hour to complete, and clinician participants will be compensated $20 via Visa gift card for their time.

5 DATA ANALYTIC PLAN

5.1 PRIMARY OUTCOME MEASURES

1. Mean Change in UCLA Loneliness Scale Score (Both Cohorts) [Time Frame: up to 6 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. The UCLA Loneliness Scale is administered in both cohort 1 (Baseline, Mid-treatment, Post-treatment, up to 3 months) and cohort 2 (Baseline, Mid-treatment, Post-treatment, up to 6 months).

2. Mean Change in Medical Outcomes Study (MOS) Social Support Survey – Total Score (Both Cohorts) [Time Frame: up to 6 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. The MOS Social Support Survey is administered in both cohort 1 (Baseline, Mid-treatment, Post-treatment, up to 3 months) and cohort 2 (Baseline, Mid-treatment, Post-treatment, up to 6 months).

5.2 SECONDARY OUTCOME MEASURES

1. Mean Change in Social Interaction Anxiety Scale (SIAS) Score (Both Cohorts) [Time Frame: up to 6 months]

   The Social Interaction Anxiety Scale (SIAS) is a 20 item scale. Answers are on a 4 point scale starting at 0 with options "none at all", "slightly", "moderately", "very", and "extremely". Possible scores range from 0 to 80. Higher scores reflect higher levels of social anxiety. Scoring a 43 or higher may indicate a diagnosis of social anxiety, and scores between 34 and 42 may indicate social phobia(s). The SIAS is administered in both cohort 1 (Baseline, Mid-treatment, Post-treatment, up to 3 months) and cohort 2 (Baseline, Mid-treatment, Post-treatment, up to 6 months).

2. Mean Change in Psychological Wellbeing Scale Short Form - Total Score (Both Cohorts) [Time Frame: up to 6 months]

The Psychological Wellbeing Scale (Short Form) is an 18 item scale. Answers are on a 6 point scale with options "strongly disagree", "moderately disagree", "slightly disagree", "slightly agree", "moderately agree", and "strongly agree". Possible scores range from 18 to 108. Higher scores reflect higher levels of psychological wellbeing. The Psychological Wellbeing Scale is administered in both cohort 1 (Baseline, Mid-treatment, Post-treatment, up to 3 months) and cohort 2 (Baseline, Mid-treatment, Post-treatment, up to 6 months).

5.3 TERTIARY/EXPLORATORY OUTCOME MEASURES

1. Mean Change in Medical Outcomes Study (MOS) Social Support Survey - Emotional/Informational Support Subscale Score (Both Cohorts) [Time Frame: up to 6 months]

   The MOS Social Support Survey - Emotional/informational support subscale is an 8 item subscale. 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 8 to 40. Higher scores reflect higher feelings of emotional and informational social support (more perceived emotional and informational social support). The MOS Social Support Survey - Emotional/informational support subscale is administered in both cohort 1 (Baseline, Mid-treatment, Post-treatment, up to 3 months) and cohort 2 (Baseline, Mid-treatment, Post-treatment, up to 6 months).

2. Mean Change in Medical Outcomes Study (MOS) Social Support Survey - Tangible Support Subscale Score (Both Cohorts) [Time Frame: up to 6 months]

   The MOS Social Support Survey - Tangible support subscale is a 4 item subscale. 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 4 to 20. Higher scores reflect higher feelings of tangible social support (more perceived tangible social support). The MOS Social Support Survey - Tangible support subscale is administered in both cohort 1 (Baseline, Mid-treatment, Post-treatment, up to 3 months) and cohort 2 (Baseline, Mid-treatment, Post-treatment, up to 6 months).

3. Mean Change in Medical Outcomes Study (MOS) Social Support Survey - Affectionate Support Subscale Score (Both Cohorts) [Time Frame: up to 6 months]

   The MOS Social Support Survey - Affectionate support subscale is a 3 item subscale. 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 3 to 15. Higher scores reflect higher feelings of affectionate social support (more perceived affectionate social support). The MOS Social Support Survey - Affectionate support subscale is administered in both cohort 1 (Baseline, Mid-treatment, Post-treatment, up to 3 months) and cohort 2 (Baseline, Mid-treatment, Post-treatment, up to 6 months).

3. Mean Change in Medical Outcomes Study (MOS) Social Support Survey - Positive Social Interaction Subscale Score (Both Cohorts) [Time Frame: up to 6 months]

   The MOS Social Support Survey - Positive social interaction subscale is a 3 item subscale. 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 3 to 15. Higher scores reflect higher feelings of positive social interaction (more perceived positive social interaction). The MOS Social Support Survey - Positive social interaction subscale is administered in both cohort 1 (Baseline, Mid-treatment, Post-treatment, up to 3 months) and cohort 2 (Baseline, Mid-treatment, Post-treatment, up to 6 months).

4. Mean Change in Psychological Wellbeing Scale Short Form - Environmental Mastery Subscale Score (Both Cohorts) [Time Frame: up to 6 months]

   The Psychological Wellbeing Scale (Short Form) - Environmental Mastery Subscale is a 3 item scale. Answers are on a 6 point scale with options "strongly disagree", "moderately disagree", "slightly disagree", "slightly agree", "moderately agree", and "strongly agree". Possible scores range from 3 to 18. Higher scores reflect higher levels of environmental mastery. The MOS Social Support Survey - Environmental Mastery subscale is administered in both cohort 1 (Baseline, Mid-treatment, Post-treatment, up to 3 months) and cohort 2 (Baseline, Mid-treatment, Post-treatment, up to 6 months).

5. Mean Change in Psychological Wellbeing Scale Short Form - Personal Growth Subscale Score (Both Cohorts) [Time Frame: up to 6 months]

   The Psychological Wellbeing Scale (Short Form) - Personal Growth subscale is a 3 item scale. Answers are on a 6 point scale with options "strongly disagree", "moderately disagree", "slightly disagree", "slightly agree", "moderately agree", and "strongly agree". Possible scores range from 3 to 18. Higher scores reflect higher levels of personal growth. The Psychological Wellbeing Scale - Personal Growth subscale is administered in both cohort 1 (Baseline, Mid-treatment, Post-treatment, up to 3 months) and cohort 2 (Baseline, Mid-treatment, Post-treatment, up to 6 months).

6. Mean Change in Psychological Wellbeing Scale Short Form - Self-Acceptance Subscale Score (Both Cohorts) [Time Frame: up to 6 months]

   The Psychological Wellbeing Scale (Short Form) - Self-Acceptance subscale is a 3 item scale. Answers are on a 6 point scale with options "strongly disagree", "moderately disagree", "slightly disagree", "slightly agree", "moderately agree", and "strongly agree". Possible scores range from 3 to 18. Higher scores reflect higher feelings of self-acceptance. The Psychological Wellbeing Scale - Self-Acceptance subscale is administered in both cohort 1 (Baseline, Mid-treatment, Post-treatment, up to 3 months) and cohort 2 (Baseline, Mid-treatment, Post-treatment, up to 6 months).

7. Mean Change in Psychological Wellbeing Scale Short Form - Autonomy Subscale Score (Both Cohorts) [Time Frame: up to 6 months]

   The Psychological Wellbeing Scale (Short Form) - Autonomy Subscale is a 3 item scale. Answers are on a 6 point scale with options "strongly disagree", "moderately disagree", "slightly disagree", "slightly agree", "moderately agree", and "strongly agree". Possible scores range from 3 to 18. Higher scores reflect higher levels of autonomy. The Psychological Wellbeing Scale - Autonomy subscale is administered in both cohort 1 (Baseline, Mid-treatment, Post-treatment, up to 3 months) and cohort 2 (Baseline, Mid-treatment, Post-treatment, up to 6 months).

8. Mean Change in Psychological Wellbeing Scale Short Form - Positive Relationships Subscale Score (Both Cohorts) [Time Frame: up to 6 months]

   The Psychological Wellbeing Scale (Short Form) - Positive Relationships subscale is a 3 item scale. Answers are on a 6 point scale with options "strongly disagree", "moderately disagree", "slightly disagree", "slightly agree", "moderately agree", and "strongly agree". Possible scores range from 3 to 18. Higher scores reflect higher levels of positive relationships. The Psychological Wellbeing Scale - Positive Relationships subscale is administered in both cohort 1 (Baseline, Mid-treatment, Post-treatment, up to 3 months) and cohort 2 (Baseline, Mid-treatment, Post-treatment, up to 6 months).

9. Mean Change in Psychological Wellbeing Scale Short Form - Purpose in Life Subscale Score (Both Cohorts) [Time Frame: up to 6 months]

   The Psychological Wellbeing Scale (Short Form) - Purpose in Life subscale is a 3 item scale. Answers are on a 6 point scale with options "strongly disagree", "moderately disagree", "slightly disagree", "slightly agree", "moderately agree", and "strongly agree". Possible scores range from 3 to 18. Higher scores reflect higher feelings of purpose in life. The Psychological Wellbeing Scale - Purpose in Life subscale is administered in both cohort 1 (Baseline, Mid-treatment, Post-treatment, up to 3 months) and cohort 2 (Baseline, Mid-treatment, Post-treatment, up to 6 months).

10. Qualitative Summaries of Participant Experience in Post-Treatment Feedback (Both Cohorts) [Time Frame: up to 6 months]

    This qualitative data will be collected post-treatment from clients and clinicians. Focus groups and 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. Feedback is elicited at post-treatment in both cohort 1 (Month 3) and cohort 2 (Month 6).

11. Quantitative Summaries of Participant Experience in Post-Treatment Feedback (Both Cohorts) [Time Frame: up to 6 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. Feedback is elicited at post-treatment in both cohort 1 (Month 3) and cohort 2 (Month 6).

12. Mean Change in Questionnaire about the Process of Recovery - Total Score (Cohort 2 Only) [Time Frame: up to 6 months]

    The Questionnaire about the Process of Recovery (QPR) - Total Score is a 15-item scale. Answers are rated on a 5-point scale with options "disagree strongly", "disagree", "neither agree nor disagree", "agree", and "agree strongly. Possible scores range from 0 to 60. Higher scores are indicative of recovery. The QPR is administered in only cohort 2 (Baseline, Mid-treatment, Post-treatment, up to 6 months).

13. Mean Change in Modified Colorado Symptom Index - Total Score (Cohort 2 Only) [Time Frame: up to 6 months]

    The Modified Colorado Symptom Index - Total Score is a 14-item scale. Answers are rated on a 4-point scale with options "not at all", "once during the month", "several times during the month", "several times a week", and "at least every day". Possible scores range from 0 to 56. Higher scores indicate greater emotional distress. The Modified Colorado Symptom Index is administered in only cohort 2 (Baseline, Mid-treatment, Post-treatment, up to 6 months).

14. Mean Change in Social Anxiety Scale for Social Media Users - Total Score (Cohort 2 Only) [Time Frame: up to 6 months]

    The Social Anxiety Scale for Social Media Users (SAS-SMU) - Total Score is a 21-item scale. Answers are rated on a 5-point scale with options "never", "rarely", "sometimes", "often", and "always". Possible scores range from 21 to 105. Higher scores reflect greater anxiety related to social media usage. The SAS-SMU is administered in only cohort 2 (Baseline, Mid-treatment, Post-treatment, up to 6 months).

15. Mean Change in Social Anxiety Scale for Social Media Users - Shared Content Anxiety Subscale Score (Cohort 2 Only) [Time Frame: up to 6 months]

    The Social Anxiety Scale for Social Media Users (SAS-SMU) - Shared Content Anxiety subscale is a 7-item scale. Answers are rated on a 5-point scale with options "never", "rarely", "sometimes", "often", and "always". Possible scores range from 7 to 35. Higher scores reflect greater anxiety related to sharing or creating content on social media. The SAS-SMU - Shared

Content Anxiety subscale is administered in only cohort 2 (Baseline, Mid-treatment, Post-treatment, up to 6 months).

16. Mean Change in Social Anxiety Scale for Social Media Users - Privacy Concern Anxiety Subscale Score (Cohort 2 Only) [Time Frame: up to 6 months]

    The Social Anxiety Scale for Social Media Users (SAS-SMU) - Privacy Concern Anxiety subscale is a 5-item scale. Answers are rated on a 5-point scale with options "never", "rarely", "sometimes", "often", and "always". Possible scores range from 5 to 25. Higher scores reflect greater anxiety related to privacy concerns on social media. The SAS-SMU - Privacy Concern Anxiety subscale is administered in only cohort 2 (Baseline, Mid-treatment, Post-treatment, up to 6 months).

17. Mean Change in Social Anxiety Scale for Social Media Users - Interaction Anxiety Subscale Score (Cohort 2 Only) [Time Frame: up to 6 months]

    The Social Anxiety Scale for Social Media Users (SAS-SMU) - Interaction Anxiety subscale is a 6-item scale. Answers are rated on a 5-point scale with options "never", "rarely", "sometimes", "often", and "always". Possible scores range from 6 to 30. Higher scores reflect greater anxiety related to social interactions over social media. The SAS-SMU - Interaction Anxiety subscale is administered in only cohort 2 (Baseline, Mid-treatment, Post-treatment, up to 6 months).

18. Mean Change in Social Anxiety Scale for Social Media Users - Self-Evaluation Anxiety Subscale Score (Cohort 2 Only) [Time Frame: up to 6 months]

    The Social Anxiety Scale for Social Media Users (SAS-SMU) - Self-Evaluation Anxiety subscale is a 3-item scale. Answers are rated on a 5-point scale with options "never", "rarely", "sometimes", "often", and "always". Possible scores range from 3 to 15. Higher scores reflect greater anxiety related to negative self-evaluation. The SAS-SMU - Self-Evaluation Anxiety subscale is administered in only cohort 2 (Baseline, Mid-treatment, Post-treatment, up to 6 months).

19. Mean Change in Perceived Autonomy Support Scale - Total Score (Both Cohorts) [Time Frame: up to 20 weeks]

    The Perceived Autonomy Support Scale - Total Score is a 6-item scale. Answer are on a 7-point scale with options "strongly disagree", "moderately disagree", "slightly disagree", "neutral", "slightly agree", "moderately agree", and "strongly agree". Possible scores range from 6 to 42. Higher scores reflect greater perceived autonomy support. The Perceived Autonomy Support Scale is administered in both cohort 1 (Mid-treatment, Post-treatment, up to 6 weeks) and cohort 2 (1.5 Months, Mid-treatment, 4.5 Months, Post-treatment, up to 20 weeks).

20. Mean Change in Working Alliance Inventory for Guided Internet Interventions - Total Score (Both Cohorts) [Time Frame: up to 20 weeks]

The Working Alliance Inventory for Guided Internet Interventions (WAI-I) - Total Score is a 12-item scale. Answers are on a 5-point scale with options "seldom", "sometimes", "fairly often", "very often", and "always". Possible scores range from 12 to 60 (summed) or 1 to 5 (averaged). Higher scores reflect greater therapeutic alliance. The WAI-I is administered in both cohort 1 (Mid-treatment, Post-treatment, up to 6 weeks) and cohort 2 (1.5 Months, Mid-treatment, 4.5 Months, Post-treatment, up to 20 weeks).

21. Mean Change in Working Alliance Inventory for Guided Internet Interventions - Bond Subscale Score (Both Cohorts) [Time Frame: up to 20 weeks]

    The Working Alliance Inventory for Guided Internet Interventions - Bond subscale score is a 4-item scale. Answers are on a 5-point scale with options "seldom", "sometimes", "fairly often", "very often", and "always". Possible scores range from 4 to 20 (summed) or 1 to 5 (averaged). Higher scores reflect greater bond with a clinician. The WAI-I - Bond subscale is administered in both cohort 1 (Mid-treatment, Post-treatment, up to 6 weeks) and cohort 2 (1.5 Months, Mid-treatment, 4.5 Months, Post-treatment, up to 20 weeks).

22. Mean Change in Working Alliance Inventory for Guided Internet Interventions - Goal/Task Subscale Score (Both Cohorts) [Time Frame: up to 20 weeks]

    The Working Alliance Inventory for Guided Internet Interventions - Goal/Task Score is an 8-item scale. Answers are on a 5-point scale with options "seldom", "sometimes", "fairly often", "very often", and "always". Possible scores range from 8 to 40 (summed) or 1 to 5 (averaged). Higher scores reflect greater shared goals and tasks with a clinician. The WAI-I - Goal/Task subscale is administered in both cohort 1 (Mid-treatment, Post-treatment, up to 6 weeks) and cohort 2 (1.5 Months, Mid-treatment, 4.5 Months, Post-treatment, up to 20 weeks).

23. Mean Change in Twente Engagement with E-health Technologies Scale - Total Score (Cohort 2 Only) [Time Frame: up to 6 months]

    The Twente Engagement with E-health Technologies Scale - Total Score is a 9-item scale. Answers are on a 5-point scale with options "strongly disagree", "disagree", "neutral", "agree", and "strongly agree". Possible scores range from 0 to 36. Higher scores reflect greater engagement. The Twente Engagement with E-health Technologies Scale is administered in only cohort 2 (Baseline, 1.5 Months, Mid-treatment, 4.5 Months, Post-treatment, up to 6 months).

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 well-powered and randomized pilot trials of Horyzons in North Carolina.

5.5 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 DeDoose program for qualitative analysis. All analyses will be conducted by the study research coordinator (Elena Pokowitz) and graduate student (Bryan Stiles).

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. All documents such as consent and feedback measure/questionnaire 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 will be instructed via email or phone call before the focus groups to identify an appropriate location for the group discussion (i.e., private space) if held virtually rather than in person. All documents such as consent documents will be sent to providers 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, 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 well being 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 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 (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 of this intervention when implemented 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 the therapeutic pathways, 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 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 cafe).

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). Feedback interviews/focus groups 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/focus groups) will be password protected and stored securely, and will only be directly accessible by the research study coordinators, clinicians and peer support specialists, involved in this project, or PI (Dr. Penn).

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 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 and focus groups will be stored on a secure, password-protected server.

Identifiable data will only be shared with the clinicians 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 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.

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 events (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

Study subjects will be drawn from the four first episode psychosis clinics in North Carolina (OASIS, Encompass, SHORE, and Eagle) and the UNC-affiliated STEP clinics (Carr Mill Mall, Vilcom Center, Main Wake Clinic). 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 30 client participants will be recruited from the four 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 four participating clinics; therefore, we expect approximately 20 providers 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 for potential eligibility. Providers 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 clinicians 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 verbal consent as recorded by the study coordinator.

10 REFERENCES

1. Dixon, L. B., Goldman, H. H., Srihari, V. H., & Kane, J. M. (2018). Transforming the treatment of schizophrenia in the United States: the RAISE initiative. *Annual Review of Clinical Psychology*, *14*, 237-258.
2. Nossel, I., Wall, M. M., Scodes, J., Marino, L. A., Zilkha, S., Bello, I., ... & Dixon, L. (2018). Results of a coordinated specialty care program for early psychosis and predictors of outcomes. *Psychiatric Services*, *69*(8), 863-870.
3. Singh, S. P. (2010). Early intervention in psychosis. *The British Journal of Psychiatry*, *196*(5), 343-345.
4. Alvarez-Jimenez, M., Parker, A. G., Hetrick, S. E., McGorry, P. D., & Gleeson, J. F. (2011). Preventing the second episode: a systematic review and meta-analysis of psychosocial and pharmacological trials in first-episode psychosis. *Schizophrenia Bulletin*, *37*(3), 619-630.
5. Gafoor, R., Nitsch, D., McCrone, P., Craig, T. K., Garety, P. A., Power, P., & McGuire, P. (2010). Effect of early intervention on 5-year outcome in non-affective psychosis. *The British journal of psychiatry*, *196*(5), 372-376.
6. Norman, R. M., Manchanda, R., Malla, A. K., Windell, D., Harricharan, R., & Northcott, S. (2011). Symptom and functional outcomes for a 5 year early intervention program for psychoses. *Schizophrenia research*, *129*(2-3), 111-115.
7. Alvarez-Jimenez, M., Bendall, S., Lederman, R., Wadley, G., Chinnery, G., Vargas, S., ... & Gleeson, J. F. (2013). On the HORYZON: moderated online social therapy for long-term recovery in first episode psychosis. *Schizophrenia research*, *143*(1), 143-149.