Horyzons: Implementation and Integration in Clinical Practice

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University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

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Title of Study: Horyzons: Implementation and Integration in Clinical Practice
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CONCISE SUMMARY

This is a research study designed to learn more about how individuals engage with Horyzons, an online social media platform for persons experiencing psychosis. If you decide to participate in this study, you will be oriented to the Horyzons platform by a peer support specialist, clinician, or graduate student in clinical psychology at UNC-Chapel Hill. You will also be asked to provide some demographic information, including the name of a clinician you wish to be contacted in case of an emergency. You will be given access to the platform for a period of 12 months during which time you will be connected with an online therapist. Online therapists monitor the site daily to ensure a safe and supportive environment for its users. Induction to the platform should last approximately 30 minutes. You will be compensated for this initial visit and completion of briefs surveys at midpoint, post-study, and follow-up, but will not compensated for using the platform. Risks of this study include distress or discomfort using the platform (e.g., anxiety posting about your experiences) as well as possible breach of confidentiality. If you are interested in learning more about this study, please continue reading below.

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary. You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of the study is to evaluate a new online program, Horyzons, for individuals receiving services at one of the following clinics across North Carolina: Outreach and Support Intervention Services (OASIS) clinic in Chapel Hill, the UNC Encompass Program in Raleigh, SHORE Program in Wilmington, Eagle Program in Charlotte, AEGIS in Asheville, STEP Carr Mill in Carrboro, STEP Vilcom Center in Chapel Hill, Wake STEP Clinic in Raleigh, or TIDES in Wilmington. Horyzons was developed in Melbourne, Australia by researchers associated with the Orygen Youth Health Research Centre and Australian Catholic University.

Horyzons has a number of features, including online therapy material and social networking. The online therapy has been designed to help young people recover from psychosis and includes various "tracks" that are embedded within therapy "journeys" (such as managing anxiety and depression, and engaging in mindfulness and meditation, among others). You can choose which pathways to complete and can do so at your own pace.

The social networking feature (called "the community") can do many of the same things that Facebook can do, such as allow the user to display their own profile and link up online with other people engaged in services at FEP clinics in the Horyzons online "Community." However, it differs from Facebook in a number of important ways. First, Horyzons is a **private** online networking site, only open to people in this study (in addition to clinic and research staff). Second, there are online therapists and coaches on Horyzons, who are peer support specialists, clinicians and/or graduate students in the Department of Psychology and Neuroscience, that help clients make the most of the system and encourage a positive and supportive experience. Online therapists' primary role is to provide encouragement and engage with inactive participants. Drs. David Penn and Kelsey Ludwig, licensed clinical psychologists, will supervise all online therapists.

Ultimately, we are interested in whether Horyzons will be a good addition to the treatment you receive at your clinic and whether it is something useful to add to the peer support program.

Are there any reasons you should not be in this study?

You should not be in this study if you are:

1. Not currently receiving services at one of the following clinics in North Carolina: OASIS, Encompass, Eagle, SHORE, AEGIS, STEP Carr Mill, STEP Vilcom Center, STEP Main Wake Clinic, TIDES

2. Not between the ages of 16-35
3. Do not have a schizophrenia spectrum disorder or other unspecified psychotic disorder diagnosis
4. Currently experiencing active thoughts of suicide (i.e., frequent thoughts of suicide, presence of a plan and/or intent to die by suicide)
5. Not proficient in the English language
6. Do have a legally authorized representative (LAR, or legal guardian)
7. Do not have access to the internet via computer/laptop, tablet, or smartphone

How many people will take part in this study?

A total of approximately 50 participants will take part in this study, including approximately 15 clients from each participating first episode psychosis clinics across North Carolina.

How long will your part in this study last?

Your overall participation in this study will last approximately 12 months.

What will happen if you take part in the study?

If you agree to take part in the study, the following will take place:

(a) The study coordinator, peer support specialist, clinician and/or the principal investigator will orient you to the study. This will include an explanation of guidelines on the appropriate use of Horyzons, as well as how to logon. In addition, we will discuss rules that all users are expected to follow, such as being respectful and keeping all messages confidential, so as to keep Horyzons safe and private. Inappropriate use of Horyzons (e.g., derogatory or disrespectful comments) may lead to temporary or permanent suspension of your Horyzons account. Lastly, you will be asked to complete a questionnaire about your demographics and characteristics that describe you.

(b) Online therapists will monitor Horyzons twice daily on weekdays and once per day over the weekend. However, it has not been designed and it is not equipped to respond to emergency situations.

(c) It is up to you when and how often you log on to Horyzons, and what you do when you log on. However, we encourage all participants to log on at least daily. In addition, the online therapist might prompt you to engage with certain features of the site (based on consultation with your treatment team) or contact you via text message and/or telephone if you haven't logged on in a while.

(d) You will be asked to use the Horyzons platform for a 12-month period. While you use Horyzons, the platform will be passively collecting information about you. Specifically, researchers will be able to track which aspects of Horyzons you have used, such as how often you logged on, as well as how often you post comments or use the "like" button.

(e) You will be given the opportunity to identify your character strengths (e.g., curiosity, love of learning) through the Horyzons induction procedure. If you choose to complete these measures, we will share your self-identified strengths and other relevant clinical impressions to your treatment team.

(f) Horyzons is being offered to you as part of routine clinical care at your clinic. In some cases, this platform is being integrated as part of the peer support program at the Outreach and Support Intervention Services (OASIS), Eagle, SHORE, UNC Encompass, AEGIS, STEP clinics, and TIDES clinic. As Horyzons will be considered part of the peer support program and/or overall clinical program,

your participation in Horyzons and activity on the site will be shared with your treatment team. Your treatment team may also share relevant clinical information with the peer support specialists and other research personnel involved in this project.

(g) We will follow-up with you periodically at 6 months (mid-treatment), 12 months (post-treatment), and 3 months post-study to complete virtual assessments with questions about your social supports and other psychological symptoms. This will include answering survey questions with the study coordinator or other member of the research team over secure virtual meeting. These assessments will be brief and will take no longer than 30 minutes to complete. You will be compensated for completing each of these assessments.

(h) You may also be invited to "meet" the other clients of the clinic, including Horyzons users, each month. The primary purpose of these meetings is to meet and spend time with Horyzons users and other clients engaged in the peer support program at your clinic. Due to the platform being offered at clinics across North Carolina state, all meet-ups will be held virtually in order for all who would like to attend being able to do so. Please note that your attendance to these meet-ups is purely **optional**, and will not impact your ability to engage with other components of the site.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. The proposed study may also increase your sense of belonging and social support. In particular, if you actively engage in the therapeutic pathways of Horyzons, you might develop cognitive behavioral and mindfulness-based skills. In addition, you might experience positive changes in your mood, symptoms, and functioning. You will also be assisting the researchers in determining whether Horyzons is a feasible adjunct intervention for the clients receiving mental health services from participating clinical programs in North Carolina.

What are the possible risks or discomforts involved from being in this study?

There are a variety of risks associated with using the Horyzons online platform. These include: 1) dissemination of personal details by other users or by unauthorized hackers; 2) distress resulting from inappropriate or offensive communication from other users; and 3) increased paranoia resulting from participation in the system, especially in the event of deterioration in mental health.

Risk of anxiety, embarrassment or distress due to experiences using this online platform is minimized by consistent moderating of the site as well as therapists' use of a nonjudgmental clinical attitude. All users who decide to be involved in this project will review and agree to the terms of use. In addition, you will be able to "switch off" your profile and hide all of your existing comments on the system should you become concerned about privacy during the course of participation. If any user does not comply with the guidelines for safe use of Horyzons (e.g., discriminatory comments towards other users), they will be removed from the system.

If we notice a decline in your mental health or become concerned about your wellbeing, we will reach out to you and contact your treatment provider. There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?

The developers of Horyzons, in conjunction with clinicians at from the Orygen Youth Health clinical program (Melbourne, Australia), experts from information systems, and consultation with legal counsel have created a rigorous safety protocol. The safety protocol comprises 3 levels of security, including system and privacy protection, online safety, and clinical safety.

System and privacy protection will be monitored by the study programmer. Online safety will be monitored by Horyzons moderators (clinician, peer support specialist, graduate students in the Department of Psychology and Neuroscience at UNC) with supervision from the Principal Investigator.

A range of measures are in place to ensure the security of the Horyzons website and the usage information passively collected by the site. The application is hosted on a secure server, and measures are in place to prevent unauthorized access to the server. In addition, the team developing the web application has placed measures within the application to secure the application and database against unauthorized access. Any paper documentation or papers related to the research study will be stored in locked filing cabinets in the Department of Psychology and Neuroscience in Howell Hall and/or secure administrative office areas at the Outreach and Support Intervention Services (OASIS) clinic, Eagle program, SHORE clinic, Encompass, AEGIS, STEP clinics, and TIDES clinic. The project electronic database will be password projected, stored securely and will only be directly accessible by the research study personnel or the principal investigator.

Horyzons will only be made available to individuals in the study who are receiving clinical services at one of the participating clinics across North Carolina (OASIS, Eagle, SHORE, Encompass, AEGIS, STEP clinics, TIDES). Participants will have the option of whether they want to use their real name or pseudonym on Horyzons, as well as being able to switch off their profile and hide all existing comments/activity on the system should they become concerned about their privacy during the study. It is possible that users might break the rules and communicate things in Horyzons that may upset others. There is a "report button" in Horyzons that anyone can use to notify the moderator about any inappropriate content. In addition, if you become concerned about how Horyzons is being used by others, you can contact us by phone or email to report your concerns.

If there are safety issues (i.e. you express intent to harm yourself or others), we will notify all appropriate parties, including your treatment team, the Principal Investigator, and 911.

As noted previously, it is important to know that your participation and activity on Horyzons will be shared with the treatment team at your clinic. Horyzons will be considered part of the peer support program and

overall clinical care provided to you. Additionally, providers and members of your treatment team and other FEP clinics may have access and be able to view the Horyzons platform. The treatment team may also provide relevant clinical information to project personnel to ensure your safety and facilitate progress toward your goals for using the site and engaging in mental health care services at the clinic.

The investigator and staff involved with the study will keep all personal information collected for the study strictly confidential to the extent allowed by law. At the beginning of the study, you will be assigned a random number that will be used to identify your data. Your name and contact information will be kept separate from the data you provide. All data will be kept in locked filing cabinets in secured offices at UNC and only study personnel will have access to your data.

If researchers engage in conversations with clients or conduct assessments online via videoconference, the video or audio from these interviews will not be saved or recorded. The server used will be a virtual private network and will be secure.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

Participation in Horyzons requires you to agree not to reveal anything you learn about other users with individuals not involved in the platform. This includes information gleaned from posts/comments made within the site, other users' profiles, group discussions, meet-ups, or other activities.

Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety. We may use de-identified data from this study in future research without additional consent.

The study team would like to message you by text messaging and email, however you may say "no" to receiving these messages and still participate in this study. If you say "yes", messages may contain personal information about you and may be sent or received by the study team's personal electronic devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team. This information may include information such as reminders and notifications to contact the study team.

If you wish to stop receiving unprotected communication from the study team or have lost access to your device, please notify the study team using the study contact information on the first page of the addendum

to the consent. After the study is complete and all research activities finished, or you withdraw from the study or request to stop receiving unprotected communication, you will no longer receive un-encrypted (un-protected) messages specific to this study.

_____ Yes, I consent to the study team utilizing the following cell phone number and email to send communication:

_____ No, I do not consent to receive un-protected communication from the study team.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do. By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty, and without affecting your services from your clinic. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, have failed to follow instructions, or because the entire study has been stopped.

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Will you receive anything for being in this study?

You will receive $20 for completing the baseline visit including this informed consent and questionnaires with an additional $10 for each survey visit for a total of up to $50 if all study visits are completed. You will not receive additional payment for using and engaging with the Horyzons platform as part of your clinical services.

Will it cost you anything to be in this study?

It will not cost you anything to be in this study.

What if you are a UNC student?

You may choose not to be in the study or to stop being in the study before it is over at any time. This will not affect your class standing or grades at UNC-Chapel Hill. You will not be offered or receive any special consideration if you take part in this research.

What if you are a UNC employee?

Taking part in this research is not a part of your University duties and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

Who is sponsoring this study?

This research is funded by the State of North Carolina Government (Sponsor), and supported by UNC-Chapel Hill. This means that the research team is being paid by these organizations for doing the study. Horyzons technology is owned by Australian Catholic University (ACU) and is being used in this study. In addition, David Penn participates in paid activities, which are not part of this study, with the Australian Catholic University (ACU). These activities may include consulting, service on committees or advisory boards, giving speeches, or writing reports. If you would like more information, please ask the researchers listed in the first page of this form.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study, complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant Consent:

Do you have any questions?

Do you agree to be in this study? Yes No

To continue with the study, and in order to maintain the safety and care of all participants, we ask that you please list your current clinician and a family member (or other contact person) so that we may contact

them in case of any perceived emergency that may arise during the study. If not given, the default clinician will be listed as Dr. David Penn.

What is the name and phone number of your self-identified contact person?

Name:
Phone:
Email:

Do you give consent for the researchers of this study to contact your self-identified contact person in case of any perceived emergency or question concerning my care? Yes No

What is the name and phone number of your clinician?

Name:
Phone:
Email:

Do you give consent for the researchers of this study to contact your clinician, or Dr. David Penn if none is listed, in case of any perceived emergency or question concerning my care? Yes No

Do you give consent for the researchers to contact you regarding future studies? Yes No

Please provide your mailing address for receipt of compensation:

Printed Name of Research Participant: _____

Signature of Research Participant: _____

Printed Name of Research Staff Obtaining Consent: _____

Signature of Research Staff Obtaining Consent: _____

Date: _____