# Altitudes for Caregivers

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

**Consent Form Version Date:** 9/7/2023
**IRB Study #** 23-1676
**Title of Study**: Altitudes for Caregivers: A Pilot Study
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**CONCISE SUMMARY**

This is a research study designed to learn more about how parents and guardians engage with Altitudes, an online social media platform for parents and caregivers of individuals experiencing psychosis. If you decide to participate in this study, you will be oriented to the Altitudes platform by research personnel, family peer worker, 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 an emergency contact you wish to have contacted in case there is a concern or issue. You will be given access to the platform for a period of 6 months during which time you have the option to be connected with a clinical moderator. Clinical moderators track 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 questionnaires at midpoint, and post-study, 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 platform, Altitudes, for parents and family members of individuals receiving services at one of the following clinics across North Carolina: Outreach and Support Intervention Services (OASIS) clinic in Chapel Hill and SHORE Program in Wilmington. Altitudes was developed in Melbourne, Australia by researchers associated with the Orygen Youth Health Research Centre and Australian Catholic University in adjunct with feedback and insight of parents with individuals experiencing first episode psychosis (FEP) from the OASIS and SHORE programs.

Altitudes has a number of features, including psychoeducational and therapeutic material and social networking. The educational and therapeutic content has been designed to help parents and family members better understand psychosis, their loved one, and develop skills, which are found in various "tracks" that are embedded within "journeys" (such as what is psychosis, identifying early warning signs, self-care practices, 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 parents and family members with loved ones experiencing psychosis in the Altitudes online "Community." However, it differs from Facebook in a number of important ways. First, Altitudes is a **private** online networking site, only open to people in this study (in addition to clinic and research staff). Second, there are clinical moderators and coaches on Altitudes, who are family peer workers, clinicians and/or graduate students in the Department of Psychology and Neuroscience, that help users make the most of the system and encourage a positive and supportive experience. Clinical moderators' primary role is to provide encouragement, guidance, and engage with inactive participants. Drs. David Penn and Kelsey Ludwig, licensed clinical psychologists, will supervise all clinical moderators.

Ultimately, we are interested in whether Altitudes will be a good addition to the treatment you receive at your loved one's clinic and whether it is something useful for parents and family members whose loved ones are entering treatment for early psychosis.

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

You should not be in this study if you are:

1. Not a parent or caregiver of a young person who is currently receiving treatment from an FEP clinic or who recently graduated from their FEP clinic
2. Not at least 18 years of age
3. Not recruited from OASIS or SHORE (2 of North Carolina's 5 FEP clinics)
4. Loved one has been experiencing psychosis for more than 5 years.
5. Not proficient in the English language
6. Currently engaged in legal action against your loved one who is receiving services from the FEP clinic

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 30 participants will take part in this study, including approximately 15 parents and/or family members from each participating first episode psychosis clinics in North Carolina (i.e., OASIS and SHORE).

**How long will your part in this study last?**

Your overall participation in this study will last approximately 6 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, family peer worker, clinician and/or the principal investigator will orient you to the study. This will include an explanation of guidelines on the appropriate use of Altitudes, 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 Altitudes safe and private. Inappropriate use of Altitudes (e.g., derogatory or disrespectful comments) may lead to temporary or permanent suspension of your Altitudes account. Lastly, you will be asked to complete a questionnaire about your demographics and characteristics that describe you.

(b) Clinical moderators will track Altitudes at least once daily to ensure safety. 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 Altitudes, and what you do when you log on. However, we encourage all participants to log on at least daily. In addition, the clinical moderator might prompt you to engage with certain features of the site (based on your goals and aims in using the platform) 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 Altitudes platform for a 6-month period. While you use Altitudes, the platform will be passively collecting information about you. Specifically, researchers will be able to track which aspects of Altitudes 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 different attributes and characteristics (e.g., how you spend your time, goals, etc.) through the Altitudes induction procedure.

(f) Altitudes is being offered to you as an adjunctive service to clinical offerings for families of individuals experiencing FEP. In some cases, Altitudes may be considered part of your overall clinical program (e.g., family psychoeducation and therapy, multi-family group). For this reason, your participation in Altitudes and activity on the site may be shared with the family therapist or clinician.

(g) We will follow-up with you periodically at 3 months (mid-treatment) and 6 months (post-treatment), to complete virtual assessments with questionnaires about your social supports, experiences, and other wellbeing measures. This will include answering survey questions with the study coordinator or other member of the research team over secure virtual meeting. The mid-treatment assessment will likely take no longer than 45 minutes to complete while the post-treatment assessment will be longer (approximately an hour and a half) as in addition to the questionnaires there will be an interview about your experience with Altitudes. You will be compensated for completing each of these assessments.

(h) You may also be invited to "meet" other Altitudes users each month. The primary purpose of these meetings is to meet and spend time with Altitudes users engaged with the platform. Due to the platform

being offered at two 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 psychoeducation and therapeutic pathways of Altitudes, you might develop deeper understanding of psychosis, cognitive behavioral techniques and mindfulness-based skills. In addition, you might experience positive changes in your mood and functioning. You will also be assisting the researchers in determining whether Altitudes is an acceptable and feasible adjunct intervention for the parents and family members of individuals 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 Altitudes 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 anxiety resulting from participation in the system.

Risk of anxiety, embarrassment or distress due to experiences using this online platform is minimized by consistent moderating of the site as well as moderators' 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 Altitudes (e.g., discriminatory comments towards other users), they will be removed from the system.

If we become concerned about your wellbeing, we will reach out to you and potentially your emergency contact or provider you designated during the induction visit (e.g., primary care physician, mental health counselor). 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 Altitudes, 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 Altitudes moderators (clinician, family peer worker, 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 Altitudes 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, Department of Psychiatry in Wing D, and/or secure administrative office areas at the Outreach and Support Intervention Services (OASIS) or SHORE clinics. 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.

Altitudes will only be made available to individuals in the study who are a parent or family member of an individual receiving clinical services at one of the participating clinics (OASIS or SHORE). Participants will have the option of whether they want to use their real name or pseudonym on Altitudes, 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 Altitudes that may upset others. There is a "report button" in Altitudes that anyone can use to notify the moderator about any inappropriate content. In addition, if you become concerned about how Altitudes 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 emergency contact, designated provider, the Principal Investigator, and/or 911.

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 individuals or conduct visits 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.

Participation in Altitudes 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 or your loved one's 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/hour prorated to the nearest half hour for completing each study visit. The baseline

visit is estimated to be approximately an hour and a half so the compensation would be approximately $30 for its completion, including this informed consent and questionnaires. The mid-treatment visit is estimated to be approximately 45 minutes therefore compensation would be approximately $20 for its completion. The post-treatment visit is estimated to be an hour and a half so compensation would be approximately $30 for its completion, including an interview providing feedback about your experience with Altitudes. You can earn up to approximately $80 if all study visits are completed. You will not receive additional payment for using and engaging with the Altitudes platform.

**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. Altitudes 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

Do you agree to be audio recorded? 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 a designated provider (e.g., primary care physician, mental health counselor) and an emergency contact 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 provider?

**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:** _____

**DocuSign Consent**

I consent to the use of UNC's enterprise instance of DocuSign to record and store my consent. I understand that revocation or request of deletion from DocuSign may impact my ability to continue to participate in the study.

Participant Printed Name: _____

Participant Signature: _____

Research Team Member Obtaining Consent Signature: _____