Informed Consent Form

Title: Engagement and Clinical Impact of the Teleo Virtual Therapy Platform in Clinical Settings

NCT06364137

Last Updated: 03/31/2025

☐ I am the parent or guardian granting permission for a child in this study (the use of "you" refers to "your child" or "your ward.")

Print parent's name here: I am the parent or guardian granting consent for a minor in this study.

_____

Print minor's name here:

_____

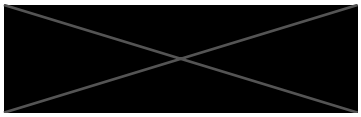
The following information applies to the individual or to his/her minor child. If the subject is a minor, use of "you" refers to "your child".

Are you participating in any other research studies? _____ Yes _____ No

Are you willing to be contacted in the future for other research studies? ____ Yes ____ No

Date: _____

FOR QUESTIONS ABOUT THE STUDY, CONTACT:
David S. Hong, MD and Eric Kuhn, Ph.D.



INFORMED CONSENT:

You and your child are invited to participate in a research study examining telehealth platforms used for psychotherapy in children with mood and anxiety symptoms. This study is designed to examine the similarities and differences in standard videoconferencing tools typically used in telehealth, as well as platforms specifically designed for use in psychotherapy with youth, i.e. Teleo. Our study expects to enroll ~50 families. Your family was selected as a possible participant in this study because you have been identified as someone who is or will be receiving psychotherapy via telehealth.

Your family's participation in this study is entirely voluntary. Your family's decision not to participate will not have any negative effect on your family or your medical care. You and your child may decide to participate now, but withdraw consent later and stop being in the study without any loss of benefits or medical care to which you are entitled. You and your child have the right to refuse to answer particular questions.

Your participation in the study can last up to four sessions (approximately one month), depending on the duration of your involvement in psychotherapy, though your ongoing clinical treatment with your provider may last longer than this time. As part of the study, your family will have a fifty percent chance of using a standard telehealth platform employed by your therapist, such as Zoom, Microsoft Teams, etc., and a fifty percent chance of using the Teleo telehealth platform.

If you and your child decide to participate, Drs. Hong, Kuhn and their associates will ask you and your child to participate in one or more of the following tests (marked with an "x"):

☐ Questionnaires and Clinical Metrics: As part of your telehealth psychotherapy treatment, you are periodically completing behavior questionnaires to monitor progress. You and your child are willing to share the results of your clinical questionnaires used by your therapist with our research team. These questions relate to your family and child's functioning, including topics such as frequency, intensity and duration of symptoms and overall functioning. Clinical metrics, such as frequency of cancellations/no-shows, and duration of treatment will also be collected.

☐ Photographs, Audiotaping, and Videotaping: If you agree, your teletherapy sessions will be digitally audiotaped and/or videotaped while taking part in the study. These digital audio/video recordings would be used to code the effectiveness of engagement in a telehealth setting.

If you allow audio/video samples to be used for research, they will be shared only with core research staff from this study to develop these algorithms. All recordings will be stored under a unique number and would not be associated with your name or other identifiable information. All photographs, audio recordings and video recordings will be stored on password-protected workstations and will be kept in a secure, HIPAA-compliant

server. You and your child's name or other public identifiers will not be included with any data shared with other investigators. You and your child's videos will not be shared without your express permission (see section below). All photographs, audio and videotapes will be destroyed six years after the end of the study.

Your privacy is very important to us, and we will use safety measures to protect it. Despite all of the safety measures that we will use, we cannot guarantee that your identity will never become known.

You and your child have the right to refuse to allow your videos to be studied now or saved for future study. You and your child may withdraw from this study at any time.

I give consent to have non-identifiable photos, audio, and videos of me and my child participating in the parent-child interaction therapy session to be taken while involved in the study. Please initial: _____ Yes _____ No

EXCLUSION:

If you, your child and your therapist are willing to participate, your family will be included. However, there are some exclusion criteria for this study – including presence of intellectual disability, autism spectrum disorder, psychotic disorders, high-risk suicidal behaviors requiring immediate hospitalization, substance use disorders, or other physical or mental condition that would prohibit your child from engaging in telehealth settings.

RISKS/DISCOMFORTS:

There are no risks to you or your child from the recording of therapy sessions or sharing of questionnaires. If you or your child feel uncomfortable during any portion of the research, the recording may be stopped.

BENEFITS:

The possible general benefit for science resulting from participating in this study consists of adding to the knowledge of whether psychotherapy for children can be improved in telehealth settings by using platforms such as Teleo. WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.

If you and your child do decide to participate, we invite you to ask questions about any part of the project. The only alternative to participating in this study is not participating in this study.

Participant's Responsibilities: As a participant, your responsibilities include:

- Follow the instructions of the Protocol Directors and study staff.
- Tell the Protocol Directors or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Complete your questionnaires as instructed.

- Ask questions as you think of them.
- Tell the Protocol Directors or research staff if you change your mind about staying in the study.

PARTICIPANT'S RIGHTS:

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Directors.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study. It is possible that, based on information gained from this study, the researchers may have serious concerns (relating to matters such as severe depression, physical abuse, etc.) about your health and/or safety; in such a case, the researchers may contact you (and/or your parents) and provide a referral for your care. It is possible that, based on information gained from this study, the researchers may be required to report information (e.g., information relating to suicide, physical or sexual abuse) to the appropriate authorities.

Withdrawal from Study: You and your child will be eligible to get the same quality of medical care with your usual provider if he or she is at the Stanford University Medical Center, even if you or your child decide not to participate in the project. Once started, you or your child can also change your mind at any time about whether you want to continue in the project. This also will not change or affect your child's medical care. At the discretion of the protocol director, subjects may be taken out of this study due to unanticipated circumstances.

Some possible reasons for withdrawing a subject from the study include:

- failure to follow instructions
- the investigator decides that continuation could be harmful to you or your child.
- your child needs treatment not allowed in the study.
- the study is canceled
- other administrative reason(s)

CONFIDENTIALITY:

No traditionally-used identifying information about you, such as your name, address, telephone number, or social security number, will be shared with anyone outside of the research study. Electronic records containing information that could identify you or your child, including photographic images and digital video will be kept in a password-protected, encrypted database and written records will be kept in a locked cabinet accessible only to research staff. Any data that may be published in scientific journals will not reveal the identity of your child, with the exception if you have consented to sharing images of you or your child as indicated above.

We will keep your child's study data as confidential as possible, with the exception of certain information that we must report for legal or ethical reasons, such as suspected child abuse or neglect, suspected elder abuse or neglect, or intent to harm him/herself or others. It is also possible that, based on information gained from this study, the researchers may be required to report information (e.g., information relating to suicide, physical or sexual abuse) to the appropriate authorities.

Identifiers might be removed from identifiable private information and/or identifiable specimens and, after such removal, the information and/or specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

If your family is using the Teleo platform in the study, access to the platform is through a browser without a personal login. No data is transmitted from the Teleo platform into the research study – data for this research will be acquired separately as described above. For general use of Teleo independent of the research, Teleo's privacy policy can be accessed at https://www.teleo.space/privacy.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, or harm to self or others.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

PAYMENT:
Payment is offered for participation in this study in the amount of $100.

COST:
There will be no cost to you for participation in this study.

SPONSOR:
This study is sponsored by the National Institutes of Health.

Authorization To Use Your Health Information For Research Purposes

Because information about you/your child and your/your child's health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your/your child's health information will be used or disclosed in the study. Your/your child's information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will our health information be utilized in the study? Your child is invited to participate in a research study examining telehealth platforms used in psychotherapy sessions. This study is designed to determine if some telehealth platforms perform different from others. You and your child's recordings will be used in the study analyses and resulting findings will be published.

Do I have to sign this authorization form? You do not have to sign this authorization form. But if you do not, you and your child will not be able to participate in this research study. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later? If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your/your child's health information (and to discontinue any other participation in the study) at any time. After any revocation, your/your child's health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your/your child's health information in this study, you must contact: Dr. David S. Hong, 401 Quarry Road MC 5795, Stanford, CA 94305.

What personal information will be used or disclosed? Personal health information from your/your child's health information related to this study, may be used or disclosed in connection with this research study, including,

but not limited to your name, telephone number, address, electronic mail address, birth date, and audio/video recordings of therapy sessions.

Who May Use or Disclose the Information? The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Directors (Dr. David S. Hong and Eric Kuhn)
- The Stanford University Administrative Panel on Human Subjects in Medical Research
- The Study Coordinators
- Teleo (MainSquare Co.)

Who May Receive/Use the Information? The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire? Your authorization for the use and/or disclosure of your health information will expire on February 1, 2088.

Will access to my medical record be limited during the study? To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make medical or billing decision about you (e.g., if included in your official medical record).

_____ _____

Signature of Adult Participant Date

_____

Printed Name of Adult Participant

_____ _____

Signature of Legally Authorized Representative (LAR) Date

_____ _____

Printed Name of LAR LAR's Authority to Act for Subject (e.g., parent, guardian or conservator)

CONTACT INFORMATION:

Appointment Contact: If ou need to chan e our appointment, please contact the study team [redacted]

- Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director. You may contact him now or later at (Dr. David S. Hong at [redacted]).
- Injury Contact: If you feel you have been hurt by being a part of this study, or need immediate assistance please contact (Dr. David S. Hong at [redacted])
- Alternate Contact: If you cannot reach the Protocol Director, please call or text the research team at [redacted]
- Independent of the Research Team Contact: If you are not satisfied with the manner in which this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a research study subject, please contact the Stanford Institutional Review Board (IRB) to speak to an informed individual who is independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. Or write the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Signing your name means you agree to be in this study and that you were given a copy of this signed and dated consent form.

_____ _____

Printed Name of Adult Participant Date

_____

Signature of Adult Participant

_____ _____

Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____ _____

Printed Name of LAR LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

The IRB determined that the permission of one parent is sufficient for research in accordance with 45 CFR 46.408(b).

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent