Agile Development of a Digital Exposure Treatment for Youth with Chronic Musculoskeletal Pain

Informed Consent Form

NCT05079984

May 15, 2024

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Approval Date: May 15, 2024
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STANFORD UNIVERSITY Research Consent Form

Protocol Title: iGET Living: A smartphone-delivered Graded Exposure Therapy Intervention for Pediatric Chronic Pain

Please acknowledge that you are either an:

☐ I am an adult participant in this study.

Or

☐ 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.")

DESCRIPTION:

Why is this research being conducted? What is its purpose?

You and your child are invited to participate in a new treatment research study at Stanford University. The primary goal of this study is to examine the effectiveness of a digital, exposure-based intervention for adolescents with chronic pain. The intervention is called iGET Living. During iGET Living, you will participate in the online treatment daily, working through different treatment modules covering topics such as education about chronic pain and working on goals to support chronic pain management. Each daily module takes 5-15 minutes. The intervention will take about 6-weeks to complete. Parents will access a separate website that also has education and exercise to complete.

Who is conducting this research study, and where is it being conducted?

This research is being conducted by Dr. Lauren Harrison, PhD at the Stanford Pediatric Pain Management Clinic. This study will be conducted through Stanford University, although actual participation in the intervention will take place via the internet. This research is funded by the National Institute of Arthritis and Musculoskeletal and Skin Diseases at the National Institute of Health.

How are individuals selected for this study? How many will participate?

We are asking you and your child to participate in this study because your child is between the ages of 10-18. In addition, they:

- Have a diagnosis of chronic pain (> 3 months)
- Experience difficulties in daily functioning as a result of their pain

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What do I have to do if I am in this research study?

- **Daily diary:** If you and your child agree to join this study, you and your child will be asked to complete a daily diary each day for one week before you start the treatment. The daily diary will be completed using the LifeData app. When you download the app, you will need to agree to the app's End User License Agreement, Terms of Use, and Privacy Policy. The End User License Agreement,Terms of Use, and Privacy Policy is separate from this consent form and should be read carefully before you download the app onto your device. Answering questions in the daily diary will take approximately 2 minutes to complete each day. You will also be asked to fill out the electronic diary during treatment and for one week at 3-month post end of treatment.

- **Biomechanical Assessment:** At your baseline and discharge visit, you will be assessed for your range of motion and activity using video motion capture. Please note that the biomechanical assessment sessions will be video-recorded for quality assurance purposes of administration of the treatment, training future clinicians, and to present at research and clinical meetings to disseminate this treatment approach. These recordings will be de-identified and stored securely in the lab to protect your privacy. Only limited members of our study team will have access.

- **Treatment:** During iGET Living, your child will participate in the treatment daily for 5-15 minutes for 6 weeks. Parents will also receive a log-in for a separate online treatment and will be able to review parent-specific content and complete exercises. In iGET Living, you will work through different treatment modules covering topics such as education about chronic pain and setting goals of things you would like to work on during the course of treatment. Although this intervention is accessed through your smart phone, tablet, or computer, you will have regular contact with your treatment team through a messaging function. For example, you can ask your treatment team questions about specific topics or assignments. The treatment team will also provide you feedback on completed tasks and assignments. The primary therapist in this intervention will be a licensed clinical psychologist with experience in this kind of treatment.

- **Maintain your current treatment plan:** We want to minimize the introduction of new treatments while involved in this treatment regimen. We ask that you continue any treatments that you are currently doing. If you will be starting any new treatments as a result of your multidisciplinary pain clinic evaluation, we will wait a few weeks to start iGET Living so that you can get used to that treatment before starting iGET Living. If you choose to start a new treatment after iGET Living begins, you will decide with the treatment team if it makes sense to continue with iGET Living treatment or focus on the other treatment option.

- **Surveys:** Along with the Daily Diary, you will also fill out questionnaires before

treatment, when treatment ends, and during the 3-month follow up period. The questionnaires that you complete ask about how you think and feel about your pain and how pain impacts daily functioning. It will take you about 30-45 minutes to do the questionnaires each time. You can choose not to answer a question on the surveys at any time.

- **Exit Interview:** After the 6-week intervention, we will hold an optional exit interview, via zoom, with you to gain your insight on your experience participating in the intervention. The exit interview will take about 30 minutes to complete.

RISKS AND BENEFITS:

What are the risks of this research study? What could go wrong?

The study may present a small amount of risk to you and your child, but there is also potential for direct benefit. More specifically, your child may experience some emotional discomfort when participating in iGET Living, but we do not believe participation to be harmful or dangerous to your child and their pain. We anticipate any emotional discomfort your child may experience would be equivalent to what they might feel during outpatient psychological treatment.

Use of online technologies to collect and store research data inherently involves a certain level of risk. Despite our rigorous security measures and protocols, there is still a potential risk of a data breach. In such an event, your information could be accessed by unauthorized individuals. To minimize this risk, we store all identifying information in secure databases and encrypted folders. We assign all participants non-identifiable study ID's and email addresses to keep data de-identified.

There is some risk of emotional discomfort when responding to questionnaire items, as answering questions about psychological or behavioral problems can sometimes make people uncomfortable. However, we hope to minimize any emotional discomfort with the assurance that you are free to skip any question that makes you uncomfortable. Remember that all information will be kept confidential. Additionally, Dr. Harrison (PI) and/or Dr. Simons (PD) will be available by voicemail (605-498-2486—Dr. Harrison; 650-736-0838—Dr. Simons) for consultation.
If we detect a risk for harm to self or suicidality, a suicide risk assessment will be conducted and a mental health clinician will decide on the best course of action to ensure the safety of the child or parent. This may also include notifying you, the parent(s), therapist(s) if applicable, or other individuals. If this were to occur, we would not be able to assure confidentiality. To deal with potential discovery of child abuse, the Child Protection Team at Lucile Packard Children's Hospital will be and reported to the police if needed.

What are the benefits of this research study?

Potential benefits of this study include improved daily functioning; including a return to previously avoided daily activities, and potentially a reduction in pain symptoms. You may feel positively about contributing to research that may help future patients with pain, as the study will contribute to our understanding of pediatric chronic pain treatment. The study's results will also provide important information about the efficacy of iGET Living in adolescents with chronic pain and expand treatment options for children struggling with chronic pain.

Are there costs associated with this research study?
There will be no costs to you or your child for participating in this research study.

If I do not want to take part in this research?
Your participation in this study is voluntary. You may withdraw at any time. Your decision not to participate or withdraw will not affect the care your child receives from this institution.

Why would I be taken off the study early?
If you or your child fails to follow the study requirements, the Principal Investigator may take you off the study early. The PI also may take you off the study early if she feels it in the best interest of you/your child to be taken off this study.

TIME INVOLVEMENT: Your participation in this study will span approximately 3 months. Exact duration will be dependent on the individually tailored number of modules completed. Each module will take approximately 5-15 minutes to complete and will be done every day for 6 weeks. Also, daily diaries will be sent each day for one week before the start of treatment and during the treatment (6 weeks). The daily diaries will take approximately 2 minutes to fill out. In addition, the optional exit interview will take about 30 minutes to complete.We will contact you for follow-up at 3 months post-therapy, and during this time we will ask you to fill out questionnaires and daily diaries for 7 days.

PAYMENTS: Your child will also be compensated at various stages of the study in the form of Amazon Gift Cards. This includes:

- $[redacted] gift card at the start of treatment after baseline completion of questionnaires, daily diaries, and biomechanical testing;
- $[redacted] gift card after completion of treatment, daily diaries, end of treatment questionnaires, and biomechanical testing;
- $[redacted] gift card at the 3-month follow-up for completion of questionnaires and 7-day daily diary.
- $[redacted] gift card for completing the optional exit interview.
- $[redacted] gift card if you withdraw from the study between the baseline, discharge or 3 month follow-up timepoints

PARTICIPANT'S RIGHTS:

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If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. The results of this research study may be presented at scientific or professional meetings or published in scientific journals.

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.

You have the right to refuse to answer particular questions.

CERTIFICATE OF CONFIDENTIALITY

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 the National Institute for Arthritis and Musculoskeletal and Skin Diseases (NIAMS) 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.

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The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document such as including research data in the medical record.

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Authorization To Use You or Your Child's Health Information For Research Purposes

Because information about you and your child's health is personal and private, it generally cannot be used in this research study without your written authorization. If you agree to this form, it will provide that authorization. The form is intended to inform you about how you or your child's health information will be used or disclosed in the study. Your 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 agreeing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of this study is to examine the feasibility and effectiveness of a digitally delivered intervention for adolescents with chronic pain. You or your child's health information will contribute to our understanding of this intervention for adolescents with chronic pain and their parent.

Do I have to agree to this authorization form?

You do not have to agree to this authorization form. But if you do not, you 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 agree, 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 you or your child's health information (and to discontinue any other participation in the study) at any time. After any revocation, you or 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 you or your child's health information in this study, you must write to:

Dr. Lauren Harrison
3145 Porter Drive
Palo Alto, CA 94304
(650)-498-2486

What Personal Information Will Be Obtained, Used or Disclosed?
You or 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, medical record number, zip code, birth date, telephone number, electronic mail address, familial chronic pain medical history and video/audio recordings.

Who May Use or Disclose the Information?
You or your child's health information is protected by a law called the Health Information Portability and Accountability act (HIPAA). In general, anyone who is involved in this research and regulating the study may see the data, including information about you. The following parties are authorized to use and/or disclose you or your child's health information in connection with this research study:

- Dr. Lauren Harrison and/or Dr. Laura Simons
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff at Stanford University involved in this study

Who May Receive or Use the Information?
The parties listed in the preceding paragraph may disclose you or your child's 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
- National Institutes of Health-National Institute of Arthritis and Musculoskeletal and Skin Diseases

When will my authorization expire?
Your authorization for the use and/or disclosure of you or your child's health information will end on December 31, 2050 or when the research project ends, whichever is earlier.

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WITHDRAWAL FROM STUDY

There may be circumstances under which your participation may be terminated by the investigator.

- **You are not able to attend the study visits required by the study.**
- **You no longer meet the eligibility criteria**
- **If Dr. Harrison feels it is in your best interest to be taken out of this study.**

If you do withdraw from the study at any time between one of the previously mentioned milestones (baseline, discharge, or 3 month follow-up), you will be compensated with a $[redacted] gift card for your effort

CONTACT INFORMATION:
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 Principle Investigator, Dr. Lauren Harrison (605-498-2486) or the Protocol Director, Dr. Laura Simons (650- 736-0838). You should also contact her at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650) 723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Appointment/Alternate Contact: If you need to change your appointment or you cannot reach the Dr. Harrison or Dr. Simons, please contact our research coordinators at ([redacted]) [redacted]-[redacted].

Do you agree to participate in this study?

☐ I agree

☐ I agree and will participate in the exit interview

☐ Decline to participate

Please print a copy of this page for your records. If you agree to participate in this study, please complete the following surveys.