GET Living: Graded Exposure Treatment for Children and Adolescents with Chronic Musculoskeletal Pain

National Clinical Trial Identifier: NCT03699007

March 4, 2021

STANFORD UNIVERSITY Research Consent Form

Protocol Title: GET Living: Graded Exposure Treatment for Adolescents with Chronic Musculoskeletal Pain

Are you participating in any other research studies? _____ Yes _____No

DESCRIPTION:

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

You are invited to participate in a new treatment clinical trial research study at Stanford University. The primary goal of this study is to examine the differences and effectiveness of Graded Exposure Treatment (GET Living) compared to the Standard Pain Management provided at the clinic in children and adolescents with chronic pain. In GET Living you will meet with a psychologist and physical therapist at the same time in treatment. In Standard Pain Management you will meet with a psychologist and physical therapist for separate sessions. The amount of treatment that you will receive is equal. In order to understand the differences and effectiveness, you will be randomized into either the GET Living or Standard Pain Management group, which is the top-quality standard treatment provided by the clinical team at the Pediatric Pain Management Clinic.

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

This research is being conducted through a collaboration between Dr. Laura Simons, PhD at the Stanford Pediatric Pain Management Clinic, Physical Therapy in the Department of Rehabilitation Services, and the Motion and Sports Analysis Lab at Stanford Children's Health (SCH). This study will be conducted at Stanford University.

Considerations for the COVID-19 pandemic:

GET Living treatment delivery and data collection will be conducted virtually through Stanford Zoom (encrypted and HIPAA-compliant system) for all research participants until applicable Covid-19 restrictions are lifted by Stanford University. Virtual study participation may remain an option for a sub-set of participants through the end of the study.

Return to in-person treatment delivery & data collection:

We are currently re-opening enrollment for local participants who wish to attend in-person study sessions in 2021. This study has been approved by the appropriate Stanford officials to return to in-person operations, and all patient-facing clinicians will receive COVID-19 vaccinations prior to resuming in-person treatment sessions. At the time of consent, participants will indicate whether they wish to attend study sessions in person or virtually via Stanford Zoom.

Baseline Testing: All participants who elect to attend in-person study sessions at 321 Middlefield Road, Menlo Park will participate in **mandatory baseline COVID-19 testing** at one of 3 Stanford testing sites (Palo Alto, Sunnyvale, or Emeryville). These tests will be ordered by a nurse practitioner and/or MD at the Stanford Pediatric Pain Management Clinic. Once orders are placed, patients will be contacted for appointments. If you are signed up for MyHealth, you can self-schedule at certain locations.

You will be contacted by phone by a member of the pain clinic's staff only if the test results are positive for COVID-19, and both positive/negative test results will be available via MyChart. In-person participants must receive a negative COVID-19 test before attending any in-person study sessions. Positive test results will be reported by Stanford testing sites to Santa Clara county as per local county reporting requirements.

The baseline COVID-19 test is billed to your insurance as standard of care at this clinic. If SCH is out of network for your insurance provider, you may be charged an out-of-network fee.

Participants who previously tested positive and have recovered and completed their isolation will not be asked to retest for 90 days. The CDC does not recommend retesting within 90 days because reinfection is uncommon during this period and a positive PCR test without new symptoms more likely represents persistent shedding of viral RNA, rather than an active infection.

COVID-19 Safety: Participants, caregivers, and study staff will be screened for COVID-19 symptoms by SCH staff prior to entering the 321 Middlefield facility. Study participants and staff will follow all SCH COVID-19 safety guidelines (mask-wearing, social distancing, etc.). Study staff will be supplied with personal protective equipment (PPE) and cleaning supplies to ensure all areas used for study sessions are properly sanitized before and after use.

How are individuals selected for this study? How many will participate?
You have been referred to this treatment study by your treatment provider because your child has chronic pain that causes difficulty in their everyday living. Up to 74 children with chronic pain will participate in this study.

We are asking you and your child to participate in this study because your child is between the ages of 8-18. In addition, they:

- Have musculoskeletal or neuropathic pain not due to an acute trauma or any specific or systematic disease;
- AND experience difficulties in daily functioning as a result of their pain

Randomization into a treatment group will happen after consenting into this study, and how you are selected into a treatment group is similar to drawing from a hat.

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

- **Treatment & daily diary:** If you and your child agree to join this study, you will be randomly selected to either receive GET Living or Standard Pain Management treatment. Your start date will be approximately two weeks after you consent. How you are selected for the treatments and the number of days before you start treatment will be chosen by chance (like choosing a number out of hat). You will be asked to complete a daily diary each day before you start. Answering questions in the daily diary will take approximately 2 minutes to complete each day. Second, a biomechanical expert will test how you move before beginning and at the end of treatment. Last, you will be asked to wear a small, electronic device on your wrist that tracks your activity level and sleep. You will be asked to wear this from the start of the study until your last treatment session. You will be responsible for returning this electronic device at the end of your treatment period. You will also be asked to fill out the electronic diary during treatment and for one week at 3-month and 6-month follow-up.

☐ I will make sure that the Actigraph is returned to the researcher at the end of my child's treatment period.

x_____ Initials

- *GET Living*: Once treatment begins, you and your child will attend twice weekly sessions for one hour in duration for a total of 12 visits. GET Living sessions are facilitated together by a cognitive-behavioral therapist (a licensed clinical psychologist or a predoctoral psychology trainee/postdoctoral fellow in pain psychology supervised by a licensed clinical psychologist) and a physical therapist, both trained in this modality of treatment.
- *Standard Pain Management:* If randomized into standard care, you and your child will be provided the current top-quality standard care that is provided by the clinic. Your child will attend twice weekly sessions for one hour in duration for a total of 12 visits (6 visits with a cognitive-behavioral therapist [a licensed clinical psychologist or a postdoctoral fellow in pain psychology supervised by a licensed clinical psychologist] and 6 sessions of physical therapy.
  *Please note that the therapy sessions will be audio and video (when possible) 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.

- **Maintain current treatment regimen:** We want to minimize the introduction of new treatments while involved in this treatment regimen. We want you to continue any treatments that you are currently involved in. If you will be initiating any new treatments for your child as a result of their multidisciplinary pain clinic evaluation, we will begin their baseline period after any initial effects of these treatments have 'stabilized' (e.g., approximately 2-6 weeks). If you and your child choose to initiate a new treatment after GET Living treatment begins, you will decide with the treatment team if it makes sense to continue with GET Living treatment or focus on pursuing the other treatment regimen.
- **Questionnaires:** Along with the Daily Diary, you and your child will also be asked to complete a series of questionnaires at the start of treatment, the end of treatment and at follow up evaluations 3 and 6 months after treatment. We will ask your child to use a computer tablet to rate their feelings about doing daily activities. The other questionnaires that you complete ask about how you and your child think and feel about your child's pain. You/your child will likely need about 30 to 45 minutes to complete the study questionnaires. You may refuse to answer a question or questionnaire at any time, with no risk of being excluded from the study.
- **Biomechanical Assessment:** At your baseline and discharge visit, you will be assessed for your range of motion and activity by the Motion and Sports Performance Laboratory of Stanford Children's Health. We will ask you to move your body to test improvements. We may ask you to participate in virtual biomechanics assessments at the 3 & 6-month follow-up time points. *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.

☐ I consent to being contacted for possible future follow-up or studies (Optional)

x_____ Initials

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 or physical discomfort when participating in GET Living, but we do not believe participation in GET Living to be harmful or dangerous to your child and their pain. We anticipate any emotional and physical discomfort your child may experience would be equivalent to what they might feel during outpatient psychological treatment or outpatient physical therapy. To ensure that is it in your child's best interest to participate in GET Living and that they are able, your child is required to receive medical and psychological clearance from their evaluating pain physician and psychologist before participating in this treatment study.

Due to the individually tailored nature of this treatment, we can work together with you and your child to ensure that treatment proceeds at a pace that is comfortable to them, while still maintaining their motivation to move forward and continue to reach their specified treatment goals. Ever still, your child may opt out of any activity that they are not ready to do and may stop treatment at any time.

If during treatment the treating physical therapist or your child suspects an injury or notices physical abnormalities which warrant examination by an MD, your referring physician will be available for consultation and evaluation.

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. Simons (PI) will be available by voicemail (650) 736-0838 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.

Compensation for Research Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical

treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. You will be responsible for any associated co-payments or deductibles as required by your insurance.

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

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 GET Living in children and adolescents with chronic pain and expand treatment options for children struggling with chronic pain.

Are there costs associated with this research study?
If you participate in this study, the study will pay for those services, supplies, procedures, and care associated with the study that are not a part of your routine medical care. However, there may be additional costs to you. These include basic expenses like transportation and the personal time it will take to come to the study visits. You and/or your health insurance must pay for services, supplies, procedures, and care that are required during this study for routine medical care. You will also be responsible for any co-payments and/or deductibles as required by your insurance. Participation in this study is not a substitute for health insurance.

In-person trial participants may be required to obtain a baseline COVID-19 test at Stanford prior to resuming study procedures on site. This test is billed to your insurance as standard of care at this clinic. If SCH is out of network for your insurance provider, you may be charged an out-of-network fee.

Will my employment or medical care be affected by this study?
Your decision whether or not to participate in this study will not affect your employment/medical care.

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 9 months. Exact duration will be dependent on the individually tailored number of therapy sessions. Each therapy session will take approximately 1 hour twice a week for approximately 12 sessions and daily diaries will take approximately 2 minutes to fill out. We will contact you for follow-up at 3 and 6 months post-therapy, and during this time we will ask you to fill out questionnaires and daily diaries for 7 days. We may ask you to complete a virtual biomechanics assessment at these follow-ups.

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

- $30.00 gift card at the start of treatment after baseline completion of questionnaires, daily diaries, and biomechanical testing;
- $30.00 gift card after completion of treatment, daily diaries, end of treatment questionnaires, and biomechanical testing;
- $50.00 gift card at the 3-month follow-up for completion of questionnaires, 7-day daily diary, and virtual biomechanics assessment (if applicable);

PARTICIPANT'S RIGHTS: 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. However, your identity will not be disclosed.

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.
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.

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 sign 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 signing it.

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

The primary goal of this study is to understand children's pain-related behaviors, as well as parent behavior related to the child's chronic pain. This study involves understanding pain and other emotions throughout the two weeks as it relates to daily functioning. You or your child's health information will contribute to our understanding of these chronic pain-related behaviors and may help future pain clinic patients.

Do I have to sign this authorization form?

You do not have to sign 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 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 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. Laura Simons
1070 Arastradero Rd.
Palo Alto, CA 94304
(650) 736-0838

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 including those funding 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:

- The Protocol Director, 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
- Medical staff at Stanford University directly involved in your care related to the research or arises from it.

- People at Stanford University who oversee, advise, and evaluate research and care. This includes the ethics board and quality improvement program
- People from agencies and organizations that provide accreditation and oversight of research.
- People that oversee the study information such as data safety monitoring boards, clinical research organizations, data coordinating centers, and others.
- Sponsors or others who fund the research, including the government or private sponsors.
- Companies that manufacture drugs or devices used in this research.
- Federal and state agencies that oversee or review research information, such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities
- People or groups that are hired to provide services related to this research or research at Stanford University, including services providers, such as laboratories, and others
- Your health insurer for portions of the research and related care that are considered billable.

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 you or your child's health information will end on December 31, 2025 or when the research project ends, whichever is earlier.

Adult Participant (if applicable)

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

Parent/Legal Guardian Permission (if applicable)

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

_____ _____
Print Name of LAR LAR's Authority to Act for Participant

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. Simons feels it is in your best interest to be taken out of this study.**

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 Protocol Director, Dr. Laura Simons, at (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 Protocol Director, please contact our research coordinators at (650) 665-3253.

EXPERIMENTAL SUBJECTS BILL OF RIGHTS: As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;

- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

The extra copy of this signed and dated consent form is for you to keep.

Adult Participant (if applicable)

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

Parent/Legal Guardian Permission (if applicable)

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

_____ _____
Print Name of LAR LAR's Authority to Act for Participant

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

_____ _____
(If available) Signature of Other Parent or Guardian Date

_____	_____
Print Name of Other Parent or Guardian	Authority to Act for Participant
_____	_____
Signature of Person Obtaining Consent	Date
_____	
Print Name of Person Obtaining Consent	