Official Study Title: Culturally Adapted Mobile Treatment of Chronic Pain in Adolescent Survivors of Pediatric Cancer

CTG Number: NCT05746429

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CULTURALLY ADAPTED MOBILE TREATMENT OF CHRONIC PAIN IN ADOLESCENT SURVIVORS OF PEDIATRIC CANCER

Note: When we say "you" in this informed consent document, we mean "you or your child." When we talk about research, it can be called a clinical trial, research study (study), or research protocol.

Key Information

To start, we highlight here the risks, benefits and study requirements that we think you should know before deciding if you want to take part in this research study. If you're still interested, we'll then get into more details.

A. **Why are you being asked to voluntarily take part in this study?**
You are being asked to take part in this clinical trial, a type of research study, because you are a survivor of pediatric cancer and are experiencing pain.

B. **What is the usual approach to this condition/cancer?** Standard treatment for pain that continues after cancer and its treatment may include medication and/or cognitive behavioral therapy. Cognitive behavioral therapy (CBT) is a treatment that focuses on helping people change how they think and feel about pain. Our research team has adapted CBT intervention to be more user friendly across different cultures.

C. **Why is this study being done?** Survivors of childhood cancer with lasting pain may have problems with daily life, such as paying attention, sleeping, or doing fun things with their friends. A mobile cognitive behavioral therapy program for your phone (App) and non-invasive brain stimulation may be helpful for survivors with pain. Researchers at St. Jude Children's Research Hospital want to see if we can use these tools to improve pain in survivors.

D. **What will happen if you decide to take part in this study?** We will ask you to use a culturally adapted mobile cognitive behavioral therapy (CBT) program and wear a non-invasive brain stimulation device called Transcranial Direct Current Stimulation (tDCS) for 20 minutes a day, twice a week, for 6 weeks. You will only complete tDCS two days per week but can use the CBT program every day to practice skills you learn.

E. **What are the research risks and benefits of taking part in this study?** The risks of being in the study are low. The time commitment could be seen as a burden. There may be questions that make you feel uncomfortable. There is a risk of privacy loss. The most common risk of using tDCS has been noted as mild tingling and itching during the stimulation. About 1% of people reported headache, nausea or trouble sleeping after use.

F. **How many people will take part in this study?**
Approximately 30 participants (10 Black, 10 Hispanic, and 10 non-Hispanic White) will be enrolled.

G. **What are your options?**
   1) Taking part in this research study is completely your choice.
   2) If you decide to take part in this study, you can change your mind and stop at any time.
   3) If you decide not to take part in this study, you may still be able to receive care at St. Jude.
   4) You may choose no treatment or to seek treatment somewhere else.

If you are still interested in taking part in this research study, ADAPTED, more detail is provided below in the following pages.

Study Contact Details and Further Information

You are encouraged to ask any questions you wish, before, during or after your treatment. If you have any questions about the study, please speak to your doctor, who will be able to provide you with the up-to-date information about the drug(s)/procedure(s) involved. If there is anything that you do not understand, or if you have any other questions, please contact any of the people below.

Who to talk to for…	You can contact…	At…
• Any new or unexpected symptoms, side effects or discomforts • General study questions • Research related injuries • Any research concerns or complaints • Any medical or surgical treatments done outside of St. Jude such as with your local doctor or another hospital during this study	**Tara Brinkman, PhD or your St. Jude Doctor** 262 Danny Thomas Place Memphis, TN 38105	[redacted] (Main Hospital Number)
• Your rights as a research participant • Any research concerns or complaints	**Institutional Review Board (IRB)/Research Participant Advocate** * IRB is a group of scientists and community members who make sure research meets legal and ethical standards * Research Participant Advocates are individuals who are not part of the research study team and are available to you to discuss problems, concerns and questions. The Advocate can help you obtain information and can relay any input you may have concerning the research to the research study team and the IRB.	[redacted] or [redacted]

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1. Why are you being asked to voluntarily take part in this research study?

You are being asked to take part in this study because you are a survivor of pediatric cancer and report pain. This study will see if a culturally adapted mobile CBT program for pain and non-invasive brain stimulation are able to be done at your home and if they help improve pain. Taking part in this study is completely your choice. Please take your time in deciding and feel free to discuss it with your family, friends, and St. Jude staff. Before agreeing, it is important that you read this informed consent document (consent form) that describes the study. After you understand the study and if you agree to take part, you will be asked to sign this consent form. You will be given a copy to keep.

2. Who is sponsoring this study?

St. Jude Children's Research Hospital, with funding from the National Institute of Health, is sponsoring the study. The principal investigator in charge of this study is Dr. Tara Brinkman, PhD., and she can be reached at St. Jude Children's Research Hospital number, [redacted].

3. What is the purpose of this study?

Feasibility Study –

The purpose of this study is to evaluate the use of a culturally adapted CBT program for chronic pain combined with tDCS in pediatric cancer survivors. We want to see if survivors can complete the interventions at home and if they help improve pain.

4. What will be done in this study?

After a thorough consent process, the feasibility study will take place using an online virtual platform:

Consent: After reading this consent form and discussing with the study team if you decide to be in the study, we will have you sign the consent.

Cognitive Behavioral Therapy (CBT): The mobile cognitive behavioral therapy App called WebMAP mobile is the program you will be using. The app is available on Android and iOS operating systems and is an interactive, self-guided intervention with six treatment modules that focus on 1) pain education, 2) stress, emotions, and thoughts, 3) relaxation, 4) lifestyle and social interactions, 5) staying active, and 6) maintenance and relapse prevention.

Transcranial Direct Current Stimulation (tDCS): You will complete training session(s) of tDCS with the assistance of a study team member to be sure you feel comfortable with the device and instructions. Study staff will observe correct placement of the headset via virtual online platform.

Each session will involve placing electrodes on your scalp using direct current of 1 mA applied for 20 minutes, twice a week. Amperage or amp is a measurement of the strength of an electric current. The device used in this study will administer one (1) milliamp or 1/1000 of an amp. 1 mA is a very small amount of electric current.

You may be assigned placebo or what we call "sham;" this is a time when no actual current is moving through the electrodes. You will not be told if you are receiving active tDCS or sham.

You then wear the tDCS device while using the CBT application for 20 minutes twice a week for 6 weeks.

Questionnaires – You will be asked to complete several questionnaires at the beginning of the study and at the end. These will ask about symptoms such as pain, worry, and sleep.

ADAPTED Research Study Activities							
	Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6
Cognitive Behavioral Therapy (CBT)		2 times a week for 20 minutes	2 times a week for 20 minutes	2 times a week for 20 minutes	2 times a week for 20 minutes	2 times a week for 20 minutes	2 times a week for 20 minutes
Transcranial Direct Current Stimulation (tDCS)		2 times a week for 20 minutes	2 times a week for 20 minutes	2 times a week for 20 minutes	2 times a week for 20 minutes	2 times a week for 20 minutes	2 times a week for 20 minutes
Questionnaires	Complete before CBT+ tDCS						Complete after CBT+ tDCS

5. What are the risks and benefits of taking part in this study?

a. Risks

CBT: The risks of participating in the CBT is low. Time commitment could be a burden and some of the activities may make you feel frustrated. You can take a break from the program at any time.

tDCS: tDCS has been shown to be safe at the levels proposed in this study. You may notice some mild tingling where the sponges are placed on your scalp. It is also possible that you may feel tired after treatment or have some itching under the places where the sponges were on your scalp. These effects are temporary and go away after stimulation. There is a small chance you will experience a headache, nausea, or trouble sleeping (insomnia--1%). Recent studies have shown that the risk for side effects is no greater than placebo/sham conditions (no treatment).

Questionnaires: You may become tired from the amount of time needed to fill out the questionnaires. A few of the questions you will be asked may upset you. You are not required to answer any questions that make you feel uncomfortable; however, we ask that you do respond to as many questions as possible.

Interactive Virtual Platform: Because you will take part in these study activities at home, the research team will meet with you by an interactive virtual platform. This requires an internet connection and use of a laptop video camera; therefore, there is a slight risk of loss of privacy. This risk is reduced by using interactive virtual platforms dedicated to the research study team members and by using the appropriate controls on this platform, such as locking all sessions.

Loss of privacy: Very rarely, personal information from your records could be given out by accident. This might make you upset, embarrass you or affect your ability to get insurance.

b. Benefits

You may benefit from using the CBT program combined with the tDCS device for pain.

6. What are the risks to pregnancy, to an unborn child, and to the ability to have children (fertility) when taking part in this study?

There are no known risks to pregnancy, to an unborn child, and the ability to have children (fertility) when taking part in this study.

7. Can you stop taking part in this study?

a. Can you change your mind about participating in this research study?

You may change your mind about taking part in this research study and stop at any time. If available, you may continue to receive routine medical care at St. Jude or participate in another study. This decision will not affect your relationship with your doctor at St. Jude.

If you change your mind about participating in this study, samples or related information that have already been used by researchers will not be returned or removed.

b. Can you be taken out of this study without your consent?

You may be taken out of the study without your consent if it is determined that it is no longer appropriate or safe for you to continue.

8. What are your other options and can you have other treatments while taking part in this study?

a. Options

This study is completely optional. You can always choose to not take part in this research.

b. Can you participate in other research studies at the same time?

Yes, you may participate in other research studies at the same time.

9. How much will it cost you to take part in this study?

There are no costs to study participants.

10. Will you be paid for your time or expenses while taking part in this study?

Your child will be compensated for their time with a $25 electronic gift certificate when they complete questionnaires at the beginning and end of the study. You (parent or caregiver) will receive a $10 electronic gift certificate for completing questionnaires about your child at each time point.

11. What if there is a problem while taking part in this study?

If you are injured from being in this research study, please notify your St. Jude Doctor or the study doctor, Dr. Tara Brinkman, PhD, St. Jude will offer you reasonable and necessary medical treatment for that injury. If you need more care than St. Jude can provide or if you prefer to seek treatment elsewhere, we will help you find medical care somewhere else. St. Jude may bill your insurance company or other third parties, if appropriate.

It is not the hospital's policy to provide payment for other types of costs, such as lost wages, disability, or discomfort if you are injured from being in this study. You are not giving up any of your rights by signing this consent form.

12. How will new findings related to your participation in this study be shared with you?

The researcher will tell you of any new information learned during your study participant which might cause you to change your mind about continuing the study.

13. How will you find out the results of this study?

St. Jude researchers share information with people in studies in many ways including:

- Articles on www.stjude.org
- In newsletters
- In medical or scientific journals
- In the media
- A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by the U.S. Law. This website will not include information that can identify you. At most the website will include a summary of the results. You can search this website at any time.

Published research results will only describe groups of people who took part in the study. Information that points out a single person will not be in research journals or other reports.

14. Will any genetic tests be done and what are the risks of genetic testing?

No genetic testing will be done.

15. What about identifiable private information and identifiable biospecimens (blood, tissue, urine, cells, and any type of data and/or samples) obtained from you during the study?

If you choose to take part in this study, your data and/or specimens will be used to answer the research question(s) and to publish the findings of this study. Published research results will only describe groups of people who took part in the study. Information that points out a single person will not be in research journals or other reports. You will not own your research data and/or specimens. If researchers use your data and/or specimens to create a new product or idea, including those that may have commercial value, you will not benefit financially. There is no plan to share any money with you.

St. Jude's researchers and their collaborators will store the data and specimens collected in this study in electronic databases and other locations and will store specimens in the biorepository or other locations. They may use the data and/or specimens collected in this study for future research purposes and may share some of the data or specimens with others without seeking further consent from you. You may not receive results from that future research.

Sharing data and/or specimens is part of research. It may increase what can be learned from this study and future studies. Often data sharing is required as a condition of funding or for publishing study results. It is also needed to allow other researchers to validate study findings and to come up with new ideas.

Your data and/or specimens may be shared with government agencies, research collaborators, and other researchers and organizations conducting research that may not be related to this study.

Future research using your samples and data is likely to include studies that look at genomic and genetic information to understand causes and cures for health conditions. Because science constantly advances, we do not yet know what other future uses of research data and/or specimens may include. There is no time-limit on sharing of information.

This future research may be unrelated to the current study and may include outside researchers and organizations from around the world. These organizations may include for-profit companies conducting medical research. We or others who distribute data or samples may be paid for data or samples, including yours. You will not receive payment if this happens.

St. Jude will do its best to protect and maintain your data and/or specimens in a safe way. One of the ways we protect your data and/or specimens is by limiting the uses of the information and the type of information that is shared, especially your personal information. This may occur through data sharing agreements and review by oversight groups within St Jude. Often the data and specimens may be coded to protect your identity before they are shared, and we will keep the key to the code in a secure way.

If data and/or specimens are used or shared with any information that may be likely to identify you, such as your name, address, or medical record number, further institutional review and approval would be required. In these cases, we will review whether additional consent from you is required.

Generally, if your data and/or specimens are used and shared without any personal identifiers or only with information that is less likely to identify you (such as the date of a procedure), further review and approval is not needed, and you will not be contacted.

Data sharing could change over time and may continue after the study ends.

The use and sharing of your data and/or specimens is required for participation in this research study. The purpose of research is to learn and discover new information to make improvements to patient care and/or treatments. To make these improvements, research results must be shared with others. By agreeing to take part in research studies, you are agreeing for your information or data to be used and shared with others. If you are generally not comfortable with the use and sharing of your data and/or specimens in future research as explained this consent, you should talk with your doctor before agreeing to take part in this study.

16. What about permission to use your data/information (HIPAA Privacy Rule), privacy and confidentiality?

Permission to Use Your Data/Information- HIPAA Privacy Rule and Privacy

The HIPAA Privacy Rule defines the situations in which PHI (protected health information) may be used or given to someone outside of the hospital to be used or released for research and other purposes. PHI includes information such as your name, MRN, date of birth, or other identifying information, including research information placed in your medical record.

To do this research, St. Jude Children's Research Hospital (St. Jude) will need to collect, use, and share your private health information. St. Jude is required by law to protect your health information. By signing this consent form, you give St. Jude permission to use and/or release (share) your private health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

If you sign this consent form, you give permission to all researchers and their staff involved in the study at St. Jude to use or release (share) your health information that identifies you for the research study described in this document.

The health information that we may use or release includes things learned from the procedures and treatments describes in this consent form, as well as all information from your medical record (which may include information such as HIV status, drug, alcohol, or STD treatment, genetic test results, or mental health condition and/or treatment, physical examinations, and lab tests).

If you sign this consent form, you give St. Jude permission to share your information for future research studies about disease or advancing science and for future unspecified research. You also give permission for us to place this information on databases as described below under Privacy and Confidentiality.

Information from research testing will be analyzed in a CLIA-certified (medical) laboratory or a research-only laboratory. By signing, you give St. Jude permission to put your research information obtained from a CLIA-certified laboratory into your medical record. Results from research-only laboratories will not be put into your medical record and will not generally be available to you or your doctor.

Any information placed in the medical record becomes a permanent part of your record, is kept indefinitely, and is not protected by a Certificate of Confidentiality (Certificate of Confidentiality, if included with this study, is described below under Privacy and Confidentiality). It is protected like any other part of your medical record as described in the Notice of Privacy Practices. You have the right to see, copy, and ask for changes to your PHI that will be used or shared. However, research information may not be available until after the end of the study.

When you first registered at St. Jude, you received a copy of the St. Jude Notice of Privacy Practices. It tells how your PHI, including research information placed in your medical record, may

be used or given to someone outside of St. Jude. You have the right to read the Notice of Privacy Practices before you sign this consent form. It may have changes since you first registered at St. Jude. You can find it at the bottom of every page on the St. Jude internet website: www.stjude.org

The people who may view, request, receive, or use your private health information include St. Jude researchers and their staff, and other doctors, nurses, and staff members. Additionally, St. Jude may share your information with other people or groups of people. These include:

- Office of Human Research Protections (OHRP)
- National Institutes of Health (NIH), HEAL Initiative: The Helping to End Addiction Long-term initiative
- Other government agencies
- Your insurance company and other health benefits plan
- St. Jude Children's Research Hospital Institutional Review Board (IRB)
- Other committees or people involved in overseeing research studies

You do not have to sign this consent form which gives your permission, but if you do not, you may not receive research-related treatment.

Please note that you may change your mind and take back (revoke) this permission at any time. Even if you take back this permission, St. Jude Children's Research Hospital may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To take back this consent form/permission, you must write to:

HIPAA Privacy Officer
St. Jude Children's Research Hospital
262 Danny Thomas Place, Mail Stop 280
Memphis, TN 38105

This permission does not have an expiration date.

Confidentiality

We will protect the confidentiality of your information to the extent reasonably possible.

Researchers and study staff are required by law to report suspected child abuse, threat of harm to self or others, and certain diseases that spread from person to person.

If you consent to take part in this study, all information learned from the study, as well as information about disease signs and symptoms, will be entered into a database maintained by the Department of Psychology and Behavioral Sciences and the Department of Epidemiology and Cancer Control. The information will be held securely on paper and electronically. Your name will not be passed on to anyone else outside the research team, who is not involved in the study. You will be assigned a study number, which will be used as a code to identify you on all study forms. Any research-related information about you that leaves the hospital will be identified only by your research study number.

Data obtained from the sessions and questionnaires will be de-identified before data analysis.

There are two types of databases used for sharing research data. One is a public, unrestricted access database and the other is a controlled access database. Each is described below.

Unrestricted access databases:

The information from research studies using your samples, genetic information, and some health information may be freely available in a public, unrestricted database that anyone can use. A public database could include information on hundreds of thousands of genetic variations in your DNA code, as well as your ethnic group and sex. Summary-level information about all participants included in a dataset, including you, but not genetic data for each individual, may be shared.

Some examples of information that may be shared includes how different genes are associated with different traits or diseases across the many participants in the dataset, or how often certain gene changes are seen across participants from many studies. However, the risk of anyone identifying you with this information is very low. This public information will not be labeled with your name or other information that could be used to easily identify you.

Controlled access databases:

Your individual genomic data and health information may be put in a controlled-access database. This means that only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your genomic data and health information will not be labeled with your name or other information that could be used to easily identify you.

Researchers approved to access information in the database must agree to protect the information and not to try to identify you. Examples are the St Jude Cloud, which is run by St. Jude, the database of Genotypes and Phenotypes which is run by the Federal Government, and the European Genome-Phenome archive. These are databases available to researchers to use genomic information from tumor and non-tumor samples to study genetic changes in pediatric diseases.

17. Optional Research Tests or Procedures

There are no optional research tests or procedures for this study.

If you decide you would like to take part in this research study, please ask any questions you have, and read and sign this consent form. You will be given a copy of it to keep. A copy of this consent form will also be put in your patient notes, one will be put with the study records, and one may be sent to the Research Sponsor.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this informed consent document and to consider taking part in this study.

18. Signatures

PARENT/Legal GUARDIAN STATEMENT (Required for participants younger than 18 years):

I have read this consent form or it was read to me. I have been encouraged to ask questions and all my questions have been answered. I give my permission for my child to be in this research study.

_____ _____ _____AM/PM

Parent/Legal Guardian Signature Date Time (circle one)

ASSENT DISCUSSION (Required for participants 7-17 years old)

□ The research was explained to the minor participant aged 7 to 13 years in age-appropriate terms and the minor verbally agreed to take part in the study.

□ Minor Age 14 to 17 years old Assent Signature:

I have read this consent form or it was read to me and discussed in a way that I could understand. I have been encouraged to ask questions and all of my questions were answered. I agree to take part in this research study.

_____ _____
_____AM/PM

Minor Assent Signature Date Time (circle one)

□ Minor declined to take part in the study. The minor declined for the following reason(s):

_____
_____

□ An assent discussion was not initiated with the minor for the following reason(s):

□ Minor is under 7 years of age.

□ Minor is incapacitated.

□ Minor refused to take part in the discussion.

□ Other_____

RESEARCHER/DESIGNEE STATEMENT:

I have explained the research to the participant and his/her parent(s) or legal guardian(s). The research participant and parent(s)/guardian(s) were encouraged to ask questions and all questions were answered to their satisfaction. A copy of this consent form has been given to the participant or his/her representative.

_____ _____ _____AM/PM

Researcher/Designee Signature Date Time (circle one)

_____

Researcher/Designee Print Name

_____ _____ _____AM/PM

Interpreter (if needed) Signature Date Time (circle one)

For non-English speaking participants, an interpreter is required. The interpreter may serve as the research participant advocate unless mandated otherwise by the IRB.

PLEASE UPLOAD COMPLETED CONSENT FORM TO EPIC.