26.02.2026

INFORMATION SHEET FOR ADULT PARTICIPANTS
PHASE 3

Project title: *PsyCARTkids: Bio-psychological impact of cognitive training and mindfulness in children after CAR-T therapy, hematopoietic transplantation, or chemotherapy: mixed methods study and randomized controlled trial.*

Principal investigator, department/unit, and center: *Dr. Eduardo Fernández Jiménez, Department of Psychiatry, Clinical Psychology, and Mental Health, La Paz University Hospital (Madrid).*
Version number and date: *version 2.0, January 12, 2024.*

Introduction
We would like to provide you with information about the third phase of a study in which we invite you to participate. This study is part of a larger project that combines different methodologies (a first phase of psychological and neuropsychological evaluations; a second phase of group discussion sessions; and this third phase of online interventions). We want you to receive accurate and sufficient information so that you can decide whether or not you want to participate in this study. We will answer any questions you may have at any time. You can also ask other people if you need to.

Voluntary participation
We would like to inform you that your participation is voluntary and that you can decide not to participate or change your mind and withdraw your consent at any time. This change of mind will not affect your relationship with the healthcare team treating you, nor will it change your treatment.

Description and general objective of the study
This third phase of the study will analyze the effect of two psychological treatments, both offered online to children and adolescents who have received CAR-T therapy, a hematopoietic transplant, or chemotherapy alone: a brain training treatment (to improve attention, memory, mental control, etc.), and another treatment to improve emotion management using a technique called mindfulness (which trains people to focus on the present moment, without getting caught up in emotions or self-criticism). To prove that both treatments work, psychological and neuropsychological assessments will be carried out before, after, and 6 months after both treatments. Neuropsychological tests are used to understand how a person's brain works by evaluating aspects such as attention span, memory, language, and reasoning. While these tests are being performed, the brain's electrical activity will be measured using patches placed on the scalp. In addition, some data will be collected from the tests that are usually performed at the hospital and found in your medical records. Below, we explain what you and your parents will be asked to do:

DESCRIPTION OF THE TWO INTERVENTIONS

A) Brain training

This treatment consists of playing games on a computer program (similar to a video game) to train your mental agility, attention, memory, planning skills, etc. This platform is called Sincrolab and you will have access to it free of charge. This treatment will last 3 months and you will play the games 4 days a week, for 15 minutes each time. In addition, once a week for one hour, there will be a group session via video call with four other children to discuss any difficulties you are having with the games and the reasons why you are unable to use them as instructed. In total, this treatment will take two hours per week. In turn, to encourage you to use these games, you or your parents/guardians may also receive a weekly phone call from one of us.

B) Mindfulness-based emotional management treatment
This treatment consists of exercises to pay attention to your breathing, other bodily sensations, thoughts, and feelings, without trying to change how they appear. This treatment will last 3 months

and consist of a one-hour group session per week, via video call, with approximately 5 other children of your age. In addition, we will give you homework assignments of about 15 minutes each, 4 days a week, to put into practice what you have learned in these group video calls. The material for these assignments will be available free of charge.

Treatments A and B will be carried out consecutively after completing the previous one, with a one-week break between them, during which you will have to complete another questionnaire, called the intermediate phase questionnaire (the BASC-3 questionnaire), which will be filled out by both you and your parents/guardians. However, another group of participants will start with treatment B first and then continue with treatment A. In total, the combined time for both interventions will take 6 months.

EVALUATION BEFORE AND AFTER COMPLETING BOTH TREATMENTS

Patient:

- *You will need to complete the following online questionnaires, which will take approximately 50 minutes for each of the two assessment sessions (before and after completing both treatments):*
    - *BASC-3 (version completed by you): This questionnaire measures adaptability, attention problems, emotional problems, and behavioral problems observable at the family, social, and school levels.*
    - *BPI: This questionnaire measures pain.*
    - *AIQ: This questionnaire measures sleep quality.*
    - *PROMIS: This questionnaire measures sleep quality.*
    - *CAMM: This questionnaire measures your personal style of focusing on what is happening right now (and not getting distracted by things from the past or future), being kind to yourself, without criticizing yourself.*
- *We suggest you take the following neuropsychological tests and have your brain's electrical activity measured. These will be carried out at the hospital, and each of the two assessment sessions (before and after completing both treatments) will last approximately 90 minutes:*
    - *SDMT: This test assesses processing speed (mental agility)*
    - *K-CPT-2/CPT-3: This test assesses sustained visual attention.*
    - *ECM: This test assesses different types of memory.*
    - *TFV: This test assesses verbal fluency.*
    - *STROOP: This test assesses the ability to inhibit automatic responses.*
- *Measurement of your brain's electrical activity. This will be done with patches placed on your hair while you perform the neuropsychological tests described above.*

Parents/Legal Guardians:

- *We suggest you complete the following online questionnaires, which will take approximately 40 minutes:*
    - *BASC-3 (parent-reported version): This questionnaire measures adaptability, emotional problems, and observable behavioral problems.*
    - *BRIEF-2: This questionnaire measures higher brain functions such as planning, organization, self-monitoring, emotional control, and self-control, etc.*

INTERIM ASSESSMENT

Patient:

- *You will need to complete the following online questionnaire, which will take approximately 20 minutes:*
    - *BASC-3 (self-report version): This questionnaire measures adaptive skills, attention problems, emotional difficulties, and observable behavioral problems at the family, social, and school levels.*

Parents/Legal Guardians:

- *We ask that you complete the following online questionnaire, which will take approximately 20 minutes:*
    - *BASC-3 (parent-report version): This questionnaire measures adaptive skills, emotional difficulties, and observable behavioral problems.*

6-MONTH FOLLOW-UP ASSESSMENT AFTER COMPLETION OF BOTH TREATMENTS

Patient:

- *You will need to complete the following online questionnaires, which will take approximately 50 minutes:*
    - *BASC-3 (versión rellenada por ti): Este cuestionario mide la capacidad de adaptación, problemas atencionales, emocionales y problemas de conducta observables a nivel familiar, social y escolar. BASC-3 (self-report version): This questionnaire measures adaptive skills, attention problems, emotional difficulties, and observable behavioral problems at the family, social, and school levels.*
    - *BPI: This questionnaire measures pain.*
    - *AIQ: This questionnaire measures sleep quality.*
    - *PROMIS: This questionnaire measures sleep quality.*
    - *CAMM: This questionnaire measures your personal style of focusing on what is happening right now (rather than getting distracted by the past or the future), and being kind to yourself without self-criticism.*

Parents/Legal Guardians:

- *We ask that you complete the following online questionnaires, which will take approximately 40 minutes:*
    - *BASC-3 (parent-report version): This questionnaire measures adaptive skills, emotional difficulties, and observable behavioral problems.*
    - *BRIEF-2: This questionnaire measures higher-level brain functions such as planning, organization, self-monitoring, emotional control, self-regulation, etc.*

Risks and Discomforts Associated with Participation in the Study

Since previous studies have shown that the two treatments used in this phase are safe, no risks are expected as a result of your participation. You will only need to dedicate some extra time at home to complete the tasks for each online treatment, and your hospital visits will be slightly longer due to the evaluation assessments. Additionally, the patches (EEG) used to measure brain activity are also a safe method and do not cause any physical or emotional harm. With some exercises from the treatment called mindfulness, you may feel a little restless when trying to concentrate, but this does not always occur and usually goes away as you continue practicing the treatment.

Possible Benefits

Since previous studies have shown that brain training and emotional regulation training using mindfulness techniques are effective, you may notice improvements in areas such as your ability to concentrate, mental agility, memory, mental organization, and how you manage your emotions in everyday life. However, it is possible that in your particular case you may not notice any changes.

Financial Compensation

We do not offer payment for participating in the study. There will also be no cost to you.

Contact

If you have any questions about the use of your data, any other concerns, or complaints about the study, you should contact ***Dr. Eduardo Fernández Jiménez at phone number +34630305521498401.***

26.02.2026

INFORMATION SHEET FOR ADULT PARTICIPANTS
PHASE 3

Project Title: *PsyCARTkids: Bio-psychological Impact of Cognitive Training and Mindfulness in Minors After CAR-T Therapy, Hematopoietic Transplant, or Chemotherapy: Mixed-Methods Study and Randomized Controlled Trial.*

Principal Investigator, Department/Unit and Center: Dr. Eduardo Fernández Jiménez, Department of Psychiatry, Clinical Psychology and Mental Health, Hospital Universitario La Paz (Madrid).

Version Number and Date: *Version 2.0, January 12, 2024.*

Consent
I (first and last name of the patient)_____on my own behalf,

Have read the information sheet provided to me and have been able to ask questions and receive sufficient information about this third phase of the study. I understand that I may withdraw from the study at any time without giving any explanation and without this affecting my medical care.

Withdrawal of this informed consent will not affect activities already carried out or the use of data obtained based on the informed consent prior to its withdrawal.

- By providing my data, I confirm that I have read and fully accepted its use as explained to me.
- I freely give my consent to participate in this third phase of the study.

Signed in Madrid on_____of_____20___.

Signature:..... Signature:.....

Investigator:_____ Patient:_____

[COPY FOR THE INVESTIGATOR]

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- I freely give my consent to participate in this third phase of the study.

Signed in Madrid on_____of_____20___.

Signature:..... Signature:.....

Investigator:_____ Patient:_____

[COPY FOR THE PATIENT]

26.02.2026

CONFIDENTIALITY / DATA PROTECTION
RESEARCH STUDY CONSENT
PHASE 3

By means of this document, and in compliance with current data protection regulations, I acknowledge that I have been informed and fully authorize the use of data from my medical record, as well as data resulting from my participation in the study entitled: *PsyCARTkids: Bio-psychological Impact of Cognitive Training and Mindfulness in Minors After CAR-T Therapy, Hematopoietic Transplant, or Chemotherapy: Mixed-Methods Study and Randomized Controlled Trial.* The Data Controller is Hospital Universitario La Paz (including Hospital Carlos III – Hospital Cantoblanco), whose Data Protection Officer (DPO) is the "PDP Committee of the Madrid Regional Ministry of Health," located at C/ Melchor Fernández Almagro nº 1; 28029 Madrid. The purpose of this final phase of the study is to analyze the effect of two psychological treatments, both delivered online: a brain training treatment and a treatment to improve emotional regulation using a technique called mindfulness.

The legal basis that authorizes the processing of data is your consent, as well as Law 14/2007 of July 3 on Biomedical Research, Organic Law 3/2018 of December 5 on Personal Data Protection and Guarantee of Digital Rights, and other applicable legislation. For this purpose, your data will be retained for the years necessary to comply with applicable legal obligations, as well as for as long as it remains useful for the purpose for which it was collected, and in any case for at least five years. Access to your personal information will be restricted to the study investigator, collaborators, and other study staff, health authorities, the Hospital Research Ethics Committee, and the sponsor's monitors and auditors, who will be bound by professional confidentiality when required to verify study data and procedures, always maintaining confidentiality in accordance with current legislation. No additional data disclosures will be made except where required by law.

By providing your data, you confirm that you have read and expressly accepted its processing as indicated. You may exercise your rights of access, rectification, erasure, objection, restriction of processing, and data portability, where applicable, by written communication to the Data Controller at Hospital Universitario La Paz, Paseo de la Castellana 261, 28046 Madrid, specifying your request and including your national ID card or equivalent document. You are also informed of your right to file a complaint with the Spanish Data Protection Agency, as well as your right to withdraw your consent for data processing, which will not affect activities already carried out or the use of data obtained based on informed consent prior to its withdrawal.

Signed in Madrid on_____of_____20___.

SIGNED:

Mr./Ms. (patient's name),_____,

With ID No._____, on my own behalf.