Informed Consent Form
Participants aged > 18 year

Introduction

You are being invited to voluntarily participate in the study entitled **e-Natureza Blue Care – The impact of virtual reality on pain perception, mood states, and analgesic use in patients with oncologic pain: a randomized clinical trial**. To decide whether you would like to take part, it is important that you understand what participation involves, including potential risks and benefits, and confirm your agreement by signing this informed consent form.

If you have any questions after or during the reading of this form, please feel free to contact the principal investigator or any member of the study team to address your concerns.

Participation in this study is entirely voluntary. You may choose not to participate or to withdraw at any time, without any negative consequences for your treatment or professional relationship with the institution.

The aim of this research is to contribute to the therapeutic arsenal for the treatment of cancer patients with chronic pain through the use of immersive virtual reality.

Study Procedures

Your participation in this study will be divided into two groups:

Group 1 (Control Group):

In this group, you will be asked to complete four questionnaires: a sociodemographic and professional background questionnaire, a pain level assessment scale, a scale to evaluate your mood and well-being, and a scale to

assess your connection with nature. It is estimated that completing these questionnaires will take approximately 20 minutes.
Important: In this group, immersive virtual reality (VR) with nature imagery will not be used. You will continue to receive only the analgesic treatment prescribed by your physician.

Group 2 (Intervention Group):
After completing the same four questionnaires described for Group 1, you will participate in an immersive virtual reality experience using VR goggles that display natural environments, such as beaches and waterfalls. This experience lasts approximately eight minutes. The goggles are sanitized between uses, and disposable face covers are used to ensure your safety.
All questionnaires will be provided in printed format. After completion and signing, they must be returned to the research staff.

After signing this informed consent form, you will be randomly assigned to one of the two groups (Group 1 or Group 2). Regardless of which group you are placed in, your medical prescription will remain unchanged, and you will continue with your standard pain management therapy.
Important: There will be no costs or additional charges related to your participation in the study.After agreeing to participate and being assigned to a group, you will complete a pain assessment using a visual analog scale from zero to ten, where zero indicates no pain and ten indicates the worst pain imaginable. You will also complete a questionnaire assessing your current mood, well-being, and connection with nature. This step is estimated to take 20 minutes.
General data such as gender, age, diagnosis, and pain level will be extracted from

your medical record by the principal investigator, who is part of the hospital's pain management team.

After 24 hours, regardless of the group to which you were assigned, the principal investigator will review your electronic medical record to check for any changes in analgesic use (whether increased or decreased).
In addition, you will be asked to complete the pain assessment scale and the mood and well-being scale again. This stage is expected to take approximately 15 minutes.

Risks and Discomforts

Participants in the study may feel discomfort, such as nausea or dizziness, when using the virtual reality goggles. If you feel uncomfortable or experience any inconvenience during the study, you may stop your participation at any time without any change to the way you receive your treatment.

Only the researchers will have access to the personal information and data of the participants. There is a risk of data leakage and breach of confidentiality, which will be minimized by adhering to ethical principles for conducting research with human subjects and by not sharing this information through physical or digital means. All data will be stored securely within the institution, which uses specific platforms to prevent such occurrences and to ensure the safety of patient participation in the studies conducted.

Benefits of the Study

The study will allow patients in the intervention group to directly experience the benefits provided by virtual reality (VR) and the associated improvements in well-being resulting from this research. We expect a significant improvement in the quality of care and treatment for this patient population, as well as an increase in knowledge and related clinical practices.

On the other hand, patients in the control group will play an essential role in the research by completing questionnaires, which will allow comparison of results with the standard treatment in use. Thus, they will continue to receive their established analgesic treatment, contributing valuable data for the development of new therapeutic approaches.

Alternatives to Participation in the Study

Your participation is entirely voluntary. If you choose not to participate in the study, your prescribed analgesic therapy will be maintained, with options proposed by your medical team.

Participant Rights

Your participation is voluntary, and you may withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

There will be no cost to you resulting from this study, nor will you receive any payment for your participation. However, if any unforeseen expenses arise, you will be reimbursed.

By signing this consent form, you do not waive any legal rights, including the right to seek compensation for injury resulting from your participation.

If you wish, you may request information about the results of any tests or examinations conducted during this study at any time.

Injuries

If an injury or any harm occurs as a result of your participation in this research, you will receive full medical care without any cost to you for as long as necessary.

Confidentiality

The study team will have access to your data; however, your anonymity is guaranteed. Any scientific publications resulting from this study will not identify you as a participant under any circumstances. All data collected will be handled with strict confidentiality.

Ethics

This study was approved by the Research Ethics Committee (CEP), a group dedicated to protecting research participants and evaluating studies involving human subjects at our institution.
For any ethical questions or concerns related to participant rights, please contact the Research Ethics Committee of Hospital Albert Einstein by phone at +55 (11) 2151-3729 or by email at cep@einstein.br. The committee operates Monday through Friday, from 7 a.m. to 5 p.m., and is located at Centro de Ensino e Pesquisa Albert Einstein – Campus Cecília e Abram Szajman, Rua Comendador Elias Jafet, 755, Floor L4, Room 407-G / 407-F - Morumbi, São Paulo / SP - ZIP Code 05653-000.
For questions related to the study itself, please feel free to contact the study coordinators, Eliseth Ribeiro Leão at +55 (11) 2151-1032 (Monday to Friday, 8 a.m. to 5 p.m.) or Cibele Teixeira Souza at +55 (11) 94299-4012.

Complaints, compliments, and suggestions may be directed to the Customer Service System (SAC) by phone at +55 (11) 2151-0222, through the “Contact Us” form available on the clinical research webpage, or in person.

Consent **Signatures**

I have been informed of all details related to the study in which I will participate. I will receive a signed, dated, and initialed copy of this Informed Consent Form, and the researcher will keep another signed, dated, and initialed copy.

_____

Full Name of the Research Participant

_____Date:___/___/___

Signature of the Research Participant

_____

Full name and legible signature of the Principal Investigator

_____Date:___/___/___

Signature of the Principal Investigator