Patient Information Sheet and Informed Consent Form

Evaluating the Potential of Virtual Reality in Alleviating Pain and Anxiety among Thalassemia Patients During Intravenous Cannulation: An Interventional Cross-Over Study, 2023-2024

Informed Consent to Participate in a Research Study

1. Study Title: Evaluating the Potential of Virtual Reality in Alleviating Pain and Anxiety among Thalassemia Patients During Intravenous Cannulation: An Interventional Cross-Over Study, 2023-2024

The above-mentioned study has been approved by the Dubai Scientific Research Ethics Committee, DHA]

Principal Investigator: Sameer Khan

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Medical Record Number (MRN): _____

Site where the study will be conducted:

You/your child are invited to participate in this research study conducted at Dubai Thalassemia Centre - Dubai Health. Please, take your time to read the following information carefully, before you decide whether you wish to take part in this research study or not. You are encouraged to ask the study investigator if you need any additional information or clarification about what is stated in this form and/or in the research study as a whole. You are also free to take this information sheet and consult with your doctor or other health professionals. Please note that, should you/your child decide to participate, you/your child are free to withdraw at any time without any consequence.

In the following section indicate:

The purpose of the Research Study and Overview of Participation
We are exploring the use of an adjuvant medical device (VR headset) to reduce anxiety and better

manage associated symptoms such as fatigue, pain, anxiety and depressive syndrome, with the aim of improving patients' quality of life for patients like yourself/your child.

What is the duration of the study?
3 months, from April 15th to June 15th

Participation in the study – Why participate, what will happen on participation, what is required of the patient.

You/your child have been diagnosed with thalassemia, or are a thalassemia carrier. Thalassemia is a disease that affects men and women of all ages. Therapeutic management has many factors that can be physically and psychologically demanding. One can experience certain amounts of pain and anxiety during a procedure such as intravenous cannulation.

If you/your child agree to take part in this research, after dating and signing the consent form, you/your child will be seen in the hospital by a doctor or nurse according to your appointment. You may be accompanied by your family or friends. You/your child will benefit from the same standard care offered in referral center.

You/your child will benefit from the standard of care for your first visit, then you will have a VR session on your second visit, then another session in VR for your third visit. The VR session starts 5 minutes before the intravenous cannulation procedure, 10 minutes during the procedure and 5 minutes after, for a total of 20 minutes.

During the 3 appointments, you/your child will be asked to complete 3 questionnaires to assess various parameters associated with the clinical research (anxiety, pain and cognitive status), before and after the cannulation procedure. Statistical analyses will then be carried out, firstly to compare the data of patients who received virtual reality with those who did not. All results will be communicated to you during a follow-up consultation.

All the information collected concerning your/your child's health will be communicated at your request, before, during or at the end of the research.

Any Risks as a Result of Participating in the Study

The risks associated with this study are theoretically negligible. However, the occurrence of adverse events is possible such as virtual sickness, caused by travel in VR, the main symptoms of which are

nausea and dizziness for patients in the virtual reality group. In the event of the slightest intolerance to virtual reality, the study will be stopped, and you/your child will immediately be taken care of as normal.

Any Benefits as a Result of Participating in the Study

This study could improve or even change the management of anxiety, pain and depression in patients undergoing cannulation procedure.

This study could lead to further research, in particular with a view to improving and sustainably modifying the practice of caregivers during cannulation procedure with non-drug management, encouraging doctors to integrate these new technologies into their everyday practice.

Any Alternative Treatment:

Not applicable, we are not providing any treatment outside of your/your child's normal Standard of C

If you/your child agree to take part in this research study, please, be assured that the obtained information will be kept confidential. Those responsible for quality control in research involving the human body (laws of the UAE Public Health Code) will take all necessary precautions to ensure the confidentiality of information relating to the research, to the persons involved, and in particular to their identity, and to the results obtained.

These persons, in the same way as the investigators themselves, are bound by professional secrecy (under the conditions defined by articles of the UAE laws penal code).

During and at the end of research involving the human person, data collected on subjects and transmitted to the sponsor by the investigators (or any other specialist) will be rendered non-identifying.

Thus research data will be treated with the most discretion and will be accessible only to authorized personnel who need the data to perform their duties in connection with the research project. On CRFs and other project-specific documents, participants are identified only by a unique participant number. The information will be encrypted and stored in a secured server. Unless required by law, only the study investigator or designee, the MBRU-Institutional Review Board (MBRU-IRB), the Dubai Scientific Research and Ethics Committee (DSREC) and/or inspectors from governmental agencies will have direct access to your/your child's information.

If you/your child are harmed by taking part in this research project, there are no special compensation arrangements. If harmed due to someone's negligence, or have any concerns about any aspect of the

way you/your child have been approached or treated during the course of this study, you can contact Dubai Scientific Research Ethics Committee, DHA on 800 342 or email on DSREC@dha.gov.ae

Investigator's Statement:

I have reviewed, in detail, the informed consent document for this research study with (name of patient, legal representative, or parent/guardian) the purpose of the study and its risks and benefits. I have answered all the participant's questions clearly. I will inform the participant in case of any changes to the research study.

_____	_____	_____
Name of Investigator or Designee	**Signature**	**Date & Time**

Patient's Participation:

I have read and understood all aspects of the research study and all my questions have been answered. I voluntarily agree to be a part of/for my child to be a part of this research study and I know that I can contact at or any of his/her team involved in the study in case I have any questions.

If I feel that my questions have not been answered, I can contact the DSREC (DSREC@dha.gov.ae). I understand that sections of any of my medical notes may be looked at by responsible individuals from [Dubai Thalassemia Center] or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my/my child's records. I understand that I am free to withdraw this consent and discontinue participation in this project at any time, even after signing this form, and it will not affect my/my child's care or benefits. I know that I will receive a copy of this signed informed consent.

I agree to take part in/for my child to take part in the above study.

Name of Patient/Legal Representative or Parent/Guardian	**Signature**	**Date & Time**

Name of the Witness (if patient, representative or parent does not read)	**Witness's Signature**	**Date & Time**