Official title of the study: “Adaptive Virtual Reality for coping with involuntary early pregnancy loss – feasibility study”

Unique Protocol ID nº 07/2023

Document Date: February 6, 2023

(Logo) SESARAM The Health Services of the Autonomous Region of Madeira EPERAM

(Logo) Autonomous Region of Madeira

SESARAM, EPERAM's Health Ethics Committee

Decision regarding the document number 07/2023

A – REPORT

The Health Ethics Committee (CES) of the Autonomous Region of Madeira's Health Services, EPERAM (SESARAM, EPERAM), analysed the Research Project/Research:

"Virtual reality for post early miscarriage support - feasibility study"

SESARAM, EPERAM's Lead researcher: Doctor Patricia Silva

This is an experimental research that aims to examine an impact model application based on virtual reality for post early miscarriage support.

The Ethics Committee raised some questions about the research, about its nature, the form of recruitment, where it would take place and who will bear the expenses with occasional travels and other aspects related to the security of the data obtained.

The Ethics Committee received from the Doctor Mónica Cameirão, the lead researcher, a document where these same questions were answered, namely the reason for the research, what it consists of, who participates, risks and benefits and also about the security of the data collected, these responses were considered satisfactory.

B - CONCLUSION

CES/SESARAM, EPERAM decided to issue an Approving Decision as no ethical issues were raised.

Approved unanimously at the CES meeting on February 6th of 2023

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Adaptive Virtual Reality for coping with involuntary early pregnancy loss – feasibility study

Research team:

University of Madeira:

Mónica Cameirão, Assistant Professor

Sergi Bermúdez i Badia, Associate Professor

Rita Costa, Master's student

Diana Mendes, PhD student

Gabriel Agrela, Master's student

SESARAM:

Patrícia Silva, Hospital Assistant, Gynecology and Obstetrics Service

Inês Sargaço, Intern of Specific Training, Gynecology and Obstetrics Service

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INTRODUCTION

Early involuntary gestational loss

An involuntary early pregnancy loss, or miscarriage, occurs in about 20% of pregnancies (Quenby *et al*., 2021), catching parents by surprise and often resulting in long periods of grief and psychological stress (Brier, 2008; deMontigny *et al.*, 2017). In the present study, we define early pregnancy loss as a loss that occurs in the first 20 weeks of gestation. A gestational loss, even in the earliest stages, can lead to chronic grief that goes on for years, not showing the typical decline of grief seen in other situations, even after the birth of another child (Markin, 2017). However, despite the high incidence of miscarriages, parents' psychological distress is often devalued (Radford & Hugues, 2015; Bellhouse *et al.* 2018), leading to an increase in feelings of isolation and implying a high risk for the development of psychological disorders (Kulathilaka *et al.* , 2016; Farren *et al.* , 2020). A recent study of 492 women who experienced an early pregnancy loss showed that after one month, 29% had symptoms of post-traumatic stress, 24% symptoms of moderate/severe anxiety, and 11% symptoms of moderate/severe depression; these decreased over time but were still clinically relevant nine months after the loss (Farren *et al.* , 2020). It should be noted that satisfaction with health services regarding loss management is crucial for a faster resolution of psychological distress. A study examining the impact of satisfaction with health services on the duration of grief symptoms showed that women dissatisfied with the treatment they received still had grief symptoms two years after the loss (deMontigny *et al.* , 2017).

The high incidence of psychological morbidity after a miscarriage highlights the importance of psychological support to manage grief after the event. In fact, several studies have shown a decrease in symptoms of grief, post-traumatic stress, depression and anxiety when women underwent psychological interventions that helped them cope with their losses (Kersting *et al.* , 2013; Johnson & Langford, 2015). Unfortunately, only a limited number of women have access to professional

psychological support after a miscarriage, since this service is often unavailable or unsolicited (Kersting & Wagner, 2012). The use of Information and Communication Technologies (ICT) has great potential to increase access to emotional and psychological support. In the literature, only a limited number of studies explored the use of ICTs applied to post-gestational loss support, all were via the internet, but the results are very encouraging, showing a decrease in symptoms of post-traumatic stress, grief, and depression (Ashford, 2016).

Virtual reality

Virtual Reality (VR) is a technology with a lot of potential that allows the flexible creation of personalized treatment environments based on neuroscientific and clinical guidelines. VR enables the creation of well-controlled simulations oriented to the needs of patients, using feedback and reward mechanisms, and increasing motivation by incorporating treatments into game-like tasks. In addition, it allows you to monitor and quantify the performance and evolution of patients over time. VR has been widely used in mental health interventions directed at different domains, with the most affected disorders being anxiety, substance dependence and eating disorders, with very positive results (Cieślik *et al.* , 2020) . In particular, post-traumatic stress disorder is the one that has been most often addressed with VR, usually for exposure treatments after a traumatic event (Eshuis *et al.* , 2021) . In this context, VR has the advantage of recreating and exposing patients to traumatic situations in a safe space where their emotions can be freely expressed. The adaptability of VR is also a key feature, as it allows an easy adjustment of interventions through changes in the elements of the simulated environment, as well as adapting the scenarios to the users' individual preferences. In addition, VR has been shown to be clinically appropriate for implementing psychotherapy techniques such as Cognitive Behavioral Therapy (CBT), making it a robust tool for providing such services (Lindner *et al.* , 2019; I want *et al.* , 2019) .

Concerning the use of VR for interventions in the area of grief, not necessarily derived from a gestational loss, there is very little work. As far as we know, only one

study addressed the use of VR for patients suffering from complicated grief (grief that does not resolve over time) (Quero *et al.* , 2019) . A CBT protocol was followed using the traditional face-to-face or VR method, and the results were compared at the end of treatment, and at 6 and 12 months of follow-up. Although both methods led to significant improvements over time, the VR group was superior in clinically significant long-term change (Quero *et al.* , 2019) . The VR system used was EMMA's World, a system that has already been used in the treatment of post-traumatic stress and adjustment disorders (Guillén *et al.* , 2018) . The purpose of this system is to help process emotions associated with stressful events using 3D objects, sounds, music, and elements of personal meaning to the user. This system is also currently being used to provide psychological support after pregnancy loss, but at this time, only the protocol has been published (Corno *et al.* , 2020) . Currently, there are no published results on the use of VR systems explicitly targeted for gestational loss.

AViR Project

The AViR project is a project funded by FCT - Foundation for Science and Technology (EXPL/CCI-INF/0298/2021) that aims to fill this gap in the literature by proposing the use of a multi-scenario VR prototype that uses the adaptability of VR and traditional psychological support protocols to provide an adaptable intervention and personalized specifically oriented to grief after an early gestational loss. This prototype encompasses different virtual scenarios to address various aspects of the grief management process. All contents are defined with the collaboration of health professionals with experience in psychological support after gestational loss. The virtual scenarios are implemented in a VR display to increase the level of immersion and presence (Butussi & Chitaro, 2018), allowing the participant to be in a safe space where their emotions can be shared freely.

The present research study proposal aims to evaluate the feasibility of the proposed approach by testing the prototype system in a controlled pilot study with 20 women who suffered an early gestational loss in the last six months. We hypothesize that using the proposed VR paradigm will result in a significant reduction in symptoms

of grief, depression, anxiety, and post-traumatic stress, and that this reduction will be significantly superior when compared to the control group.

The study we propose is very innovative regarding the target population and the use of VR, specifically designed to address gestational loss. In addition, it opens a new avenue of research on a topic that is still silenced and considered taboo in our society. Thus, this interdisciplinary research has an expected scientific, technological, and social impact, namely: 1) contributes to a better understanding of the process of psychological recovery after an early gestational loss; 2) contributes to the advancement of technologies aimed at psychological support; 3) has the potential to accelerate the resolution of grief by bringing emotional and psychological support to women who do not have access to other means of support; and 4) contributes to reducing the economic burden on health care by providing tools to improve the well-being of patients.

GOALS

This study has two main objectives:

1) Evaluate the impact of the proposed VR paradigm in women who suffered a gestational loss in the first 20 weeks of gestation, compared to a control group that follows the usual follow-up;
2) Evaluate the usability, user experience, and acceptance of the proposed approach.

METHODOLOGY

Sample and recruitment

The target population of this pilot study are women who have suffered involuntary pregnancy loss in the first 20 weeks of gestation. The recruitment of participants will be led by Dr. Patrícia Silva, in collaboration with the Obstetrics and Gynecology Service of SESARAM. We intend to recruit a sample of 20 participants who will later be divided into two groups, an intervention group using VR and a control group that will have access to standard monitoring.

Inclusion and exclusion criteria

Considering the objective and target population of the AViR project, the sample will be composed of women who have experienced early gestational loss, meeting the following **inclusion criteria:**

1. Have experienced an involuntary gestational loss in the first 20 weeks of pregnancy, in the last six months;
2. Be at least 18 years of age.

As **exclusion criteria**, we consider the following factors:

1. Have a diagnosis of mental disorder;
2. Be performing psychological intervention;
3. Being pregnant;
4. Having some visual deficit that may interfere with the normal performance of VR tasks.

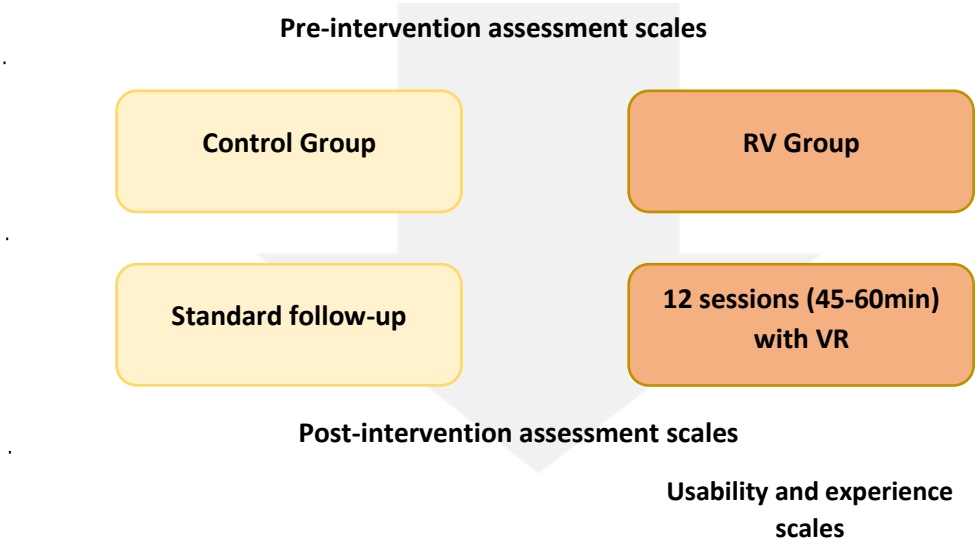
Study design

To test the research hypothesis, the proposed study follows an experimental design, namely, a randomized controlled study with two independent

conditions/groups (VR and Control). Participants who meet the inclusion criteria will be randomly allocated to one of the two groups described.

Data collection procedure

The pilot study will encompass a 4-week intervention and two evaluation moments: pre-intervention (baseline) and post-intervention, in which both groups, VR and Control, will participate. The VR group will have an intervention program lasting four weeks, with three weekly sessions of 45-60 minutes, using the developed prototype.



The VR prototype consists of VR glasses (Oculus Quest 2) where participants will experience different therapeutic modules, the contents of which were developed in collaboration with health professionals with experience in psychological support after pregnancy loss. The four modules cover: 1) **Psychoeducation**, to provide information about the grieving process, its phases, emotional and behavioral manifestations typical of this period; 2) **Validation of loss**, to recognize the loss and allow the performance of farewell and remembrance rituals; 3) Social sharing, to create a safe and judgment-free environment, conducive to sharing the experience

with others; and 4) **Adaptation to loss**, with a narrative that highlights the importance of physical well-being, social contact and the surrounding environment as fundamental elements for a healthy lifestyle. The intervention sessions with VR will be held by the master's student and graduate in Psychology, Dr. Rita Costa, who will decide which modules to apply in each session depending on each participant's response. The control group will do the standard follow-up, normally provided by SESARAM to this specific population. After the post-intervention evaluation, the control group will be given the possibility to use the VR system for four weeks, as in the case of the VR group.

The pre- and post-intervention evaluation of both groups includes a set of instruments that aim to assess symptoms of grief, depressive and anxious, and post-traumatic stress. The evaluation of usability and user experience will be carried out only by the VR group after the intervention. All evaluations will be carried out by Dr. Rita Costa. All participants will be duly informed of the objectives and procedures of the study, and will sign the participant information document and informed consent. The data collection sessions will take place in the spaces designated for this purpose in LifeTech Madeira (https://lifetech.web.uma.pt), according to the protocol signed by the University of Madeira and the Regional Secretariat of Health.

Data collection tools

To infer the possible effects of the intervention, all participants will respond to the following instruments validated for the Portuguese population, pre- and post-intervention:

- **Perinatal mourning**: *Perinatal Grief Scale* (*PGS*), a version adapted for the Portuguese population (Rocha, 2004).
- **Post-Traumatic Stress**: *Post-traumatic Stress Disorder Checklist* (PCL-5) (DSM-5 (Diagnostic and Statistical Manual of Mental Disorders, 5th edition), Portuguese adaptation (Carvalho *et al.* , 2020) .

- **Depressive and Anxious Symptomatology:** *Hospital Anxiety and Depression Scale* (HADS), version adapted for the Portuguese population (Pais-Ribeiro *et al.* , 2007).

To assess the **usability and user experience** regarding the VR prototype, after the intervention, the participants allocated to the intervention group will complete questionnaires for the corresponding objectives, namely:

- **Usability:** *System Usability Scale* (SUS) (Brooke, 1996).
- ***Presence*****:** *Sense of Presence Inventory* (ITC), adapted for the Portuguese population (Vasconcelos-Raposo *et al.* , 2019) .
- **User experience:** a questionnaire with open questions on different aspects related to the experience of using the VR system.

In addition to the instruments mentioned, a **participant form** with relevant socio-demographic and clinical information will also be completed. All the instruments referred to are attached to this document.

Data processing and analysis

The results of this study will be explicitly presented in tables and graphs. In terms of data description, categorical variables will be presented as absolute values or percentages, and quantitative variables will be presented through means, medians, standard deviations and quartiles. Regarding the statistical analysis tests, the chi-square test will be used to compare independent categorical variables; the Student's t-test to compare parametric variables; the Wilcoxon test to compare intra-subject nonparametric variables; and the Mann-Whitney test to compare nonparametric inter-subject variables. Correlations between variables will be performed using Pearson's coefficient for parametric variables and Spearman's coefficient for nonparametric variables. For all statistical comparisons, a significance level of 5% ($p < .05$) will be established. The data will be analyzed through the computer program SPSS 24.0 (IBM, NY, USA).

Dissemination of results

Considering the proposed project and the innovation of the paradigm and the interdisciplinary nature of this work, we aim to produce scientific publications in conferences and journals in the areas of Gynecology and Obstetrics, Psychology, Informatics applied to health, and/or human-computer communication. We also intend to disseminate the results obtained at regional and national level, specifically in health institutions. The goal will be to inform end-users and health professionals of the benefits that a system such as the one proposed can have on the population that has experienced an early pregnancy loss. Dissemination activities will also play an important role in raising awareness of this issue in society in general, thus contributing to increased psychological support interventions.

ETHICS

General considerations

Considering the good research practices by which we guide our scientific work, all the conditions inherent in the ethical principles associated with clinical trials with people will be considered. Since this project aims to carry out a study that involves collecting data on people, processing of personal data and observing patients, the application of appropriate legislation and regulations will be ensured before, during and after the implementation of the study. The protocol that has been detailed here is under the rules and regulations applied in Portugal and Europe. The professionals involved in this project have experience in this area of research and have previously coordinated and executed clinical trials that involved collaborations between universities and hospitals.

The project complies with European standards, such as:

- The Charter of Fundamental Rights of the European Union (in particular Article 3 - right to respect for physical and mental integrity and Article 8 - right to protect personal data).
- Declaration of Helsinki:
    - Directive 2001/20/EC of the European Parliament and Council of 4 April 2001 on the harmonization of laws, regulations and administrative provisions of the Member States concerning the implementation of good clinical practice in conducting clinical trials on medical devices for human use.
    - Council Directive 95/46/EC of the European Parliament and Council of 24 October 1995 for the protection of individuals with regard to the processing of personal data and mobility.
- Treaty on European Union: Article 6.
- Charter of Fundamental Rights of 7 December 2000.
- The project complies with Portuguese standards, such as:
    - Article 35 of the Portuguese Constitution – use of information technologies;
    - Law 67/98 – The Personal Data Protection Act.

Data protection

This protocol is in accordance with the following procedures, with regard to the processing of personal data:

- Data cannot be collected without authorization. Before starting the study, all participants will be informed verbally and in writing of the study's details, including any risk involved. All participants sign an informed consent before participating in the study.

- DBirth minutes and other personal data that can identify the person will be encrypted to protect the privacy of the patient and the data collected.
- All the information obtained will only be used within the project's scope and will not be saved for other purposes.
- Personal information will not be published or sold to third parties.
- Strict technical controls will be used to ensure that the information is not inadvertently made available to marketing institutions or third parties.

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Information To Participant and Informed Consent Form

Study Title: Virtual Reality for Support After Involuntary Early Gestational Loss – Feasibility Study

Principal Investigators: Mónica Cameirão, University of Madeira, Tlm 966926660, monica.cameirao@staff.uma.pt; Patrícia Silva, SESARAM,Tlm 969568488, patriciapereira401@hotmail.com

Other researchers: Inês Sargaço, insilva17@hotmail.com; Rita Costa, rita.costa@arditi.pt; Diana Mendes, diana.mendes@nlincs.uma.pt; Gabriel Agrela, gabrielagrela99@gmail.com; Sergi Bermudez, sergi.bermudez@staff.uma.pt

WHY IS THIS STUDY BEING CARRIED OUT?

This study aims to investigate a new approach to provide psychological support to women who, like you, have experienced an early and involuntary gestational loss. It consists of the use of a Virtual Reality system, through which it will be possible to rally different intervention sessions, with the aim of helping women who may have some difficulty in managing the grieving process.

WHAT DOES THE STUDY CONSIST OF?

This is a study that will include 20 women who experienced a pregnancy loss at the first 20 weeks of gestation. There are 2 groups: a group that uses the Virtual Reality system and a control group that does the usual follow-up in SESARAM. The assignment of the group in which you will be will be random. The study will have a duration of 4 weeks and will encompass an evaluation through questionnaires at the beginning of the study and another at the end. The assessment will be to record the symptoms of bereavement, anxiety, depression, and post-traumatic stress before and after the study. All tasks and assessments will be individual. If your group is the control group, after the final assessment, you can use the Virtual Reality system for 4 weeks.

HOW MANY SESSIONS DOES THE STUDY INCLUDE?

The Virtual Reality system group will perform 12 individual sessions of 45-60 minutes, 3 times a week, for 4 weeks. The control group shall carry out the normal follow-up indicated by the Gynecology and Obstetrics Service. Both groups will hold a 90-minute individual assessment session at the beginning of the study, and a 90-minute individual assessment session at the end of the study. The sessions will take place at the Penteada Campus of the University of Madeira.

WHO CAN PARTICIPATE IN THE STUDY?

You may participate in this study if: 1) You are 18 years of age or older; and 2) Has experienced an involuntary pregnancy loss in the first 20 weeks of gestation; and 3) the loss has occurred within the last 6 months. You cannot participate if: 1) You have other mental health situations; 2) You are performing some type of psychotherapeutic follow-up; 3) You are pregnant; or 4) You have a vision problem that does not allow you to use the Virtual Reality device.

ARE THERE RISKS FOR THOSE PARTICIPATING IN THIS STUDY?

Participation in this study does not present risks greater than the risks of any other intervention directed at grief. Some participants may experience a slight feeling of nausea (Cybersickness) when navigating the virtual environment with the virtual reality display. However, this risk will be mitigated by taking breaks during the sessions on your own initiative and/or that of the investigator.

ARE THERE BENEFITS FOR THOSE PARTICIPATING IN THIS STUDY?

You may not have any direct benefit from participating in this study. However, your participation will contribute to the development of new psychological support tools that, in the future, may help other women who find themselves in the same situation as yours.

ARE THERE COSTS FOR THOSE PARTICIPATING IN THIS STUDY?

There are no costs associated with participation in this study. Eventually, you may have travel costs to go to the sessions at the University of Madeira.

ARE THERE COMPENSATIONS FOR THOSE WHO PARTICIPATE IN THIS STUDY?

There are no compensations associated with participation in this study. You will receive a certificate of participation at the end of the study.

WHO WILL HAVE ACCESS TO THE DATA? HOW WILL CONFIDENTIALITY AND ANONYMITY BE ENSURED?

Only the researchers involved in the study have access to the data, which are exclusively for research purposes, and confidentiality is maintained. The data published and disclosed will be anonymous and confidential. The identification data collected will only be those necessary for the conduct of the study. These will not be used in conjunction with the data collected, and an identifier code will be used in all procedures and documents throughout the study. In addition, the signed terms of informed consent will be stored in a separate place from the data collected, to prevent the association of the data. Identifiable data will not be transmitted to any member who is not part of the investigation team. All sessions will be held in the privacy of an enclosed space, in a room adapted for this purpose.

WHEN AND HOW WILL THE DATA BE DESTROYED?

The data will be destroyed two years after the publication of the study results, with digital data deleted from any digital archives and paper documents destroyed in a paper shredder.

WHAT ARE THE RIGHTS OF THOSE WHO PARTICIPATE IN THIS STUDY?

Your participation is voluntary. You are free to refuse to participate or to discontinue your participation at any time. Refusal to participate or interruption of participation will not imply any loss of any benefits or health care to which you are entitled. The principal investigator may decide, in a reasoned manner, to discontinue his/her participation in this study. If this situation occurs, it will not result in any loss of any benefits or rights.

WHO CAN I CONTACT FOR ANY QUESTIONS OR CONCERNS ABOUT THIS STUDY?

If you have questions about this study, you can ask all the questions now. If you would like to ask questions later, would like more information, or wish to discontinue your participation in the study, please contact the Principal Investigators by phone or email. Contact information is available at the beginning of the first page of this document.

INFORMED CONSENT Form

I, undersigned, have been informed that the Research Study "**Virtual Reality for support after involuntary early gestational loss - feasibility study**" is intended to evaluate the impact of a Virtual Reality system on the management of grief after an involuntary early gestational loss. I know that in this study it is planned to carry out sessions with the Virtual Reality device and evaluations through questionnaires, having been explained to me what they consist of and what their possible effects are. I have been assured that all data relating to the identification of the Participants in this study are confidential and that anonymity will be maintained. I know that I can refuse to participate or interrupt participation in the study at any time, without any kind of penalty for this. I understood the information I was given; I had the opportunity to ask questions and my doubts were clarified.
I agree to participate of my own free will in the above-mentioned study. I also authorize the dissemination of the results obtained in the scientific environment, guaranteeing anonymity.

PARTICIPANT'S	SIGNATURE DATE
SIGNATURE OF THE RESEARCHER	DATA

Optional Authorization
I understand that researchers may want to use photographs or video for illustrative reasons in the presentations and publications of this work, for scientific or educational purposes. I give permission to do so, as long as anonymity is maintained.

Sign in the desired place:_____ YES _____NO