Plan Overview

A Data Management Plan created using DMPTool

Title: Immersive Virtual Reality in the treatment of patients with Parkinson's disease (ReVIEP)..

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Project abstract:

Aims. Develop a ReVIEP exercise protocol for the improvement of symptoms in people diagnosed with Parkinson's disease, capable of being implemented in an Immersive Virtual Reality environment. After its implementation and start-up, the usability of the immersive virtual reality tool, the safety for its use in PD patients and its short- and long-term effects on people diagnosed with PD will be evaluated, while analyzing whether there is a relationship between the ReVIEP protocol and a slowing of the progression of Parkinson's disease. Methodology. Single blind randomized controlled clinical trial. Sample: 44 patients of both sexes (30-80 years), distributed in 2 groups and with little evolution (6 months to 3 years from diagnosis; Hoehn and Yahr stage: I-III). Intervention: 6 months, followed by a follow-up of another 6. Frequency of sessions: 3 / week. Measurements: pre-intervention, and 3 and 6 months after its onset, as well as 1, 3 and 6 months after its completion. Assessment of aspects intrinsic to the immersive virtual reality program (safety, usability, personal experience and adherence) and of functional aspects (balance, gait and risk of falling, functional balance, functional autonomy and symptoms and follow-up in the progress of PD) and quality of life.

Start date: 01-14-2022

End date: 12-30-2024

Last modified: 02-15-2021

Copyright information:

Immersive Virtual Reality in the treatment of patients with Parkinson's disease (ReVIEP)..

Data Collection

What data will you collect or create?

The data that will be used in this project are characterized by having a quantitative and qualitative typology. Obtaining them will be carried out through: 1. Questionnaire of socio-demographic characteristics of the patients: From the clinical information that each association / neurologist has about their patients, an "ad hoc" record sheet will be created that It will include data on: age, gender, academic level, socio-economic level, as well as a clinical anamnesis of the same (pathologies, symptoms and associated pharmacology). 2. Aspects intrinsic to the immersive Virtual Reality program: Safety: evaluated using the Simulator Sickness Questionnaire; Usability: evaluated using the System Usability Scale; Personal Experience: evaluated by Game Experience Questionnaire-post-game; Adherence to the program: An ad hoc registration sheet will be made. 3. Functional and quality of life aspects: Balance, gait and risk of falling: using the Tinetti Test; Functional balance: through the "Five Times Sit to Stand test-FTSTS; Functional autonomy: through the Timed Up and Go test with the WIVA application; Symptomatology and Follow-up in the advance of Parkinson's disease: through the MDS-Unified Parkinson's Disease Rating Scale (MDS-UPDRS); and Quality of Life: through the PDQ-39 questionnaire.

How will the data be collected or created?

The data will be stored in a data file of the statistical program SPSS v25 and will be kept by the main researcher. The data will be stored until the publication of the relevant scientific contributions (congresses, articles, seminars). The data will be available to researchers, upon written request (email to IP: gfuentes@uvigo.es). After one year of the publication of scientific contributions, these data will be destroyed.

Documentation and Metadata

What documentation and metadata will accompany the data?

The database will be accompanied with labels that allow their interpretation. This information / documentation / metadata are in a folder old to the data where they will be unofficial.

Ethics and Legal Compliance

How will you manage any ethical issues?

This project will be developed following the ethical principles for medical research on human subjects, the Declaration of Helsinki, and will guarantee compliance with all the provisions established in Organic Law 3/2018, on Protection of Personal Data and Guarantee of Digital Rights (Law Organic 3/2018, of May 25), according to which the data will be kept strictly confidential, as well as the results of the tests carried out. The research team will send the present project to the Autonomous Committee of Research Ethics of Galicia (CAEI) for its approval or, failing that, make any methodological corrections it deems appropriate. In this request an informed consent will be collected, which will reflect all the procedures required based on the regulations and applicable agreements for this field of research. Once we have the approval of the same, the design of the investigation will be registered in the U.S. National Library Medicine: https://www.clinicaltrials.gov/

How will you manage copyright and Intellectual Property Rights (IP/IPR) issues?

The owner of the data is the research group that will develop the project and the scientific institution Galicia Sur Health Research Institute (IIS Galicia Sur). Sergas-UVIGO, to which they belong. The data must be requested from the IP of the project, in writing indicating the purpose of your request. No restrictions will be placed on the use of the data.

Storage and Backup

How will the data be stored and backed up during the research?

The servers of the Galicia Sur Health Research Institute (IIS Galicia Sur). Sergas-UVIGO, feel sufficient capacity to store them, so no additional charges will be included. The project IP will be responsible for their backup, recovery and destruction. The data will be recovered from the primary information collection tools used at the different moments of the evaluation.

How will you manage access and security?

The data will always be anonymized in the database and the only person who will have the identification codes will be the IP of the project. Access will be controlled by registration of request via email. Collaborators will not be able to access the database, the only authorized person will be the IP. In our case, the collaborators will be in charge of collecting the primary data, but the transfer to the database will be carried out by the IP, who is responsible at all times for the project data.

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

All data will be destroyed once a year has elapsed from the publication of results. All data will be destroyed. The data obtained will be used to communicate to the different associations involved in Parkinson's disease and to make scientific articles to be disseminated among the scientific community.

What is the long-term preservation plan for the dataset?

The data will be stored on the server of Galicia Sur Health Research Institute (IIS Galicia Sur). Sergas-UVIGO, and access to them will be by request and authorization. Access to them will have no cost. No, there is no budget for data preparation and sharing

Data Sharing

How will you share the data?

Users will find out about the data, through communication in papers, conferences and seminars. The data will be fully shared without any kind of restriction. The data will be located on the server of the Galicia Sur Health Research Institute (IIS Galicia Sur). Sergas-UVIGO and the use will be through request. The data will be made available once the appropriate publications and communications have been made and will be destroyed one year after making them available.

Are any restrictions on data sharing required?

Responsibilities and Resources

Who will be responsible for data management?

The person in charge of implementing the DMP will be the IP of the project, and he is also responsible for managing the data. No, the data will be the property of the research group and the research center to which the Galicia Sur Health Research Institute (IIS Galicia Sur) belongs. Sergas-UVIGO.

What resources will you require to deliver your plan?