Plan Overview

A Data Management Plan created using DMP Tool

Title: Immersive virtual reality as therapeutic tool for rehabilitation in patients with Parkinson's Disease (InViPark)

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Project abstract:

Parkinson's disease (PD) is a complex neurodegenerative process that usually appears after the 6th decade of life and affects up to 2% of older people (65 years or older). The global prevalence of PD is projected to double by 2,040, making it the fastest growing neurodegenerative disorder ahead of Alzheimer's disease. There is currently no curative treatment for PD, but there are various drugs available that improve the patient's symptoms both in the initial stages of the disease and in those more advanced. However, prolonged use of these pharmacological therapies will cause motor complications, such as motor disorders generated by levodopa, the appearance of "on" and "off" phenomena, mental illness, and the appearance of constipation, headache, depression, disorders sleep, etc. For this reason, it is advisable to develop, in a complementary way, non-pharmacological therapies that help in the more adequate management of the disease, this being a multidisciplinary approach. Although PD is an important cause of motor disability, exercise therapies are only present in less than a third of outpatients, being underused compared to medical treatments. Physical neurorehabilitation has been positioned as a valid solution not only for motor symptoms, but also for its neuroprotective effects and its positive influence on some NMS. The use of various exercise therapies in the parkinsonian population with the aim of attenuating the deterioration related to the disease has a significant presence in the scientific literature. In the current health emergency situation caused by the Covid-19 pandemic, concepts such as tele-rehabilitation or

neurorehabilitation programs through electronic devices constitute one of the healthcare services most demanded by patients. In recent years, Virtual Reality (VR) has acquired great relevance in the rehabilitation of motor and non-motor dysfunctions in patients of neurological origin and also in the maintenance of functional capacities in the senior group, providing an innovative approach to involve and motivate to patients during treatment sessions. At present, there are VR systems such as the IREX, CAREN, ARMEO or JINTRONIX that have been developed specifically for the field of rehabilitation, but have the limitation of being very complex and high-cost devices, making their implantation in centers unfeasible. therapeutic agents and / or their general use in the population. For this reason, VR technology based on commercially available gaming platforms, such as Nintendo Wii, Microsoft Xbox or Sony PlayStation, have become increasingly popular, representing an economical and motivating alternative. Different scientific studies have concluded that exergaming programs based on these platforms, or on their adaptations, have been feasible for their therapeutic use, improving capacities such as balance, quality of life and achieving high levels of satisfaction and adherence in people with EP. For this reason, pleasant and challenging activities with VR play an important role in avoiding problems derived from lack of motivation, providing feedback, and improving motor learning and adherence to therapeutic exercise programs. To enhance this feedback, the novel concept of immersive virtual reality (RVI) arises. This system provides a first-person perspective and involves the provision of a head-mounted display (HMD), which allows users to experience the virtual world in a much more realistic way through a multisensory approach, thus enhancing the immersion in the experience o game. This technology allows the patient to perform activities or tasks comparable to real situations, allowing a graduation of their intensity or difficulty and, finally, offering information in real time of the achievements obtained. In the recent literature, IVR has been used as support in psychotherapy in disorders such as agorophobia, psychotic disorders or anxiety, and as a treatment or assessment of cognitive-behavioral pathologies, such as hemineglect and / or executive function disorders. However, in the field of physical and functional rehabilitation of the elderly, this research team has been able to verify in a Systematic Review accepted for publication in Virtual Reality Journal (Immersive Virtual Reality as Physical Therapy in Older Adults: Present or Future) , that there is little evidence and, the existing one, is very preliminary for a future application of these immersive tools. Due to this, this research project is presented whose hypothesis is to know if the use of therapeutic exercise programs applied in fully immersive virtual environments are feasible in a population diagnosed with Parkinson's disease and can contribute to an improvement in their symptoms and a slowing down of the progression of the disease. For this, an experimental design will be carried out through a randomized and crossover controlled clinical trial. The sample will be made up of a total of 22 participants diagnosed with Parkinson's disease in stage I-III, which will be divided into two groups (Group A and Group B). The duration of the intervention will be 60 (24 + 36) weeks, between which there will be a washout period of 12 weeks. After the last intervention period (36 weeks) there will be a 12-week follow-up period, after which the residual effect of the immersive virtual reality program will be analyzed. Due to the duration of the intervention, 6 moments have been proposed to carry out the evaluations in which aspects intrinsic to the virtual reality program (Security, Usability, Personal Experience and Adherence to the program) and Functional and quality of life aspects will be assessed (Balance, gait and risk of falling, Functional balance, Functional autonomy, Symptoms and Follow-up in the progress of Parkinson's Disease and Quality of Life). In the first moment, the socio-demographic characteristics of the patient will also be assessed. Likewise, and due to the characteristics of the study, a monitoring and evaluation will be carried out in each of the sessions and throughout the life of the project, with the aim of identifying possible contraindications, for this we will analyze the security, usability, personal experience , Adherence to the program, Effort made, Perception of Effort and Performance. The expected results, based on the experience of the research team in previous pilot studies, should reflect a high adherence to the program, a functional and symptomatic improvement of the disease, as well as an improvement in the quality of life.

Start date: 09-01-2021

End date: 09-01-2024

Last modified: 07-08-2024

Copyright information:

Immersive virtual reality as therapeutic tool for rehabilitation in patients with Parkinson's Disease (InViPark)

Data Collection

What data will you collect or create?

- Socio-demographic characteristics of the patients: age, gender, academic level, socio-economic level, as well as a clinical anamnesis of the same (pathologies, symptoms and associated pharmacology).
- Aspects intrinsic to the immersive Virtual Reality program:
  - Security: It will be tested using the Simulator Sickness Questionnaire. (Kennedy, 1993)
  - Usability: It will be tested using the system's usability scale. (Brooke, 1996)
  - Personal Experience: It will be tested through Game Experience Questionnaire-post-game. (Ijsselsteijn, 2013)
  - Adherence to the program: An ad hoc record sheet will be executed.
- Functional and quality of life aspects:
  - Balance, gait and risk of falling: It will be evaluated using the Tinetti Test. (Kegelmeyer, 2007)
  - Functional balance: It will be evaluated through the "Five Times Sit to Stand test-FTSTS. (Duncan, 2011)
  - Functional autonomy: it will be sent through the Timed Up and Go test with the WIVA application. (Mollinedo et al., 2018)
  - Symptoms and Follow-up in the progression of Parkinson's disease: It will be presented through the (MDS-UPDRS) (Rodríguez-Violante, 2012)
  - Quality of Life through the PDQ-8 questionnaire (Jenkinson et al. 2007)

- Monitoring and control of sessions. Due to the lack of previous experiences in the application of this type of immersive virtual therapies in the population diagnosed with Parkinson's, it is necessary to carry out a control and monitoring during each of the sessions of the InViPark program in order to identify possible contraindications. For them we will apply the following tests and trials:
  - Safety: It will be evaluated through the Simulator Sickness Questionnaire. (Kennedy, 1993)
  - Usability: It will be evaluated using the System Usability Scale. (Brooke, 1996)
  - Personal Experience: It will be evaluated through Game Experience Questionnaire-post-game. (Ijsselsteijn, 2013)
  - Adherence to the program: An ad hoc registration sheet will be made o Effort made: You will be monitored through a wrist-based heart rate monitor.
  - Perception of Effort: It will be evaluated through the Modified Borg Scale. (Sousa, 2016)
  - Performance: Score given by the system in the activity carried out.

How will the data be collected or created?

The data will be collected through a computer application on (limesurvey) and will be stored in the server that the work team has at the Faculty of Education and Sports Sciences. Two folders will be created in which two files will be saved at the beginning, one with the personal and identifying data of each patient (InViPark_Iv1) and another with the data to be evaluated that will always be encoded (InViPark_Dv1). Each time any of the files is updated, the version will be changed. Each folder will

have two odd / even subfolders in which the file will be saved depending on the odd or odd version. The database created by limesurvey will be imported into STATA or SPSS, for data analysis. Each time the database is updated, the PI of the project, the person in charge of the database, will perform a frequency analysis to identify possible errors in the introduction of the same.

Documentation and Metadata

What documentation and metadata will accompany the data?

The data will be labeled according to the authors of the tool used, so access and interpretation of them will be subject to knowledge of the tool used. The subjects will be coded, and for their identification it is necessary to access the file: (InViPark_Iv1). All data will refer to the evaluation tool used.

Ethics and Legal Compliance

How will you manage any ethical issues?

The research team will send the present project to the Autonomous Committee of Research Ethics of Galicia (CAEI) for its approval or, failing that, face the methodological corrections it deems appropriate. In this request an informed consent will be collected, which reflects all the procedures required based on the regulations and applicable agreements for this field of research.

All ethical problems that arise during the development of the project will be consulted with CAEI

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

Issues related to copyright and intellectual property rights will be discussed in regular meetings of the research team. The data is the property of the IP of the investigation. And the entire scientific community will have access to them through the relevant application

Storage and Backup

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

The data will be stored on a server located in the Faculty of Education and Sports Sciences of Pontevedra, periodically backing up to the central server of the University of Vigo

How will you manage access and security?

Access and data security will be supervised and controlled by Uvigo's IT services, the security measures being those stipulated on the server used.

Selection and Preservation

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

The data that will be kept are the following:

- Aspects intrinsic to the immersive Virtual Reality program:
  - Security: It will be tested using the Simulator Sickness Questionnaire. (Kennedy, 1993)
  - Usability: It will be tested using the system's usability scale. (Brooke, 1996)
  - Personal Experience: It will be tested through Game Experience Questionnaire-post-game. (Ijsselsteijn, 2013)
  - Adherence to the program: An ad hoc record sheet will be executed.
- Functional and quality of life aspects:
  - Balance, gait and risk of falling: It will be evaluated using the Tinetti Test. (Kegelmeyer, 2007)
  - Functional balance: It will be evaluated through the "Five Times Sit to Stand test-FTSTS. (Duncan, 2011)
  - Functional autonomy: it will be sent through the Timed Up and Go test with the WIVA application. (Mollinedo et al., 2018)
  - Symptoms and Follow-up in the progression of Parkinson's disease: It will be presented through the (MDS-UPDRS) (Rodríguez-Violante, 2012)
  - Quality of Life through the PDQ-8 questionnaire (Jenkinson et al. 2007)

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

Its conservation is important to see the evolution of the disease after this process and to be able to compare it with other intervention programs.

These data are in the research team's own repository and access to them is free.

Data Sharing

How will you share the data?

The data will be shared, upon request of the interested party at no cost. The data will be transferred anonymized and in the file excell / SPSS / STATA

Are any restrictions on data sharing required?

The file with the identification data will not be transferred

Responsibilities and Resources

Who will be responsible for data management?

The person responsible for managing the data will be the IP of the Research (José Mª Cancela Carral; chemacc@uvigo.es) and the data manager: Pablo Campo Prieto

What resources will you require to deliver your plan?

The resources we need to implement the research data management plan will be from experts in server and database management. We will request these resources from the Institution: Universidade de Vigo