Universidad Rey Juan Carlos

Effectiveness of Immersive Virtual Reality Combined with Occupational Therapy in Reducing Fall Risk and Frailty Among Older Adults (VIRTO-FRAIL)

NCT number: Pending
Date: July 1, 2025

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INFORMATION SHEET AND INFORMED CONSENT FORM FOR PARTICIPANTS

PROJECT TITLE: Effectiveness of Immersive Virtual Reality Combined with Occupational Therapy in Reducing Fall Risk and Frailty Among Older Adults

PRINCIPAL INVESTIGATOR: Cristina García Bravo

We appreciate your interest in this study. In order for you to participate, your informed consent is required. Therefore, we kindly ask you to take the necessary time to carefully read the following information, and to ask any questions you may have to the investigator listed above, so that your decision to participate is truly informed.

Please note that your participation in this study is entirely voluntary, and that even if you decide to participate, you may withdraw your consent at any time without any consequences to you.

What is the purpose of this study?

This study aims to evaluate the effectiveness of immersive virtual reality, used in conjunction with occupational therapy, as an intervention for older adults. The primary objectives are to reduce the risk of falls, prevent or alleviate frailty and frailty syndrome (FS), enhance quality of life, and increase participants' motivation and satisfaction with the rehabilitation process.

The motivation for this research stems from a growing interest in exploring and promoting innovative intervention strategies tailored to the needs of the elderly population. This project seeks to provide participants with access to emerging therapeutic approaches that complement traditional occupational therapy, with the potential to deliver meaningful improvements in quality of life, fall prevention, and frailty management.

Who is conducting this study?

The principal investigator is Cristina García Bravo, an occupational therapist and professor at Rey Juan Carlos University. She can be contacted by phone at +34 914 884 877 or via email at cristina.bravo@urjc.es. Please feel free to reach out with any questions or if you require further information.

The study will be conducted in collaboration with Melissa Helen Zegarra Ramos, an occupational therapist at the Bouco Madrid Ferraz Care Home, along with professors Mª Pilar Rodríguez Pérez, Elisabet Huertas Hoyas, and Sara García Bravo, all affiliated with Rey Juan Carlos University. These professionals will be responsible for carrying out both the assessments and the intervention being studied.

How long will the study last?

The study is expected to last approximately five months. Initially, a physical assessment will be conducted to evaluate your current condition. This will be followed by an eight-week intervention period, consisting of two 60-minute sessions per week. Upon completion of the intervention, a second evaluation will be carried out. A final follow-up assessment will take place three months after the end of the treatment.

There will be no need for you to travel, as all sessions and evaluations will be conducted at the care facility.

How will the study be conducted? What does my participation involve, and are there any risks?

The study will take place at the Bouco Madrid Ferraz Care Home, specifically in the occupational therapy room or other designated areas within the facility.

You will be asked to complete seven assessment tests before and after the intervention—during the first and last weeks of the program, and again three months after its conclusion.

These assessments will consist of questionnaires and observational measures focused on your performance, gait, and balance.

You will be expected to actively participate in occupational therapy sessions according to the schedule established for you, over a period of eight weeks.

Each week will include two sessions, each lasting one hour, held Monday through Friday. No participation will be required on weekends.

Family members will not be allowed to attend the intervention sessions.

The sessions may occasionally involve low-impact physical activity. Hydration will be provided to support your comfort during these exercises. Some activities will also require attention and focus.

Participation in this study includes the use of immersive virtual reality (VR) technology. Although generally safe, some individuals may experience temporary discomfort known as "cybersickness." These symptoms may include dizziness, imbalance, blurred vision, disorientation, unsteady walking, nausea, headache, or postural discomfort. In most cases, these symptoms are mild and resolve spontaneously within a few minutes.

If you experience any of these symptoms during or after the VR experience, the session will be stopped immediately. You will be provided with a quiet, well-ventilated space, a comfortable seat, and water to help you recover. Study personnel will monitor your condition for at least 10 to 15 minutes to ensure you are feeling well before resuming any activities.

Any discomfort you experience will be documented, including a description of the symptoms, their duration, and the measures taken. This information will help us improve the experience and enhance safety in future sessions.

If symptoms persist or worsen, you will be advised to consult a healthcare professional and to discontinue your participation in the study.

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What data will be collected for this study?

The data collected for this study will include:

- Name, age, sex, and the number of treatment hours received per week.
- Scores obtained from the assessment scales administered before and after the intervention.
- Personal signature (for informed consent purposes).

How will the confidentiality and protection of my personal data be ensured? This study involves the processing of personal data. The researchers will ensure the confidentiality of all data at all times, in strict compliance with applicable data protection regulations—specifically, the European General Data Protection Regulation (EU) 2016/679 of April 27, and Spain's Organic Law 3/2018 of December 5 on the Protection of Personal Data and Guarantee of Digital Rights.

Personal data collected during the study will be used exclusively for research purposes and will not be shared with external parties. All information obtained will be analyzed solely for scientific and academic purposes.

In accordance with data protection laws, participants will be pseudonymized upon inclusion in the study:

Each participant will be assigned a unique alphanumeric code composed of the letter "P" followed by a sequential number based on the order of enrollment (e.g., P01, P02, P03, etc.). This code will be used in all study documents and databases to ensure confidentiality and protect participant identities.

The correspondence between these codes and the participants' personal data will be recorded in a master list, which will be securely stored and accessible only to the principal investigator.

DATA CONTROLLER

The data controller is Rey Juan Carlos University, located at C/Tulipán s/n, 28233 Móstoles, Spain.

CONSENT AND PURPOSE

Your personal data will be processed with your explicit consent, within the framework of the research activities carried out at Rey Juan Carlos University. The sole purpose of this processing is to conduct the research described in this study. Your data may only be used for additional and compatible research purposes after being anonymized.

You may withdraw your consent at any time, without any negative consequences for you.

DATA DISCLOSURE

Your personal data will not be shared without your explicit consent, except where required by law or after pseudonymization, in such a way that re-identification is only possible for the purpose of notifying participants about the results of their intervention.

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DATA RETENTION

Your personal data will be retained only for the period strictly necessary for potential anonymization. After this process, the data will be securely destroyed.

EXERCISE OF DATA SUBJECT RIGHTS

In accordance with your rights under personal data protection laws, you are informed that you may exercise your rights of access, rectification, erasure, restriction of processing, objection, and any other rights recognized under the General Data Protection Regulation (GDPR) and Spain's Organic Law 3/2018 on the Protection of Personal Data and Guarantee of Digital Rights.

Requests may be submitted to Rey Juan Carlos University at C/ Tulipán s/n, 28933 Móstoles, through the official registry, via the electronic headquarters, or by email to: protecciondedatos@urjc.es.

You may also request clarification or further information regarding the exercise of these rights by contacting the Data Protection Officer (DPO) of Rey Juan Carlos University at: protecciondedatos@urjc.es.

Furthermore, if you believe your rights have not been fully upheld, you have the right to file a complaint with the national supervisory authority for data protection—the Spanish Data Protection Agency (Agencia Española de Protección de Datos), located at C/ Jorge Juan, 6 – 28001 Madrid, or via their website: www.aepd.es.

For more information on how your personal data is protected, please visit: https://www.urjc.es/proteccion-de-datos.

THIS CONCLUDES THE INFORMATION SHEET FOR YOUR CONSIDERATION REGARDING PARTICIPATION IN THE STUDY

We remind you that you are welcome to ask any questions or request further clarification to ensure you have all the information you need to make an informed decision.

If you decide to take part in the study, we kindly ask you to complete and sign the following Informed Consent Form, indicating that you agree to participate in the study after having received and understood all relevant information.

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INFORMED CONSENT

I (name of the participant/patient or their legal representative):

- On my own behalf (check if applicable)
- On behalf of another person (check if applicable).
  Name of the person I represent:

Having taken into account any previously expressed wishes or objections regarding this study, I hereby confirm the following:

I have read the information sheet provided to me. I declare that I have understood its contents and that I have been given the opportunity to ask any questions I deemed necessary to fully understand the study. Therefore, I freely and knowingly agree to voluntarily participate in this research study.

I acknowledge that I have received a copy of this consent form. By signing below, I expressly consent to the processing of my personal data for the purposes previously stated, in connection with the management and execution of the research project.

In _____ on the ____ day of _____20

Full Name of the Participant/Representative:	**Full Name of the Researcher:**
Signature	**Signature**

RIGHT TO WITHDRAW CONSENT

(To be completed if you wish to exercise your right to withdraw consent)

I (name of the participant/patient or their legal representative):

- On my own behalf (check if applicable)
- On behalf of another person (check if applicable).
  Name of the person I represent:

Having taken into account any previously expressed wishes or objections regarding this study,

hereby revoke the informed consent previously given, as of today, the _____ day of _____, 20, and I no longer wish to participate in the study. My participation is therefore considered terminated as of the date stated above. I also confirm that I have received a copy of this withdrawal declaration.

Full Name of the Participant/Representative:	**Full Name of the Researcher:**
Signature	**Signature**