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Acceptance and validation of virtual reality technologies for enhancing wellbeing and the early detection of cognitive decline in older adults

Submission date
05/09/2025

Recruitment status
Recruiting

Registration date
23/09/2025

Overall study status
Ongoing

Last Edited
19/09/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
As people live longer, conditions like mild cognitive impairment (MCI) and dementia are becoming more common. Detecting early signs and finding ways to support wellbeing are essential. This study is part of the European project COMFORTage and includes two sub-studies:
Study 1: To explore how involving older adults in the design of new health technologies (co-creation) can improve their acceptance, usability, and overall wellbeing.
Study 2: To test a Virtual Reality (VR) tool called GRADIOR DLA PREVENTION, which helps screen for early cognitive changes through memory and attention tasks.
The overall aim is to develop approaches that improve quality of life and wellbeing, and to understand how new technologies can be better accepted and used by older people.

Who can participate?
Study 1: Adults aged 60 years or older with subjective memory complaints or a diagnosis of mild cognitive impairment (MCI).
Study 2: Adults aged 55 years or older with subjective memory complaints or a diagnosis of mild cognitive impairment (MCI).

What does the study involve?
Study 1: Participants will use rehabilitation technologies with and without nudge strategies to determine their effectiveness in technology acceptance and intervention enhancement. Data will be collected through questionnaires, interviews, and short cognitive tests.
Study 2: Participants will use a Virtual Reality (VR) tool designed for cognitive assessment and wellbeing. Assessments will include questionnaires and cognitive tests.

What are the possible benefits and risks of participating?
Study 1:
Benefits: Opportunity to influence the design of new health tools, contribute to research, and engage in stimulating group activities that may improve wellbeing.

Risks: No specific health risks expected, other than possible mild fatigue from participation in sessions.
Study 2:
Benefits: Access to innovative health technology, possible improvements in wellbeing, and contribution to new approaches for early detection and support.
Risks: VR use may cause mild dizziness, or fatigue, but sessions are short and designed to minimize discomfort.

Where is the study run from?
The study is coordinated by Fundación INTRAS (Valladolid, Spain) and supported by European partners within the COMFORTage project.

When is the study starting and how long is it expected to run for?
Recruitment begins in February 2025 and is expected to run until October 2026, including recruitment, interventions, and follow-up. Overall study runs until December 2027.

Who is funding the study?
The study is funded by the European Union's Horizon Europe programme under the COMFORTage project (grant 101137301).

Who is the main contact?
INTRAS Foundation, rld@intras.es

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
PI-24-581-O

Study information

Scientific Title
COMFORTAGE – Improving technology acceptance and user experience in the use of assistive technologies for the early detection of cognitive decline and the enhancement of quality of life and well-being

Acronym
COMFORTage

Study objectives
The study has two main objectives, which together constitute two sub-studies.

Sub-Study 1: Study on the Role of Self-Efficacy and Social Influence in the Acceptability of a Multisensory Virtual Reality-Based Technology Aimed at Improving Emotional Regulation, Quality of Life, and Well-Being in Older Adults with Mild Cognitive Impairment (MCI)

Objectives:
1.2. General Objective:
To explore the factors involved in the acceptance of a cognitive and multisensory stimulation technology (named GRADIOR Multisensorial - hereafter “the technology”) based on virtual reality and designed to improve affectivity, quality of life, and well-being in older adults with cognitive impairment. In particular, the study will focus on the role of self-efficacy and social influence in such acceptance. For this purpose, an intervention will be implemented based on the modification of the user’s decision architecture (“nudge”) as a method to enhance acceptance of the innovative treatment, thereby improving adherence and the overall effectiveness of the technology.

1.3. Specific Objectives:
SO.1. Evaluate the effectiveness of the nudge strategy in achieving better acceptance and patient experience with the selected technology.
SO.2. Analyze the role of self-efficacy and social influence in the acceptability of this technology.
SO.3. Assess the impact of greater adherence to the intervention through the innovative solution on affective state, quality of life, and well-being.

Sub-Study 2: Analysis of the Effectiveness, Usability, and User Experience of a Virtual Reality and Artificial Intelligence-Based Tool for the Early Detection of Cognitive Decline

Objectives of the Study:
1.1. General Objective:
To assess the effectiveness of the GRADIOR DLA PREVENTION virtual reality (VR) cognitive assessment system in predicting the conversion of healthy individuals over 55 years old to Mild Cognitive Impairment (MCI), and of individuals with MCI to dementia.

1.2. Specific Objectives:
SO.1. Evaluate the predictive validity of the memory subtest of GRADIOR DLA PREVENTION for the conversion from healthy status to MCI, and from MCI to dementia.
SO.2. Evaluate the predictive validity of the executive functions subtest of GRADIOR DLA

PREVENTION for the conversion from healthy status to MCI, and from MCI to dementia.
SO.3. Evaluate the predictive validity of the spatial navigation subtest of GRADIOR DLA PREVENTION for the conversion from healthy status to MCI, and from MCI to dementia.
SO.4. Assess the acceptability and user experience regarding the proposed virtual methodology.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/01/2025, Comité De Ética De La Investigación Con Medicamentos de las Áreas de Salud de Valladolid (CEIm de las Áreas de Salud Valladolid) (C/ Ramón y Cajal 7, Valladolid, 47005, Spain; 983 423077; jalvarezgo@saludcastillayleon.es), ref: PI-24-581-O

Study design
Sub-study 1: pre-post design, three groups, two quasi-control; Sub-study 2: prospective cohort study

Primary study design
Interventional

Study type(s)
Diagnostic, Quality of life, Screening

Health condition(s) or problem(s) studied
Mild cognitive impairment (MCI)

Interventions
Participants will use a virtual reality (VR) tool designed for cognitive assessment and wellbeing. Assessments will include questionnaires and cognitive tests.

Sub-study 1 (interventional; pre–post, three groups; quasi-controls):
Participants will use rehabilitation technologies with and without nudge strategies to determine their effectiveness in technology acceptance and intervention enhancement. Data will be collected through questionnaires, interviews, and short cognitive tests.
Purpose: Evaluate whether a nudge strategy improves acceptance, usability and well-being when using a multisensory VR-based cognitive–affective stimulation technology (GRADIOR Multisensorial).
Arms and brief methodology:
Arm A: Technology + Nudge: Participants use GRADIOR Multisensorial after acceptance-enhancing nudges strategies.
Arm B: Technology without Nudge: Same technology and session structure, but without nudge elements.
Arm C: Usual support: No exposure to the technology or nudge strategies during the intervention phase.

Intervention dose and timeline (all arms):
Intervention period: 4 months
Session frequency and length (Arms A/B): two sessions per week, ~45 minutes/session (on-site).
Follow-up (all arms): no applicable.
Allocation / randomisation: Non-randomised (quasi-experimental); participants are assigned to groups pragmatically by centre scheduling and feasibility. No blinding is planned.

Sub-study 2 (prospective cohort; instrumental/diagnostic):
This is an instrumental study since it is aimed at examining the psychometric properties of a test for detecting the conversion of healthy individuals to mild cognitive impairment (MCI) and from MCI to dementia. To this end, a prospective cohort study has been designed to achieve an outcome measurement.

Purpose: Assess the effectiveness and usability of GRADIOR DLA PREVENTION (VR cognitive assessment with AI analytics) to predict conversion: (i) healthy mild cognitive impairment (MCI) and (ii) MCI dementia.

Methodology and timeline:
Assessments: In-person VR cognitive assessment plus standard neurocognitive and functional measures.
Schedule: Baseline, then 12 months and 24 months to ascertain conversion status and predictive validity.
Allocation/randomisation: Not applicable (observational cohort; no allocation).

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Multisensory VR-based cognitive–affective stimulation technology (GRADIOR Multisensorial)

Primary outcome(s)
Sub-study 1:
1. Quality of life measured with EuroQol-5D (EQ-5D) at pre and post intervention
2. Health status measured with Short Form Health Survey (SF-12) at pre and post intervention
3. Perceived loneliness measured with UCLA Loneliness Scale (UCLA-LS) at pre and post intervention
4. Social connectedness measured with Lubben Social Network Scale (LSNS) pre and post intervention
5. Post-use satisfaction/usability measured with Post-Study Usability Questionnaire (PSSUQ) at post intervention
6. Perceived usability measured with System Usability Scale (SUS) at post intervention
7. Technology acceptance/intention to use measured with Unified Theory of Acceptance and Use of Technology (UTAUT/UTAUT2) at post intervention
8. Depressive symptoms measured with Geriatric Depression Scale (GDS; Yesavage) or Beck Depression Inventory-II (BDI-II) at pre and post intervention

Sub-study 2:
1. Clinical severity / conversion status measured with CDR–Sum of Boxes (CDR-SB) at baseline, 12 months, 24 months
2. Cognitive reserve measured with Cognitive Reserve Index Questionnaire (CRIq) at baseline
3. Subjective memory complaints measured with Subjective Memory Complaints Questionnaire (SMCQ/CMS) at baseline, 12 months, 24 months
4. Mood measured with Geriatric Depression Scale (GDS, short form) or Beck Depression Inventory (BDI-II) at baseline, 12 months, 24 months
5. Episodic memory measured with TAVEC Verbal Learning Test at baseline, 12 months, 24

months
6. Attention and executive control measured with Stroop Test at baseline, 12 months, 24 months
7. Visuoconstruction measured with Rey–Osterrieth Complex Figure at baseline, 12 months, 24 months
8. Visuospatial working memory measured with Corsi Block-Tapping at baseline, 12 months, 24 months
9. GRADIOR DLA PREVENTION VR subtests (memory, executive functions, spatial navigation) at baseline, 12 months, 24 months
10. Usability assessed with System Usability Scale (SUS) at baseline, 12 months, 24 months

Key secondary outcome(s))

Sub-study 1:
1. Multimorbidity burden measured with Cumulative Illness Rating Scale (CIRS) at pre and post intervention
2. Dementia risk profile measured with Cardiovascular Risk Factors, Ageing, and Dementia Scale (CAIDE) at pre and post Intervention
3. Alcohol use risk measured with Alcohol Use Disorders Identification Test (AUDIT) at pre and post Intervention
4. Physical activity measured with International Physical Activity Questionnaire (IPAQ) at pre and post Intervention
5. Global cognition measured with Mini-Mental State Examination (MMSE) at pre and post intervention
6. Clinical staging measured with Clinical Dementia Rating (CDR) (global) at pre and post intervention
7. Basic ADLs measured with Katz Index of Activities of Daily Living (ADL) at pre and post intervention
8. Instrumental ADLs measured with Lawton and Brody Instrumental Activities of Daily Living Scale (IADL) at pre and post intervention
9. Cognitive reserve measured with Cognitive Reserve Index Questionnaire (CRIq) pre intervention
10.Subjective cognitive complaints measured with Subjective Memory Complaints Questionnaire (SMCQ/CMS) at pre and post intervention

Sub-study 2:
1. Multimorbidity burden measured with Cumulative Illness Rating Scale (CIRS) at baseline, 12 months, 24 months
2. Dementia risk profile measured with Cardiovascular Risk Factors, Ageing, and Dementia Scale (CAIDE) at baseline, 12 months, 24 months
3. Alcohol use risk measured with Alcohol Use Disorders Identification Test (self-administered version) (AUDIT) at baseline, 12 months, 24 months
4. Physical activity measured with International Physical Activity Questionnaire (IPAQ) at baseline, 12 months, 24 months
5. Global cognition measured with Mini Mental State Examination (MMSE) at baseline, 12 months, 24 months
6.Quality of life measured with EuroQol-5D (EQ-5D) at pre and post intervention at baseline, 12 months, 24 months

Completion date

31/12/2027

Eligibility

Key inclusion criteria
Sub-study 1:
1. ≥60 years old
2. MMSE score between 20 and 30
3. Ability to understand and provide informed consent to participate in the study
4. Signed consent for participation and processing of study data (the transfer of collected data to a database is optional and does not imply exclusion from the study)
5. Expressed desire to receive support in relation to the use of technologies and/or willingness to participate in co-creation groups

Sub-study 2:
1. ≥55 years old
2. MMSE score between 20 and 30
3. Ability to understand and provide informed consent to participate in the study
4. Signed consent for participation and processing of study data (the transfer of collected data to a database is optional and does not imply exclusion from the study)
5. Expressed desire to receive support in relation to:
5.1. Use of technologies
5.2. Mood
5.3. Cognitive stimulation

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
55 years

Sex
All

Key exclusion criteria
1. Sensory difficulties that hinder the use of the device
2. Psychiatric conditions or neurological problems that prevent participation in the study

Date of first enrolment
18/02/2025

Date of final enrolment
30/10/2026

Locations

Countries of recruitment
Spain

Study participating centre
Fundación INTRAS
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Sponsor information

Organisation
Fundación INTRAS

ROR
https://ror.org/00rwgk448

Funder(s)

Funder type
Government

Funder Name
Horizon 2020

Alternative Name(s)
EU Framework Programme for Research and Innovation, Horizon 2020 - Research and Innovation Framework Programme, European Union Framework Programme for Research and Innovation

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request.
1. Governance and security (quantitively managed; the process is measured and controlled

/verified). Data handling procedures at INTRAS are defined according to GDPR.
2. Security levels:
2.1. Technical measures: data storage in dedicated servers segmented on network environment; authorized access with data access audit logs; VPN regulated access to the data processing data centre. Data communication and transfer protected by Secure Socket Layer (SSL) and Transport Layer Security (TLS) protocols.
2.2. Data will be stored in firewall-protected computers with authorized access. Access will be limited to members of the research team. In case of data transfer, this will take place via SSH or SSL protocols. Pseudo-anonymised data will be stored separately from records including subjects' personally identifiable information (e.g., signed consent forms).
2.3. Data privacy officer: dpo@intras.es

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes