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# Virtual reality training of health caregivers in managing the psycho-behavioral symptoms of dementia: a randomized-controlled effectiveness study

**Submission date**
20/09/2023

**Recruitment status**
No longer recruiting

**Registration date**
25/09/2023

**Overall study status**
Completed

**Last Edited**
17/10/2023

**Condition category**
Mental and Behavioural Disorders

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

**Plain English summary of protocol**

Background and study aims
Behavioral and psychological symptoms, such as aggressiveness, agitation, or care refusal, are a common challenge for healthcare professionals when managing patients with dementia, and effective verbal and nonverbal communication skills are crucial in caring for such patients. The aim of this study is to investigate the effectiveness of a virtual reality (VR) training program for healthcare professionals in managing such symptoms.

Who can participate?
Nurses and certified nursing assistants working at Broca University Geriatric Hospital in Paris, France

What does the study involve?
Out of the 50 willing professionals, 10 will participate in a focus group for co-creating two contextual scenarios of interactions between a patient and a healthcare provider. The remaining 40 will be randomly assigned into two groups of 20 to undergo a training program: the first group will receive conventional training with clinical cases based on the co-written scenarios from the focus groups followed by a classical classroom-based training session on verbal and non-verbal skills, and the second group will undergo training via virtual reality (two virtual reality movies representing a virtual healthcare provider in interaction with a fictional patient played by an actor) followed by a Moodle training session on verbal and non-verbal skills. Total participation time will not exceed 120 minutes, including 60 minutes for clinical case reading or virtual reality film viewing, quizzes, debriefing, theoretical teaching or Moodle training, and 60 minutes for questionnaire completion for the assessment of the participants' satisfaction and the effectiveness of the training program.

What are the possible benefits and risks of participating?
Participants will contribute to scientific research and access to training on verbal and nonverbal communication with patients suffering from the psycho-behavioral symptoms of dementia.

Exposure to virtual reality may disrupt the sensory system and cause symptoms such as nausea, dizziness, sweating, paleness, and loss of balance. These symptoms may manifest in sensitive individuals within minutes of use and may also temporarily affect sensory, motor, and perceptive abilities, altering manual dexterity or body orientation. They also include the feeling of motion sickness or nausea and dizziness caused by virtual reality experiences or other types of immersive technologies. Additionally, exposure to flashing lights emitted by LED screens can trigger epileptic seizures in individuals with a predisposition to them.

Where is the study run from?
Broca University Geriatric Hospital of Assistance Publique Hôpital de Paris (France)

When is the study starting and how long is it expected to run for?
May 2021 to December 2023

Who is funding the study?
Fondation de l'Avenir pour la Recherche Médicale Appliquée (France)

Who is the main contact?
Maribel Pino, maribel.pino@aphp.fr

# Contact information

### Type(s)
Principal investigator

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
AP-LMG-21-001

# Study information

### Scientific Title
Feasibility, user satisfaction and pedagogical effectiveness of a virtual reality training program for healthcare professionals to manage disruptive behavioral and psychological symptoms of dementia (BPSD): a randomized-controlled study

### Acronym
FORMSPC Realvi

### Study objectives
The virtual reality (VR) training group will show significant improvement in their knowledge and self-perceived competence for verbal and nonverbal skills in managing disruptive psycho-behavioral symptoms of dementia (BPSD) compared to the control group (traditional training course). Additionally, the VR training group will also report higher satisfaction levels with the training program compared to the control group.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
approved 17/05/2022, Ethics Committee for Research of the University of Paris Cité (85 Boulevard St Germain, Paris, 75006, France; +33 (0)1 57276567; cer@u-paris.fr), ref: 00012022-25

### Study design
Monocentric simple randomized controlled study

### Primary study design
Interventional

### Study type(s)
Efficacy

### Health condition(s) or problem(s) studied
Behavioral and psychological symptoms in dementia (BPSD)

### Interventions
The overall design of this study protocol involves an intervention experiment in which healthcare staff (nurses and certified nursing assistants) at a Parisian university geriatric hospital will be randomly assigned (using simple randomization) to one of two types of training methods for verbal and nonverbal communication skills with patients with BPSD: traditional and VR-mediated.

To participate in the study, all participants must provide written consent after reading the information letter and receiving any additional information they may require. Participants will be assured that their data will be anonymized and that the results will have no impact on their professional evaluation.

The evaluating psychologists will have no prior professional relationship with the potential participants. Participants will not receive any financial compensation for their involvement in the study.

Out of the 50 willing professionals, 10 will participate in a focus group for co-creating contextual scenarios. The remaining 40 will be randomly assigned into two groups of 20 to undergo the training program: the first group will receive conventional training with clinical cases based on the co-written scenarios from the focus groups, and the second group will undergo training via virtual reality.
Total participation time will not exceed 120 minutes, including 60 minutes for clinical case reading or virtual reality film viewing, quizzes, debriefing, theoretical teaching or Moodle training, and 60 minutes for questionnaire completion.

Protocol workflow
Step one: Scenario design phase
In this phase, 10 healthcare professionals (out of 50 participants) who have given written consent to participate in the study, will be invited to a focus group. The researchers will provide them with two scenarios, each describing a clinical context involving a patient with disruptive BPSD (aggression, opposition, agitation, and/or anxiety) and a professional caregiver.

Participants will be asked to provide feedback on the scenarios based on their own professional experience and knowledge, as well as to suggest modifications or additions to the dialogues and gestures of the fictional characters in order to either aggravate the conflict or soothe the patient, depending on the situation.

To evaluate later the pedagogical value of the scenarios, participants will be asked to propose multiple-choice questions. These quizzes will be used to evaluate the subsequent participants for their ability to identify appropriate and inappropriate verbal and nonverbal communication by the fictional healthcare professional, as well as their knowledge about optimal ways to behave with demented patients with disruptive BPSD, as represented by the fictional patient in the scenarios.

Furthermore, the researchers and healthcare professionals who participate in the focus groups will collaborate in co-creating a Moodle platform. This platform will highlight the appropriate- to be, and inappropriate behaviors, potentially, employed when communicating with patients based on the scenarios.

Step two: VR movie design
Based on the two scenarios codesigned by the investigators and the 10 focus group participants, a virtual reality movie will be performed. Virtual reality software is being developed as part of the project to enable the display of virtual agents, resembling a virtual professional caregiver and a patient played by an actor, on a virtual reality helmet screen. During the viewing, the participant will be fully immersed in a 3D environment that is predetermined by the scenarios designed upon the completion of the focus group (as detailed in Step One of the project), which could be a patient's room, unit corridors, or a care station.

Step three: Randomization of the remaining participants
Upon signing the consent form to participate in the study, the remaining 40 healthcare professionals (excluding those 10 participants involved in the focus group) will undergo a simple randomization process, whereby they will be randomly assigned to one of two distinct groups of 20: one group (n 20) will be assigned to a standard training program (comprising scenario

reading and theoretical training course) and the other one (n 20) will be assigned to the VR training (VR 3D immersive scenario viewing and Moodle training) arm.

During a single visit, each participant will engage in an individual training session lasting 2 hours. The training sessions will be conducted over a period of 10 days, with 20 classical course sessions and 20 virtual reality (VR) training sessions being held in parallel. Both types of sessions will be conducted simultaneously in the morning and afternoon, with the first session running from 9 am to 11 am, and the second session from 2 pm to 4 pm.

At the beginning of each training session, participants will complete a questionnaire (the Verbal and Nonverbal Communication Training Needs Questionnaire) to assess their training needs for communicating with patients who have BPSD.

Participants will then either read the first scenario (for the classical training group) or watch the first virtual reality (VR) movie through a 3D immersive video headset (for the VR training session). The scenarios are based on those codesigned during Step One of the study protocol by the investigators and focus group participants. Afterwards, the participants will complete a multiple-choice quiz designed to assess their knowledge and understanding of the correct and inappropriate V and N/V behaviors exhibited by healthcare professionals in interaction with patients with BPSD, as described in the scenario or the script based on the scenario content.

Following this, participants will receive a debriefing with psychologist investigators to discuss the choices made during the multiple-choice quiz and to receive feedback on their performance followed by a training session (either a classroom theoretical training course taught by the investigators or a Moodle training: see the content in Materials paragraph below), before proceeding to read the second scenario or watch the second VR movie based on their assigned group. This will be followed by another debriefing and training session. Each session will last 1 hour. Upon completing the training sessions, participants will be assessed based on outcome measures.

Step four. Assessments
After each scenario reading or VR scenario visioning, a multiple-choice quiz session will take place to assess the knowledge of participants of suitable verbal and non-verbal communication with patients suffering from BPSD. The scores based on the percentage of correct answers to multiple-choice questions for Scenario 1 and Scenario 2, will be returned to the participants to track their progress and acquisition of knowledge. The main outcome of the study which is the pedagogical effectiveness of the training will be based on the participants' knowledge progress between scenario 1 and scenario 2 of the VR movies.

The participants will also have to complete questionnaires evaluating their satisfaction with the training methods (scenario reading and classical training versus VR scenario movie and Moodle training) and self-perceived level of competence (see Data collection and assessment tools). The VR training group will also have to fulfil two additional questionnaires, one evaluating participant's satisfaction with the two VR scenarios and the second assessing the usability of the VR 3D training method. The maximum completion time for the overall assessments will not exceed 1 hour.

## Intervention Type
Other

## Primary outcome(s)

The evaluation of the pedagogical effectiveness of the training (main outcome measure) will be based on the participants' differential scores obtained for quizzes administered after Scenario 1 and 2, depending on the participant's arm (paper scenario or VR scenarios). This calculation will be made at the end of the 1-hour training session.

### Key secondary outcome(s))
1. The evaluation of healthcare professionals' training needs in verbal and nonverbal communication (V/NV) will be carried out prior to the training (traditional and VR-mediated training sessions), at baseline, using a V/NV communication training needs' questionnaire, specifically designed for this research
2. The satisfaction of participants with the training methods will be assessed by asking them to rate their overall satisfaction with the training program they received, either the classical theoretical program or the virtual reality training program, using a Likert scale, just after the training session of 1H overall (the participation/assessment day).
3. The evaluation of the participants' satisfaction of the VR scenarios (VR-trained group of 20 participants only) will be carried out using a satisfaction questionnaire developed by the researchers (see S3 File) at the end of the training session of 1H overall (the participation /assessment day).
4. The usability of the VR 3D training method will be assessed using the System Usability Scale (SUS) at the end of the training session of 1H overall for the group of VR training of 20 participants.
5. The learners' self-perceived level of competence will be quantitatively analyzed using a questionnaire created by the researchers which is based on the "perceived competence" section of the "Intrinsic Motivation Inventory" at the end of the training session of 1H.

### Completion date
31/12/2023

## Eligibility

### Key inclusion criteria
1. Participants (nurses and certified nursing assistants) will be recruited voluntarily through posters placed in the geriatric wards of the Broca University gériatric hospital in Paris, or during team meetings in the hospitalization units. Those who are interested in participating will be asked to contact the researchers responsible for the project.
2. There will be no specific age or gender criteria for inclusion
3. Provide written consent after reading the information letter and receiving any additional information they may require
4. Both daytime and night-time shift workers will be eligible to participate

### Participant type(s)
Health professional

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit

18 years

**Sex**
All

**Key exclusion criteria**
1. History of epilepsy
2. Pregnant women
3. History of motion sickness, balance problems, or migraines

**Date of first enrolment**
23/10/2023

**Date of final enrolment**
06/11/2023

# Locations

**Countries of recruitment**
France

**Study participating centre**
**Broca Hospital**
Department of Geriatrics - APHP Centre
54-56 rue Pascal
Paris
France
75013

# Sponsor information

**Organisation**
Université Paris Cité

**ROR**
https://ror.org/05f82e368

# Funder(s)

**Funder type**
Research organisation

### Funder Name
Fondation de l'Avenir pour la Recherche Médicale Appliquée

### Alternative Name(s)
Fondation de l'Avenir

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Trusts, charities, foundations (both public and private)

### Location
France

## Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Hermine Lenoir (hermine.lenoir@aphp.fr) and the main results will be published as the result publication or as a supplement to the results publication. The type of data that will be shared are the individual results of participants to different assessments. No information on age, profession, or gender will be provided. The data will become available after publication of the results in a high impact peer-reviewed journal.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | | | 25/09/2023 | No | Yes |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |