

# EXPERIENCE: Is virtual reality suitable to identify differences between depressed and healthy individuals?

|  |   |  |
|--|---|--|
| <b>Submission date</b><br>15/11/2022   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>29/12/2022 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>17/04/2025       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input checked="" type="checkbox"/> Results          |
|  |   | <input type="checkbox"/> Individual participant data |

## Plain English summary of protocol

### Background and study aims

Current diagnostic protocols for affective disorders such as depression, anxiety and eating disorders are commonly based on self-reports and verbal communication between the patient and the psychiatrist. Thus, an appropriate psychiatric diagnosis is heavily influenced by the patient's ability to correctly express him or herself, as well as the psychiatrist's ability to correctly understand and identify said symptoms. In this study, we aim to investigate whether measures based on behaviors and implicit reactions to specific stimuli can be used as diagnostic tools and whether these are comparable to traditional procedures based on self-reports (interviews, questionnaires). For this purpose, we will use an immersive virtual reality (VR) environment where behavioral tasks should be explored and completed in a narrative-driven serious game (SG).

A literature review was conducted with the aim to identify behavioral measures that have the potential to distinguish depressed and healthy individuals in virtual reality. The findings of this review were used to design a specific virtual reality environment for the assessment of these measures and thus the severity of depressive symptoms. The current study aims to test whether this environment and the implemented behavioral measures can differentiate depressed and healthy individuals.

### Who can participate?

Adults (18-35 years) who are moderately to severely depressed; and also healthy individuals who are free from any disease/disability that would impair one's ability to interact in the VR environment requiring the use of a headset and controllers (e.g., blindness, intellectual disability)

### What does the study involve?

Participants will be asked to explore the VR environment on their own. A battery of psychometric diagnostic scales will also be administered before and after participants are exposed to the VR environment. Data on engagement with the virtual environment, performance on cognitive tasks and collected and ECG and GSR will be retrieved and analyzed for group level differences and via classification models, and the classification models will be compared to existing psychometric diagnostic scales.

What are the possible benefits and risks of participating?

Possible benefits for participants include getting the chance to try virtual reality. A possible risk of participation is that virtual reality might induce symptoms of cyber sickness.

Where is the study run from?

University of Padua (Italy)

When is the study starting and how long is it expected to run?

January 2022 to May 2023

Who is funding the study?

European Commission H2020 Framework Program (Grant No. 101017727)

Who is the main contact?

1. Claudio Gentili, c.gentili@unipd.it (Italy)

2. Vladimir Carli, vladimir.carli@ki.se (Sweden)

## Contact information

### Type(s)

Scientific

### Contact name

Dr Vladimir Carli

### ORCID ID

<https://orcid.org/0000-0001-6922-0675>

### Contact details

Granits väg 4

Solna

Sweden

17177

+46 (0)709354038

vladimir.carli@ki.se

### Type(s)

Scientific

### Contact name

Prof Claudio Gentili

### ORCID ID

<https://orcid.org/0000-0002-2579-8755>

### Contact details

Via Venezia 8

Padua

Italy

35135

+39 (0)498276587  
c.gentili@unipd.it

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

4688

## Study information

### Scientific Title

Pilot study on the EXPERIENCE system for the investigation of behavioral differences between depressed and healthy-control participants in Virtual Reality

### Acronym

EXPERIENCE

### Study objectives

A battery of behavioral and cognitive measures (RVIP; TMT; 2-back test; WCST; metacognitive sensitivity; curiosity; persistence; engagement with emotionally valenced stimuli; mood induction) embedded within a Virtual Reality serious game (SG) combined with physiological measures (ECG and GSR) can differentiate between individuals with varying levels of depression when analyzed by Machine Learning algorithms.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 10/03/2022, Ethics Committee for Psychological Research at the University of Padua (Via Venezia 8, 35131, Padova, Italy; +39 (0)498276587; comitato.etico.area17@unipd.it), ref: 4249B85C26A719639545360E3D0D9722

### Study design

Single-center cross-sectional observational study

### Primary study design

Observational

### Study type(s)

Diagnostic

### Health condition(s) or problem(s) studied

Assessment of depressive symptom severity

### Interventions

The study requires one visit per participant, which includes (1) a pre-VR questionnaire battery, (2) a 20–30-minute engagement with a VR environment, (3) and a post-VR questionnaire battery.

All participants receive the same battery and same exposure to VR (regardless of affiliation with the healthy-control or depressed group) and there is no planned follow-up.

After giving informed consent, all participants receive a questionnaire battery on paper. The pre-VR battery is composed of the following:

1. Background questionnaire (e.g., demographic data, diagnosis and medication)
2. Patient Health Questionnaire (PHQ-9)
3. Anxiety component of the Depression Anxiety Stress Scales (DASS-21)
4. Positive and Negative Affect Schedule (PANAS-SF)
5. Curiosity and Exploration Inventory-II (CEI-II)

Hereinafter, all participants fulfilling the criteria for either the healthy-control or the depressed group (assessed based on the answers provided in the pre-VR battery) receive the VR headset and controllers. Participants will be placed in a virtual hallway and receive an audio message that explains the narrative of the scenario. Specifically, they will be expected to explore numerous rooms and they can do so by opening doors by solving tasks. (These tasks are four cognitive tasks: N-back; Rapid Visual Information Processing; Wisconsin Card Sorting Test; and Trail Making Test.) After a tutorial on how to move around in the environment and how the controllers' function, participants reach the first door and have to complete a cognitive task to move forward. After completion, they will be asked to evaluate their own performance on a visual scale and also be asked whether they want to reattempt the task or move forward. Once the door is open, they arrive at a central room, equipped with numerous objects (e.g., table, sofa, bookshelf) and some interactive elements (e.g., boxes, picture frames, buttons). From the central room, there are three more rooms available, each of which is behind a door that requires participants to complete another cognitive task. One of these rooms is equipped with positive and another with negative mood induction – the third is neutral in terms of mood induction. Similarly to the central room, these rooms as well contain various interactive elements (e.g., desk with computer and pens; whiteboard to draw). After having visited all rooms, an exit sign lights up. Participants are free to exist in the environment or go back and spend more time exploring it.

After engagement with the VR environment, a second test battery is administered which includes:

1. Anxiety component of the Depression Anxiety Stress Scales (DASS-21)
2. Positive and Negative Affect Schedule (PANAS-SF)
3. Acceptability questionnaire

Data collected during engagement with the VR environment will be used to train a Machine Learning algorithm for the classification of depressed and non-depressed participants. The algorithm will be informed by current depressive symptoms and prior clinical diagnosis as assessed and registered via the pre-VR test battery.

## **Intervention Type**

Other

## **Primary outcome(s)**

Performance on four cognitive tasks measured during engagement with the virtual reality environment:

1. Working memory function measured using the N-back task
2. Executive functions and cognitive flexibility measured using the Wisconsin Card Sorting Test
3. Processing speed measured using the Trail Making Test Parts A & B
4. Sustained attention measured using the Rapid Visual Information Processing task

## **Key secondary outcome(s)**

Behavioral outcomes:

1. Number of interactions with objects and explored areas, and time spent in certain virtual rooms measured during engagement with the virtual reality environment
2. Eye-tracking data measured during engagement with the virtual reality environment
3. Physiological response assessed using electrocardiogram (ECG) measured with an electrocardiograph and galvanic skin response (GSR) measured with electrodes during engagement with the virtual reality environment
4. Metacognitive sensitivity measured using a self-evaluation of performance questionnaire during engagement with the virtual reality environment
5. Persistence measured using the number of tries on cognitive tasks during engagement with the virtual reality environment

## **Completion date**

11/05/2023

## **Eligibility**

### **Key inclusion criteria**

Patients with depression:

1. Aged between 18 and 35 years old
2. Active moderate/severe depressive symptoms (a score > 9 on the PHQ-9 scale)
3. No diagnosis of psychiatric disorders other than depressive and anxiety disorders
4. If on current psychological or pharmacological treatment, treatment is stable since at least 4 weeks

Healthy volunteers:

1. Aged between 18 and 35 years old
2. No previous or current diagnosis of mood or anxiety disorder
3. No diagnosis of other psychiatric disorders
4. A score <5 on the PHQ-9 scale

### **Participant type(s)**

Mixed

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Total final enrolment**

100

## Key exclusion criteria

1. Any disease/disability that would impair one's ability to interact in the virtual reality environment requiring the use of a headset and controllers (e.g., blindness, intellectual disability)
2. Migraine if prophylactic medication is taken

## Date of first enrolment

24/11/2022

## Date of final enrolment

30/04/2023

## Locations

### Countries of recruitment

Italy

### Study participating centre

University of Padua

Department of General Psychology Via Venezia 8

Padua

Italy

35135

## Sponsor information

### Organisation

Karolinska Institute

### ROR

<https://ror.org/056d84691>

## 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 analyzed during the current study are not expected to be made available due to lack of ethical approval for a data sharing policy.

## IPD sharing plan summary

Not expected to be made available

## Study outputs

| Output type                                   | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>               |         | 16/04/2025   | 17/04/2025 | Yes            | No              |
| <a href="#">Participant information sheet</a> |         | 26/10/2020   | 25/11/2022 | No             | Yes             |