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

Submission date
15/11/2022

Recruitment status
No longer recruiting

Registration date
29/12/2022

Overall study status
Completed

Last Edited
17/04/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

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

Primary study design
Observational

Study design
Single-center cross-sectional observational study

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?
Results article		16/04/2025	17/04/2025	Yes	No
Participant information sheet		26/10/2020	25/11/2022	No	Yes