VR-CAST: Forecasting outcomes in depression treatment with Virtual Reality.

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1. Investigate whether characteristics of laboratory stress response predict depressive symptom severity measured by the Inventory of Depressive Symptomatology - Self-Report (IDS-SR) after 6 months among adults receiving treatment for depressive...

Ethical review	Approved WMO
Status	Pending
Health condition type	Mood disorders and disturbances NEC
Study type	Observational non invasive

Summary

ID

NL-OMON57115

Source
ToetsingOnline

Brief title
VR-CAST

Condition

- Mood disorders and disturbances NEC

Synonym
depression, Depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Depression, Depressive disorder, Ecological Momentary Assessment, psychological, Stress

Outcome measures

Primary outcome

Primary baseline parameters (T0) include physiological stress response as measured by heart rate variability (HRV) in the frequency and time domains, salivary cortisol (CRT) and electrodermal activity (EDA) in response to a psychosocial stressor (TSST-VR); and psychological stress response as measured by the State-Trait Anxiety Inventory - short form (STAI-6). The primary endpoint is change in depression symptom severity measured by the Inventory of Depressive Symptomatology (IDS-SR).

Secondary outcome

Secondary study outcomes include anxiety symptom severity measured by the Beck Anxiety Inventory (BAI) and psychosocial functioning measured by the Interpersonal Relationships and Social Role subscales of the Outcome Questionnaire (OQ-45). Other study parameters include real-life stress response measured with EMA and wearable sensors, and potential factors moderating the relationship between stress response and depressive symptoms (family history of depression, stressful life events, personality traits and coping styles).
Secondary parameters are described in more detail in the research protocol.

Study description

Background summary

In patients with depressive disorders, there is an altered physiological and psychological stress response that may vary with chronicity, symptomatology, and childhood maltreatment history. Because the responsiveness of physiological and psychological stress systems is an indicator of mental health and resilience, these alterations are an important research target. The Trier Social Stress Test (TSST) is a commonly used, standardized laboratory method of exposure to a social stressor. The TSST - Virtual Reality (TSST-VR) is a variant that uses a virtual reality environment to consistently provoke social stress under identical experimental conditions. However, recent insights suggest that the use of artificial stressors lacks ecological validity, and may not produce the full range of stress responses that occur in real life. Ecological Momentary Assessment (EMA) is a method in which experiences, emotions, thoughts, and behaviours can be assessed in a naturalistic environment. Paired with continuous physiological measurements from wearable sensors, EMA offers the opportunity to assess real-life stress responses. Indices of acute stress response to both laboratory and real-life stressors might represent a measure of ability to bounce back from stress and could form the basis for a multimodal resilience marker that could predict disease outcome and treatment response. This would illuminate the role of stress response in the course of depression and inform future research into stratification strategies to target interventions. More detailed information about the background of the study can be found in section 1 of the research protocol.

Study objective

1. Investigate whether characteristics of laboratory stress response predict depressive symptom severity measured by the Inventory of Depressive Symptomatology - Self-Report (IDS-SR) after 6 months among adults receiving treatment for depressive disorders.

2
a.Investigate whether characteristics of laboratory stress response predict the 5-year trajectory of depressive symptom severity measured by the IDS-SR among adults receiving treatment for depressive disorders.

b.Investigate whether characteristics of laboratory stress response predict the 5-year trajectory of anxiety symptom severity measured by the Beck Anxiety Inventory (BAI) among adults receiving treatment for depressive disorders.

c.Investigate whether characteristics of laboratory stress response predict the 5-year trajectory of psychosocial functioning measured by the Interpersonal Relationships and Social Role subscales of the Outcome Questionnaire (OQ-45) among adults receiving treatment for depressive disorders.

d.(Exploratory) Investigate whether potential risk and protective factors (family history of depression, stressful life events, personality traits, coping styles, perceived optimism, and cognitive flexibility) moderate

associations between stress response characteristics and treatment outcome after 6 months.

e.(Exploratory) Investigate whether characteristics of the real-life stress response predict depressive symptom severity measured by the IDS-SR after 6 months among adults receiving treatment for depressive disorders.

f.(Assess safety) Describe the extent to which individuals with a depressive disorder experience lasting impact from the TSST-VR one week after the experiment.

Study design

Single-centre prospective cohort study with 5-year follow-up.

Study burden and risks

The participants are not expected to experience lasting negative effects due to the induction of a stress response. There is a theoretical risk of epileptic seizure caused by the use of head mounted displays with a low refresh rate. Although current research suggests that VR devices are likely benign unless they involve specific provocative content such as light flashes, due to the theoretical risk, use of the TSST-VR is contraindicated in individuals with epilepsy. No major adverse events are expected or have been documented in the use of versions of TSST-VR software at the UCP or developed by other institutions. Mild adverse events associated with exposure to VR includes mild cybersickness, including transient nausea or dizziness. Cybersickness has been reported in the use of other TSST-VR software and one study reported transient panic reactions above the intended stress level. No studies were halted because of these events. More information and sources are described in the research protocol.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1

Groningen 9713GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Clinical diagnosis of a depressive disorder according to the DSM-V diagnosed by the MINI: MDD, PDD or unspecified depressive disorder;
2. Participants have an IDS-SR score at baseline of >= 18;
3. Participants are recruited as new referrals or during intake at the UCP, including patients who will participate in the once-weekly and thrice-weekly group programs and patients receiving individual outpatient sessions;
4. Age 18-64.

Exclusion criteria

1. Previous exposure to the TSST (in vivo or VR version); 2. Photosensitive epilepsy or organic brain damage; 3. Insufficient command of the Dutch language; 4. Intellectual disability (estimated IQ < 70); 5. Corticosteroid medication use; 6. Use of heart-rate altering medication (e.g., beta-blockers, antiarrhymics, calcium antagonists); 7. Chronic illness such as diabetes, liver or thyroid disease, high blood pressure, heart disease and known heart rate disorders.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2024
Enrollment:	104
Type:	Anticipated

Medical products/devices used

Generic name:	Trier Social Stress Test - Virtual Reality (TSST-VR)
Registration:	No

Ethics review

Approved WMO

Date:	29-08-2024
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL84306.042.24