A Study on the Efficacy of Virtual Reality Exposure Therapy (VRET) for Survivors of Childhood Sexual Abuse and War related Trauma

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This study will examine the efficacy of this Virtual Reality Exposure Therapy (VRET) in a CSA and war related trauma sample by comparing it with treatment as usual (TAU). It will also attempt to develop protocols to implement this new technology…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40447

Source
ToetsingOnline

Brief title
Efficacy of VRET for CSA and War related Trauma

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym
posttraumatic stress, Trauma

Health condition

stemmingsstoornissen en -symptomen

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus Universiteit Rotterdam
Source(s) of monetary or material Support: NWO

Intervention

Keyword: PTSD, Trauma, Treatment, Virtual reality

Outcome measures

Primary outcome

Primary dependent variables will be self-reported symptoms of PTSD and

depression at pre, post and follow-up measurements, assessed with the PCL-5 and

BDI-II.

Secondary outcome

Secondary dependent variable will be symptom reduction and improvement of

well-being at pre, post and follow-up measurements, assessed with the OQ-45-2.

Study description

Background summary

Childhood Sexual Abuse (CSA) is a commonly reported form of abuse and represents a worldwide problem. Sexual contact involving an adult and a child is reported in large numbers by both men and women and is associated with serious mental health problems such as posttraumatic stress disorder (PTSD) and depression in adulthood, which mediate suicide. Also combat related war-trauma is associated with PTSD, whereas 5% to 8% of the Dutch military personnel is diagnosed with PTSD after deployment. PTSD is characterized by symptoms as persistent re-experiencing of the traumatic event, avoidance of stimuli associated with the trauma, numbing of general responsiveness, and symptoms of increased arousal such as irritability or outbursts of anger and it is one of the most prevalent axis 1 disorders for which psychotherapy is widely practiced. Depression is one of the most common co morbid disorders when PTSD

is diagnosed. Exposure to the traumatic memories or cues of the traumatic event often plays an important role in reducing symptoms of PTSD. There is also an important connection between the specificity of the autobiographical memory and PTSD and depression symptoms; these symptoms have been related to a reduced specificity in autobiographical memory.

Study objective

This study will examine the efficacy of this Virtual Reality Exposure Therapy (VRET) in a CSA and war related trauma sample by comparing it with treatment as usual (TAU). It will also attempt to develop protocols to implement this new technology into clinical practice and collect data to develop a treatment progress prediction model.

Study design

A randomized controlled intervention study.

Intervention

Virtual Reality Exposure Therapy (VRET)

Study burden and risks

Each participant will receive treatment (VRET or TAU). Based on previous results, it is expected that VRET will be effective for clients as compared to TAU. No significant risks are associated with participation. In case of symptom persistence or increase contact with a therapist or an independent expert is available for participants. The benefit of participation is reduction of mental health issues as symptoms of PTSD and depression.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) principal diagnosis meeting DSM-IV criteria for PTSD and/or major depression following CSA or war related trauma
2) between the ages of 18 and 70-years-old
3) having sufficient fluency in Dutch to complete treatment and research protocol

Exclusion criteria

1) current bipolar disorder
2) current psychotic disorders
3) current suicidality
4) high dissociation level (DES cut-off score >= 40)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-01-2015
Enrollment:	144
Type:	Actual

Ethics review

Approved WMO Date:	10-06-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-09-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL46279.078.13