A symptom reduction study in body integrity identity disorder using augmented reality

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48656

Source
ToetsingOnline

Brief title
A symptom reduction study

Condition

- Other condition

Synonym
Anxiety, depression

Health condition

A psychiatric disorder this is currently unclassified in DSM-V

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Augmented reality, BIID, Symptom reduction

Outcome measures

Primary outcome

- Augmented reality task, the main study parameters consist of self-reports measured by a VAS and physiological recordings of heart rate and Skin Conductance level (SCL) measured by the VU-AMS.

- Non-augmented reality task, the main study parameters consist of self-reports measured by a VAS and physiological recordings of heart rate and Skin Conductance level (SCL) measured by the VU-AMS.

Secondary outcome

N/A

Study description

Background summary

Head mounted display (HMD) technology can be defined as a pair of special computer goggles that can be used to render different forms of stereoscopic virtual content to the user. The two different types of content include both virtual reality (VR) and augmented reality (AR). Virtual reality can be defined as a non-invasive, stereoscopic, computer-generated reality that enables an individual to experience all three dimensions of a virtual environment from any perspective, i.e. the first or third person perspective. Therefore, VR entirely separates individuals from their natural environment. Virtual reality has been studied extensively in the context of managing chronic pain in both physically identifiable [Hoffman 2000, Hoffman 2001, Hua 2015, Gershon 2004, Schneider 2004] and phantom pain [Cole 2009, Wake 2015] conditions. Collectively, these

studies suggest that virtual reality can serve as a powerful distractor for managing pain. No research, however, has been conducted within this field using augmented reality. Augmented reality can be defined as a non-invasive, monoscopic or stereoscopic, realty that is created by combining both the real world and a computer-generated world. This blended reality allows individuals to view virtual images that are imposed over parts of their natural environment.

Study objective

The main objective of this study is to investigate whether body ownership directly influnces the perception of pain in individuals with BIID. The secondary outcome examines whether or not AR is also an effective tool for ameliorating physical and mental discomfort by providing patients with BIID with a compelling visual manipulation of their current physical appearance into their "ideal self".

Study design

This is a case study with behavioral outcome measures.

Intervention

Augmented reality.

Study burden and risks

The risk and burden associated with participation can be considered minimal. There will be a total of 1 'AR' task and 1 'non-AR' task, each of which takes around 35 minutes to complete.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 5
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 5
Amsterdam 1105AZ

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

The recruitment of participants takes place as follows. Practitioners at the department of Psychiatry will inform BIID patients that are currently or have previously been treated within our institution about our study. If someone is willing to participate in the study, we will personally visit with them at the Psychiatry department to inform them of the entire procedure. Moreover, they will receive an information letter by email that reviews all of the information again in detail in order to ensure that they have the opportunity to fully understand the procedure. After this, If they are still interested in participating, they will sign an informed consent and we will perform screening for inclusion and exclusion criteria.;Inclusion criteria:
-Men and women.
-Age between 25-65.
-Recently diagnosed with body integrity identity disorder.
-Desire to amputate lower extremity/extremities (leg/legs).

Exclusion criteria

- A desire for paralysis or other amputations that are not their lower extremities.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-04-2019
Enrollment:	2
Type:	Actual

Medical products/devices used

Generic name:	Oculus Rift DK2
Registration:	No

Ethics review

Approved WMO

Date:	06-03-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL66440.018.18