Bringing Exposure Therapy to Real Life Context with Augmented Reality and Telepsychiatry

Study Protocol

NCT03649347

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Software
The software was developed in collaboration with the AR industry and connects the clinician's computer to the AR headset via Local Access Network (LAN). It provides the clinician with a 3D visual of the surfaces surrounding the participant, obtained from the AR device mapping of the environment. The clinician can use the keyboard to adjust their view of the map 360º to have a better view of any surface. A simple drop-down menu allows the clinician to choose a hologram and a sub-type of the feared object (wolf, jumping, black widow); furthermore, the feared object's color (brown, white, yellow), size, direction of motion, and speed of motion are all clinician-directed manipulations offered. Five unique spider webs are available to place on and between surfaces. At any time, the program can be paused with a single click such that all objects disappear for as long as the clinician sees fit.

The software outputs the number of spiders in the environment, the number of spiders in the participant's field of view, the largest spider, and the distance to the closest spider at any moment. Participant's subjective units of distress (see measures below) can be directly entered into the software during the session. A short video demonstrating the software can be seen here: https://drive.google.com/file/d/1qrHNVjLlVOM8NIguuCtMFnc2fr9IjIkY/view

Device
Microsoft ® HoloLens, a holographic AR device, was utilized. This device was selected for its accurate spatial mapping, a preferred feature for realistic positioning of virtual object on real surfaces. This device is wireless, and operates through LAN connections, granting participants the ability to move and interact freely with the environment and the augmented objects.

Participants
Participants were designated to single session ARET or no treatment control based on the order of enrollment (block designation ABAB; parallel trial design). Inclusion criteria included: 1) current untreated arachnophobia, 2) adults of any sex between the ages of 18 and 45, and 3) willing and able to give written informed consent. Exclusion criteria included: 1) current or previous diagnosis of a psychotic disorder, 2) presence of a substance use disorder within the past six months, 3) current use of psychotropic medications, 4) history of seizure, head trauma, or neurological disease, or 5) an uncorrected visual impairment. All participants provided written informed consent and all study procedures were approved by the Wayne State University Institutional Review Board (IRB# 107517B3F). All research activities occurred at an office clinic at Wayne State University in urban Detroit.

We initially aimed to recruit n=15 individuals per group as part of NCT03649347 Bringing Exposure Therapy to Real-Life Context with Augmented Reality (ARET). This clinical trial is to test the feasibility and efficacy of a novel augmented reality software for the treatment of spider and snake phobias. The sample size of 15 per group, 30 total was chosen for arachnophobia as a pilot feasibility and efficacy trial of the software. This sample size was chosen based on samples found in previous studies for pilot feasibility and efficacy testing of VR and AR platforms (14-20). A priori power analyses were not conducted, however post hoc power analyses were conducted and are reported in the results section. Recruitment and study sessions ran within the year 2019.

Procedure

Treatment group
Prior to the treatment, principles of exposure therapy, using the AR device, and process of the treatment were explained. Participants were told they would be informed of each new level of exposure and would not be surprised or tricked without prompt. They were informed that towards the end of the treatment, if they agreed (which all did), placement and motion of the objects would not be prompted.

For potentiating contextualization of safety learning, exposure therapy took place in two different looking clinic offices. Initially participants were in a bright, windowed office, sitting on a chair in one corner. A small, augmented wolf spider was placed on the floor at the point most distant from the participant. Then a small, augmented jumping spider was presented, followed by a small black widow. At each stage, when the participant reached SUDs of below 4, they would advance to the next level with a larger augmented spider, or to the types of augmented spiders or colors (yellow, brown, white) the participant found scarier. Then augmented spiders were moved horizontally, then slowly toward the participant. Gradually the number, speed of motion, proximity to the participant, and the size of the augmented spiders increased; augmented spiders were also placed, or crawled on the walls or the ceiling, or on a clinical assistant present in the room. Participants were encouraged to walk towards the augmented spiders, sit next to them, and do the same while the augmented spiders were moving. When participants could hold their hand very close to a moving spider with SUDs below 4, this stage was concluded.

Next the participants moved to a darker, windowless office. The same process was repeated. At this stage, participants were also encouraged to walk through an augmented spider web placed on an open doorway, with augmented spiders on it. Ultimately, the participant would be walking around the room, surrounded by tens of augmented spiders crawling around without prompt.

At SUDs below 4, the clinician left the room, and communicated with the participant via telecom. This was to allow the participants to feel comfortable with the feared objects on their own, assuring sense of control and autonomy. This stage usually took less than ten minutes until participants found it comfortable to walk around the room and touch the moving augmented spiders of various size. Treatment ended when the SUDs were below 4.

After the post-treatment BAT, participants were reminded of the principles of exposure therapy and advised to practice at home.

Control group
After filling out the questionnaires, the participants did the BAT. They returned one week, and then one month later for repeating the questionnaires and the BAT.