0-phobia: Towards a virtual cure for specific phobias

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To determine (1) the clinical effects of 0phobia to reduce anxiety symptoms and (2) the feasibility of the intervention and 3) effects on depression, general anxiety and mastery. Ultimately, the goal is to investigate the user-friendliness of 0-...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON45728

Source
ToetsingOnline

Brief title
0-phobia

Condition

- Anxiety disorders and symptoms

Synonym
acrophobia and fear of heights

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: NWO: Stichting STW en KIEM

Intervention

Keyword: fear of heights, mobile app, specific phobias, virtual reality

Outcome measures

Primary outcome

The main parameter will be the Acrophobia Questionnaire (AQ, Cohen; 1977) subscale anxiety, a 20-item self-report questionnaire to measure fear of heights (fear and avoidance). The 20-item anxiety subscale has a 7-point Likert scale (*not anxious* to *extremely anxious*), total score 0-120. The questionnaire is widely-used and has good psychometric properties (Cohen, 1977). This measure will be given at baseline, post-test and follow-up and takes 5 minutes to complete. To be considered for inclusion, individuals have to score at least a 45.45 on the AQ-Anxiety (one standard deviation below the mean of a previous acrophobic sample; Cohen, 1972; Steinman and Teachman, 2011)

Secondary outcome

Secondary parameters are:

* The Attitudes Towards Heights Questionnaire (ATHQ; originally Abelson & Curtis, 1989, with minor modifications to the wording reported in Coehlo, Santos, Silvério, & Silva, 2006) is a 6-item measure in which individuals read pairs of dichotomous adjectives describing ways people may feel about heights (e.g., *Good/Bad,* *Safe/Dangerous*), and rate how they feel about elevated places on a scale of 0 (which corresponds with the first adjective) to 10 (which corresponds with the second adjective). The ATHQ has been used in several height fear treatment studies and is sensitive to treatment effects

(Coehlo et al., 2006; Emmelkamp, Bruynzeel, Drost, & van der Mast, 2001). Reliability is good (Steinman & Teachman, 2014).

* Beck Anxiety Inventory (BAI; Beck et al., 1988) is a 21-item self-report questionnaire assessing symptoms of anxiety. Patients record how much they have been bothered by each symptom during the past week, including the day the questionnaire is administered. Each item is rated on a 4-point Likert scale ranging from 0 = not at all to 3 = severely: I could barely stand it. The total score ranges from 0 to 63. The following guidelines are recommended for the interpretation of scores: 0*9, normal or no anxiety; 10*18, mild to moderate anxiety; 19*29, moderate to severe anxiety; and 30*63, severe anxiety. Internal consistency is high (0.90-0.94) and convergent validity is good (Brown et al., 1997).

* Igroup Presence Questionnaire (IPQ; Schubert, Friedmann and Regenbrecht 2001), a 14-item questionnaire which assess realism and *presence* in the VR environment. Each of the items has five response categories from fully disagree (1) to fully agree (5). Chronbach`s alpha is good (* = .73). This questionnaire will be completed at post-test.

* System Usability Scale (SUS; Bangor et al., 2008): 10 items about user friendliness of the online intervention. The SUS is composed of 10 statements that are scored on a 5-point scale of strength of agreement. Final scores for the SUS can range from 0 to 100, where higher scores indicate better usability. This means that products that are at least passable have SUS scores above 70, with better products scoring in the high 70s to upper 80s. Truly superior products score better than 90. Products with scores less than 70 should be

considered candidates for increased scrutiny and continued improvement and should be judged to be marginal at best. Reliability is good (Bangor et al. 2008). This questionnaire will be completed at post-test.

* Mastery (Pearlin Mastery Scale; Pearlin and Schooler, 1978), 7 items to measure self-experienced control over a situation. Each of the 7 items has five response categories from 1 (totally disagree) to 5 (totally agree). The questionnaire has good psychometric properties. (Pearlin & Schooler, 1978). This questionnaire will be completed at baseline, post-test and follow-up.

* The nine-item mood module of the Patient Health Questionnaire (PHQ-9 ; Kroenke et al, 2007) is used to screen and to diagnose patients with depressive disorders. The 9 items are each scored 0*3, total score range is 0*27. In a review of Wittkampf et al. (Wittkampf et al., 2007), a sensitivity of 0.77 (0.71*0.84) and a specificity of 0.94 (0.90*0.97) was found for the PHQ-9.This questionnaire will be completed at baseline, post-test and follow-up.

* Assessment of current anxiety level directly before and after exposure.

* The GAD-7 (Spitzer et al., 2006) is a 7-item self-report questionnaire to asses generalized anxiety symptoms. Each of its 7 questions is rated 0 - 3 (*not at all* to *nearly every day*), and the total score range is 0 - 21. Psychometric properties are good (Donker et al., 2011; Spitzer et al., 2006).This questionnaire will be completed at baseline, post-test and follow-up.

Study description

Background summary

Specific phobias, such as intense fear of flying, heights, or spiders, are the most common form of mental health disorder worldwide. Specific phobias have a lengthy history of clinical research and very effective exposure treatment exists (Wolitzky-Taylor et al., 2008).However, due to high costs, stigma, and long waiting lists, access to evidence-based therapy is currently limited. Meta-analyses on treatment effectiveness for people suffering from specific phobias have shown that Virtual Reality Exposure Therapy (VRET) is as effective as traditional forms of exposure therapy (Marino et al., 2015; Parsons and Rizzo 2008; Powers and Emmelkamp 2008; Opris et al., 2012). VRET, however, involves relatively high costs and limited accessibility which make it prohibitive for the larger part of the population. This project capitalizes on novel technology and recent scientific advances to develop an affordable treatment modality that is available for anybody, anywhere. Specifically, 0-phobia, a self-help virtual reality (VR) exposure therapy for fear of heights, that is delivered through a smartphone application (app) in combination with rudimentary cardboard VR goggles will be developed and tested. We hypothesize that 0-phobia is feasible and effective in reducing anxiety symptoms and is feasible to use.

Study objective

To determine (1) the clinical effects of 0phobia to reduce anxiety symptoms and (2) the feasibility of the intervention and 3) effects on depression, general anxiety and mastery. Ultimately, the goal is to investigate the user-friendliness of 0-phobia for commercial purpose. Results from this study will provide insight to create a business model and marketing strategy.

Study design

This study will be a randomized controlled trial with two arms: the intervention condition (0-phobia) and a waitlist condition.

Intervention

The intervention 0-phobia is 3-week self-help virtual reality (VR) exposure therapy for fear of heights, that is delivered through a smartphone application (app) in combination with rudimentary cardboard VR goggles. 0phobia includes modules of psychoeducation, case examples, exposure through VR, cognitive techniques, monitoring of symptoms, and a relapse prevention module. Participants in the waitlist condition will be offered the intervention after post-test.

Study burden and risks

The burden of participation consists of completing online baseline questionnaires (15 minutes) and performing the intervention (3 weeks x 5-20 minutes and daily exposure practice during 2 weeks of 10 minutes). In addition, participants will be asked to complete an online post-intervention assessment immediately after completion of the last module of 0-phobia (less than 5 minutes), the intervention (20 minutes) and a follow up after 3 months (20 minutes). There is minimal risk involved and the burden to participants is limited.Participants may feel stress and anxiety, may experience motion sickness or in the unlikely event, may fall during VR exposure.

Note that this study recruits healthy participants who have symptoms of fear of heights. There is minimal risk and burden on participants is limited. Participants may feel stress and anxiety, but in order for the intervention to be effective, participants need to experience anxiety during VR exposure (this is only 1 module out of 6 modules). Participants will practice with a hierarchy of fear situations using gradual exposure (from low fear situations to high fear situations) in which participants learn to manage their anxiety so their anxiety levels will be tolerable. The probability of cyber sickness is minimized by the optimization of the frame rate. In addition, there is no use of fast-moving objects and subjects can not move very quickly through the VR environment. Chances are minimized by safety instructions: they are instructed to hold on to a solid object and removing sharp objects in their immediate environment. Elderly (> 65 years) are more vulnerable when they are to be excluded from the study. Participants are instructed to remover their cardboards in case they experience cyber sickness, high distress or if they feel out of balance. By removing them, levels of high distress, cyber sickness or out of balance are immediately reduced. Should there nevertheless occur undesirable effects, than the subject can approach the research team by email or phone for the necessary support. . Severely depressed and suicidal individuals will be excluded from the study. In the unlikely case that a participant shows suicidal ideation at post-test, he or she will be contacted by the research assistant and asked to give permission to contact his or her GP, who may refer the participant for specific mental health treatment.

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

-scoring above 45.45 on the AQ-Anxiety
-are between 18-64 years old
-have access to a smart phone (Android) and internet
-willing to participate in the research study and providing informed consent
-willing to fill in questionnaires (4 times)

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
-present with symptoms of severe depression or suicidality respectively as measured with the PHQ-9; total score > 19 or a score 3 on the suicidal ideation question of the WSQ (Donker et al. 2009)
-have insufficient knowledge of the Dutch language
-are under current treatment for specific phobia or psychotropic medication (unless on stable dosage for the previous 3 months and no changes planned during the study period)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-03-2017
Enrollment:	154
Type:	Actual

Medical products/devices used

Generic name:	0-Phobia
Registration:	No

Ethics review

Approved WMO Date:	22-02-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-04-2017
Application type:	Amendment
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	NL59777.029.16