0-phobia: towards a virtual cure for specific phobias

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27979

Source
Nationaal Trial Register

Brief title
0-phobia

Health condition

Specific phobia: Acrophobia, fear of heights.

Specifieke fobie: hoogtevrees

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

The main study parameters are the post-test differences in anxiety symptoms between the experimental and control condition, and follow-up differences in anxiety symptoms between baseline and follow-up in the experimental condition.

The main parameter will be the 20-item anxiety subscale of the Acrophobia Questionnaire (AQ, Cohen; 1977). The anxiety subscale has a 7-point Likert scale (‘not anxious’ to ‘extremely anxious’), total score 0-120.

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).

• System Usability Scale (SUS; Bangor et al., 2008): 10 items about user friendliness of the app. 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.

• 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 (α = .73). This questionnaire along with some open questions about user experience of the VR environment 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 subjects 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.

• One question about suicidal ideation from the Screening Questionnaire (Gega et al., 2005) and translated for the Dutch population in the WSQ (Donker et al., 2009): “has the idea of harming yourself, or taking your own life, recently come into your mind?” Answer options are” (1) Definitely not; (2) I seriously considered it but I stopped myself”; (3) “I would do it given the opportunity

• Assessment of current anxiety level directly before and after exposure

Study description

Background summary

Specific phobias, such as intense fear of flying, heights, or spiders, are the most common form of mental health disorders 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 VRET for fear of heights, that is delivered through a smartphone application (app) in combination with rudimentary cardboard Virtual Reality (VR) Google Cardboards will be developed and tested. We hypothesize that 0-phobia is effective in reducing anxiety symptoms and is user-friendly to use.

Study objective

We hypothesize that 0-phobia is effective in reducing fear of heigths anxiety symptoms and is user-friendly to use.

Study design

baselin, post-test, 3-mo follow-up

Intervention

The intervention 0-phobia is 6-week self-help VRET for fear of heights, that is delivered through a smartphone application (app) in combination with rudimentary cardboard VR goggles. 0-phobia 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 directly after post-test.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

-are between 18-64 years old

-scoring above 45.45 on the AQ-Anxiety (one standard deviation below the mean of a previous acrophobic sample; Cohen, 1972; Steinman and Teachman, 2011)

-have access to a smart phone (Android) and internet

-willing to participate in the research study and providing informed consent

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:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2017
Enrollment:	180
Type:	Actual

Ethics review

Positive opinion

Date:	06-03-2017
Application type:	First submission

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
NTR-new	NL6101
NTR-old	NTR6442
Other	METC : 2016-563

Study results

Summary results
not yet