ZeroPhobia: Towards a virtual cure for avio- and arachnophobia

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

Summary

ID

NL-OMON49232

Source
ToetsingOnline

Brief title
ZeroPhobia: Aviophobia/Arachnophobia

Condition

- Anxiety disorders and symptoms

Synonym
specific phobia fear of flying/spiders

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: NWO (aspasia grant)

Intervention

Keyword: fear of flying, fear of spiders, specific phobia, virtual reality

Outcome measures

Primary outcome

The most important outcome measurements are the Fear of Flying Questionnaire, 'Flight Anxiety Situations questionnaire' (FAS; van Gerwen et al., 1999), and the Fear of Spiders Questionnaire (FSQ, Szymanski & O*Donohue, 1995). The FAS is a 32-item self-report flight anxiety questionnaire. The anxiety subscale has a 7-point Likert-scale ('no anxiety' to 'very severe anxiety'). The total score can be between 0 - 115. The FSQ is a 18-item self report spider anxiety questionnaire. .

Secondary outcome

- Aviophobia: The self-report Flight Anxiety Modality questionnaire (FAM; van Gerwen et al., 1999) has 18 items measuring anxiety and anticipation anxiety symptoms in flight situations. The FAM has a 5-point Likert answering scale type, from 1 (com-pletely not) to 5 (very intense). The reliability is good (Nousi et al., 2008).

- Questions related to aviophobia or arachnophobia: duration of the problem, amount of flights undertaken/interactions with spiders, safety behaviours, presence of negative flight/spider experiences (at baseline) and questions about whether participants have taken a flight/interacted with a spider after ZeroPhobia (post-test, follow-up)

- Arachnophobia: The Spider Phobia Questionnaire (Klorman, Hastings, Weerts, Mela-med, & Lang, 1974), a 31-item self-report questionnaire for measuring spider anxiety. This questionnaire is often used for research into spider fear. The SPQ has been found to be high in internal consistency (Johnsen & Hugdahl, 1990).

-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 admin-istered. 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 anx-iety; 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).

-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.

-The Web Screening Questionnaire (WSQ; Donker, van Straten, Marks, and Cuijpers, 2009) is a 15-item questionnaire aimed to screen for depressive disorder, alcohol abuse/dependence, GAD, PTSD, social phobia, panic disorder, agoraphobia, specific phobia, and OCD. Only three items of the WSQ will be asked for the purposes of this study * panic disorder, agoraphobia, and OCD. The questionnaire has been found to have both good sensitivity (0.72 * 1.00) and specificity (0.44 * 0.77) (Donker et al., 2009).

-The Interpersonal Reactivity Index (IRI; Davis, 1980) is a self-report questionnaire measuring different types of empathy. 7 items from the sub-section *Fantasy* will be given to participants as baseline. This will be used to measure general ability to fanta-sized and experience absorption or transportation into fantasy worlds. This questionnaire has been found to be reliable and valid (Davis, 1994).

- Demographic variables (gender, age, education level, marital status, employment status).

- 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 high-er 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.

- User-friendliness of ZeroPhobia as a treatment will be in part measured with the 6- item self-report treatment expectation scale called the Credibility/Expectancy Questionnaire (CEQ; Devilly & Borkovec, 2000). The CEQ measures expectations of the participants before the start of the treatment. This questionnaire will be used alongside the post-test Client Satisfaction Questionnaire (CSQ; Attkisson & Zwick, 1982) to determine if ZeroPhobia did in fact meet expectations.

- User-friendliness will also be measured using single item questions directly asking about the user experience of ZeroPhobia and the realism of the VR environments. This also includes one open question asking for any other feedback on the app a participant would like to give.

- 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 along with some open questions about user experience of the VR environment will be completed at post-test.

- Ecological Momentary Assessment: One question about current anxiety level during exposure in VR

- Usage data from the ZeroPhobia app: frequency and duration of practice during expo-sure in VR, frequency and duration of time spent in the modules.

- Flight usage questions, including when was the last time you flew on an airplane, how many times have you flown in the past 3/12 months and how long was each of these flights?

- Professional treatment (medication and other psychiatric treatment) will be asked during the screening process, but also at post-test and follow up timepoints in order to control for possible other therapeutic effects.

- Negative Effects Questionnaire (NEQ) to asses side effects of psychological treatments (Rozenthal et al., 2014).

Study description

Background summary

Specific phobias, like intense fears of flying (aviophobia) or spiders (arachnophobia), are the most common forms of psychological disorder world wide. Specific phobia has a long history of clinic study, and very effective treatments using exposure therapy exist (Wolitzky*Taylor et al., 2008). However, because of the high costs, stigma, and long waitlists, access to evidence based therapy is currently limited. Meta-anlyses about the effectiveness of virtual reality exposure therapy (VRET) for people with a specific phobia have shown that VRET is as effective as traditional forms of

exposure therapy (Marino et al, 2015;. Parsons en Rizzo 2008; Powers en Emmelkamp 2008; Opris et al., 2012). VRET, however, has relatively high costs and therefore low accessibility to the majority of the population. This project uses new technology and new scientific developments in order to create an affordable treatment modality that would be available to everyone anywhere. ZeroPhobia is a self-help virtual reality (VR) exposure therapy for fear of flying and fear of spiders that is delivered via a smart phone application (app) in combination with rudimentary, cardboard VR glasses. Our hypothesis is that ZeroPhobia will be practical and effective in minimizing symptoms of anxiety.

Study objective

The objectives of the study are to see whether or not ZeroPhobia 1) minimizes symptoms of flying/spider phobias and 2) whether these effects are maintained at follow-up timepoints.The ultimate goal is to judge whether or not ZeroPhobia can be feasibly released for commercial use. Secondary objectives are to understand whether ZeroPhobia (3) is user-friendly, (4) if it is effective in reducing depression and anxiety, (5) to determine whether usage intensity and presence in the VR environment influences the effects of ZeroPhobia, (6) to determine whether exposure or evaluating thoughts mediate anxiety outcomes, and (7) whether ability to fantasize influences the effectiveness of VRET.

Study design

This study will be a randomized controlled trial with two arms: ZeroPhobia experimental condition and a waitlist control condition.

Intervention

The intervention ZeroPhobia is 6-week self-help VRET for aviophobia and arachnophobia that is delivered through a smartphone application (app) in combination with rudimentary cardboard VR glasses. ZeroPhobia includes modules of psychoeducation, case examples, exposure through VR, cognitive techniques, monitoring of symptoms, and relapse prevention. Participants in the waitlist condition will be offered the intervention directly after post-test.

Study burden and risks

Burden of participation consists of completing online baseline questionnaires (15 minutes) and completing the intervention (6 weeks x 5-20 minutes and daily exposure for 3 weeks, 10 minutes each). In addition, participants are asked to complete an online post-intervention evaluation immediately after the intervention (20 minutes) and, for those in the control condition, and, for those who received active treatment, a follow-up after 3 and 6 months (15 minutes each). For those in the control group for arachnophobia, participants

will be asked to fill in the primary outcome measure (1-2 minutes) after the intervention.

There is minimal risk and the burden for participants is limited. The risk of cyber sickness has been minimized by optimizing the frame rate. In addition, fast moving objects are not used and test subjects cannot move through the VR environment very quickly either. The chance of falling is only present when practicing in the VR environment (after module 3 in the app). The risk of falling is minimized by safety instructions: they are instructed to hold on to a solid object and to remove sharp objects in their immediate environment. Elderly people (> 65 years) who are more vulnerable to falling are excluded from the study.

The participants are instructed to remove their VR glasses if they experience cyber sickness, high anxiety, or loss of balance. This will quickly reduce the symptoms. Should an undesirable effect nevertheless occur, the test subject can approach the research team by email or telephone for the necessary support.

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

- Aviophobia: scoring above 56 on the Flight Anxiety Situations questionnaire (FAS; van Gerwen et al., 1999; 2018; Nousi et al., 2008)
- Arachnophobia: scoring above 80 on the Fear of Spiders Questionnaire (FSQ; Szymanski & O*Donohue, 1995)
- between 18-64 years old
- have access to a smart phone and internet
- must live in the Netherlands and have a Dutch telephone number
- willing to participate in the research study and providing informed consent

Exclusion criteria

- 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)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2019
Enrollment:	263
Type:	Anticipated

Ethics review

Approved WMO Date:	11-10-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-12-2020
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

ID: 24641
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL70238.029.19
OMON	NL-OMON24641
OMON	NL-OMON27993