ZeroPhobia: Self-guided app-based CBT for fear of flying

No registrations found.

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

Summary

ID

NL-OMON24641

Source
NTR

Brief title
TBA

Health condition

Specific Phobia: Aviophobia, fear of flying

Sponsors and support

Primary sponsor: NWO
Source(s) of monetary or material Support: NWO ASPASIA (015.014.032)

Intervention

Outcome measures

Primary outcome

Our primary research objective is to determine the clinical effects of ZeroPhobia: whether (1) there is a reduction in phobic anxiety symptoms within-participants and between-participants (experimental vs control) post-test and whether (2) effects are sustainable at 3 and 12 month follow-up. Therefore, this primary outcome of anxiety symptoms will be measured using the Flight Anxiety Situations questionnaire (FAS; van Gerwen et al., 1999).

Secondary outcome

The Flight Anxiety Modality questionnaire (FAM; van Gerwen et al., 1999) will also be used as a secondary measurement of this primary outcome. The FAS focuses on the degree of anxiety evoked by different flight situations, whereas the FAM focuses on the degree of different anxiety symptoms and sensations one could experience during a flight situation (i.e. racing heart rate). General anxiety as measured by the Beck Anxiety Inventory (BAI; Beck et al., 1988) as well as depressive symptoms as measured by the Patient Health Questionnaire (PHQ-9; Kroenke et al., 2007) will be secondary measurements of anxiety and mood changes before and after intervention, which are associated with specific phobia. Questions pertaining to panic disorder, agoraphobia, and OCD from the Web Screening Questionnaire (WSQ; Donker, van Straten, & Cuijpers, 2009) will be assessed as confounding factors.
Our secondary research objectives include determining: (3) the user-friendliness of the intervention, (4) if the usage intensity and/or (5) the feeling of presence influence the primary outcome of ZeroPhobia, (6) if exposure or evaluating thoughts mediate anxiety outcomes, and (7) whether or not ability to fantasize influences the effectiveness of VRET.
User-friendliness will be assessed using the Credibility Expectancy/Satisfaction Questionnaires (CEQ and CSQ; Devilly & Borkovec, 2000). The CEQ is given at pre-test and the CSQ at post-test. The System Usability Scale (SUS; Bangor et al., 2008) will also be given at post-test to understand user-friendliness of the app itself. Usage data will be collected from the app, including when modules are completed and duration spent using ZeroPhobia, to assess whether usage intensity affects primary outcomes.
The IGroup Presence Questionnaire (IPQ; Schubert, Friedmann, and Regenbrecht, 2001) will be used to assess realism and sense of presence in the VR environments. Usage data on frequency and duration using VRET collected from the app will be used to assess its mediating factors on anxiety outcomes.
The Interpersonal Reactivity Index: Fantasy Sub-scale (IRI; Davis, 1980) will be used to assess participant's general ability to fantasize and experience absorption/transportation into storylines and artificial situations. This measurement will be further explored in a separate paper.
An assessment of anxiety directly before and after each VR exposure will also be collected for analysis of changes in anxiety. Flight usage will also be assessed (whether or not an individual has flown recently, how long the flight was, etc.) to further assess flight anxiety severity.
Demographic information and whether or not an individual has received other treatment (medication or therapy) during our treatment to remove confounding variables.
A final research objective - to assess whether drop-out is different between guided and un-guided VRET - will be in part assessed using this data; participants of this study will receive unguided VRET, whereas those of our ZeroPhobia: Arachnophobia study will receive guided VRET. Differences in dropout rates will be compared.

Study description

Background summary

Specific phobias, such as intense fear of flying, heights, and 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 rules out VRET as a treatment option 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, ZeroPhobia, a self-help VRET for aviophobia, delivered via a smartphone application (app) in combination with rudimentary cardboard Virtual Reality (VR) glasses will be developed and tested.

Study objective

We hypothesize that ZeroPhobia will effectively reduce fear of flying anxiety symptoms, will be sustained at three and twelve month follow ups, and is user-friendly. We also hypothesize that VRET will be less effective for individuals who are less prone to experiencing emotional transportation and have a lowered ability to fantasize.

Study design

Measurements are taken at baseline, post-test (six weeks), and follow up (three month and 12
month).

Intervention

ZeroPhobia is a 6-week, self-help VRET for fear of flying, that is delivered through a smartphone application 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.

Contacts

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Eligibility criteria

Inclusion criteria

- Aviophobia: scoring above 56 on the Flight Anxiety Situations questionnaire (FAS; van Gerwen
et al., 1999; 2018; Nousi et al., 2008)
- between 18 - 64 years old (excluding 65 and older due to higher risk of falling)
- have access to a compatible smart phone with internet/data access
- willing to participate in the research study and provide 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:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-11-2019

Enrollment:	114
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	04-11-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49232
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8257
CCMO	NL70238.029.19
OMON	NL-OMON49232

Study results

Summary results

Donker, T., Van Esveld, S., Fischer, N., & Van Straten, A. (2018). 0Phobia–towards a virtual cure for acrophobia: study protocol for a randomized controlled trial. Trials, 19(1), 433.
Donker, T., Cornelisz, I., Van Klaveren, C., Van Straten, A., Carlbring, P., Cuijpers, P., & van

Gelder, J. L. (2019). Effectiveness of self-guided app-based virtual reality cognitive behavior therapy for
acrophobia: a randomized clinical trial. JAMA psychiatry.