Take a DEEP breath: Testing the Effectiveness of a Virtual Reality Biofeedback Video Game for Anxiety Regulation

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27657

Source
Nationaal Trial Register

Health condition

Anxiety; Stress; Emotion Regulation; Intervention; Video Game; Virtual Reality; Biofeedback

Sponsors and support

Primary sponsor: Radboud University Nijmegen, Behavioural Science Institute
Source(s) of monetary or material Support: NWO Creatieve Industrie (314-99-115); Stimuleringsfonds

Intervention

Outcome measures

Primary outcome

1. Pre-test (before 1st session), Post-test (after final session), and 3-month follow-up anxiety symptoms as measured by the Dutch version of the State-Trait Anxiety Inventory(STAI-DY; Van der Ploeg, Defares, & Spielberger, 1981)

2. Patterns of self-reported state anxiety (STAI-DY) and physiological arousal (PAQ; Dieleman, Van der Einde, Verhulst, & Huizink, 2010) over the course of all the lab-sessions.

Secondary outcome

1. Changes in physiological measurements of heart-rate variability, breathing patterns and skin conductance over the course of all the lab-sessions.

2. Changes in evaluations and appraisals e.g. engagement, self-efficacy, agency, and mindset over the course of all the lab-sessions.

3. Game/application evaluation: How much they liked it, what they liked about it (open-ended), what they did not like about it (open-ended), whether they would want to use it in the future and whether they would recommend it to someone else.

Study description

Background summary

This study will test the effectiveness of Virtual Reality Biofeedback Video Game DEEP in improving anxiety symptoms and related physiological arousal and appraisal patterns. Individuals with elevated anxiety symptoms will be randomly assigned to play DEEP or a commercially available (free) phone application that guides individuals through a deep breathing exercise. Both applications will be used in 4 separate sessions over the course of 2-3 weeks. Anxiety symptoms will be assessed before the first session, after the final session and at a 3-month follow-up. Measurements of secondary outcomes such as changes in physiological arousal and appraisal patterns will be measured throughout all sessions.

Study objective

This study will test the effectiveness of Virtual Reality Biofeedback Video Game DEEP in improving anxiety symptoms and related physiological arousal and appraisal patterns. It is expected that this game will lead to a greater improvement in these areas than a commercially available application that is focused on breath-based relaxation training.

Study design

1. Screening (max 2 weeks before first session)

2. Pre-test (before first session): demographics, anxiety symptoms

3. Throughout all intervention sessions: self-reported state anxiety, physiological arousal, appraisals and physiological measures.

4. Post-test (after final session): anxiety symptoms, game/application evaluation

5. 3-month follow up: anxiety symptoms

Intervention

1. Participants will be recruited through the SONA system of the Radboud University, an online recruitment system where individuals can sign up to participate in scientific studies. Once they have signed up they receive a link to the screening questionnaire. If they meet the criteria they are invited for further participation.

2. Individuals are randomly assigned to the intervention or control condition. Individuals in the intervention condition will play DEEP, a Virtual Reality biofeedback video game that is controlled by diaphragmatic breathing. Individuals in the control group will use a commercially available (free) phone application (Paced Breathing) that guides individuals through a deep breathing exercise.

3. Both groups will first participate in 4 lab-sessions, distributed over 2-3 weeks, and a 3-month follow up. In all sessions they will be playing DEEP or using the breathing app for 10 minutes.

4. In the first session participants will have to do a performance task where they have to give an oral presentation to see how they respond to anxiety-provoking situations. Subsequently they will either be playing DEEP or they will be using the breathing app for 10 minutes.

5. In the second session, participants will again be playing either DEEP or they will be using the breathing app.

6. In the third session, participants will be either using the breathing app (control) or they will be playing DEEP, which will include an exposure element.

7. In the final session, participants will again be either using breathing app (control) or they will be playing DEEP, which will include an exposure element. Subsequently, they will again have to give an oral presentation.

8. After three months, participants will receive an e-mail asking them to fill out a follow-up questionnaire

Contacts

Public
Montessorilaan 3 kamer A. 6.11a

Joanneke Weerdmeester

Nijmegen 6525 HR
The Netherlands
+31 (0)24 3612551
Scientific
Montessorilaan 3 kamer A. 6.11a

Joanneke Weerdmeester
Nijmegen 6525 HR
The Netherlands
+31 (0)24 3612551

Eligibility criteria

Inclusion criteria

1. Individuals between the ages of 18 to 30 years old

2. Elevated anxiety and stress symptoms on the DASS-21 screening questionnaire. This means that they score above the normal cut-off for anxiety (>8) and/or stress (>15).

3. Active consent from participants

Exclusion criteria

No active consent from participants

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-11-2017
Enrollment:	200
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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	NL6635
NTR-old	NTR6821
Other	ECSW2016-2208-412a : ECSW2016-2208-412

Study results