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

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Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27657

Bron
Nationaal Trial Register

Aandoening

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

Ondersteuning

Primaire sponsor: Radboud University Nijmegen, Behavioural Science Institute
Overige ondersteuning: NWO Creatieve Industrie (314-99-115); Stimuleringsfonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

No active consent from participants

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	03-11-2017
Aantal proefpersonen:	200

Type: Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6635
NTR-old	NTR6821
Ander register	ECSW2016-2208-412a : ECSW2016-2208-412

Resultaten