VRelax at work

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Expected benefits include immediate relaxation, reduction of perceived stress and burn-out symptoms and improved functioning.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23543

Bron
NTR

Verkorte titel
TBA

Aandoening

Burn-out

Ondersteuning

Primaire sponsor: University Medical Center Groningen, Groningen, the Netherlands
Overige ondersteuning: Zilveren Kruis

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

As the primary outcome data has a multilevel structure (multiple VAS session scores within participants), VAS scores are analyzed with mixed model multilevel regression analyses (MIXED command), including factor time (length of baseline and before vs. after session). Models have a random intercept for participant. The estimation method is set to restricted maximum likelihood and the covariance structure to unstructured. The immediate effects of

VRelax is analyzed by comparing mean VAS scores between multiple baseline and intervention periods, and before and after sessions. Covariates include sociodemographic characteristics and baseline level of stress, symptoms and functioning.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Work-related stress is highly prevalent among workers in the Netherlands. Stress is a key factor in development and unfavourable course of burn-out problems. Societal costs as a result of work production loss are € 2.8 billion for work-related stress. Mental and occupational healthcare resources are lacking to meet all treatment demands. Effective and easy self-management stress reduction interventions are urgently needed to increase well-being and reduce mental health problems of workers. Virtual Reality (VR) relaxation may provide a solution.

Objective: Primary Objective: to evaluate the immediate and short-term effect of a self-management immersive VR relaxation application on perceived stress and burn-out problems in workers presenting to occupational health services with work-related stress. Secondary Objective(s): to explore level of functioning, work absenteeism and work engagement before and after use of VR relaxation.

Study design: Non concurrent multiple baseline (randomized to 3, 6 or 9 days baseline measures) intervention study.

Study population: Employees of companies affiliated with insurance company Zilveren Kruis, who present with psychosocial stress and burn-out symptoms at occupational health services.

Intervention: Daily 20-minute use of self-management VR relaxation tool at home during three weeks.

Main study parameters/endpoints: the immediate effect on level of psychological stress, measured with two Visual Analogue Scales (VAS; range 0-100) once daily during 3, 6 or 9 days before start of the VRelax intervention, and before and after each VRelax session: “I feel relaxed” and “I feel calm”. Secondary outcomes include level of perceived stress, burn-out symptoms, functioning, work engagement and absenteeism.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participants are randomized to 3, 6 or 9 days baseline measure of once daily two VAS items (2 minutes). They will fill in a digital questionnaire before and after the intervention period (20 minutes each). They complete two VAS items before and after each of the daily 20-minute VR relaxation sessions during three weeks. Risks are negligible; some people will experience mild and transient discomfort (nausea, dizziness) caused by the VR Head Mounted Display. Expected benefits include immediate relaxation, reduction of

perceived stress and burn-out symptoms and improved functioning. As there is no control group, all participants will receive the VR relaxation intervention.

Doel van het onderzoek

Expected benefits include immediate relaxation, reduction of perceived stress and burn-out symptoms and improved functioning.

Onderzoeksopzet

1. A potential participant is informed about the study by the occupational healthcare service he/she attends. It should be noted that the use of VRelax is regular practice; the study only concerns the evaluation of VRelax in the companies' occupational healthcare setting.

2. If the potential participants agrees, the occupational health service worker sends his/her contact details to the VRelax study team by email.

3. Additional information will be provided by a return email, including the document 'proefpersoneninformatie' and informed consent form.

4. If a person decides to participate, he/she signs the informed consent form digitally. This process cannot be done in person, given the anticipated large number of companies and participants across the entire country.

5. Next, the participant will receive the baseline digital questionnaire. After completion he/she is randomized to 3, 6 or 9 days baseline VAS item measures.

6. During the baseline days, participants receive links to the VAS items via sms on their smartphone. After completing the last day of VAS items, a user code is automatically sent, by which VRelax can be activated. VAS items will continue during intervention and 6 days after intervention.

6. The participant has received a HMD with the VRelax application from the occupational health services he/she attends. He/she is instructed to use VRelax (at least) once daily for 20 minutes. Before and after each session, two VAS items are completed within the VRelax application. Scores are automatically uploaded to the study database.

7. After three weeks, the participant returns the HMD to the occupational health service. The VRelax study team sends a link to the follow-up digital questionnaire by email to the participant. After three and ten days, a reminder email is sent to the participant if the questionnaire has not been completed.

Onderzoeksproduct en/of interventie

Daily 20-minute use of self-management VR relaxation tool at home during three weeks.

Contactpersonen

Publiek

UMCG
Bart Lestestuiver

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- >18 years of age.
- Parttime or fulltime employed.
- At least moderate level of self-reported psychosocial stress.
- At least mild burn-out symptoms, judgement of occupational health service worker.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- IQ <70.
- Poor vision.
- Actual epilepsy (convulsion during past 12 months).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	10-03-2021
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	09-03-2021
Soort:	Eerste indiening

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	NL9316
CCMO	NL74671.042.20

Resultaten