Testing daily smartphone-delivered interventions in individuals with workstress

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29391

Source
Nationaal Trial Register

Health condition

Individuals who experience work stress, defined as an effort-reward imbalance ratio of >1

Sponsors and support

Primary sponsor: Leiden University
Source(s) of monetary or material Support: ZonMw (Top Grant)

Intervention

Outcome measures

Primary outcome

Ambulatory measured heart rate variability, timepoint: post-intervention (i.e., 4-weeks)

Secondary outcome

• Ambulatory measured heart rate variability, timepoint: 2-weeks.

• Ambulatory measured heart rate, timepoint: 2-weeks, post-intervention.

• Implicit Positive and Negative Affect as measured with Implicit Positive and Negative Affect Test, timepoint: 2-weeks, post-intervention.

• Implicit stress as measured with the Implicit Association Test, timepoint: 2-weeks, post-intervention.

• Explicit positive and negative affect as measured with the four basic emotions, timepoint: 2-weeks, post-intervention.

• Five Facet Mindfulness Questionnaire score, timepoint: 2-weeks, post-intervention.

• Effort-Reward Imbalance score, timepoint: post-intervention

• Trait worry, as measured by Penn State Worry Questionnaire, timepoint: 2-weeks, post-intervention.

• Anxiety symptoms as measured by GAD-7, timepoint: 2-weeks, post-intervention.

• Depressive symptoms as measured by PHQ-9, timepoint: 2-weeks, post-intervention.

Study description

Background summary

Psychosocial stress is a widespread problem and a substantial co-determinant of organic disease, including cardiovascular disease (CVD). One of the most important stressors are work stressors, that increase CVD risk up to 3.6 times (Bosma, Peter, & Siegrist, 1998; Matthews & Gump, 2002) in a dose response fashion (Chandola et al., 2008), with follow-up times between 4-12 years. There is a general agreement that stressors exert their unhealthy effects in the long run via prolonged physiological stress responses (e.g., lower heart rate variability, prolonged blood pressure, excessive cortisol excretion). In recent years, a new hypothesis has been put forward stating that a large part of these prolonged physiological stress responses is due to implicit or unconscious stress (Brosschot, Verkuil, & Thayer, 2010). The best way to show that unconscious stress causes prolonged activity in real life, which is the main premise of this new theory, is to manipulate unconscious stress, in this case to decrease it, since the reverse would be unethical. To our knowledge however, no intervention exists that reduces unconscious stress. In this project we therefore want to study the effect of a smartphone-programmed mindfulness-based therapy on conscious (e.g., effort-reward imbalance) and unconscious (work) stress (i.e., Implicit Positive and Negative Affect Test and Implicit Association Test) and physiological stress (i.e., heart rate variability and heart rate) in daily life. More specifically, we expect that administering an evidence-based intervention (mindfulness) reduces the prolonged physiological stress response, and conscious as well as

unconscious stress.

Study objective

•Participants in the experimental (i.e., mindfulness exercises) and control (i.e., emotion registration) condition will experience a decrease in prolonged cardiovascular activity, indicated by a increase in heart rate variability and an decrease in heart rate

•Participants in the experimental (i.e., mindfulness exercises) and control (i.e., emotion registration) condition will experience a decrease on the implicit negative affect scale of the Implicit Positive and Negative Affect Test and a decrease on implicit stress as measured by the Implicit Association Test.

•The decrease in both physiological and psychological complaints will be larger in the experimental and control condition, compared to the waitlist condition.

•The decrease in both physiological and psychological complaints will be larger in the experimental condition, compared to the control condition.

Study design

At the start of the intervention, after two weeks and after 4 weeks the cardiovascular activity and psychological measures will be completed.

Intervention

Experimental condition: Problem-solving techniques, worry postponement, mindfulness exercises

- Dose: daily, 5 times a day (between 9 AM – 11 PM)

- Duration: 4 weeks (29 days)

- Mode of administration: via an application on a smartphone

Active control condition: daily registration of basic emotions

- Dose: daily, 5 times a day (between 9 AM – 11 PM)

- Duration: 4 weeks (29 days)

- Mode of administration: via an application on a smartphone

Waitlist condition: No treatment

Contacts

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Eligibility criteria

Inclusion criteria

Dutch speaking individuals who are employed, are 18 years or older, have an effort-reward imbalance ratio of >.89, and who have sufficient knowledge of how to work with a smartphone.

Exclusion criteria

Person is not currently employed, has a latex allergy, currently being treated for a psychological or psychiatric disorder, has or has had a cardiovascular disease, substance abuse, no current or recent reports of suicidal ideation, history or presence of severe psychological disorders.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-09-2014
Enrollment:	180
Type:	Anticipated

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	NL4607
NTR-old	NTR4758
Other	Registration number of Ethics Commission of Leiden University : 2865487857

Study results