

Testing a daily smartphone-delivered intervention in individuals with work stress

No registrations found.

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

Summary

ID

NL-OMON28067

Source

NTR

Health condition

stress, work load

Sponsors and support

Primary sponsor: Leiden University

Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

- Implicit Positive and Negative Affect as measured with Implicit Positive and Negative Affect Test, time-point: post-intervention (i.e., 4-weeks).
- Implicit stress as measured with the Implicit Association Test, time-point: post-intervention.

Secondary outcome

- Implicit Positive and Negative Affect as measured with Implicit Positive and Negative Affect Test, time-point: 2-weeks.
- Implicit stress as measured with the Implicit Association Test, time-point: 2-weeks.
- Explicit positive and negative affect as measured with the four basic emotions, time-point: 2-weeks, post-intervention.
- Five Facet Mindfulness Questionnaire score, time-point: 2-weeks, post-intervention.
- Effort-Reward Imbalance score, time-point: post-intervention
- Trait worry, as measured by Penn State Worry Questionnaire, time-point: 2-weeks, post-intervention.
- Anxiety symptoms as measured by GAD-7, time-point: 2-weeks, post-intervention.
- Depressive symptoms as measured by PHQ-9, time-point: 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) in daily life. More specifically, we expect that administering an evidence-based intervention (mindfulness) reduces conscious as well as unconscious stress.

Study objective

- Participants in the experimental condition (i.e., mindfulness exercises) will experience a larger decrease on the implicit negative affect scale of the Implicit Positive and Negative Affect Test compared to the waitlist condition
- Participants in the experimental condition will experience a larger decrease on implicit stress, as measured by the Implicit Association Test, compared to the waitlist condition.

Study design

At the start of the intervention, after two weeks and after 4 weeks the psychological questionnaires and tasks 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

Waitlist condition: no treatment

Contacts

Public

Wassenaarseweg 52

A. Versluis
Leiden 2300 RB
The Netherlands
071-527 6343

Scientific

Wassenaarseweg 52

A. Versluis
Leiden 2300 RB
The Netherlands

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, currently being treated for a psychological or psychiatric disorder, 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:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-11-2014
Enrollment:	120
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 NL4675

NTR-old NTR4827

Other Registration number of Ethics Commission of Leiden University : 5097802079

Study results