MindRest: Mindful Network Dynamics Regulation under Stress

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49673

Source
ToetsingOnline

Brief title
MindRest

Condition

- Other condition

Synonym
anxiety, stress

Health condition

Psychological Distress

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Mindfulness, Stress, Students

Outcome measures

Primary outcome

The primary outcome measure is perceived stress, which is measured by the Perceived Stress Scale (PSS) post-treatment.

Secondary outcome

We will also assess secondary outcome measures, including both self-reported questionnaires measuring depressive symptoms (Q-IDS-SR), anxiety (State and Trait Anxiety Inventory), alcohol use (AUDIT), childhood trauma (MACE-X), personality traits (NEO-FFI), repetitive negative thinking (PTQ), cognitive reactivity (LEIDS-R), allowing of emotions (Acceptance and Action Questionnaire), mindfulness skills (short version of the Five-Facet Mindfulness Questionnaire), self-compassion (short version of the Self-Compassion Scale), stress Resilience (CD-RISC), and positive mental health (Mental Health Continuum). Moreover, we will perform neurocognitive tasks that are selected specifically to assess exogenously as well as endogenously driven stress-regulation with and without task demands, including a fear conditioning and extinction paradigm, an emotional conflict resolution task, a resting state task under stress, and a real-time fMRI neurofeedback task. During these tasks we will record task performance, neuroimaging data (i.e. fMRI data), as well as

physiological data (heart rate, respiration, skin conductance, pupil size, and salivary cortisol). In addition, we will administer ecological momentary assessments, coupled with physiological measures (heart rate, skin conductance, skin temperature, and movement), to assess stress reactivity in daily life.

Study description

Background summary

Prolonged stress exposure can put people at risk of developing stress-related symptomatology, such as burnout, sleeping disorders, depression and anxiety. Students reporting high levels of perceived stress are an at-risk population that could potentially benefit from a stress-reduction intervention (LeBlanc, 2014; Lyndon et al., 2014). One approach to reduce stress is Mindfulness Based Stress Reduction (MBSR). Although proven effective, additional evidence is required on the effectiveness of MBSR in reducing stress-related symptoms in student sample pre-selected on high stress. Furthermore, the working mechanisms of MBSR are only marginally understood. This is problematic, because gaining better mechanistic insight on how MBSR works might lead (1) to basic scientific insights into stress and stress resilience and (2) clinically, to the opportunity to better allocate treatment for the individual. In the light of preliminary psychological study results on MBSR we hypothesize that (in contrast to other stress-management strategies) MBSR will not only foster stress-reduction via cognitive control but also via experiential exposure. In accordance with this hypothesis and based on neurocognitive findings in basic stress research and previous mechanistic studies on MBSR, we will assess whether MBSR indeed leads to improved stress-regulation by enhancing both cognitive and affective processing, which will be reflected in neural network configuration.

Study objective

The main objective of this study is to assess the effectiveness of MBSR to reduce perceived stress in a highly stressed student population. Our main objective regarding working mechanisms of MBSR is to assess possible MBSR induced changes in large-scale neural network configuration and self-regulation of these networks. Additionally, this study aims to explore possible mediators and moderators of the treatment effect, both in terms of psychological traits, and neural patterns.

Study design

We will perform a randomized, wait-list controlled trial. Participants will be randomised into a treatment and wait-list group after baseline Clinical Assessments (CA), Neurocognitive Assessments (NA), and Ecological Momentary Assessments (EMA). In the following two months the treatment group will participate in an MBSR training and the control group will wait for two months. Another CA and NA and EMA will take place post- treatment. Three months later there will be a follow-up CA.

Intervention

Participants in the treatment group will follow an MBSR training which consists of 8 weekly sessions lasting 2,5 hours; a silent day of approximately 6 hours; and daily home practice assignments of about 45 minutes. The control group will follow the training at the end of the study, therefore acting as a wait-list control group during the measurements.

Study burden and risks

Participants will have to attend a short screening meeting, 2 visits at the MRI lab and 2 visits at behavioural labs for neurocognitive measurements, and will also have to answer multiple questionnaires as part of the CA and EMA. The risks of participation in the MBSR treatment as well as the MRI measurements are negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age above 18 years.
Able to give informed consent.
Score in Perceived Stress Scale score >= 16

Exclusion criteria

Current specialised psychological or psychiatric treatment or medication.
Insufficient comprehension of the Dutch language.
Physical, cognitive, or intellectual impairments interfering with participation, such as deafness, blindness, or sensori-motor handicaps.
Formerly/currently involved in MBCT or MBSR training.
Current drug or alcohol addiction.
Contraindications for MRI scanning (e.g., pacemaker, implanted metal parts, deep brain stimulation, claustrophobia, epilepsy, brain surgery, pregnancy).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2021
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	20-01-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-02-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL74345.091.20