DEcrease STress through RESilience training for Students

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Individual-directed resilience training can reduce chronic stress and prevent burnout among students

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

Samenvatting

ID

NL-OMON20777

Bron
Nationaal Trial Register

Verkorte titel
DESTRESS

Aandoening

Chronic stress

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Studie Voorschot Middelen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Perceived Stress Scale (PSS)

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Chronic stress and burnout are increasing among students which can negatively affect their health and well-being, capacity to engage in meaningful learning, study results, and future skills as a professional. In healthcare this has a deleterious effect on the quality of provided care and the sustainability of the healthcare system. Stress management and resilience are important skills that students need to acquire in order to meet the demands of the (healthcare) professions.
Objective: The primary objective of the study is to assess whether introducing resilience training reduces perceived chronic stress in students at the Erasmus University Medical Center Rotterdam (Erasmus MC). The main secondary objectives are to evaluate:
• The effect of resilience training on symptoms of burnout, mental well-being, quality of life, mental and physical stress-related symptoms, resilience, healthcare utilization, study weighted average, study cumulative EC points, and BMI.
• Which intervention is most effective in reducing perceived chronic stress and symptoms of burnout and in improving mental well-being
• Participants' preferences for, and adherence to, the interventions
• Factors (individual and in the academic environment) that predict perceived stress, symptoms of burnout, and mental well-being.
Study design: Hybrid design: longitudinal observational cohort, nested randomized controlled trial (RCT), sequential multiple assignment, multistage adaptive interventions, taking into account participants’ preferences.
Study population: All students at the Erasmus University Medical Centre Rotterdam aged 16 years or older who give informed consent are included in the cohort study. Within this observational cohort, students with a score of 14 or higher on the Perceived Stress Scale are invited to take part in the RCT (n=706).
Intervention: Following informed consent, participants eligible for the RCT are randomized in a ratio of 1:6 to control vs active intervention. Participants randomized to the control group and non-randomized participants in the cohort receive passive web-based education about chronic stress and burnout through referral to specific websites on the topic. Participants randomized to the intervention group receive one of 8 active interventions: mindfulness training, running, yoga, aikido, music, and stress management training, of which 3 are in e-health format and 5 in blended format. Participants in the active intervention arm are able to select and rank order 4 (out of the 8) preferred interventions and are randomized to one of these 4 with equal probability. Non-response to the intervention is followed by sequential randomized assignment to another intervention in the next period, with an increased chance of randomization to higher ranked preferred interventions, which is repeated once more, for a total maximum of 3 sequential interventions.
Main study parameters/endpoints: The primary outcome is perceived chronic stress (Perceived Stress Scale). Secondary outcomes are symptoms of burnout (Oldenburg Burnout Inventory – student version), mental well-being, quality of life (Visual Analogue Scale), mental and physical stress-related symptoms (Four-Dimensional Symptom Questionnaire), resilience (Brief Resilience Scale), study progress: student’s weighted average grade (WAG) and

cumulative European Credit points (EC points), preference for and adherence to lifestyle practices, body-mass index (BMI), perfectionism, and healthcare utilization.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participants in the active intervention arm of the RCT will follow a maximum of 3 intervention periods of 8 weeks each. All participants, both in the cohort and RCT, will receive questionnaires at baseline, before and after each 8-week intervention period, and at 2–year follow-up. All interventions are low risk lifestyle interventions which are widely available to the general public.

Doel van het onderzoek

Individual-directed resilience training can reduce chronic stress and prevent burnout among students

Onderzoeksopzet

Baseline, Post-intervention (3 times), 1- and 2- year followup

Onderzoeksproduct en/of interventie

Control Intervention
All participants in the cohort study and RCT will receive psychoeducation about chronic stress and the prevention of burnout through the study web-portal. The psychoeducation consists of explanation of chronic stress, how burnout develops, the role of self-care, and stress management. The control group in the RCT will in addition receive an email with this information.

Active Intervention
Multiple behavioral interventions will be evaluated in parallel and sequentially as dynamic intervention regimens. The duration of all intervention periods is 8 weeks, which is the duration of the Mindfulness-Based Stress Reduction (MBSR) course. Interventions will be offered either in an e-health format or in a blended format or both. Blended interventions consist of a group intervention with weekly meetings with e-health practice at home. All active interventions encompass at least three components: relaxation, focused attention, and (self-)awareness.
The interventions are mindfulness-based stress reduction (e-Health and blended), yoga (blended), running (blended), aikido (e-Health and blended), music (e-Health), and stress management training (e-Health and blended).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All medical students, research master students, PhD students, nanobiology and clinical technology students at the Erasmus MC are eligible for the longitudinal cohort study. In order to be eligible for participation in the nested RCT, a subject must
- Participate in the cohort study
- have a score of 14 or higher on the Perceived Stress Scale (PSS-10).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A subject who meets any of the following criteria will be excluded from participation in the RCT, but can participate in the cohort study:
- Not insured for health care (for care provided in the Netherlands)
- Diagnosis of, or previously treated for, psychosis or mania
- Response to at least one of the 4DSQ items 33 or 46 is “often” or “very often or constantly”

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	07-02-2019
Aantal proefpersonen:	706
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:	22-03-2019
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	NL7623

Register	ID
Ander register	METC Erasmus MC : MEC-2018-1645

Resultaten