Stress reduction in formerly preeclamptic women; sofa or sports?

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To investigate whether online mindfulness-based stress reduction (MBSR) therapy and an aerobe training intervention both leading to stress reduction and reduced circulatory risk in formerly preeclamptic women with increased mental stress levels...

Ethical review	Approved WMO
Status	Completed
Health condition type	Maternal complications of pregnancy
Study type	Interventional

Summary

ID

NL-OMON50491

Source
ToetsingOnline

Brief title
Sofa or Sports?

Condition

- Maternal complications of pregnancy
- Vascular hypertensive disorders

Synonym
preeclampsia

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: exercise, mindfullness, preeclampsia, stress

Outcome measures

Primary outcome

The main endpoint is mental stress, measured by validated questionnaires about anxiety, perceived stress and symptoms of depression.

Secondary outcome

Secondary endpoints are the results of pre- and post-intervention pre-conceptionally cardiovascular assessments, which with take place as *care-as-usual*. These measures include: body surface area, 30-minutes blood pressure and heart rate measures, venous blood samples for metabolic syndrome, echocardiography and plasma volume. Additionally, cortisol concentration in hair and head-up tilt test are analyzed. During intervention period, daily life stress and heartbeat monitoring with be measured through continious physiological recordings using smartwatches and will be analyzed to monitor compliance to intervention and examine the relationship between daily life functioning clinical efficacy of MBSR or aerobe cycling training. Results of validated questionnaires STAI, EPDS and Symptom-Checklist-90 (SCL-90) 12 weeks after intervention will be used as follow-up.

Study description

Background summary

Approximately one out of three women with pre-term pre-eclampsia (PE) develops a post-traumatic stress disorder or depression after labour. This could related

to the psychological impact of PE and premature birth. It could also be possible that stress correlates with reduced circulatory reserves, which is more indicative of physiological dysfunction. Limited circulatory reserves are also associated with basal increased sympathetic tone, decreased orthostatic stress response capacity and the later development of PE. These women report more complaints of perceived stress. This raises the question whether increased stress originates in the psyche or whether it is a psychological reflection of underlying reduced circulatory reserves and which intervention is needed to reduce stress. We hypotheze that women with reduced plasma volume status have higher levels of cortisol and mental stress, and therefore both aerobe training and mindfulness-based stress reduction are effective to reduce stress and cortisol levels, leading to decreased circulatory risk calculation.

Study objective

To investigate whether online mindfulness-based stress reduction (MBSR) therapy and an aerobe training intervention both leading to stress reduction and reduced circulatory risk in formerly preeclamptic women with increased mental stress levels determined by the questionnaire

Study design

This will be a multicenter randomized controlled trial, lasting for approximately 1 year. Recruitment will take place in a group of women with severe preeclampsia in a previous pregnancy, and wishing to conceive, that are referred by their healthcare professional to the extant pre-conceptionally cardiovascular evaluation (Obstetrics department, Maastricht University Medical Center). Participants will be randomised into a treatment or wait-list group after baseline Pre-conceptionally Cardiovascular Assessment (PcCA) and Stress Assessment (SA). Another SA and will take place post-treatment, combined with regular scheduled re-assessment of PcCA. Approximately 24 months after baseline online validated questionnaires about mental stress will be used as follow-up measure.

Intervention

One group receives a 12-weeks during online MBSR therapy, consisting of 8 weekly group meetings, one day silent retreat, and daily homework. The other group attend a aerobe training program, consists of 12-weeks of HR-controlled training on a cycle trainer at 70-80% individual HR reserve (HRR) for 2 to 3 times per week. A third control group on waiting list for therapy will be asked to continue normal physical activities and not undertake MBSR therapy during study period.

Study burden and risks

Most outcomes were measured in all patients as part of *care-as-usual* preconceptionally cardiovascular assessment appointments with two times an addition of a stress assessment, including donating a sample of hair, a head-up tilt (HUT) and a couple of questionnaires about basic characteristics. The hair sample is cut near the scalp on the back of the head, without leaving a visible bald spot. The burden and risks associated with participation are therefore minimal and approved by the local ethical committee of Maastricht UMC+ registered under number 14-4-118. The 12-weeks aerobe cycling training program could be physical and physiological intense and take a large time investment, but is a normal and save training procedure. Previous study with this aerobe training protocol used HUT as outcome measure. The risks of this minimal invasive diagnostic test are low and the burden minor and combined with training approved earlier by ethical committees and registered under CMO number 2008-226 (id: NCT00900458). Online MBSR therapy was performed and approved in a previous RCT and registered under CMO number 2020-6682 (NL-nr: 74345.091.20). The validated follow-up questionnaires will be performed online and takes 40 minutes to complete.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Informed consent given
- Age * 18 years
- Good understanding of Dutch language
- Preeclampsia in prior pregnancy, defined as the combination of gestational hypertension (>=140/90mmHg, measured twice, six hours or more apart), and proteinuria (consistently >=300mg/24 hours) after 20 weeks of pregnancy in previously normotensive women, according to ISSHP definition (Brown, 2018).
- Normotensive at the time of baseline measurements
- Perceived Stress Scale score >= 16 or State-Trait Anxiety Inventory (STAI) score >= 41 or Edinburgh Postnatal Depression Scale (EPDS) score >= 10

Exclusion criteria

- Pre-existent diabetes mellitus, autoimmune disease, HIV positivity or overt cardio-vascular disease.
- Use of medication or supplements that might affect the cardiovascular system
- (Physical) inabilities to complete 12 weeks of moderate exercise training
- Currently involved in psychological therapy or MBSR training.
- Pregnancy
- Women who intend to become pregnant within 12 weeks after baseline assessment

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	04-04-2022
Enrollment:	84
Type:	Actual

Ethics review

Approved WMO Date:	16-12-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-03-2022
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
ClinicalTrials.gov	NCT00900458
CCMO	NL78063.091.21