OPTICARE-RESST: OPTImizing CArdiac REhabilitation by REfining Sleep and STress

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The primary objective of this project is to investigate the effectiveness and costs of integrating a behavioural program targeting sleep and stress (the RESST intervention) into CR. In addition to overall effectiveness, we will also study whether...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON56876

Source
ToetsingOnline

Brief title
OPTICARE-RESST

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
cardiac patients, cardiovascular disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Cardiac Rehabilitation, Cardiovascular Disease, Sleep, Stress

Outcome measures

Primary outcome

The primary outcomes of the study include both objective and subjective measures of sleep, as well as perceived stress. These outcomes will be assessed before and after the intervention, as well as at a 6-month follow-up.

Secondary outcome

Secondary outcomes encompass quality of life, chronic stress biomarkers, cardiometabolic risk factors, physical fitness, lifestyle components and psychosocial wellbeing. These outcomes will be assessed before and after the intervention, as well as at a 6-month follow-up.

Study description

Background summary

Cardiac rehabilitation (CR) focuses on the secondary prevention of cardiovascular disease (CVD) by promoting a healthy lifestyle and is a valuable approach to improve quality of life, mortality and hospital readmissions. However, optimization of CR is necessary. Current CR programs pay insufficient attention to sleep and stress problems, despite more than 50% of CVD patients experiencing sleep problems and high stress levels. Both sleep and stress are associated with adverse cardiovascular health and a decreased quality of life. We hypothesize that adding a behavioural intervention will improve sleep and perceived stress (primary outcomes), along with positive outcomes on biomarkers of chronic stress, QoL, cardiometabolic risk factors, physical fitness, lifestyle components, and psychosocial well-being

Study objective

The primary objective of this project is to investigate the effectiveness and costs of integrating a behavioural program targeting sleep and stress (the

RESST intervention) into CR. In addition to overall effectiveness, we will also study whether parameters regarding diversity (e.g., sex, ethnicity, socioeconomic position) are associated with intervention effectiveness. Furthermore, we aim to explore the (bidirectional) relation between sleep and stress on the one hand, and other lifestyle components and health outcomes on the other hand.

Study design

The project involves a multicenter randomized controlled trial.

Intervention

The intervention group will receive standard CR along with the RESST intervention, consisting of 5-6 on-site group sessions integrating principles from Acceptance and Commitment Therapy and Cognitive Behavioral Therapy. Controls will receive standard CR only.

Study burden and risks

All participating patients will receive CR as recommended by the guidelines. Subjects randomized to the RESST intervention will receive on top of that a behavioural group intervention focussing on improving sleep and stress. This intervention will consist of 5 till 6 meetings of 90 till 120 minutes in the local rehabilitation centre during a time period of 3 till 4 months. Regardless of randomization, all participants are invited to visit the rehabilitation centre three times during the study period (at start, 3-4 months and 6 months) for a 45 min physical examination (weight, length, blood pressure, smoking behaviour), for the collection of a small hair sample and for collecting information on prior sleep and stressproblems and currect medication use. At these time points patients also receive a set of questionnaires to fill out at home (30-45 min). Furthermore, at these time point, subjects will receive a GENEACTIV wristwatch (an activity monitor measuring physical behaviour and sleep) to wear around their wrist for a period of 7 days and nights and are asked to keep an electronic diary during the same week. The burden of these measurements is expected to be minimal. Nevertheless, questionnaires may be personal and/or confrontational for patients. Additionally, the experience of hair sample collection might be impactful for some patients. Therefore, patients have the option to refuse the collection of this hair sample and are still be able to participate in the study. Burden of wearing small activity monitors and filling out electronics diaries is expected to be low, based on experience in previous studies (e.g. MEC-2016-655, MEC-2016-622). To lower the burden for participants, visits for measurements will be combined with other visits to the rehabilitation centre whenever possible. Furthermore, travel costs for the visit of these measurements will be reimbursed. Patients will have no direct benefit from participating in this study, although patients

randomized to the intervention group might benefit of the novel intervention by improving sleep and stress levels which in turn is expected to result in an improved physical and mental health. With regard to risks, it has been reported that cognitive behavioural therapy for sleep problem due to insomnia can lead to negative side effects such as a difficulty remembering things, headache, fatigue, difficulty with concentration, reduced energy, and irritability. Nevertheless, these side effects are short lived and have been attributed mainly to strict sleep restriction components that are not imposed in our intervention.

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

1) Participating in cardiac rehabilitation 2) age above 18 years, 3) proficient

in the Dutch language, 4) experiencing sleep and/or stress problems as indicated by a high score on the Pittsburgh Sleep Quality Index (PSQI score >5) or Perceived Stress Scale-10 (PSS-10 score >13)

Exclusion criteria

1) severe psychiatric, cognitive or physical comorbidity that would impede cardiac rehabilitation participation.
2) active treatment for sleep disorders, stress, or other forms of (behavioural) therapy at the start of the study or expected to start within the first 6 months of the study, that could interfere with the RESST intervention.
Note: Participants with previously diagnosed sleep disorders are eligible if they still experience sleep or stress problems, unless they fall under the above criteria. Participants who received a prior treatment that is still ongoing but has resulted in a stable sleep and stress condition in the 3 months before the cardiovascular event (e.g., Continuous Positive Airway Pressure (CPAP)) are eligible.

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-08-2024
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	03-07-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-10-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NCT06505109
CCMO	NL86677.078.24