Mindfulness in Cardiac Obesity Rehabilitation Using E-health

Published: 27-01-2022
Last updated: 05-04-2024

Primary Objective: To determine the feasibility and protocol implementation of a specially designed MBSR training in CR for obese patients.Secondary Objective(s): 1) To explore the potential effect of MBSR on kinesiophobia in obese patients who are...

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

Summary

ID

NL-OMON51768

Source
ToetsingOnline

Brief title
MINDCORE

Condition

- Other condition
- Cardiac disorders, signs and symptoms NEC
- Lifestyle issues

Synonym
Obesity, Rehabilitation

Health condition

obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Franciscus Gasthuis & Vlietland
Source(s) of monetary or material Support: Onderzoeksfonds van Capri hartrevalidatie

Intervention

Keyword: cardiac rehabilitation, mindfulness, obesity, prevention

Outcome measures

Primary outcome

The main study endpoint is the feasibility of MBSR training in CR in obese patients. Several parameters will be collected to study the feasibility.

- Number of eligible patients

- The proportion of patients that is willing to participate in MBSR training

- The proportion of patients that attend all 8 courses and complete MBSR training

- Inclusion rate per month

- Response rate to questionnaores

- Compliance rate

- Overall contentment of the MBSR training. Participants will be asked to rate their answers to this question on a5-point scale from 'strongly disagree' to ' strongly agree'

Secondary outcome

To explore the potential effect of MBSR training on kinesiophobia, participants will be asked to complete the TSK-NL Heart questionnaire before start of the training and after completing of the training. The TSK-NL Heart questionnaire is developed to measure kinesiophobia in cardiac patients.

In order to investigate the effect of mindful eating, participants will complete the Mindfulness Eating Behaviour Questionnaire (MEBS). The MEBS is a validated questionnaire that focuses on the physical sensation and emotion while eating or in a food-related environment. It is a 17-item self-report instrument that focuses on five mindful eating domains: awareness, disinhibition, distraction, emotional response, and external cues. The results of the MEBS will be used to explore whether MBSR has a potential effect on eating patterns in obesity.

In order to explore the effect on MBSR training on the participants, the Five Facet Mindfulness Questionnaire (FFMQ) will be completed.The FFMQ is a validated and self-scorable measurement on the five facets of mindfulness: observation, description, aware actions, non-judgemental inner experience, and non-reactivity. The test consists of 39 items that measure these five facets and the score provides an estimate on where participants stand in terms of mindfulness and self-awareness.

All participants will be asked to wear a bracelet, Corsano CardioWatch during the 8 weeks of MBSR training and up until one month after completing the MBSR, in order to monitor the possible effect of MBSR on HRV and steps per day. The bracelet detects the heart rate, rhythm, and HRV using photoplethysmogram (PPG) sensor. The Corsano CardioWatch is expected to receive CE Class IIa certification in December 2021. Details about the Corsano CaridioWatch are

provided in the IMDD.

Study description

Background summary

The number of cardiac patients with obesity is rising, however, their number of referral to cardiac rehabilitation (CR) is not. Obesity is a complex, multifactorial disease that should be viewed as a heterogeneous problem. Obese patients report a higher level of anxiety, a greater fear of movement after a cardiac event, a poor relationship with food and frequently a negative body and self-image. These challenges and behavioural patterns could be the obstacle for obese patients in obtaining and maintaining a healthy lifestyle after completing the regular CR program after a cardiac event. Mindfulness Based Stress Reduction (MBSR) training is a promising treatment that has not been investigated in this population. MBSR is an 8-week evidence-based group program that employs mindfulness meditation, breathing exercises, body awareness, and exploration of patterns of behaviour. MBSR could support cardiac obese patients in improving their lifestyle decisions. By exploring patterns of fear and anxiety, increasing awareness and friendliness towards oneself through guided mindful exercises, cardiac obese patients could be offered the tools that are needed to maintain a healthy lifestyle in the long-term.

Study objective

Primary Objective: To determine the feasibility and protocol implementation of a specially designed MBSR training in CR for obese patients.

Secondary Objective(s):
1) To explore the potential effect of MBSR on kinesiophobia in obese patients who are referred to CR.

2) To explore the possible effect of MBSR on eating behaviour in obese patients referred to CR.

3) To explore whether MBSR in obese patients referred to CR leads to an improvement in HRV.

Study design

The mindfulness CR study is an investigator driven observational, exploratory pilot study to assess the feasibility of a specially designed MBSR training for obese patients attending CR.

In a period of 4 months, a total of 20 patients will be prospectively recruited for participation at locations of *Capri Hartrevalidatie* in Rotterdam and The Hague. The program for obese patients, OPTICARE-XL, consists of different phases, including exercise training, lifestyle counselling, dietary counselling, risk factor control and patient education and can include a stress-management program as well. The MBSR training will be offered as an additive after the regular supervised CR program is completed. It will be given in a group format and will be designed for obese patients with a focus on fear of movement and mindful eating. Training will be given online through Zoom once a week for a total of 8 weeks. The duration of each training will be 2 hours. The MBSR training will be given by a certified MBSR trainer with experience in healthcare. During the weekly training, mindfulness exercises will be practiced and discussed with the group. Participants will receive a specially designed workbook with information and exercises to do at home in between the training sessions. All patients will receive a smartwatch (CardioWatch, Corsano) to wear for the duration of 8 weeks during the MBSR training and one month after completing MBSR to track changes in steps per day, heart rate, and heart rate variability (HRV). Patients will receive questionnaires at baseline, after completion of MBSR, and at 1-, 3- and 6-month follow-up.

Intervention

The intervention is a 8 week MBSR training. Weekly 2 hour sessions will be given digitally through the platform Zoom. During the sessions meditation techniques will be practiced. The sessions will be given by a certified mindfulness trainer. The participants will receive the MBSR workbook which contains exercises and additional information for each session. Participants will be asked to practice meditation at home in between the weekly sessions.

Study burden and risks

For this study, patients will receive an 8-week MBSR training and will have to fill out questionnaires and wear a bracelet to monitor their physical activity and heart rate. The MBSR training and questionnaires can be time consuming, but do not imply any risk for the patient. The MBSR training that will be offered can be of benefit for the patients, as it helps to deal with stressful and negative thoughts and feelings and can help improve and maintain a healthy lifestyle for obesity patients after a cardiac event. With the rising prevalence of obesity and subsequent cardiac disease and referral to CR, the risk to and burden for the subjects will be in proportion to the potential benefit for the patient and value of this research.

Contacts

Public
Franciscus Gasthuis & Vlietland

Kleiweg 500
Rotterdam 3045PM
NL
Scientific
Franciscus Gasthuis & Vlietland

Kleiweg 500
Rotterdam 3045PM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Obese patients with a BMI of >= 30 who are referred to CR with documented coronary artery disease (CAD) (myocardial infarction [ST-segment elevation myocardial infarction; non- ST-segment elevation myocardial infarction], unstable angina pectoris, chronic coronary syndrome) or nonvalvular AF and who fulfill the guidelines for CR participation

Exclusion criteria

- Non-Dutch speaking participant.
- Incapable of understanding and utilizing digital communication.
- Severe psychological or cognitive impairment that limit participation in group interventions.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-03-2022
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	27-01-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL79733.100.21