Effects of a mindfulness based stress reduction program on psychological wellbeing of cardiac rehabilitation patients.

Published: 19-05-2011
Last updated: 20-06-2024

Since October 2010 the Catharina-hospital in Eindhoven offers a cardiac rehabilitation program to cardiovascular patients. As an optional section of the program an adjusted training of MBSR is offered, called *stress reduction in cardiovascular...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Myocardial disorders
Study type	Interventional

Summary

ID

NL-OMON39938

Source
ToetsingOnline

Brief title
Effects of mindfulness in cardiac rehabilitation patients.

Condition

- Myocardial disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
heart attack, myocardinfarct

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: afdeling Medische Psychologie Catharina-ziekenhuis

Intervention

Keyword: cardiac rehabilitation, heart focused anxiety, mindfulness

Outcome measures

Primary outcome

Demographic and clinical characteristics

Age, sex, marital status, level of education and employment will be determined by questionnaire. Biomedical variables will be obtained form the medical records, including medications, diagnose and co-morbidity.

Psychological well-being

Psychological well-being will be assessed by using the following five constructs: symptoms of depression and anxiety, perceived stress, quality of life and self-worth. Symptoms of depression and anxiety will be assessed using two self-report questionnaires: the Hospital Anxiety Depression Scales (HADS) and the Patient Health Questionnaire (PHQ-9). The HADS is a 14-item self-report screening measure originally developed to evaluate the presence of anxiety and depressive states in a medical setting20. It consists of two 7-item scales: anxiety and depression. Evidence for a two-factor solution is found, although anxiety and depression subscales were strongly correlated. Internal consistency of the two subscales has been shown to be satisfactory to good (range .71 to .90) and test-retest stability for anxiety, depression and total scale scores

proved to be very high (.89, .86 and .91 respectively).

The PHQ is a self-report questionnaire used to make criteria-based diagnoses of depressive and other mental disorders commonly used in primary care21. The PHQ-9 is the depression module, which inquires all nine DSM-IV criteria on a 4-point scale, ranging from 0 (not at all) to 3 (nearly every day). Major depression is diagnosed if 5 or more of the 9 depressive symptom criteria have been present more than half the days in the past 2 weeks, and at least depressed mood or anhedonia is reported. Next to establishing depressive disorder diagnoses, the PHQ-9 can also establish grade depressive symptom severity. Both internal reliability (Cronbach*s α = .89) and test-retest reliability (.84) have been shown to be excellent. Criterion, construct and external validity have been shown to be good as well.

Perceived stress will be assessed using the Dutch version of the Perceived Stress Scale (PSS). This self-report questionnaire consists of 10 items with a five-point Likert scale ranging from 0 (never) to 4 (very often). It aims to asses the degree to which situations in one*s life are appraised as stressful during the past month. The PSS has an internal consistency coefficient of .85, a test-retest reliability of .85 and is often used in research to determine the level of perceived stress22.

Quality of life will be measured using the Dutch translation of the Quality of Life after Myocardial Infarction (QLMI) questionnaire. This self-report questionnaire is developed on the basis of frequent and important problems experienced post-MI23. The items are divided in three scales: emotional, physical and social quality of life. Test-retest reliability is shown to be

high (.75 and .87 for the three domains and total score). Relations between QLMI and other measures indicates its validity in discriminating between patients post-MI according to their health-related quality of life, and in measuring changes in health-related quality of life in time.

Self-esteem will be measured using the Dutch translation of the Rosenberg Self Esteem Scale (RSES). This is the most widely used instrument for assessing global self-esteem, defined as a person*s overall evaluation of his or her worthiness as a human being24. The RSES consists of 10 items and is designed to represent a continuum of self-worth statements. This questionnaire was originally designed to asses global trait-like self-esteem and represents a one-dimensional scale. Research has indicated high internal consistency (Cronbach*s α = .86), high construct validity with extraversion and conscientiousness (.32 and .35 respectively) as well as high congruent validity.

Psychological Mindedness

The degree of PM will be determined by use of the Balanced Index of Psychological Mindedness (BIPM). This questionnaire consists of two scales representing the two theoretical core dimensions of PM: a) interest in attending to one*s psychological phenomena and b) ability for insight into these phenomena25. These 7-item subscales called Interest and Insight have shown good internal consistency (Cronbach*s α =.85 and.76 respectively), test-retest reliability (.63 and .71 respectively) and construct validity with related constructs (>.40).

Attention problems and hyperactivity

To measure attention problems and hyperactivity a Dutch translation of the ADHD DSM-IV rating scale, called *Zelf-rapportage vragenlijst voor aandachtsproblemen en hyperactiviteit in de volwassenheid* is used. This is a 23-item self report questionnaire, with each item to be rated on a four-point scale. The items are spread over two separate dimensions: inattention (IA) and hyperactivity-impulsivity (HI)26. These scales had a Cronbach*s alpha of .83, .75 and.72 respectively. Research supports the external validity of this questionnaire as well.

Negative affectivity.

Negative affectivity will be measured by the Type D Scale-14 (DS14). The DS14 is developed to assess Negative affectivity (NA), Social Inhibition (SI) and Type D personality. The questionnaire exists of 14 questions of which seven questions to assess NA and seven questions to assess SI. Participants answer the questions on a five-point Likert scale, ranging from 0 (false) to 4 (true). Both scales can be scored as continuous variables. The seven questions to assess NA will be used in this research. All of the seven NA items had an loading ranging between 0.62 and 0.82 on their trait factor. Test-retest correlation with an interval of three months for the NA scale is .72 .

Heart-focused Anxiety

HFA can be measured with the Cardiac Anxiety Questionnaire. The questionnaire exists of 18 questions that can be answered on a five-point Likert scale as to

how frequently the behavior typically occurs with response anchors from 0 (never) to 4 (always). The total score can be obtained by adding up all responses to the items and dividing the sum total by 18, i.e. the mean. The questionnaire exits of three subscales: fear, avoidance and heart-focused attention. Higher scores indicate greater HFA. Internal consistency is high for the CAQ with Cronbach*s alpha=0.83.

Secondary outcome

Not applicable

Study description

Background summary

Introduction
Cardiovascular diseases caused by atherosclerosis are one of the two most important causes of morbidity and mortality in the Netherlands. Research has revealed that cardiovascular diseases often lead to psychological complaints, like feelings of anxiety or depression. These negative emotions themselves have been related to an increased morbidity and worse prognosis of cardiovascular diseases. Therefore it is necessary to study interventions that might reduce these feelings of anxiety, stress or depression in this patient group.
Heart-focused anxiety (HFA) is defined in Hoyer et al. (2008) as: *a specific fear of cardiac-related stimuli and sensations because of their expected negative consequences.* Earlier research suggests that HFA is significantly correlated with increased symptoms of general anxiety, depression and lower health-related quality of life among patients who have to undergo a cardiac surgery (Ong, Nolan, Ivine & Kovacs, 2011). Patients dealing with HFA are consulting their physicians more often and require more physical examinations to get reassurance that everything is all right (6). In addition to a relieve of the anxiety of the patient, treatment of HFA may help reduce excessive use of care and health care costs (Fischer et al., 2012)
A relatively new kind of psychological intervention, aimed at reduction of psychological symptoms of distress and enhancement of quality of life, is based on Mindfulness. Mindfulness focuses on cultivating awareness of whatever happens at each successive moment of perception and to do so in an open-minded and non-judgmental way. Objects of perception range from internal psychological states and processes, proprioceptive information from the body to external

stimuli. By practicing meditation people learn to recognize thoughts and feelings as only mental events instead of part of the self or the right reflection of the truth. The mindfulness stress reduction (MBSR) intervention is a mindfulness based therapy. It is provided in eight to ten group meetings. Psycho-education is used as well as practicing mindfulness skills and homework assignments. Several studies have found that MBSR can reduce perceived feelings of stress and negative affect and can increase positive affect and quality of life. A recent meta-analysis revealed a medium to large effect size on anxiety and depression depending on the patient group studied. The usefulness of this intervention has also been revealed for a broad range of chronic disorders and problems. However, relatively few researchers have examined the effectiveness of MBSR in cardiovascular patients. Only one pilot study revealed significant reductions in scores of anxiety and emotional control in women diagnosed with heart disease.
Psychological Mindedness (PM) is the awareness and understanding of psychological processes, like thoughts, feelings and behaviour. The aim of MBSR is to increase awareness of these psychological states and processes. Therefore a high degree of PM may facilitate this awareness and the degree of PM is expected to influence the effectiveness of MBSR. Brown and Ryan have found that PM and mindfulness correlate. Other research has found evidence for a possible moderating role of PM on the effectiveness of MBSR in a healthy population: the effectiveness of MBSR is larger for people who score high on PM compared to people who score low on PM.
Beside PM the effectivity of MBSR might be influenced by any problems of inattention or hyperactivity while it is important to be able to focus attention on anything you want to observe. Research has found that mindfulness is negatively associated with ADHD. Problems of inattention or hyperactivity might impede focussing attention on these stimuli and thereby might reduce awareness and acceptation. No empirical research has been carried out to examine this possible moderating role of attention problems or hyperactivity on the effectiveness of MBSR. A study towards the effect of a personalized health plan with cardiac patients showed that patients in the active treatment group had higher cardiac risk reduction compared with the usual care group. To accomplish better results and to identify the best treatment for each individual it would be interesting to do some more research to patients characteristics. In a sample of patients with diabetes, negative affectivity was found to significantly moderate the effect of mindfulness based cognitive therapy on levels of anxiety. MBCT appeared to be more effective in reducing symptoms in individuals with a high level of negative affectivity when compared with individuals with lower levels of negative affectivity

Study objective

Since October 2010 the Catharina-hospital in Eindhoven offers a cardiac rehabilitation program to cardiovascular patients. As an optional section of the program an adjusted training of MBSR is offered, called *stress reduction in cardiovascular diseases*. It is needed to investigate the effects of this

mindfulness intervention on psychological well-being of this specific patient group either to make sure the best care is provided and to improve the care if necessary. As mentioned earlier patients with cardiovascular diseases concern a group that often show psychological complaints, like feeling of anxiety or depression which makes it even more important to examine their psychological care. That is why the main aim of the study is to examine the effectiveness of this mindfulness based stress reduction intervention on the psychological well being of heart revalidation patients and to examine whether these effects last in the long term. Based on previous research medium to large effect sizes are expected for the effects of the mindfulness based stress reduction intervention on psychological well-being and these effects are hypothesised to last in the long term.
Because the effectiveness might depend on the degree of PM, problems of attention and hyperactivity and negative affectivity, it is needed to examine the possible moderating role of these variables. If one of these turns out to be a moderator, the care for this patient group may become more patient centered in the future. Therefore the second aim of the study is to examine the possible moderating role of these psychological variables on the effectiveness of the mindfulness intervention. It is hypothesised that the degree of PM, attention problems, hyperactivity and negative affectivity all four will moderate the effectiveness of the intervention on psychological well-being.

Study design

The study is a controlled trial and a quasi-experimental research with two groups. The study is prospective in nature and will have repeated measures.

At the end of the information module about the psychological load of having a cardiovascular disease patients get informed about the training *stress reduction in cardiovascular diseases* and the corresponding study. All patients that attend the information module receive an information letter. This letter contains a coupon where people can indicate whether they are interested in participating the training and/or the study. Together with the letter people receive a postage-payed envelope by which the coupon can be returned. For patients who return their coupon, inclusion and exclusion criteria are checked. Participants have to fill in a couple of questionnaires on three moments before the course starts, at the end of the course and a year after. The questionnaires contain questions about anxiety, depression, quality of life and other psychological variables. The questionnaires can be returned in a postage-payed envelope. A written informed consent is also attached to these questionnaires.

Intervention

The applied intervention is a mindfulness training based on MBSR, developed by dr. J. Kabatt-Zinn at the University of Massachusetts19,8. The adjusted program

offered in this study is less intensive.

The intervention consists of four weekly meetings of 1,5 to 2 hours with an evaluation meeting as final meeting. The first meeting will be focusing on the body and bodily sensations. Aim is to enhance the awareness of the body and posture. Meditation exercises will be done and there is an opportunity to share experiences. In the second meeting the emphasis is on feelings. Aim is to observe feelings and to accept them. It is taught that emotions are only a reaction on a stimulus. Thoughts are the topic of the third meeting. Exercises will be done to learn how to think *neutral* and without judging. The fourth and last meeting is about evaluating the course and the experiences in real life. It is a group intervention with four to six participants per group. The meetings will be supervised by a clinical psychologist - psychotherapist, who is experienced in leading attention- and meditation trainings. Participants receive an information booklet with exercises defined.

Study burden and risks

The intervention is a simplified training based on MBSR. MBSR is a mindfulness based stress reduction program. There are no riscs attached to participation in the training. Participants have to fill in questionnaires at three moments.

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

Documented cardiovascular disease
Age: 18-85 years
Participation in the cardiac rehabilitation program

Exclusion criteria

Severe somatic co-morbidity
Psychiatric co-morbidity
insufficient command of the Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-05-2011
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	19-05-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-03-2014
Application type:	Amendment
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

ID: 20355
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL34522.060.11