A Positive Psychology Intervention for Cardiovascular Patients: a Single Case Experimental Design

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To examine whether the Positive Psychology group intervention *Goed leven met een hartaandoening* [Living well with heart disorder] is effective in increasing mental well-being, ability to adapt, positive skills (e.g. savouring, positive re-...

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

Summary

ID

NL-OMON51503

Source
ToetsingOnline

Brief title
A Positive Psychology Intervention for Cardiovascular Patients

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
heart attack, heart failure, surgery due to heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Twente
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: CVD, Heart disease, Positive Psychology Intervention

Outcome measures

Primary outcome

The main study outcome is mental well-being, measured with the psychological well-being subscale of the Dutch version of the Mental Health Continuum - Short Form (MHC-SF, Lamers, et al., 2011).

Secondary outcome

The secondary outcome measures will be assessed weekly. In order to prevent from too much burden associated with repeated measures, a small number of items for each outcome measure will be used in the weekly measures. But the full versions of the scales for those outcome measures will be measured at three time points: at the start (together with demographic questions and questions concerning the heart disease), after the intervention ends and eight weeks follow-up.

The ability to adapt will be assessed with two items of the ten-item Generic Sense of Ability to Adapt Scale (GSAAS; Franken et al., under review). Items will be scored from *not at all* to absolutely, on a five point scale. The chosen items were those with the highest factor loading of the study of Franken et al. (under review).

Distress will be assessed with four items, depression with the two item Patient Health Questionnaire (PHQ-2) and anxiety with the two item Generalized Anxiety

Disorder (GAD-2). Löwe et al. (2004) assessed the construct validity of the PHQ-2 in medical outpatients and concluded that it is promising for monitoring depression outcomes over time. Donkers et al. (2011) evaluate the GAD-2 in a sample of Dutch adults and concluded that web-based version is a valid and reliable tool to screen for a GAD in a clinical research setting.

Lastly, the positive skills savoring, gratitude, positive reinterpretation and self-reassurance will be assessed with two items each. The two items on gratitude are retrieved form the 16 item Gratitude Resentment and Appreciation Scale (GRAT-16 or S-GRAT; Thomas and Watkins, 2003). The two savoring items are retrieved form the savoring past subscale of the Savoring Beliefs Inventory (SBI; Bryant, 2003). The two items on positive reinterpretation are retrieved from the positive reinterpretation and growth subscale of the COPE inventory (COPE-I; Carver, 1989). Lastly, the two items on self-reassurance are retrieved from the eponymous subscale of the FSCRS (Gilbert et al., 2004). These items will be scored on a seven point Likert scale from strongly disagree (1) to strongly agree (7) and formulated so participants answer the items about the previous week, to meet the aim of weekly measures.

The three times (pre, post and at follow-up) questionnaire exists of demographic questions (e.g. age, gender), the MHC-SF, the full scale of the GSAAS for ability to adapt, the longer version of the PHQ, namely the nine item Patient Health Questionnaire (PHQ-9; Spitzer et al., 1999) for depression, the longer version of the GAD, namely the seven item Generalized Anxiety Disorder

(GAD-7; Kroenke et al., 2001) for anxiety and the full versions of the GRAT for gratitude, SBI savoring past subscale for savoring, the positive reinterpretation and growth subscale of the COPE-I for positive reinterpretation, and the self-reassurance subscale of the FSCRS for self-reassurance.

In addition to these mental well-being related questionnaires will health related behavior (i.e. adherence to medication, diet and physical activity) be measured. Adherence to medication will be measured with a Self-Report Medication Adherence scale, that was previously used for the pilot study of this intervention (Tönis et al., 2022) and based upon Lu et al (2008). Participants will fill in (on a 10% scale) what percentage of time they took the medication they were prescribed to use over the past two weeks. Adherence to diet and physical activity will be measured with (relevant) questions of the Medical Outcomes Study Specific Adherence Scale (MOS-SAS, DiMatteo et al.,1992). These items were translated into Dutch for the pilot study (Tönis et al., 2022).

The experiences of the participants with the intervention will be evaluated by individual semi-structured (phone-based) interviews. The aim of the interviews is to gain insight into the process of change during the intervention. The interviews will be carried out by a trained junior-researcher.
In addition, participants will be asked to fill in the eight item Client Satisfaction Questionnaire (CSQ-8) to measure satisfaction with the

intervention. The CSQ-8 aims to assess the satisfaction of users with (mental) health services (Attkisson & Greenfield, 1994).The short length makes it appropriate for mailed surveys (De Wilde & Hendriks, 2005). The eight items will be scored from one to four and overall satisfaction will be expressed in a mean over the eight items (De Wilde & Hendriks, 2005). A high internal consistency of the CSQ-8 was found in a sample of 110 Dutch mental health outpatient (De Brey, 1983) and 262 Dutch substance addicted patients (De Wilde & Hendriks, 2005).

The interventionists will be asked to fill in a logbook for each session in order to get insight into treatment fidelity. In the logbook, questions on the performed exercises (e.g., whether exercises could be carried out) and it will be asked if interventionists made changes to the treatment protocol.

Study description

Background summary

Cardiovascular diseases (CVDs) are conditions of blood vessels and the heart, such as strokes and heart attacks (National Health Service, n.d.; World Health Organization [WHO], 2021). CVDs represented an estimated 32% of the deaths globally in 2019 (WHO, 2021). In the Netherlands, every day an average of 100 people die as a result of CVD in 2020, representing 22% of national deaths (Koop, et al., 2021). In addition, over 1.5 million Dutchmen suffered from CVD in 2020 (Koop, et al., 2021). In 2017, 10.2 billion euros were spent on CVD patients care, representing 11.7% of the healthcare costs in the Netherlands (Plasmans, et al., n.d.).
In addition to the economic burden, CVDs also affect the mental health of an individual patients. Depression and anxiety are common in CVD patients (Celano, et al, 2016; Hare, et al., 2014). Around one in five CVD patients experience a (major) depression (Celano and Huffman, 2011; Gehi, et al., 2005; Rutledge, et al., 2006) or increased anxiety levels (Celano, et al., 2016).

Importantly, anxiety or depression are associated with poorer outcomes in CVD patients. Depression is associated with mortality (Jiang, et al., 2001), more days spent in hospital (Reese, et al., 2011), rehospitalisation (Jiang, et al., 2001; Reese, et al., 2011), increased health care use (Rutledge, et al., 2006), medication non-adherence (Gehi, et al., 2005), and more visits to the emergency department (Reese, et al., 2011). Anxiety is associated with the recurrence of cardiac events and mortality (Celano, et al., 2015; Roest, et al., 2010).
Mental well-being (subjective happiness and positive functioning) on the other hand is associated with positive outcomes such as longevity, better health behaviors and a reduction in the risk of a secondary event (Sin, 2016). Mental well-being or health is not merely the absence of anxiety or depression, but the presence of positive mental functioning (Keyes, 2002; Westerhof & Keyes, 2010). For example, optimism is associated with a lower risk for rehospitalisation (Huffman, et al., 2016; Scheier, et al., 1999; Tindle, et al., 2012), increased depression treatment response (Tindle, et al., 2012), a reduction in the risk of depressive symptoms (Rondaldson, et al., 2015), better physical health status (Rondaldson, et al., 2015), more physical activity (Huffman, et al., 2016), and healthy behavior such as vegetable and fruit consumption and smoking cessation (Rondaldson, et al., 2015). In addition a reduction of positive affect is found to be a predictor of a secondary event (myocardial infarction) (Denollet, et al., 2007; Kim, et al., 2013) and death (Denollet, et al., 2007). Purpose in life is associated with a significant reduced risk of a secondary event (myocardial infarctions) (Kim, et al., 2013). These findings suggest that increasing mental well-being and reducing distress in CVD patients can contribute to better medical outcomes. In addition, mental well-being can be seen as an indicator of positive functioning and adaptation of CVD patients (Bohlmeijer & Westerhof, 2021; Sin, 2017).
Positive psychology interventions (PPIs) are interventions that aim to foster positive behaviors, feelings and cognitions (Sin & Lyubomirksy, 2009) with the aim to enhance mental well-being and reduce distress. Research suggests that PPIs not only have positive effects on mental well-being but also on depression (Bolier, et al., 2013; Carr, et al., 2021; Sin & Lyubomirksy, 2009), anxiety and stress (Carr, et al., 2021). Carr et al. (2021) focused on the clinical status of participants in their meta-analysis and found larger effects on mental well-being, depression and strengths for clinical participants in comparison to healthy participants. In addition, Brown, et al. (2019) found positive effects of PPIs on anxiety in medical patients. These findings suggest that clinical populations, including CVD patients, could potentially benefit from PPIs. PPIs could improve mental well-being, depression and anxiety, which might then lead to improvements in outcomes such as health behavior or treatment and medication adherence.
PPIs can thus be implemented as prevention in the revalidation program for CVD patients, especially for those with mild to moderate distress and lower levels of mental well-being. However, PPIs to promote mental well-being are lacking in the current Dutch revalidation program. Programs that are currently implemented mainly target physical recovery (physical and relaxation exercises), patient education (concerning CVD and lifestyle) and are aimed at

reducing distress with for example cognitive behavioral therapy or stressmanagement (Hartstichting, n.d., Achttien, et al., 2011).
Several PPIs have been developed for CVD patients (e.g. Huffman, et al., 2011; Redwine, et al., 2016), however none was implemented and evaluated in the Dutch population. This raises questions concerning the fit in the Dutch recovery program for CVD patients. Recently, an evidence-based, transdiagnostic group PPI has been developed for people with mental or physical disorders. An adaptation was made for people with CVDs: Living Well With Hearth Disorder. This PPI aims to promote positive skills that promote mental well-being and adaptation to and psychological recovery from a serious illness. The feasibility and acceptability of the intervention have been evaluated in a pilot-study (n = 5) at the ZGT-hospital. Participants were enthusiastic about the quality of the intervention, with satisfaction being scored with 8.6/10 points, and recommendation with 8.8/10 points.
The current study aims to assess the effectiveness of this Dutch PPI as part of the cardiac rehabilitation to increase mental well-being with a Multiple Baseline Design (MBD), a type of Single Case Experimental Study Design (SCED). A MBD can give a good and efficient assessment of the effects of an intervention with limited resources and a limited number of patients (Tate & Perdices, 2019). SCED *represents a rigorous scientific methodology that can draw causal relations between interventions and behavior change* (Kazdin, 2009, p. 16). In contrast to the between-group level (effectiveness) analysis of a (large and expensive) Randomized Controlled Trial (RCT), the within-group level analysis of a SCED can show the number of participants that were (clinically important) affected by the intervention (Kazdin, 2019). A MBD was chosen instead of a Randomized Controlled Trial because (1) participants act as their own control group, therefore nobody will be withheld from the intervention as is normally the case for the control condition and (2) a SCED requires a much smaller sample size, but causal inferences can still be drawn. In comparison with RCTs, SCEDs require strongly reduced resources and time, but still yield strong evidence for the effects of interventions.

(voor bronnen zie het bijgevoegde protocol)

Study objective

To examine whether the Positive Psychology group intervention *Goed leven met een hartaandoening* [Living well with heart disorder] is effective in increasing mental well-being, ability to adapt, positive skills (e.g. savouring, positive re-interpretation) and decreasing distress (anxiety and depressive symptoms) of CVD patients.

Study design

A multiple baseline Single Case Experimental Design with a five to seven weeks baseline phase, an eight week treatment phase and an eight week follow-up

phase.

Intervention

The intervention *Goed leven met een hartaandoening* consists of 8 group sessions (6-8 participants) of 2 hours. This intervention is an adaptation of the transdiagnostic, evidence based *Living well with bipolar disorder* intervention. Each session focuses on a skill that promotes mental well-being, e.g. self-compassion, knowing one*s strengths, optimism, savoring (Kraiss, et al., 2018). A pilot study (n = 5) showed high acceptance and appreciation of the intervention and reliable changes in personal recovery in four patients.

Study burden and risks

The intervention consists of eight guided group sessions combined with homework (daily practice with the exercises). In addition, participants will be asked to fill in one brief questionnaire each week, for five to seven weeks (depending upon the condition they will randomly assigned to) during the baseline phase, one brief questionnaire a week for eight weeks during the (eight week lasting) intervention phase, and one brief weekly questionnaire for eight weeks after the intervention ends, during the follow-up phase. No risks are foreseen based on experiences with this intervention for other target groups (e.g. bipolar disorder patients) and the pilot study of this intervention with the current target group. In addition, participants may benefit from the study with an increase in positive functioning and adaptation.

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) diagnosis of heart failure, heart attack or recently undergone surgery due to a heart disease with 2) sufficient (clinical) stability and physical recovery (as indicated by the cardiologist and nurse specialist)
3) clear motivation to work on mental well-being and willingness to spend two hours a week on homework
4) able to function in the group as indicated by the psychologist (e.g. being able to speak and understand Dutch)
5) possessing a smartphone with internet access for data collection.

Exclusion criteria

1) current anxiety disorder (Mini International Neuropsychiatric Interview, MINI; Van Vliet & De Beurs, 2007) or major depressive episode (MINI, major depression domain)
2) current psychological or psychiatric treatment outside this study since this can influence potential effects of the intervention
3) personal circumstances that interfere with attending to the course (e.g. an addiction) as indicated by the psychologist,
4) limited life expectancy (< 2 years),
5) on waiting list for major surgery or other medical intervention,
6) insufficient Dutch language skills to follow the group sessions or complete homework exercises.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-01-2024
Enrollment:	14
Type:	Actual

Ethics review

Approved WMO

Date:	30-11-2022
Application type:	First submission
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
CCMO	NL82786.091.22