

Effects of a mindfulness based stress reduction program on psychological and physiological measures in cardiac patients.

Gepubliceerd: 13-04-2012 Laatste bijgewerkt: 15-05-2024

Compared to a control group, the mindfulness group intervention is expected to result in: 1. A decrease in symptoms of psychological distress; 2. An increase in quality of life; 3. An increase in heart rate variability; 4. A decrease in blood...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26707

Bron

Nationaal Trial Register

Verkorte titel

MindfulHeart

Aandoening

cardiac patients undergoing a percutaneous coronary intervention; psychological stress, anxiety and depression; quality of life; elevated blood pressure

Ondersteuning

Primaire sponsor: Tilburg University and
St. Catharina Hospital Eindhoven

Overige ondersteuning: Tilburg University and
St. Catharina Hospital Eindhoven

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Psychological distress (symptoms of perceived stress, anxiety and depression) at post-intervention.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

Compared to a control group, the mindfulness group intervention is expected to result in:

1. A decrease in symptoms of psychological distress;
2. An increase in quality of life;
3. An increase in heart rate variability;
4. A decrease in blood pressure in those with elevated blood pressure;
5. Decrease in low-grade inflammation.

Onderzoeksopzet

1. Pre-intervention (T1);
2. Post-intervention (T2);
3. 1-year follow-up (T3).

The following measures are taken at all time points:

Perceived Stress Scale (PSS); Symptoms of Anxiety and Depression (SAD-4); WHOQoL-Bref and Seattle Angina Questionnaire (for quality of life); Global Mood Scale (GMS); Freiburg Mindfulness Inventory-short (FMI-s); Balanced Index of Psychological Mindedness.

The following measures are taken at T1 and T2: Systolic and diastolic blood pressure (means of 3 measurements); heart rate variability; C-reactive protein.

Onderzoeksproduct en/of interventie

The applied group (6-8 patients) intervention is a mindfulness training, which is loosely based on the Mindfulness-Based Stress Reduction (MBSR) program, as developed by Kabat-Zinn (1990). The adjusted program in this study is less intensive, including only three weekly 90 to 120 minutes meetings and an additional evaluation session two weeks later.

The control group is an active control group: A self-help intervention consisting of a booklet based on the group training and written by the same clinical psychologist. The psychoeducation and exercises are identical to the information given in the group intervention. The participants who receive the self-help booklet are asked to read the theory and to practice the exercises daily as indicated.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients who had a percutaneous coronary intervention in the previous month;
2. Age 18-70.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Serious medical co-morbidity (e.g., heart failure; cancer);
2. Serious psychiatric co-morbidity (e.g., suicidal ideation; psychoticism);
3. Past or present brain-damage;
4. Inadequate knowledge of the Dutch language;
5. Acute infection in past two weeks;
6. Use of anti-inflammatory drugs, except aspirin.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-02-2008
Aantal proefpersonen:	128

Type:

Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:

13-04-2012

Soort:

Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 32039

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3245
NTR-old	NTR3397
CCMO	NL19795.060.07
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON32039

Resultaten

Samenvatting resultaten

N/A