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Compassionate mind training for patients with heart problems

Submission date	Recruitment status	[ ] Prospectively registered
01/10/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/10/2023	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/10/2023	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
There is a large group of patients who report mental ill-health who also have the diagnosis of symptomatic ectopic heartbeats. No psychological intervention has been tried so far on this patient group.
The study aimed to investigate the effects of compassionate mind training on reducing mental ill-health in patients with extra heartbeats compared with treatment as usual.

Who can participate?
Adults over 18 years, with ectopic heartbeats.

What does the study involve?
Participants were randomly allocated to receive a psychological programme (6 week long) focusing on stress reduction and cultivating the flow of compassion; receiving compassion, giving compassion to others and self-compassion or treatment at usual.

What are the possible benefits and risks of participating?
Potential benefits of participating in the study are increased mental health by reducing symptoms of percieved stress, anxiety and depression as well as increased compassion and benevolence, sleep quality and satisfaction with life. There are no anticipated risks of participating as participants are screened by physicians and because the intervention, which is only a complement to their usual treatment, has been evaluated in multiple studies without any known risk factors. The study started in 2015 and ended in 2019.

Where is the study run from?
Karolinska Institutet (Sweden)

When is the study starting and how long is it expected to run for?
January 2014 to March 2019

Who is funding the study?
Skandia Research (Sweden)

Who is the main contact?
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Study information

Scientific Title
Compassionate mind training for patients with symptomatic ectopic heartbeats – A pilot randomized controlled trial

Study objectives

The compassionate mind training group has a beneficial effect on participants' levels of perceived stress, anxiety and depression symptoms, sleep quality, satisfaction with life, self-compassion and benevolence compared to treatment as usual.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 24/08/2016, Stockholm (Tomtebodavägen 18A, Stockholm, 17165, Sweden; +46 10-4750800; registrator@etikprovning.se), ref: 2016/1418-31/1

2. Approved 07/03/2018, Stockholm (Tomtebodavägen 18A, Stockholm, 17165, Sweden; +46 10-4750800; registrator@etikprovning.se), ref: 2017-1984-32-1

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Prevention, Treatment, Efficacy

Health condition(s) or problem(s) studied
Symptomatic ectopic heartbeats

Interventions
The study adopted a randomized controlled trial design, with one between-group factor (intervention group: compassionate mind training and treatment as usual) and one within-group factor (timepoint: pre- and post-intervention).

Participants were randomised to groups using random.org.

The compassionate mind training is based on Compassion-focused therapy developed by Professor Paul Gilbert and self-compassion practices from Mindful Self-compassion developed by professor Kristin Neff and psychologist Christopher Germer. The Swedish program was designed by Christina Andersson together with Dr. Chris Irons, one of the world's leading researchers on CFT. The program included six weekly 2 hour sessions, including compassion theory, exercises, and homework in between sessions.

Intervention Type
Behavioural

Primary outcome(s)
Perceived stress measured using PSS, perceived stress scale at pre and post the intervention, at baseline and after 6 weeks.

Key secondary outcome(s)
Measured pre and post-intervention:
1. Anxiety and depression symptoms was measured by the Hospital Anxiety and Depression

Scale (HADS).
2. Sleep quality was measured by the Karolinska Sleep Questionnaire (KSQ)
3. Satisfaction with life was measured by the satisfaction with life scale (SWLS)
4. Self-Compassion was measured by using the Self-Compassion Scale Short-Form (SCS-SF)
5. Benevolence was measured by using the Benevolence scale (BS)

Completion date
02/03/2019

Eligibility

Key inclusion criteria
Extra symptomatic heartbeats recorded on Holter electrocardiogram (ECG).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
21

Key exclusion criteria
Other untreated cardiovascular diseases (e.g., hypertonia), and untreated sleep apnea.

Date of first enrolment
01/01/2017

Date of final enrolment
09/09/2018

Locations

Countries of recruitment
Sweden

Study participating centre
Danderyds Hospital
Entrevägen 2
Stockholm
Sweden
182 88

Study participating centre
Stockholm Heart Center
Kungsgatan 38
Stockholm
Sweden
11135

Sponsor information

Organisation
Karolinska Institutet

ROR
https://ror.org/056d84691

Funder(s)

Funder type
Industry

Funder Name
Skandia Research and Advisory

Results and Publications

Individual participant data (IPD) sharing plan
The dataset generated and analysed during the current study will be stored in a non-publicly available repository. Contact information: Christina Andersson christina.andersson80@telia.com

IPD sharing plan summary
Stored in non-publicly available repository, Available on request