

Compassionate mind training for patients with heart problems

Submission date 01/10/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/10/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/10/2023	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 as 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 perceived 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?

Christina Andersson, PhD, christina.andersson80@telia.com

Contact information

Type(s)

Public, Scientific

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Additional identifiers

EudraCT/CTIS number

Nil Known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

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

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Study setting(s)

Hospital, Workplace

Study type(s)

Prevention, Treatment, Efficacy

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

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 measure

Perceived stress measured using PSS, perceived stress scale at pre and post the intervention, at baseline and after 6 weeks.

Secondary outcome measures

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)

Overall study start date

01/01/2014

Completion date

02/03/2019

Eligibility**Key inclusion criteria**

Extra symptomatic heartbeats recorded on Holter electrocardiogram (ECG).

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

80 Years

Sex

Both

Target number of participants

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

Sponsor details

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Sponsor type

University/education

Website

<https://ki.se>

ROR

<https://ror.org/056d84691>

Funder(s)

Funder type

Industry

Funder Name

Skandia Research and Advisory

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

01/11/2023

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
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IPD sharing plan summary

Stored in non-publicly available repository, Available on request