

# Compassionate mind training for patients with heart problems

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<b>Registration date</b> 09/10/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/10/2023	<b>Condition category</b> 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](mailto:christina.andersson80@telia.com)

## Contact information

### Type(s)

Public, Scientific

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil Known

### Protocol serial number

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](mailto: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](mailto:registrator@etikprovning.se)), ref: 2017-1984-32-1

## **Study design**

Interventional randomized controlled trial

## **Primary study design**

Interventional

## **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](http://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