

Psychotherapeutic INtervention for DEpression Treatment in patients with chronic Heart Failure

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| Submission date 30/03/2007 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 30/05/2007 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 19/10/2021 | Condition category Circulatory System | <input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.klinikum.uni-heidelberg.de/HELPS.105744.0.html#c36863>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

PINDET-HF - 01GI0205/21

Study information

Scientific Title

Psychotherapeutic INtervention for DEpression Treatment in patients with chronic Heart Failure

Acronym

PINDET-HF

Study objectives

Psychotherapeutic treatment in patients with chronic heart failure and comorbid depression leads to a significant reduction of depression severity in comparison to usual care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical approval for the study was obtained from the institutional review board of the medical faculty of the University of Heidelberg on the 5th March 2007 (ref.: 302/2006)

Study design

Randomised controlled intervention trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Chronic heart failure, depression

Interventions

Eight sessions in a psychotherapy group (six to nine patients per group), 90 minutes each, over three months, versus care as usual (patients are informed about depression diagnosis and are motivated to talk about treatment options with their GP). Psychotherapy is based on cognitive behavioural techniques and follows a manual. Elements of therapy are:

1. Psychoeducation
2. Cognitive techniques
3. Setup of positive activities

4. Relaxation skills
5. Keeping a study diary

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Depression severity according to PHQ-9 summary score at the end of the intervention.

Secondary outcome measures

1. PHQ-9 summary score three months after the intervention
2. Generic (36-item Short Form health survey [SF-36]) and disease-specific (Kansas City Cardiomyopathy Questionnaire [KCCQ]) quality of life
3. Anxiety severity (7-item Generalised Anxiety Disorder scale [GAD-7])
4. Resilience (Resilience Scale)
5. Hopelessness
6. Vital exhaustion
7. Self-reported adherence to heart failure self-management

Overall study start date

01/01/2007

Completion date

31/05/2008

Eligibility**Key inclusion criteria**

1. Outpatients with documented, stable chronic heart failure
2. New York Heart Association (NYHA) functional class I to III
3. Any depressive disorder or major depressive disorder according to 9-item Patient Health Questionnaire (PHQ-9) AND dysthymia or adjustment disorder or major depressive disorder with mild or medium severity according to Structured Clinical Interview for Depression Interview (SCID-I)
4. Age equal or greater than 18 years

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

130

Key exclusion criteria

1. Acute physical illness that makes participation impossible, according to investigator's assessment
2. Participation in other clinical intervention trial
3. Dementia or other psychiatric disorder, that compromise patients' abilities to study compliance
4. Alcohol or drug abuse
5. Severe major depressive disorder
6. Acute suicidal tendency
7. Current psychotherapeutic treatment

Date of first enrolment

01/01/2007

Date of final enrolment

31/05/2008

Locations**Countries of recruitment**

Germany

Study participating centre

Department of Psychosomatic and General Internal Medicine

Heidelberg

Germany

69120

Sponsor information**Organisation**

German Federal Ministry of Education and Research (Bundesministerium Für Bildung und Forschung [BMBF]) (Germany)

Sponsor details

Hannoversche Str. 28-30

Berlin

Germany

10115

Sponsor type

Government

Website

<http://www.bmbf.de/en/index.php>

ROR

<https://ror.org/04pz7b180>

Funder(s)

Funder type

Government

Funder Name

German Federal Ministry of Education and Research (Bundesministerium Für Bildung und Forschung [BMBF]) (Germany) (ref: 01GI0205/21)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration