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Psychotherapeutic INtervention for DEpression Treatment in patients with chronic Heart Failure

Submission date	Recruitment status	[ ] Prospectively registered
30/03/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/05/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/10/2021	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
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Sponsor information

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

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes