

# Psychotherapeutic INtervention for DEpression Treatment in patients with chronic Heart Failure

<b>Submission date</b> 30/03/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/05/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/10/2021	<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**  
Not provided at time of registration

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

## Contact information

**Type(s)**  
Scientific

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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