

# A before and after study to investigate the effectiveness of an individual psychological intervention in reducing anxiety and depression for heart failure patients

<b>Submission date</b> 28/09/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 28/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 11/09/2012	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

## Contact information

### Type(s)

Scientific

### Contact name

Mrs Annie O'Donoghue

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

N0124183305

# Study information

## Scientific Title

### Study objectives

Is psychological therapy for heart failure combined with normal care better than normal care by itself at reducing depression and anxiety, improving coping and helping patients to address a self-identified heart failure related issue and/or a nurse consultant identified heart failure related issue?

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

## Participant information sheet

### Health condition(s) or problem(s) studied

Mental and Behavioural Disorders: Anxiety disorders

### Interventions

Patients will be randomised into either an immediate treatment or a waiting treatment group. Patients in both groups will be asked to complete questionnaires at beginning of treatment, end of treatment and at 3 months follow-up.

### Intervention Type

Other

### Phase

Not Specified

**Primary outcome measure**

Significant difference between groups in depression, anxiety, coping style, self-identified problem rating, nurse identified problem rating.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/07/2006

**Completion date**

01/07/2009

## Eligibility

**Key inclusion criteria**

Heart failure patients scoring 8 or higher on the Hospital and Anxiety Scale, with an issue identified by the nurse consultant that could benefit from psychological input or identified by heart failure patients and discussed with the nurse consultant.

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

Not provided at time of registration

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/07/2006

**Date of final enrolment**

01/07/2009

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**Heart Failure Service**  
London  
United Kingdom  
SE13 6LH

## Sponsor information

### Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

### Sponsor details

The Department of Health, Richmond House, 79 Whitehall  
London  
United Kingdom  
SW1A 2NL  
+44 (0)20 7307 2622  
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### Sponsor type

Government

### Website

<http://www.dh.gov.uk/Home/fs/en>

## Funder(s)

### Funder type

Government

### Funder Name

University Hospital Lewisham NHS Trust (UK)

### Funder Name

NHS R&D Support Funding

## 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