ISRCTN49123202 https://doi.org/10.1186/ISRCTN49123202

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

Submission date
28/09/2007

Recruitment status
No longer recruiting

Registration date
28/09/2007

Overall study status
Completed

Last Edited
11/09/2012

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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
dhmail@doh.gsi.org.uk

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