ISRCTN96793588 https://doi.org/10.1186/ISRCTN96793588

Psychotherapy of depression in patients with breast cancer

Submission date	Recruitment status
01/07/2008	No longer recruiting
Registration date	**Overall study status**
07/08/2008	Completed
Last Edited	**Condition category**
17/07/2015	Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
107457 & 109379 (Mainz) and 107870 & 109381 (Leipzig)

Study information

Scientific Title
Effectiveness of psychodynamic short-term psychotherapy of depression in patients with breast cancer

Study objectives
In this study we evaluate a manualised supportive-expressive psychodynamic short-term psychotherapy for patients with breast-cancer, with hypotheses as follows:
1. The probability of remission of the depression is higher in breast cancer patients treated by psychodynamic short-term psychotherapy than in the 'treatment as usual' control group
2. Six months after the end of treatment a lower rate of depression and a higher quality of life exists among the 'psychotherapy group' compared to the 'treatment as usual group'

On 31/08/2012 the overall trial end date was changed from 30/09/2010 to 31/12/2012.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Landesärztekammer Rheinland Pfalz (Medical association of Rhineland-Palatinate), Mainz, 29/11/2006, ref: 837.90.06 (5478)

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Depressive disorder in patients with breast cancer

Interventions
Because this is a multicentre study there are two study centres (University of Mainz and University of Leipzig). Each study centre inserts half of the targeted number of patients (N = 90 Mainz and N = 90 Leipzig) within an identical study protocol:

Manualised short-term psychotherapy for patients with breast cancer (based on 'Supportive-Expressive Psychotherapy (SET)' versus treatment as usual (TAU). Short-term psychotherapy will consist of 25 sessions; each session 50 minutes long, frequency one session/week for sessions 1 - 18 and one session/two weeks for sessions 19 and 20.

Follow up will be 6 months after finishing SET in the intervention group and approximately 6 months after baseline diagnostics in the control group.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Remission of depression:
1. HADS: decrease of at least 2 points
2. SCID-I: no diagnosis of depressive disorder

Timepoints:
Screening = T0 = 0 months
Baseline = T1 = 0 months
End of treatment = T2 = ca. 6 months after baseline diagnsotics
Follow-up = T3 = ca. 12 months after baseline diagnostics

Secondary outcome measures
Improvement of quality of life.

Timepoints:
Baseline = T1 = 0 months
End of treatment = T2 = ca. 6 months after baseline diagnsotics
Follow-up = T3 = ca. 12 months after baseline diagnostics

Overall study start date
01/10/2007

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Breast cancer, curative treatment intent
2. Elevated score (greater than or equal to 8) of depression on the Hospital Anxiety and Depression Scale (HADS) and diagnosis of depression (International Classification of Diseases [ICD-10] diagnoses depressive episode [F32], recurrent depressive disorder [F33], dysthymia [F34.1], adjustment disorders [F43.21]) according to the Structured Interview for Diagnostic and Statistical Manual of Mental Disorders - fourth edition (SCID-I-DSMIV)
3. Aged 18 - 70 years, females

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
180

Key exclusion criteria
1. Severe medical conditions (metastases, cognitive impairments)
2. Severe psychiatric disorders (psychotic disorder, risk of self-harm, acute substance-related disorder, personality disorders except for cluster C, organic mental disorder)
3. Concurrent psychotherapeutic treatment

Date of first enrolment
01/10/2007

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Germany

Study participating centre

University of Mainz
Mainz
Germany
D-55131

Study participating centre
University of Leipzig
Leipzig
Germany
04103

Sponsor information

Organisation
German Cancer Aid (Deutsche Krebshilfe) (Germany)

Sponsor details
Buschstr. 32
Bonn
Germany
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Sponsor type
Research organisation

Website
http://www.krebshilfe.de

ROR
https://ror.org/01wxdd722

Funder(s)

Funder type
Research organisation

Funder Name
Deutsche Krebshilfe

Alternative Name(s)

Stiftung Deutsche Krebshilfe, German Cancer Aid

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Germany

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	05/12/2012		Yes	No
Results article	results	01/02/2014		Yes	No
Results article	results	01/08/2015		Yes	No