

Psychotherapy of depression in patients with breast cancer

Submission date 01/07/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 07/08/2008	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 17/07/2015	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

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Type(s)
Scientific

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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 diagnostics

Follow-up = T3 = ca. 12 months after baseline diagnostics

Key secondary outcome(s)

Improvement of quality of life.

Timepoints:

Baseline = T1 = 0 months

End of treatment = T2 = ca. 6 months after baseline diagnostics

Follow-up = T3 = ca. 12 months after baseline diagnostics

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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)

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

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?
Results article	results	01/02/2014		Yes	No
Results article	results	01/08/2015		Yes	No
Protocol article	protocol	05/12/2012		Yes	No