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If chronic depressive patients choose their treatment... Psychoanalytic and cognitive-behavioural long-term treatment for chronic depression

Submission date
21/04/2009

Recruitment status
No longer recruiting

Registration date
10/07/2009

Overall study status
Completed

Last Edited
12/08/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
As chronic depression is often treatment-resistant and causes considerable disease burdens, it has been recognized as one of the major challenges for mental health care. Yet, there is a lack of good clinical trials both on psychotherapeutic and pharmacological treatments. The long-term outcome of cognitive-behavioral (a type of talking therapy) and psychoanalytic therapies (a type of therapy focusing on the emotional state, feelings and perceptions) of chronic depressed patients remains open to debate and there has been a paucity of high quality studies investigating long-term therapies. The study is the first comparing the long-term effectiveness of controlled cognitive-behavioral (CBT) and psychoanalytic therapies (PAT) of chronic depressed patients and to investigate the effects of preferential vs. randomized assessment.

Who can participate?
Adults aged 21 to 60 with major depression

What does the study involve?
In a partial randomization preference trial, patients are asked if they have a preference for one specific treatment (PAT or CBT). Treatments are outlined to them in terms of a general description. If they articulate a specific preference, they are assigned accordingly (preference arm). Assessment is conducted before assignment to treatments, and over a course of five years (including treatment). These include structured clinical interviews, questionnaires and health care utilization (self-report and health insurance data).

What are the possible benefits and risks of participating?
Participants may benefit from getting written information about the therapies before their decision to make a treatment choice. Participants may benefit from the improvement in their treatment however there is a risk that their mental health could get worse.

Where is the study run from?
Clinic for Psychosomatic Medicine and Psychotherapy (Germany)

When is the study starting and how long is it expected to run for?
October 2007 to February 2019

Who is funding the study?
1. German Society for Psychoanalysis, Psychotherapy, Psychosomatics and Depth Psychology (DGPT) (Germany)
2. Heidehof Stiftung GmbH (Germany)

Who is the main contact?
Professor Manfred E Beutel

Contact information

Type(s)
Scientific

Contact name
Prof Manfred E Beutel

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Psychoanalytic and cognitive-behavioural long-term treatment for chronic depression: short- and long-term effects of preferential treatment and randomised allocation

Acronym
LAC

Study objectives
1. Preferential treatment allocation will lead to better outcomes than randomised treatment allocation
2. Cognitive-behavioural treatment will achieve quicker effects than psychoanalytic treatment
3. Psychoanalytic treatment leads to more stable long-term effects
4. Reduction of health costs through the therapy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Landesärztekammer Rheinlandpfalz approved on the 15th May 2007 (ref: 837.124.07[5659])

Study design
Randomised controlled multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Can be found at: http://www.klinik.uni-mainz.de/fileadmin/kliniken/pt/Dokumente/Studien/0612_LAC_Patientenfolder_10_RZ.pdf

Health condition(s) or problem(s) studied
Chronic major depression in outpatient care

Interventions
Arm 1: Preferential treatment. The participants in this arm will choose either psychoanalytic treatment or cognitive-behavioural treatment.
Arm 2: Randomised allocation. The participants in this arm will be randomly allocated to either psychoanalytic treatment or cognitive-behavioural treatment.

Both treatments will last for a minimum of one year. This trial will take place in Berlin, Frankfurt, Hamburg and Mainz.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Depressive sympomatology, assessed with BDI 2 and QIDS-C at pre- and post-treatment. Treatment response is defined as at least 50% decrease in BDI 2 and QIDS-C scores.
2. Remission, defined as a QIDS-C score of less than 6
3. SKID
4. Operational psychodynamic diagnosis (Operationalisierte Psychodynamische Diagnostik) (OPD2)

All primary and secondary outcomes will be assessed at the initial examination (t0) and after 1, 2 and 3 years of treatment.

Secondary outcome measures
1. Symptom Checklist-90-R (SCL-90-R)
2. Social and Occupational Functioning Assessment Scale (SOFAS)
3. Depressive Experiences Questionnaire (DEQ)
4. Reduction in health costs, assessed using health insurance data

All primary and secondary outcomes will be assessed at the initial examination (t0) and after 1, 2 and 3 years of treatment.

Overall study start date
01/10/2007

Completion date
24/02/2019

Eligibility

Key inclusion criteria
1. Both males and females, age range 21 - 60 years
2. Major depression (by SKID I, the German version of Structural Clinical Interview I [SCID I]) and /or dysthymia (by SKID I)
3. Complaints for at least 12 month
4. Quick Inventory of Depressive Symptomatology - clinician rating (QIDS-C) greater than 9
5. Beck Depression Inventory II (BDI II) greater than 17
6. Sufficent knowlege of the German language
7. No restriction of intellectual capacity
8. Consent to the study protocol, secrecy containment to the treating physician

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
240

Total final enrolment
252

Key exclusion criteria
1. Current or in the case history psychotic symptomatology, schizoaffective, schizophrenic or bipolar affective disorder
2. Substance dependence current or during the last 3 years
3. Dementia
4. Borderline, schizotypal and antisocial personality disorder
5. Acute suicidality
6. Serious physical illness that strongly affects the depression or is causally for the depression

Date of first enrolment
01/06/2007

Date of final enrolment
12/07/2013

Locations

Countries of recruitment
Germany

Study participating centre
Clinic for Psychosomatic Medicine and Psychotherapy
Mainz
Germany
D-55131

Sponsor information

Organisation
German Society for Psychoanalysis, Psychotherapy, Psychosomatics and Depth Psychology (DGPT) (Germany)

Sponsor details
Johannisbollwerk 20
Hamburg
Germany
20459

Sponsor type
Research organisation

Website

http://www.dgpt.de/

ROR
https://ror.org/01hd27x96

Funder(s)

Funder type
Research organisation

Funder Name
German Society for Psychoanalysis, Psychotherapy, Psychosomatics and Depth Psychology (DGPT) (Germany) - main funder

Funder Name
Heidehof Stiftung GmbH (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration.

Intention to publish date

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	26/07/2012		Yes	No
Results article	results	01/01/2019	14/02/2020	Yes	No
Results article		09/08/2024	12/08/2024	Yes	No