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INpatient and Day-clinic treatment for DEPression: who profits well and who don´t?

Submission date
16/07/2012

Recruitment status
No longer recruiting

Registration date
31/07/2012

Overall study status
Completed

Last Edited
02/09/2020

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
Depression is one of the most common diseases and a leading cause of disability worldwide. The German health care system provides outpatient care, but also inpatient and day hospital treatment, covering a considerable part of health care for people with mental illnesses. Hospital programs have the advantage of providing a multimodal approach, combining a daily structure with individual, group and additional treatment components. Day hospital programs for acute psychosomatic care are very similar to inpatient programs with the difference that patients return home at evenings and weekends. In Germany, there is an increasing interest in day care programs because of the lower costs of this treatment modality. The treatment of depression is a high priority task, but there is still a lack of studies on inpatient or day hospital treatment. Furthermore, depression in one subject is not like depression in another. Tailoring treatments to the needs of subgroups of patients with special characteristics may improve overall outcome. This study aims to find out about the effects of inpatient and day hospital treatment for major depression in routine care. It further aims at identifying prognostic (associated with general outcome) and prescriptive (associated with the differential outcome in both settings) variables, which can help to discriminate subgroups of patients with differences in course and treatment needs. This is especially important in clinic treatment, as patients referred to hospital usually show a more complicated course of their illness or considerable co-morbidity (other illnesses).

Who can participate?
Patients aged 18-65 years with a diagnosis of a major depressive episode treated in the study centres during the recruitment period.

What does the study involve?
After informed consent participants will get diagnostic interviews and additional questionnaires for evaluation. They will be interviewed and receive questionnaires at the time of discharge from the hospital. At 3 and 12 months after discharge they will be interviewed again and asked to fill in questionnaires to assess depressive symptoms, overall functioning, quality of life and further treatment.

What are the possible benefits and risks of participating?
All participants receive comprehensive diagnostic interviews. As all participants get the standard treatment of the study centres, there are no additional risks compared to routine care.

Where is the study run from?
Department of Psychosomatic Medicine, University of Freiburg and the following cooperating centres: Department of Psychosomatic Medicine, University of Ulm; Department of Psychosomatic Medicine, University of Mainz; Clinic for Psychosomatic Medicine, Robert-Bosch-Krankenhaus Stuttgart; Thure-von Uexküll-Klinik, Freiburg; Bürgerhospital, Stuttgart; Rhein-Klinik, Bad Honnef.

When is the study starting and how long is it expected to run?
The study has started in March 2011 and ends in February 2015.

Who is funding the study?
The Heidehof-Stiftung GmbH, Stuttgart, Germany.

Who is the main contact?
Prof. Almut Zeeck
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
59055.02.1/2.10

Study information

Scientific Title
INpatient and Day-clinic treatment for DEPression: symptom course and response prediction

Acronym
INDDEP

Study objectives
First, the study aims to describe changes in depressive symptomatology after inpatient and day clinic treatment for depression and to identify subgroups with a good or less favourable symptom course (explorative).

Secondly, inpatient and day clinic treatment will be compared (matched samples). It is hypothezied that type of depression (introjective/high level of perfectionism vs. anaclitic/high level for dependency) will be associated with differential outcome in each setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the University Clinic of Freiburg, 22/02/2011, ref: No. 39/11

Study design
Naturalistic multicentre study

Primary study design
Interventional

Secondary study design
Other

Study setting(s)
Hospital

Study type(s)
Screening

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
Major Depression (inpatient and day clinic treatment)

Interventions
We include all patients who are consecutively admitted to the study centres over a period of 2.5 years. To compare inpatient and day clinic treatment (especially differences in predictors of symptom course and response rates), patient samples will be parallelized according to known predictors of outcome:

1. Gender
2. Age
3. Number of additional axis-I diagnoses
4. Number of previous episodes of major depression
5. Duration of the recent episode of MDE.

Criteria 1-3 will be matched 1:1, criteria 4 & 5 are used as lenient criteria, to be matched 1:1 if possible.

Interventions comprise the standard programms of psychosomatic clinics: individual psychotherapy sessions, group psychotherapy, sessions with nurses, art therapy or music therapy, movement therapy, physicians rounds, psychopharmacological treatment. Day clinic and inpatient programms are comparable, although the settings differ in a crucial aspect: in a day clinic intense, multimodal treatment and experiences in daily life are closely linked.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Depressive symptomatology, assessed with the QIDS-C (Quick-Inventory of Depressive Symptomatology, expert rating) at pre, post and follow-ups (3 and 12 month after discharge)
1. Change in symptoms will be assessed:
1.1. Dimensional (change in QIDS-score)
1.2. Categorial: reduction < 20%= no effect; reduction between 20% and 50%=modest change; reduction > 50=partial remission; falling below the cut-off for depression=complete remission)

Secondary outcome measures
1. Global severity index (GSI), Symptom-Check-List-90-R
2. Social and Occupational Functioning Assessment Scale (SOFAS)
3. Quality of Life SF-12

Predictor analyses include:
1. Symptomatology (characteristics of depression, co-morbodity, axis-II-diagnoses) and overall disturbance
2. Demographics
3.Personality and interpersonal problems (DEQ: Depressive Experience Questionnaire; DAS: Dysfunctional Attitudes Scale; IIP: Inventory of Interpersonal Problems)
4. Traumatization (CTQ: Childhood-Trauma-Questionnaire)

Follow up: 3 and 12 months after discharge.

Overall study start date
01/03/2011

Completion date
01/03/2015

Eligibility

Key inclusion criteria
1. Major depressive episode (MDE), unipolar, according to Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) as main diagnosis
2. Age 18-65 years
3. Quick Inventory of Depressive Symptomatology (QIDS)-expert rating score > 10
4. Informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
600 (after matching procedure: 240 vs. 240)

Total final enrolment
604

Key exclusion criteria
1. Psychotic disorder
2. Bipolar disorder
3. Substance abuse (current or last three years)
4. Current suicidal ideation
5. Antisocial personality disorder
6. Cognitive impairment
7. Admission for diagnostic reasons (not for treatment)
8. Second admission during recruitment period

Date of first enrolment
01/03/2011

Date of final enrolment
01/03/2015

Locations

Countries of recruitment
Germany

Study participating centre
Department of Psychosomatic Medicine and Psychotherapy
Freiburg
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Sponsor information

Organisation
Heidehof Foundation Ltd. (Heidehof Stiftung GmbH) (Germany)

Sponsor details
Heidehofstrasse 35A
Stuttgart
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Sponsor type
Government

ROR
https://ror.org/02xq7zd76

Funder(s)

Funder type
Government

Funder Name
Heidehof Foundation Ltd. (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

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	26/03/2013		Yes	No
Results article	results	15/11/2015	25/06/2020	Yes	No
Results article	results	01/07/2020	25/06/2020	Yes	No
Results article	results	07/08/2020	02/09/2020	Yes	No