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Psychoanalytic therapy (PT) and cognitive-behavioral therapy (CBT) in outpatients with anxiety (panic disorder/agoraphobia) and comorbid personality disorders.

Submission date
12/09/2014

Registration date
12/12/2014

Last Edited
15/02/2021

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
In this study, we want to investigate patients that suffer from both anxiety order and personality disorder. There is, at present, not enough evidence to suggest psychoanalytic therapy is a successful treatment for anxiety disorders and few studies have been carried out that have investigated the high number of these patients suffering from other mental disorders at the same time (comorbidity). As a relatively high number of patients with panic disorder and/or agoraphobia also have a personality disorder, we want to carry out a study comparing psychoanalytic therapy (PT) and cognitive-behavior therapy (CBT) for this combined condition. Both treatments are examined in terms of how successful they are at treating the patients, how long patients remain well after treatment and how cost effective the two treatments are over time.

Who can participate?
Participants should be adults that are at least 21 years old. They must also have been diagnosed with a panic disorder and/or agoraphobia and have at least one personality disorder.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 receive PT. Those in group 2 receive CBT. Patients receiving either treatment are able to see several therapists before selecting one to work with and therapists, in turn, are able to refuse to treat a specific patient. Both treatments, PT and CBT, are basically described in the German guidelines. PT and CBT manuals for treating patients with panic and personality disorders have also been developed for the study. However, the CBT manual should only serve as a compass for the CBT study therapists, who are otherwise free to carry out “CBT as usual”. All study therapists have had several years of training and a license to practice as psychological or medical psychotherapist in the particular treatment. To guarantee treatment integrity, all sessions are audio-recorded. Each participant is followed up once a year for a period of six years from the start of their treatment. They are asked to take part in interviews and complete questionnaires.

Questionnaires include general information (age, sex, level of education, school/profession, family status/partnership, etc.) as well as covering subjects such as symptoms, interpersonal problems (problems with building and maintaining relationships with others), life satisfaction, working alliance (relationship between themselves and healthcare professionals), and others. Therapists also fill in a number of questionnaires on, for example, their patient's diagnosis, the number and frequency of the treatment sessions, any changes in the therapeutic setting and how they think the treatment progressed.

What are the possible benefits and risks of participating?
Benefits for patients participating in the study are that they receive a therapy for their condition within a particular therapeutic setting. Possible risks are known unwanted side-effects of psychotherapy treatments. Additionally, some patients may be given a treatment that does not meet their expectations of psychotherapy. It is assumed that both CBT and PT lead to significant improvements. However, these improvements are expected to be longer term for patients treated with PT.

Where is the study run from?
University of Kassel (Germany).

When is the study starting and how long is it expected to run for?
April 2012 to April 2024.

Who is funding the study?
German Society for Psychoanalysis, Psychotherapy, Psychosomatics and Depth Psychology (Deutsche Gesellschaft für Psychoanalyse, Psychotherapie, Psychosomatik und Tiefenpsychologie - DGPT) (Germany).

Who is the main contact?
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Study website
http://www.aps-studie.de

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Psychoanalytic therapy (PT) and cognitive-behavioral therapy (CBT) in outpatients with anxiety (panic disorder/agoraphobia) and comorbid personality disorders: a multicenter prospective randomized superiority trial

Acronym
APD study (anxiety and personality disorders)

Study objectives
Patients treated with PT show a significantly better long-term outcome (six years after baseline) than those with CBT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Board of the Faculty of Human Sciences, University of Kassel, approved on 16/11/2011
Ethics Board of the Faculty of Medicine, University of Heidelberg, approved on 29/12/2011
Ethics Board of the Ärztekammer Hamburg, approved on 25/07/2013.

Study design
Multicenter prospective randomized superiority trial with two parallel arms

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Panic disorder, Agoraphobia, Personality disorder

Interventions
Participants will be randomised into one of the two arms:
1. Psychoanalytic therapy (PT)
2. Cognitive-behavior therapy (CBT)
They will be assessed at the study centrebefore treatment, after termination of treatment and at a 6-year follow-up. Additional self-report questionnaire and LIFE-Interviews once a year.

Intervention Type
Behavioural

Primary outcome measure
Primary outcome measure as of 23/05/2016:
1. Overall symptomatic burden according to LIFE-interview over the 6 year follow-up-period
2. Individual change in patients self-reports (combination symptomatic burden, SCL-90-GSI, interpersonal problems, IIP, and life satisfaction, FLZ) between beginning of treatment and 6-year-follow-up

Original primary outcome measures:
1. Individual change in mental disorders (according to SCID-Interviews, Axis I and Axis II) between beginning of treatment and 6-year-follow-up
2. Individual change in patients self-reports (combination symptomatic burden, SCL-90-GSI, interpersonal problems, IIP, and life satisfaction, FLZ) between beginning of treatment and 6-year-follow-up

Secondary outcome measures
Secondary outcome measure as of 23/05/2016:
1. Individual change in criteria for personality disorders (according to SCID-interview, axis II)
2. Patients Health Questionnaire (PHQ)
3. Assessment of DSM-IV Personality Disorders (ADP-IV)
4. Panik- und Agoraphobieskala (PAS)
5. Experiences in Close Relationships - Revised (ECR)
6. Structural Impairment, assessed with: Inventory of Personality Organization short form (IPO-16), Operationalized Psychodynamic Diagnostics (OPD), and Scales of Psychological Capacities (SPC)
7. Short Form Health Survey (SF-12)
8. Willingness-to-pay (WTP)

Original secondary outcome measures:
1. Overall symptomatic burden according to LIFE over the 6 year follow-up-period
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7. Short Form Health Survey (SF-12)
8. Willingness-to-pay (WTP)

Overall study start date
01/04/2012

Completion date
01/04/2024

Eligibility

Key inclusion criteria
1. Panic disorder (including partial remission, i.e., maximally 2 months without significant symptoms) and/or agoraphobia plus:
2. At least one of the following PDs: avoidant PD, dependent PD, obsessive-compulsive PD, depressive PD, negativistic PD, histrionic PD, borderline PD without acute suicidality, narcissistic PD, PD not otherwise specified (i.e., in at least two of the PD categories listed above only 1 criterion is missing to fulfill the diagnosis)
3. Age: at least 21 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
21 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Bipolar affective disorder, psychotic disorder, acute eating disorder, substance-related disorder (except caffeine and nicotine), Cluster-A PDs, antisocial PD, borderline PD with acute suicidality
2. Neurological diseases (with psychologically significant consequences, e.g., epilepsy)
3. Insufficient knowledge of the German language
4. Strong preference for one of the two treatment conditions
5. Current medication with benzodiazepine

Date of first enrolment
01/04/2012

Date of final enrolment
01/04/2024

Locations

Countries of recruitment
Germany

Study participating centre
University of Kassel
Mönchebergstraße 19
Kassel
Germany
34125

Sponsor information

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

Sponsor details
Johannisbollwerk 20
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20459

Sponsor type
Research organisation

ROR
https://ror.org/01hd27x96

Funder(s)

Funder type
Research organisation

Funder Name
German Society for Psychoanalysis, Psychotherapy, Psychosomatics and Depth Psychology (Deutsche Gesellschaft für Psychoanalyse, Psychotherapie, Psychosomatik und Tiefenpsychologie - DGPT) (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	01/09/2016	15/02/2021	Yes	No