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Effects and mechanisms of psychotherapy in the treatment of attention deficit hyperactivity disorder in adults: the first randomised multicentre study

Submission date 19/10/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/04/2007	**Overall study status** Completed	
Last Edited 23/11/2023	**Condition category** Mental and Behavioural Disorders	

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
2006-000222-31

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Code: 070170

Study information

Scientific Title
Effects and mechanisms of psychotherapy in the treatment of attention deficit hyperactivity disorder in adults: the first randomised multicentre study

Study objectives
1. A disorder specific psychotherapy is more effective in reducing symptoms of adult Attention Deficit Hyperactivity Disorder (ADHD) than a control condition in terms of clinical management
2. The combination of a disorder specific psychotherapy and medication is superior to medication or psychotherapy alone

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethik-Kommission der Albert-Ludwigs-Universität Freiburg, 19/10/2006, ref: 217/06

Study design
Controlled randomised multicentre 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
Attention Deficit Hyperactivity Disorder (ADHD)

Interventions
Experimental intervention:
1. Psychotherapy following a weekly structured group-program for 12 weeks (according to Hesslinger et. al.) and placebo and after that monthly group sessions and placebo
2. Psychotherapy (see point one) and medication (methylphenidate, according to the German guidelines for adult ADHD)

Control intervention:
3. Medication alone with clinical management weekly for the first 12 weeks and monthly

thereafter
4. Placebo alone with clinical management weekly for the first 12 weeks and monthly thereafter

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Methylphenidate

Primary outcome measure
Conners Adult ADHD Rating Scale (CAARS-O, blind-observer rated).

Secondary outcome measures
1. Conners Adult ADHD Rating Scale (CAARS-S, patient rated)
2. Symptoms CheckList (SCL-90-R)
3. Depression
4. Clinical Global Impression (CGI)
5. Quality of Life

Overall study start date
01/11/2006

Completion date
31/10/2011

Eligibility

Key inclusion criteria
ADHD according to the Diagnostic and Statistical Manual of Mental Disorders - fourth edition (DSM-IV) criteria

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
448

Total final enrolment
433

Key exclusion criteria

1. Mental handicap
2. Schizophrenia
3. Bipolar disorder
4. Suicidal behaviour
5. Substance abuse/dependence within six months prior to screening
6. Neurological diseases
7. Seizures

Date of first enrolment
01/11/2006

Date of final enrolment
31/10/2011

Locations

Countries of recruitment
Germany

Study participating centre
Hauptstrasse 5
Freiburg
Germany
D-79104

Sponsor information

Organisation
University of Freiburg Medical School (Germany)

Sponsor details
Hauptstrasse 5
Freiburg
Germany
D-79104

Sponsor type
University/education

Website
http://www.uniklinik-freiburg.de/ims/live/index_en.html

ROR
https://ror.org/0245cg223

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung

Alternative Name(s)
Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

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
Not provided at time of registration

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	01/12/2010		Yes	No
Other publications	enrollment and characteristics of the study sample	01/03/2014		Yes	No
Results article	results	01/12/2015		Yes	No
Results article	results	03/05/2019	04/09/2019	Yes	No
Results article	results	01/07/2019	04/09/2019 03/05	Yes	No

Results article	01/04/2022	/2022	Yes	No
Results article	18/11/2023	23/11 /2023	Yes	No