

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

☒ Protocol

Registration date
30/04/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
23/11/2023

Condition category
Mental and Behavioural Disorders

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Germany
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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