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Psychotherapy, atomoxetine, or combined treatment for ADHD in children

Submission date
13/12/2017

Recruitment status
No longer recruiting

Registration date
18/01/2018

Overall study status
Completed

Last Edited
20/01/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Attention-Deficit/Hyperactivity Disorder (ADHD) is a prevalent condition in youths, with symptoms that include inattentiveness, hyperactivity and impulsiveness. It is associated with a significant impact on functioning and high costs. The aim of this study is to compare the effectiveness of a combined treatment (CBT/REBT + ATX) with two reference treatments (CBT /REBT and ATX) for ADHD symptoms in children.

Who can participate?
Children aged 6 to 11 with ADHD

What does the study involve?
Participants are randomly allocated to one of three groups. Participants in the psychotherapy group receive 16 weekly individual psychotherapy sessions, involving both parents and children, based on Cognitive Behavioral Therapy (CBT) and Rational Emotive Behavior Therapy (REBT) enhanced with one session of attention training delivered via virtual reality. Participants in the medication group receive atomoxetine (ATX) once daily. Participants in the combined group (ATX+ REBT/CBT) receive both medication and psychotherapy as previously described. The total duration of treatment is 16 weeks. Clinical psychologists and multiple assessors (parents, teachers) assess the participants' ADHD symptoms before and after treatment.

What are the possible benefits and risks of participating?
Possible benefits include free treatment for ADHD which is not covered in Romania by health insurance. Risks involving adverse medication effects, which are monitored by psychiatrists.

Where is the study run from?
1. The Institute for the Advanced Studies of Psychotherapy and Applied Mental Health, Babeș-Bolyai University (Romania)
2. The Clinic of Child and Adolescent Psychiatry (Romania)

When is the study starting and how long is it expected to run for?
August 2006 to November 2008

Who is funding the study?
National Council for Research (Romania)

Who is the main contact?
Prof. Daniel David
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
716/30.01.2008

Study information

Scientific Title
A comparative study of three types of treatment for Attention-Deficit/Hyperactivity Disorder in children

Study objectives
The primary aim is to compare the efficacy of the combined treatment (CBT/REBT + ATX) with two reference treatments (CBT/REBT and ATX) in a superiority format for ADHD symptoms in children.

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. The Ethics Committee of Babes-Bolyai University, 01/08/2006, ref: 30713
2. The National Agency for Medication, 30/01/2008, ref: 716

Study design
Interventional randomized controlled trial

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Attention-Deficit/Hyperactivity Disorder (ADHD)

Interventions
Randomization was done using a random number generator (www.random.org). Participants were randomly assigned to one of the three treatment groups:

1. Psychotherapy (cognitive-behavioral therapy/rational emotive behavior therapy CBT/REBT)
Participants in the psychotherapy condition received 16 weekly individual psychotherapy sessions, involving both parents and children. The protocol was based on Cognitive Behavioral Therapy (CBT) and Rational Emotive Behavior Therapy (REBT) enhanced with one session of attention training delivered via virtual reality (VR).

2. Medication (atomoxetine ATX)
Participants in the medication condition received atomoxetine (ATX) once daily in the morning, with an initial dose of 0.5 mg/kg/day, increased weekly (maximum increase 1.8 mg/kg/day).

3. Combined treatment (ATX+ REBT/CBT)
Participants in the combined group (ATX+ REBT/CBT) received both medication and psychotherapy as previously described.

The total duration of treatment was 16 weeks. Blinded clinical psychologists and multiple assessors (parents, teachers) assessed ADHD symptoms both at pretreatment and posttreatment.

Intervention Type
Mixed

Primary outcome measure
1. Clinician-based interviews on ADHD symptoms and impairment. ADHD diagnosis was assessed using the Structured Clinical Interview for DSM-IV Childhood Diagnoses (KID-SCID; Hien et al., 1994), while impairment was assessed using the Global Assessment of Functioning (GAF; APA, 1994); both conducted at baseline and post-treatment (16 weeks)
2. Parent-rated ADHD total symptoms, inattention and hyperactivity symptoms, measured using the ADHD-rating scale IV-Parent Version (ADHD-RS IV; DuPaul, Power, Anastopoulos, & Reid, 1998) at baseline and post-treatment (16 weeks)

Secondary outcome measures
1. Parent-rated externalizing and internalizing symptoms assessed using the Child Behavioral Checklist (CBCL; Achenbach & Rescorla, 2001) at baseline and post-treatment (16 weeks)
2. Teacher-rated ADHD total symptoms, inattention and hyperactivity symptoms assessed using The ADHD-rating scale IV-Teacher Version (ADHD-RS IV; DuPaul et al., 1998) at baseline and post-treatment (16 weeks)
3. Teacher-rated externalizing and internalizing symptoms assessed using Teacher's Report Form (TRF; Achenbach & Rescorla, 2001) at baseline and post-treatment (16 weeks)

Overall study start date
01/08/2006

Completion date
01/11/2008

Eligibility

Key inclusion criteria
1. Aged between 6 and 11 years old
2. Diagnosed with ADHD by a child psychiatrist and/or certified psychologist
3. Attending elementary school
4. With sufficient understanding of the Romanian language
5. With an IQ score of at least 80 on Colored Raven Matrices
6. No previous treatment for ADHD received

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
11 Years

Sex
Both

Target number of participants

58 participants

Key exclusion criteria
1. Mental retardation
2. Neurodevelopmental disorders (autism spectrum disorders)
3. Severe depression
4. Psychotic disorders
5. Intolerance to atomoxetine
6. Body weight < 20 kg
7. Any severe medical conditions or clinically significant laboratory or ECG abnormalities

Date of first enrolment
01/01/2007

Date of final enrolment
01/07/2008

Locations

Countries of recruitment
Romania

Study participating centre
The Institute for the Advanced Studies of Psychotherapy and Applied Mental Health, Babeş-Bolyai University
Republicii St., No. 37
Cluj-Napoca
Romania
400015

Study participating centre
The Clinic of Child and Adolescent Psychiatry
Ospătăriei St.
Cluj-Napoca
Romania
400660

Sponsor information

Organisation
Babes-Bolyai University

Sponsor details

No. 1, Kogalniceanu Street
Cluj-Napoca
Romania
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Sponsor type
University/education

Website
ubbcluj.ro

ROR
https://ror.org/02rmd1t30

Funder(s)

Funder type
Research council

Funder Name
National Council for Research (CEEX No. 78/2006)

Results and Publications

Publication and dissemination plan
Study protocol and detailed plan of analysis will be available upon request from the contact person, after the publication of the data. Planned publication of the study results in a high-impact peer reviewed journal in 2018.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Daniel David (danieldavid@psychology.ro). Data will be shared upon reasonable request after the publication of the data.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/10/2020	20/01/2022	Yes	No