Psychotherapy, atomoxetine, or combined treatment for ADHD in children

Recruitment status No longer recruiting	Prospectively registered		
	☐ Protocol		
Overall study status	Statistical analysis plan		
Completed	[X] Results		
Condition category Montal and Robaviousal Disorders	Individual participant data		
	No longer recruiting Overall study status Completed		

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, Babeş-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 danieldavid@psychology.ro

Contact information

Type(s)

Scientific

Contact name

Prof Daniel David

Contact details

Republicii St., No. 37 Cluj-Napoca Romania 400015 +40 (0)264 434141 danieldavid@psychology.ro

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

- 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)

Key secondary outcome(s))

- 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)

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 years

Upper age limit

11 years

Sex

All

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

ROR

https://ror.org/02rmd1t30

Funder(s)

Funder type

Research council

Funder Name

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

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes