

# Psychotherapy, atomoxetine, or combined treatment for ADHD in children

<b>Submission date</b> 13/12/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 18/01/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/01/2022	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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, 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

**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](http://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  
-

**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](mailto: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?
<a href="#">Results article</a>		02/10/2020	20/01/2022	Yes	No