Third Generation Cognitive Behavioural Therapy vs Treatment-as-usual for ADHD (Hyper-mCBT)

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT03437772

Recruitment Status: Not yet recruiting
First Posted: February 19, 2018
Last Update Posted: February 20, 2018
See Contacts and Locations

Sponsor:
Centre Hospitalier Universitaire de Nîmes

Information provided by (Responsible Party):
Centre Hospitalier Universitaire de Nîmes

- Study Details
- Tabular View
- No Results Posted
- Disclaimer
- How to Read a Study Record

Study Description
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Brief Summary:
The investigators hypothesize that the mindfulness Cognitive Behavioral Therapy program will lead to a reduction in attention deficit and hyperactivity disorder symptoms, anxiety and depression, and improve self-confidence, emotional control, social integration and school results.

<table>
<thead>
<tr>
<th>Condition or disease</th>
<th>Intervention/treatment</th>
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</thead>
<tbody>
<tr>
<td>Adhd</td>
<td>Behavioral: Mindfulness Cognitive Behavioral Therapy program</td>
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Study Design
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Study Type: Observational
Estimated Enrollment: 744 participants
Observational Model: Cohort
Time Perspective: Prospective
Official Title: Third Generation Cognitive Behavioural Therapy Versus Treatment-as-usual for Attention Deficit and Hyperactivity Disorder: a Randomized, 2-parallel-group, Evaluator Blinded, Superiority Trial

Anticipated Study Start Date: February 2018
Estimated Primary Completion Date: April 2021
Estimated Study Completion Date: April 2021

Groups and Cohorts

<table>
<thead>
<tr>
<th>Group/Cohort</th>
<th>Intervention/treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBT with mindfulness</td>
<td>Behavioral: Mindfulness Cognitive Behavioral Therapy program 16 simultaneous-but-separate therapy sessions for parents and children.</td>
</tr>
<tr>
<td>Treatment as Usual: Barkley therapy</td>
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Outcome Measures

Primary Outcome Measures:
1. ADHD symptom severity [Time Frame: baseline]
   - clinical-rated ADHD rating scale (ADHDRS-PI) questionnaire; score ranges 0-54

2. ADHD symptom severity [Time Frame: Month 5]
   - clinical-rated ADHD rating scale (ADHDRS-PI) questionnaire; score ranges 0-54

3. ADHD symptom severity [Time Frame: Month 8]
   - clinical-rated ADHD rating scale (ADHDRS-PI) questionnaire; score ranges 0-54

Secondary Outcome Measures:
1. Parenting styles [Time Frame: Baseline]
   - Parental Authority Questionnaire (PAQ); 30 items per parent

2. Parenting styles [Time Frame: Month 5]
   - Parental Authority Questionnaire (PAQ); 30 items per parent

3. Parenting styles [Time Frame: Month 8]
   - Parental Authority Questionnaire (PAQ); 30 items per parent

4. The quality of life for parents. [Time Frame: Baseline]
5. The quality of life for parents. [Time Frame: Month 5]
   Parental - Developmental Disorders - Quality of Life (PAR-DD-QoL) questionnaire; score ranges from 17-85

6. The quality of life for parents. [Time Frame: Month 8]
   Parental - Developmental Disorders - Quality of Life (PAR-DD-QoL) questionnaire; score ranges from 17-85

7. Global function [Time Frame: Baseline]
   Clinical Global Impression Scale (CGI-S) questionnaire; score from 1-7

8. Global function [Time Frame: Month 5]
   Clinical Global Impression Scale (CGI-S) questionnaire; score from 1-7

9. Global function [Time Frame: Month 8]
   Clinical Global Impression Scale (CGI-S) questionnaire; score from 1-7

10. Global function [Time Frame: Baseline]
    Children's Global Assessment Scale (CGAS) questionnaire; score ranges from 0-100

11. Global function [Time Frame: Month 5]
    Children's Global Assessment Scale (CGAS) questionnaire; score ranges from 0-100

12. Global function [Time Frame: Month 8]
    Children's Global Assessment Scale (CGAS) questionnaire; score ranges from 0-100


CONNERS for school teachers; cut-off for significant behavioral problem >15

15. Social well-being and school parameters for children [Time Frame: Month 8]

CONNERS for school teachers; cut-off for significant behavioral problem >15


Multidimensional Anxiety Scale for Children (MASC) questionnaire; 39-item, 4-point Likert scale

17. Anxiety in children [Time Frame: Month 5]

Multidimensional Anxiety Scale for Children (MASC) questionnaire; 39-item, 4-point Likert scale

18. Anxiety in children [Time Frame: Month 8]

Multidimensional Anxiety Scale for Children (MASC) questionnaire; 39-item, 4-point Likert scale


Children depression inventory (CDI) questionnaire; score ranges from 0-54

20. Depression in children [Time Frame: Month 5]

Children depression inventory (CDI) questionnaire; score ranges from 0-54

21. Depression in children [Time Frame: Month 8]

Children depression inventory (CDI) questionnaire; score ranges from 0-54

22. Anxiety and depression in parents [Time Frame: Baseline]

Hospital Anxiety and Depression Scale (HADS) questionnaire; 2 subscores each ranging from 0-21
23. Anxiety and depression in parents  [Time Frame: Month 5 ]
   Hospital Anxiety and Depression Scale (HADS) questionnaire; 2 subscores each ranging from 0-21

24. Anxiety and depression in parents  [Time Frame: Month 8 ]
   Hospital Anxiety and Depression Scale (HADS) questionnaire; 2 subscores each ranging from 0-21

   Rosenberg scale; score ranges from 0-40

   Rosenberg scale; score ranges from 0-40

27. Self-Esteem and behaviour for children.  [Time Frame: Month 8 ]
   Rosenberg scale; score ranges from 0-40

   CONNERS questionnaire for parents; cut-off for significant behavioral problem >15

29. Self-Esteem and behaviour for children.  [Time Frame: Month 5 ]
   CONNERS questionnaire for parents; cut-off for significant behavioral problem >15

30. Self-Esteem and behaviour for children.  [Time Frame: Month 8 ]
   CONNERS questionnaire for parents; cut-off for significant behavioral problem >15

Eligibility Criteria
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Information from the National Library of Medicine
Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study: 7 Years to 15 Years  (Child)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No
Sampling Method: Non-Probability Sample

Study Population
Families consulting for attention deficit and hyperactivity disorder

Criteria

Inclusion Criteria:

- If deemed able, the patient must have given his/her informed and signed consent
- The parents (or legal guardian) of minor patients must have given their informed and signed consent.
- The patient and participating parents must be insured or beneficiary of a health insurance plan
- The patient is equal to or greater than 7 years old and less than or equal to 15 years old
- The patient presents with attention deficit and hyperactivity disorder with an ADHDRS-PI score > 27
- The patient is currently not under treatment - OR - is treated with methylphenidate with a stable posology (not expected to vary in the near future) but remains symptomatic

Exclusion Criteria:

- The patient is participating in, or has participated in over the past three months, another trial or another study that may interfere with the results or conclusion of the present study
- The patient is in an exclusion period determined by a previous study
- The participating parent(s) is(are) under judicial protection, or is an adult under guardianship
- It is impossible to correctly inform the patient or his/her parent or legal guardian
- Patients or parents refusing participation, signature of the signed consent or follow-up procedures
- Previously documented mental retardation (IQ < 70) or suspicion thereof by the investigator
- The patient has already participated in cognitive behavioural therapy (individual or group) in the six months preceding inclusion
- Patients diagnosed with autism spectrum disorder, psychotic disorder or bipolar disorder
- The family has participated in a parental guidance programme in the last 6 months.
- The family has already participated in the present study

Contacts and Locations

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Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): NCT03437772

Contacts

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Locations

France

CH Charles Perrens  Not yet recruiting