Evaluation of a Parent/Child Cognitive-Behavioral Therapy Program in ADHD Children with Emotional Dysregulation Profile (DP-KID)

This study is not yet open for participant recruitment. (see Contacts and Locations)

Verified May 2017 by University Hospital, Montpellier

Sponsor:
University Hospital, Montpellier

Information provided by (Responsible Party):
University Hospital, Montpellier

ClinicalTrials.gov Identifier:
NCT03176108

First received: May 30, 2017
Last updated: June 2, 2017
Last verified: May 2017

Purpose
Attention Deficit Disorder (ADD) with or without Hyperactivity/Impulsivity (ADHD) is a neurodevelopmental syndrome that has a lasting impact on the child's daily lifestyle and leads to functional impairment. ADHD is recognized as the most common psychiatry disorder in children and it's considered as a public health problem.

ADHD is frequently associated with a new diagnostic entity "Disruptive Disorder with Emotional dysregulation". This disorder is characterized by crisis of anger with verbal or physical aggression, intensity disproportionate to the context and developmental age.

Few studies have examined the elements of emotional dysregulation in ADHD in children. Many studies have shown the interest of CBT in multimodal management of ADHD symptoms and associated disorders.

The main objective is to evaluate the effectiveness of a Cognitive-Behavioral Therapy Parent/Child program versus a body mediation focused on emotional and behavioral aspects in ADD children aged 7-13 years with dimensional emotional dysregulation at 6 months after intervention. Secondary objectives are to evaluate the impact of this program, at short-term (at the end of CBT) and at 6 months after intervention, on socio-communicative capacities, quality of life, children's functioning and parental stress.

It's a biomedical research, prospective, controlled, randomized, monocentric, two parallels, with an evaluation of the criteria of blind judgment.

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<tr>
<th>Condition</th>
<th>Intervention</th>
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Full Text View

Tabular View

No Study Results Posted

Disclaimer

How to Read a Study Record

Condition | Intervention |
Attention Deficit Disorder With Hyperactivity Disorder
Attention-Deficit-Disordered Children
Behavioral: Cognitive Behavioral Therapy (CBT)
Behavioral: Body mediation

Study Type: Intervventional

Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: No masking
Primary Purpose: Supportive Care

Official Title: Evaluation of a Parent/Child Cognitive-Behavioral Therapy Program in ADHD Children With Emotional Dysregulation Profile: a Study Prospective, Controlled and Randomized

Resource links provided by NLM:

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder
U.S. FDA Resources

Further study details as provided by University Hospital, Montpellier:

Primary Outcome Measures:
- Variation between the initial assessment and the month evaluation after the end of the intervention on the score of the "Aggressive behavior" subscale at the CBCL (Child Behavior Checklist) [Time Frame: Evaluation at inclusion, 6 months and 12 months]
The Questionnaire is completed by parents

Secondary Outcome Measures:
- Variation of total score on CBCL and score on "Dysregulation profile" (CBCL-DP) on Child Behavior Checklist [Time Frame: Evaluation at inclusion, 6 months and 12 months]
The Questionnaire is completed by parents

- Variation of scores on "Strengths and Difficulties Questionnaire" [Time Frame: Evaluation at inclusion, 6 months and 12 months]
  Description: The Questionnaire is completed by parents and teachers

- Variation of scores on "Parenting Stress Index" [Time Frame: Evaluation at inclusion, 6 months and 12 months]
The Questionnaire is completed by parents
Variation of score on "Beck Depression Inventory" [Time Frame: Evaluation at inclusion, 6 months and 12 months]
The Questionnaire is completed by parents

Variation of scores on "Kidscreen-27" [Time Frame: Evaluation at inclusion, 6 months and 12 months]
The Questionnaire is completed by parents

Variation of score on "PAR-ENT-Qol" [Time Frame: Evaluation at inclusion, 6 months and 12 months]
The Questionnaire is completed by parents

Variation of score on "Children's Global Assessment Scale" (C-GAS) [Time Frame: Evaluation at inclusion, 6 months and 12 months]
The Questionnaire is completed by the evaluator who receive parents and their child.

Estimated Enrollment: 68
Anticipated Study Start Date: June 20, 2017
Estimated Study Completion Date: June 20, 2019
Estimated Primary Completion Date: January 20, 2019 (Final data collection date for primary outcome measure)

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<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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<tbody>
<tr>
<td>Experimental: CBT Group</td>
<td>Behavioral: Cognitive Behavioral Therapy (CBT)</td>
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<tr>
<td></td>
<td>Cognitive Behavioral Therapy (CBT)</td>
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<tr>
<td>Sham Comparator: Control</td>
<td>Behavioral: Body mediation</td>
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<tr>
<td>Group</td>
<td>Body mediation (theatre)</td>
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Detailed Description:
68 patients (parents and children) will be recruited within Montpellier University Hospital. They will be divided into a CBT group and a control group (body mediation).

The CBT group benefits from an intervention based on the program "Better manage its anger and its frustrations" of 15 sessions for the children.

The control group participates in an intervention of body mediation (theatre) of 15 session for the children.

The parents of CBT and Control groups participate in an CBT intervention of 8 sessions every 15 days.

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### Eligibility

**Ages Eligible for Study:** 7 Years to 13 Years (Child)

**Sexes Eligible for Study:** All

**Accepts Healthy Volunteers:** No

#### Criteria

**Inclusion Criteria:**

- Children and adolescents aged 7-13 years;
- Children with a diagnostic of ADHD (diagnostics criteria from DSM-V);
- Score CBCL-DP ≥ 180 ("Aggressive behavior", "Anxious-depression" and "Attention problems");
- Children follow-up in Montpellier University Hospital;
- Parents and children benefit of social security.

**Exclusion Criteria:**

- Children with a developmental delay or severe language disorder;
- Families non-french speaking;
- Absence of consent signed by parents and child;
- Children not living with at least one parent.

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### Contacts and Locations

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, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT03176108

#### Contacts

Contact: Cecile VACHER, Psychologist  +33.4.64.33.71.97  e-vacher@chu-montpellier.fr

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### Sponsors and Collaborators

University Hospital, Montpellier

### Investigators

Principal Investigator: Elodie COURTABESSIS, MD PHD  University Hospital, Montpellier
More Information

Responsible Party: University Hospital, Montpellier

ClinicalTrials.gov Identifier: NCT03176108

History of Changes

Other Study ID Numbers: 9729

Study First Received: May 30, 2017

Last Updated: June 2, 2017

Individual Participant Data

Plan to Share IPD: No

Studies a U.S. FDA-regulated Drug Product: No

Studies a U.S. FDA-regulated Device Product: No

Additional relevant MeSH terms:

Attention Deficit Disorder with Hyperactivity
Attention Deficit and Disruptive Behavior Disorders
Neurodevelopmental Disorders
Mental Disorders

ClinicalTrials.gov processed this record on June 05, 2017