A Study of Identity Building in Children With ADHD (SID-ADHD)

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: NCT03565250

Recruitment Status: Not yet recruiting
First Posted: June 21, 2018
Last Update Posted: June 21, 2018
See Contacts and Locations

Sponsor:
University Hospital, Caen

Collaborators:
Institut National de la Santé Et de la Recherche Médicale, France
Ecole Pratique des Hautes Etudes

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

Study Description

Go to Brief Summary:

Context: Attention Deficit Hyperactivity Disorder (ADHD), a major public health issue, is a neurodevelopmental disorder characterized by disturbance of attention, pathological impulsivity and a variable level of psychomotor hyperactivity. In addition to medium-term repercussions such as school failure or family dysfunction, these children have difficulties in dealing with emotions, metacognition and self-awareness that have serious consequences for self-regulation and identity construction.

Objective: To investigate identity building in children with ADHD and explore its links with the severity of the disorder and associated neuropsychological disturbances.

Material and method: 20 childrens with ADHD and 20 controls will be recruited over a 24-month period. They will be administered the Damon and Hart's Self-Understanding Interview, exploring 7 identity domains: Physical, Active, Social, Psychological, Continuity, Agentivity, Distinction Self/Other. The severity of ADHD, neuropsychological functioning (attention, working memory, executive functions, long-term memory), self-esteem and internal/external attributive style (locus of control) will be assessed by validated scales. The overall level of identity development and in each dimension will be compared between patients and controls. Within patients, the correlations between level of identity development and the severity of ADHD will be explored, as well as with neuropsychological functioning, with statistical control of age.

Assumptions: The investigators hypothesize that children with ADHD will exhibit a significantly lower level of identity development than controls, which will be positively correlated with neuropsychological functioning, and negatively correlated with the severity of ADHD.
Detailed Description:
Visit 1: the physician will check inclusion and non-inclusion criteria and co-morbidities of patients and controls using a semi-structured interview (K-SADS-PL). He/She will also assess the overall functioning level of patients and controls (GAF) and will evaluate for patients only the severity of ADHD using ADHD-RS.

Visits number 2 and 3: Cognitive and neuropsychological evaluations:
2 consultations to be distributed in one month depending on the availability of patients (no time limit imposed between the 2 consultations) In order to investigate any cognitive dysfunctions, patients and controls will be referred to the neuropsychologists of the department concerned (pediatrics or child and adolescent psychiatry). They will perform the WISC-V, CPT, Wisconsin SCD, CMS Stories Test. Several questionnaires will be completed by parents and/or children: BRIEF, Self-esteem Questionnaire, Causal Style Questionnaire. This whole assessment will require a total of 2 consultations, one of 1:30 and the second of about 1 hour. Patients on methylphenidate medication should be discontinued the same day during the second session of the neuropsychological check-up.

Visit number 4: Self-Understanding Interview: 1 hour consultation The interview specifically assessing self-understanding will be conducted with children suffering from ADHD and control children. This investigation consists of an interview requiring 1h consultation for which patients should have taken their usual treatment by MPH if necessary. An audio recording of this test will be made.

Inclusion and the first psychological assessment session (visit 1 and visit 2) can be done on the same day. All 3 appointments must be completed in a period of less than 3 months after inclusion.

Study Design
Study Type: Interventional (Clinical Trial)
Estimated Enrollment: 40 participants
Allocation: Non-Randomized
Intervention Model: Parallel Assignment
Masking: None (Open Label)
Primary Purpose: Basic Science
Official Title: A Study of Identity Building in Children With Attention Deficit Hyperactivity Disorder (ADHD)
Estimated Study Start Date: June 20, 2018
Estimated Primary Completion Date: August 4, 2020
Estimated Study Completion Date: December 31, 2020

Resource links provided by the National Library of Medicine
MedlinePlus related topics: Attention Deficit Hyperactivity Disorder
U.S. FDA Resources

Arms and Interventions
Arm | Intervention/treatment
Experimental: ADHD patients children aged 8-12 ans with ADHD

Other: self understanding interview semi-structured interview designed for assessment of identity according to Damon & Hart's 7-dimension developmental model

Active Comparator: control children aged 8-12 ans without ADHD

Other: self understanding interview semi-structured interview designed for assessment of identity according to Damon & Hart's 7-dimension developmental model

Outcome Measures

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Primary Outcome Measures :

1. Identity building [ Time Frame: baseline ]

   Self understanding interview (Damon and Hart): analysis and developmental characterization of the child's discourse on himself,

   Model distinguishes the two components of Self:
   
   o the me-self: aggregation of self-knowledge;
   
   o The I self: the Self-as-subject; the subjective component that performs the act of self-knowledge.

   to attest to identity development:

   o The average level of identity development for me-self as a whole is calculated by summing the total number of segments in each developmental level multiplied by his cardinal, all divided by the total number of segments

   o Breakdown of segments of speech in the 4 modal levels (superficial, self-centered, interactive, codified) for each of the identity dimensions of the component of me-self (Physics, Active, Social, Psychological, Continuity, Agentivity, Distinction Self / Other) ,

   o The best developmental level for each dimension of the I-Self component 0 à 4

Secondary Outcome Measures :

1. • Intensity score of ADHD [ Time Frame: baseline ]

   18 items exploring hyperactivity, impulsivity and inattention symptoms rated on a scale of 4 points:

   o 0: Rarely or never
   
   o 1: Some times
   
   o 2: Often
   
   o 3: Very often

   a score greater than or equal to 28 is required to qualify a significant ADHD. (min=0-max=54)

2. attention test [ Time Frame: baseline ]

   Sustained attention in continuous performance test

3. Self esteem [ Time Frame: baseline ]
The Child Perception Profile is the French adaptation (Pierrhumbert) of the Self-Perception Profile for Children (Harter). This self-questionnaire for children aged 8 to 13 explores self-esteem through 30 questions about daily life, coded on a scale from 1 to 4. First, the young person chooses the description that looks the most; he then determines how much he looks like him.

It provides an overall self-esteem score and six sub-scores: academic, social, physical, appearance, driving and self-worth.

Each dimension is explored by 5 questions, the sub-scores are obtained by adding the items, the overall self-esteem score is obtained by adding the sub-scores.

The higher the score, the higher the self-esteem

4. Causal style [Time Frame: baseline]

The Child Causal Style Questionnaire is a self-administered questionnaire that assesses the child's "locus of control", that is, how much does he attribute responsibility for his failures and successes to oneself (internal locus) or to others (external locus). It consists of 24 items describing plausible events, 12 positive and 12 negative, for which the child must choose a cause.

5. Global Assessment of Functioning Scale [Time Frame: baseline]

The Global Assessment of Functioning (GAF) is a numeric scale used by mental health clinicians and physicians to rate subjectively the social, occupational, and psychological functioning of an individual, e.g., how well one is meeting various problems-in-living. Scores range from 100 (extremely high functioning) to 1 (severely impaired).

6. Working memory [Time Frame: baseline]

memory of numbers, memory of images in Wechsler Intelligence Scale for Children 5

7. Executive functions [Time Frame: baseline]

BRIEF Wisconsin sorting card test

8. Long-term memory [Time Frame: baseline]

History recall test (from children memory scale; Cohen)

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.

<table>
<thead>
<tr>
<th>Ages Eligible for Study:</th>
<th>8 Years to 12 Years (Child)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sexes Eligible for Study:</td>
<td>All</td>
</tr>
<tr>
<td>Accepts Healthy Volunteers:</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Criteria**

**Inclusion Criteria:**

**Patient group:**
- Child aged 8 to 12,
- Clinical diagnosis of ADHD according to DSM-V criteria
- Informed consent signed by the holder(s) of the exercise of parental authority and specifying the decision of the child himself,
- Subject having French as mother tongue,
- Subject affiliated to the social security system.

**Control group:**
- Child aged 8 to 12,
- Not suffering from ADHD according to DSM-V criteria
- Informed consent signed by the holder(s) of the exercise of parental authority and specifying the decision of the child himself,
- Subjects with French as their mother tongue,
- Subject affiliated to the social security system.

**Exclusion Criteria:**
- Sensory disorders,
- Pathology of the brain (head trauma, epilepsy, others),
- Major psychiatric comorbidity (current depressive episode, schizophrenia, bipolar disorder, autism spectrum disorders),
- Anticonvulsant treatment
- Consumption of toxic (drug, alcohol).
- Mental retardation QI less than 70

**Contacts and Locations**

Go to 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): NCT03565250

**Contacts**

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**Sponsors and Collaborators**

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Ecole Pratique des Hautes Etudes

**More Information**
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Other Study ID Numbers: 17-011
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Individual Participant Data (IPD) Sharing Statement:
Plan to Share IPD: No

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

Keywords provided by University Hospital, Caen:
Attention Deficit Disorder with Hyperactivity
Self concept
Child
Neuropsychology

Additional relevant MeSH terms:
Attention Deficit Disorder with Hyperactivity
Hyperkinesis
Attention Deficit and Disruptive Behavior Disorders
Neurodevelopmental Disorders
Mental Disorders

Dyskinesias
Neurologic Manifestations
Nervous System Diseases
Signs and Symptoms