NEUROFEEDBACK on Event-Related Potential (ERP) (MyB)

This study is currently recruiting participants. See Contacts and Locations

Verified September 2017 by Hospices Civils de Lyon

Sponsor:
Hospices Civils de Lyon

ClinicalTrials.gov Identifier:
NCT03289793

First Posted: September 21, 2017
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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.

Information provided by (Responsible Party):
Hospices Civils de Lyon

Purpose
This project aims to assess the evolution of symptoms in ADHD children from 8 to 17 years, with various types of attention training.

Different groups A, B and C will be evaluated: the first with Neurofeedback training, the second with a similar training but not indexed on brain activity and the third without training.

30 patients will be randomly assigned to groups A and B according to a ratio 2:1.

Others patients who meet the same criteria but for logistical reasons cannot comply with the training constraints will be assigned to group C.

Children included in groups A and B will participate in training sessions (Neurofeedback and control training, respectively) as well as in four evaluation sessions. Children in group C will only participate in evaluation sessions (baseline control group).

Patients of groups A and B will be followed over 6 months: 4 months of training and a follow-up evaluation 2 months after training.

Patients of group C will be followed each 2 months for 6 months. This study uses electro-encephalography measures, serious video game, neuropsychological tests and questionnaires.

It also uses actigraphy measures to evaluate sleep quality.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
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<tbody>
<tr>
<td>Attention Deficit Disorder</td>
<td>Other: Neurofeedback training</td>
</tr>
<tr>
<td>With Hyperactivity</td>
<td>Other: Active Sham control</td>
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<tr>
<td></td>
<td>Other: Baseline control group</td>
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</tbody>
</table>
Official Title: Clinical Evaluation of a Brain Computer Interfaces (BCI)-Based Training of Attention in Children With Attention Deficit Hyperactivity Disorder (ADHD)

Resource links provided by NLM:

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder

U.S. FDA Resources

Further study details as provided by Hospices Civils de Lyon:

Primary Outcome Measures:

- Evaluation of the relative effect on symptoms of inattention between the two proposed training techniques, A and B, with the ADHD Rating Scale in children with ADHD [Time Frame: every two months over six months.] Questions with odd numbers interested in the dimension "inattentive" will particularly be studied. The investigator expect an improvement in the type of score: "ADHD-Inattentive" children in group A compared to children in Group B. More specifically, he expect to improve responses to questions number 1, 3, 5, 7, 9, 11, 13, 15 and 17. By definition, an evolving response would be to move from "2=Often; 3=Very often" to "1=Sometimes; 0=Rarely/Never".

Secondary Outcome Measures:

- Neuropsychological assessments of effects of training on the symptoms of inattention in ADHD children [Time Frame: every months over six months.] ADHD Rating Scale (questions with odd numbers) will be performed ADHD children from groups A, B and C will be compared

- Neuropsychological assessments of effects of training on the symptoms of inattention in ADHD children [Time Frame: every months over six months.] Bron/Lyon Attention Stability test (BLAST) test will be performed ADHD children from groups A, B and C will be compared

- Neuropsychological assessments of effects of training on the symptoms of inattention in ADHD children [Time Frame: every months over six months.] Wechsler Intelligence Scale for Children (WISC) subtests will be performed ADHD children from groups A, B and C will be compared

- Neuropsychological assessments of the effects of the lack of training on the symptoms of inattention in ADHD children [Time Frame: every months over six months.] Wechsler Intelligence Scale for Children (WISC) will be performed ADHD children from groups A, B and C will be compared

- Neuropsychological assessments of the effects of the lack of training on the symptoms of inattention in ADHD children [Time Frame: every months over six months.]
ADHD Rating Scale (questions with odd numbers) will be performed ADHD children from groups A, B and C will be compared

- Neuropsychological assessments of the effects of the lack of training on the symptoms of inattention in ADHD children [Time Frame: every months over six months]

Bron/Lyon Attention Stability test (BLAST) will be performed ADHD children from groups A, B and C will be compared

- Compare the effects of the two types of trainings on the hyperactivity symptoms in ADHD children using neuropsychological assessments. [Time Frame: every two months over six months]

ADHD Rating Scale (questions with even numbers), Test d'évaluation de l'Attention (TAP) and Continuous Performance Test (CPT) will be performed ADHD children from groups A, B and C will be compared

- Neuropsychological assessments of the effects of the two types of trainings on the hyperactivity symptoms in ADHD children [Time Frame: every two months over six months]

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Test d'évaluation de l'Attention (TAP) will be performed ADHD children from groups A, B and C will be compared

- Neuropsychological assessments of the effects of the two types of trainings on the hyperactivity symptoms in ADHD children [Time Frame: every two months over six months]

Continuous Performance Test (CPT) will be performed ADHD children from groups A, B and C will be compared

- Neuropsychological assessments of the effects of the lack of training on the impulsivity symptoms in ADHD children [Time Frame: every two months over six months]

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Test d'évaluation de l'Attention (TAP) will be performed ADHD children from groups A, B and C will be compared.

- Quantify whether the changes in inattentive symptoms in groups A (Neurofeedback training) correlate with changes in specific EEG parameter, namely the P300 wave. [Time Frame: every two months over six months]

ADHD Rating Scale (questions with odd numbers) will be evaluated ADHD children from groups A, B and C will be compared.

- Quantify whether the changes in inattentive symptoms in groups A (Neurofeedback training) correlate with changes in specific EEG parameter, namely the P300 wave. [Time Frame: every two months over six months]

TAP will be evaluated ADHD children from groups A, B and C will be compared.

- Quantify whether the changes in inattentive symptoms in groups A (Neurofeedback training) correlate with changes in specific EEG parameter, namely the P300 wave. [Time Frame: every two months over six months]

CPT will be evaluated ADHD children from groups A, B and C will be compared.

- Quantify whether the changes in inattentive symptoms in groups A (Neurofeedback training) correlate with changes in specific EEG parameter, namely the P300 wave. [Time Frame: every two months over six months]

BLAST will be evaluated ADHD children from groups A, B and C will be compared.

- Quantify whether the changes in inattentive symptoms in groups A (Neurofeedback training) correlate with changes in specific EEG parameter, namely the P300 wave. [Time Frame: every two months over six months]

Attention and Distractibility Questionnaire (for children) will be evaluated ADHD children from groups A, B and C will be compared.

- Quantify whether the changes in inattentive symptoms in groups B (Neurofeedback training) correlate with changes in specific EEG parameter, namely the P300 wave. [Time Frame: every two months over six months]

ADHD Rating Scale (questions with odd numbers) will be evaluated ADHD children from groups A, B and C will be compared.

- Quantify whether the changes in inattentive symptoms in groups B (Neurofeedback training) correlate with changes in specific EEG parameter, namely the P300 wave. [Time Frame: every two months over six months]

TAP will be evaluated ADHD children from groups A, B and C will be compared.

- Quantify whether the changes in inattentive symptoms in groups B (Neurofeedback training) correlate with changes in specific EEG parameter, namely the P300 wave. [Time Frame: every two months over six months]

CPT will be evaluated ADHD children from groups A, B and C will be compared.

- Quantify whether the changes in inattentive symptoms in groups B (Neurofeedback training) correlate with changes in specific EEG parameter, namely the P300 wave. [Time Frame: every two months over six months]

BLAST will be evaluated ADHD children from groups A, B and C will be compared.

- Quantify whether the changes in inattentive symptoms in groups B (Neurofeedback training) correlate with changes in specific EEG parameter, namely the P300 wave. [Time Frame: every two months over six months]

Attention and Distractibility Questionnaire (for children) will be evaluated ADHD children from groups A, B and C will be compared.
Quantify whether the changes in inattentive symptoms in groups C (Neurofeedback training) correlate with changes in specific EEG parameter, namely the P300 wave. [Time Frame: every two months over six months]
ADHD Rating Scale (questions with odd numbers) will be evaluated ADHD children of groups A, B and C will be compared

Quantify whether the changes in inattentive symptoms in groups C (Neurofeedback training) correlate with changes in specific EEG parameter, namely the P300 wave. [Time Frame: every two months over six months]
TAP will be evaluated ADHD children of groups A, B and C will be compared

Quantify whether the changes in inattentive symptoms in groups C (Neurofeedback training) correlate with changes in specific EEG parameter, namely the P300 wave. [Time Frame: every two months over six months]
CPT will be evaluated ADHD children of groups A, B and C will be compared

Quantify whether the changes in inattentive symptoms in groups C (Neurofeedback training) correlate with changes in specific EEG parameter, namely the P300 wave. [Time Frame: every two months over six months]
BLAST will be evaluated ADHD children of groups A, B and C will be compared

Quantify whether the changes in inattentive symptoms in groups C (Neurofeedback training) correlate with changes in specific EEG parameter, namely the P300 wave. [Time Frame: every two months over six months]
Attention and Distractibility Questionnaire (for children) will be evaluated ADHD children of groups A, B and C will be compared

Quantify the evolution of the classical Neurofeedback biomarkers Slow Cortical Potential (SCP))
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Attention and Distractibility Questionnaire (child) will be evaluated ADHD children of groups A, B and C will be compared

Assess whether the classical Neurofeedback biomarkers correlate with the evolution of behavioral and primary neurophysiological measures (P300) in all groups. [Time Frame: every two months over six months]
ADHD Rating Scale (questions with odd numbers) will be evaluated ADHD children of groups A, B and C will be compared

Assess whether the classical Neurofeedback biomarkers correlate with the evolution of behavioral and primary neurophysiological measures (P300) in all groups. [Time Frame: every two months over six months]
TAP will be evaluated ADHD children of groups A, B and C will be compared
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neurophysiological measures (P300) in all groups. [Time Frame: every two months over six months]
Attention and Distractibility Questionnaire (child) will be evaluated ADHD children of groups A, B and C will be compared

• Quantify the evolution of the classical Neurofeedback biomarkers Theta/Beta Ratio (TBR) [Time Frame: every
two months over six months]
ADHD Rating Scale (questions with odd numbers) will be evaluated ADHD children of groups A, B and C will be compared

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• Quantify the evolution of the classical Neurofeedback biomarkers Theta/Beta Ratio (TBR) [Time Frame: every
two months over six months]
Attention and Distractibility Questionnaire (child) will be evaluated ADHD children of groups A, B and C will be compared

• Assess whether the classical Neurofeedback biomarkers TBR correlate with the evolution of behavioral and
primary neurophysiological measures (P300) in all groups. [Time Frame: every two months over six months]
ADHD Rating Scale (questions with odd numbers) will be evaluated ADHD children of groups A, B and C will be compared

• Assess whether the classical Neurofeedback biomarkers TBR correlate with the evolution of behavioral and
primary neurophysiological measures (P300) in all groups. [Time Frame: every two months over six months]
TAP will be evaluated ADHD children of groups A, B and C will be compared

• Assess whether the classical Neurofeedback biomarkers TBR correlate with the evolution of behavioral and
primary neurophysiological measures (P300) in all groups. [Time Frame: every two months over six months]
BLAST will be evaluated ADHD children of groups A, B and C will be compared

• Assess whether the classical Neurofeedback biomarkers TBR correlate with the evolution of behavioral and
primary neurophysiological measures (P300) in all groups. [Time Frame: every two months over six months]
Attention and Distractibility Questionnaire (child) will be evaluated ADHD children of groups A, B and C will be compared

• Quantify the evolution of the classical Neurofeedback biomarkers Sensori-Moteur Rythm (SMR) [Time Frame: every
two months over six months]
ADHD Rating Scale (questions with odd numbers) will be evaluated ADHD children of groups A, B and C will be compared.

- Quantify the evolution of the classical Neurofeedback biomarkers Sensori-Moteur Rythm (SMR) [Time Frame: every two months over six months]
  TAP will be evaluated ADHD children of groups A, B and C will be compared.

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  Attention and Distractibility Questionnaire (child) will be evaluated ADHD children of groups A, B and C will be compared.

- Assess whether the Neurofeedback biomarkers SMR correlate with the evolution of behavioral and primary neurophysiological measures (P300) in all groups. [Time Frame: every two months over six months]
  ADHD Rating Scale (questions with odd numbers) will be evaluated ADHD children of groups A, B and C will be compared.

- Assess whether the Neurofeedback biomarkers SMR correlate with the evolution of behavioral and primary neurophysiological measures (P300) in all groups. [Time Frame: every two months over six months]
  TAP will be evaluated ADHD children of groups A, B and C will be compared.

- Assess whether the Neurofeedback biomarkers SMR correlate with the evolution of behavioral and primary neurophysiological measures (P300) in all groups. [Time Frame: every two months over six months]
  BLAST will be evaluated ADHD children of groups A, B and C will be compared.

- Assess whether the Neurofeedback biomarkers SMR correlate with the evolution of behavioral and primary neurophysiological measures (P300) in all groups. [Time Frame: every two months over six months]
  Attention and Distractibility Questionnaire (child) will be evaluated ADHD children of groups A, B and C will be compared.

- Evaluate the impact of the trainings on the sleep quality in ADHD children. [Time Frame: every two months over six months]
  Sleep questionnaires will be distributed ADHD children in groups A, B and C will be compared.

- Evaluate the impact of the trainings on the sleep quality in ADHD children. [Time Frame: every two months over six months]
  The sleep data may also be collected using an actigraph (ancillary study). ADHD children in groups A, B and C will be compared.

- Evaluating the impact of the trainings on the quality of life in ADHD children. [Time Frame: every two months over six months]
  The Child Behavior CheckList (CBCL) questionnaire will be performed.
  Groups A, B and C will be compared.
• Evaluating the impact of the trainings on the quality of life in ADHD children. [Time Frame: every two months over six months]

Information about the quality of life will be also collected in a logbook by family members and provided at each visit.

Groups A, B and C will be compared.

<table>
<thead>
<tr>
<th>Estimated Enrollment:</th>
<th>60</th>
</tr>
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<tbody>
<tr>
<td>Actual Study Start Date:</td>
<td>February 2, 2017</td>
</tr>
<tr>
<td>Estimated Study Completion Date:</td>
<td>October 2, 2019</td>
</tr>
<tr>
<td>Estimated Primary Completion Date:</td>
<td>October 2, 2019 (Final data collection date for primary outcome measure)</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
</table>
| Experimental: Group A  
Children will be assigned to this group in a random fashion according to a ratio 2:1 with respect to group B (see below).  
20 subjects will be included in this group. | Other: Neurofeedback training  
Children in group A will receive BCI-based training implemented through original P300-based controlled games.  
They will attend 30 1-hour long training sessions at a pace of 2 sessions per week.  
Each session includes: installation of the child, the EEG system and an eye-tracking system, a 5-minutes relaxation phase, a short EEG recording at rest, a brief reminder of the instructions, 30 minutes of training by playing video games and finally a time for the child to wash her/his hair.  
Moreover, 4 neuropsychological sessions will complement the 30 training sessions. During these sessions neuropsychological tests and quality of life questionnaires will be answered. |
| Active Comparator: Group B  
Children will be assigned in this group in a random fashion. 10 subjects will be included in this group. | Other: Active Sham control  
Children in group B will receive a training that is not based on brain activity, but in a blind fashion. They will attend 30 1-hour long training sessions at a pace of 2 sessions per week.  
Each session includes: installation of the child, setting up the EEG and eye-tracking systems, a 5-minutes relaxation phase, short EEG recording at rest, a brief reminder of the instructions, 30 minutes of video game based training and finally a time for the child to wash her/his hair.  
Besides, 4 neuropsychological sessions will complement the 30 training sessions. During these sessions neuropsychological tests and quality of life questionnaires will be performed. |
| Active Comparator: Group C  
Will be included in this group children who meet the | Other: Baseline control group  
The children included in this group will not receive any |
inclusion criteria and who, with their families, are motivated to participate in the study but cannot claim to be part of groups A or B (because of logistical constraints: living too far away to comply with the frequency of the visits required by the training).

Group C allows to follow the natural evolution of children with ADHD with no intervention.

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Eligibility

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: 8 Years to 17 Years (Child)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Children and teenagers aged from 8 to 17 years old
- Children and teenagers with a deficit attention disorder with or without hyperactivity, in the mixed form or in a pure inattentive form according to Diagnostique et Statistique des troubles Mentaux (DSM)-V.
- Children and teenagers having a score in Verbal Comprehension Index (or Index Verbal Reasoning) and Perceptual Reasoning Index (or Index Reasoning fluid) ≥ 80 of WISC IV or V test, not older than two years.
- Children and teenagers without psychostimulant treatment
- Children and teenagers with psychostimulant treatment agreed to achieve a therapeutic break at each visit day and with a stable dose during all the study.
- Children and teenagers whose parents have agreed and signed informed consent form of the study.

Exclusion Criteria:

- Children aged less than 8 and teenagers are more than 18 years old.
- Children and teenagers having a score in Verbal Comprehension Index (or Index Verbal Reasoning) and Perceptual Reasoning Index (or Index Reasoning fluid) < 80 of WISC IV or V test, not older than two years.
- Children and teenagers with developmental disorder except "Dys" disorders.
- Children and teenagers with pure hyperactivity (without attentional deficit)
- Children and teenagers with epilepsy except benign epilepsies (without brain damage), free of crisis for two years and without treatment.
- Children and teenagers with ADHD with conduct disorders and aggression
- Children and teenagers with ADHD and Tourette's syndrome.
- Patients treated by anti / epilepsy or psychotropic treatments (with the exception of psychostimulant treatment).
- Patients with psychostimulant treatment and whose parents aren't agreed to achieve a therapeutic break at each visit day.
- Patients with visual deficiency uncorrectable with lenses or glasses.

Contacts and Locations

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): **NCT03289793**

**Contacts**

Contact: Alexis ARZIMANOGLOU, MD  4 27 85 77 04 ext +33  aarzimanoglou@orange.fr  
Contact: Lucie Le Carrer  4.72.13.89.02 ext +33  lucie.le-carrer@chu-lyon.fr

**Locations**

**France**

Hospices Civils de Lyon  
Bron, France, 69500  
Contact: Alexis ARZIMANOGLOU, MD  4 27 85 77 04 ext +33  aarzimanoglou@orange.fr  
Contact: Lucie Le Carrer, MD  4.72.13.89.02 ext +33  lucie.le-carrer@chu-lyon.fr  
Principal Investigator: Alexis ARZIMANOGLOU, MD  
Sub-Investigator: Pierre FOURNERET, MD  
Sub-Investigator: Hugues Desombre, MD  
Sub-Investigator: Daniel Gérard, MD

**Sponsors and Collaborators**

Hospices Civils de Lyon

**Investigators**

Principal Investigator: Alexis ARZIMANOGLOU  Hospices Civils de Lyon

**More Information**

Responsible Party: Hospices Civils de Lyon  
ClinicalTrials.gov Identifier: NCT03289793  History of Changes  
Other Study ID Numbers: 69HCL15_0214  
First Submitted: August 4, 2017  
First Posted: September 21, 2017  
Last Update Posted: September 21, 2017  
Last Verified: September 2017

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

Keywords provided by Hospices Civils de Lyon:  
Attention Deficit Disorder with Hyperactivity  Hyperactivity  
ADHD  Neurofeedback  
Children  Neuropsychology  
Inattention

Additional relevant MeSH terms:  
Attention Deficit Disorder with Hyperactivity  Dyskinesias  
Hyperkinesis  Neurologic Manifestations  
Attention Deficit and Disruptive Behavior Disorders  Nervous System Diseases  
Neurodevelopmental Disorders  Signs and Symptoms  
Mental Disorders