NIRS Neurofeedback as a Treatment for Attention Deficit Hyperactivity Disorder

This study is currently recruiting participants. (see Contacts and Locations)

Verified January 2015 by Hospital de Clinicas de Porto Alegre

Sponsor:
Hospital de Clinicas de Porto Alegre

Information provided by (Responsible Party):
Hospital de Clinicas de Porto Alegre

ClinicalTrials.gov Identifier:
NCT02333422

First received: December 30, 2014
Last updated: January 6, 2015
Last verified: January 2015

Purpose

The investigators therefore propose a pilot study to establish the effectiveness of NIRS Neurofeedback training in reducing the intensity of ADHD symptom expression on children, improvement of the cognitive and global functions associated with ADHD, effects on cerebral blood perfusion in the cortex and safety plus possible unknown side-effects.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attention Deficit Hyperactivity Disorder</td>
<td>Other: NIRS Neurofeedback</td>
<td>Phase 2</td>
</tr>
</tbody>
</table>

Study Type: Interventional

Study Design:
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Clinical Trial Using NIRS Neurofeedback on Children With Attention Deficit Hyperactivity Disorder (ADHD)
Further study details as provided by Hospital de Clinicas de Porto Alegre:

Primary Outcome Measures:
- Diagnostic and severity measure [Time Frame: 3 months] [Designated as safety issue: No]
  Swanson, Nolan and Pelham Questionnaire version IV (SNAPIV)

Secondary Outcome Measures:
- Basic processing [Time Frame: 3 months] [Designated as safety issue: No]
  Using Two-choice Reaction Time Task
- Inhibition control [Time Frame: 3 months] [Designated as safety issue: No]
  Using Go/No-Go test
- Conflict Control [Time Frame: 3 months] [Designated as safety issue: No]
  Using Modified Stroop Task
- Time processing [Time Frame: 3 months] [Designated as safety issue: No]
  Using Time Anticipation (400ms e 2000ms)
- Delay Aversion [Time Frame: 3 months] [Designated as safety issue: No]
  Using Choice Delay Task combined with Delay Reaction Time
- Cerebral blood perfusion [Time Frame: 3 months] [Designated as safety issue: No]
  Using SPECT (Single Photon Emission Computed Tomography) toward identifying changes to cerebral blood perfusion in the trained areas (F7, Fp1, Fp2 e F8) and all cortex
- Psychiatric and social function measure [Time Frame: 3 months] [Designated as safety issue: No]
  Children's Global Assessment Scale (CGAS) is an adaptation of the Global Assessment Scale (GAS) for young people aged 4-16 years
- Treatment response assessment [Time Frame: 3 months] [Designated as safety issue: No]
  CGI (Clinical Global Impression)
- Quality of life [Time Frame: 3 months] [Designated as safety issue: No]
  Quality of life evaluation scale (AUQEI)

- Side Effects [Time Frame: 3 months] [Designated as safety issue: No]
  Using SERS (Barkley's Side Effect Rating Scale)

Estimated Enrollment: 10

Study Start Date: July 2014

Estimated Study Completion Date: July 2015

Estimated Primary Completion Date: July 2015 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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</thead>
<tbody>
<tr>
<td>Experimental: NIRS Neurofeedback</td>
<td>NIRS Neurofeedback training of frontal and pre frontal lobes activation. The intervention consists of 24 NIRS neurofeedback sessions over 12 weeks, 2 sessions per week.</td>
</tr>
<tr>
<td>Other: NIRS Neurofeedback</td>
<td>The sensor will be placed on 4 specific regions defined by the International 10/20 System for Electrode Placement. F7, Fp1, Fp2 and F8. Each region will be initially trained for 4 minutes, with the eyes open, gradually increasing training time throughout the sessions to a maximum of 10 minutes. Training will amount to 24 sessions, occurring 2 times per week over a period of 3 months. The procedure will be interrupted at any time, should the subject demonstrate the desire to stop. Other Name: Near Infrared Spectroscopy Neurofeedback</td>
</tr>
</tbody>
</table>

**Detailed Description:**

Background:

Attention Deficit Hyperactivity Disorder (ADHD) is a mental condition originating in childhood, characterized by symptoms of lack attention, hyperactivity and impulsiveness associated with significant functional impairment. Currently, the use of neurofeedback as a non-drug alternative technique for treatment of ADHD has increasingly spread among the clinical and academic fields, producing relevant findings with regard to its effectiveness. The SCP Neurofeedback and EEG Neurofeedback have been the most studied techniques until the moment, with equipments and systems made available to the market at prices between US$ 10,000 and US$ 20,000, while NIRS Neurofeedback equipments can be found for around US$ 2,000. Due to the low cost of the necessary equipment's and easy access to the technology, the use of NIRS Neurofeedback was opted for in the search to evaluate the techniques effectiveness in the improvement of ADHD symptoms as well as the patients' cognitive performance.

This research is an open label treatment trial with NIRS Neurofeedback training of frontal and pre frontal lobes activation in children school-aged 7 - 12 years old with ADHD. Ten participants will be recruited over 3 months and will be offered 24 NIRS Neurofeedback sessions over 12 weeks, 2 sessions per week. The present study will be
carried out as part of the care routine of the Child and Adolescent Psychiatry Services at Hospital de Clínicas de Porto Alegre. Primary outcome will be standard clinical behavioural rating scales. Secondary outcomes will include neuropsychological parameters, neurofunctional parameters using SPECT (Single Photon Emission Computed Tomography), global function, quality of life assessment, side effects and tolerability.

Eligibility

Ages Eligible for Study: 7 Years to 12 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Diagnosed with ADHD clinically.
- Cognitive dysfunction: ≥11/2; standard deviation above norm in at least two neuropsychological measurements: executive functions (inhibitory control), gratification aversion and time processing
- Not having used ADHD medication in at least three months with parental consent for not treating ADHD with medication

Exclusion Criteria:

- Existence of another co-morbid mental disorder which is clinically relevant and demands treatment
- IQ < 80

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: NCT02333422

Contacts

Contact: Clarissa F. Paim 55 51 33598000 ext 8094 cfpaim@hcpa.ufrgs.br
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Locations

Brazil

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Sub-Investigator: Igor Londero, Psychologist
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Sub-Investigator: Carine Hunther, Psychologist
Sub-Investigator: Guilherme Moritz, Psychologist

Sponsors and Collaborators

Hospital de Clinicas de Porto Alegre

Investigators
Principal Investigator: Luis AP Rohde  Hospital de Clínicas de Porto Alegre

More Information

No publications provided

Responsible Party: Hospital de Clinicas de Porto Alegre

ClinicalTrials.gov Identifier: NCT02333422  History of Changes

Other Study ID Numbers: 13-0061

Study First Received: December 30, 2014

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Health Authority: Brazil: National Health Surveillance Agency

Keywords provided by Hospital de Clinicas de Porto Alegre:

NIRS Neurofeedback

Attention Deficit Hyperactivity Disorder

Near Infrared Spectroscopy

ADHD

Additional relevant MeSH terms:

Attention Deficit Disorder with Hyperactivity

Disease

Hyperkinesis

Attention Deficit and Disruptive Behaviour Disorders

Mental Disorders

Mental Disorders Diagnosed in Childhood

ClinicalTrials.gov processed this record on January 06, 2015