Effectiveness of a Personalized Neurofeedback Training Device (ADHD@Home) in Attention-Deficit/Hyperactivity Disorder (Newrofeed)

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

Verified May 2016 by Mensia Technologies SA

Sponsor:
Mensia Technologies SA

Collaborator:
European Union H2020 SME Instrument

Information provided by (Responsible Party):
Mensia Technologies SA

ClinicalTrials.gov Identifier:
NCT02778360

First received: May 12, 2016
Last updated: May 17, 2016
Last verified: May 2016

Purpose
The main objective of the study is to demonstrate the non-inferiority of the personalized Neurofeedback Training device versus Methylphenidate in the treatment of children and adolescents with Attention-Deficit/Hyperactivity Disorder.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attention Deficit-Hyperactivity Disorder</td>
<td>Device: Neurofeedback NFT Drug: Methylphenidate MPH</td>
<td>Phase 1 Phase 2</td>
</tr>
</tbody>
</table>

Study Type: Interventional

Study Design:
Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment
Official Title: Effectiveness of a Personalized Neurofeedback Training Device (ADHD@Home) as Compared With Methylphenidate in the Treatment of Children and Adolescents With Attention-Deficit/Hyperactivity Disorder: A Multicentre Randomized Clinical Study

Resource links provided by NLM:
MedlinePlus related topics: Attention Deficit Hyperactivity Disorder
Drug Information available for: Methylphenidate Methylphenidate hydrochloride
U.S. FDA Resources

Further study details as provided by Mensia Technologies SA:

Primary Outcome Measures:

- Change from Day 0 at Day 90 of the total score of the ADHD RS IV (Attention Deficit Hyperactivity Disorder Rating Scale IV) [ Time Frame: 3 times (Day 0, Day 60, Day 90) ] [ Designated as safety issue: No ]
  ADHD RS IV (Attention Deficit Hyperactivity Disorder Rating Scale IV): total score assessed by the clinician

Secondary Outcome Measures:

- ADHD RS IV Inattention and Hyperactivity Sub-Scores [ Time Frame: 3 times (Day 0, Day 60, Day 90) ] [ Designated as safety issue: No ]
  ADHD RS IV (Attention Deficit Hyperactivity Disorder Rating Scale IV): Inattention and Hyperactivity sub-scores assessed by the clinician

- Clinical responders [ Time Frame: 1 time (Day 90) ] [ Designated as safety issue: No ]
  Clinical responders are subjects who will present a decrease of the total clinician ADHD RS score of more or equal to 25%

- Parents ADHD RS IV Total, Inattention and Hyperactivity Scores [ Time Frame: 3 times (Day 0, Day 60, Day 90) ] [ Designated as safety issue: No ]
  ADHD RS IV (Attention Deficit Hyperactivity Disorder Rating Scale IV): Total, Inattention and Hyperactivity scores assessed by the parents

- Teacher ADHD RS IV Total, Inattention and Hyperactivity Scores [ Time Frame: 2 times (Day 0, Day 90) ] [ Designated as safety issue: No ]
  ADHD RS IV (Attention Deficit Hyperactivity Disorder Rating Scale IV): Total, Inattention and Hyperactivity scores assessed by the teacher

- Clinical Global Impression (severity) (CGI-S) [ Time Frame: 7 times (Day 0, Day 7, Day 14, Day 21, Day 28, Day 60, Day 90) ] [ Designated as safety issue: Yes ]
Severity of the illness assessed by the clinician

- Clinical Global Impression (improvement) (CGI-I) [ Time Frame: 6 times (Day 7, Day 14, Day 21, Day 28, Day 60, Day 90) ] [ Designated as safety issue: Yes ]

Improvement of the patient's condition assessed by the clinician

- Behavior Rating Inventory of Executive Function (BRIEF) [ Time Frame: 2 times (Day 0, Day 90) ]
  [ Designated as safety issue: No ]

Executive Function Tests by the Behavior Rating Inventory of Executive Function (BRIEF)

- Conners Continuous Performance Test 3rd Edition (Conners CPT 3) [ Time Frame: 2 times (Day 0, Day 90) ]
  [ Designated as safety issue: No ]

Conners Continuous Performance Test 3rd Edition

- Strengths and Difficulties Questionnaire (SDQ) [ Time Frame: 2 times (Day 0, Day 90) ]
  [ Designated as safety issue: No ]

Behaviour assessment by the parents and the teacher with the Strengths and Difficulties Questionnaire

- quantitative Electro-Encephalogram (qEEG) [ Time Frame: 3 times (Day 0, Day 60, Day 90) ]
  [ Designated as safety issue: No ]

Quantitative electroencephalogram to assess EEG biomarkers, progress in brain modulation

- Columbia suicide severity rating scale (C-SSRS) [ Time Frame: 7 times (Day 0, Day 7, Day 14, Day 21, Day 28, Day 60, Day 90) ] [ Designated as safety issue: Yes ]

Columbia suicide severity rating scale

- Sleep Disturbance Scale for Children (SDSC) [ Time Frame: 7 times (Day 0, Day 7, Day 14, Day 21, Day 28, Day 60, Day 90) ] [ Designated as safety issue: Yes ]

Sleep Disturbance Scale for Children

- Pediatric adverse event rating scale (PAERS) [ Time Frame: 7 times (Day 0, Day 7, Day 14, Day 21, Day 28, Day 60, Day 90) ] [ Designated as safety issue: Yes ]

Pediatric adverse event rating scale

- Physical examination [ Time Frame: 1 time (Day 0) ] [ Designated as safety issue: Yes ]

Physical examination will include assessments of height, weight, cardiac frequency, cardiac exam and blood pressure.

Investigator will question the parents about the cardiac history of the family and on individual risk factors. If a risk factor is detected, the patient will be addressed to a cardiologist for an electrocardiogram (ECG).
Medical/surgical history [ Time Frame: 1 time (Day 0) ] [ Designated as safety issue: Yes ]
Assessment especially related to the eligibility criteria

Concomitant treatments collection [ Time Frame: 7 times (Day 0, Day 7, Day 14, Day 21, Day 28, Day 60, Day 90) ] [ Designated as safety issue: Yes ]
All the treatments taken during the participation will be collected (trade name, indication, dose, onset/end dates).
The use of concomitant medications will be summarized by therapeutic class.

Adverse events collection [ Time Frame: 6 times (Day 7, Day 14, Day 21, Day 28, Day 60, Day 90) ] [ Designated as safety issue: Yes ]
All the adverse events occurred during the participation will be collected until resolution or stabilization (description/symptoms, onset/end dates, frequency, intensity, evolution, causality to treatment attributed, seriousness).
All adverse events will be described in each arm. A comparison will be done, especially concerning number and percentage of patients who experienced at least one adverse event (on the whole and by system/organ), at least one adverse event leading to discontinue the treatment, and at least one serious adverse event.

Estimated Enrollment: 179
Study Start Date: July 2016
Estimated Study Completion Date: August 2017
Estimated Primary Completion Date: July 2017 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental: Neurofeedback NFT</td>
<td>Device: Neurofeedback NFT</td>
</tr>
<tr>
<td>Neurofeedback Training based on real time</td>
<td>The ADHD@Home Device is composed of a software for NF Training deployed on a Windows</td>
</tr>
<tr>
<td>electroencephalography (EEG) signal.</td>
<td>tablet, and connected to an EEG headset and an amplifier.</td>
</tr>
<tr>
<td>The patient is trained</td>
<td>The training is personalized according to patient's characteristics.</td>
</tr>
<tr>
<td>to modulate his brain activity thanks</td>
<td>Other Names:</td>
</tr>
<tr>
<td>to a tablet installed with serious game.</td>
<td>Neurofeedback training</td>
</tr>
<tr>
<td>Initiation/Discovery period during 21</td>
<td>ADHD@Home</td>
</tr>
<tr>
<td>days: initiation and discovery sessions</td>
<td></td>
</tr>
<tr>
<td>Treatment period during 9 weeks: 36</td>
<td></td>
</tr>
<tr>
<td>training sessions at home</td>
<td></td>
</tr>
</tbody>
</table>
Active Comparator: Methylphenidate MPH
Methylphenidate long acting preparation.
Open titration protocol during 21 days: 10 mg/day as a start until optimal dose is reached (maximum dose: 60 mg/day).
Treatment period during 9 weeks: optimal dose with MPH LA 10 and 30 mg (dose range: 10 mg/day to 60 mg/day).

Drug: Methylphenidate MPH
Drug prescribed with a first titration period until an optimal dose.
Other Names:
Methylphenidate long acting
Medikinet retard

**Detailed Description:**

The main objective of the present study is to demonstrate the non-inferiority of the personalized Neurofeedback Training device ADHD@Home versus Methylphenidate in the treatment of children and adolescents with Attention-Deficit/Hyperactivity Disorder.

Furthermore, it is aimed to learn more about the mechanisms underlying NeuroFeedback.

The study is prospective, multicentric (9 centres), randomised, reference drug-controlled.

ADHD@Home is a neuromarker™-based personalized medicine device to treat children suffering from Attention Deficit Hyperactivity Disorders (ADHD) with Neurofeedback Training (NFT) based on real time electroencephalography (EEG) signal.

Neurofeedback Training is based on direct training of brain function, by which the brain learns to function more efficiently. For each session of the ADHD@Home solution, the child is trained to modulate his brain activity in a serious game, which is a real-time metaphor of the EEG biomarker that needs to be 'normalized', following a typical operant learning process.

**Eligibility**

Ages Eligible for Study: 7 Years to 13 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

**Criteria**

**Inclusion Criteria:**
- Children or adolescents (male or female) aged 7-13 years
- ADHD diagnosis positive with Kiddie-Sads
- ADHD RS IV >6 for attention, with or without hyperactivity
- Patient having already had corrective actions for ADHD (formal and informal educational support, psychoeducation, psychotherapy, occupational therapy remediation, at-school programs and remediations)
- Signature of inform consent form by parent and child
- Wireless internet connection at home

**Exclusion Criteria:**
- ADHD hyperactive/Impulsive without inattention component
- Established diagnosis of epilepsy or other neurological disorders
- Severe psychiatric disorder other than ADHD diagnosed with Kiddie-Sads such as autism, schizophrenia, severe generalized anxiety disorder, major depression or severe tics
• Patient with comorbid disorder requiring psychoactive medication other than ADHD medication
• Patient having already been treated with psycho-active drug (MPH and others) or EEG-NF for ADHD in the last 6 months, or more than 4 weeks more than 6 months ago
• Unable to use the solution (tablet use and/or headset set-up and/or understanding instructions) according to the investigator
• Absence of wireless internet connection at home
• Medical disorder requiring systemic chronic medication with confounding psychoactive effects
• IQ < 80 using the 3 subtest form of the WASI or the WISC
• Plans to move requiring centre change during the next 6 months
• Plans to start other ADHD treatment, including psychotherapy, cognitive behaviour training in the next 6 months
• Patient with chronic medical illness such as seizure, cardiac disorders, untreated thyroid disease or glaucoma (contra-indication for treatment with MPH)
• Significant suicidal risk based on clinical opinion

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: NCT02778360

Contacts
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Sponsors and Collaborators
Mensia Technologies SA
European Union H2020 SME Instrument

Investigators
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More Information

Additional Information:
Opinions on NFT for ADHD  EXIT
Responsible Party: Mensia Technologies SA

ClinicalTrials.gov Identifier: NCT02778360

Other Study ID Numbers: Newrofeed

Study First Received: May 12, 2016

Last Updated: May 17, 2016

Health Authority:
- France: Agence Nationale de Securite du Medicament et des produits de sante (ANSM)
- Germany: Federal Institute for Drugs and Medical Devices (BfArM)
- Swiss: Institut suisse des produits therapeutiques (Swissmedic)
- Spain: Agencia Espanola de Medicamentos y Productos Sanitarios (AEMPS)
- Belgium: Agence Federale des Médicaments et des Produits de Santé (AFMPS)

Keywords provided by Mensia Technologies SA:
- Attention deficit
- Neurofeedback
- ADHD
- Methylphenidate

Additional relevant MeSH terms:
- Attention Deficit Disorder with Hyperactivity
- Hyperkinesis
- Attention Deficit and Disruptive Behavior Disorders
- Dyskinesias
- Mental Disorders
- Nervous System Diseases
- Neurodevelopmental Disorders
- Neurologic Manifestations
- Signs and Symptoms
- Methylphenidate
- Central Nervous System Stimulants
- Dopamine Agents
- Dopamine Uptake Inhibitors
- Membrane Transport Modulators
- Molecular Mechanisms of Pharmacological Action
- Neurotransmitter Agents
- Neurotransmitter Uptake Inhibitors
- Physiological Effects of Drugs

ClinicalTrials.gov processed this record on May 22, 2016