

# Acoustic and Vestibular Noise as Possible Non-pharmacological Treatment of ADHD in School Children

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ClinicalTrials.gov Identifier: NCT03425669

Recruitment Status : Not yet recruiting

First Posted : February 7, 2018

Last Update Posted : February 7, 2018

See **Contacts and Locations**

## Sponsor:

Lund University

## Information provided by (Responsible Party):

Lund University

## • Study Details

- Tabular View
- No Results Posted

- Disclaimer
- How to Read a Study Record

## Study Description

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Brief Summary:

Attention Deficit Hyperactivity disorder (ADHD) is one of the most frequent childhood disorders with an estimated prevalence of about 5-7% (e.g. Ullebo et al., 2012). Today the most common treatment approach is stimulant medication, e.g. methylphenidate (Greenhill et al., 2002; Wigal et al., 2011). However there are many concerns about medication: i) best dose for cognitive functioning and adapted school behavior differs (Hale et al., 2011), ii) it is not even evident that medication improves learning processes (Molina et al., 2009), iii) concerns regarding potential for drug abuse (Gordon et al., 2004); and iv) uncertainties regarding long term effects of drug use on the developing brain (Andersen, 2005).

In both national and international guidelines of ADHD care multimodal treatment is recommended (Young & Amarasinghe, 2010), but most patients only receive pharmacological treatment, sometimes in combination with parent training. If auditory or vestibular noise, as the present project suggests, could be a complement or an alternative to stimulant medication it could fundamentally change the treatment of ADHD and the school situation for those children.

2. Noise benefit in ADHD Auditory noise benefit: The original findings from our research group, that auditory noise enhances cognitive performance in inattentive children without diagnosis as well as children with an ADHD diagnosis, have been replicated several times (Baijot et al., 2016; Söderlund et al., 2016; Söderlund & Nilsson Jobs, 2016; Söderlund et al., 2007). In a new study, the benefit of noise was shown to be in parity with or even larger than the benefit of pharmacological ADHD treatment on two cognitive tasks, episodic word recall and visuo-spatial working memory task. In the study a group of children diagnosed with ADHD were tested on and off medication, at separate occasions, in noisy vs. silent environments while performing the tasks (Söderlund, Björk et al., 2016). Inattentive and low achieving school children have been shown to improve their memory recall when exposed to noise, whereas attentive and high achieving children perform worse during noise exposure (Helps et al., 2014; Söderlund & Sikström, 2008, 2012; Söderlund et al., 2010).

Vestibular noise benefit: Vestibular stimulation has since long been demonstrated to increase hippocampal activity and hippocampus is well demonstrated to be of crucial importance in detecting and holding on to spatial targets showing that hippocampus is of fundamental for both spatial orientation and learning in general (Moser et al.,

2015). Therefore it is not surprising that external stochastic vestibular stimulation (SVS) exerts beneficial effects in different domains, e.g. balance in healthy astronauts (Mulavara et al., 2011), in Parkinson patients (Pal et al., 2009; Samoudi et al., 2014) and response times in continuous performance task (Yamamoto et al., 2005). The theory about noise benefit is thoroughly described by Sikström and Söderlund (2007). 1. The first objective is to systematically evaluate the effects of stochastic vestibular noise on cognitive task performance and to compare these results with the ones of stimulant medication using a double blind RTC design.

2. The second objective is to implement a practical application, to evaluate if auditory noise can be beneficial in an every day school setting by the use of an iPhone application (see: [www.smartnoise.se](http://www.smartnoise.se)).

Participants and recruitment: Participants with an ADHD diagnosis using medication will be recruited from Child and Adolescent Psychiatry in Lund and Malmö. Typically developing children (TDC) and inattentive children without diagnosis will be recruited from schools in collaboration with the municipality.

Experimental design: All participants will perform a double-blind placebo cross over control study. ADHD participants will perform the entire test battery at three occasions with 2-3 weeks intermission in between tests. One occasion with placebo medication and sham SVS stimulation; one occasion with active SVS stimulation; and one occasion with active medication. TD children will only be tested twice while they will not be given any medication or placebo and just perform under SVS vs. sham conditions.

Test battery: 1) Episodic memory will be tested through Auditory Verbal Learning Test (AVLT) (e.g. Dige et al., 2008). 2) Visuo-spatial working memory will be tested through the Spanboard task (Westerberg et al., 2004). 3) Motor-neurological investigation. 4) A finger tapping task. 5) Evaluation of an iPhone auditory noise application in a normal school setting. Our research group has developed an iPhone application ([www.smartnoise.se](http://www.smartnoise.se)) that is available at App-store right now. The study will last for about 5 months and participants will be 50 voluntary secondary school pupils that have documented attention difficulties as judged by their teachers. The application will be evaluated both by pupils, teachers and parents.

| Condition or disease | Intervention/treatment   |
|----------------------|--|
| ADHD                 | Device: Stochastic Vestibular Stimulation<br>Drug: Central Stimulant<br>Drug: Placebo oral capsule |

## Study Design

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Study Type : Interventional (Clinical Trial)

Estimated Enrollment : 70 participants

Allocation: Randomized

Intervention Model: Crossover Assignment

Intervention Model Description: Patients will be recruited from Child and Adolescent Psychiatry in Lund and Malmö. Typically developing children (TDC) and inattentive children without diagnosis will be recruited from schools.

All participants will perform a double-blind placebo cross over control study. ADHD participants will perform the entire test battery at three occasions with 2-3 weeks intermission in between tests. One occasion with placebo medication and sham SVS stimulation; one occasion with active SVS stimulation; and one occasion with active medication. TD children will only be tested twice and just perform under SVS vs. sham conditions.

Test battery: 1) Episodic memory will be tested through Auditory Verbal Learning Test (AVLT) (e.g. Dige et al., 2008). 2) Visuo-spatial working memory will be tested through the Spanboard task (Westerberg et al., 2004). 3) Motor-neurological investigation. 4) A finger tapping task. 5) Evaluation of an iPhone auditory noise application in a normal school

setting.

Masking: Triple (Participant, Care Provider, Outcomes Assessor)  
Masking Description: Participants will be randomized to placebo or stimulant medication during assessments. Participants will be unaware if they will get sham stimulation or SVS (but not the test administrator).

Primary Purpose: Treatment  
Official Title: Acoustic and Vestibular Noise as Possible Non-pharmacological Treatments of ADHD in School Children

Anticipated Study Start Date : February 28, 2018

Estimated Primary Completion Date : May 31, 2019

Estimated Study Completion Date : May 31, 2019

### Resource links provided by the National Library of Medicine

MedlinePlus related topics: Noise

U.S. FDA Resources

### Arms and Interventions

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| Arm   | Intervention/treatment   |
|---|--|
| Active Comparator: Placebo medication and sham stimulation<br>Patients will be randomly chosen to the group who will get a combination of placebo and sham stimulation. | Drug: Placebo oral capsule<br>Placebo capsule for methylphenidate is given.<br>Device: Sham stimulation<br>Patients will receive sham stimulation in place of active vestibular stimulation.   |
| Active Comparator: Active medication<br>Patients are randomly chosen to the group who will get active medication without stimulation.                                   | Drug: Central Stimulant<br>Central stimulant medication with methylphenidate versus placebo will be given.   |
| Sham Comparator: Active stimulation<br>Patients are randomly chosen to the group who will get active stimulation without taking medicine.                               | Device: Stochastic Vestibular Stimulation<br>Stochastic vestibular stimulation will be given by electric stimulation through electrodes placed over the mastoid processes behind each ear. Auditory stimulation with stochastic white noise will be administered through ear phones.<br>Other Name: Auditory white noise stimulation |
| Active Comparator: Controls with sham stimulation<br>Controls without ADHD are randomly chosen to the group who will get sham stimulation.                              | Device: Sham stimulation<br>Patients will receive sham stimulation in place of active vestibular stimulation.  |
| Sham Comparator: Controls with active stimulation<br>Controls without ADHD are randomly chosen to the group who will get active stimulation.                            | Device: Stochastic Vestibular Stimulation<br>Stochastic vestibular stimulation will be given by electric stimulation through electrodes placed over the mastoid processes behind each ear. Auditory stimulation with stochastic white noise will be administered through ear phones.<br>Other Name: Auditory white noise stimulation |

### Outcome Measures

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Primary Outcome Measures :

1. Spanboard task [ Time Frame: Ten weeks ]

Test of visuo-spatial working memory

2. AVLT [ Time Frame: Ten weeks ]

Auditory Verbal Learning Test

3. Go No- go test [ Time Frame: Ten weeks ]

Test of impulse inhibition

#### Secondary Outcome Measures :

1. Soft- signs test [ Time Frame: Ten weeks ]

Test of minor neurological deficits

2. Flower trail [ Time Frame: Ten weeks ]

Test of perception, fine motor function and motor planning

3. Finger tapping task [ Time Frame: Ten weeks ]

Test of timing

#### 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](#).*

Ages Eligible for Study: 9 Years to 18 Years (Child, Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: Yes

#### Criteria

Inclusion Criteria: Children and adolescents with a diagnosis of ADHD and control children without at diagnosis.

Exclusion Criteria: Intellectual disability, psychosis, severe depression or anxiety

## Contacts and Locations

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No Contacts or Locations Provided

## More Information

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Responsible Party: Lund University  
ClinicalTrials.gov Identifier: NCT03425669 [History of Changes](#)  
Other Study ID Numbers: Sponsor  
First Posted: February 7, 2018 [Key Record Dates](#)  
Last Update Posted: February 7, 2018  
Last Verified: February 2018

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

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

Keywords provided by Lund University:  
Acoustic and vestibular noise stimulation

Additional relevant MeSH terms:  
Central Nervous System Stimulants  
Physiological Effects of Drugs