Trial Description

Title

Long term effects of personnel FM-systems in children with auditory processing disorder and difficulties in understanding speech in noise

Trial Acronym

[---]*

URL of the trial

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Brief Summary in Lay Language

Persons with auditory processing disorder (APD) have a normal functioning inner ear, but have difficulties in in recognizing and interpreting sounds, e.g. speech understanding in background noise. APD is a significant disadvantage for school children. They often fail to achieve a learning success that would be expected from their intelligence and motivation. Personal FM systems are reported to protect those children from many disadvantages at school. Personal FM systems are special hearing aids for school children that receive the speech sound from a teacher microphone via frequency modulation (FM) broadcasting. Many studies confirmed a significantly improvement of the level difference between the teacher's voice and the background noise (signal-to-noise-ratio SNR) for school children, typically 15-20 dB, but the outcome on central auditory processing and higher order language related functions remains still unclear. Thus, we intend to study whether personnel FM-systems may improve these functions and whether the outcome is superior compared to a “direct” training by a “classical” speech-language therapy.

Brief Summary in Scientific Language

Auditory processing disorder (APD) is a significant disadvantage for school children. They often fail to achieve a learning success that would be expected from their intelligence and motivation. Personal FM systems are reported to protect those children from many disadvantages at school.

Personal FM systems are special hearing aids for school children that receive the speech sound from a teacher via frequency modulation (FM) broadcasting. Many studies confirmed a significantly improvement of the signal-to-noise-ratio (SNR) for school children, typically 15-20 dB, but the outcome on central auditory processing and higher order language related functions remains still unclear. Thus, we intend to study whether personnel FM-systems may improve these functions and whether the outcome is superior compared to a “direct” training by a “classical” speech-language therapy. If so, personnel FM systems may become a standard therapy for children with APD.

Hypotheses:
H0: after 6 and 12 months, the two treatment groups do not differ in all of the outcome measures mentioned below.

H1: after 6 and 12 months, the two treatment groups do differ in at least one of the outcome measures mentioned below (α < 5 %).

Organizational Data

- DRKS-ID: **DRKS00005192**
- Date of Registration in DRKS: **2013/08/19**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **11-193 , Ethik-Kommission Universität zu Lübeck Medizinische Fakultät des Universitätsklinikums Schleswig-Holstein**

Secondary IDs

Health condition or Problem studied

- ICD10: **F80.20 - [generalization F80.2: Receptive language disorder]**

Interventions/Observational Groups

- Arm 1: **The study is indented to examine whether FM systems do not only improve speech understanding noise in children with auditory processing disorders, but also improve long-term sound perception performance.**

  A pre-post study with a waiting group design is planned. Group 1 (intervention group, arm 1) will bilaterally be provided with FM receivers within 1 month after diagnosis. Group 2 (waiting / control group, arm 2) is provided with FM receivers 6-7 months after diagnosis. The test persons are randomly assigned to one of the two groups after diagnosis.

  Personal FM systems are special hearing aids for school children that receive the speech sound from a teacher microphone via frequency modulation (FM) broadcasting. The acoustic situation for the child, in particular the sound level difference between the teacher's voice and the background noise is clearly enhanced.

  The outcome parameters for the intervention group (N=29) are measured at the time of diagnosis, at fitting the FM systems, 6-7 months after fitting, and 12 months after fitting.

- Arm 2: **The members of the waiting / control group (N=29) receive the same treatment as the intervention group, but delayed by 6-7 months. The outcome parameters for the waiting / control group are measured at the time of diagnosis, 6-7 months after diagnosis, at fitting the FM systems, 6-7 months**

after fitting, and 12 months after fitting.

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The outcome measures for the study are related to auditory processing performance and cognitive auditory perception performance, which are critical for academic performance in school. A child which learns to write has to be able to distinguish between phonemes, recognize them in spoken language, and memorize what has been said. A therapy for APD has to improve performance in these key issues.

The primary outcome is speech sound discrimitation (Heidelberger Lautanalyse- und Differenzierungstest H-LAD, Brunner et al. 1998): improved T-scores and/or percentages.

The primary outcome parameter is measured at the time of diagnosis, 6-7 months after diagnosis (control group only), at fitting the FM systems, 6-7 months after fitting, and 12 months after fitting.

Secondary Outcome

1. Auditory memory (Mottier test and K-ABC--subtest): improved raw scores, T-scores and/or percentages

2. Phonological awareness (subtests from the Psycholinguistic Development Test (PET)): improved raw scores, T-scores and/or percentages

3. Perception errors (Diagnostic Spelling Test (DRT, WRT)): improved T-scores and/or percentages

The outcome parameters are measured at the time of diagnosis, 6-7 months after diagnosis (control group only), at fitting the FM systems, 6-7 months after fitting, and 12 months after fitting.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Abteilung für Phoniatrie und Pädaudiologie, Lübeck**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2013/12/02**
- Target Sample Size: **58**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **6 Years**
- Maximum Age: **14 Years**

Additional Inclusion Criteria

Regular hearing threshold in quiet (air conduction ≤15dB, bone conduction ≤ 10 dB on both sides)

Regular tympanogram on both sides.

Detectable TEOAE, stimulus stability ≥ 90% (80%), reproducibility ≥ 75% (60%), SNR ≥ 3dB in at least 3 frequencies

Regular speech understanding in quiet (Freiburger Monosyllabic Speech Test: at least 95% correct at 65 dB, Göttinger Pediatric Speech Test: at leat 90 % correct at 65 dB

Visual perception: standard values ≥ 85 (e.g., Motor Free Visual Perception Quotient, MVPR Vers. 3), non-verbal IQ ≥ 85 (e.g., CMM 1-3 oder or HAWIK Vers. IV)

APD diagnosed according to consensus paper DGPP (Gross et al. 2010), considering current norm values (e.g., Kiese-Himmel and Risse 2009)

Exclusion criteria

Hyperacusis, which could prevent subjects from wearing FM receivers in the study. Confirmation through regular loudness scaling results (Würzburger loudness scaling in frequencies from 500 Hz - 4000 Hz)

Attention and concentration deficit (DCL-HKS questionnaire)

Usage of psychotropic drugs (e.g., Methylphenidat)

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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  E-mail: **[---]***
  URL: **www.dfg.de**
- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

  Phonak GmbH
  Max-Eyth-Str. 20
  70736 Fellbach
  Germany

  Telephone: **0711 510700**
  Fax: **[---]***
  E-mail: **[---]***
  URL: **www.phonak.de**

Status

- Recruitment Status: **Recruiting withdrawn before recruiting started**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.