

**The effects of Remote Microphone Hearing Aids (RMHAs) on classroom listening,
listening-in-noise and attention skills in children, aged 7-12, with Auditory Processing
Disorder (APD)**

(Student Study)

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Summary

Children with Auditory Processing Disorder (APD) have poor auditory processing skills in the presence of normal peripheral hearing. These children are found to have worse listening-in-noise skills than typically developing peers, while other commonly reported symptoms include poor attention and distractibility. One of the management strategies for children with APD is the use of Remote Microphone Hearing Aids (RMHAs), which can help improve the signal-to-noise ratio in the child's ears. The aim of this randomised control trial was to examine whether RMHA use improves classroom listening for children with APD, and to further test their effects on children's listening-in-noise and attention skills following a 6-month intervention.

The principal research question is whether RMHAs improve classroom listening, listening in noise performance, listening in spatialised noise and auditory attention, in children with Auditory Processing Disorder (APD). We hypothesize that RMHA use will lead to improved classroom listening and improved speech-in-noise skills after 6 months of RMHA use. Additionally, we hypothesise that listening in spatialised noise and attention skills will remain unchanged following the intervention period.

Twenty-six (26) children with a diagnosis of an APD from the Great Ormond Street Hospital Audiology clinic will be recruited. The children need to fulfil the following criteria:

1. Diagnosis of APD based on routine clinical tests, administered by qualified audiologists, and requiring the following conditions:
2. No neurological or pervasive disorder or developmental delay. Children with a diagnosis of Attention Deficit Hyperactivity Disorder, epilepsy, Autism Spectrum Disorder, Developmental Language Disorder, Down Syndrome were excluded from the study.
3. Non-verbal cognitive ability score (IQ) of 85 or more.
4. Aged between 7-12 years.
5. Native English speakers.
6. No prior use of RMHAs.

Background and justification of the study

Auditory Processing Disorder

Auditory Processing Disorder (APD) is a disorder where the functions of the ear (outer, middle, inner) are normal but the person has difficulty identifying or discriminating sounds (1). For children with APD it is particularly difficult to hear when the listening conditions are not ideal. For example, when there is background noise it becomes really challenging to focus on the speaker. Two other factors that influence their hearing ability are reverberation and the distance

from the speaker (2). Some of the most commonly reported symptoms in these children are difficulties listening in background noise and inattentiveness, also reflected in findings from behavioural tests (3,4). Children with APD perform worse in behavioural tests measuring Speech-in-Noise (SiN) skills compared to typically developing children (5,6) and have worse performance in sustained auditory attention compared to children suspected of APD but not meeting APD diagnostic criteria (7).

Remote Microphone Hearing Aids

One of the management strategies recommended to children with APD is the use of Remote Microphone Hearing Aids (RMHAs). These are wireless listening devices that pick up the speaker's voice and transmit it to a receiver in the listener's ear. The use of this system helps improve the signal-to-noise ratio for children and bypasses the negative effects of background noise and reverberation in the classroom (8,9,2). However, only a handful of studies examined the effects of RMHA use on children with APD on specific measures (i.e. SiN, listening in noise, language and communication, and memory skills) (9–12).

Previous research suggests that children with APD after a prolonged use of RMHAs benefit from improved speech perception which is possibly linked to an enhanced auditory system (9). Adding to that, children with APD have shown improved speech in noise perception when using the RMHA, hence emphasizing the advantages of the device in discriminating speech in background noise (9,12).

Attention and ability to listen in spatialised noise in children with APD after the use of an FM system has been looked at by one uncontrolled study (12). As the central point of this study will be the use of the RMHA by children with APD for 6 months, it is expected that the findings could add valuable information on the subject. In addition, possible benefits of the system will be examined in detail. More particularly, possible long-term improvements in speech in noise performance (unaided), listening in spatialised noise (unaided), and auditory attention (unaided) will be examined.

Listening in noise and attention

A study compared the scores in the Hearing in Noise test of 10 children with APD at baseline unaided and after 5 months of daily RMHA use at school (9). The use of RMHAs during the aided test condition at 5 months gave a gain of approximately 10 dB in the SiN test compared to the unaided testing at baseline, with the authors concluding that RMHA use improved the auditory system in children with APD (9). However, this SiN improvement in the aided condition may reflect an auditory acclimatisation benefit similar to the one reported for hearing aids (13), as there was no significant improvement between pre- and post-intervention in unaided SiN testing. Another APD study used low-gain hearing aids equipped with a directional microphone and noise reduction (14), to examine changes in aided SiN skills in 14

children with APD. They reported improved aided SiN test results¹ after 6 months of RMHA use. Another intervention trial examined the ability to listen in spatial noise² on 28 children with APD who used RMHAs for 5 months (12). Children were tested on two tasks, easy words and hard words, and two conditions, with and without the RMHA at baseline and post-intervention. Results showed a significant improvement only in the easy words task when comparing the unaided with the aided conditions (12). All three trials lacked control groups and randomised designs, thus further validation in controlled trials, especially in unaided conditions, is required.

Furthermore, to date only one study looked into the long-term impact of RMHAs on behavioural attention tests in children with APD. Specifically, sustained auditory and sustained visual attention was examined in 28 children with APD after a 5-month RMHA intervention, without showing any significant change over the intervention period (12). One other study used the Children's Auditory Performance Scale questionnaire, completed by parents at baseline and after 6 months of using the directional microphone hearing aids at school (14). While the Auditory Attention Span subscale of the questionnaire showed significantly improved scores post-intervention, it still remained below what was considered normal cut-off. Parents observed their children at home, when hearing aids were not used, suggesting that the improvement in the subscale scores may have been due to lasting effects on their attentive behaviours. The findings from these two studies are conflicting, but none of the trials used a randomised control design (14).

Aim and hypotheses

In the present study we aim to test the impact of long-term RMHA use on self-reported listening, behavioural SiN performance and to assess behaviourally whether listening-in-spatialised-noise skills change after prolonged RMHA use and to assess the impact RMHA use has on attention skills.

Research questions:

The principal research question was to examine the effects of RMHAs on classroom listening, listening in noise performance, and auditory attention in children with APD.

Hypotheses:

- i. Children with APD who use RMHAs will show greater improvements in classroom listening, listening in noise and sustained auditory attention (unaided) after 6 months of RMHA use in comparison to the APD control group.

¹ The North Western University word-list was used in combination with speech-shaped noise coming from 180° that was individually adjusted (14).

² Words from the Lexical Neighbourhood Test were presented from the front, while a 100-talker babble recording was presented left, right, and behind the subject (12).

- ii. Children with APD who use the RMHA will not show greater improvements in listening in spatialised speech noise and divided and visual attention measures after 6 months of RMHA use in comparison to the APD control group.

Summary of main issues

Research suggests that children with APD after a prolonged use of RMHAs benefit from improved speech perception which is possibly linked to an enhanced auditory system (9). Adding to that, children with APD have shown improved speech in noise perception when using RMHAs (in an uncontrolled study); hence emphasizing the advantages of RMHAs in discriminating speech in background noise (9). There are not many studies, though, that focus on the use of RMHAs on children with APD.

This study will assess the effects of RMHA use on a range of outcome measures. As the central point of this study will be the use of RMHAs by children with APD for 6 months, it is expected that the findings could add valuable information on the matter. In addition, possible benefits of RMHAs will be examined in detail. More particularly, possible improvements in auditory attention, listening in spatialised noise and speech in noise discrimination (unaided) will be looked into.

Intervention ethical issues:

We will split the children with APD into (a) children who will only receive the RMHA, (b) children who will not receive any intervention for the study period (this group will receive the RMHA after we complete the study, at 6 months under this conditions: The recommendations by the APD clinic at GOSH include RMHA use as management strategies.

Currently from an audit conducted at GOSH APD Clinic, only 1 in 3 children who are recommended to have a RMHA obtain this by school funding (or by their parents funding the device) and this takes place several months after the recommendation has been made. Therefore, provision of this device is not standard practice. As such RMHAs are issued as part of this research study under the condition mentioned above.

An inclusion of a control, no intervention group, is essential for the Randomised Control Trial design we follow.

School and teacher involvement:

The teachers of the children who receive the FM systems will be provided with an information sheet and consent form and will be required to wear the microphone (which picks up the teacher's voice and transmits it wirelessly to the ear receivers in the child's ear) for the duration of the class. Remote microphone hearing aids are provided (funded by the school budget) to some children after clinical recommendations and this is not an unusual situation within the school environment.

We will liaise with the teacher as well as the Special Educational Needs Co-ordinator (SENCO) of the school in order to ensure that the school will be aware that the student has been issued with the RMHA. A general guide for the system will be made available in addition to information conveyed by the Research Fellow (PhD student) who will visit the school once per term.

Informed consent:

The child's parents will be given detailed written information and consent forms to sign about taking part in the study. They will be given up to a week to study and decide whether they wish for their child to participate in the study. They will only be allowed to take part once they have understood the purpose and procedures of the study and they have signed the consent forms. In addition, children will also be given information sheets adjusted to their age. Written assent from the children in the presence of their parents or carers will be sought.

Rights to withdraw from the study:

This will be outlined on both the information sheet and consent form and explained verbally throughout. This information will state that participants will be allowed to withdraw from the study at any point should they wish to do so. Withdrawal from the study will not involve any penalty or loss of benefit to them –this information is clearly underlined at the information sheet and will be made clear to them verbally.

Data protection:

The parents of the participant and the participant will be informed that their information will be anonymised and kept confidential. Data will be anonymised prior to analysis by the use of participant codes. Storage of the data will be within a secure password protected database and locked filing unit within UCL, in accordance with the data protection act 1998. If withdrawals take place the participants' data will be deleted.

Research Design and Methodology

Participants and Recruitment

We will recruit 26 children, 7-12 years old. All children will have been diagnosed and referred from the Auditory Processing Disorders Clinic at Great Ormond Street Hospital. The total sample size is decided using this power sample: $N = 24$ (total sample size) calculated using the F test for repeated measures between-within interaction Analysis of Variance (ANOVA) based on an estimated 0.5 effect size $f(U)$, 80% power, at 5% significance, using 2 groups and 3 measurement points. To account for a 10% loss due to follow-up, the total sample size of this study was 26 children, aged 7-12.

Inclusion criteria:

1. Diagnosis of APD based on routine clinical tests, administered by qualified audiologists, and requiring the following conditions:

- a) Reported parental SiN and other reported listening difficulties.
 - b) Normal peripheral hearing and middle ear function; i.e. air conduction PTA below 20 dB in all octave frequencies between 250 Hz and 8 KHz (31), middle-ear pressure between -150 to +50 daPa, middle-ear admittance between 0.3 to 1.6 cm³ and ear-canal volumes between 0.4 to 1.0 cm³ (32).
 - c) Abnormal performance on the Auditory Figure Ground (AFG) SiN test of the SCAN-3 C (i.e. at the 1st percentile score as per UK norms), and
 - d) Abnormal performance (-2 SDs from the normative mean) on at least one auditory processing test (i.e. Frequency Pattern Test [FPT], Dichotic Digits Test [DDT], duration pattern test, Gaps-in-Noise [GiN] or random gap detection pattern tests), or a score of -3 SDs from the normative mean on only one auditory processing test (any test from conditions 'c' and 'd'), and/ or abnormal performance (-2 SDs from the mean) on the Spatial Advantage and Total Advantage/ High-cue Speech Reception Threshold (SRT) subtests of the Listening in Spatialised Noise – Sentences (LiSN-S) test.
2. No neurological or pervasive disorder or developmental delay. Children with a diagnosis of Attention Deficit Hyperactivity Disorder, epilepsy, Autism Spectrum Disorder, Developmental Language Disorder, Down Syndrome were excluded from the study.
 3. Non-verbal cognitive ability score (IQ) of 85 or more.
 4. Aged between 7-12 years.
 5. Native English speakers.
 6. No prior use of RMHAs.

Subjects will be semi-randomly assigned to each of two intervention arms. The two groups will be stratified for age and balanced for sex.

Children will be given RMHAs to use at school and will be compared to the control (no intervention) group. Children will be enrolled in the study for 6 months. All groups will be tested before the start of the RMHA intervention, after 3 months, and at the end of the study (after 6 months of use of the interventions).

Following are the assessments to be performed for both groups at UCL Ear Institute (detailed explanation of these tests is given later):

- Baseline (before recruitment, 0 months into the study):
 - Pure Audiometry Test (PTA)
 - Non-verbal IQ test (Weschler test of Non-verbal intelligence)
 - Children Questionnaires (LIFE-R)
 - Attention test (TEACH)
 - Listening in Spatialised noise (LiSN-S)
 - Questionnaires (CHAPS, CCC-2)
- At 3 months

- Children Questionnaires (LIFE-R)
- Attention test (TEACH)
- Listening in Spatialised noise (LiSN-S)
- Questionnaires (CHAPS, CCC-2)
- At the end of the study (6 months later):
 - Children Questionnaires (LIFE-R)
 - Attention test (TEACH)
 - Listening in Spatialised noise (LiSN-S)
 - Questionnaires (CHAPS, CCC-2)

Explanation of each test:

1. A hearing test (Pure Tone Audiometry approx. 10mins). To determine their hearing is normal.
2. Non-verbal IQ test (Weschler test of non-verbal intelligence). To be performed by the PhD Student. (approx. 15mins). To assess determine whether their intelligence level is above normal.
3. Listening in spatialised noise test (LiSN-S, approx. 15mins). To be administered through the use of headphones by the PhD student. To determine their listening in spatialised speech noise abilities.
4. An attention test. The Test of Everyday Attention for Children (TEACH). To be conducted as play type activities by the PhD student after receiving sufficient training by the clinical psychologist. (approx. 45mins possibly cut down to 30mins). To assess their attention.
5. Two questionnaires to be filled by the children's parents.
 - a. The Children's Communication Checklist-2 (CCC-2). A 70-item questionnaire which screens for communication problems (including language disorders and autism).
 - b. The Children's Auditory Performance Scale (CHAPS). It assesses aspects of children's listening.
6. One questionnaire to be completed by the children (Listening Inventory For Education-Revised [LIFE-R] for assessing their listening difficulty.

Data analysis:

Data were analysed in SPSS 22 statistics software, using a mixed ANOVA, with group as the between-subjects factor with two levels (i.e. control or RMHA) and time the within-subjects factor with three levels (i.e. baseline, 3, and 6 months) .

Other issues:

None of these tests are invasive or unpleasant, and they are conducted in comfortable sound levels (slightly higher than the usual conversational level). Any additional information on the children that might emerge during the study will be reported back to the clinician at the APD clinic to inform the child's management.

All children who participate will receive a book voucher of £10 at the end of each test session. Travel expenses will also be reimbursed (up to £10).

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