

# A randomised controlled trial of screening for adult hearing loss during preventive health checks

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## SUMMARY

**Background:** Prophylactic strategies to counter acquired hearing impairment may involve routine audiometric screening of asymptomatic working-age adults attending general practice for regular health checks.

**Aim:** To evaluate the effect of adult hearing screening on subsequent noise exposure and hearing.

**Design of study:** A randomised controlled population-based study of health checks and health discussions in general practice.

**Setting:** The project was initiated in the district of Ebeltoft, Aarhus county, Denmark.

**Method:** Intervention group participants' hearing thresholds were determined audiometrically at 0.5, 1, 2, 3, and 4 kHz in each ear. Participants were advised to get their ears checked if the average hearing loss exceeded 20 dB hearing level (dBHL) in either ear. Noise avoidance was emphasised when thresholds exceeded 25 dBHL bilaterally at 4 kHz. Follow-up included questionnaires and audiometry.

**Results:** Hearing loss was observed among 18.9% of the study sample at baseline. At the five-year follow-up we recorded no significant differences between the control and the intervention groups regarding subjective or objective hearing, or exposure to occupational noise. However, there was a tendency towards reduction in exposure to leisure noise among intervention participants ( $P = 0.045$ ). Approximately 20% reported hearing problems; 16.5% reported tinnitus-related complaints; 0.8% used hearing aids; 35.0% reported frequent noise exposure; and occluding wax was suspected in 2.1%.

**Conclusion:** Preventive health checks with audiometry did not significantly affect hearing, but leisure noise exposure tended to become less frequent. The poor effect may be ascribed to inadequate audiological counselling or a higher priority to other advice, e.g. on cardiovascular risk or lifestyle.

**Keywords:** Ear, nose and throat; hearing loss; randomised controlled trial, middle-aged people.

## Introduction

PREVENTION of acquired hearing impairment is a worldwide concern<sup>1</sup> that may benefit from general practitioner (GP) involvement.<sup>2-7</sup> Adult hearing deterioration is partly owing to modifiable extrinsic factors of which excessive occupational noise is probably the most common.<sup>8,9</sup> Noise during leisure time activities is also suspected to play an increasing role.<sup>10</sup>

A British population study estimates a prevalence of moderate to severe hearing impairment in the range from 1.5% among 17 to 30-year-olds, to 45.2% among 71 to 80-year-olds, defined as hearing loss in the worse hearing ear of at least 40 dB hearing level (dBHL), averaged across 0.5, 1, 2, and 4 kHz. Corresponding estimates relating to the better hearing ear are 0.2% and 29.7%.<sup>11,12</sup> Even if the actual prevalence depends on the criteria applied, the underlying data suggest acquired hearing deterioration in a considerable proportion of young and middle-aged adults. We currently lack extensive long-term prospective studies on the multifactorial causes of hearing deterioration, but we may expect that a significant proportion of elderly suffer from noise-induced hearing impairment.

An American randomised study demonstrated hearing screening and subsequent provision of hearing aids could actually reverse some of the important adverse effects on the quality of life caused by hearing loss in the elderly.<sup>13</sup> Audiometric assessment in primary care produced a three-fold increase in the provision of hearing aids in 50 to 85 year-olds, as described in non-randomised studies.<sup>14,15</sup> The multiphasic screening programmes with audiometric testing of middle-aged adults, launched more than two decades ago, give little evidence to support prophylactic action as results have not been reported.<sup>16-18</sup> Even so, several of these authors have advocated early and continuous hearing conservation programmes;<sup>19,20</sup> however, clear evidence of the benefit of routine screening for hearing impairment, in particular among asymptomatic working-age adults, is still lacking.<sup>21</sup>

The aim of this study was to evaluate the effect of adult hearing screening on subsequent noise exposure and hearing thresholds as well as on noise exposure. Screening was performed as part of general health checks in general practice.

## Method

### Protocol

The present study is part of the Ebeltoft Health Promotion Project in Denmark. The project is a five-year prospective, randomised controlled population-based study on the use-

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**HOW THIS FITS IN***What do we know?*

Adult hearing loss is quite prevalent and is partly due to modifiable factors.

*What does this paper add?*

Audiometric screening is practicable in general practice. Five-year follow-up showed minor impact of intervention in its present form. However it certainly warrants adoption of preventive strategies to minimise future needs for audiometric rehabilitation.

fulness of health promotion in general practice using health checks and health discussions.<sup>22-24</sup> The project was initiated in 1991 in the district of Ebeltøft, Aarhus County, including approximately 13 000 inhabitants in a coastal town and rural surroundings. Permission to conduct the study was given by the Ethics Committee of Aarhus County and the Danish Registry Board.

The study population was drawn from 3464 30 to 49 year-olds (1 January 1991) registered with a GP in the district via the national health insurance system. A random sample of 2000 were invited to participate using a two-page mailed questionnaire. A total of 1507 (75%) subjects accepted the invitation to participate and were randomly divided into a control group (one-third of the total) and two intervention groups (of one-third each). All participants received extensive mailed questionnaires at baseline, after one year, and after five years of follow-up. Questions referred to in this paper relate to subjective hearing and noise exposure. Tinnitus was defined as buzzing, ringing or other sounds lasting more than five minutes.

Subjects in the two intervention groups were invited to a general health check, including manual pure-tone air-conduction audiometry at baseline and again one year later. Audiometry was performed in a quiet room with ambient noise levels largely in conformance with the ISO 8253-1.<sup>23,25</sup> Hearing thresholds were determined in the range zero to 70 dBHL, in 5 dB steps using the shortened version of the ascending method.<sup>25</sup>

Participants in both groups received personal, written feedback from their GP. Specific advice was given when a test result exceeded the predefined normal range.<sup>22</sup> Hearing thresholds were averaged for all five frequencies (0.5, 1, 2, 3, and 4 kHz) for each ear. When values exceeded 20 dBHL, indicating at least mild hearing loss, participants were advised to get their ears checked by their GP and wax removed if necessary. The results obtained at Year 1 included the 4 kHz threshold and general advice on hearing protection usage. When bilateral thresholds exceeded 25 dBHL, indicating possible noise-induced impairment, advice on noise avoidance was emphasised. All participants in the second intervention group were invited to an annual 45-minute consultation with their GP. Participants were encouraged to prioritise a maximum of three goals for health-related lifestyle changes.

At the final five-year follow-up, all participants in both control and intervention groups were offered a health check and, if they wished, a health discussion. The final health check was identical to the previous ones, except for an addi-

tional otoscopy. On suspicion of acoustically obstructing wax, we offered to remove the wax and to perform a second audiometry — mostly at a later date. Trial completion was defined as returned questionnaire and participation in the final health check, irrespective of participation in other study phases.

The study outcome measures at the five-year follow-up were: subjective hearing status, hearing aid use, tinnitus, frequency of acoustically obstructing ear wax, audiometric test result, reported noise exposure, and hearing protection usage. Pre-intervention primary outcome measures or minimum important differences in hearing were not defined because multiple elements were involved in the health check. The sample size was pragmatically chosen to be as large as practically possible. Assuming 75% participation at the time of randomisation and another 75% at the five-year follow-up, there would be 375 participants in the control group and 750 in the intervention groups. The detectable differences in proportions were estimated (using SamplePower™ 1.0) and given an  $\alpha$ -value equal to 5%. With a study power of 80%, the study could detect a difference of 9% at the 50% prevalence proportion level, of 7% at the 25% level, and of 5% at the 10% level. The two intervention groups were primarily pooled for analysis because all participants with a hearing loss were advised to see their GP. Thus, the additional effect of a discussion on hearing was considered insignificant. Participation at baseline and at the five-year follow-up was calculated when all health checks had been carried out.

Hearing threshold levels in dBHL were averaged across two frequency ranges in each ear after removal of wax, if any: (a) 0.5, 1, 2, and 4 kHz ( $HL_{(0.5-4\text{ kHz})}$ ), and (b) 3, and 4 kHz ( $HL_{(3-4\text{ kHz})}$ ). On this basis either ear was categorised as better (BE) or worse (WE). Hearing impairment was noted if the average hearing threshold was equal to or above 25 dBHL. Study group outcome measures were compared on an intention-to-treat basis using  $\chi^2$  statistics for categorical variables and the Mann-Whitney U test for continuous variables. The level of significance was set at 5%. Differences between the proportions in the two independent groups (intervention-control) were supplemented by a 95% confidence interval (95% CI).

**Assignment**

Randomisation was carried out by an employee of Aarhus County who was not involved in the study. Individuals were allocated by proportional, stratified randomisation according to GP, sex, age, body mass index, and cohabitation status; couples living together were allocated to the same group to avoid bias between groups. Participants were informed of the assignment if they responded to the extensive baseline questionnaire. The intervention did not allow blinded allocation.

**Results***Participant flow and follow-up*

Figure 1 summarises participant flow during the five-year follow-up. In total 1093 out of 1507 randomised participants (73%) completed the trial. Seven subjects had emigrated

and 12 had died before the five-year follow-up health check. Three subjects were excluded as audiometry was not repeated after removal of possibly acoustically occluding wax at the five-year follow-up. Table 1 features baseline characteristics of the sample subjects. Control and intervention group baseline characteristics were not significantly different either at the time of randomisation or subsequently. A total of 171 intervention group subjects (18.9%) were advised to have their ears checked owing to poor hearing at the baseline audiometry. Statistically, their participation did not differ significantly from that of those who received no such advice. Following audiometry at Year 1, 18.2% ( $n = 150$ ) received advice owing to poor average thresholds, while 9.7% ( $n = 80$ ) had bilateral thresholds below 25 dBHL at 4 kHz.

### Analysis

Outcome status at follow-up is listed in Table 2. Differences in subjective and objective hearing between the intervention groups and the control group did not reach statistical significance. Exposure to leisure noise was significantly lower in the intervention groups than in the control group ( $\chi^2 = 4.00$ ;  $df = 1$ ;  $P = 0.045$ ). Exposure to occupational noise and the use of hearing protection were largely the same in all groups. Occluding wax was suspected in 2.1% ( $n = 22$ ) of whom 19 were audiometrically tested after wax removal. Hearing sensitivity improved to 10 dBHL<sub>(0.5-4 kHz)</sub> in at least one ear in seven (36.8%) of these participants, even in four who claimed normal hearing.

The two intervention groups did not differ significantly in terms of any of the outcome measures. The five-year follow-up was attended by 129 (74%) of 171 subjects who were advised to have their ears checked owing to poor hearing at the baseline audiometry. In this subgroup the intervention groups did differ significantly. Intervention participants had experienced a median average hearing deterioration of 0.0 dBHL<sub>(0.5-4 kHz)</sub> and 2.5 dBHL<sub>(3-4 kHz)</sub> without any significant differences between the two groups.

At baseline, 443 subjects (97.1%) chose to participate in the health discussion. Nine were referred to an ear, nose and throat (ENT) specialist or audiologist for further examination, and seven stated a personal goal was to minimise their exposure to loud noises. Three of these seven subjects participated in the five-year follow-up; two reported using hearing protection during noisy occupation while one reported never having used hearing protection.

### Discussion

The audiometric screening cut-off was set at 20 dB to permit advice to be given to participants with even mild degrees of unilateral hearing impairment, as well as to secure early identification of individuals at potential increased risk of hearing deterioration. Hearing screening may have an indirect effects on objective and subjective hearing:

1. It may focus the individual and hence reduce his or her exposure to harmful noise and thereby impact on future hearing loss;
2. hearing may be improved by removing wax or by middle ear surgery on conductive disorders (in other cases subjective hearing may be improved by use of a hearing aid);
3. subjects with only subjective hearing problems may find themselves relieved by the absence of objective signs;
4. inversely, subjects without subjective hearing problems may start experiencing subjective hearing problems when informed of a hearing impairment.

Study participation was considered acceptable. Selection bias had little effect on the study, as study group baseline characteristics were generally similar at the five-year follow-up. The two intervention groups were pooled for analysis because outcome measures were generally similar.

Intervention had no detectable impact on subjective or objective hearing but tended to cause reported exposure to leisure noise to diminish following the intervention. Nevertheless, the single statistically significant difference in leisure noise must be interpreted with caution as multiple outcomes were analysed. Still, some individuals did decide to protect themselves better, but they were few compared with how many subjects received written advice owing to poor hearing. Self reporting may be unreliable but we expect this source of error to be minimal. Subjects advised to reduce noise exposure might be more likely to under-report their actual exposure, or might become more aware of actual noise exposure, in which case they will tend to over-report exposure.

The validity of audiometry is generally acceptable;<sup>23</sup> however, study design limitations may have hampered detection of an effect. Thus, the median deterioration of 2.5 dB observed at 3-4 kHz is small compared with the unit of measurement (5 dB). Five years may be too short a period for monitoring differences in this age group, or the accuracy

Table 1. Characteristics of groups of participants at baseline.

	Invited	Randomised	Participating at baseline		
			Control	Intervention <sup>a</sup>	Intervention <sup>b</sup>
Number	2000	1507	465	449	456
Sex (% males)	51.6	48.6	47.7	47.2	47.8
Mean age (years)	40.5	40.5	40.3	40.4	40.6
Subjective hearing problems (%)			14.7	14.7	14.1
Noise exposure (%)			26.7	28.4	25.9
Hearing loss >20 dBHL <sup>c</sup>				18.5	19.3

<sup>a</sup>Health check. <sup>b</sup>Health check followed by a consultation. <sup>c</sup>Average of 0.5, 1, 2, 3, and 4 kHz in worse hearing ear.

Table 2. Outcome status at the five-year follow-up according to questionnaire and audiometry: prevalence proportion in the control and the intervention groups, difference specified (intervention – control) = %; n = 1093.

	Control group	Intervention groups	Difference (95% CI)
Subjective hearing (questionnaire) ( $n_{\text{valid}} = 1063\text{--}1088$ )			
Have experienced hearing problems within the last year	21.2	22.6	1.4 (-3.8–6.6)
Have experienced hearing problems restricting daily activities within the last year	4.1	5.4	1.3 (-1.4–3.9)
Indicate that their hearing is not normal	23.9	24.0	0.1 (-5.2–5.5)
Cannot carry on a face-to-face conversation if there is noise, e.g. from TV, radio or playing children	8.2	7.1	-1.1 (-4.5–2.3)
Cannot understand what is being said when three to four persons are talking eagerly with one another	21.1	18.7	-2.4 (-7.5–2.7)
Hearing has been reduced during the past five years	29.3	31.3	2.0 (-3.8–7.8)
Have a hearing aid	1.4	1.3	-0.1 (-1.6–1.4)
Use a hearing aid	0.8	0.9	0.0 (-1.1–1.2)
Tinnitus lasting more than five minutes	16.1	12.7	-3.4 (-7.9–1.1)
Tinnitus preventing sleep, making it impossible to read, or disturbing concentration	3.3	3.4	0.1 (-2.2–2.4)
Audiometry ( $n_{\text{valid}} = 1090\text{--}1093$ )			
Acoustically obstructing wax in one or both ears suspected at otoscopy	1.4	1.9	0.6 (-1.0–2.1)
Hearing impairment, BEHL <sub>(0.5–4 kHz)</sub> $\geq 25$ dBHL <sup>a</sup>	5.2	4.0	-1.1 (-3.8–1.5)
Hearing impairment, WEHL <sub>(0.5–4 kHz)</sub> $\geq 25$ dBHL <sup>b</sup>	15.8	13.0	-2.7 (-7.2–1.7)
Hearing impairment, BEHL <sub>(3–4 kHz)</sub> $\geq 25$ dBHL <sup>a</sup>	17.4	14.7	-2.7 (-7.4–1.9)
Hearing impairment, WEHL <sub>(3–4 kHz)</sub> $\geq 25$ dBHL <sup>b</sup>	32.6	30.1	-2.6 (-8.4–3.3)
Noise exposure (questionnaire) ( $N_{\text{valid}} = 990\text{--}1023$ )			
Feel inconvenience at work or at home because of noise <sup>c</sup> more than two days a week	35.4	29.6	-5.9 (-12.0–0.2)
Exposure to occupational noise <sup>c</sup>	50.5	46.4	-4.0 (-10.6–2.6)
Seldom or never use hearing protection in case of occupational noise <sup>c</sup> ( $n = 473$ )	53.0	58.4	5.4 (-4.0–14.7)
Exposure to noise <sup>c</sup> in leisure time	48.7	42.0	-6.7 (-13.2– -0.1)
Seldom or never use hearing protection in case of noisy <sup>c</sup> work in leisure time ( $n = 441$ )	63.8	62.6	-1.2 (-10.5–8.1)

<sup>a</sup>BEHL refers to better hearing ear. <sup>b</sup>WEHL refers to worse hearing ear. <sup>c</sup>Definition of noise: you have to raise your voice in order to talk to other people.

may have to be improved, for example, by using smaller audiometry steps than 5 dB.<sup>26</sup> Study power could also be increased if longitudinal follow-up of hearing thresholds in the control group was possible. However, it seems unethical to include baseline audiometry without informing the participants of the results.

If the audiological counselling was improved it might have focused participants more on preventive options, but this would hardly be feasible in relation to multiphasic screening where it is easily outweighed by cardiovascular risk and general lifestyle. The general aim of the study — to better utilise existing general practice resources — may have run counter to the specific target of preventing hearing impairment. This could have been remedied by specifically instructing the participating GPs on preventive actions.

Our baseline data have previously been found to suggest that the Danish sample shows slightly less hearing impairment than the British sample.<sup>24,27</sup> But the Danish prevalence of obstructing wax suspected at otoscopy compares well with British figures.<sup>11</sup> A remarkable figure of 0.8% (with reservations for occlusion criteria and small numbers) in this 36 to 55-year-old population apparently had acoustically occluding wax. General practice could easily tackle this problem and hence significantly improve hearing.

The present study indicates a thought-provoking discrepancy between relatively prevalent subjective hearing problems as well as objective hearing impairment and the few cases of hearing actually being given priority owing to the intervention. The present study may not have shown a significant impact of intervention in its present form. However, it certainly warrants adoption of preventive strategies targeting young and middle-aged adults to minimise future needs for rehabilitation of the over-50s age group.

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