

1 **Hearing aid use and long-term health outcomes: hearing handicap, mental health, social**
2 **engagement, cognitive function, physical health and mortality**

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20 **Abstract**

21 *Objective:* To clarify the impact of hearing aids on mental health, social engagement, cognitive
22 function, and physical health outcomes in older adults with hearing impairment. *Design:* We
23 assessed hearing handicap (Hearing Handicap Inventory for the Elderly; HHIE-S), cognition
24 (Mini Mental State Exam, Trail Making, Auditory Verbal Learning, Digit-Symbol Substitution,
25 Verbal Fluency, incidence of cognitive impairment), physical health (SF-12 physical component,
26 basic and instrumental activities of daily living, mortality), social engagement (hours per week
27 spent in solitary activities) and mental health (SF-12 mental component) at baseline, 5 years
28 prior to baseline, and 5 and 11 years after baseline. *Study sample:* Community-dwelling older
29 adults with hearing impairment (N=666) from the Epidemiology of Hearing Loss Study cohort.
30 *Results:* There were no significant differences between hearing aid users and non-users in
31 cognitive, social engagement or mental health outcomes at any time point. Aided HHIE-S was
32 significantly better than unaided HHIE-S. At 11 years hearing aid users had significantly better
33 SF-12 physical health scores (46.2 versus 41.2; $p=0.03$). There was no difference in incidence of
34 cognitive impairment or mortality. *Conclusion:* There was no evidence that hearing aids promote
35 cognitive function, mental health, or social engagement. Hearing aids may reduce hearing
36 handicap and promote better physical health.

37 Hearing impairment is common among older adults. In the Epidemiology of Hearing Loss Study
38 (EHLS), 45.9% of adults aged over 48 years had hearing impairment (defined as an average
39 threshold >25dB over 500 to 4000Hz in the worse ear; Cruickshanks et al., 1998). Hearing
40 impairment is associated with reduced emotional, social and physical well-being (Mulrow et al.,
41 1990; Strawbridge et al., 2000; Arlinger, 2003; Dalton et al., 2003; Chia et al., 2007; Gopinath et
42 al., 2009). Hearing impairment also may be associated with cognitive decline and dementia
43 (Peters et al., 1988; Uhlmann et al., 1989; Lindenberger & Baltes, 1994; Baltes &
44 Lindenberger, 1997; Lin et al., 2004; Gallacher et al., 2012; Lin et al., 2013; Gurgel et al., 2014;
45 Dawes et al., 2015).

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47 The primary treatment for hearing impairment is provision of hearing aids. Research from
48 observational studies, quasi-experimental studies and randomized controlled trials (RCTs)
49 reviewed below provides consistent evidence that hearing aids reduce hearing handicap. There is
50 limited and inconsistent evidence for the impact of hearing aids on a wider range of outcomes
51 including mental health, physical health, cognitive function and social engagement.

52

53 To begin with studies that utilized an observational design, the results of a large industry-
54 sponsored observational survey of people with hearing loss in the US (N=2069) concluded that
55 hearing aid users had better social engagement, mental health and physical health than non-users
56 (Kochkin & Rogin, 2000). However, hearing aid users tended to be more affluent than non-
57 users, and this potential confounder was not accounted for in the comparison. A wide range of
58 health- and quality of life-related factors are strongly associated with socio-economic status

59 (Mackenbach et al., 1997; Marmot et al., 2012), so it is difficult to know whether the apparent
60 advantage of hearing aid users is due to hearing aid use or to socio-economic differences.

61

62 Appolonio et al (1996) surveyed quality of life and mortality in Italian adults (N=1192) with and
63 without hearing and/or vision impairment. Appolonio et al compared three groups; i) no
64 functional sensory impairment, ii) corrected impairment (hearing aid and/or glasses) and iii)
65 uncorrected impairment. Sensory impairment and the effectiveness of correction were
66 determined via binocular visual acuity testing and a free-field whispered voice test. Appolonio et
67 al reported that uncorrected sensory impairment was associated with poorer social engagement
68 and poorer mental health. Quality of life outcomes were similar for the groups with no sensory
69 impairment and corrected impairment. In longitudinal analysis, uncorrected sensory impairment
70 was associated with increased 6-year mortality in men only. A difficulty with Appolonio et al's
71 study is that hearing impairment and hearing aid use were not reported separately from vision
72 impairment and glasses use, so it is difficult to know what the contribution of hearing aid use
73 was to quality of life and mortality outcomes.

74

75 In a cross-sectional analysis of data from the Baltimore Longitudinal Study of Aging, Lin et al
76 (2011) reported that more severe hearing loss (average hearing threshold across 0.5, 1, 2, and 4
77 kHz in the better ear) was associated with poorer mental status (Mini-Mental State Exam),
78 memory (Free and Cued Selective Reminding Test) and executive function (Stroop Test; Trial
79 Making B) in regression modelling that included age, sex, ethnicity, education level, diabetes,
80 smoking and hypertension. Among those with clinically significant levels of hearing loss

81 (N=142), Lin et al found that there was no difference in cognition between hearing aid users
82 (N=46) and non-users.

83
84 Chisolm et al's (2007) systematic review of the impact of hearing aids on health-related quality
85 of life identified 16 studies, including 14 studies that used a quasi-experimental design, with non-
86 random allocation to experimental and control groups or no control group. The remaining two
87 studies included in Chisolm et al's review were randomized controlled trials (mentioned in the
88 following paragraph). Chisolm et al concluded that hearing aids were associated with small
89 positive effects on general health-related quality of life measures (such as the SF-36 and EQ5D),
90 with medium to large positive effects on measures of hearing disability (such as the HHIE).

91
92 In relation to randomized controlled trials (RCTs) of the impact of hearing aids, a recent review
93 on behalf of the U.S. Preventive Services Task Force (Moyer, 2012) identified four RCT studies
94 (Mulrow, Aguilar et al., 1990; Jerger et al., 1996; Yueh et al., 2001; Tolson et al., 2002). Three
95 RCTs reported reductions in hearing handicap in the hearing aid group versus the control group
96 (Mulrow, Aguilar et al., 1990; Yueh, Souza et al., 2001; Tolson, Swan et al., 2002); no
97 significant impact of hearing aid use on hearing handicap was detected by Jerger et al (1996).

98 Limited information is available from RCTs on the effect of hearing aids on cognitive function,
99 social engagement, mental health and general health. Mulrow et al (1990) reported small
100 improvements in social engagement, mental health and cognition. No improvements in mental
101 health, social engagement or quality of life for hearing aids versus the unaided condition were
102 reported by Jerger et al (1996).

103

104 In summary, there is converging evidence from observational, quasi-experimental and RCT
105 studies that hearing aids reduce hearing handicap. There is limited and inconsistent evidence for
106 the impact of hearing aids on mental health, physical health, cognitive function and social
107 engagement. Further, all studies to date have been limited to relatively short term outcomes
108 associated with hearing aid use. One would expect that the positive impact of hearing aid use on
109 some outcome variables may only emerge after a longer time frame. For example, cognitive
110 decline in older adults is gradual and only observable over a timescale of years (Salhouse,
111 1991). Any protective effect of hearing aid use against cognitive decline may therefore only be
112 observable over a timescale of a few years. Practical and ethical constraints preclude RCT
113 studies of hearing aid use with outcomes measured over several years. An alternative is to
114 examine outcomes associated with hearing aid use in longitudinal data sets that contain outcome
115 data of interest, while controlling statistically for any potential confounders between hearing aid
116 users and non-users.

117
118 The aim of the present study was to determine the association of hearing aid use with a wide
119 range of outcome measures in hearing impaired adults controlling for demographic differences
120 between hearing aid users and non-users. Outcomes included mental health, cognitive function,
121 incident cognitive impairment, hearing handicap, social engagement, general health, and
122 mortality. Outcomes were modeled in the Epidemiology of Hearing Loss Study (EHLS), a
123 longitudinal data set with outcomes assessed with 5 years and 11 years of follow-up. The
124 hypothesis was that among hearing impaired adults, hearing aid use would be associated with
125 better outcomes.

126

127 **Method**

128 *Participants*

129 The present study involved a subsample of the Epidemiology of Hearing Loss Study (EHLS)
130 cohort. This cohort was described in detail elsewhere (Cruickshanks et al., 1998). Briefly, the
131 EHLS aimed to estimate the prevalence of hearing impairment in adults aged 48-92 years living
132 in Beaver Dam, Wisconsin. The first round of testing (pre-baseline, for the purposes of this
133 paper) took place between 1993 and 1995 and included audiometric examination and a
134 questionnaire on hearing-related medical history, potential risk factors for hearing impairment
135 and self-perceived hearing handicap. Of the 4,541 people eligible to take part, 3,753 (82.6%)
136 participated. There were 2,800 participants in the baseline examination (1998-2000), 2,395 in 5-
137 year (2003-2005), and 1,812 in 11-year (2009-2010) examinations. A subsample of EHLS
138 participants was included in the present study (N = 666) on the basis of having hearing
139 impairment but no hearing aid at pre-baseline. Among those with hearing impairment 130 were
140 excluded because they reported using hearing aids at pre-baseline. Hearing impairment was
141 defined as having an average threshold over 3 and 4 kHz greater than 40 dB HL in the better ear.
142 This corresponds to at least a moderate level of hearing loss affecting audiometric frequencies
143 important for speech perception. This level of hearing loss would be expected to result in
144 communication disability and indicates candidacy for a hearing aid, according to the WHO
145 definition of disabling hearing loss as hearing loss greater than 40dB in the better ear in adults
146 (<http://www.who.int/mediacentre/factsheets/fs300/en/>). Participants were further grouped
147 according to either having obtained hearing aids by the time of the baseline examination and who
148 reported using hearing aids at least some of the time at baseline (HA user, N = 69) or not (Non-
149 user, N = 597).

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Measurements

Measures at each time point are shown in table 2 and are described as follows. Note that not all measures were completed at every time point.

Hearing handicap. Participants completed the Hearing Handicap Inventory for the Elderly and for Adults – Screening version (HHIE-S; Ventry & Weinstein, 1983). The HHIE-S assesses the social and emotional impact of any perceived hearing impairment. Higher scores correspond to greater perceived handicap, with scores greater than 8 suggesting clinically significant levels of handicap. The HHIE-S may be completed for either aided or unaided listening.

Cognition. Participants completed the Mini Mental State Examination (MMSE; Folstein et al., 1975), a screening test to identify cognitive impairment. Other cognitive measures included the Trail Making Test (TMT; Bowie & Harvey, 2006), the Digit Symbol Substitution Test (DSST; Wechsler, 1991), Auditory Verbal Learning Test (AVLT; Schmidt, 1996), and the Verbal Fluency Test (VFT; Strauss et al., 2006). Incident cognitive impairment was identified between baseline and 11 year follow-up if a participant scored less than 24 points on the MMSE, or Alzheimer’s Disease or significant dementia was reported by the participant or by proxy report.

Physical health. Physical health was indexed by the Physical Component Score (PCS) from the SF-12 short form health survey (Ware et al., 1996). The PCS is a measure of self-perceived quality of physical health. Scores range between 0 and 100 with lower scores indicating higher levels of perceived disability. Participants also completed the Activities of Daily Living (ADL; Katz at al., 1970) and Instrumental Activities of Daily Living (IADL;

173 Lawton & Brody, 1969). The ADL and IADL are indexes of disability in relation to basic self-
174 care tasks and daily activities which are not necessary for basic self-care but are required for
175 independent living within the community, respectively. Mortality was recorded via the
176 Wisconsin Department of Health and Family Services or the National Death Index for all known
177 deaths as well as persons with whom we had lost contact.

178 *Social engagement.* A proxy measure of social engagement was taken as the average
179 number of hours per week spent in solitary activities using a computer, watching TV, or reading,
180 according to self-report.

181 *Mental health.* The Mental Component Score (MCS) from the SF-12 (Ware, Kosinski et
182 al., 1996) was used as a measure of self-perceived quality of mental health. Scores range
183 between 0 and 100 with lower scores indicating higher levels of perceived disability.

184

185 *Statistical analyses*

186 Demographic and hearing characteristics at pre-baseline and baseline were first compared for the
187 new hearing aid users group (n=69) versus the non-users (n=597) without adjustment for the
188 other covariates of age, sex and severity of hearing impairment. The chi-square test for
189 association (for sex, education and income) or the t-test for difference in means (for age and
190 severity of hearing impairment) was used to assess the significance of the group comparisons.
191 Sample sizes for the chi-square tests were adequate based on expected cell sizes for the r x c
192 categorical tables. The usual adjustment for unequal sample sizes was used for the two-sample t-
193 tests. Hearing handicap, cognition, physical health, social engagement, and mental health
194 outcomes at pre-baseline, baseline, and at 5 and 11 years after baseline were modeled with
195 analysis of covariance (ANCOVA) models comparing the new hearing aid users with the non-

196 users categorized according to use at baseline, controlling for potential confounders age, gender
197 and severity of hearing impairment (based on the average of the audiometric threshold across .5,
198 1, 2 and 4 kHz in the better ear). Any comparisons that were significant or marginally significant
199 ($p < 0.10$) were examined with additional potential confounders including cardiovascular disease,
200 total cholesterol, diabetes, current alcohol consumption, history of heavy drinking, hypertension
201 and smoking measured at baseline. Selection of potential confounders was based on associations
202 that have been previously reported between chronic disease and lifestyle factors and hearing
203 impairment (for a review, see Cruickshanks et al., 2010).

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205 A Cox proportional hazard model was used to model the cumulative incidence of cognitive
206 impairment between baseline and 11 year follow-up comparing hearing aid users with non-users,
207 controlling for potential confounders age, sex and severity of hearing impairment. Kaplan-Meier
208 survival estimates were calculated for the new hearing aid and the non-user groups for the time
209 between baseline and 11 year follow-up. Risk of death during that period for the two groups was
210 compared using Cox proportional hazards models. All analyses were performed using the SAS
211 System (SAS Institute Inc, Gary, NC).

212

213 **Results**

214 There were no significant differences between hearing aid users and non-users in any
215 demographic index (Table 1). Hearing aid users had a significantly greater level of hearing loss
216 than non-users. Based on self-report measures, all users wore their hearing aids at least some of
217 the time, 73% of hearing aid users wore their aids every day and 67% wore them more than 8
218 hours per day. The groups differed significantly with respect to hearing handicap (Table 2).

219 Hearing aid users had significantly ($p < 0.01$) higher HHIE-S scores at pre-baseline and baseline.
220 There were no significant cognition, physical or mental health group differences at baseline
221 (Table 2). At the 5 year follow-up, 137 of the original 666 participants had died, and 37 were
222 unavailable for assessment. At the 11 year follow-up, a further 167 had died, with 13 participants
223 unavailable.
224
225 (Table 1 here)
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227 At the 5 year follow-up (Table 2), as observed at baseline, unaided HHIE-S scores were
228 significantly higher in the hearing aid user group than in the non-user group ($p < 0.01$), but both
229 groups had average scores slightly higher than at baseline and were within the clinical range
230 suggesting significant hearing handicap. The mean aided HHIE-S score among the users (10.5)
231 was very close to the mean unaided HHIE-S score among the non-users (10.8). Among hearing
232 aid users, the aided HHIE-S score was statistically significantly lower than the unaided score
233 (Paired t-test for difference; $p < 0.01$, Cohen's $d = 1.4$). The mean HHIE-S score among EHLS
234 participants with normal hearing (i.e. thresholds less than 40dB HL at 3 and 4 kHz in the better
235 ear) was 3.2, statistically significantly lower than the aided HHIE-S score among hearing aid
236 users (adjusting for age and sex; $F(2,1221) = 62.3$, $p < 0.01$, Cohen's $d = 0.5$) (data not shown).
237 Hearing aids appear to reduce hearing disability among those with hearing impairment, although
238 levels of self-reported hearing disability remain higher than for those with normal hearing. There
239 were no significant differences in cognitive, physical health, social engagement, or mental health
240 scores between hearing aid status groups, adjusting for age, gender and average hearing loss. A

241 slightly higher SF-12 Physical Component Score among hearing aid users (46.0) compared to
242 non-users (42.7) was not statistically significant ($p = 0.06$).
243 (Table 2 here)

244 At 11 years post baseline, hearing aid users reported significantly higher levels of hearing
245 disability as measured by the unaided HHIE-S than non-users ($p < 0.01$). There were no
246 significant differences between hearing aid users and non-users in any of the cognitive tests. By
247 the 11 year follow-up, the rate of incident cognitive impairment was 11.1% for the hearing aid
248 users versus 15.5% for non-users. The difference was not statistically significant ($p = 0.49$).

249 Hearing aid users had a statistically significantly ($p = 0.03$) higher (better) mean SF-12 Physical
250 Component Score than non-users (46.2 vs. 41.2, respectively). There were no significant
251 differences between groups in any of the other physical or mental health measures. The
252 significant and marginally non-significant ($p < 0.10$) comparisons were re-tested with more
253 extensive adjustment for additional potential confounders (cardiovascular disease, total
254 cholesterol, diabetes, current alcohol consumption, history of heavy drinking, hypertension and
255 smoking measured at baseline). Unaided HHIE-S score remained statistically significantly
256 poorer in hearing aid users, although there were no significant differences in the remaining
257 measures of cognition, mental or physical health. By the end of the 11 year examination, 47.6%
258 of non-hearing aid users had died versus 47.8% of hearing aid users. Adjusted for age, sex and
259 severity of hearing loss, the p -value for comparing mortality among users and non-users was
260 0.18, and with further adjustment for additional covariates (cardiovascular disease, total
261 cholesterol, diabetes, current alcohol consumption, history of heavy drinking, hypertension and
262 smoking measured at baseline), $p = 0.16$.
263

264 All analyses were re-run excluding any non-HA users at baseline who subsequently began using
265 a HA (n=91) and HA users who gave up using a hearing aid (n=7) between baseline and 11-year
266 outcome assessment (Supplemental table). The results of this analysis were similar to those for
267 the whole sample. The differences in the adjusted mean Physical Component Score between HA
268 users and non-users were very close in the two samples (whole sample = 5.0; sub-sample = 4.6).
269 However, because of the appreciable reduction in sample size in the sub-sample, the difference
270 was now marginally significant ($p = 0.07$). In the sub-sample, the HA users had a significantly
271 lower adjusted mean number of limitations on ADL than non-users (HA users = 0.2; non-users =
272 1.0, $p = 0.04$).

273 **Discussion**

274 This study modeled hearing handicap, cognitive function, physical health, social engagement,
275 and mental health measures associated with hearing aid use in a longitudinal cohort. Participants
276 were all identified as having hearing impairment. Participants were grouped according to
277 whether or not a new hearing aid had been acquired in the 5 years prior to baseline and the
278 experience of these groups with respect to the outcomes were compared at the 5 year and at the
279 11 year follow-up periods. Adjustment for demographic and hearing level factors was performed.
280

281 All participants reported high levels of hearing handicap. Hearing aid users tended to report
282 higher levels of handicap, and this difference was statistically significant after controlling for
283 differences in hearing threshold. This may be because the recognition of hearing difficulties is a
284 major determinant of hearing aid uptake (Vestergaard Knudsen et al., 2010), or may be due to
285 insufficient control for differences in hearing impairment. For hearing aid users, self-reported
286 hearing handicap was significantly lower for aided than unaided listening. However, aided scores

287 still suggested clinically significant levels of hearing handicap. Aided scores were statistically
288 significantly higher than the unaided scores of those with no hearing impairment and not
289 significantly different from the unaided scores of those with hearing impairment but no hearing
290 aid. Our interpretation is that hearing aids were associated with reduced handicap, but that
291 hearing aid users were still likely to experience significant levels of handicap. This is consistent
292 with research that suggests that hearing aids reduce hearing handicap (Mulrow et al., 1990;
293 Tesch-Römer, 1997; Yueh, Souza et al., 2001; Tolson, Swan et al., 2002; Stark & Hickson,
294 2004; Chisolm et al., 2007).

295

296 There has been recent renewed interest in the link between hearing impairment and cognitive
297 decline, with some suggesting that hearing aid use may be protective against cognitive decline
298 and dementia (Lin, 2012; Dawes, Emsley et al., 2015). Previous research which assessed
299 cognitive performance as an outcome associated with HA use is inconsistent (Mulrow, Aguilar et
300 al., 1990; Tesch-Römer, 1997; Lehl et al., 2005; Van Hooren et al., 2005; Acar et al., 2011;
301 Choi et al., 2011; Lin et al., 2011), and no study that we are aware of has examined the long-term
302 protective effects of HA use against cognitive decline. In the present study, there were no
303 differences in cognitive performance or the incidence of cognitive impairment between hearing
304 aid users and non-users. This is not supportive of a robust effect of hearing aid use as being
305 protective against cognitive decline.

306

307 There were no significant differences in social engagement or perceived mental health between
308 hearing aid users and non-users. This is consistent with some previous intervention studies which
309 reported that hearing aid use was associated with a reduction in hearing handicap, but not with

310 any change in social engagement or mental health measures (Tesch-Römer, 1997; Stark &
311 Hickson, 2004). However, one previous RCT reported an improvement in social engagement and
312 a small reduction in symptoms of depression (Mulrow, Aguilar et al., 1990). Note that Mulrow et
313 al's (1990) study was with a select population (elderly white male US veterans with moderate-to-
314 severe hearing loss), and so may not be applicable to wider populations. Another study reported
315 a slight improvement in SF-36 mental health component scores in hearing aid users versus non-
316 hearing aid users over 10 years (Gopinath et al., 2012). It is difficult to interpret this finding
317 however; hearing aid use was not the primary focus of the study, and no data on the
318 demographics nor SF-36 scores for hearing aid users and non-users were reported.
319 Hearing aid users tended to score slightly better than non-users on a measure of perceived quality
320 of physical health (SF-12 Physical Component Score) in the present study. Hearing aid users
321 continued to demonstrate a higher SF-12 Physical Component Score at 5 and 11 years post-
322 baseline. Hearing aids may promote better general health, perhaps by reducing hearing handicap
323 and promoting a more active, engaged lifestyle. But there was no significant difference in
324 hearing handicap between hearing aid users with their hearing aids and non-users where this was
325 measured. There was also no significant difference on a measure of social engagement between
326 hearing aid users and non-users.

327

328 The main strength of the study is that a wide range of outcomes were examined in a population-
329 based sample 5 to 11 years post baseline. We are not aware of any study that has examined
330 outcomes over such a long duration. The impact of hearing aid use on some outcomes (for
331 example, on cognitive performance via amelioration of cognitive decline) may only be
332 observable after a period of several years. The measures used in the present study have

333 established high validity and reliability, and are widely used in epidemiological studies. A
334 battery of cognitive tests was administered in the 11 year follow-up. Self-reported usage data
335 indicated that most HA users wore their hearing aids consistently.

336

337 The present study was observational, and it was not possible to ascribe causal effects to the
338 associations that were observed. Allocation to hearing aid user and non-user groups was not
339 random, and there may be differences between groups that were either not measured or not fully
340 accounted for by statistical adjustment. The proportion of hearing aid users in the present study
341 was small (10.4% at baseline), although comparable to levels that have been reported nationally
342 for the US (Chien & Lin, 2012) and internationally (Shield, 2006; Dawes et al., 2014). It is
343 possible that small differences in outcome were not detectable with the statistical power of the
344 present study. In the case of the cognitive measures, for example, there was a (non-statistically
345 significant) trend for hearing aid users to score more poorly than non-users. However, the study
346 was well-powered to detect medium sized effects. If differences in outcome between hearing and
347 users and non-users do exist, they are likely to be small and may not be clinically relevant. The
348 inclusion of people who use hearing aids occasionally or for only part of the day may have
349 reduced the impact of hearing aids on the outcomes of interest. However, hours of hearing aid
350 use does not necessarily reflect hearing aid benefit (Humes, 1999; Laplante-Lévesque et al.,
351 2013). Additionally, because the present study utilized a population-based sample, the levels of
352 hearing aid use in the present study are likely to reflect the patterns of hearing aid use and the
353 associated benefits that could realistically be expected in real life. Data on the amount of self-
354 reported hearing aid use were available, but other data on factors (such as the type of hearing aid,
355 how well hearing aids were fitted to audiometrically prescribed levels of amplification, use of

356 alternative communication strategies) were not available. These factors may impact the
357 effectiveness of aural rehabilitation and impact outcomes. Not all measures were included at
358 every time point; additional measures were added to successive waves of assessment. However,
359 the study does provide the most detailed range of outcome measures at the 11-year time point,
360 which can be interpreted in respect to the baseline and pre-baseline characteristics of hearing aid
361 users and non-users. The aim of the study was to compare outcomes for those who began hearing
362 aid use between pre-baseline and baseline, compared those who did not report using hearing aids
363 at baseline. We identified that some HA users became non-users and some non-users became HA
364 users within the 11 year follow-up period. However, most participants remained either HA users
365 or non-users, and analysis of a sub-sample of consistent HA users and non-users yielded similar
366 results to those for the main sample; some positive associations between HA use were found for
367 physical health measures, but not mental health, social engagement or cognitive function.

368

369 **Conclusion**

370 Few studies have examined broader outcomes associated with hearing aid use including mental
371 health, physical health, social engagement, and cognitive function. No study to our knowledge
372 has examined long-term outcomes of hearing aid use. In the present study, there was no evidence
373 that hearing aids are effective in promoting perceived mental health, cognitive function, or social
374 engagement in the long term. However, hearing aids may be effective in reducing hearing
375 handicap, and may promote better perceived quality of physical health.

376

377 Ethical and practical constraints preclude randomized controlled trials of the impact of hearing
378 aid use among people with hearing impairment that utilize the long study durations that would be

379 required to observe effects on some outcomes (such as on cognitive decline). It would not be
380 ethical to randomize someone with hearing impairment to a ‘no hearing aid’ condition for a
381 study that would run for several years. An alternative approach is to investigate differences in
382 long-term outcomes in a similar manner to the present study, i.e. by comparing outcomes in
383 hearing aid users versus non-users while controlling statistically for potential confounders.
384 Future studies could examine outcomes in existing longitudinal data sets, or follow people with
385 hearing loss prospectively. Future studies could improve on the present one by investigating
386 factors that may impact on the effectiveness of aural rehabilitation, such as the goodness of
387 hearing aid fit to audiometrically prescribed levels of amplification, the degree of improvement
388 in audibility with hearing aid use, the type of hearing aid, patterns of hearing aid use, use of
389 alternative communication strategies and audiological support.

390

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394

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401

402 **References**

- 403 Acar B., Yurekli M.F., Babademez M.A., Karabulut H. & Karasen R.M. 2011. Effects of hearing
 404 aids on cognitive functions and depressive signs in elderly people. *Archives of*
 405 *Gerontology and Geriatrics*, 52, 250-252.
- 406 Arlinger S. 2003. Negative consequences of uncorrected hearing loss-a review. *International*
 407 *Journal of Audiology*, 42, 2S17-12S20.
- 408 Baltes P.B. & Lindenberger U. 1997. Emergence of a powerful connection between sensory and
 409 cognitive functions across the adult life span: a new window to the study of cognitive
 410 aging? *Psychology and aging*, 12, 12-21.
- 411 Bowie C.R. & Harvey P.D. 2006. Administration and interpretation of the Trail Making Test.
 412 *Nature Protocols*, 1, 2277-2281.
- 413 Chia E.M., Wang J.J., Rochtchina E., Cumming R.R., Newall P., et al. 2007. Hearing
 414 impairment and health-related quality of life: The Blue Mountains hearing study. *Ear &*
 415 *Hearing*, 28, 187-195.
- 416 Chien W. & Lin F.R. 2012. Prevalence of hearing aid use among older adults in the United
 417 States. *Archives of internal medicine*, 172, 292-293.
- 418 Chisolm T., Hnath T., Johnson C.E., Danhauer J.L., Portz L.J.P., et al. 2007. A systematic
 419 review of health-related quality of life and hearing aids: Final report of the American
 420 Academy of Audiology task force on the health-related quality of life benefits of
 421 amplification in adults. *Journal of the American Academy of Audiology*, 18, 151-183.
- 422 Choi A.Y., Shim H.J., Lee S.H., Yoon S.W. & Joo E.J. 2011. Is cognitive function in adults with
 423 hearing impairment improved by the use of hearing aids? *Clinical Journal of*
 424 *Experimental Otorhinolaryngology*, 4, 72-76.
- 425 Cruickshanks K.J., Wiley T.L., Tweed T.S., Klein B.E.K., Klein R., et al. 1998. Prevalence of
 426 Hearing Loss in Older Adults in Beaver Dam, Wisconsin The Epidemiology of Hearing
 427 Loss Study. *American Journal of Epidemiology*, 148, 879-886.
- 428 Cruickshanks K.J., Zhan W. & Zhong W. 2010. Epidemiology of age-related hearing
 429 impairment. *The Aging Auditory System*, 259-274.
- 430 Dalton D.S., Cruickshanks K.J., Klein B.E.K., Klein R., Wiley T.L., et al. 2003. The impact of
 431 hearing loss on quality of life in older adults. *The Gerontologist*, 43, 661-668.
- 432 Dawes P., Emsley R., Moore D., Cruickshanks K.J., Fortnum H., et al. 2015. Hearing loss and
 433 cognition: the role of hearing aids, social isolation and depression. *PLOS One*.
- 434 Dawes P., Fortnum H., Moore D.R., Emsley R., Norman P., et al. 2014. Hearing in middle age: a
 435 population snapshot of 40-69 year olds in the UK. *Ear and hearing*, 35.
- 436 Folstein M.F., Folstein S.E. & McHugh P.R. 1975. "Mini-mental state": a practical method for
 437 grading the cognitive state of patients for the clinician. *Journal of psychiatric research*,
 438 12, 189-198.
- 439 Gallacher J., Ilubaera V., Ben-Shlomo Y., Bayer A., Fish M., et al. 2012. Auditory threshold,
 440 phonologic demand, and incident dementia. *Neurology*, 79, 1583-1590.
- 441 Gopinath B., Schneider J., Hickson L., McMahon C.M., Burlutsky G., et al. 2012. Hearing
 442 handicap, rather than measured hearing impairment, predicts poorer quality of life over
 443 10 years in older adults. *Maturitas*, 72, 146-151.
- 444 Gopinath B., Wang J.J., Schneider J., Burlutsky G., Snowdon J., et al. 2009. Depressive
 445 symptoms in older adults with hearing impairments: the Blue Mountains Study. *Journal*
 446 *of the American Geriatrics Society*, 57, 1306-1308.

- 447 Gurgel R.K., Ward P.D., Schwartz S., Norton M.C., Foster N.L., et al. 2014. Relationship of
448 Hearing Loss and Dementia: A Prospective, Population-Based Study. *Otology &*
449 *Neurotology*, 35, 775-781.
- 450 Humes L.E. 1999. Dimensions of hearing aid outcome. *Journal of the American Academy of*
451 *Audiology*, 10, 26-39.
- 452 Jerger J., Chmiel R., Florin E., Pirozzolo F. & Wilson N. 1996. Comparison of conventional
453 amplification and an assistive listening device in elderly persons. *Ear and hearing*, 17,
454 490-504.
- 455 Katz S., Downs T.D., Cash H.R. & Grotz R.C. 1970. Progress in the development of the index of
456 ADL. *Gerontologist*, 10, 20-30.
- 457 Kochkin S. & Rogin C. 2000. Quantifying the obvious: The impact of hearing instruments on
458 quality of life. *Hear Rev*, 7, 6-34.
- 459 Laplante-Lévesque A., Jensen L.D., Dawes P. & Nielsen C. 2013. Optimal Hearing Aid Use:
460 Focus Groups With Hearing Aid Clients and Audiologists. *Ear & Hearing*, 34, 193-202.
- 461 Lawton M.P. & Brody E.M. 1969. Assessment of older people: self-maintaining and
462 instrumental activities of daily living. *Gerontologist*, 9, 179-186.
- 463 Lehl S., Funk R. & Seifert K. 2005. The first hearing aid increases mental capacity. Open
464 controlled clinical trial as a pilot study. *HNO*, 53, 852-862.
- 465 Lin F.R. 2012. Hearing loss in older adults. Who's listening? *JAMA*, 307, 1147-1148.
- 466 Lin F.R., Ferrucci L., Metter E.J., An Y., Zonderman A.B., et al. 2011. Hearing loss and
467 cognition in the Baltimore Longitudinal Study of Aging. *Neuropsychology*, 25, 763.
- 468 Lin F.R., Yaffe K., Xia J., Xue Q., Harris T.B., et al. 2013. Hearing loss and cognitive decline in
469 older adults. *JAMA internal medicine*, 173, 293-299.
- 470 Lin M.Y., Gutierrez P.R., Stone K.L., Yaffe K., Ensrud K.E., et al. 2004. Vision impairment and
471 combined vision and hearing impairment predict cognitive and functional decline in older
472 women. *Journal of the American Geriatrics Society*, 52, 1996-2002.
- 473 Lindenberger U. & Baltes P.B. 1994. Sensory functioning and intelligence in old age: a strong
474 connection. *Psychology and aging*, 9, 339.
- 475 Mackenbach J.P., Kunst A.E., Cavelaars A.E., Groenhouf F., Geurts J.J., et al. 1997.
476 Socioeconomic inequalities in morbidity and mortality in western Europe. *The lancet*,
477 349, 1655-1659.
- 478 Marmot M., Allen J., Bell R., Bloomer E. & Goldblatt P. 2012. WHO European review of social
479 determinants of health and the health divide. *The Lancet*, 380, 1011-1029.
- 480 Moyer V.A. 2012. Screening for Hearing Loss in Older Adults: US Preventive Services Task
481 Force Recommendation Statement. *Annals of internal medicine*, 157, 655-661.
- 482 Mulrow C.D., Aguilar C., Endicott J.E., Tuley M.R., Velez R., et al. 1990. Quality-of-life
483 changes and hearing impairment. A randomized trial. *Annals of Internal Medicine*, 113,
484 188-194.
- 485 Mulrow C.D., Aguilar C., Endicott J.E., Velez R., Tuley M.R., et al. 1990. Association between
486 hearing impairment and the quality of life of elderly individuals. *Journal of the American*
487 *Geriatrics Society*, 38, 45.
- 488 Peters C.A., Potter J.F. & Scholer S.G. 1988. Hearing impairment as a predictor of cognitive
489 decline in dementia. *Journal of the American Geriatrics Society*, 36, 981-986.
- 490 Salthouse T.A. 1991. *Theoretical perspectives on cognitive aging*. Hillsdale, NJ: Lawrence
491 Erlbaum Associates.

- 492 Schmidt M. 1996. *Key auditory verbal learning test: a handbook*: Western Psychological
493 Services Los Angeles.
- 494 Shield B. 2006. Evaluation of the social and economic costs of hearing impairment. Belgium:
495 hear-it AISBL.
- 496 Stark P. & Hickson L. 2004. Outcomes of hearing aid fitting for older people with hearing
497 impairment and their significant others. *International Journal of Audiology*, 43, 390-398.
- 498 Strauss E., Sherman E.M.S. & Spreen O. 2006. *A Compendium of Neuropsychological Tests:*
499 *Administration, Norms, and Commentary*. New York, N.Y.: Oxford University Press.
- 500 Strawbridge W.J., Wallhagen M.I., Shema S.J. & Kaplan G.A. 2000. Negative Consequences of
501 Hearing Impairment in Old Age A Longitudinal Analysis. *The Gerontologist*, 40, 320-
502 326.
- 503 Tesch-Römer C. 1997. Psychological effects of hearing aid use in older adults. *The Journals of*
504 *Gerontology Series B: Psychological Sciences and Social Sciences*, 52, P127-P138.
- 505 Tolson D., Swan I. & Knussen C. 2002. Hearing disability: a source of distress for older people
506 and carers. *British journal of nursing*, 11, 1021-1025.
- 507 Uhlmann R.F., Larson E.B., Rees T.S., Koepsell T.D. & Duckert L.G. 1989. Relationship of
508 hearing impairment to dementia and cognitive dysfunction in older adults. *JAMA*, 261,
509 1916-1919.
- 510 Van Hooren S.A.H., Anteunis L.J.C., Valentijn S.A.M., Bosma H., Ponds R., et al. 2005. Does
511 cognitive function in older adults with hearing impairment improve by hearing aid use?
512 *International journal of audiology*, 44, 265-271.
- 513 Ventry I.M. & Weinstein B.E. 1983. Identification of elderly people with hearing problems.
514 *Asha*, July, 37-43.
- 515 Vestergaard Knudsen L., Oberg M., Nielsen C., Naylor G. & Kramer S.E. 2010. Factors
516 influences help seeking, hearing aid uptake, hearing aid use and satisfaction with hearing
517 aids: A review of the literature. *Trends in Amplification*, 14, 127-154.
- 518 Ware J.E., Kosinski M. & Keller S.D. 1996. A 12-Item Short-Form Health Survey: construction
519 of scales and preliminary tests of reliability and validity. *Medical care*, 34, 220-233.
- 520 Wechsler D. 1991. *WAIS-R Wechsler adult intelligence scale-III*. . New York, N.Y.:
521 Psychological Corporation.
- 522 Yueh B., Souza P.E., McDowell J.A., Collins M.P., Loovis C.F., et al. 2001. Randomized trial of
523 amplification strategies. *Archives of Otolaryngology - Head & Neck Surgery*, 127, 1197.

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532 Table 1. Demographic and hearing characteristics of hearing aid users and non-users at baseline

Characteristic	Hearing aid users (n=69)	Non-users (n=597)	P-value ^b
<u>Demographics</u>			
Age (yrs) (SD)	69.5 (9.8)	68.0 (9.7)	.20
Male gender (%)	68.1	74.4	.26
<u>Education (%)</u>			
0-11 yrs	36.2	30.8	.71
12 yrs	44.9	46.2	
13-15 yrs	11.6	12.1	
16+ yrs	7.3	10.9	
<u>Household income (%)</u>			
< \$10,000	5.2	11.3	.32
\$10,000-19,999	24.1	28.1	
\$20,000-29,999	29.3	20.0	
\$30,000-44,999	25.9	22.9	
\$45,000+	15.5	17.8	
Caucasian (%)	100.0	99.2	-
<u>Hearing</u>			
Pure tone average ^a (SD)	38.9 (10.5)	29.8 (9.0)	< .0001

533 ^aAverage of hearing thresholds at .5, 1, 2 and 4 kHz in the better ear, in dB HL.534 ^bP-values are from the chi-square test for association (categorical comparisons), or t-test for difference in means.

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Table 2. Communication, cognition, and health characteristics of hearing aid users and non-users at pre-baseline, baseline, 5 years and 11 years.

Characteristic	Pre-baseline ^a			Baseline ^a			5 year outcomes ^a			11 year outcomes ^a		
	Hearing aid users (n=69)	Non-users (n=597)	P-value ^b	Hearing aid users (n=69)	Non-users (n=597)	P-value ^b	Hearing aid users (n=50)	Non-users (n=440)	P-value ^b	Hearing aid users (n=31)	Non-users (n=271)	P-value ^b
Communication												
Hearing handicap (HHIE-S) score, with hearing aid	-	-	-	10.2 (1.3)	-	-	10.5 (1.5)	-	-	-	-	-
Hearing handicap (HHIE-S) score, without hearing aid	11.9 (0.9)	6.8 (0.3)	<.0001	19.8 (1.0)	8.3 (0.3)	<.0001	21.2 (1.4)	10.8 (0.4)	<.0001	22.6 (1.9)	12.4 (0.6)	<.0001
Cognition												
MMSE score	-	-	-	26.7 (0.4)	26.5 (0.1)	.62	26.8 (0.4)	26.9 (0.1)	.77	25.9 (0.5)	26.9 (0.2)	.10
Trail-making test A score (sec)	-	-	-	-	-	-	-	-	-	65.0 (7.8)	57.5 (2.4)	.37
Trail-making test B score (sec)	-	-	-	-	-	-	-	-	-	147.5 (14.4)	148.3 (4.4)	.96
AVLT score (0-15)	-	-	-	-	-	-	-	-	-	3.2 (0.5)	4.1 (0.1)	.09
DSST score (0-93)	-	-	-	-	-	-	-	-	-	34.0 (2.1)	35.3 (0.7)	.59
VFT score	-	-	-	-	-	-	-	-	-	26.2 (2.3)	29.2 (0.7)	.21
Physical health												
SF-12 HRQOL survey- Physical Component Score	-	-	-	46.1 (1.2)	44.5 (0.4)	.24	46.0 (1.6)	42.7 (0.5)	.06	46.2 (2.1)	41.2 (0.7)	.03
# limitations on ADL	-	-	-	0.3 (0.1)	0.5 (0.0)	.12	0.7 (0.2)	1.0 (0.1)	.26	0.7 (0.3)	1.0 (0.1)	.39
# limitations on IADL	-	-	-	1.4 (0.2)	1.3 (0.1)	.67	1.9 (0.4)	2.1 (0.1)	.68	2.5 (0.6)	2.4 (0.2)	.74
Social engagement												
TV/computer/reading (hrs/wk)	-	-	-	-	-	-	37.9 (2.9)	35.6 (0.9)	.45	-	-	-
Mental health												
SF-12 HRQOL survey- Mental Component Score	-	-	-	53.6 (0.9)	54.3 (0.3)	.50	54.7 (1.1)	55.2 (0.4)	.68	56.7 (1.5)	54.7 (0.5)	.19

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537 ^aMeans and standard errors (SE) are adjusted for age, gender, and PTA_{0.5,1,2,4} kHz, better ear538 ^bP-values are from ANCOVA models adjusted for age, gender, and PTA_{0.5,1,2,4} kHz, better ear

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Characteristic	5 year outcomes			11 year outcomes		
	least squares mean		P-value ^a	least squares mean		P-value ^a
	Hearing aid users (n=26)	Non-users (n=200)		Hearing aid users (n=26)	Non-users (n=200)	
<u>Communication</u>						
Hearing handicap (HHIE-S) score, without hearing aid	26.0	8.6	< .0001	23.9	10.2	< .0001
<u>Cognition</u>						
MMSE score	27.7	27.5	.68	26.7	27.0	.70
Trail-making test A score (sec)	-	-	-	55.1	56.4	.87
Trail-making test B score (sec)	-	-	-	143.9	150.0	.71
AVLT score (0-15)	-	-	-	3.4	4.0	.23
DSST score (0-93)	-	-	-	36.2	34.6	.50
VFT score	-	-	-	26.4	28.8	.38
<u>Physical health</u>						
SF-12 HRQOL survey- Physical Component Score	47.8	43.6	.09	46.2	41.6	.07
# limitations on ADL	0.5	0.4	.72	0.2	1.0	.04
# limitations on IADL	1.1	1.1	.98	1.7	2.2	.40
<u>Social engagement</u>						
TV/computer/reading (hrs/wk)	39.2	34.8	.27			-
<u>Mental health</u>						
SF-12 HRQOL survey- Mental Component Score	54.5	57.1	.11	57.5	54.8	.12

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544 ^aP-values are from ANCOVA models using t-tests for least squares means adjusted for age, gender, and PTA_{0.5,1,2,4}
 545 kHz, better ear

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547 Includes only those consistently using or consistently not using hearing aids from EHLS2 through EHLS4.

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