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Listen Carefully protocol: an exploratory case–control study of the association between listening effort and cognitive function

Alix Feldman ,[1] François Patou,[1,2] Monika Baumann,[3] Anders Stockmarr,[4] Gunhild Waldemar,[5,6] Anja M Maier,[1,7] Asmus Vogel[5,8]

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ABSTRACT

Introduction A growing body of evidence suggests that hearing loss is a significant and potentially modifiable risk factor for cognitive impairment. Although the mechanisms underlying the associations between cognitive decline and hearing loss are unclear, listening effort has been posited as one of the mechanisms involved with cognitive decline in older age. To date, there has been a lack of research investigating this association, particularly among adults with mild cognitive impairment (MCI).

Methods and analysis 15–25 cognitively healthy participants and 15–25 patients with MCI (age 40–85 years) will be recruited to participate in an exploratory study investigating the association between cognitive functioning and listening effort. Both behavioural and objective measures of listening effort will be investigated. The sentence-final word identification and recall (SWIR) test will be administered with single talker non-intelligible speech background noise while monitoring pupil dilation. Evaluation of cognitive function will be carried out in a clinical setting using a battery of neuropsychological tests. This study is considered exploratory and proof of concept, with information taken to help decide the validity of larger-scale trials.

Ethics and dissemination Written approval exemption was obtained by the Scientific Ethics Committee in the central region of Denmark (De Videnskabsetiske Komiteer i Region Hovedstaden), reference 19042404, and the project is registered pre-results at clinicaltrials.gov, reference NCT04593290, Protocol ID 19042404. Study results will be disseminated in peer-reviewed journals and conferences.

Strength and limitations of this study

- This exploratory proof-of-concept study will be the first to examine both behavioural and objective measures of listening effort and cognitive function in participants with and without cognitive dysfunction.
- This is the first study to integrate pupillometry, an objective measure of listening effort, into a cognitive care setting.
- With the inclusion of patients with mild cognitive impairment, we are able to investigate the cognitive processes underlying a patient group who are at a higher risk for further cognitive decline yet have preserved function in daily activities.
- Given the high prevalence of hearing loss among an older age group, the number of eligible participants may be limited.

INTRODUCTION

Research suggests an association between hearing loss and cognitive decline, with even mild levels of hearing loss being associated with the long-term risk of cognitive decline and dementia.[1–3] A seminal report in *The Lancet* has also suggested that hearing loss is one of the most prominent modifiable risk factors for dementia in mid-to-late stages of life.[3 4] Age-related hearing loss is also a marker for frailty in older age.[5–7] Despite increasing awareness of the links between sensory and cognitive deterioration as well as increasing research in the fields of hearing loss and cognitive decline, little is known about the mechanisms linking hearing loss to cognitive decline or whether any of these mechanisms may account for some of the cognitive challenges observed in individuals with mild cognitive impairment (MCI).[8 9] Beyond audiometric variations in hearing, research increasingly shows that cognitive factors such as attention and memory also play an important role in speech understanding.[10–12] Even if individuals achieve the same level of speech intelligibility, they may disproportionately distribute cognitive resources to do so.

One possible pathway involves listening effort, defined by McGarrigle *et al.*[13] and the British Society of Audiology as 'the mental exertion required to attend and understand an auditory message' (p. 2). Speech understanding depends on phonological and semantic factors which are reliant on working memory capacity.[14–16] When the speech input does not easily match an individual's

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Correspondence to
Alix Feldman; afeld@dtu.dk

phonological representation, explicit and deliberate working memory processes are engaged. When the signal is distorted or presented alongside increased noise, for example, increased capacity is required to reach understanding. As the signal is maintained in working memory, fewer cognitive resources remain for retention.

In the framework for understanding effortful listening, listening effort is separated from pure intelligibility and is described as a deliberate allocation of mental resources. This dimension varies over time as a function of an individual's capacity to meet the demand and their motivational arousal.[17 18] Described as intentional attentional engagement, the motivation dimension reflects the individual assessment of arousal and fatigue on the valuation of the task in relation to the expenditure of available resources. In Strauss and Francis' taxonomic model of attention in effortful listening, sensory processing relies on the interaction between externally directed perceptual attention and internally directed central attention that employs executive functions such as working memory.[12]

Listening effort has also been explained alongside the notion of cognitive compensation, where a decline in sensory processing occurs alongside an increase in the recruitment and use of other cognitive areas.[17 19 20] The decline requires an increased reliance top-down mechanisms and is supported by neuroimaging research that demonstrates the association between patterns of over-activation and age-equivalent performance. Over time, these compensatory effects decrease and may no longer able to offset the further deterioration of cognitive function. This not only increases fatigue but also decreases the amount of resources available to meet the demands of a given task.[5 21–24]

Previous research investigating hearing and cognition have primarily demonstrated associations with processing speed, executive function and memory.[2 25 26] Speech perception, particularly in noisy environments, requires processes such as inhibitory control, attention and working memory.[17] The assessment of hearing loss has traditionally focused on pure tone and speech audiometry as measurements of speech and sound recognition at standardised thresholds. However, the effort exerted or the fatigue experienced in complex listening situations—a common patient complaint within audiology—is not assessed.[17]

Jayakody *et al*.[27] found that older adults with moderately severe hearing loss performed significantly worse on non-verbal tests of spatial working memory, episodic visuospatial memory, learning and association ability and psychological function than did older adults with normal hearing. A recent meta-analysis and systematic review demonstrated that a combined cognitive and auditory training approach was most optimal for improving cognition among adults with hearing loss.[28] Although no causal links have been established, research has also found that hearing rehabilitation in the form of hearing aid use is associated with improved cognition and a delayed dementia diagnosis.[29–31]

MCI generally refers to a stage of cognitive dysfunction that lies between normal cognitive function and dementia. Those with MCI have preserved function in daily activities; however, they may have minor impairment in complex instrumental functions and all score below normative levels on objective cognitive tasks. Those with MCI are also at higher risk for further cognitive decline and the later onset of dementia. For those with MCI who are later diagnosed with dementia, functions such as memory, attention, perceptual speed and executive functioning are further impaired.[32]

In this study, we investigate the association between listening effort and cognitive functioning among older adults without cognitive dysfunction and with MCI—all without significant levels of hearing loss. A significant association between listening effort and cognitive function may act as an entry point for future research into listening effort and cognitive decline. The insights gained from our current research are aimed at assessing a population at risk for cognitive decline—particularly those who have begun to experience increased listening effort without clear signs of peripheral hearing loss. This study is the first to examine both behavioural and objective measures of listening effort and cognitive function in participants with and without cognitive dysfunction.

Research questions

Overall research question

The aim of this study is to investigate the association between cognitive functioning and listening effort among older healthy adults and in older memory clinic patients with MCI.

Secondary research question

This study also aims to determine whether there is a significant difference in listening effort between older healthy adults and MCI patients.

METHODS AND ANALYSIS

Research design

This is an exploratory proof-of-concept study with a case (MCI) and control group (cognitively healthy), where we will investigate the associations between listening effort and cognitive function.

Study procedures

Study sample

We will recruit 30–50 participants over a one-year interval. As we are investigating a potential factor in early stages of cognitive decline, potentially occurring in mid-stages of life, a wide age range is used (40–85 years) to ensure external validity for participants both with and without cognitive dysfunction. Half of these participants (n=15–25) will be individuals who have been diagnosed with MCI (see table 1). They will be recruited at the Danish Dementia Research Centre, Rigshospitalet, Denmark and will be diagnosed by a multidisciplinary team after

Table 1 Inclusion/exclusion criteria

	MCI participants	Cognitively healthy participants
Inclusion criteria	▶ MCI diagnosis, according to recommendations in Winblad *et al.*[32]: – Not normal, not fulfilling diagnostic criteria for dementia. – Functional activities are mainly preserved. – Evidence of cognitive decline, measured by self-report in conjunction with deficits on objective cognitive tasks, operationalised as test scores below −1.5 SD below age and education adjusted normative data. ▶ 40–85 years old. ▶ Mini Mental State Examination score≤26. ▶ Clinical Dementia Rating global score=0.5. ▶ No other significant neurological or psychiatric disease. ▶ Normal hearing, defined as a pure tone threshold of ≤20 dB 250 Hz–1 kHz; ≤25 dB between 2 and 3 kHz; ≤30 dB at 4 kHz (one 5 dB increase in one ear, one frequency is accepted). ▶ Danish as native language. ▶ Has live-in informant.	▶ 40–85 years old. ▶ Mini Mental State Examination score≥26. ▶ Clinical Dementia Rating global score=0. ▶ No significant neurological or psychiatric disease. ▶ Normal hearing, defined as a pure tone threshold of ≤20 dB 250 Hz–1 kHz; ≤25 dB between 2 and 3 kHz; ≤30 at 4 kHz (one 5 dB increase in one ear, one frequency is accepted). ▶ Danish as a native language.
Exclusion criteria (all)	▶ Medication or treatment that could impact the pupillary dilation: eye drops (eg, atropine or phenylephrine). ▶ Medication that could impact cognitive function. ▶ Alcohol or drug abuse. ▶ Unable to comply with study procedures.	

MCI, mild cognitive impairment.

comprehensive diagnostic work-up including neurological examination, blood tests, neuropsychological assessment and structural imaging (MRI) and in most cases functional imaging using fluorodeoxyglucose positron emission tomography (FDG-PET) and lumbar puncture. The control group of participants (n=15–25) will be cognitively healthy individuals, recruited via advertisements in local newspapers, community centres in and around Copenhagen and a website for recruiting research participants in Denmark (forsoegsperson.dk). Table 1 shows the inclusion and exclusion criteria for MCI and cognitively healthy participants. All participants will undergo both listening effort testing, coupled with pupillometry, and cognitive performance testing, based on a battery of neuropsychological tests (see table 2).

Eligibility

Pure-tone audiometry

During screening, hearing will be assessed using pure-tone audiometry, a pure-tone air conduction audiometric test method that matches the International Standards Organization (ISO) 8253-1:2010 guidelines.[33] This measure involves the peripheral and central auditory systems, identifying the hearing threshold levels of an individual and providing a basis for traditional hearing loss diagnosis and management. Otoscopy will also be used to examine the ear canal for impacted cerumen. We define normal hearing based on the World Health Organization (WHO) hearing impairment grading system and have adapted thresholds above 25 dB at 4 kHz to account for the average hearing levels for men and women in older age groups, as described by ISO-7029.[34 35]

Mini Mental Status Examination

The Mini Mental State Examination includes tests of orientation, attention, memory, language and visual-spatial skills. It is a widely used test of cognitive dysfunction.[36 37]

Clinical Dementia Rating

The Clinical Dementia Rating is a five-point scale used to assess cognitive function through a semistructured

Table 2 Tests used to measure cognitive function

Test	Cognitive abilities measured
Stroop Test[40]	Processing speed, selective attention, automaticity and inhibition
Trail Making Test[61]	Visual search speed, scanning, speed of processing and mental flexibility
Symbol-Digit Modalities Test[41 62]	Attention, processing speed, oculomotor scanning, working memory, motor persistence and visuomotor coordination
Verbal fluency tests (category, lexical)	Language representations of semantic concepts, central executive component of working memory and mental speed
Rey Complex Figure Test[43]	Visuospatial abilities, non-verbal memory and planning
Logical Memory Test (part A)[44]	Narrative episodic verbal memory, delayed recall and verbal recognition

interview with both the patient and a reliable informant, such as a family member. This 0–3 scale covers six domains: memory, orientation, judgement and problem-solving, community affairs, home and hobbies and personal care.[38 39]

Measures

Cognitive function

Assessment scores for cognitive function will be recorded in a clinical setting and will be based on a battery of neuropsychological tests (see table 2).

The Stroop Test is a demonstration of cognitive interference where a delay in the reaction time of a task occurs due to a mismatch in stimuli. A 40-item version will be applied, which will assess processing speed, selective attention and automaticity.[40]

The Trail Making Test (part A and B) measures visual attention and task switching. It consists of two parts, whereby the subject is instructed to connect a set of 25 numbers and number/letters as quickly as possible while still maintaining accuracy.

The Symbol-Digit Modalities Test is a symbol substitution test that examines attention and speed of processing. This test requires a person to substitute geometric symbols for numbers while scanning a response key.[41]

Verbal fluency tests are widely used as measures of language and executive functions. Category fluency tasks rely on language representations of semantic concepts, whereas lexical and action word tasks rely more on the central executive component of working memory.[42]

The Rey Complex Figure Test is an assessment where examinees are asked to reproduce a line drawing, first by copying it freehand and then drawing it from recall.[43]

The Logical Memory Test is a subtest of the Wechsler Memory Scale—Third Edition, and is a standardised assessment of narrative episodic memory.[44] A short story is orally presented and the examinee is asked to recall the story verbatim (immediate recall). Approximately 20 min later, free recall of the story is again elicited (delayed recall) and recognition is also measured. Only part A is administered in this study.

Listening effort

The framework for understanding effortful listening, the ease of language understanding model and Strauss and Francis'[12] taxonomic model of attention in effortful listening outline a number of cognitive and linguistic factors that moderate both effort and performance hearing ability.[12 15 17] Beyond subjective and behavioural measures, physiological measures have the benefit of time-bound insight into cognitive load changes and resource allocation during the process of understanding.[45] They may also provide deeper insight into the neurocognitive mechanisms underlying listening effort.[12]

Pupil dilation has been shown to fluctuate with changes in cognitive task load, indicating the variation in cognitive demands and the cognitive load required to perform these tasks.[46] Dilation of the pupil is also associated with the locus coeruleus-noradrenergic system, suggesting its ability to both control the muscles of the iris and reflect wider changes in attention.[47] Pupillometry is increasingly being used as an objective indicator of effort allocation for listening, memorising and auditory conflict tasks.[45 48–50]

Pupillometry hardware and software

In this study, the participants are fitted with Pupil Labs' eye-tracking add-on for the HTC Vive virtual reality head-mounted display. To prevent floor and ceiling effects that are independent to baseline pupil size, the illumination within the display is individually adapted to the individual's pupil size midpoint prior to data collection between dim (~30 lux) and bright (~230 lux), with an average illuminance of 110 lux. A software suite allows the capture and postprocessing of the data feed, including pupil diameter, dilation at sentence baseline and latency between sentence onset and peak pupil diameter. The Pupil Labs software is controlled via a MATLAB interface. Participants will be instructed not to drink coffee at least 4 hours before testing and will be asked to wash off or refrain from wearing any eye makeup. Real-time monitoring of the eye during pupil measurement will occur to check for eye closures and head movements, and the CI on the Pupil Labs' software will be regularly observed. After measurement, all data will undergo a subjective quality check with a sampling rate of 60 Hz, blink span removal below 35 and above 75 ms, moving average span 0.5 s, baseline from 4.2 to 5.2 s and peak pupil diameter range from 5.2 to 8.5 s. To detect dilation speed outliers, the median absolute deviation will be used. If the ratio of missing pupil data in a list exceeds 40% after deblinking, it will be discarded from analysis.

Sentence-final word identification and recall (SWIR) test

The objective measure of listening effort, task-evoked pupil dilation, will be recorded during a SWIR test, a dual-task behavioural test used to measure the effect of listening on performance on a secondary memory task.[51 52] The test consists of a single condition of two tasks performed in a seven-sentence series. The participants are asked to report the final word after each sentence has been played (identification task) and they are encouraged to guess if they are unsure of the word. After reporting the final word of the seventh sentence, there is a 0.5 s beep tone and they are instructed to recall, in any order, all the words that they had previously reported (free recall task). The order of sentence presentation within each set is randomised between participants. Playing from a loudspeaker placed at 0° azimuth, the target speech (sentences), spoken by a male speaker, is set at 65 dB and played simultaneously with the International Speech Test Signal (ISTS) (noise), a single female talker which includes non-intelligible speech properties from American English, Arabic, Chinese, French, German and Spanish.[53] This masker signal begins 2 s before sentence onset and ends 2 s after sentence onset (see figure 1).

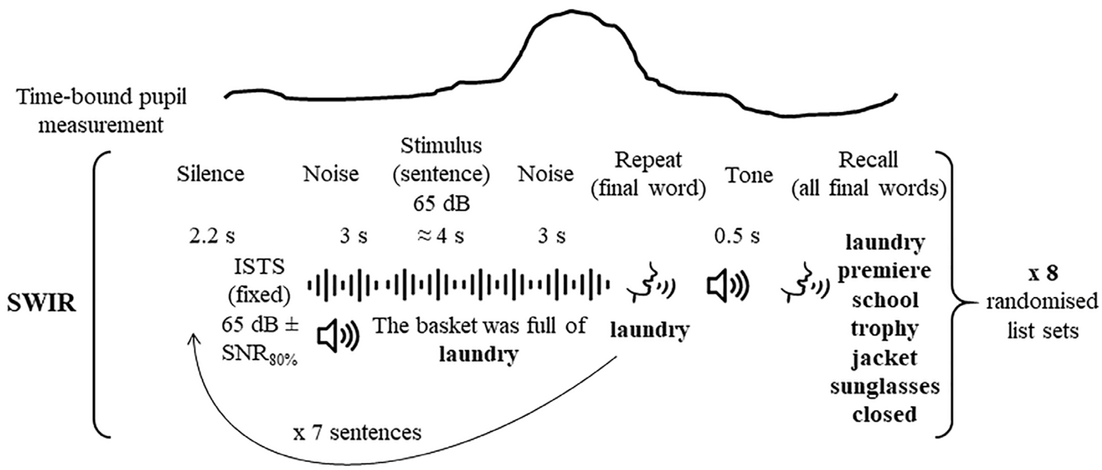

Figure 1 SWIR Test procedure. For the purpose of this figure, sentence and final word examples are translated from Danish to English. SWIR, sentence-final word identification and recall. ISTS, International Speech Test Signal. SNR, signal-to-noise ratio.

Prior to the test, participants undergo an adaptive Danish Hearing in Noise Test (HINT) to determine the appropriate level of background noise during the SWIR test.[54] The HINT contains a list of equally intelligible sentences to be repeated in varying dB levels of white noise. This results in the individual's speech reception threshold, set at 80% correct responses (see figure 2). This value is used to set the SWIR masker level either above or below the 65 dB level of the target track. Listening effort changes as a function of the signal-to-noise ratio, and is moderated by both the demands of the task and individual motivation. Previous research using the SWIR test with pupillometry has only been administered among a population without cognitive dysfunction. Based on the framework for understanding effortful listening, it is possible that fatigue, motivation and/or the evaluation of demands on available capacity may influence the allocation of effort during recall and thereby the pupil dilation response.[17] Given previous research using older adults both with and without hearing loss, we expect a speech reception threshold at 80% to load working memory without overloading its capacity, making interindividual differences in effort apparent while maintaining attentional engagement.[49 55–58]

Data analysis

Group by group comparisons will be applied to assess significant differences in listening effort and its association with cognitive function between normal cognition controls and MCI patients. To assess the presence of a significant association between cognitive functioning and listening effort, a data analysis plan will be used. The primary analysis will use three neuropsychological variables: (1) Stroop Test (time on incongruent version), (2) Symbol-Digit Modalities Test and (3) Logical Memory Test (recall score part 1). Correlation analysis with these measures and the following listening effort measures will be administered: (1) average peak pupil diameter (on a per sentence measure, across lists), (2) average peak pupil latency (on a per sentence measure, across lists) and (3) proportion of correctly recalled final words from the SWIR list (averaged across lists).

Correlation analyses (eg, Pearson correlation coefficient) will be completed for the entire participant group on all measures. If significant associations are found, further analysis will be conducted separately in the two participant groups. If significant, linear regression will be performed using the significant cognitive test scores as dependent variables and listening effort outcomes as independent variables (together with relevant covariates, eg, gender, age and case/control). If significant associations are demonstrated between the three selected neuropsychological tests and the listening effort parameters, additional cognitive measures will be included for further analysis. If no significant associations are found in the initial analysis, further analysis will not be conducted.

Collinearity is a consideration when interpreting regression analyses using the measures of cognitive function and listening effort, as the resultant CIs and SEs will be wider.[59] Moderate-to-high collinearity could influence statistical power and would preclude the assumption that listening effort predicts the score on particular measures of cognitive functioning. In this case, it is important to interpret the results of coefficient estimates in accordance with the overlap between certain cognitive measures. We have identified a subset of three neuropsychological tests for the initial analysis to limit the effect of multiplicity.

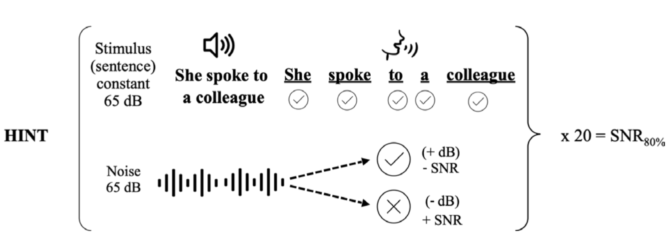

Figure 2 HINT procedure. For the purpose of this figure, the sentence example has been translated from Danish to English. HINT, Hearing in Noise Test. SNR, signal-to-noise ratio.

Table 3 Mean and SD of independent and dependent variables

Measure	μ	σ	Correlation with age
Symbol-Digit Modalities Test[40]	45.5	7.1	−0.55
Logical Memory Test[63]	15.8	4.1	−0.24
Stroop Test[40]	19.8	4.9	−0.14
Peak pupil diameter[64 65]	0.1	0.012	0.06 (not used in analysis)

Power estimation

The power is exemplified by both the difference between groups and the relationship between the subset of three neuropsychological tests and one listening effort measure, average peak pupil diameter. The formula for the estimating the relationship between the cognitive scores (Y) for the Symbol-Digit Modalities Test, Logical Memory Test and Stroop Test, age and peak pupil diameter is given by $Y=\alpha+\beta Age+\gamma PPD+\varepsilon$. The mean, SD and coefficients with age are stated in table 3.

The peak pupil diameter values for cases are estimated to be 30% higher than those for healthy participants, explained by the increase in cognitive load for patients with cognitive dysfunction. The estimated power for peak pupil diameter between groups is presented graphically in figure 3. The coefficients in the equation $Y=\alpha+\beta Age+\gamma PPD+\varepsilon$ are determined from the values in table 3 and the varying correlation between the cognitive score Y and

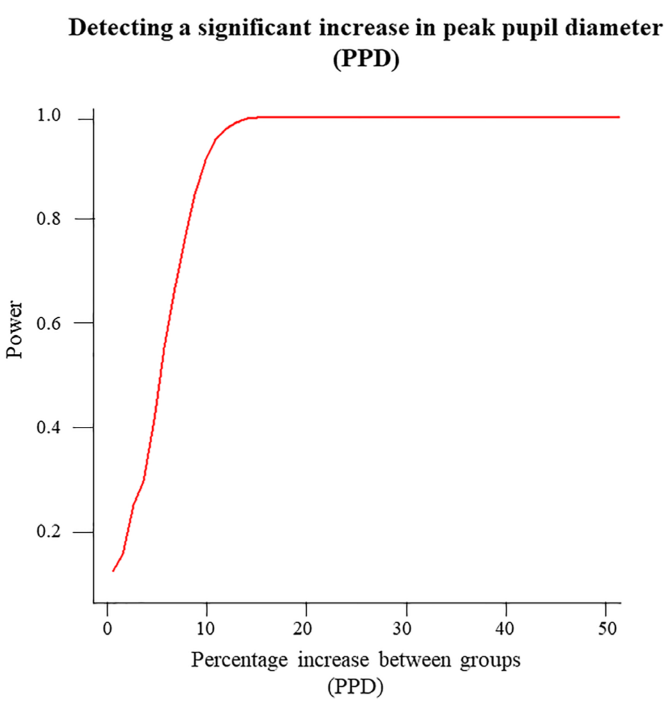

Figure 3 Power estimate for listening effort. Percentage increase in peak pupil dilation between those with and without cognitive dysfunction.

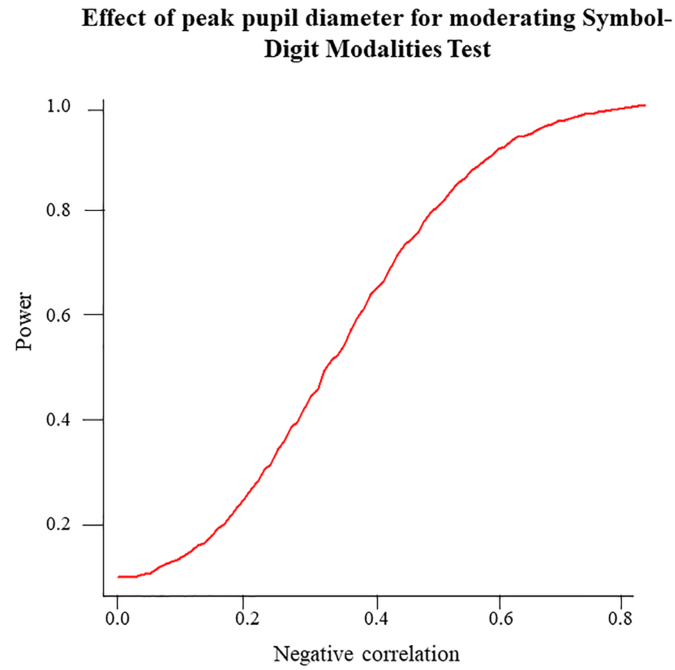

Figure 4 Power for Symbol-Digit Modalities Test. Correlation needed to detect an effect of peak pupil diameter for moderating performance.

peak pupil diameter. The β is the same for all choices of correlation with peak pupil parameter, while γ varies.

Using these coefficients, we simulated our defined sample size of 25 healthy control participants and 25 patients with cognitive dysfunction from a normal distribution and performed a linear regression on the simulated data. For each correlation between Y and peak pupil diameter and for each cognitive score Y (Symbol-Digit Modalities Test, Logical Memory Test and Stroop Test), the procedure is repeated 10 000 times. For each Y and each correlation value, the power was determined as the average frequency of statistical significance from the above procedure. The power is presented graphically, whereby power is depicted as a function of the correlation (see figures 4–6). The values of the correlations between peak pupil diameter and the cognitive test scores that may be detected with 80% and 50% statistical power are listed in table 4. Given the high negative correlation between Symbol-Digit Modalities Test and age (see table 3), we expect to see an effect on this variable with a higher power.

Participant and patient involvement

There was no direct patient or public involvement in the study design. Input and feedback from participants during the course of the study will be taken into consideration during the planning of future research. The Listen Carefully research project has been presented to potential future stakeholders within the municipality, such as those working within dementia care coordination and welfare innovation. Those who have been consulted and

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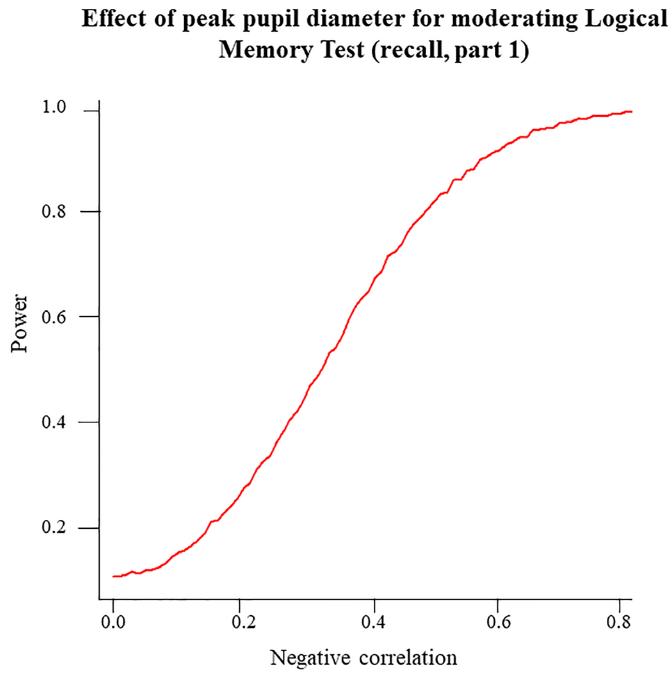

Figure 5 Power for Logical Memory Test. Correlation needed to detect an effect of peak pupil diameter for moderating performance.

collaborated with throughout the research will receive a summary of results. Patients and participants will also be provided with a summary of results upon request.

Study timeline

Recruitment for the study began in July 2020. The first participant visit took place in August 2020 and the last participant visit was December 2021.

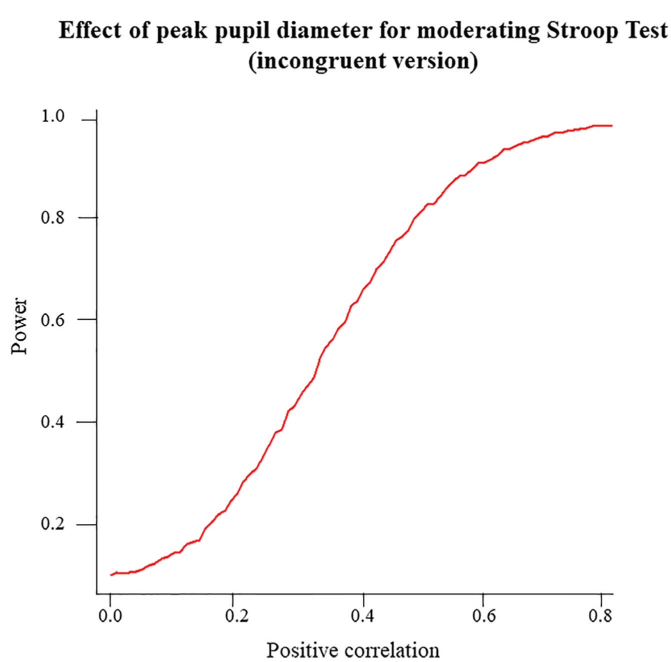

Figure 6 Power for Stroop Test. Correlation needed to detect an effect of peak pupil diameter for moderating performance.

Table 4 Correlations with peak pupil dilation estimated for statistical power

Cognitive test	80% power	50% power
Symbol-Digit Modalities Test	0.49	0.32
Logical Memory Test	0.48	0.33
Stroop Test	0.48	0.33

DISCUSSION

Despite increasing research in the fields of hearing loss and cognitive decline, little is known about the mechanisms linking hearing loss to cognitive decline and whether some of these mechanisms may account for some of the cognitive challenges observed in individuals with MCI, including those who do not demonstrate significant hearing loss. In particular, if listening effort does play a role in the association between hearing and cognitive decline, it may be reasonable to expect that individuals with MCI exhibit different patterns of listening effort in comparison to those without cognitive dysfunction. This may be particularly relevant in relation to working memory and internally directed central attention.[12] This may also aid the understanding of which cognitive factors are influenced by effortful listening. Furthermore, the sensitivity of pupillometry may allow us to assess the engagement and the experience of fatigue among a group with cognitive dysfunction when completing the dual-task behavioural SWIR test. It is expected that this study will provide valuable insights for the future use of pupillometry among those with cognitive dysfunction, and should help refine our understanding of factors that could later inform complex hearing and cognitive healthcare interventions.[60]

ETHICS AND DISSEMINATION

Access to study records will be limited to the study team, which includes the relevant researchers at the Memory Clinic in Copenhagen. This includes source documents, regulatory documents, data collection instruments and study data.

Only the investigators will have access to the data and will be responsible for data processing. This will not include the participant's contact or identifying information. Individual participants and their personal data will be identified by a unique study identification number. Only fully anonymised data will be published in reports, scientific publications or clinical study outcomes. Regardless of findings, the results of the research will be published.

Author affiliations
[1]Engineering Systems Design, Department of Technology Management and Economics, Technical University of Denmark, Kongens Lyngby, Denmark
[2]Research and Technology Group, Oticon Medical, Smørum, Denmark
[3]Centre for Applied Audiology Research, Oticon, Smørum, Denmark
[4]Statistics and Data Analysis, Department of Mathematics, Technical University of Denmark, Kongens Lyngby, Denmark
[5]Danish Dementia Research Centre, Department of Neurology, Rigshospitalet, Copenhagen, Denmark

[6]Department of Clinical Medicine, University of Copenhagen, Copenhagen, Denmark
[7]Department of Design, Manufacturing and Engineering Management, Faculty of Engineering, University of Strathclyde, Glasgow, UK
[8]Department of Psychology, University of Copenhagen, Copenhagen, Denmark

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Competing interests MB and FP are affiliated with Demant subsidiaries, of which Oticon provided audiometric testing equipment for the purposes of this study.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

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ORCID iD
Alix Feldman http://orcid.org/0000-0002-2608-560X

REFERENCES

1 Uhlmann RF, Larson EB, Rees TS, *et al*. Relationship of hearing impairment to dementia and cognitive dysfunction in older adults. *JAMA* 1989;261:1916–9.
2 Lin FR, Yaffe K, Xia J, *et al*. Hearing loss and cognitive decline in older adults. *JAMA Intern Med* 2013;173:293–9.
3 Livingston G, Huntley J, Sommerlad A, *et al*. Dementia prevention, intervention, and care: 2020 report of the Lancet Commission. *Lancet* 2020;396:413–46.
4 Livingston G, Sommerlad A, Orgeta V, *et al*. Dementia prevention, intervention, and care. *Lancet* 2017;390:2673–734.
5 Panza F, Solfrizzi V, Logroscino G. Age-Related hearing impairment-a risk factor and frailty marker for dementia and AD. *Nat Rev Neurol* 2015;11:166–75.
6 Rodríguez-Mañas L, Féart C, Mann G, *et al*. Searching for an operational definition of frailty: a Delphi method based consensus statement: the frailty operative definition-consensus conference project. *J Gerontol A Biol Sci Med Sci* 2013;68:62–7.
7 Gobbens RJJ, Luijkx KG, Wijnen-Sponselee MT, *et al*. In search of an integral conceptual definition of frailty: opinions of experts. *J Am Med Dir Assoc* 2010;11:338–43.
8 Ge S, McConnell ES, Wu B, *et al*. Longitudinal association between hearing loss, vision loss, dual sensory loss, and cognitive decline. *J Am Geriatr Soc* 2021;69:644–50.
9 Lin MY, Gutierrez PR, Stone KL, *et al*. Vision impairment and combined vision and hearing impairment predict cognitive and functional decline in older women. *J Am Geriatr Soc* 2004;52:1996–2002.
10 Peelle JE. Listening effort: how the cognitive consequences of acoustic challenge are reflected in brain and behavior. *Ear Hear* 2018;39:204–14.
11 Akeroyd MA. Are individual differences in speech reception related to individual differences in cognitive ability? A survey of twenty experimental studies with normal and hearing-impaired adults. *Int J Audiol* 2008;47 Suppl 2:S53–71.
12 Strauss DJ, Francis AL. Toward a taxonomic model of attention in effortful listening. *Cogn Affect Behav Neurosci* 2017;17:809–25.
13 McGarrigle R, Munro KJ, Dawes P, *et al*. Listening effort and fatigue: what exactly are we measuring? A British Society of Audiology Cognition in Hearing Special Interest Group 'white paper'. *Int J Audiol* 2014;53:433–45.
14 Rönnberg J. Cognition in the hearing impaired and deaf as a bridge between signal and dialogue: a framework and a model. *Int J Audiol* 2003;42 Suppl 1:68–76.
15 Rönnberg J, Lunner T, Zekveld A, *et al*. The ease of language understanding (ELU) model: theoretical, empirical, and clinical advances. *Front Syst Neurosci* 2013;7:31.
16 Rönnberg J, Holmer E, Rudner M. Cognitive hearing science and ease of language understanding. *Int J Audiol* 2019;58:247–61.
17 Pichora-Fuller MK, Kramer SE, Eckert MA, *et al*. Hearing impairment and cognitive energy: the framework for understanding effortful listening (FUEL). *Ear Hear* 2016;37 Suppl 1:5S–27.
18 Kahneman D. *Attention and effort*. Englewood Cliffs N.J.: Prentice-Hall, 1973.
19 Reuter-Lorenz PA, Cappell KA. Neurocognitive aging and the compensation hypothesis. *Curr Dir Psychol Sci* 2008;17:177–82.
20 Pichora-Fuller MK, Schneider BA, Daneman M. How young and old adults listen to and remember speech in noise. *J Acoust Soc Am* 1995;97:593–608.
21 Reuter-Lorenz PA, Lustig C. Brain aging: reorganizing discoveries about the aging mind. *Curr Opin Neurobiol* 2005;15:245–51.
22 Gregory S, Long JD, Klöppel S, *et al*. Operationalizing compensation over time in neurodegenerative disease. *Brain* 2017;140:1158–65.
23 Wayne RV, Johnsrude IS. A review of causal mechanisms underlying the link between age-related hearing loss and cognitive decline. *Ageing Res Rev* 2015;23:154–66.
24 Griffiths TD, Lad M, Kumar S, *et al*. How can hearing loss cause dementia? *Neuron* 2020;108:401–12.
25 Rönnberg J, Lunner T, Ng EHN, *et al*. Hearing impairment, cognition and speech understanding: exploratory factor analyses of a comprehensive test battery for a group of hearing aid users, the n200 study. *Int J Audiol* 2016;55:623–42.
26 Tun PA, McCoy S, Wingfield A. Aging, hearing acuity, and the attentional costs of effortful listening. *Psychol Aging* 2009;24:761–6.
27 Jayakody DMP, Friedland PL, Eikelboom RH, *et al*. A novel study on association between untreated hearing loss and cognitive functions of older adults: baseline non-verbal cognitive assessment results. *Clin Otolaryngol* 2018;43:182–91.
28 Lawrence BJ, Jayakody DMP, Henshaw H, *et al*. Auditory and cognitive training for cognition in adults with hearing loss: a systematic review and meta-analysis. *Trends Hear* 2018;22:233121651879209.
29 Dawes P, Emsley R, Cruickshanks KJ, *et al*. Hearing loss and cognition: the role of hearing AIDS, social isolation and depression. *PLoS One* 2015;10:e0119616.
30 Mahmoudi E, Basu T, Langa K, *et al*. Can hearing AIDS delay time to diagnosis of dementia, depression, or falls in older adults? *J Am Geriatr Soc* 2019;67:2362–9.
31 Maharani A, Dawes P, Nazroo J, *et al*. Longitudinal relationship between hearing aid use and cognitive function in older Americans. *J Am Geriatr Soc* 2018;66:1130–6.
32 Winblad B, Palmer K, Kivipelto M, *et al*. Mild cognitive impairment--beyond controversies, towards a consensus: report of the International Working Group on Mild Cognitive Impairment. *J Intern Med* 2004;256:240–6.
33 International Standards Organization. ISO 8253-1:2010(en), Acoustics — Audiometric test methods — Part 1: Pure-tone air and bone conduction audiometry, 2010. Available: https://www.iso.org/obp/ui/#iso:std:iso:8253:-1:ed-2:v1:en
34 Humes LE. Examining the validity of the world Health organization's long-standing hearing impairment grading system for unaided communication in age-related hearing loss. *Am J Audiol* 2019;28:810–8.
35 International Standards Organization. ISO - ISO 7029:2017 - Acoustics — Statistical distribution of hearing thresholds related to age and gender, 2017. Available: https://www.iso.org/standard/42916.html
36 Folstein MF, Folstein SE, McHugh PR. "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res* 1975;12:189–98.
37 Folstein MF, Folstein SE, McHugh PR. *Mini-Mental State Examination User's Guide*. Odessa, FL: Psychological Assessment Resources, 2001.
38 Hughes CP, Berg L, Danziger WL, *et al*. A new clinical scale for the staging of dementia. *Br J Psychiatry* 1982;140:566–72.

39 Berg L. Clinical dementia rating (CDR). *Psychopharmacol Bull* 1988;24:637–9.
40 Vogel A, Stokholm J, Jørgensen K. Performances on symbol digit modalities test, color trails test, and modified Stroop test in a healthy, elderly Danish sample. *Aging, Neuropsychol Cogn* 2013;20:370–82.
41 Smith A. *Symbol digit modalities test. manual (Revised)*. Los Angeles, CA: Western Psychological Services, 1982.
42 Birn RM, Kenworthy L, Case L, *et al*. Neural systems supporting lexical search guided by letter and semantic category cues: a self-paced overt response fMRI study of verbal fluency. *Neuroimage* 2010;49:1099–107.
43 Meyers JE, Meyers KR. *Rey complex figure test and recognition trial (RCFT)*, 2019.
44 Weschsler D. *Wechsler memory scale*. 3rd edn. San Antonio, TX: The Psychological Corporation, 1997.
45 Winn MB, Wendt D, Koelewijn T, *et al*. Best practices and advice for using pupillometry to measure listening effort: an introduction for those who want to get started. *Trends Hear* 2018;22:233121651880086.
46 Beatty J. Task-evoked pupillary responses, processing load, and the structure of processing resources. *Psychol Bull* 1982;91:276–92.
47 Laeng B, Sirois S, Gredebäck G. Pupillometry. *Perspect Psychol Sci* 2012;7:18–27.
48 Bönitz H, Lunner T, Finke M, *et al*. How do we allocate our resources when listening and memorizing speech in noise? A pupillometry study. *Ear Hear* 2021;42:846–59.
49 Koo M, Jeon J, Moon H, *et al*. Effects of noise and serial position on free recall of spoken words and pupil dilation during encoding in normal-hearing adults. *Brain Sci* 2021;11:277–14.
50 Zekveld AA, van Scheepen JAM, Versfeld NJ, *et al*. The influence of hearing loss on cognitive control in an auditory conflict task: behavioral and pupillometry findings. *J Speech Lang Hear Res* 2020;63:2483–92.
51 Ng EHN, Rudner M, Lunner T, *et al*. Relationships between self-report and cognitive measures of hearing aid outcome. *Speech Lang Hear* 2013;16:197–207.
52 Ng EHN, Rudner M, Lunner T, *et al*. Effects of noise and working memory capacity on memory processing of speech for hearing-aid users. *Int J Audiol* 2013;52:433–41.
53 Holube I, Fredelake S, Vlaming M, *et al*. Development and analysis of an international speech test signal (ISTS). *Int J Audiol* 2010;49:891–903.
54 Nielsen JB, Dau T. The Danish hearing in noise test. *Int J Audiol* 2011;50:202–8.
55 Ng EHN, Rudner M, Lunner T, *et al*. Noise reduction improves memory for target language speech in competing native but not foreign language speech. *Ear Hear* 2015;36:82–91.
56 Wendt D, Koelewijn T, Książek P, *et al*. Toward a more comprehensive understanding of the impact of masker type and signal-to-noise ratio on the pupillary response while performing a speech-in-noise test. *Hear Res* 2018;369:67–78.
57 Ohlenforst B, Zekveld AA, Lunner T, *et al*. Impact of stimulus-related factors and hearing impairment on listening effort as indicated by pupil dilation. *Hear Res* 2017;351:68–79.
58 Micula A, Rönnberg J, Fiedler L, *et al*. The effects of task difficulty predictability and noise reduction on recall performance and pupil dilation responses. *Ear Hear* 2021;42:1668–79.
59 Vanhove J. Collinearity isn't a disease that needs curing. *Meta-Psychology* 2021;5.
60 Feldman A, Patou F, Maier AM. From evidence to implementation: how systems design can foresee complex healthcare interventions. *Proceedings of the Design Society: DESIGN Conference. Cambridge University Press*, 2020.
61 Reitan R. *Manual for administration and scoring*. Tucson, AZ: Reitan Neuropsychology Laboratory, 2014.
62 Parmenter BA, Weinstock-Guttman B, Garg N, *et al*. Screening for cognitive impairment in multiple sclerosis using the symbol digit modalities test. *Mult Scler* 2007;13:52–7.
63 Vogel A, Stokholm J, Andreasen R, *et al*. Psychometric properties and reference data for Danish versions of free and cued selective reminding test, category cued memory test and logical memory. *Scand J Psychol* 2018;59:496–502.
64 Winn MB. Rapid release from listening effort resulting from semantic context, and effects of spectral degradation and cochlear implants. *Trends Hear* 2016;20:233121651666972–17.
65 Zekveld AA, Kramer SE, Festen JM. Cognitive load during speech perception in noise: the influence of age, hearing loss, and cognition on the pupil response. *Ear Hear* 2011;32:498–510.