



Development of measures to assess listening-related effort and fatigue in daily life among hearing aid users

protocol for a quantitative field trial

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Published in:
BMJ Open

Link to article, DOI:
[10.1136/bmjopen-2023-082041](https://doi.org/10.1136/bmjopen-2023-082041)

Publication date:
2024

Document Version
Publisher's PDF, also known as Version of record

[Link back to DTU Orbit](#)

Citation (APA):
Micula, A., Hoy Konvalinka Christensen, J., Wendt, D., Innes-Brown, H., Johnsrude, I., Apps, M., Dau, T., & Flensburg-Madsen, T. (2024). Development of measures to assess listening-related effort and fatigue in daily life among hearing aid users: protocol for a quantitative field trial. *BMJ Open*, *14*(12), e082041-e082041. <https://doi.org/10.1136/bmjopen-2023-082041>


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BMJ Open Development of measures to assess listening-related effort and fatigue in daily life among hearing aid users: protocol for a quantitative field trial

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To cite: Micula A, Høy Konvalinka Christensen J, Wendt D, *et al.* Development of measures to assess listening-related effort and fatigue in daily life among hearing aid users: protocol for a quantitative field trial. *BMJ Open* 2024;**14**:e082041. doi:10.1136/bmjopen-2023-082041

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<https://doi.org/10.1136/bmjopen-2023-082041>).

Received 13 November 2023
Accepted 22 November 2024



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ABSTRACT

Introduction Individuals with hearing loss and hearing aid users report higher levels of listening effort and fatigue in daily life compared with those with normal hearing. However, there is a lack of objective measures to evaluate these experiences in real-world settings. Recent studies have found that higher sound pressure levels (SPL) and lower signal-to-noise ratios (SNR) are linked to increased heart rate and decreased heart rate variability, reflecting the greater effort required to process auditory information. This study aims to establish physiological and acoustic predictors of self-reported listening effort and fatigue in daily life. Additionally, the moderating effects of cognitive abilities, personality traits, stress, fatigue, suprathreshold abilities, noise annoyance, lifestyle and health on the development of listening effort and fatigue will be investigated.

Methods and analysis A 4-week field trial will be conducted, in which physiological responses will be continuously recorded using Empatica Embrace Plus wristbands. Ambient acoustics will be captured every 20 s via the participants' (n=60) personal hearing aids, and the participants will provide self-reported momentary assessments through a mobile app throughout the day. Questionnaires will be used to assess personality traits, fatigue, stress and noise annoyance, and gather relevant background information. Cognitive and suprathreshold abilities will also be evaluated. Associations between physiological responses, ambient acoustics and momentary assessments, as well as the potential influence of participant characteristics, will be analysed using multilevel regression models and time-series analyses.

Ethics and dissemination Informed consent will be obtained from all participants. The study has been exempted from ethical application by the Science Ethics Committee for the Capital Region of Denmark (journal no. F-23028367). Results will be presented at conferences and submitted for publication in peer-reviewed journals.

INTRODUCTION

People with hearing loss and hearing aid (HA) users appear to experience more fatigue than age-matched normally hearing listeners in daily-life, most likely due to the increased

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Collection of longitudinal data, including both objective physiological responses and ambient acoustics, alongside self-reported measures.
- ⇒ Repeated-measures design within participants, generating large amounts of data.
- ⇒ Data are recorded relatively unobtrusively during the test participants' regular daily activities.
- ⇒ Potential technology bias due to recruitment being limited to participants comfortable using smartphones.
- ⇒ Variability in participant compliance with self-reported assessments.

effort that they need to invest in everyday listening situations.^{1 2} Listening effort has been defined as 'the deliberate allocation of mental resources to overcome obstacles in goal pursuit when carrying out a listening task'.³ Fatigue is a complex construct that is best defined from the perspective of the relevant discipline, but it is often described as 'a feeling/mood state or in terms of a decrement in physical or cognitive performance'.^{2 3} Another term that is encountered in the literature is sound-induced auditory fatigue, which has been defined as 'a sensation of fatigue from within the ear, with the affected individual seeking quietness after a day at work in communication-intense sound environment'.^{4 5} The authors hypothesise that this phenomenon has multiple causes besides sound and noise exposure, such as cognitive factors, mental fatigue and work-related stress.

Even though HAs have been shown to counteract increased cognitive load and listening effort investment,⁶⁻⁸ HA users still experience listening as effortful: they report feelings of mental fatigue in everyday life and might even 'zone out' of ongoing conversation because participation requires too much effort.^{9 10} It



has been argued that in noisy conditions that are characteristic of everyday life, HA users typically need to invest much higher levels of effort to understand speech than do those with normal hearing abilities. Over time, this increased effort may lead to stress and listening-related fatigue.¹¹ Hearing loss and the resulting listening effort have been linked to a higher risk for cognitive decline and dementia—the possible causes are still under investigation but may include depletion of cognitive resources that can be allocated to cognitive functions other than hearing, impoverished auditory input and underlying pathologies that are common to both hearing loss and dementia.^{12–15} Furthermore, the fatigue state may reduce HA satisfaction and usage, as well as quality of life.¹ This may lead to withdrawal from social events and eventually chronic social isolation, which is also a risk factor for dementia,¹⁶ all-cause mortality¹⁷ and chronic disease outcomes.¹⁸ At present, the progression of listening-related fatigue as it occurs in the daily-life of HA users is not well understood.

Laboratory research has successfully documented that pupillometry, heart rate, heart rate variability and electrodermal activity are physiological markers of listening effort.^{8 19–23} Although these physiological markers of listening effort have been captured in a laboratory setting, more research is needed on how to assess and measure listening effort and fatigue outside the laboratory. Several recent field studies have investigated how daily-life factors contribute to experiences of listening-related fatigue in individuals with hearing loss. Most studies rely on subjective questionnaires or ecological momentary assessments (EMAs) that are either performed at the end of the day or sparsely throughout the day.^{1 24} This work has found inconsistent evidence of daily-life listening-related fatigue. In a recent EMA study with both normal-hearing and hearing-impaired adults, the two groups did not differ in terms of self-reported listening-related fatigue over a 2-week period. However, for the hearing-impaired adults, around 60% of the EMA responses were performed in the participants' own home and 50% of them were related to non-specific listening, indicating that the EMAs did not effectively represent listening conditions typically associated with effortful listening.²⁴ At the same time, HA users report that they experience fatigue on a day-to-day basis and that it affects their well-being.^{1 25} Thus, paradoxically, although HA users report that they experience listening-related fatigue in daily life, the EMA outcomes in these studies provide little evidence for it. Additionally, it has been found that aided speech-in-noise recognition measures that are typically included in laboratory research were not able to predict data collected during real life.²⁶ Often, speech-in-noise recognition measures are administered at SNR levels that result in a speech recognition level of 50% or at negative SNR levels. These situations are rarely encountered in real life.²⁷ Furthermore, the task of repeating what was heard of a sentence does not reflect the complexities of real-life communication. These aspects highlight the importance

of developing measures that can be administered during daily life to capture listening-related fatigue in real-life settings.

A challenge related to momentary assessment is that they may be sparse, with typically only a few observations per day.²⁸ In addition, providing subjective feedback as requested at unpredictable times may be obtrusive to daily life. Furthermore, physiological or cognitive effects of fatigue that may not have reached conscious awareness are left unreported. To overcome these limitations, self-reporting of listening-related fatigue and effort can be combined with objective data, namely, automatic acoustic data logging from the listener's HAs. Data logging provides acoustic ambient data, such as SPL or SNR, as well as contextual data, such as classification of listening environments into 'speech in noise' or 'quiet', for example. According to Andersson *et al*,²⁶ combining EMA with acoustic data logging offers the possibility for more targeted evaluations of listening experiences and even HA benefit. Moreover, as mentioned above, a variety of physiological responses, including heart rate and pupil dilation, respond to stress and fatigue and might be useful for understanding daily-life listening-related fatigue in individuals with hearing loss.

Only a few studies have investigated the impact of noise and daily-life sound exposure on physiological responses during daily life. The findings demonstrated that higher SPLs were associated with increased heart rate, both in HA users²⁹ and in individuals with normal hearing.^{30 31} Importantly, Christensen *et al* found that not only sound intensity but also SNR are associated with heart rate. Higher SNR (ie, a better listening condition), was associated with lower heart rate. These findings indicate that more adverse sound conditions, which increase auditory perceptual load and listening effort,¹¹ result in higher heart rate indicative of an imbalance in autonomic nervous system activation (eg, increased sympathetic nervous system activity).³² While the cardiovascular effects of sound intensity are fairly well documented,^{32 33} Christensen *et al* were the first to draw attention to the influence of ambient signal-to-noise levels on heart rate. This is of particular interest since it reveals the potential moderating effect of listening activity. That is, noisy conditions might not necessarily cause stress if a person is not engaged in a listening activity. However, such conditions may become stressful when listening is required, while also being difficult due to the noise.³⁰ Thus, it is essential to differentiate between such situations, for which EMA and acoustic data logging are valuable tools.

Listening effort is modulated by task demands (eg, hearing difficulties and/or background noise) and available cognitive resources,^{3 22} as well as a listener's motivation to expend mental effort in challenging listening situations.³ Consequently, if the demands of a listening activity exceed the available cognitive resources, the listeners may reach the point of 'giving up', that is, abandoning the listening task.²² Importantly, the motivation factor is essential for understanding why listeners may

give up even in situations when the demands do not exceed the available cognitive resources.^{3 10} A factor that may influence this is differences in individual traits, such as personality.³⁴ Acoustic data logging and physiological responses together with EMA may reveal under which circumstances listeners give up and withdraw from a conversation or other activities that require listening.

Several individual factors, such as cognition, stress, fatigue, noise annoyance and personality traits, may influence an individual's willingness to engage in (effortful) communicative/listening situations, as well as the development of fatigue. A listener may remain engaged in a challenging listening situation as long as sufficient cognitive resources, alongside motivation, are available to meet the task demands. A depletion of cognitive resources may lead to listening-induced fatigue and thereby a loss of motivation to continue expending effort.³ Additionally, individual differences in suprathreshold abilities, such as the detection of spectrotemporal modulation, have also been shown to predict how susceptible a listener is to challenges such as background noise.³⁵ Listeners with hearing loss report employing withdrawal from or avoidance of social contexts as a common strategy to prevent fatigue and stress.¹ Furthermore, it has been shown that personality traits are associated with social engagement in older adults, with more agreeable seniors being engaged in social roles to a higher degree.³⁶ It has also been shown that extraverted and conscientious behaviours not only are linked to positive mood and lower fatigue but also lead to higher mental depletion after a 3-hour lag.³⁷ Cognitive ability has been shown to be related to various listening effort measures as well. Better cognitive ability was associated with lower listening effort, presumably due to individuals with better cognitive ability using their resources more efficiently.³⁸ Consequently, it is important to take these individual factors into account in order to understand the communicative contexts and listening experiences of individuals with hearing loss.

Another important consideration is the individual factors that may influence cardiovascular function and other physiological responses to fatigue or stress. Personality traits and cognitive ability have also been shown to play a role in this case.^{39–41} For example, Francis *et al*⁴¹ found that personality traits had an influence on cardiovascular responses and electrodermal activity when listening to speech in noise. Additionally, cardiovascular responses were associated with demands on cognitive ability. Bibbey *et al*³⁹ reported that neuroticism was associated with lower cortisol and heart rate reactivity to stress, while openness and agreeableness were associated with higher cortisol and heart rate reactivity to stress. Furthermore, a group of researchers have proposed that the effect of fatigue on effort and the associated cardiovascular responses are determined by the difficulty of a task together with outcome expectancy, so that effort and cardiovascular responses are higher when success is considered attainable and worthwhile, and vice versa.^{42 43} Perceived noise annoyance from both traffic noise⁴⁴ and

neighbour noise⁴⁵ experienced in individuals' living spaces has also been associated with higher risk of cardiovascular disease. Heart rate is also influenced by factors related to health status.⁴⁶

Study aims

The present study aims to develop measures that predict self-reported listening effort and fatigue. The measures will be based on a combination of objective, longitudinal data related to physiological signals and ambient acoustic characteristics and self-reported listening activities and motivational factors. Furthermore, the study aims to investigate how factors related to cognitive abilities, personality, perceived stress, perceived fatigue, suprathreshold abilities, noise annoyance, lifestyle and health affect the development of listening effort and fatigue. Potential confounding factors which are unrelated to listening activities, such as time-of-day, individual baseline differences and physical activity, will be controlled for.

METHODS AND ANALYSIS

Participants

Sixty current HA users over the age of 18 years will be recruited from the database at Eriksholm Research Centre (Snekkersten, Denmark). There are no specific requirements for the type, onset or degree of hearing loss, but a minimum 1 year of experience with HA use is required.

Individuals with pacemakers or individuals who take anti-arrhythmic/chronotropic medication will be excluded from the study, as these factors may interfere with the physiological measurements.

Assessment tools

Physiological responses

Physiological responses will be continuously acquired via Empatica EmbracePlus (Empatica Srl, Milano, Italy) medical-grade wristbands. These can be worn unobtrusively throughout the day and automatically store data on Empatica Cloud, where it can be accessed within 24 hours after successful upload.

The physiological signals that will be recorded from the wristband include continuous timestamped logs of pulse plethysmography (PPG), electrodermal activity, skin temperature, physical activity levels by a three-axis accelerometer and sleep detection. From the PPG, instantaneous heart rate is derived and heart rate variability is computed using the root mean square of successive differences between normal heartbeats.

Ecological momentary assessment

Participants will provide in situ subjective reports via smartphone-based EMAs targeting the participants' listening activity, as well as the perceived importance of hearing well and overall listening experience.

When opening the EMA app, the participants will first be asked to categorise the current listening activity based on scenarios inspired by the Common Sound Scenarios

Table 1 Instruction and scenario options that can be selected in the ecological momentary assessment app (right column) and corresponding listening intentions according to the CoSS framework (left column)

	Choose your primary listening activity
Speech communication	Conversation: one person
	Conversation: several people
	Conversation: phone/online
Focused listening	Listening: speech
	Listening: music
	Listening: streaming
Non-specific listening	Listening: sounds around me
	Listening: nothing specific

(CoSS) Framework.⁴⁷ The CoSS Framework identifies three listening intentions, namely, speech communication, focused listening and non-specific listening. All the scenarios are encompassed within one of the three listening intentions. Table 1 shows the scenario options that are displayed in the app, as well as the listening intentions that the scenarios are categorised under according to the CoSS framework. The participants select a single scenario that best represents their current listening activity.

The first three scenarios presented in table 1 refer to situations in which the participant is involved in a conversation with one person or more people or the conversation happens through a device (phone or online meeting). The scenario ‘Listening: speech’ refers to a situation during which the participant is listening to speech (eg, news, movie, play) or a conversation that they are not directly involved in. The scenario ‘Listening: music’ covers listening to music in free field, regardless of whether it is thorough a device or live. Situations during which the participant uses their own HAs in order to stream music, podcasts or other media are covered by the scenario ‘Listening: streaming’. Finally, the last two scenarios address situations where either the participant is aware of the sounds around them, such nature sounds or traffic noises, or the participant is not focused on listening at all, such as when reading a book.

Next, the participant will be asked to rate how important it is for them to hear well at that moment (translated from Danish: ‘Importance of hearing well’). The rating is given by sliding a marker on a visual analogue scale between ‘not important’ and ‘very important’.

Last, the participants will be asked to answer three questions which assess their listening experience. The questions address perceived listening difficulty, degree of invested effort and the degree of mental tiredness (translated from Danish: ‘Difficulty hearing sounds or speech’, ‘Degree of listening effort’ and ‘Degree of tiredness (not physical)’). The questions are answered on a visual analogue scale between ‘very difficult’ to ‘very easy’, ‘very



Figure 1 Screenshot of the ecological momentary assessment app.

effortful’ to ‘not effortful’ and ‘very tired’ to ‘not tired’, respectively.

After completing an EMA report, the participants can submit the responses and exit the app. Figure 1 shows a screenshot of the EMA app. The participants are instructed to fill out EMA reports whenever and as often as possible (see ‘Procedure’).

‘Giving up’ tags

In addition to the EMA reports, the participants will be instructed to report experiences of ‘giving up’, that is, situations during which they are not able to follow what is being said due to noise or other factors and therefore mentally withdraw. This is done by pressing one of the wristband buttons for 1 s, thereby tagging the event (figure 2).

Ambient acoustic data

Ambient acoustic data will be recorded by the participants’ own HAs and logged on the associated smartphones. Estimates of the SPL and the SNR are recorded every 20 s. The HAs additionally supply a continuous binary estimate of whether the test participant is speaking or not.

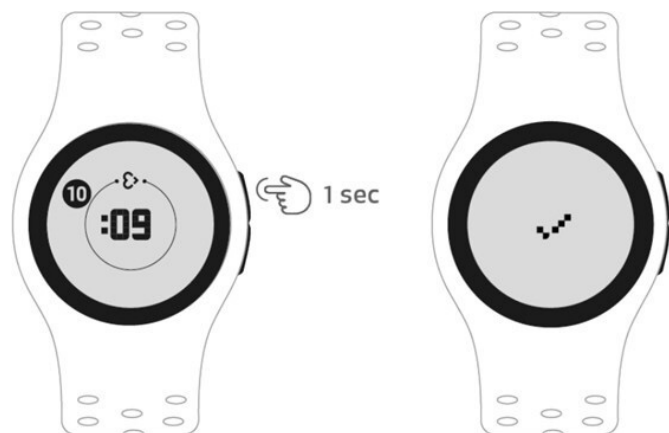


Figure 2 Event tagging on the Empatica EmbracePlus wristband (image from <https://support.empatica.com/hc/en-us/articles/16650492516381-Tagging-Events-with-EmbracePlus>).

Cognitive abilities

The Intelligenz-Struktur-Test 2000 R (I-S-T 2000 R)⁴⁸ will be used in order to evaluate the participants' intelligence and cognitive abilities. The I-S-T 2000 R was translated into Danish by Hogrefe Publishers. It includes nine subtests in total, but only three will be administered in the present study: sentence completion, verbal analogies and number series. For each subtest, there are time limits of 6 min, 7 min and 10 min, respectively. Each subset contains 20 items, the total raw score thus ranging between 0 and 60. The task of the sentence completion subtest is to select a word out of the five options that most correctly completes a sentence. In the verbal analogies subtest, a word pair is presented that has a specific relationship (eg, light and dark), as well as a third word (eg, wet). The task is to identify the corresponding relationship between the third word and one of five options (eg, dry). The number series subtest consists of rows of seven digits that follow a certain rule. The task is to add the eighth digit following the rule of that specific row. The three I-S-T 2000 R subtests will be administered online via the Hogrefe Testsystem platform at the end of the field trial.

Personality traits

The Danish version of the NEO Five-Factor Inventory-3 (NEO-FFI-3) will be applied as an assessment of personality.⁴⁹ The NEO-FFI-3 is a well-validated 60-item questionnaire that assesses the five domains of personality: neuroticism, extraversion, openness, agreeableness and conscientiousness. The questionnaire takes approximately 10–15 min to complete. All items are answered on a five-point Likert Scale from 0 (strongly agree) to 4 (strongly disagree). For each personality domain, 12 items are included. The total score range for each personality domain is therefore between 0 and 48. The questionnaire is administered online via the Hogrefe Testsystem platform. Since personality traits tend to be stable over longer periods of time, the NEO-FFI-3 is only administered once, at the beginning of the field trial.

Stress

The 10-item Perceived Stress Scale (PSS-10), which was validated in Danish,⁵⁰ will be applied to evaluate individual perceived stress levels over the past month. Answers are given on a five-point Likert Scale from 'never' to 'very often' for all items. The total score of the PSS-10 ranges between 0 and 40, and it takes approximately 5–10 min to complete. The PSS-10 is administered twice, once at the beginning and once at the end of the field trial.

Fatigue

In order to evaluate the state of fatigue, the Danish version of the 20-item Multidimensional Fatigue Inventory (MFI-20) will be administered.⁵¹ This tool assesses five dimensions of fatigue: general fatigue, physical fatigue, mental fatigue, reduced activity and reduced motivation. General fatigue refers to fatigue expressed in terms of feelings of, for example, being tired or rested. Physical fatigue refers to physical sensations of tiredness. Mental fatigue is related to perceived reduced cognitive function. Reduced activity and reduced motivation refer to not performing useful activities and the lack of motivation to begin such activities, respectively. For all items, the answers are given on a five-point Likert Scale between 'yes, that is true', and 'no, that is not true'. There are four items for each fatigue dimension. One score is calculated for each dimension by summing the answers of its corresponding items. Thus, the total score range is between 4 and 20 per dimension, which can also be converted to percentage scores between 0 and 100. The duration of the MFI-20 is approximately 5–10 min. The participants are instructed to think of 'the previous days' when filling out the MFI-20. Thus, the questionnaire is administered four times at intervals of 1 week during the field trial.

Noise annoyance

Noise annoyance will be assessed using a standardised question proposed by the International Commission on Biological Effects of Noise,⁵² which has also been published in the International Organization for Standardization.⁵³ The question was specified as follows: 'Thinking about the last 12 months or so, when you are here at home, how much does noise from (insert noise source) bother, disturb or annoy you?' The Danish translation of the question⁵⁴ will be used in the present study, in order to evaluate noise annoyance from traffic noise and neighbour noise. The response is given on an 11-point scale from 0 ('not at all') to 10 ('extremely').^{55 56} Noise annoyance will be assessed at the end of the field trial.

Background information

Relevant background information will be collected via a questionnaire, which addresses topics related to hearing loss, level of education, occupation, lifestyle and health. These questions will be answered at the beginning of the field trial.

The participants report the number of years since perceived onset of hearing loss and years of HA use. The

level of education is assessed based on the length and type of education that the participant has completed after high school. Separate items regarding occupation are filled in depending on whether the participant is active in the job market or retired. Retired participants answer an additional question describing how they perceive their life since retirement. Furthermore, all participants report how many hours per week they spend on volunteer work. The participants also indicate whether they live alone and if relevant, who they live with, as well as how often they spend time together with people outside their household. Health-related issues are evaluated by selecting diseases from a list (eg, diabetes, cardiovascular problems, cancer, neurodegenerative diseases). Additionally, physical activity level, sleep quality and smoking habits are assessed.

Suprathreshold hearing abilities

The Audible Contrast Threshold (ACT) test is a psychoacoustic suprathreshold test, which measures spectrotemporal modulation sensitivity. The ACT test supplements the standard pure-tone audiometry and is proposed to capture how well participants understand speech in noise.^{35 57} The ACT test is clinically feasible and language independent, and the task is to discriminate between spectrotemporally modulated noise and non-modulated noise. The responses are given by pressing a button when the participant hears the modulated noise. An adaptive procedure is used, so that correct responses result in a decrease in modulation and vice versa. The test yields a threshold for the smallest modulation a participant can detect. The duration of the ACT test is approximately 10 min, and it will be conducted at the beginning of the field trial.

Procedure

The present study is part of a project ranging from 1 April 2023 to 30 September 2025 and consists of an observational field trial with a duration of 4 weeks. The field trial will begin with a visit at Eriksholm Research Centre, where the participants receive the necessary information and instructions, as well as the wristbands. Since the EMA app is only supported on Apple devices, participants who do not own an iPhone will be provided with one.

Additionally, the ACT test will be administered and the participants will fill out the NEO-FFI-3, PSS-10, MFI-20 and the background information questionnaire.

The participants will be instructed to behave as they usually would during the 4-week field trial, as well as to wear the wristband as much as possible. To help participants remember to fill out reports via the EMA app, a notification will be sent every morning at 8:00 and then pseudo randomly throughout the day (up to eight times with a minimum 1 hour between each). The pseudo randomisation and varying number of reminders per day were chosen to cover different times of the day while avoiding annoyance from a repetitive notification pattern. The participants will also be encouraged to report their listening experiences via the app whenever and as often as they would like to. Furthermore, an email will be sent out weekly, reminding the participants to continue logging their listening experiences via the EMA app as frequently as possible, as well as to fill out the MFI-20. Since activities may vary between weekdays and weekends, it was decided that the MFI-20 questionnaires following the one that is filled out during the introductory visit will be filled out by all participants on Wednesdays. Thus, the second MFI-20 is completed on the Wednesday of the week after the introductory visit.

At the end of the field trial, the participants will attend the debriefing visit, during which the equipment is returned. During this session, the I-S-T 2000 R will be performed, the PSS-10 will be repeated and noise annoyance will be evaluated. It was decided to administer the I-S-T 2000 R in a different visit than the first one, in order to avoid tiredness after filling in several questionnaires. **Figure 3** illustrates the procedure of the field trial. The participants receive written instructions which they can consult if they have doubts about the field trial procedures, including EMA app item descriptions and equipment trouble shooting.

The participants are encouraged to continue collecting data during travel when possible. If the participants have commitments that prevent them from collecting data for several days, the field trial is scheduled to avoid these periods. However, collecting data over an extended period of time ensures that sufficient data are collected,

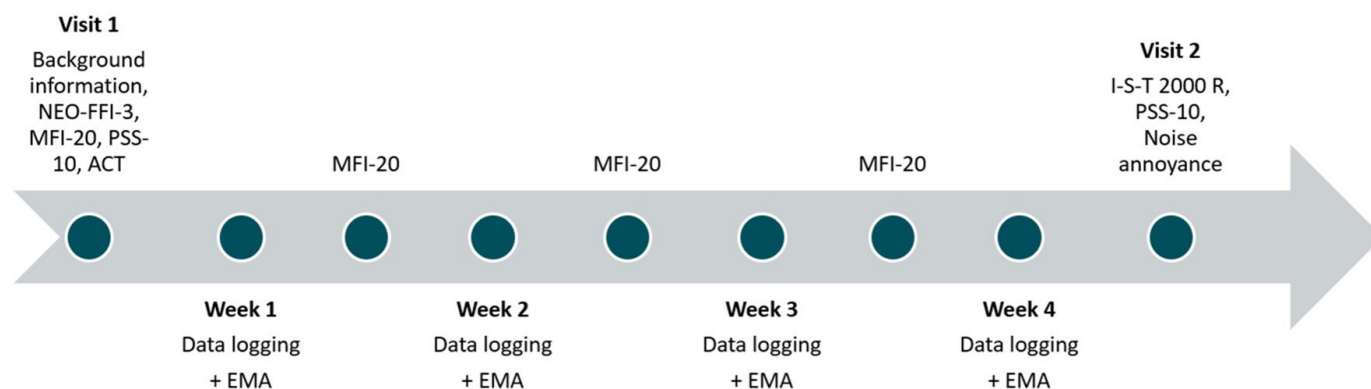


Figure 3 Field trial timeline and procedure.

even if data collection is unexpectedly interrupted for a short time.

Statistical analysis

The planned sample size of 60 participants in the present protocol was estimated based on the few studies that have investigated the relationship between ambient acoustics and heart rate. If needed, additional participants will be recruited on an ongoing basis to compensate for potential dropout. Two published studies have investigated this in both participants with normal hearing³¹ and HA users.²⁹ There was high agreement between the outcomes of both studies, showing that an increase of 1 dB was associated with an approximately 1.5% increase in mean heart rate calculated during a 5 min window. This corresponds to an effect size (partial R^2) of approximately 0.05. It should be noted that these associations were found across the entire raw data set. By taking into account the subjective momentary assessments and being able to ‘zoom in’ specifically on communicative situations and situations where hearing well is important, a larger effect size is expected. In a more recent study that also included momentary assessments (Christensen *et al*, in preparation), a partial R^2 of 0.1 was obtained. Based on this, an a priori power analysis was conducted in G*Power.^{58 59} Thus, setting the alpha error probability to 0.05, the power to 0.80 and the partial R^2 to 0.1, the estimated total sample size is 58.

The data are composed of variables related to physiological responses, ambient acoustics information, momentary assessments, cognition, personality dimensions, perceived stress, fatigue dimensions, suprathreshold abilities, noise annoyance, sex, years with hearing loss, years of HA use, occupation, perception of life during retirement, volunteer work, cohabitants, social frequency, physical activity, diseases, sleep and smoking. The table in the supplementary materials provides a detailed overview of all variables (online supplemental table-variable overview). The physiological responses, ambient acoustics and momentary assessments will be preprocessed in order to synchronise this data, that is, group the data that were collected around the same timepoint. This will be done by selecting a time window prior to each ambient acoustics log and calculating the mean of the physiological responses in that specific time window. Furthermore, each momentary assessment (EMA and giving up tags) will be associated with a specific time window prior to the ambient acoustics data log and corresponding physiological responses. For the purpose of dimensionality reduction, a factor analysis will be conducted on the variables related to participant characteristics.

Association analysis and predictions will be based on multilevel regression models emphasising model parsimony. This statistical method is suitable for repeated measures designs with unequal amounts of data per participant, as a result of individual variations in wristband wear time and momentary assessments frequency.⁶⁰ The physiological and acoustic data together with self-reported listening activity and listening importance will be

treated as independent variables while momentary assessments concerning self-reported effort and fatigue will be set as dependent variables. Significant factors emerging from the factor analysis of the participant characteristics will be investigated as moderators. Last, test participant, time of day, step count and activity count will be treated as confounders to control for inter-individual differences not otherwise accounted for by our data. Additionally, time series analyses (eg, Granger causality, growth curve analysis) will be performed in order to investigate the direction of effects for how ambient acoustics, momentary assessments and physiological responses might influence each other and how their relationship might change over time.

Patient and public involvement statement

Neither patients nor the public were involved in the planning or design of the present protocol.

Ethics and dissemination

All participants will be required to sign a written consent form prior to participation in the study. The participants may choose to withdraw from the study at any time without the need to provide justification and without any consequences for their status as test participants at Eriksholm Research Centre. All participant data will be anonymised. A query was sent to the Science Ethics Committee for the Capital Region of Denmark, and the present study was exempted from ethical application (journal no. F-23028367).

Upon completion of the study, the outcomes will be reported in manuscripts, which will be submitted for publication in peer-reviewed journals. Additionally, the findings of this study will be presented at various conferences as well as on various media platforms.

Acknowledgements The authors thank Soffi Skovlund Jensen and Lena Havtorn from Eriksholm Research Centre, Snekkersten, Denmark, for the help with data collection and Juan Camilo Gil-Carvajal from Oticon A/S, Smørum, Denmark, for the support on the EMA app.

Contributors AM, JHKC, DW, HIB, IJ, TD, MA and TFM created the research concept and design. AM and JHKC prepared the manuscript draft. TFM, DW, HIB, IJ, MA and TD provided critical revision of the manuscript. AM is the guarantor.

Funding The present research is part of a collaborative project between the University of Southern Denmark and Eriksholms Research Centre. This research is funded by the William Demant Foundation.

Competing interests None declared.

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.

Provenance and peer review Not commissioned; externally peer reviewed.

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