STUDY PROTOCOL

Effect of rehabilitation training on an elderly population with mild to moderate hearing loss: study protocol for a randomised clinical trial [version 1; peer review: 1 approved]

Parisa Rasouli Fard, Farnoush Jarollahi, Seyyed Jalal Sameni, Mohammad Kamali
Department of Audiology, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran, 15459-13487, Iran

Abstract
Background: Age-related hearing loss (presbycusis) is a form of hearing loss in over 60-year-olds and has a negative impact on quality of life. The pathophysiology of presbycusis is multifactorial and is predominately characterised with a loss of speech perception in noise. In the cochlea, auditory filters decompose broadband sound into a series of narrowband output signals, which contains two kinds of temporal information: slow changes in overall amplitude envelope (ENV) and faster variations in temporal fine structure (TFS). TFS is important for recognition of target speech in noise. The main aim of the study is to evaluate the effect of TFS rehabilitation training in participants over the age of 60 years with mild to moderate hearing loss.

Methods: A randomised clinical trial will be conducted on 30 participants with mild (loss of 20-39dB) to moderate (40-69dB) hearing loss, aged between 60 and 75 years old. Participants with conductive hearing loss, abnormal middle ear pathology and central nerve system disease will be excluded. Participants will be randomly selected to an intervention and control group with a 1:1 ratio. Rehabilitation for the intervention group will be 30-minute sessions three times a week for a total five weeks of vowel consonant vowel words that are used to eliminate ENV and keep only TFS. Word in noise test, binaural TFS test, and Speech, Spatial and Qualities of Hearing Scale scores will be performed at the beginning and end of study to evaluate the effect of rehabilitation training.

Conclusion: Life expectancy in the elderly has improved, leading to an increased prevalence of age-related diseases including presbycusis. A literature review highlighted that TFS damage is permanent; however, in this study we will attempt to prove that TFS training may lead to speech in noise perception restored.

Trial registration: Registry of Clinical Trials, IRCT2019625044006N1 (7th August 2019).

Keywords
Age related hearing, Presbycusis, Temporal Fine Structure, Rehabilitation Training
Introduction
Presbycusis (age-related hearing loss) is one of the most common disorders worldwide\(^1\). The cause of presbycusis is multifactorial, including pathophysiological degeneration, extrinsic and intrinsic damage, genetic predisposition and comorbidities (conditions like diabetes, hypertension and stroke)\(^1\).\(^2\).

In cochlea high frequency sounds evoke greatest vibration of the basilar membrane at the base while lower frequency sounds evoke greatest vibration at the apex\(^3\). Sounds are decomposed to narrow band signals (envelope; ENV) and rapid oscillations (temporal fine structure; TFS)\(^4\)-\(^12\). The ENV frequency range is between 2-50 Hz. Some of the most important task of ENV is to identify speech in quiet environments\(^1\).\(^2\). TFS frequency range is between 0.6-10 kHz\(^5\), and TFS cues are important in perception of pitch, tone separation\(^6\), and identify target speech in interfering sounds\(^7\). Presbycusis is associated with loss of speech perception in noisy environments\(^8\) and deterioration of the processing of TFS information\(^9\)-\(^13\).

Previous studies indicate that sensorineural hearing loss is associated with a reduction in speech recognition and is dependent on deterioration of TFS\(^14\), showing the importance of TFS for listening with background sounds\(^15\). Studies by Hopkins et al. suggest that TFS is important to recognise the temporal dips in fluctuating background noise\(^16\).\(^17\). In an elderly population with high frequency hearing loss, even when absolute thresholds are within the normal range, the TFS can be damaged\(^18\). It is speculated that TFS information is useful for separation of the target speech in background speech\(^19\).

Objectives
The main aim of the study is to evaluate the impact of special rehabilitation training based on TFS on improvement of speech in noise perception in an elderly population with mild to moderate hearing loss.

Protocol
This is version 1 of the protocol. There is no plan for further trial modifications.

Study overview
We will conduct a randomised clinical trial of rehabilitation training on speech in noise perception performance on an elderly population with mild to moderate hearing loss at the Audiology Clinic of School of Rehabilitation Sciences, Iran University of Medical Sciences (Tehran, Iran). It is assumed that the inability to use TFS speech cues is the main cause of speech perception problem in noise in elderly individuals, and it is possible by designing appropriate rehabilitation exercises to reduce the difficulty of speech perception in noise.

The Medical Ethics Committee at the Iran University of Medical Sciences approved the registered study protocol (IR. IUMS>REC.1398.003). The study was registered on the Iranian Registry of Clinical Trials (registration number, IRCT2019625044006N1), a Primary Registry in the World Health Organization Clinical Trials Registry Network. The protocol does not involve complications for precipitants in the study. All participants will be informed both orally and writing about the study process. Written consent to participant will be obtained from the participants before the study start (see Extended data: S1).

Terminology used in this study
Mild to moderate hearing loss: auditory thresholds ≤25dB within the frequency<2000 Hz and 25-70 dB with frequency 2000–8000 Hz.

TFS-LF test: software designed by Hopkins and Moore in 2010. The test is originally based on measuring the inter-aural phase differences\(^15\).

Inter aural phase difference (IPL): lowest difference in the phase of the wave in each ear and dependent frequency sound waves and difference in time between ears\(^2\).

Signal to noise ratio (SNR): ratio of the power of a signal (meaningful information) to the power of background noise (unwanted signal), expressed in decibels (dB). Larger numbers for signal characteristics mean better and more useful than unwanted noise information\(^2\). In this study the signal-to-noise ratio levels were 0, 4, 8, 12, 16, 20, and 24 dB.

Speech in noise score: measured by PARWIN list, which is expressed as a percentage by performing a single syllable word test. The PARWIN test is a version of the Richard H. Wilson WIN test, in which the background noise in this test is baffle noise\(^3\). PARWIN test is used to estimate SNR (50%) using Spearman Karber equation.

Speech, Spatial and Qualities of Hearing Scale (SSQ) questionnaire: used in previous studies in elderly individuals with communication disorders caused by hearing loss. From the original version of the SSQ questionnaire, its validity and reliability native version were confirmed (validity, 96% reliability) and included 47 items in three subgroups of speech perception, spatial hearing, and auditory quality. Based on the results of the questionnaire, the mean score of each item and item of each index will be measured for the research participants.

Rehabilitation training: auditory rehabilitation will be based on TFS. The intervention group will be asked to identify vowel consonant vowel words (VCVs) that have only TFS preserved and their envelope discarded. It is based on that VCVs that processing and converting to TFS speech. In this process the ENV of VCVs will be eliminated and only TFS will be kept.

Participants
Participants will be recruited from elderly people, aged between 60 and 75 years old, referred to the audiology clinics of Iran University of Medical Sciences and will be informed by phone about the study. They will be selected based on previous clinical examination, including otoscopy, tympanometry and pure tone audiometry test (PTA) to identify type and level of a...
hearing loss. In a preliminary interview, speech perception difficulty will be evaluated with a question if they had difficulty in understanding speech in noise. Those who respond yes will be entered into the study. We will perform Mini Mental State Examination (MMSE) questionnaire in order to rule out prominent cognition difficulty in participants.

Participants can withdraw from the study at any time. Privacy concerning information and results of participants will be respected.

The schematic diagram of study procedures is shown below (see section Outcomes below).

**Inclusion and exclusion criteria.** Inclusion criteria: individuals with mild to moderate hearing loss and aged between 60–75 years, having diploma or higher degree; right-handedness (assessed using Edinburgh handedness inventory); speaking native language and being monolingual; complaint about speech in noise perception difficulties and normal condition of middle ear function.

Exclusion criteria: those who do not meet the inclusion criteria, unwillingness for participation in each step of study, conductive hearing loss and abnormal middle ear, central nervous system disease, head trauma, history of seizure attack and epilepsy, and use of psychiatric and nervous system drugs. Individuals with obvious cognitive problems, as diagnosed by Mini Mental State Examination (MMSE), will also be excluded.

**Sample size.** The following formula is used to determine the number of samples in each group with the concern that the two groups are independent and dependent variables in this study are quantitative.

\[
 n = \frac{(Z_{\alpha} + Z_{\beta})^2(\sigma_1^2 + \sigma_2^2)}{(\mu_1 - \mu_2)^2}
\]

\(\alpha\): standard deviation of the studied variable in the first group (case, exposed, or intervened)

\(\alpha_2\): standard deviation of the studied variable in the second group (control, unexposed, or compared)

\(\mu_1\): mean of the studied variable in the first group

\(\mu_2\): mean of the studied variable in the second group

\(\alpha=0.05\)

\(\beta=80\%\)

\(Z=1.96\)

Based on previous studies, a power of 85% and level of significance of 95% was determined for this study. We obtained a sample size of 15 individuals for each group (total = 30), which takes into consideration a 20% drop out.

**Study design**

The study will not involve complications for participants, but if there is extreme difficulty with cooperation for participants the test will be discontinued. All participants will be informed both orally and in writing about the study process. Written consent to participant will be obtained before the study start. There is no criteria for intervention modification in this study protocol. To improve adherence to intervention protocols, every training session the examiner will provide feedback to all participants and will inform them about the training progress. The rehabilitation sessions and duration are flexible for participant.

We will randomly assign participants in 1:1 ratio, intervention and control group. The intervention group will undergo the rehabilitation training program.

The two groups will be matched for age and gender. Those in the control group will not receive any rehabilitation programs during the study. The randomization will be applied by random number table (those assigned an odd number, control group; those assigned an even number, intervention group).

**Study procedures.** Pre-rehabilitation, the SNR (50%) of all participants will be measured using the WIN test. In addition, a binaural TFS test and the SSQ questionnaire score of all participants will be evaluated (see section Outcomes below).

**Rehabilitation training.** Participants will identify the set of 16 consonants using one-interval forced-choice procedure and feedback with correct answer. On each test the participants will select one of the stimuli from the set of 16 syllables. The participants will be informed while the stimulus is presented that they should identify its middle consonant. Following each stimulus presentation, a 4 × 4 visual display of the response alternatives will appear on a computer monitor and the participant will select the response by using the computer mouse.

The participant will select a box, if they click the box correctly, the box will turn green and if they chooses the wrong answer, the box will turn red. The participant will be given visual feedback by showing the correct VCV with a yellow box. No time limit will be imposed on the participant’s responses. Each experimental run consists of 64 trials derived from a different random-order presentation of the 64 syllables in the stimulus set. Each run will last 16 to 30 min depending on the participant’s response time. The total duration of rehabilitation sessions will be five weeks. Experiments are controlled by a desktop PC.

Only the intervention group will undergo the rehabilitation and control group will not be informed about details of the intervention study procedure.

**Speech stimulus process**

The TFS speech consists of single syllable recorded in / a / C / a / with various 16 consonant format which included Aja,
Aka, Ara,… and it will be pronounced by a native-speaking man. The analogue signals will be converted to digital a 16-bit at 44.1 KHz sampling frequency. The stimulus synthesis process will be performed in MATLAB software and the software will be provided in C programming language.

The original bandpass will be filtered into 16 bands of equal bandwidth on a log frequency scale spanning 80 to 8020 Hz. Each Bandpass signal will be decomposed to ENV and TFS by Hilbert transform. The ENV component will be discarded and TFS component will be normalized and TFS component in each band summed lastly creating TFS speech.

After rehabilitation, the SNR (50%) using the WIN test, and a binaural TFS test and SSQ questionnaire will be evaluated again in intervention group. Results will be compared in intervention and control groups before and after the rehabilitation program.

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Outcomes. SNR (50%): single syllable words in the presence of noise at different signal-to-noise ratios (0, + 4, + 8, + 12, + 16, + 20, + 24) as binaural in two study groups and compare the SNR (50%). Differences in scores before and after rehabilitation training between the two groups will be compared.

The Words-in-Noise (WIN) materials were developed to evaluate the ability of listeners to understand words in multitalker babble. The WIN involves in which the level of the noise is fixed and five words are presented at seven signal-to-noise ratios from 24 to 0 dB in 4 dB decrements. The 35 words are spoken by a native male speaker. The metric of interest is the signal-to-noise ratio (S/N) at which recognition performance is 50%, which is a value determined with the Spearman Karber equation see (Extended data: S2).

Binaural TFS test: determines the binaural change of phase difference at different frequencies in intervention and control groups before and after rehabilitation training.

The correlation between the results of speech perception test scores in the presence of noise with the results of binaural TFS test in the two groups after rehabilitation program will be assessed.

SSQ questionnaire score: provided to each group before and after rehabilitation training. Scores between intervention and control groups will be compared (Extended data: S3).

Statistical analysis

In descriptive analysis of data, central tendency and dispersion indices (mean, median and standard deviation) will be used. Kolmogorov–Smirnov test will be used to test whether two random samples are drawn from the same normal distribution. Otherwise its nonparametric equivalent will be used. Depending on the circumstances, paired t-test and analysis of covariance will be used to compare pre- and post-rehabilitation program. Other analytical tests will be used as required during the data processing phase. SPSS software (V20.0, IBM Corporation, New York, USA) will be used for statistical data analysis and the significance level for all tests will be 0.05.

Dissemination

The results of our research will be disseminated through presentations at regional and national audiology conferences. The study outcomes will be published through peer-reviewed journals. There is no limit in the publication of the trial results.

Monitoring

Eight independent audiologists expert who are the academic members of rehabilitation schools in Shahid Beheshti University of Medical Sciences (SBMU) and Iran University of Medical Sciences (IUMS) will monitor patient safety and treatment efficacy. They approved the relevance, clarity and simplicity material of the study.

Study status

The enrolment of the patients has been performed and the allocation will be performed in the near future. The study started in November 2019 and will continue until December 2020.

Discussion

Elderly populations are growing rapidly worldwide, and this higher number of older individuals is associated with an increase in prevalence and incidence of age-related disorders. Age-related hearing loss (presbycusis) is one the most common disorders with an increase in age. Speech perception in noisy environments is very serious difficulty with presbycusis, which can impact negatively on the quality of life of individuals. Loss of speech perception in noisy environments with presbycusis is mostly caused by damage of processing of TFS information. In this study, we will attempt to prove by special rehabilitation training based on TFS damage that age-related hearing loss can be re-established.

Data availability

Underlying data

No data is associated with this article.

Extended data

Open Science Framework: Effect of rehabilitation training on an elderly population with mild to moderate hearing loss: study protocol for a randomised clinical trial, https://doi.org/10.17605/OSF.IO/VU9CH².

This project contains the following extended data:

- S1: Questionnaire.
- S2: Words-in-Noise (WIN) test to measure single syllable words (SNR) 50%
• S3: Speech, Spatial and Qualities of Hearing Scale (SSQ) questionnaire
• Figure S1: Schematic diagram of study procedures and timeline

Open Science Framework: Effect of rehabilitation training on an elderly population with mild to moderate hearing loss: study protocol for a randomised clinical trial, https://doi.org/10.17605/OSF.IO/VU9CH

Data are available under the terms of the Creative Commons Zero “No rights reserved” data waiver (CC0 1.0 Public domain dedication).

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References

Open Peer Review

Current Peer Review Status: ✓

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Mojtaba Tavakoli
Department of Audiology, School of Rehabilitation, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

Thanks for the valuable article posted.

The selection of cases is well done and the research path is well described. Given the problems of people with hearing loss with more falls, please explain if the results are positive, is it possible to do this protocol in more hearing loss or not?

In the section on formal validity and reliability, please indicate the number obtained from the information collected from eight academic members of the university.

In the future perspective of this protocol, if the results are positive, it is appropriate to have auditory rehabilitation in the control group. Please explain why the degree of education must be at least a diploma?

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Yes

Competing Interests: Psychology of hearing loss people

Reviewer Expertise: Hearing aid
I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Author Response 25 Jun 2020

Parisa Rasouli Fard, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran, Iran

Dear Reviewer,

Thank you very much for very important comments and suggestions.

In our study the primary results is very positive and participants in intervention group have significantly better speech perception in noisy environments. We will perform rehabilitation training program in subjects with other causes of hearing loss like noise related hearing loss (NRHI).

The Waltz & Bausell method is used to examine validity of the test. The stimulus was sent to eight independent audiologists expert. They assessed relevance, clarity and simplicity of the test by Likert scale from one (non-relevant, non-simple and non-clarity) to four scale (complete-relevant, complete-simple and complete-clarity) in each item. The analyze of their evaluation showed content validity index (CVI) 87% validity for the test.

In this study to increase homogeneity of our study population we decided to eliminate education as nuisance variable (unwanted variable) (1). All participants had to have at least high school diploma which it is more applicable to evaluate the difficulty of test by participants. In future to increase the power of the study and higher external validity the study population with education degree less than high school diploma will be included.

It is very interesting suggestion, we will perform the test auditory rehabilitation in the control group.


Competing Interests: No competing interests were disclosed.
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