

ClinicalTrials.gov Supporting Document

Official Title:

The Effects of Operating Room COVID-19 Personal Protective Equipment on Speech Perception and Listening Effort

NCT Number: Not yet assigned

Document Date: 02 February 2026

Document Type: Study Protocol / Methods Description

Place of Research – Sample

The experimental part of the study was conducted in November 2021 in the XXXXXXXX University Audiology laboratory. Experimental research was conducted with 35 operating room nurses and technicians whose medical history did not include vestibular disease or ear surgery, and who were shown to have normal hearing (NH) by hearing tests.

Participants were invited to work with the researchers' personal connections. Participants' hearing thresholds were evaluated using pure-tone audiometry. Speech audiometry tests were applied to assess speech perception. Participants with a pure tone average of 20 dB or better in the air conduction, a type A tympanogram, and positive acoustic reflexes were considered NH.¹⁵

Ethic

Ethical approval was obtained from the Non-Interventional Research Ethics Committee (2021/55-23), institutional permission, and participants' informed consent were obtained. The study was conducted in accordance with the Declaration of Helsinki.

Procedure

Explanations for Audiometric Devices: Pure tone audiometric evaluation and speech audiometry were performed in a soundproof room with acoustic sponge walls. The Madsen OTOflex 100, a compact, portable immittance meter, was used for the tympanometric evaluation. The audiological assessment that determined the hearing thresholds was performed with the Otometrics Madsen Astera 2 Audiometer.

Explanations for the Audiologist: Speech audiometry procedures were conducted using standard clinical protocols by a Turkish-speaking female audiologist who is experienced in producing acoustically controlled speech stimuli and maintaining a consistent speech level. The audiologist maintained a normal speech rate, clarity, and volume during the hearing test. The audiologist maintained the speech volume using the volume unit meter on the audiometer screen.

Explanations of the Audiological Tests: Speech perception was assessed using the speech recognition threshold (SRT) and speech discrimination (SD) tests. SRT was defined as the minimum intensity level at which at least 50% of the presented words were repeated correctly.¹⁵ For the SRT test, words from the Turkish multisyllabic standard word list were read using live sound approximately 20-30 dB above the pure tone average. After each correct repeated word by the participant, the volume was reduced by 10 dB. When it was not sharp, it was increased by 5 dB to reduce the minimum intensity level.

For the SD test, the most comfortable sound level (MCL) was found by adding 30-40 dB to the obtained SRT level and asking the participant. Afterward, 25 words at the MCL level were read from the list of monosyllabic phonetically balanced Turkish words.¹⁶ Every word that could not be repeated and/or incorrectly/incompletely repeated was evaluated as incorrect. The number of correctly repeated words was multiplied by 4 to obtain a percentage score for each ear. Participants were tested at separate times to eliminate bias, and individual word sets were used for each listening condition in each participant.

Simulated Background Noise: The “Sound Level Meter Application” on an Android phone, calibrated with a Bruel & Kjaer Sound Level Meter, was used to determine OR SBN values. Five minutes of recording were taken at the beginning of operations from three separate ORs (Ear-Nose-Throat, pediatric, orthopedics). The average of the highest and lowest noise intensities was determined as 60 dB. Since the result was consistent with previous studies, the SBN level was set to 60 dB in the wideband.^{11,14,17,18}

PPE Components: The surgical masks were three-layer polypropylene, and the N95 masks were without an exhalation valve. Other PPE included transparent face shields that thoroughly covered the face, standard surgical caps, and plastic protective coveralls.

Explanations of Study Phases: The conditions created in the three-stage experimental study are summarized in Figure 1.

Phase I: The first phase of the experiment was used to evaluate whether the participants' hearing thresholds were normal. The tympanometric evaluation was performed to assess middle ear functions and rule out retrocochlear pathology. Attention was paid to the fact that all participants had type A tympanograms and bilateral acoustic reflexes. Pure tone air conduction thresholds (at 125-250-500-1000-2000-4000-6000-8000 Hz) and pure tone bone conduction thresholds (at 500-1000-2000-4000 Hz), SRT, SD, MCL, and UCL were applied with headphones. Different word lists were used for each ear and each test. In Phase I, audiologists and participants wore surgical masks due to the pandemic mask requirement. Thirty-five participants with NH were included in phases II and III.

Phase II: In Phase II, SRT and SD tests were performed in the quiet room, free field, 60 dB wideband SBN, and standard OR PPE conditions. In Phase II A, noise and speech stimuli were presented from the front (at 0° azimuth); in Phase II B, noise from the back (at 180° azimuth) and speech from the front were presented. The speakers were 1 meter apart. The audiologist administered the SD test at 60 dB.

Phase III: SRT and SD tests were repeated in Phase III A and III B under the same conditions detailed in Phase II (quiet room, free space, distance, noise direction, word lists) and with OR COVID-19 PPE (Audiologist: N95 mask+surgical mask+face shield; Participants: N95 mask+ Surgical mask+face shield+surgical cap+coverall) (Figure 2).

The Descriptive Part: Within the scope of this study, the effects of using OR COVID-19 PPE on the listening comprehension effort of OR professionals were examined in a separate sample group using descriptive research and self-report. A total of 184 OR professionals (surgeons, anesthesiologists, nurses, and anesthesia technicians) with experience working with OR COVID-19 PPE participated in the study. The questionnaire, consisting of 17 items, was administered to participants via Google Forms. Questionnaire items were prepared by the researchers using literature, experiences, and anecdotes.^{8,19,20} The first six items evaluate listening efforts with these PPEs, the 7-10 items evaluate the difficulties experienced, and the 11-14 items evaluate the effects of these difficulties on OR workers. In the last three items, the existence of institutional strategies to reduce OR COVID-19 PPE-related listening comprehension problems was assessed.

Evaluation of Data and Statistical Analysis

Statistical analysis of the obtained data was conducted using the Statistical Package for the Social Sciences v.27.0.1.0 (SPSS-IBM Corporation) program. Frequencies, percentile distributions, means, standard deviations, and minimum and maximum values were examined for descriptive analyses. The normality of the variables was evaluated using the Shapiro-Wilk test. The Mann-Whitney U test, a nonparametric method, was used to compare the groups because the data did not fit a normal distribution. The findings were evaluated at the 95% confidence interval, with $p < 0.05$ as the significance level.