Clinical Study Document

Study Title:
The Effect of Obesity on Contralateral Suppression in Patients with Multiple Sclerosis

NCT Number:
NCTXXX

Document Date:
August 14, 2025

Statistical Analysis Plan

Statistical Analysis Plan

Data were analyzed using SPSS version 21 (Statistical Package for the Social Sciences). The normality of the data was assessed using the Shapiro-Wilk test. Data were tested for conformity to a normal distribution. For normally distributed data, mean standard deviation (x SD) was used, while for non-normally distributed data, median (minmax) was reported. Students t-test was applied for comparisons between groups when data followed a normal distribution, whereas the Mann-Whitney U test was used for non-normally distributed data. Chi-square analysis was performed to evaluate relationships between categorical variables. Results were interpreted with a 95% confidence interval, and statistical significance was set at $P < 0.05$.

Sample Size Calculation

The sample size was calculated using G*Power (version 3.1.7). Based on a previous study that reported a large effect size (Cohens d = 0.8), an a priori power analysis was conducted. The analysis revealed that a total of 52 participants (26 per group) would be required to achieve a power of 0.80 with a significance level of 0.05 (two-tailed).

Study Protocol

Study Title

The Relationship Between Anthropometric Measurements and Efferent Auditory System in Patients with Multiple Sclerosis

Study Objectives

This study aims to investigate the relationship between anthropometric measurements (such as BMI) and the function of the efferent auditory system, measured by contralateral suppression of distortion product otoacoustic emissions (DPOAEs), in individuals diagnosed with Multiple Sclerosis (MS).

Study Design

This is a cross-sectional observational study. Participants will be assessed at a single time point within 12 months following their diagnosis of MS. Data collection will include demographic information, anthropometric measurements, and DPOAE testing with contralateral suppression.

Participants and Eligibility Criteria

Inclusion Criteria:

- Age between 18 and 50 years
- Confirmed diagnosis of Multiple Sclerosis
- Ability to cooperate with the procedures
- Normal ENT and otoscopic examination
- No history of noise exposure
- Not pregnant or menstruating (for female participants)

Exclusion Criteria:

- Presence of middle ear pathology
- Abnormal tympanometry
- Hearing loss > 20 dB HL between 500-4000 Hz
- Other neurological or psychiatric disorders
- Use of ototoxic medication
- History of otologic surgery or trauma

- BMI < 18.5 or > 40
- Diagnosis of metabolic or endocrine disorders

Study Procedures

Participants will complete a demographic questionnaire and undergo anthropometric measurement. DPOAE testing will be conducted in a sound-treated room using standardized protocols. Contralateral suppression will be measured by presenting noise to the opposite ear during DPOAE recording.

Ethical Considerations

The study has been approved by the Ondokuz Mays University Clinical Research Ethics Committee. All participants will provide written informed consent before participation. The study involves no risk to the participants and their personal data will be kept confidential.

Ethics Committee Approval (English Translation)

Institution

Ondokuz Mays University Clinical Research Ethics Committee

Details

Committee Registration Number: [Insert if available]

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Approval Details

Date of Approval: June 11, 2025

Protocol Number: 2022/300

Applicant: Dr. Asuman Kkner

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Statement

The Clinical Research Ethics Committee of Ondokuz Mays University has reviewed and approved the above-mentioned research project in its session dated June 11, 2025, in accordance with the relevant ethical principles and national regulations on clinical research involving human participants.

This approval includes the review of the study protocol, informed consent forms, and participant information sheets. The researcher is responsible for conducting the study in compliance with ethical standards.

Signature

Signed on behalf of the Ethics Committee

Prof. Dr. Ramis olak

Chair, Ondokuz Mays University Clinical Research Ethics Committee