

Study Design

This study was designed as a randomized controlled experimental trial. The aim of the study was to comparatively evaluate the effects of a functional lower extremity exercise program and neuromuscular electrical nerve stimulation (NMES) on muscle strength, muscle thickness, walking performance, and fall risk in elderly individuals.

Research Setting and Duration

The study will be conducted at the Galatasaraylılar Foundation Nursing Home and in the participants' home environments. The total duration of the study is 10 months, with participant recruitment, implementation, and evaluation phases spread over this period. Following ethics committee approval, the implementation period will begin in November 2025.

Sampling and Randomization

A power analysis performed using G*Power 3.1. 9.7 software identified 42 participants with an 80% confidence interval. Participants will be randomly assigned to two groups (1:1 ratio) provided that they meet the inclusion criteria: - Group 1: Functional lower extremity exercise program - Group 2: Neuromuscular electrical stimulation (NMES) program. Randomization will be performed using OpenEpi software.

Application Protocols

1. Functional Exercise Group: - 2 days a week, 12 weeks in total. - Session duration: 40 minutes (5 minutes warm-up, 30 minutes exercise, 5 minutes cool-down). - Exercises: Sit-to-stand from a chair, stepping forward and backward, climbing stairs, semi-squatting, heel rises, etc. - Thera-Band resistance exercises are added in weeks 9–12 (yellow–red–green resistance progression).

2. NMES Group: - 2 days a week, 12 weeks in total. - Application: Bilateral electrode placement on the vastus medialis/lateralis and tibialis anterior muscles. - Parameters: 50 Hz frequency, 300 μ s phase duration, symmetrical biphasic waveform, at least 10 contractions per session.

Assessment Parameters

Primary measurements: - Muscle thickness: Ultrasonography (EDAN DUS 60, 7.5 MHz linear probe) - Muscle strength: Lafayette digital dynamometer

Secondary measurements:

- 10-Meter Walking Test - Timed Up and Go (TUG) Test - One-Leg Stand Test - Sit-to-Stand Chair Test - Fall risk with Fullerton Advanced Balance Scale (FAB-T) - Participant satisfaction scale (VAS, 0–10 point range)

Statistical Analysis

All data will be analyzed with SPSS software; appropriate parametric or nonparametric tests (t-test, Mann-Whitney U, ANOVA, etc.) will be used for comparisons between groups. The level of significance will be accepted as $p < 0.05$.

Scientific Quality of the Study

The research directly compares two different non-pharmacological interventions— functional exercise and NMES—for which there are few comparative studies in the literature. In this respect, the study is expected to provide original and clinically important contributions in terms of; - evaluating direct effects on fall risk, - analyzing muscle strength and thickness with quantitative methods, - developing applicable and low-cost methods.

VOLUNTARY INFORMED CONSENT FORM

We invite you to participate in the study titled "Effects of Lower Extremity Functional Exercise Program and Neuromuscular Electrical Nerve Stimulation on Muscle Strength, Thickness, Walking, and Fall Risk in the Elderly." Before deciding whether to participate in this study, you should understand the purpose and method of the study, the potential benefits, risks, and discomforts of this study for volunteers, and make your decision freely within the framework of this information. Therefore, it is crucial that you read and understand this form. This form contains the written form of the information provided to you verbally by us, as the research directors. Before signing the form, please take the time to carefully read the following information, which was also provided to you verbally. If you agree to participate, you will receive a copy of this form, signed by you and the witness present during the information session, for safekeeping. The purpose of this study is: The aim of this study is to evaluate and compare the effects of a lower extremity functional exercise program and neuromuscular electrical nerve stimulation on muscle thickness, muscle strength, walking, and fall risk in the elderly. If you participate in the study, you will receive functional lower extremity exercises and neuromuscular electrical stimulation to increase muscle strength. Participants in both study groups will participate in a total of 12 weeks of training, two days a week. The exercise group will be assigned to functional lower extremity exercises for a total of 40 minutes. The electrical stimulation group will receive electric current applied to the lower extremity muscles using disposable personal electrodes for a total of 20 minutes. Participants who meet the study criteria and volunteer to participate will be administered various tests related to muscle thickness, muscle strength, balance, and fall status, as well as a satisfaction survey, before and after the 12-week period. If the results of the study indicate that one method is more effective than the other, this method will be applied to the participants by the same physiotherapist using the same principles for 12 weeks after the study is completed.

Participation in the study is entirely voluntary. You have the right not to participate in the study or to withdraw from the study at any time after participation. You have the right not to answer any questions you do not wish to answer. We would like to inform you that you will not be subject to any sanctions or loss of rights in all three cases.

We would also like to state that the relevant articles of the "Personal Data Protection Law" will be taken into account in the study/research to be conducted.

Research Officer

(Name-Surname-Title-Signature)

VOLUNTARY CONSENT

I have read the information section regarding the research whose subject and purpose are stated above and have been informed first verbally and then in writing by the undersigned. I fully understand the scope and purpose of the study in which I am asked to participate and my responsibilities as a volunteer. I have had the opportunity to ask and discuss the study and have received satisfactory responses. The potential risks and benefits of the study have also been explained to me verbally. I understand that my participation in the study is voluntary, that I can withdraw from the study at any time, with or without justification, and that I may be excluded from the study by the researcher regardless of my wishes.

In these circumstances:

- 1) I agree to participate in this research voluntarily, without any pressure or coercion (including my child's/guardian's participation in this study).
- 2) If necessary, I consent to the access of my personal information to the persons/institutions/organizations specified in the legislation.
- 3) I consent to the information obtained in the study (on the condition that my identity remains confidential) being used for publication, archiving, and, if necessary, for scientific contribution purposes, being transferred outside our country.

I consent to participate in this research without the need for any further explanation, without being under any pressure, and with full knowledge.

Volunteer's (In their own handwriting)

Name-Surname:

Contact

Date:

Signature:

For Those Under Custody or Guardianship: Parent or Guardian's (In their own handwriting) Name-Surname:

Contact:

Date:

Signature:

If the Volunteer has a Language/Communication Problem:

I have translated all explanations given to the Volunteer. I read and translated all pages of this form, which includes the information and consent sections, for the volunteer. The information I translated was understood and approved by the volunteer.

Translator's Name and Surname:

Signature:

Your Rights to Participate in/Withdraw from the Research and the Researcher's Guarantee of Your Rights Protection

Participation in this research is entirely voluntary. You may decline participation in the research or withdraw at any time after it begins. There will be no penalty or loss of any rights you may have if you refuse to participate, withdraw, or are withdrawn from the study. You or your legal representative will be notified if new information regarding the research topic becomes available that may affect your desire to continue the research.

The results of the research will be used for scientific and educational purposes. All information obtained from you will be used solely for research purposes and will be kept confidential. The confidentiality of your identity, if any, will be maintained even when the research is published.

(If audio, photograph, or video recordings will be used, please specify this here.) Contact

Person(s)

Name and Surname: Phone:

This two-page Informed Consent Form was prepared in two copies, and one copy was delivered to the volunteer.