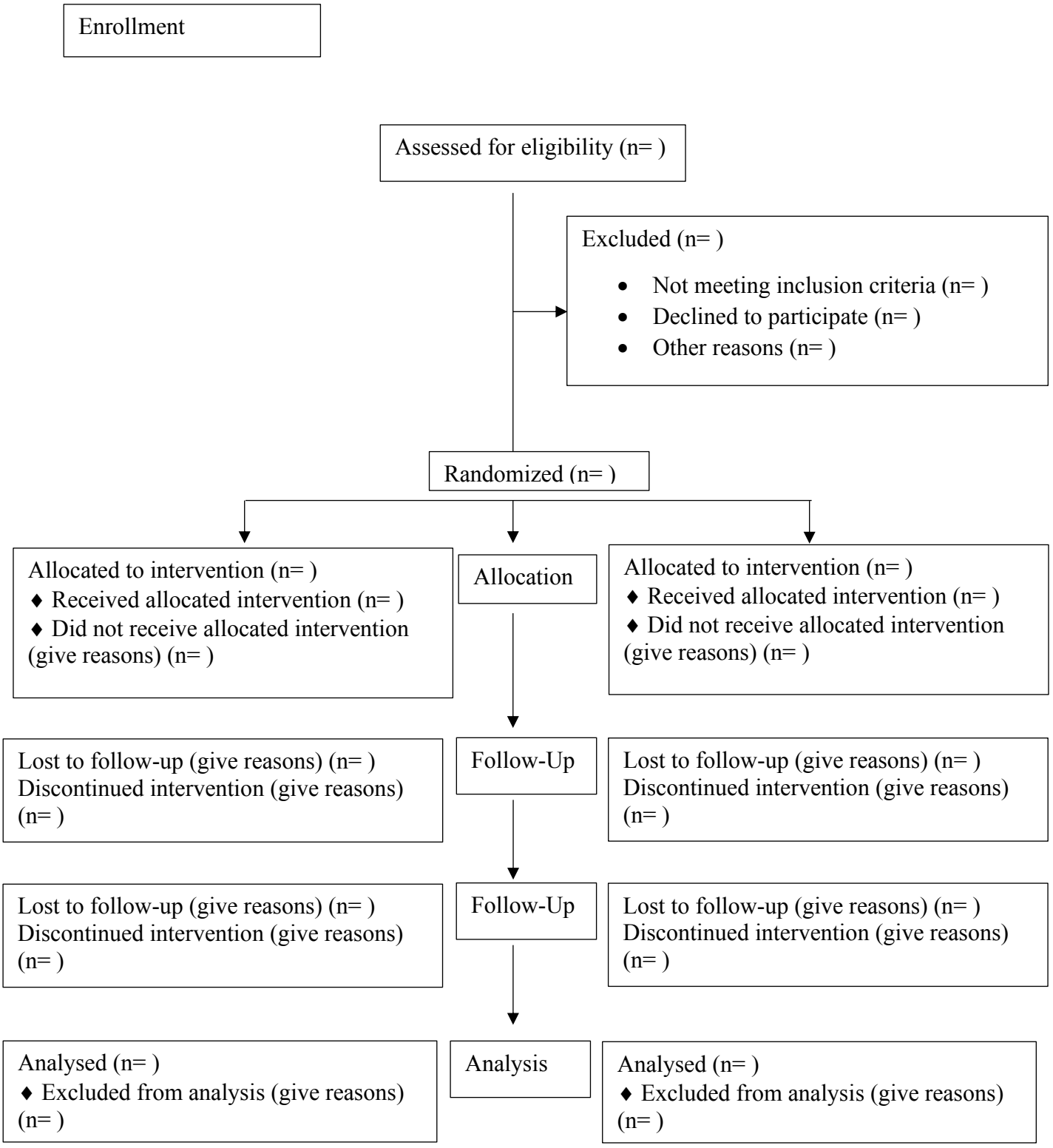
CLINICAL STUDY PLAN

The Effects of Neuromuscular Electrical Stimulation on Swallowing Functions in Stroke Patients With Dysphagia

ClinicalTrials.gov Results Data Element Definitions for Interventional and Observational Studies

▼1. Participant Flow

"



Arms	Assigned Interventions
Experimental: Neuromuscular Electrical Stimulation (NMES) with TDT	Device: Procedure: Neuromuscular Electrical Stimulation with TDT The skin to be treated will be cleaned and dried. NMES will be implemented with signals received from two channels. In the first channel, the upper electrodes will be placed horizontally just above the hyoid bone. This is the place where the cupping is felt when the finger is pressed right under the chin. In the second channel, the lower electrodes will be placed horizontally, just above the thyrohyoid muscle. This is the place where you can feel a cupping when pressed with your finger, on both sides of the apple in the larynx. The device will be set to start at the lowest power, with very short pulses of approximately 700 microseconds, at intervals of 1 second. The power will be gradually increased according to the device and the power that the patient feels vibration will be stopped. The power to be applied will not exceed 25 milliamps. NMES application and Traditional Dysphagia Therapy will be applied for 45 minutes a day, 5 days a week for 3 weeks.
Active Comparator: Traditional Dysphagia Therapy (TDT)	Behavioral: Procedure: Traditional Dysphagia Therapy (TDT) Traditional dysphagia therapy includes diet modification training, teaching postural compensatory methods, training of oral motor control exercises and tongue root exercises, training of swallowing maneuvers, and practice of chin-resistance exercise, which is the exercise of opening the upper esophageal sphincter. Traditional Dysphagia Therapy will be applied for 45 minutes a day, 5 days a week for 3 weeks.

Period(s) *

Our study was created by planning a 3-month follow-up period. Information about the number of patients at the beginning and end of the study will be reported when the study is completed. Definition: Discrete stages of a clinical study during which numbers of participants at specific significant events or points of time are reported.

▼2. Baseline Characteristics

Patients' age, gender, educational status, height and weight, additional diseases, medications used, time after the patient's stroke, duration of hospitalization in the acute period after stroke, stroke type (ischemic / hemorrhagic), lesion region, degree of ambulation according to functional ambulation classification will be recorded at the beginning of the study.

Arms	Assigned Interventions
Experimental: Neuromuscular Electrical Stimulation (NMES) with TDT	Device: Procedure: Neuromuscular Electrical Stimulation with TDT The skin to be treated will be cleaned and dried. NMES will be implemented with signals received from two channels. In the first channel, the upper electrodes will be placed horizontally just above the hyoid bone. This is the place where the cupping is felt when the finger is pressed right under the chin. In the second channel, the lower electrodes will be placed horizontally, just above the thyrohyoid muscle. This is the place where you can feel a cupping when pressed with your finger, on both sides of the apple in the larynx. The device will be set to start at the lowest power, with very short pulses of approximately 700 microseconds, at intervals of 1 second. The power will be gradually increased according to the device and the power that the patient feels vibration will be stopped. The power to be applied will not exceed 25 milliamps. NMES application and Traditional Dysphagia Therapy will be applied for 45 minutes a day, 5 days a week for 3 weeks.
Active Comparator: Traditional Dysphagia Therapy (TDT)	Behavioral: Procedure: Traditional Dysphagia Therapy (TDT) Traditional dysphagia therapy includes diet modification training, teaching postural compensatory methods, training of oral motor control exercises and tongue root exercises, training of swallowing maneuvers, and practice of chin-resistance exercise, which is the exercise of opening the upper esophageal sphincter. Traditional Dysphagia Therapy will be applied for 45 minutes a day, 5 days a week for 3 weeks.

Overall Number of Baseline Participants *

A total of 38 patients were planned to be included in the study, including 19 in each group.

Baseline Measure Information *

Patients' age, gender, educational status, height and weight, additional diseases, medications used, time after the patient's stroke, duration of hospitalization in the acute period after stroke, stroke type (ischemic / hemorrhagic), lesion region, degree of ambulation according to functional ambulation classification will be recorded at the beginning of the study. The change in Functional Oral Intake Scale (FOIS) will be our primary outcome measure in our research.

Baseline Measure Title *

Definition: The name of the baseline or demographic characteristic measured in the clinical study. Select as many as needed.

- Study-Specific Measure *§ *(Select as many as needed)*
- Age * *(Select at least one of the following):*
  - Age, Continuous: For example - mean or median age
- Sex/Gender * *(Select at least one of the following):*
  - Sex: Female, Male
- Race and Ethnicity *§
  - Race and Ethnicity Not Collected

Measure Type *

Count of Participants

Measure of Dispersion *

Not Applicable (only if Measure Type is "Number", "Count of Participants", or "Count of Units")

Baseline Measure Data *

When the investigation is completed, information about each baseline measures data will be updated.

Unit of Measure *

height (cm) and weight (kg)

▼3. Outcome Measures

Primary Outcome Measure:

- Change in Functional Oral Intake Scale (FOIS)

Functional Oral Intake Scale (FOIS) is a scale that shows the functional oral intake of patients with dysphagia. FOIS used for evaluation is a two part scale consisting of 7 levels. It is used to show whether the individual is dependent on the feeding tube and the level of oral intake. On this scale, 7 shows the best and 1 shows the worst functional oral intake. The change in FOIS will be our primary outcome measure in our research. It has been evaluated as an appropriate tool to demonstrate the change in functional oral intake in stroke patients. It is suitable as an independent measure of functional oral intake in prospective studies of stroke-related dysphagia.
[Time Frame: before intervention, immediately after intervention, 3 months after the intervention]

Secondary Outcome Measures:

- Change in Eating Assessment Tool-10 (EAT-10) Score

Eating Assessment Tool-10 (EAT-10) is used to assess participants' dysphagia symptoms, symptom severity, and risk of oropharyngeal dysphagia. This scale is a scale of 10 questions that the patient himself answers, which questions the symptoms of dysphagia. The answer points for each question range from 0 (no problem) to 4 (serious problem). If EAT-10 score is ≥3, it is considered as "risk of oropharyngeal dysphagia". It is a useful tool to evaluate the severity of dysphagia symptom in the clinic, to monitor the progression and effectiveness of the disease.
[Time Frame: before intervention, immediately after intervention, 3 months after the intervention]

- Change in Swallowing-related Quality of Life (SWAL-QOL) Score

Swallowing-related quality of life scale (SWAL-QOL) is used to evaluate the effect of swallowing disorders on quality of life. It was created to evaluate the quality of life of patients with oropharyngeal dysphagia. It includes a total of 44 questions under eating disorder, eating time, eating desire, food selection, communication, anxiety, mental health, social functionality, fatigue, and sleep subgroups. Each question is evaluated with a score ranging from 1 (worst) to 5 (best). The subgroup scores of the scale and the total score of the scale can be used to assess the change in patients.
[Time Frame: before intervention, immediately after intervention, 3 months after the intervention]

- Change in Visual Analog Scale (VAS)

Patients' difficulty in swallowing will be questioned using the Visual Analogue Scale (VAS). On a scale of ten centimeters, patients will be asked to mark the appropriate level of dysphagia 0: No dysphagia, 10: Very severe dysphagia.
[Time Frame: before intervention, immediately after intervention, 3 months after the intervention]

- Change in Laryngostroboscopy Examination

In the Istanbul Faculty of Medicine Otorhinolaryngology Diseases Clinic, evaluations will be made by the Ear Nose Throat Specialist. Whether there is vocal cord paresis and paralysis and whether glottic patency is evaluated in the laryngostroboscopic examination.
[Time Frame: before intervention, immediately after intervention]

- Change in Fiberoptic Endoscopic Evaluation of Swallowing (FEES)

FEES will be performed by the otolaryngologist doctor before and immediately after the treatment. In the fiberoptic endoscopic swallowing assessment, the condition of the patient according to the penetration aspiration scale will be checked. Grade 1 represents the best and grade 7 the worst on the penetration aspiration scale.
[Time Frame: before intervention, immediately after intervention]

- Change in Voice-Related Quality of Life (V-RQOL) Score

This ten-item scale is a scale designed for adult populations with voice disorders to measure both social-emotional and physical-functional aspects of voice problems. The answer points for each question range from 1 (few problems) to 5 (serious problems). A total score change on this scale will be used to evaluate patients.
[Time Frame: before intervention, immediately after intervention, 3 months after the intervention]

Arms	Assigned Interventions
Experimental: Neuromuscular Electrical Stimulation (NMES) with TDT	Device: Procedure: Neuromuscular Electrical Stimulation with TDT The skin to be treated will be cleaned and dried. NMES will be implemented with signals received from two channels. In the first channel, the upper electrodes will be placed horizontally just above the hyoid bone. This is the place where the cupping is felt when the finger is pressed right under the chin. In the second channel, the lower electrodes will be placed horizontally, just above the thyrohyoid muscle. This is the place where you can feel a cupping when pressed with your finger, on both sides of the apple in the larynx. The device will be set to start at the lowest power, with very short pulses of approximately 700 microseconds, at intervals of 1 second. The power will be gradually increased according to the device and the power that the patient feels vibration will be stopped. The power to be applied will not exceed 25 milliamps. NMES application and Traditional Dysphagia Therapy will be applied for 45 minutes a day, 5 days a week for 3 weeks.
Active Comparator: Traditional Dysphagia Therapy (TDT)	Behavioral: Procedure: Traditional Dysphagia Therapy (TDT) Traditional dysphagia therapy includes diet modification training, teaching postural compensatory methods, training of oral motor control exercises and tongue root exercises, training of swallowing maneuvers, and practice of chin-resistance exercise, which is the exercise of opening the upper esophageal sphincter. Traditional Dysphagia Therapy will be applied for 45 minutes a day, 5 days a week for 3 weeks.

Analysis Population Information

Overall Number of Participants Analyzed *

A total of 38 patients were planned to be included in the study.

Type of Units Analyzed [*]

The analysis will be based on participants.

Outcome Measure Data Table

Measure Type *
Count of Participants

Measure of Dispersion/Precision *
80% Confidence Interval

Statistical Analyses [*]
The required sample size was determined by power analysis based on previous studies. [G * Power, Version: 3.1.9.2 Statistical Packages, Power Analysis for Repeated (ANOVA) Type 1 error probability was 0.05%, power of the test was 80%.] The minimum required number of people for each group was calculated as 17. It was predicted that 10% of the patients would be excluded during the study, and a total of 38 patients were planned to be included in the study, including 19 in each group.
Descriptive statistics of numerical variables will be given as mean, standard deviation, median, minimum and maximum. Descriptive statistics of qualitative variables will be given as numbers and percentages. Whether numerical variables show normal distribution will be investigated with Shapiro Wilk test.
In the comparison of two independent groups, Student's t test will be used for variables with normal distribution and Mann Whitney U test will be used for non-normally distributed variables. In comparing two dependent groups, Paired t test will be used for variables with normal distribution and Wilcoxon test will be used for non-normally distributed variables. A statistical significance level of 0.05 will be taken, p <0.05 will be considered statistically significant. SPSS package program will be used in calculations.

▼4. Adverse Event Information

Information for completing three tables summarizing adverse events.

1. All-Cause Mortality: *§ Mortality is not expected in our study.
2. Serious Adverse Events: * Serious adverse events are not expected in our study.
3. Other (Not Including Serious) Adverse Events: * Adverse event due to the study is not expected. If any adverse event will be seen it will be reported.

Time Frame *§
Adverse event data will be collected between 15 April 2020 and 15 April 2021.

Adverse Event Reporting Description [*]
Patients will be invited for a checkup immediately after the intervention and three months

after the intervention. When patients encounter any problem beyond the specified times, they will reach out to the researcher through the contact number given to them and report the problem.

Collection Approach for Table Default * § (*or Collection Approach for each Adverse Event Term required*)

Systematic Assessment: Patients will be invited for a checkup immediately after the intervention and three months after the intervention.

Arm/Group Information *

Patients who meet the inclusion criteria will be randomized into two groups by computer program after being enumerated according to the order of application. Traditional dysphagia therapy and neuromuscular electrical stimulation (NMES) will be applied to 19 patients selected for Experimental Group. Traditional dysphagia therapy will be applied to 19 patients selected for Active Comparator Group.

Arm/Group Title *

Arm: Experimental: Neuromuscular Electrical Stimulation (NMES) with TDT

Arm: Active Comparator: Traditional Dysphagia Therapy (TDT)

Arm/Group Description * §

Traditional dysphagia therapy and neuromuscular electrical stimulation (NMES) will be applied to 19 patients selected for the Experimental Group. NMES application and Traditional Dysphagia Therapy will be applied for 45 minutes a day, 5 days a week for 3 weeks.

Traditional dysphagia therapy will be applied to 19 patients selected for Active Comparator Group. Traditional Dysphagia Therapy will be applied for 45 minutes a day, 5 days a week for 3 weeks.

Total Number Affected by All-Cause Mortality * §

0

Total Number at Risk for All-Cause Mortality * §

0

Total Number Affected by Any Serious Adverse Event *

0

Total Number at Risk for Serious Adverse Events * (*or Number at Risk for each Serious Adverse Event Term required*)
0

Frequency Threshold for Reporting Other (Not Including Serious) Adverse Events *
5

Total Number Affected by Any Other (Not Including Serious) Adverse Event Above the Frequency Threshold *
0

Total Number at Risk for Other (Not Including Serious) Adverse Events * (*or Number at Risk for each Other, [Not Including Serious], Adverse Event Term required*)
0

Adverse Event Term *
Unexpected impact that affects the course of the study.

Organ System *
General Disorders

Collection Approach * § (*or Collection Approach for Table Default required*)
Systematic Assessment: Patients will be invited for a checkup immediately after the intervention and three months after the intervention.

Number of Participants Affected *
0

Number of Participants at Risk *
0

▼5. Limitations and Caveats

Overall Limitations and Caveats
In our study, we compare two groups of patients who received therapy. However, creating a third group of patients and not applying any therapy program to this group may be more beneficial in terms of demonstrating the effectiveness of the therapies.

▼6. Certain Agreements

Information indicating whether there exists an agreement between the sponsor or its agent and the principal investigators (unless the sponsor is an employer of the principal investigators)

that restricts in any manner the ability of the principal investigators (PIs), after the completion of the study, to discuss the results of the study at a scientific meeting or any other public or private forum, or to publish in a scientific or academic journal information concerning the results of the study. This does not include an agreement solely to comply with applicable provisions of law protecting the privacy of participants.

Are all PIs Employees of Sponsor? *

Definition: Indicate whether the principal investigator is an employee of the sponsor. Select one.

- Yes: The principal investigator is an employee of the sponsor

If "No" the following information is required:

PI Disclosure Restriction Type

Definition: There are no varying agreements.

▼7. Results Point of Contact

Point of contact for scientific information about the clinical study results information.

Name or Official Title *

Definition: Dr. Elif Tarihçi

Organization Name *

Definition: Istanbul University

Phone: * § +902124142000

Extension (Ext.): 31737

Email: * § eliftarihci@hotmail.com