

EFFECT OF EXPIRATORY MUSCLE TRAINING ON STOMATOGNATHIC SYSTEM IN PATIENTS WITH STROKE

Ömer DURSUN PT, PhD¹. Tamer ÇANKAYA, PT, Assoc. Prof. Dr². Erdal DİLEKÇİ, MD, Assoc. Prof. Dr³.

INFORMED CONSENT FORM

This study that you have enrolled is scientific research and entitled with "Effect of Expiratory Muscle Training on Stomatognathic System in Patients with Stroke". The aim of this study is to assess the effect of expiratory muscle training on dysphagia, reduction in temporomandibular joint range of motion, mastication impairment, sensitivity in masticatory muscles, loss in oral hygiene that may develop after stroke. Instructions that you need to follow during the assessments and measurements will be told by the researcher. The estimated maximum timeline for the measurement is 30 minutes, and the number of participants is minimum 15 for each group. Any invasive procedure will not be applied, in case of enrollment to the expiratory muscle training group assessments will be performed twice. Assessment form includes the followings, sociodemographic data, Fonseca Questionnaire consists of 10 questions for temporomandibular joint assessment, general oral health assessment index consisting of 12 questions for the oral health assessment, deep neck flexor muscle endurance test for assessing the deep neck flexor muscles endurance, repetitive saliva swallow test for deglutition assessment, algometer for the assessment of pressure pain threshold of the masticatory muscles, digital caliper for temporomandibular joint range of motion measurement, eating assessment tool for deglutition assessment, sieve test for masticatory performance assessment, digital pH gauge for salivary pH assessment, Lateral and anterior photograph analysis for the assessment of facial integrity and head posture. For the expiratory muscle training you will be asked to daily use the device for 3 weeks with 50 repetitions.

It is your responsibility to answer objectively to the questions of the questionnaires, follow the instructions that given by the researcher during the measurements, and to comply the expiratory muscle training protocol in case of enrollment to the expiratory muscle training group.

There is no risk or harm that may develop during the assessment and measurement. Following completion of the study, results of the study will be shared with you. Enrollment to the expiratory muscle training group will be beneficial for you as strengthening your muscles. You can also strengthen your expiratory muscles via commercially available devices.

In case of any development concerning, you during the study, you or your trustee will be informed. For further information or any side effect occurrence you can contact Tamer ÇANKAYA via phone call.

No charge will be paid for the participants for the enrollment to the study. Also, no charge will be taken from you or the insurance company for the assessments and measurements that will be performed.

It is completely up to you to participate to the study. You can refuse to participate or leave any stage of the study, and this will not end up with any penalty or situation that will be any harm for you. Researcher can exclude you from the study by acknowledging you or not due to noncompliance to the study procedure. Results of the study will be used only for scientific purposes, in case of exclusion from the study by the researcher or your own will, medical records of yours will be used for scientific purposes as well.

All medical and identical records of yours will be confidential, even the research is published, your identity will not be shared. Only needed, the Ethical board and official authorities can access to this information.

Approval to Participate:

I have read all the explanations in the informed consent form. I have been informed in verbally and written by the below mentioned researcher about the topic and aim of the study was given above. I confirm that I participated the study voluntarily, and I can quit the study in any time with or without excuse. I accept to participate this study with my own will without any pressure or force.

Sign copy of this form will be handed to me.

Participant, Name-Surname: Adress: Phone: Date and Signature:	Researcher, Name-Surname: Assignment: Adress: Phone: Date and Signature:
Parent or Trustee, Name-Surname: Adress: Phone: Date and Signature:	Witness to the consent obtainment, Name-Surname: Assignment: Adress: Phone: Date and Signature: