KÜTAHYA HEALTH SCIENCES UNIVERSITY
CLINICAL RESEARCH ETHICS COMMITTEE

MINIMUM INFORMED VOLUNTEER CONSENT FORM

Dear Participant,

This information and consent form was prepared for the study named **"Evaluation of the Effect of Muscle Activity on Subjective Tinnitus in Temporomandibular Disorders" .** The aim of this study; To treat the symptoms of clenching with the use of night plaque in patients with clenching accompanied by tinnitus, thereby reducing the level of pain in tinnitus and chewing muscles.

In this study, night plaque treatment will be applied to patients with clenching accompanied by tinnitus and will be evaluated clinically and radiologically in terms of quality of life and symptoms after treatment. This study will last for 9 weeks on average and will be carried out with 70 volunteers. In the study, demographic data such as age, gender, and systemic disease, drug and trauma history data will be taken.

Clenching data (time of onset, whether it is felt during the day/night, fatigue, difficulty in opening mouth in the morning, stressful period) will be questioned, examination findings (disc displacement, masseter hypertrophy on inspection, linea alba, attrition of teeth, fractures in restorations and teeth, muscle and joint pain) , facial asymmetry, mouth opening) will be recorded. The characteristics of tinnitus (objective/subjective, duration, in which ear, increasing and decreasing factors, type) and hearing loss, dizziness will be questioned.

Right-left M. Masseter superficial EMG evaluation will be performed before the treatment. Tinnitus and bruxism will be evaluated by the patient with the VAS score. Then, a night plate will be prepared for the patients. It will be recommended to use them for 8 weeks. Superficial EMG will be taken from the patients after using the night plate. In the light of the data obtained; Age, gender, disease findings and preoperative and postoperative VAS scores will be evaluated by comparing data on EMG.

If you do not want to use the night plate for the desired time, if you do not want to continue the control examinations and the requested examinations, your participation in the research will end.

In this study, the volunteers have no responsibility. In the treatment of teeth clenching; night plaque, painkillers, muscle relaxants, antidepressant drugs, botox are used. Night plate is the most non-invasive method. Since night plaque is routinely used in the treatment of teeth clenching and our research is for symptoms, the superficial EMG method that also evaluates muscle activity; Our study does not include an experimental part and you will not face any risks, as it is applied in a non-invasive way with minimal discomfort in patients with jaw joint and/or clenching . At the same time, the level of discomfort is almost non-existent in the superficial EMG method, since needle tips are not used and there is no electrical stimulation. We think that by using this treatment, your clenching will be resolved and your muscular pains and tinnitus will decrease. Thus, it is planned to increase the quality of life.

This work is completely voluntary. Your participation in the research is voluntary and you can refuse to participate or withdraw from the research at any time, without incurring any penalty or sanction, without losing any of your rights.

KÜTAHYA HEALTH SCIENCES UNIVERSITY
CLINICAL RESEARCH ETHICS COMMITTEE

MINIMUM INFORMED VOLUNTEER CONSENT FORM

The team leading the trial, the Ethics Committee, the Institution and other relevant health authorities may have direct access to your original medical records. However, this information will be kept confidential. By signing the written informed consent form, you agree that you or your legal representative will grant such access. In accordance with the relevant legislation, the records that will reveal the identity of the participant will be kept confidential and will not be disclosed to the public; Even if the research results are published, the identity of the volunteer will remain confidential. You or your legal representative will be notified in a timely manner as new information becomes available on the subject of the research that may affect your willingness to continue participating in the research.

For more information about your rights in the trial, or about any trial-related adverse event, you can contact:
Berkan Altay- 05356557441
Dt. Elif Çoban- 05344776065

I have read all the explanations in the Informed Consent Form. Written and verbal explanations regarding the research, the subject and purpose of which are stated above, were given to me by the physician whose name is mentioned below. I know that I participated in the research voluntarily and I can leave the research at any time with or without justification. I agree to participate in the research in question voluntarily, without any pressure or coercion. I "allow" or "under no circumstances allow" the use of the data obtained within the scope of the "Treatment of Bruxism with Subjective Tinnitus with Occlusal Splint: Evaluation with MRI" to be used in the above-mentioned research or in all future studies.

	Name surname	Signature	History
Volunteer-Legal Representative			
Researcher			
Witness			