EXPLANATION FOR POTENTIAL RESEARCH PARTICIPANTS

I am Dr. Bunga Saridewi Nurmansyah from the Department of Medical Rehabilitation, Cipto Mangunkusumo National General Hospital – Faculty of Medicine, University of Indonesia, conducting a study entitled:

The Effect of Tongue-to-Palate Resistance Training on the Penetration-Aspiration Scale (PAS) and Suprahyoid Muscle Electrical Activity in Geriatric Patients with Oropharyngeal Dysphagia

I will provide information to you regarding this study and invite you to participate in this research.

You may participate in this study by signing this form. If you agree to participate, you are free to withdraw from the study at any time without any consequences. Declining to participate or withdrawing from the study will not affect your relationship with me or the services provided at this hospital.

If you do not understand any statement in this form, you may ask me for clarification.

1. Purpose of the Study

This study aims to determine the effect of swallowing exercises involving pressing the tongue against the palate, hereinafter referred to as **Tongue-to-Palate Resistance Training (TPRT)**, on the degree of food entering the airway as measured by the **Penetration-Aspiration Scale (PAS)** and the electrical activity of the suprahyoid muscles in geriatric patients with

oropharyngeal dysphagia (swallowing disorders caused by neurological impairment).

2. Participation in the Study

The study will be conducted over a total period of 8 weeks. If you agree to participate, you will receive either the standard swallowing management protocol or perform TPRT with 30 repetitions of the exercise per day, 5 times a week, for 8 weeks, based on the study randomization results.

3. Reason for Selection

You have been selected for this study because you meet the inclusion criteria, which are: aged ≥ 60 years with oropharyngeal dysphagia, initial suprahyoid muscle electrical activity ≤37.1 μVRMS, cooperative and willing to participate by signing the **informed consent form** after receiving this explanation, having a caregiver who is cooperative and willing to ensure compliance with the exercise program according to the study protocol.

4. Study Procedures

a. You will be provided with an explanation of the study objectives and potential benefits.

b. If you agree, you will be asked to complete and sign the informed consent form.

c. You will be interviewed by a physician to obtain your name, age, medical history, medication use, and allergies.

d. You will undergo a physical examination by a physician to assess your health status.

e. Your medical records will be reviewed to evaluate any necessary supporting examinations.

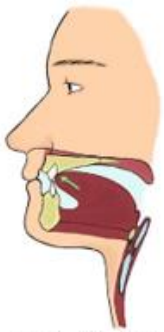
f. You will undergo a swallowing function assessment to evaluate your ability to swallow various food consistencies through **Videofluoroscopic Swallow Study (VFSS)**, including PAS scoring, hyoid movement, pharyngeal transit time (PTT), and baseline measurement of

suprahyoid muscle electrical activity.

g. The VFSS will be conducted according to the standard operating procedures at Cipto Mangunkusumo National General Hospital as follows: the examination begins with anterior-posterior (AP) and lateral X-rays to evaluate the videofluoroscopy equipment settings, followed by video recording of the swallowing process from the lateral position during administration of barium-mixed food according to the clinical consistency sequence, AP position evaluation, assessment of the esophageal phase, and modification of swallowing movements with compensatory maneuvers if necessary. In the event of aspiration, you will be asked to cough, and a decision will be made on whether to continue the procedure.

h. You will perform exercises according to the randomization results, either following the standard swallowing management protocol or performing TPRT with the instruction: "Press the tongue against the palate as hard as possible, hold for 10 seconds, and repeat for 30 movements per day," performed at home, 5 times per week for 8 weeks, with completion of a logbook.

Instruksi :
"Dorong lidah ke arah langit-langit sekuat-kuatnya, dan tahan selama 10 detik, ulangi hingga 30 kali gerakan dalam satu hari."



Gambar. Latihan *Tongue-to-Palatal Resistance Training* (TPRT)

i. You will undergo suprahyoid muscle activity assessment at the 4th and 8th weeks.

j. You will undergo a follow-up **Videofluoroscopic Swallow Study (VFSS)** to evaluate and assess the **Penetration-Aspiration Scale (PAS)**, hyoid movement, and pharyngeal transit time after the intervention (week 8).

5. Risks, Side Effects, and Management

This study carries risks including discomfort, choking, or coughing during the VFSS swallowing examination. In the event of choking, you will be asked to cough for protection, and the assessment with specific food textures causing choking will be discontinued. Side effects may include allergic reactions to barium or contrast agents used in VFSS; to prevent this, individuals with known allergies to these substances will be excluded from the study. Additionally, you may experience whitish stools for one to two days, which is considered normal. Should side effects such as nausea, vomiting, abdominal pain, diarrhea, or constipation occur that cannot be managed with increased fluid intake or symptomatic treatment (as appropriate to the symptoms), you will be referred to the Emergency Department, with costs covered by **Badan Penyelenggara Jaminan Sosial (BPJS)** – the Social Security Administration Agency for Health in Indonesia.

6. Benefits

This study uses the gold-standard diagnostic tool for swallowing disorders, **VFSS**. It allows precise identification of abnormalities causing dysphagia, enabling rehabilitation management tailored to the patient's condition. **Tongue-to-Palate Resistance Training (TPRT)** offers a simple, effective, and feasible intervention for oropharyngeal dysphagia without increasing the risk of COVID-19 exposure. You will also receive cognitive function

screening, suprahyoid muscle electrical activity assessment, and VFSS evaluations of PAS, hyoid movement, and pharyngeal transit time at no cost. Your participation will contribute significantly to improving dysphagia management in the future.

7. Compensation

Research parameter measurements will be conducted three times: pre-intervention, week 4, and week 8. For each additional visit outside the standard therapy schedule, you will receive transportation compensation of IDR 50,000 per visit.

8. Funding

All research costs will be fully covered by the investigator.

9. Confidentiality

All data collected in this study will be kept strictly confidential. Presentation of research findings at scientific meetings or publication in scientific journals will not include your name.

10. Obligations of Research Participants

As a research participant, you are required to follow the rules or instructions of the study as described above. If any part is unclear, you may ask the research team for further clarification.

11. Right to Refuse or Withdraw

You are not obliged to participate in this study if you do not wish to. You must understand that even if you agree to participate, you have the right to withdraw from the study at any time. Declining participation or withdrawing will not affect your relationship with me or the standard services provided at this hospital. At the end of this explanation, you will be given

the opportunity to consider your decision.

12. Additional Information

You are encouraged to ask any questions regarding unclear aspects of this study. Should you require further explanation at any time, you may contact Dr. Bunga Saridewi Nurmansyah at the Department of Medical Rehabilitation, Cipto Mangunkusumo National General Hospital, Jakarta, or via phone at: +62 852-6304-0728.

RESEARCH PARTICIPANT CONSENT FORM

After receiving an explanation regarding the study conducted by Dr. Bunga Saridewi Nurmansyah, I have understood the information provided. By signing this form, I voluntarily agree to participate in the study without any coercion from any party. Should I experience any form of harm at any time, I have the right to withdraw my consent.

Participant's Signature:

_____ Date: _____

Name of Participant's Guardian (if applicable):

Witness Signature:

_____ Date: _____

Name of Witness:

I, the undersigned, have explained to the participant the purpose, benefits, and procedures of the study, as well as the potential risks. I have also addressed any questions related to the study to the best of my ability.

Researcher's Signature:

_____ Date: _____

Dr. Bunga Saridewi Nurmansyah