Cover Page

Official Title: Postoperative Myofunctional Therapy Enhances Surgical Outcomes in Patients with Obstructive Sleep Apnea: A Prospective Comparative Study

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Informed Consent Form

Study Title: Postoperative Myofunctional Therapy Enhances Surgical Outcomes in Patients with Obstructive Sleep Apnea: A Prospective Comparative Study

Principal Investigator: WU CHENGJUNG, MD **Study Site:** Taipei Medical University - Shuang Ho Hospital **Sponsor:** Taipei Medical University Shuang Ho Hospital & Taipei Medical University

1. Introduction and Invitation

You are being invited to participate in a research study. This document is designed to provide you with the information you need to make an informed decision about whether to participate. Please read this form carefully and ask any questions you may have before deciding. Your participation is entirely voluntary.

2. Purpose of the Study

The purpose of this study is to find out if adding a special program of mouth and throat exercises, called Myofunctional Therapy (MFT), after surgery for Obstructive Sleep Apnea (OSA) can lead to better results than surgery alone. We hope to learn if this combined approach can improve breathing during sleep more effectively.

3. Study Procedures

If you agree to join this study, you will be asked to do the following:

1. **Undergo Surgery:** All participants will receive standard surgery for OSA, which includes uvulopalatopharyngoplasty (UPPP) and nasal turbinate reduction.
2. **Group Allocation:** After surgery, you will be placed into one of two groups based on your personal willingness:
    - **Group A (OP+MFT):** You will receive a 12-week MFT exercise program starting about three weeks after your surgery. This involves learning exercises from a speech-language pathologist, practicing at home twice a day with video guidance, and attending regular follow-up sessions.

    - **Group B (OP-only):** You will receive the standard postoperative care and follow-up without the additional MFT exercise program.
3. **Sleep Studies:** You will undergo an overnight sleep study (polysomnography or PSG) at three different times: before your surgery, and at 3 months and 12 months after your surgery. This is a standard, non-invasive test to measure your breathing while you sleep.

4. Potential Risks and Discomforts

- **Surgery Risks:** The risks associated with the surgery are the same as for any patient undergoing this procedure and include, but are not limited to, pain, bleeding, infection, and changes in voice or swallowing. These will be discussed in detail by your surgeon.
- **MFT Risks:** The MFT exercises are non-invasive and considered very low risk. You may experience temporary muscle fatigue or minor strain in your mouth or throat, similar to exercising other muscles. The training will be introduced gradually to minimize this.
- **PSG Discomfort:** The sleep study involves having sensors attached to your skin, which may cause minor skin irritation or be uncomfortable for sleeping.

5. Potential Benefits

You may not receive any direct benefit from participating in this study. However, possible benefits include a potentially greater improvement in your sleep apnea symptoms if you are in the MFT group. The information learned from this study may help improve future treatments for other people with OSA.

6. Confidentiality

Your privacy will be protected. All information collected during this study will be kept confidential. Your name will not be used in any reports or publications. Instead, you will be assigned a code number. The research records, with your identifying information removed, may be reviewed by the study team and the Taipei Medical University Joint Institutional Review Board (TMUJIRB).

7. Voluntary Participation and Withdrawal

Your participation in this study is completely voluntary. You can choose to stop participating at any time for any reason, without penalty or loss of benefits to which you are otherwise entitled. Your decision will not affect your future medical care.

8. Contact Information

If you have any questions about the research, you can contact the Principal Investigator, WU CHENGJUNG, or the study contact, Lok-Yee Joyce Li.

If you have questions about your rights as a research participant, you can contact the Taipei Medical University Joint Institutional Review Board (TMUJIRB).

9. Consent Statement

I have read (or have had read to me) the information in this consent form. I have had the opportunity to ask questions and all of my questions have been answered to my satisfaction.

By signing this form, I voluntarily agree to participate in this study.

_____ Participant's Printed Name

_____ Participant's Signature

_____ Date

_____ Printed Name of Person Obtaining Consent

_____ Signature of Person Obtaining Consent

_____ Date