Novel Myofunctional Water Bottle to Reduce OSA and Snoring study

NCT05371509

April 5, 2024

MAYO CLINIC

Name and Clinic Number

Approval Date: **April 5, 2024**
Not to be used after: **April 9, 2025**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Novel Myofunctional Water Bottle to Reduce OSA and Snoring study

IRB#: 22-001883

Principal Investigator: Umesh Goswami, M.B.B.S, M.D., and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to see whether the myofunctional therapy (MT) with a novel water bottle nozzle could be used and is effective at exercising the muscles of the tongue and soft palate to improve sleep apnea and primary snoring. Myofunctional therapy is an exercise-based therapy for your mouth and tongue. The exercises are designed specifically to train proper breathing, speaking, chewing and swallowing. You have been asked to take part in this research because you have been diagnosed with Obstructive Sleep Apnea (OSA) and primary snoring.
What's Involved	Study participation involves drinking 1.2 L (40 Fl Oz) of water using the water bottle with the myofunctional therapy (MT)novel nozzle or placebo nozzle every day. You will be asked to complete a questionnaire on your quality of life at the beginning and end of the

	study. You will also complete a commercially available home sleep apnea test called WatchPAT ONE™. You may be asked to complete this test twice during the study. The strength of the muscles of your tongue, lips, and the muscle in your jaw/cheek area will be measured. This process is called a myofunctional assessment. The myofunctional assessment will be done at day 0 and day 60. The device used to measure the strength of these muscles is called an Iowa Oral Performance Instrument. A very small balloon like bulb with a thin plastic tube is placed on your tongue and you are asked to press on it with your tongue. That tube is connected to the device that records the strength measurement. This standard, non-invasive test will be conducted by a licensed Speech Language Pathologist at Mayo Clinic.
Key Information	The use of this water bottle nozzle is a low risk, low burden exercise device. You may experience soreness and fatigue as the tongue and swallowing muscles are exercised by ongoing use of the reusable water bottle with the nozzle. This is expected to improve with continued use. You will receive a total of $150 remuneration for completing all study visits. $50 will be received after visit 1, and $100 will be received after visit 2. You may continue to use the water bottle and the MT nozzle after completion of the study duration if you choose. If you are in the placebo nozzle group, you may request the MT nozzle after study completion for your personal use if desired.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

MAYO CLINIC

Name and Clinic Number

Approval Date: **April 5, 2024**
Not to be used after: **April 9, 2025**

Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigators:** **Arizona** Umesh Goswami, M.B.B.S, M.D. **Phone:** (480) 301-8000 Mayo Clinic 13400 E Shea Boulevard Scottsdale, AZ 85259 **Rochester, MN** John G. Park, M.D. **Phone:** (507) 293-1031 **Study Team Contact:** Study Coordinator **Phone:** (800) 753-1606 **Institution Name and Address:** Mayo Clinic 200 First Street SW Rochester, MN 55905
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Approval Date: **April 5, 2024**
Not to be used after: **April 9, 2025**

Other Information:
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you have been diagnosed with mild to moderate Obstructive Sleep Apnea and primary snoring.

About 40 people will take part in this research study at Mayo Clinic.

The participants enrolled in the study will be randomly assigned (like flipping a coin) to either the intervention group (myofunctional therapy (MT) novel nozzle) or the control group (placebo nozzle) (20 participants each). The placebo bottle nozzle will look similar to the MT novel nozzle; but is not expected to function the same as the MT novel nozzle. After analyzing the results, we hope to see that those with the therapeutic nozzle show that the muscles of their tongue and mouth have been well-exercised, leading to improvement in their sleep apnea and primary snoring when compared with those with the placebo nozzle. This data can then be used to support further trials with the myofunctional therapy (MT) novel nozzle, including potential future improvements to the therapeutic nozzle design.

Why is this research study being done?

This research study is being done to determine whether the repetition and resistance from the daily use of the myofunctional therapy (MT) nozzle will improve obstructive sleep apnea and primary snoring. Myofunctional therapy is an exercise-based therapy for your mouth and tongue. The exercises are designed specifically to train proper breathing, speaking, chewing and swallowing.

The currently available daily exercises of tongue and swallowing muscles are challenging for people to adhere to long-term. The MT nozzle simplifies this exercise regimen by pairing them with a routine activity of drinking water throughout the day for OSA patients and primary snorers.

Tightening of the muscles in the throat and soft palate can help keep the airway open during sleep. This can be achieved by increasing daily swallows. Tightening of the tongue muscle prevents the tongue from falling back in the throat while sleeping. This is achieved by both the tongue suction and tongue press exercises provided by the myofunctional therapy (MT) novel nozzle.

Swallowing is a complex motion that requires activation and coordination of most throat muscles. These same muscles are also involved in the ability of a person to breathe, with airflow passing to and from the respiratory system through the oral and nasal passages.

By providing resistance and repetitions during the oral phase of swallowing, most muscles of the tongue and soft palate can be effectively exercised.

Information you should know

Who is Funding the Study?
This study is being funded by a grant received by Mayo Clinic from the National Institutes of Health (NIH).

Information Regarding Conflict of Interest:
Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

How long will you be in this research study?

You will be in this study for a maximum of 3 months.

What will happen to you while you are in this research study?

You will be randomly assigned to one of two groups for this study. One group will receive a water bottle with the myofunctional therapy (MT) nozzle, and the other group will receive a placebo nozzle. The placebo nozzle looks exactly like the MT nozzle but will not act like the MT nozzle. We use placebos in research studies to learn if the effects seen in research participants are truly from the nozzle being studied. You will have a 1 in 2 chance of receiving the MT nozzle. The study coordinator will know which nozzle you will receive. You and the rest of the study team will not know which nozzle you receive.

If you are assigned to the placebo group, a MT nozzle will be shipped to you after you complete all of the Final Visit procedures.

If you are actively using a CPAP, a mandibular advancement device, or a sleep positioning device, you will be asked to discontinue your use of these devices for 3 nights prior to your visits – this is to wash-off the remnant effects of the standard of care (SOC) Obstructive Sleep Apnea treatment on the upper airway. These devices can be used throughout the remainder of the study. If you are unsure whether you can discontinue your standard of care treatment, the study doctor will be happy to review and provide you with advice so that you may make your choice.

You may enroll in this study virtually or come to Mayo Clinic to enroll in the study. You will also need to come to Mayo Clinic for the study visits with the Speech Language Pathologist (SLP) to conduct the Iowa Oral Performance Instrument (IOPI) and myofunctional assessment. The IOPI is used by clinicians to measure your tongue and lip strength and determine whether exercise for these muscles may be useful for you. This device measures your maximum strength and provides biofeedback for exercises in the clinic.

Both smartphone applications that will be used for this study are commercially available for download for Apple and Android smartphones. Security for both smartphone applications are managed by the company that developed and maintains each application. Mayo Clinic does not control or endorse these applications and does not guarantee the security of the applications.

The HidrateSpark™ application will receive your direct identifiers (full name, date of birth, and email address) when you set up your profile to track the results during your participation. Your information will remain on the company's servers indefinitely; this is similar to other commercially available smartphone applications used for the intent of tracking activities like food or exercise.

Approval Date: **April 5, 2024**
Not to be used after: **April 9, 2025**

Enrollment Visit:
A member of the study team will review the consent form with you, virtually or in person. You will be given an opportunity to ask any questions you may have. If you agree to participate, you will sign the form, either electronically (using a platform called DocuSign) or on paper. Once you have signed the consent form, the following will be completed:

- You will be assigned to your group and will be given a reusable water bottle with either the placebo nozzle or MT novel nozzle to use daily to drink 1.2 L (40 Fl Oz) for 2 months. (If your enrollment visit is virtual, your water bottle will be shipped to you.)
    - The water bottle is Bluetooth enabled to measure water consumption (HidrateSpark ™). Instructions on how to clean the water bottle and nozzle will be included.
    - You will need to download the HidrateSpark™ smartphone application on your phone so that it can measure the water you are drinking.
        - The application will ask for an email address and password to create an account. You may use whatever email address you choose. Once registered, you will need to share this information with study staff, so they are able review compliance.
        - Once the study is complete, and if you decide to continue using the application, you will need to change your password.
    - If the HidrateSpark™ app is deleted and reinstalled, you will be able to reactivate your account and the information collected previously will still be available. You may continue using the HidrateSpark™ bottle and app after you have completed participating in the study. Mayo Clinic will not collect any information from HidrateSpark™ after you have completed your study participation.
- You will receive a kit that contains a disposable home sleep test, the WatchPAT ONE™. (If you complete your enrollment visit virtually, your home sleep apnea test will be shipped to you.) A study team member will go over the instruction on how to set up and use the test. There is also a short video that can show you how to set the test up.
    - You are not to use the apnea test until the day of your visit with Speech and Language Pathology. The study team will review this with you. If you have completed this apnea test in the 3 months prior to this visit, you will not have to use it this time.
    - WatchPAT ONE™ results are not viewed on the smartphone app. Results are uploaded to the cloud by way of the WatchPAT ONE™ smartphone application automatically. The data is sent to a remote server to be analyzed by Itamar Medical, the company that owns the WatchPAT ONE™ technology being used in this study. The results are then sent to the study team.
    - You will receive a 4-digit pin from the study team. You will need to enter this pin to set up the application.

Phone Calls

- If you use a sleep device, a member from the study team will call you to remind you to stop using your device for three days prior to your first and final visits with the Speech Language Pathologist (SLP).
- You will receive a phone call from the study team 3 days after your Baseline Visit to see if you are having any issues using the water bottle and nozzle.

3 Days Prior to Baseline and Final Visit

- If you use a sleep device, you will stop using your device for 3 days before your first and final visits with the SLP.
    - Prior to the Final Visit, you will be mailed another WatchPAT ONE™ in order to complete the home sleep apnea test.

Baseline Visit and Final Visit
3 Days Prior to Baseline and Final Visit

- If you use a sleep device, you will stop using your device for 3 days before your first and final visits with the SLP.
    - Prior to the Final Visit, you will be mailed another WatchPAT ONE™ in order to complete the home sleep apnea test.

Baseline Visit and Final Visit:

- You will receive study questionnaires for you and your partner to complete through email or the questionnaires will be distributed via paper to you at the Baseline Visit. For the Baseline Visit, you will need to complete these questionnaires on the day of your SLP visit before your visit takes place. For the Final Visit, you will be asked to complete the questionnaires no more than 15 days after the visit.
    - If you do not have a partner, the partner questionnaire will not be applicable.
    - Completed questionnaires must be returned to study staff via one of the following routes: 1) scanning or taking a photo of the document and sending it through email; 2) mail in using a pre-paid envelope; or 3) fax.
    - Responses on the questionnaires are not reviewed by members of the study team in real-time. If you have concerns about your mood, or are having thoughts of suicide or self-harm, please contact your primary care provider or call 911 if it is an emergency.
    - You will complete a questionnaire asking about how your sleeping affects your quality of life.
    - You will answer questions on your experience using the water bottle and nozzle (Final Visit only)
    - Your partner will be asked to complete a questionnaire asking about your snoring.

  - The questionnaire emails will come from the study coordinator's Mayo Clinic email address. If you do not receive the email in your inbox, check to see if it is in your spam folder.
- An initial myofunctional assessment by SLP will be completed.
- You will use the apnea test that you received during the enrollment visit on the night of the Baseline visit. You will use the apnea test that you receive through the mail on the night of the Final Visit.
  - You may review watch set up and use by watching the instruction video at any time.

The data results of this research study will be disclosed if requested. Please contact the Principal Investigator to request your home sleep apnea results and myofunctional assessment results in writing. The results will be shared with you at the end of the study via a provided email address.

What are the possible risks or discomforts from being in this research study?

This study uses a commercially available water bottle with a patent-pending nozzle designed to effectively exercise the tongue and soft palate muscles. The risks associated with this study are minimal. You may experience some soreness from using the water bottle, as it is exercising your tongue and swallowing muscles. This is expected to improve in a few days with continued use of the nozzle.

The brief interruption in your standard of care obstructive sleep apnea therapy prior to study visits may result in excessive daytime sleepiness, if this occurs it is suggested that you avoid driving or using heavy machinery during the wash-out periods.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator or the research staff if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator, or Mayo Clinic may stop you from taking part in this study at any time:

- If it is in your best interest,
- If you don't follow the study procedures,
- If the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

What if you are injured from your participation in this research study?

Where to get help:
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?
The chance of a research injury in this study is very low. Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

What are the possible benefits from being in this research study?

This study may not make your health better. However, the hope is that with using the bottle as directed, you will experience an improvement of your obstructive sleep apnea and snoring.

What alternative do you have if you choose not to participate in this research study?

You don't have to be in this study to receive treatment for your condition. Your other choices include: a daily regular myofascial exercise regimen, machines to use during sleep (CPAP, BiPAP, ASV), other oral appliances (also called mandibular advancement devices), and Upper Airway Stimulation. Depending on your situation, lifestyle changes may also be considered such as weight loss and eliminating alcohol consumption right before bedtime.

Talk to the Principal Investigator or your doctor if you have any questions about any of these treatments or procedures.

What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study.

These tests and procedures are:

- The reusable water bottle with the myofascial nozzle.
- The Assessments with the Speech Language Pathologist.
- Home sleep apnea tests using the WatchPAT ONE™ device.

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

You will receive a total of $150 remuneration for your participation in the study. You will receive $50 after completing visit 1 and $100 after completing visit 2.

Payment for participation in research is considered taxable income and reportable to the Internal Revenue Service (IRS). Accounts Payable at Mayo Clinic will be given your name, address and Social Security number in order to issue a check for your study participation. If you receive research payments totaling $600 or more in a calendar year, a tax Form 1099 will be sent to you. For Mayo Clinic employees, research payments are included in your paycheck with applicable taxes withheld and reported on your Form W2 after calendar year-end.

Will your information or samples be used for future research?

Your information collected for this study will not be used or shared for future research studies even if the identifiable information such as your name, Mayo Clinic number or date of birth is removed.

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

To protect your data and confidentiality, a code will be used as an identifier. The code will be a registration number assigned specifically to you by the Mayo Clinic Registration Office or Study Sponsor, if applicable. Your correlating Mayo Clinic number and your name for reference will be maintained in a secure database accessible by Mayo Clinic assigned research staff.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Past, present, and future medical records.
- Research procedures, including research office visits, tests, interviews, and questionnaires.

Approval Date: **April 5, 2024**
Not to be used after: **April 9, 2025**

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- A group that oversees the data (study information) and safety of this research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.
If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic, or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private, and it may no longer be protected by the Privacy Rule.

MAYO CLINIC

Name and Clinic Number

Approval Date: **April 5, 2024**
Not to be used after: **April 9, 2025**

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
Plummer Building PL 3-02
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts until the end of this study unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

MAYO CLINIC

Name and Clinic Number

Approval Date: **April 5, 2024**
Not to be used after: **April 9, 2025**

There is no expiration or end date related to the Sponsor's use of your health information received from Mayo Clinic as part of this study.

Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature