STUDY20231615

The Impact of Technology in Obstructive Sleep Apnea Myofunctional Therapy

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CASE WESTERN RESERVE UNIVERSITY EST. 1826

BIOMEDICAL INFORMED CONSENT DOCUMENT

The Impact of Technology in the Myofunctional Therapy Treatment of Obstructive Sleep Apnea Syndrome

You are being asked to participate in a research study conducted by researchers at Case Western Reserve University. This consent form contains important information about this project and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate. Your participation in this research is voluntary.

KEY INFORMATION FOR YOU TO CONSIDER:

The term "Myofunctional therapy" describes a carefully designed exercise program that strengthens your facial, mouth and tongue muscles. By increasing the strength and tone of these muscles, the idea is that it will result in healthier tongue posture and increased airway opening which may result in improved symptoms in patients with Obstructive Sleep Apnea. The purpose of this study is to test the effectiveness of myofunctional exercises in patients with Obstructive Sleep Apnea when these exercises are delivered through a smartphone application or through a worksheet. You have been identified for this study because you have been formally diagnosed with Obstructive Sleep Apnea and are currently not in treatment for your condition. We will randomize you to determine whether you will be using the smartphone app or the worksheet. We will be monitoring your progress and your compliance through a variety of ways, including health questionnaires, the use of medical grade sleep rings and compliance journals over the course of a 3 month study period. You will present for one baseline appointment as well as be asked to return for 3 monthly follow-up appointments over the course of this study. For those who will be delivered myofunctional exercises via smartphone app, you will be required to provide your own smartphone that is compatible with the study-related application.

It is important to note that individual benefits cannot be guaranteed and is also largely contingent on compliance with the prescribed myofunctional therapeutic exercises. Potential benefits of participating in this study may include access to OSA treatment specialists that will closely monitor your condition with regular follow-ups. We also expect those who adhere to exercises in both groups to have increased breathing and sleep efficiencies. Finally, there will be financial compensation for your active participation in our study.

While every effort will be made to ensure your safety, it is important to be aware of potential risks and discomforts associated with this study**.** Any time information is collected, there is a potential risk for loss of confidentiality. Given that breach of confidentiality is non-reversible, HIPAA standards will be strictly maintained for the duration of this study. Possible risks and/or discomforts associated with the procedures described in this study include boredom and emotional distress. Given the nature of the intervention to OSA being studied in this study, your condition may not improve or may worsen while you are taking part in this study if there is no adherence to the prescribed myofunctional exercise schedule. Finally, participation in this study may involve risks that are currently unforeseeable due to the nature of this research. However, if any new risks become known in the future, you will be informed of them.

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Please refer to the Detailed Consent for additional information.

DETAILED CONSENT

You have been identified for this study because you have been formally diagnosed with Obstructive Sleep Apnea and are currently not in treatment for your condition.

We hope to recruit **around 34** people to volunteer for this research.

Purpose

You are being asked to participate in a study of treating Obstructive Sleep Apnea with myofunctional exercises. The goal of the study is to compare the effects of myofunctional exercises in subjects diagnosed with OSA when using a smartphone application versus a traditional analog delivery method and also to compare the compliance with such exercises maintained over this 3-month period when using a smartphone app versus a traditional analog method.

You will be one of 34 participants enrolled in this research which are all being recruited from this facility to participate in this study.

Procedures

As a participant in this study, you will be asked to come to the CWRU dental school orthodontic department for all study procedures. Your participation in this study will last 3 month and will involve 4 total visits (1 Baseline appointment and 3 subsequent Follow-Up appointments).

Baseline – (This part of the study will last 1 appointment for about 45 mins total)

At this visit, the following baseline procedures will be performed to establish your baseline demographics and to enroll you into the study. Participants that are found to be ineligible for the study will not receive compensation for their time in the study. Basic demographic data (age, sex, height, weight) will be self-reported and/or calculated (BMI). You will also be given several SOC OSA questionnaires to complete to assess your baseline OSA risk assessment and breathing efficiency (STOP-Bang, NOSE, Pittsburgh Sleep Quality Index). Tongue strength and lip strength will be measured with the Iowa Oral Performance Instrument. This is done by asking you to press an air-filled bulb against the roof of your mouth with your tongue. This bulb is connected to an instrument that will then give quantitative data on your tongue strength and lip strength. You will be fitted and educated on a removable Belun Ring which will records patient's Oxygen Saturation,

Heart Rate Variation during sleep, Sleep Stage Assessment, and Sleep Efficiency during sleep. For those subjects randomized into the smartphone app group, you will also be instructed to download and set-up the Airway Gym app at the first appointment. You will be required to provide your own smartphone that is compatible with the study-related application. For those subjects randomized into the traditional analog myofunctional exercises group, you will be given a set up exercises where instructions will be given on paper but also demonstrated by study coordinator in person as needed. Finally, subjects in the analog group will be given a calendar to track compliance with exercises.

Randomization/Study Intervention

If you participate in this study, you will be assigned to a study group by chance using a process similar to the flip of a coin. This process is called randomization. Neither you nor study staff will select the group to which you will be assigned.

For those subjects randomized into the smartphone app group, you will be instructed to download and set-up the Airway Gym app at the first appointment. You will be delivered myofunctional exercise instructions via the smartphone app and your compliance will also be tracked via the app.

For those subjects randomized into the traditional analog myofunctional exercises group, you will be given a set up exercises where instructions will be given on paper but also demonstrated by study coordinator in person as needed. Finally, subjects in the analog group will be given a calendar to track compliance with exercises by hand.

Follow-up Procedures – (This part of the study will last for about 30 mins total and you will be expected to return for 3 of these Follow-Up appointments)

You will be followed up monthly at +1 months, +2months and +3 months where data from Belun ring will be collected, Tongue strength and lip strength will be recorded with IOPI device and STOP-Bang & PSQI questionnaires will be given. Airway Gym app will be assessed for compliance or calendars will be collected for compliance. At your final appointment, you will be asked to return all devices disbursed to you back to the possession of the CWRU Ortho department.

Withdrawing or being Withdrawn from the Study

If you withdraw from the study prior to its completion, you will be asked to return all study materials. Please note that data collected up to the time of withdrawal may still be used for research purposes unless you expressly request the omission of all your data in our research

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Foreseeable Risks and Discomforts

Risks to your confidentiality

Any time information is collected, there is a potential risk for loss of confidentiality. Probability of breach of confidentiality is low because patient documents are stored and maintained correctly and study coordinator will have the proper storage allocated for this study. Given that breach of confidentiality is non-reversible, HIPAA standards will be strictly maintained for the duration of this study.

Risks to Your Health

There are no other known risks of harms or discomforts associated with this study beyond those encountered in normal daily life. Possible risks and/or discomforts associated with the procedures described in this study include boredom and emotional distress. Given the nature of the intervention to OSA being studied in this study, your condition may not improve or may worsen while you are taking part in this study if there is no adherence to the prescribed myofunctional exercise schedule. Any incidental findings found as a reported by the Belun Ring during study procedures will result in a referral of the subject to follow-up with their PCP and Sleep Physician.

Risks in the Study Procedures

There is the potential inconvenience that you will be using your own personal phone as a primary study device. Given that this inconvenience leads to one of the variables to be researched in the scope of this study (compliance), we acknowledge this risk and this risk is an active variable to our study. In answering our questionnaires, you may refuse to answer any of the questions, take a break, or stop your participation in this study at any time.

Finally, participation in this study may involve risks that are currently unforeseeable due to the nature of this research. However, if any new risks become known in the future, you will be informed of them.

Anticipated Benefits

As we are researching the benefits of myofunctional therapy in regards to the treatment of your OSA, we expect those who adhere to exercises in both groups to have increased breathing and sleep efficiencies in line with previously published research results. However, enrollment in this study does not guarantee benefits and experiencing no benefit is a possibility.

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Your participation in this study may aid in our understanding of how the delivery method of myofunctional exercises, be it through a smartphone app or by paper, may affect the efficacy of this treatment modality.

Compensation

There will be no overall costs to you for study participation. Any costs incurred to you will be covered as part of this study as per the compensation schedule. Parking, transportation to the site as well as the cost of the smartphone application ($5) will be indirectly reimbursed via compensation.

You will receive payments of the following denomination for each appointment you present for; to a total amount of $100.

1. $25 for your first follow-up appointment
2. $25 for your second follow-up appointment
3. $50 for your final follow up appointment.

If you decide to withdraw from the study or are withdrawn by the research team, you will receive compensation for the visits that you have completed.

Participants that are found to be ineligible for the study will not receive compensation for their time in the study.

Alternatives to Study Participation

Because of the nature of this research the only alternative is to not participate in this study.

Voluntary Nature of the Study

Your participation is voluntary. If you choose not to participate, it will not affect your current or future relations with the University or other institutions that you are affiliated with for your treatment of OSA. There is no penalty or loss of benefits for not participating or for discontinuing your participation.

You are free to withdraw from this study at any time. If you decide to withdraw from this study, you should notify the research team immediately. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, or if your safety or welfare are at risk.

If you elect to withdraw or are withdrawn from this research study, the researchers will discuss with you what will happen to your study data. The researchers will ask for your permission to retain and analyze the study data already collected. If the data collected are de-identified (anonymous) the researchers will not have the ability to remove your study data.

If you elect to withdraw or are withdrawn from this research study, you may choose to terminate the continued use or disclosure of your protected health information (PHI) for research purposes. The request to end the use or disclosure of your PHI must be made in writing to the Principal Investigator. If the data collected are de-identified (anonymous) the researchers will not have the ability to remove your study data.

Privacy of Protected Health Information (PHI)

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of Case Western Reserve University. This Authorization form is specifically for a research study entitled "**The impact of technology in the myofunctional therapy treatment of Obstructive Sleep Apnea Syndrome**" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Dr, Juan Martin Palomo, and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally, the Principal Investigator and study staff at Case Western Reserve University who are working on this research project will know that you are in a research study and they will see and use your PHI. The researchers working on this study will collect the following PHI about you:

- Age
- Height
- Weight
- Relevant health history (See Inclusion Criteria, page 2)
- Recent Polysomnography result
- Nightly sleep results
- Stop-BANG score
- Pittsburgh Sleep Quality Index result
- Iowa Oral Performance Instrument result

- Airway Gym app data

This PHI will be used to screen your eligibility to participate in this study as well as crucial data points to the outcomes of this study. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Dan Yang (Study Coordinator), Dr. Ambrose Chiang (Co-Investigator), Dr. Denise Dewald (Co-Investigator)**,** and Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Juan Martin Palomo at 9601 Chester Ave, Cleveland, OH 44106 CWRU Orthodontic Department ATTN: Dr. Palomo; If you have a complaint or concerns about the privacy of your health information, you may also write to the University's Director of Privacy Management, Lisa Palazzo at lisa.palazzo@case.edu or 216-368-4286 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office for Civil Rights, US Department of Health and Human Services, 233 N. Michigan Ave., Suite 240, Chicago, IL 60601.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. Case Western Reserve University is [are] committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of, Case Western Reserve University, there is a risk that your PHI may no longer be protected.

Confidentiality

Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Research records will be kept in a secure location and access will be limited to the researchers, the University review board responsible for protecting human participants, regulatory agencies. In any sort of report we might publish, we will not include any information that will make it possible to identify a participant.

However, you should understand that in cases where we suspect elder or child abuse or neglect or imminent harm to self or others, we will take the necessary action in an effort to prevent such harm or injury, including reporting to authorities.

No other personal information about you will be included in the presentation.

Data Retention

The researchers intend to keep the research data:

- Until analysis of the information is completed;
- Until the research is published and/or presented;

Sharing of Data:

This study is collecting data from you. We would like to make these available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study, but it could also be unrelated. These studies may be done by researchers at this institution, other institutions, including commercial entities. Our goal is to make more research possible.

Your deidentified information may be shared with other researchers or databases. If your identifying information is removed from the data you provided, they may be shared without your additional consent. We cannot guarantee anonymity of your personal data even if identifying information is removed.

It is your choice whether or not to let researchers share your coded data for research in the future. If you change your mind and no longer wish to have us store or share your identifiable/coded data and biospecimens, you should contact Dr. Juan Martin Palomo. We will do our best to honor your request and retrieve any data that have been shared with other researchers or databases. However, there may be times we cannot. For example, if the data has already been used for new research.

Do you agree to allow for the sharing of your identifiable data?

_____ YES, use my identifiable/coded data in other research studies
_____ NO, do NOT use my identifiable/coded data in other research studies

If any significant new finding develop that may affect your decision to participate these will be provided to you.

Disclosure of Results

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the investigators not contact you to let you know what they have found. If results are shared with you, it may be because the investigators think you could have a health risk and want to recommend follow-up testing in a diagnostic setting. If you choose to undergo additional testing or treatment, you may have to pay for these services yourself.

Significant Financial Interest

The Principal Investigator and/or other members of the research team have NO significant financial interest in the sponsor of this research OR the product being investigated in this study. If you have any questions about this interest, please discuss it with the Principal Investigator.

Financial Information

There is no cost to you or your insurance for participation in this protocol.

You will receive a total of $100 dollars for your participation in this research study. It will be paid as per the following schedule:

1. $25 for your first follow-up appointment
2. $25 for your second follow-up appointment
3. $50 for your final follow up appointment.

If you withdraw from the study, you will be paid for the portions that you completed.

Research-Related Injury

In the event you suffer a research related injury as a result of being in this study, please immediately contact the Principal Investigator of the research study. In the event that a research activity results in injury, you/your medical insurance may be charged for the cost of diagnosing and treating your condition. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you were not in the study, that is not considered a “research injury”. Case Western Reserve University does not plan to pay for your treatment if you suffer a research related injury as a result of being in this study or to provide other forms of compensation (such as lost wages or other indirect losses). You are not waiving any legal rights by signing this form, including the right to seek compensation for an injury. To help avoid injury, it is very important to follow all study directions.

The costs for medical treatment as a result of a research related injury may be billed to you or your medical insurance plan, if applicable. Medical insurance plans may or may not cover costs for medical treatment of research related injuries. If you have insurance, you should check with your medical insurance plan before deciding to participate in this research study. In the event your medical insurance plan covers some or all of the treatment costs, you may still be responsible for co-pays or deductibles as required by your medical insurance plan.

Student/Employee Rights

Should you be affiliated with CWRU, choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor the will results be shared with your supervisor.

Termination of Participation

Your participation in this study may be discontinued by the sponsor or investigator without your consent if you are non-compliant with study procedures in ways such as but not limited to missing appointments or actively disrupting the study procedures as listed in this consent. You are responsible to bring the Belun Ring to each Follow-Up appointment. While you are not financially responsible for the device, the loss or breakage of the device terminates your data collection and thus your future participation in the study. As it states in the consent, previously collected data may still be included in statistical analysis.

Contacts and Questions

The researchers conducting this study are Dr. Juan Martin Palomo, Dr. Dan Yang, Dr. Ambrose Chiang and Dr. Denise Dewald. You may ask any questions you have now. If you have any additional questions, concerns or complaints about the study, you may contact the researchers:

Dr. Dan Yang (Study Coordinator) – dxy267@case.edu, (443) 272-1131
Dr. Juan Martin Palomo (Principal Investigator) – jmp5@case.edu, (216) 368-8665
Dr. Ambrose Chiang (Co-Investigator) – Ambrose.Chiang@uhhospitals.org, (216) 844-7378
Dr. Denise Dewald (Co-Investigator) - dxd387@case.edu

If you would like to talk to someone *other than the researchers* about questions or complaints regarding this study, research participant rights, research-related injuries, or other concerns, please contact:
Case Western Reserve University Institutional Review Board
10900 Euclid Ave.
Cleveland, OH 44106-7230
(216) 368-4514; cwru-irb@case.edu

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Statement of Consent

Your signature below certifies the following:

- You are at least 18 years of age.
- You have read (or been read) the information provided above.
- You have received answers to all of your questions and have been told who to call if you have any more questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.

You will be given a copy of this form for your records.

_____
Printed Name of Participant

_____Date: _____
Signature of Participant

_____Date: _____
Signature of Person Obtaining Consent