STUDY20221147

Evaluating Sleep Quality with Emerging Technologies

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CASE WESTERN RESERVE UNIVERSITY EST. 1826

INFORMED CONSENT DOCUMENT

Evaluating the Sleep of an Orthodontic Population using Emerging Technologies

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:

- We aim to investigate the sleep quality of the adult orthodontic patient population at the Case Western Reserve University School of Dental Medicine using the NOSE Questionnaire, STOPBANG Questionnaire, SnoreLab app, and Belun Ring.
- Participant's sleep quality will be monitored for 7 nights using the SnoreLab app and Belun Ring.
    - The SnoreLab app is activated each night before sleep on an iPad which is placed on a bedside table. It records audio while the participant is sleeping.
    - The Belun ring is placed on the finger before sleep and removed when the participant wakes up, and it records sleep data including blood oxygenation levels and sleep audio.
- Participants will be asked to complete two questionnaires regarding their sleep quality – the STOPBANG questionnaire and the NOSE questionnaire.
- Anticipated benefits for participants include contributing to the advancement and understanding of new sleep monitoring technology and possible identification of sleep disturbances
- Anticipated risks for participants include discomfort of wearing ring during sleep, risk of loss of confidentiality, and psychological discomfort of having sleep audio and patterns analyzed

Please refer to the Detailed Consent for additional information.

DETAILED CONSENT

You were selected as a possible participant because you are currently a patient at the Case Wesetern Reserve University School of Dental Medicine Orthodontics Clinic and age ≥20.

Procedures

Potential study participants will be approached at their screening appointments in the CWRU Orthodontic Clinic. After presenting the study, if the patient is interested, we will discuss the study in detail, answer any of their questions, and will then obtain informed consent from participants. Then, participants will complete the standard orthodontic records paperwork that is done at every screening appointment, which includes a medical history form and two questionnaires (the NOSE Score questionnaire and the STOP-BANG questionnaire) regarding their sleep habits, airway, and general demographic information. Participants will then be instructed on the nightly use of the Belun Ring and SnoreLab app for 7 consecutive days. Participants will be instructed to activate the SnoreLab app on the provided iPads before sleep each night, and to place the iPad on their bedside table. Participants will then be instructed to wear the Belun Ring on their index finger each night while sleeping, and to remove it when they wake up. The Belun ring and the SnoreLab app will collect sleep data such as time spent sleeping, snoring frequency and volume, pulse rate, blood oxygen saturation, and time in REM sleep. Participants will be instructed to return the iPad and Belun Ring when they have their next scheduled appointment in the CWRU Orthodontic Clinic. If participants forget to wear the Belun Ring and/or activate the

SnoreLab app, or if the Belun Ring comes off of the finger during sleep, they should proceed with resuming the study the following night, and should ensure that 7 total days of data collection is achieved.

If, at any point, the participant wishes to cease participation in the study, they may email the PI at jmp5@case.edu.

Foreseeable Risks and Discomforts

All treatments and procedures may involve some level of risk to you. We have listed below the foreseeable risks, but there may be some that are unforeseeable.

Any time information is collected, there is a potential risk for loss of confidentiality. There are no other known risks of harms or discomforts associated with this study beyond those encountered in normal daily life.

There is a risk of discomfort during sleep due to wearing the Belun Ring. This risk will be mitigated by careful selection of correct ring size for each participant prior to beginning the study.

There is a risk of psychological discomfort of having sleep audio and patterns analyzed.

You may stop your participation in the study at any time.

Anticipated Benefits

The possible benefits you may experience from the procedures described in this study include contributing to the advancement and understanding of new sleep monitoring technology and possible identification of sleep disturbances.

Compensation

There will be no costs to you for study participation.

You will not be compensated for your participation in this research study.

You will not be reimbursed for any out-of-pocket expenses, such as parking or transportation fees.

Alternative to Participation

Participation in the study is voluntary. You may stop your participation in the study at any time.

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. 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, 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 and University Hospitals. This Authorization form is specifically for a research study entitled "Evaluating the Sleep of an Orthodontic Population using Emerging Technologies" 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. J. 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 at Case Western Reserve University or University Hospitals. 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 and University Hospitals 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: name, contact information, Case Western Reserve University Dental Clinic chart number, medical history, and sleep audio. This PHI will be used to help researchers understand the potential benefits of new sleep monitoring technology and possible identification of sleep disturbances. 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. Brittany Link, Dr. J. Martin Palomo, Dr. Lucienne Menezes, and Dr. Ambrose Chiang; other staff from the Principal Investigator's medical practice group; 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. J. Martin Palomo at 9601 Chester Ave, Cleveland, OH 44106. 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 and University Hospitals are committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of, Case Western Reserve University and University Hospitals, 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, and 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, including reporting to authorities.

Subject Identifiable Information
All information that identifies you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data.

Data Retention
The researchers intend to keep the research data indefinitely.

Your identifiable information which is collected for this research may have the identifiers removed and be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

This research does not include whole genome sequencing.

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

Contacts and Questions
The researchers conducting this study are Dr. Brittany Link, Dr. J. Martin Palomo, Dr. Luciane Menezes, and Dr. Ambrose Chiang. 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. Brittany Link, DMD, MS
bnl11@case.edu
323-418-2563

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

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.

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Printed Name of Participant

_____ Date: _____

Signature of Participant

_____ Date: _____

Signature of Person Obtaining Consent