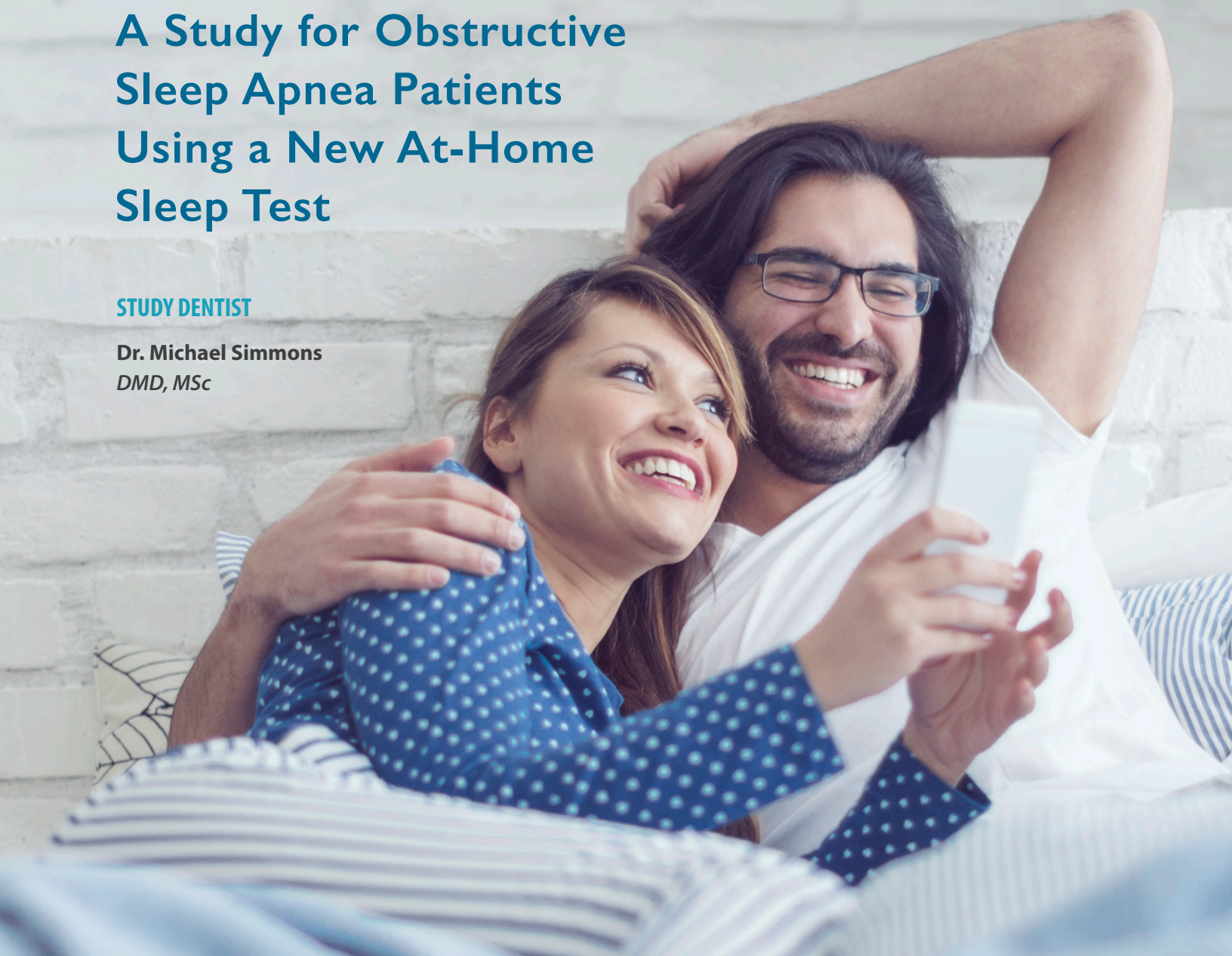


A Study for Obstructive Sleep Apnea Patients Using a New At-Home Sleep Test

STUDY DENTIST

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ARE YOU...

- Struggling with or given up on CPAP and don't know what to do?
- Using CPAP but wonder about other treatment options?
- Undiagnosed and think you might have sleep apnea?

ASK US

**ABOUT THE
STUDY**



WHAT IS OBSTRUCTIVE SLEEP APNEA (OSA)?

OSA is a medical condition that affects the sleep of over 30 million Americans. If left untreated, OSA increases the risk of motor vehicle and workplace accidents, can cause high blood pressure, and is associated with heart disease, GERD, arrhythmias, diabetes, stroke and death.

Approximately 80% of OSA cases are undiagnosed because people with the condition often fail to recognize the symptoms. Other OSA symptoms such as drowsiness, fatigue, snoring and poor-quality sleep have become so common that it can be difficult for doctors to connect these symptoms with an actual medical problem that is treatable.



HOW IS OSA TREATED?

CPAP (continuous positive airway pressure) is the most commonly prescribed treatment for OSA. Although CPAP is effective when used, many patients with OSA do not accept or tolerate this treatment long-term.

Oral appliance therapy is another treatment option for OSA. Unlike CPAP, oral appliance therapy is preferred and well accepted however it can only treat approximately 50% - 80% of the OSA population effectively.



WHAT IS MATRx PLUS?

Knowing that an oral appliance will not treat everyone, many US sleep centers are performing over-night sleep tests in the lab using a medical device, known as MATRx. The MATRx device was specifically developed to accurately select OSA patients who will be successfully treated with an oral appliance.

MATRx plus takes the in-lab MATRx technology to the home. The participants in this study will be using the MATRx plus device for an overnight sleep test in their homes to find out if oral appliance therapy can be an effective treatment option for their OSA.

Caution – INVESTIGATIONAL DEVICE, LIMITED BY FEDERAL LAW TO INVESTIGATIONAL USE.



WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

- To determine if the study participant can receive adequate instructions from the dental office staff on how to use the MATRx plus device at home
- To evaluate how convenient and practical it is for the study participant to use the investigational MATRx plus device in their home for more than one night of study
- To document the process of integrating the MATRx plus device into the existing workflow of a dental sleep medicine practice

HOW DO I QUALIFY AS A PARTICIPANT?

You must be at least 18 years of age and meet ALL of the following criteria:

- Be a suitable candidate for oral appliance therapy
- Have or will receive a prescription for oral appliance therapy
- Have an adequate mandibular range of motion (i.e. how far you can move your jaw forward)
- Have adequate dentition (i.e. the number, arrangement and condition of your teeth)
- Be able to understand and provide informed consent
- Be able and willing to meet the required schedule of dental office visits and nights of study in your home (no overnight hospital stay is required)

WHAT CONDITIONS WOULD DISQUALIFY ME?

- Loose teeth
- Full dentures
- Advanced periodontal disease
- Full dental implants

Note: If you are insured by Medicare you will not receive reimbursement for testing or for the oral appliance.



WHAT SHOULD I EXPECT IF I'M A PARTICIPANT?

You will be enrolled in one of two study pathways, either option A or option B.

The study pathways vary based on whether you have been previously diagnosed with OSA and have been referred to Encino Center for Sleep and TMJ Disorders by a sleep physician or if you are a current patient of Encino Center for Sleep and TMJ Disorders.

ENROLLMENT OPTION A

Participants enrolled into Option A must have a:

- Previous diagnosis of OSA
- Prescription for oral appliance therapy
- Referral to Encino Center for Sleep and TMJ Disorders by a sleep physician



DENTAL VISIT



2 - 3 STUDY NIGHTS

Informed consent is obtained and eligibility screening is completed.

Eligible participants will:

- Be fit with temporary dental trays and trained on MATRx plus use
- Sleep with MATRx plus at home for 2-3 successful nights

Ineligible participants will:

- Be referred back to the referring sleep physician



DENTAL VISIT

Participants will meet with the dentist to review their MATRx plus test results and discuss their therapy options.

Those who are predicted to be successful with oral appliance therapy will:

- Review appliance options
- Review their treatment plan

Those who are predicted to be unsuccessful with oral appliance therapy will:

- Be given the option to consider oral appliance therapy or be referred back to the sleep physician

ENROLLMENT OPTION B



Participants enrolled into Option B must be:

- Current patients of Encino Center for Sleep and TMJ Disorders
- Suspected of having OSA

1st DENTAL VISIT

 1 STUDY NIGHT

Informed consent is obtained and eligibility screening is completed.

Eligible participants will:

- Sleep with a recorder at home for 1-2 nights to confirm a diagnosis of OSA

Ineligible participants will:

- Continue care under Encino Center for Sleep and TMJ Disorders' Medical Officer or will be referred to an external sleep physician

2nd DENTAL VISIT

 2 - 3 STUDY NIGHTS

Participants will meet with the dentist to review their sleep recorder test results.

Those who are diagnosed with OSA and have a prescription for oral appliance therapy, will:

- Be fitted with temporary dental trays and trained on MATRx plus use
- Sleep with MATRx plus at home for 2-3 successful nights

Those who are not diagnosed with OSA and/or are not suitable candidates for oral appliance therapy will:

- Continue care under Encino Center for Sleep and TMJ Disorders' Medical Officer or will be referred to an external sleep physician

3rd DENTAL VISIT

Participants will meet with the dentist to review their MATRx plus test results and discuss their therapy options.

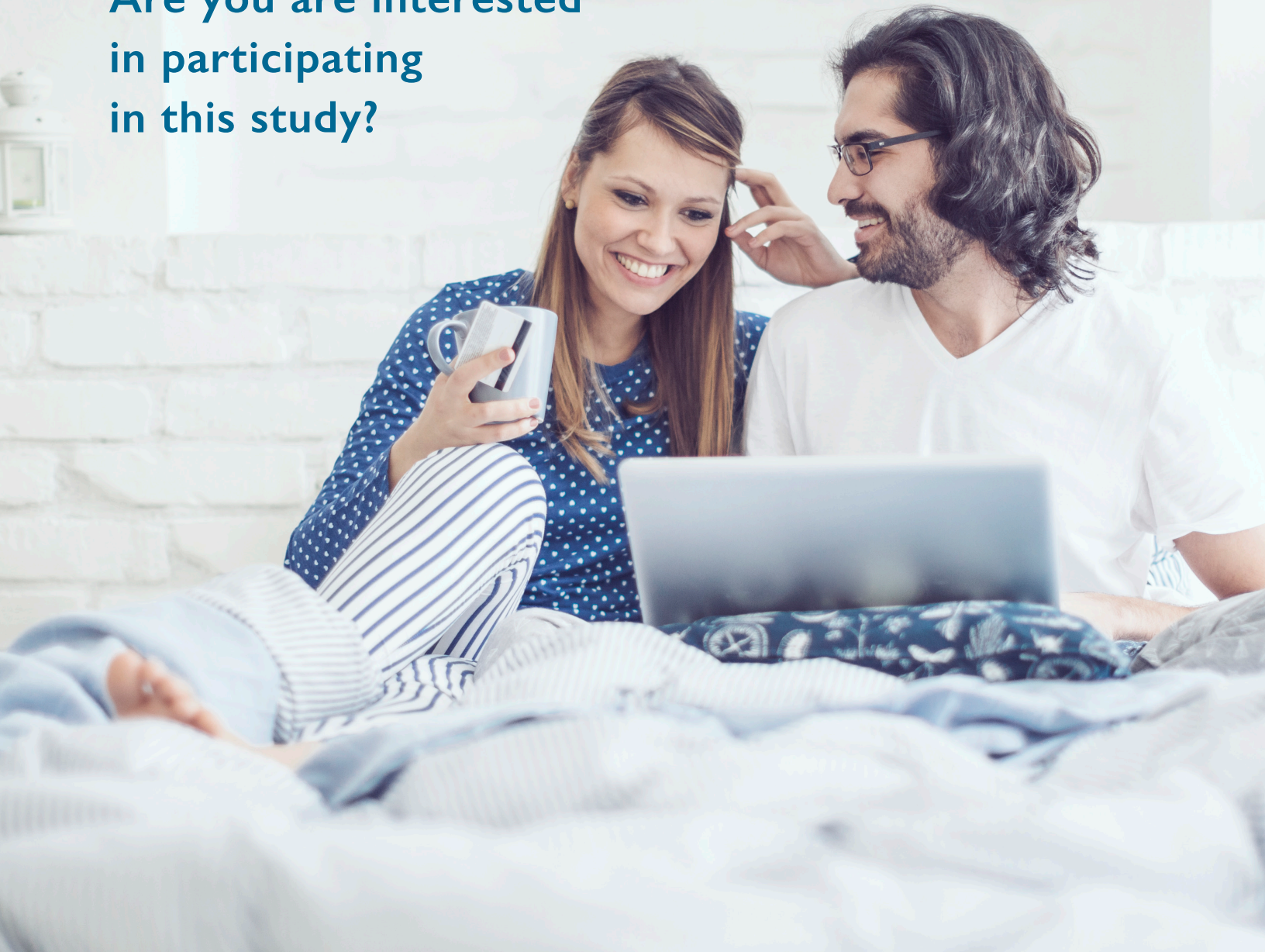
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Those who are predicted to be unsuccessful with oral appliance therapy will:

- Be given the option to consider oral appliance therapy or be referred back to the sleep physician

Are you are interested
in participating
in this study?



TALK TO US

Study Coordinator | Pamela Simmons

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This study has been approved by the Western Institutional Review Board and meets the criteria of the International Conference on Harmonization for good clinical practice. Protocol Number: ZCP2016_03V1.0. This study and this flyer have been IRB approved.

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