



ImThera Medical, Inc.
THN Sleep Therapy Study
Online Text Ads

Pre-Screening Questionnaire

The pre-screening questionnaire is the first step toward seeing if you qualify for the THN Sleep Therapy Study. The questionnaire will help determine if you meet some of the main criteria for the study. If you meet the pre-screening criteria, you will be given the option to submit your contact information directly to the THN study center in your area. Someone from your local study center will then contact you within a few days to tell you more about the study, and answer any questions you might have. Only your local study center can determine if you are eligible to join the study.

Please note that completing the pre-screening questionnaire does **NOT** obligate you to participate in the study. Rather, the pre-screening questionnaire simply helps determine if you might be a potential candidate for the study, so that you can be connected to the local THN study center in your area to learn more.

1. How did you first learn about the THN Sleep Therapy Study?
 - Web Search/Browsing
 - Facebook
 - Radio
 - TV
 - Mail
 - Newspaper/Magazine
 - Doctor/Nurse
 - Friend/Family
 - Other

(Record answer: informational only)

2. Please enter your zip code so that we can find your nearest study location.
(Sites within 200mi radius of patient will be provided)

3. Based on your zip code, the following THN Sleep Therapy study location(s) have been found in your area. Please select the location that is most convenient for you:
 - XYZ Medical Center, X miles
 - ABC Medical Center, Y miles

(If no sites are available within specified radius, patient will be brought to separate closing – see last page)

4. If you qualify and choose to join the study, you will be required to travel to this location for your THN Sleep Therapy implant procedure, as well as regular follow-up visits over a 5-year period. Are you able to commit to this schedule?
 - Yes
 - No

(If no: disqualify)

5. What is your age?
- < 18
 - 18 - 29
 - 30 - 39
 - 40 - 49
 - 50 - 59
 - 60 – 69
 - 70 – 79
 - 80 or older
- (If < 18: disqualify)**
6. Please use the Body Mass Index (BMI) calculator on the right to find your current BMI:
- BMI < 25.0
 - BMI 25.1 – 30.0
 - BMI 30.1 – 35.0
 - BMI 35.1 – 40.0
 - BMI > 40.0
- (If BMI > 35.0: disqualify)**
7. Have you ever been diagnosed by a doctor as having obstructive sleep apnea?
- Yes
 - No
- (If no: disqualify)**
8. Do you have a report of a previous PSG or are you able to obtain the report of a previous PSG?
- Yes
 - No
9. If a previous PSG cannot be obtained, would you be willing to undergo another pre-screening PSG that may require billing to insurance?
- Yes
 - No
 - Not applicable, previous PSG report is accessible
- (If no: disqualify)**
10. Have you failed or do not tolerate CPAP therapy or refuse to use CPAP therapy?
- Yes
 - No
- (If no: disqualify)**
11. This clinical study uses a small, pacemaker-like device, which is implanted during a surgical procedure. Are you willing to undergo a surgical procedure for your obstructive sleep apnea?
- Yes
 - No
- (If no: disqualify)**
12. Do you have other sleeping disorders such as narcolepsy, insomnia, or restless leg syndrome?
- Yes
 - No
- (If yes: disqualify)**
13. Are you taking any opioids, narcotics, or supplements that have an impact on your daily activities or alertness?
- Yes

- No

(If yes: disqualify)

14. Have you been diagnosed with any pulmonary conditions, such as COPD, emphysema, or asthma?

- Yes
- No

(If yes: disqualify)

15. Do you currently suffer from uncontrolled high blood pressure?

- Yes
- No

(If yes: disqualify)

16. Do you currently use supplemental oxygen (either during the day or while you sleep)?

- Yes
- No

(If yes: disqualify)

17. Are you on dialysis because of kidney failure?

- Yes
- No

(If yes: disqualify)

18. Do you have a pacemaker, defibrillator, neurostimulator, or other active implantable device?

- Yes
- No
- Not sure

(If yes: disqualify)

19. (Females only) Are you pregnant, currently breastfeeding, or do you plan to become pregnant within the next 12 months?

- Yes
- No
- I am a male

(If yes: disqualify)

20. Are you currently taking part in any other clinical research studies that involve an investigational device or drug?

- Yes
- No

(If yes: disqualify)



If Patient Passes All Criteria:

Thank you. It appears your responses have met the preliminary criteria for the study. If you're still interested, the next step is for your local THN Sleep Therapy study center to contact you directly. They can tell you more about the study and what is involved, and answer any questions you might have. By speaking with your local study site, you are not under any obligation to join the study. Also, only your local study site can determine whether or not you may be eligible to join the study.

If you would like your local study center to contact you, please provide the following information. Someone from your local study team will then contact you within the next several days. (Please note: your contact information will only be shared with your local study center so that they can follow-up with you directly to discuss the study – it is not used for any other purpose).

- Name
- Address
- Phone
- Email (optional)
- Best time to contact

Upon Submission of Contact Information:

Thank you. Your information has been sent directly to your local study center. You should be hearing from them within the next several days. They will be able to give you much more information about the study, and answer any questions you might have. Thank you again for your interest in the study and have a nice day.

If Patient Does NOT Pass Criteria:

Thank you for answering our questions. Unfortunately, based on your responses you do not qualify to participate in the study. We are required to follow very specific screening guidelines to ensure that the study criteria are met.

If you would like to receive future updates about this therapy, please visit the sponsoring company's website: <http://www.imtheramedical.com/about/contact>

Thank you for your interest in the study and have a nice day.

Unfortunately, the THN Sleep Therapy Study is not currently being offered in your local area (based on your zip code). Since this study involves frequent follow-up visits, it is required that participants live within close proximity to their nearest study center.

If you would like to receive future updates about this therapy, please visit the sponsoring company's website: <http://www.imtheramedical.com/about/contact>

Thank you for your interest in the study and have a nice day.