

TREATING OPIOID USE DISORDER (CLINICAL RESEARCH STUDY NCT04916600)





We are recruiting participants for a research study on opioid abstinence (stop using opioids and remain free of them) without the help of medication, located at Isaiah House in central Kentucky. Research studies are voluntary and include only people who choose to take part, and who meet all the eligibility criteria as determined by the study investigators.

#### STUDY DESCRIPTION

This research study is evaluating the effectiveness of a medical device (the NET® device) in treating addiction to illicit opioids (like heroin) or non-medical use of opioids that may be legally prescribed (like oxycodone), without the use of other medication. NeuroElectric Therapy™ (NET) is a non-invasive method of low-intensity electrical stimulation - which you can control - that uses adhesive electrodes placed behind your ears. This study will examine whether NET treatment helps people remain opioid abstinent without use of medication treatment.

To make sure that the ability to remain opioid abstinent is because of NET treatment and not for other reasons, people will be randomized (assigned by chance) to receive either active or non-active (sham) NET. This means if you agree to participate, you might not receive active experimental NET. You may request standard-of-care treatment that is appropriate for your condition at any time during your inpatient stay at the study site.

### WHO IS ELIGIBLE

# We aim to enroll 100 participants who:

- Have opioid use disorder
- Are between 18 and 65 years old
- Are being admitted to the study site for standard treatment for their addiction

#### IF YOU ARE ELIGIBLE

Your participation in the research will last for approximately 4 weeks of inpatient treatment at Isaiah House, and 12 weekly video calls after you are discharged to ask about your health, your drug use (if any), and to take a saliva drug test.



#### **OUR THANKS**

You will not be paid for taking part in the inpatient phase of the study. However, **you will be compensated \$25 - up to \$300 for 12 interviews** - for the time and inconvenience of every weekly video interview you

complete, no matter what the outcome of the interview or drug tests. Complete research study details can be found at www.clinicaltrials.gov (NCT04916600).



# THE STUDY

This research study (identification number NRC021) is being conducted by Wayne State University. Your data will be coded and will NOT have your name on it or any other personally identifying information. None of your personal health information will be shared with others outside of this study.

# **ELIGIBILITY REQUIREMENTS**

- Are between 18-65 years of age
- In good general health
- Currently diagnosed with opioid use disorder (OUD)
- Starting opioid discontinuation at Isaiah House
- Desire to be opioid abstinent without medication treatment



## PROCESS FOR DETERMINING ELIGIBILITY

- 1. Register for treatment at the study site for opioid use disorder.
- 2. Initial eligibility will be determined by speaking with a study coordinator by phone, who will ask you questions about your medical history.
- 3. If it appears you may be eligible for the research study, we will schedule an interview at the study site, to take place after your admission.
- 4. Note if you are currently taking benzodiazepines or sleeping pills, you must refrain from taking these for the duration of the study. You should talk to your doctor before stopping your medication.

5. If, after the interview, you meet all eligibility criteria, you will start the study as soon as your withdrawal severity reaches a moderate level.

The researchers may end your participation in the study for a number of reasons, such as if your safety and welfare are at risk, or if you do not follow instructions.

## **TO LEARN MORE**

If you are interested in speaking with Isaiah House regarding treatment for opioid addiction, please call 859-375-9200 or visit their website at www.isaiah-house.org.

www.clinicaltrials.gov (NCT04916600), Wayne State University Institutional Review Board Approved, Protocol ID: NRC021

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APPROVAL PERIOD
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INSTITUTIONAL REVIEW BOARD



