

CLINICAL TRIAL ENROLLING NOW!

VNS4PWS



Does your loved one struggle with disruptive behavior and temper outbursts? You could be eligible!

- THIS TRIAL WILL EVALUATE THE EFFECTIVENESS OF A WEARABLE MEDICAL **DEVICE**
- SEEKING PARTICIPANTS **AGES 10-40**
- HISTORY OF **TEMPER OUTBURSTS** OVER PAST 6 MONTHS



ONLY 2 IN-PERSON VISITS REQUIRED!

VNS4PWS is a phase 3 clinical trial evaluating the effectiveness of a Vagus Nerve Stimulation (VNS) device for improving disruptive behaviors and temper outbursts for people with PWS.

Eligible participants will wear a tVNS device for 4 hours each day and the caregiver will respond daily to a short 1-3 question survey to provide data on the frequency and severity of the day's outbursts. Only two in-person visits are required for the 9-month study.

WHO CAN PARTICIPATE IN THE TRIAL?

- People with PWS ages 10-40 and their caregivers
- Have a history of disruptive behaviors over the past 6 months
- Medications have been stable for the past 90 days

Participants who complete the trial will have the option of enrolling in an extension study so they may continue to use the device!

THE tVNS DEVICE

VNS uses brief electrical impulses to stimulate areas of the brain that are important for controlling emotions and behavior. The device used in our **VNS4PWS** clinical trial is:

- Small and portable
- Attaches to your ear like an ear bud
- Worn for 4 hours/day while going about your daily activities

An implantable VNS device has been approved by the FDA to treat epilepsy, chronic recurrent depression, migraines, and cluster headaches. Both implanted and wearable VNS devices have been studied in a small number of individuals with PWS with a significant reduction in both the number and severity of temper outbursts.



In two previous studies, participants experienced reductions in temper tantrums and disruptive behaviors.

VNS Study #1

The potential benefits of VNS in people with PWS were first demonstrated using a surgically implanted VNS device. While no effects on hyperphagia or weight were observed, improvements in temper outbursts were seen in two of three adult participants. The participant who showed no improvement did not have a prior history of temper outbursts. The two participants whose behavior improved asked to continue with the VNS after the study finished, and in an informal follow-up eight years later both individuals reported continuing benefits and no unexpected side effects.

VNS Study #2

A second clinical trial using transcutaneous vagus nerve stimulation (tVNS) has also shown efficacy. The external device was worn for four hours each day with an electrode in the left ear to stimulate the auricular branch of the vagus nerve. Temper outbursts improved significantly in 4 out of 5 participants after six to nine months of tVNS. Significant reductions in the number of temper outbursts were observed to the extent that they had no outbursts or, at the most, the occasional very minor outburst. No significant side effects were observed.

Questions? Ready to schedule a screening appointment?
Email us today at VNS@fpwr.org