Feasibility Trial of Transcutaneous Auricular Vagus Nerve Stimulation for People with Myalgic Encephalomyelitis

Grant Amount	£11,350
Location	University of Liverpool
Research Field	Treatment
Lead Researcher/s	Karen Lesile, under the supervision of Dr Andrew King and Dr Nicola Baker
Start Date	01/07/2024
Duration	6 years
Status	In progress
Latest Update	Physios For ME: Now Recruiting – Vagus Nerve Stimulation Study

BACKGROUND

Transcutaneous auricular vagus nerve stimulation (taVNS) is a non-invasive technique that uses electrodes applied to the ear to stimulate the auricular branch of the vagus nerve. It has been employed in the treatment of various conditions, including epilepsy, depression, and migraines, with research suggesting potential benefits for memory, inflammation, and pain management.

Recent interest in taVNS as a possible therapeutic intervention for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) has been prompted by an international survey of 116 individuals with ME/CFS who had used taVNS. Findings indicated that 56% experienced favourable effects, while 13% reported no change, and 6% noted worsening symptoms (Leslie et al., 2024). However, research in this area remains limited, with only one formal study (Natelson et al., 2023) investigating taVNS in ME/CFS patients. This open-label pilot study retained 15 of 17 participants for follow-up, producing inconsistent findings across seven patient-reported outcome measures.

Given the lack of robust evidence, further investigation is necessary to determine whether taVNS is a viable treatment option for ME/CFS.

PROJECT DETAILS

This feasibility study aims to assess whether a larger, definitive trial exploring the effects of taVNS in ME/CFS patients can be conducted. The study will focus on:

- **Assessing Feasibility:** Evaluating acceptability, adherence, recruitment, and retention rates to determine the practicality of a larger trial.
- **Defining Sample Size & Outcome Measures:** Establishing optimal sample size and appropriate methods for measuring taVNS's impact.
- **Understanding Patient Experience:** Gathering insights into how individuals with ME/CFS perceive and respond to taVNS treatment during the trial.
- **Evaluating Safety:** Ensuring the intervention does not pose significant risks for ME/CFS patients.

By systematically addressing these objectives, this study will lay the groundwork for a more comprehensive investigation into taVNS as a potential therapeutic tool.

IMPORTANCE OF FUNDING

Funding this research is essential for multiple reasons:

- **Clarifying Treatment Potential:** A well-conducted feasibility study will provide the necessary foundation for determining the viability of taVNS as an intervention for ME/CFS.
- **Supporting Patient-Centered Research:** ME/CFS remains a poorly understood condition with limited treatment options. Exploring new therapeutic possibilities could significantly improve patient care.
- **Strengthening Evidence-Based Medicine:** This study will contribute to the growing body of literature on taVNS, potentially informing future clinical guidelines and treatment approaches.

- **Providing a Foundation for Larger Trials:** Establishing feasibility will enable researchers to pursue a definitive clinical trial, ensuring rigorous evaluation of taVNS's effectiveness in ME/CFS treatment.

Investment in this research will allow for the necessary groundwork to explore taVNS as a possible treatment avenue for ME/CFS, offering new opportunities for symptom management and improved patient outcomes.

N.B. The ME Association are providing the PhD fees, while the trail is being funded by the Chartered Society of Physiotherapy. The trail is registered here: https://www.isrctn.com/ISRCTN15931869