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Study title:

An international survey of experiences and attitudes towards Transcutaneous Auricular Vagus Nerve Stimulation for people with Myalgic Encephalomyelitis /Chronic Fatigue Syndrome and Long COVID (with PEM).

INFORMATION LEAFLET

You are invited to take part in a research study. Before you decide whether or not to take part, we would like to explain why the study is being done and what it will involve. Please read the following information and ask us if anything is not clear, or if you would like more information, using one of the contact options listed above.

What is the purpose of this study?

The aim of this study is to explore the experiences of and attitudes towards Transcutaneous Auricular Vagus Nerve Stimulation (taVNS) for people with Myalgic Encephalomyelitis /Chronic Fatigue Syndrome (ME/CFS) and Long COVID (with PEM). There is growing anecdotal evidence that taVNS is being utilised as a therapy for people living with ME/CFS and Long COVID.

However, there is a lack of formal studies in this area.

Why have I been invited?

You have been invited because you have ME/CFS and/or Long COVID (with PEM) and use or have used taVNS and we believe, therefore, that you may be eligible to participate in the study. Please refer to the International Consensus criteria for ME/CFS to check if you meet the criteria for ME/CFS and to see if you are therefore eligible to take part in the study - <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3427890/>

What will happen if I decide to take part?

If you decide to take part, you will be asked to read this Patient Information Sheet and then if you fit the criteria and are happy to complete the survey to click on the link at the end of this patient Information sheet. There are 35 questions to answer, and most are multiple choice quick answers to reduce the energy required to fill out the survey.

The survey is international, and many countries use different terminology for ME/CFS including: Systemic Disease Intolerance Disease (SEID), Chronic Fatigue Immune Dysfunction Syndrome (CFIDS), Post Viral Fatigue Syndrome (PVFS). To this end, we will use the generic term “ME/CFS” so that we can survey everyone who suffers from Post Exertional Malaise (PEM). The UK NICE Guideline defines PEM as “the worsening of symptoms that can follow minimal cognitive, physical, emotional or social activity, or activity that could previously be tolerated. Symptoms can typically worsen 12 to 48 hours after activity and last for days or even weeks, sometimes leading to a relapse.” NICE guideline [NG206] Published: 29 October 2021

It is assumed that by completing the survey you are consenting to this data being collected, collated and published. There will no identifiable personal data collected, and all data will be securely stored in a password-protected University of Liverpool computer. The data will be stored for the recommended five years.

Do I have to take part?

Only if you want to.

Participation is voluntary, you may refuse to participate. You do not need to tell us why you do not want to take part. If you choose not to participate, your decision will in no way affect your future healthcare.

What are the possible disadvantages and risks of taking part?

There are no disadvantages to taking part, however, there are 35 questions to answer so this will take up to 20 minutes to complete. There may be a risk of exacerbating your post-exertional malaise.

Are there any benefits of taking part in this study?

There are no direct benefits to taking part. However, the aim of the study is to explore the use of taVNS so your answers might help people with ME/CFS and Long COVID in the future. In addition, this will inform a larger study investigating the effect of taVNS for people with ME/CFS and Long COVID(with PEM).

Are there any costs involved?

No

Withdrawal options and your rights

Your participation in this study is entirely voluntary and refusal will not affect any health care.

Unfortunately, it will be difficult to withdraw your data once you have completed the survey as the responses are all anonymous.

Data protection & confidentiality

The study complies with Government & the University of Liverpool's data protection policy as well as the University's research ethics requirements. Information to identify you are: your gender and

age. All information provided will be kept strictly confidential. The information from the study will be kept in a password-protected university computer that only the research team will have access to. The information from this study will be retained for ten years.

What if things go wrong? Who to complain to.

If you have a concern about any aspect of this study, you should ask to speak with the researchers, who will do their best to answer your questions, or contact the Principal Investigator, Dr Nicola Clague-Baker (Nicola.Baker@liverpool.ac.uk), Tel. 0151 795 8073. If you are not satisfied with the response you receive from the investigator, then there is a formal university complaints procedure.

What will happen with the results of the study?

The results will be analysed and discussed by the researcher. The results of the study may also be presented in research reports, scientific conferences and/or journals and be made available to people with ME/CFS and Long COVID via the PhysiosforME and Longcovidphysio websites. The results may act as baseline information that guides future research by other investigators.

Who has reviewed this study?

All research involving human subjects must receive approval from the University of Liverpool Ethics Committee before it can go ahead. Approval does not guarantee that you will not come to any harm if you take part. However, approval means that the committee is satisfied that your rights will be respected, that the study carries no more than minimal risk, and that you have been given sufficient information on which to make an informed decision.

Who is organising and funding the research?

This study is being conducted by a team of experts at the University of Liverpool, PhysioforME and the facebook group: A Vagus Adventure – Dawn Wiley.

Further information/Key contact details

Principal Investigator: Dr Nicola Clague-Baker at Nicola.Baker@liverpool.ac.uk

If you are happy with the above and have no questions, please complete the survey.

Thank you.

Please follow the link to complete the survey, by clicking on the link I give my informed consent:

<https://liverpool.onlinesurveys.ac.uk/jadhjfmw5-11>