Developing and Testing a Personalised Dysautonomia Management Protocol (DMP) in ME/CFS and Long Covid – A Proof-of-Concept Study

Grant Amount	£49,908.08
Location	University of Leeds
Research Field	Treatment
Lead Researcher/s	Manoj Sivan
Start Date	01/11/2024
Duration	8 months
Status	In progress
Latest Update	Professor Manoj Sivan to develop new protocol for dysautonomia in ME/CFS and Long Covid
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BACKGROUND

Dysautonomia is a clinical syndrome characterized by dysfunction of the autonomic nervous system (ANS), which regulates vital processes such as heart rate, digestion, and body temperature. Individuals with dysautonomia may experience symptoms such as abnormal heart rate fluctuations, headaches, anxiety, excessive sweating (or reduced sweating), and severe fatigue. Research indicates that dysautonomia is present in over half of patients diagnosed with Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) and Long Covid, yet standardized treatment approaches remain limited.

Given the persistent and debilitating nature of these symptoms, developing effective, evidence-based management strategies is crucial. This pilot study aims to establish and assess a personalized Dysautonomia Management Protocol (DMP) to improve symptom management, enhance quality of life, and provide a foundation for larger-scale research initiatives.

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PROJECT DETAILS

This exploratory prospective study will evaluate the effectiveness of an 8-week clinically supervised, personalized DMP in a cohort of ME/CFS and Long Covid patients with objectively confirmed dysautonomia. The DMP will include a structured combination of:

- **Hydration and Salt Intake:** Increasing fluid and salt consumption to support circulatory stability.
- **Dietary Adjustments:** Regulating food type and portion sizes to mitigate symptoms.
- **Activity Optimization:** Balancing physical, cognitive, and emotional exertion to prevent symptom exacerbation or "crashes."
- **Calf Muscle Function:** Strengthening exercises to support circulatory dynamics.
- **Pharmacological Intervention:** Selective use of medications for patients with Postural Tachycardia Syndrome (PoTS) or Orthostatic Hypotension (OH).

Each intervention will be tested sequentially for each patient to determine the most effective component, while recognizing the cumulative impact of combined interventions. The study will involve 50 participants, split equally between ME/CFS and Long Covid patients. Weekly assessments will measure progress using established dysautonomia evaluation scales such as the Yorkshire Rehabilitation Scale (YRS), Composite Autonomic Symptom Score (COMPASS-31), and objective testing through the Adapted Autonomic Profile (aAP).

IMPORTANCE OF FUNDING

Funding for this pilot study is crucial for several reasons:

- **Improving Patient Care:** ME/CFS and Long Covid continue to affect hundreds of thousands of individuals, many of whom suffer from dysautonomia-related symptoms with limited treatment options. This study may provide a structured, evidence-based approach to symptom relief.
- **Advancing Scientific Understanding:** By systematically testing interventions, this research will generate valuable insights into managing dysautonomia in these conditions.

- **Laying the Groundwork for Larger Trials:** Successful implementation of this pilot study will strengthen the case for a larger application to the National Institute for Health and Care Research (NIHR) in 2025/26, enabling more extensive investigations into treatment efficacy.
- **Long-Term Health Benefits:** A refined and validated DMP could eventually be integrated into clinical practice, bringing much-needed relief to patients struggling with these debilitating symptoms.

Through its investment in this study, the ME Association demonstrates its ongoing commitment to biomedical research that could significantly improve the lives of ME/CFS and Long Covid patients. Funding now will allow researchers to establish a strong foundation for future large-scale investigations and treatment development.