



# Massachusetts ME/CFS & FM

ASSOCIATION

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3/26/2023

Dr. Eldrin Lewis and Dr. Laurie Gutmann  
Co-chairs  
RECOVER Clinical Trials Steering Committee

Dear Drs. Lewis and Gutmann,

The Massachusetts ME/CFS & FM Association has a forty year history of advocating for people with ME/CFS. We congratulate the RECOVER initiative in recognizing the long-standing disease ME/CFS, and in recognizing the cohort of Long COVID patients with ME/CFS. We are writing to request post-exertional malaise (PEM), one of the major indicators of ME/CFS, be adequately accounted for in the RECOVER clinical trials that include exercise. Post-Exertional Malaise (PEM) is a main contributor to the difficulties Long COVID patients with ME/CFS will experience, and by its nature, can have serious and long-lasting effects on the health of patients taking part in an exercise trial.

We feel strongly that the following are essential considerations and should be incorporated in clinical trials in order to best suit the needs of Long COVID patients with ME/CFS. We recommend that RECOVER:

- Include the [DePaul Symptom Questionnaire \(DSQ-2\)](#), for **both adult and pediatric** patient populations in order to provide standardized and correct diagnoses of Long COVID patients with ME/CFS.
- For transparency and safety, identify Long COVID patients with PEM effectively and in a standardized manner.
- Recognize the limitations and profound impact of PEM on Long COVID patients with ME/CFS:
  - Recognize the evidence-based contribution of PEM to physical limitations in any exertion.
  - Minimize predicted harmful outcomes for Long COVID patients with ME/CFS by avoiding interventions which exacerbate PEM.
  - Exclude Long COVID patients with ME/CFS, who by default experience profound effects after exertion due to PEM, from any trial with graded exercise therapy.

- Utilize evidence-based and patient-supported interventions, such as the Leeds Structured Pacing Rehabilitation trial ([Parker et al 2022](#)), for Long COVID patients with ME/CFS in order to avoid PEM.
- If exercise regimens are applied to Long COVID patients with ME/CFS:
  - Incorporate clear and standardized procedures and share them with the patients before the trials begin, including disclosing all potential harmful effects.
  - Include standardized patient monitoring immediately after — and for several days following — exercise therapy, including remote monitoring.
  - Correctly document worsening PEM or other symptoms reported by Long COVID patients with ME/CFS after exercise therapy.
  - Incorporate standardized inclusion and exclusion criteria of patients with PEM throughout the clinical trials.
  - Keep a standard output measurement throughout the trial, coupled to functionality.

We hope you will appreciate our concerns for Long COVID patients with ME/CFS, and incorporate the above considerations into any clinical trials.

Respectfully,

*Hayla Sluss*

Hayla K. Sluss, Ph.D.

on behalf of the Board of the Massachusetts ME/CFS & FM Association

CC:

Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke

Dr. Gary Gibbons, Director, National Heart, Lung, and Blood Institute

Dr. Hugh Auchincloss, Acting Head of National Institute of Allergy and Infectious Diseases