

SUMMARY

This examination of the PACE trial of chronic fatigue syndrome identified several major flaws:

- * The study included a **bizarre paradox**: participants' baseline scores for the two primary outcomes of physical function and fatigue could qualify them simultaneously as disabled enough to get into the trial but already "recovered" on those indicators - even before any treatment. In fact, 13 percent of the study sample was already "recovered" on one of these two measures at the start of the study.
- * In the middle of the study, the PACE team published a **newsletter** for participants that included glowing testimonials from earlier trial subjects about how much the "therapy" and "treatment" helped them. The newsletter also included an article informing participants that the two interventions pioneered by the investigators and being tested for efficacy in the trial, graded exercise therapy and cognitive behavior therapy, had been recommended as treatments by a U.K. government committee "based on the best available evidence." The newsletter article **did not mention that a key PACE investigator was also serving on the U.K. government committee that endorsed the PACE therapies.**
- * **The PACE team changed all the methods outlined in its protocol for assessing the primary outcomes of physical function and fatigue**, but did not take necessary steps to demonstrate that the revised methods and findings were robust, such as including sensitivity analyses. **The researchers also relaxed all four of the criteria outlined in the protocol for defining "recovery."** They have rejected requests from patients for the findings as originally promised in the protocol as "vexatious."
- * **The PACE claims of successful treatment and "recovery" were based solely on subjective outcomes. All the objective measures from the trial - a walking test, a step test, and data on employment and the receipt of financial information - failed to provide any evidence to support such claims.** Afterwards, the PACE authors dismissed their own main objective measures as non-objective, irrelevant, or unreliable.
- * In seeking informed consent, the PACE authors violated their own protocol, which included an explicit commitment to tell prospective participants about any possible conflicts of interest. **The main investigators have had longstanding financial and consulting ties with disability insurance companies**, having advised them for years that cognitive behavior therapy and graded exercise therapy could get claimants off benefits and back to work. Yet prospective participants were not told about any insurance industry links and the information was not included on consent forms. The authors did include the information in the "conflicts of interest" sections of the published papers.