

# The Biopsychosocial Approach to “CFS”: PACE, Music Therapy + CBT, and Other Crap

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“Conflicts-of-Interest” — My crowdfunded donations

Zoom Talk: Norway

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# Big Question for All of This Research

\*Open Label/Unblinded Trials

\*Subjective Outcomes

Q: Can trials combining these two elements provide good data?

A: No

# Big Questions About PACE

- Does a study in which participants had already met outcome thresholds for primary measures at baseline have a legitimate place in the domain called “science”?
- Is there a place in “science” for a study in which participants were simultaneously “disabled” and “recovered”?
- Why has a study containing this paradox been defended for so long by the U.K. (and Norwegian) academic and medical establishment?

# IOM Report: 2015

- Institute of Medicine (now Academy of Medicine) and National Institutes of Health issue reports based on review of 1000s of studies.
- IOM declares that *“ME/CFS is a serious, chronic, complex, and multisystem disease that frequently and dramatically limits the activities of affected patients.”* Rejects idea that it is psychiatric disorder, or caused by deconditioning and false illness beliefs.
- Report refocuses away from “fatigue” and names “exertion intolerance” as cardinal symptom.

# PACE Trial: “Definitive” study of CBT/GET

- Open label with subjective outcomes (all objective measures failed to show success, so they dismissed them as irrelevant)
- Use of bogus Oxford criteria conflating chronic fatigue and ME
- 641 participants
- Four trial arms: CBT, GET, APT, SMC
- Principal investigators: Dr. Peter White (QMUL), Dr. Michael Sharpe (Oxford), Dr. Trudie Chalder (KCL)
- Based on unproven theory that all symptoms due to deconditioning because of patients’ “dysfunctional cognitions” about their illness

# PACE Trial

2011: First results in Lancet, 59-61 % "improved" with CBT/GET; "twice as many...back-to-normal"

Lancet commentary by Dutch: 30 percent met "strict criterion for recovery"

2013: Psychological Medicine: 22 % "recovered" with CBT/GET

October, 2015: Virology Blog publishes "Trial by Error" series

August, 2016: Tribunal orders QMUL to turn over raw trial data in scathing decision

March, 2018: BMC Psychology publishes full reanalysis of "improvement," "recovery" and long-term results

Conclusion: PACE outcome-switching changes null or placebo-induced results into decent ones. No long-term benefits from CBT/GET

# Expert Responses to PACE

Professor Bruce Levin, Columbia: “The height of clinical trial amateurism”

Professor Jonathan Edwards, University College London: “It’s a mass of incomprehensibility to me.”

David Tuller, UC Berkeley: “A piece of crap.”

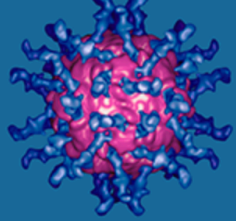
MP Monaghan: “One of the biggest medical scandals of the 21<sup>st</sup> century”

Sir Simon Wessely: “A thing of beauty”

Professor Esther Crawley, Bristol University: A “great, great” trial

# My 15,000-word expose, plus follow-ups

## Thanks to: Dr. Vincent Racaniello



**virology blog**  
About viruses and viral disease

### TRIAL BY ERROR: The Troubling Case of the PACE Chronic Fatigue Syndrome Study

21 OCTOBER 2015

By David Tuller, DrPH

David Tuller is academic coordinator of the concurrent masters degree program in public health and journalism at the University of California, Berkeley.

BY VINCENT RACANIELLO

Earth's virology Professor

Questions?

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# Reasons for Concern

- \*Bizarre outcome-switching

- \*Lack of legitimate informed consent

- \*Study design (open label/subjective outcomes) and use of Oxford criteria: Bad science but not clear that these warrant retraction

# Outcome Switching in PACE

Primary outcome: Physical function on SF-36 (0-100)

Trial: Entry score required to demonstrate disability = 65 or less

Protocol: Score of 85 = “recovery” for physical function

Lancet: “normal range” for physical function = 60

Psychological Medicine: “recovery” for physical function = 60

13 % of 641 participants were already “within normal range”/”recovered” on physical function at entry

Why were they in the trial in the first place?

Why was this important fact NOT DISCLOSED in any of the published papers?

Other outcome switching:

- Multiple examples of this in PACE

- All had effect of weakening protocol measures

# PACE Answers to Outcome-Switching

\*We changed outcome measures before seeing the results, so they were pre-specified (DT: It was unblinded/subjective outcomes.)

\*We decided our original measures were too stringent  
(DT: Why bother writing a protocol?)

\*It doesn't matter that people were "recovered" on key variables because we had other "recovery" measures as well.  
(DT: A response from outer space)

\*Reanalyzers "tweaked" our outcomes to make the results look worse  
(DT: Reanalyzers "untweaked" what was "tweaked" without justification.)

# PACE Trial did not obtain INFORMED consent

PACE Trial Protocol: Promise to adhere to Declaration of Helsinki

Declaration of Helsinki on Informed Consent:

\*Researchers must tell prospective participants about “any possible conflicts of interests” and “institutional affiliations”

\*PACE PIs have advised disability insurers that rehabilitative therapies like CBT/GET are indicated for ME/CFS claimants

\*PACE PIs did not include promised disclosures in consent forms

# PACE Answers to Lack of Informed Consent

- \*We told the journals about our possible conflicts of interest  
(DT: A non-response)
- \*Insurance companies were not involved in the study  
(DT: Another non-response)
- \*Only three of 19 investigators did work for insurance companies  
(DT: So...? Anyway, four of them had ties, not three)

# Is PACE an example of research misconduct?

- Misrepresentation of data, for example suppression of relevant findings and/or data, or knowingly, recklessly or by gross negligence, presenting a flawed interpretation of data (MRC)
- Misrepresentation of interests, including failure to declare material interests either of the researcher or of the funders of the research (MRC)
- Falsification: Manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record (NIH)

# Conclusions About PACE

\*Reported PACE results cannot be taken at face value and proved that treatments in “definitive” trial didn’t work

\*The data manipulations, lack of informed consent, and other issues could lead to the conclusion that this is research misconduct, according to standard definitions.

\*PACE authors are the “anti-science” crowd, like climate-change deniers--not PACE patients.

\*Best use of PACE—pedagogical tool

# Norwegian Study: CBT and Music Therapy for Post-GF Fatigue

- Published in high-profile BMJ Paediatrics Open
- Research Question: Can CBT prevent chronic fatigue post-GF?
- Population: Adolescents with glandular fever
- Intervention: Half got CBT plus music therapy, half did not



# Broken Peer Review System

Open peer review:

Reviewer #2: I haven't read "beyond the abstract"

In other words: Abstract was reviewed, but not the rest of the paper

THIS DID NOT BAR PUBLICATION IN BMJ PAEDIATRICS OPEN!!!!

HARD TO DESCRIBE HOW SHOCKING THIS IS—

# Main Concern: Not a Feasibility Trial

Designed in protocol as a full-scale trial

Disappointing results

Re-purposed to be a “feasibility trial” —to ask for future funding

This could be considered research misconduct!!

# Other Concerns:

\***Post-hoc outcome:** PEM not in protocol, but added later and cited positively in conclusions

\***Primary objective outcome**—average #steps/day

BOTH GROUPS WALKED—BUT INTERVENTION GROUP DID WORSE

Not mentioned in conclusion

\***Recovery measure does not include primary outcome**

# Resolution: Retract and Replace

- New Version as bad as the old one--just not referred to as a “feasibility” trial
- BMJ blames itself rather than authors for false information about trial
- PEM still included, main outcome still not mentioned in conclusions
- No mention of failure of peer review
- It is still CRAP, and findings still presented in misleading manner

# Thanks To...

- Brilliant patients/advocates who first deconstructed and dissected the science—too many to name
- Vincent Racaniello for trusting in my reporting
- UC Berkeley for valuing academic freedom
- The Center for Global Public Health for supporting me
- Faculty colleagues at SPH and Berkeley who recognize nonsense