2015-12 December - Will the PACE trial finally be repudiated?

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Editor's note: This newsletter has been a couple of months in the making. Just when we were ready to publish, more fascinating and relevant papers, advocacy actions, and investigative journalism pieces were published. The rapid release of news has slowed a bit, and December is upon us, so here it is!
There is a lot of reading here. You don't have to read all the articles, but the links are included if you wish to do so. The significance of the articles and research papers is noted so you can choose what is most interesting to you.

There are also some research and advocacy opportunities for you to consider that we are putting at the top.

We are still in the middle of the controversy regarding the PACE Trial research (the work that recommends Graded Exercise Therapy as an effective treatment for ME/CFS). The Lancet, the respected British medical journal that has been publishing the PACE studies, has been asked to retract them or subject the data to an independent review. We don't yet know whether the editors will respond to these requests. This could make a huge difference to treatment recommendations. Stay tuned!

This newsletter also contains some interesting new research on Fibromyalgia, and a report on a paper we especially liked by Mark Vink, a Dutch researcher and ME/CFS patient who carried out his research on energy metabolism from his bed, using himself as the only study subject.
We hope you will enjoy this collection of news.

Advocacy Action: Sign the "reject PACE" petition

Thanks to advocate Mary Dimmock for this announcement.

> Recently, journalist David Tuller, DrPH, published an investigative report outlining serious concerns with the conduct, analyses, and results of U.K.'s £5 million PACE trial for chronic fatigue syndrome. PACE investigated the efficacy of cognitive behavioral therapy (CBT) and graded exercise therapy (GET).
> PACE is hugely influential globally in how patients are treated in the media, by society, and especially in medical practice. In the U.S., various clinical guidelines recommend that ME/CFS patients be treated with CBT and GET, based in part on the PACE trial. In addition, the Agency for Healthcare Research and Quality (AHRQ, which is part of the Department of Health and Human Services) published a 2014 evidence review that also recommended CBT and GET, based in part on PACE. The AHRQ Evidence Review can be used to support CBT and GET recommendations in future journal articles and in the clinical guidelines of any country. Such recommendations can harm patients.
>
> Therefore, together with 11 other U.S. ME/CFS organizations, we have called on the CDC and the AHRQ to investigate the concerns raised by Dr. Tuller, other researchers and many patients. We have asked them to take the necessary steps with CDC's clinical guidelines/medical education and AHRQ's Evidence Review to protect patients. The letter to Director Thomas Frieden of the CDC and Director Dr. Richard Kronick of the AHRQ can be found here (https://dl.dropboxusercontent.com/u/89158245/CDC-AHRQ%20Request%20PACE%20Nov%202015.pdf).
>
> Add your voice to this request by signing this accompanying petition (http://my.meaction.net/petitions/call-for-cdc-and-ahrq-to-investigate-pace). While the petition is directed to CDC and AHRQ, their response will affect other countries as well so we encourage people from all countries to sign.

Research Opportunity: Dr. Nancy Klimas' ME/CFS Genes Study – how you can participate

Dr. Nancy Klimas is a prominent ME/CFS researcher and clinician at Nova Southeastern University. The goal of this innovative research is to collect and analyze 10,000 genetic profiles submitted by ME/CFS and Gulf War Syndrome patients. Many people with POTS, Lyme disease, Fibromyalgia or similar conditions may also be included as the research requires a very large genetic database. Anyone in the world can participate, as long as you can get the genetic testing done.

Here is NOVA's page explaining the study and instructions for how you can participat (http://www.nova.edu/nim/research/mecfs-genes.html)e. This page includes link to a video further explaining the study. Individuals interested in participating must email MECFSGenes "at" Nova.edu and you will then receive by email a personalized link to a secure website which houses the study. If you are having trouble understanding what to do, contact the research team directly at the email above and they will help you.

SFPN Video posted

"Fibromyalgia and Small Fiber Polyneuropathy," Dr. Farhad Khosro's recent talk to our Association, is now available as two videos and an article. Small Fiber Polyneuropathy, which is found in up to half of fibromyalgia patients, may be treatable, but many neurologists do not know much about it.
Lecture (https://youtu.be/phJGINZXQoQ) (27 minutes)
Question & Answer (https://youtu.be/DkF6h8fGb1I) (30 minutes)
Slides, recommended tests and the full text of all the research papers cited in the talk are available here. We will soon post a written summary of the talk as well.

Controversy over the British "PACE" trials continues – will this work finally be repudiated?

This is a summary of recent work pointing out significant flaws in the studies that have led to widespread recommendations that ME/CFS patients be treated with exercise and behavioral therapy, a prescription which many patients say has led to a major, and sometimes permanent, deterioration of their condition and ability to function.

Any discussion of the PACE trials, the large British study purporting to show the benefits to ME/CFS patients of Graded Exercise Therapy (GET)and Cognitive Behavioral Therapy (CBT), has to start with ME/CFS advocate and patient **Tom Kindlon's seminal paper**: "Reporting of Harms Associated with Graded Exercise Therapy and Cognitive Behavioural Therapy in Myalgic Encephalomyelitis/Chronic Fatigue Syndrome." This article was originally published in the Bulletin of the IACFS/ME (peer-reviewed) 01/2011; 19(2):59-111. The full text is available here (http://www.researchgate.net/publication/216572185_Reporting_of_Harms_Associated_with_Graded_Exercise_Therapy_and_Cognitive_Behavioural_Therapy_in_Myalgic_EncephalomyelitisChronic_Fat

PACE study – demands to The Lancet gather to have an independent review or full retraction
In late October 2015, David Tuller, journalist with a doctorate in public health, now academic coordinator of the concurrent masters degree program in public health and journalism at the University of California, Berkeley, published on Virology Blog "Trial by Error," a multi-part in-depth analysis of the PACE study. This analysis has been widely acclaimed by ME/CFS researchers and advocates.
Here is a list of the links.
Parts 1 and 2 (http://www.virology.ws/2015/10/21/trial-by-error-i/): TRIAL BY ERROR: The Troubling Case of the PACE Chronic Fatigue Syndrome Study
21 OCTOBER 2015
Part 3 (http://www.virology.ws/2015/10/22/trial-by-error-ii/): TRIAL BY ERROR: The Troubling Case of the PACE Chronic Fatigue Syndrome Study (second installment)
22 OCTOBER 2015
Part 4 (http://www.virology.ws/2015/10/23/trial-by-error-iii): TRIAL BY ERROR: The Troubling Case of the PACE Chronic Fatigue Syndrome Study (final installment)
23 OCTOBER 2015

In November **Dr. Tuller published several follow up articles** as well.
Trial By Error, Continued: Why has the PACE Study's "Sister Trial" been "Disappeared" and Forgotten? (http://www.virology.ws/2015/11/09/trial-by-error-continued-why-has-the-pace-studys-sister-trial-been-disappeared-and-forgotten)

9 NOVEMBER 2015
And finally, Trial by error, Continued: PACE Team's Work for Insurance Companies Is "Not Related" to PACE. Really? (http://www.virology.ws/2015/11/17/trial-by-error-continued-pace-teams-work-for-insurance-companies-not-related-to-pace-really/)
17 NOVEMBER 2015

You can read David Tuller's personal statement about writing these articles here (http://alumni.berkeley.edu/california-magazine/just-in/2015-11-18/reporter-excoriates-chronic-fatigue-syndrome-study-i-stopped). Be sure to read the comments, heart-breaking patient stories along with heart-felt thanks from patients.
Reporter Excoriates Chronic Fatigue Syndrome Study: I Stopped at 14,000 Words-Enough Was Enough

Requests to The Lancet. There are now several requests to the editors of The Lancet, the British medical journal which has been publishing the PACE work, to either submit the PACE trial data to an independent review or retract the work entirely. To date, the editors have not responded.

Letter from six eminent scientists to The Lancet (http://www.virology.ws/2015/11/13/an-open-letter-to-dr-richard-horton-and-the-lancet/)

Letter from the UK charity Invest in ME (http://www.investinme.org/Documents/Lancet/Letter%20to%20Editor%20of%20the%20Lancet%20November%202015.pdf) which advocates for more research into ME.

Letter from advocates (https://dl.dropboxusercontent.com/u/89158245/CDC-AHRQ%20Request%20PACE%20Nov%202015.pdf) to CDC and AHRQ calling for retraction of treatment recommendations based on the PACE study. *Note: Massachusetts CFIDS/ME & FM Association, along with a number of other ME/CFS organizations, co-signed this letter.*

In early November, the Information Commissioner's Office (ICO) (http://www.meaction.net/2015/11/06/government-orders-release-of-pace-trial-data/) ordered Queen Mary University of London to release anonymized PACE trial data to an unnamed complainant. We do not if the University has complied with this order.

Finally, a slightly hopeful article by Virginia Gerwin on **new hopes for reconciliation** in "Fighting over fatigue (http://mosaicscience.com/chronic-fatigue-syndrome-me)," an article published by Mosaic (UK)
10 November 2015
ME/CFS Patient Julie Rehmeyer sums all of this up for a lay readership in her article, "Hope for Chronic Fatigue Syndrome (http://www.slate.com/articles/health_and_science/medical_examiner/2015/11/chronic_fatigue_pace_trial_is_flawed_should_be_reanalyzed.html)," in the popular online magazine, Slate.

Action: You can SIGN THE Petition to investigate PACE

Sign the petition here! (http://my.meaction.net/petitions/call-for-cdc-and-ahrq-to-investigate-pace)
(http://my.meaction.net/petitions/call-for-cdc-and-ahrq-to-investigate-pace)

Fibromyalgia research

An update on pharmacotherapy for the treatment of fibromyalgia (http://www.ncbi.nlm.nih.gov/pubmed/26001183)
Calandre EP1, Rico-Villademoros F, Slim M
Expert Opin Pharmacother. 2015 Jun;16(9):1347-68. doi: 10.1517/14656566.2015.1047343.
None of the currently available drugs are fully effective against the whole spectrum of fibromyalgia symptoms, namely pain, fatigue, sleep disturbances and depression, among the most relevant symptoms. Combination therapy is an option that needs to be more thoroughly investigated in clinical trials. Note: full text not available.

Drugs to Treat Fibromyalgia Just as Likely to Harm as Help (http://www.cfah.org/hbns/2013/drugs-to-treat-fibromyalgia-just-as-likely-to-harm-as-help-)
Center for Advancing Health, Health Behavior News Service, Article by January 31, 2013 | By Laura Kennedy, HBNS Contributing Writer based on:
HäuserW, Urrútia G, Tort S, ÜçeylerN,Walitt B. Serotonin and noradrenaline reuptake inhibitors (SNRIs) for fibromyalgia syndrome. Cochrane Database of Systematic Reviews 2013, Issue 1. Art. No.: CD010292. DOI: 10.1002/14651858.CD010292.
KEY POINTS
- Two medications prescribed to reduce fibromyalgia pain help and harm patients in nearly equal numbers.
- Treatment for fibromyalgia with drugs alone should be discouraged.
- Combining medication, exercise and counseling may be the most helpful approach to fibromyalgia.

Research Highlights Altered CNS Processing for Fibromyalgia Patients (http://www.hcplive.com/medical-news/research-highlights-altered-cns-processing-for-fibromyalgia-patients)
Oct 23, 2015 | Bill Schu
Using a new technique, functional near-infrared spectroscopy (fNIRS), researchers in Germany have investigated cerebral activation in Fibromyalgia patients and "discovered altered central nervous processing in patients with FMS, as well as a distinction between FMS and major depression (MD)."
According to the study authors, "… FMS patients differ in their cortical activity from patients with MD but without pain by a) stronger and bilateral cortical activation upon painful stimulation, b) normal cortical activation during executive functions (VFT), and c) a higher cortical activation during the letter task of the VFT correlating with low performance."

Increased cortical activation upon painful stimulation in fibromyalgia syndrome (http://www.biomedcentral.com/1471-2377/15/210)
Nurcan Üçeyler1*†, Julia Zeller2†, Susanne Kewenig1, Sarah Kittel-Schneider2, Andreas J. Fallgatter3 and Claudia Sommer1
BMC Neurology 2015, 15:210

Post exertional malaise research

Read this intriguing and innovative work by an ME/CFS researcher who conducted his research from his bed.
Vink M (2015) The Aerobic Energy Production and the Lactic Acid Excretion are both Impeded in Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (https://sciforschenonline.org/journals/neurology/JNNB-1-112.php). J Neurol Neurobiol 1(4): doi http:// dx.doi.org/10.16966/2379-7150.112

How You Can Get Involved with Massachusetts CFIDS/ME & FM Association

Amazon Smile. Contribute funds to our Association at no cost to you! A portion of the sales price of most items you buy from Amazon.com will be sent to our Association every quarter. To set this up, click the Amazon Smile graphic on our home page or click here (/component/weblinks/weblink/55-association/51-amazon-smile-program?Itemid=267&task=weblink.go). Search for Massachusetts C F I D S Association in the charities list, and be sure to put spaces between the letters C F I D S. Then start your shopping from smile.amazon.com.

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Follow us on Facebook for weekly updates, research news, and announcements.
Due to recent changes in Facebook policy, to see postings to our page it's not enough to "Like" the page. If you "Like" us, you may get some updates posted to your news feed, but it is likely that you won't get them all. Instead, bookmark the page and go to it at least once a week to see the new posts. You don't need to be logged in to Facebook or even have a Facebook account to see the page. But you need the entire URL: https://www.facebook.com/pages/Massachusetts-CFIDS-ME-FM-Association/1417893258457858 (https://www.facebook.com/pages/Massachusetts-CFIDS-ME-FM-Association/1417893258457858). If you want to leave a comment, you do need to have a Facebook account.