

The Lightning Process Trial: A Saga of Terrible, Horrible, No Good, Very Bad Research--and Even Worse Editorial Decisions

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*Kid's book: Alexander and the Terrible, Horrible, No Good, Very Bad Day

The Lightning Process Trial

Archives of Disease in Childhood: Sept, 2017

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Original article



OPEN ACCESS

Clinical and cost-effectiveness of the Lightning Process in addition to specialist medical care for paediatric chronic fatigue syndrome: randomised controlled trial

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ABSTRACT
Objective Investigate the effectiveness and cost-effectiveness of the Lightning Process (LP) in addition to specialist medical care (SMC) compared with SMC alone, for children with chronic fatigue syndrome (CFS)/myalgic encephalitis (ME).

Design Pragmatic randomised controlled open trial. Participants were randomly assigned to SMC or SMC+LP. Randomisation was minimised by age and gender.

Setting Specialist paediatric CFS/ME service.

Patients 12–18 year olds with mild/moderate CFS/ME.

Main outcome measures The primary outcome was the 36-Item Short-Form Health Survey Physical Function Subscale (SF-36-PFS) at 6 months. Secondary outcomes included pain, anxiety, depression, school attendance and cost-effectiveness from a health service perspective at 3, 6 and 12 months.

Results We recruited 100 participants, of whom 51 were randomised to SMC+LP. Data from 81 participants were analysed at 6 months. Physical function (SF-36-PFS) was better in those allocated SMC+LP (adjusted difference in means 12.5(95% CI 4.5 to 20.5), $p=0.003$) and this improved further at 12 months (15.1 (5.8 to 24.4), $p=0.002$). At 6 months, fatigue and anxiety were reduced, and at 12 months, fatigue, anxiety, depression and school attendance had improved in the SMC+LP arm. Results were similar following multiple imputation. SMC+LP was probably more cost-effective in the multiple imputation dataset (difference in means in net monetary benefit at 12 months £1474(95% CI £111 to £2836), $p=0.034$) but not for complete cases.

Conclusion The LP is effective and is probably cost-effective when provided in addition to SMC for mild/moderately affected adolescents with CFS/ME.

Trial registration number ISRCTN81456207.

INTRODUCTION

Paediatric chronic fatigue syndrome (CFS) or myalgic encephalitis (ME) affects 0.57%–2.4%^{1–4} of children and is disabling with important impacts on mood^{5–6}, school attendance^{4,7–8}, quality of life⁹ and family functioning.¹⁰ It is defined as generalised fatigue causing disruption of daily life, persisting after routine tests and investigations have failed to identify an obvious underlying cause.¹¹ A minimum of 3 months of fatigue is required before the

What is already known on this topic?

- Paediatric chronic fatigue syndrome (CFS)/myalgic encephalitis (ME) is relatively common with a negative impact on school, mood and quality of life.
- Even with effective treatment, a significant number of children have not recovered at 6 months.
- The Lightning Process (LP) is used by children with CFS/ME in the UK but with no evidence of effectiveness.

What this study adds?

- At 6 months, children who received LP in addition to SMC had better physical function, fatigue and less anxiety.
- At 12 months, children who received LP in addition to SMC had better fatigue, anxiety, depression and school attendance.
- Adding LP is probably cost-effective but not all children wish to take part.

diagnosis can be made.¹² On average, those affected miss a year of school overall and half are bedbound at some stage.^{13,14}

There is a limited evidence base for treatment of paediatric CFS/ME.^{12–15,16} Three randomised trials have shown that cognitive-behavioural therapy (CBT) delivered individually,¹⁷ with biofeedback,¹⁸ or via the internet¹⁹ is effective at 6 months compared with waiting list or usual medical care. All three studies reported improvements in fatigue, school attendance and a reduction in disability. Family-focused CBT appears to be as effective as psychoeducation in terms of school attendance at 6 months and recovery at 24 months^{20,21}. However, even with effective treatment, over a third of children^{19,20} have not recovered at 6 and 12 months²² and 21%²¹ to 36%²² are still unwell (eg, attending school <70% of the time) at 24 months. There is therefore an urgent need to find more effective treatments.

Trial By Error launched 4 years ago this week!

Thanks to: Professor Vincent Racaniello, Columbia



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.

A few years ago, Dr. Racaniello let me hijack this space for a long piece about the CDC's persistent incompetence in its efforts to address the devastating illness the agency itself had misnamed "chronic fatigue syndrome." Now I'm back with an even longer piece about the U.K.'s controversial and highly influential PACE trial. The \$8 million study, funded by British government agencies, purportedly proved that patients could "recover" from the illness through treatment with one of two rehabilitative, non-pharmacological interventions: graded exercise therapy, involving a gradual increase in activity, and a specialized form of cognitive behavior therapy. The main authors, a well-established group of British mental health professionals, published their first results in The Lancet in 2011, with additional results in subsequent papers.

Much of what I report here will not be news to the patient and advocacy communities, which have produced a voluminous online archive of critical commentary on the PACE trial. I could not have written this piece without the benefit of that research and the help of a few

Trial By Error: Funding Sources

Trial By Error: Reporting on ME/CFS and Related Controversies

\$103,283
108%
Raised toward our \$95,000 Goal
1,125 Donors

PROJECT HAS ENDED
Project ended on April 30, at 11:59 PM PDT

Project Owners

virology blog
About viruses and viral disease

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Trial By Error: Reporting on ME/CFS and Related Controversies

So it's been a year since the last crowdfunding campaign for Trial By Error--my investigative reporting and public health project. While Trial By Error began 3+ years ago as an in-depth look

\$10 Contribute \$10

Thank you for your gift of \$10 USD!

Contribute \$10

Disclosures 1: “Conflicts of Interest” (1000-plus COIs per Professor Michael Sharpe)



Professor Sharpe's Undisclosed COIs

- PACE protocol promised to follow the Declaration of Helsinki
- Declaration of Helsinki protects human research subjects
- Helsinki mandates disclosure of “any possible conflicts of interest”
- PACE information/consent forms did not include disclosures that key investigators had financial/consulting links to disability insurers
- PACE response: “We disclosed to the journals”—a non sequitur
- Helsinki not designed to protect of journal editors and readers--BUT
TO PROTECT THE PEOPLE ON WHOM YOU ARE EXPERIMENTING

Disclosures 2:

- Conflictual relationship with lead LP study author and Bristol University
- Lead author publicly accused me of libel—and did not respond to multiple requests for documentation
- Bristol has refused to explain or apologize. Instead, vice chancellor's office complained to Berkeley's chancellor about my "behaviour"
- But: I'm still a Berkeley academic in good standing
- **BOTTOM LINE:** An academic dispute, not a Sopranos episode

Key Points:

- Tough criticism is not “libel”
- Filing FOIs and writing letters to officials about bad research is not “harassment”
- Tearing up papers in public is not “libel” or “harassment”—it is academic performance art
- There are legal remedies for libel and harassment
- Express opinions about research/editorial misconduct

Peer-Reviewed Literature

- Does peer-review work? Yes, but...
- Churchill on democracy: “...the worst form of Government except for all those other forms that have been tried from time to time.”
- John Ioannidis: “Why most published research findings are false”
- Retractions: At record levels (retractionwatch.com)
- Pressure to publish—financial, academic, reputational

Feasibility Trials, Full Trials, Prospective/Retrospective Registration

- Feasibility trial—to test whether a full trial is possible
- Full trial—to test information generated in feasibility trial
- Full trial—a completely separate trial
- Prospective registration: Trial registered in an official registry BEFORE first patient recruited
- Retrospective registration:
Patients enrolled after registration--UNPUBLISHABLE

Ban on publishing non-prospective trials

- “ICMJE journals will consider trials beginning on or after July 1, 2005 only if registration occurred before the first patient was enrolled ("prospective registration").
- Fiona Godlee, BMJ editorial director, testified about zero-tolerance policy in 2013 testimony to Parliament’s Science and Technology Committee
- “As far as we are aware, in the last two years we have not published any trial that has not been prospectively registered,” said Godlee--a statement she could not make today.
- A 2015 editorial in The BMJ called the prospective registration policy “the single most valuable tool we have to ensure unbiased reporting of research studies.”

More than 20 case definitions for the illness or cluster of illnesses variously called ME, CFS, ME/CFS, CFS/ME, SEID, etc.

- 1955—Royal Free Disease/"benign myalgic encephalomyelitis" focused on muscle weakness
- 1991—Oxford criteria--six months of unexplained, debilitating fatigue
- 1994—CDC/Fukuda criteria—six months of fatigue, four of eight other symptoms
- 2003—Canadian Consensus Criteria for ME/CFS—PEM required
- 2007—NICE guidance—four months of fatigue, plus one of ten other symptoms
- 2011—International Consensus Criteria (related to 2003 CCC)—Post-exertional malaise (post-exertion neuro-immune exhaustion), plus other symptoms
- 2015—IOM--Fatigue, post-exertional malaise (exertion intolerance), unrefreshing sleep, and cognitive dysfunction and/or orthostatic intolerance

A FEW PRELIMINARY THOUGHTS ABOUT...

- The Lightning Process
- Studying woo-woo
- “Extraordinary claims require extraordinary evidence”
- Adults & kids & research ethics

Some Key Flaws of LP Study:

1. Investigators recruited 56 out of 100 participants BEFORE THE TRIAL WAS OFFICIALLY REGISTERED.
2. Investigators swapped primary and secondary outcomes after gathering data from this 56% of the sample.
3. Investigators failed to disclose these maneuvers in the paper itself. They presented their work as a prospective trial, with pre-designated outcomes.

IF THE INVESTIGATORS HAD DISCLOSED THE TRUTH,
ARCHIVES WOULD NOT HAVE PUBLISHED THE TRIAL.

Who is LP Founder Phil Parker?

Bio from website of the European College of Holistic Medicine Healing Course

- **Phil Parker** is already known to many as an inspirational teacher, therapist, healer and author...He discovered that their [clients'] bodies would suddenly tell him important bits of information about them and their past, which to his surprise turned out to be factually correct! He further developed this ability to step into other people's bodies over the years to assist them in their healing with amazing results..

Some Skills Taught in Course

- Ability to prepare a space “so that any energy polluting the room will not interfere with the work you are doing.”
- Use of divination medicine cards and tarot to make predictions. “From a healing perspective, divination is useful in creating a strong connection with healing/spirit guides.”
- Making predictions based on the spinning of a pendulum (dowsing). “Using a pendulum in healing can focus your attention on the area of a client’s body that needs healing, as its usage relies on energy and changes in energy fields.”

What is the Lightning Process???

- Are you constantly feeling exhausted no matter how much rest you get?
- Are you stuck with re-occurring health symptoms and issues?
- Do you find yourself worrying and feeling really stressed about things?
- Do you regularly feel low and upset?
- Are you fed up with feeling stuck in your health and life?

You've probably tried everything and no matter how positive, dedicated and committed you are, you still aren't getting the results you want. It's time to do something different and the Lightning Process could be the answer.

<https://lightningprocess.co.uk>

UK Advertising Regulators

*LP practitioners have claimed to cure MS, eating disorders, and many other conditions in addition to this one.

*UK advertising regulators have sanctioned LP practitioners multiple times for claiming medical benefits of LP

*“Advertisers should take care not to make implied claims about the health benefits of the three-day course and must not refer to conditions for which medical supervision should be sought.”

Ok but what IS the Lightning Process?

- LP practitioners have completed a diploma through the Phil Parker Training Institute in Neurolinguistic Programming, Life Coaching and Clinical Hypnotherapy...Following the diploma, LP practitioners undertake a further course to learn the tools and delivery required for the LP after which they must pass both a practical and written examination.

Ok, but what IS the Lightning Process?

- *Participants taught that they can change their health through changing thought patterns
- *Participants told not to share what happens in the course.
- *Participants stand in circles on the ground, yell “STOP” to symptoms
- *Two patient surveys: Many report benefits, fewer but significant number report worsening
- *Anecdotal reports: improvements; initial improvements that wear off; post-LP crashes, despair and suicide when patients feel they have failed to heal themselves.

Why did they do the study in kids?

- Investigators said urgent need to study: parents were sending their kids and/or asking them about the LP, urged to do study by AYME
- Funded privately because this is a commercial program
- Standard practice—do studies first in adults, then kids
- Ethical concerns (secrecy, etc.) raised by patients/advocates—but rejected
- Serious troubles with recruitment—a contradiction?

Questions About Information Provided

Lead investigator:

“We heard about people getting better and people getting worse. I was kind of curious.”

Information/consent leaflet for kids:

Any side effects? “We do not think there are any side effects of the intervention.”

Disadvantages? “Teenagers with CFS/ME can get worse with any intervention offered.”

Lightning Process Study Timeline

- September, 2010: Recruitment for feasibility trial
- Summer, 2012: Registration of full trial as (falsely) “prospective”
- Summer, 2012: Full-trial protocol includes swap of primary and secondary outcomes from feasibility trial protocol
- Summer, 2012-April, 2013: Recruitment for full trial
- September, 2017: Trial published as (falsely) fully prospective with pre-designated outcomes.

LP Study Timeline 2

- Fall, 2017: Science For ME Forum discusses data questions d
- December, 2017/January, 2018: Virology Blog documents violations and alerts Archives
- June, 2018: Archives posts “editor’s note” in journal equivalent of Siberia
- March, 2019: High-profile review of pediatric illness cites LP as “effective”
- June, 2019: Archives publishes “correction/clarification” — and republishes paper with original findings

LP Trial: 100 Kids, 2 Arms—LP + SMC vs SMC

- Feasibility trial recruitment (September, 2010-Summer, 2012): 56 kids
- Full trial recruitment (Summer, 2012-April, 2013): 44 more kids
- Data from 81 analyzed
- Like PACE and other studies from the CBT/GET fan club, LP study is unblinded with self-reported outcomes—fraught with bias

Official Conclusion: “The LP is effective...when provided in addition to SMC for mild/moderately affected adolescents with CFS/ME.”

BUT:

Feasibility trial protocol primary outcome:

School attendance (self-reported + official records) at 6 months

Feasibility trial protocol secondary outcome:

Self-reported physical function (SF-36 scale) at 6 months

Full trial protocol and published paper primary outcome:

Self-reported physical function (SF-36) at 6 months

Full trial protocol and published paper secondary outcome:

School attendance (only self-reported, no mention of records)

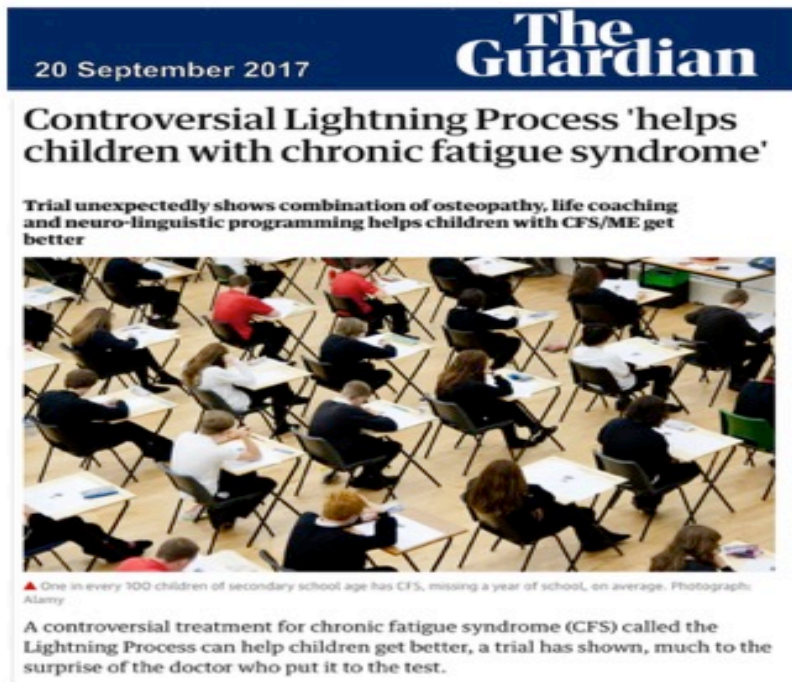
Published Results:

- Modestly positive results for SF-36 at 6 months--12 pts on 100pt scale
- Null results for school attendance at 6 months
- Positive results for secondary outcomes: anxiety, depression, fatigue, school attendance at 12 months (self-report, no mention of records)

BUT:

- Outcome-swapping NOT DISCLOSED IN PAPER
- Without outcome-swapping, investigators would have had to report null results for their primary outcome, with different conclusions

After Science Media Centre promotion, enthusiastic media coverage in UK Press



Every single week in my clinic, children came up to me and said we want to know about the Lightning Process. People have told us to try it. Should we have it?" she said.

"It was fascinating at the time. We heard about people getting better and people getting worse. I was kind of curious. I never expected that it would work."

If anything, said Crawley, she set up the trial in a way that would make it harder for it to be shown to work.

Editor's Note: June, 2018

- *Since publication, the study has been criticised for failing to meet ICMJE and BMJ policy on trial registration and for not fully adhering to CONSORT guidance on trial reporting. The journal has been criticised for not detecting these issues during editorial and peer review. We have acknowledged these comments...In addition, we have received clarifications from the authors which are under editorial consideration.*

E-mail from Fiona Godlee: Oct 12, 2018

“....[X] mentioned that you were concerned that the notice on the ADC paper was not prominent enough. We are looking into whether this can be made more prominent - our systems don't make this entirely easy!”

June, 2019: Massive Correction/Clarification

- Runs to almost 3,000 words
- Acknowledges validity of concerns raised by Virology Blog
- Republishes study with originally reported findings
- Dismay and revulsion among researchers who care about scientific integrity and understand editors' obligations to protect the medical literature.
- Public health faculty colleagues at Berkeley wonder why BMJ and Dr Godlee seem keen to damage their reputations and indifferent to protecting children's health



Adolescent health

Clinical and cost-effectiveness of the Lightning Process in addition to specialist medical care for paediatric chronic fatigue syndrome: randomised controlled trial

Esther M Crawley,¹ Daisy M Gaunt,^{2,3} Kirsty Garfield,^{2,3} William Hollingworth,² Jonathan A C Sterne,² Lucy Beasant,¹ Simon M Collin,¹ Nicola Mills,² Alan A Montgomery^{3,4}

CORRECTION NOTICE

This is a republished, corrected version. For full details please see the correction note, 10.1136/archdischild-2017-313375corr1.

ABSTRACT

Objective Investigate the effectiveness and cost-effectiveness of the Lightning Process (LP) in addition to specialist medical care (SMC) compared with SMC alone, for children with chronic fatigue syndrome/myalgic encephalitis (CFS/ME).

Design Pragmatic randomised controlled open trial. Participants were randomly assigned to SMC, or SMC plus the LP (SMC+LP). Randomisation was minimised by age and gender.

What is already known on this topic?

- ▶ Paediatric chronic fatigue syndrome/myalgic encephalitis (CFS/ME) is relatively common with a negative impact on school, mood and quality of life.
- ▶ Even with effective treatment, a significant number of children have not recovered at 6 months.
- ▶ The Lightning Process (LP) is used by children

¹Centre for Child and Adolescent Health, Bristol Medical School, Population Health Sciences, University of Bristol, Bristol, UK

²Bristol Medical School: Population Health Sciences, University of Bristol, Bristol, UK

³Bristol Randomised Trials Collaboration, Bristol Medical School, Population Health Sciences, University of Bristol, Bristol, UK

Editor's Note Accompanying Correction

- “The final version includes acknowledgement from the authors that the study was not fully ICMJE compliant.”
- Funniest line: “The process has additionally involved seeking assurance from the authors that the change in primary outcome was not influenced by (positive) findings in the feasibility phase.”
- Another funny line: “BMJ policy requires prospective registration of randomised trials but we do not consider a failure to enforce that policy grounds for retraction.”



Trial By Error: An Open Letter to Dr Godlee about BMJ's Ethically Bankrupt Actions

28 AUGUST 2019

By David Tuller, DrPH

I have sent the following letter to Dr Fiona Godlee, editorial director of BMJ, about Archives of Disease in Childhood's egregious decision to re-publish Bristol University's Lightning Process trial with the original findings intact. Given the Bristol team's flagrant methodological violations, the journal should have retracted the paper.

Failing that, Archives should have required the investigators to re-publish the paper with the initial primary outcome—school attendance at six months, which generated null results—as the final primary outcome. Dr Godlee was well aware of the issues involved, so she presumably endorsed the journal's actions. The documented facts suggest that BMJ's ethical compass is broken and that editors are more concerned about possible reputational damage than about the integrity of the medical literature or the health and

BY VINCENT RACANIELLO

Earth's virology Professor Questions?
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With David Tuller and
Gertrud U. Rey

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Virology Blog's Open Letter to Dr Godlee

- Signed by 55 experts
- “Given BMJ’s longstanding position that prospective registration is essential for safeguarding the integrity of the medical literature, it is unclear why you are now willing to exempt the Lightning Process study from this requirement.”
- “The swap thus ensured that the investigators were able to report positive rather than null results for their official primary outcome.”
- “BMJ’s actions are scientifically and ethically indefensible. They are also potentially harmful to the health and well-being of children.”

More than a dozen experts write own letters to Godlee—Demand Retraction

- **Vincent Racaniello, Columbia microbiology professor:** "As you are aware, many other scientists of repute have signed on to the original letter to you. I am sure we could have hundreds more. How many do you need before you are convinced that the work should be retracted? How much longer do you wish to risk harm to young patients?"
- **Jonathan Edwards, rheumatologist, University College London:** "I get the impression that bodies like Cochrane and the BMJ are sleepwalking into a situation where they rubber stamp commercial ventures of no merit. In this wider context I can only emphasise the view of all those copied above, that the SMILE trial paper should be retracted and that a fully independent investigation should be completed as soon as possible."

More expert letters

- **Ronald Tompkins, professor of surgery, Harvard Medical School:** “I am appalled at this situation. As a doctor of more than 40 years and a scientist, it is my opinion that a retraction of this article is in order.”
- **Brian Hughes, psychology professor, National University of Ireland, Galway:** "This paper would not have been published had you known about its irregularity at the time of initial review. Therefore it should not be published now. Therefore it should be retracted... Its existence will strongly encourage other researchers to play fast and loose with pre-registration, in the knowledge that their findings can still be published in a BMJ journal.

Waiting for Godlee

WAITING

MORE WAITING

AND MORE WAITING

Is LP study a case 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)
- 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)

Is LP trial republication a case of editorial misconduct?

- Yes, in my opinion
- Fiona Godlee is a smart person.
- She must—or should--know the study would not have been published had the researchers been honest.
- She must—or should--know it is invalid to republish the original findings.
- Her decision to enable and republish this bit of “research” is extremely troubling and completely unacceptable.
- Concern about reputational damage appears to outweigh any concern for children’s health and well-being

Thanks to...

- Brilliant patients/advocates who first deconstructed and dissected the science—too many to name
- Anil van der Zee for my PACE-Man T-shirt
- Vincent Racaniello for his steadfast support and trust in my reporting
- Professors Ronald Davis, Jonathan Edwards, Leonard Jason, Bruce Levin, Arthur Reingold—for weighing in early on.
- UC Berkeley and the Center for Global Public Health for valuing academic freedom
- My faculty colleagues at SPH and Berkeley who recognize bullshit
- Everyone who signed open letters