

PACE Trial Participants' Public Statements About the Trial

Summary:

FOR THE FIRST-TIER TRIBUNAL (INFORMATION RIGHTS) CASE EA/2015/0269

Due to the unsettling but unsubstantiated assumptions and allegations being made within QMUL's submissions that ME/CFS advocates wish to track down and harass or harm participants of the PACE trial, I have attempted to find out what actually happens when individuals (voluntarily) claim in public to have been PACE trial participants. To inform the tribunal, I have collated publicly posted comments from those who reported being participants of the PACE trial, and the responses that they received. QMUL's assertions, with regard to this issue, never seem to be supported by the evidence I have collated. Instead, their claims, to the best of my knowledge, are based on no more than speculation and (in my opinion) raises the question of whether the trial investigators have allowed a degree of prejudice to colour their submissions. The publicly available evidence, that I have been able to find, shows the opposite of their claims.

The following 19 accounts/examples are all of the statements that could be found from CFS patients who apparently participated in the PACE trial. They appear in various locations and were made over several years. The majority, though not all, are highly critical of the PACE trial. There is no evidence of any criticism or harassment of patients who have come forward, regardless of the content of their report. There is strong evidence of the opposite: many online comments from fellow patients express gratitude for the PACE participants having taken part in research into the disease and offer support for their shared health problems. Last updated: 5 April 2016.

Individual accounts:

[1. Ha Deb](#)

Public Facebook post in reply to a journalist's article on the PACE trial. October 2015. 3 likes received. No negative replies.

Ha Deb:

It will take me a while to read this lol

I took part in the pace trials and gave up after a few months. Done more damage than good. Utterly horrendous and now I've learned to live with and understand my illness I'm baffled that they even suggested it to people who suffer with this.

2 busses to get there, an hour or 2 in the hospital and 2 busses back, it took me a week to recover. Obviously created by people who have no understanding of ME.

[2. Stacy Morgan](#)

Public Facebook post in reply to a statement by Action for ME about inaccurate press coverage of the PACE trial. October 2015. 12 likes received. No negative replies.

Stacy Morgan:

I took part in the PACE trial and altho the CBT helped me accept my illness and my limitations, the GET part did nothing for me and on occasions made me worse!!! I heard this from others as well. Xxx

Hil Patten:

Sharpe and co have refused to publish the deterioration rates.

Stacy Morgan:

Funny that eh!! X

3. Jeannette Thomas

Another public Facebook post in reply to the Action for ME statement about the press coverage of the PACE trial. October 2015. 2 likes received. No negative replies.

Jeannette Thomas:

I was one of those in the trial. Neither of these methods worked for me as they rely on you doing regular things, yet the very nature of m.e. is that you can't always do things regularly, and thinking positively it's very hard when you can hardly get to the loo on time. El done AfME.

4. Gracie

Public forum post on a thread titled "Debunking the PACE trial" on the Action for ME online forum. Dec 2015. No negative replies.

Gracie:

I haven't read much about the efforts being made to retract the pace trials results but thought the press coverage was dreadful and extremely misleading.

I took part in the trials and they didn't help me. What is very worrying is that the Pace trials were only ever meant for people with mild to moderate M.E. and not Severe M.E. and yet Severe M.E. sufferers are still too often being referred to clinics to take part in pacing under the Nice guidelines. Whilst pacing can help patients they are often pushed on to fast and running the risk of having a relapse. I read just recently about a man with moderate M.E. who took part in the trials and ended up being bedridden for a year and consequently lost his job.

I'm not saying it won't work for some people but everyone is individual and think this should be taken into account.

5. othersideofvenus

Public comment made on The Guardian website regarding an article about the PACE findings. February 2011. 14 “recommendations” received. No negative replies.

othersideofvenus:

I took part in this study, and was randomised to the GET group, and I'd be very sceptical about its results.

My initial blood tests showed some signs of infection and inflammation so I was sent for another set which apparently didn't, so I could be accepted into the trial. The assessment/criteria forms which had to be filled out at the before and during the trial, did not mention symptoms after exertion or delayed onset fatigue, there was very little attention paid to pain and cognitive/mental issues were very blurred.

At the start of the trial, I had to wear an accelerometer thing for a week, presumably to measure activity levels. But at the end of the trial, this wasn't repeated. The fitness tests measured the number of steps I could do in a set amount of time, but paid no attention to the fact that I usually couldn't walk for 2 days after these assessments.

The 'handbook' I was given contained an incredibly flawed model, which GET is based on, which basically goes 'felt a bit ill - led to resting too much - led to deconditioning - led to the ME/CFS symptoms'. This completely ignores the fact that the vast majority of people don't rest early on and carry on pushing themselves despite severe pain and fatigue.

I would suggest that the criteria were so vague and the assessment so poor that a majority of the people who recovered using GET never had ME/CFS in the first place.

6. Dot Tritschler

Public comment made on the ME Agenda website on an article about the charity Action for ME. December 2008. No negative replies.

Dot Tritschler:

I am most disappointed that AFME has endorsed the Pace Trial. I was randomly selected to CBT via the trial, and it was quite apparent that the treatment was flawed from the outset.

a) The therapist misled me by saying he had a 99% recovery rate.

b) He could not answer basic questions as to how he measured recovery.

c) I had been told by Dr. Andrews (the doctor I see at the WGH) that the therapist was a clinical psychologist, only to find out he is only a psychiatric nurse who has then done a diploma in psychotherapy; I received a letter of apology re this only after bringing it to her attention and pointing out the discrepancy via Edinburgh University Pace Trial Website.

d) After I told the therapist that I was disengaging from the trial, he phoned me 3 times to attend a meeting with him – although it states that you can leave the trial at any time and don't even have to give a reason. Although the therapist had said the purpose of the meeting was to wish me well for my future, he was very angry and defensive at the meeting due to me disengaging; he obviously had pressure on him to keep his numbers up – but that was no reason to treat me in such a way.

e) It was quite apparent during the 6 sessions I had with the therapist that he was more interested in his research findings than genuinely helping me and my CFS. All in all I found the whole experience to be quite damaging, particularly as my expectations were falsely raised and the therapist behaved quite unethically at the last meeting – no doubt due to pressure upon him to get the desired results via his research subjects. I think it is incorrect for Action for ME to support and endorse such a trial, and am most disappointed that it does so.

7. Anonymous

Statement in a document compiled by ME Action UK. March 2011. There was no facility for leaving comments.

Anonymous:

I took part....I collapsed on week 3....Several of us had serious relapses. And when I was reduced to lying in bed every day, in pain, unable to do a thing for myself, these researchers did not want to know, believe me. I was on my own when it came to trying to undo the damage.

8. lady noodle

Public question posted on the Talk Health Partnership online clinic site. August 2014. No negative replies.

lady noodle:

I was diagnosed with M.E. 10 years ago and my symptoms can go from being very mild to difficult to manage. When I was first diagnosed, I took part in the PACE study and was seen by professionals on a regular basis. However, whenever that trial was over I was discharged and I now no longer see anyone and my gp admits they're not sure how to treat m.E. I now have no medical or pain support and I'm not sure who to turn to for advice on managing my M.E. now. Can anyone advise please?

9. Jessica Rolfe

Public comment left by a signatory of a petition titled, "Call for Action For M.E. Resignations" on the Care2 petition site. Approx. 2011. No negative replies.

Jessica Rolfe:

I took part in the pace trial and although it was well meaning, it placed no effort in finding a biological reason for ME. The methods used to treat patients predominantly helped for a short period for ME patients who then relapsed. Only the Cfs patients found long term benefit from the treatments. The trial did not differentiate between these illnesses in it's trial or it's conclusion. I believe this will lead to patients with ME rather than CFS actually being mistreated and potentially harmed by being associated with treatments only suitable for CFS patients. Tragically this will also lead to a lack of investment in research to the causes of ME and any hope of a genuine treatment.

10. PACE Trial Participant

Public comment on the Daily Mail website in response to an article on the PACE trial. February 2011. 53 “up votes” (combining votes from Parts 1 and 2), no negative replies.

PACE Trial Participant:

I took part in the PACE Trial under King's Hospital. I was allocated to CBT. 1. To those who say obtaining a diagnosis of ME/CFS is 'easy' and fakeable - I repeatedly raised the issue of my weird range of symptoms (including fatigue) with doctors for the best part of 18 years. I finally obtained a referral and a diagnosis of ME/CFS in 2007. 'Ease' was not a notable feature of my attempts to find out what was wrong! 2. To those who deny the existence of ME/CFS as a disease or syndrome - Until such a time as the underlying cause(s) of ME/CFS are reliably isolated, I can see why you would doubt this - we are so used to being able to 'prove' illnesses exist. It's not that many of decades since many diseases that are now controllable could be identified but not effectively treated, and prior to that, some diseases were not individually identifiable. I personally find it difficult to believe that ME/CFS exists and affects me as badly as it does.

Part 2: 3. Contrary to the above article - read the Lancet to see how the above article misreads it - the PACE Trial CFS/ME experts/specialists recognise that there is currently no effective treatment for ME/CFS - how can there be when there is no clear and proven understanding of what causes it and what cures it! What the PACE Trial was testing was the effectiveness of techniques to help ME/CFS sufferers cope with their symptoms - the PACE Trial did NOT and was NOT INTENDED TO FIND A CURE for ME/CFS. 4. Did the PACE Trial/ CBT work for me? There's no easy answer - yes the ME/CFS symptoms have decreased. But at a price - all semblance of normal life - the decrease in symptoms was obtained solely by reducing my activities until I was only working a fraction of the hours with no social life. Since then, no matter how much pain & effort I put in, I can't get back to my pre-Trial activity levels. King's told me they didn't have a 'magic bullet', but I was hoping for more than this.

11. Tasha Kelemen

Transcript of public oral testimony from the 2013 FDA Workshop on CFS/ME.

Tasha Kelemen:

Patient Tasha Kelemen fell ill after a tropical illness in Africa, and has been treated in Belgium, the UK, and the US. She reported having taken “everything.” As a patient in the PACE trials, Tasha stressed the importance of not adopting the UK treatment protocol. Specifically, she stated that GET was not a cure. Antiviral treatment has helped, but pacing is her most effective therapy. She was emphatic that the UK approach is “harmful, ridiculous and offensive” and exhorted the US not to follow its example.

12. Tricia Such

Public Facebook post in reply to an article on the PACE trial. October 2015. 2 likes. No negative replies.

Tricia Such:

I got APT as my trial test and yes it is good for those who have only had CFS for a short time, but for those that have had it for 15+ yrs we already did all of it, so their results for this part would have looked great. For the second one I chose CBT, In six weeks we didn't get past the first post because it was far too rigid. Go to bed at a certain time and get up at a certain time, don't sleep in the day, yeah ok !!!!! Sorry I couldn't read all of it Tina, will get to the rest another day.

13. Moira Less

Public comment on the ME Association website. July 2013. No negative replies.

Moira Less:

I went on the pace trial and had CBT. Before the trial I was discussing early retirement with my employer because of my ill health. I had been suffering with ME for 5 years at this point. I can't say that the CBT has cured me but it has certainly allowed me to manage my systems to the point where I am now back at work, full time, albeit at a lower responsibility. I still have ME but I am lucky enough to be able to manage it, although at the cost of a social life!

14. Carol Jermyn

Public Facebook comment in reply to a post about media coverage of publication of the PACE follow-up paper. October 2015. No negative replies.

Carol Jermyn

I agree with all that's been said, I heard the announcement on radio 2 & like Corinna couldn't listen to it. I was part of the Pace trial in Oxford, it helped me to get my life back.

15. Alison Paice

Extract from a piece in the December 2015 edition of the reMEMber newsletter. No negative replies.

Alison Paice:

I was referred to the Sussex ME Service and after a year on the waiting list I saw Dr Broughton, who carried out an extremely thorough consultation and confirmed the diagnosis, also ruling out depression. He suggested that I consider taking part in the PACE trial, on the basis that I could help to contribute to meaningful research into the treatment of ME/CFS, whilst receiving a course of treatment for 12 months. I was assured that at the end of the trial period I would be offered the choice of further treatment from the selection offered under the trial. I was randomly selected for the Graded Exercise Therapy (GET), and initially I was hopeful that I could slowly increase my activity and use this as a route to recovery — I always maintained a very positive attitude.

My exercise program consisted of walking approximately 50 metres in the morning and 50 meters in the afternoon, and the plan was to slowly increase the distance over the year, aiming to be able to complete approximately 600 metres, twice a day. After a promising start I suffered my first setback, and rang for advice, and was told to continue with the daily exercise despite feeling so unwell. I was provided with a heart rate monitor at the start of the trial period and had been monitoring this daily while I walked (recording the resting heart rate beforehand, the highest recorded rate during the walk, the rate at the finish, and the time taken to return to the resting rate). My heart rate was showing higher readings as the trial progressed and I became more and more unwell as the exercise continued daily. I was reporting back to a physiotherapist and after several months with this trend increasing she did say that they had not expected this result from the heart rate monitor — and several times asked me to re-turn the monitor as she felt these results did not bring anything useful for the trial, so she suggested we stop keeping records of the heart rate readings. I refused as I felt they were important and did not understand how a medical trial could possibly be impartial if the criteria were changed to ensure only expected results were recorded? I'm not an expert, but I certainly felt that my results were not being viewed impartially.

As the study continued I felt increasingly unwell and my own conclusion is that GET was harmful for me. When I received a report at the end of the trial it stated that nobody was harmed by GET, and I question the interpretation of my personal results. Also, I felt that the purpose of the trial seemed to be to get ill people to work, rather than to find ways to improve their health and wellbeing. Personally, I found the PACE trial set me back by several years, and improvement since has been very slow. I declined the offer of a different course of treatment, as the travelling was onerous and opted instead to be returned to the Sussex service. However Dr Broughton had left the service and there was very little help forthcoming. My GP oversaw my care, and whilst he was very kind, he did not have any specialist knowledge of ME/CFS. Since then I have undertaken a course of 6 individual sessions of Cognitive Behavioural Therapy (CBT), which served to confirm that I had a positive attitude towards my illness, with realistic expectations. However, there was nothing in the course that helped me to improve my health, so I would say it was neither helpful nor harmful.

16. #10

Extract from the ME Association's report on its ME/CFS management survey, "No decisions about me without me". No negative responses.

#10:

ME mild before course, became severe after course. Symptoms very much worse after. Course not appropriate to needs. As it was part of the PACE trial, a strict agenda was adhered to with no deviations. Also, the physio was not allowed to comment on any symptoms I may have had between sessions or as a result of treatment. The course was weekly for 4 weeks, fortnightly for 10 sessions and a last one 3 months later.

17. Lois Addy

Public comment on online Wall Street Journal article, "Patients, Scientists Fight Over Research-Data Access", given in five parts. No negative responses.

Lois Addy:

I was a participant on the PACE Trial, at King's randomised onto the CBT strand. I had initially been significantly affected by ME/CFS back in 2001 when exhaustion had prevented me from being promoted and led to me working as a part time consultant thereafter. I took the whole of 2006 as a sabbatical. This proved ineffective and led to my referral for investigations. By the time I reached King's CFS Unit I was desperate. Trudy Chalder was the first person to acknowledge I was ill and offered me hope.

The Trial was presented as a way to help others and myself: there would be no magic bullet but I should be able to stabilise and improve my activity level as a moderately affected person.

What happened? I gave up everything outside work and cut my work hours. My repeat six minute walking test acheived around half the distance of the initial one. I never reached a baseline but the grinding exhaustion eased slightly. In 2013 other medical issues pushed me into being severely affected (cont).

(cont2) One day I was unable to drive, then to climb stairs. Then unable to get and drink a glass of water, I could only crawl. That 'descent' was terrifying. It wasn't a relapse. I'd never experienced anything like it. I'd been told the illness wasn't progressive, I couldn't possibly end up in a wheelchair (my biggest fear back in 2007).

None of the techniques for CBT that I'd continued to use since the PACE Trial worked. My GP could only offer me painkillers and anti depressants. There is NO treatment. NO cure. Since then basic old fashioned convalescence has me staggering around cruising the furniture, able to use the internet, but housebound and [sic]

On balance I went into the Trial hoping for a cure, hoping my participation would help others. The CBT has helped me cope with the shock of being ill, taught me to be patient with the convalescence, helped me with the grief of becoming someone else, lesser, virtually non-existent. But no more than that. (cont)

(cont3) And my feelings on the PACE Trial? Honestly, if biomedical research came along that had a success rate for recovery of under 10%? I'd be thrilled for the 10% it helped!

So why am I not thrilled by the 10% results of the PACE Trial? Because the goalposts were moved. Maybe for good reasons, maybe not. I'm not a scientist, I don't want to know the ins and outs, I just want to be fixed. I want everyone carrying the ME/CFS label to be fixed. I want my life back, I want to be able to just walk to the loo without wondering if I'm wearing enough clothes to get there and back without turning into a block of ice lying on the floor until my energy trickles back half way. I want to be able to work. I want to be able to go to the corner shop, to the end of my (tiny) garden, to not have the half mile to my parents' house feel like it's on the moon.

In that context - as a PACE Trial participant there's a couple of things I want: (cont)

(cont4) What do I want from the PACE Trial?

1. I want the data they hold to be rerun using the original protocols (wrong word?). To see how the numbers would crunch if they hadn't moved the goals half way through. The data was consistently collected all the way through. It's how it was handled afterwards that changed. If you don't understand that, have a look at David Tuller's work referred to above.

2. I want the data underlying the papers published in reputable journals to be released so that professionals can objectively assess if it holds up. I want to be able to trust the results published. There are significant factual issues with the way the results have been presented (again see David Tuller).

3. I want the objective data, the walking and the stairs and the monitor as well as the 'how do you feel' data collected, suitably anonymised, released for other researchers to use. It's valid. It exists. There's so little research money, let's not waste what's already been spent!

(cont 5) There's probably other things I want. But writing this has used up all the energy I own today. I'm having trouble staying awake now. I hope the glimpse into how one of the 640 odd patient's lives has turned out adds a bit of humanity to the debate. We are people. People who are ill. Not just lazy or deconditioned. What we need is less arguing, and more best practice and professionalism from those who are supposed to be fixing us!

Thankyou.

18. Gemma

Public comment on Stats.org blogpost, "PACE: The research that sparked a patient rebellion and challenged medicine", March 2016. No negative responses.

Gemma:

Speaking as a patient on the trial I can tell you that there was no 'specialist medical care group' this was in fact a group that was offered nothing. I was in this group and I didn't

even have a review with my doctor – nothing, I didn't see my doctor so to call it a specialist medical care group is a bit of a stretch of the imagination. If you were in this group you were left alone. Also I've never been followed up so when they pull out these new studies on the research and patient progress every 2 years or so they are being very selective about who they follow up therefore how can any conclusions be fully representative of the trial?

19. othersideofvenus

Public comment on a recent Guardian article: “Is chronic fatigue syndrome finally being taken seriously?” No negative responses.

I took part in the PACE trial. I had my pre trial blood tests done twice because I wouldn't have been eligible for the trial on the first results. I had to wear an accelerometer for a week at the start of the trial and was told they would repeat this at the end of the year, but that changed during the trial and there was no repeat. I was 'assessed' during the trial by being asked to walk up and down steps and up and down a corridor until I couldn't go any further. Being both a people pleaser & someone who liked to do well in tests (as well as a naive fool at the time) I pushed myself as far as I could each time then could barely get home before being so ill for the next few days after each assessment that I couldn't leave the house. No one asked about this post exertional fatigue and it wasn't recorded. I'm not sure I would call that good science, would you?

Sources of participants' accounts:

1. Ha Deb

https://www.facebook.com/may12th.awareness/posts/10153037980487161?comment_id=10153038092542161&offset=0&total_comments=3&comment_tracking=%7B%22tn%22%3A%22R%22%7D

2. Stacy Morgan

https://m.facebook.com/actionforme/posts/10153677423498209?hc_location=ufi

3. Jeannette Thomas

https://m.facebook.com/actionforme/posts/10153677423498209?hc_location=ufi

(It is necessary to scroll to the end of the page and click on “View next comments” to see Ms Thomas's comment.)

4. Gracie

<https://www.actionforme.org.uk/forum/thread/22/debunking-pace-trial>

5. othersideofvenus

<http://www.theguardian.com/society/2011/feb/18/study-exercise-therapy-me-treatment?commentpage=2#comment-9627125>

6. Dot Tritschler

<https://meagenda.wordpress.com/2007/08/01/action-for-me-afme-statement-nhs-collaborative-conference/#comments>

7. Anonymous

<http://www.meactionuk.org.uk/COMPLAINT-to-Lancet-re-PACE.doc>

8. ladynoodle

<https://www.talkhealthpartnership.com/forum/viewtopic.php?f=493&t=4560>

9. Jessica Rolfe

<http://www.thepetitionsite.com/en-gb/3/call-for-action-for-me-resignations/>

10. PACE Trial Participant

<http://www.dailymail.co.uk/health/article-1358269/Chronic-fatigue-syndrome-ME-patients-exercise-best-hope-recovery-finds-study.html#comments>

(It is necessary to click on “View all” to view this comment.)

11. Tasha Kelemen

<http://www.prohealth.com/library/showarticle.cfm?libid=18077>

(Ms Kelemen’s account is summarised in the article.)

12. Tricia Such

https://m.facebook.com/story.php?story_fbid=10153051395717161&id=220534562160&ref=content_filter

13. Moira Less

<http://www.meassociation.org.uk/2013/05/us-journalist-wants-to-speak-with-people-who-were-on-the-pace-trial-13-may-2013/>

14. Carol Jermyn

[https://m.facebook.com/story.php?
story_fbid=1061003967278193&id=426481777397085&ref=content_filter](https://m.facebook.com/story.php?story_fbid=1061003967278193&id=426481777397085&ref=content_filter)

15. Alison Paice

<http://www.remembercfs.org.uk/>

(Ms Paice's account appears in the December 2015 edition of the reMEMber newsletter, which can be obtained by contacting the organisation.)

16. #10

<http://www.meassociation.org.uk/wp-content/uploads/2015-ME-Association-Illness-Management-Report-No-decisions-about-me-without-me-30.05.15.pdf>

17. Lois Addy

http://www.wsj.com/user/personalization/profile/E1_bDddfbQg%2Fic1SdSh6PDmLfHEwNPJaE%2FyjkzPySUGitI1hX4Aw06Hh%2FV3%2FYz41%2F3B_E1

18. Gemma

<http://www.stats.org/pace-research-sparked-patient-rebellion-challenged-medicine/>

19. othersideofvenus

<http://www.theguardian.com/lifeandstyle/2016/apr/04/chronic-fatigue-syndrome-cfs-taken-seriously#comment-71815151>