PACE Trial: People with ME

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[Mr Philip Hollobone in the Chair]

11.00 am

Carol Monaghan (Glasgow North West) (SNP)

I beg to move,

That this House has considered the PACE trial and its effect on people with ME.

It is a pleasure to serve under your chairmanship, Mr Hollobone.

"The doctor doesn't see me crawl on the floor. The doctor doesn't know I don't shower every day or brush my teeth twice a day like everyone else. He isn't aware of my frequent sore throats, my poor balance, my difficulties with reading, my muscle twitches, or my sound intolerance, and he certainly wasn't here to nurse me when once I was too weak to eat."

Those are the words of a junior doctor living with ME, who alongside nearly 1,000 others has contacted me prior to this debate.

Myalgic encephalomyelitis, or ME, has been described in many ways, but labels such as chronic fatigue syndrome or post-viral fatigue syndrome simply do not come close to the living hell experienced by many ME sufferers—a hell that is made worse by the lack of understanding that is faced when seeking help.

ME is estimated to affect about 250,000 people in the UK and is classified by the World Health Organisation as a disease of the central nervous system. Symptoms can include debilitating muscle pain, severe headaches that are often made worse by light or noise, significant impairment of short-term memory and post-exertion malaise that can last days and even weeks.

Jim Shannon (Strangford) (DUP)

I congratulate the hon. Lady on securing this debate. Does she agree that there is still huge concern among ME patients that the National Institute for Health and Care Excellence says it will not abandon the promotion of physio-social therapies for ME, despite the widespread scientific criticism of the PACE trial methodology, and that we must ensure that that is addressed as a matter of urgency?

Carol Monaghan

I thank the hon. Gentleman for his intervention. I will come on to the NICE guidelines later in my speech.

Although ME is a pathological, not psychological, condition, much about it remains a mystery. The reasons for that are twofold. First, many sufferers are housebound and therefore easy for society to ignore. Secondly, there is a lack of awareness among medical professionals and as a result a woeful lack of quality research. What we do know is that ME is often triggered by a viral infection such as flu, but, unlike healthy individuals, people living with ME do not recover. Into that research drought entered the PACE trial—pacing, graded activity and cognitive behaviour therapy; a randomised evaluation.

The trial was unique in medical research. It was funded by the Department for Work and Pensions to the tune of £5 million, a point to which I will return. From the very start the PACE trial was flawed. In contravention of the World Health Organisation classification, it assumed that ME was psychological and sufferers could recover if they chose so to do. Thus the PACE trial was framed in psychological terms.

Mr Jim Cunningham (Coventry South) (Lab)

I thank the hon. Lady for securing this important debate. Does she agree with me that a lot of employers do not really understand how people with ME suffer and that that can affect their employment? It can also affect housewives.

Carol Monaghan

Absolutely. The public perceive it as mere tiredness, but it is so much more than that. The debilitating pain that ME sufferers experience is something that we all should be aware of.

The participants in the PACE trial received a range of different treatments, including cognitive behaviour therapy and graded exercise therapy, where patients were encouraged to become physically active and then increase the activity's intensity. Unbelievably for a trial this large, none of the groups was given specific medical interventions. The results were published in The Lancet in 2011, with the contentious claim that CBT and GET brought 30% of patients back to normal, while 60% improved. The media reported that all ME sufferers had to do to recover was exercise. However, the report was immediately questioned by the patient community. How could exercise, the very thing that was known to worsen symptoms, actually help?

Alex Sobel (Leeds North West) (Lab/Co-op)

My friend Jo from Leeds wrote to me:

"I've had CFS/ME for 25 years. I'd had it for 10 years before it was diagnosed. When I was diagnosed in Sheffield I was told there was literally no service they could refer me to and relied largely on a local support group. I was told by a Leeds GP to 'just get on with life' despite trying to hold down a professional job and look after a young child."

That is a typical story of somebody with ME.

Carol Monaghan

I thank the hon. Gentleman for his intervention. It is typical, because the PACE trial had such publicity and was lauded by many as the answer. One participant in the original trial has contacted me:

"I was determined to be a part of the...trial because I wanted to get better—so if this 'treatment' could make me better I wanted to give it the chance to do so. I was assigned Graded Exercise Therapy. It never occurred to me that it would actually make me more ill. Nor did it occur to me that decline would not be documented, and that despite patients not recovering (or in some cases worsening), they would publish that the treatment was successful...It was stressed that I would only get better if I tried harder, and even though the graded exercise was clearly making me worse, my struggle and pain was dismissed.”

Rachael Maskell (York Central) (Lab/Co-op)

As a former physiotherapist, I recognise that all therapeutic interventions must be patient-led—led by people with the lived experience. Does the hon. Lady agree?

Carol Monaghan

Absolutely. In fact, I will be calling for the patient voice to be heard in any treatments.

Calls to publish the raw data—basic protocol in good research—were ignored. Queen Mary University spent an estimated £200,000 on keeping the data hidden. Finally, after a long battle, patients won a court order to force the PACE authors to release the data. It was discovered that the authors had altered the way in which they measured improvement and recovery, to increase the apparent benefit of the therapies. Re-analysis showed that the improvement rate fell from 60% to 21% and the recovery rate fell from 22% to just 7%.

The method of patient reporting has also been questioned. As one participant says:

“After repeatedly being asked how severe...my symptoms were—in the context of…it’s just me not trying hard enough...I started to feel like I had to put a...positive spin on my...answers. I could not be honest about just how bad it was, as that would...tell the doctors I wasn’t trying and I wasn’t being positive enough. When I was completing questionnaires...I remember second guessing myself and thinking for every answer: ‘Is it really that bad? Am I just not looking at things positively enough?’”

John Howell (Henley) (Con)

I thank the hon. Lady for securing this debate. The PACE trials have been roundly condemned by many scientists as being totally inappropriate. Does she have a feel for what an appropriate trial might have found?

Carol Monaghan

Yes. I will come on to how an appropriate trial could be done. First, I will mention the self-reporting that was a part of the trial. Questionnaires provided the data and measures of success. There were no physiological or scientific measurements. For patients the damage was done. I am a science teacher by profession and I always told my pupils that there are a number of stages to any scientific investigation: “Start with a hypothesis. Decide how you will test this theory, what measurements you will make, how you will record your results and how you will use these results to draw your conclusions. Those conclusions, which might be different from the original hypothesis, must be based on the evidence you have gathered.”

That did not happen in the PACE trial, which relied on patient self-reporting, rather than measurable physiological parameters. Furthermore, when the results were not as expected, rather than revise the original hypothesis, the investigators simply changed the success criteria. Thus patients participating in GET who had deteriorated during the study were considered recovered.

There are, of course, ways of measuring the physiological impact of exercise. The two-day cardiopulmonary exercise test can objectively measure post-exertional malaise. We know that a person with ME can perform adequately—sometimes even well—on the first day, but can have greatly reduced cardiopulmonary function on the second. The test requires the participant to exercise on a static bicycle, and allows data on oxygen consumption, workload and gas exchange to be measured. Two identical tests, separated by 24 hours, must be carried out to properly measure the impact of exercise. Results from a single test could be interpreted as a lack of fitness. Two tests change that to something quite different. A healthy person will perform better the second time; an ME sufferer will most likely be worse.

Of course, the failure of the PACE trial to do that could simply be put down to bad science, but unfortunately I believe that there is far more to it. One wonders why the DWP would fund such a trial, unless it was seen as a way of removing people from long-term benefits and reducing the welfare bill.

John Lamont (Berwickshire, Roxburgh and Selkirk) (Con)

The hon. Lady is speaking very well about the challenges that this illness presents to people, but does she share my concern that in Scotland there is only one specialist, nurse-led ME facility and there are no specialist ME consultants? She raises an important point, but in terms of NHS awareness of the condition, we need to do more to ensure that people are getting the treatment that they undoubtedly need.

Carol Monaghan

This is a worldwide issue. The PACE trial results have affected people all over the world. In my folder, I have examples of people from Australia, the United States and Canada. Although there are no specialist centres in Scotland, the ones in England are recommending graded exercise therapy, which is making people worse. We need to deal with the issue.

Helen Whately (Faversham and Mid Kent) (Con)

Will the hon. Lady give way?

Carol Monaghan

I will make some progress. The PACE trial was used to inform NICE guidelines, which has meant that symptoms have been disregarded, and sufferers are considered to be attention-seeking hypochondriacs or even, in the case of some female patients, hysterical. Although in some ways the lack of belief has been the most difficult thing for sufferers and their families, the impact of the PACE trial and the resulting NICE guidelines is far further reaching. Many sufferers have reported major difficulties in accessing financial support. Employment and support allowance assessments do not consider the impact of exertion on a person’s ability to function on subsequent days, and personal independence payment assessments, which consider ME to be psychological following the PACE report, mean that sufferers struggle to access that entitlement and simply rely on family members.

Conflicts of interest in the trial are also deeply worrying. The former chief medical adviser to the DWP sat on the trial’s steering committee, and ultimately the results of the trial have been used to penalise those with ME. When we consider the relationship between key PACE investigators and major health insurance companies such as Unum, the trial takes on a far more sinister slant. Sufferers have reported that their health insurance company would pay out only if they undertook a program of GET—an impossible task, as the insurance giants knew.

It is not only adults who are affected. Children with the disease have been subject to care proceedings because of widespread misunderstanding among health workers. ME has been mistaken for school phobia, neglect or even abuse.

Layla Moran (Oxford West and Abingdon) (LD)

Will the hon. Lady give way?

Carol Monaghan

I will in a moment. One mother contacted me, saying:

“Our 12 year old son was seen at specialist ME centre by a consultant who prescribed GET. In one year this ‘programme’ caused our youngster’s body to develop higher and higher levels of inflammation, he began limping, was in continual pain from not only the ME headaches but joint and foot pain. The comments were ‘well he managed to limp into my office’, ‘you were very active, now since the virus you are very inactive, so you will have this pain due to lack of exercise’.

GET caused his body’s immune system to go into overdrive. My son developed Juvenile Idiopathic Arthritis. This was treated by a paediatric Rheumatology Consultant who was shocked it had been left so long and told my son that his toes would be permanently swollen even after treatment as the bones had grown abnormally during the inflammation”.

Layla Moran

I, too, have been contacted by parents in my constituency. In the case of one constituent, her daughter took a year to be diagnosed and missed an entire year of school as a result. The effect on children’s lives at a very young age is palpable.

Carol Monaghan

Many parents who try to home school their children also face local authority intervention, trying to get the children back to school. We must listen to patients.

This disease is very easy to ignore. All too often, those living with ME are housebound, and suffer from what they refer to as “brain fog”, which makes it difficult to mount an organised campaign. That means that much about ME remains unknown. There is some evidence that it could be grouped with auto-immune conditions such as multiple sclerosis and rheumatoid arthritis. Some people have reported that certain anti-viral drugs improve their condition, but without properly conducted scientific research, we do not have the answers. Ultimately, the impact of the PACE trial on those with ME has been devastating.

Alison Thewliss (Glasgow Central) (SNP)

rose—

Luke Graham (Ochil and South Perthshire) (Con)

rose—

Carol Monaghan

I give way to my hon. Friend.

Alison Thewliss

My hon. Friend makes a good case. My constituent Carol Ann McGregor has had ME since 1996 and has been bedbound for seven years. She says that she has “lost my life, health, husband, my career and my home”.

Does my hon. Friend agree with my long-term family friend Maureen Bivard that the cover-up, and the way in which the PACE trial was carried out, amounts to a miscarriage of justice for patients?

Carol Monaghan

I think that when the full details of the trial become known, it will be considered one of the biggest medical scandals of the 21st century.

Luke Graham

Will the hon. Lady give way?

Carol Monaghan

I am just going to finish off. I am pleased that NICE is reviewing its guidelines on ME and has removed the recommendations to embark on harmful exercise, but I was contacted only last week by a lady who had been told recently by her GP to exercise her way to health. That highlights the huge need for education and for raising awareness among both the public and medical practitioners.

I ask the Minister: can the next set of guidelines be drawn up through listening to those living with ME? What plans does she have to introduce compulsory training for medical practitioners on ME care and treatment? Can she assure me that specialist ME treatment centres are not advertising graded exercise therapy as a method of recovery? Will she support proper funding for ME research? Lastly, will she work with DWP colleagues to ensure that new guidelines are drawn up for dealing with people with ME?

Finally, I thank the Countess of Mar and the ME Association for helping me to prepare for today. I also thank those living with ME, whose voices are not being heard.

11.18 am

The Minister for Care (Caroline Dinenage)

It is a great pleasure to serve under your stewardship, Mr Hollobone. I congratulate the hon. Member for Glasgow North West (Carol Monaghan) on securing today’s debate. As she has articulated so beautifully, the situation is clearly very concerning. I know that she has done an enormous amount of work in this area, and has met people, both in her constituency and more widely, affected by the condition, and with expertise on the condition, to hear about its impact on individuals’ lives. As MPs, we all know people in our constituencies who are affected by the condition.

As we have heard, chronic fatigue syndrome, also known as myalgic encephalomyelitis or encephalopathy, is a debilitating and very poorly understood condition, which is estimated to affect more than 200,000 people in England. We do not understand the underlying causes of it, there is no one diagnostic test to identify it, and although patients can improve and recover, there is no cure for it. The condition, which for brevity and to avoid covering you in a thin layer of spittle, Mr Hollobone, I shall refer to in the abbreviated form CFS/ME, can stop a life in its tracks, leaving sufferers unable to carry out the most basic tasks. In the most serious cases, people can be bedbound for weeks at a time. It has a complex range of symptoms, including a very disabling, flu-like fatigue and malaise, and neurological problems. Of course, the impact on friends, families and carers can be significant as well.

It is also true that the difficulties in diagnosis mean that patients with CFS/ME often experience delays in getting the treatment and support that they need. In recognising the need for GPs to be aware of the condition, the Royal College of General Practitioners identified CFS/ME as a key area of technical knowledge that GPs should have as part of their qualifying exams, which answers a question raised by the hon. Lady.

The recommended treatments for CFS/ME, namely cognitive behavioural therapy, or CBT, and graded exercise therapy, or GET, and the evidence for them are the subject of today's debate. Those treatments were first recommended for patients with mild or moderate CFS/ME in 2007 in the NICE guidance, in line with the best available evidence, which showed that the treatments offered benefits. The guidance sets out that there is no one form of treatment to suit every patient and that the personal needs and preferences of patients should be taken into account. Doctors should explain that no single strategy will be successful for all patients; that in common with all people receiving NHS care, CFS/ME patients have the right to refuse or withdraw from any part of their treatment; and that those with severe symptoms may require access to a wider range of support, managed by a CFS/ME specialist.

The results of the PACE trail, which examined pacing therapy, cognitive behavioural therapy, graded exercise and specialist medical care for chronic fatigue syndrome, were published four years after the NICE guidance. The trial ran from 2005 to 2011 and, contrary to what the hon. Lady said, was primarily funded by the Medical Research Council, not the DWP. Total funding was £5 million and the MRC contributed almost £3 million.

The study was undertaken by the Queen Mary University of London. It was the largest ever trial for CFS/ME, including more than 600 participants in England and Scotland. It sought to assess and compare the effectiveness of the four main treatments for CFS/ME—adaptive pacing therapy, CBT, GET and standardised specialist medical care.

The peer-reviewed trial results published in The Lancet found, as the hon. Lady said, that 60% of patients with CFS/ME benefited from CBT and GET when provided alongside specialist medical care. CBT and GET were found to be better than pacing therapy or specialist medical care alone in improving both symptoms and disability, and a follow-up study looking at recovery after one year further supported the benefits of interventions. The trial had ethical approval from the NHS research ethics committee and had ongoing oversight from an independent trial steering committee, which included patient representatives. Trial reports were regularly provided to a data monitoring and ethics committee that had the power to halt the trial if harm was indicated. NICE considered the PACE results in 2011 and concluded that they supported its existing recommendations on both CBT and GET.

The Government are aware that the use of CBT and GET in treating CFS/ME has long been a controversial issue for patient groups, charities and some clinicians. That began with the publication of the NICE guidance 10 years ago and continued with the PACE trial. Since 2011, PACE trial data has been shared with many independent scientists as part of normal research collaboration, including the internationally respected research organisation Cochrane, which independently validated the findings. However, in the last 18 months, the attention on the trial has increased substantially, following a tribunal ruling in August 2016 ordering the release of the trial data to a member of the public, which the hon. Lady referred to. The data has since been examined more widely and critics, including some clinical academics, have suggested that it shows that CBT and GET are not as effective as the trial results suggested.

Nicky Morgan (Loughborough) (Con)

This is clearly a very important debate. I think both the hon. Member for Glasgow North West and the Minister would agree that it is not possible to do justice to the concerns raised by all our constituents, and the 200,000 sufferers that the Minister has identified, in half an hour. Does the Minister agree that this is a subject worthy of wider debate in the House of Commons? Constituents such as Sarah Reed, who have written to me, say that because of the belief in CBT and GET, and because academics believe in the results, many other treatments have not been pursued. Does the Minister feel angry about that?

Caroline Dinenage

I thank my right hon. Friend for her intervention. As has already been said, it is important that we listen to patients. As I will go on to explain, NICE is now looking at reviewing its guidance on this and, in the light of that, it may well be worth discussing the issue more fully.

Luke Pollard (Plymouth, Sutton and Devonport) (Lab/Co-op)

Does the Minister agree that believing patients is also important here? Patients with the condition are often not believed and concerns about the PACE trial have not been believed, and that has just loaded concerns on those individuals.

Caroline Dinenage

As I have already set out, sometimes it can take a really long time for this to be diagnosed. People have to keep going backwards and forwards to GPs and others with their symptoms. Many other potential conditions have to be discounted before it can be fully diagnosed, which often leaves people feeling that their symptoms are not being taken seriously or they are being dismissed. Obviously, that is massively concerning, which is why, as we have already said, it is important that patients are listened to and that clinical professionals are well-equipped to be able to recognise the symptoms and identify them.

As I said, the data has been examined more widely. Critics, including some clinical academics, have suggested that it shows CBT and GET are not as effective as the trial results suggested. In turn, the trial authors have defended their work. They have responded to criticisms in medical journals and the wider medical printed press. I know the hon. Member for Glasgow North West raised one such criticism at the oral evidence session of the Science and Technology Committee in January, concerning possible conflicts of interest of the PACE trial authors. On that point, in line with normal practice, all such conflicts were published with the trial protocol as well as the results. If she has evidence to the contrary, I would be very happy to discuss that with her afterwards.

Carol Monaghan

I thank the Minister for that. However, they were not disclosed to the PACE participants.

Caroline Dinenage

It is very important that the hon. Lady has raised that point, and I am sure it will be taken into consideration.

Helen Whately

ME sufferers in my constituency welcome that the NICE guidelines are being reviewed, but one problem is that when they find that the existing treatments do not work for them, there is a lack of alternatives. Does the Minister recognise that alternative treatments need to be looked into urgently and offered to patients?

Caroline Dinenage

I am sure that will be part of the NICE guidance. Where there is significant evidence that alternatives deserve greater investigation, I am sure NICE will look at that. I will talk about that a little more in a second.

On conflicts of interest, it is obviously important that researchers and scientists with particular expertise in one area will have worked and shared their expertise in related fields and industries, but transparency regarding conflicts of interests is vital to the integrity of the research. The NHS Health Research Authority already issues guidance on conflicting interests and I understand it will consider whether any further clarity is needed.

Clearly, the controversy around the trial is problematic for researchers, but it is most of all distressing for patients with CFS/ME, who deserve the most appropriate treatment from the NHS and to have confidence in the treatment that is being provided. That is why we welcome the NICE decision to undertake a full review of the guidance, which will examine the concerns around the PACE trial and any implications for its current recommendations. NICE develops its guidance independently to support NHS organisations and clinicians to deliver services in line with the best available evidence. It welcomes the input of stakeholders and more than 10 CFS/ME charities and organisations are already registered to support the guideline development process. All other parties who are interested can comment on the draft scope and draft guidelines at the appropriate time during the development process. Final guidance is expected in October 2020.

Paul Blomfield (Sheffield Central) (Lab)

The Minister makes the point that final guidance is expected in October 2020, but given the significant doubt over CBT and GET and their impact now, does she recognise the strong case for NICE to suspend the current guidance, which points people towards those potentially damaging treatments?

Caroline Dinenage

As an independent organisation, that will of course be a matter for NICE, taking into consideration the evidence.

I know it is a priority for the CFS/ME community that more research into identifying the underlying causes of the condition be undertaken. I would like to reassure those affected that both the MRC and the National Institute for Health Research welcome high-quality applications for research into CFS/ME, including studies to investigate its biological causes, and it will come as welcome news that the MRC is currently funding a project to examine the relationship between abnormal brain structures and symptoms of CFS/ME.

I again thank the hon. Member for Glasgow North West for raising this important issue on behalf of those affected by the condition in her own constituency and up and down the country. I hope the debate has been helpful.

Question put and agreed to.