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PACE Trial: Chronic Fatigue Syndrome/Myalgic Encephalomyelitis

Question for Short Debate

5.25 pm

*Tabled By **The Countess of Mar***

To ask Her Majesty's Government what assessment they have made of the effects of the PACE trial (Pacing, graded Activity and Cognitive behaviour therapy: a randomised Evaluation) on provision of health and social care and welfare benefits for people with chronic fatigue syndrome/myalgic encephalomyelitis.

The Countess of Mar: My Lords, I declare my interests as chairman of Forward-ME, a vice-chair of the All-Party Parliamentary Group on ME and a patron of a number of ME charities. The PACE trial was funded by the MRC, the Department of Health, the Scottish Chief Scientist Office and the Department for Work and Pensions to the tune of £5 million. The researchers, led by chief principal investigator, Professor Peter White, have consistently and confidently advised medical professionals and the Government of the success of cognitive behavioural therapy, or CBT, and graded exercise therapy, or GET. The PIs—the principal investigators—objective was to reverse the behavioural and cognitive factors which they believe to be responsible for the perpetuation of symptoms and disability. Despite the extensive biomedical evidence base of peer-reviewed papers which undermines their belief and despite the fact that the MRC now states that there is evidence of, "inflammatory mechanisms in the brain and spinal cord", their view has prevailed.

Throughout the history of medicine there has been a predominance of doctrine over science and currently there is a similar conflict between the doctrine, which asserts that CFS/ME results from a disordered psyche, and the scientific view that it is a devastating organic disease. We do not know what disorder was being studied because in March 2011, the chief PI wrote to the editor of the *Lancet*. He said:

"The PACE trial paper ... does not purport to be studying CFS/ME but CFS defined simply as a principal complaint of fatigue".

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To whom, then, can CBT and GET be safely applied? The Minister cannot answer because on 17 January her right honourable friend Norman Lamb confirmed that no assessment of the PACE trial has been made.

Furthermore, the PACE trial results have not been presented transparently. This is not uncommon and Dr Ben Goldacre, known for his "Bad Science" column in the *Guardian*, has initiated a campaign calling for

publication of all results of all trials, not just selective results. Already more than 7,000 signatures have been collected, including from high-profile organisations such as the MRC, the Cochrane Collaboration, the Public Library of Science and the BMJ. It calls for all universities, ethics committees and medical bodies to recognise that under-reporting of trials, as occurred in the PACE trial, is misconduct. Misreporting of clinical data leads to harm, wastes money and prevents scientific progress.

As regards the PACE trial, a recent Science Media Centre press release states that,

“the authors worked hard to define recovery based on the data available from the PACE trial”.

Investigators must define their primary outcomes before a trial begins and abide by them, not define recovery based on the trial data. Once the PACE trial was under way, the PIs changed the outcome measures so that the very same score on physical functioning—the SF-36 scale—represented both eligibility to enter the trial and “normal” function at the end of it. Indeed, according to the *Lancet*, a participant could have achieved a worse score at the end of the trial yet still be classed as “recovered”.

When funding was granted and ethical approval agreed, a participant had to score 85 to be considered recovered but by the time of publication in the *Lancet*, this “recovery” score had dropped to 60, which was five points lower than that required to enter the study. This illogical situation resulted from departure from the published protocol. To overcome this, the chief PI created his own meaning of terms; for example “recovery” does not mean recovery as the world understands it, and a return to “normal” does not mean a return to normal health. The chief PI does, however, concede that,

“improvement and not reaching research criteria are different from recovery”.

We do not know how many patients reached the initial target for recovery because the PIs have refused requests to release that data. Instead, they introduced significantly lower measures of improvement and abandoned an objective measure, the wearing of an actometer. The results of the subjective reporting in the six-minute walking test after graded exercise therapy were very poor, placing participants below the performance of patients awaiting heart or lung transplant. Had the PIs achieved their anticipated level of success, a level consistent with their claims over many years and a major factor in the award of research grants, they would have achieved international acclaim.

What hit the headlines was the *Lancet* “Comment” claiming a 30% recovery rate, yet the best that has been shown from CBT and GET is a maximum 15% improvement rate. A recent paper by the PACE authors, published on 1 February and purporting to show

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recovery rates, is a masterpiece of obfuscation. The authors have substituted "recovery" for "reversal" of CFS without any explanation, yet they admit that,

"although many patients improved, the question of how many patients recovered remains unanswered".

As one of the members of the Forward-ME Group said:

"It really is quite bizarre that there is absolutely no data whatsoever in this paper on what most people would regard as markers for recovery ... a return (or ability to return) to full time employment or education ... no longer claiming any DWP sickness or disability benefits".

The original claims made for recovery made it into the media and into the minds of GPs, DWP officials, social care providers, private insurance companies and even the National Institute for Health and Clinical Excellence. Professor Trudie Chalder, one of the PACE trial PIs, said that, "twice as many people on graded exercise therapy and cognitive behaviour therapy got back to normal".

This was widely but incorrectly interpreted as "recovery".

The fact is that, as opposed to the spin that accompanied the publication of selective results, only 15% of patients improved with CBT and GET, leaving 85% with no benefit from those interventions. Furthermore, of the combined CBT/GET groups of 321 people, 91% experienced adverse events, and only those who were well enough to attend regular hospital appointments were included in the trial; the severely affected and housebound were excluded. This is not mentioned when the "recovery" rates are discussed. From where have the PIs derived the figure of 22% for recovery in their latest paper?

Where does that leave us? The only information, published in *A Cost-Effectiveness Analysis* of the PACE trial, shows that there was no significant improvement after CBT and GET in the average number of days lost from work or the number of participants who lost days at work. In fact, claims for income-related benefits, illness and disability-related benefits, and from private pensions and income protection schemes, increased across all intervention groups during the trial.

As it is cheaper for CFS/ME to be dismissed as a behavioural problem, patients are denied access to diagnostic facilities by NICE guidelines, and very few medical consultants specialise in anything but the supposed "behavioural" aspects of the disease. ME charities are inundated with cries for help as their members struggle with the benefits and social care systems. Bed-ridden and housebound claimants are put into the WRAG for ESA and are too ill to appeal. If they manage to get to an Atos assessment, they feel that they are not listened to and are told that they are fit for work. The DWP part-funded the PACE trial because it was assured that CBT and GET would get people off benefits and back to work, but the promised return-to-employment figures have still not been provided by the PIs.

I am relieved that the Medical Research Council's expert group, under the chairmanship of Professor Stephen Holgate, is launching a UK chronic fatigue

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syndrome and myalgic encephalomyelitis research collaborative on 22 April. It recognises that in light of the,

"magnitude of the disease burden on those affected and their families involving both adults and children, there is an urgent need to increase research effort in the field".

Some £1.6 million has already been allocated by the MRC. There is an equally urgent need to assess the effects that the outcome of the PACE trial has had upon people with ME. However, how can the Government act responsibly in assessing them when the results have not been presented transparently?

It is widely accepted within the ME/CFS community that the PACE trial PIs changed the primary outcome measures with the intention of artificially inflating the success of CBT and GET—treatments they promoted for more than 20 years—and that, consequently, they are guilty of scientific misconduct. They believe that White and his colleagues have shown that they are not responsible guardians of the valuable data collected in the trial. It is therefore a matter of great importance that they are re-analysed by an independent group, using the original criteria for recovery and the positive outcomes described in the published protocol. This would enable healthcare commissioners to make decisions based on data that they know have not been misrepresented.

I know that the Minister understands the problem and ask that she and her colleagues from the other affected departments order such an assessment so that we do not consign thousands of people to the shadows. To quote Orwell, we must not allow the PACE trial to, "give an appearance of solidity to pure wind".

5.36 pm

Lord Winston: We are all very grateful to the noble Countess, Lady Mar, for introducing this debate. I will be very brief and I apologise to her for missing the first minute of her speech. Very surprisingly, we were much earlier than expected and, unfortunately, the name of the previous speaker, the noble Lord, Lord Gardiner of Kimble, was still on the screen when I came into the Moses Room.

This syndrome causes persistent fatigue for more than six months, as well as various other symptoms. It is not relieved by rest, which is and has been puzzling for a long time. It is not the case that there has not been a lot of research. I have looked, for example, at MEDLINE, where we can see that there are 5,874 research papers on this condition. It was not only the Medical Research Council that funded the PACE survey; it is very clear that extensive work has been carried out and many countries have been involved.

Recently, I made a list of papers published in the past year. I will not bore your Lordships with all of them but we know of, for example, Moss-Morris at King's, Dr White at Barts, Dr Lehmann in Bavaria, Dr Fjobback in Denmark, Fukuda in Japan, Jackson in Australia, Lewis in Bethesda, Maryland—part of the NIH funders there—Wibourg from Hamburg, Bleijenberg from Amsterdam, Newton from Newcastle, Brooks from Huddersfield, Wessely from King's and Vincent from the Mayo Clinic in Minnesota. There are many other names, but these are very prestigious

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departments of medicine. Effectively, they all come to the same conclusion; namely, that at the present time, the best treatment is almost certainly along the lines of cognitive behavioural therapy.

What is different about the PACE study is that it is a detailed, controlled study which has extremely rigorous entry into it. Unlike most previous studies, I think I am right in saying that—perhaps the noble Lord, Lord Alderdice, will correct me if I am wrong—there was only one drop-out, which is fairly remarkable. It means that it is extremely comprehensive, so there are very good data. It looked at a series of issues about treatment and it seems pretty clear to me that cognitive behavioural therapy is effective in something like one-fifth of patients, which is a bit more successful than the noble Baroness claims. I do not think we should underestimate that. They go some way to explaining that were cognitive behavioural therapy to be used perhaps on a slightly more financially secure footing with rather more sessions, it would be likely to be of more benefit, particularly toward the end of the treatment.

One issue is that far too frequently, we see that many of our colleagues have been vilified. Simply because they are psychiatrists does not mean that they are not doctors. That is a real issue, and it is not only psychiatrists who have been vilified. For example, Myra McClure, who was sure that there was not a viral causation for this disease, was absolutely vilified and decided to give up her research. This is also true of Esther Crawley, who even went so far as to report her vilification to the press and changed her telephone number. As some noble Lords will know, Dr Simon Wessely claims that he had death threats, which is very serious. The problem, of course, is that to say that these vague conditions appear almost certainly to have a psychiatric basis is not to say that they are less important, or that the person who is suffering from them is in some way to blame. It means that we must find rational ways of treating them. I commend this study. It is an example of really excellent research done in a very difficult phenotype and done very well indeed. The authors are to be congratulated on demonstrating clearly that cognitive behavioural therapy and, to a certain extent, some exercise in addition, is a real improvement on what has happened for these patients before.

5.41 pm

Lord Alderdice: Like the noble Lord, Lord Winston, I am grateful to the noble Countess, Lady Mar, for giving us an opportunity to look at this question, although I have some doubts as to whether your Lordships' House is the best place to evaluate scientific evidence and do the exploration. I think that repeated research by other colleagues and demonstration within the scientific community is the way forward. I declare a previous interest as a consultant psychiatrist in the NHS, where I treated a number of patients with these types of symptoms. The history of medicine is that we have tried to clump together groups of symptoms which appear relatively regularly together, and seem to have indication

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of possible outcome, and maybe of management and treatment. However, these are temporary constructs. It is perfectly possible that they are a whole bunch of different disorders which overlap in various ways. Even to talk about it as a condition seems to be making certain presumptions. Certainly, to conclude that there is a definite organic basis, other than to say that in every disorder there are organic and psychological elements, does not mean that we dismiss the psychological—on the contrary. When we think, we can only do so because some things are going on in our brains, which are a physical substrate.

My own position would have to be that we really do not know what we are dealing with. We are dealing with a whole range of symptoms and complaints. We do not know the etiology. The prognosis is variable with different people. We must continue working as best we can.

In the mean time, it is terribly important that we try to evaluate how to manage the problems that people come along to us with. We do not properly understand the schizophrenias; that is a group of different disorders. Yet we still have to manage the large numbers of people with these problems. That is the case with these people who come along with post-exertional fatigue, memory difficulties, pains and so on.

When we try to do that, it is not uncommon for patients to tell us that such and such a thing helps and that such and such a thing does not. I am not a particularly strong advocate of CBT, as some colleagues know, but I remember when I was using CBT with some patients suffering from depression. They would come along and I would ask them to write a diary of what they were doing every half hour and evaluate it. They would say, "I do not feel like getting up in the morning. I am too depressed and I cannot get out of bed". I would say, "Look, I know that you don't feel like it, but please try to get out of bed, structure some activity for the day, do it on an hourly basis and let's see how you are". Hey presto, when they did that, the thing that they felt would not make them better actually did. They were surprised about this.

That is one of the dilemmas about what patients think will help.

Sometimes they are intuitively right and sometimes they are intuitively

mistaken. The only way that you can understand this is to do some work in a scientific way. That is what these colleagues in this paper have tried to do. Some of them will have had particular notions about etiologies, but the point is that they were simply looking at what worked and what did not. What is the outcome? The outcome is that CBT and graduated exercise training are helpful for some people to some extent, and more helpful than the other things which have been suggested. It is not helpful to everybody and it is probably not completely helpful to almost anybody but it is better than doing nothing and better than the other things that have been suggested. There are a lot of scientific tables and graphs but that is the basic outcome.

To me, that is good news because it gives us some indication of things that might be helpful. It also tells us that an awful lot more work is necessary to find out what we are dealing with. If somebody came along and said, "There are such things as chest diseases, we

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should treat them in such and such a way, and the cause is this", we would say, "Yes, that is true but there is a difference between asthma and cancer". They might say, "Oh, really? Well, let's explore that". We are at that kind of level with this set of symptoms.

It is really important that when people give themselves to scientific enterprise in this area that we do not pillory them for their efforts. They may come up with some outcomes that people do not want to believe or that are not very welcome. We psychiatrists are quite used to the idea that often people would rather have a physical explanation for things than a psychological one. It is dreadful if we encourage that by saying, "Well, of course it is not psychological", as though somehow it is a smear on a patient to have psychological difficulties. We must be very careful about that. I do not suggest that Members of your Lordships' House would do that but it is something that happens out there in the community and about which we must be careful.

I am glad that we have had the debate. I trust that we understand the very early stage we are at. It is good that there is some indication here: the paper demonstrates that CBT and GET are helpful, and probably more helpful than other things, but there is a lot more to do. We should encourage people to get into the research work, not just for the ideology issue but to find what helps, and we should not pillory people who come in because that only drives people out of the research. That is the last thing we want to see.

5.46 pm

Baroness Meacher: My Lords, I thank my noble friend Lady Mar for tabling this Question for Short Debate concerning the PACE trial. I must declare an interest as former chair of East London NHS Foundation Trust. Professor White, a leading researcher in the PACE trial, works as a

consultant in that trust in addition to his research post at Queen Mary, University of London.

CFS/ME can be a seriously disabling syndrome. I like to refer to it as a syndrome because it seems to be not one but a number of diseases. NICE compares the physical symptoms of CFS/ME with those of multiple sclerosis, systemic lupus erythematosus—if I can pronounce that correctly—and rheumatoid arthritis, probably three of the most fearsome illnesses one can think of. To make matters worse for sufferers, as the noble Lord, Lord Alderdice, so rightly said, the causes and disease processes of CFS/ME are not yet understood. That must be a deeply frightening thing for any patient.

Doctors can misdiagnose sufferers or, worse still, dismiss them as not really physically ill at all. I understand that for some, some psychological aspects may be important and for others they may not. I am aware of people who have had major viruses and suddenly been struck down, having led very active lives, getting on with things and being fine. We have to be very careful about any assumptions, whether physical, psychological or whatever.

CFS/ME is all too real. Of course we need much more research. I await the outcome of Professor White's cytokine research later this year, for example. We look to the MRC and others to prioritise this distressing

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syndrome. Thankfully, the MRC has two boards—it probably has others, too. One funds studies such as PACE and the other funds studies into the immune system, and viral and genetic considerations. The PACE study did not in any way affect funding for organic CFS/ME research. That is terribly important because there are fears that it may have done.

As the noble Lord said, the experts believe that in time a number of distinct diseases will be identified that currently fall within the CFS/ME label. In the mean time, NICE recommends CBT and/or graded exercise therapy for people with mild or moderate CFS/ME because these are the interventions for which there is the clearest evidence of benefit to patients. No doubt in time treatments that attack the causes and achieve better and faster results will be developed but in the mean time it is a great step forward that, as in the PACE trial, 22% of patients recover—I agree that there is debate about the word “recovery”—after only 13 sessions of CBT or graded exercise.

Meanwhile, 60% of patients achieve significant improvements in both fatigue and exercise levels after the same period, according to the PACE study, which certainly fits with my experience of the limited number of people—about half a dozen—who I know. A meta-analysis showed a 50% recovery rate after one year. These results are very significantly better than spontaneous recovery rates or those following alternative available treatments. From our most helpful discussion on Monday, I understand that my noble friend Lady Mar respects the PACE study but, very

reasonably in my view, has grave concerns about the spin put upon the results. People have to be very careful. We all know what happens once things get into the media but the spin that is put on these things is really important for patients. Things can be very hurtful.

I understand that the DWP may treat people as workshy if they have not undergone a CBT/GET treatment regime. At least a quarter of PCT areas do not have any specialist services for these patients. Others have nothing but grossly inadequate services at a pathetic level. It is essential that the DWP and, indeed, insurance companies take account of the non-availability of such services in many areas. Will the Minister pass on this concern to the noble Lord, Lord Freud? The DWP also needs to be aware that CFS/ME patients can take time to improve. I am not an expert but out of the people I know, several have needed much longer than one year to recover acceptable levels of functioning.

In terms of returning to work, the PACE trial had no effect whatever on the numbers of CFS/ME patients in work. I would not expect it to have done. These people have been, on average, out of work for two and a half years before they entered the trial, and from all the work that numbers of us have done over many years, we know that it is incredibly difficult to get people back into work if they have been out of work for two and a half or three and a half years. However, the social care costs and the need for family support were reduced. People were much better—not necessarily completely better but an awful lot of them were much better.

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I now want to address a few other issues arising from the PACE study, including the fact that 10% of patients deteriorated during the trial. I understand that all these deteriorations resulted from life events or other infections during the trial period. We know well that serious life events or further infections do—or can—cause relapses in this horrible set of illnesses or this syndrome. Secondly, there is the question of whether ME patients benefited from the PACE trial. I am reliably informed that 51% of the patients in the PACE trial had been defined as having ME. I know there are all sorts of debates about that definition, but there was no significant difference in the outcome of treatment for patients who had been deemed to be suffering from ME relative to patients who had been given the CFS label.

Concerns have been expressed about the 11 serious adverse reactions to treatment. The 10 “possible” adverse reactions were equally distributed across the four treatment types. There is no indication that CBT or GET caused any problems. There was one “probable” serious adverse reaction, which was in the medical treatment group and was a reaction to an anti-depressant. Some of us are very familiar with the fact that people can have reactions to anti-depressants, but there is no evidence that CBT or GET can be dangerous.

The PACE trial is the largest ever trial of treatments of this debilitating set of conditions and has received acclaim from clinicians and scientists across the world. Some have wanted to criticise it for changes to the protocol, but those were made before the analysis and were approved by the independent trial steering committee; they were not fixes. The changes were minor and did not affect the results or conclusions in any significant way. Any potential conflicts of interest were published alongside all the papers, and none applied to the statisticians who did the analysis.

It is very encouraging that the Association of Young People with ME accepts that the NICE guidelines are useful for patients and healthcare practitioners. They are right. In conclusion, will the Minister give the Committee an assurance that the Commissioning Board will, in future, give equal priority to the specialist services needed for CFS/ME to that which they give for rheumatoid arthritis and MS?

5.54 pm

Lord Layard: My Lords, I too greatly welcome this debate. This is a terrible condition and we are talking about hundreds of thousands of people who are suffering from it. While it is clear that although there have been many studies relative to the seriousness and pervasiveness of this condition, there is far too little research into what is causing it. I want to focus on treatment, as there have been terrible misunderstandings and misconceptions put about on that score.

I want to make just four points. First, the issue of what causes the condition is often quite different from how we can best treat it. This is such a basic point but it is not fully understood by many of the people suffering from this condition. Coronary heart disease may be caused by cholesterol but we treat it with a stent. In the same way, chronic fatigue may be caused

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by a virus yet the best treatment available at the moment may include psychological therapy. This form of treatment implies nothing about what we believe to be the cause. People who suffer from CFS, and who in almost all cases feel that it is not psychological in origin, are surely making a mistake when they reject psychological support for their condition on the grounds that this implies something about its cause. In their own interest, they should focus on what is the best possible treatment available on the evidence.

Secondly, we have quite a lot of evidence about which treatments work. More will surely be discovered in future and some of them will surely be biological. In the mean time, we have a large amount of evidence that both CBT and graded exercise therapy enable many more people to recover than if the only treatment they have is standard medical care. My main point here is that this is so, whatever the definition of recovery. It is wrong to suggest that this all depends upon that definition; you can put

the cut-off for recovery in many different places and you will always find that people who get CBT and graded exercise therapy do better than people who have only standard medical care. There are many studies preceding PACE to show this. Of course, that is the main finding of PACE, which I would say is a fine piece of work by all normal standards. Some of the criticisms are really misleading but some of them have been answered already.

I come back to this question of the change in the protocol to stress that this was made before any analysis was done of the results. It was not that they looked at the results and said, "Let's change the recovery criteria". The changes were made because of discussions affecting the whole research world and agreed by the trial steering committee. What is very interesting is that a separate paper has been written simply on the recovery issue, which uses five or six different criteria of recovery. Again, in the PACE study it is shown that whatever cut-off you use, you get the same difference between the outcome of CBT and graded exercise therapy. There really is not a conjuring trick going on here and it is wrong for this impression to be given to the community of people who are suffering, if that leads to them not receiving help which they could really benefit from. Instead of criticising the study, we should be rejoicing that we again have more evidence that something can be done which is better than standard medical care.

My third point has, in a way, been made before but given the strength of this evidence that we have these treatments which work, it is shocking that they are so little available. This is part of a wider story of the non-availability of psychological therapy. The survey that was done by Action for M.E. found that a large number of PCTs were providing no specialist treatment clinics for this condition—or were not providing any kind of care, let alone this most evidence-based care. That is a disgrace and I hope that the Minister can say something about that.

The treatments are not unsafe, a claim that is often put about due to the fact that, of course, some people get worse during treatment. The only argument against the treatment, if it were the case, would be if people

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who did not receive it were less likely to get worse. Again, the statistics are absolutely clear: the proportion of people who get worse in treatment is no higher than that for people who get worse who are not in treatment. There is no argument whatever that this is unsafe.

My fourth point is about how we can get a better deal for this large group of sufferers. Obviously, the worst possible way to get it is to turn the area into a battleground. It gives the commissioners the perfect excuse for doing nothing and gives people of good will, who might come in and try to help people with this condition, a serious disincentive for getting into this field. As we know, and has already been said, many—or certainly some—of the people who work in this area have received repeated insults and

even death threats. I pay particular tribute to Sir Simon Wessely at King's College London, who has led the field for many years in this area and has stuck to it, despite all this harassment. He and his colleagues—

Lord Wallace of Saltaire: My Lords, the noble Lord is in his seventh minute. We are very tight on time and I am worried that the Minister will not have time to reply.

Lord Layard: I will stop at this point.

6.02 pm

Baroness Hollins: My Lords, I also thank my noble friend Lady Mar for raising such an important topic. I have read the research very carefully in preparing my short contribution.

We know that some patients who develop symptoms of CFS/ME will recover fully but that the majority go on to have a fluctuating long-term condition. I agree with the noble Lord, Lord Alderdice, that there is no single cause for this condition. Some 10% to 12% of people who have glandular fever develop the symptoms of CFS/ME, but there are many other precipitants, too. It is a very distressing condition for people to have and is confusing and difficult for families, friends and employers, particularly because the condition may fluctuate in its effects so dramatically and vary in its severity. It is not surprising that people with CFS/ME may feel that they are not believed and that their family and friends are unsympathetic at times. Imagine living with an illness that fluctuates, recurs after mild exertion and is associated with what people describe as brain fog? As it stands, a very limited range of therapies are available and, understandably, this patient group has ended up feeling overlooked and neglected.

The greatest weapon against illness and disease is robust, peer-reviewed research. Research into both causation and the factors that sustain symptoms is important, as is research into effective interventions. I am particularly pleased that current biomedical research funded by the MRC is trying to understand some of the mechanisms at play, including by looking at mitochondrial function, autonomic dysfunction and sleep disturbance. It is essential that we continue to look at the best possible treatments.

I will speak briefly about the PACE trial, which of course most noble Lords have spoken about and which enrolled 640 participants. Just last week, the follow-up

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study, looking at recovery after one year, was published in the journal *Psychological Medicine*

. Noble Lords may know that the trial showed that an average of only 13 sessions of CBT or graded exercise therapy, over just six months and as a supplement to good specialist medical care, had rates of recovery of 22%. My understanding is that, by "recovery", the researchers included the fact that after a year these patients no longer met the criteria for CFS/ME.

This would be heralded as a fantastic outcome for the treatment of MS, Parkinson's disease or cancer. Only 8% of those receiving adaptive pacing therapy and 7% of those receiving just specialist medical care achieved the same degree of recovery. In other words, the successful treatments were three times more likely to lead to recovery than the comparison treatments. Of course, that was after just one year, but follow-up is continuing, and I look forward to hearing whether these results will be sustained. I hope the Minister will agree with me that it would be very useful for this study to be funded for follow-up for five years, particularly given the fluctuating nature of the condition.

Better outcomes are achieved for all illnesses, from heart disease and cancer to schizophrenia and depression, when the overall well-being of the patient—biological, psychological and social—is taken into account. That is not to say that there is no physical reason behind the onset of illness, or that physiological effects are not continuing to maintain or modify the disease process. My noble friend's debate today is concerned with both health and care, including access to benefits. It is yet another reminder of the importance of a holistic approach to care, an intertwining of body and mind. This complex interaction has been acknowledged since ancient times but somehow, over the past 100 years, with the elucidation of many physical causes for illness, the mind-body connection has been somewhat forgotten. Thankfully, this connection has again been brought to the fore by the Government's welcome commitment to parity of esteem between physical and mental health. The Royal College of Psychiatrists, of which I am a former president, has long been concerned about the physical effects of psychological stress and the psychological effects of physical stress. Interdisciplinary research—which brings together, for example, the neuropsychiatrist with the immunologist—is vitally important.

Could the Minister clarify whether the arrangements being made to ensure that evidence-based treatments, such as those tested in the PACE trial and recommended by NICE, are commissioned and that they do not fall through any gaps caused by what has been called an orphan status for this condition? To explain what I mean, CFS/ME can be classified under both neurological and psychiatric disorders for clinical purposes; it is not clearly claimed by any one specialist group as being its primary responsibility. This means that many people diagnosed with CFS/ME will not be referred to a specialist centre and that the treatment they need will just not be available. Research will shine more light on this condition and begin to distinguish whether subgroups of patients will be more responsive to different new treatments being evidenced and introduced. Research is needed into all aspects of the illness so that more effective treatments can be found. This must include both biological aspects and any psychological

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factors that may sustain or lead to the further deterioration of the illness such as, for example, major life events, which are known to cause a relapse in CFS/ME patients. Thankfully, the MRC has recognised the past underinvestment in this poorly understood condition—or set of conditions—by highlighting it as a priority area for research. Through the particular efforts of Professor Stephen Holgate, the CFS/ME research collaborative mentioned by my noble friend will be launched in April, bringing together researchers from all relevant disciplines with patient groups and charities. This is so important. The future is looking brighter for people with CFS/ME and the constructive collaboration of people with different perspectives and contributions will, I hope, prove to be a major step forward.

6.09 pm

Baroness Wheeler: My Lords, I, too, welcome this debate and acknowledge the work of the noble Countess, Lady Mar, on CFS/ME as chair of Forward-ME and vice-chair of the All-Party Parliamentary Group. Although a last-minute stand-in in this debate for my noble friend Lord Hunt—he is due shortly in the Chamber for the Statement on the Mid Staffs report—I am not new to this issue. As the noble Countess regularly contributes on CFS/ME to health debates I have participated in, most recently our extensive debate last November on neurological diseases, initiated by my noble friend Lady Ford. What is new to me is the focus on the PACE trial and the opportunity to hear from our expert medical and psychiatrist colleagues about the wider issues and perspectives, and about the trial itself: what it covered, who was involved, its findings and results and the wider, extensive research that is currently being undertaken across the world.

As we have heard, the PACE trial was the largest-ever randomised controlled trial of treatments of CFS/ME, primarily funded by the Medical Research Council following competitive peer review, with its main findings concerning efficacy and safety published in the *Lancet*. It was designed to compare improvements in safety after CBT and GET with outcomes after ADP and SMC. The patients were recruited from hospital clinics in England and Scotland, and were able to travel to clinics to receive treatment. The trial was not designed to test treatments in patients with severely disabling illness. As a non-expert, it seems to me that some of the criticisms and disappointments levelled at PACE do not fully recognise this.

As we have heard from noble Lords in this debate, the trial provided clear evidence that both CBT and GET were better than ADP or SMC in improving both symptoms and disability. In fact, all the treatments were found to be safe without any serious reactions to treatments in any of the treatment groups. I understand that a paper published last week showed that CBT and GET are three times more likely to bring about recovery than any other treatments.

Like other speakers, I want to underline the importance of looking to the future. On the NICE guidelines, I support noble Lords who stress that the key issue about them is making sure that they are actually implemented, so that patients can receive effective treatment and care wherever they live in the UK.

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In the debate on 20 November, the noble Baroness, Lady Northover, assured the House that all the neurological and specialist conditions would have "equal priority" under the new NHS commissioning arrangements, and that this would mean that the Cinderella conditions should be improved. Can the noble Baroness outline the steps that the Government are taking to ensure that the commissioning arrangements provide appropriate and adequate specialist care for patients suffering from illnesses such as CFS and ME which are not easily classified under normal commissioning arrangements? To help this, will the Government give CCGs guidance on which illnesses should qualify under special commissioning arrangements? Can she reassure us that this guidance will include ensuring that guided exercise training is provided by qualified and trained specialist therapists?

6.12 pm

Baroness Northover: My Lords, I thank the noble Countess for initiating this debate. I apologise for the fact that my noble friend Lord Howe cannot be here, as he is in the Chamber making the Mid Staffs Statement. I, too, am a last-minute replacement.

I know that the noble Countess has a particular and personal interest in the subject and I pay tribute to the way in which she continues to raise issues of concern in your Lordships' House, as well as her unswerving commitment to improving the experience of people living with CFS/ME. I recognise how distressing and debilitating the condition can be for individuals, their carers and their families. Equally, I recognise the difficulties that many patients face in getting the treatment and care they need to help them manage their illness and, where they can, make a recovery; we have heard that this afternoon. I am sure that we all agree that the most important thing is to ensure that patients receive the treatment and care that they need.

At this point it is worth acknowledging that, while many patients feel let down by the system, many patients have had a positive experience and have worked with health and social care professionals to manage their care effectively. It is also important to acknowledge that doctors and other professionals working in this field are highly committed to providing the best possible care for their patients. We want to see people with CFS/ME being listened to when it comes to decisions about what type of treatment and care may best meet their individual needs and, across the country, many doctors are working with their patients to achieve this. I hear what my noble friend Lord Alderdice says on this.

There is no doubt that there is widespread uncertainty surrounding this condition; that has shone through in this debate. There is controversy, disagreement and divided and often polarised opinion about its causes and the best way to treat it. The kind of issues raised by the noble Countess today have surrounded the debate for many years. We have seen how passionate but how often opposed are those seeking to address these problems in the debate this afternoon.

It is an unfortunate fact that despite a great deal of worldwide research—the noble Lord, Lord Winston, made clear how extensive this is—we do not yet know

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definitively the cause or causes of CFS/ME: whether it is a disease; a condition, as the noble Baroness, Lady Hollins, described it; or a syndrome, as the noble Baroness, Lady Meacher, described it. The noble Lords, Lord Winston and Lord Layard, surely are right that it is concerning if researchers are in any way intimidated as they seek to clarify these problems.

CFS/ME is not alone in being mystifying. We do not know the causes of most cancers and other diseases such as Alzheimer's. That lack of knowledge, however, has not stopped us from seeking the best forms of treatment. Many of these diseases are treated well even though we do not know their causes. I quite agree that more research is needed. In the mean time, patients want access to the best treatments that are available. So far, the only treatments that seem to have shown any benefit in clinical trials have been cognitive behaviour therapy and graded exercise therapy, but I have heard what noble Lords have said in regard to those.

This brings me to the PACE trial that has prompted today's debate. The MRC's decision to fund this trial was based on the fact that there was a lack of high-quality evidence to inform the treatment of CFS/ME and, in particular, on the need to evaluate the treatments that were already in use and for which there was insufficiently strong evidence from randomised controlled trials to support their effectiveness. The decision to fund this trial was based on the MRC's usual rigorous peer-review process for clinical trials, as noble Lords have emphasised. The experts who reviewed the application were satisfied that the design put forward was of high quality, would provide useful evidence to help doctors and patients decide whether any of the four treatments to be evaluated was likely to be worth pursuing, and would help to inform decisions on the provision of treatment by the NHS. The noble Lord, Lord Winston, and others argued that this was a controlled and rigorous study. All agree that research is needed.

I shall try to address the challenges that were raised by the noble Countess, Lady Mar. She expressed concern about the selection method for participants. I assure her that having neurological symptoms, such as

memory difficulties or muscle weakness, did not exclude anyone from taking part in the trial since these symptoms were medically recognised symptoms of the condition. While researchers used the Oxford definition to define the condition in the PACE trial, participants were also assessed to see whether they met the international Centers for Disease Control and Prevention criteria to see whether the effects of treatments were different in those who met this alternative definition. The independent members of the trial steering committee reviewed and agreed the plans for secondary analysis.

The noble Countess, Lady Mar, also expressed concern about the recovery statistics and other areas in relation to the protocol. As for all MRC-funded studies, it is the responsibility of the investigators and the relevant journals, guided by peer reviewers, to determine how findings are published and when. The investigators' first paper on the outcomes of the PACE study was published in the *Lancet* in March 2011. A later paper was published in August 2012, which dealt with the cost-effectiveness of the interventions. Further papers will be published, including papers showing a long-term

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follow-up after two and a half years. The noble Baroness, Lady Hollins, made a very important point about follow-up, and no doubt the MRC will bear that in mind and will look at this debate. Follow-up in all these trials is very important.

The noble Countess, Lady Mar, asked about severely disabled patients being excluded from the trial. Patients had to be able to attend hospital for treatment, but a number needed mobility aids and others received treatment by telephone when they were too unwell to attend a clinic once they had been recruited. She also asked whether the trial data could be reanalysed. As she will know, there are ethical and legal barriers to releasing data to a member of the public without consent when these data contain medical information that might identify the patient. The main outcome data have already been independently analysed by a Cochrane Collaboration group and a paper is being prepared for publication. I know that she will look at that with interest.

An often voiced criticism is that the money spent on the PACE trial would have been better spent on research into causes. As the noble Baroness, Lady Meacher, indicated, the two are not mutually exclusive. While understanding the cause of the condition is obviously important, if potential treatments are available, it is equally important to test their effectiveness so that they can be introduced into service. Of relevance to this is that the PACE trial tested adaptive pacing therapy, which had not previously been tested in a large trial and which is supported by patient organisations. Various noble Lords have paid tribute to the quality of the research, even though the noble Countess, Lady Mar, was more sceptical.

As the noble Countess is aware, the findings of the PACE study reflect the recommendations in current NICE guidance. I understand that concerns have been expressed that patients may have their choices about care restricted because the PACE trial supports their non-recommendation by NICE or that patients may be forced into treatments they do not want because they are recommended. I assure noble Lords that clinical guidelines published by NICE help to promote consistency but recognise that patients are individuals who may require different forms of management. Clinicians are therefore free to adapt the guidelines when deciding, in consultation with their patients, the most appropriate treatment. NICE routinely reviews the need to update its guidance in order to take account of the latest available evidence. As the noble Countess is aware, CFS/ME is currently a highlighted area and a high priority for the MRC. The high-quality research stimulated by the MRC's recent call will add to the future evidence base.

Concern has been expressed that the findings of the trial will be used to reduce the number of people with CFS/ME on state benefits. That was flagged up briefly by noble Lords. I should like to dispel straight away the idea that CFS/ME is not recognised by the Department for Work and Pensions as a potentially serious condition. For example, there are no targets for finding individuals fit for work in the work capability assessment process. The noble Baroness, Lady Meacher, raised this particular issue and asked whether patients who do not comply

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with the CBT or take the treatment recommended to them might have their benefits withdrawn. I can assure her that that is not the case. Entitlement to employment support allowance is not based on compliance with specific treatments and anyone claiming ESA will undergo the work capability assessment. That assessment is founded on the premise that eligibility should not be based on a person's condition or the treatment regime for it but, rather, on the way that that condition limits their functional capability. I am happy to flag this debate to the DWP, as the noble Baroness asked me to, in regard to the availability of services. The noble Baroness also asked me about the NHS Commissioning Board and whether it would give equal weight to a number of other diseases. I can assure her that the mandate to the NHS Commissioning Board will ensure that improvements are made to the quality of life for all people living with long-term conditions, including this one.

The noble Lord, Lord Layard, asked me about specialist treatment provided by PCTs. In the new system, clinical commissioning groups will be responsible for commissioning specialist CFS/ME services. As he knows, they comprise front-line clinicians. We certainly hope that they will therefore have a good understanding of their local communities, including patients with these problems. The NHS Commissioning Board will hold

those CCGs accountable for the services that they commission, as well as providing support—for

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example, through the development of commissioning guides. I understand that Martin McShane, long-term conditions lead at the NHS Commissioning Board, has already met with the CFS/ME patient groups to discuss their concerns. Those discussions will inform the board's work as things move forward.

The Government's aim is to help individuals who are suffering from these problems both to receive appropriate treatment and to get back to work where they can do so. They also seek a better understanding of the situation that these individuals are in. The PACE trial was funded to respond to the concerns of patients, carers and doctors that more research into CFS/ME was required. Of course, we all hope that health research results in people becoming healthier and fewer suffering from these kinds of problems. This is obviously a major focus for the MRC in making its individual funding decisions.

In conclusion, I hope that the noble Countess will agree that we are sympathetic to the needs of patients with CFS/ME. I appreciate, as do other noble Lords, her many concerns. I hope that I have reassured her that we are investing in improved services for CFS/ME patients and in an expanded research programme—noble Lords have emphasised the importance of research moving forward in this area—and that this should make a difference to the lives of the many people affected by this condition. That is the Government's priority.

Committee adjourned at 6.25 pm.