

**Parliamentary briefing on  
NICE guideline (CG53) for  
Myalgic Encephalomyelitis**

By #MEAction Network UK

**July 2017**



The Myalgic Encephalomyelitis Action Network (#MEAction) is an international grassroots network dedicated to working for health equality for patients with ME. #MEAction Network UK is the local affiliate operating in the United Kingdom. We are a patient voice in the consultation for the NICE submission.

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Professor Ian Gibson:  
(former MP and Chairman of the UK Government's Science and Technology Committee)

*"Science, Politics.....and ME.*

*These have not been happy bedfellows for the last generation.*

*Whilst patients want nothing more than to regain their health, the science which should be available to help them achieve that objective has been thwarted by the politics of the establishment and those who retain influence at the highest levels.*

*This must change" <sup>1</sup>*

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<sup>1</sup> Gibson, Ian and Elaine Sheriffs (2017). [Science, Politics, .....and ME: A health scandal in our generation.](#) CreateSpace Independent Publishing Platform.

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## What is Myalgic Encephalomyelitis (ME)?

It's estimated 250,000 people in the UK (17 million worldwide) have Myalgic Encephalomyelitis (ME) That's approximately 400 people within your constituency.

ME, also known as Chronic Fatigue Syndrome\* is a long term, fluctuating, multisystemic condition affecting many body systems, particularly relating to the nervous and immune systems. People with ME suffer severe, persistent fatigue. The US Institute of Medicine identified that the cardinal symptom of ME is exertional intolerance (a worsening of symptoms after minimal exertion (physical or cognitive - also known as Post Exertional Malaise (PEM)). Having ME is commonly thought of as being "just tired", yet research has shown that people with ME score lower for physical function and overall quality of life than most other chronic disease groups, including MS, cancer and stroke ([Nacul 2011](#)).

25% of patients are housebound or bedbound. For moderate to severe patients, living with ME is like living for decades with late-stage cancer, advanced stage AIDS, or congestive heart failure.

## What is the #MEAction movement about?

[#MEAction](#) began as a worldwide protest movement against the lack of commitment by governments and their health authorities into funding research and treatment into this devastating and poorly understood disease.

Here in the UK, ME patients are also distressed and angry that NHS treatment programmes for ME have, in many cases, caused their health to deteriorate rather than improve. In particular, Graded Exercise Therapy (GET) has been shown to be not only ineffective but positively harmful for 49% of respondents in a review of five major surveys by patient organisations.<sup>2</sup>

Patients' experiences of increased disability following GET are supported by accumulating biomedical research evidence that points to abnormal physiological response to exercise<sup>3</sup> and dysfunctional energy metabolism in ME/CFS.<sup>4</sup> Yet our experiences continue to be dismissed and ignored by the proponents of GET for ME and by NIHCE.

## Does the NICE guideline for 'CFS/ME' need updating?

Yes! NICE Clinical Guideline for CFS/ME (CG53) is the basis for recommending harmful graded exercise therapy and associated cognitive behaviour therapy as treatments for ME. It has been in place and unchanged for 10 years. In July 2017, NICE proposed to issue a further 'no update' recommendation causing widespread concern and distress amongst those living with, and

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<sup>2</sup> Kirke, K (2017) PACE investigators' response is misleading regarding patient survey results in Journal of Health Psychology Vol 22, Issue 9, 2017.

<sup>3</sup>

[https://www.researchgate.net/publication/284633632\\_Deviant\\_Cellular\\_and\\_Physiological\\_Responses\\_to\\_Exercise\\_in\\_Myalgic\\_Encephalomyelitis\\_and\\_Chronic\\_Fatigue\\_Syndrome\\_Frank\\_NM\\_Twisk1\\_Keith\\_J\\_Geraghty2](https://www.researchgate.net/publication/284633632_Deviant_Cellular_and_Physiological_Responses_to_Exercise_in_Myalgic_Encephalomyelitis_and_Chronic_Fatigue_Syndrome_Frank_NM_Twisk1_Keith_J_Geraghty2)

<sup>4</sup> Fluge Ø, Mella O, Bruland O, . (2016) Metabolic profiling indicates impaired pyruvate dehydrogenase function in myalgic encephalopathy/chronic fatigue syndrome. JCI Insight 1(21)

advocating for those with the condition. The following charities and patient organisations all sent submissions urging NICE to review its guideline:

- Action for ME
- Forward-ME Group
- Hope for ME & Fibro Northern Ireland
- Inclusion London
- Invest in ME Research
- #MEAction
- ME Association
- Tymes Trust
- WAMES

This was supported by 15,180 individuals (in under 2 weeks) who signed the [ME Association petition](#) agreeing that “*The NICE guideline for CFS/ME is not fit for purpose and needs a complete revision.*” It’s believed this is the “*biggest expression of no confidence in a NICE guideline ever recorded.*”<sup>5</sup>

## What is wrong with the current guideline?

The current guideline heavily reflects a psychological model of ME and doesn’t take into account recent biomedical advances in understanding the condition. It dismisses overwhelming evidence that a significant proportion of ME patients find that GET treatment makes their illness worse.

Many of the studies that the guidelines are based on recruit people with Chronic Fatigue Syndrome and assume these apply to everyone with ME. They adopt the Oxford criteria for defining ME which is too broad and crucially fails to recognise Post Exertional Malaise (PEM) as a symptom.

A recent study has shown the Oxford criteria returned an **85% error rate** in identifying ME<sup>6</sup> and the US Centres for Disease Control and Prevention has ignored studies using this criteria and removed treatments such as GET/CBT from its clinical guidelines.<sup>7</sup>

Cognitive behavioural therapy (CBT) alongside graded exercise therapy (GET) is a contentious form of treatment for people with ME. It is important to recognise that not all CBT is the same, and the style of CBT designed to treat ME (as opposed to the style aimed at coping with chronic illness disability) is derived on the basis that patients have false illness beliefs and positive thinking and gradual exercise is the treatment required to get them back to fitness. It therefore encourages patients to do more than they feel they can do.

Many patients report that their symptoms are much worse after NHS CBT/GET treatment, in some cases becoming permanently disabled by it. This isn’t reflected in the way harm is reported in the clinical studies. Participants and patients are not made aware of the risks of

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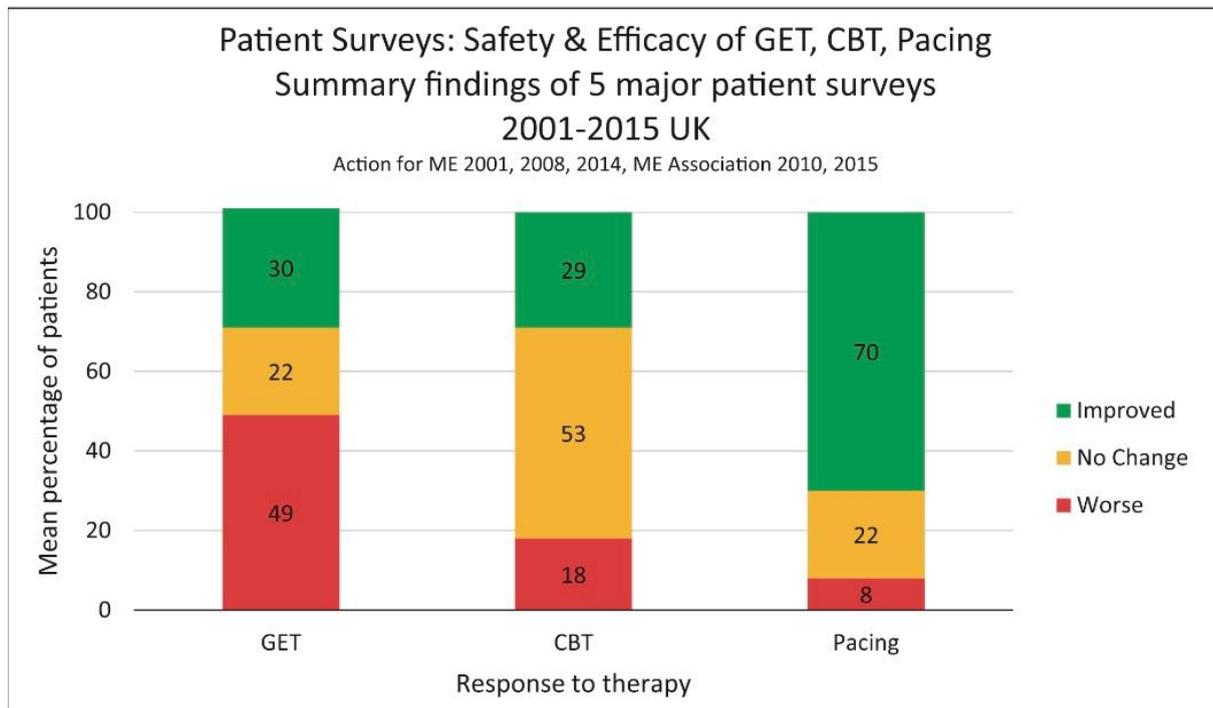
5

<http://www.meassociation.org.uk/2017/07/me-association-petition-represents-biggest-expression-of-no-confidence-in-a-nice-guideline-ever-recorded-26-july-2017/>

<sup>6</sup> Baraniuk, JN (2017), Chronic fatigue syndrome prevalence is grossly overestimated using Oxford criteria compared to Centers for Disease Control (Fukuda) criteria in a U.S. population study, *Fatigue: Biomedicine, Health & Behavior*, 1-16, doi:10.1080/21641846.2017.1353578.

<sup>7</sup> <https://www.cdc.gov/me-cfs/index.html>

undertaking CBT/GET, and the discrepancy between research and patient experience warrants further investigation.



. Summary of patient survey evidence on safety and efficacy of GET, CBT and pacing

**NB:** Pacing is different from GET. With pacing, people aim to keep below their maximum threshold of what they can do and balance all use of energy (physical and cognitive) with periods of rest. Activity can sometimes increase if underlying health improves. Studies have shown 82% of patients improve with pacing which was sustained at 12 months follow up.<sup>8</sup>

More is being understood about this illness and medical advances are coming but set against a backdrop against current NICE guideline, patients are being harmed and denied the help they need. The guideline also perpetuates the stigma and prejudice that people with ME just need positive thinking and exercise to get better. This message has been reinforced across the media and alongside funding is another reason why so few people get the support they need. In 2015 Action for ME surveyed 850 people with ME. Whilst 97% potentially met the threshold of difficulties to entitle them to a social care package, only 6% received one and 16% had a social care assessment in the last 5 years. 84% felt this was due to concerns that the assessor wouldn't believe they were genuinely disabled and wouldn't be considered deserving of help and support. Half of respondents also stated that stigma was a significant factor.<sup>9</sup>

<sup>8</sup> Goudsmit, EM, Ho-Yen, DO, and Dancey, CP (2009), Learning to cope with chronic illness. Efficacy of a multi-component treatment for people with chronic fatigue syndrome, Patient Education and Counseling, 77(2), 231-236.

<sup>9</sup> Hale, C, Chowdhury, S, Ogden, C, and Hypher, E 2015, Close to Collapse: An Interim Report on Access to Social Care and Advocacy for People With M.E./CFS, Action for M.E., viewed 17 July 2017, <https://www.actionforme.org.uk/uploads/pdfs/close-to-collapse-report-UPDATED.pdf>

## Disputed evidence on PACE trial

The largest study to be considered in the guideline is the highly controversial PACE trial. It gained £5 million of public money (including the DWP) and claimed that patients improved after CBT/GET treatment.

The main investigators had financial and consulting relationships with disability insurance companies, and advised therapies such as GET/CBT could get ME/CFS claimants off benefits and back to work. These weren't declared to participants on the trial contravening the Helsinki declaration which requires prospective participants to be “adequately informed” of any ‘possible conflicts of interest’.

There were concerns about the design, methodology and conclusion of the trial and were at odds with patients lived experience. A Freedom of Information request finally ruled that the raw data must be released despite the authors’ spending £200,000 in an attempt to block it. This revealed changes to the protocol part way through the trial and recovery claims were grossly exaggerated. Their revised definition of “recovery” was so loose that patients could get worse over the course of the trial and still be considered “recovered.” The threshold for physical function was so low that an average 80-year-old would exceed it. In Feb 2016 this prompted 42 leading scientists to sign an open letter to the Lancet demanding an independent investigation and in March 2017, over 100 signatures from experts to an open letter to Psychological medicine calling for it's retraction.<sup>10</sup>

The Journal of Health Psychology devoted an entire special edition on the flaws in the PACE trial in July 2017<sup>11</sup>

Despite the shockwaves that ran across the science and ME community alike, the recommendations of GET/CBT are still in place. Concerns about methodology extend beyond the PACE trial to include the entire body of GET/CBT research, where it relies on the flawed combination of unblinded randomisation and subjective outcomes (Helmfrid, 2016).

A [parliamentary petition](#) in March 2017 to “suspend all trials of graded exercise therapy in children and adults with ME/CFS” gained signatures in every constituency across the whole of the UK.

Prof Ian Gibson’s (former MP and chair of the UK Government’s Science and Technology Committee) witness statement to the judicial NICE review in 2007 said, *“The NICE guidelines give the false impression, to doctors, politicians, and the MRC, that effective treatments are available for ME patients. NICE would do better honestly to admit that their core therapy recommendation [of GET/CBT] are not evidence-based, and to use this admission as the starting point for an adequately funded search for a cure.”*<sup>12</sup>

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<http://www.virology.ws/2017/03/13/an-open-letter-to-psychological-medicine-about-recovery-and-the-pace-trial/>. Alternatively, a concise summary about the many problems of PACE can be found here: <https://www.statnews.com/2016/09/21/chronic-fatigue-syndrome-pace-trial/>

<sup>11</sup> <http://journals.sagepub.com/doi/full/10.1177/1359105317722370>

<sup>12</sup> Gibson I. Witness statement in support of the Judicial Review case of the NICE “CFS/ME” Guideline (CG53) online brought by ME patients:Re: Douglas Fraser & Kevin Short v NICE. Case Number: CO/10408/2007. Exclusion code 9

Physical harm has followed CBT/GET therapies, but the consequences of not complying with CBT/GET has also caused social and emotional harm. Patients report being refused benefits, counselling or house calls from their doctors if they refuse or drop out of GET. Parents sometimes have to choose between making their sick child worse or being accused of Munchausen's by Proxy/ Fabricated or Induced Illness by Carers' (FIIC) for 'resisting treatment', and the TYMES Trust have (successfully) repealed almost 200 cases where parents were wrongfully accused of child abuse.<sup>13</sup> Patients should not be punished for refusing a therapy that may harm them.

## What else needs changing in the guideline?

Current guidelines state rest should be discouraged.(CG53 section 1.4.2.4) However, 84% of patients find pacing with rest helpful in reducing the severity of the illness.<sup>14</sup> This is also supported by many studies that have found energy is limited at a cellular level with exertion causing unusual problems. Studies have refuted claims that energy problems are due to deconditioning<sup>15</sup> This outdated advice is harmful and it is confusing to warn patients of rest but not GET.

Action for ME stated *"It is unethical not to provide clinicians and patients with a balanced current understanding of the evidence base for treatment and management approaches, and that failure to do so prevents informed consent, which may contravene article 25 d of the UN Convention on the Rights of Persons with Disabilities."*

We are also concerned on the lack of research for severe ME and are alarmed that 'Graded Activity' is suggested.

### **We urgently want NICE to update its guideline on ME with patient group stakeholders in attendance with the following:**

1. That ME specific CBT is removed as a recommended treatment. (conventional talking therapy to help with the loss chronic illness brings is acceptable)
2. That Post Exertional Malaise (PEM) is a mandatory symptom when considering patients with ME for future research and to discount all studies that use the overly broad Oxford criteria.
3. That Graded Exercise Therapy be removed as a recommended treatment due to lack of evidence of efficacy and concerns about patient safety.

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<sup>13</sup> <http://www.tymestrust.org/pdfs/falseallegations.pdf>

<sup>14</sup> Geraghty, K, Hann, M, and Kurtev, S (2017), ME/CFS patients' reports of symptom changes following CBT, GET and Pacing Treatments: Analysis of a primary survey compared with secondary surveys, Journal of Health Psychology, in press, forthcoming.

<sup>15</sup> Vermeulen, RC, and Vermeulen van Eck, I (2014), Decreased oxygen extraction during cardiopulmonary exercise test in patients with chronic fatigue syndrome, Journal of Translational Medicine, 12(1), 20, doi:10.1186/1479-5876-12-20.

4. If GET remains in the guideline for those with mild ME, warnings should be given that this is a controversial treatment, with high reports of patient harm. Patients should not be blamed or denied support and benefits if they do not improve.<sup>16</sup>
5. Warnings of rest should be replaced by its recommendation.
6. That 'Activity Management' (section 1.9.3.1) be removed as a recommended treatment for severe ME. This is based on GET principles with the same risk of harm, despite no research supporting this therapy for severely affected patients. With severe patients the risks for great harm are higher, and Pacing and Rest are safer. We recommend consulting with Stonebird and 25% Severe ME groups who specialise in severe ME.
7. The NICE guidelines for ME/CFS should be removed from the static list and returned to the active list. ME is poorly funded in the UK so International research should be considered in all reviews. Some of these studies are becoming close to identifying biomarkers and treatment for ME.

## \*Is ME the same as Chronic Fatigue Syndrome?

Myalgic Encephalomyelitis was recognised by the World Health Organisation in the 1960's but Chronic Fatigue Syndrome (CFS) was introduced by psychologists in the 1980's. CFS is often rejected by patients as it trivialises their condition and broadens the spectrum of the illness to include other conditions. International consensus advocates moving away from the term CFS in favour of the term ME to better reflect the underlying disease process.

## Working together

We are keen to work with you to make sure people with ME are given appropriate care and to help future generations.

Further details and research references can be found at #MEAction Network UK response to NICE 2017 submission.<sup>17</sup>

We would be delighted to provide you with further information. Please contact [Sarah.reed@meaction.net](mailto:Sarah.reed@meaction.net) if you have any queries.

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<sup>16</sup> BA. Coulter, A. Hopkins, B. Moulton  
Montgomery v Lanarkshire Health Board: transforming informed consent  
Bull. R. Coll. Surg. Engl., 99 (2017), pp. 36-38, 10.1308/rcsbull.2017.36  
<http://publishing.rcseng.ac.uk/doi/10.1308/rcsbull.2017.36>

<sup>17</sup> <http://www.meaction.net/2017/07/23/meaction-uk-response-to-nice-2017/>