

## **1. Background**

This paper is MEAction Scotland's response to evidence published on the Scottish Parliament's Petitions Committee webpage as of 10 September 2018. We understand that further evidence has been submitted since 17 July (which is currently the date of the last evidence published) and that we will be given the opportunity to respond to this evidence before it is considered by the Petitions Committee.

Evidence from 11 organisations/individuals has been published. Nine of the submissions are from the public bodies who were asked by the Petitions Committee for their views on the action called for in the petition. These were: the Scottish Government; regional NHS boards; the Scottish Public Health Network (ScotPHN); and NHS Education Scotland (NES). We note that only five of the 14 regional NHS boards responded to the Petitions Committee request. In addition to the organisations contacted by the Committee, three organisations/individuals have submitted evidence.

We have structured our response so that the next three sections address each of the action areas in our petition. In the final section we respond to other issues raised in the submissions, highlighting questions that we have as a result of reading the submissions.

## **2. Investing in biomedical research and creating a centre of excellence for ME**

*In our petition we called for commitment to a programme of biomedical research by the Chief Scientist Office (CSO), proportional to the disease burden and a creation of a Scottish Centre of Excellence for ME.*

The call for a programme of biomedical research was supported in the evidence of NES, the ScotPHN, Professor Jonathan Edwards, Science for ME, and Professor Chris Ponting. ScotPHN refers to the recommendations of the 2010 healthcare needs assessment and says it supports this element of the petition. NES acknowledges the need to carry out biomedical research into ME *"treating it with parity to other conditions that have a significant burden and impact on quality of life"*.

The Scottish Government's submission acknowledges the importance of *"robust research"* and cites its recent three year funding of £45,000 (£15,000 a year) to part fund a PhD student as an *"important step in building ME research capacity"*. Our response to this is that funding of £15,000 a year, while welcome, is insufficient and does not meet the urgent need for research into a disease which has no effective treatment, or recognise the extent to which there has historically been a disproportionate lack of funding for ME research. We agree with Professor Chris Ponting of Edinburgh University (the beneficiary of the PhD funding) who points out in his submission that there is a need to test out many hypotheses to provide evidence that would interest researchers across the country.

The Scottish Government's submission references details of research trials open to people with ME that are available through the UK Clinical Trials Gateway website. We have searched this website and there are no clinical trials currently being conducted in Scotland. This confirms our view that there is a fundamental lack of research currently being conducted in Scotland.

We note the Scottish Government's comments that research funding is available through the CSO and agree that such funding is critical in encouraging research. A report from the CSO highlights the role that its funding plays in generating research and we urge the CSO to fulfil its remit by actively encouraging research applications and funding research on ME.

*“At any one time around 100 CSO funded studies are active with a value of around £15m. Early findings from the ResearchFish evaluation database suggest that CSO grants generate a considerable volume of additional activity, and in the most recent university Research Excellence Framework exercise 21% of the case studies submitted cited CSO support.”<sup>1</sup>*

The creation of a Centre of Excellence is supported by Professor Jonathan Edwards and Professor Chris Ponting. These submissions highlight the role that a Centre of Excellence would play in the development of research. The submission by Dumfries and Galloway NHS board indicates support of a specialist centre for patients which could develop into a Centre of Excellence.

### **3. Ensuring healthcare professionals' training and education materials reflect the latest scientific evidence**

*In our petition we called for the Government to ensure that NHS Education for Scotland (NES) is complying with the classification of ME by WHO and updates its training material based on the latest scientific evidence, and ensuring that there is no conflict of interest in the development and review of NES materials, with reference to previous studies, such as the PACE trial.*

#### **3.1 Classification of ME by NES**

ScotPHN supports this element of the petition and highlights two recommendations in the healthcare needs assessment related to this. Professor Jonathan Edwards evidences that CBT/GET “*have been subjected to methodologically inadequate trials ... and introduced based on uncritical interpretation of the results*”. He provides further evidence on why concerns about CBT and GET should be taken seriously.

The NES submission states (paragraph 13) that it includes ME in a Competency Framework for Persistent Physical Symptoms (PPS). According to the NHS, PPS, also known as Medically Unexplained Symptoms, are physical complaints that do not appear to be symptoms of a medical condition<sup>2</sup>. This categorisation was confirmed by NES in a letter to MEAction Scotland (9 March 2018) which says that “*the terms, ME, CFS and MUS are used interchangeably*”. We strongly refute this categorisation of ME; it is classified under the diseases of the nervous system by the World Health Organisation in its International Classification of Diseases. A number of publications have identified distinct neurological changes observed in patients with ME. This classification has been noted in the Scottish Good Practice Statement and acknowledged in the current NICE Guidelines for ME. The evidence provided by NES makes it clear that they treat ME as a PPS and we suggest that this approach confirms the need for a review of the NES approach to ME education and training, as identified in our petition

#### **3.2 Conflict of Interest in Development of NES materials**

The NES submission refers to a review of the ‘Developing a Shared Understanding’ module (paragraph 16). MEAction Scotland has been informed by NES that this review was conducted by Professor Trudie Chalder, Professor of Cognitive Behavioural Psychotherapy at the Institute of Psychiatry in King's College London and a

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<sup>1</sup> Delivering Innovation through Research - Scottish Government Health and Social Care Research Strategy 2015

<sup>2</sup> <https://www.nhs.uk/conditions/medically-unexplained-symptoms/>

lead investigator on the PACE research trial. PACE involved trialling a treatment the majority of patients reported deterioration from, and the research has been thoroughly refuted by the scientific community. Professor Jonathan Edwards' quote from the NICE ME/CFS guidelines review vice-chair relates to the review of the guidelines, but we also feel it is pertinent to NES review of material relating to ME: *"the situation needs urgent review.. but by people with an interest, not a vested interest."*

#### **4. Providing specialist care for patients and discontinuing the harmful treatments graded exercise therapy (GET) and cognitive behavioural therapy (CBT).**

*In our petition we called for:*

*Increased access to and investment in care for patients. Access for patients to physician-led services to provide appropriate advice along with recognition by GPs and medical practices that many people with ME require home visits due to the debilitating nature of the illness.*

*Removal of Graded Exercise Therapy and Cognitive Behavioural Therapy from the Scottish Good Practice Statement. Ensure that no healthcare services in Scotland offer Graded Exercise Therapy and Cognitive Behavioural Therapy. These therapies are based on the outdated psychosocial model, there is a lack of evidence of efficacy for both GET and CBT and, in patient surveys, the majority of patients report deterioration following these treatments.*

##### **4.1 Investment in Patient Care**

ScotPHN supports this element of the petition, but notes that specialist services should not be implemented in isolation. This element of the petition matches one of the key recommendations of the ScotPHN healthcare needs assessment: *"establishing medical consultant-led, multidisciplinary teams across Scotland, bringing together professionals to diagnose, assess and, where needed, treat and manage complex cases."* Despite this being recommended seven years ago, nothing has been done to meet this recommendation.

The Scottish Government recognises the pivotal role of the clinical nurse specialist in specialist care provision. It states, however, that it is the responsibility of NHS boards to decide how funding for specialist nursing and care is allocated. It does not mention that it has intervened recently (2015) to provide ring fenced funding of £700,000 to NHS boards for specialist MND nurses.<sup>3</sup> Since there is currently only one specialist ME nurse in the whole of Scotland we would like to see funding provided to NHS boards for specialist ME nurses.

The Scottish Government highlights the service offered by Astley Ainslie Hospital in Lothian, supported by an ME assessment clinic at the Western General Hospital. It cites *"patient satisfaction surveys"* as evidence that the service at Astley Ainslie is effective. Patient satisfaction surveys are measuring the service the patients' receive, not the effect of the treatment. Patients may have a good or bad relationship with their doctors, but that is separate to their improvement or deterioration as a result of the treatment they receive. For example, in a similar clinic in Norway for ME patients, they found that 56 % were satisfied with their stay - but ¾ disagreed strongly that their health had improved. So, patient satisfaction surveys provide no evidence as to the effectiveness of the treatment. They do not constitute reliably controlled evidence, in order to demonstrate the efficacy of the treatment offered, there needs to be measurable (objective) outcomes.

The Scottish Government highlights the work it has funded the charity Action for ME to carry out with healthcare professionals and to support those affected by ME. We understand from the Petitions Committee that the charity has submitted evidence to the Committee that has not yet been published. We are also aware

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<sup>3</sup> <https://www.bbc.co.uk/news/uk-scotland-30706731>

that Action for ME has reported to the Government on the work it has carried out with health professionals and would welcome the opportunity to see the report and the evidence submitted.

#### **4.2 Removal of CBT/GET from the Scottish Good Practice Statement**

Science for ME and Professor Jonathan Edwards provide evidence in support of this element of the petition. Science for ME's submission includes a briefing paper which sets out the reasons why the research (the PACE trial) which led to the recommendation of CBT/GET as therapies for people with ME is seriously flawed. According to this briefing *"PACE was a nonblinded trial with unimpressive or null results on its subjective measures, when analysed according to its prespecified methods. Its objective measures showed that CBT and GET did not improve patients' fitness or ability to work. PACE's long-term followup results were also null."* In addition, the authors say *"Contrary to the claims of the PACE researchers and their supporters, PACE's results show that CBT and GET do not work for this disease. In the US, the Centers for Disease Control recently withdrew its recommendation of these therapies for ME/CFS"*.

Professor Jonathan Edwards confirms the issues with CBT/GET in his evidence: *"A range of physical and psychological treatments, including graded exercise therapy (GET), cognitive behavioural therapy (CBT) and the 'Lightning Process', based on theories of psychological perpetuation of the illness, have been subjected to methodologically inadequate trials and have been introduced into mainstream healthcare based on uncritical interpretation of the results"*.

Of the five health boards that have submitted evidence, only one (NHS Borders) states that it currently uses Graded Exercise Therapy and Cognitive Behavioural Therapy. In addition, although NHS Lothian does not mention CBT/GET in its evidence, we know from previous correspondence (email in March 2018 to Ben Macpherson MSP) that the services at Astley Ainslie are with a *"basis in graded activity and cognitive behavioural principles"*.

The submission from NHS Borders is particularly worrying as, it says: *"Specifically with regard to GET (graded exercise therapy) and CBT (cognitive behavioural therapy) the view of our clinicians is that these treatments have the best evidence base."* This demonstrates our concern that CBT/GET are being given to patients as treatment or "cure", when there is no evidence these interventions help patients. We would query where NHS Borders' clinicians have sourced this "evidence" from, as they did not include it in the submission.

A further statement from NHS Borders highlights that CBT is used specifically to address beliefs that are perceived as perpetuating the illness. *"With regard to CBT in particular, it was highlighted to me that the aim of this treatment is to address the thoughts or behaviours maintaining or exacerbating the ME-CFS itself, ie. it is not confined to co-morbid (or causative in a proportion of cases) mental illness such as anxiety and depression."* This use of CBT is completely unacceptable and reinforces our call for the SGPS to remove CBT/GET.

The Scottish Government submission states that it will *"make a decision on updating the Scottish Good Practice Statement on ME once NICE has published in 2020"*. Given the number of patients who report a marked deterioration in their condition after graded exercise therapy (GET) we feel it is important to review the clinical guidelines before 2020. We acknowledge the Government's point that the current SGPS states the potential harm done by GET, but NHS Boards continue to offer GET as treatment for people with ME. There is an urgent need to issue guidance that highlights the danger of this approach and the need to withdraw GET as a form of treatment.

The NES submission also supports CBT as a primary treatment of people with ME - paragraph 19 states that it supports the description in the NES Matrix that “*CBT has the clearest evidence of benefit for people with mild to moderate CFS*”. We are not aware of the source for this evidence and ask the Committee to request access to the evidence.

In conclusion, CBT/GET is specifically being used by NHS boards across Scotland as a treatment for ME patients, with NHS boards citing “evidence” which they do not supply. In contrast, S4ME and Professor Edwards thoroughly detail the poor research practice (the PACE trial) that has led to this treatment.

#### **5. Requests for further information (prompted by the evidence submitted to date).**

- NES details the importance of Medical Colleges in setting curricula. We ask the Scottish Government to contact the Colleges asking them to review how ME is included in their curricula (including the number of hours and content).
- Trudie Chalder conducting the NES review when she has a vested interest in the PACE trial is a concern for us. We ask NES to respond to this issue and provide us with access to the Chalder review.
- We ask NES to provide evidence for its statement that CBT has the clearest evidence for treating mild to moderate CFS.
- We ask that NHS boards which have not responded to the Committee’s request be asked to respond
- We ask NHS Borders to identify where its clinicians have sourced evidence that CBT/GET have the best evidence base for treatments.
- We ask that NHS Lothian is requested to provide clarification of its refutation of the criticism of the PACE trial contained in the petition. We would also like it noted that NHS Lothian received £165,055 funding whilst participating in PACE.