Exercise & Ensuring Patient Safety

At a landmark event in Bristol last February on the theme 'Exercise & ME/CFS - the evidence' three speakers came together to present their research findings and clinical experience regarding how people with M.E. fare following exercise.

Professor Mark Van Ness from the Workwell Foundation in the USA explained how damaging aerobic exercise can be for patients, and how understanding this process can help in management and care. Their two day testing protocol has demonstrated a remarkable post exertional amplification of symptoms in ME patients. This clinical feature has long been reported as a hallmark symptom of ME. This damage to the aerobic energy system means that it is utterly counter productive to try to use aerobic exercise to improve health in these patients.

The team compared the 'CFS' patients with sedentary people who were not disabled. Physiological parameters were compared for two maximal exercise tests, separated by 24 hours. Crucially, it was on the second of the two tests that the two groups could clearly be distinguished (overall accuracy 95%). There were no significant differences on the first test, and this, taken in isolation, could be (mis)construed to indicate a deconditioning mechanism. However, for test 2, the 'CFS' patients achieved significantly lower values for oxygen consumption and workload at peak exercise and at the ventilator / anaerobic threshold, indicating post exertional abnormalities.

Prof Van Ness reported that the evidence from this research is so contrary to accepted views of exercise and graded exercise, both in ME and in other illnesses, that many people actually find it difficult to hear and take on-board what he is saying.

Professor VanNess observed that the way in which patients have described their experiences - *e.g.* in the film 'Voices From the Shadows' - is consistent with the evidence from cardiopulmonary testing.

He also explained how patients can try to find a more appropriate way of managing their activities of daily living, by trying to avoid causing any worsening of symptoms and so allowing their bodies a better chance of healing.

Dr Nigel Speight spoke about cases where he is asked to try to protect children from being mistreated by professionals who are misinformed about ME, or abdicating responsibility. Dr Speight is the medical advisor or paediatric medical advisor for several charities, including the 25% ME Group. He sees the worst cases; the cases where people are most ill and the cases where children are being mistreated and families threatened with having their ill children taken from them or forced to undergo harmful 'treatment' programmes. Dr Speight adopts a supportive and empowering management approach, which recognises that patients are suffering a severe physical illness.

Erinna Bowman is part of the 'Cure ME' team at the London School of Hygiene and Tropical Medicine. She explained some of the issues that have contributed to the confusion around the diagnosis and treatment of patients - notably the wide variety of definitions and the wide predictions of prevalence resulting from such varied definitions. The Cure ME Team is working with quite tight research criteria in comparison with general NHS custom and practice.

Erinna Bowman, Prof Mark VanNess and Dr Nigel Speight answered questions, chaired by Sue Waddle

NOTES & REFERENCE:

The research described by Prof Van Ness was published in *Physical Therapy* as - *Discriminative Validity of Metabolic and Workload Measurements to Identify individuals with Chronic Fatigue Syndrome Christopher R Snell et al. Vol 93 Nov 2013 pgs 1484-1492.* It can be read on line at http://ptjournal.apta.org

The Workwell Foundation is a US Charity: *" ... to focus on research concerning the functional aspects of Chronic Fatigue Syndrome / Myalgic Encephalomyelitis. Our goal is to facilitate an understanding of the biological basis of fatigue and provide objectively determined therapeutic interventions that will improve quality of life for this population."*

Dr Speight outlines his approach in the Special Feature 'ME in Childhood' (The Quarterly, Issue 36)

The Bristol event was hosted by Bristol North Fibro & ME/CFS Support Group with funding from the Quartet Foundation. Help was also given by the ME Association and ME Research UK. The event was NHS Continuing Professional Development accredited.

Although running counter to the general 'wisdom' prevalent in the UK today, Prof Van Ness's research is in fact in keeping with the findings of prior research studies and eminent clinical opinion.

Did You Know .....

" Like pharmaceutical therapies, prescribing exercise as therapy, an activity that is gaining in acceptance throughout the medical community, must be predicated on understanding the risks and benefits of exercise as thoroughly as possible."

Journal of Applied Physiology 2007; 103: 700–709

Dangerous exercise: lessons learned from dysregulated inflammatory responses to physical activity Cooper DM *et al.*

Evidence for the efficacy of graded exercise as applied to people with M.E. lies in – and only in - the published findings of a small number of controlled trials.

In stark contrast, feedback from ME patients who have tried to exercise *consistently* indicates that a substantial proportion have been made considerably worse.

- Reporting in 2002, the Chief Medical Officer's Working Group found that *"substantial concerns exist regarding the potential for harm"* based on patient reports. [1]
- In view of this, the Working Group found that the published trials clearly *"do not reflect the full spectrum of patients' experience."* [2]
- Clinical opinion on the Group was deeply divided, with those who endorsed exercise citing *"the evidence base"* – *i.e.* the trials - and not their clinical experience.[1]

The outcome of reliance on trial data has been nothing short of catastrophic for M.E. patients.

In a 25% ME Group membership survey, 82% of those who had undergone graded exercise reported that it had made them worse. Some had not been severely affected before trying Graded Exercise 'Therapy'. [4]

"*A referral to a paediatric consultant resulted in a diagnosis of Myalgic Encephalomyelitis in February 1992. Lynn was put on a course of graded exercise. Her condition steadily worsened as she strived to stick to the programme. She tried to explain that the more she pushed the worse she felt, but no one listened. By May that year she was totally bedridden and tube-fed with many severe and debilitating symptoms."*

Kay Gilderdale, mother of 25% ME Group member Lynn

This but is one account of the human suffering behind the statistics. It is echoed by other M.E. patients and their carers, throughout the UK. For example:

" I participated in Graded Exercise therapy via a 'CFS/ME' specialist unit. This led to a relapse, at home, and made me unable to sit upright for 1 year due to pressure in my head, and chest pain. I then relapsed and ended up in my local NHS Hospital in a cardiac care unit."

" Graded Exercise Therapy worsened me dramatically and I have no doubt had been a large factor in my being severely affected after 20 years."

" I worked with a physiotherapist, who also had no experience of M.E. I began to seriously deteriorate, and 4 months in, suffered a major relapse. I had a kind of undiagnosed 'stroke', collapsed, and became incapable of looking after myself.

When I went to the hospital I could walk 100 yd., feed, wash and dress myself.

When I left I could not weight bear at all, had no leg muscles to speak of, and needed two people to transfer me on and off the toilet and in and out of bed. I had little use of my hands and was totally bed bound. I could not tolerate sitting upright against the pillows, conversation was beyond me, and I could barely manage to feed myself by picking up food in my hands - cutlery was out of the question.

Nine years later I have improved, but I'm still bed bound." [5]

Two facts may help shed light on this apparently perplexing state of affairs:

- Firstly: "*Randomised controlled trial data is notoriously poor at reporting adverse events*." [3]
- Secondly, the trials concerned recruited people broadly on the basis that they were experiencing fatigue, considered to be a manifestation of 'chronic fatigue syndrome' (CFS). No trial using M.E. specific criteria has reported a beneficial outcome for exercise.

Why is it that people with M.E. fare so very badly on exercise? If one starts to scratch the physiological surface, then this apparently curious outcome starts to make sense.

Dr Paul Cheney has a wealth of clinical and research experience. In testimony to the US Federal Drug Administration Scientific Advisory Committee in 1993, he advised "We have carefully evaluated in the three years of our existence over 1,200 cases from 44 states and 6 foreign countries or territories." Dr Cheney provides one possible explanation as to why exercise can prove so very problematic:

"*The most important thing about exercise is not to have patients do aerobic exercise. I believe that even progressive aerobic exercise is counter-productive. If you have a defect in mitochondrial function and you push the mitochondria by exercise, you kill the DNA*"

International Congress of Bioenergetic Medicine, Lecture 5th-7th February 1999

What is the evidence for this type of dysfunction in people with M.E.?

- Mitochondrial defects have been documented for many years; the evidence continues to grow [6]
- The mitochondrial defect research in just one element of a body of published evidence of abnormal response to exercise and physiological characteristics which contra-indicate exercise in people with M.E. [7]

At the 2010 Continuing Professional Development accredited Conference held in London by 'Invest in ME', Dr Cheney reported finding diastolic cardiac dysfunction in almost every case. This was manifested on head up tilt table test. Some patients, he reported, would not be out of place on a cardiac ward awaiting transplant.

Asked about the implications of this finding for advocacy of exercise, Dr Cheney provided a considered response, advising that patients should *"move within the limits of your illness".*

On graded exercise as a route out of the illness, however, he was unequivocal:

"The whole idea that you can take a disease like this and exercise your way to health is foolishness. It is insane."

What are the implications for healthcare professionals?

***"**from the medico-legal point of view, health professionals who prescribe exercise programmes must do so with just as much caution as would be taken with medication."*

British Journal of Nursing, vol 15, No 12, 2006, pp 662-669
Dr Charles Shepherd, Medical Adviser, ME Association

In 2007 Dr Shepherd reiterated this message, noting that the medical defence organisations have repeatedly warned that prescriptions for exercise must be given with exactly the same care as with a prescription drug. On this occassion his comments were lodged in response to a UK clinical guideline, then in draft form. Dr Shepherd also pointed out that "*the MEA continues to receive reports from people with ME/CFS whose condition has relapsed following inappropriate advice about exercise"*

Unfortunately for patients, the final version of the National Institute's Guideline[8] failed to allay widely expressed concerns regarding the advocacy of exercise.

However it remains the case that the onus is on the professional to ensure that any interventions provided are safe for the patients to whom they are prescribed, and also effective.

How might it come about that a clinical guideline, ostensibly based on a review of the strongest evidence, nonetheless endorses an intervention that makes at least some of the patients it purports to relate to considerably worse?

Several factors may help explain this:

- The process of Guideline Development entails looking at – and only at – the findings of controlled trials.
- Biomedical evidence contra-indicating exercise falls outwith the purview of the Institute's Guideline Development Process.
- Harms are often only spotted outside trials, one reason being that participants in trials are often not representative of all those affected by an illness in the general population. This why the Yellow Card reporting system for adverse drug related events exists. However, no similar system exists for therapies like GET and CBT, increasing the importance of survey data. [9]
- Feedback from patients who have been made worse and not better by exercise is likewise not considered in the Clinical Guideline Development Process.

In the seven years since this guideline was circulated in the NHS, it has largely fallen to patients and their representatives to continue to draw attention to well founded concerns and try to protect people with M.E. from harmful advice and ill judged interventions. [9]

REFERENCES

1. *A Report of the CFS/ME Working Group: Report to the Chief Medical Officer of an Independent Working Group*. [London: Department of Health, 2002]
2. *Ibid. Annex 3: Patient evidence* page 3.
3. Fiona Godlee, editor in chief, British Medical Journal, speaking on The Today prog, Radio 4, 22nd March 2014
4. *Severely Affected ME (Myalgic Encephalomyelitis) analysis report on questionnaire*; 25% ME Group 1st Mar 2004.
5. Crowhurst G. *25% ME Group Submission to the Gibson Inquiry.* 2005. www.stonebird.co.uk/gibson.doc
6. Examples include: *Electrophysiological studies in the post-viral fatigue syndrome* Jamal GA & Hansen S Journal of Neurology, Neurosurgery & Psychiatry 1985;48:691-4;
   Mitochondrial abnormalities in the postviral fatigue syndrome. Behan WM *et al.* Acta Neuropathol 1991; 83: 61-5. [1792865]; /
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   Mitochondrial dysfunction and molecular pathways of disease Pieczenik SR & Neustadt J Exp Mol Pathol 2007; 83: 84-92;
   Chronic fatigue syndrome and mitochondrial dysfunction. Myhill S *et al.* J. Int J Clin Exp Med 2009;2:1-16;
   Mitochondrial dysfunction and the pathophysiology of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS). Booth NE *et al.* Int J Clin Exp Med 2012; 5: 208-20.

7. An information note covering further relevant research is available on request from the 25% ME Group.
8. *Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy): diagnosis and management of chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy) in adults and children* National Collaborating Centre for Primary Care, August 2007 [Clinical Guideline 53]
9. *Reporting of Harms Associated with Graded Exercise Therapy and Cognitive Behavioural Therapy in Myalgic Encephalomyelitis/Chronic Fatigue Syndrome* Journal of the International Association for CFS/ME 2011 Issue 19(2): 59-111 Tom Kindlon, Information Officer at the Irish ME/CFS Association.

AN APPEAL FOR APPROPRIATE CARE

In November 1991, at the age of 14, my daughter Lynn became ill after a BCG vaccination. Previously lively and extremely healthy, she contracted one infection after another and needed several courses of antibiotics. Lynn did not improve despite every effort by our GP to turn things around.

A referral to a paediatric consultant resulted in a diagnosis of Myalgic Encephalomyelitis in February 1992. Lynn was put on a course of graded exercise. Her condition steadily worsened as she strived to stick to the programme. She tried to explain that the more she pushed the worse she felt, but no one listened. By May that year she was totally bedridden and tube-fed with many severe and debilitating symptoms.

Desperately seeking help, we were referred to a psychiatric consultant who told us he believed in M.E. as a physical illness and had cured a number of patients in the past. He felt sure his *team* could help Lynn if she was admitted as an in-patient. We agreed.

Lynn stayed two and a half weeks on that psychiatric ward with devastating consequences. She deteriorated rapidly as pressure was put on her to do things she was unable to do. We watched as our daughter, under the care of those who said they could cure her, lost the ability to do almost anything. We wanted to believe what they said so much that we held on, even when we saw her deterioration, but sixteen days after her admission, we knew we had to take her home.

With the help and support of our GP we took our daughter home - she was in a pitiful state. She could do nothing for herself and needed 24 hour total care. She slept almost constantly as her exhausted body struggled to cope with the most fundamental of tasks.

We found an M.E. specialist who did domiciliary visits. He supported and advised us and prescribed medication to ease some of Lynn's awful symptoms, such as muscle spasms, nausea and pain. After many months Lynn began to show signs of improvement and we knew that we had done the right thing in taking her home and looked forward to better times ahead.

Lynn never recovered - too much damage had been done in the early months of her illness when she was forced to do what she knew her body was not able to do. I wish with all my heart that I knew at the start of Lynn's illness that graded exercise at this acute stage causes further damage. She could have been spared seventeen long years of unimaginable suffering if we had done the right thing at the beginning and listened to what she told us.

Lynn is not alone. Many M.E. patients have been made worse by the false belief that graded exercise is the answer. It is not. People need to be supported and cared for and given time to rest their sick bodies. The time for rehabilitation and exercise is when they reach the recovery stage and are no longer ravaged by an illness that steals every vestige of energy.

The last thing anyone - especially a child – needs, is to be removed from the safety of their home, into a strange and frightening environment. The havoc the illness causes is terrifying enough without being taken away from your loved ones and all that is familiar. Such actions only serve to make a bad situation far worse.

My purpose in writing this is to ask that Lynn's case is taken into account when considering the best way to treat severely affected M.E. patients. I don't want anyone else to suffer the way Lynn did through inappropriate treatment. I appeal to those who are in the profession of caring, to listen to the patient, support and guide them, but don't force upon them what they and their families are telling you is wrong.

Sincerely, Kay Gilderdale

Signed copy available from the 25% ME Group

Sadly, there came a point when Lynn Gilderdale found her life with very severe M.E. intolerable, and chose to end it.

Her mother Kay's book 'One Last Goodbye' was published by Ebury Press in 2011

The 25% ME Group is strongly of the view that the isolated silent suffering of people with M.E. following prescribed exercise regimens has continued for far too long.

The onus is on the professional to ensure that the interventions provided are safe, and also effective. In addition, there should be rigorous reporting mechanisms in place to record adverse outcomes occurring in clinical practice.

As part of our M.E. Awareness Week campaign 2014 we provided members with suggested questions for elected representatives to take up with the relevant minsters.

LATEST NEWS **..... Just published in the British Medical Journal (June 2014) is this incisive critique of over reliance on 'evidence based medicine' :**

Evidence-Based Medicine - A movement in crisis? **Greenhaulgh** ***et al. www.bmj.com/content/348/bmj.g3725***