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3 March 2011

FOR IMMEDIATE RELEASE

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RESPONSE TO UK MEDICAL RESEARCH COUNCIL PACE TRIAL ME/CFS FINDINGS

Putting the Study Findings into Context

On Feb 18, 2011 The Lancet Published a study that compared **Adaptive Pacing Therapy (APT), Cognitive Behavior Therapy (CBT), Graded Exercise Therapy (GET) and Specialist Medical Care (SMC) for ME/CFS**. The study known as the Pace Trial conducted in the UK is the world's largest, most expensive, multi-centre study conducted on one of the largest ME/CFS sample populations (n=641) at a cost of nearly \$5 million pounds.

Study Conclusions

The authors state that CBT and GET can safely be added to SMC to moderately improve outcomes, but APT is not an effective addition. This is despite the fact that *'no more than 30% of participants were within normal ranges for both outcomes'* and *'only 41% rated themselves as much better or very much better in their overall health'*

Fundamental Sample Flaws

The gold standard for any international ME/CFS research would include the use of the Canadian Criteria for sample selection. This study selected participants with the rarely used and little known Oxford and London criteria. The London criteria has never been published and has no known authors. The Oxford criteria provides a very loose operational definition for ME/CFS, and is not specific to ME/CFS the neurological condition as defined by the WHO (ICD 10 G93.3). This oversight by the study designers means that the sample under investigation is highly likely **not** ME/CFS specific.

It would be reasonable to expect in such an expensive and detailed study that all groups within the ME/CFS population be included. Of concern is the exclusion of a large proportion of any given ME/CFS population: i.e. all those under 18 years of age and all those with severe ME/CFS were excluded in the study. No-one in the sample had had the condition for longer than 6 years.

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APT was determined least beneficial, however APT was a newly constructed therapy for this study. APT is defined very differently from the 'Pacing' approach that is commonly understood and described as highly beneficial by most with ME/CFS. These two therapies cannot be compared as they are not the same.

SMC consisted of: an explanation of chronic fatigue syndrome, generic advice, specific advice on self help and symptomatic pharmacotherapy (especially for insomnia, pain, and mood). Such medical care can only be described as deficient when compared with other SMC models that are available in locations other than the study centres and more broadly around the world. The SMC undertook no further investigations, hence possible treatment; this approach in SMC for any condition is unheard of in modern medicine.

GET/CBT Compared with SMC alone, CBT plus SMC improved fatigue scores by 3.4 points on a 33-point scale, while GET plus SMC improved by 3.2. Physical function score improvements were 7.1 for GBT and 9.4 for GET on a 100 point scale. Rated on their 33-point and 100-point scales, participants improved on average only 10% and 8.25% with the two recommended interventions, which does not constitute as even "moderately effective". Not one participant returned close to their previous level of health and many were still highly bothered with symptoms. Despite noting that they screened for depression and anxiety, the discussion section comments on a 47% prevalence of mood and anxiety disorders, and it is this that may have improved with GET/CBT.

Previous studies have identified that CBT/GET can be a helpful adjunct therapy in many chronic diseases. The PACE study confirms these findings but only within a non-specific ME/CFS sample, and thus the results are not surprising. This study tells us that GET/CBT are far from being cures for ME/CFS.

OUR CONCLUSION

The study findings cannot be generalised across all patient groups especially for those groups excluded; furthermore the study claims of no harm to those with ME/CFS cannot be claimed. Recent media reports including medical reporting have provided superficial understandings of the PACE findings, hence there is concern by ME/CFS medical experts and patient groups in Australia that the study findings will be generalised and misunderstood.

Over 5,000 peer reviewed research articles have identified that ME/CFS has a biological underpinning, so it was somewhat disappointing and surprising that such an expensive tax payer funded study was conducted with such a narrow focus on psychological management. Tax-payers in the UK will be disappointed in the wastage of public monies.

With the place for GET/CBT now clearly defined as a support or adjunct therapy, for some with possible ME/CFS, it is now time to put all research efforts, with an equivalent amount of public health funding, into determining the underlying biological cause and find a cure. This is what people with ME/CFS, their family, friends, the community, health practitioners, health departments and governments want. This will return the best investment for the ME/CFS research dollar.

There is no justification or 'will' in Australia to support such a limited model of care for ME/CFS as outlined in the UK PACE study.