

3 T(ear)s for PACE Trial!

Travesty of Science

Tragedy for Patients

Tantamount to Fraud

Academy of Nutritional Medicine

Lifting the Veil III

London, June 15th 2016

Malcolm Hooper, Professor Emeritus University of Sunderland

FUNCTIONAL SOMATIC SYNDROMES: ONE OR MANY?

Wessely et al Lancet 1999;354:936-9

Gastroenterology – IBS, Non-ulcer dyspepsia

Gynaecology – PMS, chronic pelvic pain

Rheumatology – Fibromyalgia

Cardiology – Atypical or non-cardiac chest pain

Respiratory medicine – hyperreactive airway disease

Infectious Disease – PVS, Chronic Fatigue Syndrome (CFS)

Neurology – Tension headaches

Dentistry – Temporomandibular dysfunction, Atypical facial pain

ENT – Globus syndrome

ALLERGY - MCS

CANNOT EXPLAIN
CONVENTIONAL
PARADIGMS

CONVENTIONAL
THERAPY INEFFECTIVE

MORE COMMON IN
WOMEN THAN MEN

SHARE NON-SPECIFIC
SYMPTOMS

BIOPSYCHOSOCIAL MODEL/IDEOLOGY

SYNDROMES RESPOND TO SAME THERAPIES, CBT/GET, OFTEN WITH
ANTIDEPRESSANTS

SYNDROMES OF UNCERTAIN ORIGINS
Merck Manual 1999, 17th Edition

NEURASTHENIA

GULF WAR SYNDROME
GWS/I
MILITARY ME

**MULTIPLE CHEMICAL
SENSITIVITY**

OPs

HYSTERIA –PUPS/MUS

ME-CFS
FMS

NEUROLOGICAL- ANS, PNS, CNS
CARDIOVASCULAR
IMMUNE SYSTEM
GASTROINTESTINAL
RESPIRATORY
ENDOCRINE SYSTEM

“Considering the extent of the patients’
complaints and disability, the results of
ROUTINE laboratory tests were strikingly
NORMAL” S Straus

SOMATISATION- PSYCHIATRIC- IN THE MIND

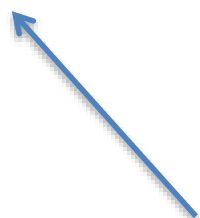
AEROTOXIC SYNDROME

Jet Engine Oils (TCPs)

Pilots

Richard Westlake

Cabin Crews



OPs



FARMERS

Shepherds(Dips)-LAW

Live stock (Pigs/Cattle)

Grains Stores

FISH FARMS

Kathleen Sullivan

Multi System Atrophy



DEPLOYED GULF WAR VETERANS, 25-30% Chronially Sick!

1. OP PESTICIDES (Diazinon +, Malathion. Chlorpyrifos etc) Govt Lies
2. Pyridostigmine Bromide, NAPS,
3. Nerve agents, SARIN

Cholinergic Triple Whammy –Ian Hill Global Illness Syndrome

[VACCINES – Non - Deployed],

TRAVESTY of Science
make ridiculous, intentionally or not

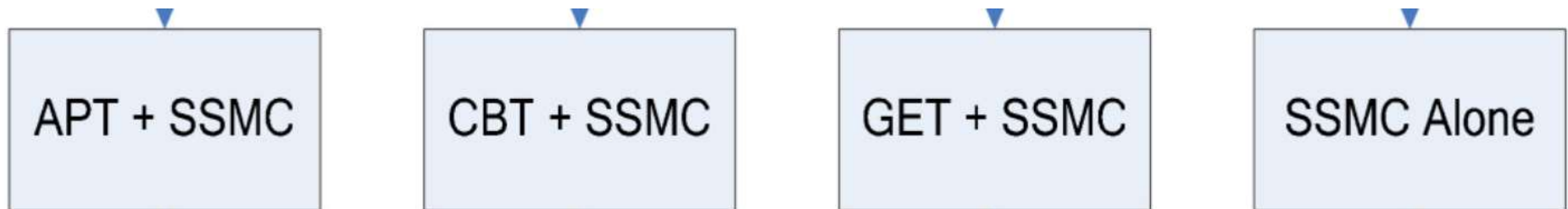


YOU CANNOT BE SERIOUS!!

PACE TRIAL – CFS/ME- VALIDATE CBT & GET A RANDOMISED ~~CONTROLLED~~-TRIAL

NO OBJECTIVE MEASUREMENTS

NO BLINDING – a *sine qua non* for Subjective data



NO CONTROL GROUP Inter Group Comparisons

ORIGINAL Entry Requirements & Primary Outcomes
CHANGED AND MANIPULATED THROUGHOUT STUDY

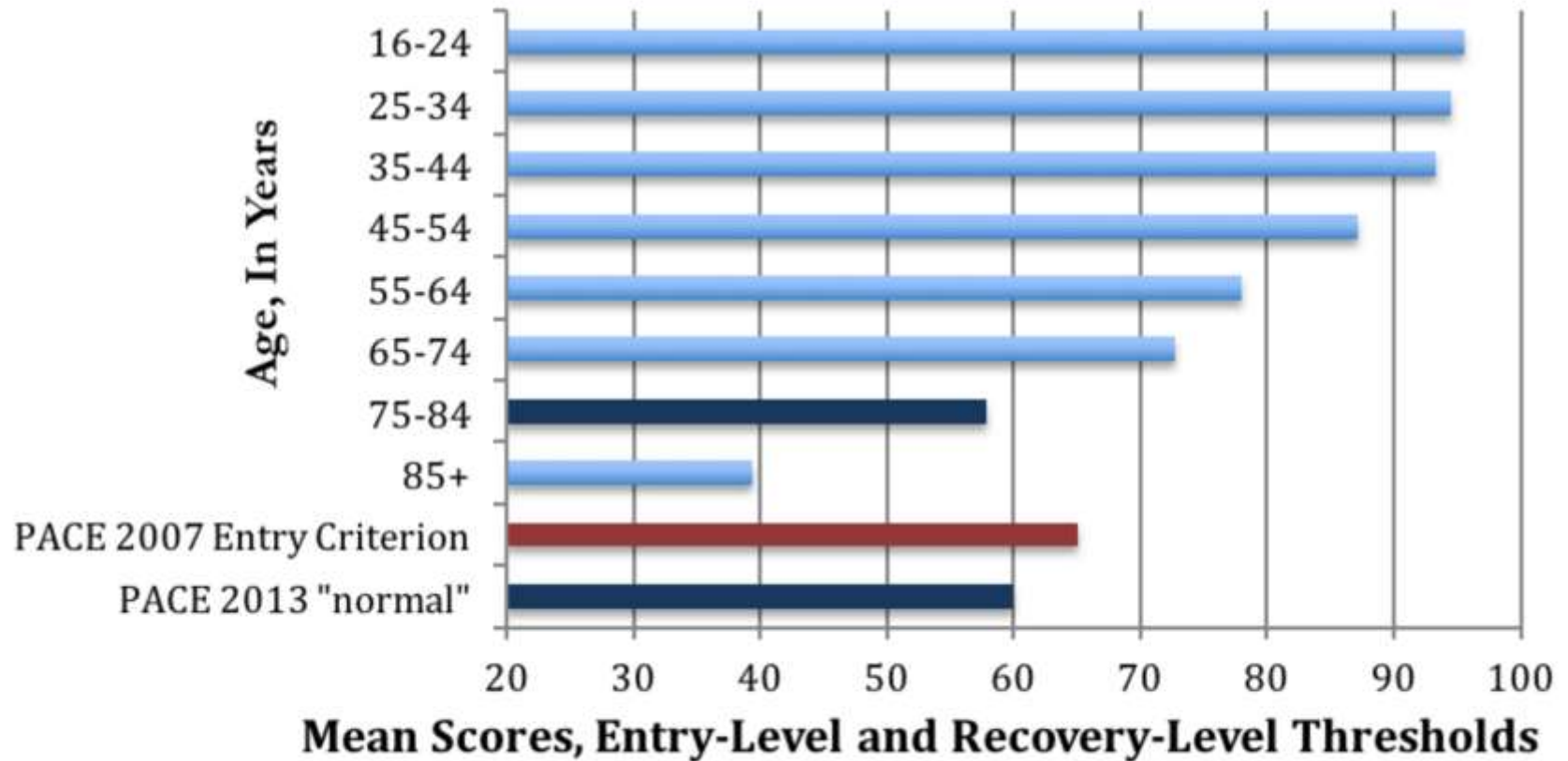


MOVING THE GOAL POSTS

ABSURDITY – Overlapping scores in Entry and show patients could have scores that showed their health had deteriorated.

13% of Entrants already met 'Recovery' Criteria

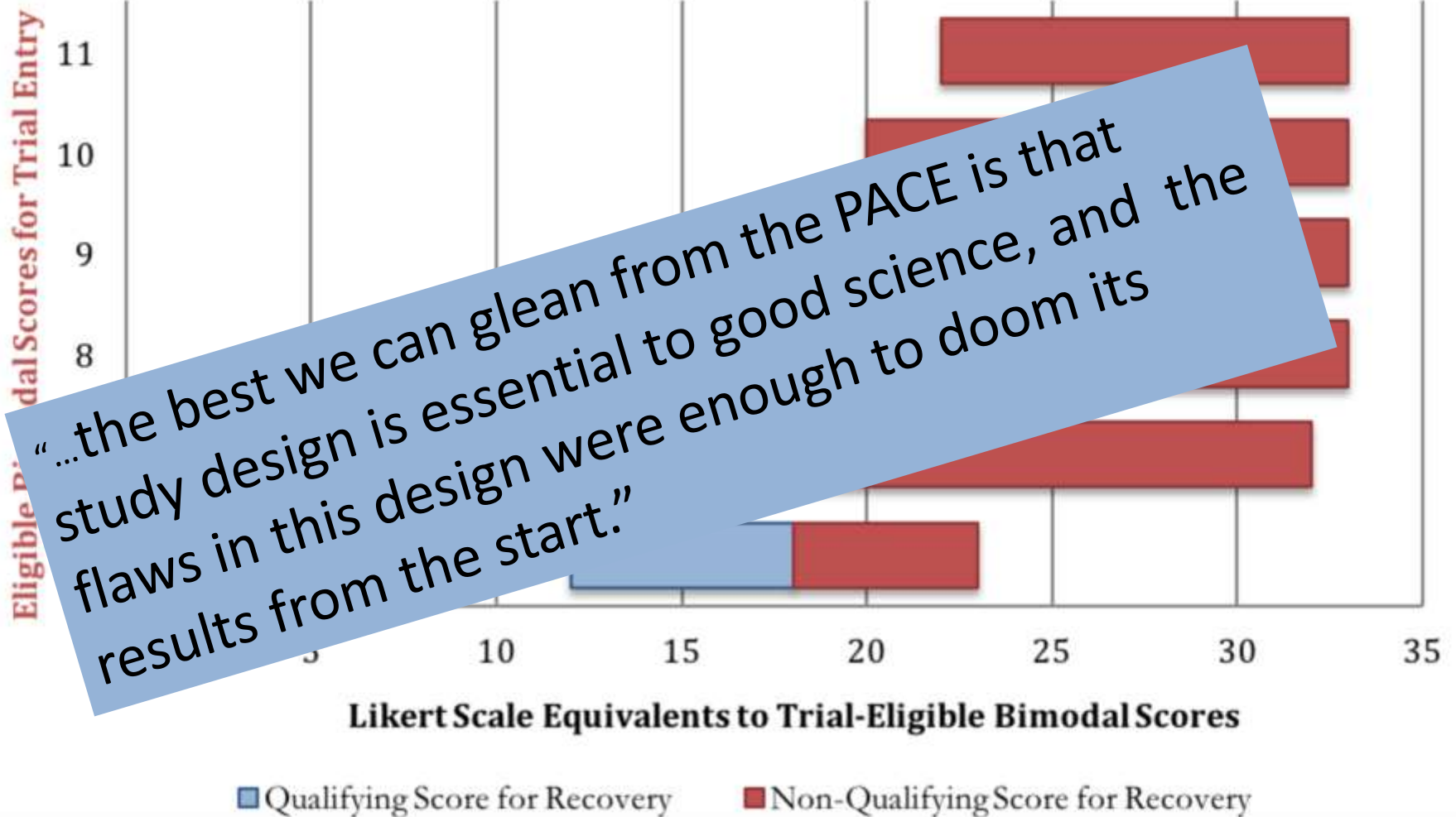
Average Physical Function Scores, Compared to PACE "Recovery" Threshold



Goldin 2016 Average age in trial = 39; SF -36 of 93- normative data
All Working Age Average ~85 ; All Ages Average ~78

Changes in Fatigue Scoring

Blue Scores Both Qualify for the Trial and also Qualify for Recovery



“...the best we can glean from the PACE is that study design is essential to good science, and the flaws in this design were enough to doom its results from the start.”

PRIMARY OUTCOMES

SF-36 SCORE - 75% OR MORE - ENTRY 70% OR LESS

FATIGUE CHALDER SCALE 3 OR LESS - ENTRY 4 OR MORE

FINE (2010) CONCLUSIONS-

.....the effect is small and not statistically significant at one year followup.....

CBT/GET, AS MEASURED BY THESE PARAMETERS IS NOT EFFECTIVE IN TREATING OR MANAGING CFS/ME

	Bimodal or binary scoring				Likert scoring			
	0	0	1	1	0	1	2	3
	* Less than usual	* No more than usual	* More than usual	* Much more than usual	* Less than usual	* No more than usual	* More than usual	* Much more than usual
* Do you have problems with tiredness?		0				1		
* Do you need to rest more?				1				3
* Do you feel sleepy or drowsy?		0				1		
* Do you have problems starting things?		0				1		
* Do you lack energy?		0				1		
* Do you have less strength in your muscles?				1				3
* Do you feel weak?		0				1		
* Do you have difficulty concentrating?		0				1		
* Do you make slips of the tongue when speaking?				1				3
* Do you find it more difficult to find the correct word?			1				2	
* How is your memory?		0				1		
Total	4				18			

The 11 questions in the Chalder Fatigue Questionnaire, as used in the PACE trial. Bimodal scoring allocates 0, 0, 1 and 1 and Likert scoring allocates 0, 1, 2, and 3 to each of these answers [Vink, 2016].

	Changes made during the trial?	What changes were made?	Changes made by the authors themselves?
Chalder Fatigue Questionnaire	Yes	1. Binary score was changed to a Likert score	Yes
	Yes	2. Binary score of 3 out of 11 was changed to a Likert score of 18 or less out of a maximum of 33	Yes
SF-36 physical function subscale	Yes	"changed from a score of ≥ 85 to" "60 or above" [5].	Yes
Self-rated CGI change score	Yes	changed from "a score of 1 only" to "scores of 1 ('very much better') or 2 ('much better')" [5]	Yes
Oxford criteria for CFS	Yes	The SF-36 physical function score was changed from a score of 60 or less to 65 or less;	Yes
	Yes	The bimodal Fatigue score of ≥ 6 out of 11 was changed to a Likert scoring of 18 or more	Yes
International CFS case definition	Yes	"the four or more symptoms needed to be present within the previous week of the assessment date, rather than the previous 6 months" [5]	Yes
ME case definition: the London criteria	No, changes were made before the trial	"because it is vital that the M.E. study groups we use in research are as 'pure' as possible, the existence of a parallel disease would be grounds for disqualification" [35], which was omitted from the version used in the trial; and the London criteria were changed without the knowledge of the original authors according to Goudsmit [36] and Shepherd [37], 2 of the original authors	Yes

Table 2: Changes made to the recovery criteria

Source: PACE trial recovery article [5]

VINK M. JNN 2016; . The PACE Trial Invalidates the Use of Cognitive Behavioral and Graded Exercise Therapy in Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: A Review

Tuller D (2015) TRIAL BY ERROR: The Troubling Case of the PACE Chronic Fatigue Syndrome Study (first installment).

<http://www.virology.ws/2015/10/21/trial-by-error-i/>

Tuller D (2015) TRIAL BY ERROR: The Troubling Case of the PACE Chronic Fatigue Syndrome Study (second installment).

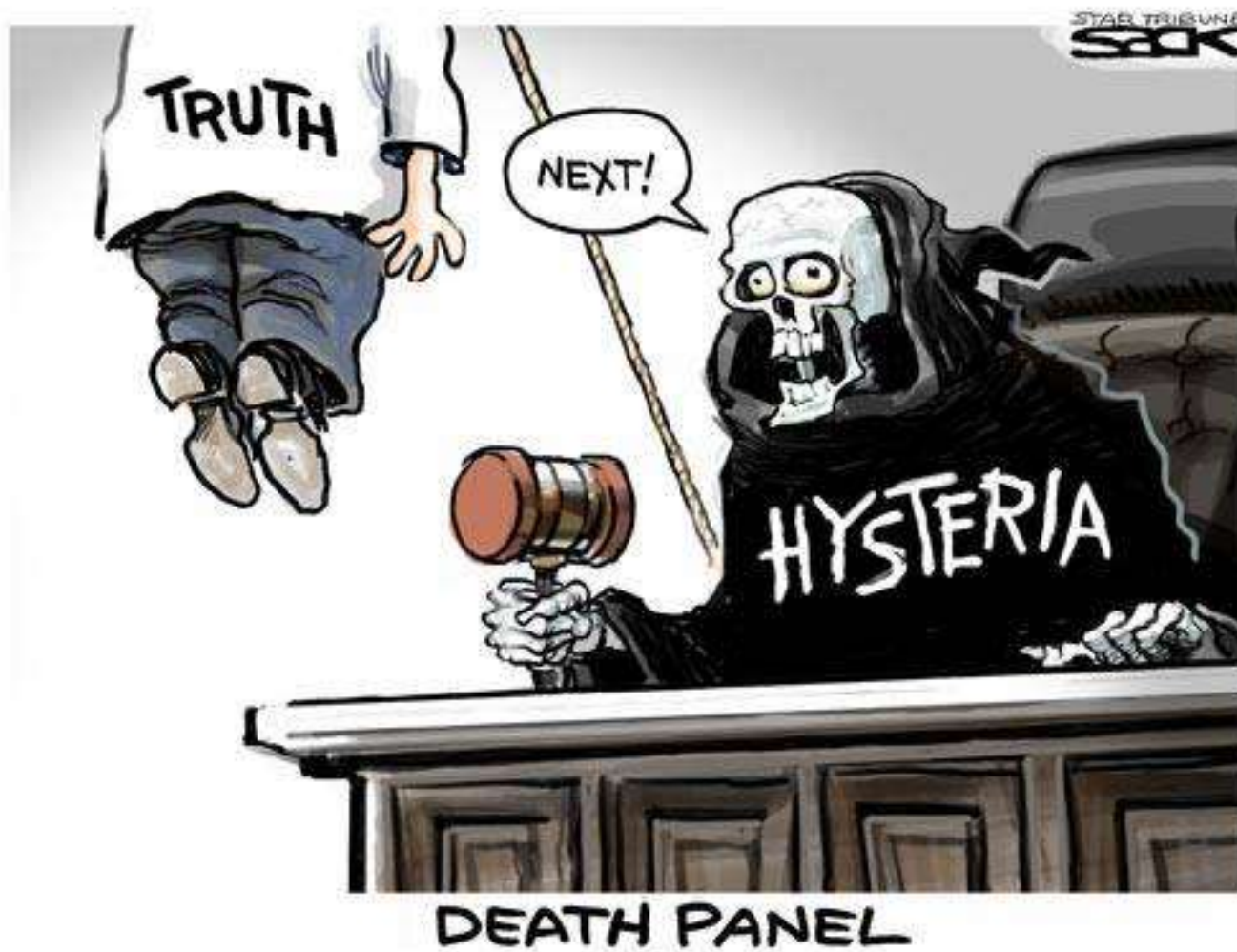
<http://www.virology.ws/2015/10/22/trial-by-error-ii/>

Tuller D (2015) TRIAL BY ERROR: The Troubling Case of the PACE Chronic Fatigue (final installment)

<http://www.virology.ws/2015/10/23/trial-by-error-iii/>

Tuller (2016)

<http://www.virology.ws/2016/02/01/trial-by-error-continued-a-few-words-about-harassment/>





Tears

GRIEF – FRUSTRATION- UNBELIEF- ABANDONMENT
CRUELTY- IDEOLOGICAL- APPROACH—EAN P, SOPHIA M.

Voices from the Shadows- Natalie Boulton



OBSTRUCTION/
DATA DENIAL



<http://erythos.com/gibsonenquiry/Report.html>

“CFS/ME is defined as a psychosocial illness by the Department for Work and Pensions (DWP) and medical insurance companies. Claimants are not entitled to the higher level of benefit payments. We recognise that if CFS/ME remains as one illness and/or both and is defined as psychosocial then it would be in the financial interest of both the DWP and the medical insurance companies.”

UK Parliamentary Group Research into M.E. (Gibson Inquiry, 2006)
Also called for investigation of the “Wessely School”:...numerous cases where advisors to the DWP also had consultancy roles in medical insurance companies. Particularly the Company UNUM Provident. The vested interest private medical insurance companies have in ensuring CFS/ME remain classified as a psychosocial illness there is blatant conflict of interest here.”

DISINGENOUS- LYING- DECEPTION- FRAUD ?

NICE GUIDELINE – “UNFIT FOR PURPOSE” – WILL CONTINUE UNCHALLENGED AND DESTRUCTIVE ADVICE WILL BE SENT OUT TO PATIENTS & DOCTORS

....interventions recommended in the original guideline, such as CBT and GET, were described as the interventions for which there is the clearest evidence-base of benefit.

This is supported by the recently published PACE trial....The results of the study are in line with current NICE guideline recommendations on the management of CFS/ME....There are no factors...which would invalidate or change the direction of the current guideline recommendations. The CFS/ME guideline should not be updated at this time”.

“The PACE findings can be generalised to patients who also meet alternative diagnostic criteria for chronic fatigue syndrome and myalgic encephalomyelitis but only if fatigue is their main symptom”. Lancet 2011




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THE COLLAPSE OF THE HOUSE BUILT ON SAND BIOPSYCHOSOCIAL MODEL/IDEOLOGY

"Since the collapse of the 19th century models (psychoanalysis, biologism and behaviourism), psychiatrists have been in search of a model that integrates the psyche and the soma. So keen has been their search that they embraced the so-called 'biopsychosocial model' without ever bothering to check its details. If, at any time over the last three decades, they had done so, they would have found it had none. This would have forced them into the embarrassing position of having to acknowledge that **modern psychiatry is operating in a theoretical vacuum.**" McLAREN 2006,1998

MYALGIC ENCEPHALOMYELITIS

"NEVER IN THE FIELD
OF MODERN MEDICINE
HAS SO MUCH HARM
BEEN DONE TO SO
MANY BY SO FEW".



What does all this mean?

The WHOLE of Government Policy based on the
model now Falls DoH, NHS, NICE, M...
(Funding), DWP/Benefits

Payments must now be made to all poisoned
Farmers, G... and Cabin Crews –
Justice

Companies can no longer refuse
payments to the sick, ME/CFS, OPs, OCs, etc

Nigel Speight, Sarah Myhill, Jean Monro and others
Have been VINDICATED – ALLELUIA!



I Thank you!

MORE ON OPs -

NEUROTOXINS – OBVIOUS - OCKHAM'S RAZOR

AChE; ButChE GWVs control Choline nerve function

NTE – OPIDN → MND !

OPICN/OPINPD – numerous effects on brain

>1000 serine esterases

Acylpeptide hydrolases

Lipases

Many in the brain and more sensitive to OPs than AChE



Koslik HJ, Hamilton G, Golomb BA. Mitochondrial Dysfunction in Gulf War Illness Revealed by ³¹phosphorus Magnetic Resonance Spectroscopy: A Case-Control Study. PLOS ONE 2014;9:e92887.
Gloom BA, Koerski AM, Koslik HJ, Devaraj S, Ritchie JB. Coenzyme Q10 benefits symptoms in Gulf War Veterans: results of a randomized double-blind study. Neural Comput 2014;26:2594-651

NEW EFFECTIVE TREATMENTS

Each received a daily dose of either 100 mg or 300 mg of CoQ10, or an identical-looking placebo [Golomb, et al. *Neural Comp.* 2014; 26\(11\): 2594-2651\).](#)

After three and a half months of treatment, a remarkable 80% of participants taking 100mg of CoQ10 daily showed significant improvements in physical functioning.

Participants reported fewer headaches and memory problems, as well as reduced irritability, muscle pain, and fatigue with exertion. The benefits of treatment were found to correlate with increased levels of CoQ10 in the blood.

Myhill S, Booth NE, McLaren-Howard J. Chronic fatigue syndrome and mitochondrial dysfunction Int J Clin Exp Med (2009) 2, 1-16.

Booth NE, Myhill S, McLaren-Howard J. Mitochondrial dysfunction and the pathophysiology of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) Int J Clin Exp Med 2012;5(3):208-

Myhill S, Booth NE, McLaren-Howard J. Targeting mitochondrial dysfunction in the treatment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) - a clinical audit. [Int J Clin Exp Med](#). 2013;6(1):1-15.

Silico analysis of exercise intolerance in myalgic encephalomyelitis/chronic fatigue syndrome.

