

## M.E. Analysis – Evaluating the results of the PACE study

a project supported by Phoenix Rising

### 6. We need better information about the prognosis of this illness (more)

Throughout history many treatments, and quack cures, have used the natural progressions or variations of an illness as evidence of their effectiveness; cold remedies are an obvious example where people will, sooner or later, recover anyway whatever the treatment.

People are also reluctant to admit that something is ineffective when they have already invested both time and money in it. In our experience it is not uncommon for there to be a seasonal component in the severity of the illness. At the most basic level, just keeping warm in the winter can be a problem.



We do not know how much patients with ME/CFS vary over the course of a year, and have very little reliable information about their chances of full recovery. Without this information, it is essential to have a proper control group with any study involving ME/CFS. (Indeed a proper control group is considered a basic essential of any scientific study.) So little is understood of the mechanisms of ME/CFS that ignoring such a factor is scientifically inappropriate. Unfortunately, the PACE trial did not have such a control group, so with weak average results, it is hard to assess the contribution that natural variations and a reluctance to admit wasting time and energy may have had on them.

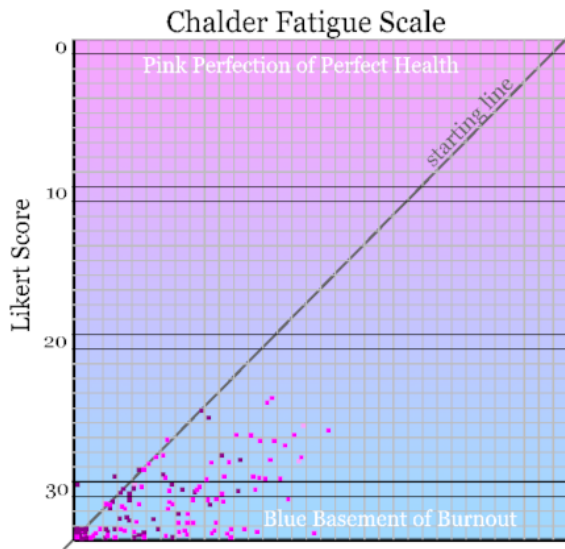
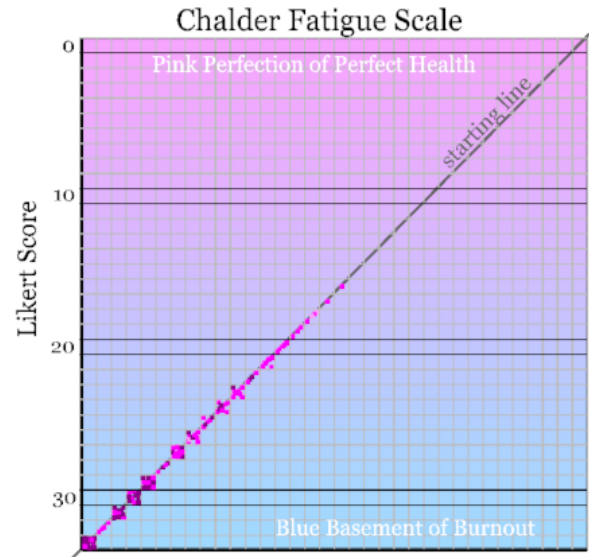
We decided to collect information from people that we knew with ME, so that we could have some feel for the natural variations that we are talking about. We asked if they would classify themselves as mild, moderate or severe (using the classification used by the Goudsmit study mentioned in 3:Chalder) where:-

- Mild was defined as being able to lead a reasonably normal life;
- Moderate was defined as not being able to work, and being able to do less than 50% of what the person could do before they became ill;
- Severe was defined as being able to do less than 25% of what the patient could do before they became ill, and being dependent on other people for activities such as cooking and shopping.

We asked them to complete the 11 point Chalder questionnaire for how they felt today, then repeat it for when (or if) they had gone through a bad patch lasting at least a week during the previous year, and again for a good patch lasting at least a week.

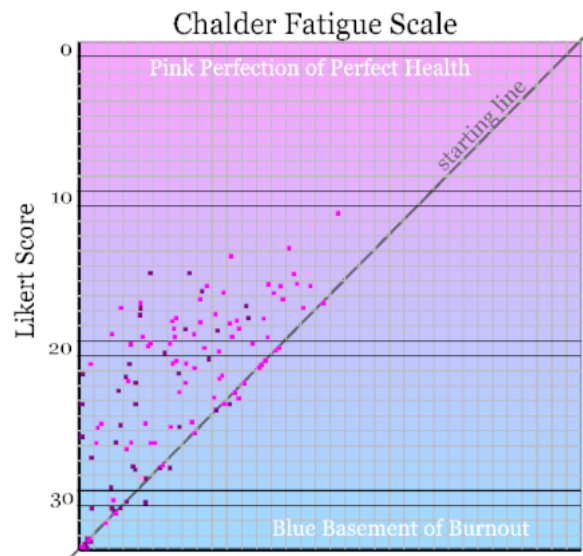
Obviously this survey would not stand up to proper scientific scrutiny: it is not designed to do that. The appropriate method would involve monitoring each patient's health over the course of a year and applying certain controls and checks, but our data should give a good indication as to whether variability could be a significant factor. The number and consistency of our results are reassuring.

This graph shows the initial scores – each coloured square represents a person, and the colour represents whether they were mild, moderate or severe. Their scores can be read on the vertical scale.



This graph on the left shows how those scores drop during a bad patch for the 123 participants.

This graph on the right shows how the scores rise during a good patch.



You may have noticed that for two people their score in their bad patch is better than their present score, and for a different two their score in a good patch is worse than their present score. This happens when one or two items, already scoring the maximum of 3, are particularly bad, but cannot be scored any worse, or when some items have much more significance than others over whether a patch is experienced as good or bad: if energy levels are so poor that a person is virtually bed-bound, it is pretty unimportant whether memory levels are good or not.

It is quite obvious from this data that the natural changes in scores over the course of a year could be quite significant, and warrant a proper investigation.