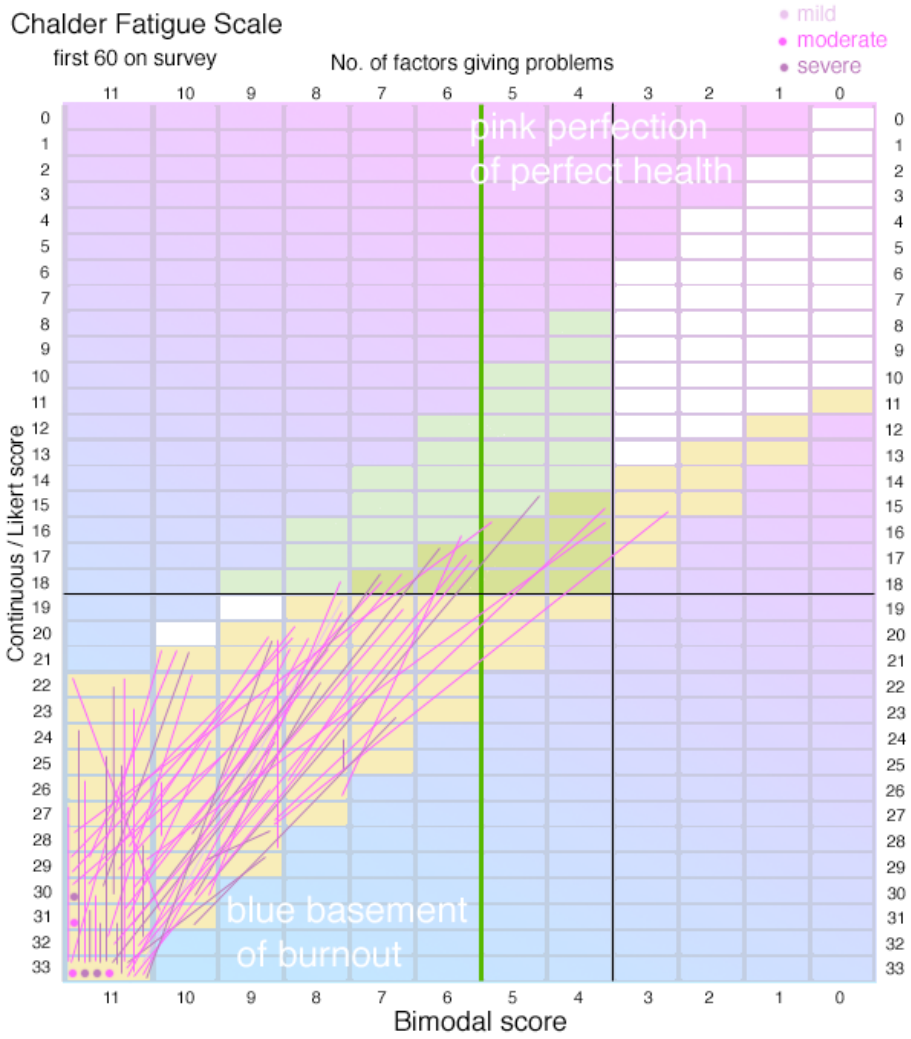
6. We need better information about the prognosis of this illness (details)

In fact, as people with ME/CFS go through good and bad patches, the changes differ greatly between individuals. For some people, the number of items that cause problems (the bimodal score) stays the same – just the severity changes. For others there is no change at all. In a few the changes are really very large: a gap of up to 10 points on the bimodal score and 18 on the Likert score.

Here is an attempt to illustrate this for the first 60 in our survey: it is easy to see that the variations in scores are widely different. Each line represents a patient; the colour represents whether that patient is mild, moderate or severe, and the line goes from their score in a bad patch to that in a good patch. Dots show no change, and vertical lines show no change in the bimodal score.



Longer lines clearly show greater changes. The further across a line goes indicates how many factors change from being a problem to not being a problem.

Out of the 60 results here, 45 of them have a bimodal score of 11 on a bad patch; 20 of them stay there on a good patch.

Looking at the general pattern of the lines, two things seem to be clear. One is that, for approximately half of

these individuals, changes in Likert scores are matched with changes in Bimodal scores (these are the diagonal lines), so either scoring system for them registers their improvements. But for many of those at the worse end of the scale, with bimodal scores of 11, if they improve at all, they stay at a Bimodal score of 11 or 10. On average, lines go up 4 Likert points for every Bimodal point across.

The conclusion to draw from this is that there is a deep well at the bottom of the scale that fails to reflect the severity of the illness, and it is difficult for patients at this level of illness to register changes. Adding to that is the fact that many lines end at 11/33, suggesting that the scale is does not go low enough. In fact most lines stop at the bottom of a column. This adds doubt as to whether the scale is able to measure deterioration fully, which in turn could relate to the debate on whether the use of this scale in the PACE trial is sensitive enough to record harm.

Several people commented on this when returning the questionnaire. Here are two examples:

"I think grading the questions is hard too as, compared with when I was well I am very bad indeed as on my best days I still can't sit up in a wheelchair for longer than a couple of mins, but you automatically try to think of grades and put some as less bad simply because you are even worse in bad patches!"

"If I was to be completely honest, compared to pre illness, I would have to score each item as 'much more than normal' but this didn't allow any latitude to record the exacerbation of symptoms during a crash."

Here is a table showing the changes in the results of the whole survey, from a bad patch to a good patch within a year.

Change in Binomial Score

Change in Likert Score	-1	0	1	2	3	4	5	6	7	8	9	10	11	total
0		11												11
1		3	1											4
2		4	1											5
3		2												2
4		1	4	1	2	1								9
5		1	1	2										4
6		2		3										5
7		1	3	1										5
8		6	4	3	1	1								15
9	1	1	1	1	1									5
10		2	2	1	5	1	1							12
11		1	1	1		1		1						5
12			3	2	3	2	2	1						13
13				1	2	2	1	1	2					9
14					3	1		3		1				8
15							2					1		3
16						1	4				1			6
17								1						1
18									1					1
total	1	35	21	16	17	10	10	7	3	1	1	1		123

If one person scores 9 on the bimodal scale and 26 on the Likert scale on a bad patch (i.e. 9 is the number of problem areas, and 26 measures the intensity of those problems), and scores 8 and 21 on a good patch, then that person changes by 1 point on the bimodal scale and by 5 points on the Likert scale (i.e. one factor is no longer a problem, and the severity score improves by 5 points). That person would then be entered in the table here in the yellow square.

It is not an easy table to read, but you can work out, for example, that three people improved by 3 points on the bimodal scale and 14 points on the Likert scale, but equally there were two people who improved by 3 points on the bimodal scale, but only by 4 points on the Likert scale.

There are totals across the bottom and down the side, and of course each of these add up to 123.

Notice that 35 (28%) of them do not change their bimodal score - even on a good patch all 11 items continue to give problems (this is the vertical column going through zero).

Also notice that one person actually goes from 10 items giving problems on a bad patch to 11 items giving problems on a better patch (hence the bimodal change of -1). Odd things do happen to patients with ME/CFS.

Using the median and quartiles (as discussed in section 2), the average person, varying from bad to good patches, changes by 2 items on the bimodal scale (i.e. two items return to a healthy level) and 8 points on the Likert scale. The middle half of this sample change between 0 and 4 on the Bimodal Scale (between zero and four factors no longer remain a problem), and the severity changes by between 4 and 12 on the Likert Scale.

Keep in mind that 33 people (27%) in the sample scored 18 or above (Likert score) on a good patch (but still, very much, had ME/CFS), and that for 87 (71%) of them the gap between today's score and a good patch was

2 Likert points or more. This calls into question the decision to set 18 as a return to normal functioning and for a 2 point improvement to constitute a clinical change, and to use these benchmarks as measures of success.

You cannot tell it from this table, but also 8 people halved their bimodal scores between today's score and a good patch - in the PACE protocol document that would have been considered a positive outcome.

If studies do not take into account the natural variations in the severity of ME/CFS, then they are, in our opinion, unlikely to produce meaningful results.

A bigger question is what if these variations are seasonally affected? Have any studies taken that into account?