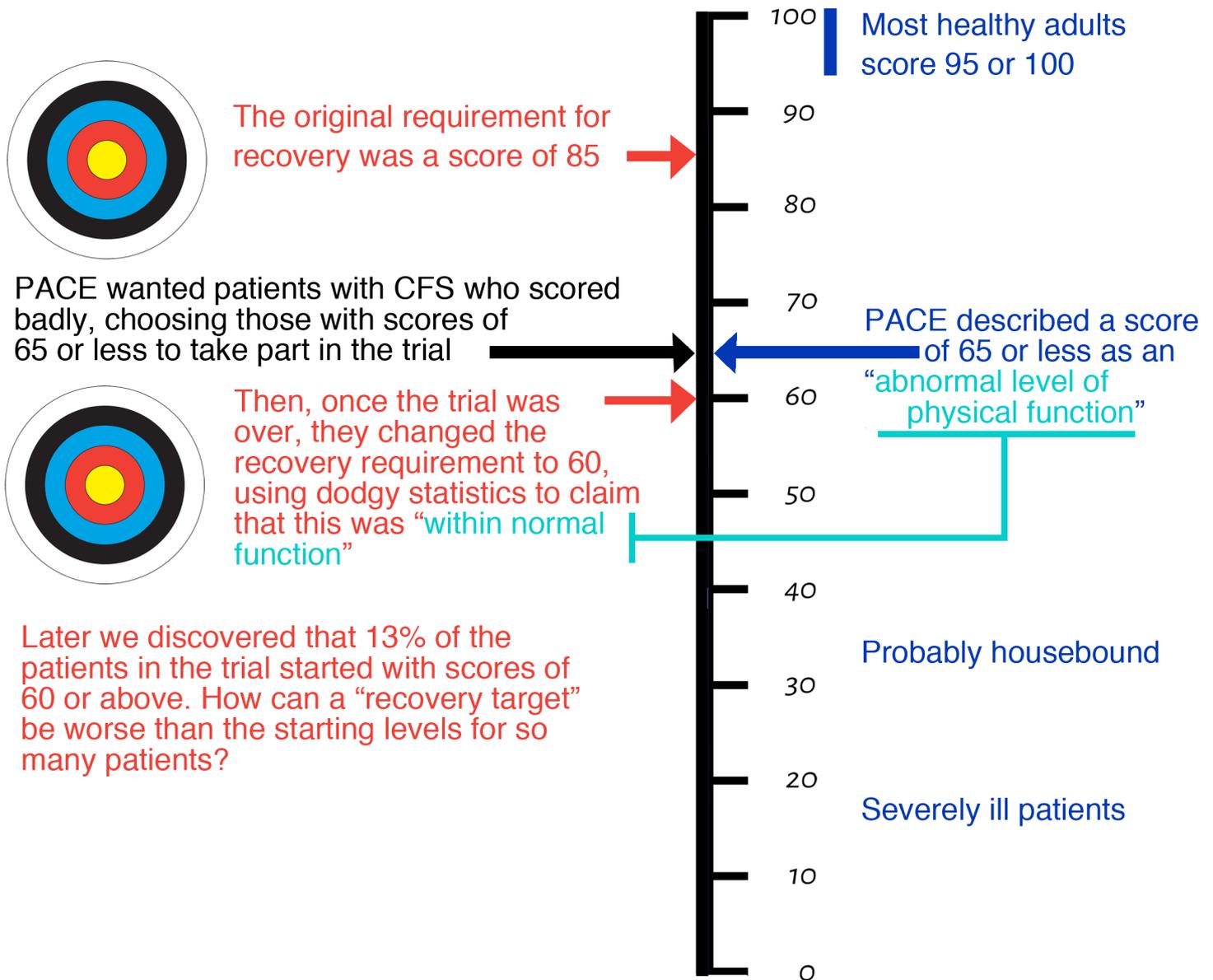


# PACE claimed that 22% of patients with CFS that were given Cognitive Behaviour Therapy recovered. What did they mean by that?

Let's look at how recovery was defined according to one of the trial's two primary outcomes: a questionnaire on physical capabilities: the sf-36



Later we discovered that 13% of the patients in the trial started with scores of 60 or above. How can a "recovery target" be worse than the starting levels for so many patients?

A similar restructuring happened to the other main assessment – a questionnaire on fatigue, which also had criteria for "recovery".

There were **no improvements** in any of the **objective** assessments:

- no improvement in **walking speed**
- no improvement in **climbing steps**
- no improvement in claiming **sickness benefits**
- no improvement in **returning to full-time or part-time employment**

see overleaf for more details.

## The sf-36 physical functioning scale

This questionnaire describes 10 activities and asks people to say whether they are limited a lot (0 points), limited a little (5 points) or not limited at all (10 points). Here is a simplified version of those activities and possible answers from someone scoring 60 out of 100.

Vigorous activities e.g. running or strenuous sports	limited a lot	0
Moderate activities like vacuuming	limited a little	5
Lifting or carrying groceries	not limited	10
Climbing several flights of stairs	limited a lot	0
Climbing one flight of stairs	not limited	10
Bending, kneeling or stooping	not limited	10
Walking more than a mile	limited a lot	0
Walking several hundred yards	limited a little	5
Walking one hundred yards	not limited	10
Bathing or dressing	not limited	10

This is the level set at the end of the trial for “recovery”. The average age of the patients was 39: is this a normal level of activity for a 39 year old?

There were no additional improvement in objective measures in walking or in climbing steps, but Cognitive Behaviour Therapy did persuade some patients to **regrade** how limited they thought they were on the above activities, and this, together with similar treatment of questions on fatigue formed the basis of the claims of recovery.

A major concern to me is that at the end of the trial, the PACE team changed the criteria for diagnosis of CFS to include a score of 65 or less on this scale. That means that anyone who regraded their answers so that they scored 70 or more on this questionnaire were said to no longer have CFS, regardless of any other symptoms they may have.

During enrolment for the trial, at least 250 patients who had a diagnosis of CFS and scored 70 or more on this questionnaire were excluded from the trial because the authors wanted to focus on those who were more profoundly affected . Those patients were considered to have CFS according to the PACE criteria at the start of the trial, but not according to the new criteria at the end of the trial. How is it possible to publish a paper in which the criteria for an illness has been changed at the end of the trial, so that fewer patients qualify as having the illness, then use these modified criteria to claim that CBT promotes “recovery”?

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To find out more, go to <http://www.meetup.org.uk/PACE>