

stated in the paper (i.e. nearly two-thirds of the patients were tested before their first-ever ECT session). The results from this subgroup were not specifically reported, but we can now report on the most meaningful analysis on these patients (those who were tested before their first-ever ECT and tested again after they had > 12 ECT sessions). This applies to 37 of the 55 patients who we reported in the paper as having had > 12 ECT sessions (average of 21) between their first and their last tests (Table 2 in the paper). The results are basically indistinguishable from those reported in Table 2, with the only significant change (an improvement) found again for the reaction time.

We welcome further research in this field, but want to reiterate that our results refer to cognitive performance, although retrograde memory problems do exist and can upset some patients. Such patients feel more reassured when they are able to compare their performance on cognitive tests pre- and post-ECT.

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Defining clinically significant change

I congratulate ter Heide *et al* on conducting an extremely timely and important clinical trial.¹ As stated by the authors, there is a conspicuous lack of clinical trials investigating the effect of eye movement desensitisation and reprocessing (EMDR) in treating traumatised refugees.

However, in order to be able to appraise/interpret the results more fully, it would be of great value if the authors could analyse their data with different cut-off points for defining clinically significant change. In their article, the authors define clinically significant change as a decrease of 10 points or more on the Clinician-Administered PTSD Scale (CAPS).² The authors report that approximately 40% of patients in both conditions achieved clinically significant improvement (Table 2).

However, there is currently no widely agreed threshold for defining clinically significant change on the CAPS and different clinical trials have used a range of different cut-off scores. For example, in two major publications Schnurr *et al*^{3,4} defined clinically significant change as a decrease of at least 10 points in total CAPS scores. Hinton *et al*⁵ used the rationally derived 15-point change² as a marker of clinically significant change. In line with the method set forth by Jacobson & Truax,⁶ Taylor *et al*⁷ defined clinically significant change as a reduction in total CAPS score of at least two standard deviations. Hien *et al*⁸ used a 30-point or greater improvement on the CAPS to determine clinically significant improvement of PTSD symptoms, whereas Bryant *et al*⁹ defined clinically significant change as a cut-off of < 45 on the CAPS at follow-up.

It is also important to take into consideration the measurement variability of the instrument.⁶ A change of 10 points on the CAPS is not necessarily even reliable. Monson *et al*¹⁰ calculated a reliable change score of 12.22 points on the CAPS, and we previously have calculated a conservative reliable change score of 14.3 points.¹¹ So a change of 10 points might simply be within the measurement variability of the CAPS.

These issues taken together, it would be very informative if the authors made use of different cut-off scores for defining clinically significant change. The Institute of Medicine¹² notes that common methods to define clinically significant change on the CAPS in the

treatment literature are to define it as a ≥ 10 -point decrease, a ≥ 30 percent decrease, or as two standard deviations below pre-treatment level. Using a 30% decrease in total CAPS score for the present sample entails a cut-off score for clinically significant change of approximately 23 points. Using two standard deviations below pre-treatment level⁶ as a marker for clinically significant change entails a cut-off score of approximately 36 points. It would be very informative if the authors re-analysed their data with at least these two thresholds for defining clinically significant change in addition to the 10-point cut-off score reported in their paper.

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Authors' reply: Dr Halvorsen quite rightly draws attention to the various definitions of clinically significant change, which all have their advantages and disadvantages. We especially agree with the comment that the threshold for clinically significant change should at least coincide with the threshold for reliable change (18.66 in our sample). However, using the threshold of 10 points, as promoted by Schnurr,¹ has specific value in our study. First, the 10-point threshold has been shown to be related to changes in quality of life in several samples.^{2,3} Second, clinically significant change refers to both clinical improvement and deterioration. Most clinicians and researchers would agree that a deterioration

of more than 10 points is clinically meaningful and undesirable. Third, treatment duration in our study was relatively short, justifying a relatively low threshold for clinically significant change.

Obviously, if the threshold for clinically meaningful change is increased, the number of participants who benefit from the treatment will decrease. In our study, using the 30% rule (which is based on each participant's score at baseline rather than on the participants' mean score at baseline), the number of participants who experience clinically significant change decreases to six in both conditions. Using the two-standard-deviations rule, the number is reduced even further, to one in the EMDR condition and three in the stabilisation condition.

However, the informative value of this, in our opinion, is limited. The general conclusion of our paper is that six 90-min sessions of EMDR preceded by three 60-min preparatory sessions are of limited efficacy. This conclusion is based not only on calculations of clinically significant change but also on the slopes of clinician-administered and self-reported measures and on the number of PTSD cases (which may also be subjected to different scoring rules⁴). An alternative conclusion would be that EMDR is not efficacious at all, but that would not be defensible given the significant decrease in self-reported PTSD severity in the EMDR sample and the significant, medium-sized differences between the EMDR condition and the non-randomised wait-list condition.

What the rules for calculating clinically significant change have in common is that they are defined *a priori* by researchers. In reference to the discussion of our paper, it may be argued that participants themselves should be invited to define at which point they feel that they have meaningfully changed and which criteria define for them where this point lies. By listening to refugee patients' opinions and insights on what is helpful and meaningful to them, we might all be in for a surprise.

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