Psychological Medicine

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Cite this article: Luyten P, Leichsenring F, Abbass A, Hilsenroth M, Rabung S, Steinert C (2019). What to conclude from a non-randomized clinical trial comparing dialectical behavior therapy and mentalization-based treatment in patients with borderline personality disorder? *Psychological Medicine* **49**, 2810–2811. https://doi.org/10.1017/S0033291719001922

First published online: 19 September 2019

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What to conclude from a non-randomized clinical trial comparing dialectical behavior therapy and mentalization-based treatment in patients with borderline personality disorder?

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The study by Barnicot and Crawford (Barnicot and Crawford, 2018) comparing clinical outcomes of Dialectical Behavior Therapy (DBT) and Mentalization-Based Treatment (MBT) in patients with Borderline Personality Disorder (BPD) in the context of a non-randomized study in the United Kingdom represents a major step forward in identifying effective treatments for BPD patients. Indeed, there is a lack of direct head-to-head comparisons of current evidence-based treatments of patients with BPD (Cristea *et al*., 2017; Fonagy *et al*., 2017). This study therefore provides important information concerning the relative effectiveness of both types of treatment, particularly because it was conducted in routine clinical care, increasing the ecological validity of its findings. Given the paucity of comparative studies, the use of appropriate analysis strategies and correct reporting of clinical trials in this area is all the more important.

However, several problems with the data analysis and reporting make it unclear what conclusions can be drawn from this trial for both research and clinical practice. Barnicot and Crawford highlight in the abstract, results and discussion section of their paper that 'reductions in self-harm and improvements in emotional regulation at 12 months were greater amongst those receiving DBT than amongst those receiving MBT' (p. 1), suggesting this was the major finding of their study. However, this conclusion seems not to be supported by the data. As noted by the authors themselves in the results section, their study found 'no differences between participants receiving DBT and those receiving MBT in number of incidents of selfharm, BPD severity, emotional dysregulation, relationships with others or dissociation' (p. 4). Hence, no significant differences were found on any of the clinical outcome measures in this study. Still, in the abstract of their paper and in the discussion section the authors argue that reductions in self-harm and improvements in emotional regulation were greater in DBT.

This erroneous conclusion appears to be based on the finding that in adjusted multilevel models there was a steeper decline in self-harm and emotional dysregulation in DBT compared to MBT. Yet, there is a clear difference between the rate of change during treatment and outcomes at the endpoint of a study. If there were no differences at the study endpoint, but there were differences in the rate of change, then patients simply followed different trajectories toward the same endpoint. If valid, these findings may have implications for clinical practice, even when DBT and MBT are equally effective at the study endpoint, as it would suggest that self-harm and associated features may improve faster in DBT.

Furthermore, Barnicot and Crawford adjusted for baseline differences in several clinical variables between patients in MBT and DBT, of which some were significant, and others were not. Thus, the basis for their selection of potential confounding variables is not clear. Moreover, it is well-known that if covariates overlap with the experimental effect, adjusting for these variables does not balance out these differences, as is often wrongly assumed, but may instead obscure treatment effects if the covariates show a significant correlation with the outcome (Field, 2013). The authors did not report whether there was an association between any of these variables and outcomes.

These considerations are relevant to the authors' analyses of several outcome measures. DBT showed significantly higher drop-out rates, hospitalization and emergency department attendance at 12-month follow-up. These differences disappeared after including covariates in the analyses. Whether this result is valid or not is not clear due to the problem of including covariates described above.

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In addition, some analyses focusing on clinical outcomes controlled for baseline differences, whereas others did not, and it is not clear from the paper why this was the case. In fact, the authors seem to have done so only when differences disadvantaged DBT, that is, in analyses showing a higher number of patients in DBT visiting crisis services and being admitted to an inpatient psychiatric service and higher drop-out rates, but not in other analyses (see Table 2). This raises questions about potential researcher allegiance.

The authors also decided to adjust all analyses for whether patients had completed treatment or not (p. 4), but it is difficult to see why this was done, as intention-to-treat (ITT) analyses (i.e. analyses that include all patients in a trial) are considered the gold standard in analyzing data from clinical trials. It is also difficult to imagine how ITT analyses could be controlled for whether patients had completed treatment or not. Yet, given that drop-out rates were significantly and markedly higher in DBT compared to MBT (72% *v.* 42%), analyses controlling for completer status can be expected to favor DBT.

We therefore ask the authors to report both ITT and completer analyses, to report bivariate correlations between variables adjusted for in these analyses and outcomes, and report results controlling only for those covariates which are not significantly related to the outcome.

Another important issue is that neither a primary outcome nor a hypothesis was specified in the paper. This problem is associated with the fact that the trial was not prospectively registered (or such pre-registration was not reported), implying that primary and secondary outcomes and the analysis strategy were not defined a priori. Studies have amply shown that the absence of pre-registration of trials presents an important risk of bias (Driessen *et al.*, 2015; Leichsenring *et al.*, 2017). Following from these concerns, we wonder why the authors focused on the rate of decreases in self-harm and emotional dysregulation in their reporting of the trial, particularly in the absence of any differences in outcome measures, including severity of BPD symptoms, dissociation or interpersonal problems.

Finally, although the authors discuss the lack of treatment fidelity evaluations for either treatment as an important limitation, no information is provided about each group of clinicians providing these treatments, their training, supervision, or implementation.

In sum, several issues related to data analysis and reporting require clarification. At present, the conclusions that can be drawn from this trial are not clear. This is important for at least two reasons. First, the authors argue that patients typically referred to DBT present with more severe problems, which they argue might explain higher drop-out rates in DBT. Yet, patients in DBT only showed greater emotional dysregulation, and somewhat higher levels of PTSD and self-harm in the previous 12 months (but not in the previous 3 months before the trial). They also did not differ in levels of dissociation and severity of BPD compared to patients referred to MBT. Hence, differences between patients typically referred to DBT and MBT might be much more specific than suggested by the authors. Furthermore, it is presently not clear whether PTSD or BPD should be addressed first in patients showing both. If so, future trials might do well to compare a sequential strategy, with treatments addressing emotional dysregulation and PTSD first. It is therefore all the more important that full results of this trial are made available.

References

Barnicot K and Crawford M (2018) Dialectical behaviour therapy *v.* mentalisation-based therapy for borderline personality disorder. *Psychological Medicine*, 1–9, doi: 10.1017/S0033291718002878.

Cristea IA, Gentili C, Cotet CD, Palomba D, Barbui C and Cuijpers P (2017) Psychotherapy for borderline personality disorder: a systematic review and meta-analysis. *JAMA Psychiatry* **74**, 319–328.

Driessen E, Hollon SD, Bockting CLH, Cuijpers P and Turner EH (2015) Does publication bias inflate the apparent efficacy of psychological treatment for major depressive disorder? A systematic review and meta-analysis of US national institutes of health-funded trials. *PLoS ONE* **10**, e0137864.

Field A (2013) *Discovering Statistics Using IBM SPSS Statistics*. London: Sage.

Fonagy P, Luyten P and Bateman A (2017) Treating borderline personality disorder with psychotherapy: where do we go from here? *JAMA Psychiatry* **74**, 316–317.

Leichsenring F, Abbass A, Hilsenroth MJ, Leweke F, Luyten P, Keefe JR, Midgley N, Rabung S, Salzer S and Steinert C (2017) Biases in research: risk factors for non-replicability in psychotherapy and pharmacotherapy research. *Psychological Medicine* **47**, 1000–1011.

https://doi.org/10.1017/S0033291719001922 Published online by Cambridge University Press