Letters

COMMENT & RESPONSE

Concerns About Potential Bias in a Randomized Clinical Trial of Integrated Prolonged Exposure Therapy vs Seeking Safety Integrated Coping Skills Therapy

To the Editor Norman et al[1] report a randomized clinical trial of behavioral therapies for alcohol use disorder and posttraumatic stress disorder (PTSD) in military veterans: an integrated prolonged exposure model (I-PE) vs Seeking Safety (SS), an integrated coping skills model. I am the developer of the SS model, and I have concerns about how the model was used in this trial and potential biases.

The trial did not meet research standards for implementing SS. In the trial protocol, published as a supplement to the article, Norman et al[1] identified Norman and a team member as a "certified trainer" for SS, which is not accurate. Norman, the corresponding author, devised her own SS training, supervision, and fidelity monitoring rather than adhering to SS research standards that are well established and prominently available.[2] Norman was years into data collection when I found out about the study, and even my communications to her in 2015 about the standards and efforts by my team to collaborate regarding the SS portion did not lead to acceptable implementation. The published article provides no information on the qualifications of SS trainers, supervisors, or fidelity monitors. SS was also adapted in unacceptable ways without consultation (eg, combining 2 SS modules into 1 session).

In addition, I believe that Norman has undeclared conflicts of interest. She has paid positions promoting prolonged exposure (PE), the therapy that I-PE is based on. She consulted on the national rollout of PE in the Veterans Administration (VA), and is the national PTSD consultation program director for the VA entity that leads the PE rollout. She is well known in the VA for her advocacy of PE.

The article by Norman et al[1] is biased in favor of I-PE. According to the published article, Norman consulted with the I-PE developer regarding model adaptation but adapted SS without consulting me. The Abstract of the article does not mention that SS had more treatment completers than I-PE (37 of 56 vs 20 of 63), as is shown in Figure 1 in the article by Norman et al.[1] The I-PE intervention had a moderate effect size difference (Cohen d = 0.41) on 1 variable, yet the discussion states that I-PE is "more efficacious" and produces "better PTSD outcomes with fewer sessions attended," essentially framing dropout as an asset.[1] A nonsignificant result is a "marginal group difference" favoring I-PE. I-PE had substantially more patients taking psychotropic medication, which likely biased results in a positive direction. In addition, twice as many I-PE patients provided no outcome data. These potential biases were not addressed in the article.

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Conflict of Interest Disclosures: Dr Najavits is author and developer of the Seeking Safety model; receives royalties from Guilford Press; and is director of Treatment Innovations, which provides consultation, research, training, and materials related to Seeking Safety and other psychotherapy models.

1. Norman SB, Trim R, Haller M, et al. Efficacy of integrated exposure therapy vs integrated coping skills therapy for comorbid posttraumatic stress disorder and alcohol use disorder: a randomized clinical trial [published online April 24, 2019]. *JAMA Psychiatry*. doi:10.1001/jamapsychiatry.2019.0638

2. Your research. Seeking Safety. https://www.treatment-innovations.org/evid-yr-research--research-central.htmlhttps://www.treatment-innovations.org/evid-yr-research-research-central.html. Accessed July 8, 2019.