May, 2019

We are happy to work with you regarding your potential interest in conducting a publishable study on Seeking Safety. We greatly value research and want to support your work.

We do need to emphasize, however, that for scientific integrity and ethics, it is required to follow developer-approved standards for ensuring that SS is conducted with adequate quality controls. Such procedures are standard for any clinical trial on any therapy model. They are *not* required for regular clinical implementation—just for publishable research in which you'll report results on Seeking Safety.

Most investigators conduct their trials admirably, but occasionally a serious issue occurs. We always want to prevent such situations in advance.

Below we provide a recent case example of inappropriate published research1 by a research team that:

1. Falsely identified themselves as "certified SS trainers" in their grant application2.

2. Did not follow required research standards for Seeking Safety (which are listed in numerous places on our website, including the sections *FAQs, Evidence, Training, Assessment* and *Contact*).

3. Did not describe in their published article the qualifications of who did the SS training, fidelity, and supervision.

4. Created their own methods for training, fidelity, and supervision.

5. Modified SS in unacceptable ways.

In sum, please remember to be in touch regarding your research if you plan to publish outcomes on SS. We truly want to help you create a success experience and will collaborate with you, respecting resource limitations, budget, etc.

Questions? Contact us at info@seekingsafety.org or 617-299-1610 (text or call).

Thanks for understanding.

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*Case example of problematic research*

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. JAMA Psychiatry. Published online April 24, 2019. doi:10.1001/jamapsychiatry.2019.0638

2. Online *Supplement* to Norman et al. (2019), section 6.E.5.

The study principal investigator (PI) applied for a research grant and herself and one of her team as "certified SS trainers" (which they were not). They received $750,000 in grant funding in 2012, and began recruiting patients February 2013, without informing us of their project. When we found out about it by chance several years later we contacted the PI and advised her of the required standards for training, fidelity, and certification for outcome research on SS, which are also listed on the SS website. She said she had no budget for that and that she and one of her staff who had been trained in SS were already doing all of the training, fidelity, and supervision of SS on the trial. We told her this was unacceptable as they had never obtained SS certification for those roles, and that simply attending a SS training was not adequate. To address her budget concerns, one of our team, a senior expert, offered to help pro bono by co-rating some counselors’ tapes as part of attempting to certify one of the study team as a fidelity rater. This was over two-and-a-half years into the data collection, which means that the study's SS counselors were trained, supervised and assessed for fidelity to SS without any attention to certification or standards other than those the PI had created on her own.

On listening to the SS tapes, our expert identified two crucial areas that needed improvement: a stronger focus on PTSD and more explicit goals for reducing substance use. We requested a conference call to discuss these concerns with the study PI and her projecte director. Unfortunately, they were unwilling to do what was needed to improve the conduct of the SS arm. For example, the senior expert had reservations about a counselor who was not addressing substance abuse strongly enough with a study patient. She asked the PI if the SS developer, Dr. Najavits, could review one of the counselor's tapes to provide additional guidance on how to proceed. The PI declined, saying this type of consultation was not covered by the Institutional Review Board (IRB) and that they were not willing to seek IRB approval. The senior expert then ended her involvement in the project due to concerns that SS research requirements were not being taken seriously. Other efforts also failed, such as when our team offered pro bono to help with their IRB process, to provide feedback on the draft of the research article, etc. In sum, the research team had no obligation to use Seeking Safety, but having selected it, had a scientific and ethical obligation to implement it per the developer-approved requirements.