Study Protocol & Analytic Plan:

Developing a Virtual Reality Training Tool for Exposure Therapy: Simulated Exposure Trainer (SET-VR)

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Protocol: Developing the Simulated Exposure Trainer (SET-VR)

RESEARCH OBJECTIVES:

Exposure-based cognitive-behavioral therapy (CBT) is highly efficacious and a front-line treatment for anxiety disorders and obsessive-compulsive disorder[8-13]. Despite clear efficacy, exposure therapy remains one of the least utilized EBPs to treat anxiety[3-5]. Even among providers with specialized training in exposure, less than half report use with anxious patients[1]. This suggests our current training paradigms for exposure therapy require a shift, incorporating innovative theory-driven approaches capable of addressing barriers to dissemination.

Effective therapist training capable of changing therapist behavior is a core component in the dissemination of EBPs[14,15]. Experiential activities (e.g., role-play) are more likely to produce a change in therapist practice as compared to passively delivered didactic instruction[16]. Virtual training environments are well-equipped to overcome issues related to representativeness, replicability, individualization, standardization and economic scalability, all of which limit the efficacy and reach of role playing and other (non-technological) experiential training tasks. To our knowledge, virtual reality (VR) has yet to be leveraged as an experiential training strategy for promoting the delivery of psychotherapeutic strategies. VR platforms have strong support for their efficacy in treating patient anxiety. Accordingly, VEs may be especially successful in promoting "exposure to exposure" during the training of exposure therapists.

This study will develop **SET™** utilizing simulated interactions with an anxious VP to target and reduce therapist negative beliefs about exposure. **SET™** will be developed to be delivered via two media methods: Head Mounted Display (HMD; hypothesized as high-immersion) and a web-based (WB; via laptop or mobile device; hypothesized as low-immersion). The goal is to test which platform provides an ideal balance of usability, target engagement (i.e., negative belief change), and scalability.

SUBJECT RECRUITMENT:

Study setting. Study procedures will take place at Bradley Hospital.

Participants. Training trial clinicians (N=40) will be recruited from local mental health agencies as well as private practice. Trial clinicians will be naïve to exposure therapy and will self-select for the training.

METHOD AND PROCEDURES:

Overview. This study will develop **SET™** based upon clinically-derived anxious behaviors by creating VP animations and learner interaction features to target and reduce therapist negative beliefs about exposure. An experimental therapeutics framework will be applied to a brief training trial to demonstrate initial engagement of our learning target (i.e., therapist negative beliefs about exposure).

Training Trial to Test Learning Target Engagement.

Training Trial Overview. Therapists seeking exposure training (N=40) will be recruited to complete a training workshop in exchange for continuing education credits (CEs) and monetary compensation. Therapists will be randomly assigned to interact with one of the **SET™** delivery methods (i.e., HMD or WB). All therapists will receive the same 4-hour didactic instruction in exposure therapy followed by experiential VR training (2 hours) with the assigned delivery method. Our learning target (negative beliefs) measure will be given at multiple timepoints to isolate the specific, incremental effect of the experiential component on our beliefs target (see Table 1). The two conditions will operate as a tandem case-series analysis that evaluates whether therapists in both conditions reach an a-priori target engagement benchmark.

Training Trial Outcome Measures. **Therapist Negative Beliefs about Exposure Scale (TBES)**[2]. The TBES assesses the extent to which therapists endorse 21 negative beliefs about exposure therapy. The TBES is the primary outcome measure for assessing target engagement. **Exposure Knowledge.**[6] We have condensed the original 49 multi-choice item measure by selecting 12 multiple-choice items that best fit the didactic content of our training. **Exposure Self-Efficacy.**[6] This is a 27-item measure of therapists' confidence in delivering exposure therapy. This measure has demonstrated high internal consistency and predictive validity in determining the frequency of self-reported clinical use of exposure therapy.

REFERENCES

1. Becker CB, Zayfert C, Anderson E. A survey of psychologists' attitudes towards and utilization of exposure therapy for PTSD. *Behaviour Research and Therapy*. 2004;42(3):277-292. doi:10.1016/S0005-7967(03)00138-4
2. Deacon BJ, Farrell NR, Kemp JJ, et al. Assessing therapist reservations about exposure therapy for anxiety disorders: The Therapist Beliefs about Exposure Scale. *J Anxiety Disord*. 2013;27(8):772-780. doi:10.1016/j.janxdis.2013.04.006

3. Wolitzky-Taylor K, Zimmermann M, Arch JJ, De Guzman E, Lagomasino I. Has evidence-based psychosocial treatment for anxiety disorders permeated usual care in community mental health settings? *Behaviour Research and Therapy*. 2015;72:9-17. doi:10.1016/j.brat.2015.06.010
4. Whiteside SPH, Deacon BJ, Benito K, Stewart E. Factors associated with practitioners' use of exposure therapy for childhood anxiety disorders. *Journal of Anxiety Disorders*. 2016;40:29-36. doi:10.1016/j.janxdis.2016.04.001
5. Hipol LJ, Deacon BJ. Dissemination of evidence-based practices for anxiety disorders in Wyoming: A survey of practicing psychotherapists. *Behav Modif*. 2013;37(2):170-188. doi:10.1177/0145445512458794
6. Harned MS, Dimeff LA, Woodcock EA, Contreras I. Predicting adoption of exposure therapy in a randomized controlled dissemination trial. *Journal of Anxiety Disorders*. 2013;27(8):754-762. doi:10.1016/j.janxdis.2013.02.006
7. Geller DA, March J. Practice parameter for the assessment and treatment of children and adolescents with obsessive-compulsive disorder. *Journal of the American Academy of Child & Adolescent Psychiatry*. 2012;51(1):98-113. doi:10.1016/j.jaac.2011.09.019
8. Chorpita BF, Daleiden EL, Ebesutani C, et al. Evidence-based treatments for children and adolescents: An updated review of indicators of efficacy and effectiveness. *Clinical Psychology: Science and Practice*. 2011;18(2):154-172. doi:10.1111/j.1468-2850.2011.01247.x
9. Connolly SD, Bernstein GA, Work Group on Quality Issues. Practice parameter for the assessment and treatment of children and adolescents with anxiety disorders. *J Am Acad Child Adolesc Psychiatry*. 2007;46(2):267-283. doi:10.1097/01.chi.0000246070.23695.06
10. Barlow DH, Allen LB, Basden SL. Psychological treatments for panic disorders, phobias, and generalized anxiety disorder. In: *A Guide to Treatments That Work*. 3rd ed. Oxford University Press; 2015:351-394.
11. Kazdin AE, Weisz JR. Identifying and developing empirically supported child and adolescent treatments. *Journal of Consulting and Clinical Psychology*. 1998;66(1):19-36. doi:10.1037//0022-006x.66.1.19
12. Kendall PC, Robin JA, Hedtke KA, Suveg C, Flannery-Schroeder E, Gosch E. Considering CBT with anxious youth? Think exposures. *Cognitive and Behavioral Practice*. 2005;12(1):136-148. doi:10.1016/S1077-7229(05)80048-3
13. Olatunji BO, Cisler JM, Deacon BJ. Efficacy of cognitive behavioral therapy for anxiety disorders: A review of meta-analytic findings. *Psychiatric Clinics*. 2010;33(3):557-577. doi:10.1016/j.psc.2010.04.002
14. Gunter RW, Whittal ML. Dissemination of cognitive-behavioral treatments for anxiety disorders: Overcoming barriers and improving patient access. *Clin Psychol Rev*. 2010;30(2):194-202. doi:10.1016/j.cpr.2009.11.001
15. Beidas RS, Kendall PC. Training therapists in evidence-based practice: A critical review of studies from a systems-contextual perspective. *Clin Psychol (New York)*. 2010;17(1):1-30. doi:10.1111/j.1468-2850.2009.01187.x
16. El-Tannir AA. The corporate university model for continuous learning, training and development. *Education and Training*. 2002;44(2):76-81. doi:10.1108/00400910210419973

Analytic Plan

Statistical analyses were carried out using SAS version 9.4 1M7 (The SAS Institute, Cary NC). Knowledge, Self Efficacy, and TBES were assessed longitudinally and analyzed via binomial Generalized Estimating Equations (GEE). SUS, VPE, and TARS were only assessed at the conclusion of the study and were analyzed using a binomial generalized linear model. Both sets of analyses used the binomial distribution to constrain the model space to the range of the measures being used. The scores were first shifted to have a minimum score of zero by subtracting the minimum score possible. This was used as the binomial number of "successes", and the range of the score was used as the number of "trials". Classical sandwich estimation was then used to better incorporate any differences in empirical variances and covariances. Both raw and adjusted (where appropriate) p-values were presented as well as unadjusted 95% confidence intervals. For GEEs, 16 different hypotheses were tested using orthogonal linear estimates: a) changes from baseline conditions in each condition (8 total), b) high- and low-immersion training conditions compared at each time point cross sectionally (4), and as c) condition comparisons in changes from baseline for each follow-up (4). The Holm test was used to calculate adjusted p-values maintaining familywise alpha at 0.05 across all 16 hypothesis tests in GEEs. For all other models, only one hypothesis was tested comparing the conditions.