Preregistration

Transdiagnostic Written Exposure Therapy: a Randomized Control Trial

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Study Information

Title	Transdiagnostic Written Exposure Therapy: a Randomized Control Trial
Description	The goal of the current project is to evaluate a self-administered, brief online written exposure therapy (WET) intervention. This intervention was adapted from WET for PTSD (Sloan & Marx, 2019) and is designed to be transdiagnostic, focus on participants' core fears (Huppert & Zlotnick, 2012) and use an immersive perspective similar to imaginal exposure (IE; Asnaani et al., 2016). The intervention will be tested in an online randomized controlled trial with a trans-diagnostic sample of individuals with high levels of anxiety. Therefore, we will test treatment efficacy as measured by change in anxiety and functioning. Furthermore we will investigate patterns of change and potential mechanisms of change.

Hypotheses

1. WET is more effective than control in reducing trait anxiety.
2. Changes in proposed mechanisms change together with changes in trait anxiety, supporting the notion that treatment effect is mediated by mechanism.

Design Plan

The study is a Randomized Controlled Trial (RCT).

Study type **Experiment**. A researcher randomly assigns treatments to study subjects, this includes field or lab experiments. This is also known as an intervention experiment and includes randomized controlled trials.

Blinding For studies that involve human subjects, they will not know the treatment group to which they have been assigned. Personnel who interact directly with the study subjects (either human or non-human subjects) will not be aware of the assigned treatments.

Study design

- Participants will be randomly assigned to one of two groups: the treatment group (WET) and the control group (expressive writing).
- Both groups will engage in four sessions of writing and a follow-up session.
- Symptom measures and mechanisms will be assessed before the first and after the last writing sessions.
- Symptoms will be measured again at the follow-up session.
- State anxiety and thought action fusion will be measured at each writing session.

Treatment efficacy will be investigated within a pretest-posttest control group design. The primary outcome will be change in OASIS, though change in WSAS and all measured mechanisms will be considered secondary outcomes. Furthermore,

we will investigate the covariation between changes in OASIS and change in each mechanism.

Randomization

Participants will be randomly assigned to the treatment and control groups in a 2:1 ratio, with the treatment group being twice the size of the control group. Furthermore, participants with low anxiety (OASIS<8) will be randomized separately from participants with high anxiety (OASIS>=8), to ensure equal distribution of severity between the groups. This will be accomplished through block randomization, where participants are randomly assigned within predetermined blocks. The randomization process is integrated into the experiment program code (Qualtrics).

Sampling Plan

Existing data

Registration prior to creation of data. As of the date of submission of this research plan for preregistration, the data have not yet been collected, created, or realized.

Explanation of existing data

No use of existing data

Data collection procedures

Participants will be sampled on the Prolific platform of online research. Participants will be paid 9 GBP/hour for agreeing to participate. Inclusion criteria will include high trait anxiety [greater than 4 on the Overall Anxiety Severity and Impairment Scale; OASIS, Norman et al. (2006)], and impaired daily function [at least one item scored above 2 on the Work and Social Adjustment Scale. WSAS; Mundt et al. (2002)]. Exclusion criteria are severe depression [greater than 14 on the PHQ; Kroenke et al. (2009)], post-trauma [greater than 6 on the PCL-5; Blevins et al. (2015)], or psychotic symptoms [items 19 or 20 from the DIAMOND screener; Tolin et al. (2018)]. In addition, English as a fluent language is required. Furthermore, participants who have reported head Injury or reading and writing difficulties in the Prolific system will be excluded. Finally, only experienced users on the Prolific platform with an approval rate of above 95, and with minimum previous submissions of 300 will be allowed to participate in this study. We will request that prolific sample an ethnically representative sample.

Sample size

We aim to recruit a minimum of 60 participants and possibly up to 150 participants in increments of 30. The recruitment process will continue until we reach the maximum participant count or until the difference between groups on the OASIS reaches a region of practical equivalence (ROPE) of 90% for a two-point effect size (see model below).

Sample size rationale

A power analysis was conducted with the assumption of an intraclass correlation coefficient (ICC) of 0.5 and an effect size of 0.4, revealing that a sample size of 148 participants would provide 0.8 power. However, in consideration of financial constraints, a Bayesian stopping criteria was implemented to enable early termination of the study.

Stopping rule

See above. Additionally we will recruit until we reach our sample size, or after 6 months from the beginning of the recruitment.

Variables

Manipulated variables

We manipulate the task participants engage in by providing different instructions. The treatment group receive instructions to write about their core threats, whereas the control group receive instructions to write about a daily activity.

Measured variables

Symptoms

1. Trait anxiety will be measured via the Overall Anxiety Severity and Impairment Scale [OASIS; Norman et al. (2006)].
2. Daily functioning will be measured via Work and Social Adjustment Scale [WSAS; Mundt et al. (2002)].

Mechanisms

1. Thought Fusion Inventory [TFI; Wells et al. (2001)]
2. Metacognition Questionnaire [MCQ; Wells & Cartwright-Hatton (2004)]
3. Distress Tolerance Scale [DTS; Simons & Gaher (2005)]

4. Impact of Future Events Scale [IFES; Deeprose et al. (2011)]
5. Brief Core Schema Scale [BCSS; Fowler et al. (2006)]
6. Imaginal Behavior Approach Test (iBAT; Barzilai & Huppert, manuscript in preparation)
7. Self compassion scale - short form [SCS-SF; Babenko & Guo (2019)]

Indices We do not plan to create indices

Analysis Plan

Statistical models We use a pre-test post-test control group design. We will analyze the data using a multilevel ANCOVA design (Bodner & Bliese, 2018; van Breukelen, 2013). Responses will be modeled as ordered logit, using a cumulative link function (McCullagh, 1980). Furthermore, they will be treated within a graded response model IRT approach (Samejima, 2016). A similar approach can be found in Wang and Nydick (Wang & Nydick, 2020).

The model is defined as follows:

$$R_{itq} \sim \text{Ordered-logit}(\phi_{itq}, \kappa) \quad \text{(likelihood)}$$

$$\phi_{itq} = \alpha_q \cdot (\theta_{itq} - \beta_q) \quad \text{(IRT model)}$$

$$\theta_{it} = \gamma_{0i} + t \cdot \tau_i \quad \text{(trait model)}$$

$$\tau_i = \delta_{1i} \cdot C_i \quad \text{(change model)}$$

$$\begin{bmatrix} \gamma_{0i} \\ \delta_{1i} \end{bmatrix} \sim \text{MVNormal}\left(\begin{bmatrix} \bar{\theta} \\ \bar{\tau} \end{bmatrix}, \rho \right) \quad \text{(person effects)}$$

$$\kappa \sim \text{Normal}(0, 1.5) \quad \text{(cutpoints)}$$

$$\bar{\theta} \sim \text{Normal}(0, 0.3) \quad \text{(latent baseline trait)}$$

$$\bar{\tau} \sim \text{Normal}(0, 0.3) \quad \text{(treatment effect on trait)}$$

$$\beta_q \sim \text{Normal}(0, 0.3) \quad \text{(IRT location parameter)}$$

$$\alpha_q \sim \text{Log-Normal}(0, 1) \quad \text{(IRT discrimination parameter)}$$

$$\rho \sim \text{LKJcorr}(2) \quad \text{(correlation matrix)}$$

Where R_{itq} is the response to question q at time t by participant i. And C_i is the condition of participant i (condition will be contrast encoded).

To this base model we will attempt to add gender as a predictor of both the latent trait θ and latent change τ. We will add them each separately, and evaluate them via WAIC (Watanabe, 2010), where the criterion for inclusion is an improvement of at least 10 points in the WAIC.

All estimates will be performed in a Bayesian framework, and when appropriate will use non-centered parameterization.

Hypothesis 1: WET is more effective than control.

The primary outcome is the effect size of WET. The estimand of interest is the treatment effect τ, though we will simulate outcomes to interpret the results. We will run the base model for each of the symptoms and mechanisms measured.

Hypothesis 2: Proposed mechanisms and symptoms change together.

We expect mechanisms of treatment to change at the same rate as the treatment. The lack of such a correlation suggests that there is no causal relationship between mechanism and symptoms. We will investigate this notion by choosing all mechanisms that are found to change, then we will estimate each of these mechanisms within the same model as the OASIS. The only difference being that the trait (θ) and change (τ) parameters of both models will be sampled from the same multivariate normal distribution. This will allow to directly estimate the correlation between the two change scores.

Transformations

We do not plan to transform the data. Time will be zero base encoded (pre-treatment will be coded 0). Category and gender will be contrast encoded.

Inference criteria

We will use a credible interval of 89% (McElreath, 2020). Models will be selected via WAIC (Watanabe, 2010) and PSIS (Vehtari et al., 2021), where the criterion for prefering a model is a relative weight of .9.

Data exclusion	We will treat measurements with a penalty greater than 1 in the WAIC and Pareto k greater than .5 in the PSIS as outliers. If these are relatively few, and we fail to model them, they will be excluded from analysis.
Missing data	All subjects that start the intervention in the first session will be included in the analysis. Missing data will be imputed via Bayesian imputation. We will assume that missining may be affected both by baseline trait levels and by difficulty completing the task (notably, any missingness due to innefectivness of the task can not be estimated in this study).
Exploratory analyses (optional)	We intend to explore the effects of treatment when controlling for treatment adherance as encoded by external judges.

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