Preregistration

Transdiagnostic Written Exposure Therapy: a Randomized Control Trial comparing WET to past and future events

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Study Information

Title	Transdiagnostic Written Exposure Therapy: a Randomized Control Trial comparing WET to past and future events
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). Furthermore, it aims to compare the processes underlying exposure to past vs. future events. The interventions will be tested within an online randomized controlled trial with a trans-diagnostic sample of individuals with high levels of anxiety. 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 as a function of treatment group.

Hypotheses

1. WET is more effective than control in reducing pathological anxiety, in both past and future conditions.
2. Changes in likelihood thought action fusion, and in distress tolerance, will change together with changes in pathological anxiety. This could indicate the possibility that these mechanism serves as mediators, and provide motivation for further studies.
3. Changes in details valence will be larger in congruent conditions
4. Changes in valence of memory details will be related to changes in valence of details in future imagery, and vice versa.

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 three groups:
  - Past WET (past)

  - Future WET (future)
  - Expressive writing (control)

- Furthermore, one third of participants will be randomly assigned to a two week waiting list where symptoms and mechanisms will be measured twice.
- All groups will engage in four sessions of writing and follow-up sessions after one week and three months.
- Symptom measures and mechanisms will be assessed before the first and after the last writing sessions.
- Symptoms will be measured at each writing session. And again at the follow-up sessions.
- Though action fusion will be measured at the follow-up sessions.

Treatment efficacy will be investigated within a pretest-posttest control group design (see below). 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 110:110:50 ratio, with the treatment groups being larger than the control group. Furthermore, participants with low anxiety (4 <= 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 £/hour for participation. Inclusion criteria will include high pathological 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 short 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 autism, 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 diverse sample.
Sample size	Our target sample size is 243 participants. We will attempt to recruit up to 270, assuming that not all will complete the full task.
Stopping rule	We will recruit until we reach our sample size, or until after 6 months from the beginning of the recruitment.

Variables

Manipulated variables	We manipulate the task participants engage in by providing different instructions. • The past group receive instructions to write about a significant memory. • The future group receive instructions to write about their core threats. • The control group receive instructions to write about a daily activity.

Measured variables

Symptoms

1. Pathological 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 Action Fusion questionnaire; broken into moral and likelihood subscales (TAF; Amir et al., 2001)
2. Distress Tolerance Scale (DTS; Simons & Gaher, 2005)
3. Brief Core Schema Scale (BCSS; Fowler et al., 2006)
4. Transdiagnostic Intrusive Imagery Inventory (TIII)
5. Anxiety Control Questionnaire- Revised (ACQ; Brown et al., 2004)
6. State Mindfulness questionnaire (SMS; Tanay & Bernstein, 2013)
7. Five Facet Mindfulness Questionnaire (FFMQ; Baer et al., 2022)
8. White Bear Suppression Inventory (WBSI; Wegner & Zanakos, 1994)
9. Self appraisal illness questionnaire (SAIQ; Marks et al., 2000)
10. Self report insight
11. Self Compassion Scale (SCS; Babenko & Guo, 2019)

Memory Details

We will code the *memory* and *future imagery* narratives provided by the participants at the first session and at the post session according to the Autobiographical Interview standardized coding system (Levine et al., 2002). This produces a valence score for each narrative.

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). Change is modeled as an additive process where changes within the treatment are considered linear.

The model is defined as follows:

$$
\begin{aligned}
R_{itq} &\sim \text{Ordered-logit}(\phi_{itq}, \kappa) && \text{(likelihood)} \\
\phi_{itq} &= \alpha_q \cdot (\theta_{it} - \beta_q) && \text{(IRT model)} \\
\theta_{it} &= -b_{0i} \cdot t \cdot 1_{\{t<0\}} \\
&\quad + b_{1i} \\
&\quad + b_{2i} \cdot \min(t-1,\ 3) \cdot 1_{\{t>0\}} \\
&\quad + b_{3i} \cdot 1_{\{t=5\}} \\
&\quad + b_{4i} \cdot 1_{\{t=6\}} && \text{(change model)} \\
b_{0i} &= \bar{b} + u_{0i} && (\Delta \text{ of waitlist}) \\
b_{1i} &= \bar{b}_{1,\text{condition}} + u_{1i} && (\theta \text{ at baseline}) \\
b_{2i} &= \bar{b}_{2,\text{condition}} + u_{2i} && (\Delta \text{ at intervention}) \\
b_{3i} &= \bar{b}_{3,\text{condition}} + u_{3i} && (\Delta \text{ at FU\_1}) \\
b_{4i} &= \bar{b}_{4,\text{condition}} + u_{4i} && (\Delta \text{ at FU\_2}) \\
\kappa &\sim \text{Normal}(0, 1.5) && \text{(cutpoints)} \\
\beta_q &\sim \text{Normal}(0, 1) && \text{(IRT location)} \\
\alpha_q &\sim \text{Log-Normal}(0, 0.5) && \text{(IRT discrimination)} \\
\bar{b}_{1,\text{condition}} &\sim \text{Normal}(0, 1.5) && (\theta \text{ intercept}) \\
\bar{b}_{[0,2,3,4],\text{condition}} &\sim \text{Normal}(0, 0.5) && (\theta \text{ slopes}) \\
\sigma_{0\ldots4} &\sim \text{Exponential}(1) && \text{(scale for } u) \\
\rho &\sim \text{LKJcorr}(5) && \text{(correlation matrix)} \\
\Sigma &= \text{diag}(\sigma_{0\ldots4}) \cdot \rho \cdot \text{diag}(\sigma_{0\ldots4}) && \text{(covariance matrix)} \\
\begin{bmatrix} u_{0i} \\ u_{1i} \\ u_{2i} \\ u_{3i} \\ u_{4i} \end{bmatrix} &\sim \text{MVNormal}\left(\begin{bmatrix} 0 \\ 0 \\ 0 \\ 0 \\ 0 \end{bmatrix}, \Sigma \right) && \text{(person effects)}
\end{aligned}
$$

Where R_{itq} is the response to question q at time t by participant i. And *condition* is the condition of the participant. Time is coded so that the baseline is 0 and waitlist are negative.

We will evaluate models 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 estimands of interest are the treatment effects at followup vs. the effect at waitlist.

- $\Delta_0 = 2 \cdot \bar{b_0}$
- $\Delta_{1,condition} = 3 \cdot \bar{b}_{2,\text{condition}} + \bar{b}_{3,\text{condition}}$
- $\Delta_{2,condition} = 3 \cdot \bar{b}_{2,\text{condition}} + \bar{b}_{4,\text{condition}}$

We will report the combined effect of the active treatments vs. the control. Our main outcome is OASIS, though we will explore the outcome of running the model for each of the symptoms and mechanisms measured.

- We expect the effect of both treatments to be better than wait list ($\Delta_{1,treatment} > \Delta_0$).
- We expect no difference between the treatment groups ($\Delta_{1..2,past} \approx \Delta_{1..2,future}$.
- We expect treatments (combined) to be better than control $\Delta_{1..2,treatment} > \Delta_{1..2,control}$.

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 estimating each of these mechanisms within the same model as the OASIS. We will use the same measurement model and link. However, individual change parameters (u) of both models will be sampled from the same multi-variate normal distribution (Baldwin et al., 2014; Suvak et al., 2009). This will allow to directly estimate the correlation between the two change scores. In particular, we hypothesis the posterior correlation between the individual change parameters of the OASIS and mechanisms will be greater than one. This hypothesis applies in particular to TAF-likelihood and DTS, the correlation for the other mechanisms will be explored.

Hypothesis 3: Changes in details valence will be larger in congruent conditions

- We expect the valence of memory details to change more in the WET past condition than the WET future condition.
- We expect the valence of future imagery details to change more in the WET future condition than the WET past condition.

Hypothesis 4: Changes in valence of memory details will be related to changes in valence of details in future imagery, and vice versa.

For Hypothesis 3 and 4, we will replace the IRT model with the simple sum score.

Transformations We do not plan to transform the data. Time will be zero base encoded (pre-treatment will be coded as negative).

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. However, we will exclude any individual that clearly did not participate in the task, for example: individuals that wrote gibberish or text that clearly did not relate to the task.

Missing data will be imputed via Bayesian imputation. We will assume that missingness 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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