PROTOCOL TITLE:

A Randomized Controlled Trial of an Exposure-Based Intervention for Perfectionism

PRINCIPAL INVESTIGATOR:

Sarah A. Redden
Department of Psychology
redden@psy.fsu.edu

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	5/15/22	Changes to consent based on feedback from IRB	Yes
2	5/24/22	Increase sample size, increase number of intervention sessions, and change STICSA to GAD-7	Yes

Table of Contents

1.0 Study Summary

Study Title	A Randomized Controlled Trial of an Exposure-Based Intervention for Perfectionism
Study Design	Randomized Intervention Trial
Primary Objective	Evaluate the efficacy of an exposure-based intervention for perfectionism.
Secondary Objective(s)	Evaluate the effect of the intervention on depressive, anxiety, and eating disorder symptoms.
Research Intervention(s)	Exposure-Based Intervention for Perfectionism (see details below)
Study Population	FSU student subject pool participants and community participants
Sample Size	84
Study Duration for individual participants	6 weeks
Study Specific Abbreviations/ Definitions	Exposure-based intervention for perfectionism (ETP)

2.0 Objectives*

2.1 The purpose of this study is to test the efficacy of an exposure-based intervention for perfectionism. The aims of the study include:

- Evaluating whether a short-term computerized intervention can decrease perfectionism symptomatology (as measured by the Frost Multidimensional Perfectionism Scale (FMPS)).
- Seeing if this intervention also decreases levels of anxiety, depression, and symptoms of eating disorders.

2.2 We hypothesize that the exposure-based intervention for perfectionism (ETP) group will have significantly lower levels of perfectionism than the stress management group at post-test and follow-up. We also hypothesize that the ETP group will have decreased levels of anxiety, depression, and eating disorder symptoms at post-test and follow-up than those in the stress management group, after controlling for baseline scores.

3.0 Background*

3.1 Perfectionism is a transdiagnostic concept that has been conceptualized as multidimensional. Frost et al. (1990) indicated that there were five dimensions of perfectionism including (1) concern over mistakes, (2) personal standards, (3) doubts about actions, (4) parental expectations, (5) parental criticism, and (6) organization. Similarly, Hewitt and Flett (1990) also reported that perfectionism is multidimensional and includes self-oriented, other-oriented, and socially prescribed perfectionism. A recent review of these conceptualizations showed that they continue to be accurate and relevant (Smith et al., in press).

Perfectionism has been associated with depression, anxiety, eating disorders, obsessive-compulsive disorder, and personality disorders, making it a transdiagnostic concept (Dimaggio et al., 2015; Egan et al., 2011; Fairburn et al., 2003; Limburg et al., 2017). Perfectionism is an important target for intervention as it spans many different disorders and has a negative impact on intervention outcome. Higher levels of perfectionism have been found in individuals with anorexia or bulimia nervosa than in controls (Sassaroli et al., 2008). Bardone-Cone et al. (2007) suggested that repeatedly attempting to hide mistakes may lead those high in perfectionism to develop an eating disorder.

In addition, poor intervention response has been predicted by high levels of perfectionism (Bizuel et al., 2001; Blatt, 1995; Blatt et al., 1998; Elkin et al., 1989; Shahar et al., 2004; Zuroff et al., 2000). More specifically, Blatt (1995) found that heightened perfectionism interfered with intervention for depression. In those with anorexia nervosa, perfectionism contributed to intervention resistance, drop out, and relapse (Bastani et al., 1995; Sutandar-Pinnock et al., 2003).

Several interventions for maladaptive perfectionism have been developed, including face to face and self-guided interventions. Cognitive behavioral therapy (CBT) has been the most commonly evaluated intervention for perfectionism thus far. A recent meta-analysis reviewed the efficacy of cognitive behavioral therapy (CBT) for perfectionism, including 15 randomized-controlled trials

that included waitlist, placebo, and active control groups (Galloway et al., 2021). They found that CBT for perfectionism is efficacious with medium to large effect sizes reported for personal standards, concern over mistakes, and clinical perfectionism. Furthermore, medium effect sizes were reported for eating disorders and depression, and small-medium effect sizes were reported for anxiety. Additionally, a meta-analytic review of perfectionism intervention research had similar findings including significant reductions in perfectionism when compared to waitlist, general stress management, self-help, and a CBT-based general psychology group (Suh et al., 2019). Lloyd et al. (2015) also completed a meta-analytic examination of CBT for perfectionism and found that CBT, both in person and online, outperformed waitlist, self-help, and stress management control conditions with medium to large effect sizes. Decreases in depression and anxiety were also found post-intervention (Lloyd et al., 2015; Suh et al., 2019).

Though exposures have been used within cognitive behavioral therapy, only one intervention study thus far has focused on an intervention focusing completely on exposures (Redden & Cougle, under review). The exposure-based intervention for perfectionism (ETP) included several tasks designed to elicit accidental and intentional mistake-making to target elevated levels of concern over mistakes. These tasks were completed by undergraduate participants during five intervention sessions for two weeks (one session every three days). Compared to waitlist, ETP significantly decreased levels of overall perfectionism, concern over mistakes, levels of depression and social anxiety, and eating disorder symptoms. Effect sizes were comparable to previously evaluated longer interventions (e.g., 6 to 12 weeks of cognitive behavioral therapy for perfectionism).

3.2 The knowledge gained from this study will add to the existing literature by obtaining information about a computerized intervention for perfectionism. We would like to further research on ETP by comparing it to a stress management condition and observing if the effects remain one month after the intervention has been completed.

4.0 Study Endpoints*

4.1 The primary endpoint will be scores from the Frost Multi-Dimensional Perfectionism Scale (FMPS)- Concern Over Mistakes Subscale at post-test. We will evaluate pre vs. post differences. The secondary endpoint will include scores from the Center for Epidemiological Studies Depression Scale (CES-D), the Generalized Anxiety Disorder-7 (GAD-7), the Social Phobia Inventory (SPIN), and the ED-15 to see if there are any decreases from pre to post assessment.

4.2 Additionally, we will evaluate post-test versus one month follow-up differences on the above stated measures.

5.0 Study Intervention

5.1 Description: Exposure-Based Perfectionism Intervention (EPT) involves repeated engagement in computerized tasks that instruct participants to purposefully make mistakes. There are three main tasks:

Shape Ordering Task: The first task presents participants with a series of shapes followed by a question asking in which order they saw the shapes. They have 20 seconds to decide in which order the shapes were presented. The task begins by showing three shapes and then

asking their order and increases to eight shapes. Participants automatically advance after the 20 seconds they are given to decided. A feedback screen then appears with correct or incorrect based on their responses.

Spelling Task: Participants are instructed to read a sentence then type the sentence in a textbox below misspelling three words. The screen immediately following displays their sentence with the spelling errors and tells participants to read the sentence. After 10 seconds, they are automatically advanced to a feedback screen that displays "incorrect".

Math Task: Simple math problems (e.g., addition, subtraction, multiplication, and division) are displayed to participants. Some of the math problems include both correct and incorrect answers while others only include incorrect answers, with participants actively choosing an incorrect answer to proceed in the task. For questions with both correct and incorrect answers, a "correct" or "incorrect" screen appears based on their response. For questions with only incorrect answers, a feedback screen appears with "incorrect".

6.0 Procedures Involved*

6.1 The study will be a randomized control design, with 50% of participants receiving the ETP and 50% of subjects receiving the stress management condition.

- The stress management condition will consist of psychoeducational videos about exercise, diet, hygiene, social support, and sleep. This will be followed by relaxing videos of the rainforest, wildlife, or space. This condition is based on previous studies run by our lab, including Cougle et al. (2017).

6.2 Participants will be identified using the mass screening survey distributed to the pool of psychology students maintained by the psychology department (SONA) or using a brief, 3 question screener that includes three questions from the FMPS-CM. Participants who score a 9 or higher on the screener will be invited to participate in the current study and be provided with the study passcode to sign up if they are interested.

Once they sign up, all participants will be emailed a link to the informed consent form, which will be administered using a Qualtrics survey. All participants must first complete the informed consent before beginning other study procedures. After consenting, the participant will be directed to complete the FMPS and questions to assess exclusion criteria. If the participant scores a 28 or lower on the FMPS-CM or do not meet all inclusion, they will be given credit for their time (.5 credits) and the experiment will end.

In addition to student participants recruited via the mass screener and SONA, participants from the community will be provided the opportunity to participate for monetary compensation in the form of Amazon gift cards, which will be sent to them via email. Community participants will be given a link to the informed consent form before beginning study procedures. After consenting, community participants will be directed to complete the FMPS and questions to assess exclusion criteria. If they score lower than 29 on the FMPS-CM or meet any

exclusionary criteria, they will be told they do not qualify for the study and will not be compensated.

If participants meet inclusion criteria, they will be randomized to either the exposure-based perfectionism intervention (ETP) group or the stress management group. Based on that randomization, they will be sent one of two Qualtrics links:

1. Stress Management Condition Qualtrics Link: This link will include questionnaires asking about their perfectionism, mood, and behaviors. A detailed list of questionnaires is provided below. After completing questionnaires, participants will be directed to a screen explaining that they will watch a series of videos educating them on health behaviors, including exercise, diet, sleep, and social support, and will then watch relaxing videos about nature. They will also be informed that they will be asked to click on a link to complete the first session immediately following this video and complete the sessions at home 7 times: 2, 4, 6, 8, 10, 12, and 14 days after the baseline visit. A Qualtrics link to the first session will be provided on the page after this explanation. At the end of the session, they will be directed to a screen reminding them that they will receive Qualtrics links 7 more times over the next two weeks: 2, 4, 6, 8, 12, and 14 days after the baseline visit. They will be instructed to complete each intervention session within 24 hours of receiving the link.

2. ETP Qualtrics Link: This link will include questionnaires asking about their perfectionism, mood, and behaviors. A detailed list of questionnaires is provided below. After completing questionnaires, participants will be directed to a screen providing information about perfectionism and the rationale of the intervention. They will also be informed that they will be asked to click on a link to complete the first intervention session immediately following this video and complete the intervention at home 7 more times: 2, 4, 6, 8, 10, 12, and 14 days after the baseline visit. A Qualtrics link to the first intervention session will be provided on the following page.

They will then complete the first intervention session using the provided link. This will include three tasks, each targeting specific symptoms of perfectionism. Detailed information about the tasks is provided above. At the end of the intervention session, they will be directed to watch a video reminding them that they will receive Qualtrics links 7 more times over the next two weeks: 2, 4, 6, 8, 12, and 14 days after the intervention. They will be instructed to complete each intervention session within 24 hours of receiving the link.

Sixteen days after the baseline visit, participants in both groups will be asked to complete the post-assessment questionnaires via a link that will be sent to them via email. One month after completing the post-test measures, they will be sent the same questionnaires to complete again. SONA participants will receive 3 credits after completing the post-test questionnaires and 1 credit after completing the follow-up questionnaires. Community participants will receive an Amazon gift card via email for $10 after completing the post-test questionnaires and an additional Amazon gift card, delivered via email, for $10 after completing the follow-up questionnaires.

All participants will be debriefed after completing follow-up assessments.

After completing all assessments for the study, participants will be emailed to ask for feedback about the treatment. The text of the email will say:

"We are interested in your feedback on the treatment for perfectionism you received. What were your general impressions of the treatment? Were there parts of the treatment you would change to make it better? If so, what would you recommend?"

They may opt-out or not reply if they choose.

Questionnaires:

Frost Multidimensional Perfectionism Scale (FMPS; Frost et al., 1990)
Credibility and Expectancy Questionnaire (Borkovec & Nau, 1972)
Center for Epidemiological Studies Depression Scale (CES-D; Radloff, 1977)
Social Phobia Index (SPIN; Connor et al., 2000)
Generalized Anxiety Disorder-7 (GAD-7; Spitzer et al., 2006)
ED-15 (Tatham et al., 2015)
Irrational Procrastination Scale (IPS; Steel, 2010)
Massachusetts General Hospital Hair Pulling Scale (MGH-HPS; Keuthen et al., 1995)
Skin Picking Scale Revised (SPS-R; Snorrason et al., 2012)

6.3

- Participants who have previously completed ETP reported no adverse effects (Redden & Cougle, under review).
- To lessen the risks, participants will be explained what the conditions will look like and what the rationale behind it is before engaging in interventions.
- All data collection materials can be found in the appendix of the IRB submission.

6.4 Data collected during the study will be obtained via self-report from subjects. Data will include demographics and self-report questionnaire responses.

7.0 Data and Specimen Banking*

7.1 Data will be kept in password protected files on encrypted computers that only study staff will have access to.

7.2 The data stored will include demographics and all responses to self-report questionnaires. Subjects will be assigned an ID number. Data will not be linked to participants' names.

8.0 Sharing of Results with Subjects*

8.1 Individual or study results will not be shared with subjects directly.

9.0 Study Timelines*

9.1 Subjects will be in the study for 6 weeks total. We anticipate 1 year to enroll all study subjects.

10.0 Subject Population*

10.1 Individuals (ages 18-65) from the psychology subject pool and the community will be recruited for the study.

10.2 The subject population will consist of individuals with high levels of perfectionism (based on scores on the Frost Multidimensional Perfectionism Scale). Subjects must be between the ages of 18 and 65 and score at least a 29 on the FMPS-CM. Exclusion criteria include currently being in psychotherapy and any changes to psychotropic medications in the past 4 weeks.

10.3 We will exclude the following populations:

- Adults unable to consent
- Individuals who are not yet adults (infants, children, teenagers)
- Prisoners

11.0 Vulnerable Populations*

N/A

12.0 Local Number of Subjects

12.1 84 subjects will be recruited, with 42 in the ETP group and 42 in the stress management group.

13.0 Recruitment Methods

13.1 Subjects will be recruited at Florida State University using the psychology subject pool and through the community using flyers and online advertisements.

13.2 Subjects will be identified using the mass screening survey. They may also respond to the posting on SONA, a flyer, or an online advertisement.

13.3 Questions from the FMPS will be used on the mass screening survey in order to recruit subjects. Study slots will be posted on SONA, which potential subjects can see if they are eligible to sign up for.

14.0 Withdrawal of Subjects*

14.1 Subjects may be withdrawn from the study without their consent if a risk arises that could harm the participant or others. For example, if a subject discloses intent to harm themselves or others, they may be withdrawn from the study.

14.2 When subjects withdraw from the research before the completion of the study, we will ask if they are willing to complete the post-test assessment.

15.0 Risks to Subjects*

15.1 The risks to human subjects in the proposed study are minimal. Nevertheless, precautions will be taken to minimize participants' risk in the study. All individuals will be informed of the nature of the investigation and the types of assessments and procedures. Participants will be given an opportunity to have any questions answered to their satisfaction and then will be asked to sign an informed consent statement prior to participating in the project. The specific potential risks involved in the proposed investigation are enumerated below.

Self-report measures:

There are no foreseeable risks associated with these assessment procedures. While some participants may be hesitant to answer the assessment forms, others may derive benefit from the self-assessment as it could increase their awareness of the relationship between their symptoms and environmental, cognitive, and interpersonal factors. In addition, referrals to appropriate clinical services (e.g., ABHC, FSU Psychology Clinic) will be provided for any participants seeking intervention after the study. Phone numbers for these clinical services will be provided within the debriefing form, which will be available for participants to read on Qualtrics after completing the follow-up questionnaires.

Intervention risks:

The perfectionism intervention is exposure-based, which means that it is expected to involve some discomfort for the subject. The intervention may lead to distress for subjects. They are told that they may feel psychologically uncomfortable, but that it is expected during this intervention. Participants will be able to stop intervention at any time. The benefits of exposure-based interventions have shown that though anxiety-provoking, the distress is temporary and there is often symptom-relief both in the short and long-term. For the stress management condition, similar tasks have been used in previous research (Cougle et al., 2017; Smith et al., 2018; Smith et al., 2019) and are very unlikely to cause any significant distress or discomfort.

General Protection Against Risks:

At their request, participants will be referred to clinicians with whom they may speak about their discomfort or distress.

Safeguards for maintaining confidentiality:

The confidentiality of all participants in this study will be maintained. Each participant will be assigned an Identification Code with which all questionnaires will be labeled. This Identification Code will be used as the participant's username for the study website. The information from the website will be secure and only accessible to study personnel. All answers to the participants' questions will be identified by the code number. Names will not appear on any of the results. No individual responses will be reported in any publications. All project staff and participants will be well informed about regulations pertaining to confidentiality. The link between subject and identification number will be destroyed following completion of the study. No records or assessment information will be released to any other person. No audio or videotapes will be used.

Safeguards for maintaining patient safety: Persons who express high risk symptomatology (e.g., suicidal ideation or other forms of serious threat to themselves or others) at any time they are in contact with the study personnel will receive ethically and legally appropriate courses of action. This would include assessment of seriousness of danger or disablement and referral for immediate crisis management (e.g., hotlines, crisis centers, hospitals, or contacting emergency psychiatric teams or police if necessary). Study personnel who have direct contact with study participants (e.g., scheduling staff) will be trained in methods of crisis

management. A detailed step-by-step protocol will be available for dealing with such crises (see uploaded suicide risk procedures form).

In view of the safeguards detailed above, the possibility of a medical or psychological incident arising is remote.

15.2 This is a new intervention and thus may have unforeseeable risks.

16.0 Potential Benefits to Subjects*

16.1 Potential individual benefits to subjects include decreasing their levels of perfectionism and/or decreasing levels of depression, anxiety, or eating disorder symptomatology.

17.0 Data Management* and Confidentiality

17.1 The data analysis plan begins with univariate and multivariate outliers being identified and transformed via Winsorization (Tukey & McLaughlin, 1963). Skewness and kurtosis will also be evaluated. Baseline differences between groups will then be identified using Chi-squared tests and independent samples t-tests. To analyze main outcomes, hierarchical intent-to-treat regression models will be used. These models will control for baseline variables. Multiple imputation using 20 iterations will be used to account for missing data. Effect sizes will be calculated using R^2 change values and were interpreted using Cohen's guidelines: small = .01, medium = .09, large = .25 (Cohen, 1988).

Secondary analyses include intervention response on measures of depression, trait anxiety, social anxiety, and eating disorder symptoms. Baseline values will be covaried in the regression models.

17.2 The data will be password protected on an encrypted computer only accessible by the research team. All identifying information will be removed and subjects will be referred to by ID numbers. Consent forms that include subjects' names will be stored on an encrypted computer only accessible to the research staff.

17.3 How data will be handled:

- Information in the data will include an ID number, demographics and all self-report assessment responses.
- Data will be stored in password-protected files on an encrypted computer that only the study team has access to.
- Data will be stored for a minimum of 4 years after study completion.
- Only members of the study team (i.e., those listed on the IRB submission) will have access to the data.
- The investigator is responsible for receipt or transmission of the data.
- If data needs to be transported, it will be done via password protected files on encrypted computers.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

N/A

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1 To protect subjects' privacy interests, all study information will only be available for members of the research team. All data will be identified by using an ID number and not subjects' names.

19.2 To make sure that subjects feel at ease with the research situation we will encourage them to ask questions both during the consent process and afterward. We will tell subjects that they are free to refuse to answer any question without penalty. We will explain the risks of the study and inform them in advance that the intervention may be uncomfortable, but that they are able to stop it at any time.

20.0 Compensation for Research-Related Injury

N/A

21.0 Economic Burden to Subjects

21.1 Subjects will not be responsible for any research-related costs.

22.0 Consent Process

22.1 We will be obtaining written informed consent*:*

- The consent process will take place online via Qualtrics.
- Subjects will be given contact information for study personnel in order to ask questions about the study before clicking that they consent to participating. Participants will be reassured that they are able to discontinue the study at any time without penalty.
- We will be following SOP: Informed Consent Process for Research (HRP-090).
- Participants will be presented with a screen in which they can choose to download a copy of the consent form after signing it.

Non-English-Speaking Subjects

N/A

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)

N/A

Subjects who are not yet adults (infants, children, teenagers)

N/A

Impaired Adults

N/A

Adults Unable to Consent

N/A

Adults Unable to Consent

N/A

23.0 Process to Document Consent in Writing

23.1 We will be following SOP: Written Documentation of Consent (HRP-091). Consent forms can be downloaded from Qualtrics after completion and will be kept on the encrypted Cougle lab drive.

24.0 Setting

24.1 All baseline questionnaires and procedures, intervention sessions, post-test questionnaires, and follow-up questionnaires will take place outside of the lab online via Qualtrics.

25.0 Resources Available

25.1

- A power analysis based on multiple regression was conducted. The results of this power analysis gave a total sample size of 68 subjects (34 subjects per group). We will recruit up to 80 participants to account for potential drop-out.
- The time devoted to this study will last about 1.5 years.
- Baseline, post-test, and follow-up assessments will take place online via Qualtrics.
- The study team will be thoroughly trained by the investigator before the study begins. We will meet with them individually and review the protocol and consent form. We will provide them with a checklist detailing the steps involved in the study.

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