An Exposure-Based Treatment for Perfectionism

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PROTOCOL TITLE:

An Exposure-Based Treatment for Perfectionism

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	7/11/19	Additional treatment task added and addition of community sample	No
2	7/30/19	Change in inclusion criteria and addition of behavioral tasks	Yes
3	9/12/19	Change in exclusion criteria, sample size, and questionnaires	Yes
4	7/17/20	Adapt study to be administered online, add study personnel, increase sample size	Yes
5	10/28/20	Change in cutoff for contacting people from mass screener for recruitment and addition of SONA screener for recruitment	No

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1.0 Study Summary

Study Title	An Exposure-Based Treatment for Perfectionism
Study Design	Randomized Intervention Trial
Primary Objective	Evaluate the efficacy of an exposure-based treatment for perfectionism.
Secondary Objective(s)	Evaluate the effect of the treatment on depressive, anxiety, obsessive-compulsive, and eating disorder symptoms.
Research Intervention(s)	Exposure-Based Treatment for Perfectionism (see details below)
Study Population	FSU student subject pool participants and participants from the community
Sample Size	80
Study Duration for individual participants	2 weeks
Study Specific Abbreviations/ Definitions	Exposure-based perfectionism treatment (EPT)

2.0 Objectives*

2.1 The purpose of this study is to test the efficacy of an exposure-based treatment 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 and depression, and possibly other symptoms related to obsessive-compulsive disorder (OCD) and eating disorders.

2.2 We hypothesize that the intervention group will have significantly lower levels of perfectionism symptoms than the wait-list control group at post-test. We also hypothesize that the intervention group will have decreased levels of anxiety and depression at post-test than those in the wait-list control group, after controlling for baseline scores.

3.0 Background*

3.1 Perfectionism can be defined as refusing to accept standards less than perfection, or the state of being flawless, sometimes leading to distress and functional impairment (Mirriam-Webster, 1993). The three-component conceptualization was described by Hewitt & Flett (1991) as being self-oriented, being self-critical and holding very high personal standards; socially-oriented, believing that others have incredibly high standards for them; or other-oriented, having extremely high standards of other people. Frost et al. (1990) developed a dimensional model of perfectionism with six parts: (1) excessive concern over mistakes; (2) excessive high personal standards; (3) high parental expectations; (4) parental criticism; (5) exaggerated emphasis on precision, order, and organization; and (6) doubts about actions. The concern over mistakes (CM) dimension is characterized by perceiving errors, even if they are minor, as failure. This can lead to problems like excessive checking, procrastination, reassurance seeking, and distress (Shafran & Mansell, 2001).

The construct of perfectionism can be conceptualized as transdiagnostic with a presence in many disorders, such as obsessive-compulsive disorder, social anxiety disorder, eating disorders, personality disorders, and depression (Egan et al., 2011; Dimaggio et al., 2015). Several studies have reported poorer treatment outcome due to perfectionism (E.g., Elkin et al., 1989; Blatt et al., 1995; Blatt et al., 1998; Zuroff et al., 2000, Shahar et al., 2004; Bizuel et al., 2001). Perfectionism is an important target for treatment as it spans many different disorders and has a negative impact on treatment outcome.

Few treatments have been studied for perfectionism; however, more recently it has gained attention. A mindfulness-based cognitive approach was compared to behavioral self-help for perfectionism by James & Rimes (2017). Participants

were university students high in perfectionism who were randomized to receive either the mindfulness-based cognitive therapy or the CBT self-help therapy. Those in the mindfulness-based cognitive therapy group had significantly lower levels of perfectionism and stress than those in the CBT self-help therapy group. Handley et al. (2015) investigated the effects of group CBT for perfectionism versus wait-list control. Participants who partook in the group CBT had decreased perfectionism as well as reductions in symptoms of anxiety and depression. They also reported increased self-esteem and quality of life. Shafran and colleagues (2017) completed a replication study of a randomized controlled trial of guided internet-based CBT for the treatment of perfectionism, first performed in Sweden. Both studies found significant effects of the treatment on perfectionism, including on the concern over mistakes subscale of the Frost Multidimensional Perfectionism Scale. Another web-based CBT study found significant changes from pre to post-test for perfectionistic concern over mistakes (Radhu et al., 2012).

Exposure therapy is when one is repeatedly exposed to anxiety-provoking stimuli or a feared situation in order to habituate to it so that it no longer leads to significant distress. Though behavioral experiments are described as part of the treatment presented in *When Perfect Isn't Good Enough*, no formal evaluations of pure exposure-based therapy have been conducted to date. This study will expand on the treatment literature in an area that is lacking information. The aim of this study is to develop a novel treatment for perfectionism.

Therapies for many disorders that are associated with those high in perfectionism include an exposure component. An exposure target of perfectionism specifically, however, has not been evaluated.

3.2 The knowledge gained from this study would add to the existing literature by obtaining information about a potential new computerized treatment for perfectionism. We would like to use an exposure-based intervention because exposure-based treatments have proved beneficial for several disorders, including social anxiety disorder, obsessive-compulsive disorder, and eating disorders (E.g., Bulik et al., 1998; Foa et al, 2005; Rodebaugh et al., 2004), all of which are disorders that overlap with perfectionism (Egan et al., 2011).

4.0 Study Endpoints*

4.1 The primary endpoint will be scores from the Frost Multi-Dimensional Perfectionism Scale (FMPS)- Concern Over Mistakes Subscale. We will evaluate pre vs post differences. The secondary endpoint will include scores from the Center for Epidemiological Studies Depression Scale (CES-DS), the State-Trait Inventory for Cognitive and Somatic Anxiety (STICSA), the Social Phobia Inventory (SPIN), Eating Attitudes Test (EAT-26), Error Sensitivity Index (ESI), and the Obsessive-Compulsive Inventory- Revised

(OCI-R) to see if there were any decreases from pre to post assessment. An additional secondary endpoint will be group differences on the behavioral tasks.

5.0 Study Intervention

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

Misspelling Task: Participants will be presented with a phrase or a short sentence and be asked to copy that in the text box below. They will also be instructed to spell at least three words wrong in the sentence and then review the text as a whole after making the spelling errors. After they finish, they will click the next button and be given feedback stating that they copied the phrase or sentence incorrectly. This sequence will be repeated using different phrases or sentences, lasting approximately ten minutes total.

Simple Math Task: Subjects are presented with a simple math problem (e.g., 5+5) and told to select the answer from the choices below within a 20 second time limit. The response options only include incorrect answers. After selecting a response, a feedback screen will appear stating that their response was incorrect. This sequence will be repeated with different simple math problems (addition, subtraction, multiplication, and division) for a total of approximately 10 minutes.

Shape Ordering Task: Subjects will be presented with a series of eight shapes, each shape lasting 1 second on screen, and be instructed to recall the order in which they were presented after viewing. Participants will be given 20 seconds to decide the order in which they think the shapes are presented before being automatically advanced to the next trial. After each trial they will be given feedback stating that their response was incorrect.

Distress Ratings: Before subjects begin the tasks and after the tasks end, participants will be asked to rate their current and peak levels of distress and frustration. Additionally, participants will rate characteristics of their perfectionism (using questions from the FMPS-CM) before and after the tasks.

6.0 Procedures Involved*

6.1 The study will be a randomized wait-list control design, with 50% of subjects receiving the intervention and 50% of subjects being on the wait-list.

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 8 or higher on the screener will be invited to participate in the current study and provided with the study passcode to sign up if they are interested. Additionally, an optional pre-screener not associated with research credit on SONA that includes the same three question screener that is used in the mass screener (3 items from the FMPS-CM) will be available for individuals who would like to participate in the study.

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. If the participant scores a 29 or lower on the FMPS-CM, they will be given credit for their time (.5 credits) and the experiment will end.

If they score a 29 or above on the FMPS, they will be emailed a link to a HIPAA-Compliant Zoom session scheduled for the appointment time for which they signed up on SONA. The HIPAA-Compliant Zoom meeting with have a waiting room and will be password protected. Participants will be directed to click on the HIPAA-Compliant Zoom link at the time in which their appointment starts. A member of the study team will administer the MINI International Neuropsychiatric Interview (MINI) and the Structured Clinical Interview for the DSM-IV (SCID) Cluster C Personality Disorders Modules via HIPAA-Compliant Zoom. Participants who do not meet inclusion criteria based on this clinical interview will be given .5 credits for their time and the experiment will end.

If participants meet inclusion criteria, they will be randomized to either the intervention group or the wait-list control group. 50% of subjects will be randomized to the treatment group and 50% of subjects will be randomized to the wait list group. Based on that randomization, they will be sent one to two Qualtrics links:

1. Wait List 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 informed that they have been assigned to the wait list control group. They will be asked to complete the post-assessment questionnaires via a link that will be sent to them via email at the start of their post-assessment appointment time, which they signed up for on SONA. Additionally, they will be asked to refrain from seeking treatment for perfectionism for the duration of the study.

2. Intervention 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 watch a pre-recorded video with study personnel 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 4 times: 3, 6, 9, and 12 days after the baseline visit. A Qualtrics link to the first treatment session will be provided on the page after the video.

Those in the intervention group will then complete the first treatment 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 treatment session, they will be directed to watch a video reminding them that they will receive Qualtrics links 4 times over the next two weeks: 3, 6, 9, and 12 days after the treatment. They will be instructed to complete each treatment session within 24 hours of receiving the link.

The first session will last approximately 45 minutes for those assigned to the wait list and 1 hour and 15 minutes for those assigned to the intervention.

Two weeks later, subjects will receive a Qualtrics link for the post-test assessment, in which the following will occur:

- The participants will be asked to complete questionnaires about their perfectionism, mood, and behaviors.
- Subjects will be debriefed.

Questionnaires:

Frost Multidimensional Perfectionism Scale (FMPS)
MINI International Neuropsychiatric Interview (MINI)
Structured Clinical Interview for the DSM-IV (SCID) Cluster C Personality Disorder Modules
Eating Attitudes Test (EAT-26)
Center for Epidemiological Studies Depression Scale (CES-DS)
Social Phobia Index (SPIN)
State-Trait Inventory for Cognitive and Somatic Anxiety (STICSA)
Obsessive-Compulsive Inventory- Revised (OCI-R)
Error Sensitivity Index (ESI)

6.3

- To lessen the risks, participants will be explained what the treatment will look like and what the rationale behind it is before engaging in the intervention.
- 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, information from a clinical interview, 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, information from the clinical interview, 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 2 weeks total, with two visits online. We anticipate 1.5 years to enroll all study subjects.

10.0 Subject Population*

10.1 Students (ages 18-65) from the psychology subject pool will be recruited for the study. Additionally, participants from 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. The FMPS cutoff score of 29 was chosen based on Shafran et al., 2017. Exclusion criteria include currently being in psychotherapy, had any changes to psychotropic medications in the past 4 weeks, current or past psychotic disorder or bipolar disorder, or current moderate or severe substance use disorder.

10.3 We will exclude the following populations:

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

11.0 Vulnerable Populations*

N/A

12.0 Local Number of Subjects

12.1 80 subjects will be recruited, with 40 in the intervention group and 40 in the wait-list control group.

13.0 Recruitment Methods

13.1 Subjects will be recruited at Florida State University using the psychology subject pool and members of the community will be recruited using referrals from care providers and/or flyers.

13.2 Subjects will be identified using the mass screening survey. They may also respond to the posting on SONA. Community participants will be identified if they respond to care provider referrals or flyers.

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. If people from the community reach out based on a referral or a flyer, they will be eligible to sign up for a screening in which they complete the FMPS.

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 treatment after the study.

Intervention risks:

The perfectionism treatment is exposure-based, which means that it is expected to involve some discomfort for the subject. The treatment may lead to distress for subjects. They are told that they may feel psychologically uncomfortable, but that it is expected during this treatment. Participants will be able to stop treatment at any time. The benefits of exposure-based treatments have shown that though anxiety-provoking, the distress is temporary and there is often symptom-relief both in the short and long-term.

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. Upon arrival at the experimental session, 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 the 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. Furthermore, all responses will be kept in a filing cabinet in the Cougle Laboratory. The data will be coded and kept in a file behind the locked doors of the laboratory. 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., laboratory assessors,

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. In the highly unlikely event that accidental injury occurs in the laboratory, the participant will be aided in contacting a physician for emergent care (to be paid for by the participant).

15.2 This is a new treatment 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 or anxiety symptomatology.

17.0 Data Management* and Confidentiality

17.1 The data analysis plan begins with conducting one-way ANOVAs to assess for baseline group differences. To measure main effects of condition we will use intent-to-treat multiple 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 separately in a locked filing cabinet in a locked room only accessible to the research staff.

17.3 How data will be handled:

- Information in the data will include an ID number, demographics, information from the clinical interview, 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 be 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).

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).

24.0 Setting

24.1 The research team will be based in Dr. Jesse Cougle's research suite in the psychology building (Room A419). All baseline and post-test research procedures will be conducted in the lab. The computerized intervention will be conducted by subjects outside of the lab, with the exception of the first treatment session.

25.0 Resources Available

25.1

- A power analysis based on a repeated measures ANOVA was conducted. The results of this power analysis gave a total sample size of 68 subjects (34 subjects per group). In order to account for attrition, the sample size will be increased to 80 (40 subjects per group).
- The time devoted to this study will last about 1.5 years.
- Baseline and Post-Test assessments will take place in Dr. Jesse Cougle's research suite.
- 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. They will observe a session before conducting one by themselves.

26.0 References

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