

PROTOCOL SUMMARY

i. COVER SHEET

Study title: Feasibility and Acceptability of an App-Based Mindfulness Training for Individuals with Eating Disorders

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ii. PURPOSE OF THE STUDY AND BACKGROUND

BACKGROUND

Eating disorders (EDs) include anorexia nervosa (AN) and bulimia nervosa (BN) are serious psychiatric disorders with high comorbidity and one of the highest mortality rates of any psychiatric disorder.^{1,2} EDs chronic and disabling; with most individuals never achieving full remission, even after intensive treatment. Relapse after acute treatment for EDs remain common, with more than half of individuals who present to acute care relapsing within one year after admission.³ Furthermore, readmission to acute care is expensive, costing an average of \$20,817 per person at discharge.⁴ Novel and efficacious relapse prevention interventions for EDs, especially those targeting core mechanisms that maintain EDs, are urgently needed.

A large and diverse body of research⁵⁻⁷ suggests that emotion dysregulation (deficits in the ability to recognize and accept emotions, modulate emotions, and engage in goal-directed behavior while experiencing negative emotions) is a core mechanism in the development and maintenance of EDs. Importantly, emotion dysregulation does not improve with weight restoration,⁸ and emotion dysregulation predicts an increase in eating disorder psychopathology after intensive treatment.⁹ Furthermore, processes related to emotion dysregulation (e.g., comorbidity) are related to relapse in EDs.¹⁰

A particularly effective approach for targeting emotion dysregulation is mindfulness treatment.^{11,12} Mindfulness treatment involves meditation training to foster awareness- and acceptance-based skills for recognizing, tolerating, and responding to negative emotions in adaptive ways. Mindfulness treatment is efficacious across many psychiatric illnesses.¹³ Importantly, mindfulness treatment appears particularly efficacious in preventing relapse (e.g., for depression and substance use disorder^{14 15}) and alters neural systems associated with emotion regulation.¹² Initial findings from our pilot data, and those of colleagues,¹⁶ suggest that

mindfulness treatment for EDs may be promising. Digital treatments (e.g., computerized, web-delivered, app-based) are valuable as they are highly scalable, and address the shortage of specialists providing ED treatment. Importantly, digital mindfulness treatments are feasible and efficacious in other clinical populations.

PURPOSE OF THE STUDY

The objectives of this study are to provide pilot data to inform the development of an app-based mindfulness treatment for EDs, called *Mindful Courage*. We will recruit 50 individuals with EDs. Additionally, participants will receive eight weeks of *Mindful Courage* content, consisting of: (1) six 50-minute long multimedia web module with videos, audio-guided mindfulness practices, and interactive questions, as well as briefer modules with guided meditations; (2) weekly brief phone coaching calls by members of the research team to provide accountability as well as motivational and technical support; (3) 3-4 text reminders per week to engage in the app, (4) additional phone and text contact as needed for participants not engaging in the app, and (5) additional technical support as needed by phone or text.

In this study, we will develop eight weeks of *Mindful Courage* content and assess its acceptability (usability, understandability, and helpfulness) and feasibility (completion of modules).

HYPOTHESES TO BE TESTED

- I. At least 50% of participants will complete the web module and at least 50% of the mini modules
- II. Acceptability outcomes (usability, understandability, and helpfulness) for the modules will be rated each ≥ 3 on 5-point Likert Scale.

iii. CRITERIA FOR SUBJECT SELECTION

TARGET POPULATION AND RECRUITMENT METHODS

The target population will include adults ages 18 years and older who meet diagnostic DSM 5 diagnostic criteria for an eating disorder (AN, BN). Participants will be recruited from the national community (online, through eating disorder treatment centers, flyers).

N= 50

Age: 18+ years

Gender: male or female or non-binary gender identity

Racial and Ethnic Origin: There are no enrollment restrictions based on race or ethnic origin.

Attrition: We expect approximately 20% attrition.

STUDY INCLUSION AND EXCLUSION METHODS

Inclusion:

CRITERION	METHOD OF ASCERTAINMENT
(1) Age 18+ years inclusive	Online pre-screening questionnaire/video-based screening interview
(2) Meet diagnostic DSM 5 diagnostic criteria for an ED (AN, BN)	Online pre-screening questionnaire/video-based screening interview
(3) Can read and write in English	Online pre-screening questionnaire/video-based screening interview
(4) Owns a smartphone	Online pre-screening questionnaire/video-based screening interview
(5) Ability to do video-based Zoom calls	Online pre-screening questionnaire/video-based screening interview
(6) Willing and able to participate in a six-week long research study	Online pre-screening questionnaire/video-based screening interview
(7) Have a private quiet space at home or headphones to complete modules	Online pre-screening questionnaire/video-based screening interview

Exclusion:

CRITERION	METHOD OF ASCERTAINMENT
(1) Recent alcohol or drug dependence	Online pre-screening questionnaire/video-based screening interview
(2) Recent untreated psychotic or bipolar disorder	Online pre-screening questionnaire/video-based screening interview
(3) Current suicidal intent	Video-based screening interview only
(4) Significant cognitive impairment that would impair the ability to use <i>Mindful Courage</i> effectively	Online pre-screening questionnaire/video-based screening interview
(5) BMI <15 or medically unstable	Online pre-screening questionnaire/video-based screening interview

iv. METHODS AND PROCEDURES

STUDY PROCEDURES

Screening Procedures:

Online Pre-Screening Questionnaire

All potential participants will be recruited via advertisement via clinician/treatment center referrals, clinical announcements, email (e.g., alumni network email, current email), social media (e.g., Pwiter, Facebook, Reddit, Google, Instagram), and the research sites lab website.

Participants who are interested will be directed to a website on Qualtrics to determine preliminary eligibility. Electronic informed consent for screening will be obtained at the beginning of the eligibility screen.

The brief survey will include a brief overview of the project and survey questions including name (first name only) and contact information (phone and email), demographics (age, gender, race/ethnicity, height, weight), ED diagnosis (measured via the Eating Disorder Diagnostic Scale, or EDDS), other psychiatric disorders (measured via DSM-5 Self-Rated Level 1 Cross-Cutting Symptom Measure), medical problems, access to devices with Internet connection, and access to a private, quiet space at home to complete the video-based study assessments and web modules. If participants are deemed ineligible based on the pre-screening questionnaire, their name and contact information will be deleted immediately.

Zoom-Based Screening Interview:

If potential participants appear eligible based on their responses to the online pre-screening questionnaire, they will be contacted by phone by a research coordinator to arrange an appointment for the Zoom-based screening interview, which will last approximately 15 minutes. At the beginning of the Zoom-based screening interview, the research coordinator will obtain electronic informed consent. The Zoom-based screening interview will involve interview questions on current BMI, current enrollment in ED treatment, medical problems, alcohol or drug dependence, current bipolar or psychiatric disorder, suicidal ideation/intent/plan, and recent ED diagnosis (measured via the SCID interview ED module). Of note, if a participant endorses ideation, suicidal intent or plan, a risk protocol will be in place such that the research assistant will contact Drs. Roos (Licensed Clinical Psychologist) or Sala (Licensed Clinical Psychologist), who will assess the level of immediate risk and possibility of hospitalization.

If potential participants are eligible for the study based on the screening interview, they will be invited to enroll in the study, and will be invited to proceed to attend the Zoom-based baseline study assessment.

Study Procedures After Enrollment:

Zoom-Based Baseline Study Assessment

The baseline assessments will include trait-level questionnaires, and will last approximately 20 minutes. Trait-level questionnaires will include the Cognitive and Affective Mindfulness Scale-Revised (CAMS-R) to measure trait mindfulness, the Difficulties in Emotion Regulation (DERS) to measure emotion regulation, the positive and negative affect schedule (PANAS) to measure positive and negative affect, the Eating Disorder Examination-Questionnaire (EDE-Q) to measure eating disorder symptoms, and Body Shape Questionnaire (BSQ) to measure body satisfaction, the Savoring Beliefs Inventory (SBI), the General Anxiety Disorder (GAD-7) scale to measure anxiety, the Patient Health Questionnaire (PHQ-9) to measure depression, and the

Clinical Impairment Assessment Questionnaire (CIA) to measure eating disorder impairment. (see Table 1)

Daily EMA Questionnaires: Participants will complete 4 brief assessments per day with 4 surveys randomly administered in four evenly spaced out 90-minute timeblocks occurring between 8am – 8:30pm a week before beginning the app, and a week after the last study visit. EMA will be conducted to assess acceptability and feasibility of EMA with this population, and to understand momentary processes and behaviors.

Zoom-Based Treatment Initiation Visit

Participants will complete another visit where they meet with a research assistant and start using the app. During the visit, they will complete the initial 40-minute digital module with videos, audio-guided mindfulness practices, and interactive questions. Specifically, the module will include a two minutes introduction video, a 4-5 minute audio-guided mindfulness practice, psychoeducation on mindfulness and how it relates to anorexia nervosa recovery, psychoeducation on the a Breathe, Observe, Accept, Take a Moment (BOAT) practice, an 8 minute guided BOAT mindfulness practice, and reflection questions. While participants complete the module, the research coordinator will be available over Zoom to answer any questions. After completing the first module participants will engage in a one-on-one user testing interview session and will complete self-report measures too (see Table 2). The one-on-one user testing interview session will be audio-recorded (with the consent of participants).

Ongoing engagement in the app: After completing the treatment initiation visit, participants will be asked to complete 31 additional digital modules (ranging from 10 to 30 min each) over an 8-week period. They will receive 3-4 weekly text reminders encouraging them to engage in the app. Text reminders will include general reminders and encouraging statements to promote engagement in the app, as well as praise for continued engagement in the app. They will also complete weekly brief phone-coaching calls for motivational and technical support by graduate students from the MEAL lab at Yeshiva University, supervised by Drs. Sala and Roos. The phone check-ins will occur to provide supportive accountability¹⁷ and will involve a safety/clinical check-in (i.e., brief validated suicidality measure), outpatient treatment engagement/enrollment, and a weight check-in.

End of Study Visit: Upon completion of the eight weeks, participants will also complete an acceptability and feasibility questionnaire related to the entire program. Participants will complete follow-up questionnaires and user-testing (see Table 2).

2-month follow-up: At two month follow-up, participants will complete the same baseline assessments that they completed at baseline (see Table 2).

Criteria for study withdrawal: Patients will be withdrawn prematurely from the study for safety reasons if they evidence any urgent medical or mental health issues (e.g., suicidal intent, need for hospitalization, need for more intensive care), as determined by the study investigators.

Table 1. Schedule of Assessments

X	Pre-screen	Baseline Visit	End of Study	2-month Follow-Up
Informed Consent	X			
Demographics and Baseline Questionnaire	X			
DSM-5 Self-Rated Level 1 Cross-Cutting Measure	X			
Eating Disorder Diagnostic Scale (EDDS)	X			
SCID Telephone Interview for AN	X			
Trait-Level Questionnaires				
Cognitive and Affective Mindfulness Scale-Revised (CAMS-R)		X	X	X
Difficulties in Emotion Regulation Short Form (DERS-SF)		X	X	X
Positive and Negative Affect Schedule (PANAS)		X	X	X
Eating Disorder Examination Questionnaire (EDE-Q)		X	X	X
Body Shape Questionnaire (BSQ)		X	X	X
Savoring Beliefs Inventory		X	X	X
General Anxiety Disorder (GAD-7)		X	X	X
Patient Health Questionnaire (PHQ-9)		X	X	X
Clinical Impairment Assessment Questionnaire (CIA)		X	X	X
Acceptability Questionnaire		X	X	X

Table 2. User Testing Measures.

Construct	Measurement Instrument	Baseline Visit	8-week user testing period	End of Study
	Interview-Based Measures			
Interview-Based	<i>Overall, what are your thoughts/impressions after completing the session?</i>	x		

Qualitative Feedback After First Module at Baseline Visit	<i>What did you learn?</i> <i>What parts of the session were most helpful? Least helpful?</i> <i>Did you find the session engaging?</i> <i>Was there anything about the program that felt like a “barrier” or “turn-off” that would make you hesitant about using the app?</i> <i>If you had a magic wand, what would you change about the app?</i> <i>Do you have any concerns about using this app?</i>			
Interview-Based Qualitative Feedback at Post-Testing Visit	<i>In the past two months...</i> <i>What have been the most important things you learned from the app?</i> <i>What aspects of the app have been the most helpful?</i> <i>What aspects of the app have been the least helpful?</i> <i>What is your experience like as you use the app over an extended period of time? Does the program feel too fast or too slow? Is it too repetitive? Is there enough variety in the things you are learning?</i> <i>What would you have liked added to this app?</i> <i>Was there anything about the app that has felt like a “barrier” or “turn-off”?</i> <i>Have you found the app engaging? Why or why not?</i> <i>What would have helped you to engage in the app more?</i> <i>If you had a magic wand, what would you change about the app?</i> <i>Do you have any concerns about using this app?</i>			X
Self-Report Measures				
Construct	Measurement Instrument	Baseline Visit	8-week user testing period	End of Study
Acceptability	Treatment acceptability items based on the theoretical framework of acceptability (TFA) and the System Usability Scale (SUS)	X		X
Willingness to engage in program	<i>I am willing to try out a smartphone app that teaches mindfulness skills for improving one’s recovery</i>	X		
Usability	System Usability Scale (SUS)	X		X
Understandability	<i>The material covered in the session I just completed was clear and understandable (after each module)</i> <i>Overall, the material covered in the program was clear and understandable (at post-program visit)</i>	X	X	X

Engage-ability	<i>The session I just completed did a good job at keeping me engaged as I was going through it (after each module)</i> <i>Overall, the program did a good job at keeping me engaged as I was going through it (at post-program visit)</i>	x	x	X
Appeal of visual content	<i>For the session I just completed, I thought the visual content of the program was appealing and high quality (after module 1)</i> <i>Overall, I thought the visual content of the program was appealing and high quality (at post-program visit)</i>	x		X
Helpfulness	<i>I found the material covered in the session to be helpful for me and my recovery (after each module)</i> <i>Overall, I found the program helpful for me and my recovery (at post-program visit)</i>	x	x	X
Acquisition of skills	<i>I learned valuable skills after completing this session (after each module)</i> <i>Overall, I learned valuable skills after participating in the program (at post-program visit)</i>	x	x	X
Confidence implementing skills	<i>I am confident in my ability to apply these skills in my daily life</i>	x	x	X
Written Qualitative Feedback	<i>Overall, what are your thoughts/impressions after completing the session?</i> <i>What did you learn?</i> <i>What parts of the session were most helpful? Least helpful?</i>		x	

Sample Size Justification:

Given the proof-of-concept and pilot nature of this study, we are limiting the sample size to 40 enrolled individuals.

OUTCOME MEASURES/INSTRUMENTS

- *DSM-5 Self-Rated Level 1 Cross-Cutting Symptoms Measure* – A 23-item self-report questionnaires used to screen for psychiatric disorders. It will be administered at the online pre- screening assessment.
- *Eating Disorder Diagnostic Scale (EDDS)* ¹⁸ – A 22-item self-report questionnaire used to identify eating disorders according to the DSM-5. In the current study, we will only include the items to identify AN. It will be administered at the online pre- screening assessment.

- *Cognitive and Affective Mindfulness Scale-Revised (CAMS-R)* ¹⁹ A 12-item self-report questionnaire measuring trait mindfulness. It will be administered at the baseline, at the end of study, and at the two-month follow-up.
- *Difficulties in Emotion Regulation Short Form (DERS-SF)* ²⁰– A 16-item self-report questionnaire measuring emotion regulation difficulties. It will be administered at the baseline, at the end of study, and at the two-month follow-up.
- *Positive and Negative Affect Schedule (PANAS)* ²¹. A 20-item self-report questionnaire measuring trait positive and negative affect. It will be administered at the baseline, at the end of study, and at the two-month follow-up.
- *Eating Disorder Examination Questionnaire (EDE-Q)* ²² – A 28-item self-report questionnaire which is the self-report version of the Eating Disorder Examination Questionnaire, and measures core features of eating disorders. It will be administered at the baseline, at the end of study, and at the two-month follow-up.
- *Body Shape Questionnaire (BSQ)* ²³– A 34-item questionnaire that measures concerns about body shape. It will be administered at the baseline, at the end of study, and at the two-month follow-up.
- *Acceptability Questionnaire* – Participants will be asked 13 Likert-scale questions and 11 open-ended questions to measure perceived usability, understandability, and helpfulness. It will be administered at the baseline, at the end of study, and at the two-month follow-up.
- *Feasibility* – Engagement with web modules will be tracked by the app program where the modules will be hosted
- *User-Testing* – Participants will complete several user-testing measures at baseline, during weekly online assessments throughout the eight-weeks, and at the end of study visit. See Table 2 above.
- *General Anxiety Disorder-7 (GAD-7)* - A 7-item brief screening measure that tests the severity of one's anxiety symptoms. It will be administered at the baseline, at the end of study, and at the two-month follow-up.
- *Patient Health Questionnaire-9 (PHQ-9)* - A 9-item brief screening measure that tests the severity of one's depressive symptoms. It will be administered at the baseline, at the end of study, and at the two-month follow-up.
- *Clinical Impairment Assessment Questionnaire (CIA)*- A 16-item self-report measure that tests the severity of psychosocial impairment due to eating disorder features. It will be administered at the baseline, at the end of study, and at the two-month follow-up.

DATA ANALYSIS and DATA MONITORING

Descriptive statistics will be used to examine acceptability and feasibility. Open-ended acceptability questions will be analyzed via thematic content analysis, which focuses on grouping together similar patterns within the text and is often used to analyze open-ended survey questions ²⁹.

For exploratory analyses, paired samples t-tests will be conducted to evaluate: changes use of mindfulness skills, positive affect, negative affect, emotion regulation, eating disorder symptoms, body satisfaction, anxiety, depression, and clinical impairment.

DATA STORAGE and CONFIDENTIALITY

- Most of the data entry is computerized (including telephone screening interview data); questionnaires will be administered via Qualtrics survey software
- The app will be hosted on Qualtrics.
- Audio-recordings will contain no identifiable information.

CONFIDENTIALITY

Participant information will be anonymized and stored on a secure, password-protected computer. Only members of the research team will have access to the anonymized database in the future, unless required by law or by an audit of the research ethics board / quality assurance. Only members of the research team will have access to hard copies of data collection forms or information regarding the identity of the participants.

All data collected will be kept confidential and used for professional purposes only. Publications using this data will be conducted in a manner that fully protects participants' anonymity.

v. RISK/BENEFIT ASSESSMENT

RISK CATEGORY

Minimal risk: the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

ANTICIPATED RISKS and PROTECTION AGAINST RISKS

Participants will be asked to describe psychiatric symptoms, which may cause unpleasant feelings (similar to what might be expected from a doctor's visit).

Participants will receive app-based mindfulness training. However, mindfulness meditation is well-established, and is well-tolerated and has minimal risk. Furthermore, at the end of the completion of the web module at the baseline assessment, participants will be invited to share any negative reactions to the program. In addition, participants will be notified on the app at both login and logoff that any feelings or thoughts that concern them should be discussed immediately with their clinician, the research coordinator, Dr. Sala, and/or other co-investigators.

Furthermore, the weekly calls will serve as an opportunity to monitor the participant's clinical status, and ensure identification and withdrawal from the study of participants who show

significant psychological or symptomatic deterioration (and thus may require a higher level of care).

The screening of patients using the inclusion and exclusion criteria will minimize the risk of enrolling participants inappropriate for the study.

Participants will be withdrawn from the study if they show severe psychological or symptomatic deterioration, unacceptable levels of adverse events as determined by the PI or if clinically necessary for ethical or safety purposes. Participants dropped from the study for these reasons or because they wish to withdraw from the study will be referred to a higher level of care, such as an intensive outpatient or inpatient facility, when appropriate. There will be no penalty for withdrawing. For all participants, if an emergent medical or psychiatric issue emerges from any treatment or test given as part of the proposed study, these will be assessed by the investigators and appropriate referral or treatment will be delivered.

POTENTIAL BENEFITS

There are no known specific benefits for participants upon completion of study measures, other than finding the questions potentially interesting.

vi. SUBJECT IDENTIFICATION, RECRUITMENT, and CONSENT/ASSENT

PARTICIPANT RECRUITMENT

- Interested participants will complete a brief online pre-screening questionnaire
- If potential participants are eligible based on their responses to the online pre-screening questionnaire, they will be contacted by the research coordinator to arrange an appointment for a Zoom-based screening interview.
- If potential participants are eligible for the study based on the screening interview, they will be invited to enroll in the study and will be invited to proceed to attend the Zoom-based baseline study assessment.
- To ensure voluntariness of participation; compensation will be appropriate to the time required of participants and will not be so high as to be coercive; participants will be informed in writing and verbally during the informed consent process that they can end their participation at any time without penalty; and participants will be assured that services will not be affected by their decision to participate in the study.
- To ensure participants' privacy, telephone screening interviews will be held in a private location; participants will be assigned a numerical code and all identifying information will be stored in a database separate from the participant data (data will be linked to participants only via the numerical code); and all participant data will be stored on secure, password protected computers accessible only by members of the research team.

INFORMED CONSENT PROCESS and FORMS

- See attached informed consent form.
- Informed consent will be obtained by trained research assistants at the beginning of the Zoom-based screening interview.

SUBJECT COMPREHENSION

Participants will be provided with a written information sheet and will be given an opportunity to ask questions to the researcher.

COMPENSATION

Participants will be paid \$10 for baseline visit, up to \$38 for baseline EMA (\$1 for each of 28 survey, \$10 for completing 75% or more of the phone surveys), \$20 for treatment initiation visit, \$20 for completing all 32 sessions, \$30 for post-intervention visit, up to \$38 for follow-up EMA (\$1 for each of 28 survey, \$10 for completing 75% or more of the phone surveys), and \$40 for follow-up visit

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