

Outcome Evaluation Proposal - The Healthy Minds Program App

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Introduction

In-person mindfulness-based interventions (MBIs) face limitations in accessibility due to factors such as provider scarcity and high costs (Goldberg et al., 2020). Consequently, there has been a shift towards delivering MBIs via smartphone apps (Fairburn & Patel, 2017). However, a significant gap persists in the current landscape: most app-based interventions focus solely on mindfulness training, overlooking constructive or deconstructive practices crucial for enhancing mental health outcomes (Mani et al., 2015). Here, the Healthy Minds Program app (HMP) emerges as a solution, explicitly incorporating training in both constructive and deconstructive practices by utilizing the Awareness, Connection, Insight, and Purpose (ACIP) framework (see Appendix A). Moreover, its free accessibility via smartphones addresses the limitations of in-person interventions.

The purpose of evaluating HMP stems from the need to understand the app's acceptability and effectiveness among people of color, a group historically underrepresented in research. In 2020, the developers/researchers of HMP published a randomized controlled trial (RCT) investigating the effectiveness of the app in improving participants' mental health outcomes such as depression and anxiety (Goldberg et al., 2020). However, they recognized that a limitation of their study was the predominantly White, female, and college-educated sample (Jiwani et al., 2023). Thus, they aim to ensure the app's relevance across diverse communities, especially considering that historically underrepresented groups (e.g., Black and Asian) face an increased risk of racism-related negative psychological and health outcomes (Goldberg et al., 2020). This would also help the developers of the app identify potential modifications to better cater to the specific mental health needs of these communities.

This evaluation study aims to assess how HMP impacts the mental health outcomes of underrepresented groups. Additionally, it seeks to enhance inclusivity, improve the generalizability of research findings, and identify potential modifications to HMP to better cater to the specific mental health needs of these communities. The overarching research question guiding this evaluation study is: To what extent does HMP contribute to reductions in stress, depression, and anxiety among historically underrepresented groups, as assessed through an 8-week RCT, and how do these outcomes compare to the results of a previous RCT primarily involving a White sample?

Program Description

HMP is a free mobile app designed to help individuals cultivate and measure their well-being. The app is designed to be user-friendly, serving individuals who are seeking to enhance their mental health by engaging in simple practices that can be performed at their convenience. To summarize, HMP bridges a gap in existing mindfulness apps by integrating both constructive and deconstructive practices, as well as offering free accessibility via smartphones, thereby addressing limitations of in-person interventions. The evaluation of HMP seeks to understand its effectiveness and acceptability among historically underrepresented groups in research. This includes individuals from diverse backgrounds based on race, ethnicity, socioeconomic status,

and sexual orientation, spanning Black, Hispanic, Asian, Indigenous, LGBTQIA2S+, and those from lower socioeconomic strata. They will also be the ones benefitting from HMP's evaluation because the results of the evaluation will shed light on the program's accessibility and effectiveness in addressing mental health needs of these diverse groups.

The major components of HMP include the unique and scientifically based ACIP framework, and the diversification of HMP's user base. The ACIP framework consists of four essential pillars: Awareness, Connection, Insight, and Purpose. Research suggests that each pillar is intricately linked to specific brain networks that can be nurtured and strengthened through meditation and other forms of mental training. By using this framework, HMP empowers users to develop crucial skills that enhance their overall well-being, fostering a sense of balance and fulfilment in their lives. Another major program component is the diversification of HMP's user base, which the program actively works towards improving after assessing its current limitations.

Recognizing that everyone's journey to well-being is unique, HMP offers a wide range of activities that cater to diverse preferences and lifestyles. The program encourages users to engage with these activities at their own pace, allowing them to take ownership of their well-being journey. Overall, the program activities include users engaging in a range of podcast-style lessons and accompanying practices that aim to strengthen their self-awareness, connection, insight, and purpose. In order to diversify their user base, HMP aims to promote the program to people from different backgrounds through various outreach methods such as sharing information with health clinics and through online platforms.

The program outputs of HMP are multifaceted, encompassing measurable improvements in users' awareness, connection, insight, and purpose. These improvements are quantifiable through various metrics such as: enhanced attentional skills and focus, measured by task completion time and accuracy (awareness); strengthened interpersonal relationships, assessed through measures of trust and satisfaction levels (connection); greater awareness of the transient nature of thoughts and emotions, gauged by mindfulness practice frequency (insight); and improved alignment of actions with personal values, assessed via behavior consistency metrics (purpose). Additionally, a measurable output for the diversification of HMP's user base involves tracking the percentage of individuals from different groups/identities within the user base.

The program outcomes of HMP include both short-term and long-term effects, each contributing to users' overall well-being and the program's efficacy. In the short term, users experience tangible improvements in awareness, connection, insight, and purpose, which manifest as enhanced internal states and more fulfilling relationships with others. In the long term, HMP aims for deeper transformations in users' mental health, reflected by lower levels of anxiety, depression, and stress. These long-term outcomes are a result of sustained improvements across the ACIP domains, indicating a holistic shift towards better mental health. Moreover, as a long-term outcome, HMP strives for a more robust and diverse user base, fostering inclusivity and accessibility for individuals from various backgrounds.

Equity Assessment

In assessing equity for HMP, it is crucial to identify and involve key stakeholders integral to the program's success and impact. Among these stakeholders are Dr. Richard Davidson and his team who are the developers and initial researchers of the HMP app. They play a pivotal role as stakeholders because they have the expertise and authority to make improvements to the app based on insights gained from understanding its effects on the mental health of individuals from historically underrepresented groups. Their involvement in the evaluation process is essential for ensuring that the app remains responsive to the diverse needs of its users. Additionally, funders and donors are significant stakeholders in the evaluation of HMP. Their role as stakeholders lies in their ability to contribute resources for enhancing the app, implementing changes, and adding features to improve accessibility. Engaging with funders and donors in the evaluation process is critical for gaining continued support for HMP and ensuring its sustainability as a tool for promoting mental well-being among diverse populations. Furthermore, health equity and social justice organizations are vital stakeholders in the evaluation study. Collaborating with these organizations allows for a comprehensive examination of disparities in access to mental health care and resources. Their involvement in the evaluation process can help identify areas where HMP can better address the needs of marginalized communities and advocate for systemic changes to improve equity in mental health care. Lastly, it is imperative to contextualize HMP's operation alongside other app-based mental health tools. This comparative analysis is important for assessing equity in access and outcomes across different digital platforms. By understanding how HMP performs in comparison to similar tools, particularly in serving historically marginalized communities, the evaluation can identify areas where HMP excels or falls short in promoting equity. However, engaging with these stakeholders in the evaluation process may be challenging. One potential issue is the differing priorities and interests among stakeholders, which may lead to conflicting perspectives on the evaluation goals and outcomes. Additionally, ensuring meaningful engagement and representation of diverse voices within stakeholder groups can be challenging, requiring constant efforts to address power dynamics and ensure equitable participation.

A culturally responsive framework will be used to help the proposed evaluation study achieve equity. This framework is designed to recognize and appreciate the program's culture and its stakeholders, raising issues of differential service delivery and access attributed to race, gender, socioeconomic status, and power dynamics. It also aims to question underlying assumptions and deficit perspectives held by program personnel about historically marginalized groups. To implement this framework in the proposed evaluation study, several actionable steps will be taken, some of which include: 1) assembling an evaluation team by recruiting individuals with diverse backgrounds and perspectives, including those from historically underrepresented groups, to ensure the evaluation process is inclusive and culturally competent, 2) choosing evaluation instruments that are sensitive to cultural nuances and tailoring them as needed to ensure validity and reliability across diverse populations, and 3) clarifying the goals of the evaluation study, with a specific focus on addressing equity issues and promoting inclusivity within HMP.

Literature Review

The literature review reveals several consistent themes and disparities across smartphone-based mental health interventions like HMP. While mental health apps offer promising avenues for mental health support, particularly through cost-effective and scalable delivery methods, there are significant gaps in representation and access among marginalized communities (Saad et al., 2023). These disparities are reflected in demographic disparities within user bases, with certain groups such as racial and ethnic minorities facing greater barriers to engagement (Jiwani et al., 2023). Additionally, the literature highlights mixed evidence regarding the effectiveness of mental health apps in addressing the mental health needs of diverse populations, indicating a significant gap in the literature (Saad et al., 2023). Despite the potential of digital mental health interventions to cater to the unique needs of marginalized groups, barriers such as technological access, housing instability, and social support limitations persist, hindering equitable utilization of such apps (Schueller et al., 2019). Overall, the literature highlights the importance of understanding and addressing disparities in access and engagement to ensure the effectiveness and inclusivity of smartphone-based mental health interventions (Goldberg et al., 2020).

The proposed evaluation study aims to contribute to the existing literature by investigating the mechanisms through which users may experience improvements in their mental health by using app-based interventions like HMP. By examining how activities through the app strengthen users' awareness, connection, insight, and purpose, the study seeks to provide insights into the underlying processes driving positive mental health outcomes. Moreover, the study will explore strategies for actively diversifying HMP's user base to reach a wider population, thereby addressing disparities in access and engagement identified in the literature.

Methodology

A quantitative study design has been chosen for this evaluation. This choice aligns with the project's aim of measuring the effectiveness of HMP in reducing mental health symptoms of anxiety, depression, and stress among its users, all of which are quantitative measures for the scope of this study. Using a quantitative approach will help conduct a systematic comparison of participants' levels of anxiety, depression, and stress before and after the intervention, providing objective data to assess changes in mental well-being. Additionally, this method will facilitate comparisons between individuals who received the intervention and those who did not, allowing for a robust evaluation of HMP's impact.

Evaluation Design

The proposed study includes conducting an outcome (summative) evaluation using an 8-week RCT with a pretest-posttest control group design. In this study, participants will be randomly assigned to either the intervention group, which receives the HMP app, or the control group, which does not. Pre-intervention assessments will gather baseline data on depression, anxiety, and stress to establish participants' initial levels of psychological distress, which serves as the primary outcome measure. Post-intervention assessments will measure changes in

depression, anxiety, and stress levels following HMP usage, compared to the control group. The pretest-posttest control group design is the most appropriate for addressing the evaluation question because it establishes a cause-effect relationship between HMP usage and changes in participants' psychological distress, thereby assessing the extent to which HMP's objectives are achieved. Moreover, an RCT design ensures that both groups are equivalent except for exposure to the intervention, helping assess whether changes in outcome measures are truly the result of the intervention or occur by chance/group differences. Strengths of this design include its clear interpretation of intervention effects, stakeholder persuasiveness of HMP's effectiveness, assessment of changes over time, and practical feasibility. However, weaknesses include potential high costs, time sensitivity, risk of participant attrition (especially at posttest), and the potential for social desirability bias. Considering the study's outcome-focused nature and the presence of an intervention, alternative designs would be infeasible as they lack the ability to draw robust conclusions about the efficacy of HMP and may not provide the necessary control over confounding variables that could influence the study's outcomes.

Data Collection

The proposed study will use quantitative data collection methods, utilizing surveys administered via REDCap at pretest and posttest. These surveys will serve as self-reports for participants and will be distributed via email, ensuring ease of access and participation. Baseline and posttest data will be collected on anxiety, depression, and stress levels for all participants, regardless of group assignment, to assess changes in psychological distress over time. Posttest assessments will occur at 4 and 8 weeks post-baseline to capture both short-term and longer-term effects of the intervention. Participants will complete a baseline demographic survey, including questions on age, gender, race/ethnicity, education, income, sexual orientation, and prior/current usage of mental health apps (see Appendix B). This information will aid in controlling for demographic factors and prior app usage during data analysis. The independent variable in the study is participation in the HMP program (control or intervention group), while the dependent variables include measures of psychological distress – anxiety, depression, and stress. Participants will be compensated \$25 for completing surveys at each time point to aid with retention. Additionally, participants' HMP app usage will be directly measured through the app, providing objective data on intervention engagement. Standardized scales, including the 8-item Patient-Reported Outcome Measures Information System (PROMIS) Depression and Anxiety Scales for anxiety and depression (see Appendices C & D), and the 10-item Perceived Stress Scale (PSS) for psychological stress (see Appendix E), will be used to assess participants' psychological distress. These scales demonstrate high internal consistency and are widely used in research studies (Goldberg et al., 2020). The eligibility criteria for participants in the study are drawn from a previous RCT on HMP, including individuals from marginalized groups, aged 18 years or older, with access to a smartphone or compatible device for the intervention app, and limited meditation experience (Goldberg et al., 2020). The sampling technique involves convenience sampling within historically underrepresented groups, prioritizing individuals'

availability and accessibility. Recruitment will be conducted through emails, flyers, and outreach to colleges, community organizations, and support groups to encourage individuals from various underrepresented backgrounds to participate. Ethical considerations involve obtaining participants' written consent prior to enrolment in the study, IRB approval to protect participants' rights and welfare, ensuring confidentiality of data, and addressing concerns about withholding HMP intervention from control group participants who may benefit from it.

Data Analysis

The chosen quantitative statistical technique for this study is Repeated Measures Analysis of Variance (ANOVA), primarily due to its ability to analyze changes in outcome measures (anxiety, depression, stress) over time within each group (pretest to posttest) and to compare these changes between the control and intervention groups. This technique is particularly suitable because it involves the same test units being measured multiple times under different conditions (e.g., baseline, and 4- and 8-weeks post baseline). The ANOVA test will assess statistically significant differences in mean outcome scores (anxiety, depression, stress) between the intervention and control groups, with significance determined by the chosen p-value ($p < 0.05$). The analysis will involve performing a repeated-measures ANOVA with one between-subjects factor (treatment and control) and one within-subjects factor (pre- and post-intervention). The interpretation of results from this test will aid in understanding the impact of HMP participation on reducing users' anxiety, depression, and stress compared to the control group. Additionally, the examination of effect size will be crucial to assess the magnitude of observed differences between the intervention and control groups. The data will be analyzed using SPSS.

Dissemination Plan

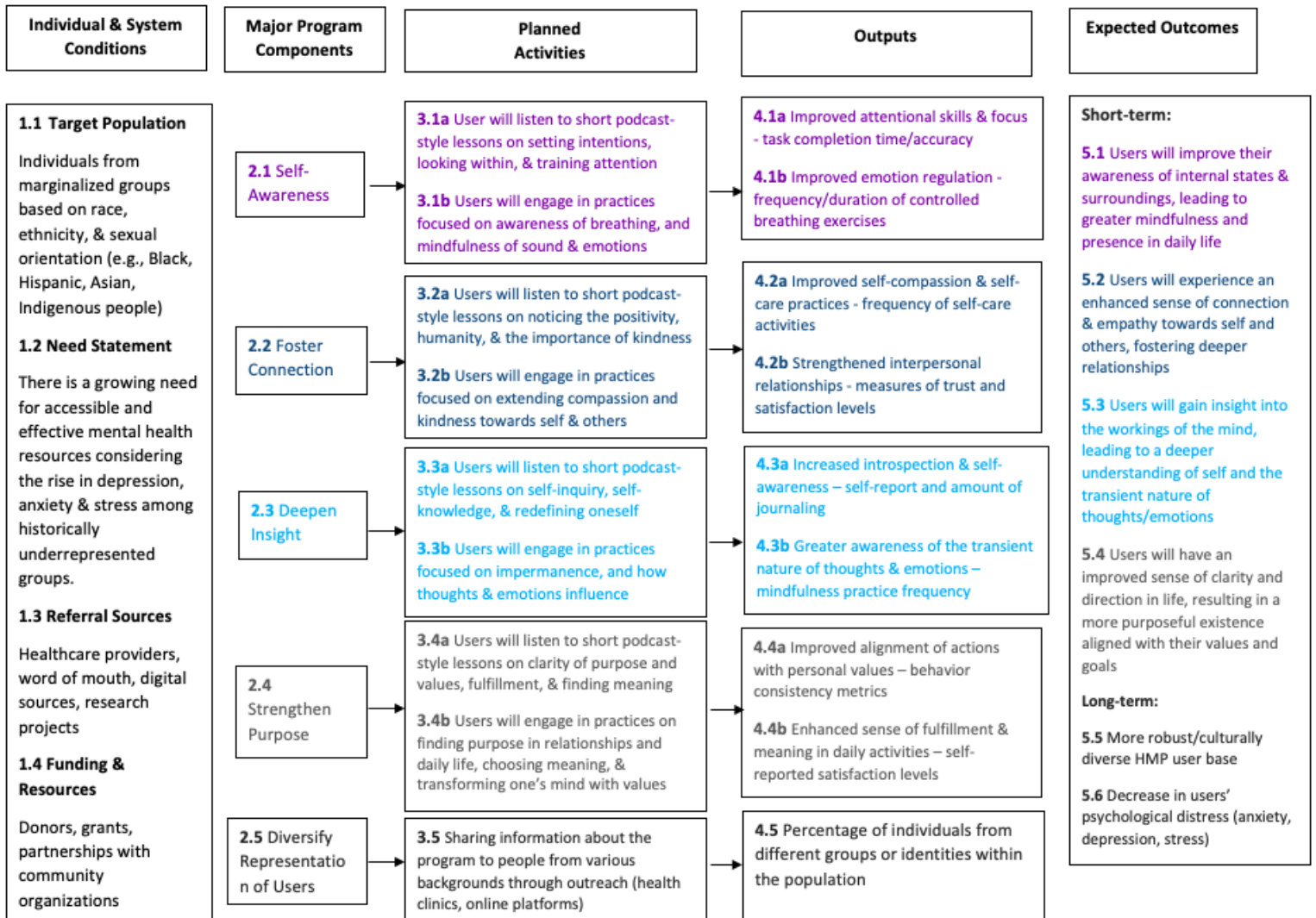
The proposed methods for sharing the evaluation results to stakeholders include academic publication, internal reports, and the distribution of flyers. Academic publication will serve to contribute to the existing literature on the effectiveness of app-based MBIs in improving mental health outcomes of individuals from historically underrepresented groups, allowing for comparison with the original RCT on HMP. Moreover, it will provide valuable insights for researchers, practitioners, and policymakers working in this domain. The internal report will be shared with funders and program developers, highlighting the app's strengths and weaknesses and providing recommendations for improvement to improve cultural sensitivity and accessibility. Additionally, the distribution of flyers to community organizations and advocacy groups is crucial for gathering perspectives and feedback from historically underrepresented groups. This feedback will shape the refinement of HMP to better meet the needs and preferences of diverse populations. Moreover, spreading awareness about the app through flyers will hopefully facilitate increased usage among these groups. By ensuring that the evaluation results are disseminated through various channels targeting different stakeholders, the findings will be more likely to be used in refining HMP and making it more effective and accessible for diverse groups.

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Appendix A

Logic Model: The Healthy Minds Program App



Appendix B
Demographic Survey

1. *Please select the category that includes your age:*
 - a) 18-24
 - b) 25-34
 - c) 35-44
 - d) 45-54
 - e) 55-64
 - f) 65+
2. *Please indicate your assigned sex at birth:*
 - a) Female
 - b) Male
 - c) Intersex
 - d) Prefer not to share
3. *Please indicate the gender identity you currently identify with. Choose all that apply:*
 - a) Male
 - b) Female
 - c) Genderqueer/genderfluid
 - d) Nonbinary
 - e) Transgender
 - f) Two-spirit
 - g) Prefer not to share
 - h) Other
4. *Please indicate your race/ethnicity. Choose all that apply:*
 - a) White or Caucasian
 - b) Black or African American
 - c) Hispanic or Latino
 - d) Asian or Pacific Islander
 - e) Native American or Alaskan Native
 - f) Multiracial or Multiethnic
 - g) Prefer not to share
 - h) Other
5. *Please indicate the highest degree or level of school you have completed:*
 - a) Less than high school
 - b) High school diploma or GED
 - c) Some college or associate's degree
 - d) Bachelor's degree
 - e) Graduate or professional degree
 - f) Prefer not to share

6. *Please indicate your current employment status:*
 - a) Employed full-time
 - b) Employed part-time
 - c) Unemployed
 - d) Student
 - e) Retired
 - f) Homemaker
 - g) Prefer not to share
 - h) Other
7. *Please indicate your current household income:*
 - a) Less than \$25,000
 - b) \$25,000-\$49,999
 - c) \$50,000-\$74,999
 - d) \$75,000-\$99,999
 - e) \$100,000-\$149,999
 - f) \$150,000+
 - g) Prefer not to share
8. *Please indicate your current marital status:*
 - a) Single, never married
 - b) Married or domestic partnership
 - c) Separated
 - d) Divorced
 - e) Widowed
 - f) Prefer not to share
9. *Please indicate your prior and/or current use of mental health apps (e.g., Headspace, Calm, and Healthy Minds Program App):*
 - a) Yes, I currently use mental health apps
 - b) Yes, I have used mental health apps in the past, but not currently
 - c) No, I have never used mental health apps
 - d) Other
10. *Please indicate how often you use/have used mental health apps:*
 - a) Daily
 - b) Several times a week
 - c) Once a week
 - d) Several times a month
 - e) Rarely
 - f) Never
 - g) Other

Appendix C

Patient-Reported Outcome Measures Information System (PROMIS) – Depression

LEVEL 2—Depression—Adult* *PROMIS Emotional Distress—Depression—Short Form

Name: _____

Age: _____

Date: _____

If the measure is being completed by an informant, what is your relationship with the individual receiving care? _____

In a typical week, approximately how much time do you spend with the individual receiving care? _____ hours/week

Instructions: On the DSM-5-TR Level 1 cross-cutting questionnaire that you just completed, you indicated that *during the past 2 weeks* you (the individual receiving care) have been bothered by “no interest or pleasure in doing things” and/or “feeling down, depressed, or hopeless” at a mild or greater level of severity. The questions below ask about these feelings in more detail and especially how often you (the individual receiving care) have been bothered by a list of symptoms **during the past 7 days**. Please respond to each item by marking (✓ or x) one box per row.

| | | | | | | Clinician Use |
|----------------------------------|---|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| In the past SEVEN (7) DAYS.... | | | | | | Item Score |
| | | Never | Rarely | Sometimes | Often | Always |
| 1. | I felt worthless. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 2. | I felt that I had nothing to look forward to. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 3. | I felt helpless. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 4. | I felt sad. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 5. | I felt like a failure. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 6. | I felt depressed. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 7. | I felt unhappy. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 8. | I felt hopeless. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| Total/Partial Raw Score: | | | | | | |
| Prorated Total Raw Score: | | | | | | |
| T-Score: | | | | | | |

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Appendix D

Patient-Reported Outcome Measures Information System (PROMIS) – Anxiety

LEVEL 2—Anxiety—Adult*

*PROMIS Emotional Distress—Anxiety—Short Form

Name: _____

Age: _____

Date: _____

If the measure is being completed by an informant, what is your relationship with the individual? _____

In a typical week, approximately how much time do you spend with the individual? _____ hours/week

Instructions to patient: On the DSM-5-TR Level 1 cross-cutting questionnaire that you just completed, you indicated that during the past 2 weeks you (individual receiving care) have been bothered by “feeling nervous, anxious, frightened, worried, or on edge”, “feeling panic or being frightened”, and/or “avoiding situations that make you anxious” at a mild or greater level of severity. The questions below ask about these feelings in more detail and especially how often you (individual receiving care) have been bothered by a list of symptoms **during the past 7 days**. Please respond to each item by marking (✓ or x) one box per row.

| | | | | | | Clinician Use |
|----------------------------------|---|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| In the past SEVEN (7) DAYS.... | | | | | | Item Score |
| | | Never | Rarely | Sometimes | Often | Always |
| 1. | I felt fearful. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 2. | I felt anxious. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 3. | I felt worried. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 4. | I found it hard to focus on anything other than my anxiety. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 5. | I felt nervous. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 6. | I felt uneasy. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 7. | I felt tense. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| Total/Partial Raw Score: | | | | | | |
| Prorated Total Raw Score: | | | | | | |
| T-Score: | | | | | | |

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Appendix E
Perceived Stress Scale (PSS)

PERCEIVED STRESS SCALE

The questions in this scale ask you about your feelings and thoughts during the last month. In each case, you will be asked to indicate by circling *how often* you felt or thought a certain way.

Name _____ Date _____

Age _____ Gender (Circle): **M** **F** Other _____

0 = Never 1 = Almost Never 2 = Sometimes 3 = Fairly Often 4 = Very Often

- | | | | | | |
|--|---|---|---|---|---|
| 1. In the last month, how often have you been upset because of something that happened unexpectedly? | 0 | 1 | 2 | 3 | 4 |
| 2. In the last month, how often have you felt that you were unable to control the important things in your life? | 0 | 1 | 2 | 3 | 4 |
| 3. In the last month, how often have you felt nervous and "stressed"? | 0 | 1 | 2 | 3 | 4 |
| 4. In the last month, how often have you felt confident about your ability to handle your personal problems? | 0 | 1 | 2 | 3 | 4 |
| 5. In the last month, how often have you felt that things were going your way? | 0 | 1 | 2 | 3 | 4 |
| 6. In the last month, how often have you found that you could not cope with all the things that you had to do? | 0 | 1 | 2 | 3 | 4 |
| 7. In the last month, how often have you been able to control irritations in your life? | 0 | 1 | 2 | 3 | 4 |
| 8. In the last month, how often have you felt that you were on top of things? | 0 | 1 | 2 | 3 | 4 |
| 9. In the last month, how often have you been angered because of things that were outside of your control? | 0 | 1 | 2 | 3 | 4 |
| 10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them? | 0 | 1 | 2 | 3 | 4 |