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Does baseline psychiatric symptom severity predict well-being improvement in low-intensity mindfulness interventions?

Alexandra K. Gold, PhD[*,a,b], **Dustin J. Rabideau, PhD**[b,c], **Daniel Nolte, MS**[c], **Caylin M. Faria, BS**[a], **Spencer (Yunfeng) Deng, BA**[a], **Nevita George, BS**[a], **Chelsea Boccagno, PhD**[a,b,d], **Christina M. Temes, PhD**[a,b], **Masoud Kamali, MD**[a,b], **Nur Akpolat, BS**[a], **Andrew A. Nierenberg, MD**[a,b], **Louisa G. Sylvia, PhD**[a,b]

[a]Department of Psychiatry, Massachusetts General Hospital, Boston, MA, USA

[b]Harvard Medical School, Boston, MA, USA

[c]Biostatistics, Massachusetts General Hospital, Boston, MA, USA

[d]Department of Epidemiology, Harvard T.H. Chan School of Public Health, Boston, MA, USA

Abstract

Regardless of baseline psychiatric symptom severity, individuals can improve from psychotherapy, including from low-intensity psychosocial treatments. We conducted a secondary analysis of a randomized trial of low-intensity mindfulness interventions to explore if and how specific indices of baseline symptom severity were associated with well-being trajectories during treatment and follow-up. In the original study, participants (N = 4, 411) with physical and mental health conditions were randomly assigned to one of two low-intensity mindfulness interventions (eight-session mindfulness-based cognitive therapy or a three-session mindfulness intervention). In this secondary analysis, we pooled across treatment groups and stratified participants into subgroups based on self-reported baseline levels of anxiety, depression, and social functioning. We used linear mixed effects models and descriptive trajectory plots to evaluate differences in well-being trajectories between subgroups. Baseline symptom severity was associated with well-being trajectory such that those with more severe anxiety, depression, or social functioning at baseline had generally lower well-being across time. All subgroups experienced initial improvement in well-being during the treatment period, though individuals with worse symptom severity tended not to sustain improvements and rebounded back towards baseline well-being levels during follow-up. These data suggest that, for individuals with more severe mental health symptoms, eight or three-session mindfulness-based interventions may still be clinically useful (as patients with more severe symptoms in this study were able to experience initial improvement in well-being from such interventions). However, for such patients, offering these mindfulness-based interventions for a longer duration may have prevented symptom rebounding.

Keywords

low-intensity treatments; anxiety; depression; social functioning

[*]Corresponding Author: Alexandra K. Gold, PhD, Dauten Family Center for Bipolar Treatment Innovation, Massachusetts General Hospital, 50 Staniford Street, Suite 580, Boston, MA 02114, akgold@mgh.harvard.edu.

1. Introduction

Research has evaluated whether severity of psychiatric symptoms at pre-treatment affects improvement from psychotherapy. Many studies have examined this relationship in the context of clinical trials investigating cognitive-behavioral therapies (CBT). Results have been varied: some studies have found that baseline symptom severity has no differential impact on improvement from CBT for adults with major depression, when compared to pill-placebo control (Furukawa et al., 2017), but other studies have found that higher baseline symptom severity is associated with greater improvements from psychotherapy (Andersson et al., 2019; Driessen et al., 2010; Scholten et al., 2023). These latter studies included a meta-analysis on CBT for social anxiety disorder (Scholten et al., 2023), a meta-analysis on psychological treatments for depression compared to control (i.e., waiting list, usual care, pill placebo) treatment (Driessen et al., 2010), and a meta-analysis on internet-delivered CBT for anxiety, depression, and other psychological conditions (Andersson et al., 2019). The meta-analysis by Driessen and colleagues, which resembles the review by Furukawa and colleagues, specifically found larger treatment effect sizes among high-severity patients (relative to low-severity patients) and included a larger range of psychotherapies (i.e., interpersonal psychotherapy, behavioral activation) than did the meta-analysis by Furukawa and colleagues, the latter of which could have been a factor in the disparate findings. It is also worth acknowledging that, for patients with higher symptom severity, there may be a greater possibility for change (i.e., because higher symptoms may mean that treatment is more necessary; Andersson et al., 2019) and greater potential numerical improvement on a rating scale (i.e., because someone who has a lower symptom severity pre-treatment has less room for symptom improvement). Similarly, some research has also found that mindfulness interventions (i.e., mindfulness-based stress reduction, mindfulness-based relapse prevention) may be more effective for those with a higher baseline symptom severity (Arch and Ayers, 2013; Roos et al., 2017). The first study randomly assigned patients (N = 71) with anxiety disorders to receive 10 weeks of mindfulness-based stress reduction or group CBT and evaluated three moderators (baseline depression, anxiety sensitivity, diagnostic severity) of post-treatment anxiety disorder severity (Arch and Ayers, 2013). At post-treatment, CBT performed better than mindfulness-based stress reduction among patients with no to mild depressive symptoms and very high anxiety sensitivity whereas, at follow-up, mindfulness-based stress reduction performed better than CBT for those with moderate to severe depressive symptoms and average anxiety sensitivity (within this sample; Arch and Ayers, 2013). The second study was a secondary analysis from a study that randomly assigned patients with substance use disorders (N = 286) who had completed initial intensive outpatient or inpatient substance use treatment to 10 weeks of mindfulness-based relapse prevention, cognitive-behavioral relapse prevention, or treatment-as-usual (i.e., abstinence-based groups similar to Alcoholics/Narcotics Anonymous in structure) (Bowen et al., 2014; Roos et al., 2017). This analysis, which used a latent class moderation approach, found a significant, large effect of mindfulness-based relapse prevention on substance use among patients who were categorized within “high/high” (high substance use disorder severity, high anxiety and depression symptoms) and “high/low” (high substance use disorder severity, low anxiety and depression symptoms) latent classes (Roos et al.,

2017). Taken together, these few studies suggest that a range of patients (including more clinically symptomatic patients) can experience benefit from some psychosocial treatments, including mindfulness-based psychosocial treatment.

It remains unknown whether a similarly broad range of patients can benefit from low-intensity CBT, or low-intensity psychosocial treatments more generally. Low-intensity psychosocial treatments are brief, often self-guided, manualized treatments that can be administered in a wide range of formats (e.g. online, in-person) and that are intended for those with mild to moderate mental health symptoms (Ali et al., 2017; Society, 2011). A proposed definition of low-intensity CBT by Shafran and colleagues (2021) defines such programs as involving the use of self-help materials, total clinician contact time of 6 hours or less, and a potential for the intervention to be administered by supportive staff who have been trained specifically in the intervention (i.e., even if the staff do not have specific professional accreditations in psychotherapy) (Shafran et al., 2021). One major strength of low-intensity treatments is that, because they involve limited clinician contact and are low-cost, these treatments can greatly increase access to care (Society, 2011). Low-intensity CBT has shown benefits for decreasing mental health symptoms (i.e., anxiety, depression) in clinical trials (Avramchuk et al., 2022; Cremers et al., 2022). The first study randomly assigned participants with social anxiety disorder (N = 222) to 4 weeks of low-intensity CBT or a waiting list control treatment. Low-intensity CBT involved reading materials and seven, 50-minute online sessions (with six hours of clinical contact time). The control treatment involved an initial consultation with a psychologist and receipt of reading materials. Study results reflected greater reductions in social anxiety disorder symptom severity (partial eta-squared: 0.15) and in impairments associated with depression (partial eta-squared: 0.16) or generalized anxiety disorder (partial eta squared: 0.29) among participants in the low-intensity CBT group versus the control group, with a greater likelihood of social anxiety disorder relapse for participants in the control group (Avramchuk et al., 2022). The second study was a systematic review of 23 studies investigating low-intensity psychological interventions for improving the well-being of older adults (Cremers et al., 2022). These interventions included psychoeducation, guided CBT, self-help, and bibliotherapy. Overall, 15 out of 23 studies suggested the effectiveness of low-intensity psychological interventions for mild to moderate mental health problems (i.e., anxiety, depression), three of the 23 studies reported mixed results with some findings in support of low-intensity psychological interventions, and five of the 23 studies did not have results supporting low-intensity psychological interventions. Some studies report that gains from low-intensity CBT may not persist: one study evaluated relapse rates after one year among remitted participants who completed low-intensity CBT for depression and anxiety. The authors found that 53% of patients relapsed within one year, with 79% relapsing within six months post-treatment (Ali et al., 2017).

Despite evidence that low-intensity psychosocial treatments may be beneficial, few studies have evaluated the role of baseline psychiatric symptom severity on the effectiveness of these psychosocial interventions, which could help to better tailor these interventions. In a meta-analysis of low-intensity psychosocial interventions for moderate to severe depression, Bower and colleagues (2013) did not find marked differences in treatment effects following low-intensity interventions for those with higher versus lower baseline symptom severity

(Bower et al., 2013). Another study comparing two, low-intensity interventions for individuals with depression found that those with higher baseline depression severity who received a low-intensity mindfulness and values intervention (i.e., daily 10-minute mindfulness practice for 2 weeks, plus 1 values identification session) had a significantly greater reduction in depressive symptoms compared to those who received a low-intensity values intervention alone (i.e., 1 values identification session). Notably, patients with lower depression severity at baseline did not experience a meaningful decrease in depression from either treatment (Kingston et al., 2020). Taken together, these data may reflect some consistency with the broader literature evaluating the effect of baseline symptom severity on improvements from evidence-based psychotherapies. Specifically, those with more severe symptoms at baseline may be able to experience at least as much (or, in some cases, greater) benefit from low-intensity interventions compared to those with less severe symptoms at baseline.

To date, studies evaluating the role of baseline symptom severity on clinical outcomes following psychosocial treatment have generally focused on symptom outcomes (i.e., anxiety, depression). We are not aware of specific studies evaluating the role of baseline symptom severity in a psychosocial treatment trial on the clinical outcome of well-being. According to the Centers for Disease Control and Prevention, well-being is an important and “holistic” clinical outcome with public health implications given that well-being encompasses both mental health and physical health (CDC, 2018; Dunn, 1973). Thus, well-being is an outcome that may hold relevance in both psychiatric and non-psychiatric populations. To that end, prior work evaluating the relationship between baseline symptom severity and clinical outcomes has generally been conducted in psychiatric populations. Understanding how baseline mental health symptom severity impacts outcomes following psychosocial treatment in a broader clinical population (i.e., those with mental health conditions, as well as physical health conditions) could allow for a clearer understanding of how low-intensity treatments translate more widely towards outcomes with far-reaching clinical relevance (i.e., well-being).

The Healthy Mind Healthy You (HMHY) study was a randomized trial comparing two low-intensity interventions for improving well-being: an eight-session mindfulness-based cognitive therapy (MBCT) intervention versus a three-session mindfulness intervention (Sylvia et al., 2022). The aim of the current exploratory post-hoc analysis was to evaluate whether specific indices of baseline symptom severity (across domains of anxiety, depression, and social functioning) were predictors of differential well-being trajectories over the course of the 20-week study period.

2. Methods

2.1 Study Overview

Participants (N = 4, 411; ages 18+) were recruited from 17 online organizations that focus on specific conditions and community interests (i.e., people with mood disorders, arthritis, Alzheimer’s disease). To be eligible for the study, participants had to be a member of one of these 17 organizations or a caretaker or family member of a patient. Participants in both treatment groups completed their assigned intervention during weeks 0–8 and follow-up

assessments in weeks 9–20. Refer to (Sylvia et al., 2022) for more information on the study design and the three-session and eight-session mindfulness interventions. Mindfulness-based interventions were selected as the study interventions given evidence that mindfulness-based interventions can be effective in improving psychosocial outcomes for a broad range of physical and mental health conditions, and can improve such outcomes among patients' caregivers (Erdoğan Yüce et al., 2024; Greeson and Chin, 2019; Kuyken et al., 2016).

2.2 Study Assessments

Participants completed the following self-report assessments bi-weekly during the intervention period (weeks 0–8; 5 assessment periods at weeks 0, 2, 4, 6, and 8) and monthly during the follow-up period (weeks 9–20; 3 assessment periods at weeks 12, 16, and 20):

The WHO-5 Well-Being Index (World Health Organization, Geneva, Switzerland) was used to assess subjective well-being over the course of the prior 2 weeks (Topp et al., 2015). Items include "I have felt cheerful and in good spirits" and response options range from 0 (*not at all*) to 5 (*all of the time*). The 5 items were added and then per scoring guidelines multiplied by 4, resulting in a total "percentage" WHO-5 score ranging from 0–100.

The 1) Patient-Reported Outcomes Measurement Information System (PROMIS; PROMIS Health Organization, River Forest, IL, USA): Emotional Distress-Depression Short Form (PROMIS-Depression), 2) Anxiety Short Form (PROMIS-Anxiety), and 3) Ability to Participate in Social Roles and Activities Short Form (PROMIS-Social Roles) were used to assess symptoms of depression ("I felt worthless"), anxiety ("I felt fearful"), and social functioning ("I am satisfied with my ability to do things for fun outside my home") (Cella et al., 2010; Hahn et al., 2010), respectively. Response options range from *never* to *always*.

2.3 Statistical Methods

Prior to the analysis, each of the 4,411 participants enrolled in the Healthy Mind Healthy You study was categorized as either "Within Normal Limits", "Mild", "Moderate", or "Severe" for each baseline PROMIS measure (Anxiety, Depression, and Social Roles) separately. PROMIS symptom severity thresholds were based on existing guidelines (HealthMeasures, 2023). After determining there was not sufficient statistical evidence to suggest that randomized treatment group (3- vs. 8-session) moderated the potential relationship between baseline symptom severity and well-being (i.e., all treatment by baseline PROMIS subgroup by time interaction p-values > 0.20), we pooled both randomized treatment groups for the remainder of the analysis.

First, to determine *if* the mean well-being trajectories differed by self-reported baseline level of anxiety, depression, and social functioning, we fit three linear mixed effects models (one for each PROMIS measurement) with WHO-5 as the outcome, random participant intercepts and slopes to account for individual variability, natural cubic splines to account for potential non-linear trends in well-being over time, and additional terms for baseline PROMIS subgroup and baseline PROMIS by time interactions. We compared each of these "full" models with interaction terms (which allow for 4 completely distinct well-being trajectories by baseline symptom severity) to reduced models without interaction terms

(which constrain the 4 well-being trajectories to have the same shape over time) using omnibus likelihood ratio tests.

Next, to investigate *how* the mean well-being trajectories differed between baseline PROMIS subgroups, we generated descriptive mean trajectory plots with crude and model-based estimates and pointwise 95% confidence intervals. Given the exploratory nature of this phase of the analysis, we did not conduct formal hypothesis tests to make specific subgroup comparisons, but rather report descriptive data visualizations and comment on notable differences and patterns in these data.

3. Results

Table 1 summarizes the distribution of baseline levels for each PROMIS measure. For each of the baseline symptoms (PROMIS anxiety, depression, social roles), the plurality (40–57%) were “within normal limits”. However, at baseline, a greater proportion of participants were experiencing anxiety beyond normal limits (60%) compared to the proportion experiencing depression (48%) or social dysfunction (43%) beyond normal limits.

Results from the mixed-effects models indicated that participants with different levels of baseline anxiety, baseline depression, and baseline social functioning had different well-being trajectories over time (all omnibus $p<0.0001$ for interaction terms). Descriptive mean trajectory plots of well-being with model-based estimates and pointwise 95% confidence intervals for each of the baseline symptoms is presented in Figure 1. In inspecting Figure 1, we discovered three notable features across the symptom subgroup trajectories (first one common feature, and then two distinguishing features). 1.) First, we noted that, on average, all participants experienced improvements in well-being during the initial treatment period (i.e., Weeks 0 to 8), regardless of the severity of their initial baseline anxiety, depression, and social functioning. This initial improvement in well-being was common across all symptoms and severity subgroups. 2.) Second, although all subgroups experienced initial improvement, worse symptom severity at baseline was associated with generally worse well-being across time. This finding is supported by the fact that, for each symptom measure, the well-being trajectory (and its corresponding pointwise 95% CI) for those with “severe” symptoms lies entirely below the well-being trajectory (and 95% CI) for those with “moderate” symptoms, which lies entirely below the trajectory (and 95% CI) for those with “mild” symptoms, which lies entirely below the trajectory (and 95% CI) for those with symptoms “within normal limits”. 3.) Third, as supported by the omnibus $p<0.0001$ for interaction terms mentioned above, we also noted differences in the *shapes* of the curves between levels; these differences in *shape* are relatively consistent across the three PROMIS measures. Across anxiety, depression, and social functioning domains, participants with symptoms beyond normal limits tended to experience a more notable downward shift in longitudinal well-being during the follow-up period (i.e., Weeks 8 to 20), with this downward shift being progressively more pronounced with greater symptom severity (i.e., patients with “severe” symptoms demonstrate a more notable downward shift compared to patients with “mild” or “moderate” symptoms). Conversely, participants with less severe baseline symptoms (i.e., those who had baseline anxiety, depression, and social functioning impairments that were

"within normal limits" or "mild") tended to sustain their initial improvements in well-being that were experienced during the initial 8-week treatment period throughout the follow-up period.

4. Discussion

In this exploratory analysis, we evaluated whether participants with different baseline symptom severity (across 3 domains of anxiety, depression, and social functioning) experienced differential well-being trajectories from 2 low-intensity mindfulness treatments. First, we found strong evidence (all $p<0.0001$) that symptom severity at baseline was associated with generally different average well-being trajectories over the study period. We observed that, on average, individuals experienced at least initial improvements in well-being during the 8-week intervention period, regardless of their baseline symptom severity. We found that, although all subgroups demonstrated initial symptom improvement, increased symptom severity at baseline was associated with worse well-being across time. Also, individuals with symptoms beyond "normal limits", though sometimes their initial gains were more notable, tended to experience a more notable downward shift in well-being during the follow-up period (weeks 8–20) with this downward shift more pronounced for those with greater symptom severity (i.e., patients with "severe" symptoms exhibited a more notable downward shift compared to patients with "mild" or "moderate" symptoms). Conversely, individuals with lower baseline symptom severity generally sustained improvements experienced during the initial eight-week treatment period through week 20, or at least did not have worsened symptoms through week 20.

These observations suggest that individuals with a range of mental and physical health conditions can benefit from low-intensity mindfulness treatments, regardless of initial psychiatric symptom severity. However, individuals with more severe baseline psychiatric symptoms may experience less sustained treatment effects. Thus, for individuals with more severe baseline psychiatric symptoms, a low-intensity treatment may need to be offered for longer periods of time to allow for sustained improvement. Similar to Bower and colleagues' (2013) suggestion, we believe these findings reflect the potential value of a stepped care model of treatment. A stepped care model is an approach to care in which individuals are provided with the least intensive treatment option that may produce clinical improvement (Seekles et al., 2009). This type of model has the potential to increase access to care, since the initial "step" in such a model often involves low-intensity, self-guided treatments that do not require trained professionals (Richards et al., 2012). If individuals are willing to participate in and can benefit from low-intensity treatments, even those individuals with more severe symptoms, the threshold to refer someone to the second "step" of the model could be relatively high.

However, it is also important to note the possibility that our findings may not be applicable to all low-intensity interventions. In this study, mindfulness-based cognitive therapy centered on a program of guided meditation exercises through which participants learned about acceptance and non-judgmental awareness of challenging thoughts, feelings, and physical sensations while also learning how to attend to mindful negative thought patterns in their daily lives and to disengage from such thoughts. The three-session mindfulness intervention

focused on teaching participants a single breath-awareness meditation exercise and applying this skill to their daily lives. It is possible that the specific content of these interventions was broadly accessible to participants such that participants could attain clinical benefit, even those with higher initial symptom severity.

This study is associated with some important limitations. We did not formally assess for specific psychiatric or medical diagnoses. This study was also impacted by missing data and study dropouts (see Sylvia et al., 2022 for information on missing data rates in this trial). We also recruited a more heterogeneous population of individuals given that we recruited through a range of online organizations that cater to different conditions and community interests. This sample heterogeneity is also a study strength, perhaps reflecting a more generalizable disease population. This secondary data analysis of a randomized trial was exploratory in nature and, thus, the findings should be viewed as hypothesis-generating rather than confirmatory.

Our study offers several important clinical contributions. Our exploratory analysis had a unique primary treatment outcome of well-being, rather than the standard mental health outcomes (i.e., depression, anxiety) measured in previous work. Well-being as a clinical variable may capture dimensions of both physical and mental wellness, and thus may be a broader outcome than the mental health outcomes assessed in prior studies. In addition to a novel clinical population (i.e., range of mental health and physical health conditions) and a unique outcome (i.e., well-being), our study is among the first to evaluate the relationship between baseline symptom severity and a well-being outcome over time (at both post-treatment and over a 12-week follow-up period). Previous studies evaluating the relationship between baseline symptom severity and psychotherapy outcomes have looked at post-treatment as the end-point, rather than also measuring a longer-term follow-up period (Andersson et al., 2019; Bower et al., 2013; Kingston et al., 2020; Scholten et al., 2023). In addition, one of the baseline clinical symptoms we evaluated was social functioning (Cella et al., 2010; Hahn et al., 2010), which has been a neglected baseline symptom in previous studies. Given that the capacity to complete social roles and activities is associated with both physical and mental wellness (Galderisi et al., 2015; Holt-Lunstad, 2022), we believe that social functioning is an important metric that warrants investigation as both a baseline symptom of consideration and an outcome variable in future psychotherapy trials.

Overall, this study provides further evidence that individuals with a range of physical and mental health conditions can experience clinical benefit from low-intensity mindfulness interventions, regardless of initial symptom severity. For those individuals with less severe symptoms, these benefits may persist for longer durations. However, for those with more severe symptoms, a more intensive and/or longer treatment period may be needed.

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Alexandra K. Gold

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Caylin M. Faria

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Spencer (Yunfeng) Deng

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Chelsea Boccagno

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Christina M. Temes

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Masoud Kamali

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Nur Akpolat

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Andrew A. Nierenberg

Dr. Nierenberg is on the scientific advisory board of Altimate, Flow, Milken Center for Strategic Philanthropy, Myriad, and 4M Therapeutics. He is also a consultant at Alkermes, Clexio, Ginger/Headspace Health, Janssen, Merck, Neuronetic, NeuroRX, Otsuka, Protagenics, SAGE, Sunovion, and Unravel Bioscience. He receives honoraria from Belvior, Psychiatric Annals Slack Publication, and Wiley Depression and Anxiety. He also receives royalties from Guilford Publications, and unravel Bioscience. Finally, he is in the adjudication committee for Novartis. He has received grant funding from PCORI.

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Highlights

- We explored the role of baseline symptom severity on well-being over time.
- Participants were enrolled in a study comparing two mindfulness interventions.
- All participants had initial improvement in well-being during treatment.
- Participants with worse baseline symptom severity did not sustain improvements.
- Participants with worse baseline symptom severity may need a longer treatment.

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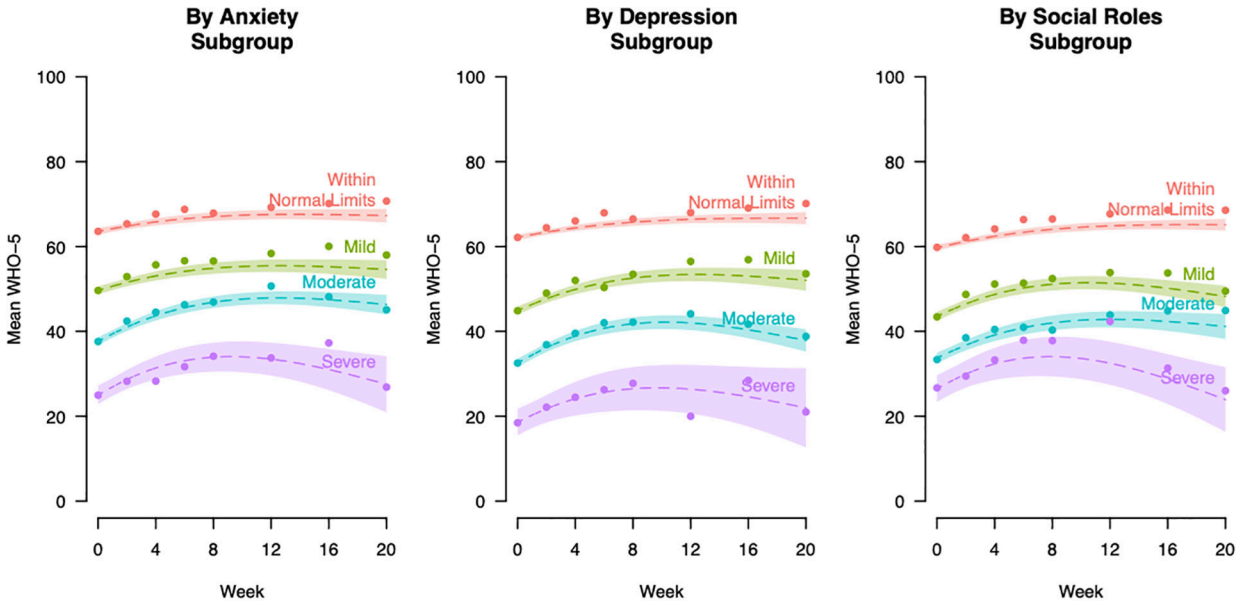

Figure 1. Well-being Trajectories by Baseline PROMIS Measure and Level.

Mean WHO-5 trajectories over study period by baseline PROMIS Anxiety subgroup (left), by baseline PROMIS Depression subgroup (middle), and by baseline PROMIS Ability to Participate in Social Roles subgroup (right). Points represent observed means, dashed lines represent linear mixed model-based means, and shaded regions represent model-based pointwise 95% confidence intervals. Linear mixed models included natural cubic splines to account for non-linear trends in mean WHO-5 trajectories.

Table 1.

Distribution of Baseline Levels for each PROMIS Measure.

	Anxiety		Depression		Social Roles	
	n	**%**	**n**	**%**	**n**	**%**
Within Normal Limits	1,755	40	2,286	52	2,503	57
Mild	1,193	27	1,068	24	1,030	23
Moderate	1,236	28	956	22	760	17
Severe	227	5	101	2	118	3
Total	**4, 411**	**100**	**4,411**	**100**	**4,411**	**100**

Note. Each of the 4,411 participants enrolled in the Healthy Mind Healthy You study was categorized as either “Within Normal Limits”, “Mild”, “Moderate”, or “Severe” for each baseline PROMIS measure (Anxiety, Depression, and Social Roles) separately. PROMIS symptom severity thresholds were based on existing guidelines (HealthMeasures, 2023).