

# Can Mindfulness Mechanistically Target Worry to Improve Sleep Disturbances?

**May Gao<sup>1</sup>**, Alexandra Roy, BA<sup>1</sup>, Alana Deluty, BA<sup>1</sup>, Katherine M. Sharkey, MD, PhD<sup>2</sup>, Elizabeth A. Hoge, MD<sup>3</sup>, Tao Liu, PhD<sup>4</sup>, Judson A. Brewer, MD, PhD<sup>1,5</sup>

<sup>1</sup>Mindfulness Center, Brown University School of Public Health, <sup>2</sup>Department of Internal Medicine and Psychiatry, Brown University, <sup>3</sup>Department of Psychiatry, Georgetown University Medical Center, <sup>4</sup>Department of Biostatistics, Brown University School of Public Health, <sup>5</sup>Department of Psychiatry, Warren Alpert School of Medicine at Brown University

## Overview

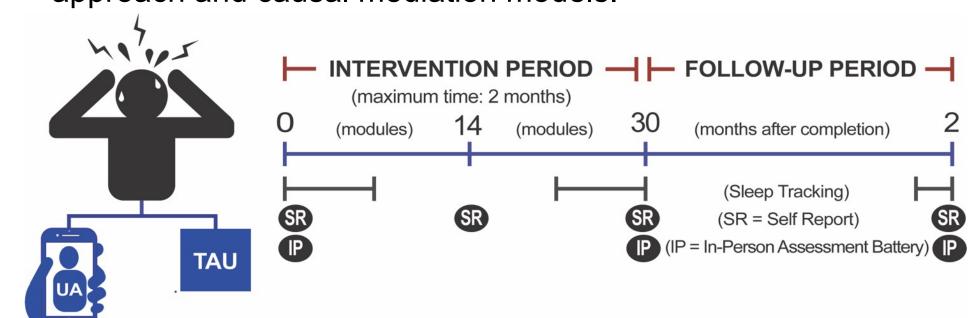
Using a randomized controlled trial, we tested: 1) if a mobile mindfulness training program for anxiety, Unwinding Anxiety, can help individuals decrease worry with concomitant improvements in sleep; 2) the mediating role of mindfulness in reducing worry and improving sleep quality.

## Background

- Sleep disorders are a highly prevalent problem experienced by nearly 20% of Americans.
- Approximately 1 in 3 U.S. adults experience any anxiety disorder at some point in their lives.
- Worry, a core defining component of anxiety disorders, and poor sleep are bidirectionally related. There is an approximately 70% comorbidity between generalized anxiety disorder (GAD) and insomnia.
- Mindfulness training (MT) is a promising intervention that disrupts habitual worrying. Defined as nonjudgmental present-centered awareness, mindfulness is a form of mental training that increases interoceptive awareness to reduce reactivity to stress.

## Study Design

- 80 participants reporting worry interfering with sleep were recruited from the Providence area and randomly allocated to treatment as usual (TAU) or TAU + mindfulness training (MT).
- Statistical analysis: Generalized Estimating Equations (GEE) were used to analyze changes in outcomes from baseline to treatment completion, accounting for within-subject covariance over time. Mediation analyses were conducted using the Baron & Kenny approach and causal mediation models.



**Figure 1.** Self-report (SR) measures: non-reactivity subscale from Five Facet Mindfulness Questionnaire, Patient-Reported Outcomes Measurement Information System sleep measures, Multidimensional Assessment of Interoceptive Awareness, Penn State Worry Questionnaire, and the Worry Interfering with Sleep Questionnaire. In-person (IP) assessment: Fitbit and paper sleep diary data collected. UA = Unwinding Anxiety application.

### Results

71 participants were included in intent-to-treat analysis (TAU + MT: n=36, TAU: n=35) after accounting for 11% attrition.



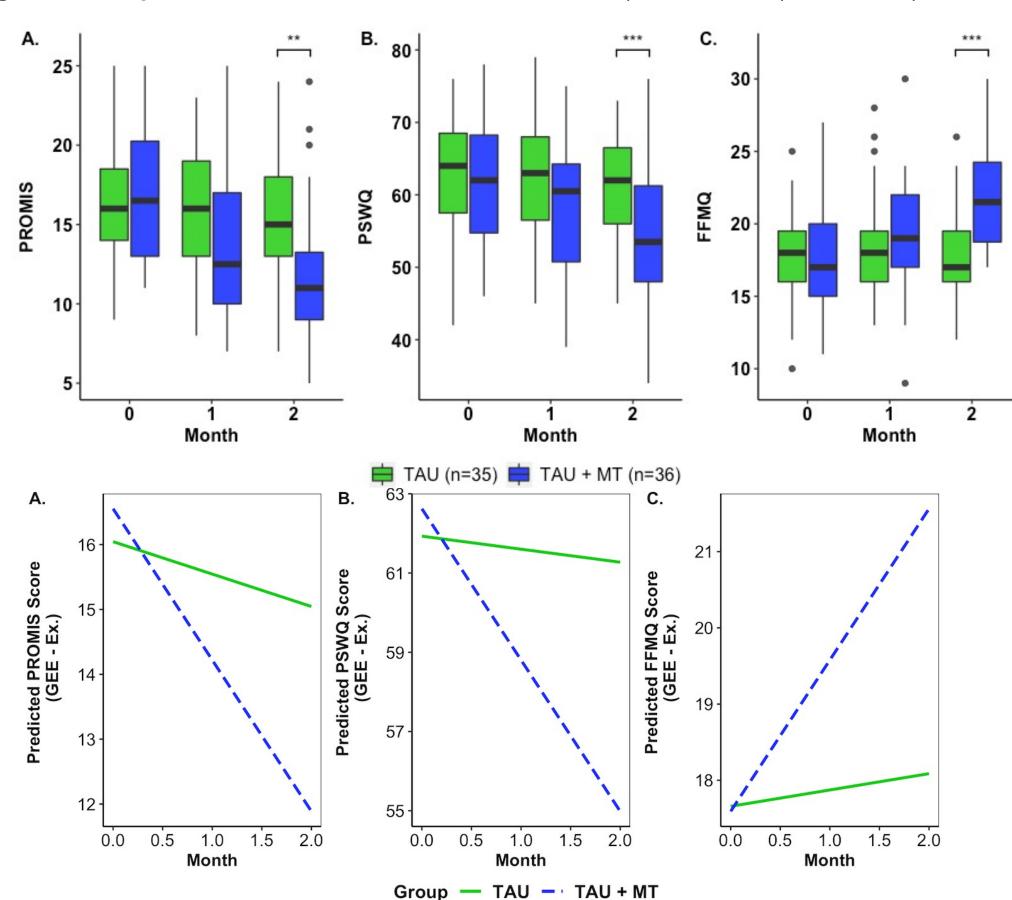


Figure 3. GEE models constructed for each outcome: A) PROMIS, B) PSWQ, C) FFMQ

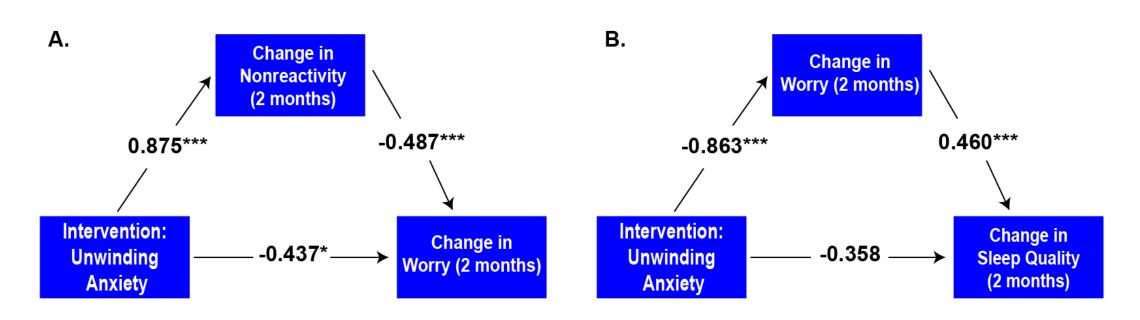
#### PROMIS – Sleep quality

- At two months, there was a significant difference in median PROMIS scores between groups (P=0.001, r=0.39; see **Figure 2A**).
- Time at one month was significantly associated with a 3.2 decrease in average PROMIS scores for the TAU + MT group (P<0.001). At two months, time was significantly associated with a 4.7 decrease in average PROMIS scores for the TAU + MT group (P<0.001; see **Figure 3A**)

## **About the Intervention**

MT was delivered through an app-based platform, which includes 30 core modules and eight "theme weeks" (that reinforce core concepts) of brief didactic and experience-based MT (videos and animations, ~10 min/day), app-initiated check-ins, user-initiated guided meditations (5-15 min), and brief on-demand mindfulness exercises (30-sec) to help break worry cycles in the moment.

Modules introduce how to mindfully work with worry cues and affective states using RAIN (Recognize, Accept, Investigate, and Note what emotions feel like as they arise and pass away).



**Figure 4. Mediation analysis models**: (A) Effect of MT on changes in worry mediated by changes in non-reactivity; (B) Effect of MT on changes in sleep quality mediated by changes in worry.

The relationship between MT and reduction in worry was partially mediated by increases in non-reactivity at two months ( $\beta_{indirect} = -0.43$ , P<.001; see **Figure 4A**). Decreases in worry fully mediated the relationship between MT and improvement in sleep quality at two months ( $\beta_{indirect} = -0.39$ , P<0.001; see **Figure 4B**).

#### Penn State Worry Questionnaire (PSWQ) – Worry

- At two months, there was a significant difference between the TAU + MT and TAU groups (P<0.001, d=.84; see **Figure 2B**).
- Time at one month was significantly associated with a 3.6 decrease in average PSWQ scores for the TAU + MT group (P=0.001). At two months, time was significantly associated with a 7.6 decrease in average PSWQ scores for the TAU + MT group (P<0.001; see **Figure 3B**)

#### Five Facet Mindfulness Questionnaire (FFMQ) – Nonreactivity

- At two months, the TAU + MT group had a significantly higher average non-reactivity score compared to the TAU group (P<0.001, d=1.11; see **Figure 2C**).
- Time at one month was not significantly associated with a change in average non-reactivity scores for the TAU + MT group (P=.06). At two months, time was significantly associated with a 4.0 increase in average non-reactivity scores for the TAU + MT group (P<0.001; see **Figure 3C**).

## Conclusion

- App-based MT effectively increased non-reactivity and decreased worry with reported improvements in sleep quality.
- We found a clear mechanistic link between worry and sleep quality that supports mindfulness theory. By noting anxious thoughts without becoming attached to them (non-reactivity), participants demonstrated a decrease in worry at two months that improved sleep quality.
- Given the results of this study, mechanistically-based and targeted mindfulness-based interventions may be helpful, in addition to medication and other therapies that exist, to improve sleep quality.

Research was supported by the National Institutes of Health (NIH) Science of Behavior Change Common Fund Program (R21DA046957). ClinicalTrials.gov Identifier: NCT03684057