Healthy Mind Healthy You: A Study of Mindfulness

Andrew Nierenberg, MD

Study & Project Aims

- **Aim 1**: Determine if standard (eight-session) mindfulness-based cognitive therapy (MBCT) compared to a brief, three-session mindfulness intervention will improve well-being in Patient Powered Research Network (PPRN) participants.

- **Aim 2**: Explore the heterogeneity of treatment effects (HTE) to both interventions.

- **Aim 3**: Contribute to PCORnet Commons by (1) conducting an analysis of the factors contributing to successful collaboration between PPRNs including the data infrastructure and co-registration; (2) providing access to questionnaires, online screening procedures, and therapeutic material; (3) making the code available that allows other networks to implement online resources; and (4) providing guidance for future online interventions.

- By using the PCORnet infrastructure, we will be able to connect with participants seamlessly across PCORnet in this large project that will not only potentially improve the well-being of individuals who experience stress but also demonstrate the capabilities of the PCORnet infrastructure to conduct such large-scale projects.

Methods

- We will recruit and randomize 8,500 adult and children participants or their caregivers across all PPRNs to internet-based MBCT or mindfulness-light.

- Each PPRN will link with the Genetic Alliance Community Network for Engaging All (CENA) PPRN web-based Platform for Engaging Everyone Responsibly (PEER) for obtaining consent, determining eligibility, baseline assessment, and randomization.

- Via PEER, participants will connect to MoodNetwork to receive the interventions.

- PEER will conduct bi-weekly outcome assessments for eight weeks and monthly follow-up assessments for an additional three months (see Figure 1).

- Through the link between PEER and each PPRN network, PEER will provide each network with their patient level data for the study while simultaneously retaining a central repository of all data.

- This project will involve all 21 PPRNs (patient and stakeholder partners, PPRN PIs and teams) across PCORnet, with additional potential involvement from CDRNs, to recruit and randomize the target goal of 8,500 participants.

Research Objectives

- Many people who have a chronic disease and their caretakers experience stress and decreased well-being. One of the most acceptable and effective interventions for improving one's overall well-being is mindfulness-based treatment. However, we do not know what is the briefest, least burdensome intervention that could decrease stress and enhance well-being effectively.

- Standard (eight-session) and briefer (three-session) mindfulness based treatments have never been compared directly in terms of efficacy and acceptability across a wide range of conditions and special populations as represented in PCORnet.

- Patients have had an integral role in this project since early conversations held at each PPRN between patient and stakeholder partners to discuss the focus of the project.

- Patients and stakeholder partners are integrated in the governance structure of the project and will be involved throughout the research process, from assisting with the intervention module design and incentive system to working directly within their home PPRN to best disseminate the study and generate the greatest impact.
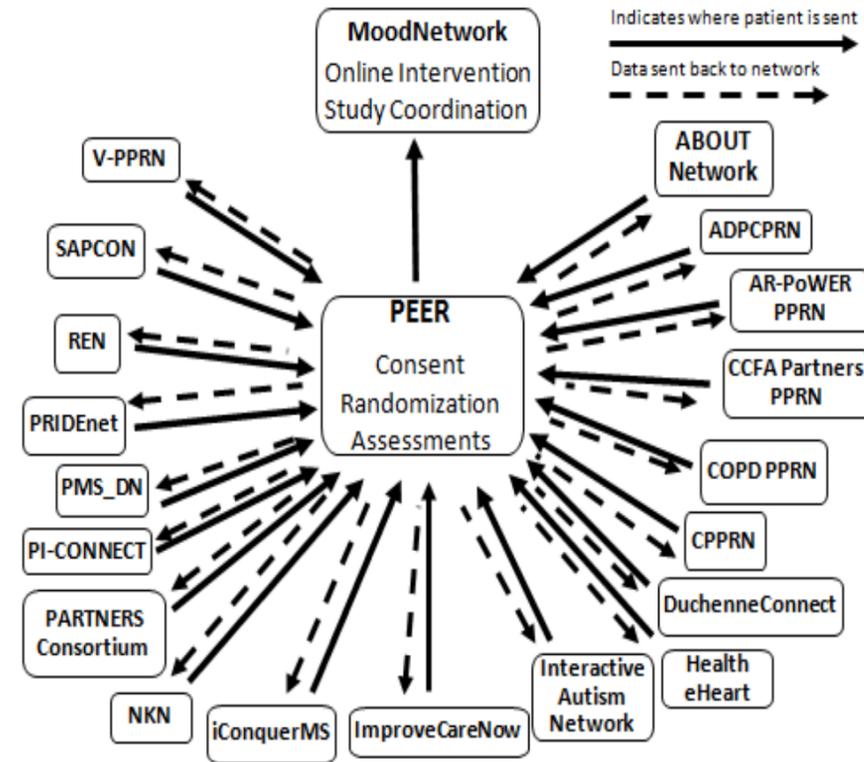

Figure 1. Via PEER, participants will be connected from each of the PPRNs with the MoodNetwork PPRN to receive the interventions (MBCT or mindfulness light).

Initial Findings and/or Hypothesis

- **Main Hypothesis**: Because MBCT is the longer and more comprehensive intervention, we hypothesize that standard MBCT will be superior to mindfulness-light in increasing well-being, quality of life, functioning and mindfulness, and decreasing stress, anxiety, and depression.

- We will explore moderators that can help match patients to either intervention (e.g., PPRN site, age, well-being, stress, anxiety).

- Through our collaboration with stakeholders and participating PPRNs and CDRNs, we hope to find the proper dose of mindfulness across conditions and special populations represented in PCORnet to decrease stress and increase well-being.

DISCLOSURES

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CONTACT INFORMATION

Andrew Nierenberg, MD
anierenberg@mgh.harvard.edu