

An increasing number of digital mental health technologies such as web-based programs and mobile apps are being developed to expand access to mental health treatments and deliver them in a cost-effective manner. Although efficacy trials of these technologies have often demonstrated improved patient outcomes relative to usual care, especially when used in combination with supportive coaching, there is little evidence to suggest that such digital tools are widely implemented and sustained in routine care settings. Developing digital mental health technologies that are scalable and evaluating their effectiveness in real world clinical settings is therefore a priority for mental health services research and for delivery systems within the Mental Health Research Network (MHRN).

Perinatal depression is one area of significant public health concern where testing the effectiveness and implementation of digital mental health technology in real-world healthcare systems is especially important. Approximately 30-40% of women with histories of depression experience relapse during the perinatal period, a majority show poor adherence to antidepressants (ADs), the most common prevention treatment, and a majority express a preference for non-pharmacologic treatments. However, effective and easily accessible non-pharmacologic treatments are not widely available. Inadequate preventive treatment for perinatal depression poses unique risks compared to the general population of adults with depression, including potential obstetrical and neonatal complications associated with perinatal depression itself and with fetal exposure to ADs. It is therefore imperative to test the implementation of effective and scalable non-pharmacological treatments to reduce the risk of depression relapse in the perinatal period.

Mindfulness Based Cognitive Therapy (MBCT) is a promising preventive intervention for pregnant women with recurrent depression (as well as for adults in general), demonstrating significant reductions in rates of depressive relapse and residual depressive symptoms. MBCT is an eight-session in-person group intervention targeting risk factors for depressive relapse through a combination of mindfulness meditation and cognitive-behavioral strategies. Because of challenges in delivering in-person MBCT (difficulty for health systems to scale up the intervention, barriers to access for pregnant women), we developed a mobile-first digital adaptation of MBCT for pregnant women, Mindful Mood Balance for Moms (MMBFM).

The critical next phase of our work is to evaluate the potential of MMBFM as an effective intervention that can be more widely adopted, implemented and sustained across heterogeneous patient populations and health care systems represented by the MHRN. In response to [RFA-MH-19-225, Announcement for A Practice-Based Research Network to Transform Mental Health Care: Science, Service Delivery & Sustainability](#), we propose a large pragmatic hybrid type II effectiveness--implementation trial comparing MMBFM to usual care (UC) among pregnant women at risk for recurrent depression at four MHRN sites: KP Colorado (KPCO), KP Southern California (KPSC), HealthPartners (HP), and KP Georgia (KPGA) to address the following aims:

**AIM 1:** Test the effectiveness of MMBFM in reducing depression symptom burden, reducing risk of relapse or clinically significant worsening, and improving perinatal outcomes and maternal functioning when implemented in real-world healthcare systems. Hypothesis 1: pregnant women with histories of depression who are randomly assigned to the MMBFM program will experience less depression (primary outcome), stress, and anxiety, better infant outcomes, and improved maternal function, compared to those randomly assigned to receive UC.

**AIM 2:** Evaluate the incremental cost effectiveness of MMBFM compared to UC. Hypothesis 2: MMBFM will demonstrate acceptable incremental cost effectiveness relative to the UC group.

**AIM 3:** Evaluate healthcare system's implementation of MMBFM using the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) model. Hypothesis 3: MMBFM will show meaningful reach, adoption, implementation, and maintenance from a population health perspective.