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Official Title: Responsive e-Health Intervention for Perinatal Depression in Healthcare Settings

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STUDY PROTOCOL

Participant Recruitment, Enrollment, and Randomization

Depressed perinatal women were recruited from NorthShore University HealthSystem – a Chicago-based healthcare system that has 6 hospitals, over 3,000 primary care physicians and specialists. Study recruitment followed a step-wise process embedded within NorthShore's Perinatal Depression Program (PDP) beginning with universal screening approximately 26-28 weeks into pregnancy and 6 weeks postpartum using the Edinburgh Postnatal Depression Scale (EPDS; score > 12). PDP social workers called women with positive depression screens in order to tailor recommended treatment, including community mental health referrals. Based on their clinical judgment and knowledge of the eligibility characteristics of women to be considered for Northshore's Mom Mood Study, social workers also provided a brief description of the study in the call.

Interested women were referred to the study coordinator who provided a more complete study description and determined final eligibility using the following criteria: <1 year postpartum, ≥18 years of age, no active suicidal ideation, access to broadband internet via computer (desktop/laptop, tablet or smartphone), and English language proficiency. Women with affirmative answers to question of EPDS self-harm were included in the study if social work deemed them low-risk for suicide. Patients with active suicidal ideation were excluded.

REDCap (Version 8.10.5) was used to accomplish all subsequent onboarding steps, including informed consent, randomization to group, online assessments, tailored emails, and data management. Eligible women remained blind regarding their allocation to treatment group until being informed by the study coordinator who used REDCap's randomized tool blocked on perinatal status (pregnant or postpartum) and the two groups. Following randomization, the research team was not blind as to participant group.

Perinatal Depression Program (PDP)

NorthShore's well-established PDP includes universal perinatal outpatient depression screening with both centralized scoring and a referral network of community mental health providers, a 24/7 crisis hotline to respond to urgent/emergent patient needs, and relevant curriculum for obstetricians and nurse midwives.

MomMoodBooster + Perinatal Depression Program (MMB2+PDP)

Women in the MMB2+PDP group could use MMB2 and the PDP. MMB2 recommends increasing pleasant activities to regain life balance, interrupting negative thoughts and increasing positive thoughts, seeking support from others, and tracking mood. MMB2 included videos, audios, animations, and editable lists in a browser-based Web app that responsively adapted to each user's device (smartphone, tablet, laptop, and desktop). During the 12-week active treatment phase, each of the six MMB2 sessions becomes available sequentially according to a weekly schedule. Thereafter, users could continue visiting MMB2 for 7 additional months. The study coordinator enrolled women to MMB2 using the program's administrative website. Each pregnant woman's due date was used by MMB2 to ask the participant if they had delivered their baby in order to change from pregnant to postpartum program content. Two team outreach calls were made by a NorthShore team member not trained in mental health treatment. Call #1, 2-4 weeks following randomization, focused on resolving any difficulties signing into MMB2. Call #2, scheduled after the posttest, collected open-ended feedback about the program.

Measures and Assessments

Participant characteristics were assessed at baseline and outcomes were assessed at baseline and the 12-week posttest. Participants who completed all assessments received a $100 e-gift card.

In terms of primary outcomes, the Patient Health Questionnaire (PHQ-9) used to assess the severity of depressive symptoms has been well-validated, found reliable and sensitive, and widely used with perinatal depressed women – including in our prior MMB research, and other studies in large healthcare systems. We used the Depression Anxiety Stress Scale (DASS-21) Anxiety scale to assess anxiety symptom severity because perinatal anxiety is commonly comorbid with depression and has been related to adverse perinatal outcomes.

For secondary outcomes, the DASS-21 stress scale was used to assess stress severity, the Behavioral Activation for Depression Scale (BADS-Short Form) to measure behavioral activation, the short-form version of the Automatic Thoughts Questionnaire (ATQ-SF) to measure negative thoughts associated with depression, and a measure of behavioral self-efficacy to assess use of MMB2 strategies to manage activities, positive/negative thinking, support, relaxation, and goal setting.

Additional measures included MMB2's continuous and unobtrusive tracking of each user's MMB2 visits, session visits (date, number, duration), and activities (e.g., number/duration of videos and animations viewed, personal list updates). In addition, women who visited MMB2 (confirmed by unobtrusive engagement metrics) were asked on the posttest to rate MMB2's usability and helpfulness, the helpfulness of team outreach calls, and whether they would recommend MMB2. Participants in both groups were asked whether they used other mood management products or programs while in the study.

STATISTICAL ANALYSIS PLAN

Preliminary analyses examined distributional properties of measures, baseline equivalency, and missing data. Intent-to-treat analyses of group effects were performed using fixed effects growth models fit (SAS PROC MIXED; Version 9.4) and estimated with maximum likelihood. Individual variability in outcomes from baseline to posttest were predicted by a two-level dummy coded group variable (coded 0 for PDP and 1 for MMB2+PDP), a time variable (coded in months elapsed between baseline and posttest), and a group × time interaction. Effect sizes for the group × time interaction are equivalent to Cohen's d. Moderation of group × time effects for the primary depression outcome (PHQ-9) were evaluated by adding in separate models, the main effects of baseline perinatal status (pregnant/postpartum), the EPDS primary screen, baseline PHQ-9, and all two- and three-way higher order interactions with group and time.