Does Mothers and Babies Work for You?
Variations in Intervention Effects Across Sub Groups

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Mothers and Babies Program

• The Mothers and Babies Program (MB) uses cognitive-behavioral therapy (CBT) approaches to promote a healthy mood and bonding with one’s baby, and provide strategies for pregnant women and new moms to cope with stress in their lives.¹

• The content of MB is tailored to specific needs and issues related to the pregnancy and the postpartum periods.

• There are two evidence-based intervention modalities:
  – 1-on-1 (12 sessions, 15-20 minutes/each)
  – Group (6 sessions, 60-120 minutes/each)
Study Background

- Previous research has established the effectiveness of the MB Group modality in reducing depressive symptoms and preventing the onset of major depression when led by a mental health professional (MHP).²⁻⁴
- There have been studies comparing the delivery of CBT interventions between professionals and lay health workers to treat depression and anxiety,⁵ however, there have been no published studies in the United States testing the use of lay health workers to prevent depression.
- Lay health workers can provide services at a lower cost than professionals, remove barriers to service delivery (i.e., service setting, stigma), and potentially aid in reducing mental health service disparities in underserved populations.⁵,⁶
MB Group Comparative Effectiveness Trial: Lay Home Visitors vs. Mental Health Professionals

• 3-year project funded by the Patient-Centered Outcomes Research Institute (PCORI) (Award #: AD-1507-31473)\(^7\)

• Cluster randomized trial conducted with 37 home visiting programs across 7 states (IL, IA, MI, MO, MN, OH, WV)
  - Three study arms: Usual home visiting, MB delivered by lay home visitors (LHV), MB delivered by MHPs
Study Aims

1. To compare the effectiveness of MB Group when led by a LHV to usual home visiting services (“superiority” aim).
2. To compare the effectiveness of MB Group when led by a LHV to MB Group delivered by a MHP (“non-inferiority” aim).
3. To evaluate whether effectiveness of the two versions of MB varies according to patient characteristics.
4. To examine the feasibility and acceptability of MB Group delivered by LHV and MHP.
Methods

• Primary Outcome: Depressive Symptoms (as measured by Quick Inventory of Depressive Symptoms at 4 time points)

• Pre-specified covariates:
  – Participant race/ethnicity
  – Whether participant is a first-time mother
  – Currently experiencing a major depressive episode
  – Primary language of intervention receipt (for MHP and LHV arms) or primary language in which the participant completed assessments (for control arm)
  – Participant education
  – Participant mental health service use at baseline
Methods

• Descriptive statistics
  – mean ± standard deviation/median[interquartile range] or N(%) 

• Linear mixed model
  – Fixed effect: arm and baseline characteristics listed above 
  – Random site effect to account for the correlation within site (to provide more precise estimates on fixed effects) 

• Tukey-adjusted p-value for pairwise comparisons
### Participant Demographics

<table>
<thead>
<tr>
<th></th>
<th>Overall</th>
<th>Control</th>
<th>MHP</th>
<th>LHV</th>
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</thead>
<tbody>
<tr>
<td>Overall N (%)</td>
<td>824 (100)</td>
<td>149 (18.08)</td>
<td>293 (35.56)</td>
<td>382 (46.36)</td>
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<tr>
<td>Age: Mean (SD)</td>
<td>26.30 (5.83)</td>
<td>26.10 (5.41)</td>
<td>26.01 (5.97)</td>
<td>26.59 (5.87)</td>
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<tr>
<td>Racial/Ethnic Minority: N (%)</td>
<td>579 (70.27)</td>
<td>54 (36.24)</td>
<td>217 (74.06)</td>
<td>308 (80.63)</td>
</tr>
<tr>
<td>First-time Mother: N (%)</td>
<td>298 (36.17)</td>
<td>55 (36.91)</td>
<td>112 (38.23)</td>
<td>131 (34.29)</td>
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<tr>
<td>Meets Criteria for MDE: N (%)</td>
<td>29 (3.52)</td>
<td>4 (2.68)</td>
<td>6 (2.05)</td>
<td>19 (4.97)</td>
</tr>
<tr>
<td>Spanish Intervention Receipt: N (%)</td>
<td>110 (13.35)</td>
<td>16 (10.74)</td>
<td>58 (19.80)</td>
<td>36 (9.42)</td>
</tr>
<tr>
<td>Education Level (At least some college): N (%)</td>
<td>331 (40.17)</td>
<td>71 (47.65)</td>
<td>110 (37.54)</td>
<td>150 (39.27)</td>
</tr>
<tr>
<td>Mental Health Service Utilization at Baseline (medication and/or therapy): N (%)</td>
<td>136 (16.50)</td>
<td>22 (14.77)</td>
<td>39 (13.31)</td>
<td>75 (19.63)</td>
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Results

- We found two significant three-way interactions between time, arm, and participant demographic:
  - A significant decrease in QIDs scores over time for first-time mothers in both study arms (p<0.001)
  - A significant decrease in QIDS scores over time for racial minority participants in the LHV-led study arm (p<0.001)
Results Cont.

Graph showing the average depressive symptom scores over time for different study groups:
- Usual Care
- Mental Health Professional-Led
- Home Visiting Paraprofessional-Led

The graphs compare the scores for "Not a First-time Mother" and "First-time Mother" groups at various study time points:
- Study entry
- After intervention
- 3 Months Postpartum
- 6 Months Postpartum

The graphs illustrate the trend of decreasing depressive symptom scores over time for each group.
Results Cont.

[Graph showing data on Belonging to White/Caucasian Race Category and Belonging to Minority/Non-White Race Category over different study time points.]
Conclusions

• Evidence that MB Group may be more effective with first-time mothers and women from racial minority groups (especially when delivered by a LHV).

• Supports a precision home visiting approach that suggests home visiting programs consider prioritizing delivery of interventions to certain clients who may reap greater benefits.
Future Directions

• Are there modifiable variables and/or lifestyle variables that moderate intervention effects?
  – Examples of modifiable variables: level of social support, ability to regulate one’s mood, facilitator/participant race concordance
  – Examples of lifestyle variables: physical activity, diet, sleep

• Are there active ingredients of the MB intervention that moderate intervention effects?
  – Example: Do participants who complete more personal projects between intervention sessions demonstrate better outcomes?
Future Directions Cont.

• Effects of a Prenatal Depression Preventive Intervention on Parenting and Young Children's Self-Regulation and Functioning (EPIC)
  – 5-year NICHD-funded study looking at long-term outcomes of MB Group on parenting and early child development
  – Moderators to be examined in EPIC include sociodemographic variables and father/paternal variables

• A Pilot Study of Sequential Multiple Assignment Randomized Trial Aimed at Reducing Depressive Symptoms among Home Visiting Clients
  – HARC pilot study
  – Uses an “adaptive” trial design to “re-randomize” women not initially responding to MB to receive more intensive intervention content
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*The views, statements, and opinions in this presentation are solely the responsibility of the authors and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee.
References


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