Pre-Analysis Plan

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123-MOMS: RCT Evaluation of a Three-Phase Intervention on Maternal Mental Health and Child Development to Lay the Foundations for Economic Opportunity and Wellbeing.

Previously known as Poverty, Mental Health and Child Development

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In what follows we present a pre-analysis plan for the evaluation of our 123-Moms intervention. Evaluation will be based on a randomized controlled trial where the randomization unit is the individual.

Detailed Structure of the Intervention: Our intervention package includes a bundle of three interventions delivered in three phases: CBT, parenting skills, and parent-led infant stimulation. As part of this project, we will adapt all interventions for online delivery and pilot-test these adaptations.

Phase 1: *We implement the MOMS Partnership® Stress Management CBT for mothers in the second trimester of pregnancy. MOMS Stress Management Course*, launched in New Haven and being scaled across the U.S., is a brief (8-week) CBT-based group intervention targeting maternal depressive symptoms. The CBT has successfully reduced depressive symptoms among over-burdened, under-resourced mothers. Unlike many other social services, the MOMS Partnership® reaches people in their own communities. The *MOMS Stress Management Course* encourages active participation and skill acquisition through interactive exercises, discussion, and practice. Participants learn: a. Skills to recognize their mood (using the Quick Mood Scale); b. Skills to change their mood through intentionally changing thoughts and behaviors (e.g., Fixing Unhelpful Thoughts, Relaxation Breathing). c. Executive Function skills including response inhibition, metacognition, and flexibility (e.g., 5 Steps to Effective Problem Solving). Sessions will be recorded to measure treatment fidelity. In our prior work with this intervention, the average CES-D score, which measures depressive symptoms, decreased by about 30% from beginning to endpoint of the intervention ($p<.0001$), and the average perceived maternal stress scores decreased 26% ($p<.0001$). Mothers' perceived social support from family and peers increased significantly ($p<.0001$).

Phase 2: *MOMS Parenting D.A.N.C.E.* intervention in the immediate postpartum period (8 weeks of attachment-based parenting intervention using video feedback) The *MOMS Parenting D.A.N.C.E.* intervention is a brief, strengths-based parenting program. Developed by the MOMS Partnership®, it includes both group and individual sessions—allowing individualized reinforcement of skills through video feedback. Parents learn: a. Skills/behaviors that build positive qualities in the parent-child relationship; b. Skills for tuning into, understanding, and managing children's (and their own) emotions. The Parenting D.A.N.C.E. is delivered in six 90-minute group sessions and two 45-minute individual sessions. Video clips of parent-child interaction—demonstrating positive examples of target parenting skills—are reviewed and reinforced in individual and group sessions. Sessions will be recorded to measure treatment fidelity.

Phase 3: *Reach up and Learn*® parenting intervention and infant stimulation *(9 months of weekly group sessions).* Following MOMS Partnership® interventions, participants will receive the parent-led infant stimulation intervention for nine months. Results by some of the PIs in India have shown that most of the benefit accrues with the first year of intervention. *Reach up and Learn*® offers a curriculum, introducing activities that address the cognitive, language and socio-emotional development of children. Caregivers are provided materials to continue the activities during the week. The intervention is delivered remotely on the tablets, in weekly group sessions. The sessions review the progress of children and introduce progressively harder elements as appropriate. The curriculum will be adapted for virtual delivery and to the cultural context of the target women. The emphasis of the intervention will be on training parents, in the presence of their children, to carry out age-appropriate stimulation activities. Sessions will be recorded to assess fidelity, as with the MOMS interventions.

Virtual Delivery will be made possible by providing all women with iPad tablets and internet data plans provided by Yale and using the Yale HIPAA compliant Zoom platform and Yale-maintained encryption software.TH has become prominent in the time of COVID-19 and is predicted to persist into the future becoming increasingly cost effective. Patients and providers uniformly report high levels of satisfaction with TH services and there is good evidence for the clinical equivalency of psychiatric and psychological treatments delivered virtually [23,24]. Thus, TH groups offer tremendous promise for the *scalability* of interventions given their lower overall costs to deliver and higher Medicaid reimbursement rates (group care).

Control group: The provision of iPads and data connectivity may in itself have an impact, on psychological, developmental and economic outcomes. Thus, our control group will also receive an iPad tablet and an internet connection as well as the basic services (i.e., information on safe sleep and nutrition), but no further treatment. Otherwise, the only contact with the control group will be for data collection and tracking any changes in address and contact information.

Population: We will recruit low-income pregnant women in their second trimester of pregnancy from the Yale-New Haven Health System prenatal care clinics. The hospitals and clinics serve a diverse group of women racially, ethnically and economically. Women are eligible for the study if they are: (1) in their second trimester of pregnancy; (2) are at least 18 years of age; (3) currently have an annual income below 250% FPL; (4) struggle with depressive symptoms (as measured by the CES-D depressive symptom screener); (5) can use an iPad and provide informed consent; and (6) do not present with acute psychosis or suicidal ideation at the time of enrollment. Based on prior studies with this population, we estimate that well over 1000 pregnant women will be eligible annually for this study.

Randomization: When we recruit a new set of 18-20 women, we will randomize them to intervention or control in equal numbers. The randomization unit will be the pregnant woman. To improve ex-post balance and increase the precision of estimation we will stratify women in each group by lower/higher age, and parity (0 vs. 1+).

Timeline

Project Timeline	
December 2020 – July 2021	Hiring/training of staff; preparation for pilot phase
March 2022- August 2022	Pilot phase
October 2022	RCT begins; First cohort recruited and randomized
January 2024; April 2024	First RCT cohort completes endpoint assessment; Last RCT cohort recruited and randomized
July 2025	Last RCT cohort completes endpoint assessment
March 2026	Complete endpoint analysis and report
July 2026	One Year Follow up

Preparation involves recruiting personnel (project manager and research clinician), adapting the intervention to an online setting, identifying an app developer for the online intervention and working with the app developer to prepare for the delivery. Also setting up the data collection mechanisms.

An important element defining the timeline is the fact that pregnant women have to be recruited gradually as they appear to the health system. Under current experience this will effectively take two years. The intervention will start when the first group of 18-20 women have been recruited and randomized to treatment and control, following baseline data collection. Then as new groups

are recruited, they will receive intervention. We expect that the last cohort/group will have been recruited by April 2024.

The remaining elements of the time line are driven by the time it takes to offer the intervention to the subjects. The first cohort will complete the intervention in September 2023.

Data will be collected longitudinally using multiple methods. Through web-based questionnaires we will collect baseline family demographic and socioeconomic information, as well as depressive symptoms of the mother. Mothers' depressive symptoms will be collected every three months through web-based questionnaires, along with secondary, mother-reported measures of maternal economic outcomes, parenting, the home environment, and child developmental milestones. We will collect health information from the Electronic Health Record (EHR), including neonate birth weight and Apgar score, followed by child health/development indicators at well-child visits. We will collect video-recorded behavioral samples every three months, after the child is born. Mothers will be instructed to make and send brief video clips interacting with their child using the study-provided iPads, which will be coded by the study team. We will test the children at the end of the intervention to assess their developmental outcomes. A year after the end of the intervention the mothers and the children will be reassessed and the same method of impact analysis will be implemented. We also plan to follow the mothers and children for longer-term outcomes beyond a year, subject to funding.

Outcomes: We propose **two primary** outcomes of the intervention: maternal depressive symptoms and child cognitive development both defined by a comparison between the treated group and the control group. Depressive symptoms will be measured via the CES-D, a standardized depressive symptom measure. The child cognitive outcome will be measured by the Bayley^{TM}-4 because of its accuracy and ability to discriminate at a young age. Maternal depression will be measured every three months beginning at baseline, providing us with longitudinal information on the persistence of interventions effects. Child cognitive development will be measured at the end of the intervention (endpoint assessment) and one year later. The assessors will be blinded to treatment status.

Power calculations are based on 80% power and 5% false positive rate (type 1 error). All outcomes will be measured in standard deviation units. We are planning on recruiting 300 pregnant women half of which will be allocated ***randomly*** to treatment and half to control. Given this, the minimum detectable effect at the end of the intervention for each of our two outcomes is 0.32 Stand. deviation units.

Secondary outcomes will include child health and development, including birth weight and Apgar, gestational age at delivery; language and socio-emotional development scales from the Bayley^{TM}-4 at endpoint and follow-up. We will also use the Survey of Well-being of Young Children (SWYC)™ and specifically assess: (1) the developmental domain (including language, cognitive, social, and motor development) and (2) emotional behavioral domain. To better understand the mechanisms, we will measure impacts on parenting quality and behavior (Parent Child Relationship Inventory; Coding Interactive Behavior), the home environment (based on the Family Care Indicator FCI) and social connectedness (Modified Social Support Survey). We will also look at impacts on maternal employment and earnings, as well as utilization of healthcare services at assessment timepoints during the intervention, at endpoint and at the one-year follow-up. Finally, for the purposes of further research and improved understanding of measurement we will pilot the possibility of adding some additional items to those of the Bayley and we will evaluate the performance of a composite score based on factor analytic approaches.

Impact Analysis.

Primary results. The impact analysis for the two primary outcomes will be based on a direct comparison of means between treatment and control as well as on regression analysis where we will include a number of baseline characteristics of the mother. These characteristics will include maternal age and education, parity and family composition, CES-D score at baseline, presence of partner and relationship status if present and their education if known, income, receipt of welfare benefits. Subject to being able to collect data on this it is our intention to also control for the strength of the co-parental relationship. The rationale for these controls is that they have been shown to correlate both with mother's mental health and with child developmental outcomes. Consequently, by controlling for these variables we can expect an improvement in the precision of the estimates. No other covariates will be included.

We will apply listwise deletion for missing outcome data, and dummy variable adjustment for missing covariates.

Since we will be considering two primary outcomes, we will report stepdown p-values as originally defined by Romano and Wolf (2005), which account for multiple testing. The advantage of these p-values is that they offer optimal testing power.

Secondary outcomes.

The method of analysis and the included covariates will be the same for the secondary outcomes. Here we will also use multiple testing for subgroups of hypotheses. One group will include the language and socio-emotional scale of the Bayley™-4. A second group will include the elements of the Survey of Well-being of Young Children (SWYC)™ and a third group will include outcomes relating to parent quality and behavior. Finally, we will consider social connectedness, as a separate group.

Impact Heterogeneity:

As an exploratory analysis, motivating further future research, we will investigate heterogeneity of impacts as a way to motivate future research. First, we will compare the distribution of outcomes in treatment and control to understand better which part of the distribution improves most: does the entire distribution shift or just one of the tails? Second, we will interact the treatment indicator with pre-baseline receipt of mental health treatment and measures of treatment fidelity. We will explore whether the size of the impact varies by mother and child characteristics, including maternal age and income, child gender, birth weight and birth order. To understand better the mechanisms involved we will also implement a mediation analysis, exploiting both the various outcomes we will have collected and the longitudinal nature of the data. This part of the analysis is considered suggestive and will help us define future methodological parameters and research questions.

Reference

Romano Joseph P. and Michael Wolf (2005) Stepwise Multiple Testing as Formalized Data Snooping, *Econometrica*, Volume 73, Issue 4, July, Pages 1237-1282