Title: Protocol for a Breastfeeding Support Intervention for Women with Hypertensive Disorders of Pregnancy: the **sheMATTERS** Trial

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Background: Women with hypertensive disorders of pregnancy (HDP) are at increased risk for premature cardiovascular disease. Although breastfeeding can lower blood pressure (BP) and other cardiovascular risk factors, women with HDP have lower rates of breastfeeding duration and exclusivity. Tailored interventions to enhance maternal breastfeeding self-efficacy (BSE) can improve breastfeeding outcomes but have yet to be tested among women with HDP.

Objective: To assess the impact of a nurse-led breastfeeding self-efficacy intervention (BSEI) on BP and breastfeeding outcomes among women with HDP.

Methods: This open-label, randomized-controlled trial will recruit 276 breastfeeding women with HDP who gave birth at ≥ 34 weeks gestation from three centers. Women will be randomized to usual care (control arm) or the BSEI (intervention), and 45 non-breastfeeding women with HDP will be recruited for comparison (observational arm). The nurse-led BSEI includes 2 in-hospital BSE-enhancing counseling sessions; weekly follow-up phone calls for the first 6 weeks postpartum; a telephone or virtual BSEI "booster" session at 3 months; and retroactive telephone support to 6 months. The primary outcome is mean systolic BP at 12 months. Secondary outcomes include number of weeks of exclusive and any breastfeeding, and rates of metabolic syndrome and cardioprotective behaviors (weight loss, healthy eating, physical activity) at 12 months. Follow-up data on cardiovascular events to 15 years post-RCT will be obtained via linkage with administrative health data.

Conclusion: We expect that the BSEI will improve breastfeeding and cardiovascular outcomes among women with HDP. SheMATTERS is registered at http://www.ClinicalTrials.gov , #NCT04580927.