# Breastfeeding and blood Pressure patterns in MOthers with recent hypertensive coMplications of pregnancy - BP-MOM Study

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
18/01/2019	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
29/01/2019	Completed	Results
Last Edited	Condition category	Individual participant data
14/10/2022	Pregnancy and Childbirth	<ul><li>Record updated in last year</li></ul>

## Plain English summary of protocol

Background and study aims

Women with hypertensive (high blood pressure) disorders of pregnancy including preeclampsia and gestational hypertension are at increased risk for later cardiovascular (heart) disease. Breastfeeding may lower maternal blood pressure and other cardiovascular risk factors, and interventions designed to improve mothers' breastfeeding self-efficacy (i.e., confidence about breastfeeding) have been helpful for healthy postpartum women. However, such breastfeeding support interventions have not yet been tested specifically in women who have had hypertensive disorders of pregnancy, a group who may benefit substantially from breastfeeding. This study tests a nurse-led self-efficacy based breastfeeding intervention in women with hypertensive disorders of pregnancy, to measure whether the intervention is feasible in this population and whether it improves breastfeeding rates and/or lowers maternal blood pressure.

# Who can participate?

Women at least 18 years old who have been diagnosed with a hypertensive disorder of pregnancy (preeclampsia or gestational hypertension), have given birth to a live-born single infant delivered at 34 weeks gestation or later, who intend to breastfeed and have started breastfeeding before hospital discharge, speak and understand English or French, and have access to a telephone.

## What does the study involve?

Participants are randomly allocated to receive either usual postpartum care, or usual postpartum care plus additional breastfeeding support. Additional breastfeeding support will include the nurse-led intervention designed to improve women's confidence about breastfeeding.

What are the possible benefits and risks of participating?

Participants who receive additional breastfeeding support may benefit from the nurse-led breastfeeding intervention. The study involves collection of test results from blood draws that are part of routine postpartum care. Blood draws may cause temporary discomfort, minor bleeding, light-headedness, and rarely, fainting.

Where is the study run from?
McGill University Health Centre (MUHC), Montreal (Canada)

When is the study starting and how long is it expected to run for? May 2018 to December 2021

Who is funding the study?
The study is supported by startup funds of the principal investigator, Natalie Dayan

Who is the main contact? Natalie Dayan Natalie.Dayan@mcgill.ca

# Contact information

## Type(s)

Scientific

#### Contact name

Dr Natalie Dayan

#### Contact details

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# Additional identifiers

# **EudraCT/CTIS** number

Nil known

## **IRAS** number

# ClinicalTrials.gov number

Nil known

# Secondary identifying numbers

2019-4726

# Study information

Scientific Title

Pilot randomized trial of a nurse-led self-efficacy based breastfeeding intervention in women with hypertensive disorders of pregnancy

## Acronym

**BP-MOM** 

## **Study objectives**

The trialists hypothesize that a self-efficacy based breastfeeding intervention in women with hypertensive disorders of pregnancy will be feasible in this population. They further hypothesize that there will be a trend toward protective effects on maternal health as measured by blood pressure, weight, and continued breastfeeding, at 6 months postpartum, with continued but dampened protective effects at 12 months postpartum.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Research Ethics Board of the McGill University Health Centre (MUHC), 2155 Guy Street, 2nd floor, Montreal, Quebec, H3H 2R9, Tel: +1 (0)514 934 1934 ext. 36077, Email: sheldon. levy@muhc.mcgill.ca, 20/11/2018, protocol number: 2019-4726

## Study design

Single-centre pilot randomized open-label trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Other

### Participant information sheet

## Health condition(s) or problem(s) studied

Hypertensive disorders of pregnancy, including preeclampsia and gestational hypertension

#### **Interventions**

Nurse-led breastfeeding enhancing intervention, including a maternal assessment followed by the provision of tailored lactation management strategies to enhance breastfeeding self-efficacy and support exclusive breastfeeding. Participants are randomized 1:1 to the intervention or usual postpartum care.

## Intervention Type

Behavioural

## Primary outcome measure

Feasibility, including recruitment, retention and participant satisfaction with the intervention:

- 1. Recruitment rate is defined as the number of eligible women who consented/number of eligible women who were approached, calculated at baseline
- 2. Retention rate is defined as the number of women who complete 12-month follow-up for the study/all women who consent to participate, calculated at 12-month follow-up
- 3. Participant satisfaction with the breastfeeding intervention will be measured using a self-administered questionnaire that includes quantitative and qualitative items on participants' satisfaction with the support received from the study nurse, measured at 3 months and 6 months postpartum

## Secondary outcome measures

- 1. Exclusive breastfeeding assessed by self-report at 6 months and 12 months postpartum
- 2. Total breastfeeding duration assessed by self-report at 6 months and 12 months postpartum
- 3. Blood pressure measured by the study nurse at 12 months postpartum
- 4. Use of anti-hypertensive medication as ascertained from the participant's medical chart at 12 months postpartum

## Overall study start date

01/05/2018

## Completion date

01/12/2021

# Eligibility

## Key inclusion criteria

- 1. Age >18 years
- 2. Diagnosis of hypertensive disorder of pregnancy (preeclampsia or gestational hypertension)
- 3. Singleton live birth delivered at >34 weeks gestation
- 4. Mother intends to breastfeed and breastfeeding initiated before hospital discharge
- 5. Patient speaks and understands English or French
- 6. Patient has telephone access

## Participant type(s)

Patient

## Age group

Adult

# Lower age limit

18 Years

#### Sex

Female

## Target number of participants

75

## Total final enrolment

45

## Key exclusion criteria

- 1. Maternal contraindication to breastfeeding
- 2. Maternal condition that interferes with breastfeeding
- 3. Neonatal condition that interferes with breastfeeding
- 4. Infant born before 34 weeks gestation
- 5. Maternal ICU admission lasting >24 hours

# Date of first enrolment

02/01/2019

## Date of final enrolment

21/11/2019

# Locations

## Countries of recruitment

Canada

H4A 3J1

# Study participating centre

McGill University Health Centre 1001 Boulevard Décarie Montreal Canada

# Sponsor information

## Organisation

McGill University Health Centre

## Sponsor details

1001 Boulevard Décarie Montreal Canada H4A 3J1

## Sponsor type

Hospital/treatment centre

## **ROR**

https://ror.org/04cpxjv19

# Funder(s)

## Funder type

Hospital/treatment centre

#### **Funder Name**

McGill University Health Centre (startup funds)

# **Results and Publications**

## Publication and dissemination plan

The study protocol will be available on request. The trialists will disseminate their findings to:

- 1. Members of the general public via press releases to local, national, and international media organizations, and via commercial and community organizations dedicated to women's health such as Nourri-Source, La Leche, the Preeclampsia Foundation, and Johnson & Johnson
- 2. Clinicians involved in perinatal care, e.g., knowledge users from the Society of Obstetricians and Gynaecologists of Canada (SOGC), Canadian Association of Women's Health, and Canadian Lactation Consultant Association
- 3. Policy makers, in particular the World Health Organization and American Academy of Pediatrics as they relate to breastfeeding recommendations, and the SOGC, Hypertension Canada, and the Canadian Cardiovascular Society as they relate to hypertension and cardiovascular risk management

## Intention to publish date

30/12/2022

## Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

# IPD sharing plan summary

Data sharing statement to be made available at a later date