

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

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

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

McGill University Health Center- Research Institute (MUHC-RI)

Center for Outcomes Research and Evaluation (CORE)

5252 de Maisonneuve West

2nd Floor

Suite 2B.40

Montreal

Canada

H4A 3S5

+1 (0)514 934 1934 ext. 76125

Natalie.dayan@mcgill.ca

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Other

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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

Study participating centre

McGill University Health Centre

1001 Boulevard Décarie

Montreal

Canada

H4A 3J1

Sponsor information

Organisation

McGill University Health Centre

ROR

<https://ror.org/04cpxjv19>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

McGill University Health Centre (startup funds)

Results and Publications

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