

# Effectiveness of interventions in improving continued exclusive breastfeeding in Brunei Darussalam

<b>Submission date</b> 28/04/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/05/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/03/2024	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Despite the known benefits of breastfeeding for both infants and mothers, the rates of exclusive breastfeeding in Brunei Darussalam remains suboptimal. This study is a single-blinded randomised controlled trial that aims to evaluate effectiveness of antenatal breastfeeding workshop and postpartum brief motivational intervention in improving primiparous mother's exclusive breastfeeding practice.

### Who can participate?

First-time pregnant women who are above 18 years old with no medical conditions that require medications can participate in this trial.

### What does the study involve?

These women who attend their antenatal health educational talks at Gadong and Berakas Maternal Child Health Clinics in Brunei will be randomly assigned to either the intervention group (breastfeeding workshop and brief motivational intervention) or the control group (breastfeeding workshop only). They are then followed up until six months after their infant is born to assess their exclusive breastfeeding practice.

### What are the possible benefits and risks of participating?

There are no risks to participants for joining this trial and there are no direct financial or other benefits for participants.

### Where is the study run from?

Ministry of Health (Brunei)

### When is the study starting and how long is it expected to run for?

October 2020 to December 2023

### Who is funding the study?

Ministry of Health (Brunei)

Who is the main contact?

Dr Faezah Amin, faezah.amin@moh.gov.bn

## Contact information

### Type(s)

Scientific

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

Nil known

## Study information

### Scientific Title

A single-blinded randomised controlled trial to assess the effectiveness of an antenatal breastfeeding workshop and postnatal brief motivational intervention in improving continued exclusive breastfeeding in the first 6 months among primiparous mothers

### Study objectives

Interventions of antenatal breastfeeding workshop and postnatal brief motivational intervention are effective at improving exclusive breastfeeding (EBF) rates for infants less than 6 months among primiparous mothers.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 27/01/2021, Medical and Health Research & Ethics Committee (MHREC Executive Screening Suite, Basement Carpark Level 1, Raja Isteri Pengiran Anak Saleha Hospital, Bandar Seri Begawan BA1710, Negara Brunei Darussalam, Brunei; +673-2381640; mhrec@moh.gov.bn), ref: MRHEC/MOH/2020/20(1)

### Study design

Single-blinded randomized controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Community

### Study type(s)

Other

### Participant information sheet

See additional file ISRCTN55245820\_PIS (added 01/06/2021)

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

Exclusive breastfeeding among primiparous mothers

### Interventions

First-time pregnant women are recruited during their routine antenatal health educational talk at two maternal and child health centres. Those who fit the eligibility criteria are then assigned

randomly into either control or intervention groups with a 1:1 allocation as per a computer generated randomization schedule stratified by site using permuted blocks of random sizes.\* The block sizes will not be disclosed, to ensure concealment.

1. Intervention group: In addition to the routine care, first-time mothers assigned to the intervention group will be invited to attend antenatal breastfeeding workshop. They will also receive a 15-minute Brief Motivational Intervention (BMI) via phone call at the first and third month postpartum.

2. Control group: In addition to the routine care, first-time mothers assigned to this group will be invited to the antenatal breastfeeding workshop in addition the routine care. They will however not receive any BMI via phone call postpartum.

\*Sealed Envelope Ltd. 2021. Simple randomisation service. [Online] Available from: <https://www.sealedenvelope.com/simple-randomiser/v1/> [Accessed 6 May 2021].

### **Intervention Type**

Behavioural

### **Primary outcome measure**

Mother's breastfeeding status (whether they are still exclusively breastfeeding, partially breastfeeding, or not breastfeeding). This is routinely assessed by community health nurse at their infant's follow-up at first week, second month, fourth month and sixth month of age.

### **Secondary outcome measures**

Mother's breastfeeding self-efficacy measured using the Hill & Hummenic questionnaire which will be assessed at first week, second month, fourth month and sixth month of infant's age during child health clinic visits.

### **Overall study start date**

11/10/2020

### **Completion date**

31/12/2023

## **Eligibility**

### **Key inclusion criteria**

Primigravida (first-time pregnant mothers)

### **Participant type(s)**

Healthy volunteer

### **Age group**

Adult

### **Sex**

Female

### **Target number of participants**

**Key exclusion criteria**

1. Has medical conditions requiring to take medications
2. Has attended other breastfeeding interventions in addition to the antenatal breastfeeding workshop they are recruited from

**Date of first enrolment**

01/07/2022

**Date of final enrolment**

30/04/2023

**Locations****Countries of recruitment**

Brunei Darussalam

**Study participating centre****Maternal & Child Health Clinic**

PAPMHMB Gadong Health Centre  
Spg 256 – 23, Kampong Rimba, Gadong  
Negara Brunei Darussalam  
Bandar Seri Begawan  
Brunei Darussalam  
BE3119

**Study participating centre****Maternal & Child Health Clinic**

Berakas Health Centre  
Bandar Seri Begawan  
Brunei Darussalam  
BB3713

**Sponsor information****Organisation**

Ministry of Health (Brunei)

**Sponsor details**

Commonwealth Drive  
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**Sponsor type**  
Government

**Website**  
<http://moh.gov.bn>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
Ministry of Health (Brunei)

## Results and Publications

**Publication and dissemination plan**  
Planned publication in a high-impact peer-reviewed journal.

**Intention to publish date**  
01/01/2025

**Individual participant data (IPD) sharing plan**  
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request (faezah.amin@moh.gov.bn)

**IPD sharing plan summary**  
Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>			01/06/2021	No	Yes