

Effectiveness of interventions in improving continued exclusive breastfeeding in Brunei Darussalam

Submission date 28/04/2021	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/05/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/03/2024	Condition category 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

Contact name

Dr Faezah Amin

Contact details

Ministry of Health
Commonwealth Drive
Bandar Seri Begawan
Brunei Darussalam
BB3900
+673 (0)8305515
faezah.amin@moh.gov.bn

Type(s)

Scientific

Contact name

Dr Lubna Razak

ORCID ID

<https://orcid.org/0000-0002-1026-8401>

Contact details

Health Promotion Centre
Ministry of Health
Commonwealth Drive
Bandar Seri Begawan
Brunei Darussalam
BB3900
+673 (0)238 5800
lubna.razak@moh.gov.bn

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Other

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(s)

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.

Key secondary outcome(s)

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.

Completion date

31/12/2023

Eligibility

Key inclusion criteria

Primigravida (first-time pregnant mothers)

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

Funder(s)

Funder type

Government

Funder Name

Ministry of Health (Brunei)

Results and Publications

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?
Participant information sheet			01/06/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes