

Exclusive breastfeeding and predominant breastfeeding rate at one month postpartum in Thailand

Submission date 15/11/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 23/03/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/09/2011	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Study information

Scientific Title

Midwifery antenatal breastfeeding education intervention for increasing the rate of breastfeeding postpartum at one month in Thailand

Study objectives

A midwife provided antenatal breastfeeding educational programme will be effective in increasing the rate of breastfeeding at one month following birth.

Please note, as of 22/09/2011 various updates have been made to the trial record. These changes can be found under this date of update in the relevant fields below.

The original public title was 'Breastfeeding rate at one month postpartum in Thailand'.

Both start and end dates have been updated. The original start date was 02/01/2011 and the original end date was 31/07/2012.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Newcastle Human Research Ethics Committee approved on 13/04/2011. Variation approved on 20/09/2011 (ref: EC00144)

Study design

Two group randomised controlled trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Pregnancy and breastfeeding

Interventions

1. 1.5 hours sessions of group-based breastfeeding education.
2. The sessions will be designed and conducted in line with midwifery philosophy, self-efficacy theory and adult learning principles.
3. Women will commence their first session of group-based education at approximately 28 - 32 weeks gestation.
4. Group-based education will be provided to participants and their partners every fortnight.
5. The control group will receive standard care from the midwives at antenatal clinics.
6. The standard care does not include group-based antenatal education.

Additional contact names and email addresses:

Associate Professor Ashley Kable: Ashley.Kable@newcastle.edu.au

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Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Current primary outcome measure as of 22/09/2011:

The rate of exclusive breastfeeding and predominant breastfeeding at one month

Previous primary outcome measure:

The effectiveness of a midwifery antenatal breastfeeding intervention which can be used by other midwives in Thailand to increase breastfeeding rates. (Evaluation of Group-Based Breastfeeding Programme: The intervention group, including partners, will be invited to complete an evaluation tool and comment on the strengths and limitations of the programme.)

Key secondary outcome(s)

Current secondary outcome measures as of 22/09/2011:

- 1) Evaluation of the breastfeeding program
- 2) Initiation of breastfeeding
- 3) Self-efficacy
- 4) Perceive breastfeeding support
- 5) Breastfeeding intention

Previous secondary outcome measure:

The rate of breastfeeding at one month which will be affected by the antenatal breastfeeding programme. (Data from completed telephone interviews tool will be analysed based on intention to treat and treatment received.)

Completion date

31/12/2012

Eligibility

Key inclusion criteria

Current inclusion criteria as of 22/09/2011:

- 1) All primiparous pregnant women aged greater than 13 years old
- 2) Gestational ages between 24 and 28 weeks
- 3) Ability to speak Thai language
- 4) Neither intellectually nor mentally impaired in ways that would preclude effective group interaction
- 5) No serious concurrent diseases in ways that would preclude effective group interaction

Previous inclusion criteria:

1. Low risk pregnant women aged greater than 13 years old
 2. Gestational ages between 24 and 29 weeks
- (Other points remained unchanged)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Current exclusion criteria as of 22/09/2011:

- 1) Threatened premature labour after 20 weeks
- 2) Serious medical and obstetrical complications, e.g. heart disease, eclampsia and cervical incompetence
- 3) Alcohol use

Previous exclusion criteria:

1. Moderate to high risk pregnant women
2. Threatened abortion before 20 weeks
3. Threatened premature labour after 20 weeks
4. Serious medical and obstetrical complications, e.g. heart disease, eclampsia and cervical incompetence
5. Hypertension
6. Illicit drug use or alcohol use
7. Multiple pregnancies

Date of first enrolment

02/10/2011

Date of final enrolment

31/12/2012

Locations

Countries of recruitment

Australia

Thailand

Study participating centre

School of Nursing and Midwifery, Richardson Wing

Newcastle

Australia

2308

Sponsor information

Organisation

The University of Newcastle (Australia)

ROR

<https://ror.org/00eae9z71>

Funder(s)

Funder type

University/education

Funder Name

The University of Newcastle (Australia) - Faculty of Health, School of Nursing and Midwifery

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration