

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

<b>Submission date</b> 15/11/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/03/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 22/09/2011	<b>Condition category</b> 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

Mrs Podjanee Parkpoom

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

# 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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Quality of life

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## 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

Dr Virginia Skinner: Virginia.Skinner@newcastle.edu.au

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

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.)

## **Secondary outcome measures**

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.)

## **Overall study start date**

02/10/2011

## **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

### **Age group**

Adult

### **Sex**

Female

### **Target number of participants**

Updated 22/09/2011: 166 participants randomly allocated (83 per group) (At time of registration: 470 participants randomly allocated (235 per group))

### **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)

**Sponsor details**  
University Drive  
Callaghan  
Newcastle  
Australia  
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Ashley.Kable@newcastle.edu.au

**Sponsor type**  
University/education

**Website**  
<http://www.newcastle.edu.au/>

**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

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration