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

Submission date	Recruitment status	[X] Prospectively registered
15/11/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/03/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/09/2011	Pregnancy and Childbirth	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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, ecalmpsia 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)

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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