ISRCTN85493925 https://doi.org/10.1186/ISRCTN85493925

Women who are breastfeeding: Increasing Self-Efficacy to improve outcomes (WISE) Trial

Submission date
15/07/2013

Recruitment status
No longer recruiting

Registration date
26/07/2013

Overall study status
Completed

Last Edited
19/01/2018

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The World Health Organization, Canadian Paediatric Society and the American Academy of Pediatrics all recommend breastfeeding as the best method of infant feeding. These recommendations suggest that infants be breastfed exclusively for the first 6 months of life and then, once other foods have been introduced, continue to be breastfed until 2 years and beyond. This strong recommendation is based on evidence that breastfeeding offers important health benefits for both mothers and infants. Despite these benefits and a breastfeeding initiation rate of 90% in Canada, a recent nation-wide survey found that only 27% of mothers are exclusively breastfeeding to 6 months after giving birth (postpartum). Exclusive breastfeeding and breastfeeding duration depends on a mothers confidence in her ability to breastfeed (breastfeeding self-efficacy) in a period shortly after giving birth. The goal of this study is to determine whether or not a breastfeeding self-efficacy enhancing intervention (BSEI) can improve breastfeeding exclusivity rates at 6 months postpartum.

Who can participate?
This trial aims to recruit 956 breastfeeding, first-time mothers (primiparous) aged ≥ 18 years from across participating hospitals in the Greater Toronto Area (GTA). Participants must have access to a telephone, speak and understand English, have a singleton birth, and the infant must be ≥ 37 weeks old at the time of delivery. Mothers must have the intention to exclusively breastfeed. Both the mother and infant must be discharged from hospital together and not have a health condition that could interfere with breastfeeding (e.g., severe illness, major congenital anomaly). The mother should not have had a breast reduction surgery.

What does the study involve?
All in-hospital, primiparous (pregnant for the first time), breastfeeding mothers will be briefly introduced to the study by a staff nurse on the postpartum unit and asked for permission to be contacted by the research nurse. If the mother agrees, the research nurse will provide a detailed study explanation, assess for eligibility, and obtain written informed consent. Following the collection of baseline information, all eligible, consenting mothers will be randomly allocated to the intervention group (BSEI) or control group (the standard in-hospital and community postpartum care). A research assistant will telephone all participants at 3, 6, 9, 12 and 18 months postpartum to collect follow-up information.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part. However, the results from this trial are likely to present valuable information regarding breastfeeding behaviours across the first year postpartum in a diverse Canadian sample. If participants indicate that they may harm their baby or any other children, child welfare services will be contacted, as required by law. In the event of any immediate safety concerns or danger, emergency services (9-1-1) will be called. In these rare instances, participation may indicate possible social and legal risks.

Where is the study run from?
The trial has been set up by the Womens College Hospital and University of Toronto in collaboration with three large hospitals in Ontario. The Data Coordinating Centre is located at the University of Toronto.

When is the study starting and how long is it expected to run for?
The recruitment phase was successfully conclude in December 2017. Participants follow-up interviews will continue for another 18 months postpartum

Who is funding the study?
Funding has been provided by the Canadian Institutes of Health Research (CIHR).

Who is the main contact?
Principal Investigator Dr. Cindy-Lee Dennis, cindylee.dennis@utoronto.ca
Research Manager Alvaro Ferreira, mothering.transitions@utoronto.ca

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled trial to evaluate the effect of a breastfeeding self-efficacy enhancing intervention on breastfeeding exclusivity among primiparous mothers

Acronym
WISE

Study objectives
What is the effect of a breastfeeding self-efficacy enhancing intervention provided by combined nurse and peer mentor support on breastfeeding exclusivity among primiparous mothers at 6 months postpartum?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University of Toronto Office of Research Ethics, 30/01/2014, protocol # 29656
2. The Scarborough Hospital Research Ethics Board , 20/01/2014, protocol # PAED-12
3. William Osler Health System Research Ethics Board, 09/02/2014
4. Thunder Bay Regional Health Sciences Centre Research Ethics Office, 11/03/2014, protocol # 2013156

Study design
Multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Breastfeeding exclusivity among primiparous mothers at 6 months postpartum

Interventions

Current interventions as of 19/01/2018:
Participants allocated to the intervention group will receive standard postpartum care plus four individualized self-efficacy enhancing sessions with a trained research nurse; mothers will also be offered telephone-based peer support following hospital discharge up to 18 months postpartum.

Previous interventions:
Participants allocated to the intervention group will receive standard postpartum care plus four individualized self-efficacy enhancing sessions with a trained research nurse; mothers will also be offered telephone-based peer support following hospital discharge up to 12 months postpartum.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Breastfeeding exclusivity as identified by the Infant Feeding Questionnaire administered at 6 months postpartum

Secondary outcome measures
What is the effect of the breastfeeding self-efficacy intervention (BSEI) on:
1. Breastfeeding exclusivity at 3 months postpartum?
2. Breastfeeding duration at 3, 6, 9, and 12 months postpartum?
3. Breastfeeding difficulties at 3 6, 9, and 12 months postpartum?
4. Health service utilization at 3, 6, 9, and 12 months postpartum?
5. Cost implications
6. Mothers evaluations of their BSEI and peer support experience
7. Nurses and peers reports of the type and intensity of their BSEI activities

Overall study start date
31/01/2014

Completion date
31/01/2020

Eligibility

Key inclusion criteria
In-hospital breastfeeding mothers who meet the following criteria:
1. Primiparous
2. Aged above 18 years
3. Singleton birth
4. Infant greater than or equal to 37 weeks gestational age at delivery
5. Can speak and understand English.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
956

Key exclusion criteria
1. Maternal/infant health condition that could interfere with breastfeeding (e.g., severe illness, major congenital anomaly)
2. Infant not expected to be discharged home with mother
3. No telephone access
4. Maternal breast reduction surgery
5. Maternal intention to not exclusively breastfeed

Date of first enrolment
31/01/2014

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Canada

Study participating centre
Lawrence S. Bloomberg Faculty of Nursing
Toronto
Canada
M5T 1P8

Sponsor information

Organisation
Women's College Hospital (Canada)

Sponsor details
76 Grenville St.
Toronto, ON

Canada
M5S 1B2
+1 416 323 6400
Diana.Raymond-Watts@wchospital.ca

Sponsor type
Hospital/treatment centre

Website
http://www.womenscollegehospital.ca/

ROR
https://ror.org/03cw63y62

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

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