ISRCTN17875591 https://doi.org/10.1186/ISRCTN17875591

A complex breastfeeding promotion and support intervention in a developing country

Submission date
20/07/2013

Recruitment status
No longer recruiting

Registration date
12/08/2013

Overall study status
Completed

Last Edited
22/07/2024

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims

Breastfeeding has countless benefits to mothers, children and the community at large, especially in developing countries. Exclusive breastfeeding is a cost-effective preventive public health measure that has a major impact on diseases and death in infants. Research in Lebanon reports disappointingly low breastfeeding exclusivity and continuation rates. This is predominantly due to a bottle-feeding culture fuelled by mothers misconceptions such as insufficiency of breast milk and lack of satisfaction in the baby, breastfeeding causing maternal weight gain or breast sagging, harmful mothers milk during certain situations such as grief, illness or pregnancy, and breastfeeding causing pain, sleep deprivation and exhaustion. The impact of this on the public health in a country with limited healthcare resources and a burden of different diseases such as Lebanon is significant. This study aims to test whether providing breastfeeding promotion and support to pregnant women from early pregnancy until the newborn is six months of age increases exclusive breastfeeding rates at six months.

Who can participate?

Healthy pregnant women who are in their first trimester and who intend to breastfeed after delivery can participate in this study. Mothers who have breastfed at least one child for 2 months and can read and write Arabic are eligible to train as support mothers.

What does the study involve?

Pregnant women will be randomly assigned to one of two groups: either to receive the package consisting of breastfeeding education and counseling to improve their knowledge and expectations, professional support to build appropriate breastfeeding skills, and peer support through a mother-to mother breastfeeding support network, or to receive standard prenatal and postnatal care. They will be followed-up from early pregnancy to 5 years after delivery. The support package will be delivered in 10 to 14 structured scheduled visits or phone calls to the participating mother, starting from the date of enrolment, through delivery, first week after the birth, monthly up until 6 months, and then yearly for 5 years. During the visits or phone calls, information will be collected regarding mothers pregnancy and delivery, family conditions, quality of life, breastfeeding knowledge, satisfaction with the experience in being a participant in this research study, the health and nutrition of the baby, and success in breastfeeding future babies in years 3 to 5.

What are the possible benefits and risks of participating?
The benefits of this study are increased breastfeeding duration and potential improvement of the health of the mother and the baby. The study will also help researchers better understand how to improve breastfeeding rates in Lebanon, and hopefully other countries with a similar problem. There are no physical or emotional risks beyond the risks of daily life. The home visits and/or phone calls to mothers may however be foreseen as intrusion of privacy.

Where is the study run from?
The study will be conducted in maternity clinics of the American University of Beirut Medical Center and Sahel General Hospital, in Beirut, Lebanon.

When is the study starting and how long is it expected to run for?
The study will start in October 2013 and is expected to be completed in 5 years.

Who is funding the study?
The American University in Beirut (Lebanon)

Who is the main contact?
Dr Mona Nabulsi
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Contact information

Type(s)
Scientific

Contact name
Dr Mona Nabulsi

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Additional identifiers

Protocol serial number
PED.MN.08

Study information

Scientific Title
A complex breastfeeding promotion and support intervention in a developing country: a randomized clinical trial

Study objectives
We hypothesize that a complex intervention targeting new mothers breastfeeding knowledge, skills and social support within a Social Network and Social Support theory framework will increase exclusive breastfeeding duration among women in Lebanon.

Ethics approval required
Old ethics approval format

Ethics approval(s)
American University of Beirut Institutional Review Board, 20/03/2013; IRB number PED.MN.08

Study design
Single-blind randomized clinical trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Breastfeeding practice in the first six months postpartum

Interventions
A. Intervention group:
1. Prenatal breastfeeding education
1.1. Antenatal classes
1.2. Pamphlet and video on breastfeeding
2. Professional lactation support
3. Social network and social support

B. Control group:
Standard prenatal and postnatal care

Duration of interventions is 6 months, follow up period is for 5 years from delivery for data collection. This is applicable for both groups.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Percent difference in 6-month breastfeeding exclusivity rates between the intervention and control groups.

For all outcomes we will use questionnaires that will be administered at baseline and later at different time points. For the primary outcome, it is a questionnaire about infant diet at 6 months of age.

Key secondary outcome(s)
Differences between the two study groups with respect to the following:
1. Breastfeeding exclusivity rates at 1 and 3 months
2. Breastfeeding continuity rates at 1, 3 and 6 months
3. Breastfeeding knowledge and attitudes of mothers at 6 months
4. Success of mother-to-mother support system measured as satisfaction rates of breastfeeding mothers, support mothers, and nurses; referral rate of breastfeeding mothers to physicians, and adverse events at 6 months
5. Cost-benefit analysis of the complex intervention
6. Quality of life at 1, 3 and 6 months
7. Success in exclusive breastfeeding of future babies, measured as the percent difference in 6-month breastfeeding exclusivity rates between the two groups in subsequent babies up to 5 years later

For secondary outcomes, we will use validated questionnaires about breastfeeding knowledge, attitude and behaviour, and the postpartum quality of life questionnaire.

Completion date
19/07/2021

Eligibility

Key inclusion criteria
A. Pregnant women
1. Healthy pregnant women in their first trimester of pregnancy
2. Willing to breastfeed after delivery
3. Available during pregnancy and for 6 months postpartum

B. Support mothers
1. Breastfed at least one child for 2 months
2. Has positive perceptions about breastfeeding
3. Able to attend 2 half-day training sessions to learn how to support mothers as well as when to refer mothers to professional resources
4. Can read and write Arabic (middle school level)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
362

Key exclusion criteria
1. Pregnancy beyond the first trimester
2. Presence of chronic medical condition
3. Abnormal fetal screen (ultrasound/blood/amniocentesis)
4. Not willing to breastfeed after delivery
5. Not living in Lebanon for at least six months after delivery
6. Twin gestation
7. Preterm birth (at <37 weeks gestation)

Date of first enrolment
01/10/2013

Date of final enrolment
21/01/2016

Locations

Countries of recruitment
Lebanon

Study participating centre
Department of Pediatrics and Adolescent Medicine
Beirut
Lebanon
1136044C8

Sponsor information

Organisation
American University of Beirut (Lebanon)

ROR
https://ror.org/04pznsd21

Funder(s)

Funder type
University/education

Funder Name
Medical Deans Program Projects in Biomedical research; American University of Beirut (Lebanon)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study will be available as anonimsed datasets upon request from the principal investigator Dr Mona Nabulsi, email: mn04@aub.edu.lb. Anonymised datasets will become available as of February 2021 for the subsequent five years. Relevant data will be provided to interested researchers for secondary data analyses. The participant consent did not mention data sharing plans since this was not anticipated at that time. Data sharing will be governed by a contract between the principal investigator and the requesting investigator through the Office of Grants and Contracts of the American University of Beirut.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/06/2019	05/07/2019	Yes	No
Results article	substudy results	01/05/2017	11/07/2019	Yes	No
Results article	substudy results	01/11/2016	11/07/2019	Yes	No
Results article	substudy results	01/05/2016	11/07/2019	Yes	No
Results article	substudy results	23/10/2019	24/10/2019	Yes	No
Results article	results	04/09/2020	07/09/2020	Yes	No
Protocol article	protocol	15/01/2014		Yes	No
Other publications	questionnaire validation	09/06/2020	15/06/2020	Yes	No
Other publications	Cost-benefit analysis	19/07/2024	22/07/2024	Yes	No