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Effectiveness of counselling on breastfeeding duration, infant growth velocity and postpartum weight loss in overweight women

Submission date
22/02/2019

Recruitment status
No longer recruiting

Registration date
27/02/2019

Overall study status
Completed

Last Edited
25/01/2021

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Maternal overweight, infant feeding and early growth velocity are risk factors for obesity later in life. The first one thousand days are a window of opportunity to program health and disease. Exclusive breastfeeding may protect against obesity; however, it is not consistently practiced and obesity rates have been increasing worldwide. Overweight women have lower rates of breastfeeding. Breastfeeding counselling is a successful strategy to support breastfeeding in normal weight women, but there is a lack of evidence on its effectiveness in overweight women. The aim of this study is to test a new approach of exclusive breastfeeding counselling based on Carl Rogers' Centered-Client Theory in overweight women, and to examine its effects on breastfeeding duration, infant growth velocity and maternal postpartum weight loss.

Who can participate?
Overweight pregnant women aged over 18 recruited in a Baby Friendly Hospital in Bogotá, Colombia

What does the study involve?
Participants are randomly allocated to the intervention (breastfeeding counseling) or control group (standard breastfeeding support).The intervention is exclusive breastfeeding counselling based on Rogers' theory but adapted to support overweight women; it is performed during the last month of pregnancy, 24 hours after delivery and during early infancy. Exclusive breastfeeding duration, infant growth velocity and maternal weight loss are measured at the 1st, 3rd and 4th months after the birth.

What are the possible benefits and risks of participating?
The intervention may result in an increase in the initiation and duration of exclusive breastfeeding, allowing adequate infant growth velocity and maternal weight loss after delivery; it is hoped that the results of this trial will provide evidence to support public health policy on supporting breastfeeding in this vulnerable group of women. Benefits include a report of nutritional status at every appointment, economic support for transportation to the institution at every appointment and if the woman is allocated to intervention group she will receive

breastfeeding counseling at three timepoints during the study. The study uses an intervention with minimum risk and represents a low health risk for the women related to providing blood and breast milk samples.

Where is the study run from?
Centro de Atención Prioritaria en Salud, Suba, Subred Norte (Columbia)

When is the study starting and how long is it expected to run for?
January 2018 to December 2019

Who is funding the study?
1. Pontificia Universidad Javeriana (Columbia)
2. Administrative Department of Science, Technology and Innovation, COLCIENCIAS (Columbia)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
U1111-1228-9913

Study information

Scientific Title
Effectiveness of a new approach for exclusive breastfeeding counselling on breastfeeding duration, infant growth velocity and postpartum weight loss in overweight women: a randomized controlled trial

Study objectives
Compared to standard management, the implementation of a new approach in EBF counselling to overweight woman will result in:
1. An increase in the prevalence of duration of BF and EBF from birth up to four months of age.
2. Slower growth velocity in infant weight for length from birth up to four months of age.
3. An increase in weight loss in the overweight woman after delivery to the fourth month postpartum.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee at the Faculty of Sciences at the Pontificia Universidad Javeriana and the Ethical Committee at the institution selected for the study, Mrs. Piedad Zuluaga, Subred Integrada de Servicios de Salud Norte E.S.E., U.S.S. Simón Bolívar - Quinto Piso, Tel: 571 4431790 Ext. 4023, Email: investigacionsubrednorte@gmail.com, 28/04/2018, Code Approval SNCI-021-CEI Acta 08

Study design
Single-centre two-arm randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pregnant overweight and obese women

Interventions
Participants are randomised to the intervention (breastfeeding counseling) or control group (standard breastfeeding support), partially blinded to the researcher. Randomization assignments will be prepared by a member of the team who has no contact with the study subjects, using randomized blocks. Assignments will be stored in sealed opaque envelopes. It will be not possible to blind researchers doing the intervention and collecting anthropometric and food intake data, but laboratory measurements will be blinded.

A new approach towards EBF counselling was designed based on Rogers' client-centered theory. The women assigned to the intervention group will receive the intervention at three key timepoints:
1. Last month of gestation to prepare and promote the importance of early contact, BF initiation in the first postpartum hour, and to prepare the women to face difficulties in establishing BF
2. 24 hours postpartum to ensure that EBF is being established and to identify any difficulties the mother is experiencing
3. Early infancy (1st and 3rd months postpartum) to identify breastfeeding problems and

empower the women to continue exclusive breastfeeding
The intervention will be conducted by a certified breastfeeding counsellor with listening skills, understanding the situation, analysing the environment and maternal BF problems in order to reach consensus solutions (woman and counsellor).

Intervention Type
Behavioural

Primary outcome(s)
Measured at the 1st, 3rd and 4th months postpartum:
1. Duration of EBF and BF ascertained by asking the mother about infant feeding practices during the last 24 hours at birth and 4th month postpartum
2. Growth velocity in weight and length as the change in the indicators weight for length (W/L) and length for age (L/A) from birth up to 4 months
3. Maternal weight loss after delivery using the measurement of maternal weight at 24 hours as baseline and 4 months after delivery

Key secondary outcome(s))
Maternal serum levels of prolactin and prolactin concentration and macronutrients in the breast milk, measured at 1 and 4 months after delivery

Completion date
31/12/2019

Eligibility

Key inclusion criteria
Women:
1. Singleton pregnancy
2. Overweight for gestational age (defined as BMI/GE≥ 28.1 kg/m2 using Atalah's criteria) at the 32nd week
3. Older than 18 years
4. No pre-eclampsia or diabetes
5. Permanent residence in Bogota, Colombia
6. Intention to breastfeed
7. No professional practice of sports
8. Without history of breast surgery or maternal intensive care stay
9. Without postpartum depression risk based on the Edinburgh Postnatal Depression Scale

Infant:
1. Healthy term newborn (≥37 wk), birth weight ≥2500 g - 4000 g
2. Without any condition or malformation that interferes with BF practice

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Mixed

Sex
All

Total final enrolment
90

Key exclusion criteria
Women:
1. Twin pregnancy
2. Normal or low weight for gestational age (defined as BMI/GE < 28.1 kg/m2 using Atalah's criteria) at the 32nd week
3. Younger than 18 years
4. Pre-eclampsia or diabetes
5. Permanent residence in another city different to Bogota, Colombia
6. No intention to breastfeed
7. Professional practice of sports
8. Breast surgery or maternal intensive care stay
9. Postpartum depression risk based on the Edinburgh Postnatal Depression Scale

Infant:
1. Preterm newborn (<37 weeks)
2. Birth weight <2500 g or > 4000 g
3. Condition or malformation that interferes with BF practice

Date of first enrolment
01/07/2018

Date of final enrolment
31/08/2019

Locations

Countries of recruitment
Colombia

Study participating centre
Centro de Atención Prioritaria en Salud, Suba, Subred Norte
Carrera 92 Nº 147 C - 30
Bogotá
Colombia
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Sponsor information

Organisation
Pontificia Universidad Javeriana

ROR
https://ror.org/03etyjw28

Funder(s)

Funder type
University/education

Funder Name
Pontificia Universidad Javeriana

Funder Name
Departamento Administrativo de Ciencia, Tecnología e Innovación

Alternative Name(s)
Administrative Department of Science, Technology and Innovation, Département administratif des sciences, de la technologie et de l'innovation, Departamento Administrativo de Ciência, Tecnologia e Inovação, COLCIENCIAS

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Colombia

Funder Name
Institute of Child Health, University College London

Alternative Name(s)
UCL Great Ormond Street Institute of Child Health, GOS ICH

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/01/2020	06/01/2021	Yes	No
Basic results		23/01/2021	25/01/2021	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes