ISRCTN14819650 https://doi.org/10.1186/ISRCTN14819650

LatchOn: a breastfeeding support study

Submission date
19/12/2018

Recruitment status
No longer recruiting

Registration date
11/02/2019

Overall study status
Completed

Last Edited
07/01/2026

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 provides the best start for babies and is linked with many health benefits for both mother and baby. However, Ireland has one of the lowest rates of breastfeeding worldwide. In particular, women with a high bodyweight are less likely to start breastfeeding and breastfeed for a shorter amount of time. There are many complex reasons for this, but the research suggests that women would be more likely to breastfeed if breastfeeding was considered the normal way to feed a baby, and if she had good social and family support. In 2016, an intervention was tested to improve breastfeeding by providing special support from a lactation consultant before and after a mother had her baby. A support partner was invited to attend classes and provided her with a dedicated phone line to contact the lactation consultant if she had any problems. The intervention was carried out in the National Maternity Hospital, Dublin and Wexford General Hospital and it was very successful in improving rates of breastfeeding and self-confidence, but it needs to be tested out using good scientific methods, and to also see if this intervention would improve breastfeeding rates among women with high bodyweights, as these women and their children will potentially benefit the most from improved support. For this reason only women with body mass index (BMI) over 25 are included in this new study. This study aims to increase breastfeeding rates at 3 months, improve attitudes toward breastfeeding, increase breastfeeding self-confidence and support women in thinking breastfeeding is the normal way to feed her baby. The study also aims to find out which parts of the intervention are most effective in promoting breastfeeding.

Who can participate?
Women aged 18 and over who are pregnant for the first time (single pregnancy) with BMI 25 and over

What does the study involve?
Women are randomly allocated to either receive the breastfeeding support intervention as described above or to receive normal breastfeeding care at the hospital they are attending. Feeding methods are assessed using questionnaires completed by the mother at 3 months after birth.

What are the possible benefits and risks of participating?
It is predicted that those in the intervention will receive better breastfeeding support than currently provided in each hospital, and will therefore be more likely to start breastfeeding and

to breastfeed for a longer time, compared to the women in the normal care group. It is not thought that there will be any risks linked to taking part in the intervention, or any benefits or risks for women in the normal care group.

Where is the study run from?
Four hospitals within the Ireland East Hospital Group (National Maternity Hospital, Dublin, Wexford General Hospital, St Luke's Hospital Kilkenny, and Regional Hospital Mullingar)

When is the study starting and how long is it expected to run for?
August 2018 to November 2023

Who is funding the study?
Nursing and Midwifery Planning and Development Unit (Ireland)

Who is the main contact?
Prof. Fionnuala McAuliffe

Contact information

Type(s)
Scientific

Contact name
Prof Fionnuala McAuliffe

Contact details
UCD Perinatal Research Centre
National Maternity Hospital
65-66 Lower Mount Street
Dublin 2
Ireland
D02 YH21

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
LatchOn: a protocol for a multi-centre, randomised controlled trial of perinatal support to improve breastfeeding outcomes in women with overweight and obesity

Acronym
LatchOn

Study objectives
The trialists hypothesise that the women in the intervention group will have higher rates of breastfeeding initiation, longer breastfeeding duration and higher breastfeeding self-efficacy

than those in the control. They anticipate that the inclusion of the support partner will improve support-structure for the women in her home setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 03/09/2021:
Approved 18/12/2018, Amendment 1 (COVID-19 amendment to recruitment) approved 01/10 /2020, Amendment 2 (extension to timeline for recruitment due to COVID-19) approved, National Maternity Hospital Ethics Committee (Holles Street, Dublin 2, Ireland; +353 6373588; ethicsresearch@nmh.ie), ref: EC.24.2018

Previous ethics approval:
National Maternity Hospital Ethics Committee, 18/12/2018, ref: EC.24.2018

Dr John Murphy, Ethics Research Committee, National Maternity Hospital, Holles Street, Dublin 2, Ireland. Tel: 6373588. Email: ethicsresearch@nmh.ie

Study design
Multi-centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Breastfeeding

Interventions
Current interventions as of 03/09/2021:
Randomisation will be 1:1 allocation. The randomisation will be performed stratified by Overweight: Obese in a 2:1 ratio (e.g. 20 Overweight for every 10 Obese). Randomisation will be also stratified by site, in a 4:1:1:2 ratio for Dublin: Kilkenny: Mullingar: Wexford. Given the nature of the intervention, neither the participants nor the researchers will be blinded to allocation.

Intervention arm: This multi-component intervention targets both prospective mothers and their support partners and spans the perinatal period from late pregnancy to six weeks postpartum. Intervention components include group antenatal education for prospective mothers and their support partners, individual education for new mothers in the immediate postnatal period, and professional support for new mothers to six weeks postpartum. A version of the antenatal class the trialists propose to deliver as part of this study has been used in the feasibility study conducted at The National Maternity Hospital. However, the trialists will revise this class based on feedback from participants in the feasibility study and specific midwives trained to deliver the class. For example, based on the feasibility study the midwives suggested to provide a separate postnatal intervention class on a Friday afternoon-evening and the antenatal class will be held on Friday evening to enable support partners to attend. Through collaborating midwives at each study site, the trialists will identify volunteer breastfeeding mothers from the areas local to each study site to attend the antenatal class with her infant. This

volunteer mother will be available to study participants after the class to answer any questions they may have about practical aspects of breastfeeding. If possible, the volunteer mother will also provide a live demonstration, breastfeeding her own baby in the class. Providing a live breastfeeding demonstration is an original approach that, to our knowledge, has not been previously reported in a breastfeeding intervention study.

Attitudes toward breastfeeding will be targeted by providing education to mothers and their support partners, and by exposure to a breastfeeding mother. Subjective norms around infant feeding will be targeted by providing education to the pregnant woman's support partner, by exposure to a breastfeeding mother, and by provision of breastfeeding support groups postpartum which will be attended by other breastfeeding mothers, normalising the behaviour. The mother's perceived behavioural control of her ability to feed her baby (breastfeeding self-efficacy) will be targeted by providing antenatal and postnatal education that is realistic and describes what to expect when breastfeeding, including potential challenges that may arise and how to manage these challenges. This education will equip women with the skills and confidence to manage breastfeeding, increasing their self-efficacy.

Education will be reinforced by weekly phone calls in the postpartum period from an International Board Certified Lactation Consultant (IBCLC) to answer any questions.

Control arm: Women assigned to the control group will be provided with written information on antenatal and postnatal support for breastfeeding that is available in the study site hospital and community, and will receive routine antenatal care.

Previous interventions:
Randomisation will be 1:1 allocation and stratified by study site. Given the nature of the intervention, neither the participants nor the researchers will be blinded to allocation.

Intervention arm: This multi-component intervention targets both prospective mothers and their support partners and spans the perinatal period from late pregnancy to six weeks postpartum. Intervention components include group antenatal education for prospective mothers and their support partners, individual education for new mothers in the immediate postnatal period, and professional support for new mothers to six weeks postpartum. A version of the antenatal class the trialists propose to deliver as part of this study has been used in the feasibility study conducted at The National Maternity Hospital. However, the trialists will revise this class based on feedback from participants in the feasibility study and specific midwives trained to deliver the class. For example, based on the feasibility study the midwives suggested to provide a separate postnatal intervention class on a Friday afternoon-evening and the antenatal class will be help on Friday evening to enable support partners to attend. Through collaborating midwives at each study site, the trialists will identify volunteer breastfeeding mothers from the areas local to each study site to attend the antenatal class with her infant. This volunteer mother will be available to study participants after the class to answer any questions they may have about practical aspects of breastfeeding. If possible, the volunteer mother will also provide a live demonstration, breastfeeding her own baby in the class. Providing a live breastfeeding demonstration is an original approach that, to our knowledge, has not been previously reported in a breastfeeding intervention study.

Attitudes toward breastfeeding will be targeted by providing education to mothers and their support partners, and by exposure to a breastfeeding mother. Subjective norms around infant feeding will be targeted by providing education to the pregnant woman's support partner, by exposure to a breastfeeding mother, and by provision of breastfeeding support groups postpartum which will be attended by other breastfeeding mothers, normalising the behaviour.

The mother's perceived behavioural control of her ability to feed her baby (breastfeeding self-efficacy) will be targeted by providing antenatal and postnatal education that is realistic and describes what to expect when breastfeeding, including potential challenges that may arise and how to manage these challenges. This education will equip women with the skills and confidence to manage breastfeeding, increasing their self-efficacy.

Education will be reinforced by weekly phone calls in the postpartum period from an International Board Certified Lactation Consultant (IBCLC) to answer any questions.

Control arm: Women assigned to the control group will be provided with written information on antenatal and postnatal support for breastfeeding that is available in the study site hospital and community, and will receive routine antenatal care.

Intervention Type
Behavioural

Primary outcome(s)
Feeding method assessed using self-reported questionnaires completed by the mother, Questionnaire on Infant Feeding (O'Sullivan et al., 2017) at 3 months postpartum

Key secondary outcome(s))
1. Intention to breastfeed following the antenatal component of the intervention, assessed by open ended and closed ended questions in a questionnaire completed by the mother at pre-antenatal class
2. Initiation rates of breastfeeding, collected using hospital discharge data at discharge from hospital
3. Exclusive and any breastfeeding prevalence. assessed using a questionnaire completed by the mother, Questionnaire on Infant Feeding (O'Sullivan et al., 2017), at hospital discharge, 6 weeks and 6 months postpartum
4. Maternal and support partner attitudes toward breastfeeding, assessed by open ended and closed ended questions in a questionnaire completed by the mother at pre-antenatal class, 6 weeks, 3 months, and 6 months postpartum
5. Breastfeeding self-efficacy, assessed using Breastfeeding Self-Efficacy Short Form (Dennis, 2003) at pre-antenatal class, 6 weeks, 3 months, and 6 months postpartum

Completion date
01/11/2023

Eligibility

Key inclusion criteria
1. Primiparous women
2. Singleton pregnancy
3. BMI ≥25 kg/m2 at booking visit
4. 26 – 34 weeks' gestation at recruitment
5. Aged ≥18 years
6. Good understanding of English
7. Ability to give informed consent
8. Have a support partner available and willing to participate in the trial if they are randomised to the intervention group. This support partner may be the infant's father, the pregnant woman' s male or female partner, the pregnant woman's mother or sister or a friend.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
Female

Total final enrolment
225

Key exclusion criteria
1. Preterm (<37 weeks' gestation) delivery
2. Any condition requiring medication that is contraindicated for breastfeeding

Date of first enrolment
01/05/2019

Date of final enrolment
01/11/2022

Locations

Countries of recruitment
Ireland

Study participating centre
National Maternity Hospital
Holles Street
Dublin
Ireland
D02 YH21

Study participating centre
Wexford General Hospital
Newtown Rd

Wexford
Ireland
Y35 Y17D

Study participating centre
St Luke's General Hospital
Freshford Road
Kilkenny
Kilkenny
Ireland
R95 FY71

Study participating centre
Regional Hospital Mullingar
Mullingar,
Co Westmeath
Ireland
N91 NA43

Sponsor information

Organisation
University College Dublin

ROR
https://ror.org/05m7pjf47

Funder(s)

Funder type
Government

Funder Name
Nursing and Midwifery Planning and Development Unit

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Fionnuala McAuliffe. Data collected will be of quantitative nature, and will only be available post-completion of the trial. Consent will be obtained from participants to allow anonymous data sharing.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/02/2024	07/01/2026	Yes	No
Protocol article		08/04/2021	03/09/2021	Yes	No