

# LatchOn: a breastfeeding support study

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| <b>Submission date</b><br>19/12/2018   | <b>Recruitment status</b><br>No longer recruiting     | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>11/02/2019 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>03/09/2021       | <b>Condition category</b><br>Pregnancy and Childbirth | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Prevention

## **Participant information sheet**

## **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

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## **Intervention Type**

Behavioural

## **Primary outcome measure**

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

## **Secondary outcome measures**

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

## **Overall study start date**

01/08/2018

**Completion date**

01/11/2023

## Eligibility

**Key inclusion criteria**

1. Primiparous women
2. Singleton pregnancy
3. BMI  $\geq 25$  kg/m<sup>2</sup> at booking visit
4. 26 – 34 weeks' gestation at recruitment
5. Aged  $\geq 18$  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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

220

**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

**Sponsor details**

Belfield  
Dublin 4  
Ireland  
D04 N2E5

**Sponsor type**

University/education

**Website**

www.ucd.ie

**ROR**

<https://ror.org/05m7pjf47>

## Funder(s)

**Funder type**

Government

**Funder Name**

Nursing and Midwifery Planning and Development Unit

## Results and Publications

**Publication and dissemination plan**

The trialists plan to publish a study protocol with a plan for data analysis, but this is not available yet. Study results will be published in peer-reviewed journals and presented orally and/or in poster format at conferences. The trialists may also create a policy brief aimed at government policymakers and others who are interested in formulating or influencing policy. It may take the form of a concise summary of breastfeeding issues in Ireland, the policy options to deal with it, and some recommendations on the best options as observed from the RCT.

**Intention to publish date**

01/12/2023

**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? |
|----------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a> |         | 08/04/2021   | 03/09/2021 | Yes            | No              |