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The Breastfeeding Study: Prevention of early breastfeeding cessation in mothers and infants

Submission date 27/10/2023	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol
Registration date 17/11/2023	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 13/08/2025	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

While there's a lot of strong evidence supporting the benefits of breastfeeding for both moms and babies, and it's considered a matter of public health, many new mothers end up stopping breastfeeding early because they don't get the best care, information, or support they need. Even though most expectant mothers want to breastfeed, the number of people doing so has been going down in Sweden for the past two decades. There are multiple reasons for this decline, but a couple of big ones are that the people taking care of new moms and babies often don't know enough about breastfeeding, and sometimes, they give formula to newborns in the maternity ward even when there's no medical reason to do so.

When moms and babies stop breastfeeding early because they're not getting the help they need, they miss out on important health benefits. That's why the United Nations says parents should be given information about why breastfeeding is good for their children. Supporting moms to breastfeed is a smart and cost-effective thing to do, and there's a global agreement on how to do it – guidelines for promoting, protecting, and supporting breastfeeding.

It's not always easy to put these guidelines into practice in everyday healthcare. That's where the Breastfeeding Study at Uppsala University comes in. It's all about using solid evidence to create better information and routines for breastfeeding. The main goal is to help more moms breastfeed successfully. The program follows the ten steps for successful breastfeeding set by the Baby-Friendly Hospital Initiative (BFHI). It involves supporting parents, training healthcare professionals, and improving how we take care of moms and babies. They used something called Intervention Mapping to design the program.

Who can participate?

The study population consists of staff and patients in separate groups. The study sample among health care professionals includes assistant nurses, nurses, midwives and physicians (obstetricians and paediatricians) and among among patients the study sample consists of full-term healthy children and their parents. Among patients, the exclusion criteria are severe maternal disease or parents who use drugs. Infants with a chromosomal abnormality or birth defect that might affect breastfeeding (such as cleft lip and cleft palate), infants who are small for gestational age, preterm or transferred to neonatal care.

What does the study involve?
The Breastfeeding Study is a comprehensive program that involves making changes to how healthcare is provided and educating healthcare professionals. This program consists of a training day for healthcare professionals that focuses on the practical aspects of their work, as well as providing them with helpful information materials to aid in providing support for breastfeeding. For parents, the program includes informative leaflets. The program will go through a process of development, testing to see if it's practical, and evaluation to determine its effectiveness.

What are the possible benefits and risks of participating?
Research involving infants requires careful ethical considerations, especially since infants cannot give consent to participate. Assessing potential benefits and risks is a crucial part of the research process.

Potential benefits for infants in these studies include a higher likelihood of successful breastfeeding, advantages of skin-to-skin contact (SSC), improved emotional bonding with parents, and reduced stress. These benefits also extend to mothers and, in part, to the other parent. However, there are safety concerns regarding SSC and co-sleeping, as these practices are closely related to breastfeeding. Parents will receive written guidance on enhancing safety during SSC and co-sleeping, and healthcare professionals will be educated on these topics.

Both parents' well-being is vital for a healthy family, and data will be collected for both parents in the studies. Ethical considerations also include respecting mothers' choices on infant feeding, providing support to mothers who choose not to breastfeed, and addressing the needs of foreign-born parents who may not speak Swedish.

To ensure ethical integrity, participants will not be pressured to discuss sensitive topics, and their personal information will be handled confidentially. The research design will focus on facilitating healthcare professionals' work without overburdening them, with an emphasis on interpersonal skills and positive practices. Resource utilization and cost-effectiveness will also be considered.

The study has received approval from the Ethical Review Board in Sweden, and parents will be informed that their participation is voluntary and confidential. Data will be securely stored in accordance with data protection regulations, and healthcare professionals will be informed that their participation in questionnaires is voluntary and anonymous.

Where is the study run from?
The study runs from four regions in Sweden: Uppsala, Gotland and Gävleborg (Sweden)

When is the study starting and how long is it expected to run for?
October 2012 to November 2029

Who is funding the study?
The study is funded by Uppsala University and Region Gävleborg (Sweden)

Who is the main contact?
Eva-Lotta Funkquist, eva-lotta.funkquist@kbh.uu.se

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Skin-to-skin contact and breastfeeding during the neonatal period

Acronym
The Breastfeeding Study

Study objectives
An intervention based on the "Ten Steps to Successful Breastfeeding" will improve breastfeeding outcomes.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 14/12/2016, Uppsala Regional Ethical Review Board (Etikprövningsmyndigheten, Box 1964, Uppsala, 75 149, Sweden; +46 18 471 7400; registrator@uppsala.epn.se), ref: 2016/392

2. Approved 10/08/2020, Uppsala Regional Ethical Review Board (Etikprövningsmyndigheten, Box 2110, Uppsala, 750 02, Sweden; +46 10 475 08 00; registrator@etikprovning.se), ref: 2020-01417

Study design
Quasi-experimental study design

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community, GP practice, Hospital, Medical and other records

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Prevention of early breastfeeding cessation in mothers and infants

Interventions
Baseline data was collected prior to implementation of the intervention, thereafter data was collected from the intervention group.

The intervention consisted of education of health care professionals, standardised information to parents and breastfeeding-friendly care routines.

Data was collected from medical records and questionnaires to parents and health care professionals. Saliva from parents and infants.

Follow up for 12 months.

Intervention Type
Behavioural

Primary outcome measure
Exclusive breastfeeding in infants two months of age measured using a survey at infant age 2 months

Secondary outcome measures
1. Breastfeeding duration, breastfeeding self-efficacy and breastfeeding pattern are measured using a survey at 2, 6 and 12 months
2. Skin-to-skin contact is measured using a survey during hospital stay.
3. Care routines during hospital stay is measured using journal review.
4. Stress in infants and parents are measured using cortisol analysis at infant age of 2 months.
5. Parental style is measured using survey at infant age of 2, 6 and 12 months.
6. Evaluation of the breastfeeding education of health care professional is measured using survey after the education.

Overall study start date
17/10/2012

Completion date
31/08/2025

Eligibility

Key inclusion criteria
1. Newborn infants and their parents
2. Health care professionals working with newborn

Participant type(s)

Patient, Health professional

Age group
Mixed

Lower age limit
0 Days

Upper age limit
65 Years

Sex
Both

Target number of participants
1,000

Key exclusion criteria
1. Severe maternal disease or parents who use drugs.
2. Infants with a chromosomal abnormality or birth defect that might affect breastfeeding (such as cleft lip and cleft palate)
3. Infants who are small for gestational age, preterm or transferred to neonatal care.

Date of first enrolment
01/10/2017

Date of final enrolment
21/11/2029

Locations

Countries of recruitment
Sweden

Study participating centre
Uppsala Univesrity
Uppsala universitet; Dag Hammarskjöldsväg 14B.
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Sponsor information

Organisation
Uppsala University

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Sponsor type
University/education

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ROR
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Organisation
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Sponsor type
Government

Website
https://www.regiongavleborg.se/regional-utveckling/forskning-och-samhallsmedicin/cfug/

Funder(s)

Funder type
University/education

Funder Name
Uppsala Universitet

Alternative Name(s)
Uppsala University, UU_University, Uppsala Universitet, Sweden, UU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Sweden

Results and Publications

Publication and dissemination plan
The data will be published in peer-reviewed journal as well as in three doctoral theses. The data will also be presented during national and international congresses.

Intention to publish date
20/10/2030

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request: eva-lotta.funkquist@kbh.uu.se

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Breastfeeding patterns in one-year-old children was not affected by a breastfeeding support intervention	16/04/2024	22/04/2024	Yes	No
Other publications	Experiences of healthcare professionals in a breastfeeding training program	12/08/2025	13/08/2025	Yes	No