

Early interventions to increase breastfeeding and reduce the use of infant formula

Submission date 04/06/2026	Recruitment status Recruiting	☐ Prospectively registered ☐ Protocol
Registration date 28/10/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 28/10/2026	Condition category Other	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Breastfeeding provides important health benefits for both mothers and babies and is considered a key public health issue. Despite this, many mothers stop breastfeeding earlier than they would like. A common reason is that they do not receive enough information or support during the first days after birth. In Sweden, breastfeeding rates have also dropped significantly over the past twenty years.

As part of a larger study, the aims here are to find out whether a targeted breastfeeding support program for healthcare professionals—offered to parents before birth and during the first days afterwards—can help improve breastfeeding initiation, exclusivity, and duration, as well as decrease the use of infant formula. Furthermore, another goal is to evaluate the quality of care provided to newborns and their mothers. In addition, the study will explore parents' experiences of breastfeeding and early parenthood, as well as their knowledge about the safe preparation and use of infant formula when needed.

The program is based on the World Health Organization's "Ten Steps to Successful Breastfeeding", known in Sweden as the Baby-Friendly Hospital Initiative. It includes support for parents, training for healthcare staff, and improvements in care routines. WHO and UNICEF emphasize that these ten steps are important in all countries, regardless of income level, and previous research shows that interventions based on the ten steps can be effective.

Overall, the aim of the breastfeeding support program is to provide evidence-based, responsive support that helps new parents feel confident in breastfeeding and, when necessary, in safely using infant formula. By strengthening early support, the project hopes to give families a better start and improve the care of newborns and their mothers.

Who can participate?

Expectant and new parents and their infants.

What does the study involve?

It involves an intervention in the care continuum. For healthcare staff across the care continuum, the intervention includes a training package consisting of web-based courses, as well as a processoriented training day focused on improving care practices and routines, as well as safe

formula feeding when there is a need to use it. For expectant and new parents, support will be provided through evidencebased information brochures and educational materials designed to complement the verbal guidance offered by healthcare staff.

What are the possible benefits and risks of participating?

Breastfeeding is a key factor in achieving global goals related to nutrition, health, child survival, economic development, and environmental sustainability. Breastfeeding protects infants against infectious diseases such as diarrhoea, respiratory infections, and otitis media, as well as against diabetes, overweight, leukemia, necrotizing enterocolitis, and sudden infant death syndrome. Breastfeeding also supports cognitive development and is associated with higher IQ in children. For women, breastfeeding provides protective effects against breast cancer, ovarian cancer, and diabetes. Many women are not fully informed about the health benefits for themselves and their child, and many decisions regarding breastfeeding are made without the opportunity for informed choice. The right of study participants—and of all parents—to receive up to date, evidencebased care, which this research project aims to support, outweighs the potential risk of misunderstandings that may arise in interactions between participants and researchers. The project is designed to strengthen informed decisionmaking and ensure that parents have access to accurate, evidencebased information about breastfeeding and safe infant feeding.

The study has received approval from the Ethical Review Board in Sweden. Parents will be informed about the study and that the participation is voluntary and confidential. Data will be securely stored according to data protection regulations.

Where is the study running from?

The study is coordinated by Uppsala University and conducted at a clinical site within the Gävleborg Region in Sweden.

When is the study starting and how long is it expected to run for?

October 2026 to March 2029

Who is funding the study?

The study is supported by the Centre for Research and Development, Uppsala University, Region Gävleborg, Gävle, Sweden.

Who is the main contact?

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Study information

Scientific Title
Evaluation of an educational intervention to increase breastfeeding, reduce infant formula use, and enhance care practices

Study objectives
An intervention based on the 'Ten Steps to Successful Breastfeeding' will improve breastfeeding outcomes and care practices, and reduce the use of infant formula

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/08/2020, Swedish Ethics Review Authority (Box 2110, Uppsala, 75002, Sweden; +46 (0)10-475 08 00; etikprovningensmyndigheten.se), ref: Dnr 2020-01417

Primary study design

Interventional

Allocation

Non-randomized controlled trial

Masking

Open (masking not used)

Control

Uncontrolled

Assignment

First, a control group of parent-infant pairs is recruited. Then, a planned educational intervention for healthcare professionals in the healthcare continuum is carried out. After the intervention is completed, additional parent-infant pairs are recruited to form the intervention group.

Purpose

Supportive care

Study type(s)**Health condition(s) or problem(s) studied**

Breastfeeding among healthy term infants and their parents

Interventions

For healthcare staff across the care continuum, the intervention includes a training package consisting of web-based courses, as well as a processoriented training day focused on improving care practices and routines, as well as safe formula feeding when there is a need to use it. For expectant and new parents, support will be provided through evidencebased information brochures and educational materials designed to complement the verbal guidance offered by healthcare staff.

First, data is collected from the control group (parent-infant pairs) in the baseline measurement over an expected 6-month period; then, data collection is paused for an expected 4 months, and the intervention is implemented in the health care continuum. Then, data is collected from the intervention group (new parent-infant pairs) over an expected 6-month period.

Intervention Type

Behavioural

Primary outcome(s)

1. Breastfeeding use measured using medical record review and survey responses at hospital discharge and when the child is 1 week, 2 months, 4 months, 6 months, and 1 year of age
2. Infant formula use measured using medical record review and survey responses at hospital discharge, and when the child is 1 week, 2 months, 4 months, 6 months, and 1 year of age

3. Compliance with the WHO's and UNICEF's Ten Steps to Successful Breastfeeding measured using medical record review and survey responses at during hospital stay and when the child is 1 week old

Key secondary outcome(s)

1. Breastfeeding self-efficacy measured using the Self-Efficacy Scale - Short Form at when the child is 1 week, 2 month, 4 months, 6 months, and 1 year old

2. Parenting experience measured using the Swedish Parenting Stress Questionnaire at when the child is 1 week, 2 month, 4 months, 6 months, and 1 year old

Completion date

30/03/2029

Eligibility

Key inclusion criteria

1. Healthy full-term newborns
2. Mother must want to breastfeed and be fluent in the Swedish language

Healthy volunteers allowed

Yes

Age group

All

Lower age limit

0 Days

Upper age limit

65 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Exclusion criteria for the infant are growth retardation, malformation or illness that prevents the possibility of breastfeeding, and need for care in the neonatal unit.
2. Exclusion criteria for the mother are serious mental illness or any known illness that negatively affects breastfeeding or requires supplemental feeding with infant formula for the child.

Date of first enrolment

01/10/2026

Date of final enrolment

30/03/2028

Locations

Countries of recruitment

Sweden

Study participating centre

Hudiksvall hospital, Region Gävleborg, Sweden

Sweden

Sponsor information

Organisation

Uppsala University

ROR

<https://ror.org/048a87296>

Funder(s)

Funder type

Funder Name

Uppsala Universitet

Alternative Name(s)

upsalauni, Uppsala Universitet, Sweden, Uppsala University, UU

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Sweden

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available