

# Benefits of using an online consultation nursing for the monitoring and establishment of breastfeeding

<b>Submission date</b> 02/07/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/07/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/07/2024	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The World Health Organization (WHO) defines breastfeeding as the best way to provide children with the nutrients necessary for healthy development and growth. The WHO and the American Academy of Pediatrics (AAP) recommend its exclusivity during the first six months of life, extending until two years of age, according to the mutual desire of the mother and the infant. Numerous research has shown that exclusive breastfeeding (EBF), understood as a diet based exclusively on breast milk (except vitamin, mineral or pharmacological supplements), provides benefits for both the newborn and the mother in the short and long term. Monitoring and support of breastfeeding by nursing professionals promotes an increase in breastfeeding rates. Many studies show the positive results of educational interventions on breastfeeding. More than 80% of women initiate breastfeeding in the United States (this percentage represents any breastfeeding, not EBF). The epidemiological data for EBF at 3 months is 46.3% and for EBF at 6 months is 25.8%. The WHO has proposed as a nutrition goal for the year 2025 to increase the EBF rate in the first six months of age to at least 50% (WHO, 2014). With official data, this objective is far from being achieved.

### Who can participate?

Women aged between 18 and 45 years old after receiving a cesarean section at the La Paz University Hospital

### What does the study involve?

This study has two groups. Participants will be randomly assigned to an intervention or control group. The intervention group will be followed by a nursing professional expert in breastfeeding, through the Red Sinapsis online platform, while the control group will receive standard follow-up by the midwife or Primary Care nurse.

The follow-up of the intervention group is explained in more detail below:

- Once the patients are assigned to participate in the intervention group, the use of the platform is explained to them in a general way, giving them a dossier with brief instructions on it.
- 2-3 days after registering on the platform, they are sent a welcome message and they are

asked to respond to this message to verify that they have accessed the platform and that they control its management.

- Through the messaging section of the platform every week during the first month of participation in the study, patients receive information based on the available scientific evidence about breastfeeding and newborn care. So that:

- o 1st Week: adaptation tips

- o 2nd Week: key aspects for breastfeeding

- o 3rd Week: infant colic massage

- o 4th Week: milk extraction and storage

During all this time, questions from patients are answered.

- After 15 and 30 days, questionnaires are sent to them for completion.

- After the month of monitoring has passed, and after having sent the LATCH and BSES-SF questionnaires, a satisfaction questionnaire related to the monitoring carried out through the platform is sent.

- Once the answers to the questionnaires have been received, the patients are informed that the study has concluded.

The LATCH scale and BSES-SF were used in the follow-up at 15 days and 30 days postpartum, respectively, to be completed through Google Forms.

What are the possible benefits and risks of participating?

The benefit of participating in the study is having the advice of a professional specialized in breastfeeding. Participants do not assume any risk by participating in the study.

Where is the study run from?

La Paz University Hospital

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

October 2017 to March 2018

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Jenifer Araque García, [jenifer.araque@uam.es](mailto:jenifer.araque@uam.es)

## Contact information

### Type(s)

Public, Principal investigator

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Scientific

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## **Additional identifiers**

**Clinical Trials Information System (CTIS)**

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

LM2017

## **Study information**

**Scientific Title**

Benefits of using an online consultation for the monitoring and installation of breastfeeding

**Study objectives**

The development of an online nursing consultation during the immediate and late puerperium (post-partum period of about 6 weeks) reduces complications and decreases the abandonment of breastfeeding.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

approved 25/05/2017, Research Ethics Committee (La Paz University Hospital, Paseo de la Castellana, 261, Madrid, 28046, Spain; +34 917277000; [ceic.hulp@salud.madrid.org](mailto:ceic.hulp@salud.madrid.org)), ref: PI-2763

**Study design**

Interventional randomized controlled trial

**Primary study design**

Interventional

**Study type(s)**

Prevention, Efficacy

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

Establishment of breastfeeding in puerperal women after cesarean section

**Interventions**

Randomization will be applied using a program to generate pseudo-random numbers. The distribution was carried out through the correlative assignment of numbers following the order in which the participants agreed to be part of the study.

Once the patients are assigned to participate in the intervention group, they are registered on the Red Sinapsis platform and access codes are assigned.

Through the messaging section of the platform every week during the first month of participation in the study, patients receive information based on the available scientific evidence about breastfeeding and newborn care. So that:

- o 1st Week: adaptation tips

- o 2nd Week: key aspects of breastfeeding

- o 3rd Week: infant colic massage o 4th Week: milk extraction and storage

After 15 and 30 days, the LATCH and BSES-SF questionnaires are sent to them respectively for completion.

After the month of monitoring has passed, and after having sent the LATCH and BSES-SF questionnaires, they are sent a satisfaction questionnaire related to the monitoring carried out through the platform.

Once the patients are assigned to participate in the control group, it is explained that they belong to this group and that the midwife of the health center will be the one who will monitor breastfeeding, without being able to count on the support of the Red Sinapsis platform 15 and 30 days after hospital discharge, the LATCH and BSES-SF questionnaires are sent, respectively, for completion.

**Intervention Type**

Mixed

**Phase**

Not Applicable

**Primary outcome(s)**

1. The needs of the infant and the mother at the beginning of breastfeeding measured using the LATCH scale at 15 days postpartum
2. Breastfeeding self-efficacy measured using the BSES-SF scale at 30 days postpartum

**Key secondary outcome(s)**

1. Sociodemographic variables measured using a questionnaire prepared for this purpose at the beginning of the study
2. Variables related to breastfeeding measured using a questionnaire prepared for this purpose at the beginning of the study

**Completion date**

01/03/2018

# Eligibility

## Key inclusion criteria

1. Postpartum women who want to breastfeed their newborn child
2. Puerperal women whose birth was a cesarean section, given that at this time in the hospital skin-to-skin deliveries are not performed by cesarean section and consequently breastfeeding did not begin in the first 2-3 hours of life. Crucial moment for the beginning and establishment of breastfeeding
3. Postpartum women who wish to participate in the study once they have been informed of its characteristics and have given informed consent
4. Postpartum women who speak and understand Spanish, given that the interface and management of the platform are developed in that language

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Upper age limit

45 years

## Sex

Female

## Total final enrolment

74

## Key exclusion criteria

1. Postpartum women who do not have an electronic device with internet access
2. Minor puerperal women
3. Postpartum women with multiple gestations, given that breastfeeding in this circumstance is different
4. Postpartum women who choose artificial breastfeeding
5. Postpartum women with premature newborns, given that these babies are not born with the same sucking reflex as a full-term baby and directly influence the beginning of breastfeeding
6. Postpartum women discharged with their newborn with a circumstance that makes exclusive breastfeeding on demand impossible in most cases

## Date of first enrolment

17/10/2017

## Date of final enrolment

03/01/2018

# Locations

## Countries of recruitment

Spain

## Study participating centre

La Paz University Hospital

Paseo de la Castellana, 261

Madrid

Spain

28046

# Sponsor information

## Organisation

Hospital Universitario La Paz

## ROR

<https://ror.org/01s1q0w69>

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Jenifer Araque García ([jenifer.araque@uam.es](mailto:jenifer.araque@uam.es))

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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[Participant information sheet](#) version 2.1 01/05/2017 12/07/2024 No Yes

[Participant information sheet](#) Participant information sheet 11/11/2025 11/11/2025 No Yes