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

Submission date
02/07/2024

Recruitment status
No longer recruiting

Registration date
17/07/2024

Overall study status
Completed

Last Edited
16/07/2024

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

Contact information

Type(s)
Public, Principal investigator

Contact name
Prof Jenifer Araque García

Contact details
La Paz University Hospital, Paseo de la Castellana, 261
Madrid
Spain
28046
+34 609768948
jenifer.araque@uam.es

Type(s)
Scientific

Contact name
Dr Azucena Pedraz Marcos

ORCID ID
https://orcid.org/0000-0002-4641-6891

Contact details
C/Arzobispo Morcillo, 4
Madrid
Spain
28029
+34 914 972 229
azucena.pedraz@uam.es

Additional identifiers

Clinical Trials Information System (CTIS)
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), 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)

IPD sharing plan summary
Available on request

Study outputs

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