Project Information:

Project Code	: A21010491
Title	: Promotion of Breast Milk Donation in Breastfeeding Mothers Through a Mobile Health Intervention Utilizing an Innovative Technological Tool
Research Line	: Nutrition and Human Development
Location	: Metropolitan Lima Area

Ethical evaluation record of research studies: Study code N°: 0123-2023

Approval Date	: July 21, 2023

I. Executive Summary:

In Peru, 71% of preterm newborns (PN) die due to various complications during their recovery. Breastfeeding in preterm infants is often interrupted, necessitating donated breast milk (BM). Human Milk Banks (HMB) serve as critical allies in reducing mortality rates among preterm newborns; however, the number of donors is insufficient to meet current demand. Low donation rates are attributed to a lack of awareness regarding BM donation, as well as perceptions, beliefs, and attitudes that influence the predisposition to donate. As a solution, the development of an Innovative Technological Tool (ITT), the Amamantapp mobile application, has been developed to promote a culture of BM donation. For the development of the intervention, the Design Thinking methodology was employed to identify participant requirements, prioritize key topics, and define the most suitable ITT. A randomized controlled trial (RCT) will be conducted involving breastfeeding mothers treated at the National Maternal and Perinatal Hospital (NMPH). Subsequently, the mobile application will be implemented over a 60-day period within the intervention group. Knowledge, attitudes, and practices will be evaluated using a KAP questionnaire before and after the intervention.

II. Keywords:

Human Milk Bank, Breast Milk Donation, Breastfeeding

III. Background:

International Background

A study published in 2016 implemented an intervention using a bilingual and interactive educational program on tablets regarding breastfeeding; this achieved increased knowledge of the subject and breastfeeding intention (1). In 2017, another study developed an intervention program through a website that consisted of exchanging advice, resolving doubts, and providing follow-up to participating breastfeeding mothers. The study concluded that the program had a positive effect on breastfeeding duration rates during the 6-month follow-up period (2). In 2018, a study conducted in Thailand consisted of an intervention to promote breastfeeding through a mobile application. It was concluded that the application has high utility for mothers, but usability was low due to design aspects (3).

In 2020, an observational study based on the description of a breastfeeding mobile application found that the support provided by the tool is linked to the needs corresponding to the infant's developmental stage. Between 15 days and 3 months of age, mothers consult on topics such as breastfeeding crises/complications and returning to work. From 3 months to 1 year, mothers seek support on issues related to complementary feeding and weaning. When the user's infant reaches 1 year of age, the most searched topics are weaning and breastfeeding (4)

National Background

A study conducted in Lima, Peru, in 2019 regarding beliefs, attitudes, and practices (BAP) surrounding breast milk (BM) donation found that 98.2% of those surveyed believe that BM is the best food for both healthy and ill newborns. Additionally, while 75.7% had heard of Human Milk Banks (HMB), they were unaware of their locations. Furthermore, although the majority of participants agreed with donating to an HMB, only 16.5% had ever donated (5).

State of the Art

BM provides the ideal balance of nutrients for the infant, containing bioactive ingredients such as immunoglobulins, hormones, oligosaccharides, and others (6,7). Children who do not receive BM are at a higher risk of suffering from gastrointestinal, respiratory, and urinary infections, which may be more severe and lead to hospital admissions; in the long term, they face an increased risk of asthma, obesity, diabetes mellitus, and cancer (8).

In preterm newborns, BM decreases the prevalence of necrotizing enterocolitis, digestive intolerance to enteral feeding, bronchopulmonary dysplasia, nosocomial infections, retinopathy of prematurity, neurocognitive delay, and re-hospitalization after discharge (9). When circumstances do not allow for breastfeeding, the HMB becomes vital. This bank is responsible for the promotion and support of breastfeeding, as well as the collection, processing, quality control, and dispensing of donated BM to any child in need, particularly the preterm newborn (10).

To fulfill its mission, the HMB requires donors; therefore, it is vital to provide them with sufficient information and support regarding breastfeeding and BM donation, as the possibilities of successful breastfeeding increase the likelihood of them becoming donors (9). The appropriation of BM donation practices depends largely on the dissemination of positive experiences regarding breastfeeding and donation, internalized scientific knowledge, and the positioning of the topic in the media (11).

In recent years, the use of mHealth interventions to promote breastfeeding has expanded due to the widespread use of mobile phones. In Peru, 82% of citizens access the internet via a mobile phone. mHealth is defined as digital technological tools and resources used to capture, manage, store, and exchange information through mobile devices (12,13). Evidence suggests that mHealth has the potential to promote, educate, and support breastfeeding women. It is noteworthy that there is limited evidence regarding mHealth interventions aimed at fostering BM donation (4,14).

Problem Statement

PAHO and WHO (2019) demonstrated that, globally, 45% of children under 2 years of age were breastfed (15, 16). In Peru, 66.4% of infants consumed BM, with this percentage being higher in the Andean region (77%) and rural areas (79.6%) (17).

Even though breastfeeding is widely practiced in Peru, there are cases where breastfeeding is interrupted: low-birth-weight newborns (LBW) with a risk of digestive pathology or immune deficiency, and newborns whose mothers cannot provide sufficient milk due to various health reasons. These infants are candidates to receive donated BM (18).

At a global level, evidence shows that during the 2009–2015 period, there were 1,563,240 female donors, with South America being the region with the highest percentage of donors (96.6%) (19). In Peru, the first HMB was founded in 2010 at the NMPH. The number of donors increased from 368 to 1,642 in the 2010–2018 period (10). However, this increase is insufficient to cover the growing annual rate of preterm births (1,620), which demand approximately 500 liters of donated BM per month (20). This situation has worsened in the context of the COVID-19 pandemic, which reduced the number of monthly donors from 200 to 50 (20).

Evidence shows that factors related to the low number of BM donors include perceptions, beliefs, and attitudes such as: the belief that donating carries a risk of transmitting HIV or cancer, and a low interest in donating due to lack of knowledge (21).

As part of the profile development for this project, interviews were conducted with breastfeeding mothers and healthcare personnel to understand their perception of BM donation. The results revealed a lack of knowledge regarding HMBs and BM donation, and a perception among mothers that they should exclusively donate when they have surplus milk. However, upon learning about the assistance they could provide to newborns, they adopted a positive attitude toward donation (22).

Based on the above, there is clear evidence of a real problem concerning the deficit of human milk donors in Peru.

IV. Justification:

Considering that the proportion of deaths among preterm newborns in the country has increased over the last decade (from 62.6% in 2011 to 71% in 2019) (23), it is necessary to promote knowledge regarding BM donation to favor an increase in the volume of such donations.

The WHO states that BM promotes the cognitive and sensory development of infants, in addition to protecting them against various diseases and aiding in their prompt recovery (24). Low-birth-weight preterm newborns face a high risk of growth failure and comorbidities that result in neurodevelopmental delay and lower academic performance; likewise, it has been demonstrated that BM intake is beneficial in reducing hospital stay and complications, and is associated with a larger head circumference and better scores in global and verbal cognitive areas at five years of age (25). Since the first HMB was inaugurated in Peru in 2010, the quantity of BM donations has been increasing; thus, by 2018, the NMPH in Lima managed to collect 1,390 liters of BM between January and October, benefiting 1,771 preterm infants (26). However, the demand for donations exceeds the amounts donated, meaning that not all infants who may require this nourishment are able to obtain it. Additionally, in 2020, the newspaper La República reported on the reduction of BM donations due to the quarantine context facing Peru at that time (20).

In summary, there is a need to implement a project that fosters knowledge of BM donation to benefit preterm infants, their families, and the country across different dimensions. Furthermore, this study is designed as a randomized controlled trial, which will allow us to accurately measure the effect of our mobile intervention on breastfeeding mothers, aiming to provide a robust and reliable scientific contribution to solve this problem and save the lives of more preterm infants.

V. Contribution and Impact:

The project will allow for the assessment of the success of mHealth implementation through the use of an ITT, Amamantapp mobile application, which may serve as a precedent for the future implementation of educational projects under this modality. This will assist in the dissemination of this and other health-related topics of interest in various regions of the country. Furthermore, the results of this trial will offer a deeper understanding of mothers' diverse perspectives regarding the promotion of BM donation and the potential for these

types of interventions to increase knowledge levels concerning BM donation and the status of HMBs.

Simultaneously, this work seeks to contribute to and foster the development of future research related to the proposed topic, as it is unfortunately not yet widely disseminated, and similar projects to the one proposed are currently lacking.

Finally, the use of this project as a baseline for a multicenter study is suggested, involving all HMBs in Peru to provide more robust and significant evidence. This would allow for an adequate approach to the target population, leading to an increase in the number of BM donors with the goal of decreasing the neonatal mortality rate and, consequently, generating a positive impact on the country's public health.

VI. **Hipótesis**:

General Hypothesis:

- The intervention through an Innovative Technological Tool promotes breast milk donation among breastfeeding mothers.

Specific Hypotheses

- The intervention through an innovative technological tool increases the knowledge level regarding breast milk donation among breastfeeding mothers.
- The intervention through an innovative technological tool improves the attitude toward breast milk donation among breastfeeding mothers.
- The intervention through an innovative technological tool increases the proportion of breastfeeding mothers who initiate breast milk donation practices.

VII. **Objectives**:

General Objective:

To evaluate the effect of an intervention using an innovative technological tool on the promotion of breast milk donation among breastfeeding mothers.

Specific Objectives:

- To measure the effect of an intervention using an innovative technological tool on the level of knowledge regarding breast milk donation among breastfeeding mothers.
- To evaluate the effect of an intervention using an innovative technological tool on the attitude toward breast milk donation among breastfeeding mothers.
- To identify the effect of an intervention using an innovative technological tool on the proportion of breastfeeding mothers who initiated breast milk donation practices.

VIII. **Methodology:**

Research Design

A randomized controlled trial (RCT) will be conducted.

Population and Sample

Sampling for the Qualitative Component

- **Population:** Breastfeeding mothers treated at the National Maternal and Perinatal Hospital (NMPH).
- **Sample Size:** 10 breastfeeding mothers (in-depth interviews), determined by non-probability sampling.

Inclusion Criteria:

- Breastfeeding mothers within 40 days postpartum.
- Breastfeeding mothers with living children.
- Breastfeeding mothers who have access to an Internet connection.
- Breastfeeding mothers who have the necessary equipment to access platforms with video-calling capabilities.
- Breastfeeding mothers who are proficient in the use of platforms with video-calling capabilities.

Exclusion Criteria:

- Mothers for whom breastfeeding is contraindicated.
- Breastfeeding mothers with a diagnosis of mental illness.
- Breastfeeding mothers who are or have been donors to the Human Milk Bank of the National Maternal and Perinatal Hospital.

Sampling for Intervention Development

Population: Breastfeeding mothers treated at the National Maternal and Perinatal Hospital (NMPH).

Sample Size: The sample size was determined using the OpenEpi program, with the option "Sample size to compare two means", considering a IC of 95%, a power of 80%, a sample size ratio equal to 1, a minimum mean difference of 2.1 (in the breastfeeding knowledge score) and a SD of 3.4 for both groups, similar to that found in the study by Joshi et al (1).

Therefore, the net sample size required for this study was 86 participants, distributed as follows: 43 in the control group and 43 in the intervention group. However, considering a potential loss of 30% between the initial and the final assessment, the sample size was increased by 112 mothers in total.

Inclusion Criteria:

- Breastfeeding mothers within 40 days postpartum.
- Breastfeeding mothers with living children.
- Breastfeeding mothers with an active Internet connection.
- Breastfeeding mothers who possess the technological equipment required to access the innovative technological tool (smartphone, tablet, or computer).
- Breastfeeding mothers residing within the jurisdiction of the National Maternal and Perinatal Hospital.

Exclusion Criteria:

- Breastfeeding mothers who are illiterate.
- Breastfeeding mothers with a diagnosis of mental illness.
- Breastfeeding mothers with significant difficulties in operating technological equipment.
- Breastfeeding mothers who are current users of any milk bank.
- Breastfeeding mothers who are or have been donors to the Human Milk Bank of the National Maternal and Perinatal Hospital.

Techniques and procedures

The time of participation in the study will be approximately 3 months, divided into the following phases: enrollment (15 days), baseline assessment (7 days), exposure to the intervention (60 days), and final assessment (7 days).

The development of the mobile intervention was based on the Human-Centered Design (HCD) approach (27). *AmamantApp* app includes modules on breastfeeding basics, benefits of breastfeeding for mother and child, breast milk donation, benefits of donating breast milk, myths and beliefs about human milk donation, requirements to be a donor, and where to donate.

To reduce bias, participants will be randomly assigned to the intervention and control groups in a 1:1 ratio according to their order of inclusion in the study. A master randomization list will be generated using the Spanish version of the free OxMaR software (28).

The intervention group will receive education on human milk donation via a mobile app, and the control group will receive information on human milk donation through printed leaflets. The app will be installed and explained to the mothers with hospital discharge orders on their mobile phones. The intervention will continue while the mothers are at home. The research team will hold an interactive session to introduce the mobile app to the participants. This will begin with an initial explanation of the app's features, followed by a period in which participants will be able to explore and use the application in real time. Furthermore, participants will receive weekly training on how to use the app to reinforce their knowledge of its operation.

The intervention period will last 60 days, during which knowledge, attitudes, and practices (KAP) will be assessed using a KAP questionnaire. This instrument will be administered face-to-face at baseline (pretest) and online via Google Forms after the intervention (posttest).

Design and Evaluation of the Mobile App

The process of designing the intervention with the Amamantapp app was based on Human Centered Design (HCD) through the application of the Design Thinking technique [29, 30]. This technique consisted of 6 stages:

Stage 1: Recognition

Aimed at empathizing, researchers defined the user profile, as well as the sociodemographic characteristics of the breastfeeding mothers. In this stage, 12 in-depth interviews were used to collect information concerning their KAP related to breastfeeding/breastmilk donation and the use of technology. At this stage, it was found that mothers were not aware that they

could donate their breast milk, nor were they aware of the existence of HMB. The mothers also expressed a favorable attitude towards human milk donation, but stated that they had not engaged in that practice due to a lack of knowledge.

Stage 2: Identification of Needs

An empathy map was drawn up with the responses obtained to identify the needs of the users and the prioritization of the issues to be addressed regarding breastfeeding and milk donation. In this second stage, the mothers' need for easily accessible information on human milk donation, the requirements to be a donor, the mechanisms for donating, and the locations of human milk banks were identified.

Stage 3: Ideation of Solutions

A team of 6 researchers devises different innovative solutions (eg, digital educational booklet, mobile app, telephone counselling, SMS, and MMS), which were then evaluated using the impact and innovation matrix; a vote was taken considering the criteria of impact, innovation, added value, and scalability. Finally, the mobile app was the top-rated vote.

Stage 4: Prototyping

The intervention is prototyped as a mobile app, based on the HCD model [27,31]. This model comprises sequential phases that range from defining the user requirement, designing the proposal, and through the implementation, verification, and maintenance of the intervention with the mobile app. The prototype was developed following the sequence previously described, which involved outlining the didactic content, the bibliographic search for educational content, the search for graphic resources, and the design of the screens, sections, and navigation routes.

The design process followed an iterative User Centered Design approach [32], incorporating feedback from experts in nutrition, health technology, human-computer interaction, and software development. The app employed a wireframe–based development approach, allowing early feedback on design decisions before implementation. The frontend was built with Flutter's Dart programming language, a cross-platform mobile development framework, to ensure broad accessibility on Android and iOS devices. The backend relies on a cloud–based infrastructure for data processing and secure storage. The app features personalized content delivery, ensuring that users receive relevant donation guidelines based on their location and eligibility. In addition, it includes built-in accessibility features, such as adjustable text sizes, to accommodate the diverse needs of users. The technical architecture prioritizes scalability, allowing for potential expansion across Peru and multiple countries in Latin America.

Stage 5: Usability Evaluation

The content was validated thorough an iterative process to improve the technological innovation tool until its final version. This iterative process evaluated the usability of the mobile app through a mixed study with a quantitative and qualitative phase that determined the experience of 32 breastfeeding mothers hospitalized in the postpartum ward of a mother and child hospital in Lima. As a result, the application of a validated 5-point Likert scale reported usefulness and satisfaction of the tool and ease of use with scores of 4.1. Access to information and comfort of use scored 4.3 and 3.9, respectively. These positive ratings demonstrated the high usability of the app. The results of the in-depth interviews during the validation of Amamantapp showed that users highlighted the detailed information on milk

donation, the ease of donating, and recommended the use of the mobile app because it provides mothers with relevant information.

Stage 6: Effect Evaluation

With the final version of the technological innovation tool, the randomized controlled trial will be implemented for a period of 60 days. The research team will continuously conduct field evaluations of the tool's performance (verification) and ensure the maintenance of the intervention through push notifications, reminders, text messages (SMS), or other complementary resources. At this stage, a baseline and final measurement of indicators will also be assessed for both the intervention and control groups using a KAP questionnaire developed by the researchers. As part of this last stage, the qualitative component of the evaluation of the effect of the mobile intervention will be implemented. Purposive sampling will be used to recruit participants. Any breastfeeding mother from the intervention group who has completed the mobile intervention will be eligible to take part.

Analysis Plan

Qualitative Analysis Plan

The information gathered from the in-depth interviews will be transcribed, processed, and analyzed using specialized qualitative data analysis software. Consequently, matrices and graphic organizers will be generated.

Statistical Analysis Plan

The information collected during the intervention will be processed in MS Excel and analyzed using IBM SPSS statistical software.

Inferential analysis will be by intention to treat (ITT), to ensure the equivalence of the study groups. The sociodemographic and baseline characteristics of the control and intervention groups will be compared using Pearson's Chi-square test, Fisher's exact test, or Student's t-test, depending on the type of variable.

To determine the effect of the intervention, changes in milk donation knowledge scores among breastfeeding mothers in the intervention group will be compared with the control group throughout the study period (baseline and endline variation) using a double difference regression model.

For qualitative variables (attitudes, practices), a Cochran's Q test will be applied to evaluate changes following the intervention period. Regarding donation practices, Fisher's exact test will be applied, and the Odds Ratio (OR) will be calculated to determine the utility of the intervention in breast milk donation. Finally, only descriptive statistics will be presented regarding user satisfaction.

Ethical Considerations

All procedures will be conducted in accordance with the Declaration of Helsinki. After identifying that the applicants meet the inclusion criteria, they must sign an informed consent form to formalize their enrollment in the intervention. In this study, participants' personal information will be collected and stored. This information will only be used to monitor the proper execution of the intervention (exposed group) and for coordination purposes (unexposed group). Participants will be identified using codes (anonymization), and their

personal information will be stored in a separate file, which will be deleted once the intervention concludes. In addition, the data collected were coded to ensure privacy and confidentiality.

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NATIONAL UNIVERSITY OF SAN MARCOS
(University of Peru, DEAN OF THE AMERICAS)
FACULTY OF MEDICINE
RESEARCH ETHICS COMMITTEE
"Year of Unity, Peace, and Development"

ETHICAL EVALUATION RECORD FOR RESEARCH STUDIES

STUDY CODE N°: 0123-2023

In Lima, on the twenty-first day of July, during a Session of the RESEARCH ETHICS COMMITTEE, following the evaluation of the Research Project titled: "Promotion of breast milk donation in breastfeeding mothers through a Mobile Health (mHealth) intervention using a technological innovation tool" presented by Violeta Magdalena Rojas Huayta, faculty code OA3072, from the Research Group: Public Food and Nutrition - NIANP, to be conducted at the Faculty of Human Medicine of the National University of San Marcos.

AGREES:

To APPROVE the aforementioned Project, considering that it has satisfactorily complied with the Scientific, Technical, and Ethical recommendations for research involving Human Subjects.

"This document is effective as of this date and expires on July 20, 2024."

Lima, July 21, 2023

PhD. Juan Carlos Ocampo Zegarra
Chair of the REC/FM/UNMSM

This document is a faithful and accurate English translation of the original. Signatures have been removed from this document.