Received: 17 April 2020 | Revised: 26 June 2020 | Accepted: 23 July 2020

DOI: 10.1111/jan.14534

PROTOCOL

JAN Leading Global Nursing Research WILEY

The CRIAA Program complex intervention in primary care to support women and their families in breastfeeding: Study protocol for a pilot trial

Camila Lucchini-Raies[1,2] | Francisca Marquez-Doren[1] | Paulina Beca[3] | J. Carola Perez[4] | Solange Campos[1] | Olga Lopez-Dicastillo[5]

[1]School of Nursing, Pontificia Universidad Católica de Chile, Santiago, Chile

[2]Universidad de Navarra, Pamplona, Spain

[3]School of Medicine, Family Health Center San Alberto Hurtado ANCORA, Pontificia Universidad Católica de Chile, Santiago, Chile

[4]Faculty of Psychology, Universidad del Desarrollo, Santiago, Chile

[5]Faculty of Health Science, Universidad Pública de Navarra, Pamplona, Spain

Correspondence
Francisca Marquez-Doren, Universidad de Navarra, Pamplona, Spain.
Email: fmarquez@uc.cl

Funding information
This research project is funded by the Interdisciplinary Research Fund, 2018. School of Nursing and School of Medicine. Project ID: PIEM 04-19.

Abstract

Aim: To report a pilot study protocol to assess the feasibility of a complex intervention, in the primary healthcare context, to support women and their families in breastfeeding.

Design: A pilot/feasibility trial with control and intervention groups.

Methods: The study will be conducted in two primary healthcare centres with 40 childbearing women (20 control group; 20 intervention group), with their partner/meaningful person and their respective healthcare professionals. Intervention group participants will receive the intervention: (a) in a breastfeeding workshop during their third trimester of pregnancy; and (b) via virtual breastfeeding support for six months postpartum. Health professionals will be trained to deliver the intervention. The control group will receive standard care in the outpatient clinic. The pilot will help determine the intervention's feasibility. Data collected pre-intervention, 10-days postpartum and two-, four-, and six-months postpartum will provide estimates of the intervention's preliminary effects on self-efficacy and main outcomes. Research Ethics Committee approval was obtained in April 2019.

Discussion: Breastfeeding support is a complex reality influenced by multiple factors. Therefore, approaches to breastfeeding are also, requiring interventions that address its multidimensional nature, including all actors involved. The proposed intervention will be applied by an interdisciplinary professional health team, allowing for its incorporation into standard practice and its perpetual maintenance.

Impact: The study will produce an original, comprehensive, complex intervention addressing contextual, and organizational factors to promote breastfeeding support using an interdisciplinary and family-based approach; breastfeeding self-efficacy is the core concept. The program evaluation and feasibility study will permit exploration of the integration of the intervention's novel aspects into the daily work of professionals and reveal how to better use existing resources in a full-scale clinical trial.

Trial registration: ClinicalTrials.gov ID: NCT03944642.

KEYWORDS

breastfeeding self-efficacy, breastfeeding support, complex intervention, midwives, nursing, pilot study, primary health care

1 | INTRODUCTION

Breastfeeding is a multidimensional process involving women, their children and their families throughout the course of their lives; it does not occur in isolation (Primo & Brandão, 2017). Breastfeeding is multidimensional given its biological, social, and cultural components, which are determined by the context of the lived breastfeeding experience (Asiodu, Waters, Dailey, & Lyndon, 2017; Srebro, 2017). As breastfeeding comprises a complex social system, a systemic approach is required to understand its various dimensions and how they interact (Griswold, 2017; Srebro, 2017). Therefore, although robust evidence exists about the experiences and circumstances affecting women's decision to breastfeed, a more comprehensive understanding of the complex dimensions of the process is required. Investigation of life events of women and families must be studied in all their complexity to elucidate the individual, social, and cultural factors of breastfeeding that affect its beginning, maintenance, and cessation (Primo & Brandão, 2017).

As such, breastfeeding behaviour is a complex relational event with dynamic interactions between a mother and her child and between this dyad and the family, social and cultural context where they develop. Thus, breastfeeding behaviour goes beyond the personal and interpersonal system and is positioned as a social interaction (Lucchini-Raies et al., 2019). Social interaction allows women to develop their breastfeeding perceptions not only according to their own emotions and experiences but also in consideration of their families' and other meaningful persons' experiences around breastfeeding. Thus, it is necessary to identify the significant people in mothers' social networks and understand their interactions, as the influence of a woman's social support networks affects the decision she makes concerning child feeding (Primo & Brandão, 2017).

Breastfeeding is also as a 'care relationship' where the woman simultaneously plays two roles: caregiver for her child and receiver of care from her support network (partner/meaningful person and health professionals). This contextualizes her vulnerability, as she must develop the skills to care for her new-born in the context of others also caring for her. Hence, the relationships a woman establishes with family members and health professionals are important, constituting her sources of support (Srebro, 2017).

Health professionals have approached breastfeeding from a medicalized perspective; interventions have used a problem-solving approach to breastfeeding, addressing physiological aspects but neglecting social and emotional dimensions. A partial view of breastfeeding and breastfeeding care misses the opportunity to address the complexities of the phenomenon (Torres, 2014). To have more impact, future interventions must address all the relevant aspects, including components that address related biological and socio-emotional complexities, acknowledging that breastfeeding is not simply an infant-feeding practice (Asiodu et al., 2017; Griswold, 2017; Primo & Brandão, 2017; Srebro, 2017). Additionally, such interventions must use a systematic approach to breastfeeding care, analysing current practices in the health system into which they will incorporate changes. Intervention components must be adaptable to women's and new-borns' socio-emotional needs and physical needs.

1.1 | Background

Many existing intervention initiatives aim to support mothers and their families during breastfeeding. However, the available evidence is not conclusive as to which elements of the interventions are effective (Sutton, O'Donoghue, Keane, Farragher, & Long, 2016). This is due, partially, to the diversity of the interventions, the multiplicity of intervening variables and, in some cases, the lack of methodological rigour and theoretical support of the studies (Sutton et al., 2016).

However, interventions that have produced positive results—with women exclusively using breastfeeding to feed their infants—incorporate various educational methods, incorporate the partners, include more than one meeting between professionals and mothers, were developed in a context of continuous contact with health professional staff and/or address different dimensions of support. Likewise, interventions that consider modalities such as the use of electronic platforms or devices, which ensure care continuity from pregnancy through the postnatal period and those that emphasize women's interactions, adapting to their individual needs, are also more effective. Theoretical intervention frameworks that incorporate the self-efficacy concept achieve positive results in 'exclusive breastfeeding' rates (Sutton et al., 2016). The primary healthcare context provides opportunities for interventions that promote these aspects of breastfeeding. At this level of care, health promotion activities are planned and implemented for people living in the community to address population's needs, ensuring broad access and coverage in an equitable, comprehensive, and continuous manner (Rollins et al., 2016; WHO; UNICEF; HIS; SDS, 2018).

Breastfeeding research and care would benefit from complex intervention approaches addressing women's and families' behaviours in the community, incorporating a diverse team of health professionals and encompassing breastfeeding's social aspects. The complex interventions framework (Corry, Clarke, While, & Lalor, 2013; Craig et al., 2008) provides a systematized orientation to guide the development of evidence- and theory-based interventions that achieve their expected impacts on a population's health. The framework proposes that the intervention be carried out through four phases: development, pilot/feasibility, evaluation, and implementation. These stages allow for: (a) designing interventions with local context pertinency; (b) adjusting them according to the assessment of acceptability and feasibility in the pilot phase; (c) determining their effectiveness with a large scale trial; and (d) implementing them as public policy (Craig et al., 2008, 2013). This protocol provides the details of the pilot/feasibility stages that allow the evaluation of the project and its broader future implementation. Feasibility studies explore whether an intervention can be done, if it is worthwhile and, if so, how to proceed (Eldridge, Lancaster, et al., 2016). 'Feasibility' is an umbrella concept that can include various designs, such as the pilot study presented in this protocol which uses a smaller scale to identify all the relevant aspects, as mentioned above, for the feasibility of studies (Eldridge, Lancaster, et al., 2016).

The development phase of the present study was completed previously. It included an umbrella review of the available evidence on the

effectiveness of interventions supporting breastfeeding (Lucchini-Raies & Lopez-Dicastillo, 2017) and a qualitative study that clarified the relevant key aspects of women's and health professionals' experiences regarding breastfeeding and breastfeeding care (Lucchini-Raies et al., 2019). The qualitative research revealed that providing and receiving support during breastfeeding is a dynamic and multidimensional experience. Mothers' and health professionals' previous breastfeeding care and support experiences and the context of care are meaningful, affecting their interactions regarding breastfeeding care. Mothers' and professionals' perceptions of breastfeeding care have contextual, organizational and relational support dimensions that interventions must address (Lucchini-Raies et al., 2019).

The findings from the systematic review and the qualitative study were combined to design the program we intended to test, 'Programa CRIAA: Cuidados Respetuosos a través de una Intervención de Acompañamiento al Amamantamiento' [CRIAA Program: Respectful Care Through a Breastfeeding-Support Intervention]. The program's purpose is to address the complexity of breastfeeding care at the primary healthcare level and increase breastfeeding rates by promoting professionals' and mothers' self-efficacy. The program includes a series of proven components from international recommendations for supporting breastfeeding. Therefore, the program will be universally applicable, with some relevant local adjustments for cultural contexts.

1.1.1 | Theoretical framework

The CRIAA's theoretical framework is based on the development stage for complex interventions, including the following:

1. Early Childhood Development

A powerful determinant of health, early childhood development is vital to human health and society (Mikkonen & Raphael, 2010). The basic architecture of the brain develops through a continuum that begins during pregnancy and lasts into adulthood. Early experiences affect the quality of that architecture, establishing a solid or fragile foundation for subsequent health and behaviour. Interactive influences between genes and experiences shape the developing brain and cognitive, emotional, and social abilities are inextricably intertwined throughout life. Emotional well-being and social competence provide a solid basis for cognitive abilities to emerge and, together, they build the foundations of human development. Thus, the first three years of life are a sensitive period in development, influenced by dynamic interactions between genetics, environmental conditions, and experiences. Optimal development requires support for perinatal mothers'/children's nutrition and the development of parents/caregivers parenting skills (Center on the Developing Child, 2016).

2. Social Cognitive Theory and self-efficacy

Self-efficacy, derived from Bandura's Social Cognitive Theory, relates to perceived personal confidence about the ability to regulate motivation, thought processes, emotional states, and social environments in the performance of a specific behaviour (Bandura, 1994). Self-efficacy is essential in breastfeeding, since it reflects a mother's perceptions about her abilities but does not necessarily reflect her actual abilities. These perceptions of self-efficacy relate to beliefs about the ability to breastfeed and are linked to contextual factors. The individual expectations of breastfeeding self-efficacy are specific to each situation and are diverse (Dennis, 1999). Known correlations and associations identify self-efficacy as predictive of breastfeeding initiation and maintenance (Dennis, 2003; Dennis, Heaman, & Mossman, 2011; Eksioglu & Ceber, 2011; Oliver-Roig et al., 2012).

3. Health Promotion Model

This model illustrates the multifaceted nature of people's interactions with their environment when pursuing a desired state of health. It emphasizes relations between personal characteristics and experiences, knowledge, beliefs, and situational aspects linked to health behaviours or desired behaviours (Pender, 2011). This model exposes the relevant aspects that intervene in behaviour modification for human beings and their attitudes and motivations towards health-promoting actions.

From these theoretical foundations, we identified the key intervention components:

- Breastfeeding as a health-promoting behaviour—breastfeeding satisfies the nutritional needs of the child and the emotional and affective needs promoting a relationship with the mother and family and the child's development (Mistry et al., 2012; Pender, 2011);
- Breastfeeding self-efficacy—the mother's confidence in her ability to breastfeed her child (Dennis, 1999);
- Professionals' self-efficacy—health professionals' confidence in their ability to support breastfeeding mothers using their socio-emotional skills (Antoñanzas-Baztan, Belintxon, Marín-Fernández, Redín-Areta, & Lopez-Dicastillo, 2017); and
- A systemic approach—integrating and identifying various elements of the women's support network that must be mobilized to provide support to breastfeeding families, considering the organizational and social context where the program will be conducted (Solar & Irwin, 2010).

Figure 1 shows the theoretical framework and key components of the CRIAA Program.

2 | THE STUDY

2.1 | Aim

2.1.1 | Specific objectives

The study has three assessment objectives for assessing a complex primary healthcare intervention supporting women and their families for breastfeeding:

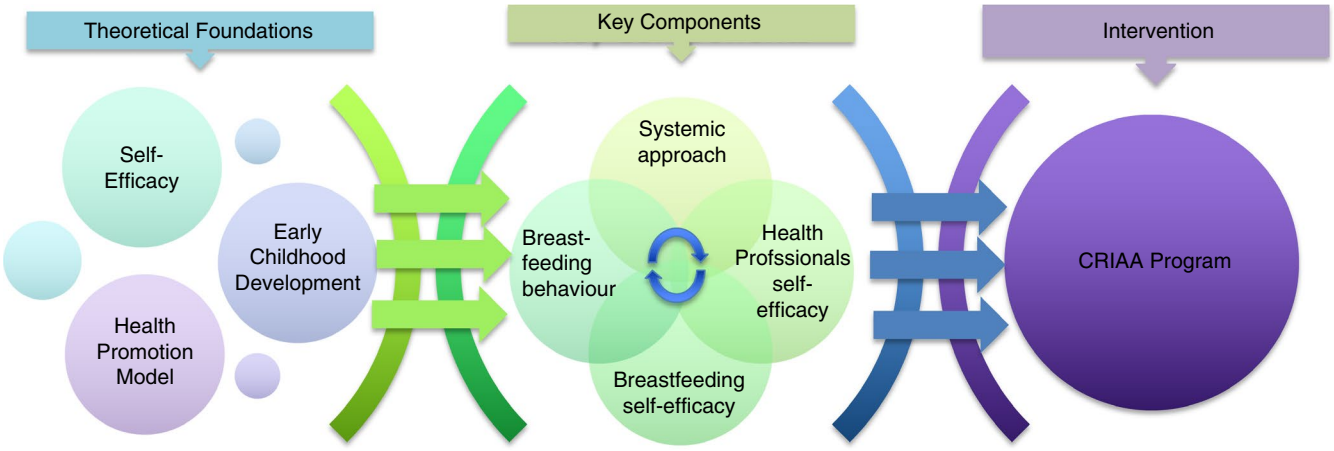

FIGURE 1 CRIAA Program theoretical framework [Colour figure can be viewed at wileyonlinelibrary.com]

1. Evaluate the feasibility of the intervention's components and the evaluation process.
2. Explore the participants' perceived acceptability of the intervention.
3. Estimate the intervention's preliminary effect on maternal breastfeeding self-efficacy and professional self-efficacy regarding their ability to support breastfeeding mothers.

A qualitative approach will be used to evaluate the intervention's feasibility, based on the following assumptions: (a) A qualitative approach allows for understanding participants lived experiences relating to intervention's facilitators and barriers; (b) A person's conscious experience is revealed through their written or spoken testimony; and (c) including narrative and descriptive records of each intervention activity enables the identification of strengths and weaknesses of the intervention components to identify adjustments needed prior to large-scale implementation (Streubert & Rinaldi Carpenter, 2011).

Verifying hypotheses or determining the effects of the intervention is not required. The pilot study's purpose is to evaluate the intervention's feasibility and acceptability (In, 2017). However, calculation of the sample size of a future randomized controlled trial using the pilot study's results requires an estimation the effect size of the intervention's primary outcome (Eldridge, Lancaster, et al., 2016). For this study, this corresponds to maternal breastfeeding self-efficacy and professionals' self-efficacy in their ability to support breastfeeding mothers.

2.2 | Design

The study design of this protocol corresponds to a pilot study with control and intervention groups.

2.2.1 | Methodological framework

This protocol describes the pilot/feasibility phase of the complex intervention framework (Craig et al., 2013). A pilot study involves testing the intervention on a small scale to examine its quality, efficiency, acceptability, feasibility, and to identify the necessary safety recruitment and randomization processes (In, 2017). Thus, the necessary modifications to improve the intervention/study design are made before investing resources and time on a larger scale (Craig et al., 2008, 2013), conserving resources and facilitating the implementation and transfer of knowledge to clinical contexts (Blatch-Jones, Pek, Kirkpatrick, & Ashton-Key, 2018).

2.2.2 | Intervention description

A multilevel and multidimensional intervention has been designed to support breastfeeding mothers and their partner/meaningful person. This intervention is called the CRIAA Program.

At the organizational level, existing breastfeeding support activities must be identified and mapped. A flowchart will be designed to describe the existing activities, their objectives and referral criteria. The flowchart will be a tool used by participating health professionals to integrate existing resources to optimize referral. A reformulation of the current prenatal workshop will be done involving health professionals. The new workshop will maintain timing and location and include content and methodology that consider a childbearing women/partner-centred focus, with group modality based on adult education and a training professional to guide and support group interactions.

At the professional level, a 16-hr adult education-centred course will be delivered for all the health professionals involved in breastfeeding care. Updates to issues in breastfeeding, impacts on healthy child development and significant support to mothers and their families will be addressed. Participants will include nurses, midwives, and physicians to provide direct care to mothers and their children in the intervention group.

Regarding mothers and partner/meaningful person, the intervention will involve participation in the reformulated prenatal workshop and inclusion of the women in a virtual support group (WhatsApp). The virtual support group will be used as a tool

for women to receive messages reinforcing their breastfeeding self-efficacy; the group may also generate questions related to breastfeeding.

Participants in the intervention group will receive standard prenatal care. They will be invited to participate in the breastfeeding workshop during the third trimester of pregnancy, with active and intentional participation of the childbearing women and their partners/relatives. Trained health professionals and members of the research team will deliver the workshop using adult education methodology. After delivery, mothers will receive regular postnatal care for themselves and their children; they will have continuous support for their breastfeeding process for up to six months of the child's life through the virtual support group.

The control group will regularly receive standard pre- and postnatal care for mother and child. Professionals who provide direct care will maintain their usual attention. Once the study is finished, they will be offered the training course. Intervention description details are presented in Table 1 according to TIDieR checklist (Hoffmann et al., 2014).

2.3 | Sample/participants

Participants will include childbearing women attending two primary health centres in Santiago de Chile and their partners/significant family members and the health professionals working in these health centres. The pilot will include Spanish-speaking pregnant women, 18 years and older, in the third trimester of pregnancy and their partners/meaningful persons. They must provide informed consent. Health professionals—nurses, midwives, and physicians—who provide direct care to women and families during breastfeeding and those providing prenatal and postnatal care for women and/or involved in children's health care.

The exclusion criteria for the study are women with pregnancy pathologies that entail breastfeeding difficulties; multiple pregnancies; breastfeeding special situations (cleft lip and palate, congenital heart disease and new-born's hospitalization); and preterm birth (at <37 weeks gestation). Once each patient participant's child is born, the inclusion criteria will be rechecked. Professionals will be excluded if, at the time of training, they are not providing direct support to mothers and/or their children.

2.3.1 | Sample size determination

A sample size of 40 mothers (20 in control group; 20 in intervention group) will be considered, based on the CONSORT (2010) recommendations for randomized pilot and feasibility studies indicating 20 participants per arm, considering a small effect size (Cohen's 0.10 to 0.30), 0.05 alpha level, and power of 0.80 (Eldridge, Chan, et al., 2016). When there is no data on the expected effect size, it is appropriate to assume a small effect size (Whitehead, Julious, Cooper, & Campbell, 2015). The effect size value of a pilot study will allow sample size estimation for the subsequent randomized controlled trial. Professionals working in both health centres will receive training to implement the CRIAA program.

2.3.2 | Randomization and recruitment

Two centres with similar characteristics have been selected to carry out the study. Randomization is not possible as the health professionals who work in these centres are concurrently participants in the intervention and include those in charge of delivering the program to women and their families. Thus, the intervention will be delivered in one centre; the other will be used as a control to avoid contamination bias. The recruitment and follow-up process of the participants has been designed following the recommendations of the CONSORT 2010 Statement for randomized pilot and feasibility trials (Eldridge, Lancaster, et al., 2016) as described in the workflow (Figure 2).

2.4 | Data collection

The evaluation process will be multi-method (scales, questionnaires, interviews, and focus groups) and multi-information (mothers, their partners/meaningful persons, and professionals). See Table 2 for data collection and evaluation times.

Semi-structured interviews will be used to collect mothers' and professionals' views regarding the intervention, using topic guides with questions about positive and negative aspects of the components of the CRIAA Program and their perceived impact.

The program administrator will keep a diary of field notes where they will record:

a. The proportion of participating mothers/mothers invited to participate (to measure the recruitment process of the CRIAA Program).
b. The duration, in minutes, of the breastfeeding workshop (scheduled time vs. time used) to measure the implementation of the CRIAA Program.
c. Participants recruited and, as a follow-up, participants who complete the CRIAA Program (i.e. recruited/completed—to measure the CRIAA Program's participant retention).

The intervention's preliminary effect on breastfeeding self-efficacy will be estimated by the following primary outcomes:

1. Mothers breastfeeding self-efficacy: Changes in maternal breastfeeding self-efficacy, measured using the Spanish validated version of Breastfeeding Self-Efficacy Scale-Short Form (BSES-SF) (Oliver-Roig et al., 2012) (Cronbach's alpha: 0.92). BSES-SF is a 14-item, unidimensional, self-report instrument developed to measure a mother's confidence in her ability to breastfeed. All items are presented with a 5-point Likert-type

TABLE 1 Intervention description ([a])

	TIDieR items	Intervention group	Control group
1.	Brief name	CRIAA Program (acronym meaning in the background section). A complex intervention in primary care to support women and their families to breastfeed	Standard pre- and postnatal regular care for mother and child
2.	Why	Interventions must use a systematic approach to breastfeeding care, analysing current practices within the health system. Its components must be adaptable to women's and newborns' socio-emotional needs and not only physical ones. Primary care level of healthcare provides opportunities for interventions to promote breastfeeding. Key concepts of the theoretical framework are (1) Early Childhood Development, (2) Social Cognitive Theory and Self-efficacy, (3) Health Promotion Model. In the background section is a detailed description of the theoretical framework.	—
3. 4.	What Material Procedure	**Health professionals**: training will be provided regarding the breastfeeding process and its relationship with child and family health promotion; the breastfeeding benefits and the risks of not breastfeeding; the clinical approach to the most frequent lactation problems; and the recognition of emotional support therapeutic tools to provide a meaningful support to breastfeeding mothers and families. Existing breastfeeding support instances will be unveiled, showing their objectives and referral criteria, so that professionals can efficiently integrate existing resources and optimize referrals.	—
		Women and their families: training dealing with breastfeeding benefits for mother, child, family, and society; types of breast milk; requirements for successful breastfeeding initiation and installation; breastfeeding positions and techniques; and the importance of couple/family role in supporting breastfeeding. In addition, self-efficacy and peer support will be reinforced.	Standard care offers the possibility for mothers to participate in a prenatal workshop designed by the Chile CreceContigo program, which is planned to be carried out during pregnancy
5.	Who Provided	**Health professionals**: the training will be delivered by four research team members who are breastfeeding experts, three of them certified as IBCLC and two experts in therapeutic tools for emotional support will be invited.	—
		Women and their families: the training will be delivered by certified IBCLC professionals and the nurse in charge of the children's program at the intervention health centre who has previously done the training.	The workshop offered in standard care is run by a professional from the health centre
6.	How	**Health professionals**: The training course "Breastfeeding as a health promoting behavior" will be face-to-face in small groups of six to eight health professionals. It will consist on participatory classes, group work, case analysis, and demonstrations. The course will be structured in three units to address the contents mentioned before. It will be created in an online repository of material for professionals to access it after the course. In addition, as a poster with a flowchart with the description of the existing breastfeeding support instances, their objectives and referral criteria, has been created and will be made available in the health centres so health professionals can use it as a tool to efficiently integrate existing resources and optimize referrals.	—
		Women and their families: Prenatal workshop "Preparing to breastfeed our babies": it will take place in small group, with six to eight families taking part in each one, with a participatory methodology based on adult education, where the professional guides and supports the dialogue of the participants. The workshop material will consist on a set of laminated sheets that will illustrate the topics to be covered. These sheets will be introduced through questions and each participant should choose a sheet to answer the question and shared it in the group. In addition, newborns and breasts phantoms will be used. At the end of the workshop, printed material will be delivered to reinforce the most relevant aspects (benefits, breastfeeding technique, and breast milk extraction and conservation technique).Virtual support: the WhatsApp application will be used to deliver self-efficacy messages and facilitate peer support.	Standard workshop is carried out in unique session with a methodology in which the professional is the protagonist, with little participation from mothers, most of whom attend without their partner or family member. This workshop has historically had a low attendance of mothers
7.	Where	**Health professionals:** the course will take place at the School of Nursing facilities where the researchers who will teach the course work	—
		Women and their families: the workshop will take place at the intervention health centre facilities and the virtual support at the online setting.	Standard workshop takes place at health centres facilities

(Continues)

TABLE 1 (Continued)

	TIDieR items	Intervention group	Control group
8.	When and How Much	**Health professionals:** Before the intervention takes place in two sessions of 8-hr each.	—
		Women and their families: the workshop will be held from 28 weeks of gestation in a single one-hour session on Saturdays, twice monthly. Virtual support: mothers will receive weekly messages, from the children birth until the child is six months old.	During pregnancy in 1-hr duration workshop scheduled monthly in working days
9.	Tailoring	All participants will receive the same intervention	—
10.	Modifications	Since this is a report of the protocol of the study, this item cannot be described until the study is complete	—
11.	How Well Planned	The researcher will keep a field diary to keep a record of the development of each of the intervention´s component to maintain and guarantee fidelity.	—
12.	Actual	Since this is a report of the protocol of the study, this item cannot be described until the study is complete	—

[a]Hoffmann, T. C., Glasziou, P. P., Boutron, I., Milne, R., Perera, R., Moher, D., … Michie, S. (2014). Better reporting of interventions: Template for intervention description and replication (TIDieR) checklist and guide. *BMJ (Online), 348*(March), 1–12.https://doi.org/10.1136/bmj.g1687

scale where "1" indicates " not at all confident" and "5" indicates "always confident" (scores: minimum 14; maximum 70). Higher scores indicate higher levels of breastfeeding self-efficacy.

2. Professionals' self-efficacy regarding their ability to support breastfeeding mothers: Changes in professional self-efficacy will be measured using the APCLA Scale (Professional Self Efficacy for Breastfeeding Care Scale) (Antoñanzas-Baztan et al., 2017) (Cronbach's alpha: 0.967). The APCLA scale is a 14-item, unidimensional, self-report instrument developed to measure a professional's confidence in her/his ability to support a breastfeeding mother. All items are presented with a 5-point Likert-type scale where "1" indicates "not at all confident" and 5 indicates "always confident" (scores: minimum 14; maximum 70). Higher scores indicate higher levels of breastfeeding support self-efficacy. This scale was constructed and validated in Spanish based on the Spanish version of BSES-SF.

The following secondary outcomes will also be explored:

1. Socio-demographics: A questionnaire designed for this study will be used to collect socio-demographic characteristics of participants.
2. Breastfeeding rate: Percentage of children with exclusive breastfeeding, measured by the type of feeding that the baby is receiving as registered by the professional at the supervision health control centre.
3. Postnatal depression: Postnatal depression screening using results of the Edinburgh Postnatal Depression Scale, which is routinely used in this region in the care of all mothers postpartum, collected by health professionals.
4. Decision-making participation: Mothers and their partners/meaningful person perceptions of decision-making participation about their baby's feeding type decision using the CollaboRATE scale (Bravo, Contreras, Dois, & Villarroel, 2017). CollaboRATE (Cronbach alpha > 0.89) is a three questions tool which can be answered on a scale of 1 to 7 points. The Chilean version of CollaboRATE is a reliable instrument for capturing the degree of patients' participation in health decision-making.

2.5 | Data collection and follow-up

Data will be gathered in person by the research team members starting before the prenatal workshop, in the case of mothers/meaningful persons and before the training course, in the case of professionals. The follow-up will be done by telephone with the mothers/partner and by e-mail with the professionals. The program administrator will use the diary field notes previously mentioned to keep an audit trail of the study by collecting information about the study phases and events that could occur during the follow-up process.

2.6 | Ethical considerations

Ethical principles that protect the participants' dignity will be maintained throughout the study by the informed consent process, which will ensure compliance with the ethical requirements for clinical studies (Emanuel, Wendler, Killen, & Grady, 2004). The research team members will present the objectives and the possible benefits and risks for the participants and will invite them to the study. It will be clearly and continually stated that participation is voluntary and that participants may withdraw at any time without affecting their health care or working conditions. All personal information will be handled confidentially, made anonymous and used only for research purposes. Written consent will be signed after information has been provided to participants by one of the research team members in verbal and written form before data collection starts. The Scientific Ethical Committees of the corresponding university and

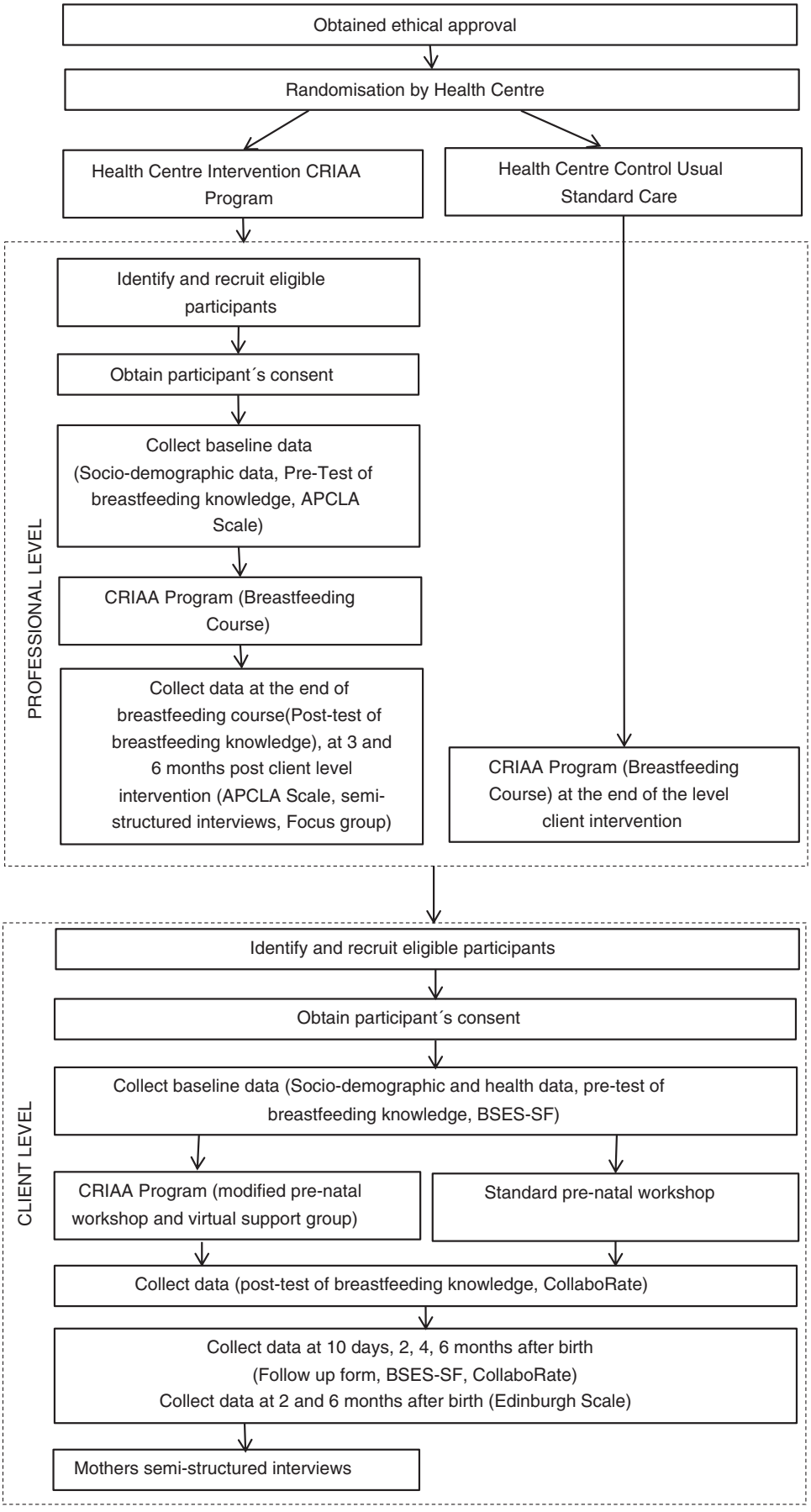

FIGURE 2 Workflow

TABLE 2 CRIAA Program data collection and evaluation times

Outcomes	Measurement Tools	Informant	Evaluation times				
			T0	T1	T2	T3	T4
Mothers' and professionals' views regarding the intervention	Diary field notes	Programme administrator	X	X	X	X	X
Acceptability of the intervention	Semi-structured interviews	Women					X
		Health professionals		X			
	Focus gropus	Health professionals					X
Breastfeeding self-efficacy	BSES-SF Spanish version	Women	X	X	X	X	X
	APCLA Scale	Health professionals	X	X			X
Socio-demographic data	Sociodemograpic quesionnaire	Women/health professionals	X				
Exclusive Breastfeeding	% exclusively Breastfeeding	Women		X	X	X	X
Postnatal depression	Edinburgh Postnatal Depression Scale	Women			X		X
Decision-making participation	CollaboRate Spanish version	Women and a meaningful person	X	X	X	X	X

T0: Before intervention
T1: 10 days after giving birth for women and 3 months after intervention for health professionals
T2: 2 months after giving birth for women
T3: 4 months after giving birth
T4: 6 months after birth for women and after intervention for health professionals

health institutions approved the study in March and April of 2019, respectively (ID: 181129006).

2.7 | Data analysis

For the analysis of interviews and focus groups, content analysis will be carried out (Braun & Clarke, 2006) using Dedoose online software to identify thematic categories and subcategories. For the analysis of the quantitative data, descriptive statistics analysis (average and standard deviation for continuous variables and frequencies for categorical variables) with 95% confidence intervals will be performed. In the baseline measurement, continuous variables will be compared between groups using Student's independent samples, *t*-tests, or a Mann–Whitney *U* test, as appropriate (according to variables' normality). Shapiro–Wilk and Levene's tests will be used to assess the normality and homoscedasticity of variables. The z-test comparing two proportions will be used for categorical variables.

To identify the differences in the evolution of continuous dependent variables between intervention and control groups, a mixed-ANOVA will be used with the "conditions" as the between-subject factors and the "measurements over time" as the within-subject factors.

Given the sample size, in the case that the assumptions of the analysis will be not met, non-parametric tests will be used. In the case of continuous variables, we will use the Friedman Test to estimate the change in time in each group and the Mann–Whitney *U* test to compare both groups at the initial and final measurements. In the case of categorical variables, Cochran's Q and Chi-square tests will be used, respectively. In all analyses, an alpha value of 5% will be considered. The effect size will be estimated under three modalities: (a) as Cohen's d in each of the measurement moments; and (b) as partial eta squared (η2), which accounts for the effect size for the total of the measurements made and (c) Odds Ratio for categorical variables (Faul, Erdfelder, Bucher, & Lang, 2007). For the analysis of quantitative data, SPSS software will be used.

2.8 | Validity and reliability

The study will use previously validated data collection instruments. Likewise, a validation by experts will be carried out to adjust to the local Spanish language with instruments validated in Spain to ensure participants' comprehension. For qualitative analysis, methodological rigour of criteria credibility, fidelity, confirmability, and transferability will be ensured (Streubert & Rinaldi Carpenter, 2011). Each of the components of the CRIAA Program have been designed and validated by content experts and reviewed by the grant entity and the respective ethics committees. The CONSORT 2010 statement was used to design the study protocol (Eldridge, Lancaster, et al., 2016).

2.9 | Progression criteria to a full-scale trial

The recommendations for progression to a full-scale trial are adapted from those provided for internal pilot studies (Avery

TABLE 3 Progression Criteria for the final trial

Criteria	Information that will be provided with this Feasibility pilot study	Aspects to consider for the full-scale trial
Recruitment and enrolment	• Rate of childbearing women recruited per month by health centre • Percentage of childbearing women who agree to participate • Percentage of childbearing women excluded by each exclusion criteria • Percentage of health centre professionals who provide direct care to women and families during breastfeeding who accept to participate in the training course • Percentage of health centre professionals who provide direct care to women and families during breastfeeding who agree to participate and complete the training course • Percentage of healthcare professionals excluded by each exclusion criteria • It will be calculated the sample size necessary for the full trial. Additionally, the information collected regarding the acceptance rate to participate and the exclusion criteria will allow estimating the feasibility of reaching the stipulated sample size	These findings will allow identification of the cut-off points of use of the traffic light system (green, amber, red) for determining to proceed, amend, or stop the full trial,and evaluate the needs of an internal pilot phase before the full-scale trial
Adherence	• Percentage of attendance at the Prenatal workshop by participating women and their partner/family • Percentage of women enrolled in the virtual support group and remaining in the group at 2, 4, and 6 months • Number of health professionals who moved off the health centre after receiving the training course • Number of health professionals that incorporated to the health centre after the training course is finished • Defined the degree of adherence necessary the full trial	If necessary, amendments will be made,considering the findings and the general complex interventions approach
Acceptability of the intervention components	• General acceptability of the CRIAA program and each component • A definition of parameters for good acceptability will be provided	If acceptability is low, it will be necessary to review components and reasons before full-scale trial
Follow-up and missing data	• Rate of participating women who remain in the telephone follow-up after the health checks of 10 days, 2, 4, and 6 months • Percentage of Health professionals who respond the APCLA Scale at 3 and 6 months • Missing data during follow-up will be identified, and the reasons for this to happen will be explored • The acceptable degree of loses in the follow-up and of missing data will be calculated regarding key outcomes, as well as the percentage of participants with missing data	Actions will be required if the rate of participants decreases over time or missing data are high, considering new techniques to follow them up or to complete the scales
Others	• Gather information on possible unexpected effects of the intervention, such as low adherence to controls of the healthy child or vaccination during the child's first 6 months	For the full-scale trial, context-specific changes (technological, organizational, sociological, and epidemiological) will be considered to decide whether the intervention needs to be modified for the final trial to ensure the intervention remains relevant and feasible

et al., 2017; Herbert, Julious, & Goodacre, 2019), as the complex intervention framework does not provide specific criteria (see Table 3 for scalation criteria for a CRIAA program full trial). Outcomes regarding recruitment and enrolment, adherence, follow-up data, missing data, and the intervention's acceptability will guide this scalation.

3 | DISCUSSION

The purpose of this study was to pilot the effect of a complex intervention to promote breastfeeding, addressing mothers' breastfeeding self-efficacy, and professionals' self-efficacy in supporting breastfeeding mothers. The proposed complex intervention is based on a series of aspects that support the relevance of the study.

Breastfeeding support is an important consideration for improving exclusive breastfeeding rates. There is robust evidence that breastfeeding women require support from healthcare professionals, their most direct family members, and the general community to achieve breastfeeding goals (McFadden et al., 2017; Mitchell-Box & Braun, 2013; Negin, Coffman, Vizintin, & Raynes-Greenow, 2016).

Globally and nationally, various efforts and interventions have been implemented to achieve improvements in breastfeeding rates. However, exclusive breastfeeding rates are lower than expected (Duran-Aguero Samuel & Castro Villarroel Paolo, 2018). This outcome can be attributed, among other factors, to the lack of timely, relevant

and continuous healthcare support to families that initiate breastfeeding practice. Monitoring and constant support, sensitively adapted to the particular needs of each woman and her family, must be available (MacVicar, Kirkpatrick, Humphrey, & Forbes-McKay, 2015).

Many factors influence decision-making regarding the type of feeding that the mother and people close to her choose for their child (El-Houfey, 2017). One of these factors is breastfeeding self-efficacy, understood as the mother's confidence in her ability to breastfeed her child (Dennis, 1999). Several studies have shown that interventions intended to increase breastfeeding self-efficacy improve breastfeeding initiation and exclusivity and duration rates (Brockway, Benzies, & Hayden, 2017).

Additionally, healthcare professionals' participation and motivation should be considered. Professionals' perceptions of self-efficacy depend on how secure and confident they feel when providing support to breastfeeding mothers and those close to them (Antoñanzas-Baztan et al., 2017). Continuous training is necessary; this training must be aimed at not only updating breastfeeding information but also developing health professionals' skills and attitudes necessary to provide significant professional support (Gavine et al., 2017).

Previous research indicates that breastfeeding support is a complex reality influenced by multiple biological, psychological, emotional, and cultural factors, both individually and collectively. Therefore, breastfeeding approach is also complex and requires interventions that address its multidimensional nature, including all actors involved in the breastfeeding process. Accordingly, this study follows the complex interventions framework, which recommends first developing the intervention and then piloting it on a small scale, to be able to adjust it to the local reality and ensure its implementation over time (Craig et al., 2013). The proposed intervention will be carried out by an interdisciplinary professional health team, which also contributes to the incorporation of the intervention into regular healthcare practice and its maintenance over time.

3.1 | Limitations

The expected results will help to ensure the quality and relevance of the intervention and the research processes when designing and conducting a large-scale study (Craig et al., 2008). Although using a small-scale pilot study could be considered a limitation, pilot studies are currently recommended prior to the implementation of large-scale studies to assess intervention safety and ensure the feasibility of a study's completion before investing large sums of money in developing interventions that may not be effective (Leon, Davis, & Kraemer, 2011; Thabane et al., 2010). The results of this pilot study will allow progress towards large-scale implementation and evaluation of the intervention.

4 | CONCLUSION

The results from this pilot study could contribute to the implementation of an intervention for supporting breastfeeding mothers, their partners and others close to them. This intervention considers breastfeeding in its multidimensional nature, proposing a more comprehensive approach to support that focuses on women's and families' needs. Subsequently, it will be necessary to move towards an impact evaluation of a large-scale intervention, as proposed by the complex interventions' framework guiding this study (Craig et al., 2008).

The protocol for the proposed study allows for estimates of the preliminary effects of a novel complex intervention to support breastfeeding and maternal and professional self-efficacy. The pilot's purpose is to identify the feasibility of the future full-scale study and contribute to refining the intervention—maintaining positive aspects and re-designing negative/irrelevant aspects—according to the pilot study's findings. This will allow the full-scale trial to use the best suitable intervention for supporting breastfeeding in the local context. The knowledge can be transferred to other settings appropriate for introducing an interdisciplinary perspective for breastfeeding support.

ACKNOWLEDGEMENTS

The authors thank the Interdisciplinary Research Grant Committee and the Faculty of Medicine, of the Pontificia Universidad Católica de Chile. We also acknowledge the support of the Research Directorate of the School of Nursing of the Pontificia Universidad Católica de Chile.

CONFLICT OF INTEREST

No conflict of interest has been declared by the authors.

AUTHORS' CONTRIBUTIONS

All authors have agreed on the final version and meet at least one of the following criteria:

1. substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
2. drafting the article or revising it critically for important intellectual content.

PEER REVIEW

The peer review history for this article is available at https://publons.com/publon/10.1111/jan.14534.

ORCID

Camila Lucchini-Raies https://orcid.org/0000-0001-5704-9778
Francisca Marquez-Doren https://orcid.org/0000-0001-8093-4687
Olga Lopez-Dicastillo https://orcid.org/0000-0001-7375-8072

REFERENCES

Antoñanzas-Baztan, E., Belintxon, M., Marín-Fernández, B., Redín-Areta, M., & Lopez-Dicastillo, O. (2017). Design and validity of an instrument to evaluate health professionals' perceived self-efficacy to care for nursing mothers. *Horizonte De Enfermería*, *28*(3), 5–21. Retrieved from https://www.researchgate.net/publication/333114747_Diseno_y_valid

ez_de_un_instrumento_para_evaluar_la_autoeficacia_percibida_por_los_profesionales_de_la_salud_acerca_de_su_capacidad_para_procurar_cuidados_a_las_madres_que_amamantan_Design_and_validity

Asiodu, I. V., Waters, C. M., Dailey, D. E., & Lyndon, A. (2017). Infant feeding decision-making and the influences of social support persons among first-time African American mothers. *Maternal and Child Health Journal*, *21*(4), 863–872. https://doi.org/10.1007/s10995-016-2167-x

Avery, K. N. L., Williamson, P. R., Gamble, C., O'Connell Francischetto, E., Metcalfe, C., Davidson, P., … Blazeby, J. M. (2017). Informing efficient randomised controlled trials: Exploration of challenges in developing progression criteria for internal pilot studies. *British Medical Journal Open*, *7*(2), e013537. https://doi.org/10.1136/bmjopen-2016-013537

Bandura, A. (1994). Self-efficacy. In H. Friedman (Ed.), *Encyclopedia of human behavior* (Vol. 4, pp. 71–81). San Diego: Academic Press.

Blatch-Jones, A. J., Pek, W., Kirkpatrick, E., & Ashton-Key, M. (2018). Role of feasibility and pilot studies in randomised controlled trials: A cross-sectional study. *British Medical Journal Open*, *8*(9), e022233. https://doi.org/10.1136/bmjopen-2018-022233

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, *3*(2), 77–101. https://doi.org/10.1191/1478088706qp063oa

Bravo, P., Contreras, A., Dois, A., & Villarroel, L. (2017). Adapting and validating the generic instrument CollaboRATETM to measure women's participation in health-related decision-making during the reproductive process. *Atención Primaria*, *50*(5), 274–281. https://doi.org/10.1016/j.aprim.2017.04.003

Brockway, M., Benzies, K., & Hayden, K. A. (2017). Interventions to improve breastfeeding self-efficacy and resultant breastfeeding rates: A systematic review and meta-analysis. *Journal of Human Lactation*, *33*(3), 486–499. https://doi.org/10.1177/0890334417707957

Center on the Developing Child at Harvard University. (2016). *From best practices to breakthrough impacts: A science-based approach to building a more promising future for young children and families*. Retrieved from www.developingchild.harvard.edu

Corry, M., Clarke, M., While, A. E., & Lalor, J. (2013). Developing complex interventions for nursing: A critical review of key guidelines. *Journal of Clinical Nursing*, *22*(17–18), 2366–2386. https://doi.org/10.1111/jocn.12173

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., & Petticrew, M. (2008). Developing and evaluating complex interventions: The new Medical Research Council guidance. *BMJ*, *337*, a1655. https://doi.org/10.1136/bmj.a1655

Dennis, C. (1999). Theoretical underpinnings of breastfeeding confidence: A self-efficacy framework. *Journal of Human Lactation*, *15*(3), 195–201. https://doi.org/10.1177/089033449901500303

Dennis, C. (2003). The breastfeeding self-efficacy scale: psychometric assessment of the short form. *Journal of Obstetric, Gynecologic, & Neonatal Nursing*, *32*(6), 734–744. https://doi.org/10.1177/0884217503258459

Dennis, C.-L., Heaman, M., & Mossman, M. (2011). Psychometric testing of the breastfeeding self-efficacy scale-short form among adolescents. *Journal of Adolescent Health*, *49*(3), 265–271. https://doi.org/10.1016/j.jadohealth.2010.12.015

Durán-Agüero, S., & Castro Villarroel, P. (2018). Evolución de la lactancia materna exclusiva en Chile entre 2011 y 2015: ¿influyó el Permiso Postnatal Parental? *Revista Española De Nutrición Humana Y Dietética*, *22*(1), 14–20. Retrieved from http://renhyd.org/index.php/renhyd/article/view/376

Eksioglu, A. B., & Ceber, E. (2011). Translation and validation of the Breastfeeding Self-efficacy Scale into Turkish. *Midwifery*, *27*(6), e246–e253. https://doi.org/10.1016/j.midw.2010.10.009

Eldridge, S. M., Chan, C. L., Campbell, M. J., Bond, C. M., Hopewell, S., Thabane, L., …the PAFS Consensus Group. (2016). CONSORT 2010 statement: Extension to randomised pilot and feasibility trials. *Pilot and Feasibility Studies*, *2*(1), 64. https://doi.org/10.1186/s40814-016-0105-8

Eldridge, S. M., Lancaster, G. A., Campbell, M. J., Thabane, L., Hopewell, S., Coleman, C. L., & Bond, C. M. (2016). Defining feasibility and pilot studies in preparation for randomised controlled trials: Development of a conceptual framework. *PLoS One*, *11*(3), 1–22. https://doi.org/10.1371/journal.pone.0150205

El-Houfey, D. A. A. (2017). Factors that influence exclusive breastfeeding: A literature review. *International Journal of Nursing Didactics*, *7*(11), 24–31. https://doi.org/10.15520/ijnd.2017.vol7.iss11.264.24-31

Emanuel, E. J., Wendler, D., Killen, J., & Grady, C. (2004). What makes clinical research in developing countries ethical? The benchmarks of ethical research. *Journal of Infectious Diseases*, *189*(5), 930–937. https://doi.org/10.4324/9781315244426-24

Faul, F., Erdfelder, E., Bucher, A., & Lang, A.-G. (2007). G*Power 3: A flexible statistical power analysis program for the social, behavioral and biomedical sciences. *Behavioral Research Methodods*, *39*(2), 175–191. https://doi.org/10.3758/BF03193146

Gavine, A., MacGillivray, S., Renfrew, M. J., Siebelt, L., Haggi, H., & McFadden, A. (2017). Education and training of healthcare staff in the knowledge, attitudes and skills needed to work effectively with breastfeeding women: A systematic review. *International Breastfeeding Journal*, *12*(6), 10. https://doi.org/10.1186/s13006-016-0097-2

Griswold, M. K. (2017). Reframing the context of the breastfeeding narrative: A critical opportunity for health equity through evidence-based advocacy. *Journal of Human Lactation*, *33*(2), 415–418. https://doi.org/10.1177/0890334417698691

Herbert, E., Julious, S. A., & Goodacre, S. (2019). Progression criteria in trials with an internal pilot: An audit of publicly funded randomised controlled trials. *Trials*, *20*(1), 1–9. https://doi.org/10.1186/s13063-019-3578-y

Hoffmann, T. C., Glasziou, P. P., Boutron, I., Milne, R., Perera, R., Moher, D., … Michie, S. (2014). Better reporting of interventions: Template for intervention description and replication (TIDieR) checklist and guide. *BMJ (Online)*, *348*(March), 1–12. https://doi.org/10.1136/bmj.g1687

In, J. (2017). Introduction of a pilot study. *Korean Journal of Anesthesiology*, *70*(6), 601–605. https://doi.org/10.4097/kjae.2017.70.6.601

Leon, A. C., Davis, L. L., & Kraemer, H. C. (2011). The role and interpretation of pilot studies in clinical research. *Journal of Psychiatric Research*, *45*(5), 626–629. https://doi.org/10.1016/j.jpsychires.2010.10.008

Lucchini-Raies, C., & Lopez-Dicastillo, O. (2017). Interventions that promote iniciation, duration and exclusivity of breastfeeding. An umbrella review. *Revista Horizonte De Enfermería*, *28*(3), 33–49. 107764/Horiz_Enferm.28.3.33

Lucchini-Raies, C., Márquez Doren, F., Garay Unjidos, N., Contreras Véliz, J., Jara Suazo, D., Calabacero Florechaes, C., … Lopez-Dicastillo, O. (2019). Caring during breastfeeding: Perceptions of mothers and health professionals. *Investigación Y Educación En Enfermería*, *37*(2), e09–e09. https://doi.org/10.17533/udea.iee.v37n2e09

MacVicar, S., Kirkpatrick, P., Humphrey, T., & Forbes-McKay, K. E. (2015). Supporting breastfeeding establishment among socially disadvantaged women: A meta-synthesis. *Birth*, *42*(4), 290–298. https://doi.org/10.1111/birt.12180

McFadden, A., Gavine, A., Renfrew, M. J., Wade, A., Buchanan, P., Taylor, J. L., … MacGillivray, S. (2017). Support for healthy breastfeeding mothers with healthy term babies. *Cochrane Database of Systematic Reviews*, *2017*(2), CD001141. https://doi.org/10.1002/14651858.CD001141.pub5

Mikkonen, J., & Raphael, D. (2010). *Social determinants of health: The Canadian facts*, Toronto: York University School of Health Policy

and Management. Retrieved from https://thecanadianfacts.org/The_Canadian_Facts.pdf

Mistry, K. B., Minkovitz, C. S., Riley, A. W., Johnson, S. B., Grason, H. A., Dubay, L. C., & Guyer, B. (2012). A new framework for childhood health promotion: The role of policies and programs in building capacity and foundations of early childhood health. *American Journal of Public Health*, *102*(9), 1688–1696. https://doi.org/10.2105/AJPH.2012.300687

Mitchell-Box, K., & Braun, K. (2013). Impact of male-partner-focused interventions on breastfeeding initiation, exclusivity and continuation. *Journal of Human Lactation*, *29*(4), 473–479. https://doi.org/10.1177/0890334413491833

Negin, J., Coffman, J., Vizintin, P., & Raynes-Greenow, C. (2016). The influence of grandmothers on breastfeeding rates: A systematic review. *BMC Pregnancy and Childbirth*, *16*(1), 91. https://doi.org/10.1186/s12884-016-0880-5

Oliver-Roig, A., D'Anglade-González, M. L., García-García, B., Silva-Tubio, J.-R., Richart-Martínez, M., & Dennis, C. (2012). The Spanish version of the Breastfeeding Self-Efficacy Scale-Short Form: Reliability and validity assessment. *International Journal of Nursing Studies*, *49*, 169–173. https://doi.org/10.1177/0890334414523836

Pender, N. (2011). *Health Promotion Model manual*. University of Michigan Deep Blue. Retrieved from http://hdl.handle.net/2027.42/85350

Primo, C. C., & Brandão, M. A. G. (2017). Interactive theory of breastfeeding: Creation and application of a middle-range theory. *Revista Brasileira De Enfermagem*, *70*(6), 1191–1198. https://doi.org/10.1590/0034-7167-2016-0523

Rollins, N. C., Bhandari, N., Hajeebhoy, N., Horton, S., Lutter, C. K., Martines, J. C., … Victora, C. G. (2016). Why invest and what it will take to improve breastfeeding practices? *The Lancet*, *387*(10017), 491–504. https://doi.org/10.1016/S0140-6736(15)01044-2

Solar, O., & Irwin, A. A. (2010). *A conceptual framework for action on the social determinants of health: Determinants of health discussion (policy and practice)*. Geneva: World Health Organization. https://www.who.int/sdhconference/resources/ConceptualframeworkforactiononSDH_eng.pdf

Srebro, A. (2017). Towards an anthropology of care: Breastfeeding as a care work. *Glasnik Etnografskog InstitutaBulletin De L'institut Etnographique*, *65*(1), 223–230. https://doi.org/10.2298/gei1701223s

Streubert, H. J., & Rinaldi Carpenter, D. (Eds) (2011). *Qualitative research in nursing. Advancing the humanistic imperative* (5th Ed). Philadelphia: Lippincott Williams & Wilkins.

Sutton, M., O'Donoghue, E., Keane, M., Farragher, L., & Long, J. (2016). *Interventions that promote increased breastfeeding rates and breastfeeding duration among women. An Umbrella review*. Retrieved from http://www.hrb.ie/uploads/tx_hrbpublications/Interventions_that_promote_increased_breastfeeding_rates_2016.pdf

Thabane, L., Ma, J., Chu, R., Cheng, J., Ismaila, A., Rios, L. P., … Goldsmith, C. H. (2010). A tutorial on pilot studies: The what, why and how. *BMC Medical Research Methodology*, *10*(January), 1. https://doi.org/10.1186/1471-2288-10-1

Torres, J. M. C. (2014). Medicalising to demedicalize: Lactation consultants and the (de) medicalisation of breastfeeding. *Social Science and Medicine*, *100*, 159–166. https://doi.org/10.1016/j.socscimed.2013.11.013

Whitehead, A. L., Julious, S. A., Cooper, C. L., & Campbell, M. J. (2015). Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. *Statistical Methods in Medical Research*, *25*(3), 1057–1073. https://doi.org/10.1177/0962280215588241

WHO; UNICEF; HIS; SDS. (2018). *Declaration of Astana. Global Conference on Primary Health Care*. Retrieved from https://www.who.int/docs/default-source/primary-health/declaration/gcphc-declaration.pdf

How to cite this article: Lucchini-Raies C, Marquez-Doren F, Beca P, Perez JC, Campos S, Lopez-Dicastillo O. The CRIAA Program complex intervention in primary care to support women and their families in breastfeeding: Study protocol for a pilot trial. *J Adv Nurs*. 2020;76:3641–3653. https://doi.org/10.1111/jan.14534