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Evaluation of the impact of breastfeeding support groups in primary health centers in Andalusia, Spain

Submission date 20/05/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/06/2020	**Overall study status** Completed	
Last Edited 31/07/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
The World Health Organization (WHO) recommends exclusive breastfeeding up to 6 months of age to achieve adequate growth. Despite this recommendation, the exclusive breastfeeding rate at 6 months is low. The aim of this study is to evaluate the impact of breastfeeding support groups in primary health centers in Andalusia, Spain.

Who can participate?
Adult women who have established exclusive or mixed breastfeeding once they attend the postnatal check with their midwife, and who have attended the breastfeeding group session included in their primary health centre's antenatal classes

What does the study involve?
Participants are randomly allocated to the control group or the intervention group. The control group will receive the usual care consisting of group prenatal education on breastfeeding offered by their center. The intervention group will receive the usual care and they will also participate in monthly breastfeeding support sessions reinforced with a WhatsApp and/or Facebook group led by other lactating mothers (peer support) and coordinated by their reference midwife. Measurements will be carried out at 10 days postpartum and after 2, 4 and 6 months to evaluate the rate of breastfeeding using a questionnaire. Factors related to the success of breastfeeding will be identified.

What are the possible benefits and risks of participating?
Participants may breastfeed for longer. Risks are not expected.

Where is the study run from?
This study will run from primary health centers in Andalucia, Spain

When is the study starting and how long is it expected to run for?
January 2020 to December 2023

Who is funding the study?
Consejería de Salud y Familias de la Junta de Andalucia (Spain)

Who is the main contact?
Fatima Leon-Larios
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
08/2019 project

Study information

Scientific Title
Evaluation of the impact of breastfeeding support groups in primary health centres in Andalusia, Spain: a cluster randomized controlled trial (Galma Project)

Acronym
Galma Project

Study objectives

Women who attend breastfeeding support groups breastfeed exclusively longer than women who do not attend any support group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/02/2020, Investigation Ethics Committee of the hospitals Virgen Macarena and Virgen del Rocio (c/o Carlos García Pérez, University Hospitals Vírgen Macarena-Virgen del Rocío, Seville, Spain; +34 (0)600 16 24 58; administracion.eecc.hvm.sspa@juntadeandalucia.es), ref: Code1936-N-19

Study design
Interventional multicentre cluster randomized clinical trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
Participants will be randomized without blinding due to the impossibility of achieving it with patients or researchers (open, masking not used). Women will be allocated by clusters (primary health centers) by simple random sampling.

Intervention group: participation in monthly breastfeeding support sessions reinforced with a WhatsApp and/or Facebook group led by other lactating mothers (peer support) and coordinated by their reference midwife, follow up every 2 months, and 10 days after birth, follow up through telephone, app or online questionnaire via WhatsApp.

Control group: usual care about breastfeeding: antenatal lessons and follow up in the outpatient clinic.

Measurements will be carried out at the postpartum 10 days, 2, 4 and 6 months to evaluate the rate of breastfeeding using the validated questionnaire of self-efficacy of breastfeeding, general self-efficacy questionnaire and problems identified related to breastfeeding. Factors related to the success of breastfeeding will be identified.

Intervention Type
Behavioural

Primary outcome measure
Percentage of exclusive breastfeeding, mixed breastfeeding, or formula, measured using study app or online questionnaire completed by the mother at 10 days after birth, 2, 4, 6 months after birth

Secondary outcome measures
1. Sociodemographic outcomes (mother's age, level of education, marital status, employment status, country of origin) measured with closed-ended questions using study app or online questionnaire completed by the mother and the midwife before birth
2. Breastfeeding self-efficacy assessed using breastfeeding self-efficacy scale-short form (Spanish Version) at baseline (10 days after birth), 2, 4, 6 months after birth
3. A breastfeeding observation assessed using WHO Breastfeeding assessment tool at 10 days after birth
4. Breastfeeding self-efficacy assessed using General Self-efficacy scale (Spanish Version) at 10 days, 2, 4, 6 months after birth
5. Motivation for interruption of breastfeeding assessed with open-ended questions completed by the mother using study app or online questionnaire at 2, 4, 6 months after birth
6. Problems related to breastfeeding measured by open-ended questions completed by the mother using study app or online questionnaire at 2, 4, 6 months after birth
7. Obstetric outcomes (type of birth, type of onset of labour, type of analgesia used, perineal trauma, skin-to-skin technique) measured by closed-ended questions completed by the mother using study app or online questionnaire at 10 days after birth

Overall study start date
01/01/2020

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Healthy women with exclusive or mixed breastfeeding 10 days after birth, and attended antenatal lessons in the Primary Health Centre
2. Women over 18 years of age
3. Women who accepted and signed the informed consent

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex

Female

Target number of participants
Target: 371 women. In total, 10 clusters (10 centres in 5 cities).

Total final enrolment
382

Key exclusion criteria
1. HIV positive
2. Cancer
3. Tuberculosis infection
4. No intention to breastfeed
5. Impossibility or contraindication to breastfeed due to medical conditions
6. Communication difficulties due to language

Date of first enrolment
01/10/2021

Date of final enrolment
01/12/2023

Locations

Countries of recruitment
Spain

Study participating centre
Servicio Andaluz de Salud
Av Constitución, 18
Seville
Spain
41071

Sponsor information

Organisation
Consejería de Salud y Familias de la Junta de Andalucia

Sponsor details
Avenida de la Innovación s/n. Edificio Arena 1
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Sponsor type
Government

Website
https://www.juntadeandalucia.es/organismos/saludyfamilias.html

Organisation
University of Seville

Sponsor details
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Sponsor type
University/education

Website
http://www.us.es/eng

ROR
https://ror.org/03yxnpp24

Organisation
Fundación Pública Andaluza para la Gestión de la Investigación en Salud de Sevilla

Sponsor details
Hospital Universitario Virgen del Rocío. Avda. Manuel Siurot, s/n., Edif. de Laboratorios 6º planta.
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Sponsor type
Research organisation

Website
http://fisevi.com/

ROR
https://ror.org/01bp61317

Funder(s)

Funder type
Government

Funder Name
Consejería de Salud y Familias de la Junta de Andalucia

Results and Publications

Publication and dissemination plan
1. Publication of protocol
2. Publication of preliminary results
3. Publication of main results

Intention to publish date
01/03/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Fátima León-Larios (fatimaleon@us.es). The database will be available when the study is finished. Data will be anonymous and will be able to be used for scientific purposes.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	18/07/2020	21/07/2020	Yes	No
Results article		28/03/2024	04/04/2024	Yes	No
Results article	breastfeeding rates, postpartum depression and general self-efficacy	10/01/2024	31/07/2025	Yes	No