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

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| **Submission date**<br>20/05/2020 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>17/06/2020 | **Overall study status**<br>Completed | |
| **Last Edited**<br>31/07/2025 | **Condition category**<br>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
fatimaleon@us.es

# Contact information

### Type(s)
Public

### Contact name
Dr Fatima Leon-Larios

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
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

## Study type(s)
Other

## 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(s)
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

## Key secondary outcome(s))
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
Female

### 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

**Organisation**
University of Seville

**ROR**
https://ror.org/03yxnpp24

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

**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

## 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? |
|---|---|---|---|---|---|
| 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 |
| Protocol article | protocol | 18/07/2020 | 21/07/2020 | Yes | No |