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Influence of practising the Pilates method during pregnancy on the quality of life of pregnant women

Submission date
09/06/2024

Recruitment status
No longer recruiting

Registration date
11/06/2024

Overall study status
Ongoing

Last Edited
19/06/2024

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Pregnancy is a significant event in a woman's life that can lead to a change in her lifestyle, potentially affecting her quality of life. Pregnancy influences a woman's perceived quality of life, with differences found between pregnant and non-pregnant women, with variations occurring naturally during pregnancy.
In response to these changes, regular moderate physical exercise has positive effects on pregnant women, potentially providing benefits.
Currently, among the types of activities that can be performed during pregnancy, the Pilates method is gaining importance and is recommended as a valid physical activity program during pregnancy. The objective of this method is to achieve muscular harmony through strengthening and flexibility of weaker muscles, practising exercises in a controlled manner guided by a professional. A Pilates program during pregnancy requires adaptation of exercises to the new situation and changes in the body, and participants can start Pilates at any time during pregnancy regardless of whether they have previously trained in the method.
The aim of this study is to determine the influence of practising the Pilates method during pregnancy on the quality of life of pregnant women, evaluate whether it reduces pain in the lower back and pelvis, and determine if it improves the mental health of pregnant women.

Who can participate?
Pregnant women aged over 18 years at 20 weeks of gestation at the beginning of the program

What does the study involve?
Participants will be asked about their attendance or non-attendance to maternal education and Pilates classes held at the Quironsalud Campo de Gibraltar Hospital in Los Barrios, Algeciras (Cádiz). Depending on their response (yes/no), they will be assigned to either the Pilates group or the control group. The intervention/experimental group (which will receive the Pilates method) will attend a physical activity program using the Pilates method, consisting of two sessions per week for eight weeks, with each session lasting 40-45 minutes, at the Quironsalud Campo de Gibraltar Hospital in Los Barrios, Algeciras (Cádiz), supervised by qualified personnel during 4 months. The control group (who will not receive the Pilates method) will not engage in

structured physical activity (i.e., at a sports center or under the guidance of a sports professional).
Participants complete a questionnaire twice, once at the beginning and once at the end of the study. An initial evaluation (pretest) will be conducted using a questionnaire for the group that does not practice Pilates and the group that practices Pilates, for comparison of results between both groups. After completing this survey, the Pilates program will commence at the Quironsalud Campo de Gibraltar Hospital in Los Barrios, Cádiz. When the program ends, a final evaluation (post-test) will be conducted in both groups using the same questionnaire for result comparison.

What are the possible benefits and risks of participating?
Participation in this study will not provide any direct benefit, but it is hoped that the information obtained will contribute to expanding scientific knowledge about how Pilates practice during pregnancy can influence quality of life, pain, and mental health, potentially helping other pregnant women in the future. The procedures that will be used during the study are non-invasive and will not involve an increase in the number of prenatal care visits or the tests normally performed during pregnancy. Likewise, no additional visits or tests will be conducted solely for participating in the study. As part of the inconveniences arising from the study, participants will be asked to complete a questionnaire at the beginning and end of the study, as well as sign an informed consent form and practice Pilates.

Where is the study run from?
Hospital Quirónsalud Campo de Gibraltar (Spain)

When is the study starting and how long is it expected to run for?
April 2024 to September 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Mr Juan Manuel Mérida Téllez, juanmanuel.merida@alu.uhu.es

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IPPECV-2024

Study information

Scientific Title
Influence of practising Pilates exercises within a physical activity program developed during pregnancy on perceived quality of life compared to women who have not practised it

Acronym
IPPQL

Study objectives
Practising the Pilates Method during pregnancy improves the quality of life of pregnant women compared to those who do not practice it.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/05/2024, Research Ethics Committee of Cádiz (Hospital Universitario Puerta del Mar. Despacho 817. 8ª Planta, Cadiz, 11009, Spain; +34 (0)956 002 005; ceic.hpm.sspa@juntadeandalucia.es), ref: SICEIA-2024-000936

Study design
Single-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Perceived quality of life among pregnant women

Interventions
The study design involves a randomized controlled trial (RCT) where pregnant women will be randomly assigned (using a simple randomization process through the generation of random numbers) to either an experimental group receiving a Pilates-based physical activity program or a control group receiving standard care, with assessments of health outcomes using the SF-36 questionnaire before and after the intervention.

A physical activity program using the Pilates method will commence between weeks 26-28 of gestation and conclude between weeks 34-36, lasting 8 weeks, twice a week, with each session lasting 40-45 minutes. The control group will not engage in any structured physical activity program.

Intervention Type
Other

Primary outcome measure
Quality of life measured using the SF-36 health-related quality of life questionnaire at baseline and 8 weeks

Secondary outcome measures
1. Pain assessed using one of the specific domains of the SF-36 questionnaire at baseline and 8 weeks
2. Mental health assessed using one of the specific domains of the SF-36 questionnaire at baseline and 8 weeks

Overall study start date
01/04/2024

Completion date
14/09/2025

Eligibility

Key inclusion criteria
1. Be over 18 years old
2. Women who have practiced the Pilates Method within a physical activity program during the study period and wish to participate in the study
3. Be at 20 weeks of gestation at the beginning of the program
4. Not suffer from any illness that constitutes a medical contraindication
5. Not have any injury that prevents the performance of physical exercise
6. Not participating in another physical activity program
7. Not having a multiple pregnancy
8. Not taking any medication that may influence the results

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Target number of participants
140

Key exclusion criteria
1. Lack of verbal, reading, and written comprehension of the Spanish language
2. Serious medical complications during pregnancy requiring urgent medical intervention
3. Development of medical conditions contraindicating the continuation of physical exercise, such as preeclampsia or threatened premature labor
4. Severe adverse events related to the practice of Pilates, such as musculoskeletal injuries or falls
5. Significant non-compliance with the exercise program or study protocol follow-up
6. Voluntary withdrawal of informed consent by the participant

Date of first enrolment
01/03/2025

Date of final enrolment
30/06/2025

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Quirónsalud Campo de Gibraltar
Av. de los Empresarios, Edificio Arttysur S/N
Los Barrios (Cadiz)
Spain
11379

Sponsor information

Organisation
Hospital Quirónsalud Campo de Gibraltar

Sponsor details
Av. de los Empresarios, Edificio Arttysur S/N
Los Barrioz
Spain
11379
+34 (0)956 79 83 00
DPO@quironsalud.es

Sponsor type
Hospital/treatment centre

Website
https://www.quironsalud.com/campo-gibraltar

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/06/2026

Individual participant data (IPD) sharing plan
Since this study does not have any source of funding, there may not be a formal individual participant data (IPD) sharing plan in place.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			11/06/2024	No	Yes

Statistical Analysis Plan	11/06/2024	No	No
Protocol file	19/06/2024	No	No