

Protocol of study

**INFLUENCE OF PRACTISING THE
PILATES METHOD DURING PREGNANCY
ON THE QUALITY OF LIFE OF
PREGNANT WOMEN**

SUMMARY

This research project focuses on the effects of a physical activity program using the Pilates method during pregnancy and childbirth. It is structured into the following sections:

1. Background and current state of the topic
2. Justification
3. Objectives
4. Methodology
5. Ethical aspects
6. Timeline
7. Bibliographic references

During pregnancy, a woman's body undergoes numerous anatomical and physiological changes aimed at facilitating fetal development. In response to these changes, regular moderate exercise has positive effects on a healthy pregnant woman, providing benefits during pregnancy, childbirth, and the postpartum period.

Pregnancy influences the perceived quality of life (QoL) of women, with differences observed between pregnant and non-pregnant women. This self-perception undergoes variations associated with inherent changes during pregnancy. Dividing the gestation into trimesters reveals a notable increase in perception during the first trimester and the beginning of the second trimester, followed by a decline from the third trimester, reaching its lowest point at the end of the pregnancy. In areas related to QoL affected in pregnant women compared to non-pregnant women, physical mobility, increased pain/discomfort, and increased reported anxiety/depression are notable. Therefore, it is necessary to improve the QoL of women during pregnancy so they can more fully enjoy their pregnancy, obtaining beneficial outcomes throughout the process. Some studies even indicate poorer obstetric outcomes related to low perceived QoL levels. Various alternatives with scientific evidence are available to improve this perception when necessary, such as physical exercise, aquatic physical activity, and social support.

Regarding recommended physical activity, various sources emphasize engaging in light to moderate exercise (walking, cycling, or running). In recent years, exercise models with higher physical demands, focusing on stretching and posture correction, have gained importance. There is also some consensus on the optimal time to start the exercise routine, with week 20 recommended as the starting point for moderate-intensity exercises. Authors generally agree on the session duration (between 45 and 60 minutes) and frequency (2 or 3 times a week). Thus, well-directed physical activity poses no risk to maternal-fetal health.

Currently, among the types of activities to develop, the Pilates method is gaining importance, recommended as physical activity during pregnancy. The goal of this method is to achieve muscular harmony by strengthening weaker muscles and increasing the elasticity of hypertrophied muscles, enabling better body control, strength, and flexibility, without straining the back or joints. A Pilates program during pregnancy requires adapting exercises to the body's new situation and changes, and participants can start Pilates at any gestation phase, even if they have never practiced the method before.

Despite a literature search, no relevant information was found analyzing the positive effects of the Pilates method on QoL, pain, and mental health in this patient group. Therefore, the research project's objective is to assess the efficacy of an eight-week physical activity program using the Pilates method in pregnant women regarding QoL, pain, and mental health.

A randomized clinical trial will be conducted on pregnant women, consisting of applying a Pilates-based physical activity program, specifically designed for this population, to evaluate pretest and posttest measures. To minimize possible follow-up losses, the final sample will include 70 patients per group (140 in total). The intervention group will attend a Pilates-based physical activity program, with two weekly sessions for eight weeks, each lasting 40-45 minutes, conducted at the Quironsalud Hospital in Los Barrios, Algeciras (Cádiz), by qualified personnel.

As measurement tools, we will use the SF-36 questionnaire to evaluate QoL, with domains related to pain and mental health also analyzed.

In conclusion, an eight-week physical activity program using the Pilates method could improve QoL in pregnant women, reduce pain, and benefit their mental health.

BACKGROUND AND CURRENT STATE OF THE TOPIC

Pregnancy is an event in a woman's life with various physical and mental modifications that can lead to lifestyle changes, even affecting perceived QoL. Changes during gestation, such as excessive weight gain, possible negative sleep quality alterations, and the onset of pain in the area, among others, can affect a woman's physical-mental comfort and well-being, leading to a decrease in perceived QoL. QoL is an essential indicator used to evaluate the effect of a process, pathology, or problem, even in the absence of pathologies, on a person's health. It can be defined as subjective and perceived by the person, and it is also susceptible to change.

Pregnancy influences women's perceived QoL, with differences observed between pregnant and non-pregnant women. This self-perception undergoes variations associated with inherent changes during pregnancy. Dividing the gestation into trimesters reveals a notable increase in perception during the first trimester, the beginning of the second trimester, and a decline from the third trimester, reaching its lowest point at the end of the gestation. Areas related to QoL affected in pregnant women compared to non-pregnant women include physical mobility, increased pain/discomfort, and increased reported anxiety/depression. Therefore, it is necessary to improve the QoL of women during pregnancy so they can more fully enjoy their pregnancy, obtaining beneficial outcomes throughout the process. Various alternatives with scientific evidence are available to improve this perception when necessary, such as physical exercise, aquatic physical activity, and social support.

The Pilates Method (PM) originated as an exercise method developed by German Joseph Hubertus Pilates. In his childhood, J.H. Pilates faced several health problems that led him to practice various sports disciplines to improve his physical condition, also taking an interest in Greco-Roman philosophy and civilization. For several years, he dedicated himself professionally to various sports activities until he was assigned to work in a hospital with war-wounded patients during World War I. He began training them using a technique based on the use of bed springs as a recovery method for bedridden patients, observing that they regained muscle tone more quickly. J.H. Pilates's

original method has evolved to the present day, where modern Pilates uses the principles, philosophy, and exercises of J.H. Pilates with modifications that make it appropriate for people of any age or adapted to different special situations in life, such as during pregnancy. PM is a physical activity based on exercises that work the body-mind binomial, requiring central stability (understood as the activation of deep trunk muscles or Core that stabilize the lumbar spine and pelvis), strength, and flexibility, as well as attention to muscle control, body posture, and breathing. Benefits of practicing PM include increased flexibility, increased muscular endurance, and improved mental health outcomes. Exercises can be done on the floor, on a mat, or using auxiliary materials.

Practicing PM can be a useful tool to safeguard Core muscles and improve the QoL of women during pregnancy, as it is a form of physical activity that has physical and psychological benefits, favoring the improvement of self-perception and perceived QoL of its practitioners. It can also affect lumbopelvic pain and the mental health of pregnant women.

It is worth considering as a research line the effects of exercise during pregnancy on psychological well-being and general perceived health among women from different sociocultural subgroups. General physical activity is associated with higher general QoL at the end of pregnancy, and specifically, PM improves general QoL, particularly physical and social function, being feasible and safe during pregnancy. Pregnant women with depressive symptoms have lower QoL scores than those without depressive symptoms.

Studies reveal that the physical fitness level reported in QoL-related questionnaires is a determining factor, especially in the General Health dimension, influencing pregnant women's well-being. As pregnancy progresses, physical domain scores in perceived QoL questionnaires decrease. Self-perception of QoL significantly decreases over time during pregnancy (especially between the 4th and 8th months of gestation), more noticeably in the presence of pregnancy-associated pathology. Maintaining weight gain during pregnancy within recommendations leads to good levels of perceived QoL. Higher perceived QoL levels are observed in women with normal weight before pregnancy and overweight at the end of gestation, while the lowest levels are seen in obese women both at the beginning and end of gestation. Therefore, physical activity

and PM could be beneficial measures to reduce weight gain. Another factor that improves with physical activity during pregnancy is the self-perception of restorative sleep, where PM practice could benefit rest/sleep, as sleep problems negatively influence various QoL spheres.

Pregnancy can influence a woman's self-perception, impacting perceived QoL, with lumbar and pelvic pain being one of the main influencing factors, decreasing physical domain values in questionnaires. Some women experience neuropathic pain associated with pregnancy-related lumbar pain, negatively affecting their QoL. Pain management has been shown to improve QoL in pregnant women. Practicing PM can be a treatment option for managing pregnancy-associated lumbar and pelvic pain.

Regarding postpartum, a cesarean delivery can negatively influence the physical dimension of perceived QoL, even among women who have a vaginal birth after a cesarean, showing better QoL levels compared to those who have another cesarean after a previous one. Therefore, practicing physical exercise during pregnancy, specifically PM, can reduce cesarean rates with the benefit of improving QoL.

It is necessary to offer and highlight the importance of incorporating physical activity throughout pregnancy to pregnant women, emphasizing the last trimester, as it can reduce psychological issues that negatively impact the pregnant woman's QoL, particularly in the psychological domain.

Another dimension in evaluating QoL is social support, considered a significant predictor of QoL, playing an important role in maternal well-being. Therefore, practicing PM in a group of pregnant women could benefit the physical and mental domains present in the questionnaires.

However, it is important to investigate existing knowledge related to the topic to emphasize the need to incorporate PM into a healthy pregnancy, promoting QoL during pregnancy, childbirth, and postpartum. Thus, the study aims to evaluate the QoL of pregnant women practicing PM during pregnancy and identify its influence on LBP and mental health, both being influential indicators of perceived QoL.

JUSTIFICATION OF THE STUDY

Pregnant women are susceptible to perceiving changes in their QoL due to the physiological changes they experience during pregnancy at physical, psychological, and social levels. As healthcare professionals, we aim to promote people's health. Specifically, the group of pregnant women can benefit from a practice that can improve their QoL, obtain mental health benefits, and either improve or reduce the incidence of pain, as it is a frequent issue during gestation.

With the results obtained from this research, we aim to provide pregnant women with information on the benefits of practicing the Pilates method and provide updated scientific evidence on exercise during pregnancy and its influence on physical, mental, and QoL aspects.

OBJECTIVES

General Objective

- Analyze the influence of Pilates exercises within a physical activity program developed during pregnancy on perceived QoL in a sample of pregnant women.

Specific Objectives

- Evaluate the effect on pain with the practice of the Pilates-based physical activity program.
- Study the mental health level of pregnant women before and after the Pilates-based physical activity program.
- Determine the perceived QoL in pregnant women who do not practice physical activity.

METHODOLOGY

Study Design

The study will be a randomized controlled trial (RCT) with pre- and post-intervention measures.

Study Setting

The study will be conducted at the Quirónsalud Campo de Gibraltar Hospital, located in Los Barrios, Cádiz. Participants will include pregnant women who practice Pilates as part of a physical activity program and those who do not.

Methodology

In collaboration with Quirónsalud Campo de Gibraltar Hospital, a randomized controlled trial (RCT) will be conducted with pre- and post-intervention measures using the SF-36 Health-Related Quality of Life Questionnaire. The experimental group will follow a physical activity program based on the Pilates method adapted for pregnancy, while the control group will receive usual care.

STUDY VARIABLES

Universal/Sociodemographic Variables

- Age, gender, socioeconomic status, education level, place of residence, marital status, religion, race.
- A specific questionnaire will be used to record these data.

Independent Variable

- Pilates Method.
- A specific questionnaire will be used to record data (attendance to sessions, any notable incidents/observations).

Dependent Variables

Primary:

- Quality of life (measured using items included in the SF-36 Questionnaire).

Secondary:

- Pain (measured using items related to the pain domain in the SF-36 Questionnaire):
 - "Did you have pain in any part of your body during the last 4 weeks?"

- "During the last 4 weeks, to what extent did pain interfere with your normal work (including work outside the home and housework)?"
- Mental Health (measured using items related to the mental health domain in the SF-36 Questionnaire):
 - "Have you been very nervous?"
 - "Have you felt so down in the dumps that nothing could cheer you up?"
 - "Have you felt calm and peaceful?"
 - "Have you felt downhearted and blue?"
 - "Have you been a happy person?"

Sample

To address the main objective of the study, a sample size calculation was performed to compare standardized mean differences of 0.5 points on the global SF-36 score pre-post between the experimental and control groups with unknown but equal variances. With a 95% confidence level and 80% power, and a 1/1 sample ratio, 43 patients per group are needed. To minimize potential losses to follow-up, the sample will be increased by 10%, resulting in a final sample size of 50 patients per group (100 total). The sample size calculation was done using EpiDat 3.1 software.

Randomization

Participants will be randomized based on those pregnant women who attend a pregnancy check-up at 20 weeks and are asked about their attendance at maternal education and Pilates classes offered at Quirónsalud Campo de Gibraltar Hospital. Depending on their response, they will be assigned to the Pilates or non-Pilates group. If the response is affirmative, they will be informed about the research project and asked if they wish to participate.

Inclusion Criteria

- Over 18 years old.
- Women who have practiced the Pilates Method within a physical activity program during the study period and wish to participate.
- At 20 weeks gestation at the start of the program.

- No medical contraindications.
- No injuries preventing physical exercise.
- Not participating in another physical activity program.
- Not having a multiple pregnancy.
- Not taking any medications that could influence the results.

Exclusion Criteria

- Lack of verbal, written, and reading comprehension of Spanish.

Withdrawal Criteria

- Severe medical complications during pregnancy requiring urgent medical intervention.
- Development of medical conditions contraindicating continued exercise, such as preeclampsia or threatened preterm labor.
- Serious adverse events related to Pilates practice, such as musculoskeletal injuries or falls.
- Significant non-compliance with the exercise program or study protocol.
- Voluntary withdrawal of informed consent by the participant.

Data Management

Data management and custody will be handled by the principal investigator. All data obtained or generated will be protected through periodic backup procedures, and confidentiality and integrity will be ensured through encryption. Access to personal data identifying the study participants will be restricted to the principal investigator, the only authorized person employed by Quirónsalud Campo de Gibraltar Hospital. Other researchers involved in the project, not affiliated with Quirónsalud Campo de Gibraltar Hospital, will work with anonymized data.

Procedure

An initial evaluation (pre-test) using the SF-36 questionnaire will be conducted for both the control and experimental groups to compare the results. After this survey, the Pilates program will begin at Quirónsalud Campo de Gibraltar Hospital. At the end of the

program, a final evaluation (post-test) using the same questionnaire will be conducted to compare the results.

Instruments

SF-36 Health Questionnaire

To assess quality of life, the Spanish version of the SF-36 Health-Related Quality of Life Questionnaire will be used. This questionnaire, developed in the 1990s, is widely used to evaluate health-related quality of life and can detect both positive and negative health states. It is applicable to individuals aged 14 and older and includes eight health scales:

- Physical Functioning: 10 items measuring the extent to which health limits physical activities.
- Role Physical: 4 items measuring the extent to which physical health interferes with work and daily activities.
- Bodily Pain: 2 items measuring pain intensity and its impact on work and daily activities.
- General Health: 5 items assessing personal health perceptions, future health outlook, and disease resistance.
- Vitality: 4 items assessing energy and vitality levels versus feelings of tiredness and exhaustion.
- Social Functioning: 2 items measuring the extent to which physical or emotional health interferes with social life.
- Role Emotional: 3 items assessing the impact of emotional problems on work and daily activities.
- Mental Health: 5 items assessing general mental health, including depression, anxiety, behavioral control, and general well-being.

Responses will be coded and scaled from 0 to 100, where 0 indicates the worst health perception and 100 indicates the best.

Physical Activity Program

After the initial assessment, only the experimental group will participate in an eight-week Pilates program, twice a week, with sessions lasting 40-45 minutes. The program will be conducted in the maternal education room at Quirónsalud Campo de Gibraltar Hospital, ensuring appropriate conditions for the safety of pregnant women (temperature, lighting, and humidity). Groups of 10-12 pregnant women will follow the Pilates method. The program will be supervised and designed by professionals, adhering to various authors' recommendations. Women will start the Pilates program between the 26th and 28th week of gestation and finish between the 34th and 36th week. Attendance of at least 90% of the sessions (14-16 sessions) will be required. The control group will not participate in any structured physical activity program.

Session Description

The program will be based on the Pilates method specifically designed for pregnant women, using floor (Mat) exercises and accessories (fitballs, magic rings, elastic bands, small balls), with basic (level 1) and intermediate (level 2) activities, following a progressive increase in the number of exercises and repetitions.

Each session will include:

- Posture awareness
- Warm-up phase (5-8 minutes)
- Aerobic and toning phase (25-30 minutes)
- Flexibility phase (5-10 minutes)
- Cool-down phase (5-10 minutes), including relaxation techniques

Sessions will use fitballs, elastic bands, magic rings, and small balls, focusing on correct posture and performing strength and flexibility exercises, with 3 to 5 repetitions per exercise.

Reference: "Manual de Pilates aplicado al embarazo," paperback edition, March 11, 2021, Panamericana Editorial, authors Mayte Fernández Arranz, Roberto Lambruschini, and Julita Fernández Arranz. ISBN: 978-8498359022.

Location: Quirónsalud Campo de Gibraltar Hospital, CP 11379 Palmones, Los Barrios (Cádiz).

Supervised by Dr. Luciano Rodríguez Díaz, Professor at the University of Ceuta, Specialist Nurse in Obstetric-Gynecological Nursing (Midwife), and Pilates Specialist for Pregnant Women, who will act as the research coordinator.

Final Evaluation (Post-test)

After the physical activity program concludes, the SF-36 questionnaire will be administered again to both groups of pregnant women. The results will be compared with the pre-test results to draw conclusions.

Statistical Analysis

A descriptive analysis will be performed to assess the sociodemographic and clinical baseline characteristics of the pregnant women, using measures of central tendency and dispersion for quantitative variables and frequency distribution for qualitative variables. A comparison between the intervention and control arms will be performed to assess any imbalances in sociodemographic or clinical variables, using the chi-square test, with continuity correction, or Fisher's exact test for expected values below 5.

To determine pre-post-intervention differences regarding the main outcome variables (global SF-36 score and subscales), generalized linear models for repeated measures will be constructed, including the study arm as an intra-subject factor and adjusting for any imbalanced variables.

Outcome variables will be evaluated by intention to treat, and statistical significance will be set at $p < 0.05$ (two-tailed). An interim analysis will be conducted to evaluate the need for early study termination due to benefit, with a primary outcome variable significance level of $p < 0.01$.

Statistical analysis will be performed using SPSS 26.0 for Windows (SPSS: an IBM Company, Armonk, NY).

Participant Recruitment Responsibilities

Principal Investigator: Juan Manuel Merida Tellez

- Role: Supervise the entire recruitment process and ensure ethical compliance.

- Responsibilities:
 - Approve selection criteria.
 - Review and approve recruitment materials.
 - Coordinate with the medical and research teams.
 - Monitor participant recruitment progress.
 - Oversee data collection, ensuring adherence to protocols.

Medical Team: Nurse Doctor Luciano Rodríguez Díaz

- Role: Conduct medical evaluations and identify potential participants.
- Responsibilities:
 - Conduct 20-week pregnancy check-ups.
 - Screen candidates based on selection criteria.
 - Inform potential participants about the study.
 - Refer interested participants to the research team.

Research Team: MD Daniel María Lubian López

- Role: Manage participant intake, consent, and baseline data collection.
- Responsibilities:
 - Provide detailed study information to potential participants.
 - Obtain informed consent.
 - Conduct baseline assessments using the SF-36 questionnaire.
 - Assign participants to control or experimental groups based on randomization.
 - Schedule and coordinate initial Pilates sessions for the experimental group.

Data Management Team:

- Role: Ensure accurate and secure data collection and storage.
- Responsibilities:
 - Develop data collection tools and procedures.
 - Train the research team on data entry protocols.
 - Maintain data confidentiality and security.
 - Perform regular data quality checks.

- Prepare data for statistical analysis.

Participant Follow-Up Responsibilities

Principal Investigator: Juan Manuel Merida Tellez

- Role: Oversee participant follow-up and data collection.
- Responsibilities:
 - Monitor participant adherence to the study protocol.
 - Address any medical issues or concerns related to the intervention.
 - Ensure timely administration of post-test assessments.
 - Review and approve follow-up data collection plans.

Medical Team:

- Role: Conduct follow-up medical evaluations and monitor participants' health.
- Responsibilities:
 - Provide ongoing medical support during the study.
 - Monitor participants for any adverse events.
 - Conduct final medical evaluations at the end of the intervention period.

Research Team:

- Role: Manage follow-up assessments and data collection.
- Responsibilities:
 - Schedule and coordinate post-test assessments for both groups.
 - Administer the SF-36 questionnaire at the end of the intervention period.
 - Ensure consistent follow-up with participants to encourage retention.
 - Record and report any deviations from the study protocol.

Data Management Team:

- Role: Ensure accurate and secure data collection and storage during follow-up.
- Responsibilities:
 - Continue data quality checks throughout the study.
 - Update and maintain the study database with follow-up data.
 - Prepare follow-up data for statistical analysis.

Ethical Considerations

The study will be conducted following the principles outlined in the Declaration of Helsinki and in compliance with the International Council for Harmonization Good Clinical Practice (ICH-GCP) guidelines. The study protocol, informed consent form, and other relevant documents will be submitted for approval by the Quirónsalud Campo de Gibraltar Hospital Ethics Committee before study commencement. Informed consent will be obtained from all participants before enrollment. Participants will be informed about the study's purpose, procedures, potential risks and benefits, and their right to withdraw from the study at any time without penalty.

No clinical history data of the participants will be collected. All data will be provided by the participants themselves. All participants in the study will have access to and a copy of an information sheet about the study, which they must read, understand, and discuss any questions with the principal investigator before signing this sheet and the corresponding informed consent form.

The data collected in the study will be treated with the utmost confidentiality, in accordance with the provisions of Organic Law 3/2018 of Spain, of December 5, on Personal Data Protection and the guarantee of digital rights, and in compliance with the General Data Protection Regulation and Law 41/2002, of November 14, which regulates patient autonomy and rights and obligations regarding clinical information and documentation by the Govern of Spain.

The directors of the center where the study will be conducted are informed and have given their written approval for the study's execution. The project will be carried out in accordance with the provisions of Law 14/2007, of July 3, on Biomedical Research of the Govern of Spain.

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

Confidentiality and Data Protection

Participant confidentiality will be maintained throughout the study. Data will be anonymized, and access will be restricted to authorized personnel only. Electronic data will be encrypted, and physical data will be stored in locked cabinets. Data protection measures will comply with the General Data Protection Regulation (GDPR).

Potential Risks and Benefits

Participants may experience physical discomfort or injury related to Pilates exercises. However, the study will include measures to minimize these risks, such as professional supervision, proper instruction, and modifications for individual needs. The potential benefits include improved physical and mental health outcomes related to Pilates practice. The study findings may contribute to evidence-based guidelines for physical activity during pregnancy.

Dissemination of Results

The results of the study will be disseminated through peer-reviewed publications, presentations at scientific conferences, and reports to healthcare providers and participants. The study findings will contribute to the body of knowledge on the effects of Pilates on the quality of life of pregnant women and may inform clinical practice and guidelines for physical activity during pregnancy.

Timeline

Phase One: General Project Design

Task: Literature Review

Description:

- Search for current evidence on "Pregnancy - Pilates - Quality of Life - Pain - Mental Health"
- **Dates:** September 2024 - December 2024

Phase Two: Analysis of Study Structure, Implementation, and Data Collection

Task: Final Study Design

Description:

- Selection of the SF-36 Quality of Life Questionnaire
- Design of a four-month Pilates-based physical activity program
- Creation of the work schedule and Human Resources management

Dates: January 2025 - March 2025

Task: Pilates-Based Physical Activity Program

Description:

- Sample selection
- Delivery of informed consents
- Pretest evaluation using the SF-36 Questionnaire
- Execution of the four-month program at the Hospital Quironsalud Campo de Gibraltar in Los Barrios (Cádiz)
- Posttest evaluation using the SF-36 Questionnaire

Dates: April 2025 - June 2025

Task: Data Analysis

Description:

- Collection of data obtained from the surveys
- Analysis and comparison of the results

Dates: July 2025 - September 2025

Phase Three: Variable Analysis

Task: Statistical Analysis

Description:

- Analysis of the different studied variables
- **Dates:** October 2025 - December 2025

Phase Four: Study Writing and Presentation of Results

Task: Study Writing

- **Dates:** January 2026 - June 2026

Task: Presentation of the Wor

Description:

- Presentation of the obtained results
- **Dates:** July 2026 - October 2026

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