PARTICIPANT INFORMATION SHEET FOR A CLINICAL RESEARCH STUDY

STUDY TITLE: INFLUENCE OF PILATES PRACTICE DURING PREGNANCY ON THE QUALITY OF LIFE OF PREGNANT WOMEN

PRINCIPAL INVESTIGATOR: Juan Manuel Mérida Téllez, Nurse Specialist in Obstetric-Gynecological Nursing (Midwife) and Nurse Specialist in Mental Health Nursing. Hospital Quirónsalud Campo de Gibraltar, located in Palmones, Los Barrios (Cádiz)
Contact Email: juanmanuel.merida@alu.uhu.es
CENTER: Hospital Quirónsalud Campo de Gibraltar, located in Palmones, Los Barrios (Cádiz)
VERSION AND DATE: Version 2, 15/05/2024

INTRODUCTION

You are invited to participate in a study that has been approved by the Clinical Research Ethics Committee of Cádiz. Please read this information sheet carefully. The principal investigator, Juan Manuel Mérida Téllez, will clarify any questions you may have.

VOLUNTARY PARTICIPATION

Your participation in this study is voluntary, and you may change your decision and withdraw your consent at any time without affecting your relationship with the doctor or your treatment and the care you may need.

GENERAL DESCRIPTION OF THE STUDY

Pregnancy is a significant event in a woman's life that can lead to lifestyle changes, even affecting the quality of life. Pregnancy influences the perceived quality of life of women, with differences observed between pregnant and non-pregnant women. This perception will undergo changes that may be associated with the natural changes occurring during pregnancy.

In light of these changes, regular moderate physical exercise has positive effects on pregnant women, providing them with benefits.

Currently, among the activities you can engage in during pregnancy, the Pilates method is gaining importance and is recommended as a valid physical activity program during pregnancy. The aim of this method is to achieve muscle harmony through the strengthening and elasticity of the weaker muscles by performing exercises in a controlled manner guided by a professional. A Pilates program during pregnancy requires adapting the exercises to the new situation and body changes, and you can start Pilates at any time during pregnancy, regardless of whether the participants have previously trained in the method.

The aim of this study is to understand the influence of practicing the Pilates method during pregnancy on the quality of life of pregnant women, to evaluate if it reduces pain in the

lower back and pelvis, and to determine if it improves mental health in pregnant women who practice it.

Within the methodology we will use for the study, we would like to inform you that the procedures (in this study, the practice of the Pilates method) used during the study are non-invasive, will not increase the number of pregnancy check-ups or tests normally performed during pregnancy, and no additional visits or tests will be conducted solely because of participation in the study. As part of the study's inconveniences, you will be asked to fill out a questionnaire at the beginning and end of the study, as well as sign an informed consent form and practice the Pilates method.

Regarding the tests that are part of the study and not usually performed, nor applied to pregnant women not participating in the study, you will be required to complete a questionnaire used to assess your quality of life.

Participants will be randomly assigned to groups. Recruitment will be based on pregnant women attending consultations and asked about their attendance at maternal education and Pilates classes held at Hospital Quirónsalud Campo de Gibraltar in Los Barrios, Algeciras (Cádiz). Depending on their response (YES/NO), they will be part of the group that practices Pilates or the group that does not.

We will need a total of 140 pregnant women, divided into 70 patients in each of the 2 groups.
The intervention/experimental group (those practicing the Pilates method) will attend a physical activity program using the Pilates method, with two sessions per week for eight weeks, each session lasting 40-45 minutes, conducted at Hospital Quirónsalud Campo de Gibraltar in Los Barrios, Algeciras (Cádiz) with qualified personnel.
The control group (those not practicing the Pilates method) will not engage in any structured physical activity (that which is carried out in a sports center or with professional sports guidance).

Once you decide to participate in the study, you will be invited to fill out a questionnaire twice, once at the beginning and once at the end of the study. An initial assessment (Pretest) will be conducted using a health-related quality of life questionnaire called SF-36 in its Spanish version in both the Pilates and non-Pilates groups to compare the results between both groups. After this survey, the Pilates program will begin at Hospital Quirónsalud Campo de Gibraltar in Los Barrios, Cádiz. When the program ends, a final evaluation (Post-test) will be conducted in both groups using the same questionnaire to compare results.

As these are personal experiences, completing questionnaires allows us to assess the influence or lack thereof of practicing the Pilates method during pregnancy on your quality of life.
We must note that the Pilates method is not part of the usual care practice concerning physical activity during pregnancy.
The random assignment to groups will be based on pregnant women attending consultations and asked about their attendance at maternal education and Pilates

classes held at Hospital Quirónsalud de Los Barrios. Depending on their response, they will be part of the group that practices Pilates or the group that does not.

We will need a total of 140 pregnant women, divided into 70 patients in each of the 2 groups.
The intervention group will attend a physical activity program using the Pilates method, with two sessions per week for eight weeks, each session lasting 40-45 minutes, conducted at Hospital Quirónsalud de Los Barrios in Algeciras (Cádiz) with qualified personnel.

BENEFITS AND RISKS OF PARTICIPATING IN THE STUDY

Participation in this study will not provide you with any direct benefit, but we hope that the information we obtain will expand scientific knowledge on how practicing Pilates during pregnancy can influence quality of life, pain, and mental health, potentially helping other pregnant women in the future.

ECONOMIC COMPENSATION

Your participation in the study will not incur any cost to you.

CONFIDENTIALITY

Your personal data collected during this study will be subject to personal data processing, always respecting the provisions of the European Union General Data Protection Regulation (GDPR) and the Organic Law 3/2018, of December 5, on the Protection of Personal Data and Guarantee of Digital Rights (LOPDGDD).
The data controller is: specify the person responsible for the research project.
The contact details of the data controller are: specify the contact details of the person responsible for the research project.
The purpose of personal data processing is to conduct research on how practicing Pilates during pregnancy can influence quality of life, pain, and mental health.
Legal basis: the processing of personal data is based on the legal grounds established in arts. 6.1.a) and 9.2.a) of the GDPR, which state that processing is lawful if the data subject or their legal representative has given explicit consent for the processing of their personal data for one or more specific purposes. The data subject or their legal representative may consent to the use of their personal data for health research purposes, particularly biomedical research. The purpose may encompass categories related to general areas linked to a medical or research specialty, all in accordance with Additional Provision Seventeenth 2.a) of the LOPDGDD.
Recipients or categories of recipients: Your personal data will be treated with the utmost confidentiality and will not be disclosed to third parties outside the research project. There are no recipients or categories of recipients of your personal data. In no case will your personal data be subject to international data transfer.
If the study results are published, your personal data will not be disclosed, and your identity will remain anonymous.
Exercise of personal data protection rights: You have the right to request access to your personal data processed by the controller. You also have the right to rectify your personal data, to erase your personal data, to restrict processing, to object to processing, to data

portability, and not to be subject to decisions based solely on automated processing of your data, all in accordance with and subject to the limitations provided by the GDPR and the LOPDGDD for health and biomedical research. These rights can be exercised via the email address juanmanuel.merida@alu.uhu.es
You can exercise your right to withdraw consent for the processing of your personal data at any time, without affecting the lawfulness of the health research-based processing before its withdrawal. This right can be exercised via the email address juanmanuel.merida@alu.uhu.es
You have the right to file a complaint with the supervisory authority, which is the Transparency and Data Protection Council of Andalusia, which exercises its competence for the processing of personal data managed by the autonomous institutions of Andalusia, by the autonomous administration, by local administrations, and by other public and private entities dependent on any of them, as well as by the universities of the Andalusian university system.

FINANCING

This study does not have any funding sources.

WITHDRAWAL OF CONSENT

You can withdraw your consent at any time without giving any explanations. If you no longer wish to participate in the study, all data obtained from you will be destroyed to avoid re-analysis of the data.
You should also know that you may be excluded from the study if deemed appropriate by the study investigators.
You have the right to be informed of any new data projects of the identifiable material retained not foreseen in this study. In such a case, the researcher will need to request your new consent, which you could refuse.
Before signing, read the document carefully, ask all the questions you deem appropriate, and if you wish, take some time to think it over.

Thank you for your participation in this study.

I HAVE READ THE PARTICIPANT INFORMATION SHEET FOR A CLINICAL RESEARCH STUDY, VERSION 2, DATED 15/05/2024

Signature of Participant:

DNI/NIE:

Name of Participant:

Date:

I CONSENT TO PARTICIPATE IN THE STUDY

Principal Investigator: Juan Manuel Mérida Téllez
Position: Midwife
Contact Email: juanmanuel.merida@alu.uhu.es