Research Project Title:

THE IMPACT OF PHYSICAL EXERCISE PRESCRIPTION ON OBSTETRIC OUTCOMES IN A TERTIARY CENTER

SPONSOR:

ULS Coimbra

Coordinating Investigator:

Filipa Mendes Coutinho

Clinical Study Center:

ULS Coimbra

Investigator:

Filipa Mendes Coutinho

Adress:

Rua da Princesa Cindazunda, lote 15.4, 1ºC

Telephone:

914341629

Participant Name:

You are voluntarily invited to participate in this study because you are currently pregnant, will be monitored at this Department, and medical contraindications for participation have been excluded. The following information is intended to clarify the nature, scope, consequences, and risks of the study, enabling you to make an informed decision on whether or not to participate.

If you have no further questions, you should make your decision. If you choose not to participate, you will not face any penalty or disadvantage. If you wish to participate, you will be asked to sign and date this form. After both you and the Investigator sign, you will be given a copy to keep.

1. GENERAL INFORMATION AND STUDY OBJECTIVES

This study will take place in the Obstetrics Department and aims to evaluate the impact of an active intervention regarding physical exercise practice in the pregnant population attending prenatal consultations at our hospital center, specifically focusing on maternal and obstetric outcomes. This is an interventional clinical study, where the intervention consists of providing physical exercise counseling during pregnancy. This study was approved by the Ethics Committee of the ULS Coimbra to guarantee the protection of the rights, safety, and well-being of all participants.

2. STUDY PLAN AND METHODOLOGY

Physical exercise during pregnancy has been shown to be highly beneficial in preventing obstetric conditions and improving gestational outcomes. Potential benefits include reducing the risk of gestational diabetes, pregnancy-induced hypertensive disorders, lower risk of preterm birth, lower miscarriage rates, faster labor, and a higher prevalence of vaginal deliveries. Regarding newborns, they are more likely to be born with an optimal healthy weight. This study aims to understand whether physical exercise counseling provided during routine hospital appointments leads to better pregnancy and delivery outcomes, and if the advice successfully encourages expectant mothers to exercise more.

During your pregnancy, informational leaflets will be provided detailing the most suitable exercises for each trimester and their recommended frequency. You will also be asked to complete a questionnaire during the 2nd and 3rd trimesters to evaluate compliance with these recommendations. After delivery, the clinical records of participants will be reviewed to determine the occurrence of any complications during pregnancy (diabetes, hypertension, preterm birth) as well as delivery data (type of delivery, duration of labor, birth weight). Statistical collection and analysis of data will follow. At no stage will participants be personally identified, and all resulting publications will completely protect your anonymity.

3. DATA PROTECTION OF PARTICIPANTS

3.1 Data Controller

Filipa Mendes Coutinho

3.2 Data Collection

Directly through questionnaires completed in the 2nd and 3rd trimesters, and indirectly after delivery by reviewing the clinical files related to this pregnancy.

3.3 Categories of Data Collected

- **Age**
- **Weight (initial and final weight during pregnancy)**
- **Height**
- **Gestational diabetes criteria**
- **Gestational hypertension criteria**
- **Risk of preterm labor**
- **Other obstetric complications**
- **Fetal biometry in the 3rd trimester**
- **Duration of labor**
- **Type of delivery**
- **Birth weight**
- **Puerperal complications**

3.4 Data Processing

Data regarding pregnancy and delivery will be collected directly from the electronic obstetric system used in the department for pregnancy monitoring (ObsCare). They will be analyzed statistically to compare both

study groups. The constructed database will be destroyed once the study and its corresponding analysis are complete.

3.5 Protection Measures Adopted

Participant names will not be used in the compiled analysis database. The data will remain securely within the database managed exclusively by the principal investigator

3.6 Data Retention Period:

18 months

3.7 Publication Information

In the event of publication of the results, complete anonymity of all participants is strictly guaranteed.

4. RISKS AND POTENTIAL INCONVENIENCES FOR THE PARTICIPANT

MEDICAL LITERATURE DEMONSTRATES THAT PHYSICAL EXERCISE DURING PREGNANCY IS SAFE FOR THE MAJORITY OF PREGNANT WOMEN WHO DO NOT PRESENT CONTRAINDICATIONS TO ITS PRACTICE. YOUR GESTATIONAL STATUS WILL BE RE-EVALUATED IMMEDIATELY IF ANY WORRYING SYMPTOMS ARISE, AND AFFECTED USERS WILL WITHDRAW FROM THE STUDY. PARTICIPANTS MAY ALSO LEAVE THE STUDY AT ANY TIME BY CHOICE, WITHOUT ANY PREJUDICE TO THEIR REGULAR MEDICAL CARE

5. POTENTIAL BENEFITS

THE INHERENT BENEFITS ARE MULTIPLE, INCLUDING DOCUMENTED REDUCTIONS IN MISCARRIAGE RATES, DECREASED RISK OF PRETERM LABOR, LOWER INCIDENCE OF GESTATIONAL DIABETES AND HYPERTENSIVE DISORDERS OF PREGNANCY, REDUCED RATES OF POSTPARTUM DEPRESSION, AND IMPROVED NEONATAL OUTCOMES.

6. New Information

Any new information arising during the study that may be relevant to your condition or influence your decision to continue participating will be promptly communicated. If any change to the scope of the project occurs, a new consent process will be initiate.

7. Civil Liability

Not applicable.

8. Participation / Withdrawal of Consent

You are entirely free to accept or refuse participation. You may withdraw your consent at any time by notifying the investigator, without any negative consequences, without needing to provide justification, and without affecting your ongoing relationship with the clinical team or investigator. Withdrawal of consent does not cover data collected and processed up to that date. The investigator may also terminate your participation if it is deemed no longer in your best interest or if the study protocol is not being followed.

9. Confidentiality

Respect for the participant's right to privacy and personal data protection is strictly guaranteed, complying with the duty of secrecy and confidentiality under Article 29 of Portuguese Law no. 58/2019, of 08/08.

10 – Right of Access and Rectification

You have the right to access, rectify, or oppose the processing of your personal data, subject to legal provisions and limitations.

11. REIMBURSEMENT AND/OR COMPENSATION FOR PARTICIPANTS

Not applicable

12. COMPENSATION OF THE STUDY CENTER / INVESTIGATOR

Not applicable

13. CONTACTS

If you have any questions regarding this study, please contact:

Investigator	FILIPA MENDES COUTINHO
Address	RUA PRINCESA CINDAZUNDA, LOTE 15.4, 1ºC
Phone	914341629
Email	FILIPAMENDESCOUTINHO@GMAIL.COM

If you have questions about your rights as a study participant, you may contact:

President of the Ethics Committee of ULS Coimbra
Unidade Local de Saúde de Coimbra
Praceta Mota Pinto, 3000 075 Coimbra
Phone: 239 400 400
e-mail: secetica@chuc.min-saude.pt

DO NOT SIGN THIS INFORMED CONSENT FORM UNLESS YOU HAVE HAD THE OPPORTUNITY TO ASK QUESTIONS AND RECEIVE SATISFACTORY ANSWERS TO ALL OF YOUR QUESTIONS.

INFORMED CONSENT DECLARATION

Research Project Title

THE IMPACT OF PHYSICAL EXERCISE PRESCRIPTION ON OBSTETRIC OUTCOMES IN A TERTIARY CENTER

Participant Name:	
ID Number:	**Contact:**
Investigator name: Filipa Mendes Coutinho	

Within the scope of the above-mentioned Research Project, I declare that:

a. I have read and understood the information sheet attached to this form and voluntarily agree to participate in this study.

b. I am aware of the nature, scope, consequences, potential risks, and expected duration of the study, as well as what is expected of me as a participant.

c. I have understood all information and explanations provided. I know I can ask the investigator new questions at any time.

d. The investigator commits to providing any relevant new information that arises during the study which might alter my willingness to continue participating.

e. I agree to follow the study protocol. I also commit to informing the investigator of any changes in my health status that may occur (where applicable).

f. I authorize the use and dissemination of the study results exclusively for scientific purposes and permit sharing these results with competent regulatory authorities.

g. I know that I can exercise my right to data rectification and/or opposition within legal boundaries.

h. I am free to withdraw from the study at any time without justifying my decision and without facing any penalties, knowing that data collected up to that date will be retained.

i. The investigator has the right to decide on my premature withdrawal from the study if appropriate and commits to informing me of the reason.

j. The study may be discontinued at any time by decision of the investigator, sponsor, or regulatory authorities.

Location and date:	***Signatures***
	Participant:
	Legal Representative:
	Investigator*:

(*) I confirm that I have explained to the participant mentioned above the nature, scope, and potential risks of this study.