# UNIVERSIDAD POLITÉCNICA DE MADRID

Facultad de Ciencias de la Actividad Física y del Deporte- INEF


## Un programa de ejercicio físico supervisado durante el embarazo disminuye la incontinencia urinaria al final del embarazo y tres meses después del parto: un ensayo controlado aleatorizado

## A Supervised Exercise Program During Pregnancy Decreases Urinary Incontinence in Late Pregnancy and Three Months Postpartum: A Randomized Controlled Trial

**DOCTORAL THESIS**

Submitted for the degree of Doctor by:

**Dingfeng Zhang**

Master in physical education training, sports training and nutrition

Madrid, 2024

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Author: Dingfeng Zhang

Doctoral Programme: Physical Activity and Sports Sciences

Thesis Supervision:

Dr. Rubén Barakat Carballo, Catedrático de Universidad,

Universidad Politécnica de Madrid (Supervisor)

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# Abstract

Purpose: This study aimed to evaluate the impact of a supervised exercise program, including Pelvic Floor Muscle Training (PFMT), throughout pregnancy on Urinary Incontinence (UI).

Methods: A randomized clinical trial (NCT04563065) was conducted. Initially, 600 pregnant women were screened for eligibility, with data from 356 participants eventually analyzed. Of these, 172 were allocated to the Exercise Group (EG) and 184 to the Control Group (CG). Participants in the EG engaged in a supervised moderate exercise program three days per week, each session lasting 60 minutes, from 8-13 weeks to 38-40 weeks of gestation, achieving an adherence rate of 73.5%.

Results: Significant differences were observed between the EG and CG in the prevalence of UI during late pregnancy ($\chi^2 = 20.04$; $p = 0.001$) and at three months postpartum ($\chi^2 = 12.52$; $p = 0.03$), as well as in birth weight ($F = 4.16$; $p = 0.04$). No significant differences were found between the groups in other maternal and newborn outcomes.

Conclusion: Supervised exercise during pregnancy, which included PFMT, effectively reduced the incidence of urinary incontinence in late pregnancy and at three months postpartum.



**Keywords:** pregnancy, urinary incontinence, exercise, pelvic floor muscle training

# Resumen

Objetivo: Este estudio tuvo como objetivo evaluar el impacto de un programa de ejercicio supervisado, que incluía el entrenamiento de los músculos del suelo pélvico (EMSP), durante el embarazo sobre la incontinencia urinaria (IU).

Métodos: Se llevó a cabo un ensayo clínico aleatorizado (NCT04563065). Inicialmente, se examinó a 600 mujeres embarazadas para determinar su elegibilidad y, finalmente, se analizaron los datos de 356 participantes. De ellas, 172 se asignaron al grupo de ejercicio (GE) y 184 al grupo de control (GC). Las participantes del GE participaron en un programa de ejercicio moderado supervisado tres días a la semana, con una duración de 60 minutos cada sesión, desde la semana 8 a la 13 hasta la semana 38 a la 40 de gestación, logrando una tasa de adherencia del 73,5 %.

Resultados: Se observaron diferencias significativas entre el GE y el GC en la prevalencia de IU durante la última etapa del embarazo ($\chi^2 = 20,04$; $p = 0,001$) y a los tres meses posparto ($\chi^2 = 12,52$; $p = 0,03$), así como en el peso al nacer ($F = 4,16$; $p = 0,04$). No se encontraron diferencias significativas entre los grupos en otros resultados maternos y neonatales.

Conclusión: El ejercicio supervisado durante el embarazo, que incluyó el EMSP, redujo de manera efectiva la incidencia de incontinencia urinaria al final del embarazo y a los tres meses posparto.



Palabras clave: embarazo, ejercicio, incontinencia urinaria, entrenamiento muscular del suelo pélvico.

## Abbreviations

hCG: Chorionic gonadotropin hormone

HDL: High-density lipoproteins

LDL: Low-density lipoproteins

BMI: Body Mass Index

UI: urinary incontinence

SUI: Stress urinary incontinence

UUI: Urge urinary incontinence

MUI: Mixed urinary incontinence

PFM: Pelvic floor muscles

PFMT: Pelvic floor muscle training

RCT: Randomized Clinical Trial

CEIC: Ethical Commission of Clinical Research

UPM: Universidad Politécnica de Madrid

EG: Exercise Group

CG: Control Group

EDI: Study equity, diversity, and inclusion

HR: Heart rate

ICIQ-UI-SF: International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form

## Glossary

**Pelvic floor muscle:** located between the tailbone (coccyx) and the pubic bone within the pelvis. They support the bowel and bladder (as well as the uterus and vagina in females). Muscular bands (sphincters) encircle the urethra, vagina and anus as they pass through the pelvic floor.

**Urinary incontinence:** also known as involuntary urination, is any uncontrolled leakage of urine.

**Chorionic gonadotropin hormone:** is a hormone produced primarily by syncytiotrophoblastic cells of the placenta during pregnancy

**Placenta:** a fetal organ made up of its parenchyma, chorion, amnion, and umbilical cord

**Cardiovascular:** any disease involving the heart or blood vessels.

**Metabolism:** the chemical processes that occur within a living organism in order to maintain life.

**Gestational weight gain:** defined as the amount of weight gain a woman experiences between conception and birth of an infant.

**Gestational age:** a measure of the age of a pregnancy taken from the beginning of the woman's last menstrual period.

**Gestational hypertension:** the development of new hypertension in a pregnant woman after 20 weeks' gestation without the presence of protein in the urine or other signs of pre-eclampsia.

**Episiotomy:** also known as perineotomy, is a surgical incision of the perineum and the

posterior vaginal wall generally done by an obstetrician.

**Perineal tear:** A perineal tear is a laceration of the skin and other soft tissue structures which, in women, separate the vagina from the anus.

**Paresthesia**: the sensation of tingling, numbness, or prickling in the skin, often caused by nerve pressure or damage.

**Thrombocytopenic:** a condition characterized by abnormally low levels of platelets in the blood.

**Thyroid gland:** a small, butterfly-shaped gland located at the front of your neck under the skin.

**Progesterone:** an endogenous steroid and progestogen sex hormone involved in the menstrual cycle, pregnancy, and embryogenesis of humans and other species.

**Insulin:** a hormone produced in the pancreas by the islets of Langerhans, which regulates the amount of glucose in the blood.

**Hyperpigmentation:** usually harmless condition in which patches of skin are darker than the surrounding skin.

# 1. Introduction

The adequate development of a pregnancy and childbirth process can be crucial for the future health of both the maternal and the child. There is no period (i.e., gestation) in a human's life with such quantity and quality of changes of all kinds. This is because the gestational parent's physiology and biomechanics must adapt to the needs arising from fetal growth and development, leading to a physical, mental, and emotional adjustments in the pregnant woman. The occurrence of imbalances and complications in any of these areas can pose significant risk to the maternal, fetal, and newborn well-being [1,2]. Therefore, it is important to have a comprehensive understanding of the adaptations that occur in the body during pregnancy and to create a healthy pregnancy environment.

## 1.1. Embryonic and fetal development-major changes in maternal body

From the moment of fertilization, the woman experiences a complete transformation, in particular: several physiological functions of her body, with the basic objective of adequate embryonic/fetal growth and development (Figure 1). The uterus will host what the fetus, thus, the pregnant individual's body must adapt physiologically and biomechanically to its new requirements to allow for the adequate development of the fetus.

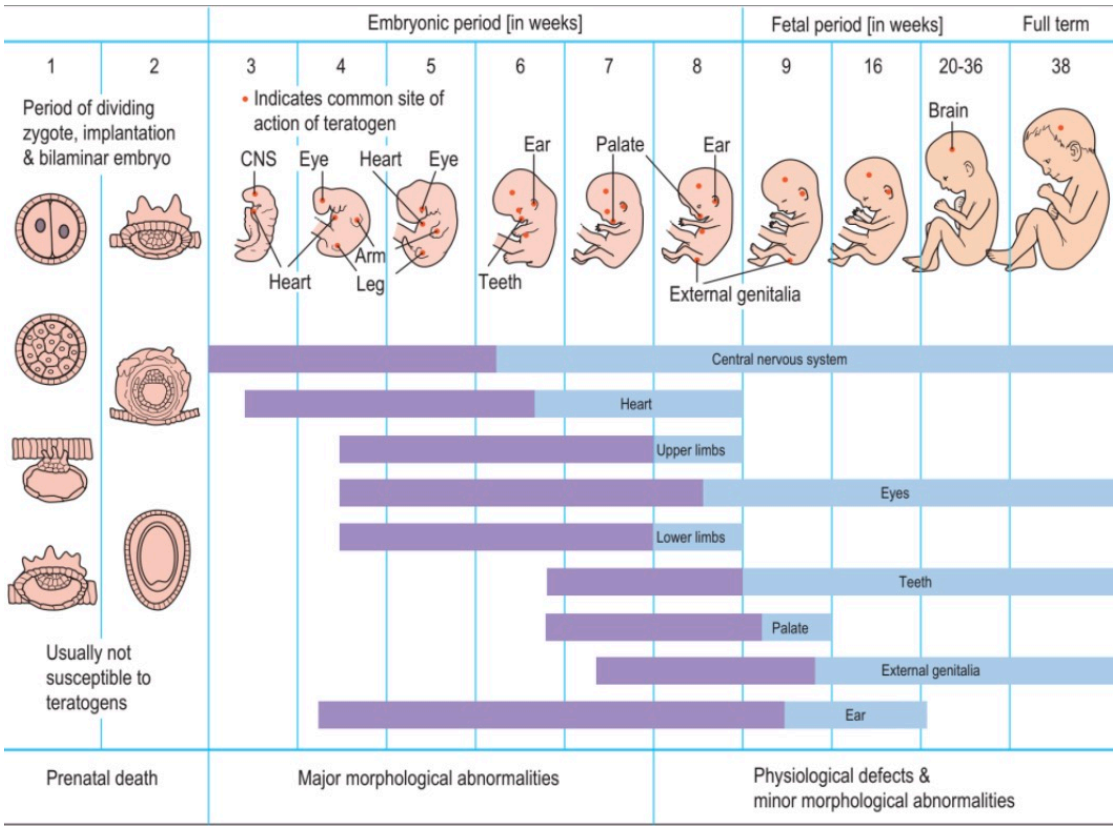


Figure 1. Critical periods of development (purple shaded areas denote highly sensitive periods) [3].

Therefore, fertilization marks the beginning of the pregnancy process and also serves as confirmation of the female menstrual cycle's proper functioning. Fertilization is the process by which sperm merges with a mature egg (or secondary oocyte), this union of genetic material takes place in the fallopian tube [4]. Later, the same fallopian tube facilitates the transport of the fertilized egg or zygote towards the uterus. During relocation, the zygote undergoes division, replicating the genetic material, and eventually settling in the endometrial wall where development will occur throughout the rest of the pregnancy, now referred to as the embryo. The successful implantation into the endometrial wall is crucial for a pregnancy's viability. Failure for the embryo

to adhere to the wall results in the shedding of the embryo via menstruation, preventing the development of pregnancy [5].

Once implantation is complete, the secretion of the chorionic gonadotropin hormone (hCG) occurs, which will be crucial during pregnancy. Simultaneously, a series of hormones are secreted to aid in the development and nourishment of the fetus. Additionally, a new organ（i.e., placenta）is developing to support and nourish the fetus until birth [6,7].

Certainly, beyond the observable alterations in the pregnant organism, it undergoes further adjustments to meet its evolving needs. Thus, these changes can be categorized into two main sections: Genital and Extra-genital. Within these categories, we will delve into specific changes, with a particular focus on those relevant to the subject of the Doctoral Thesis: urinary incontinence during pregnancy and 3 months postpartum urinary incontinence experienced by women.

## 1.2. Changes of body systems

During pregnancy (in the development of a healthy pregnancy), we can see changes to the majority of structures of the body. The main extragenital adaptations can be grouped within the following subgroups:

### 1.2.1. Changes of cardiovascular and hematological level

An increase in the volume of blood plasma is observed directly related to the gestational age of the fetus, with the volume peaking during late gestation. However, the increase in blood volume will cause a decrease in the concentration of hemoglobin and hematocrit leading to hemodilution. In some cases, iron supplementation is

necessary to address hemodilution, though in most cases hemodilution does not lead to significant health risks (Table 1)[8,9].

During pregnancy the demand for iron increases considerably, due to the increased: production of red blood cells, and demand of blood flow to the uterus and placenta. Therefore, iron needs could multiply by two to three-fold compare to non-pregnant individuals, increasing the risk of anemia (i.e., iron deficiency) [8,10].

Additionally, the progression of gestation is associated with a gradual decrease in platelet counts; however, this decrease is not considered a thrombocytopenic risk [8]. Alterations in the blood coagulation system leads to an increase in coagulant factors, potentially serving as a preventive mechanism during childbirth. However, this increase also heightens the risk of venous thrombosis [8,10].

As the pregnancy progresses, venous compression can be seen, and is more pronounced on the left side of the body, especially in the lower limbs. Given the fetus is growing inside the uterus, it can press on the vein [8], causing a decrease in venous flow, being especially important in the second and third trimester to avoid situations that compress these veins, and adopt positions that favor venous return (Figure 2 and Figure 3), this is especially important in situations such as physical exercise, trying to activity carried out on the floor do not involve an excessive amount of time in the supine position, and lateral decubitus positions can be adopted to avoid this compression.

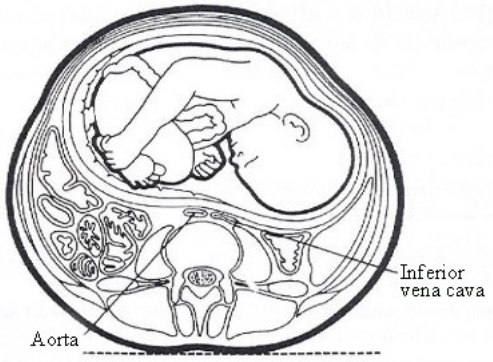


Figure 2 Uterus compressing [11]

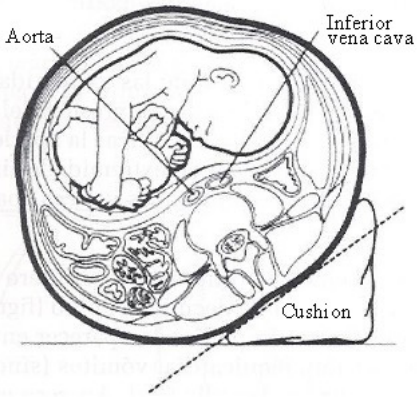


Figure 3 Relief of compression [11]

Given the increased blood flow, it is reasonable to expect other parameters to be affected. Specifically, we note a significant rise in cardiac output compared to non-pregnant individuals, serving as a compensatory mechanism to meet the heightened demands of uteroplacental perfusion and other factors. This holds critical implications for physical activity during pregnancy, as women will experience a notable increase in heart rate as gestation progresses compared to pre-pregnancy levels [12,13]. The increase in cardiac output, which can elevate the risk of experiencing pulmonary edema in those women who have cardiovascular system pathologies [8].

Similarly, blood pressure will also change, being lower in the first and second trimesters and retuning to pre-pregnancy levels in the last trimester [8,10]. The heart, the main organ for the continuous irrigation of the maternal-fetal structures, will also migrate as the fetus develops in the uterus [11]. Consequently, ventricular mass will increase and transient systolic murmurs caused by increased blood flow and heart rate have even been observed in this population [8].

Given the adaptations suffered by the cardiovascular and hematological system, it will be essential to consider the intensity of physical activity, implementing a design that take these adaptations into account).

Table 1 Main cardiovascular changes during pregnancy

| | Change | Magnitude | 1stT | 2adT | 3rdT |
|---|---|---|---|---|---|
| **Hemodynamic changes** | | | | | |
| Vascular resistance | ↓ | 30% | ↓ | ↓ | ↑ |
| Blood volume | ↑ | 40 - 45% | ↑ | ↑ | - |
| Cardiac output | ↑ | 30 - 50% | ↑ | ↑ | NC |
| Heart rate | ↑ | 15 - 30% | ↑ | ↑ | ↑ |
| Stroke volume | ↑ | 20 – 30% | ↑ | ↑ | NC |
| Systolic blood pressure | - | - | - | - | - |
| Diastolic blood pressure | ↓ | 10 mmHg | ↓ | ↓/= | ↑ |
| **Structure changes** | | | | | |
| Aorta artery elasticity | ↑ | 30% | ↑ | - | - |
| Heart size | ↑ | 30% | ↑ | ↑ | ↑ |
| Left atrial | ↑ | 16 - 40% | ↑ | ↑ | ↑ |
| **Left evntricular** | | | | | |
| Left ventricular diastolic dimension | ↑ | 20% | ↑ | - | - |
| Left ventricular systolic dimension | ↑ | 10% | ↑ | ↑ | ↑ |
| Left ventricular wall thickness | ↑ | 15 - 25% | ↑ | ↑ | ↑ |
| Left ventricular stress | ↑ | 17% | ↑ | - | ↓ |
| Left ventricular mass | ↑ | 50% | ↑ | ↑ | ↑ |
| **Systolic function** | NC | - | - | - | - |
| **Diastolic function** | ↓ | - | ↑ | ↑ | ↓ |

NC: no consensus; 1stT: first trimester; 2adT: second trimester; 3rdT: third trimester

## Implications of exercise during pregnancy on the maternal heart

The changes that occur in the maternal heart during pregnancy are reversible in healthy women, but it is estimated that approximately 1% of pregnancies are complicated by heart disease in Europe [14]. There are some risk factors associated with an unhealthy lifestyle during pregnancy that may compromise maternal and fetal health.

A growing body of evidence supports that adopting or continuing a sedentary lifestyle during pregnancy increases the risk for developing gestational hypertension or diabetes, and gaining excessive weight and these are considered risk factors for heart failure and

cardiovascular dysfunctions [15]. During labor, physically inactive women show limitations in the intensity and duration of pushes which leads to greater stress on the maternal heart and this may increase the risk for developing cardiovascular disease later in life [16].

Maintaining or starting to exercise during pregnancy may have great physiological benefits for the mother and the newborn. However, it is important to keep in mind some exercise considerations to accommodate for the naturally occurring maternal cardiovascular response to pregnancy and in order to avoid any additional stress on the maternal heart.

### 1.2.2. Changes in the respiratory system

Due to the growth of the gravid uterus, there is an increase in oxygen requirements during pregnancy. Logically, this increase will also cause an increase in oxygen consumption, which is particularly important when considering physical activity program [8].

Respiratory minute volume increases considerably (up to 50%) during pregnancy. Consequently, the increase in oxygen consumption and decrease in the partial pressure of carbon dioxide in the blood may lead to transient respiratory alkalosis [8,10].

The diaphragm will rise due to the development of the fetus inside the uterus, which may cause changes in breathing [11]. This can contribute to a feeling (more accentuated at the end of pregnancy) of hypoxia, dyspnea, which may improve with habitual moderate physical activity [8]. This elevation of the diaphragm is associated with a gradual decline throughout gestation in the residual functional capacity of the

lungs. Despite these changes, the maximum amount of air of the pregnant woman can inhale and exhale is not compromised due to the widening of the rib cage since it increases between 10-15% compared to non-pregnant women [8,11].

During pregnancy, vasodilation also occurs in the mucous membranes of the respiratory tract, especially in the nasal, pharyngeal and laryngeal areas, with nasal epistaxis being common at this stage [10,12].

### 1.2.3. Changes of the endocrine and metabolic level

Certainly, one of the most notable changes is gestational weight gain and the effect on the mental health of the gestational parent, which can pose a major public health challenge with significant consequences for the pregnant woman, fetus, and newborn. These changes hold paramount importance, primarily because their imbalance or imbalances are correlated with mental and emotional alterations [17,18].

#### 1.2.3.1. Changes of the endocrine system

Many hormonal changes occur during pregnancy. Reproductive hormone secretion increases during pregnancy, ensuring that the requirements of the fetus are met during gestation. In this sense, a series of “areas” of the organization will take on special relevance during this period [19].

The thyroid gland, located at the front of the neck below the Adam’s apple, is responsible for producing hormones that regulate the body’s metabolic rate, which when imbalanced, can lead to conditions such as hypothyroidism or hyperthyroidism. Furthermore, the contribution of one of the body’s major protein transporters (thyroxine binding globulin) increases compared to non-pregnant individuals, although it is a result

that does not significantly affect the pregnant individuals [11,20]. Due to fetus-placental flow, pregnancy is considered a stage with a relative iodine deficiency, iodine is essential component of triiodothyronine and thyroxine. This is why iodine supplementation is commonly recommended during pregnancy, as it can prevent thyroid enlargement in women with iodine deficiencies [8,20].

Another important endocrine gland is the adrenal gland, responsible for the production of steroid hormones such as adrenaline or norepinephrine. This gland increases the secretion cortisol as measured in plasma. Cortisol, a hormone, acts as a regulator in the vast majority of the body's tissues) [11,21].

Furthermore, the pituitary gland becomes especially important during pregnancy. This gland will favor the secretion of prolactin, a hormone that will directly affect the maternal breasts and the production of breast milk. Prolactin also increases the secretion of oxytocin, although this increase will reach its peak at the end of pregnancy [8,22,23]. Lastly, the corpus luteum and the placenta, both organs that develop during pregnancy, play a crucial role in hormone production. The corpus luteum secretes progesterone and hCG, among other hormones, with progesterone being responsible for halting menstruation. The corpus luteum is vital during the early stages of pregnancy, laying the groundwork for the development of the placenta [11].

#### 1.2.3.2. Metabolic changes

Similar to endocrine system, the metabolic system also undergoes alterations during pregnancy. At the beginning of pregnancy, the pregnant individual will undergo an anabolism, meaning that more cells are produced and stored than destroyed, leading

to an increase in fat reserves and greater insulin sensitivity. Towards the end of pregnancy, a catabolism will occur, increasing insulin resistance [8,11,12]. This insulin resistance, caused by the increased secretion of a variety of hormones (e.g., placental lactogen, progesterone, cortisol, prolactin, etc.) renders pregnancy a state with clearly diabetogenic characteristics, meaning it is conducive to the development of gestational diabetes. Due to hormonal changes during pregnancy, which increase insulin resistance and enhance the risk of gestational diabetes, women with pre-existing insulin issues should be particularly cautious before becoming pregnant [24]. Since hyperglycemia is more common in pregnancy, compounded by the insulin resistance experienced by women during pregnancy, their bodies will predominantly utilize lipid metabolism for energy, reducing the use of proteins for this purpose and reserving glucose and amino acids for uteroplacental flow [8].

With respect to lipids, there is an increase in both total cholesterol and triglyceride levels throughout pregnancy. It is noticeable that both high-density lipoproteins (HDL) and low-density lipoproteins (LDL) levels are significantly higher compared to non-pregnant individuals [8,10].

During pregnancy, protein demands are higher, although the catabolism of these macronutrients is lower than in non-gestational periods [8,25].

In addition, minerals such as calcium, phosphorus, iron (previously mentioned) and potassium are required to a greater extent during pregnancy. These minerals are essential for fetal development, and due to the increased demand for them, diets rich in these minerals or even additional supplementation may be recommended to meet

nutritional demand during gestation [11,26].

One of the main concerns during pregnancy, directly related to the factors mentioned, which is gestational weight gain. Gestational weight gain is also directly associated with the habits of pregnant women, which can be influenced by many social factors (e.g., socioeconomic status). Due to the majority of pregnant women gaining more weight than recommended there is an increased risk of premature births, lower or higher birth weights than normal, or even an increased risk of cesarean sections [27]. Gestational weight gain is one of the most significant changes alterations that occurs during gestation and can poses significant health risks in excess. A variety of factors altered by this process contribute to the total maternal gestational weight gain. Among the parameters mentioned (Table 2), interstitial fluid and increased deposition of adipose tissue are the factors that can exhibit the most significant variations during gestation.

Table 2 Maternal weight gain distribution by component over gestational period [11]

| | **Maternal weight gain (grams)** | | | |
|---|---|---|---|---|
| | **Week 10** | **Week 20** | **Week 30** | **Week 40** |
| Fetus | 5 | 300 | 1500 | 3400 |
| Placenta | 20 | 170 | 430 | 650 |
| Amniotic fluid | 30 | 350 | 750 | 800 |
| Uterus | 140 | 320 | 600 | 970 |
| Breast | 45 | 180 | 360 | 405 |
| Blood | 100 | 600 | 1300 | 1250 |
| Interstitial fluid | 0 | 30 | 80 | 1680 |
| Fat deposits | 310 | 2050 | 3480 | 3345 |
| Total gain | 650 | 4000 | 8500 | 12500 |

Gestational weight gain determined by the increase in fat reserves exhibits

extraordinary variability. When the gain is 11 kg, the average fat deposition at the end of gestation is 1800 grams, but it can be much higher (3-4 or more kg in gestational weight gain of 13-15 kg), be null, or even negative. Meaning that during pregnancy, a woman relies on the energy from the stored fat she had previously accumulated.

While traditionally obstetric recommendations placed maternal weight gain between 9 and 14 kg. Currently, due to the growing global prevalence of excessive gestational weight gain, the recommendation is based on pre-pregnancy Body Mass Index (BMI). For gestational weight gain recommendations to be achieved, physical activity is being essential (Table 3) [28,29].

Table 3 Current recommendations for total and rate of maternal weight gain during pregnancy based on pre-pregnancy BMI [28]

| | **Total weight gain** | | **Rates of weight gain 2nd and 3rd trimester** | |
|---|---|---|---|---|
| Pre-pregnancy BMI | Range in kg | Range in lbs | Mean (range) in kg/week | Mean (range) in lbs/week |
| Underweight (<18.5 kg/m$^2$) | 12.5-18 | 28-40 | 0.51 (0.44-0.58) | 1 (1-1.3) |
| Normal weight (18.5-24.9 kg/m$^2$) | 11.5-16 | 25-35 | 0.42 (0.35-0.50) | 1(0.8-1) |
| Overweight (25.0-29.9 kg/m$^2$) | 7-11.5 | 15-25 | 0.28 (0.23-0.33) | 0.6 (0.5-0.7) |
| Obese (≥ 30.0 kg/m$^2$) | 5-9 | 11-20 | 0.22 (0.17-0.27) | 0.5 (0.4-0.6) |

Calculations assume a 0.5-2 kg (1.1-4.4 lbs) weight gain in the first trimester [30,31]

### 1.2.4. Changes of kidney level

Due to increased vascularization during pregnancy, the urinary system experiences renal vasodilation, leading to an increase in the plasma flow through the kidneys and the glomerular filtration rate (i.e., the amount of blood per minute that the kidneys are capable of filtering) [8]. The kidneys significantly increase in size, and in line with the aforementioned factors, the excess urine experienced by the vast majority of pregnant women in these organs (or hydronephrosis) could cause this enlargement [12,32].

It is common for urine to show concentrations of proteins and glucose. However, changes in these concentrations can indicate serious conditions such as preeclampsia, so it is crucial monitor protein and glucose concentrations throughout gestation [33].

### 1.2.5. Dermatological changes

The skin also undergoes changes during pregnancy. In most pregnant women, hyperpigmentation of the skin can occur. Likewise, the presence of stretch marks on the skin are also common. These changes may also include changes in vascularization (not very common) and even changes in the body's glands [34].

### 1.2.6. Locomotor changes

The most evident changes are likely to occur at the locomotor level. As the uterus increases in size, there is a shift in the woman's center of gravity compared to the non-pregnant state (Figure 4). Postural adaptations occur to prevent falls, resulting in cervical lordosis, paresthesia in the upper in limbs, and hyperlordosis [8,11]. Proper postural education and regular physical exercise practice will be especially important to mitigate their effects.

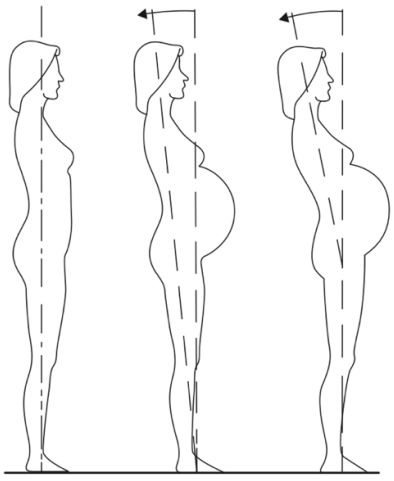

Figure 4 Deviation of the center of gravity [11]

Other common conditions may include low back pain/sciatica, carpal tunnel syndrome, and even diffuse pain (the pain is not localized to one specific area but is spread across multiple parts of the body) due to increased joint laxity during pregnancy caused by hormones such as relaxin. Additionally, the muscles of the rectus abdominis may separate, resulting in a diastasis of these muscles [35–37].

Moreover, one of the most common complications women experiences is paresthesia (Paresthesia is the sensation of tingling, numbness, or prickling in the skin, often caused by nerve pressure or damage.) in the lower limbs, which becomes more pronounced from the second half of pregnancy onwards. This is caused by several factors, including increased load on these limbs due to weight gain and changes in center of gravity and posture. And it is undoubtedly caused by increased vascularization leading to edema [8,11]. Therefore, physical exercise practice could be very important to eliminate or relieve edema.

### 1.2.7. Changes on a psychic-emotional level

The psychological realm is not unaffected by the changes that occur due to gestation. This period will be psychologically challenging for the pregnant woman, who will experience emotional significant changes throughout their pregnancy [38].

The pregnant woman will experience feelings of apprehension and fear regarding the changes that pregnancy entails, as well as achieving the best possible outcome in terms of their newborn's health outcomes. In addition, notable changes in mood and spirits will vary significantly depending on the trimester in which the woman finds herself [38].

During the early stages of pregnancy, women often experience specific nutritional cravings along with nausea and vomiting, which can lead to significant mood swings [39]. In the second trimester, as fetal development progresses, making it the most emotionally stable trimester. However, in the third trimester, emotionally lability increases notably due to the fetus' growth, the woman's weight gain, and the challenges the gestational parent faces in realizing the decrease in motor skills compared to periods when the mother was not pregnant. These emotional challenges are compounded by the constant fear of harm to the pregnant individual or fetus during pregnancy or childbirth [40]. Therefore, pregnancy presents a significant risk for the onset of psychological and mental illnesses, with maternal mental health being particularly vulnerable in the third trimester [40,41].

Furthermore, the previously described changes in the gestational parent can directly affect mental and emotional health. In this regard, women may first notice the evident signs of increasing hormonal secretion as pregnancy progresses, destabilizing their emotional well-being. Similarly, alterations in the musculoskeletal system, impairment of certain abilities (such as coordination or balance), an increase in daily pain levels, and overall noticeable changes in mobility compared to the pre-pregnancy state can further undermine this emotional lability [8].

Furthermore, it is certainly concerning to observe how an altered mental health state can directly affect other already altered parameters. For example, the onset of depressive symptoms during pregnancy has been found to be related to sleep loss, alterations in the hypothalamic-pituitary-adrenal function (responsible for controlling

stress and various bodily function such as digestion), and an altered immune/inflammatory response [42,43].

## 1.3. Genital and breast changes

Noticeable changes will occur in the genital areas and breasts during pregnancy, which are very important as they represent adaptations to accommodate the fetus and ensure proper development.

### 1.3.1. Changes of uterus

During non-gestational periods, the uterus is a relatively small organ with no significant functions; however, during pregnancy, it becomes highly relevant as the hosting organ for the fetus, driving its development by facilitating utero-placental flow between the mother and the fetus, and also promoting labor. The uterus will increase approximately 20 times in size and about 500 times in capacity [8,11].

### 1.3.2. Changes of vagina

During pregnancy, there is an increase in vascularization and connective tissues with the vagina. This preparation is necessary for childbirth, as the vagina serves as the conduit through which fetus will be delivered. The increased vascularization and connective tissue allow for greater distension, facilitating the expulsion of the baby [8,10,11].

### 1.3.3. Changes of breasts

The breasts increase significantly in size. Maternal milk production will occur, facilitated by prolactin, a hormone mentioned earlier. Therefore, due to constant steroid action, their size is larger than compared to pre-pregnancy [8].

## 1.4. Childbirth, a determining factor for physical and emotional health

During childbirth, which makes the end of a normal pregnancy, a woman must deliver both the fetus and the placenta through the vaginal canal. Throughout pregnancy, the fetus develops inside the body, while maternal body undergoes changes to prepare for delivery. However, this stage often proves particularly traumatic for many women, serving as a significant psychological barrier during pregnancy due to the distress. Often, women experience apprehension regarding childbirth, even considering the possibility of dying during it [40,44]. This apprehension can result in pregnancy denial , emotional instability, leading to reduced attachment or difficulty in bonding with the fetus, and potentially triggering depressive symptoms postpartum [40,45].

Therefore, it is crucial to identify tools that aid in stabilizing women's mental health to facilitate an optimal maternal-fetal relationship. This process (i.e., the bonding of the gestational parent and the fetus), is significant and the pinnacle of gestation, comprises distinct periods or phases, each with its own mechanisms and implications.

### 1.4.1. Dilation period

It represents the longest span of time compared to the following periods. This stage spans from the onset of labor until the woman has achieved complete dilation of the uterine cervix (approximately 10 centimeters) [46]. Furthermore, this period can be subdivided, according to previous studies, into three phases: i) a latent dilation phase (dilation is slow and variable duration), ii) a more active phase when dilation becomes significant and accelerates, and iii) descending phase which the fetus begins to descend

from the uterus towards the vaginal canal [46–48].

### 1.4.2. Expulsive period

The expulsive period extends from complete dilation until the expulsion of the newborn. At this point, the woman typically begins the process of pushing to gradually expel the fetus, and this stage usually has a significantly shorter duration than the dilation period [46].

### 1.4.3. Delivery

This stage covers the moment immediately after the baby is born until the expulsion of the placenta and fetal membranes. It is notably shorter than the preceding period and much less strenuous than the first stage. While earlier stages also pose risks, preventing significant bleeding is a primary concern during delivery. Timely expulsion of the placenta is crucial, as prolonged retention in the uterus is indicative of potential complications [46].

## 1.5. The process of pregnancy and childbirth carries an epigenetic load and influence that is determinant for the future of both mother and child

Pregnancy is associated with numerous physiological and biomechanical alterations or modifications, along with the inherent challenges of childbirth, there are significant, mental, and emotional challenge for the pregnant woman.

The future health of both mother and child can be influenced by the social determinants of health. According to a significant body of scientific literature and based on an epigenetic effect, the intrauterine environment can play a determining role in the

development of complications and pathologies (such as cardiovascular, metabolic, psychological, and emotional) in the future human being. Numerous recent scientific findings confirm the unfortunate association between an adverse intrauterine environment, due to both physical and social factors) and postnatal pathologies observable in infants [49,50]. For example there is a growing rate of childhood disorders (metabolic and emotional) associated with gestational complications [51–53].

### 1.5.1. Maternal behavior and habits

Overnutrition, (i.e., excessive intake of nutrients, which can be harmful to the health of the fetus. For example, a diet excessive in folic acid could lead to neural tube defects, congenital heart defects, and/or cancer [54–56]. Similarly, previous research has shown that a diet excessive in fatty acids could also entail risks such as increased gestational weight gain or heightened insulin sensitivity [57,58].

Poor nutrition could also cause short and long-term health problems for the fetus and newborn. For instance, various studies examining outcomes of pregnant populations during periods of severe famine have shown that exposure to poor nutrition could affect the overall health of the fetus and even increase the risk of cerebrovascular deaths, schizophrenia, and spina bifida[59–61].

### 1.5.2. Risk factors during pregnancy

One factor that can significantly affect the health of both the gestational parent and the fetus is obesity, which can lead to gestational hypertension. The risk of gestational hypertension also increases with age [62]. Obesity also can be linked to high birth

weights (i.e., macrosomia), low weight for gestational age, developmental problems, and increases the risk of newborn hypoxic ischemic encephalopathy [63,64].

External factors that negatively impact the general population's health also pose risks to pregnant women and fetuses. Tobacco consumption during pregnancy is a significant concern due to its association with increased risks of premature birth, intrauterine growth restriction, and disruptions in placental genetic patterns [65–67]. Moreover, regular tobacco use can exacerbate health issues for the mother, including heightened susceptibility to lung cancer, conditions like chronic obstructive pulmonary disease and decreased lung function [68,69]. Thus, the cessation tobacco consumption during pregnancy is crucial for maternal and fetal well-being.

Furthermore, alcohol consumption poses a significant risk to maternal-fetal health. The fetus can be susceptible to fetal alcohol spectrum disorders, which can lead to issues ranging from learning difficulties to a higher likelihood of developing alcohol, tobacco, and drug addiction [70].

## 1.6. Urinary incontinence in pregnant women

The International Continence Society defines urinary incontinence (UI) as any complaint of involuntary leakage of urine [71,72]. It is a common issue and individuals experiencing UI describe it as embarrassing, evoking substantial individual morbidity, deeply influences the quality of life and socio-economic costs [71,73].

### 1.6.1. Type of urinary incontinence among women

1) Stress urinary incontinence (SUI) refers to the involuntary leakage of urine triggered by physical movements or activities such as sneezing, coughing,

running, heavy lifting, or childbirth (but not before getting to the toilet), which lead to an increase in abdominal pressure. Typically, SUI occurs due to lack of anatomical support at the urethrovesical junction, which may include factors like urethral sphincter deficiency or urethral hypermobility (Figure 5). SUI is common in young women, especially associated with pregnancy and the postpartum period [74–76].

Urethral hypermobility is a condition where the urethra descends below the pelvic floor muscles (PFM). This descent occurs when the PFM lose their support, consequently, the bladder neck and urethra may relocate to a lower position, exerting increased pressure on the bladder neck. If the pressure on the bladder exceeds the pressure in the urethra, urine leakage occurs [74].

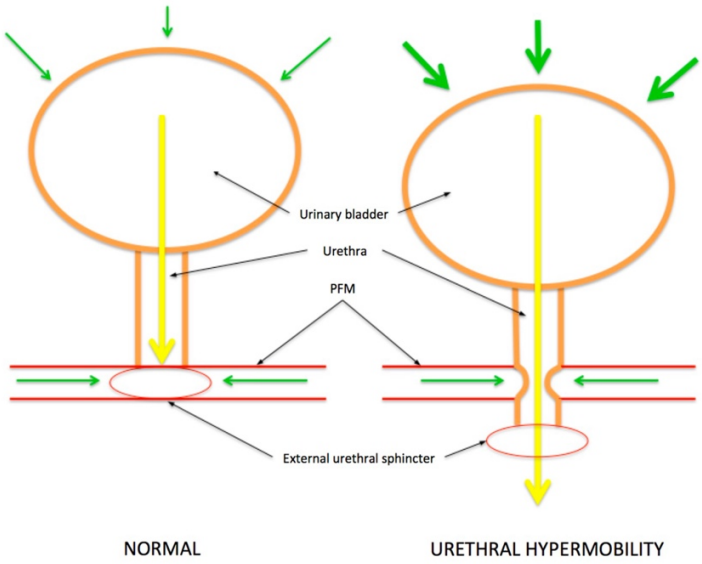


Figure 5 Urethral hypermobility [74]

2) Urge urinary incontinence (UUI) involves the involuntary leakage of urine

typically triggered by a sudden and intense urge to urinate that cannot be delayed (because of irresistible need to void, before getting to the toilet). This condition is commonly attributed to an “overactive” bladder [74,76]. UUI occurs more frequently as women age [77].

3) Mixed urinary incontinence (MUI) is a combination of stress and urge symptoms, and MUI is the most common type in older women [77].

### 1.6.2. Urinary incontinence impact on health-related quality of life

Urinary incontinence may significantly impair health-related quality of life across physical, psychological, and social well-being compared with other diseases [78]. Women experiencing urinary incontinence may rush to the restroom elevating the likelihood of falls and fractures [79]. Additionally, incontinence may impede mobility, thereby impacting activities such as exercise and travel, as many women refrain from venturing out due to the fear of urinary leakage [78]. Moreover, urinary incontinence has been associated with sleep disturbances and urinary tract infections [80]. Evidence shows that urinary incontinence predominantly impacts psychological and social functioning. The distress stemming from feelings of shame and embarrassment are associated with UI may lead women to opt for a solitary existence and potentially develop depression [81]. Depression can lead to a deeply influence to the quality of life of pregnant women.

### 1.6.3. The prevalence of urinary incontinence during pregnancy and postpartum

It appears that UI becomes more common during pregnancy, notably in the second

trimester, and then gradually declines within the initial year after childbirth. There is variability in prevalence estimates across all types of UI during pregnancy, potentially reaching rates as high as 58%. SUI affects around 31% of women who have not given birth before (i.e., nulliparous) and 42% of women who have given birth before (i.e., parous). The prevalence of persistent UI in the first three months following delivery is approximately 30% [82,83].

The notable increase in prevalence of SUI during pregnancy may stem from various factors, including gestational weight gain, which results in increased intra-abdominal pressure on the bladder and pelvic floor muscles (PFM) [84]. In addition, previous research indicates that pregnant women who experience SUI tend to have significantly less PFM strength and thickness [85], along with a larger hiatal area both at rest and during PFM contraction [86]. Furthermore, factors such as previous childbirth and a high body mass index have been identified as risk factors for developing SUI [87–89].

Pelvic floor muscle training (PFMT) refers to the performance of repeated voluntary contractions of the PFM. In many countries, it is common for women to be provided with information regarding and encouraged to engage in certain PFMT during both pregnancy and after childbirth. Throughout pregnancy, guidance on PFM exercise may come from a healthcare provider or be sourced from alternative outlets such as pamphlets and websites. However, this advice may not lead to effective training if the exercise parameters and behavior are insufficient. For women who are continent during pregnancy, PFMT is undertaken as a preventative measure. Those experiencing

symptoms of incontinence during pregnancy or postpartum may be directed to a healthcare professional for dedicated treatment and supervised exercise [73,82,90].

## 1.7. Physical exercise during pregnancy

Physical exercise is defined as planned, structured physical activity aimed at enhancing various aspects of physical fitness, plays a crucial role in healthy lifestyle, contributing to the prevention and treatment of several diseases [91]. Pregnancy is a time many individuals begin exercising, as it often comes with a heightened motivation to adopt or continue a healthy lifestyle. Additionally, the increased frequency of medical appointments during pregnancy makes it easier to monitor physical activity [91,92].

In the past, pregnant women were often told to avoid exercise due to fears of harming the fetus and encouraged to eat more. Unfortunately, because of these misguided recommendations, some of the weight gain during pregnancy persisted into the postpartum period. Higher maternal weight is linked to greater birth weight in offspring and plays a role in the intergenerational transmission of obesity [93,94]. Consequently, pregnancy has evolved as a major contributor to global obesity epidemic, leading to various related maternal and fetal health issues, some of which can have lifelong consequences.

Clinicians have traditionally worried that exercise might increase the risk of preterm delivery or miscarriage. However, a meta-analysis involving 57 studies revealed that for pregnant women engaging in moderate-intensity aerobic exercise was not associated with increased risk for preterm birth [95]. Another recent meta-analysis that included 3728 pregnant women showed that women who engaged in low-to

moderate-intensity exercise compared to those who did not exercise during pregnancy showed no increase in miscarriage risk [96]. A cohort study of Danish national birth with 671 pregnant women indicated a nearly 40% reduced risk of preterm birth among women who engaged in some form of exercise during pregnancy compared to those who did not exercise (hazard ratio = 0.82, 95% confidence interval: 0,76, 0.88) [97]. A review of 44 studies revealed that there is limited empirical evidence supporting the notion that exercise during pregnancy causes harm, and it provides little justification for the benefits of restricting physical activity [98]. 23 studies involving 7125 women indicates that exercise during pregnancy does not significantly affect the rate of miscarriage, and 13 studies with 6837 pregnant women suggest that exercise does not significantly alter the risk of perinatal mortality [99]. These findings strongly advocate for the inclusion of appropriate exercise regimes during pregnancy, highlighting that such activities are not only safe but potentially beneficial for maternal and fetal health. Regular moderate-intensity exercise can significantly reduce the risk of preterm birth and does not increase the risk of miscarriage or perinatal mortality, according to a comprehensive meta-analysis and cohort studies. These positive outcomes underline the importance of integrating physical activity into prenatal care plans.

Regular physical activity is linked to substantial health benefits such as enhanced physical fitness, improved mental health, reduced chronic disease, and lower mortality rates. Global health guidelines advise pregnant women who have no medical contraindications to participate in moderate physical activity at least 150 minutes per week. However, less than 15% of women meet the minimum guideline of 150 minutes

of moderate exercise weekly during pregnancy [100–103].

## 2. Hypothesis and objectives

### 2.1. Hypothesis

Based on the scientific evidence observed about the potential benefits of gestational physical exercise, including PFMT, we hypothesize that a supervised physical exercise program during pregnancy could reduce the prevalence of urinary incontinence in the late pregnancy and in the early phase of the postpartum period.

### 2.2. Objetives

1) To investigate the influence a randomly controlled supervised and regular exercise program throughout pregnancy on urinary incontinence in late pregnancy.
2) To examiner the impact a randomly controlled supervised and regular exercise program throughout pregnancy on urinary incontinence in the postpartum period.
3) To assess the effects a controlled supervised and regular exercise program throughout pregnancy on maternal delivery outcomes.
4) To evaluate the influence a controlled supervised and regular exercise program throughout pregnancy on newborn birth outcomes.

## 3. Material and methods

### 3.1. Study design

A Randomized Clinical Trial (registered at ClinicalTrials.gov, registration number: NCT04563065) was conducted by the INEF – Facultad de Ciencias de la Actividad

Física y del Deporte of Universidad Politécnica de Madrid in collaboration with Hospital Universitario Severo Ochoa, Hospital Universitario Puerta de Hierro, Hospital Universitario de Torrejón, Hospital Universitario Vall de Hebrón and and Zuatzu Clinic (San Sebastian), Spain. The research protocol was approved by the Ethical Commission of Research of the the Universidad Politécnica de Madrid (UPM 2020-032) and the hospital Ethical Commission of Clinical Research (CEIC) (A-704). The study procedures followed the Declaration of Helsinki ethics guidelines.

In a multicentric clinical trial involving healthy pregnant women, participants were divided into two groups: Exercise Group (EG) consisted of pregnant women who took part in a structured and supervised physical exercise program, and Control Group (CG) included women who received standard prenatal care with nutrition counseling and physical activity recommendations.

### 3.2. Study equity, diversity, and inclusion (EDI) statement

We evaluated the eligibility of all pregnant women receiving regular healthcare at our partnering center who had no contraindications to engaging in physical exercise. Our research team highlights multidisciplinary collaboration, consisting of ten professionals from areas such as gynecology, obstetrics, midwifery, and physical exercise expertise. Team members operate across various countries and healthcare systems, bringing a wide range of perspectives and experiences that enhance our approach.

Our team is composed of eight women and two men, bringing together a broad spectrum of expertise in obstetrics, gynecology, physical education, and research. We

made sure that no participant was excluded based on socio-demographic factors, focusing on healthy pregnant without regard to ethnicity, economic status, or education level. This dedication to equity, diversity, and inclusion ensures that our research is both inclusive and reflective of the diverse populations we aim to serve.

### 3.3. Study duration

In this program, participants were enrolled in cycles, with new participants joined in the intervention every three months, which approach was primarily adopted to ensure an effective physical exercise intervention with groups of 15-20 (face-to-face), 20-30 (online). It allowed for proper monitoring of the participants and ensured that the necessary facilities and materials were consistently available for the sessions. In October 2023, we stopped recruiting participants (Figure 6), the program was conducted from September 24, 2020, to January 31, 2024.

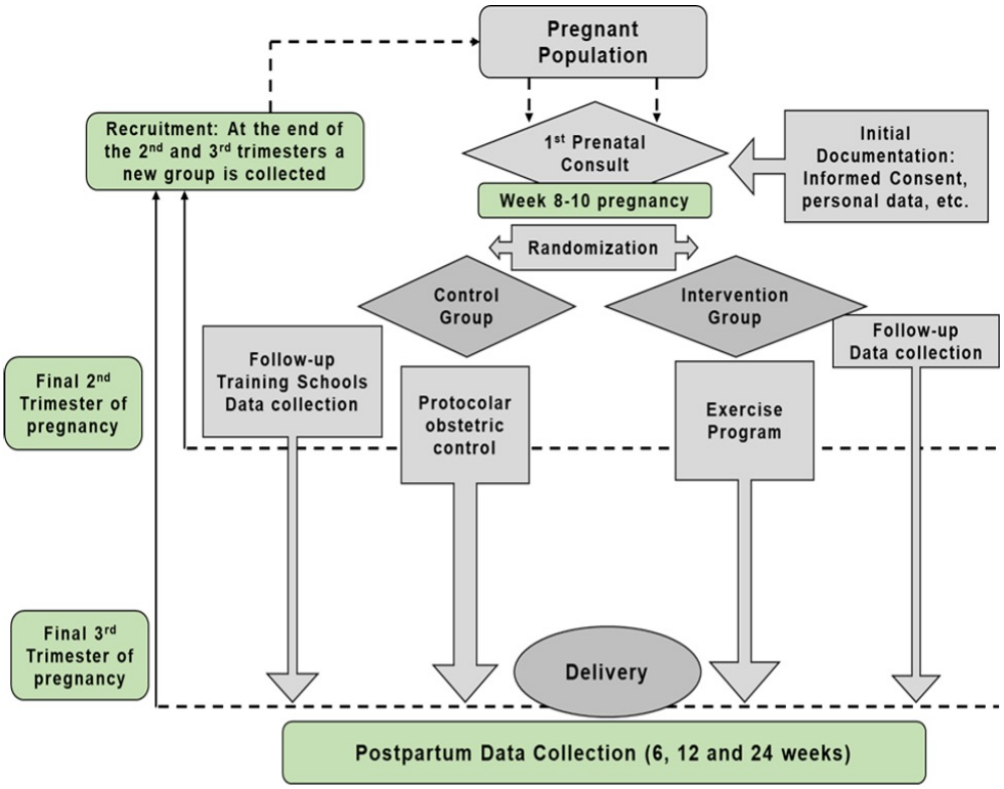


Figure 6 Research algorithm

## 3.4. Participants and randomization

### 3.4.1. Participants inclusion criteria and exclusion criteria

Pregnant women being able to communicate in Spanish were recruited and evaluated for eligibility during hospital obstetric visits (Figure 20). The inclusion criteria specified were women between the ages of 19 to 48, and no involvement in other clinical trials or exercise programs. The exclusion criteria were not intending to deliver at the same hospital, not having consistent medical supervision during pregnancy, or having absolute contraindications preventing safe exercise. Women with relative contraindications need permission from obstetric care provider prior to participate the program (Table 4) [102,104].

Table 4 Absolute and relative contraindications [105,106].

| Absolute contraindications | Relative contraindications |
|---|---|
| Ruptured membranes | Recurrent pregnancy loss |
| Premature labour | Gestational hypertension |
| Unexplained persistent vaginal bleeding | A history of spontaneous preterm birth |
| Placenta praevia after 28 weeks' gestation | Mild/moderate cardiovascular or respiratory disease |
| Pre-eclampsia | Symptomatic anemia |
| Incompetent cervix | Malnutrition |
| Intrauterine growth restriction | Eating disorder |
| High-order multiple pregnancy (e.g., triplets) | Twin pregnancy after the 28$^{th}$ week |
| Uncontrolled type I diabetes | Other significant medical conditions |
| Uncontrolled hypertension | |
| Uncontrolled thyroid disease | |
| Other serious cardiovascular | |
| Respiratory or systemic disorder | |

### 3.4.2. Participants

A total of 600 healthy pregnant women were informed during their initial perinatal

visit at the above five hospitals. Right after their first prenatal echography, those who were eligible and willing to participant the program signed the written informed consent (Appendix I), and they completed a baseline assessment of their personal data (Appendix II) at the medical center. Following this, they were randomly allocated to either the intervention (exercise) group (EG) or standard care (control) group (CG); EG: n = 220 and CG: n = 220, respectively.

### 3.4.3. Randomization

The randomization process used REDCap software [107]. Participants were randomly assigned to either the EG or CG in a 1:1 allocation ratio. A computer-generated randomization sequence was uploaded to the REDCap database. One health provider at each hospital managed access to REDCap software for the randomization process (sequence generation, allocation concealment and implementation), keeping all assignments confidential from hospital staff. Although blinding was not possible for participants and leaders of the exercise sessions due to the nature of the intervention, the outcome assessors were blinded to allocation. Participants were not involved in the development of the research.

## 3.5. Study groups

### 3.5.1. Control group

All women in the CG received standard obstetric care at their designated hospital centers, they were provided with informational materials on UI, physical activity, sleeping habits, smoking cessation and nutrition guidelines during pregnancy, similar to the EG. Their scheduled healthcare visits occurred at gestation weeks 8-12, 20-22,

26, 28, 35-36, and 41 (due to prolonged gestation periods), additional visits were also performed if it's necessary. To monitor their physical activity levels whether they have met the international clinical guidelines recommended minimum of 150 minutes of physical activity per week [101,102], they were queried about their exercise habits once per trimester using a "Decision Algorithm" through REDCap [108]. Conversely, participants in CG were provided several informative materials (files, infographics, or videos), designed to encourage the maintenance of healthy lifestyle habits throughout pregnancy. These materials were distributed regularly over the course of the study.

**Decision Algorithm**

Question#1: Since the beginning of pregnancy, have you exercised in your leisure time, in a supervised program or on your own?

a. Answer: No.

b. Answer: Yes.

Question #2: (if the previous response was "b"): Given 7 days a week, how many days per week did you exercise?

a. Answer: Less than 3 days.

b. Answer: 3 days or more.

Question #3: (if the previous response was "b"): Taking into account the total duration of physical exercise continuously, how long did you exercise every day?

a. Answer: Less than 20 minutes each day.

b. Answer: 20 minutes or more each day.

Interpretation of the "Decision Algorithm":

Pregnant women in the CG who reached level b of these three questions, were excluded from the study.

### 3.5.2. Exercise group

**Adapting prenatal exercise during COVID-19**

Women in the EG received the same standard care as those in the CG, including an identical number of healthcare visits, and they also provided general guidelines for nutrition and physical activity. In addition, participants in EG engaged in a supervised exercise program, this program designed in accordance with international clinical guideline [105,106,109], involved three weekly sessions with 55-60 minutes per session of activities specifically adapted for each trimester of pregnancy, following the Barakat Model [110].

To adapt to the impact of the COVID-19 pandemic on the implementation of exercise programs, the exercise program consisted of two phases. In the first phase, from September 24, 2020, to May 31, 2022, all session were conducted online, consisting of individual and group sessions. In the second phase, from June 1, 2022, to January 31, 2024, we replaced individual sessions with face-to-face group sessions, and other group sessions remained unchanged.

In the first phase, the exercise program was structured in two different formats: individual and group sessions. The individual format included one weekly class, featuring trainings that were easy to record and provided detailed indications along with visual information, all available on a private YouTube playlist. The group format

consisted of two weekly supervised sessions held online (Zoom Video Communications Inc., San José, CA, EEUU). These sessions were scheduled on separate days at different times to accommodate participants' schedules, and it was not possible to attend both sessions on the same day.

In the second phase, the program included both face-to-face sessions (compulsory) held once a week at the hospital, and online supervised sessions held twice a week via Zoom, Classes were scheduled on different days to coordinate with participants' calendars.

The exercise program began between 8-13 weeks of gestation, immediately after the first prenatal ultrasound to rule out obstetric contraindications for physical exercise, and it ended between 38-40 weeks of gestation. These sessions occurred three times a week (Monday, Wednesday, Thursday), lasting 55-60 minutes each session, and were conducted by three PhD students which have background with physical education training and a undergraduate student with ten years training experience.

Attendance was tracked using a computer application, resulting in a 73.5% average adherence rate. The intensity of the workload was moderate and controlled through maternal heart rate (HR) and perceived exertion. HR was monitored either via a personal monitor (pulsometer) or manually, using 55-65% of the maximum (HR), calculated with the Karvonen formula [111]. This calculation was updated every trimester to account for changes in resting MHR as pregnancy progressed. Maximum HR was determined by the formula 220 – age [112], and resting HR was measured by averaging three records taken on consecutive days upon waking. The working HR was

calculated using the formula:

WORKING HR = ((maximum HR − resting HR) × (% Intensity / 100)) + resting HR

Participants were instructed on how to determine their HR range before the exercise program, and HR were recorded during training, either with a monitor or by measuring for 10 seconds at the carotid artery (Figure 7). Additionally, perceived exertion was assessed using Borg's Rating of Perceived Exertion Scale (Figure 8) [113], targeting an effort level of 12-14, or "Somewhat Hard" (Figure 8, Figure 9). At the beginning of the program, participants were educated on using Borg's Scale. During and at the end of the session, they were asked to report their perceived effort of the workout.

Figure 7 Manual heart rate measurement

| RPE | Level of Exertion | Physical Fatigue Levels |
|---|---|---|
| 6 | No exertion | Low |
| 7 | | |
| 7.5 | Extremely light | |
| 8 | | |
| 9 | Very light | |
| 10 | | |
| 11 | Light | |
| 12 | | Moderate |
| 13 | Somewhat hard | |
| 14 | | |
| 15 | Hard | Heavy |
| 16 | | |
| 17 | Very Hard | Severe |
| 18 | | |
| 19 | Extremely hard | |

Figure 8 Borg's Rating of Perceived Exertion Scale [114]

Figure 9 Borg's Rating of Perceived Exertion Scale

**Exercise program**

The exercise program designed for the three trimesters of pregnancy was structured to meet the specific needs at each stage, adhering to the safe and basic guidelines of the Barakat Model [110] to ensure maternal and fetal wellbeing during and after physical exercise.

**General characteristics:**

a) Most of the activity will be of aerobic moderate intensity.

b) Exercise positions which are difficult to perform during pregnancy will be avoided.

c) The stretching exercises must be adapted to the pregnant condition, and will not be maintain excessively.

d) Care should be taken to maintain adequate fluid intake before and after the activity.

e) Also as a general rule and to eliminate potential risks, the following will be avoided:

• Exercises including the Valsalva maneuver.

• High ambient temperatures or very humid environments in order to avoid hyperthermia (body temperature above 38º C).

• Sudden movements.

• Extreme muscular tension positions.

**Global Structure of the Program (contents):**

- Aerobic endurance capacity (AE)
- Muscular Strengthen (MS)
- Coordination and Posture Equilibrium (balance) (C/E)
- Stretching and Relaxation (S/R)
- Pelvic Floor Training (PFT)

Table 5 Exercise distribution plan during pregnancy based on Barakat Model

| Percentages of contents during the program | | | | | |
|---|---|---|---|---|---|
| **Until week 20** | | **Until week 30** | | **Until week 38-39** | |
| Aerobic Endurance | 40 % | AE | 30 % | AE | 25 % |
| Muscular Strengthen | 30 % | MS | 25 % | MS | 25 % |
| Coordination/Postural Equilibrium (Balance) | 10 % | C/E | 15 % | C/E | 15 % |
| Stretching /Relaxation | 10 % | S/R | 15 % | S/R | 15 % |
| Pelvic Floor Training | 10 % | PFT | 15 % | PFT | 20 % |
| Emotional aspects | Emotional aspects have been treated every session (final discussion) | | | | |

**Exercise equipment**

The exercise program offered both online and face-to-face classes. For the online sessions, each participant joined from her home, while the instructor was leading from a university or home setting. The required equipment included 1-3kg dumbbells (single and pairs), a low-medium resistance elastic bands, mats, a fitball (adapted to participant's height), and tennis balls. Additional household items such as chairs, backpacks, brooms, towels, or books were also utilized. The face-to-face classes were conducted in hospital classrooms, each capable of accommodating at least 30 participants. These rooms were equipped with a storage room containing the same exercise equipment used in the online sessions, ensuring ample gear was available for all participants. Each session was also recorded on video.

The venues for activities were optimized for safety during physical exercises, with controlled temperature between 20°C to 22°C and humidity levels maintained at 40-45%, never exceeding 60% [115]. Proper ventilation was ensured, and participants were

required to wear specific sports attire, which included breathable, comfortable clothing, a sports bra, well-fitted sports shoes, and a water bottle.

**Exercise Session**

Characteristics:

The duration of every session will be 55-60 minutes. The intensity of the workload will be 55-60% of the maximum maternal Heart Rate, and controlled by Polar monitor. Likewise, once a week, the Borg Scale of Perceived Effort will be administered to participants, in order to have a more reliable assessment of the intensity of the activities, 12-14 (moderate; out of a 20 points scale) will be the level used.

Structure:

All sessions will begin with a warm-up of 7-8 minutes composed of mild movements and joint mobility of upper and lower limbs exercises. Then a central part of 35-40 minutes, four types of activities will be included (aerobic work, muscle strengthening, coordination/balance tasks, pelvic floor exercises), finally a section of flexibility, relaxation and final talk (comments and sharing) will be performed (12-15 minutes).

**Each session was divided into seven parts as following:**

1) Warming up: For 8-10 minutes, starting with fun exercise games, and games were performed that involve varied movements at different intensities without engaging in running or impact activities (like jump or falls), and include mobility exercises for the main joints.

Figure 10 Warming up

2) Aerobic exercise: 20-25 minutes, moderate-intensity exercises were carried out using sports equipment like ball, ropes, and spades, or through low-impact dance routines set to various musical styles.

Figure 11 Aerobic exercise

3) Strength exercises: this part includes 10-12 minutes, strength training exercises were performed with dumbbells (up to 3 kg) and elastic band tailored for each participants. The exercises targeted the entire body, focusing on the lower body (gluteus maximus, quadriceps, biceps femoris, adductors, abductors, calf muscles) and upper body (biceps, triceps, deltoid muscle, pectorals, Latissimus dorsi, erector spinae).

Figure 12 Strength exercises

4) Coordination and balance: for 5-7 minutes, tasks involving hand-eye and foot-eye coordination with sports equipment were conducted, along with balance exercises (both static and dynamic) in various working positions (standing or quadruped) and on different supporting surfaces.

Figure 13 Coordination and balance

Figure 14 Coordination and balance

5) Flexibility and relaxation: it involved 5-10 minutes of progressively reduced intensity, complemented by static stretching and relaxation exercises, incorporating stretches for all muscles involved in the strength training session, from top to bottom.

Figure 15 Flexibility and relaxation

Figure 16 Stretching

6) Pelvic floor muscle training: PFMT involved 5-10 minutes sessions of Kegel exercises [116]. This included slow contractions of type I fibers, performing 2-3 sets of 6-8 repetitions, each lasting 8 to 10 seconds, and fast contractions of type II

fibers, carrying out 1-2 sets of 6-8 repetitions with 14-18 contractions, each lasting 2 to 3 seconds. These exercises targeted various parts of the pelvic floor musculature, including vaginal and anal contractions. Additional leg strengthening exercises, such as the glute bridge, hip abductions, and hip rotations, were also included. The training intensity was intensity was escalated by varying the exercises' difficulty and altering the positions on a mat, a chair, or a fitball.

Figure 17 Pelvic floor muscle training

7) Final talk: in the last 3-5 minutes, participants shared their feeling and insights about the exercise session and aspects of their daily life. This exchange aimed to foster a sense of community among the pregnant women, enhancing their overall quality of life through shared experiences.


Figure 18 Final talk

## 3.6. Outcomes

Data collection was conducted using the SELENE platform, which detailed obstetric records of the mother, fetus, and newborn before, during, and after pregnancy.

### 3.6.1. Primary outcomes

The primary outcomes were urine leakage, perceived amount of urine loss, impact of urine leak on daily life, when participants experience urine loss at 34 gestation weeks and postpartum three months respectively. Women had urine leakage at least once a week or more were considerable UI (Figure 19)

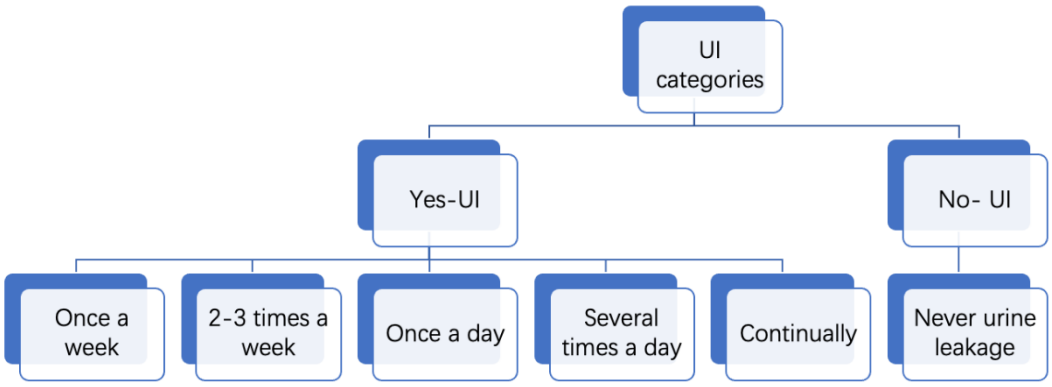


Figure 19 Categories of UI

### 3.6.2. Secondary outcomes

Secondary outcomes: for the mother, included mode of delivery, epidural use, episiotomy, perineal tear, gestational age, and gestational weight gain. For the newborn, included birth weight, birth length, birth head circumference, newborn sex, pH umbilical cord, Apgar score at 1 minute, and Apgar score at 5 minutes. Linear regression to predict mode of delivery and birth length was also as a secondary outcome. Maternal characteristics were assessed, including maternal age, height, weight, pre-pregnancy BMI, race, smoking habits prior to pregnancy, education level, parity and past occurrences of miscarriage. Pre-pregnancy BMI was calculated using the formula: [weight (kg)] / [height (m)]$^2$. At 34 weeks of gestation and three months after giving birth, the severity of UI was evaluated using the International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form (ICIQ-UI-SF) [117], (Appendix III). The gestational weight gain during pregnancy was determined by subtracting the pre-pregnancy weight from the weight at delivery, gestational weight gain was classified according to the 2009 Institute of Medicine guidelines [118].

Additional data (secondary outcomes) were extracted from medical records, the last time updated the data was in June 2024.

## 3.7. Sample size calculation

Power calculation for the primary outcome (UI), estimated a prevalence of around 15% in the intervention group and 30% in the control group. Based on this assumption, a two-sample chi-square ($\chi^2$) test with a 5% significance level and a power of 90%, it was determined that 161 participants were needed in each group. Anticipating an approximate 5% dropout rate, the study initially required about 169 women in each group at the start [119,120].

## 3.8. Statistical analysis

Data analyses were conducted with IBM SPSS software for Mac, version 27.0 (IBM Corporation, Armonk, NY, USA). The data distribution was initially evaluated using the Kolmogorov-Smirnov test to determine if there were any deviations from normality. Pearson's chi-square test was used to compare urine leakage, perceived amount of urine loss, impact of urine leak on daily life, when participants experience urine loss in late pregnancy, three months postpartum respectively, mode of delivery, epidural use, episiotomy, perineal tear, maternal race, smoking history before pregnancy, education level, parity, history of miscarriage, and sex of the newborn. Differences in gestational age, gestational weight gain, maternal age, weight, height, pre-pregnancy BMI, newborn's birth weight, birth length, head circumference, arterial cord blood pH, and Apgar scores at 1 and 5 minutes were analyzed using independent t-tests. Continuous variables are expressed as means and standard deviations, while nominal

variables are presented as numbers and percentage. A *p*-value less than 0.05 was considered statistically significant.

# 4. Results

A total of 600 pregnant women were assessed for eligibility, and 160 were excluded: 98 did not meet the inclusion criteria, 40 declined to participate, and 22 were excluded for other reasons. The participants were divided into the EG: n = 220 and CG: n = 220. In the EG, 48 participants were lost to follow-up due to lack of time (30 participants), changing hospitals (6 participants), voluntary withdrawal (5 participants), miscarriage (1 participant), and other reasons (6 participants). In the CG, 36 participants were lost to follow-up due to non-response to the questionnaire (21 participants), changing hospitals (4 participants), voluntary withdrawal (7 participants), miscarriage (1 participant), and other reasons (3 participants) (Figure 20).

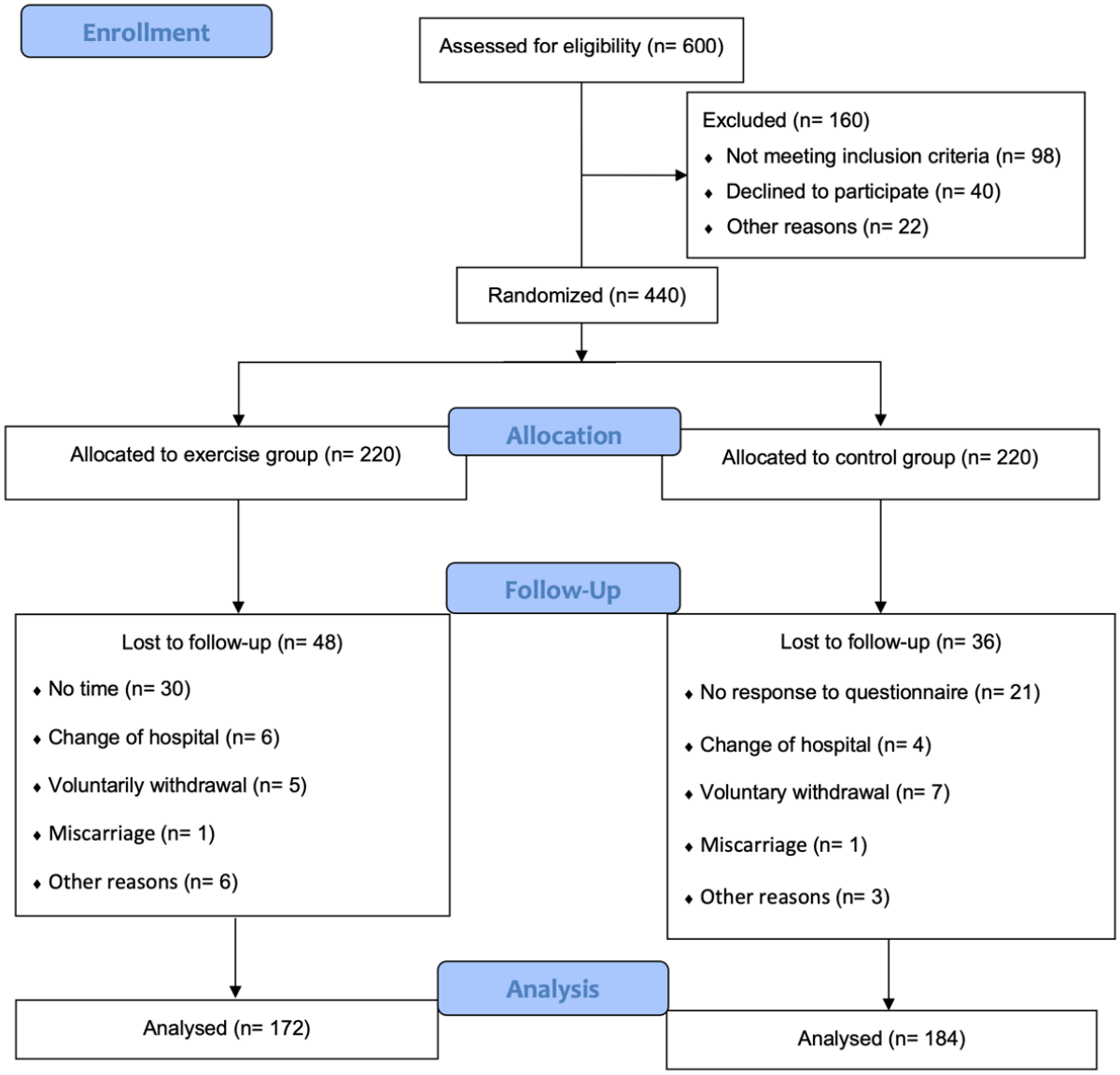


Figure 20 Study population flow chart

## 4.1. Maternal characteristics at baseline

Table 6 Characteristics of the exercise and control (usual care) groups at study entry presents the baseline characteristic of EG and CG with total 356 pregnant women. The differences in maternal age, pre-pregnancy weight, pre-pregnancy BMI, smoking before pregnancy, education level, parity, and previous miscarriage between the two groups were not significant ($P > 0.05$). Significant differences were found in maternal

height ($p$ = 0.03) and race ($p$ = 0.01), though these differences are limited in the overall comparison of characteristics.

Table 6 Characteristics of the exercise and control (usual care) groups at study entry

| **Maternal Characteristics** | | | |
|---|---|---|---|
| Variable | Exercise Group (n = 172) | Control Group (n = 184) | $p$-value |
| Maternal age (years) | 34.51 ± 4.44 | 34.06 ± 4.54 | 0.81 |
| Maternal height (cm) | 163.09 ± 5.72 | 164.27 ± 6.77 | 0.03 |
| Maternal pre-pregnancy weight (kg) | 65.98 ± 13.40 | 65.96 ± 14.25 | 0.56 |
| Pre-pregnancy BMI (kg/m$^2$) | 24.67 ± 4.68 | 24.16 ± 4.93 | 0.76 |
| Race (n/%) | | | |
| Caucasian | 139/80.8 | 166/90.2 | |
| Africa | 11/6.4 | 10/5.4 | 0.01 |
| Others | 22/12.8 | 8/4.4 | |
| Smoking before pregnancy (n/%) | | | |
| Yes | 7/4 | 11/5.9 | |
| Unknown | 49/28.5 | 36/19.5 | 0.12 |
| No | 116/67.5 | 137/74.5 | |
| Education level (n/%) | | | |
| Primary school | 2/2.2 | 3/2.5 | 0.99 |
| Secondary school | 23/25.8 | 31/25.6 | |
| University | 64/71.9 | 87/71.9 | |
| Parity (n/%) | | | |
| None | 85/61.2 | 89/51.7 | |
| One | 43/30.9 | 61/35.5 | 0.18 |
| Two or more | 11/7.9 | 22/12.8 | |
| Previous miscarriage (n/%) | | | |
| None | 94/71.7 | 107/65.2 | |
| One | 31/23.7 | 44/26.8 | 0.37 |
| Two or more | 6/4.6 | 13/8 | |

## 4.2. UI in late pregnancy between exercise group and control group

Table 7 showed the details of UI at 34 weeks gestation. Results indicated that a significantly higher proportion of women in EG reported never experiencing UI compared to the CG (64% vs 48%). What's more, the CG showed higher frequencies of UI for more severe categories; specifically, 10 % of the CG reported UI several times

a day compared to only 2% in the EG, and continual UI was reported by 1% of the CG, with none reported in the EG. Furthermore, UI once a day was reported by 7% of CG compared to 3% in the EG. These differences were statistically significant ($\chi^2 = 20.04$; $p = 0.001$), suggesting that regular exercise including PFMT may help reduce the risk of UI during pregnancy.

For the perceived amount of urine loss, 60.5% of women in EG and 46.7% in the CG reported no urine loss. Very little urine loss was experienced by 37.8% of women in EG and 44.6% in CG. Moderate urine loss was reported by 1.7% of women in EG compared to 7.6% in CG, and a large amount of urine loss was noted by 1.1% in CG and none in EG. There was a significant difference in the perceived amount of urine loss between the two groups ($\chi^2 = 12.34$; $p = 0.006$).

For the impact of urine leaks on daily life, 98.7% of women in the EG and 92.1% in the CG reported that urine leaks had no effect on their daily life. Conversely, 1.3% of women in EG and 7.9% in CG expressed that urine leaks significantly affected their daily life. Statistical analysis showed no significant difference in the impact of urine leaks on daily life between EG and CG ($\chi^2 = 7.26$; $p = 0.07$).

For the reason when women experience urine loss, 59.3% of women in the EG and 44.5% in the CG reported never experiencing urine loss. Urine loss when exerting physical effort was reported by 2.9% of women in EG and 6% in CG. Furthermore, 25.5% of women in EG and 36.9% in CG experienced urine loss when coughing or sneezing. 4% of women in EG and 4.8% in CG had urine loss before reaching the service, while 5.8% in EG and 3.8% in CG experienced it after urinating and dressing.

Continuous urine loss was reported only in CG by 1% of the women, and 2.3% of women in EG and 2.7% in CG had urine loss without an obvious reason. No significant difference was found in the patterns of urine loss between the two groups ($\chi^2 = 12.07$; $p = 0.06$).

Table 7 Frequency of urine leakage at 34 weeks' gestation

| | **Exercise group (n = 172)** | **Control group (n = 184)** | **$\chi^2$** | ***p*-value** |
|---|---|---|---|---|
| Urine leakage (n/%) | | | | |
| Never | 110/64 | 88/48 | | |
| Once a week | 38/22 | 41/23 | | |
| 2-3 times/week | 16/9 | 21/11 | 20.04 | 0.001 |
| Once a day | 5/3 | 13/7 | | |
| Several times a day | 3/2 | 19/10 | | |
| Continually | 0 | 2/1 | | |
| Perceived amount of urine loss (n/%) | | | | |
| I do not lose any urine | 104/60.5 | 86/46.7 | | |
| Very little amount | 65/37.8 | 82/44.6 | 12.34 | 0.006 |
| A moderate amount | 3/1.7 | 14/7.6 | | |
| A large amount | 0 | 2/1.1 | | |
| Impact of urine leaks on daily life (n/%) | | | | |
| Not at all | 149/98.7 | 129/92.1 | 7.26 | 0.07 |
| A lot | 2/1.3 | 11/7.9 | | |
| Explain when you experience urine loss (n/%) | | | | |
| Never | 102/59.3 | 82/44.5 | | |
| When exerting physical effort | 5/2.9 | 11/6 | | |
| When coughing or sneezing | 44/25.5 | 68/36.9 | | |
| Before reaching the service | 7/4.0 | 9/4.8 | 12.07 | 0.06 |
| After finishing urinating and has already dressed | 10/5.8 | 7/3.8 | | |
| Continuously | 0 | 2/1 | | |
| Without obvious reason | 4/2.3 | 5/2.7 | | |

## 4.3. UI at three months postpartum between exercise group and control group

Table 8 showed women who engaged in regular exercise during pregnancy experienced significantly reduced incidences of UI at three months postpartum. In the EG, 83% of the women reported no UI postpartum, compared to 67% in the CG. None of the women in the EG reported several times a day or continually UI, while 5% of women in the CG experienced UI several times a day, and 1% suffered from continually UI. These statistically significant differences ($\chi^2$ = 12.52, $p$ = 0.03) highlight the potential benefits of prenatal exercise in reducing the risk of three months postpartum UI.

For the perceived amount of urine loss, 78.3% of women in the EG reported no urine loss compared to 62.7% in the CG. In EG, 21.7% of women experienced a very small amount of urine loss, with none reporting moderate or large amounts. In contrast, 29.8% of women in CG experienced a very small amount od urine loss, 6.4% reported a moderate amount, and 1.1% reported a large amount of urine loss. A significant difference in perceived amount of urine loss was observed between groups ($\chi^2$ = 10.87; $p$ = 0.01).

For the impact of urine leaks on daily life, in EG, no women expressed effect for daily life or affect a lot for daily life. In CG, 97.3% women expressed no effect for daily life, 2.7% women expressed urine leaks affect a lot for daily life. No significant difference was observed between EG and CG for urine leaks impact on daily life ($\chi^2$ = 2.6; $p$ = 0.11).

For the reason when women experience urine loss, 76.2% of women in the EG and 61.3% in the CG reported never having experienced urine loss. Among those who did

experience urine loss, 1% of EG and 3.2% of CG noted it occurred when exerting physical effort. Additionally, 12.4% of EG and 19.4% of CG had urine loss when coughing or sneezing. Urine loss before reaching the service was reported by 6.7% in EG and 5.4% in CG, while 2.9% of EG and 4.3% of CG experienced it after urinating and dressing. Continuous urine loss was noted by 1.1% in CG, and urine loss without obvious reason was reported by 1% of EG and 5.4% of CG. No significant difference in urine loss pattern was found between the groups ($\chi^2 = 9.12$; $p = 0.17$).

Table 8 Frequency of urine leakage for 3 months postpartum

| | **Exercise group (n = 106)** | **Control group (n = 94)** | **$\chi^2$** | ***p*-value** |
|---|---|---|---|---|
| Urine leakage (n/%) | | | | |
| Never | 88/83 | 63/67 | | |
| Once a week | 12/11 | 14/15 | | |
| 2-3 times/week | 4/4 | 10/11 | 12.52 | 0.03 |
| Once a day | 2/2 | 1/1 | | |
| Several times a day | 0 | 5/5 | | |
| Continually | 0 | 1/1 | | |
| Perceived amount of urine loss (n/%) | | | | |
| I do not lose any urine | 83/78.3 | 59/62.7 | | |
| Very little amount | 23/21.7 | 28/29.8 | 10.87 | 0.01 |
| A moderate amount | 0 | 6/6.4 | | |
| A large amount | 0 | 1/1.1 | | |
| Impact of urine leaks on daily life (n/%) | | | | |
| Not at all | 97/100 | 73/97.3 | 2.6 | 0.11 |
| A lot | 0 | 2/2.7 | | |
| Explain when you experience urine loss (n/%) | | | | |
| Never | 80/76.2 | 57/61.3 | | |
| When exerting physical effort | 1/1 | 3/3.2 | | |
| When coughing or sneezing | 13/12.4 | 18/19.4 | | |
| Before reaching the service | 7/6.7 | 5/5.4 | 9.12 | 0.17 |
| After finishing urinating and has already dressed | 3/2.9 | 4/4.3 | | |
| Continuously | 0 | 1/1.1 | | |
| Without obvious reason | 1/1 | 5/5.4 | | |

## 4.4. Maternal outcomes of delivery

Table 9 shows the maternal outcomes of delivery. In EG, 55.6% of women with vaginal delivery, 24.1% with cesarean section and 20.3% with instrumental delivery. In CG, 63.4% of women with vaginal delivery, 22.9% women with cesarean section and 13.7% with instrumental delivery. No significant difference was found between EG and CG in mode of delivery ($\chi^2 = 2.59$; $p = 0.27$).

In EG, 75.4% of women used epidural during pregnancy, 24.6% of women not used epidural during pregnancy. In CG, 75.8% of women used epidural during pregnancy, 24.2% of women not used epidural during pregnancy. No significant difference was observed between EG and CG in epidural use ($\chi^2 = 0.01$; $p = 0.95$).

In EG, 14.9% of women experienced episiotomy, 85.1% of women no experienced episiotomy. In CG, 10.8% of women experienced episiotomy, 89.2% of women no experienced episiotomy. No significant difference was found between EG and CG in episiotomy ($\chi^2 = 0.97$; $p = 0.32$).

In EG, 40.8% of women did not have perineal tear, 26.7% of women had first-degree perineal tear, 30.8% of women had second-degree perineal tear, 1.7% of women had third-degree tear, no woman had fourth-degree perineal tear. In CG, 45.5% of women did not have perineal tear, 34.3% of women had first-degree perineal tear, 18.7% of women had second-degree perineal tear, 0.7% of woman had third-degree tear, 0.7% of woman had fourth-degree perineal tear. No significant difference was observed between EG and CG in perineal tear ($\chi^2 = 4$; $p = 0.15$).

Gestational weight gain was within recommended ranges for both groups,

although the EG had a lower gestational weight gain compared to the CG (9.61 ± 5.16 kg vs 10.73 ± 5.16 kg, respectively), no significant difference was found between groups. There was no significant difference in gestational age between the EG and CG (39.21 ± 1.58 weeks vs 39.18 ± 1.37 weeks, respectively; F = 3.57; $p = 0.06$).

Table 9 Maternal outcomes of delivery

| | **Exercise group** | **Control group** | **$\chi^2$/F** | ***P*-value** |
|---|---|---|---|---|
| Mode of delivery (n/%) | | | | |
| Vaginal delivery | 74/55.6 | 97/63.4 | | |
| Cesarean section | 32/24.1 | 35/22.9 | 2.59 | 0.27 |
| Instrumental delivery | 27/20.3 | 21/13.7 | | |
| Epidural use (n/%) | | | | |
| Yes | 52/75.4 | 94/75.8 | 0.01 | 0.95 |
| No | 17/24.6 | 30/24.2 | | |
| Episiotomy (n/%) | | | | |
| Yes | 18/14.9 | 15/10.8 | 0.97 | 0.32 |
| No | 103/85.1 | 124/89.2 | | |
| Perineal tear (n/%) | | | | |
| No | 49/40.8 | 61/45.5 | | |
| First-degree tear | 32/26.7 | 46/34.3 | | |
| Second-degree tear | 37/30.8 | 25/18.7 | 4 | 0.15 |
| Third-degree tear | 2/1.7 | 1/0.7 | | |
| Fourth-degree tear | 0 | 1/0.7 | | |
| Gestational age (week) | 39.21 ± 1.58 | 39.18 ± 1.37 | 3.57 | 0.06 |
| Gestational weight gain (kg) | 9.61 ± 5.16 | 10.73 ± 5.16 | 0.45 | 0.50 |

Data are reported as mean ± standard deviation, non-continuous variables are reported as number/percentage.

## 4.5. Newborn outcomes between groups

Table 10showed the outcomes for newborn from mothers who did exercise during pregnancy compared to who did not exercise. Although birth weight in both groups were within normal clinical ranges, a significant difference was observed in birth

weight (3105 ± 464 g in EG vs 3205 ± 410 g in CG; F = 4.16; $p = 0.04$). However other parameters such as birth length, head circumference, gender, umbilical cord pH level, and Apgar score at 1 and 5 minutes showed no significant differences.

Table 10 Newborn outcomes

| | **Exercise group (n=132)** | **Control group (n=151)** | **$\chi^2$/F** | ***p*-value** |
|---|---|---|---|---|
| Birth weight (g) | 3105 ± 464 | 3205 ± 410 | 4.16 | **0.04** |
| Birth length (cm) | 49.5 ± 2.28 | 49.9 ± 2.08 | 2.04 | 0.15 |
| Birth head circumference (cm) | 34.40 ± 1.41 | 34.62 ± 1.28 | 1.18 | 0.28 |
| Newborn sex (n/%) | | | | |
| Male | 60/47.6 | 65/50 | 0.15 | 0.70 |
| Female | 66/52.4 | 64/50 | | |
| pH umbilical cord | 7.23 ± 0.80 | 7.23 ± 0.80 | 0.93 | 0.34 |
| Apgar 1 | 9.01 ± 0.44 | 8.96 ± 0.47 | 0.01 | 0.92 |
| Apgar 5 | 9.85 ± 0.35 | 9.82 ± 0.49 | 1.92 | 0.17 |

Data are reported as mean ± standard deviation, non-continuous variables are reported as number/percentage.

## 4.6. Linear regression to predict birth outcomes

Table 11 shows predictors for mode of delivery and birth length in linear regression. Adherence of the sessions ($p = 0.004$) and pre-pregnancy BMI ($p = 0.003$) are significant predictors for gestational weight gain ($R^2 = 0.149$, F = 7.71, $p = 0.001$). Pre-pregnancy BMI ($p < 0.001$) and weight before pregnancy ($p < 0.001$) are significant predictors for birth length ($R^2 = 0.18$, F = 5.74, $p < 0.001$).

Table 11 Linear regression to predict mode of delivery and birth length

| | **Beta Value** | **Std Error** | **Tolerance** | **VIF** | ***p*-value** |
|---|---|---|---|---|---|
| 1 Gestational weight gain | | Adjusted $R^2 = 0.149$ | F = 7.7 | | *p* value < 0.001* |
| Adherence | -0.258 | 0.024 | 0.985 | 1.02 | 0.004 |
| Pre-pregnancy BMI | -0.735 | 0.278 | 0.125 | 8.00 | 0.003 |
| 2 Birth length | | Adjusted $R^2 = 0.18$ | F = 5.74 | | *p* value < 0.001* |
| Pre-pregnancy BMI | -1.014 | 0.12 | 0.16 | 6.25 | <0.001 |
| Weight before pregnancy | 1.04 | 0.04 | 0.16 | 6.26 | <0.001 |

VIF: Variance inflation factor; Linear regression also included: Parity, smoking during pregnancy

# 5. Discussion

## 5.1. Main findings

The primary aim of this study was to determine the influence of a supervised moderate exercise program including pelvic floor muscle training (PFMT) during pregnancy on urinary incontinence (UI) in late pregnancy and three months postpartum. We hypothesized that regular exercise program including PFMT during pregnancy would decrease UI in late pregnancy and three months postpartum. The results demonstrated that the supervised exercise program including PFMT decreased the prevalence of UI in late pregnancy and three months postpartum respectively. And study also found there was a significantly reduced birth weight in EG compared to CG, within normal ranges. However, we did not find significant differences between groups for mode of delivery, epidural use, episiotomy, perineal tear, gestational age, gestational weight gain, birth length, birth head circumference, newborn sex, pH umbilical cord,

Apgar score at 1 minute and 5 minutes. Adherence of the sessions and pre-pregnancy BMI are significant predictors for gestational weight gain, pre-pregnancy BMI and weight before pregnancy are significant predictors for birth length. Importantly, we found that regular exercise during pregnancy were beneficial for both mother and newborn, and its results make a significant scientific contribution, advocating for the integration of supervised exercise program including PFMT as an effective and accessible therapy recommended for healthcare professionals involved in prenatal care to prevent UI.

In this study, a blended method combining in-person and virtual sessions was utilized to administer the exercise program for pregnant women, allowing participants the convenience of scheduling remote sessions as needed, which significantly improved adherence to the program. This adaptable approach is a key advantage of our study, high participation is essential for maintaining the study's integrity and ensuring the accuracy of the data. The exercise was conducted by four certified sports instructors, enhancing the program's effectiveness and reliability, and thereby boosting attendance rates among the participants.

## 5.2. Exercise including PFMT and UI in late pregnancy

Consistent with our study, prenatal exercise could reduce the rate of UI in the late of pregnancy. Miquelutti et al., a birth preparation program assessed in a trial with 197 low-risk nulliparous women significantly reduced UI at 30 and 36 weeks of pregnancy and promoted physical activity. It involved physical exercise, educational activities, and home exercise, with no adverse effects on delivery or newborn health [121]. Wang et

al., study with 102 women assessed the effectiveness of a 12 weeks audio guideline PFMT every day in preventing UI during pregnancy, and results showed lower incidences UI in the intervention group at the 28$^{th}$ and 32 gestational weeks, underscoring PFMT's preventive benefits and supporting education on UI management [122]. Pelaez et al., a RCT study with 169 nulliparous women, prenatal supervised exercise including PFMT three times a week significantly prevented UI compared to usual care, the finding emphasizes the efficacy of integrating PFMT into routine prenatal care to mitigate UI risks in pregnant women, showcasing a need for widespread implementation of such preventive measures [123]. Zhang et al., a systematic review and meta-analysis with 6691 pregnant women found PFMT alone or as part of a general physical exercise program during pregnancy could effectively preventive UI during pregnancy [124]. However, Alagirisamy et al., a 16 weeks PFMT program without supervised during pregnancy did not find significant difference in self-reported UI compared to who did not PFMT [125]. Bø et al., a 12 weeks exercise program including PFMT with 105 participants twice-weekly 1 hour during pregnancy did not find significantly differences in UI between groups [126].

The divergence in study outcomes calls for further research, particularly in understanding the variables affecting the success rates of PFMT programs. Factors such as the intensity, frequency, and mode of supervision could be pivotal in designing more effective interventions. Furthermore, the consistent theme across the successful studies involves regular and supervised intervention, suggesting that these elements may be critical to the efficacy of preventive strategies against UI. While the evidence supports

the integration of PFMT and exercise into prenatal care routines, the optimal design of these programs remains a subject for future research. The goal moving forward should be to standardize exercise protocols that maximize benefits for pregnant women, ensuring widespread accessibility and implementation of these preventive measures.

## 5.3. Exercise including PFMT and UI in postpartum

Kocaöz et al., pregnant women performed a three deferent level PFMT program throughout the pregnancy 2-3 sessions per day, and each contract hold 3, 5, and 10 seconds according to their level, result showed there was a significant difference in terms of UI development in 12 weeks postpartum between EG and CG [127]. Mørkved et al., an 8-week intensive PFMT program led by a physical therapist for 45 minutes once a week and participants were asked to exercise at least three times per week, there was a significant difference reduced UI at 16 weeks postpartum period compared to women did not exercise [128]. Dinc et al., pregnant women with urinary incontinence performed a PFMT program during pregnancy and the researcher was leading participants on how to do the PFMT, result showed the study group had a significant decrease in UI in the postpartum period [129]. This study also found regular exercise including PFMT could significantly decrease the UI in the three months postpartum.

The findings from these studies make a strong case for the inclusion of structured and possibly supervised PFMT in prenatal care programs to prevent UI. Regular PFMT not only help in reducing the incidence of UI during the sensitive postpartum period but also contribute to the overall pelvic health, which can prevent other related health issues in the future. It’s also evident that the effectiveness of PFMT can be enhanced

with proper training and consistency, suggesting a need for healthcare providers to educate and motivate pregnant women about the benefits and techniques of PFMT. In conclusion, focusing on preventive measures like PFMT during prenatal care is crucial. It not only assists in managing and preventing UI postpartum but also enhances the general well-being and health quality of women after childbirth. This can be an important aspect of healthcare policies and personal health routines for expecting mothers.

## 5.4. Exercise during pregnancy and birth weight

Rodríguez-Blanque et al., a prenatal water exercise three times a week le by the principal investigator, and study found that EG had significantly lower birth weight than CG [130]. Yekefallah et al., a Yoga exercise twice a week during pregnancy and each session lasting 75 minutes in a Yoga specialized sports club, results showed Yoga group had a lower birth weight compared to routine prenatal care [131]. A 20 weeks Yoga exercise performed at home every day during pregnancy, each time 60 minutes, could significantly reduce the newborn birth weight [132]. The present study also found regular exercise during pregnancy could significantly decreased in birth weight compared to who did not exercise. These findings underscore the importance of birth weight as an indicator of neonatal health and development. Lower birth weight within normal range associated with maternal exercise might be of clinical relevance, suggesting that exercising during pregnancy, even if beneficial to the mother's health, needs to be tailored to ensure it does not adversely affect the newborn. While regular moderate exercise is generally considered safe and beneficial during pregnancy, these

findings could lead to reevaluation of exercise regimens to balance maternal health benefits with optimal newborn outcomes.

## 5.5. Predictors for gestational weight gain and birth length

Our study found that adherence of the sessions and pre-pregnancy BMI are significant predictors for gestational weight gain. This suggests that how closely expectant mothers follow the recommended exercise sessions and their BMI before pregnancy can significantly influence how much weight they gain during pregnancy. This is important as appropriate weight gain during pregnancy can affect both maternal and fetal health. Pre-pregnancy BMI and weight before pregnancy are significant predictors for birth length, which indicates that the mother's weight and BMI before pregnancy can have implications on the birth size of the baby, particularly the length at birth. This could be linked to nutritional status and overall health, which may influence fetal growth.

## 5.6. Research implications

Our research stands out due to several robust attributes including a considerable number of participants (600 pregnant women), a high rate of adherence at 73.5%, and a strict randomized controlled trial methodology. The professional oversight during exercise sessions further substantiates the reliability of our findings. These results solidify the scientific support for healthcare professionals to advise structured and supervised physical exercise during pregnancy. This can help prevent UI in late pregnancy and three months postpartum, and may have a beneficial impact on the birth weight of newborn. Notably, our study confirms that engaging in moderate physical

exercise during pregnancy dose not correlate with premature births or negatively affect the health of the newborn, understanding the safety of such exercise regimens during pregnancy. This expanded perspective reinforces the implications for clinical recommendations and future research directions.

### 5.7. Limitations

While our study with strengths, it also encompasses certain limitation. We did not evaluate the nutritional or caloric consumption, which might have provided insights into variations in gestational weight gain among the groups. Future studies should integrate dietary evaluations to complement the exercise analysis for a more holistic understanding. Furthermore, racial disparities between the participant groups could have impacted the results, understanding the necessity to include racial considerations in subsequent research endeavors.

## 6. Conclusions

- Regular, supervised exercise during pregnancy, including pelvic floor muscle training (PFMT), significantly reduces Urinary Incontinence (UI) in late pregnancy.
- Regular, supervised exercise during pregnancy, including pelvic floor muscle training (PFMT), significantly decrease Urinary Incontinence (UI) at three months postpartum.
- Regular, supervised exercise during pregnancy could significantly reduce newborn birth weight.
- Regular exercise during pregnancy without increasing risks to the mother,

fetus, or newborn. These findings support the inclusion of structured exercise programs in prenatal care, underscoring their importance for maternal and fetal health and challenging previous misconceptions about the safety of physical activity during pregnancy.

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**Appendix I**




:

# CONSENTIMIENTO INFORMADO

*Un embarazo físicamente activo*

Yo, D/Dña,……(nombre y apellidos), con domicilio en .....y DNI nº..... declaro que

He leído la hoja de información que me han entregado.

He podido hacer preguntas sobre el estudio.

He recibido suficiente información sobre el estudio.

He hablado con:

María Ángeles Díaz Blanco/Ruben Barakat/Dingfeng Zhang

Por el presente consiento participar en el mencionado estudio.

Comprendo que su participación es voluntaria.

Comprendo que puede retirarse del estudio:

1º Voluntariamente

2º Sin tener que dar explicaciones.

3º Sin que esto repercuta en sus cuidados médicos.

**Firma de la persona que participa** **Firma del investigador**:

**Nombre**: **Nombre**:

**Fecha**: **Fecha**:

# HOJA DE INFORMACIÓN

*Un embarazo físicamente activo*

INVESTIGADORES PRINCIPALES: RUBEN BARAKAT CARBALLO (Facultad de CC de la Actividad Física y del Deporte-INEF. UPM) y MARÍA ÁNGELES DÍAZ BLANCO (Servicio de Ginecología y Obstetricia. Hospital Universitario Severo Ochoa de Leganés).

Se le solicita su inclusión en el estudio titulado: *"Un embarazo físicamente activo"* que será llevado a cabo en el Hospital Severo Ochoa y en el Centro de salud Huerta de los Frailes (Leganés), en coordinación con la Facultad de Ciencias de la Actividad Física y del Deporte de la Universidad Politécnica de Madrid (UPM). Además esta hoja de información y el documento de consentimiento informado han sido aprobados Comité de Ética de Ensayos Clínicos (CEIC) del Hospital, así como también por el Comité de Ética de la Universidad Politécnica de Madrid.

El estudio pretende demostrar que el ejercicio físico moderado durante el embarazo puede actuar como un factor protector del desarrollo de una gran cantidad de alteraciones y complicaciones. Se establecerán dos grupos de estudio, uno llamado "tratamiento" (programa de ejercicio físico) y otro de control que no recibirá ejercicio físico. La asignación de las mujeres embarazadas a un grupo u otro será determinada aleatoriamente (azar).

En el caso de que su participación se determine en el grupo de Tratamiento, su colaboración en el estudio va a consistir en participar en un Programa de ejercicio físico aeróbico y moderado para embarazadas, que se llevará a cabo durante todo el período de gestación con una frecuencia de tres clases semanales de 50-55 min.

Le rogamos que lea con atención la hoja de información. No es necesario que responda ahora mismo. Puede llevarse los documentos a casa para consultarlo con sus familiares o amigos/as.

En una primera fase del estudio, se le preguntarán una serie de datos personales, como edad, ocupación laboral y hábitos de ejercicio físico pasados y actuales. También se recogerán posteriormente datos clínicos de su proceso asistencial, así como datos de su recién nacido/a e infante, de sus consultas periódicas en los controles rutinarios. Su participación en este estudio puede no aportarle ningún beneficio directo. En relación a los posibles riesgos asociados a esta intervención, la literatura científica no informa de riesgos materno-fetales asociados al ejercicio físico moderado durante el embarazo en gestantes sanas.

La finalidad de la información que le proporcionamos es la de obtener su participación en el estudio. Sus datos personales siempre serán tratados de forma confidencial, respetándose en todo momento los derechos y deberes que establece la Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales. La información médica que se obtenga durante este estudio se procesará de forma anónima y confidencial. Llegado el caso se podrá solicitar la cancelación de los datos almacenados  pero no podrá exigir que no se incorporen o se

retiren del estudio.

Si llegado a este punto su decisión es la de no participar, solo nos queda darle las gracias por el tiempo que nos ha concedido. Tenga por seguro que la atención médica que recibirá no se verá afectada por su decisión.

Muchas gracias!

Enero de 2020

**Appendix II**

UNIVERSIDAD POLITÉCNICA DE MADRID

**INFORME QUE EMITE EL COMITÉ DE ÉTICA**

**DE LA UNIVERSIDAD POLITÉCNICA DE MADRID**

A petición de la Vicerrectora de Investigación, Innovación y Doctorado de la Universidad Politécnica de Madrid,

Dª Asunción Gómez Pérez, de un dictamen sobre los aspectos éticos del

Proyecto **"ADENDA: Embarazo físicamente activo, prevención contra los efectos del COVID-19"**, cuyo investigador principal es D. Ruben Barakat Carballo, del Departamento de Ciencias Sociales de la actividad física del deporte y del ocio, de la Facultad de Ciencias de la Actividad Física y del Deporte

El Comité emite el siguiente informe:

***El solicitante declara conocer los principios éticos y las normas legales que rigen las actividades de investigación y se compromete a respetar estos principios y normas en el desarrollo del estudio propuesto. Igualmente, se compromete a no modificar los protocolos de investigación y a solicitar una nueva autorización en caso de modificación.***

***El solicitante declara conocer la legislación relativa a la protección de datos y se compromete a respetar la confidencialidad de los datos personales de este estudio, así como a hacer explícito este compromiso ante las personas que participan en el proyecto.***

***El solicitante declara conocer, en particular, el Reglamento (UE) 2016/679 del Parlamento Europeo y del Consejo, de 27 de abril de 2016, relativo a la protección de las personas físicas en lo que respecta al tratamiento de datos personales y a la libre circulación de estos datos y por el que se deroga la Directiva 95/46/CE (Reglamento general de protección de datos), y se compromete a cumplirlo.***

Por lo tanto, no hay inconveniente en **informar favorablemente la propuesta**, recomendando el efectivo cumplimiento de los compromisos declarados.

Y para que así conste, firmo el presente informe en Madrid a 9 de junio de dos mil veinte.

La Presidenta del Comité

GOMEZ PEREZ ASUNCION DE MARIA - DNI 08821929A

Firmado digitalmente por GOMEZ PEREZ ASUNCION DE MARIA - DNI 08821929A
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Asunción Gómez Pérez

El Secretario del Comité

Firmado por DUEÑAS LOPEZ JUAN CARLOS - 11802902S
Fecha: 09/06/2020 19:54:36 CEST

Juan Carlos Dueñas López

# Appendix III

UNIVERSIDAD POLITÉCNICA DE MADRID

**INFORME QUE EMITE EL COMITÉ DE ÉTICA**

**DE LA UNIVERSIDAD POLITÉCNICA DE MADRID**

A petición de la Vicerrectora de Investigación, Innovación y Doctorado de la Universidad Politécnica de Madrid,

Dª Asunción Gómez Pérez, de un dictamen sobre los aspectos éticos del

Proyecto **"ADENDA: Embarazo físicamente activo, prevención contra los efectos del COVID-19",** cuyo investigador principal es Dr. Ruben Barakat Carballo, del Grupo de investigación AFIPE, en la Facultad de Ciencias de la Actividad Física y del Deporte-INEF.

El Comité emite el siguiente informe:

En particular declara conocer y atenerse a lo dispuesto en

- la Declaración de Helsinki de la Asociación Médica Mundial (64ª Asamblea General, Fortaleza, Brasil, octubre 2013)
- el Convenio de Oviedo relativo a los Derechos Humanos y la Biomedicina (Consejo de Europa, 1997)
- la Ley 41/2002 básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica.
- la Ley 14/2007 de Investigación biomédica
- Ley 33/2011, de 4 de octubre, General de Salud Pública

***Así mismo, el solicitante declara conocer la legislación relativa a la protección de datos, en particular el Reglamento (UE) 2016/679 del Parlamento Europeo y del Consejo, de 27 de abril de 2016, relativo a la protección de las personas físicas en lo que respecta al tratamiento de datos personales y a la libre circulación de estos datos y por el que se deroga la Directiva 95/46/CE (Reglamento general de protección de datos, y se compromete a respetar la confidencialidad de los datos personales de este estudio, así como a hacer explícito este compromiso ante las personas que participan en el proyecto.***

***Igualmente, se compromete a no modificar los protocolos de investigación y a solicitar una nueva autorización en caso de modificación.***

Por lo tanto, no hay inconveniente en **informar favorablemente la propuesta**, recomendando el efectivo cumplimiento de los compromisos declarados.

UNIVERSIDAD POLITÉCNICA DE MADRID

Y para que así conste, firmamos el presente informe en Madrid a 9 de junio de dos mil veinte

| La Presidenta del Comité | El Secretario del Comité |
| --- | --- |
| GOMEZ PEREZ ASUNCION DE MARIA - DNI 08821929A<br>Firmado digitalmente por GOMEZ PEREZ ASUNCION DE MARIA - DNI 08821929A<br>Fecha: 2020.06.10 11:27:20 +02'00' | Firmado por DUEÑAS LOPEZ JUAN CARLOS - 11802902S<br>Fecha: 09/06/2020 19:56:28 CEST |
| Asunción Gómez Pérez | Juan Carlos Dueñas López |

**Appendix IV Researcher curriculum**

**Publications for articles**

https://orcid.org/0000-0002-3386-7036

1. **Zhang Dingfeng**, Bo K, Montejo R, Sánchez-Polán M, Silva-José C, Palacio M, Barakat R. Influence of pelvic floor muscle training alone or as part of a general physical activity program during pregnancy on urinary incontinence, episiotomy and third-or fourth-degree perineal tear: systematic review and meta-analysis of randomized clinical trials. Acta Obstetricia et Gynecologica Scandinavica. 2024 Jun 1.

2. **Zhang Dingfeng**, Ruchat SM, Silva-Jose C, Gil-Ares J, Barakat R, Sánchez-Polán M. Influence of physical activity during pregnancy on type and duration of delivery, and epidural use: Systematic review and meta-analysis. Journal of Clinical Medicine. 2023 Aug 5;12(15):5139.

3. **Zhang Dingfeng**, Nagpal TS, Silva-José C, Sánchez-Polán M, Gil-Ares J, Barakat R. Influence of physical activity during pregnancy on birth weight: systematic review and Meta-analysis of randomized controlled trials. Journal of Clinical Medicine. 2023 Aug 21;12(16):5421.

4. **Zhang Dingfeng**, Elias VE, Postigo SB. Effects of Whole Body Electromyostimulation Training on Maximum and Explosive Strength of Trained Female. A Pilot Study. Kronos: revista universitaria de la actividad física y el deporte. 2021 Jul 1;20(2):2-.

5. Barakat R, **Zhang Dingfeng**, Sánchez-Polán M, Silva-José C, Gil-Ares J, Franco E.

Is Exercise during Pregnancy a Risk for Gestational Age and Preterm Delivery? Systematic Review and Meta-Analysis. Journal of clinical medicine. 2023 Jul 26;12(15):4915.

6. Barakat R, **Zhang Dingfeng**, Silva-José C, Sánchez-Polán M, Franco E, Mottola MF. The Influence of Physical Activity during Pregnancy on Miscarriage—Systematic Review and Meta-Analysis. Journal of Clinical Medicine. 2023 Aug 19;12(16):5393.

7. Barakat R, Silva-Jose C, **Zhang, Dingfeng**, Sánchez-Polán M, Refoyo I, Montejo R. Influence of Physical Activity during Pregnancy on Maternal Hypertensive Disorders: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Journal of Personalized Medicine. 2023 Dec 21;14(1):10.

8. Sánchez-Polán M, Adamo K, Silva-Jose C, **Zhang Dinfeng**, Refoyo I, Barakat R. Physical Activity and Self-Perception of Mental and Physical Quality of Life during Pregnancy: A Systematic Review and Meta-Analysis. Journal of clinical medicine. 2023 Aug 25;12(17):5549.

9. Sánchez-Polán M, Nagpal TS, **Zhang Dingfeng**, Silva-Jose C, Montejo R, Barakat R. The Influence of Physical Activity during Pregnancy on Maternal Pain and Discomfort: A Meta-Analysis. Journal of Personalized Medicine. 2023 Dec 28;14(1):44.

10. Silva-Jose C, Mottola MF, Palacio M, Sánchez-Polán M, **Zhang Dingfeng**, Refoyo I, Barakat R. Impact of Physical Activity Interventions on High-Risk Pregnancies: A Systematic Review and Meta-Analysis. Journal of Personalized Medicine. 2023 Dec 21;14(1):14.

11. Silva-Jose C, May L, Sánchez-Polán M, **Zhang Dingfeng**, Barrera-Garcimartín A,

Refoyo I, Barakat R. Influence of Physical Activity during Pregnancy on Neonatal Complications: Systematic Review and Meta-Analysis. Journal of Personalized Medicine. 2023 Dec 20;14(1):6.

12. Barakat R, Silva-José C, Sánchez-Polán M, **Zhang Dingfeng**, Lobo P, De Roia G, Montejo R. Physical Activity during Pregnancy and Childhood Obesity: Systematic Review and Meta-Analysis. Journal of Clinical Medicine. 2024 Jan;13(13):3726.

**Publications for books**

1.Barakat, R., Sánchez-Polán, M., Silva-Jose, C., Uria-Minguito, A., **Zhang, Dingfeng**, Guía de Práctica Clínica sobre la Actividad Física durante el Embarazo. 01.01 (2023). ISBN: 978-84-09-49262-6

2.Barakat, R., Sánchez-Polán, M., Silva-Jose, C., **Zhang, Dingfeng**, CUIDADO Y MEJORA DE LA CALIDAD DE VIDA DE LA MUJER EMBARAZADA. LA ACTIVIDAD FÍSICA DURANTE LA GESTACIÓN COMO FACTOR DE RECUPERACIÓN Y RESILIENCIA MÁS ALLÁ DE LA PANDEMIA. 23.05 (2023). ISBN: 978-84-09-51781-7

3.Barakat, R., Sánchez-Polán, M., Silva-Jose, C., Uria-Minguito, A., **Zhang, Dingfeng,** EMBARAZO FÍSICAMENTE ACTIVO. SU IMPORTANCIA EN LA PREVENCIÓN DE ALTERACIONES. La Sociedad Española de Ginecología y Obstetricia. 11 (2023):251-272. ISBN: 978-84-09-55765-3

**International conferences**

1. Care and improvement of the quality of life of pregnant women. Physical activity

during pregnancy as a factor of recovery and resilience beyond the pandemic. Annual Seminar II, November 2023 (Spain).

2. Care and improvement of the quality of life of pregnant women. Physical activity during pregnancy as a factor of recovery and resilience beyond the pandemic. Annual Seminar I, May 2023 (Spain).

3. Care and improvement of the quality of life of pregnant women. Physical activity during pregnancy as a factor of recovery and resilience beyond the pandemic. Annual Seminar II, September 2022 (Spain).

**International investigation**

International stay during the PhD Program in Physical Activity and Sports Sciences in: East Carolina University (USA) from March to June 2024.

**Participation in projects**

1. Active Pregnancy Against COVID-19 (ACPREGCOV) NCT04563065, Universidad Politecnica de Madrid，Spain
2. Enhanced Neonatal Health and Neonatal Cardiac Effect Developmentally (ENHANCED) NCT03517293, East Carolina University，USA
3. Influence of Maternal Exercise on Infant Skeletal Muscle and Metabolomics NCT03838146, East Carolina University，USA