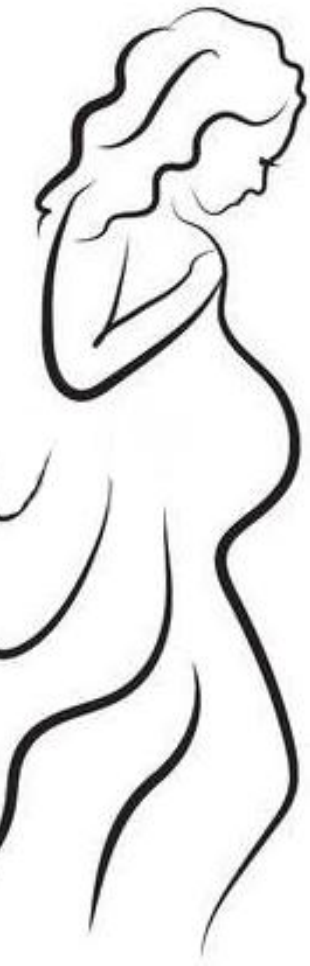
Universitat de Girona
Facultat de Medicina

Efficacy of a controlled exercise program in the prevention of excessive gestational weight gain in pregnant women.



A randomized, controlled, open-label clinical trial

FINAL DEGREE PROJECT

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ACKNOWLEDGMENT

"Knowing is not enough; we must apply.

Willing is not enough; we must do."

—Goethe

Vull donar les gràcies especialment a la meva tutora, la Dra. Alexandra Bonmatí, per la seva ajuda i tot el seu temps dedicat. Sobretot agrair també a la professora d'educació física Montse Vidal, la seva ajuda en el disseny i elaboració del pla d'exercicis i per brindar-me l'oportunitat de poder presenciar una sessió d'exercicis aquàtics amb dones embarassades. Finalment expressar el meu agraïment al servei de ginecologia i obstetrícia de l'Hospital Josep Trueta per la seva amabilitat i atenció i per tot el coneixement adquirit durant el període de rotació.

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1. ABSTRACT

Background: Excessive weight gain during pregnancy is associated with short-term obstetric outcomes (gestational diabetes, pregnancy-induced hypertension, increased risk of cesarean delivery, preterm labor, increased postpartum weight retention) and short-term neonatal outcomes (macrosomic or large-for-gestational-age infants) but few adequately powered randomized controlled trials have evaluated the efficacy of a controlled exercise program during pregnancy in order to prevent that.

Objective: This study examines whether a controlled exercise program during pregnancy could decrease the proportion of women who exceed the Institute of Medicine (IOM) recommendations for gestational weight gains and, therefore, the consequences arising from that, and increase the proportion of women who return to pregravid weights by 6 months post-partum compared to those that just attend to standard care and receive general counseling.

Methods and study design: This study is a randomized, controlled, open-label clinical trial. A sample of 338 pregnant women will enter into the study through a non-probabilistic consecutive recruitment. Participants will be pregnant, normal-weight, overweight and obese women whose age will be between 18 and 40 years. Participants will be randomly assigned within the IOM weight category (normal-weight, overweight or obese) to standard care (n=169) or to the controlled exercise program (n=169) to prevent excessive gestational weight gain. The intervention includes 2 weekly sessions: one on land (gym hall) and one as an aquatic based activity (small pool tank). Apart from that, women can go for a fast walking on flat surface during 30 minutes the rest of the week that will have to be documented to the research team. The women's weight will be measured at the 6^{th} month after delivery.

Keywords: Pregnancy, gestational weight gain, excessive gestational weight gain, controlled exercise program, gestational diabetes, hypertension, cesarean, prematurity, macrosomic.

RESUMEN

Antecedentes: El aumento excesivo de peso durante el embarazo se asocia con resultados obstétricos a corto plazo (diabetes gestacional, hipertensión inducida por el embarazo, mayor riesgo de parto por cesárea, parto prematuro, mayor retención de peso después del parto) y resultados neonatales a corto plazo (macrosomia o niños grandes para la edad gestacional), pero pocos ensayos aleatorios y controlados adecuadamente han evaluado la eficacia de un programa de ejercicios controlados durante el embarazo para prevenirlo.

Objetivo: Este estudio examina si un programa de ejercicios controlados durante el embarazo puede disminuir la proporción de mujeres que exceden las recomendaciones del Instituto de Medicina (IOM) para el aumento de peso gestacional y, por lo tanto, las consecuencias que se derivan de ello y aumentar la proporción de mujeres que recuperan el peso que tenían antes de quedar embarazadas en el periodo de 6 meses después del parto en comparación con las que sólo asisten a la atención estándar y reciben asesoramiento general.

Métodos y diseño del estudio: Este estudio es un ensayo clínico abierto, aleatorizado y controlado. Una muestra de 338 mujeres embarazadas entrará en el estudio a través de un reclutamiento consecutivo no probabilístico. Las participantes estarán embarazadas, y bien tendrán un peso normal, sobrepeso u obesidad, cuya edad será entre 18 y 40 años. Las participantes serán asignadas al azar, según la categoría de su peso de acuerdo con la clasificación de la IOM (peso normal, sobrepeso u obesidad), al grupo de atención estándar (n = 169) o bien al programa de ejercicios controlados (n = 169) para prevenir el aumento excesivo de peso gestacional. La intervención incluye 2 sesiones semanales: una en tierra (gimnasio) y otra como actividad acuática (vaso pequeño). Aparte de eso, las mujeres pueden ir a hacer caminatas a marcha rápida sobre una superficie plana durante 30 minutos el resto de días de la semana, lo cual tendrá que ser documentado al equipo de investigación. El peso de las mujeres será controlado a los 6 meses después del parto.

Palabras clave: Embarazo, aumento de peso gestacional, aumento excesivo de peso gestacional, programa de ejercicios controlados, diabetes gestacional, hipertensión, cesárea, prematuridad, macrosomia.

RESUM

Antecedents: L'augment de pes excessiu durant l'embaràs s'associa a resultats obstètrics a curt termini (diabetis gestacional, hipertensió induïda per l'embaràs, augment del risc de part per cesària, part prematur, l'augment de pes retingut després del part) i a resultats neonatals a curt termini (macrosomia o infants grans per l'edat gestacional), però pocs assaigs aleatoritzats i controlats adequadament han avaluat l'eficàcia d'un programa d'exercici controlat durant l'embaràs per tal d'evitar això.

Objectiu: Aquest estudi examina si un programa d'exercici controlat durant l'embaràs podria disminuir la proporció de dones que excedeixen les recomanacions de l'Institut de Medicina (IOM) per al guany de pes gestacional i, així també, les conseqüències que se'n deriven, i augmentar la proporció de dones que recuperen el pes que tenien abans de quedar-se embarassades al llarg dels 6 mesos després del part en comparació amb aquelles que només assisteixen a l'atenció estàndard i reben assessorament general.

Mètodes i disseny de l'estudi: Aquest estudi és un assaig clínic obert, aleatoritzat i controlat. Una mostra de 338 dones embarassades entrarà a l'estudi a través d'un reclutament consecutiu no probabilístic. Les participants seran dones embarassades, o bé amb pes normal, sobrepès o obesitat; l'edat serà d'entre 18 a 40 anys. Les participants seran assignades a l'atzar segons la seva categoria de pes de l'IOM (pes normal, sobrepès o obesitat) al grup d'atenció estàndard (n = 169) o bé al programa d'exercici controlat (n = 169) per evitar l'augment de pes excessiu. La intervenció inclou 2 sessions setmanals: una a terra (sala de gimnàs) i una com a activitat aquàtica (piscina petita). A part d'això, les dones poden anar a fer caminates a marxa ràpida sobre una superfície plana durant 30 minuts la resta de dies de la setmana, la qual cosa haurà de ser documentat a l'equip d'investigació. El pes de les dones serà controlat als 6 mesos després del part.

Paraules clau: embaràs, augment de pes gestacional, augment excessiu de pes gestacional, programa d'exercici controlat, diabetis gestacional, hipertensió, cesària, part prematur, macrosomia.

2. ABBREVIATIONS

ACOG: The American College of Obstetricians and Gynecologists

BMI: Body mass index

BP: Blood pressure

DBP: Diastolic blood pressure

EGWG: Excessive gestational weight gain

GD: Gestational diabetes

GW: Gestational weeks

GWG: Gestational weight gain

IOM: Institute of Medicine

LGA: Large-for-gestational-age

OGTT: Oral glucose tolerance test

PWR: Postpartum weight retention

SBP: Systolic blood pressure

WHO: World Health Organization

3. INTRODUCTION

3.1. Gestational weight gain: Definition, composition and components

3.1.1. *Definition*

Gestational weight gain (GWG) is a normal and expected component of healthy pregnancy (1) defined as the weight a woman gains during pregnancy (2). Is a consequence of a consistent positive energy balance (3). Pregnancy is an anabolic state that requires important changes in the metabolism of all the immediate principles, with the objective to achieve in long-term that fetus and, after that, the newborn, receives a continuous and increasing nutrient contribution. For that reason, pregnant woman needs to increase her own reserves during the first pregnancy months and, in that way, being able to cover the needs at the end of the pregnancy and during breastfeeding, when demands are maximum (4).

3.1.2. *Composition and components*

Weight gain in a normal pregnancy includes biological processes designed to promote fetal growth. Even though the GWG composition can differ among women, we can establish general items (5).

About 25 to 30% of the weight gain corresponds to the fetus, 30 to 40% in maternal reproductive tissues, placenta, extracellular fluid and blood and about 30% is composed of maternal fat deposits (5) (fig. 1).

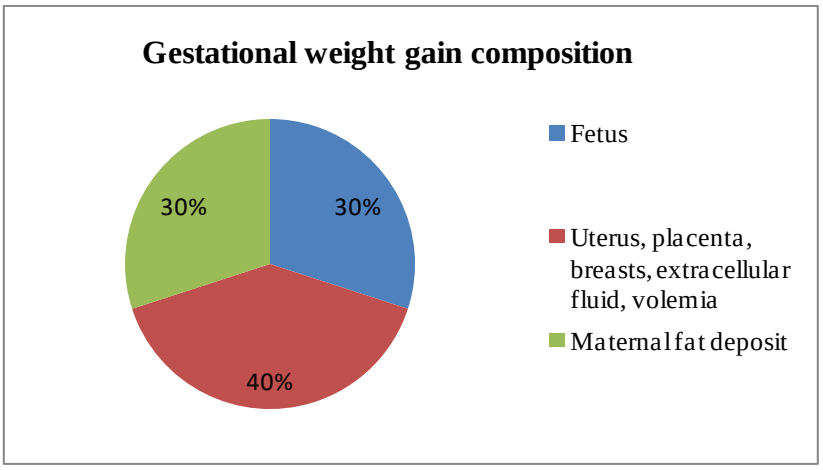

Figure 1. Gestational weight gain composition.

The normal weight gain distribution in a healthy woman with pre-pregnancy normal weight and with singleton pregnancy is detailed in the table below (6).

Table 1. Gestational weight gain components in a healthy woman with singleton pregnancy.

Conception product	Fetus	3.400 g
	Amniotic fluid	800g
	Placenta	650g
	Total	**4.850g**
Maternal tissues (without fat tissue)	Extracellular fluid	1.680g
	Uterus and breasts	1.375g
	Blood	1.250g
	Total	**4.305g**
Maternal corporal fat	Fat deposits	3.345g
Total weight gain		**12.500g**

During the first 20 gestational weeks (gw), fetal weight gain is slow, and in the following 20 weeks increases more quickly; meanwhile placenta presents an inverse behavior to the fetus. *Amniotic fluid* increases rapidly from the 10th week, being of 300 ml in the 20th gw, 600 ml in the 30th and of 1.000 ml in the 35th week. After that, there is a decrease in the amount of amniotic fluid up to 800 ml (7).

Uterus weight in a non pregnant woman is about 50-60 g, and in a pregnant woman it reaches up to 1.000-1.500 g at the end of the pregnancy. The weight increases progressively, being more quickly during the first 20 gw because of the hyperplasia. Its growth is due to the dilatation of the muscle fibers, increasing about 20 times its tissue mass. *Breasts* increase their weight during pregnancy because of the fat deposits.

Corporal water passes from 6.5 liters to 8.5 liters at the end of gestation, of which 2-4 liters is extracellular fluid. Changes in osmoregulation and in the renin-angiotensin system lead to an active reabsorption of sodium in the renal tubules and water retention (8). The water content of the fetus, placenta and amniotic fluid constitutes 3.5 liters of total body water. The majority of fluid is retained before the 30th week, but a pregnant woman who does not have edema retains 2-3 liters of extracellular fluid in the last 10gws (7).

Plasma volume increases progressively throughout normal pregnancy. Most of this 50% increase occurs by 34 gw. Maternal blood volume increases to approximately 1.200 to 1.600 ml above non-pregnant values. By the late third trimester the plasma volume increases by more than 50-60%, with a lower increase in red blood cell mass, and therefore plasma osmolality falls, so there is a fall in haemoglobin concentration, haematocrit and red blood cell count. The increase in plasma volume plays a critical role in maintaining circulating blood volume, blood pressure and uteroplacental perfusion during pregnancy (8).

The amount of *lipids* deposited in adipose tissue depends on the amount of fat and carbohydrates in the diet (4). A gain of 2.5-3 kg of fat is normal. Fat is deposited over the hips, back and upper thighs up to about 30 weeks' gestation, which is believed to be important as a caloric reserve for pregnancy and later lactation (5). Insulin secretion and its sensitivity increase, favoring the increase of lipogenesis and the fat accumulation as preparation for the greater energy needs of the growing fetus (9). So, a weight gain which is less than 7 kg indicates a consumption of fat reserves, while an increase of more than 13 kg points to an excessive accumulation of reserve fat tissue.

Fat gain is the most variable of three components (water, fat and protein) of maternal weight gain. The amount of fat gained is more strongly associated with total weight gain than any other component of GWG that contributes to higher Body Mass Index (BMI) later in life (10). Although maternal total energy intake undoubtedly influences maternal fat gain, other biological regulators, such as genetics, insulin, and leptin, probably also play a role (7).

3.2. Gestational weight gain: Recommendations

3.2.1. *Recommendations*

In 2009, the Institute of Medicine (IOM) published revised guidelines with GWG recommendations which promote optimal health by balancing risks associated with too much or too little GWG. These recommendations are based on pre-pregnancy BMI (weight [kg]/height $[m]^2$) ranges for underweight (<18.5), normal weight (18.5-24.9), overweight (25-29.9) and obese (≥30) women recommended by the World Health Organization (WHO) and are independent of age, parity, smoking history, race, and ethnic background (11). This guideline is for singleton gestations (12).

The recommendation is that pregnant woman should gain weight gradually and most of this increase should occur during the last trimester. In general terms, guidelines suggest weight gain in the following proportions (7):

- 0.5 to 2 kg in total during the first trimester
- 1.4 to 2 kg per month during the second and third trimesters

Table 2. Institute of Medicine 2009 Recommendations for Total Amount of Weight Gain During Pregnancy Based on Pre-Pregnancy Body Mass Index (BMI)[2]. Adapted from (7)

	Total Weight Gain	
Pre-pregnancy BMI	Range in Kg	Range in lbs
Underweight (<18.5)	12.5-18	28-40
Normal weight (18.5-24.9)	11.5-16	25-35
Overweight (25.0-29.9)	7-11.5	15-25
Obese (≥30.0)	5-9	11-20

Table 3. Institute of Medicine 2009 Recommendations for Rates of Weight Gain During 2nd and 3rd Trimester based on Pre-Pregnancy Body Mass Index (BMI)[2]. Adapted from (7)

	Rates of Weight Gain* 2nd and 3rd Trimester	
Pre-pregnancy BMI	Mean (range) in Kg/week	Mean (range) in lbs/week
Underweight (<18.5)	0.51 (0.44-0.58)	1 (1-1.3)
Normal weight (18.5-24.9)	0.42 (0.35-0.50)	1 (0.8-1)
Overweight (25.0-29.9)	0.28 (0.23-0.33)	0.6 (0.5-0.7)
Obese (≥30.0)	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

At each prenatal visit, series of controls are carried out, including weight determination, which provides information on the evolution of pregnancy and the nutritional status of the pregnant woman (13).

Overweight and obese women are nearly twice as likely to exceed IOM's recommended gains compared to normal weight women (5).

3.3. Gestational weight gain: Timeline

3.3.1. *Timeline*

The GWG pattern is more commonly described as sigmoid, gaining most of the weight in the second trimester of pregnancy and the beginning of the third (5).

Therefore weight gain must be gradual, since it can be symptom of some problem. Thus, it should be considered that by monitoring the weight change rate during pregnancy, a *too rapid increase* may be due, among other reasons, to a *mistake in the measurement* or recording of data, to an excessive increase preceded by a lower expected weight increase, the *formation of edemas*, the *abandonment of the tobacco habit*, even a *multiple pregnancy*, a *gestational diabetes*, etc. (Table 4). On the other hand, a *slow weight gain* or even a higher weight loss may be due to the *resolution of edemas*, the presence of *nausea, vomiting or diarrhea*. In general terms, normally early GWG reflects tissue stores, fluid accumulation and blood volume expansion while later gain is associated primarily with fetal growth. If there is excessive gestational weight gain (EGWG) and is not supported by increased calorie consumption, it is likely that woman is accumulating fluid due to edema or excess amniotic fluid (6).

Table 4. Aspects to be assessed in excessive gestational weight gain (6).

Evaluation
-Measurement error
-Weight loss at previous visit
-Edema
-Smoking cessation
-Alcohol use
-Infrequent, large meals
-High fat and/or sugar intake
-Physical inactivity
-Twin or triplet pregnancy
-Depression
-Binge eating
-Psychosocial stress
-Social isolation

To obtain easily and graphically the course in time of GWG, it may be useful to record the evolution of weight in graphs, using as reference the standard values of Figure 3, being the maximum limit p90 and the minimum p25 (14).

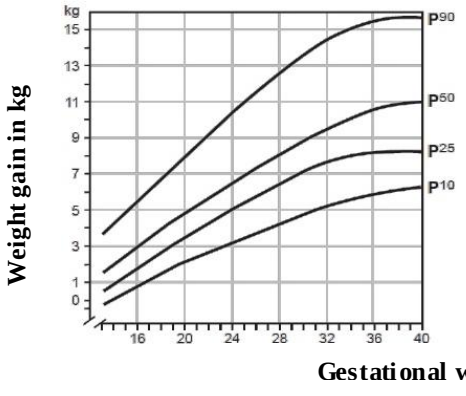

Figure 2. Gestational weight gain according to gestational weeks (14).

3.4. Epidemiology

The number of women who gain too much weight throughout pregnancy and proportions of high GWG have been found to be increasing over time in industrialized countries. There is also an increase in the number of women who are already overweight or obese at the time of becoming pregnant. These proportions are likely to increase unless successful interventions can interrupt trends towards higher gains. (3,15,16)

In recent years, according to US data, more than 40% of pregnant women gain weight during pregnancy that exceeds the amount recommended by the IOM (15,16,17).

Several modifiable and non-modifiable factors influence GWG, such as pre-pregnancy BMI, maternal age, height, parity, socio-demographic factors, socio-economic status, diet and exercise during pregnancy. A woman's BMI at the time of conception is the strongest predictor of EGWG, and women who are overweight or obese prior to pregnancy are significantly more likely to exceed weight guidelines. Those were findings from an Australian prospective multicenter cohort of 1.950 nulliparous women and an analysis of 4.619 postpartum women in Arkansas (EUA) (3,12).

Adolescents have been found to have a higher median weight gain and rate of gain throughout pregnancy compared to adults, but most studies suggest that young adolescents who are still growing, transfer less of their GWG to their developing fetuses than older adolescents or adults despite adequate weight gain and fat accumulation (6).

About the socio-demographic factors, obesity rates are 50% for black women, 40% for Hispanic women, 30% for white women, and 10% for Asian women. Yet, despite higher rates of obesity among black and Hispanic women, a retrospective study of 2.760 women from urban community in Minneapolis from 2004 to 2008 and other retrospective study of 133.000 women in South Carolina in 2014, indicate lower rates of EGWG in black and Hispanic women and demonstrate a higher risk of EGWG among white women. Socio-economic status may also affect maternal weight gain during pregnancy. Women of low socio-economic status are more likely to be obese than those of higher socio-economic status. Diet and exercise are important factors in weight gain during pregnancy. Several large observational studies have investigated the relationship between physical activity and EGWG, and have consistently demonstrated that limited

or reduced physical activity during pregnancy is associated with higher rates of EGWG and physical activity during pregnancy is associated with lower rates of EGWG. Observational studies have also been conducted to investigate the relationship between diet and EGWG, but the results are disparate and somewhat difficult to interpret (12).

According to US databases, the prevalence of obesity in women of fertile age (20-39 years old) is 34.4%, and with them up to 60% are overweight (19).

In Spain, it is estimated that 10.75% of women of fertile age (18 to 44 years) are obese and 29% are overweight (20).

The increase in women who are overweight during pregnancy is not an exclusive problem of the United States, because it can now increasingly be observed in Catalonia, as it has been reported by the heads of obstetrical service of the hospitals Vall d'Hebron (Lluís Cabero) , Clinic (Eduard Gratacós) and Sant Pau (Joaquim Calaf) (16).

Therefore, most of the epidemiological data on EGWG are the result of studies conducted in the United States, England or Sweden. In Spain there is a lack of studies analyzing the prevalence of GWG or the factors that influence it, so it would be interesting to conduct more observational studies focused on that area.

If we put our attention on the data obtained from the Hospital Universitari Doctor Josep Trueta (HUDJT) from 2011 to 2015 we can observe that according to their BMI, the number of pregnant women with a BMI within the limits of normality (BMI 18.5-25) is the most prevalent, followed by the ones that are overweight (BMI 25-30), obese (BMI >30) and finally the ones that are underweight (BMI <18.5) which represent the minority (Figure 3).

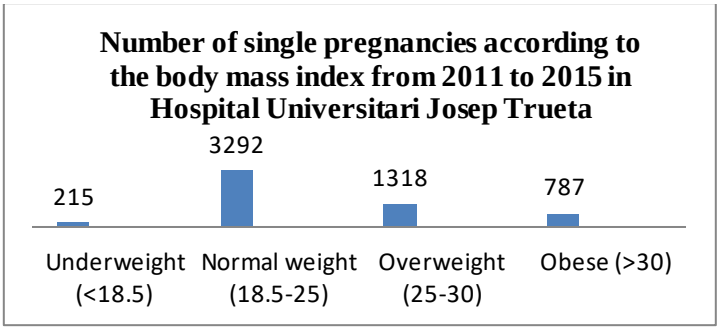

Figure 3. Number of single pregnancies according to the body mass index from 2011 to 2015 in Hospital Universitari Josep Trueta. Extracted from Hospital Universitari Josep Trueta (unpublished data).

Talking about the GWG, we can find that most of the underweight pregnant women who attended to HUDJT during the years between 2011 and 2015 gained weight within the limits of normality according to the IOM's recommendations. But also a not insignificant number of this group of women, nearly a 50%, gained a weight considered inferior to the suitable one (Figure 4).

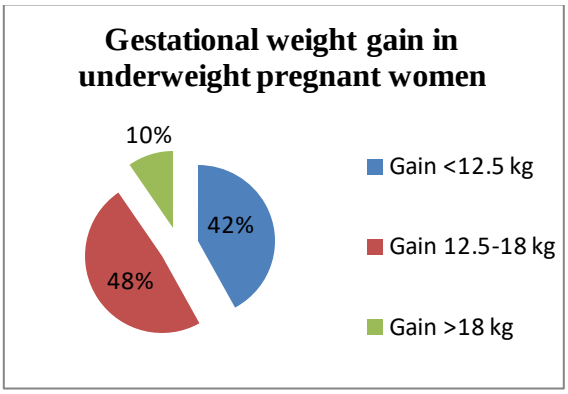

Figure 4. Gestational weight gain in underweight pregnant women with singleton pregnancies from 2011 to 2015 in Hospital Universitari Josep Trueta. Extracted from Hospital Universitari Josep Trueta (unpublished data).

About the normal weight pregnant women, the most prevalent in HUDJT, a 39% gained less weight than the one considered adequate, another 39% gained the appropriate GWG and a 22% gained more weight than the acceptable one (Figure 5).

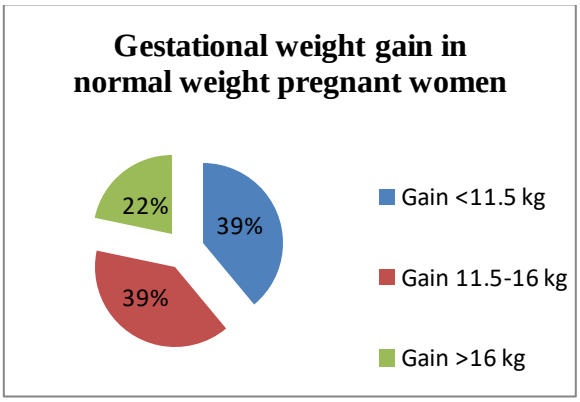

Figure 5. Gestational weight gain in normal weight pregnant women with singleton pregnancies from 2011 to 2015 in Hospital Universitari Josep Trueta. Extracted from Hospital Universitari Josep Trueta (unpublished data).

Finally, about the overweight and obese pregnant women who attended HUDJT, we can see that in both cases, almost half of them gained more weight than the recommended by the IOM (Figures 6 and 7).

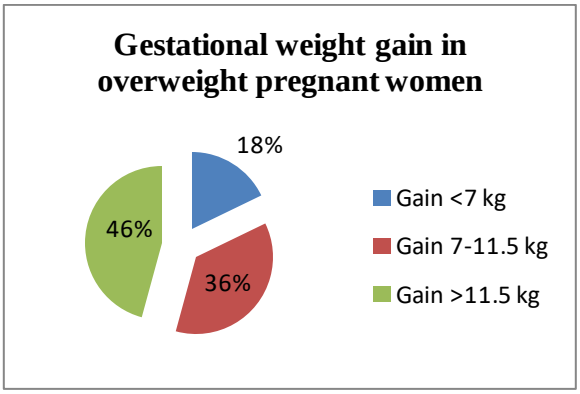

Figure 6. Gestational weight gain in overweight pregnant women with singleton pregnancies from 2011 to 2015 in Hospital Universitari Josep Trueta. Extracted from Hospital Universitari Josep Trueta (unpublished data).

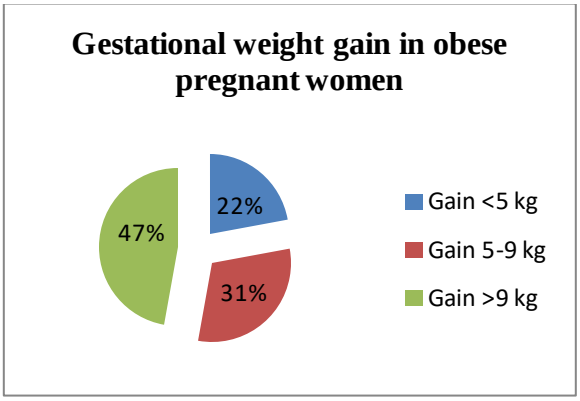

Figure 7. Gestational weight gain in obese pregnant women with singleton pregnancies from 2011 to 2015 in Hospital Universitari Josep Trueta. Extracted from Hospital Universitari Josep Trueta (unpublished data).

3.5. Complications arising from excessive weight gain during pregnancy

Gaining too much weight during pregnancy has been linked with adverse medical, obstetric and neonatal outcomes, which will be explained below.

3.5.1. *Mother outcomes*

3.5.1.1. *Gestational diabetes*

Gestational diabetes (GD) is defined as a carbohydrate intolerance (high blood glucose levels) of varying degrees of severity with onset or first recognition during pregnancy in a woman who previously did not have diabetes and can lead to the later development of type 2 diabetes in both mother and child and has a 30 to 84% greater risk of having recurrent gestational diabetes in future pregnancies (1,5,21–23). Moreover, newborns of

women with GD are more likely to be macrosomic and increase the rate of cesarean delivery (21). Normal pregnancy has been characterized as a diabetogenic event due to hormonal changes (placental hormones and cytokines) that provide increased quantities of glucose to the fetus, but also adaptively increases pancreatic β-cells function and insulin secretion. As pregnancy progresses, in susceptible pregnant women this result in β-cells insufficiency, which leads to a slow progressive insulin secretion failure, as well as an increased insulin resistance (progressive insulin resistance begins near mid-pregnancy and progresses through the third trimester) (23,24). Some studies have found a link between GWG and the risk of gestational diabetes (1,5,21). One of these studies investigated this association by using a case control study of 1.145 women, and findings suggested that subjects with greater weight gain during pregnancy had an increased risk of developing GD by 43%-74%. This effect was further exacerbated in overweight and obese women (21), because the increased fat deposition leads to an increase in adiponectin and leptin which regulate insulin sensitivity and glucose homeostasis (24).

3.5.1.2. *Pregnancy-induced hypertension*

Hypertension is defined as high blood pressure (BP). We consider high BP a repeatedly elevated BP exceeding in 140 mmHg systolic blood pressure (SBP) and /or exceeding in 90 mmHg diastolic blood pressure (DBP). Pregnancy-induced hypertension refers to high BP that develops after 20 weeks of gestation in a previously normotensive woman without proteinuria and may subside after delivery (25). A number of studies have examined whether maternal weight gain in pregnancy may influence the risk of pregnancy-induced hypertension, taking into account the considerable association between weight gain and high BP in non-pregnant adult women. Most epidemiological studies have reported a direct relationship between increased weight gain in pregnancy and the onset of hypertension. In addition, weight gain at or below IOM recommended intervals may be protective against the onset of hypertensive disorders during pregnancy (1,5).

3.5.1.3. *Cesarean delivery*

Several studies ratify that a possible effect of EGWG during labor is an increased risk for a cesarean section, which may be performed for multiple reasons, in this case especially for cephalopelvic disproportion due to fetal macrosomia. Cesarean section

rates are 30% more common among over-weight and obese compared to normal-weight women (5,21).

3.5.1.4. *Postpartum weight retention*

Several researchers have found a positive association between GWG and postpartum weight retention (PWR). They found that women who gained more weight than the recommended amount during pregnancy were three times more likely to retain 4.5 kg or more at one year postpartum and that PWR was more common in those women who initiate pregnancy with overweight or obesity. In a systematic review of maternal weight gain outcomes, Siega-Riz et al found moderate, consistent evidence linking EGWG to higher weight retention in both the immediate postpartum period and in the longer term (e.g., within 2 years postpartum). Researchers have also suggested that higher weight gains during pregnancy mean greater postpartum weight retention, which increases the likelihood of developing obesity postpartum (5,26).

3.5.1.5. *Preterm labor*

Preterm labor is diagnosed by the presence of uterine contractions of sufficient frequency and intensity to effect progressive cervical effacement and dilation prior to term gestation (<37 gw). Prematurity has association with infant mortality, long-term disability, and high economic burden for the healthcare it brings, particularly in developing countries. In literature, some studies state that EGWG is associated with a higher frequency of preterm birth because more frequently these women present more complications during pregnancy that require the practice of labor induction in order to extract the baby in an early stage. Also a higher pre-pregnancy BMI predicts an increased risk of the infant being born prematurely (3,5,27, 28).

3.5.2. *Offspring outcomes*

3.5.2.1. *Macrosomic or large-for-gestational-age*

We define a newborn as a macrosomic or large-for-gestational-age (LGA) those whose weight is >90th percentile for gestational age. In absolute values and for full-term newborns, these criteria correspond with a weight of 4.000 to 4.500 g (29). EGWG has been found to be strongly associated with macrosomia or LGA neonates, particularly

among overweight and obese women (5,26). The main situations that involve a greater risk of developing macrosomia are maternal obesity, EGWG, and poorly controlled maternal diabetes. Fetal macrosomia is associated with a higher incidence of cesarean delivery and, in vaginal delivery, there is an increase in tears in the birth canal. Obstetric trauma is another risk associated with macrosomia such as shoulder dystocia and brachial plexus injury. Babies born of women with poorly controlled GD are likely to experience hypoglycemia after birth. Cardiac malformations, birth asphyxia, and increased risk of perinatal mortality are also more frequent. Long-term effects should also be considered. Several studies link the fetal macrosomia with an increased risk of developing type 2 diabetes mellitus, obesity and metabolic syndrome in childhood or adulthood (21,29).

3.6. Physical activity and exercise during pregnancy

Physical activity, defined as any bodily movement produced by the contraction of skeletal muscles in all stages of life maintains and improves cardiorespiratory fitness, reduces the risk of obesity and associated comorbidities, and results in greater longevity.

Exercise, defined as physical activity consisting of planned, structured, and repetitive bodily movements done to improve one or more components of physical fitness, is an essential element of a healthy lifestyle, and obstetrician-gynecologists and other obstetric care providers should encourage their patients to continue or to commence exercise as an important component of optimal health (30,31).

Aerobic exercise is a medium-or low-intensity and long-lasting exercise, where the body needs to burn carbohydrates and fats to obtain energy and for this process oxygen is required. It can consist of any activity that use large muscle groups in a continuous rhythmic manner. Those exercises include running, swimming, cycling, walking, etc. It is often used to lose weight, since as we have said, with this type of exercise the fat is burnt. Also, by needing a lot of oxygen, the cardiovascular system is exercised and produces numerous benefits (31).

The WHO has issued evidence-based recommendations indicating that the beneficial effects of exercise in most adults are indisputable and that the benefits far outweigh the risks (32).

In pregnancy, physical inactivity and EGWG have been recognized as independent risk factors for maternal obesity and related pregnancy complications, including GD (21,23,24,33). Some patients and obstetrician-gynecologists are concerned that regular physical activity during pregnancy may cause miscarriage, poor fetal growth, musculoskeletal injury, or premature delivery. For uncomplicated pregnancies, these concerns have not been substantiated (18,34–37). In the absence of obstetric or medical complications or contraindications (Table 5, Table 6), physical activity in pregnancy is safe and desirable, and pregnant women should be encouraged to continue or to initiate safe physical activities, avoiding those with high risk of abdominal trauma (Table 7). Obstetricians-gynecologists and other obstetric care providers should carefully evaluate women with medical or obstetric complications before making recommendations on physical activity participation during pregnancy (30).

Table 5. Absolute contraindications to aerobic exercise during pregnancy (30).

- Hemodynamically significant heart disease
- Restrictive lung disease
- Incompetent cervix or cerclage
- Multiple gestation at risk of premature labor
- Persistent second- or third- trimester bleeding
- Placenta previa after 26 weeks of gestation
- Premature labor during the current pregnancy
- Ruptured membranes
- Preeclampsia or pregnancy-induced hypertension
- Severe anemia

Table 6. Relative contraindications to aerobic exercise during pregnancy (30).

- Anemia
- Unevaluated maternal cardiac arrhythmia
- Chronic bronchitis
- Poorly controlled type 1 diabetes
- Extreme morbid obesity
- Extreme underweight (BMI less than 12)
- History of extremely sedentary lifestyle
- Intrauterine growth restriction in current pregnancy
- Poorly controlled hypertension
- Orthopedic limitations
- Poorly controlled seizure limitations
- Poorly controlled hyperthyroidism
- Heavy smoker

3.6.1. *Anatomic and physiologic aspects of exercise in pregnancy*

Pregnancy results in anatomic and physiologic changes that should be considered when prescribing exercise. The most distinct changes during pregnancy are increased weight gain and a shift in the point of gravity that results in progressive lordosis that lead to an increase in the forces across the joints and the spine during weight-bearing exercise. As a result, more than 60% of all pregnant women experience low back pain (38). Strengthening of abdominal and back muscles could minimize this risk. There are also hemodynamic changes such as the increase in blood volume, heart rate, stroke volume and cardiac output, and the decrease in systemic vascular resistance that establish the circulatory reserve necessary to sustain the pregnant woman and fetus at rest and during exercise (13).

There are also profound respiratory changes which lead to minute ventilation increases up to 50% because of a physiologic decrease in pulmonary reserve. This causes an impaired in the ability to exercise anaerobically, and oxygen availability for strenuous aerobic exercise and increased work load consistently lags (39). Aerobic training in pregnancy has been shown to increase aerobic capacity in normal weight and overweight pregnant women (40,41).

During pregnancy there is also an increased ligamentous laxity thought to be secondary to the influence of the increased levels of estrogen and relaxin. It has to be considered when recommending flexibility exercises in order to avoid musculoskeletal injuries (31).

Temperature regulation is highly dependent on hydration and environmental conditions, thus, during exercise pregnant women should stay well-hydrated, wear loose-fitting clothing, and avoid high heat and humidity to protect against heat stress, particularly during the first trimester (30). Water exercises are recommended activities for pregnant women because promote venous return and improve body temperature (13).

Despite the fact that pregnancy is associated with profound anatomic and physiologic changes, exercise has minimal risks and has been shown to benefit most women. The most common sports-related injuries in pregnancy are musculoskeletal, in general related to lower extremities edema (80%) and joint laxity (31).

Table 7. Examples of safe and unsafe physical activities during pregnancy* (30).

The following activities are safe to initiate or continue*:

- Walking
- Swimming[ˁ]
- Stationary cycling
- Low-impact aerobics
- Yoga, modified[Ⱶ]
- Pilates, modified
- Running or jogging[˥]
- Racquet sports[˥⁜]
- Strength training[˥]

The following activities should be avoided:

- Contact sports (eg, ice hockey, boxing, soccer and basketball)
- Activities with a high risk of falling (eg, downhill snow skiing, water skiing, surfing, off-road cycling, gymnastics and horseback riding)
- Scuba diving

*In women with uncomplicated pregnancies in consultation with an obstetric care provider.

[ˁ]Swimming has not been associated with adverse effects and has the advantage of creating a buoyant condition that is well tolerated.

[Ⱶ]Yoga positions that result in decreased venous return and hypotension should be avoided as much as possible.

[˥]In consultation with an obstetric care provider, running or jogging, racquets sports, and strength training may be safe for pregnant women who participated in these activities regularly before pregnancy.

[⁜]Racquet sports wherein a pregnant woman's changing balance may affect rapid movements and increase the risk of falling should be avoided as much as possible.

3.6.2. *Fetal response to maternal exercise*

Studies have demonstrated minimum-to-moderate increases in fetal heart rate by 10-30 beats per minute over the baseline during or after exercise (42). A meta-analyses and a randomized controlled trial concluded that the differences in birth weight were minimal to none in women who exercised during pregnancy compared with controls. However, women who continued to exercise vigorously during the third trimester were more likely to deliver infants weighing 200-400 g less than comparable controls, although there was not an increased risk of fetal growth restriction (43,44). A cohort study that assessed umbilical artery blood flow, fetal heart rates and biophysical profiles before and after strenuous exercise in the second trimester demonstrated that 30 minutes of strenuous exercise was well tolerated by women and fetuses in active and inactive pregnant women (42).

3.6.3. *Benefits of exercise during pregnancy*

Regular aerobic exercise during pregnancy has been shown to improve or maintain physical fitness (35,37,44). Although the evidence is limited, some benefit to pregnancy outcomes has been shown, and there is no evidence of harm when not contraindicated. Observational studies of women who exercise during pregnancy have shown benefits such as decreased GD (21–23,45), cesarean delivery (37,46), and postpartum recovery time (37). A randomized controlled trial also showed that early maternal exercise during pregnancy reduces the incidence of pregnancy-induced hypertension and macrosomia, while protecting against having a low birth weight baby (25). In those instances where women experience low-back pain, water exercise is an excellent alternative (30). Studies have shown that exercise during pregnancy might help to prevent preeclampsia (47). Exercise has shown only a modest decrease in overall weight gain (1-2 kg) in normal weight, overweight and obese women (48).

3.6.4. *Recommending an exercise program*

3.6.4.1. *Motivational counseling*

Pregnancy is an ideal time for behavior modification and for adopting a healthy lifestyle because of increased motivation and frequent access to medical supervision. Patients are more likely to control weight, increase physical activity, and improve their diet if their physician recommends that they do so (49). Motivational counseling tools such as the Five A's (Ask, Advise, Assess, Assist, and Arrange), have been used successfully for diet and exercise counseling (50,51). Thus, this tool can be considered by obstetrician-gynecologists or other obstetric care providers to be adopted for women with uncomplicated pregnancies who have no contraindications to exercise.

3.6.4.2. *Prescribing an individualized exercise program*

The principles of exercise prescription for pregnant women do not differ from those for the general population. A thorough clinical evaluation should be conducted before recommending an exercise program to ensure that a patient does not have medical reasons to avoid exercise. Table 7 lists examples of safe and unsafe physical activities in pregnancy. Women with uncomplicated pregnancies should be encouraged to engage in physical activities before, during and after pregnancy (30).

The use of ratings of perceived exertion may be the most effective mean to monitor exercise intensity during pregnancy than heart-rate parameters, because blunted and normal heart-rate responses to exercise have been reported in pregnant women. One of the most used scales that rates the perceived exertion during exercise is the Borg scale. It matches how hard the person perceives the workout with numbers from 6 to 20; thus, it is a subjective scale. For moderate-intensity exercise, ratings of perceived exertion should be 13-14 (somewhat hard) on the 6-20 Borg scale (Table 8) (52).

Women should be advised to remain well hydrated, avoid long periods of lying flat on their backs, and stop exercising if they have any of the warning signs shown in Table 9 (30).

Table 8. The Borg scale for ratings of perceived exertion (52).

6	
7	Very, very light
8	
9	Very light
10	
11	Fairly light
12	
13	Somewhat hard
14	
15	Hard
16	
17	Very hard
18	
19	Very, very hard
20	

Pregnant women who were sedentary before pregnancy should follow a more gradual progression of exercise, because pregnancy is not a time for greatly improving physical fitness. Women who have attained a high level of fitness through regular exercise before pregnancy should exercise caution in engaging in higher levels of fitness activities during pregnancy. Further, they should expect overall activity and fitness levels to decline somewhat as pregnancy progresses (31). High-intensity or prolonged exercise in excess of 45 minute can lead to hypoglycemia and, in a long term, to weight loss, which may adversely affect fetal growth; therefore adequate caloric intake before exercise, or limiting the exercise session, is essential to minimize this risk (30).

Table 9. Warning signs to discontinue exercise while pregnant (30).

- Vaginal bleeding
- Regular painful contractions
- Amniotic fluid leakage
- Dyspnea before exertion
- Dizziness
- Headache
- Chest pain
- Muscle weakness affecting balance
- Calf pain or swelling

3.6.4.3. *Special populations*

Several reviews have determined that there is no credible evidence to prescribe bed rest in pregnancy which is most commonly prescribed for the prevention of preterm labor. The ACOG's position is that "bed rest is not effective for the prevention of preterm birth and should not be routinely recommended" (30). Patients prescribed prolonged bed rest or restricted physical activity are at risk of venous thromboembolism, bone demineralization and deconditioning. In most cases, allowing ambulation should be considered (31).

3.6.5. *Recommendations summary*

Regular physical activity in all phases of life, including pregnancy, promotes health benefits. Current guidelines make the following recommendations:

- Physical activity in pregnancy has minimal risks and has been shown to benefit most women by improving or maintaining physical fitness, helping with weight management, reducing the risk of GD and enhancing psychologic well-being; although some modifications to exercise routines may be necessary because of normal anatomic and physiologic changes and fetal requirements.
- For healthy pregnant women, the guidelines recommend at least 150 minutes per week of moderate-intensity aerobic activity.
- Women who practice physical activity have to consume a diet suited to their needs.
- A thorough clinical evaluation should be conducted before recommending an exercise program to ensure that a patient does not have a medical condition to avoid exercise, thus, women with uncomplicated pregnancies should be encouraged to engage in aerobic and strength conditioning exercises before, during and after pregnancy.
- Pregnant women with medical or obstetric complications are frequently bed rest prescribed, but in most cases, allowing ambulation should be considered.
- Additional research is needed to study effects of exercise on pregnancy-specific outcomes, and to clarify the most effective behavioral counseling methods and the optimal intensity and frequency of exercise (13,30,31).

4. JUSTIFICATION

Pregnancy is a time at which many women are at risk of gaining excessive weight (15). GWG is a normal and expected component of healthy pregnancy (1) but it becomes a problem when this gaining is excessive. Several studies talk about the influence of EGWG towards the mother and offspring health and have found that higher maternal GWGs are associated with multiple maternal and neonatal complications such as GD, hypertensive disorders, increased risk of cesarean delivery, preterm labor, increased PWR, macrosomic infants and long-term obesity (1,3,12,15,53,54).

As we have seen, in Girona there is a proportion of women with that problem that can not be underestimated and the measures applied by standard care, which are general guidelines (13), are not enough to address this problem which is increasing over time in industrialized countries (3). For all these reasons, GWG has to be taken in consideration as a serious problem for pregnant women and their offspring health and because of the great repercussions on the health system.

GWG is a consequence of a consistent positive energy balance, and for this reason, it may be modifiable by physical activity (3). As pregnancy is a period characterized by a greater awareness of health and care, pregnant women are more likely to make changes in their lifestyle (55).

Although there are physical activity recommendations according to ACOG guidelines (30) that encourage women, without contraindications, to be physically active throughout pregnancy and to have at least 20-30 minutes of moderate-intensity exercise on most of the days, this guideline does not define moderate intensity and does not describe the specific amount of weekly energy expenditure required from physical activity (55). So there is not enough data about an appropriate controlled exercise program.

Current literature has shown that exercise during pregnancy can provide several benefits (3), however, although it seems that an exercise program during pregnancy might help to prevent EGWG, there is controversy among scientific literature. Thus, a meta-analysis ratifies in a revision that most of the studies analyzed do not show statistically effects on maternal complications, and few report significant effects on adverse neonatal

outcomes. It concluded that more high-quality randomized controlled trials with adequate sample sizes are required to evaluate the effectiveness of potential interventions (53). On the other hand, some studies reveal significant associations among physical exercise and the decrease of EGWG (25,55).

All the arguments exposed encourage us to create a supervised physical exercise program for pregnant women, which tries to represent the ACOG guidelines recommendations in a set of physical exercises adapted to their needs.

Some studies that assess the role of physical exercise in pregnancy outcomes use intervention protocols that are different from ours: individual counseling at several prenatal visits (56), follow-up studies by telephone (57), observational studies in which the information related with physical activity developed by the pregnant woman is collected through questionnaires (55) or studies that evaluate the effect of a dietary and physical intervention (58).

Many pregnant women do not engage in physical activity unless they are advised by their physicians to do so (25). If controlled and safe programs are designed, supported by scientific evidence, apart from offering this safety to pregnant women with suitable guidelines to live a healthy pregnancy, cost reduction could be provided to public health by reinforcing on prevention. Offering a dynamic controlled exercise program with sessions variety, security provided by the supervision of specialists in sports science and shared with other pregnant women, presages us a high level of adherence, and therefore, effective results. Our study intervention is explicitly focused on the potential effect of physical activity because diet is difficult to quantify and we would never be sure if women involved in the study would comply with the proposed diet.

In conclusion, the aim of our study is to increase scientific evidence on the fact that a controlled exercise program applied to pregnant women who their pregnancy will be controlled by our reference ASSIR[1] (Atenció a la Salut Sexual I Reproductiva), can be a possible element on the prevention of certain pregnancy disorders. If we were able to prove that, this program could be offered as a health system service for all pregnant women.

[1] Our reference ASSIR is the ASSIR Gironès-Pla de l'Estany, which includes the population of Girona, Sarrià de Ter, Celrà and Banyoles.

5. HYPOTHESIS

- A supervised exercise program applied to pregnant women protects against excessive gestational weight gain.

- A supervised exercise program applied to pregnant women protects against the short-term obstetric outcomes (gestational diabetes, pregnancy-induced hypertension, increased risk of cesarean delivery, preterm labor, increased postpartum weight retention) and short-term neonatal outcomes (macrosomic or large-for-gestational-age infants) that result from excessive gestational weight gain.

6. OBJECTIVES

6.1. Main objective

The main goal of this study is to examine the impact of a supervised exercise program applied to pregnant women on the incidence of excessive gestational weight gain compared to patients that just attend to standard maternity care in the reference centers included in the ASSIR Gironès-Pla de l'Estany.

6.2. Secondary objectives

- To assess if the supervised exercise program also reduces other complications arising from excessive gestational weight gain.

- To identify facilitators and barriers that influence the performance of exercise during pregnancy.

- To assess the pre-pregnancy physical activity among the participant women.

7. METHODS

7.1. Study design

This study will be a randomized, controlled, open-label clinical trial. Each patient will be randomly assigned to one of the two groups in a 1:1 ratio. One group will receive the standard care counselling provided in the regularly scheduled visits with prenatal care providers which consists in general guidelines about an appropriate physical activity and general dietary intake. The other group will also receive the standard care counselling plus a controlled exercise program.

Then the groups will be stratified according to the women's pre-pregnancy BMI. Patients will be followed-up during the pregnancy, controlling their GWG and their BP as in each regular prenatal visit, also a screening of their glucose levels with the O'Sullivan test will be performed at the second trimester visit in their reference primary care centre, or at first trimester visit (in case of obesity, ≥35 years, personal history of GD or history of diabetes in first degree relatives) or at third trimester visit (in those who have not been studied in the 2nd trimester and in those who, although the study was negative, later develop complications that are characteristically associated with GD like fetal macrosomia or polyhydramnios) with the O'Sullivan test or OGTT (Oral Glucose Tolerance Test) (59). The OGTT will be performed in Santa Caterina Hospital, if it is indicated. The ultrasound controls will be done in the same way as are normally performed, that is, one per trimester in HUDJT, in order to control the fetus development. During delivery will be assessed whether the birth is natural, instrumented or if a cesarean is needed, and also if it is a preterm, full-term or post-term labor. Once the child is born, his or her weight will be controlled in order to determine if it is correct according to their gestational age or if it is a low-weight, adequate weight or macrosomic newborn. Finally, we will asses via telephone interview at 6 months post-delivery if exists postpartum weight retention. It will be calculated as the difference between maternal weight at 6 months postpartum and self-reported pre-pregnancy weight.

The study will be conducted with the patients who attend to the reference centers included in the ASSIR Gironès-Pla de l'Estany, which embraces the population of Girona, Sarrià de Ter, Celrà and Banyoles. Each locality will perform the routine

prenatal visits with midwives in their corresponding primary care centre. At the time of performing the ultrasound controls by the gynecologists and to give birth, all of them will attend to HUDJT, as it is already established. HUDJT will be the coordinator centre of the study. Thus, we can perform the pregnancy and delivery monitoring of our reference zone.

7.2. Study subjects

The population of the study will be every pregnant woman with any medical-obstetric contraindication for practicing a moderate-intensity exercise program, once they accept and sign the informed consent (see Annex 2) to participate in the study. They will be recruited when they attend to their first trimester ultrasound examination in HUDJT and complete all the following inclusion and exclusion criteria.

7.2.1. *Inclusion criteria*

- Pregnant women aged from 18 to 40 years
- Women with singleton pregnancies
- Gestational age less than 13 weeks
- Pregnant women who do not participate in any other exercise program
- Pregnant women who are able to understand and express in the Spanish or Catalan language
- Pregnant women who attend to prenatal control
- Pregnant women who undertake to attend at least 80% of classes if they are in the intervention group
- Pregnant women who have signed the informed consent form

7.2.2. *Exclusion criteria*

- Pregnant women who have pre-gestational diabetes
- Pregnant women who have pre-pregnancy hypertension
- Pregnant women who have had more than one previous abortion
- Pregnant women who have hemodynamically significant heart disease
- Pregnant women who have placenta previa
- Pregnant women with intrauterine growth restriction
- Pregnant women with premature labor risk
- Pregnant women who have incompetent cervix or cerclage

- Pregnant women who have severe anemia
- Pregnant women who have restrictive lung disease
- Pregnant women with extreme morbid obesity
- Pregnant women with extreme underweight (BMI less than 12)
- Pregnant women with orthopedic limitations
- Pregnant women who are heavy smokers
- Pregnant women with an acute infectious illness
- Pregnant women that reside outside Girona, Sarrià de Ter, Celrà or Banyoles
- Pregnant women who are not planning to give birth at Hospital Universitari Doctor Josep Trueta

7.2.3. *Subjects withdrawal criteria*

1- Patient decision: the subject can withdraw her consent to participate in this study at any time and for any reason and will be considered as a dropout. At patient request, all previously added data will be destroyed from the study database.

Withdrawal of patients from this study is not predicted to be huge because of the greater awareness of health and care that pregnant women have, and because they are more likely to make changes in their lifestyle.

2- Investigator decision: each investigator participating in this study can consider the convenience of the withdrawal of a patient in case of she does not follow the instructions of the study.

7.2.4. *Protocol withdrawal criteria*

- Belatedly identified violation of the inclusion and/or exclusion criteria.
- A failure to complete the protocol requirements.
- Apparition of warning clinical signs and symptoms (vaginal bleeding, regular painful contractions, amniotic fluid leakage, dyspnea before exertion, dizziness, headache, chest pain, muscle weakness affecting balance, calf pain or swelling) lead to discontinue the exercise program.

7.3. Sample size and selection

A consecutive and non-probabilistic sampling will be done, involving every pregnant woman who comes to HUDJT in their first trimester ultrasound examination.

Accepting an alpha risk of 0.05 and a beta risk of 0.2, to asses if there is truly difference between the standard care counselling and the realization of the controlled exercise program in the prevention of EGWG during pregnancy, 338 patients (169 in each group) are required to demonstrate a 50% reduction in the incidence of EGWG with the controlled exercise program in pregnant women, taking as reference a 34.2% rate of EGWG in the control group extracted from the Barakat et al study (25). It has been anticipated a drop-out rate of 0.1. Sample size is obtained by GRANMO power calculator with the use of ARCOSENO approximation.

7.3.1. *Time of recruitment*

Around 1.000 pregnant women with singleton gestations attend to one of the ASSIR Gironès-Pla de l'Estany reference centres to control their pregnancies and then come to give birth to HUDJT every year. Considering that about a 40% of the candidate patients may not want to participate or may not meet all the inclusion and exclusion criteria, we estimate that we will need around 12 months to recruit the 338 patients, and after that we would need 6 more months to follow-up the patients in order to assess the postpartum weight retention. Thus, we will need a total of 1 year and a half to complete the study.

7.4. Interventions

7.4.1. *Randomization*

Pregnant women will be randomized by a statistical specialist once they meet the established criteria and after the informed consent form has been signed. Randomization will be done with IBM's SPSS version 22.0 or higher. Patients' data will be confidentially maintained by assigning every patient an identification number, generated by the same software before randomization.

They will be included in one of the following groups:

- First group: pregnant women will receive standard prenatal care from a midwife recommended by the Generalitat de Catalunya Health Department (13).
- Second group: pregnant women will receive general counselling and a controlled exercise program

After randomization, every participant member, except for statistician, will know which approach the patient will undergo, as a double-blind is not possible in this trial.

Not a single member of the team will be able to modify in which approach the patient is included.

7.4.2. *Description of intervention*

General considerations for the activities design:

- All the activities done are aerobic.
- Work positions in which areas that are normally overloaded by pregnancy could become even more harmed are avoided.
- The work corresponding to the flexibility has been carried out always taking into account that they are pregnant women, this forced us once again not to include forced operating positions in the exercises, nor to maintain excessively the times of stretching of each muscle zone.
- An adequate intake of calories and nutrients is maintained prior to the activity.
- Avoid activities that include Valsalva maneuver.
- Avoid high temperatures or very humid environments with the aim of avoiding hyperthermia (body temperature greater than 38°C).
- Avoid sudden, jerky movements.
- Avoid extreme muscle tension positions.

7.4.2.1. *Duration*

Start of the program: 10-13 gestational weeks

End of the program: 37-40 gestational weeks

Sessions' number: 54-60.

Sessions' duration: land (55 minutes); aquatic activities (46 minutes)

7.4.2.2. *Frequency*

Frequency: 2 sessions per week. One day on land (Sports centre GEIEG) and the other day in water (Can Gibert del Pla Municipal Pool).

7.4.2.3. *Intensity*

Both, dry and water exercises will be carried out at a moderate intensity with an approximate caloric cost per session of 300 kcal. In all sessions the greatest increase in work intensity will be concentrated in the central part of the class. The prescribing process is carried out from the supervision of the work team obstetrician professionals and according to the nature of the pregnancy process, decreasing the intensity of the exercises towards the last two weeks of gestation, taking into account the logical increase of the growing uterus volume.

The intensity will be assessed with the Borg Scale for ratings of perceived exertion (43). As we have explained in the introduction, this scale rates from 6 to 20. For the sessions we will maintain a moderate-intensity level (ratings of perceived exertion of 13-14 (somewhat hard)).

7.4.2.4. *Facilities*

Land: Sports centre GEIEG

Multipurpose room of 180 m^2, humidity: 66% and height: 8.50 m.

Water: Can Gibert del Pla Municipal Pool

One small tank: measures: 6x12 m; depth: 70-110 cm; temperature: 28.5-29°C.

7.4.2.5. *Exercise program design*

The exercise program has been designed by Sandra Perich and Montse Vidal, a medical student and a graduate in sports science with great experience in the exercise performed on pregnant women. This program will be supervised by Dra. Alexandra Bonmatí, a member of the obstetrics and gynaecology department of the HUDJT.

The physical exercise program is composed of 2 weekly sessions as stated: one on land (gym hall) and one as an aquatic based activity (small pool tank). Apart from that,

women can go for a fast walking on flat surface during 30 minutes the rest of the week that will have to be documented to the staff responsible for the study. All the activities are based on aerobics: work with their own body weight and/or with external dumbbells up to maximum of 2 kg, light floats for resistance exercises and ping pong balls for the breathing exercises in the case of aquatic sessions. Positions involving zones normally overloaded by pregnancy are avoided. In relation to flexibility, forced positions are not included in the exercises, nor excessive movements when stretching each muscular zone. As a general rule and to eliminate potential risks, activities which include Valsalva mechanism are avoided, as well as high room temperatures or very humid environments. We consider that the correct number of women per physical trainer is about 10-15, in order to be able to control if the exercises are performed properly and correct them if necessary. As women participating in the study increase, two shifts will be needed, in order to have enough space in the aquatic activities and to have the adequate number of women per physical trainer.

7.4.2.5.1. *On land session*

The dry sessions are divided into specific parts. The first phase of activation is composed of various displacements following distinct forms and joint movements with rotation. After this, the main part, consisting of body toning which is achieved through muscular exercises directed upon all muscles, avoiding the muscular imbalance typical of pregnancies (especially pains in the paravertebral zone). A program of 20 repetitions is carried out for each muscular group, divided into the upper body muscles, the trunk and the lower body muscles. In this part we will also perform breathing and pelvic floor exercises. As to the pelvic floor exercise block, it consists of work focused on slow and fast contractions of the involved areas, in different positions and gradually increasing the volume of work. In the final cool down phase, work is centred upon the flexibility of the muscular groups most affected by the development of the sessions and by the pregnancy itself: lumbar area, gluteus, psoas, calf muscle, neck and shoulders. We have several different exercises to train the same muscle groups that we will alternate in the different sessions in order to be more varied and enjoyable for the pregnant women (see Annex 3).

Material resources: mats, 1 kg dumbbells, 2 kg dumbbells, light wooden bars and benches.

Speakers with an iPod or mobile phone connection are available which provides a continuous change in music and motivation in the classes.

7.4.2.5.2. *Aquatic activities*

As to the sessions of aquatic activities, all the exercises take place in the small pool tank for ensure safety to the pregnant women. An initial activation in the pool is established with various displacements and smooth movements of the upper and lower body. The central part of the session consists of several exercises and aquatic activities with the aim of toning and working aerobic resistance like propulsion, leg movements, standing on tiptoe and then getting back down, etc. all of this using the support material that will be detailed later. Also in this part, breathing exercises with ping pong balls will be performed in order to work the respiratory capacity that is diminished by the increase of uterus volume. The final part is composed of flexibility and relaxation exercises (see Annex 3).

Material resources: foam-rubber balls of different sizes, swimming accessories such as floats, pull-boys (buoyancy aiding devices), water noodles, kickboards, light wooden bars, ping pong balls, straws and balloons.

7.4.2.5.3. Timing of sessions

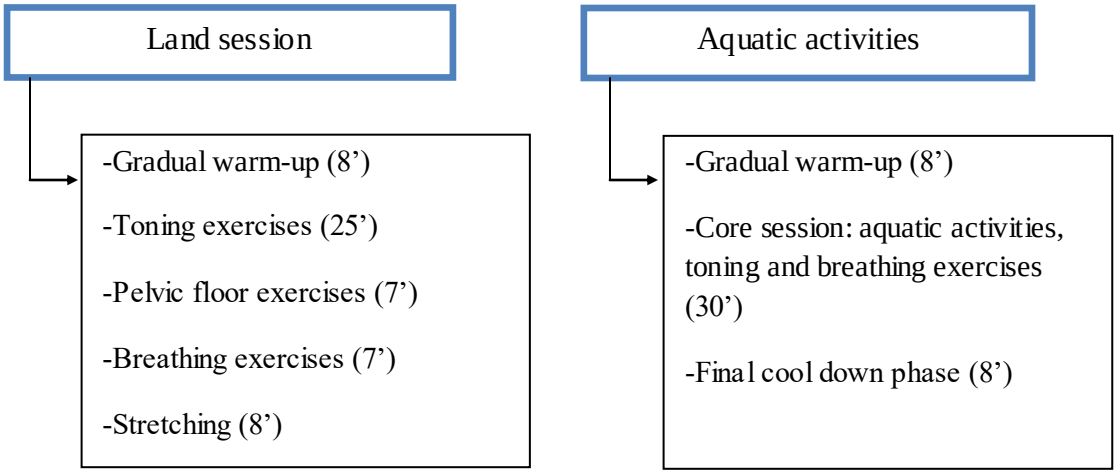

Figure 8. Timing of sessions.

7.5. Variables

7.5.1. *Independent variable*

The independent variable of this study is the *controlled exercise program* applied to pregnant women that includes two weekly sessions, one land session and another aquatic session, or receiving the *general counselling* by the midwives. Independent variable's expression will be in proportions or percentages of pregnant women receiving whether the controlled exercise program or the general counselling, as it can be defined as a nominal dichotomous qualitative variable.

7.5.2. *Dependent variable*

The main dependent variable of this study is the *excessive gestational weight gain*, defined as the proportion or percentage of pregnant women who achieve a gestational weight gain superior to the one recommended according to their pre-pregnancy BMI. Excessive gestational weight gain is a continuous quantitative variable, and in this case is expressed as well as a continuous quantitative variable.

7.5.3. *Secondary dependent variables*

Maternal variables

- *Gestational diabetes*, defined as the proportion or percentage of pregnant women in the control or intervention group who develop this disease. Gestational diabetes is a nominal qualitative variable, which will be expressed as a continuous quantitative variable, confirmed by measuring whether the following tests are positive or negative:
  - *O'Sullivan Test*: this screening test involves the determination of plasma glucose one hour after giving 50 g of oral glucose. The test is considered positive when the values are ≥140 mg/dl. This result is suspicious of gestational diabetes and to confirm the diagnosis we proceed to perform the OGTT. However, if baseline glycaemia is >126 mg/dl or a causal glycaemia is >200 mg/dl, neither O'Sullivan Test nor OGTT are required, and there is an immediate diagnosis of gestational diabetes.
  - *OGTT:* this diagnostic test involves the determination, firstly, of plasma glucose in basal conditions, and then the determination of plasma glucose in

one, two and three hours after giving 100 g of oral glucose. The finding of two or more points ≥ of the following values will be considered as a diagnosis of gestational diabetes: (basal: 105 mg/dl, one hour: 190 mg/dl, two hours: 165 mg/dl, three hours 145 mg/dl) (59).

- *Pregnancy-induced hypertension*, defined as the proportion or percentage of pregnant women in the control or intervention group who develop this medical entity during pregnancy. Hypertension induced by pregnancy is a nominal qualitative variable, but in this case is expressed as a continuous quantitative variable. Gestational hypertension is defined as elevated BP (SBP ≥140 and/or DBP≥90) that develops after 20 weeks of gestation in a previously normotensive woman without proteinuria (25).
- *Cesarean delivery*, defined as the proportion or percentage of pregnant women in the control or intervention group who have a cesarean delivery. We consider that delivery can be vaginal, instrumental or a cesarea. Cesarean delivery is a nominal qualitative variable, but in this case is expressed as a continuous quantitative variable.
- *Preterm labor*, defined as the proportion or percentage of pregnant women in the control or intervention group who develop this entity. Preterm delivery is a nominal qualitative variable, but in this case is expressed as a continuous quantitative variable. Depending on the gw at the time of delivery, this can be a preterm (<37gw), full-term (37-42gw) or post-term (>42gw) labor thus, it will be expressed also as a continuous quantitative variable.
- *Postpartum weight retention*, expressed as the proportion or percentage of pregnant women in the control or intervention group who retain too much weight after delivery (the control will be at the 6^{th} month after the delivery). This variable is defined as a continuous quantitative variable. We will consider postpartum weight retention if the weight increase from pre-pregnancy is >4.5 kg. It will be calculated as the difference between maternal weight at 6 months postpartum and self-reported pre-pregnancy weight.

Newborn variables

- *Birth weight*, defined as a continuous quantitative variable, will be expressed as the proportion or percentage of newborns who have an adequate (2.500-4.000g),

a low (<2.500g) or a macrosomic (>4.000g) weight depending on their mothers' treatment group, thus, it will be expressed also as a continuous quantitative variable.

- *Birth lenght*, defined as a continuous quantitative variable, will be expressed as the proportion or percentage of newborns who have a low (<3rd percentile), adequate (3rd-90th percentiles) or superior length (>90th percentile) depending on their mothers' treatment group, thus, it will be expressed also as a continuous quantitative variable.

7.5.4. *Co variables*

- *Age:* from 18 to 40 years old. We are going to collect this variable as a discrete quantitative variable. It will be expressed in years.
- *Pre-pregnancy BMI:* We are going to collect this variable as a continuous quantitative variable. It will be expressed in kg/m^2.
- *Height:* We are going to collect this variable as a continuous quantitative variable. It will be expressed in cm.
- *Country of origin*: We are going to collect this variable as a nominal qualitative variable. We will know it by the information in the clinical history.
- *Parity:* We are going to collect this variable as a discrete quantitative variable. It will be expressed as number of labours.
- *Marital status*: We are going to collect this variable as a nominal qualitative variable. It will be expressed as married, cohabiting, single not living with partner, others.
- *Employment status:* We are going to collect this variable as a nominal qualitative variable. It will be expressed as homemaker, not employed or employed.
- *Educational level*: We are going to collect this variable as an ordinal qualitative variable. It will be expressed as grammar school, secondary school, vocational training school or university level.
- *Socioeconomic status*: We are going to collect this variable as an ordinal qualitative variable. It will be expressed as low, medium or high.
- *Smoking habit:* We are going to collect this variable as a dichotomous nominal qualitative variable. It will be expressed whether they smoke or not (YES/NO).

- *Family history of diabetes:* We are going to collect this variable as a dichotomous nominal qualitative variable. It will be expressed whether it is present or absent (YES/NO).
- *Family history of hypertension:* We are going to collect this variable as a dichotomous nominal qualitative variable. It will be expressed whether it is present or absent (YES/NO).
- *A previous miscarriage:* We are going to collect this variable as a dichotomous nominal qualitative variable. It will be expressed whether it is present or absent (YES/NO).
- *Previous gestational diabetes in pregnancy:* We are going to collect this variable as a dichotomous nominal qualitative variable. It will be expressed whether it is present or absent (YES/NO).
- *Previous pregnancy-induced hypertension*: We are going to collect this variable as a dichotomous nominal qualitative variable. It will be expressed whether it is present or absent (YES/NO).
- *Previous pregnancy-induced overweight or obesity*: We are going to collect this variable as a dichotomous nominal qualitative variable. It will be expressed whether it is present or absent (YES/NO).
- *History of low birth weight:* We are going to collect this variable as a dichotomous nominal qualitative variable. It will be expressed whether it is present or absent (YES/NO).
- *History of preterm delivery:* We are going to collect this variable as a discrete quantitative variable. It will be expressed as number of preterm births.
- *Exercise habits before gestation:* We are going to collect this variable as an ordinal qualitative variable. It is going to be assessed by an exercise questionnaire given to pregnant women before starting the clinical trial (see annex 4). It will be stratified into 3 levels of physical activity intensity: sedentary/light, moderate or vigorous.
- *Extra exercise practice during the current gestation:* We are going to collect this variable as a dichotomous nominal qualitative variable. It will be expressed whether it is present or absent (YES/NO) and will be applied in the intervention group in case they practice physical activity more days than the ones involved in the controlled exercise program.

7.6. Measure tools

The different measure tools that we are going to use during the study are:

- *Calibrated platform scale,* to measure the pregnant women's weight in each control visit.
- *Calibrated wall stadiometer,* to measure the pregnant women's height in the first control visit.
- *Ultrasound machine,* to control the fetus development in each control visit.
- *Electronic sphygmomanometer,* to measure the pregnant women's BP in each control visit.
- *Blood tests,* to determine glucose in venous plasma, in order to diagnose GD. Blood tests will be determined by adding sodium fluoride or another similar agent when the analysis is not done immediately.
- *Calibrated pediatric balance beam scale,* to measure the newborns' weight.
- *Calibrated infantometer,* to measure the length of the newborns.
- *International Physical Activity Questionnaire (IPAQ)*: a validated Spanish version will be used (see Annex 4). The unit measure used in the test is MET (metabolic equivalent of task). Its calculation is specified at the end of the questionnaire and will be done by the research team. According to the scores obtained, the level of physical activity will be classified according to low, moderate or high.
- *Family data Questionnaire*: a validated Catalan version will be used (see Annex 5). The patient only has to mark options or fill the data requested.
- *Physical Activity Questionnaire during Pregnancy*: a validated Catalan version will be used (see Annex 6). Each of the six possible responses has a score associated from 1 to 6 (first answer = 1, second answer = 2, ...).
- *Perception of Facilitators and Barriers to perform Physical Activity during Pregnancy Questionnaire*: a validated Catalan version will be used (see Annex 7). The responses are classified whether they are facilitators (8) or barriers (13). Facilitators punctuation range from 8 to 32 and barriers punctuation range from 13 to 25. Each response score is specified in the questionnaire.

7.7. Data collection

Before starting the protocol

In each of the involved centres we will assign a principal investigator (an obstetrician), and a co-investigator (a midwife) in order to control all the variables evaluated in the pregnant women involved in the study.

First visit

Pregnant women will attend to their first trimester ultrasound examination, ideally established between the 8^{th} and 12^{th} gestational weeks, in HUDJT. Midwife will perform a good anamnesis and a complete physical exploration. If the pregnant woman is recognized as a possible candidate for the study, because she seems to accomplish the study criteria, the physician or midwife (part of the work team) will ask her to take part of it giving the necessary information. It is important to aware the patients about the possibility to not be chosen for the study because of the inclusion and exclusion criteria. If the patient wants to participate, the physician or midwife will give an information sheet (see Annex 1) explaining in an easy and understandable way how the study will be conducted. A member of the research team (a midwife) will collect the following particulars: anthropometric and body composition (weight, height and BMI), socio-demographic characteristics, pregnancy data and pre-pregnancy physical activity through two questionnaires (see Annex 4 and 5).

As we have said, physical exploration will include anthropometry and body composition measurements. Weight will be measured twice with a calibrated platform scale with the woman barefoot and in light clothing in pregnancy weeks 12, 20, 32 and 39. Height will also be measured twice, using a wall stadiometer with the woman barefoot, upright and with the sagittal midline touching the back board. BMI will be calculated as weight in kg divided by the square of the height in meters. Self-reported weight will be used to calculate pre-pregnancy BMI. Also the BP will be measured twice with an electronic sphygmomanometer by the midwife in pregnancy weeks 12, 20, 32 and 39.

The gestational age will also be stabilised by the last menstruation period or by the first trimester ultrasound measurement.

Socio-demographic characteristics will include age (years), marital status (married, cohabiting, single not living with partner, others), place of residence, country of origin, educational level (grammar school, secondary school, vocational training school and university level), socioeconomic status (low, medium, high), employment status (homemaker, not employed, employed), and pre-pregnancy weight.

Pregnancy data will include gestational age (weeks + days), number of fetuses, smoking habit, medication, health problems (preterm delivery, hypertension, GD, previous miscarriages, intrauterine growth restriction, oligoamnios, heart disease, placenta previa, premature labor risk, incompetent cervix or cerclage, anemia, lung disease, infectious illness, orthopedic limitations).

The O'Sullivan Test and, if indicated, the OGTT will be done if it is a risk pregnancy for developing GD.

With all this data the physician will be the responsible to decide if the patient meets all the requirements. The physician can notify to the patient that she can join the study during that visit or during the following days with a phone call and so the informed consent (see Annex 2) will be signed the same day of the first visit, or if there is no time, the first day of the study. If the patient can not take part of the study because she does not accomplish the criteria, physician or midwife will explain it to her in the most respectful way.

Also in this visit, the patient will receive another questionnaire about the facilitators and barriers that pregnant women identify during pregnancy about the sports practice (see Annex 7), which can be answered on the same visit or it can be delivered on the first day that the study begins.

Patients will be cited for the start of the study during the following weeks. All patients will have a meeting in the HUDJT conference room with the research team (a representative of each specialty will be present consisting of an obstetrician, a midwife and a physical trainer), where they will explain in more detail the characteristics of the exercise program such as the facilities where it will be done, schedule, attendance, types of exercises to be performed, etc. and they also will resolve any doubts that could remain.

Starting the study

The patients who have not signed the informed consent yet, will do. Patients have to know that they can quit the study at any time although they have signed the informed consent.

They will be randomly divided into one of the two groups.

Second visit

The second trimester ultrasound examination is performed between the 18th and 20th gestational weeks also in HUDJT. In this second visit we will examine the fetus development (the anatomic ultrasound), we will control again the pregnant woman's weight and BP. The O'Sullivan Test will be performed at their reference primary care centre depending on their location between the 24th and 28th gestational weeks and, if indicated, the OGTT (which is performed in Sta. Caterina Hospital) to diagnose GD. In this second visit, patients allocated in the control group will have to answer a questionnaire in order to control their physical activity during pregnancy (see Annex 6).

Third visit

The third trimester ultrasound examination is performed between the 34th and 36th gestational weeks also in HUDJT. In this third visit we will examine again the fetus condition and we will control again the pregnant woman's weight and BP. The O'Sullivan Test and, if indicated, the OGTT will be done if the pregnant women meet some of the mentioned criteria in section 7.1.

In this third visit, patients allocated in the control group will be asked again about their physical activity during pregnancy.

Delivery and post-partum period

After delivery, the following outcome measures will be collected: pregnancy data (anthropometry and body composition, pregnancy-induced hypertension, GD), delivery data (type of delivery: normal/instrumented/cesarean, time of delivery: preterm/full-term/post-term) and data of the newborn (weight, length, sex).

Data regarding to pregnancy, delivery and newborn will be collected from medical records through a questionnaire by research members.

During the post-partum period we will asses via telephone interview at 6 months post-delivery if exists postpartum weight retention. Women will be classified as having postpartum weight retention if the weight increase from pre-pregnancy is >4.5 kg. It will be calculated as the difference between maternal weight at 6 months postpartum and self-reported pre-pregnancy weight and will be registered.

7.7.1. *Study scheme*

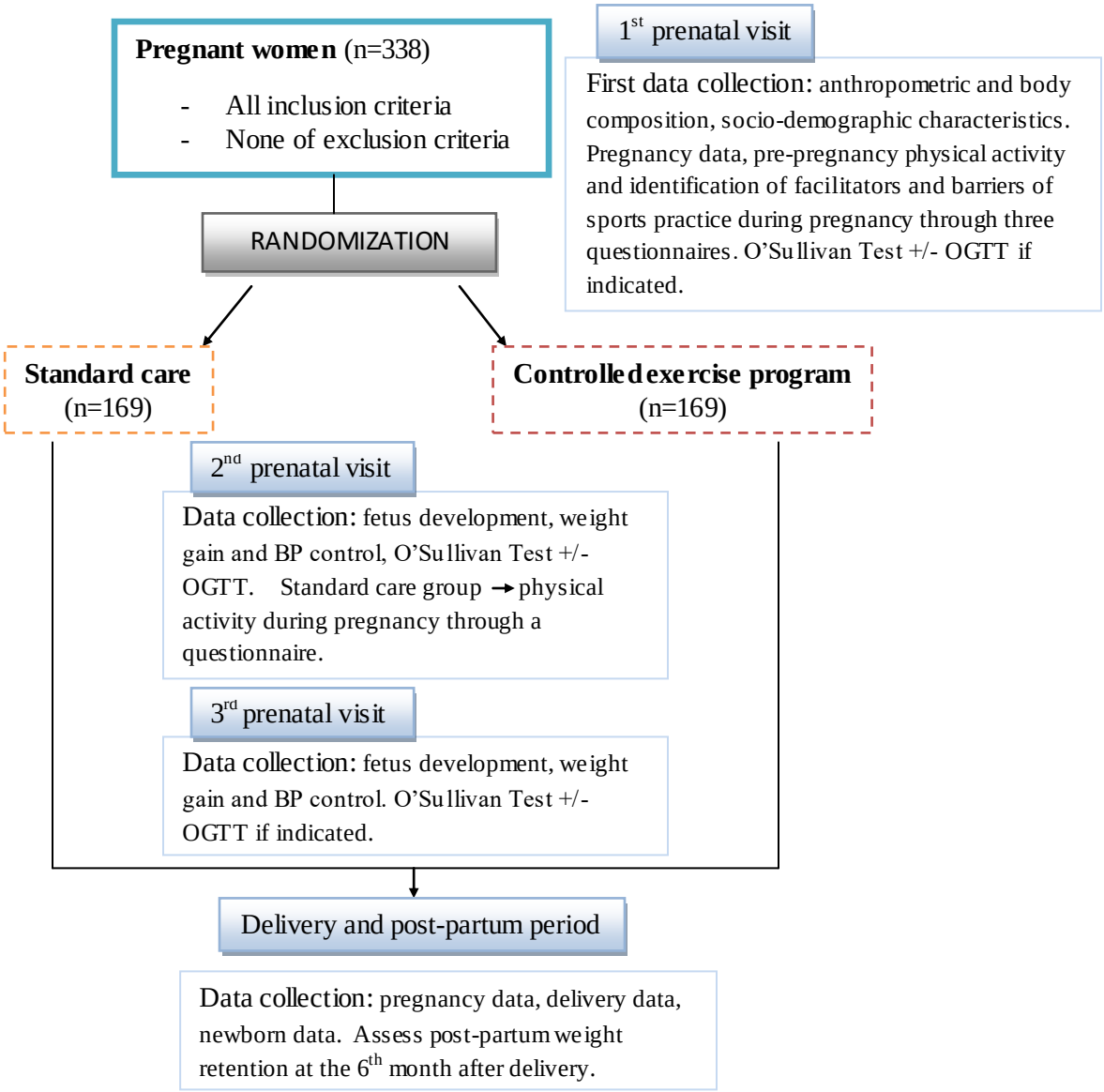

Figure 9. Study scheme.

8. STATISTICAL ANALYSIS

Statistical analysis will be performed using Statistical Package of the Social Science (SPSS) software v22.0 or higher and the computed data will be managed with Microsoft Excel program (it is available for Microsoft and Mac). Kolmogórov-Smirnov test will be applied to determine if the variables follow a normal distribution.

In all analyses, probability values $p \leq 0.05$ will be considered statistically significant and $p \leq 0.001$ will be considered as highly significant. Confidence intervals (CI) will be expressed as 95%.

In the *univariate analysis,* we will define variables as quantitative or qualitative:

- Quantitative variables will be described with the mean +/- standard deviation, presupposing a normal distribution. If the variable is not normally distributed, median and H-spread will be used.
- Qualitative variables will be described as proportions or percentages (n/%).

In the *bivariate analysis,* when we analyse the main dependent variable (excessive gestational weight gain defined as the proportion or percentage of pregnant women who achieve a gestational weight gain superior to the one recommended) and, on the other hand the secondary dependent variables, we will adjust for the pre-pregnancy BMI category as IOM recommendations are based on these categories.

- For quantitative variables, Mann-Whitney or t-Student tests will be done.
- For qualitative variables analysis, chi-squared test will be used.

In the *multivariate analysis,* a type of probabilistic statistical classification model will be performed such as a logistic regression analysis in order to add the co variables that could skew the main association we want to analyse.

Missing data: The study requires a strong presence of the patient at the hospital and in the controlled exercise program (if included in the intervention group), so it is possible to have dropouts. If this situation occurs, variables will not be collected. Intention-to-treat will be used for missing data.

9. ETHICAL CONSIDERATIONS

The research protocol has been conducted according to human's rights and ethical principles for Medical Research involving human subjects, outlined in the *World Medical Association's Declaration of Helsinki*, last time reviewed in October 2013 (Fortaleza, Brazil).

Prior to starting the study, this protocol will be presented to Clinical Research Ethics Committee (CEIC) of HUDJT for its approval.

Written Informed Consent (IC) (see Annex 2) will be obtained from each patient. The patients enrolled in the study will find all the information about the purpose of the study, the potential benefits and risks, how the investigation will be conducted and their rights as participants in the information sheet (see Annex 1); all the information will be also thoroughly explained by the investigators. The patient information won't be used without previous consent and it will be necessary sign it before taking any action.

This protocol will be developed in accordance to the Good Clinical Practices Guidelines and following the established regulatory law, as it is described in:

- Helsinki Declaration of Ethical Principles for Medical Research Involving Human Subjects, last actualization October 2013.
- Spanish data protection law "Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal", in order to protect the patients' confidentiality.
- Spanish law "Ley 14/2007, de 3 de julio, de Investigación Biomédica" about biomedical investigation.

The patients' data will be stocked up and maintained confidential in a secured system, just accessible for the investigators. Anonymization will be applied to every data introduced in the system.

Participants have the right to access, modify, oppose or remove their personal data contained in the file as well as to withdraw the study at any time.

10. STUDY LIMITATIONS

- Gestational weight gain is analyzed based on self-reported pre-pregnancy weight, which may have been underestimated by (especially) overweight and obese women, leading to an overestimation of total weight gain.
- Women in the control group are aware of participating in a trial aiming at promoting a healthy lifestyle and optimizing gestational weight gain, which may have influenced their behaviour, resulting in an underestimation of the intervention effect.
- In our study there has been no dietary control. All pregnant women receive the same dietary recommendations included in the health protocol, therefore, we consider only as independent variable the exercise. Nevertheless, it would have been interesting if there had been a nutritional control that limited possible biases.
- Our study is an open-label trial, which means that patients, doctors and the rest of the research team will know in which intervention group the patient is included. It has to be taken in consideration that it is a limitation because patients placed in the standard care group can think that they have worse conditions compared to the intervention group. For that reason, patients may want to be changed to the other group or may want to withdraw from the study.
- The study requires a lot of participation of the patient (they have to go several times to the hospital, but as a normal pregnant women, and also have to attend at least 80% of the exercise classes if they are in the intervention group). For that reason, some patients will decide to drop-out the study or would not come to the hospital or to the exercise classes all the required times. Before excluding a patient of the study, we will try to phone her to come to the appointment.
- The controlled exercise program will be conducted in Girona city. Taking into account that some of the patients participating in the study live in another location and will have to travel in their private cars or by public transport to attend to the classes, this distance in the long run can cause them to drop-out from the study, in particular during the last gestational weeks.

11. WORK PLAN

The research team involved in the study will be composed by:

- 5 obstetricians (O), one from each centre of the ASSIR Gironès-Pla de l'Estany
- 5 midwives (M), one from each centre of the ASSIR Gironès-Pla de l'Estany
- 3 physical trainers graduated in sports science (PT)
- 1 statistical specialist (SS)

The clinical trial has been designed in 5 phases:

1. **Phase 1: Coordination (3 months)**
   Activity 1: The approval of CEIC is included into this phase. One O of HUDJT will be the responsible of this.
   Activity 2: First research team meeting. Information sheet and informed consent will be designed, the final protocol will be presented and the proposed chronogram discussed. Tasks will be distributed among the research team members. O and M will discuss and organize the study's characteristics and procedures in a 4h session. PT will explain to the research team the specific characteristics of the controlled exercise program.
   Activity 3: A second research team meeting will take place, in order to review all the protocol steps and clarify any possible doubt before the start of the clinical trial.
2. **Phase 2: Recruitment, interventions and data collection (25 months)**
   Activity 4: Consecutive and non-probabilistic recruitment.
   Activity 5: Randomization
   Activity 6: Intervention
   Activity 7: Data collection
3. **Phase 3: Data analysis (3 months)**
   Activity 8: Statistical analysis will be done by the SS.
4. **Phase 4: Interpretation of results (4 months)**
   Activity 9: The research team will redact conclusions from the obtained results.
5. **Phase 5: Publication and dissemination of the research findings (6 months)**
   Activity 10: The corresponding articles will be written and research findings will be published.

12. CHRONOGRAM

			2017				2018				2019				2020
	ACTIVITY	STAFF	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Ja-M	A-J	Jul - S	Oc-De	Ja-M	Ap- Ju	Jul- S	Oct-De	Jan-Mar
PHASE 1	Ethical approval	O													
	1st meeting	ALL													
	2nd meeting	ALL													
PHASE 2	Recruiting and randomization	O, SS													
	Intervention and data collection	O, M, PT													
PHASE 3	Statistical analysis	SS													
PHASE 4	Interpretation of the results	O, M, SS													
PHASE 5	Publication of the results and dissemination of the findings	ALL													

13. FEASIBILITY

The clinical trial is performed at health centres belonging to Institut Català de la Salut (ICS), so most of the members of the research team work there, except from the statistical specialist and the physical trainers graduated in sports science, that have to be hired.

Obstetricians and midwives will receive their habitual salaries as health care workers. We only have to pay the statistic specialist and the physical trainers graduated in sports science.

As all the medical tests and measures used to obtain the data for the study are already performed routinely in the follow-up of pregnancies, this will not be an extra expense, and otherwise we will be able to take advantage of all these measures already implemented in a standardized way and which are subsidized by the ICS.

The intervention consists in a controlled exercise program carried out by experts in the field and supervised by the medical point of view of obstetricians and midwives, which provides security to the participant pregnant women and therefore, reinforces their participation. Their participation will also be increased by the fact that pregnancy is a period characterized by a greater awareness of health and care and pregnant women are more likely to make changes in their lifestyle.

The rent of the facilities and the necessary materials to carry out the exercises, as well as the contract of the physical trainers, will be the maximum cost of the study, so it is highly profitable as it can provide great benefits to pregnant women and their offspring at the expense of a non-exorbitant budget.

14. BUDGET

The budget encompasses all the possible expenses that will be needed to accomplish this study. Most of the procedures are already performed in the reference centres included in the ASSIR Gironès-Pla de l'Estany and most of the required staff already work in them, so the procedures are included in their daily duties. These tasks are counted as zero expenses.

Personnel costs		
Statistical specialist:		
30€/h x 6h/week x 3 weeks		540€
Physical trainers:		
25€/h x 3h/week x 72 weeks x 3 physical trainers		16.200€
	Subtotal	16.740€
Rental of exercise facilities and materials		
Can Gibert del Pla swimming pool + materials		
13€/h/pool line x 2h/week x 72 weeks x 3 pool lines		5.616€
GEIEG multipurpose room + materials		
30€/h x 2h/week x 72 weeks		4.320€
	Subtotal	9.936€
Other material expenses		
Questionnaires photocopies:		
0.04€/unit x 2366 units		94,64€
Information sheet and inform consent photocopies:		
0.04€/unit x 2028 units		81,12€
	Subtotal	175,76€
Publication and dissemination costs		
Approximated cost of publication		1.000€
Travel expenses		1.200€
	Subtotal	2.200€
	Total	29.051,76€
	21% indirect costs	6.100,87€
	TOTAL	**35.152,63€**

15. IMPACT ON THE NATIONAL HEALTH SYSTEM

As we mentioned the number of women who gain too much weight throughout pregnancy and the proportions of high GWG have been found to be increasing over time in industrialized countries, and specifically in the area of Girona the proportion of women with that problem can not be underestimated.

We have seen that several problems for mothers and their offspring health are associated with EGWG. These complications affect their health in the short but also in the long term many times, and as a consequence, also contribute to increase the expenses in the health system in order to treat them.

If the results obtained in this study are relevant and our hypotheses are validated we could state that this controlled exercise program is effective and can be a possible element on the prevention of all these complications, and therefore, this simple tool, as is the practice of exercise in a controlled way, could be offered as a health system service for all pregnant women.

If our study is relevant, it will lead to a decrease of all mentioned health complications which need hospital attention in the short and the long term. Not only the hospital admission and inpatient care will decrease, also the use of drugs for the treatment of diabetes or hypertension that, as we have seen, can become chronic after appearing in pregnancy, will be less used. In addition, the health of future generations would also be favored, as they will have less complications resulting from prematurity or macrosomia and therefore they will be less treated during their lifetime. In total numbers, it will be a positive fact for the society.

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17. ANNEXES

17.1. Annex 1. Information sheet

FULL D'INFORMACIÓ AL PACIENT

TÍTOL DE L'ESTUDI: Eficàcia d'un programa d'exercici controlat per la prevenció de l'augment de pes excessiu durant l'embaràs.

El seu metge o llevadora li ha proposat participar en el present estudi d'investigació. Si us plau, llegeixi amb calma la informació que a continuació li proporcionem i que li permetrà decidir, de forma totalment voluntària, si vol participar o no. No és necessari que doni una resposta en aquest moment, pot emportar-se la informació que li proporcionem i valorar-la amb calma. Pot consultar-ho amb els seus familiars, amics o altres professionals de la salut, si així ho desitja. Ha de saber que la seva participació és completament voluntària i que si decidís no participar, la seva decisió no afectaria en absolut la seva relació amb el seu metge i/o llevadora.

Per què es realitza aquest estudi i quin és el seu objectiu?

Durant l'embaràs, de forma fisiològica, les dones augmenten de pes degut al creixement i desenvolupament progressiu del fetus, l'augment de tamany de l'úter, de les mames, del volum sanguini, de les reserves de grassa per tal de poder proporcionar els nutrients necessaris per al seu correcte creixement, entre d'altres. Existeixen recomanacions que informen de l'augment de pes adequat que una dona embarassada hauria d'assolir en el transcurs del seu embaràs segons el seu índex de massa corporal (IMC) inicial abans de quedar-se en estat. El problema radica quan aquest augment de pes sobrepassa els límits recomanats i s'augmenta excessivament de pes. Nombrosos estudis han descrit la relació entre l'augment de pes excessiu durant l'embaràs i l'aparició de complicacions tan en la mare com en el nadó. Concretament en les mares s'ha vist el desenvolupament de diabetis gestacional, hipertensió induïda per la gestació, augment del nombre de naixements per cesària, augment de la taxa de parts prematurs, augment de la retenció de pes post part, i en els nadons s'ha observat augment de la taxa d'infants macrosòmics (pes massa elevat per la seva edat gestacional). Per tot això, hem dissenyat un programa d'exercici controlat especial per a dones embarassades com vostè, per tal de valorar la seva eficàcia en la prevenció de l'augment de pes excessiu durant l'embaràs i les

conseqüències derivades d'aquest per la seva salut i la del seu bebè. La pràctica d'exercici físic durant l'embaràs està recomanada i avalada per les guies de pràctica clínica ja que proporciona un gran nombre de beneficis tan per la mare com pel fetus si es realitza de forma correcta.

Per què la convidem a vostè?

La convidem a vostè perquè és una dona que actualment està embarassada i com a tal, si no té unes directrius clares a seguir durant el període d'embaràs, podria estar en risc d'augmentar excessivament de pes i desenvolupar les complicacions anteriorment descrites.

Com es realitzarà l'estudi?

Per a la realització de l'estudi es formaran dos grups, un dels quals rebrà els consells generals de salut que ja es donen actualment a les dones embarassades per part de les llevadores, i a l'altre grup, a més de donar-li aquestes pautes generals, se'ls farà assistir a un programa d'exercici controlat dos dies a la setmana d'uns 50 minuts de durada cada dia, impartit per professionals de les ciències de l'esport que durarà durant tot l'embaràs. A part d'això, les dones podran anar a fer caminates a marxa ràpida sobre una superfície plana durant 30 minuts, la resta de dies de la setmana, la qual cosa haurà de ser documentada a l'equip d'investigació. L'assignació dels pacients a un o altre grup es farà aleatòriament, és a dir, a l'atzar. Això es farà així per assegurar-nos de que els pacients dels dos grups siguin semblants. Vostè sabrà el grup al que ha sigut assignat un cop s'hagi decidit a l'atzar. Ningú pot triar ni modificar el grup al que una persona ha estat assignada aleatòriament.

Durant el transcurs de l'estudi, als dos grups se'ls farà un seguiment per tal de valorar l'evolució de l'augment de pes durant l'embaràs, l'aparició de diabetis gestacional, l'hipertensió induïda per l'embaràs i es faran els controls ecogràfics estàndards de cada trimestre per valorar el desenvolupament fetal. Al moment del part, es valoraran el nombre de dones que necessitin un part per cesària i les que presentin un part prematur, i un cop nascut el nadó, es valoraran el % de nens que hagin nascut macrosòmics (pes massa elevat). Passats 6 mesos després del part, es valorarà als dos grups, el % de dones que presentin una retenció de pes augmentada.

A totes les dones participants se'ls administraran dos qüestionaris a l'inici de l'estudi; un sobre la percepció dels facilitadors i barreres per realitzar activitat física que tenen les dones durant l'embaràs i l'altre sobre la seva activitat física abans de l'embaràs. A més, a les dones que estiguin al grup control (les que només reben els consells generals de salut) se'ls farà completar un altre qüestionari a la meitat de l'estudi per conèixer el seu grau d'activitat física en el transcurs de l'embaràs.

Quines són les meves responsabilitats?

- Assistir a totes les visites quan sigui convenient.
- Seguir les pautes que li indiquin els metges, llevadores i entrenadors físics.
- Assistir a un 80% de les classes en cas d'estar al grup d'intervenció.
- No amagar informació al personal de l'estudi i avisar-los sobre qualsevol problema que presenti en el transcurs de l'estudi.

Quins beneficis puc obtenir per participar en aquest estudi?

Els beneficis que pot obtenir participant en aquest estudi són tots aquells derivats de la pràctica esportiva amb la seguretat d'estar sota supervisió d'un professional de l'esport, a més de poder disminuir el risc d'augmentar excessivament de pes durant l'embaràs i evitar patir les complicacions descrites anteriorment.

Els resultats podran ajudar a altres dones que, en un futur, puguin estar embarassades com vostè i estiguin en risc d'augmentar excessivament de pes.

Quins riscs i/o molèsties puc patir per participar en l'estudi?

Si segueix correctament les pautes marcades no hi ha d'haver cap mena de risc ni inconvenient, ja que tots dos grups realitzen pràctiques aprovades pel consens mèdic.

Hi ha cap mena de compensació econòmica?

Cap participant rebrà cap mena de compensació econòmica, però tindrà l'oportunitat, en cas d'estar al grup d'intervenció, de poder rebre un pla d'exercici físic controlat totalment gratuït.

Quines dades es recolliran?

Es recolliran dades personals (edat, professió), dades obstètriques (fòrmula obstètrica), antecedents personals (malalties d'interès, intervencions quirúrgiques, medicació, pràctica esportiva habitual), dades sobre l'exploració física (talla a 1a visita, pes a totes les visites), dades sobre la presència de diabetis gestacional (Test O'Sullivan, TTOG), dades sobre la presència d'hipertensió induïda per la gestació, dades sobre si cal pràctica de cesària o no en l'embaràs actual, dades sobre si es tracta d'un part prematur, dades sobre el pes retingut després del part, dades sobre el pes del seu nadó al naixement i dades sobre el compliment d'assistir a les sessions d'exercici en cas d'estar al grup d'intervenció.

Aquests registres es faran a mesura que es recullin les dades.

Com es tractaran les meves dades i com es preservarà la meva confidencialitat?

Totes les seves dades de caràcter personal i informació recollida o generada durant l'estudi es tractaran confidencialment i quedaran protegides d'acord a la Llei Orgànica 15/1999 de "Protecció de Dades de Caràcter Personal" per persones relacionades amb la investigació. També podrien tenir accés les autoritats sanitàries i algun membre designat del Comitè d'Ètica d'Investigació Clínica que supervisi l'estudi, si així ho sol·licitessin. Aquests controls es realitzarien per garantir que s'hagin respectat els drets dels pacients.

No s'utilitzarà el seu nom ni cognoms per codificar la seva informació registrada; s'utilitzarà un codi que només els investigadors podran relacionar amb el seu nom.

D'acord amb la Llei Orgànica de Protecció de Dades, ha de saber que té dret a l'accés a les dades de la seva persona que siguin emmagatzemats, a rectificar-los, a cancel·lar-los i a oposar-se al seu ús, sense haver de donar cap explicació.

Em puc retirar de l'estudi?

La participació a l'estudi és totalment voluntària. Vostè podrà retirar-se en qualsevol moment si ho desitja, sense haver de donar explicacions i sense que això perjudiqui la seva relació amb el personal sanitari amb el que hagi de tenir contacte en el transcurs del seu embaràs.

De la mateixa manera, l'equip investigador pot decidir interrompre l'estudi en qualsevol moment si així fos necessari o si ho exigissin les autoritats sanitàries.

Qui supervisaria l'estudi?

El Comitè d'Ètica d'investigació Clínica de l'Hospital Universitari Doctor Josep Trueta de Girona, que és l'organisme encarregat d'avaluar la seguretat dels pacients i els aspectes ètics i metodològics d'aquest estudi, ha aprovat l'estudi, així com el present full d'informació i el formulari de consentiment informat.

Amb qui puc contactar en cas de dubte?

Els següents investigadors del Servei de Ginecologia i Obstetrícia de l'Hospital Universitari Doctor Josep Trueta seran els responsables de l'assaig clínic i d'informar i contestar els seus dubtes i preguntes:

Dra. Alexandra Bonmatí Telèfon: XXX XX XX XX

Dra. Sandra Perich Telèfon: XXX XX XX XX

Gràcies per haver llegit aquesta sol·licitud de col·laboració.

17.2. Annex 2. Informed consent

FULL DE CONSENTIMENT INFORMAT AL PACIENT

TÍTOL DE L'ESTUDI: Eficàcia d'un programa d'exercici controlat per la prevenció de l'augment de pes excessiu durant l'embaràs.

Jo_____, amb DNI_____, a data de _ _/ _ _/ _ _ _ _ declaro que:

- He llegit detingudament i he entès tota la fulla d'informació que se m'ha entregat.
- He rebut suficient informació sobre l'estudi.
- L'investigador m'ha explicat de manera clara tot el procediment.
- He pogut realitzar preguntes sobre l'estudi i tots els meus dubtes han sigut resolts de manera satisfactòria.
- Entenc que totes les meves dades seran tractades de forma estrictament confidencial.
- Entenc quin serà el meu paper com a participant de l'estudi.
- Entenc que la meva participació és voluntària, i que en qualsevol moment de l'estudi puc canviar d'opinió sense haver de donar cap tipus d'explicació i que, independentment de la meva decisió, la meva atenció mèdica i els meus drets legals no es veuran afectats.

Per tant, accepto voluntàriament a participar en aquest estudi d'investigació i permeto que s'utilitzin les meves dades per al seu anàlisis.

Firma del participant:_____ Firma de l'investigador_____

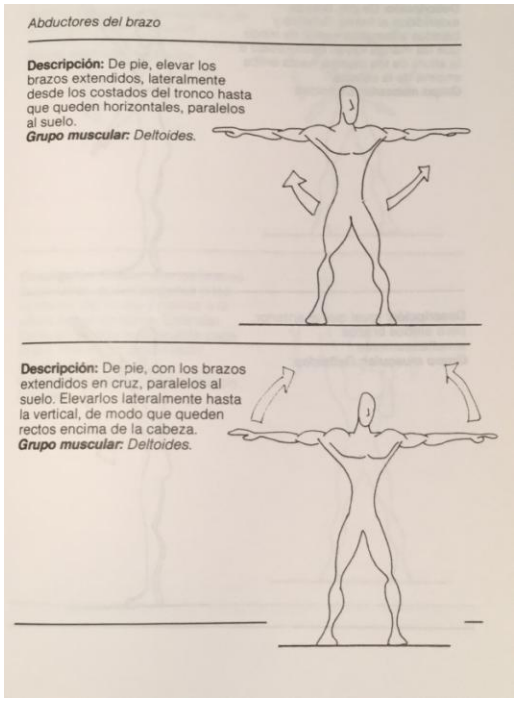
Número de telèfon de contacte_____

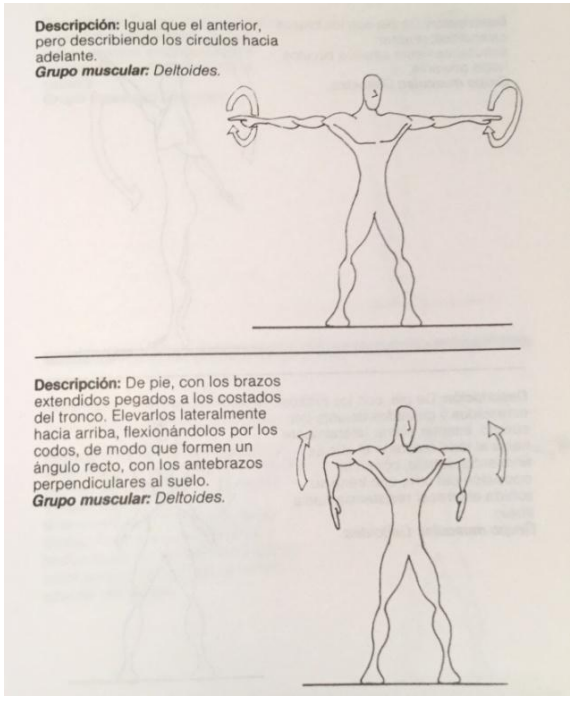
17.3. Annex 3. Exercise plan

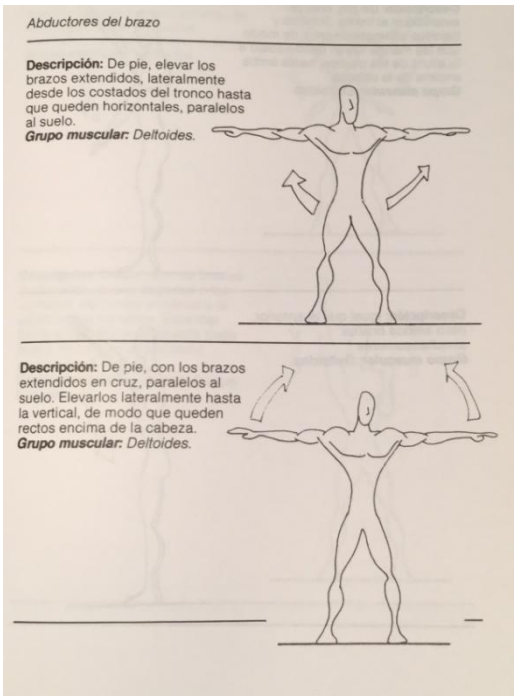
Land session

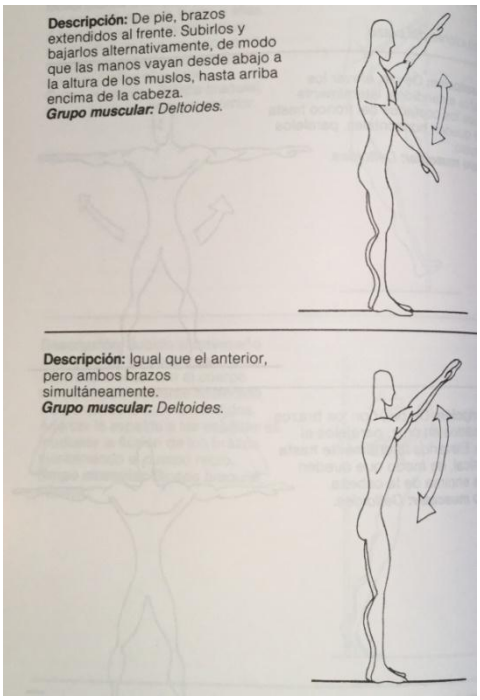
- Upper-muscles toning exercises

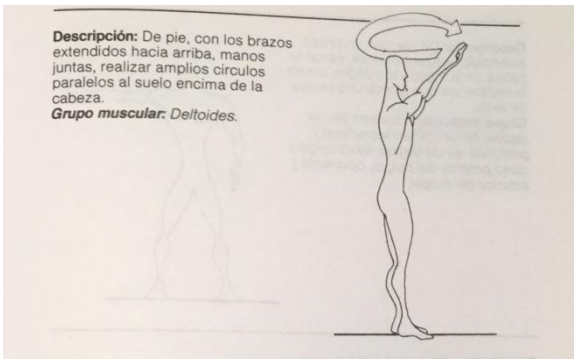
Muscular group: Deltoid

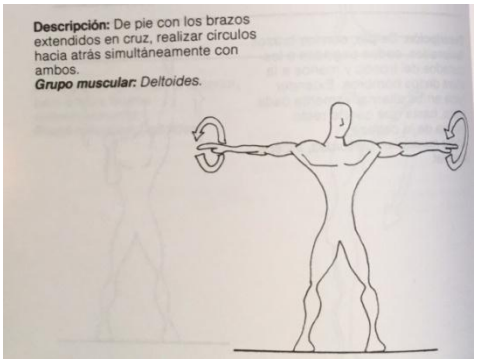


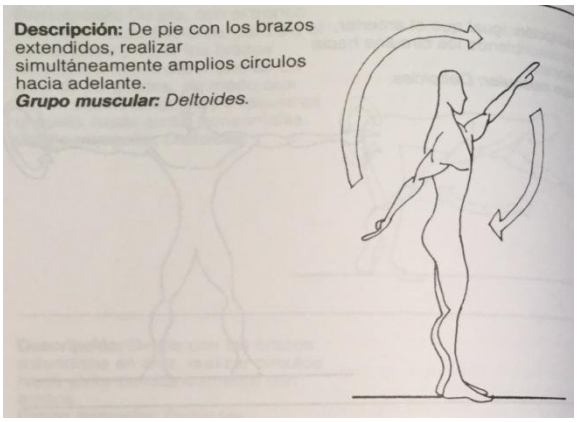


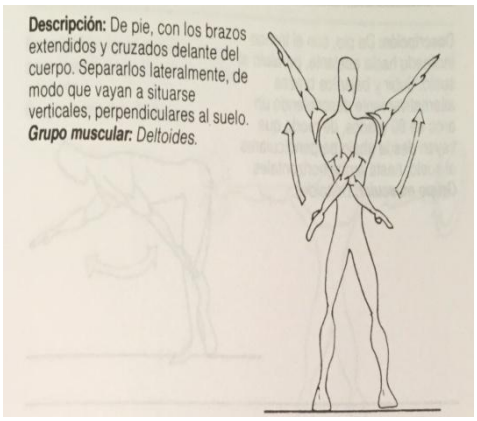


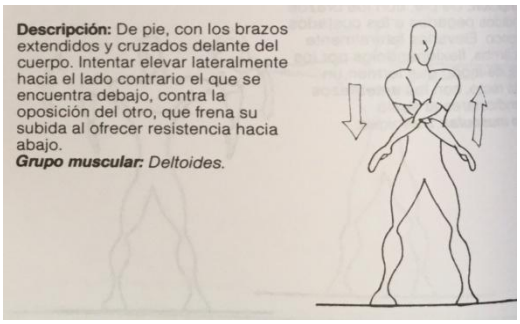


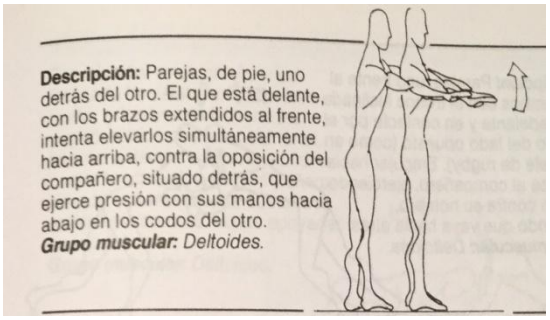




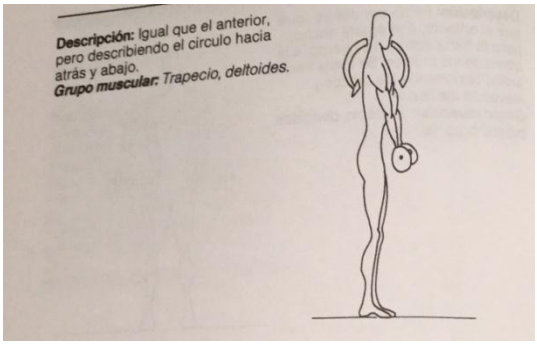


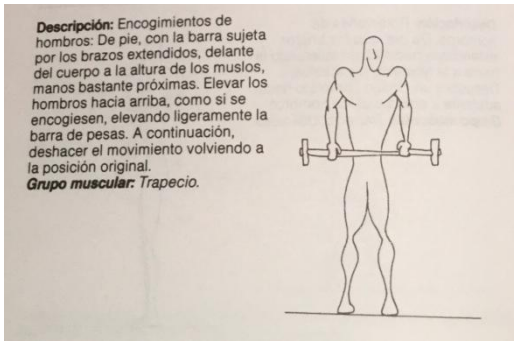




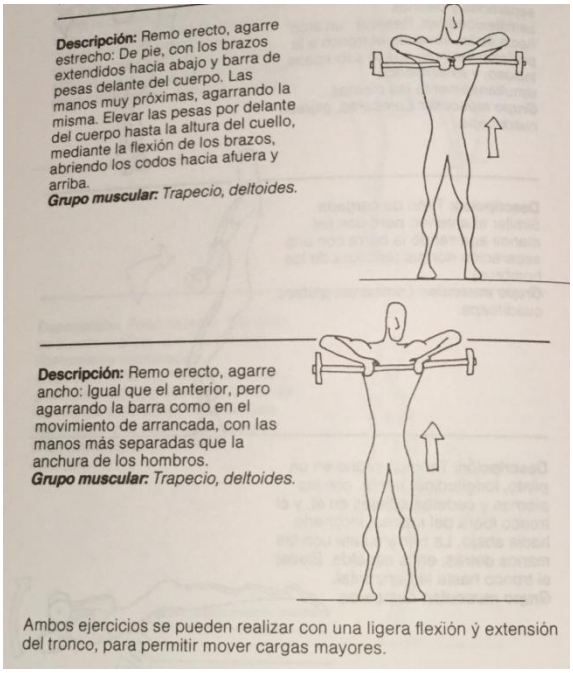


Muscular groups: Trapezius and deltoid





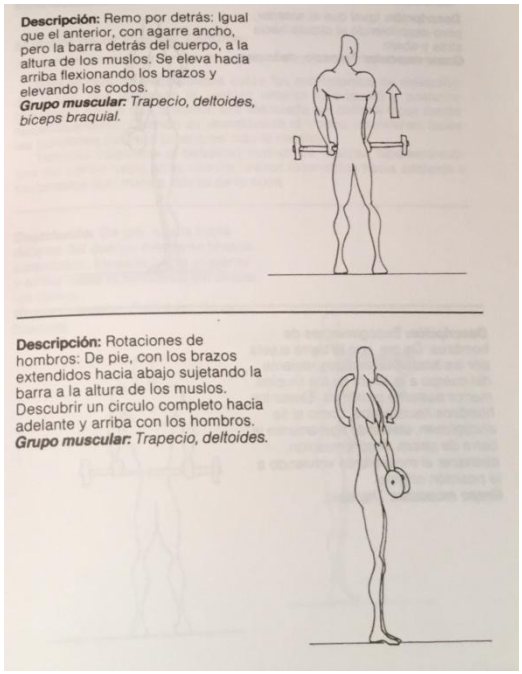
*using a light wooden bar



Descripción: Remo erecto, agarre estrecho: De pie, con los brazos extendidos hacia abajo y barra de pesas delante del cuerpo. Las manos muy próximas, agarrando la misma. Elevar las pesas por delante del cuerpo hasta la altura del cuello, mediante la flexión de los brazos, abriendo los codos hacia afuera y arriba.
Grupo muscular: *Trapecio, deltoides.*

Descripción: Remo erecto, agarre ancho: Igual que el anterior, pero agarrando la barra como en el movimiento de arrancada, con las manos más separadas que la anchura de los hombros.
Grupo muscular: *Trapecio, deltoides.*

Ambos ejercicios se pueden realizar con una ligera flexión y extensión del tronco, para permitir mover cargas mayores.

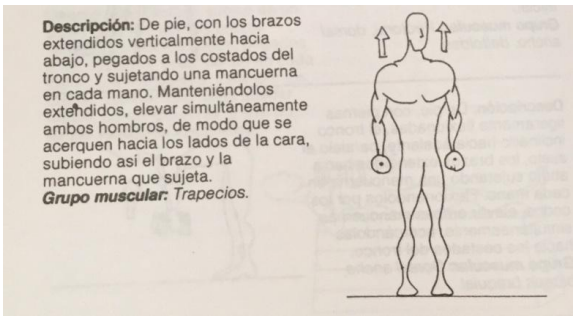


Descripción: Remo por detrás: Igual que el anterior, con agarre ancho, pero la barra detrás del cuerpo, a la altura de los muslos. Se eleva hacia arriba flexionando los brazos y elevando los codos.
Grupo muscular: *Trapecio, deltoides, biceps braquial.*

Descripción: Rotaciones de hombros: De pie, con los brazos extendidos hacia abajo sujetando la barra a la altura de los muslos. Descubrir un circulo completo hacia adelante y arriba con los hombros.
Grupo muscular: *Trapecio, deltoides.*

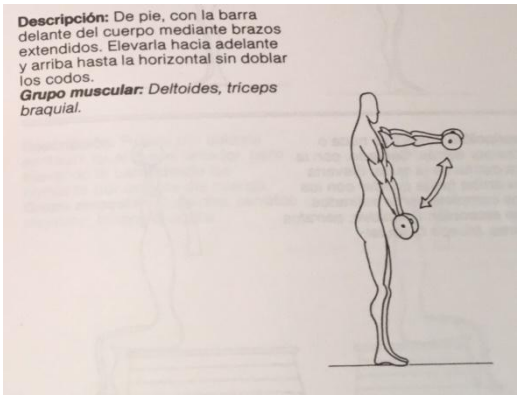
*using a light wooden bar

*using a light wooden bar

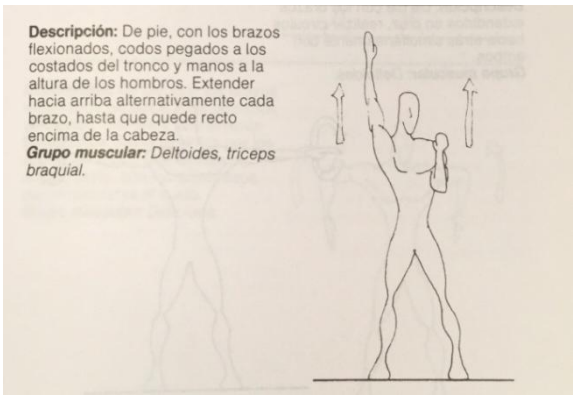


Descripción: De pie, con los brazos extendidos verticalmente hacia abajo, pegados a los costados del tronco y sujetando una mancuerna en cada mano. Manteniéndolos extendidos, elevar simultáneamente ambos hombros, de modo que se acerquen hacia los lados de la cara, subiendo así el brazo y la mancuerna que sujeta.
Grupo muscular: *Trapecios.*

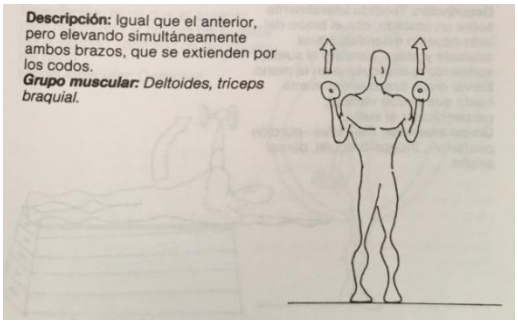
Muscular groups: Deltoids and brachial triceps

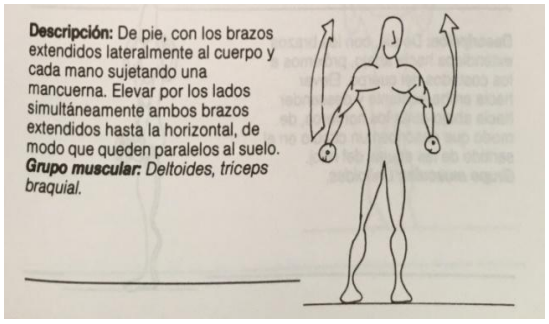


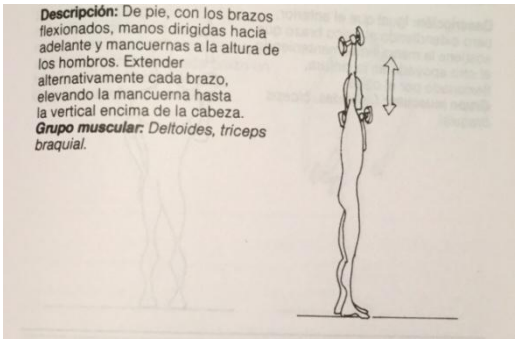
Descripción: De pie, con la barra delante del cuerpo mediante brazos extendidos. Elevarla hacia adelante y arriba hasta la horizontal sin doblar los codos.
Grupo muscular: *Deltoides, triceps braquial.*

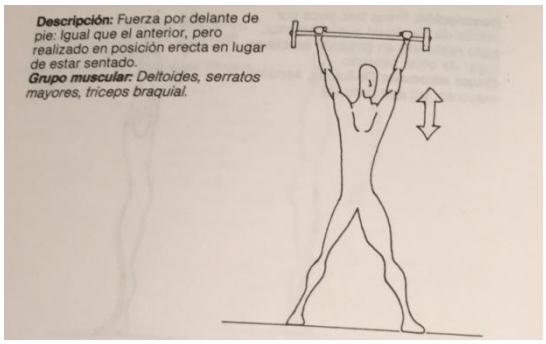


Descripción: De pie, con los brazos flexionados, codos pegados a los costados del tronco y manos a la altura de los hombros. Extender hacia arriba alternativamente cada brazo, hasta que quede recto encima de la cabeza.
Grupo muscular: *Deltoides, triceps braquial.*

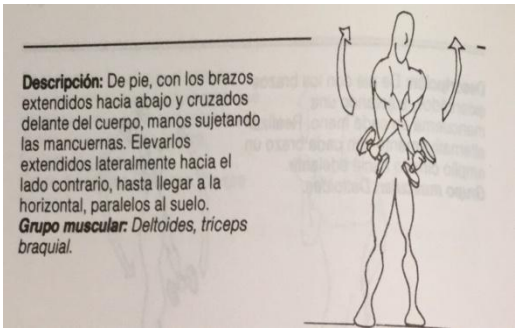


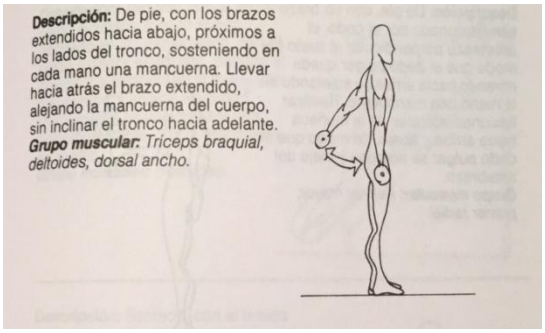


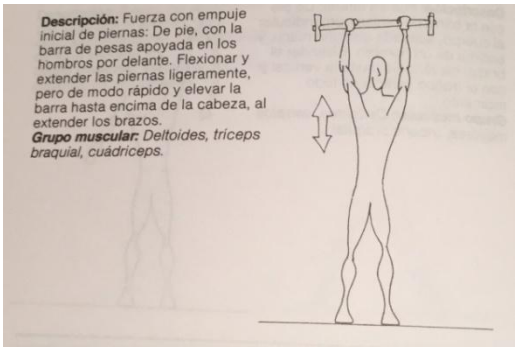




*using a light wooden bar

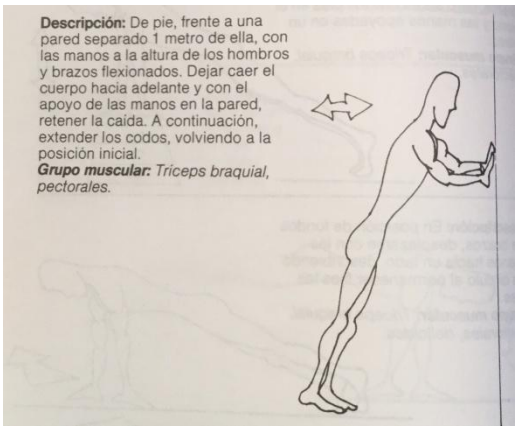




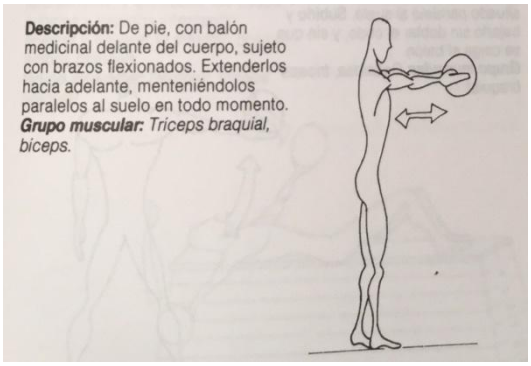


*using a light wooden bar

Muscular groups: Pectoral and brachial triceps

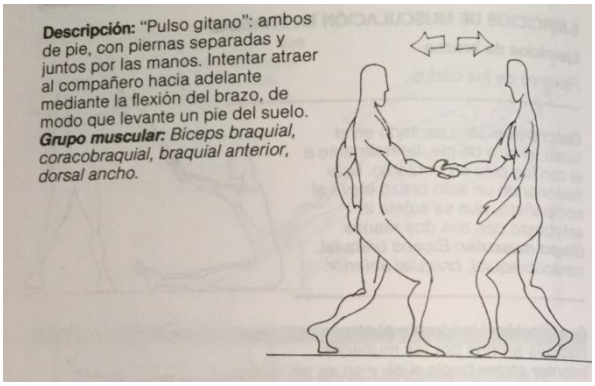


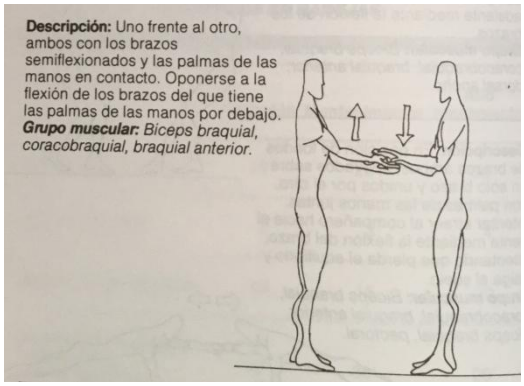
Muscular groups: Brachial triceps and biceps

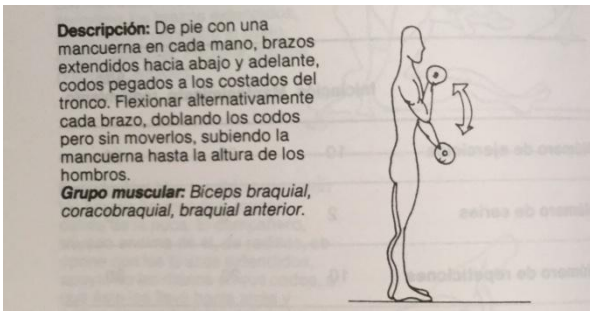


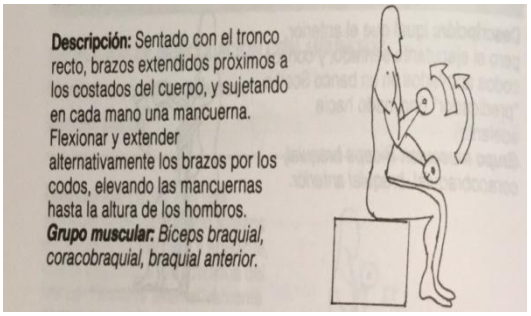
*with no medicinal ball, just with 1 kg dumbbell or without weight

Muscular groups: Biceps brachial, coracobrachial and anterior brachial

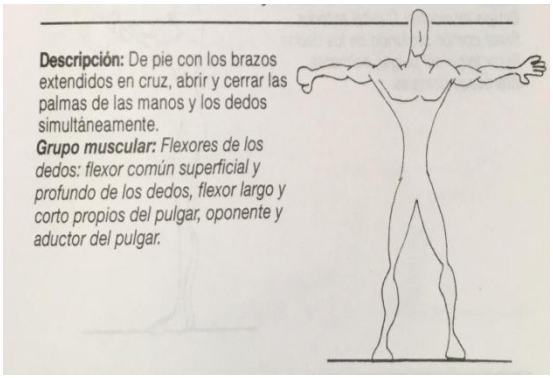


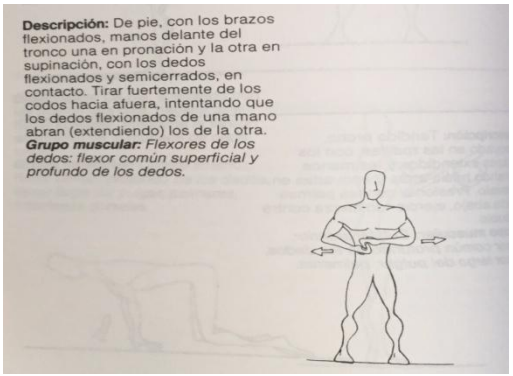


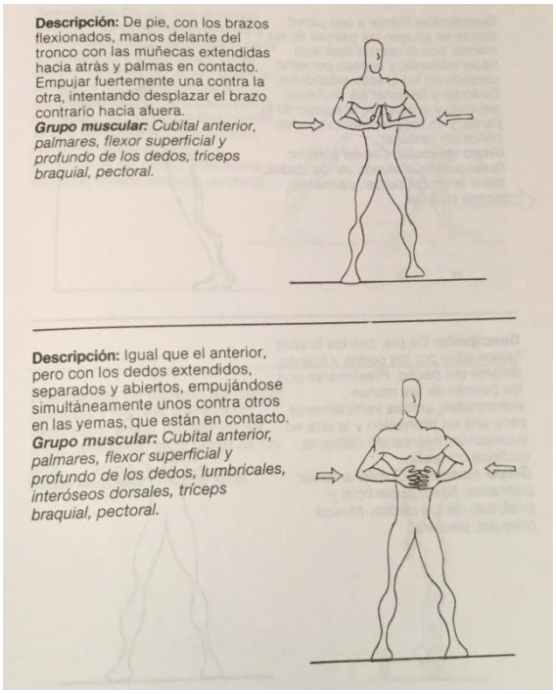


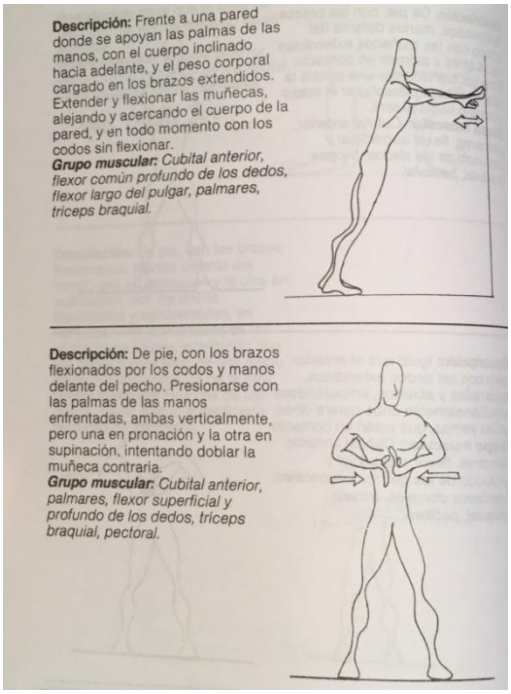


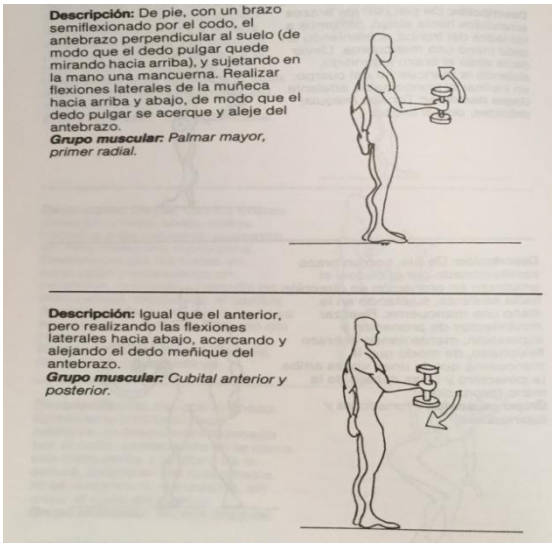
Muscular groups: Fingers' flexors, anterior and posterior cubital, palmar, pectoral, and brachial triceps



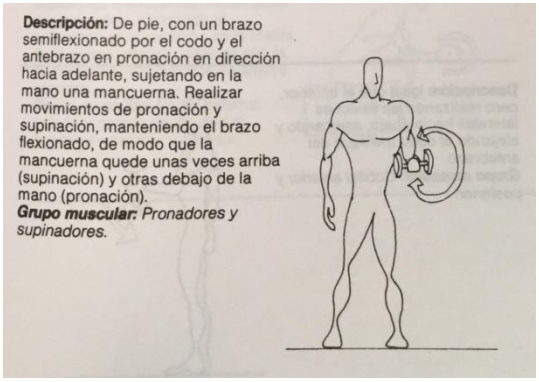






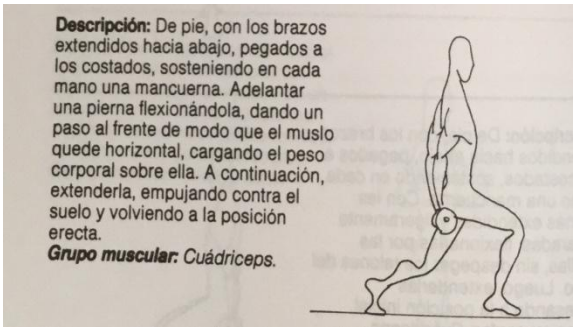


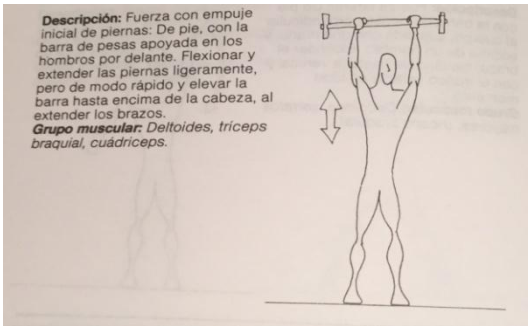
Muscular groups: Pronators and supinators



- Lower-muscle toning exercises

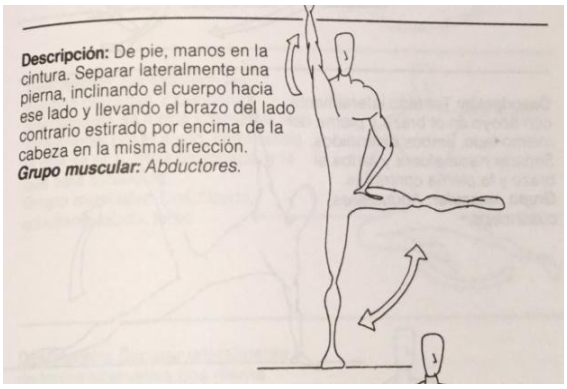
Muscular groups: Quadriceps

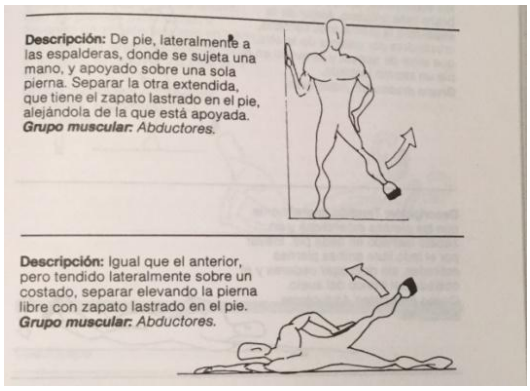




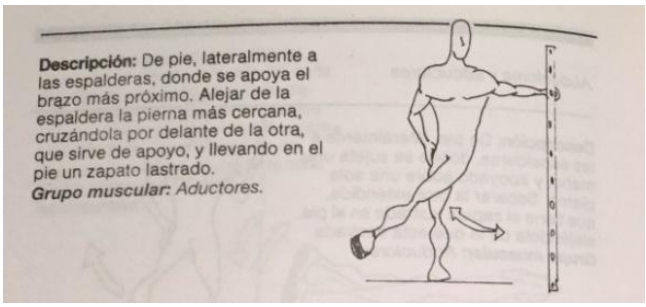
*using only a light wooden bar

Muscular groups: Abductors

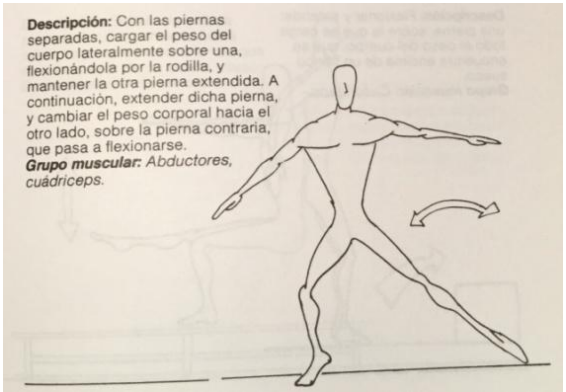




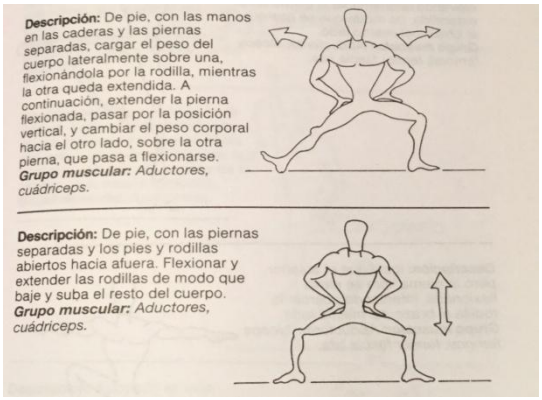
Muscular group: Adductors

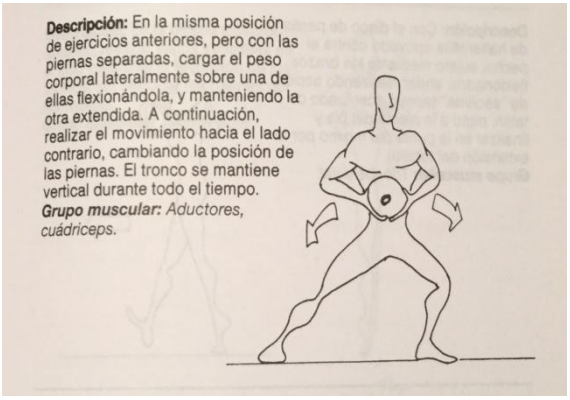


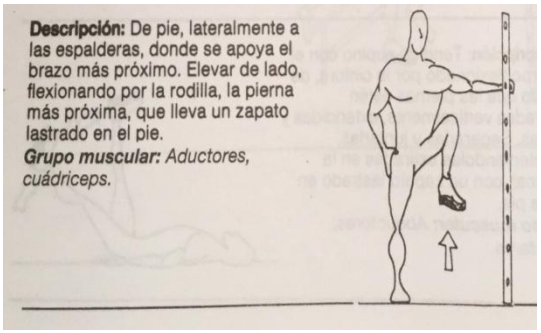
Muscular groups: Quadriceps and abductors

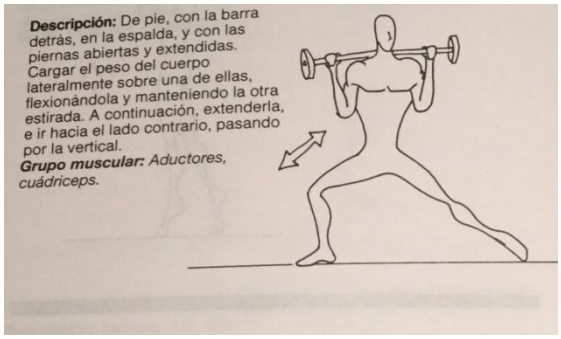


Muscular groups: Quadriceps and adductors





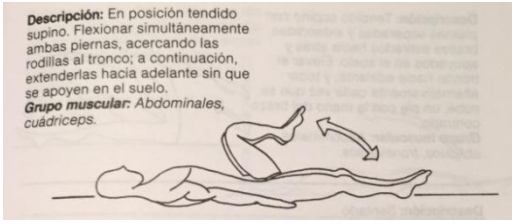




*using only a light wooden bar

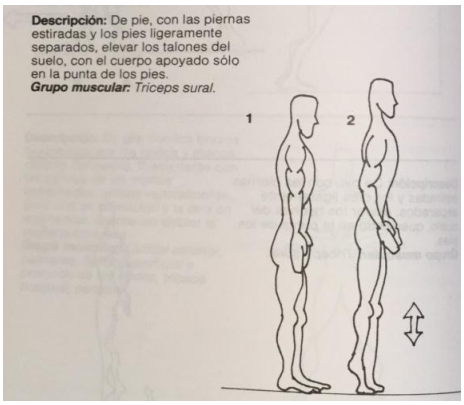
Muscular group: Quadriceps and psoas iliacus

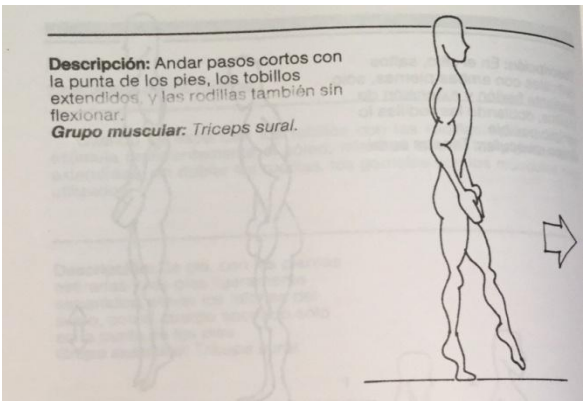
Muscular groups: Quadriceps and abs

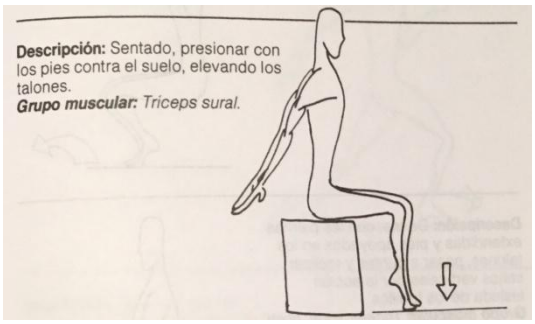


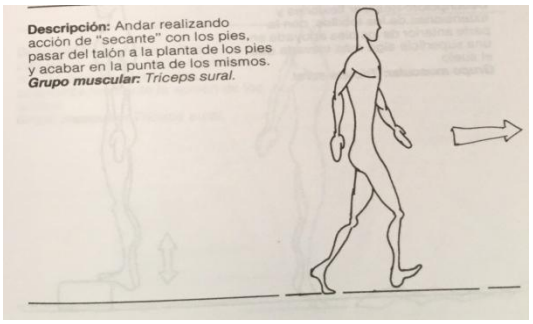
*doing soft abs

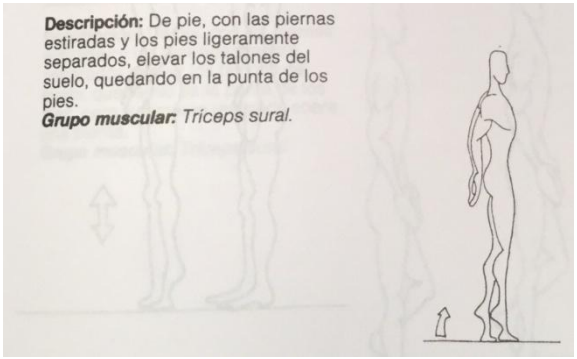
Muscular groups: Sural triceps

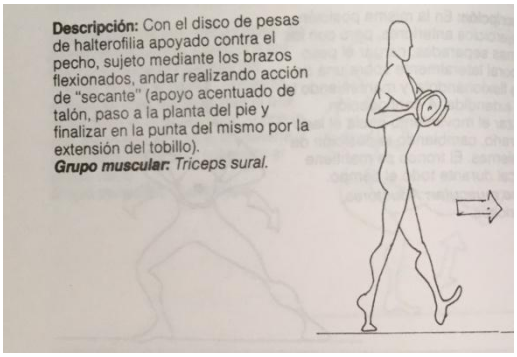




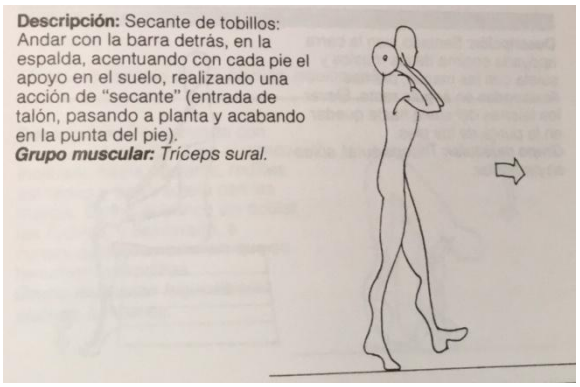


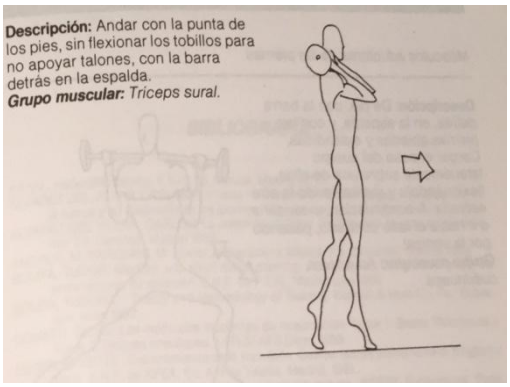






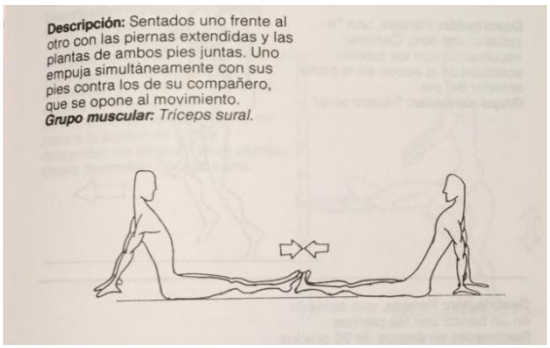
*using 2 kg dumbbell

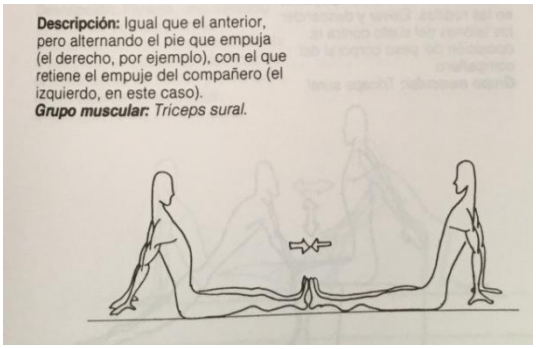


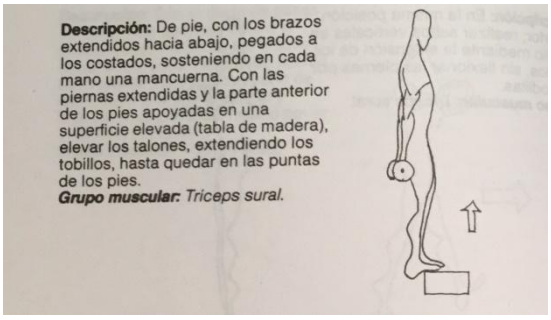


*using 2 kg dumbbell

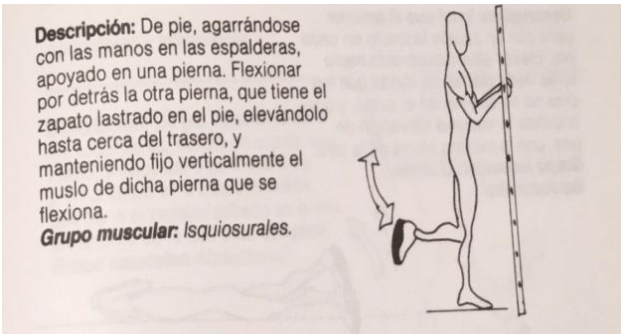
*using 2 kg dumbbell



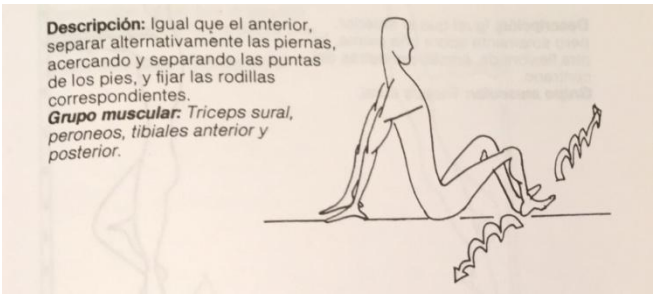




Muscular group: Ischial

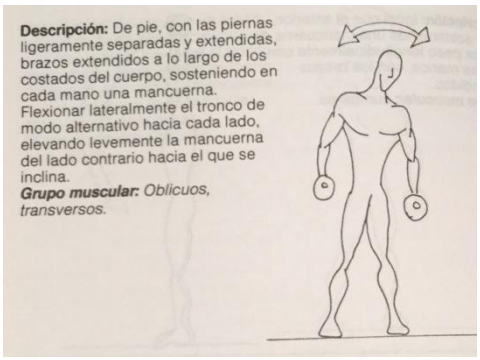


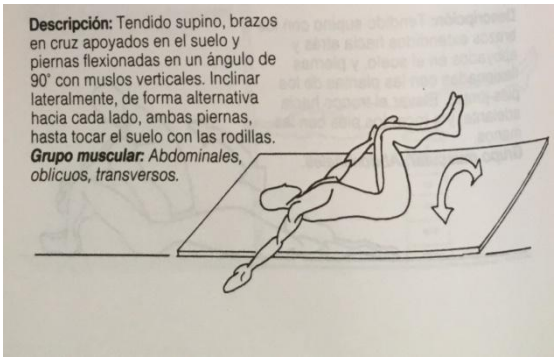
Muscular groups: Sural triceps, peroneal, anterior and posterior tibial

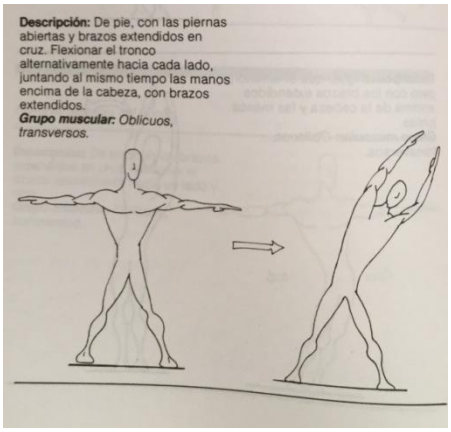


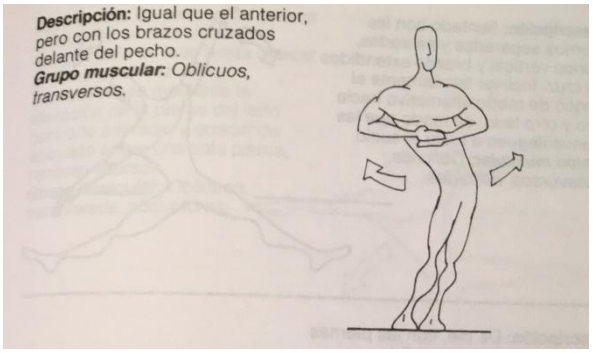
- Trunk muscles toning

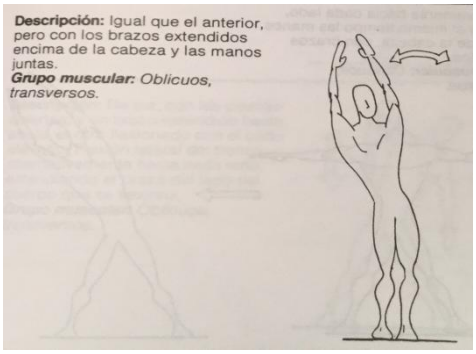
Muscular groups: Oblique and transverse

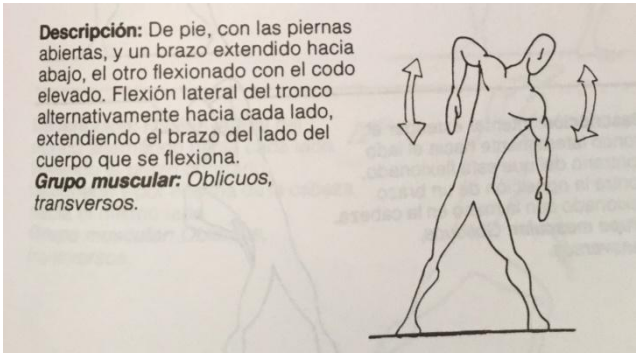


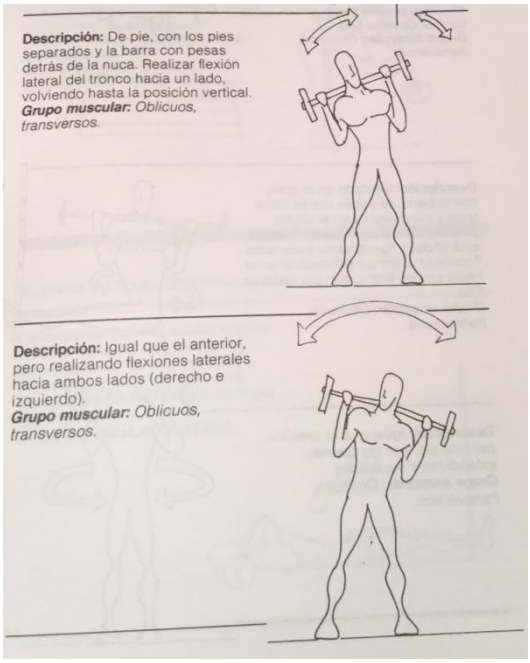


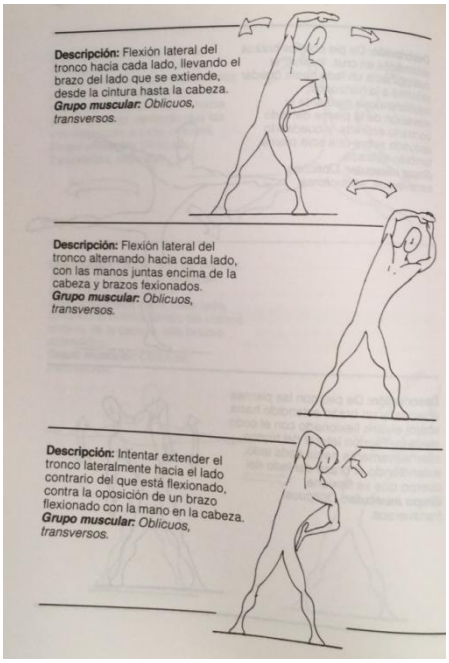




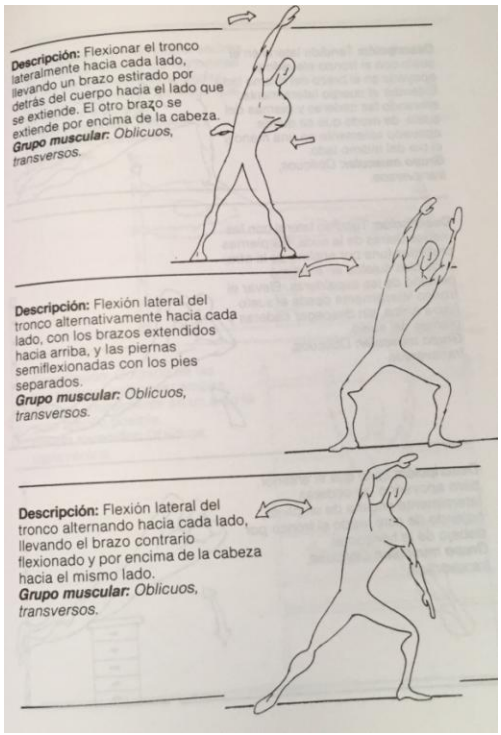


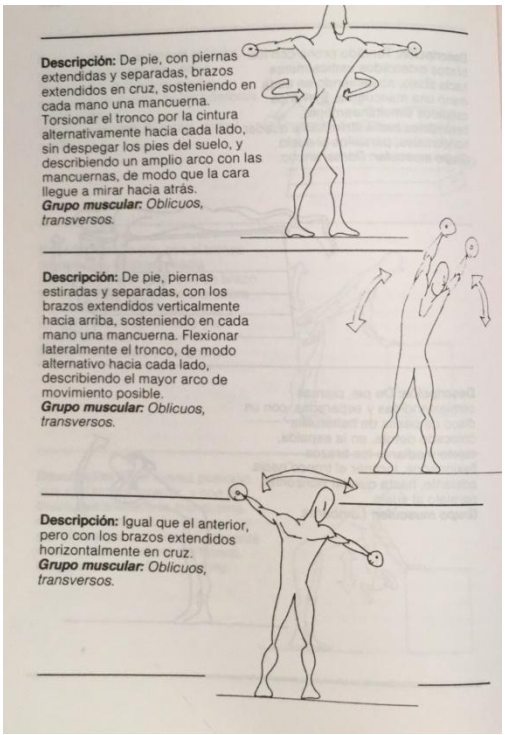




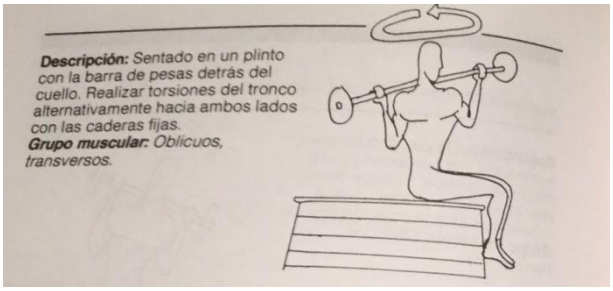


*using a light wooden bar



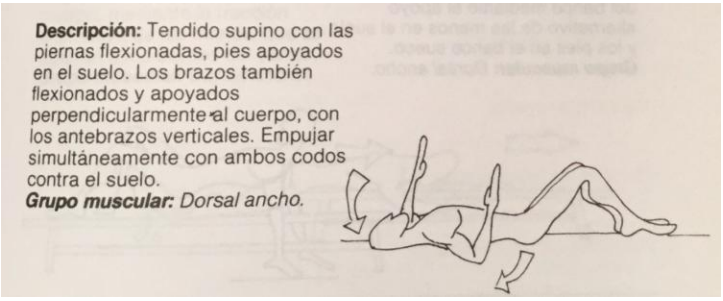


*using two 1 kg dumbbells



*sitting on a bench and using a light wooden bar

Muscular group: Latissimus dorsi



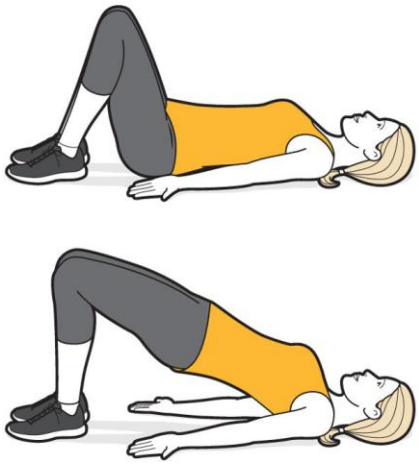
References

Images extracted from: Nespereira AB. 1000 ejercicios de musculación. Paidotribo. Barcelona; 2000. 538 p. (60).

- Pelvic floor exercises

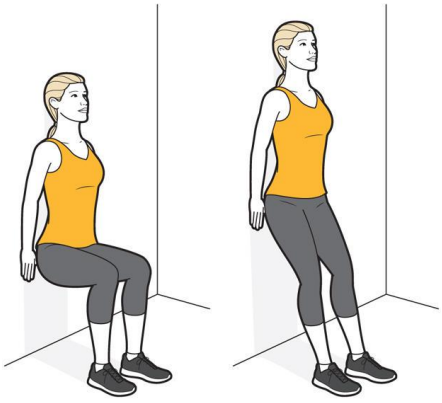
Bridge

Lie on your back with your knees bent and feet flat on the floor, hip-width apart. Inhale, engage your pelvic floor, and lift your hips. Hold for up to 10 seconds (keep breathing). Lower your hips back down and release your pelvic floor. Do 10 repetitions.



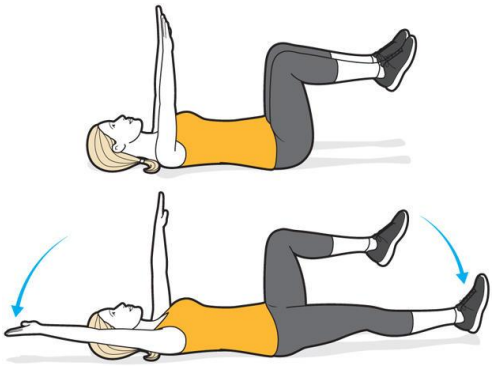
Wall squat

Stand against a wall, feet hip-width apart. Inhale, engage your pelvic floor, and lower yourself into a squat as though sitting in a chair. Hold for 10 seconds. Rise back up to standing and release your pelvic floor. Rest for 10 seconds. Do 10 repetitions.



Dead bug crunch

Lie on your back as shown. Extend your arms straight up toward the ceiling. Inhale, engage your pelvic floor, and extend your right arm beyond your head and right leg forward. Release pelvic floor and draw arm and leg back to starting position. Repeat with left arm and leg. Do 10 repetitions on each side.

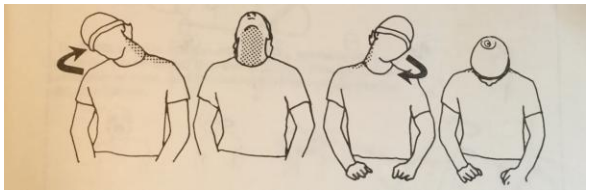


References

Images extracted from: Fowler P. 4 Essential moves to strengthen your pelvic floor. [Internet]. 2015 [cited 2016 Dec 21].
Available from: http://www.prevention.com/fitness/strength-training/pelvic-floor-exercises-prevent-urinary-incontinence (61).

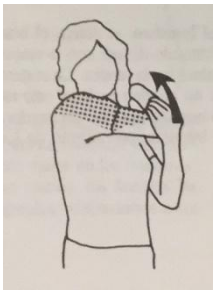
- Stretching

Stretching body area: Neck

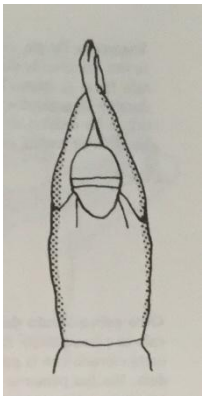


Sit in a comfortable position, turning your head very slowly to complete a circle, while keeping your back erect. When we turn our heads we feel the desire to stop at some point that we feel rigid and maintain a gentle stretch. Stretch with caution. If you maintain a certain position, you will relax and that zone will gradually lose its tension.

Stretching body area: Back, shoulders and arms

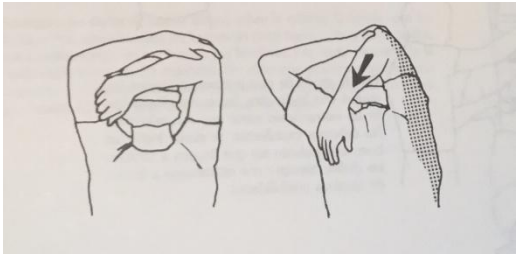


To stretch the shoulder and the middle and upper back, gently pull the elbow from the chest toward the opposite shoulder. Hold this position for 10 seconds.

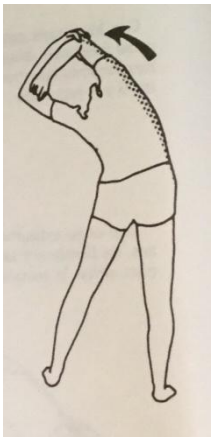


With arms extended over the head and the palms joined, stretch the arms upwards and a little backwards. Inhale as you stretch upwards, holding this position for 5 to 8 seconds.

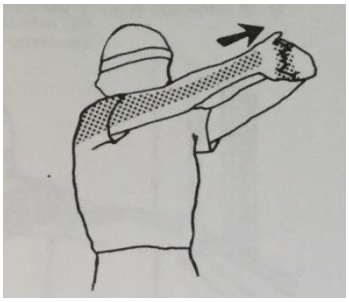
This is a very positive stretch for the outer muscles of the arms, shoulders and ribs.



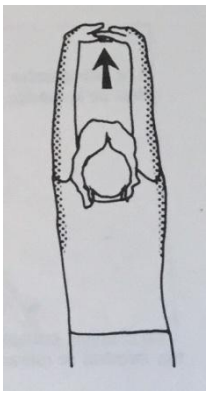
This stretch works the triceps and the upper shoulders. With your arms over your head, hold one elbow with the other arm's hand. Slowly pull the elbow to the neck, causing a stretch. Hold this position for about 15 seconds. Do it with both arms.



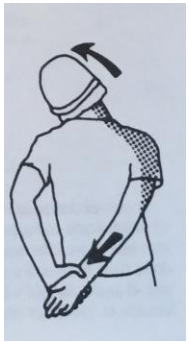
Standing with your knees slightly bent, gently pull the elbow behind the head, while doing a twist to the same side by the waist. Maintain a gentle stretch for 10 seconds. Perform the exercise on both sides.



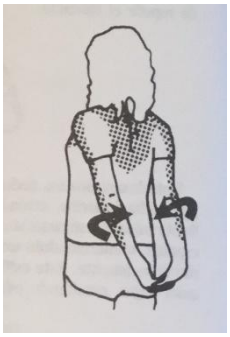
Interlace the fingers of both hands frontally and at shoulder height. Turn your palms outward as you extend your arms forward for a gentle stretch on the shoulders, the middle and upper back, arms, hands, fingers, and wrists. Hold this stretch for 15 seconds.



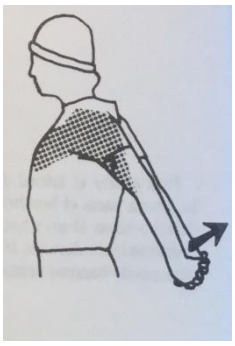
Interlace the fingers of both hands over the head. With your palms facing up, extend your arms slightly back and up. You will feel the stretch in the arms, the shoulders and the upper part of the back. Hold this stretch for 15 seconds. You should not stretch without breathing simultaneously.



To stretch the side of the neck and the upper part of the shoulder, pull your head toward the left shoulder, while the left hand pulls the right arm down and to the left behind the back. Hold the stretch for 10 seconds, doing it on both sides.



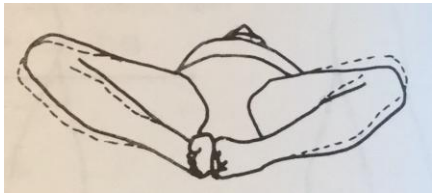
Interlace your fingers behind your back and slowly turn your elbows inward, while you stretch your arms.



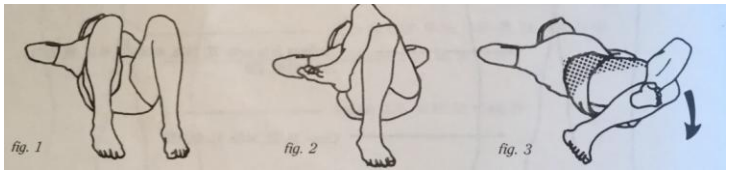
Do the same as in the previous case and raise your arms behind you until you notice the stretch in the shoulders, chest or arms. Hold the stretch for 5 to 15 seconds.

Stretching body area: Back

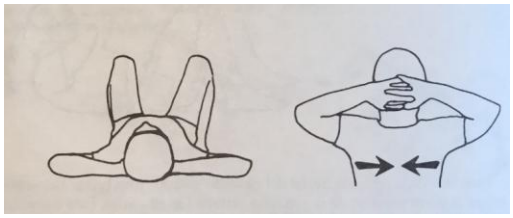
Lie on your back with your knees bent and the soles of your feet together. This position will stretch the groin. Hold position for 30 seconds. Let the force of gravity be the one that holds the stretch.



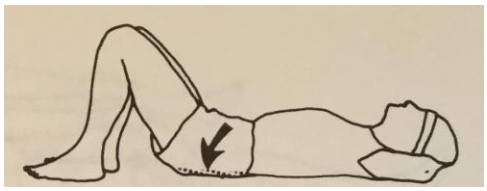
Maintaining the previous position, perform ten or twelve times with the legs an oscillation movement of 1.5 cm in each direction, as if they were a unit. This movement serves to prepare the hips and groin.



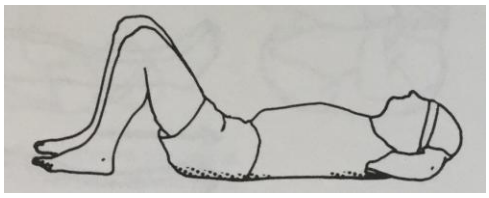
After performing the previous stretching, place your knees together, supporting your feet on the floor. Interlace vour hands behind your head while resting your arms on the floor (fig. 1). Then rest your left leg on the right (fig. 2). From this position push with your left leg to the right towards the floor (fig. 3) until you feel a gentle tension on the side of the hip and lower back. Hold this position for 30 seconds while the upper back, neck, shoulders and elbows are held on the floor. Repeat the exercise on the other side.



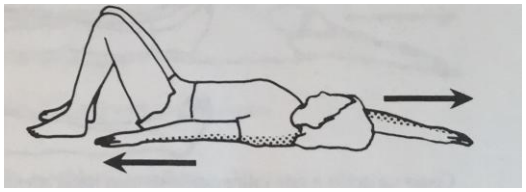
With your knees bent and your hands clasped behind your head, pull your shoulder blades inward, as if you were trying to pull them together, creating a tension in the upper back (while doing this the chest will move up). Keep this tension controlled for 4 or 5 seconds.



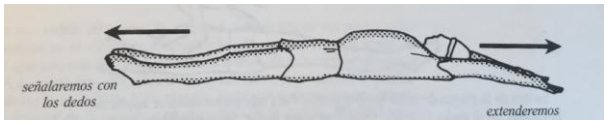
Contract the buttocks and abs until the back is flat. Maintain this tension between 5 and 8 seconds, relax and repeat the exercise two or three times. Thus, we can straighten the lower back to eliminate the tension by maintaining a correct posture.



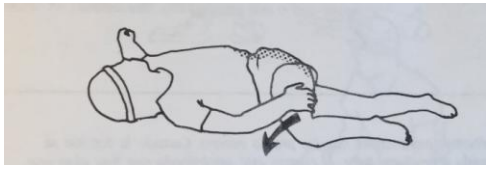
Perform the two previous exercises simultaneously and maintain this position for 5 seconds. Repeat this exercise three or four times.



With your knees bent and your head resting on the floor, extend one arm over your head (with your palm up) and the other along your side (with your palm down). Stretch them in opposite directions to create controlled tension in the shoulders and back. Maintain this stretch for 6 and 8 seconds. Repeat the exercise twice on each side.



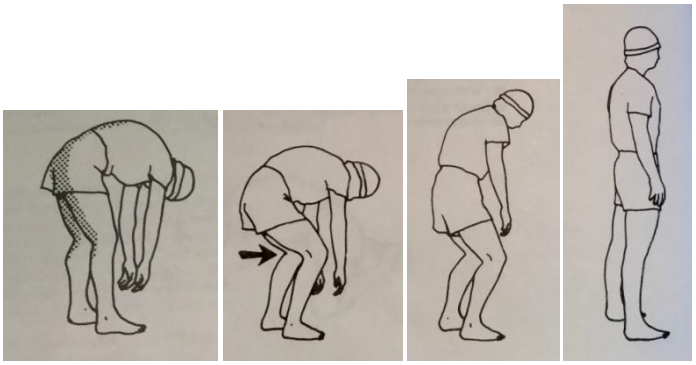
Extend your arms over your head and stretch your legs. Act as if you wanted to touch something with the tips of both ends. Hold this position for 5 seconds.



Bend one knee 90° and with the opposite hand pull that leg over the other. Turn your head until you see the hand of the other arm, which is stretched, perpendicular to the side. The hand on the thigh should pull the folded leg toward the floor until a stretch is felt in the lower back and the side of the hip. Keep your feet and ankles relaxed and your shoulder blades flat on the floor. Hold the stretch for 30 seconds on each side.

To finish the series of back stretches, lie down in fetal position.

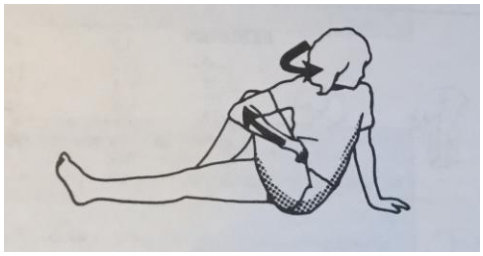
Stretching body area: Lower back, hips and groin



Begin with a flexed position of the hips forward with the feet separated by the distance between the shoulders and with the knees bent about two or three centimeters so that it does not strain the lower part of the back. The neck and arms should remain relaxed. Advance until you feel a gentle stretch on the back of the knees, thighs, buttocks and lower back. Hold this position for 15 to 25 seconds and then move to a raised position progressively.

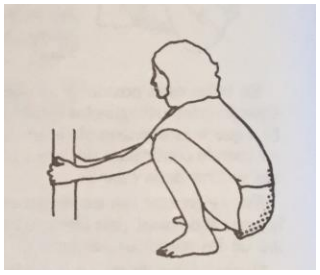
Sit with your legs stretched out and feet up; the heels shall not be more than 15 cm apart. Tilt your hips to a gentle stretch, which lasts for 20 seconds. You will feel the stretch in the back of the knees and thighs and you can feel it in the lower part of the back if you have it tense.

To stretch the adductors, bring the soles of the feet together by holding them together with your hands. Bend forward the hips until you feel a gentle stretch in the groin. Hold the position for 40 seconds.



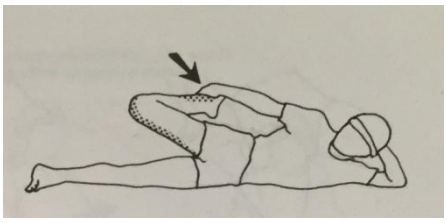
The spinal twist is a good stretch for the back, the side of the hips and the chest. Sit with your right leg extended and flex your left leg by pulling it over to the right to place your left foot on the outside of your right knee. Then flex the right arm by placing the elbow on the outside of the left thigh over the knee. Use your right elbow to keep your left leg immobile with a controlled pressure inward. In this position and with the left hand behind you, turn your head slowly to look over the left shoulder while rotating the upper body towards the left arm and hand. This stretch should be felt in the lower back and hip side. Hold this posture for 15 seconds. Repeat with the other side.

Squat with feet well supported and forming an angle of about 15˚. The heels are distanced between 10 and 30 cm. Support your back against the wall. This position is excellent for stretching the front of the legs, knees, ankles, back, Achilles tendons and groin. Hold this position for 30 seconds.

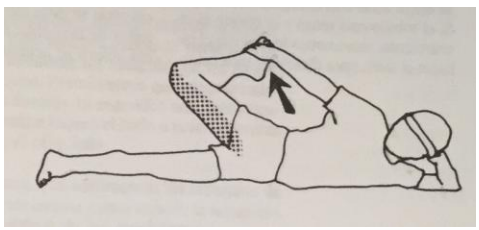


The same exercise as the previous case but using a pole or a fence to hold us with our hands.

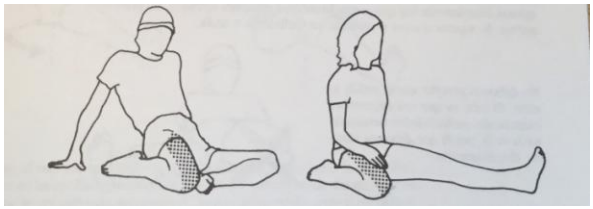
Stretching body area: Legs, ankles and hips



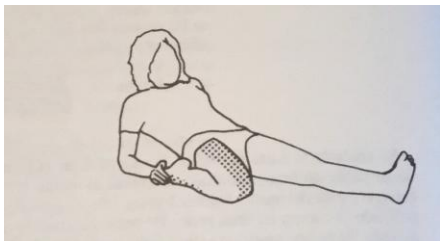
Lie on your left side, resting your head on the palm of the same hand. Hold the top of your right foot with your hand. Gently squeeze your right heel toward your buttocks and you'll stretch your ankle and quadriceps. Hold this position for 10 seconds.



Placed just as in the previous case but advance the front of the right hip, contracting your buttocks while pushing the same foot towards your hand. In this way you stretch the quadriceps. Hold this position for 10 seconds, holding the body in a straight line.



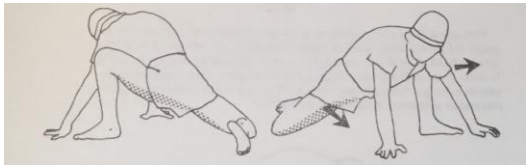
Sit with your right leg bent and your heel tucked into the gluteus. The left leg is flexed and the sole of the foot touches the inside of the right thigh. This exercise can also be performed with the left leg extended forward.



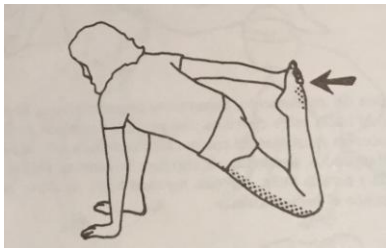
Placed just as in the previous case, slowly tilt back until you feel a gentle stretch in your quadriceps. Use the hands as balance and support, holding this position for 30 seconds.

Sit on your heels and lean on your toes. This position helps to stretch the knees, ankles and quadriceps. It also helps to relax calves.

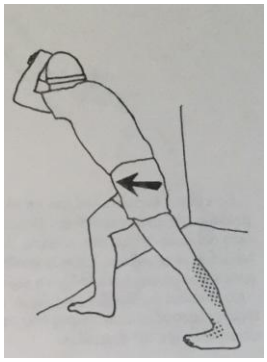
If you feel too much tension in the previous position, put the hands parallel to the legs, as support, while you lean a little forward. If on the contrary, with the previous position you do not notice anything, lean your back backwards using your hands as a support. Keep this position between 20 and 30 seconds.



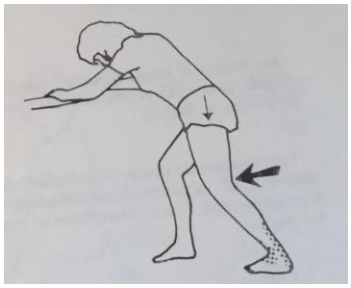
To stretch the inner thigh, place one leg forward, until the knee is above the ankle. The other knee should rest on the bent floor, moving the foot inward at an angle of 90°. Then separate the shoulders from the knee, placing the hands on the inside of the body as a fulcrum. Turn your hip slightly down until you feel the groin stretch. Hold this position for 25 seconds.



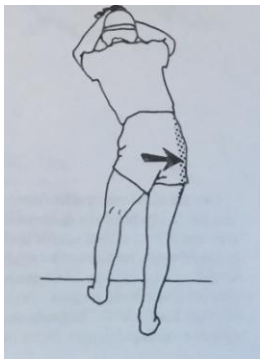
Place the right leg flexed forward with the flat foot on the floor and the left leg flexed backwards by supporting the knee on the floor and holding with the right hand the upper part of the left foot between the ankle and the fingers. Turn the front of the hip slightly down, while you are holding the left foot toward the midline of the body. Hold this position for 20 seconds.



To stretch your calf, stand a short distance from a solid support and lean against it with your forearms, resting your head on your hands. Bend one leg by placing one foot on the floor in front of you while stretching the other back. Then, slowly advance the hips, keeping straight the lower back. Hold this position for 30 seconds. Do it again with the other leg

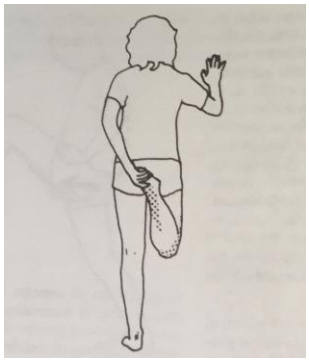


To stretch the calf and Achilles tendon, lower your hips slightly while flexing your knee slightly. Keep flat the back foot. Hold this position for 25 seconds.



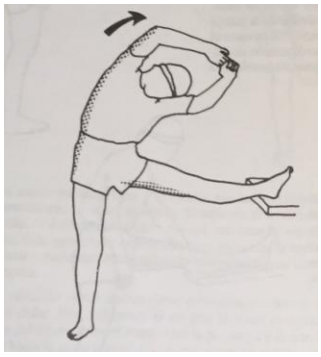
To stretch the outside of the hip, start with the same position as to stretch the calf. Turn the right hip slightly in, to feel a gentle stretch in that part. Then, move it to the side while tilting your shoulders slightly in the opposite direction. Hold this position for 25 seconds.

Place the end of the foot over a secure point of support, keeping the other leg below, with your foot pointing parallel to the point of support. Then flex the knee of the upper leg while you move your hip. This exercise causes stretching of the inner thighs. Hold the position for 25 seconds.

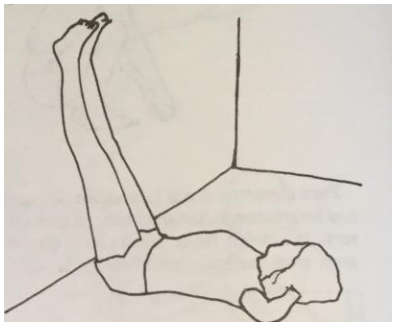


To stretch the quadriceps and knee, hold the top of the right foot with the left hand, slowly pulling it towards the buttocks. Hold this position for 30 seconds on each leg.

To stretch the inner side of the raised leg, support the back of the heel over a support point that is at waist height and keep the leg straight. Turn the foot on the floor until it is parallel to the point of support, while putting the upper part of the body in the same direction and turn the left hip slightly inwards. Slowly incline toward the left shoulder and keep the knee of the leg we leaned on the ground a little bent. Hold this position for 20 seconds and repeat with the other leg.



Position yourself in the same way as in the previous exercise and with the left hand pull the right hand and arm upwards above the head. This exercise is beneficial for the sides and the inside of the raised leg. Hold for 15 seconds, making it on both sides.



The elevation of the feet is a good way to revitalize the legs, helps to keep them light and in an energetic state for the activities of daily living. Stretches on the floor and rests his feet on a wall. The lower back should remain flat. The buttocks should be about 8 cm from the wall. Maintain this position at least 2-3 minutes.

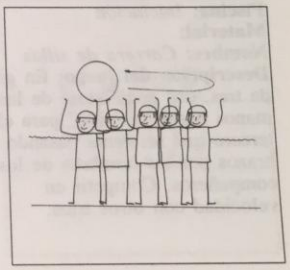
References

Images extracted from: Anderson B. Cómo rejuvenecer el cuerpo estirándose. Integral. Barcelona; 1992. 194 p. (62).

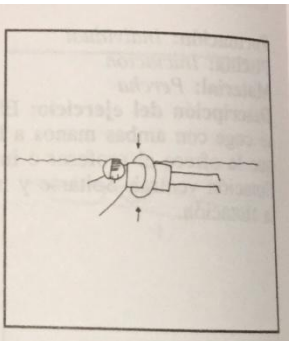
Aquatic activities

- Gradual warm-up exercises

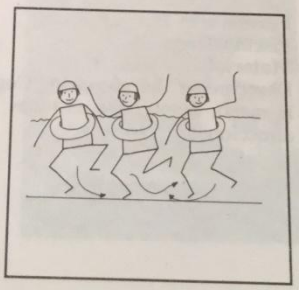
Formación: *Grupo*
Piscina: *Iniciación*
Material: *Pelotas gigantes*
Nombre: *Revelos de pelotas*
Descripción del juego: Cada equipo dispone de un balón gigante (90 cm). Se colocan en fila, el primero de la fila con el balón en alto, a la señal van pasándose el balón hacia atrás de mano en mano hasta llegar al último, que lo pasará hacia adelante y así sucesivamente cuatro veces seguidas sin que caiga la pelota. El equipo que lo consiga primero, gana.



Formación: *Individual*
Piscina: *Iniciación*
Material: *Flotador*
Descripción del ejercicio: Realizar una flotación ventral con un flotador en la cintura.



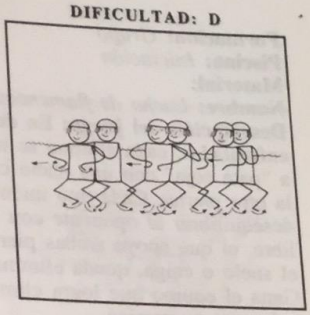
Formación: *Individual*
Piscina:*Iniciación*
Material: *Flotadores*
Descripción del ejercicio: Desplazarse por la piscina en todas direcciones.



*without floats

Formación: *Parejas*
Piscina: *Profunda*
Material:
Nombre: *Carreras de cuádrigas*
Descripción del juego: Carreras por parejas, uno en posición vertical y el compañero apoyando las manos sobre sus hombros, ambos realizan pies de braza y el primero también se impulsa con los brazos.

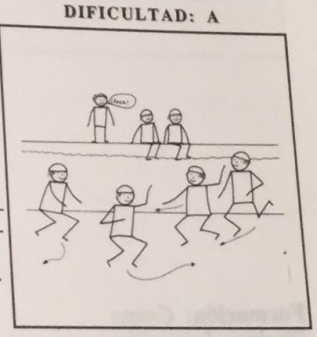
DIFICULTAD: D



• **Juegos en grupo**

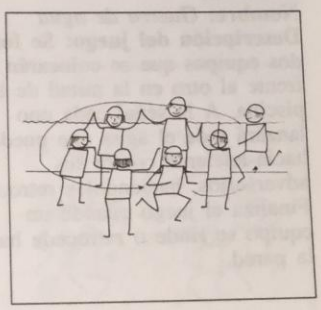
Formación: *Grupo*
Piscina: *Iniciación*
Material:
Nombre: *Foca-morsa*
Descripción del juego: Formar dos grupos, uno de "Focas" y el otro de "Morsas". Se van citando los nombres de diferentes animales que viven en el mar, al nombrar "focas" o "morsas" el grupo citado debe escapar, el otro grupo intentará "pescarlos" consiguiéndolo al tocarlos. El que es tocado debe retirarse del juego sentándose al borde de la piscina. El juego continuará mientras quede algún jugador que pescar.

DIFICULTAD: A



Formación: *Grupo*
Piscina: *Iniciación*
Material:
Nombre: *¡Que te pillo!*
Descripción del juego: Se forma un círculo cogidos de las manos y con los brazos en alto. El que "para" se desplaza por el exterior del grupo y toca al que desea en la espalda que debe salir corriendo intentando atraparle, el que huye lo hace alrededor del círculo y debe dar dos vueltas para intentar ocupar el lugar vacío del perseguidor antes de ser cogido. Si lo consigue "para" el que perdió su lugar.

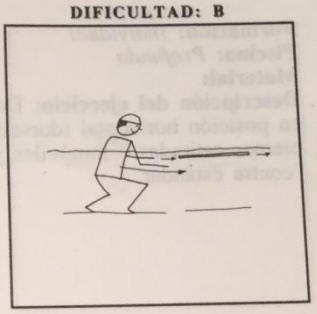
DIFICULTAD: A



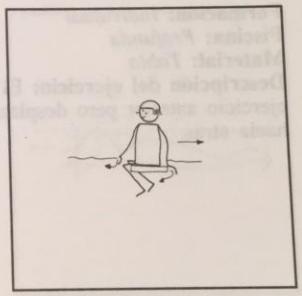
- Upper-muscles toning exercises

Formación: *Individual*
Piscina: *Iniciación*
Material: *Pica*
Descripción del ejercicio: El alumno camina por la piscina empujando una pica que flota.

DIFICULTAD: B

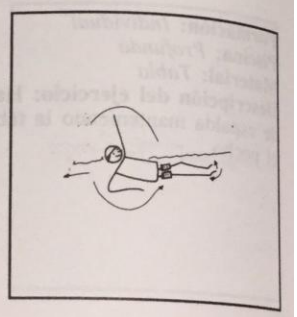


Formación: *Individual*
Piscina: *Profunda*
Material: *Tabla*
Descripción del ejercicio: Sentado sobre la tabla, con las piernas encogidas. Las manos realizan una pequeña remada empujando el agua hacia adelante, por lo que el desplazamiento será hacia atrás.

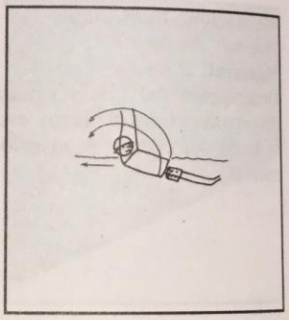


*in small tank pool

Formación: *Individual*
Piscina: *Profunda*
Material: *Rulo*
Descripción del ejercicio: Nadar espalda con el rulo entre los muslos.

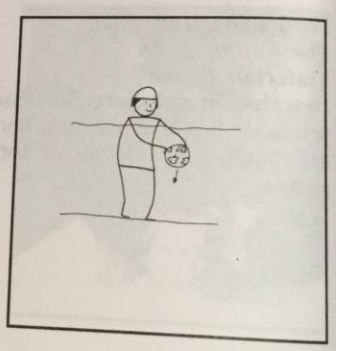


Formación: *Individual*
Piscina: *Profunda*
Material: *Rulo*
Descripción del ejercicio: Brazos de "doble espalda" con un rulo entre las piernas. Traccionar con ambos brazos a la vez.



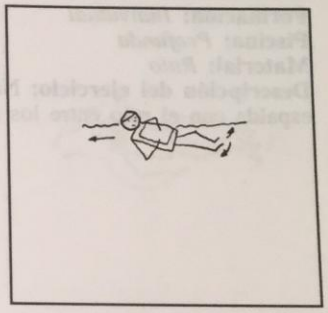
*in small tank pool

Formación: *Individual*
Piscina:*Iniciación*
Material: *Pelota*
Descripción del ejercicio: Colocar las manos sobre una pelota que flota y presionar con fuerza hasta que se sumerja completamente.



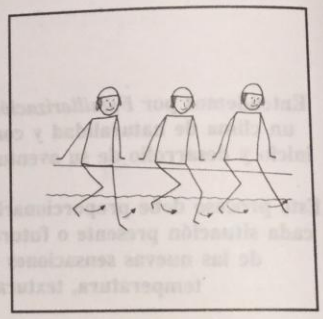
- Lower-muscles toning exercises

Formación: *Individual*
Piscina: *Profunda*
Material: *Tabla*
Descripción del ejercicio: Hacer pies de espalda manteniendo la tabla contra el pecho.

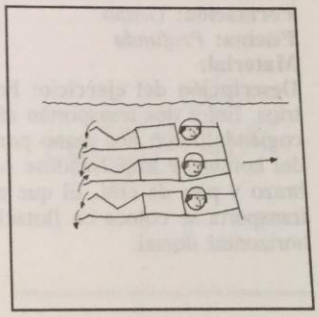


*in small tank pool

Formación: *Individual*
Piscina:*Iniciación*
Material:
Descripción del ejercicio: Sentados en el rebosadero, realizar con fuerza un batido de pies.

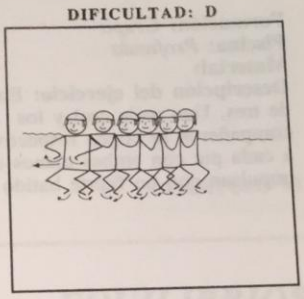


Formación: *Grupo*
Piscina: *Iniciación*
Material: *Pica*
Descripción del ejercicio: Tres alumnos cogidos a una pica se desplazan con pies de crol.



Formación: *Grupo*
Piscina: *Profunda*
Material:
Descripción del ejercicio: En posición vertical y en fila, manteniéndose con pies de "bicicleta" y las manos apoyadas en los hombros del compañero de delante, avanzar lentamente.

DIFICULTAD: D

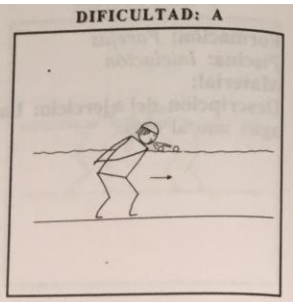


*in small tank pool

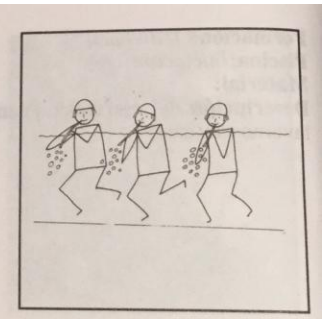
- Breathing exercises

DIFICULTAD: A

Formación: *Individual*
Piscina: *Iniciación*
Material: *Pelotas de ping-pong*
Descripción del ejercicio: Desplazarse soplando dos pelotas de ping-pong por la superficie del agua intentando que no se separen.

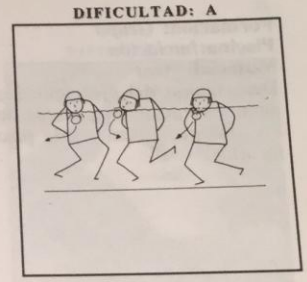


Formación: *Individual*
Piscina:*Iniciación*
Material: *Pajitas*
Descripción del ejercicio: Soplar con fuerza para ver subir las burbujas.



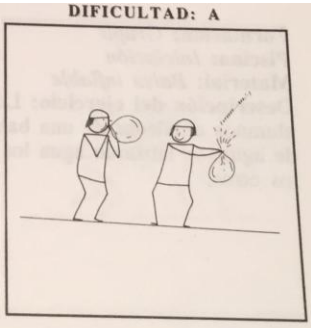
DIFICULTAD: A

Formación: *Individual*
Piscina:*Iniciación*
Material: *Pelotas de ping-pong*
Descripción del ejercicio: Soplando con fuerza, mover la pelota en todas direcciones.

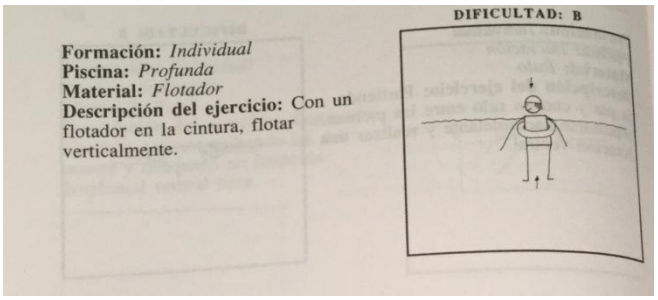


DIFICULTAD: A

Formación: *Individual*
Piscina: *Iniciación*
Material: *Globos*
Descripción del ejercicio: Con un globo cada uno, intentar inflarlo y dejar escapar el aire.



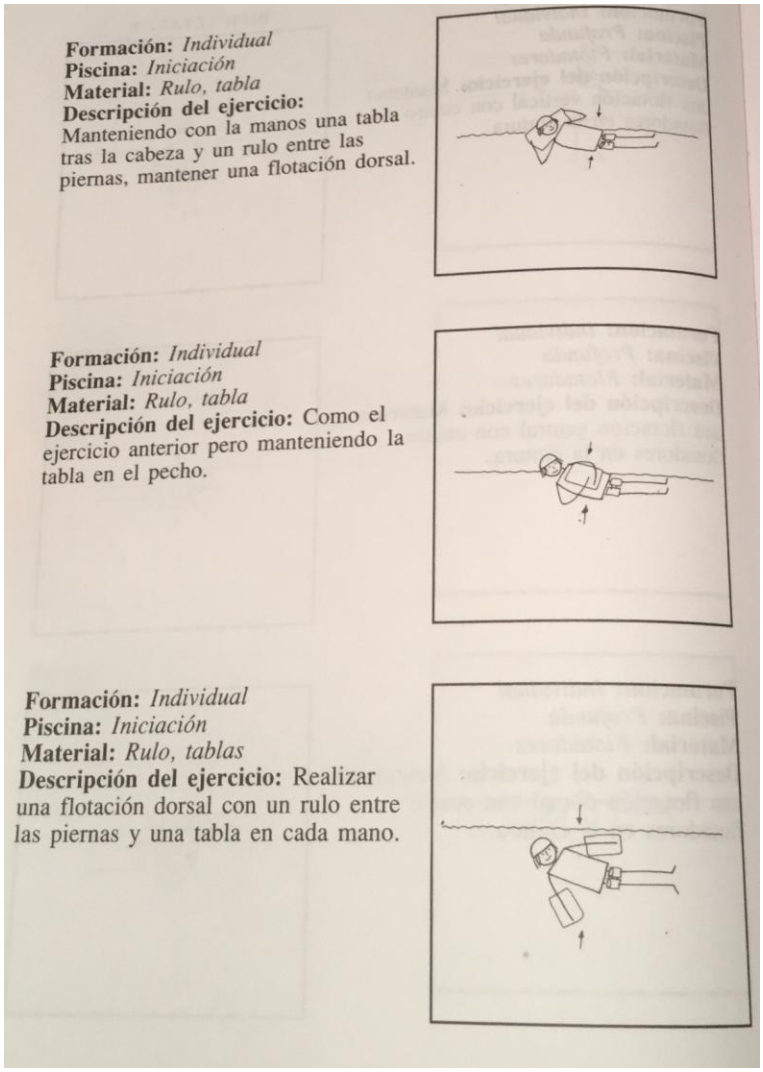
- Relaxation exercises (final cool down phase)



DIFICULTAD: B

Formación: *Individual*
Piscina: *Profunda*
Material: *Flotador*
Descripción del ejercicio: Con un flotador en la cintura, flotar verticalmente.

*in small tank pool



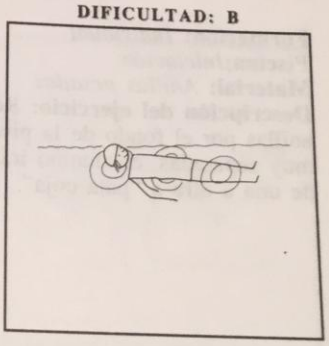
Formación: *Individual*
Piscina: *Iniciación*
Material: *Rulo, tabla*
Descripción del ejercicio: Manteniendo con la manos una tabla tras la cabeza y un rulo entre las piernas, mantener una flotación dorsal.

Formación: *Individual*
Piscina: *Iniciación*
Material: *Rulo, tabla*
Descripción del ejercicio: Como el ejercicio anterior pero manteniendo la tabla en el pecho.

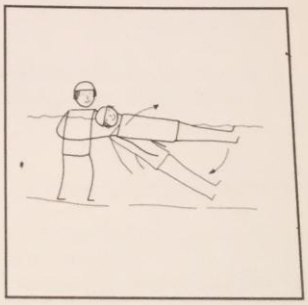
Formación: *Individual*
Piscina: *Iniciación*
Material: *Rulo, tablas*
Descripción del ejercicio: Realizar una flotación dorsal con un rulo entre las piernas y una tabla en cada mano.

Formación: *Individual*
Piscina:*Iniciación*
Material: *Flotadores circulares*
Descripción del ejercicio:
Proporcionar tres flotadores al alumno para que con su ayuda consiga una flotación horizontal en completa relajación.

DIFICULTAD: B



Formación: *Parejas*
Piscina: *Iniciación*
Material:
Descripción del ejercicio: Uno en flotación horizontal dorsal y completamente relajado, el compañero le sujeta por los hombros e intenta ponerlo en posición vertical.



References

Images extracted from: Arús F de L, Beltrán AT. 1060 ejercicios y juegos de natación. Paidotribo. Barcelona; 2000. 419 p. (63).

17.4. Annex 4. International Physical Activity Questionnaire (IPAQ)

CUESTIONARIO INTERNACIONAL DE ACTIVIDAD FÍSICA (IPAQ)

Nos interesa conocer el tipo de actividad física que usted realiza en su vida cotidiana. Las preguntas se referirán al tiempo que destinó a estar activo/a en los últimos 7 días. Le informamos que este cuestionario es totalmente anónimo.

Muchas gracias por su colaboración

1.- Durante los últimos 7 días, ¿en cuántos realizo actividades físicas intensas tales como levantar pesos pesados, cavar, ejercicios hacer aeróbicos o andar rápido en bicicleta?	
Días por semana (indique el número)	
Ninguna actividad física intensa (pase a la pregunta 3)	☐
2.- Habitualmente, ¿cuánto tiempo en total dedicó a una actividad física intensa en uno de esos días?	
Indique cuántas horas por día	
Indique cuántos minutos por día	
No sabe/no está seguro	☐
3- Durante los últimos 7 días, ¿en cuántos días hizo actividades físicas moderadas tales como transportar pesos livianos, o andar en bicicleta a velocidad regular? No incluya caminar	
Días por semana (indicar el número)	
Ninguna actividad física moderada (pase a la pregunta 5)	☐
4.- Habitualmente, ¿cuánto tiempo en total dedicó a una actividad física moderada en uno de esos días?	
Indique cuántas horas por día	
Indique cuántos minutos por día	
No sabe/no está seguro	☐
5.- Durante los últimos 7 días, ¿en cuántos días caminó por lo menos 10 minutos seguidos?	
Días por semana (indique el número)	
Ninguna caminata (pase a la pregunta 7)	☐
6.- Habitualmente, ¿cuánto tiempo en total dedicó a caminar en uno de esos días?	
Indique cuántas horas por día	
Indique cuántos minutos por día	
No sabe/no está seguro	☐
7.- Durante los últimos 7 días, ¿cuánto tiempo pasó sentado durante un día hábil?	
Indique cuántas horas por día	
Indique cuántos minutos por día	
No sabe/no está seguro	☐

VALOR DEL TEST:

1. Caminatas: 3'3 MET* x minutos de caminata x días por semana (Ej. 3'3 x 30 minutos x 5 días = 495 MET)
2. Actividad Física Moderada: 4 MET* X minutos x días por semana
3. Actividad Física Vigorosa: 8 MET* X minutos x días por semana

A continuación sume los tres valores obtenidos:

Total = caminata + actividad física moderada + actividad física vigorosa

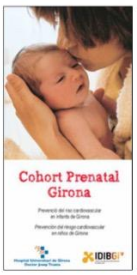
CRITERIOS DE CLASIFICACIÓN:

- Actividad Física Moderada:
  1. 3 o más días de actividad física vigorosa por lo menos 20 minutos por día.
  2. 5 o más días de actividad física moderada y/o caminata al menos 30 minutos por día.
  3. 5 o más días de cualquiera de las combinaciones de ca minata, actividad física moderada o vigorosa logrando como mínimo un total de 600 MET*.
- Actividad Física Vigorosa:
  1. Actividad Física Vigorosa por lo menos 3 días por semana logrando un total de al menos 1500 MET*.
  2. 7 días de cualquier combinación de caminata, con actividad física moderada y/o actividad física vigorosa, logrando un total de al menos 3000 MET*.

*** Unidad de medida del test.**

RESULTADO: NIVEL DE ACTIVIDAD (señale el que proceda)	
NIVEL ALTO	☐
NIVEL MODERADO	☐
NIVEL BAJO O INACTIVO	☐

17.5. Annex 5. Family data Questionnaire



Estudi Prenatal Girona

Data d'avui: _____
Nom i cognoms (mare):_____

QÜESTIONARI DE DADES FAMILIARS:
(ompliu les dades corresponents o marqueu la resposta que considereu correcta)

Dades de la mare abans embaràs:

	Nom i cognoms	Edat	Pes	Alçada	Data naixement
Mare					

	Medicació	Tabac	Alcohol		
	(Només d'ús habitual)	Nombre cig/dia	Nombre gots vi/setmana	Nombre gots cervesa/setmana	Nombre copes licor/setmana
Mare					

El seu pes al naixement va ser: <2 kg 2-3 kg 3-4 kg >4kg

Malalties familiars:	Diabetis (sucre)	Obesitat o sobrepès	Hipertensió (tensió alta)	Colesterol	Infart o embòlia	Malalties o intervencions quirúrgiques
Mare	sí / no	sí / no	sí / no	sí / no	sí / no	
Edat inici (en cas "sí")						
Avi matern	sí / no	sí / no	sí / no	sí / no	sí / no	
Àvia materna	sí / no	sí / no	sí / no	sí / no	sí / no	

	Nom i cognoms	Edat	Pes	Alçada
Avi matern				
Àvia materna				

Edat primera regla :_____

Abans embaràs:

Regles regulars? sí / no Durada regla: _____dies

Prenia anticonceptius orals? sí / no Cicle : Cada_____dies

Data última regla abans embaràs: _____/_____/_____

Dades mare durant l'embaràs del seu fill/a:

	Diabetis a causa de l'embaràs	Obesitat o sobrepès a causa de l'embaràs	Tensió alta a causa de l'embaràs	Altres malalties de l'embaràs
Mare	sí / no	sí / no	sí / no	

	Trimestre actual	Pes actual
Mare	1r / 2n / 3r	

	Medicació durant l'embaràs	Tabac embaràs	Alcohol durant l'embaràs		
	(Només d'ús habitual)	Nombre cig/dia	Nombre gots vi/setmana	Nombre gots cervesa/setmana	Nombre copes licor/setmana
Mare					

Ordre del seu fill/a respecte a germans: 1r 2n 3r 4t 5è Altre

En el cas de tenir altres fills, omplir la següent taula referent a **l'embaràs anterior**:

Diabetis durant embaràs anterior	Obesitat o sobrepès durant embaràs anterior	Tensió alta durant embaràs anterior	Altres malalties durant embaràs anterior
sí / no	sí / no	sí / no	

Dades del pare:

	Nom i cognoms	Edat actual	Pes actual	Alçada actual	Data naixement
Pare					

	Medicació	Tabac	Alcohol		
	(Només d'ús habitual)	Nombre cig/dia	Nombre gots vi/setmana	Nombre gots cervesa/setmana	Nombre copes licor/setmana
Pare					

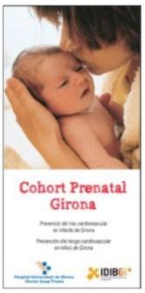
El seu pes al naixement va ser: <2 kg 2-3 kg 3-4 kg >4kg

Malalties familiars:	Diabetis (sucre)	Obesitat o sobrepès	Hipertensió (tensió alta)	Colesterol	Infart o embòlia	Malalties o intervencions quirúrgiques
Pare	sí / no	sí / no	sí / no	sí / no	sí / no	
Edat inici (en cas "sí")						
Avi patern	sí / no	sí / no	sí / no	sí / no	sí / no	
Àvia paterna	sí / no	sí / no	sí / no	sí / no	sí / no	

	Nom i cognoms	Edat	Pes	Alçada
Avi patern				
Àvia paterna				

Torneu aquest qüestionari un cop omplert a la infermera de pediatria el dia de la visita. Gràcies.

17.6. Annex 6. Physical Activity Questionnaire during Pregnancy



Estudi Prenatal Girona

Data d'avui:_____
Nom i cognoms:_____

QÜESTIONARI D'ACTIVITAT FÍSICA durant l'EMBARÀS:

Si us plau, marqueu les dades corresponents a la vostra activitat física en les següents taules:

Actualment et trobes en el teu... ○ 2n trimestre embaràs ○ 3r trimestre embaràs

Quantes hores DORMS durant la nit cada dia? **ENTRE SETMANA** ☐ **CAPS DE SETMANA** ☐

Quants minuts de MIGDIADA DORMS cada dia? **ENTRE SETMANA** ☐ **CAPS DE SETMANA** ☐

A CASA, durant aquest trimestre, quant temps dediques AL DIA a...

	hores al DIA					
	0	<½	½-1	1-2	2-3	>3
Preparar els àpats (cuinar, parar la taula, rentar plats,...)	○	○	○	○	○	○
Cuidar una persona gran	○	○	○	○	○	○
Escriure o utilitzar l'ordinador asseguda a casa	○	○	○	○	○	○
Jugar amb animals domèstics	○	○	○	○	○	○
Netejar requerint poc esforç (fer llits, rentar roba, planxar, escombrar,...)	○	○	○	○	○	○
Comprar (menjar, roba o altres)	○	○	○	○	○	○
En cas de tenir altres fills:						
Portar a coll altres fills	○	○	○	○	○	○
Vestir, dutxar o donar menjar a altres fills asseguda	○	○	○	○	○	○
Vestir, dutxar o donar menjar a altres fills a peu dret	○	○	○	○	○	○
Jugar amb els altres fills mentre estàs asseguda o a peu dret	○	○	○	○	○	○
Jugar amb els altres fills caminant o corrent	○	○	○	○	○	○

	hores al DIA					
	0	<½	½-2	2-4	4-6	>6
Mirar la televisió o vídeo	○	○	○	○	○	○
Llegir, parlar, trucar per telèfon a casa	○	○	○	○	○	○

A CASA, quant temps dediques A LA SETMANA a...

	hores a la SETMANA					
	0	<½	½-1	1-2	2-3	>3
Netejar requerint esforç (aspirar, fregar, netejar vidres,...)	○	○	○	○	○	○
Feines de jardí (segar gespa manual o màquina, escombrar fulles,...)	○	○	○	○	○	○

PER DESPLAÇAMENTS (no per lleure ni per exercici), quant temps dediques AL DIA a...

	hores al DIA					
	0	<½	½-1	1-2	2-3	>3
Caminar a poc a poc (anar a agafar l'autobús, anar a la feina,...) _____	○	○	○	○	○	○
Caminar ràpid (anar a l'autobús, anar a la feina, portar nens a l'escola,...)___	○	○	○	○	○	○
Conduir o anar amb cotxe o autobús_____	○	○	○	○	○	○

Actualment, treballes? ○ Sí ○ No

En **cas negatiu**, en quin mes d'embaràs has deixat de treballar? _____

En **cas afirmatiu**, contesta la següent pregunta i taula:

Quantes hores al dia fas de jornada laboral? [hores]

A la feina, quant temps dediques AL DIA a...

	hores al DIA					
	0	<½	½-2	2-4	4-6	>6
Llegir, escriure,... assegut a la feina o a classe_____	○	○	○	○	○	○
Estar dret o caminar a poc a poc (sense transportar res)_____	○	○	○	○	○	○
Caminar ràpid (sense transportar res)_____	○	○	○	○	○	○
Estar dret o caminar a poc a poc transportant coses pesades _____	○	○	○	○	○	○
Caminar ràpid transportant coses pesades_____	○	○	○	○	○	○

PER LLEURE o EXERCICI, quant temps dediques A LA SETMANA a...

	hores a la SETMANA					
	0	<½	½-1	1-2	2-3	>3
Caminar a poc a poc_____	○	○	○	○	○	○
Caminar ràpid_____	○	○	○	○	○	○
Caminar ràpid amb esforç (per camins amb pujades,...)_____	○	○	○	○	○	○
Córrer ("jogging" o "footing")_____	○	○	○	○	○	○
Classes prenatals _____	○	○	○	○	○	○
Nedar (lliure o classes natació)_____	○	○	○	○	○	○
Ballar_____	○	○	○	○	○	○
Anar amb bicicleta_____	○	○	○	○	○	○
Altres activitats o esports (siusplau, indicar quin/s).....	○	○	○	○	○	○

Considerant **TOTA** la teva activitat física (feina o ocupació principal, llar i lleure) com et defineixes en l'actualitat i abans de l'embaràs? **(marqueu 1 única opció)**

ABANS embaràs:	**ACTUALMENT:**		
○	○	Sedentària	(casi sempre asseguda, sense activitat física, sense fer esport)
○	○	Poc activa	(feina o activitats asseguda, esport escàs)
○	○	Moderadament activa	(feina o activitats manuals, mestressa de casa, esport moderat)
○	○	Bastant activa	(feina o activitats estant dret o caminant, esport intens)
○	○	Molt activa	(feina o activitats molt vigoroses, esport intens a diari)
○	○	Altre categoria:	

Torneu si us plau aquest qüestionari un cop omplert a la infermera de pediatria el dia de la visita. Gràcies.

17.7. Annex 7. Perception of Facilitators and Barriers to perform Physical Activity during Pregnancy Questionnaire

Llegeixi els següents ítems i indiqui com és d'important per a vostè realitzar o no activitat física.

Si us plau contesti utilitzant la següent escala:

1= Totalment en desacord

2= En desacord

3= D'acord

4= Totalment d'acord

Nº	Pregunta	Totalment en desacord (1)	En desacord (2)	D'acord (3)	Totalment d'acord (4)
1	Els meu cercle familiar o d'amistats no són físicament actius.				
2	Em veuria i em sentiria millor si la meva activitat física fos constant.				
3	L'activitat física serveix per controlar el meu pes.				
4	Realitzar activitat física em serviria per socialitzar-me amb altres persones.				
5	Em falta temps per realitzar activitat física.				
6	No realitzo activitat física perquè no tinc amb qui practicar-la.				
7	Si realitzés activitat física constantment tindria més energia.				
8	Realitzar activitat física amb regularitat milloraria la meva salut.				
9	La meva família no està d'acord en què realitzi activitat física.				
10	Les responsabilitats familiars m'impedeixen realitzar activitat física.				

11	L'activitat física alleuja l'estrés.				
12	Mantenir-me activa durant l'embaràs em permetria tenir un treball de part més favorable.				
13	El personal de salut (metge, infermera, llevadora) no em recomana realitzar activitat física.				
14	Les molèsties que tinc amb l'embaràs no em permeten tenir ganes de realitzar cap tipus d'activitat física.				
15	Realitzant activitat física tindré menys problemes al part.				
16	El clima no em permet realitzar activitat física.				
17	L'activitat física no és recomanable per la salut del meu nadó.				
18	Em preocupa el fet de que practicar activitat física durant l'embaràs em pugui provocar un avortament.				
19	Em preocupa el fet de que practicar activitat física durant l'embaràs em pugui provocar un part prematur.				
20	No em sento segura practicant activitat física durant l'embaràs.				
21	No tinc coneixement sobre quins exercicis són els més adients a practicar durant l'embaràs.				

Facilitadors = 2, 3, 4, 7, 8, 11, 12, 15

Barreres = 1, 5, 6, 9, 10, 13, 14, 16, 17, 18, 19, 20, 21