Doctoral Thesis project:

"EVALUATION OF THE EFFECTIVENESS OF A PROGRAM TO STRENGTHEN THE PELVIC FLOOR IN THE POSTPARTUM WOMEN"

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1. INTRODUCTION:

Pelvic floor dysfunction is a problem of high prevalence in the puerperal period of women. Urinary incontinence is one of the most frequent dysfunctions that most affect their health after childbirth. Recent studies expose the idea that pelvic floor muscle training using vaginal areas, generally, reduces the appearance of pelvic dysfunction, and thus improves the quality of life of these women.

Pelvic floor health is an important issue for women around the world as the impact of pelvic-perineal problems in any woman life is often considerable. Pelvic problems impair the quality of life of women who suffer them, because they feel vulnerable, and experience a great impotence by the inability to predict how will their body react to certain situations of daily life; this affects negatively their intimate relationships, work and socials activities[1].

Pregnancy and birth have historically been identified as the major etiological factors of pelvic floor dysfunctions[2]. The literature demonstrates that 33% of women experience urinary incontinence (UI) during the first three months postpartum, with no major improvements until the first anniversary of birth[3]. We also find 10% of fecal incontinence during quarantine, extended by 1% of women until 9 months postpartum[4]. There are also pelvic organ prolapse, ranging between 7.7% and 56% of women 3-6 months Postpartum[5].

As has been evidenced, a functional weakness of the pelvic floor muscles, can not only enhance the influence of the UI for women in the postpartum period, but will also be a contributing factor to fecal incontinence and prolapse of pelvic organs[2].

2. Framework:

In Spanish hospitals over the past 15 years a change is taking place in attention to normal delivery, because until relatively recently days, the episiotomy was systematic for every woman who was perceived that did not have a sufficiently elastic perineum under criterion of the professional who was attending the birth. With the perineal

consequences that subsequent healing of a lateral half cut in the pelvic floor muscles had.

Fortunately, today professionals obstetrics are more updated and have greater access to new scientific evidence that contributes to our environment, so this type of intervention, unless the professional deems strictly necessary, are not made. Unless exists a risk of loss of fetal well-being, or the need to end the labor through an instrumented delivery (forceps or vacuum), although these final decisions are always under the criterion of the professional who is attending childbirth.

The main theme that occupies our study is the women`s pelvic floor, so let's introduce a little deeper into the subject concisely describing this part of the female body anatomy.

The pelvic floor is the set of soft tissue (muscles, fascia and ligaments) that limit the pelvic cavity at the bottom. It is responsible for supporting the weight of the viscera and helps to prevent the leakage of urine and stool[5]. Therefore it is imperative that these muscles have the strength and tone needed to perform their functions and not disrupt the daily lives of women.

Pelvic floor dysfunctions are often caused by external aggression, such as surgery, vaginal delivery, or by lack of muscle strength: hypotonia, or even muscle hypertonia.

The new lines of normal delivery care, described in the "Clinical Practice Guideline for Normal Birth Care" published by the Spanish Ministry of Health in 2010 recommended the following actions (with an **A** level of recommendation):

- *It should not be practiced routine episiotomy in spontaneous labor.*
- *Episiotomy should be performed if there is a clinical need, as an instrumental birth or suspected fetal compromise.*
- *Before performing an episiotomy effective analgesia should be performed, except one due to acute fetal compromise emergency.*

- *When an episiotomy is performed, the recommended technique is mediolateral episiotomy, starting it in the posterior commissure of the labia minora and usually directed to the right side. The angle to the vertical axis should be between 45 and 60 degrees to perform episiotomy.*
- *Episiotomy should not be routinely performed during a vaginal delivery in women with tears in third or fourth grade in previous births.*

Below is a picture of the female pelvic anatomy, reflecting the network of perineal muscles that form the female pelvic floor.

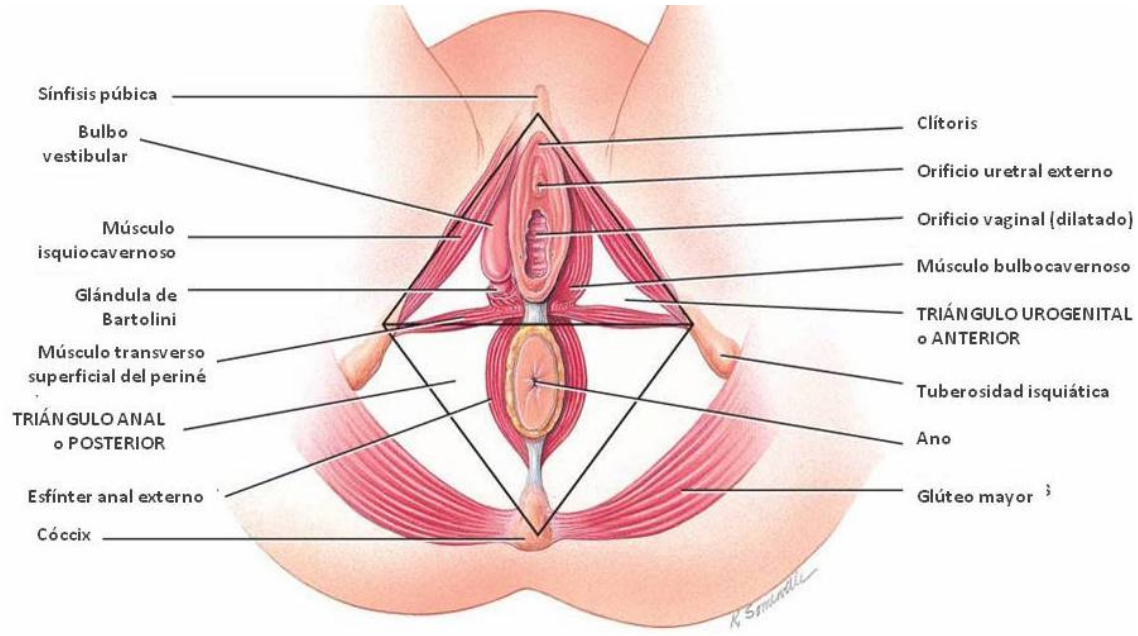


Fig. 1 pelvic anatomy. KS fte medicine.

Not being recommended episiotomy systematically in a normal delivery, the next problem that we can find in terms of disruption of the pelvic floor muscle is a perineal tear, physiologically produced at the time of delivery. Perineal tears types are as follows:

I. I degree tear: when affects only the surface of the perineum (skin and subcutaneous tissue).
II. II degree tear: It affects both vaginal and perineal pelvic muscles.
III. III degree tear: Complete muscle tear and reaches the external anal sphincter.
IV. IV degree tear: When it affects the anal sphincter.

These types of perineal trauma (both tear and episiotomy) should be sutured by the professional who is attending the delivery (midwife or obstetrician) as recommended by the Clinical Practice Guideline 2010, we mentioned earlier. Recommendations as to suture tear (recommendation A- level) are:

- *Is recommended suturing first grade lacerations in order to improve healing, unless the edges of the skin are well approximated.*
- *Perineal repair of second degree tears using continuous suture technique is recommended.*
- *If after muscle suture of a second degree tear the skin is well approximated, stitches are not need. But if the skin needs to be approached, the recommendations requires to be performed in a continuous intradermal technique.*

The type of tear occurred during delivery, or if episiotomy need to be done, and even the type of suture used for perineal repair, will affect lesser or greater the recovery of the pelvic floor postpartum. Therefore, the recommendation is always to be as less aggressive as possible, taking into account the quality of life of women pelvic floor dysfunction in short- and long-term.

2.2 Pelvic Floor Dysfunctions:

Within the pelvic floor dysfunctions (PFD) we find the most recurrent urinary incontinence (UI) form. Defined by the International Continence Society (ICS) as "the involuntary loss of urine."[6] Has a high prevalence in women of all ages[7], the most common are: stress incontinence, urge or mixed.

Below is a table with the different types of incontinence:

TIPOS DE INCONTINENCIA

Tipo	Características	Origen
De esfuerzo	Cuando se realiza cualquier pequeño esfuerzo cotidiano (reír, toser, saltar…). Es la más habitual.	Músculos del suelo pélvico dañados.
De urgencia	Siente la necesidad de ir al baño pero no es capaz de llegar.	Hiperactividad vesical.
Mixta	Combinación de las dos anteriores.	Combinación de las dos afecciones anteriores.
Por rebosamiento	Pérdidas continuadas y sin darse uno cuenta.	La vejiga no se vacía bien.
Funcional	No llega al baño por no responder adecuadamente a la sensación del deseo de orinar.	Problemas físicos, para pensar o comunicarse.
Transitoria	De carácter temporal.	Producida por medicamentos, infecciones de orina, movilidad limitada ocasional y estreñimiento severo.

FUENTE: ASOCIACIÓN DE PACIENTES CON PÉRDIDAS DE ORINA Y URGENCIA MICCIONAL (APPU).

Fig 2. Types of Incontinence. FTEs. Association of incontinent patients.

Incontinence affects five out of ten pregnant women (48.3%). Four out of ten pregnant women experience urine leakage for the first time during pregnancy (40%). In pregnant women with pre-UI severity increases during pregnancy. Urinary incontinence before and during pregnancy is associated with previous gestations[8].

In fact, the most common reason that a woman usually consult a health care professional within the field of perineal-sphincter reeducation is undoubtedly urinary incontinence, being the postpartum period and menopause the highest incidence. These data are shown in the survey conducted by Wilson on 1,505 women at three months postpartum with 34.3% of incontinents[9], while in another study with perimenopausal women Minaire discloses that 47.6% of these women report involuntary leakage of urine[10]

At other times, the reason for consultation is a pelvic organ prolapse, present in 30% of women between 29 and 59 years according to a Swedish study of 487 people by Samuelsson and Victor[11]. However, this type of dysfunctions are often associated with perineal pain, faecal incontinence or sexual dysfunction, that the patient will not initially refer. But these problems, may instead pose a bigger social problem, greater than urinary incontinence.

As we discussed earlier, vaginal delivery is a known risk factor for UI and the results of multiple studies confirm its impact on hospital clinical practice. Although severe cases persist, it is included a significant reduction in symptoms during the first 12 months as long as the perineal musculature is being toned by performing specific exercises[12].

In the immediate postpartum it is estimated that 50% of women with vaginal delivery have a transient effort UI, evolving toward regression or spontaneous healing in 50-70% of cases after spending six weeks after childbirth. However, these transient incontinence reflect a perineal alteration, represents an increased risk of 2.5% posterior developing incontinence[13].

Taking into consideration, pregnancy and childbirth as a major risk for developing

incontinence is due to a decrease of 22-35% of the strength of the pelvic floor muscles[14]. In addition, if incontinence develops during pregnancy or the postpartum period and no return address before 3 months postpartum, there is a significant risk that persists for 5 years after[15].

According to a study by Ewings in 2015 "The presence of one or more episiotomies is also a significant risk factor, however, cesarean and epidural use during childbirth, seem to be a protective factor"[16]. Although, this information continues to be controversial because, according to a study by Rotveit in 2003 with a total of 15,307 women, it was observed that compared with nulliparous women, women who had given birth by Caesarean section had a probability of 1.5 to experience any incontinence. The explanation is that not only labor, but also the weight of the fetus and postural alteration during pregnancy are risk factors of urinary incontinence in the postpartum period overloading the perineum previously[17]. In view of the results of these studies, the importance of knowing the history of our obstetrical patients and reflect it on its clinic history is clear.

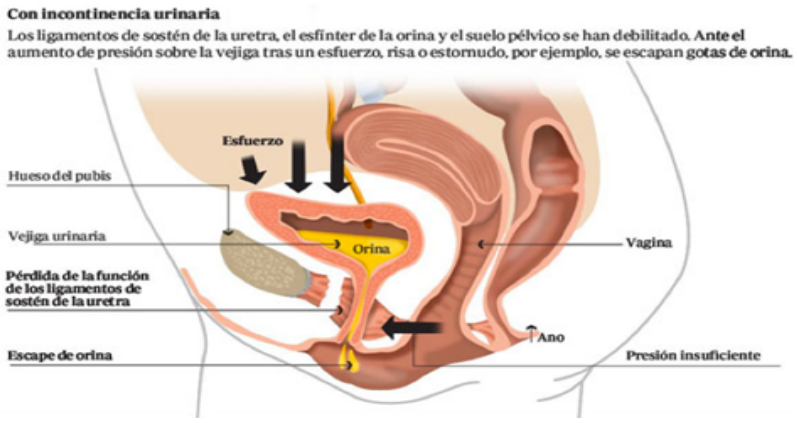


Fig.3 organic incontinent patients Fte Damages. Association of incontinent patients.

The pelvic floor muscle training (PFMT) has an important place in the treatment of UI, with a success rate of 56-75%[18], So that, a review by the Cochrane in 2011, concludes that it is consistently better than no treatment or placebo, and should be offered as first treatment for women with UI[19].

The mechanism of action of PFMT is hypertrophy of muscle fibers, improving cortical awareness of the muscle, connective tissue strength and increasing the effectiveness of recruitment of motoneurons[18].

UI significantly affects the quality of life of people, In fact 4 out of 10 women with urge UI and 6 out of 10 with mixed UI feel embarrassed in social relations or have avoidance behaviors and limitation in their daily life, forcing them to change their social activities and relationships[20].

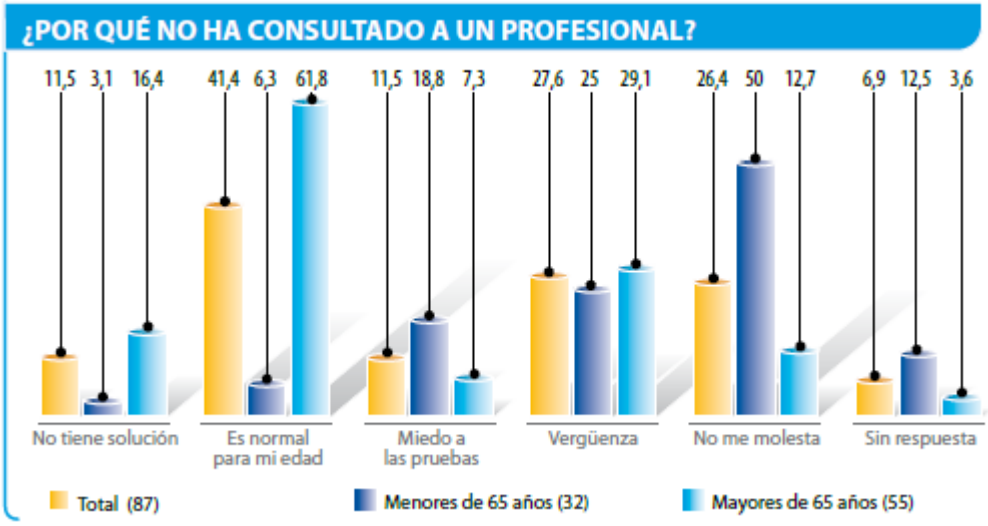


Fig. 4. Why has not consulted a professional? FTEs. Rehabilitation and pelvic floor. UY. 2003.

This section must make a special mention on sexual health of women, because of the high degree of psychological, emotional and functional impairment involving such dysfunctions and how they affect the sexual and reproductive lives of women who suffer it. You need a good diagnosis to determine the causes of it and design a personalized treatment working not only preventive and curative but also paliative[21,22,23].

To promote perineal pelvic health in women in the puerperal period, most recommended intervention, as we have seen above, is to instruct patients in performing strengthening pelvic floor exercises [21].

However, one of the alternative methods for pelvic muscle rehabilitation, we want to show with this study, is the use of vaginal balls. They operate by a mechanism of

involuntary muscle contractions to prevent possible removal of the spheres out of the vagina.

It is demonstrated in literature (last systematic review by Oblasser 2015)[25], the shortage of scientific evidence published concerning the effectiveness of vaginal balls to improve the performance of pelvic-perineal muscles and the UI during the puerperium. Most published studies suggest that vaginal spheres can be useful to improve the UI in the postpartum, but all suggest that more studies are needed to corroborate suggestions, as the current evidence is limited.

Thanks to the above references, we can confirm the dependence of pregnancy and childbirth along with a few etiological factors of pelvic floor dysfunction and, especially the UI, which is an area of interest in epidemiological research. Although the numbers of studies examining the prevalence of UI in the postpartum period are highly controversial and studies are insufficient in our midst.

3. RATIONALE:

Presently in the current literature there is no empirical knowledge to support the use of vaginal spheres or its effectiveness compared with standard pelvic floor exercises. All items and issues found require more studies to support its use for the recovery of the pelvic floor of women in the postpartum period.

UI is a disease with a high prevalence in women that does not involve an increase in mortality, but it limits the autonomy, self-esteem and significantly reduces and deteriorate the quality of life. Often it remains undiagnosed and untreated or is treated inappropriately. The short experience and few studies indicate that some professionals do certain exercises without knowing exactly muscle actions and side effects are implicit.

Vaginal spheres stimulate perineal type I fibers, which make up 80% of the perineal musculature and give response to a reflected tonic activity. While traditional rehabilitation exercises of the pelvic floor and postpartum (PFMT) stimulates type II

fibers, which are part of other 20% of the perineal musculature and are responsible for voluntary muscle activity.

It is demonstrated the effectiveness of pelvic floor muscle training (PFMT) in preventing both: urinary and fecal postpartum incontinence[8]. However, there is no evidence of the effect of vaginal balls such dysfunctions.

Therefore we must make three different intervention groups to integrate a comparative study of treatment. Currently being carried out as a method of perineal recovery after childbirth (PFMT) and vaginal areas as a new method to study. The groups would be as follows:

- Group 1 (Control) = PFMT would perform the exercises exclusively designed by the team of Physiotherapy participating in the study.

- Group 2 (Intervention a) = PFMT would perform exercises with the use of vaginal spheres.

- Group 3 (Intrervención-b) = would perform intensive treatment, designed for physiotherapy equipment vaginal areas.

4. OBJECTIVES:

4.1 Main objective:

- To determine the effectiveness of 3 types of muscle training for recovery pelvic floor postpartum and evaluate their effectiveness by perineometer, Test and Modified Oxford ICIQ Incontinence Questionnaire SF.

4.2 Specific objectives:

- Evaluate the effectiveness of three interventions on improving the symptoms of urinary incontinence in the target population (women in puerperal period Sevilla)
- Assess the impact of improving the quality of life through King`s Health Questionnaire (KHQ) in its Spanish version validated in 2013.
- Assess the sexual satisfaction of women who participated in the intervention through the questionnaire: FSFI (Female Sexual Function Index).

5. HYPOTHESIS:

Intervention based on the application of the traditional method (PFMT) with the use of vaginal balls increases the force of perineal muscles measured by modified test Oxford and perineometer. Likewise, it decreased urine leakage in women with urinary incontinence treatment versus exclusive traditional exercises pelvic floor.

Similarly intervention based on the application of the traditional method with the use of vaginal spheres improves quality of life and increases sexual satisfaction in the puerperal period compared to traditional treatment.

Therefore, women in the puerperal period, perform pelvic floor exercises (PFMT) with vaginal spheres, have more rapid and effective recovery of the perineal strength .

6. Methodology:

6.1 type design and study population:

In order to determine the effectiveness of using vaginal areas for improving the perineal strength of women in the postpartum period, we have designed a randomized experimental clinical trial. We will take as a reference population all primiparous women who give birth in the metropolitan area of Seville, in the course of a year.

The participation is voluntary and unpaid asked all women through informed consent, delivered in the puerperal visit, the midwife consultation itself.

6.2 Ethical Aspects:

Data have been obtained following the provisions of Law 15/1999, of December 13, Protection of Personal Data. To ensure confidentiality of users, each was assigned a protocol number without starting any personal information that can identify them, so we have worked with anonymous data.

In all cases, anonymity and free participation of study subjects will be respected and, following the legislation on biomedical research, a model of informed consent must be prepared for the participants in the study. The completion of such consent will be a prerequisite for participation in the project.

In this model, you will be informed of the study objectives, the duration of their participation, as well as the freedom to refuse participation, and they ensure data confidentiality.

This research arises from a previous study, which was certified to comply with ethical and scientific quality criteria accepted. To do this, he issued a permit and the Ethics Committee of the University Hospital Virgen de Valme Clinical Research, this being favorable to its realization and attached (Annex III).

6.3 Criteria for Inclusion / Exclusion:

The criteria that will be used to include or exclude women in the study are as follows:

6.3.1.Criterious inclusion:

- Primiparous women.
- Women who are in the postpartum period between 6 weeks (quarantine) and 6 months at the start of the intervention.
- Newborn births Term (from 37 weeks)
- Cease Lochia.

- Sufficient knowledge of the Spanish language, both written and spoken.
- Acceptance to participate in the study through informed consent.

6.3.2 Exclusion criteria:

- Multiparous women
- Women off limits postpartum (previous birth to 6 months after surgery)
- Women undergoing treatment of lower urinary tract (ITU treatment)
- Women who are already participating in a recovery program pelvic floor.
- Women with tear III and IV grade.
- Pregnant (or become pregnant approach in the intervention period) Women
- Starting point pelvic floor muscle balance women less than 2 points. (Where retention vaginal areas impossible)
- Inability to perform the necessary procedures for intervention.

6.4 Study variables:

Quantitative variables to be taken into account for the study, all
numeric type, they are as follows:

- Maternal age (measured in years): Discrete Variable / Quantitative Control.
- Gestational age (measured in weeks): Variable Continuous / Quantitative Control.
- Tearing Type: NT (No Tearing) / type I / type II / type III / type IV: Variable quantitative continuous / Control.
- RN weight (measured in grams): quantitative continuous variable / Control
- Objective Force 1 (Test Oxford Digital Scale 0-5): Discrete Variable / Dependent quantitative.
- objective force 2 (perineometer 0 to 12): Continuous variable / Dependent quantitative.

Coding of qualitative variables studied were as follows:

- Type of delivery: eutocic 1; Forceps 2; Suction cup 3; Cesarean 4. Variable Control
- Presentation: Cephalic 1; 2. Buttocks. Variable Control
- Analgesia: NA. 1; Regional 2; Local 3. Variable Control
- Episiotomy: yes 1; No 2. Variable Control
- ICIQ-SF: No Incontinence 1; Small losses 2; incontinence 3. Variable Control
- Exercise conducted during the study: Control 1/2 and 3 Group Intervention Group. Independent variable

6.5 Description of the study:

The study will be a Controlled and Randomized Clinical Trial, single-blind (Technical opaque envelopes), with three parallel groups for intervention and subsequent comparison:

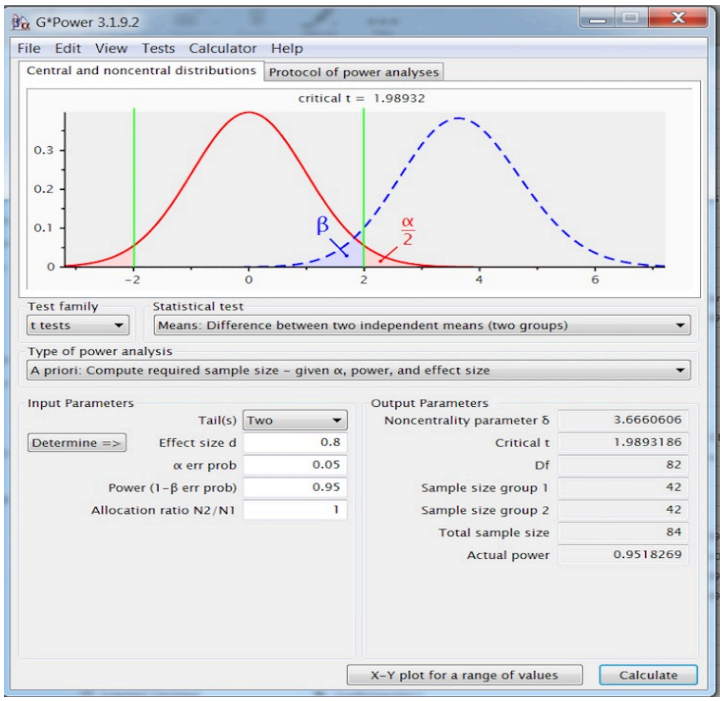
Group 1 (Control): this group will perform pelvic floor standardized exercises (PFMT), designed by the physiotherapy team that will participate in the study, following the guidelines of current clinical practice and determining a duration of at least 12 weeks to carry out the exercises.

Group 2 (Intervention-a): this group will perform pelvic floor exercises set by physiotherapy equipment while using the vaginal balls. Its duration will also be 12 weeks.

Group 3 (Intervention-b): this group will use the vaginal balls in their activities of daily life during 12 weeks of the intervention program, the intensity of the time of using the balls will be determined by the physiotherapy team that participate in the study program.

6.5.1 sample size and randomisation:

For sample size calculation will be use the GP.Power programme in version 3.1.9.2. In which we will apply an effect size of 0.8, comparing in parallel the three focus groups.



This yields a sample size of 23 women per group. But considering the bibliography, referencing a lack of adherence to exercise in previous studies[25], we assume 25% losses. What it creates groups covered by 31 women, which correspond to a total of 93 women in the sample.

6.5.2. Statistic analysis:

After a scan statistic of the data input to detect errors in the base, the same will be described as the three study groups. Quantitative variables are expressed in means and standard or medians and 25th and 75th percentiles, if skewed distributions deviations, and qualitative variables with frequency and percentage.

Next, an analysis of baseline comparability between the two groups will be performed. for analyse the relationships between qualitative variables, contingency tables will be made and the Chi-square test or non-asymptotic test methods and Monte Carlo exact test will be applied.

To see if there are differences in average of numerical variables between the two groups, T-Student's test will be used for independent samples or Mann-Whitney-U Test for non-normal distributions. Significant mean differences will be quantified with confidence intervals at 95% and, if not normal, the differences between medians with confidence intervals Hodges-Lehman 95%.

Furthermore, to contrast changes in a numerical parameter measured at different time points (possible intra-intervention assessments) within each group, the Friedman Test or the nonparametric Wilcoxon Test is applied in the case of only two moments. The change between two time points of a qualitative variable is analysed with the McNemar Test.

The data analysis will be performed with the statistical program SPSS 23.0 for Windows.

6.6 Collecting information:

New in this thesis, we have included involvement with the Faculty of Computer Science at the University of Seville.

Participation is designing a mobile phone application (APP) to facilitate monitoring, biofeedback and adherence to the exercise by patients. 4th year students of Computer Engineering degree may choose this project as Final Project during the years 2019 and 2020. The project is offered with the title and description:

"Tool for monitoring patients in therapeutic exercise period."

Description:

The project is to develop a mobile application that will support patients while performing therapeutic exercises indicated. In addition, the information collected by the application should be available to health professionals, so that you can track the patient and the analysis and subsequent operation of the data obtained.

Thereby we facilitate monitoring of patients, include the use of new technologies in the study, and we have provided a utility application health, learning and improving adherence to exercise.

7. Workplan:

- Searching: starts in January 2019 and continues throughout the study.
- APP design tracking patients: its realization is offered as a final degree project at the Faculty of Computer Engineering in April 2019.
- Start of Patient Recruitment: January 2019 to have the necessary sample for the study.
- Data analysis: After completion of sample collection (estimated time approx January 2020) until March 2020
- Interpretation of results: March and April 2020.
- Final report: July 2020.
- Reading and procedures thesis defense: September 2020.

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9. ATTACHMENTS:

HANDOUT FOR STUDY PARTICIPANTS:

It is proposed to participate in a randomized scientific study entitled "Evaluation of the effectiveness of a program to strengthen the pelvic floor WOMEN IN THE POSTPARTUM" which aims to repair the muscles of your pelvic floor muscles located in the region of the perineum involved active at the time of delivery with the aim of increasing its power and elasticity in the puerperal period. The study aims to assess the extent to which this stimulation of the pelvic floor is capable of improving the injuries of the musculature and indirectly its long-term consequences such as genital descents (bladder, vagina and uterus), incontinence or involuntary leakage of urine and even the difficulties vaginal intercourse.

Their participation would, if accepted, perform a set of exercises pelvic floor muscle exercises and lower abdominal pressure previously will be taught by midwives. The exercises would be held from 6 weeks postpartum (fulfilled quarantine) until 6 months postpartum.

If you choose to participate, you can withdraw at any time and without explanation of the study. Moreover, the research team guarantees at all times, anonymity and confidentiality of the information is encrypted and will be limited solely to their age, parity, clinical data on the evolution of pregnancy, childbirth and postpartum.

Your participation in this research study does not involve any risk to you or your baby, with the information obtained great interest in the future to increase the field of knowledge and action on women's health and quality of life .

Fieldwork will take place in health centres and at all times participants will be coordinated and supervised by professionals Obstetrics (midwives) who may at any time, consult any aspect of the study.

INFORMED CONSENT

STUDY: "Influence of an exercise program low abdominal pressure modified for pregnancy to strengthen the pelvic floor muscles in pregnant women"

I, Ms. _____, of age, I stated:

- I have successfully been informed of the nature and purpose of the study, I have described what is my participation and have notified me that no risk to my health.

- I understood perfectly the explanations you have offered me and I consent to participate in the study.

- That I have been informed of my right to withdraw this consent and leave my participation at any time, at any time of this research, without having to justify my will, without any loss as to my attention.

Today's date _____

Date of birth:

Telephone 1: Phone 2:

Health center to which it belongs:

Hospital where she has given birth:

Signed: _____

(Name, surname)

ID: _____

Urinary incontinence questionnaire ICIQ-SF

ICIQ (International Consultation on Incontinence Questionnaire) is a self-administered questionnaire that identifies people with urinary incontinence and the impact on quality of life.

ICIQ-SF: total scores questions 1 + 2 + 3.
IU diagnosis is considered anything above zero score

1. How often do you leak urine? (Check only one answer).

Never 0
Once a week 1
2-3 times / week. 2
Once a day 3
Several times a day 4
Continually 5

2. Give your opinion about the amount of urine you think that escapes, ie, the amount of urine that usually loses (whether or not wearing protection). Mark only one answer.

nothing escapes me. 0
Very little. 2
A moderate amount. 4
A lot of 6

3. To what extent these leaks urine, which has affected your daily life?

1 2 3 4 5 6 7 8 9 10
Nothing much

4. When did you leak urine? Check all that happens to you.

- Never.
- Before reaching the service.
- When coughing or sneezing.
- While he sleeps.
- When performing physical / exercise efforts.
- When you finish urinating and already dressed.
- No obvious reason.
- continuously.

JUNTA DE ANDALUCIA

CONSEJERÍA DE IGUALDAD, SALUD Y POLÍTICAS SOCIALES
Dirección General de Calidad, Investigación, Desarrollo e Innovación
Comité Coordinador de Ética de la Investigación Biomédica de Andalucía

DICTAMEN ÚNICO EN LA COMUNIDAD AUTÓNOMA DE ANDALUCÍA

D/Dª: Jose Salas Turrents como secretario/a del CEI de los hospitales universitarios Vírgen Macarena-Virgen del Rocío

CERTIFICA

Que este Comité ha evaluado la propuesta de (No hay promotor/a asociado/a) para realizar el estudio de investigación titulado:

TÍTULO DEL ESTUDIO:	Influencia de un programa de ejercicios de baja presión abdominal modificados para el embarazo para el fortalecimiento de la musculatura del suelo pélvico en la mujer embarazada
Protocolo, Versión:	PDF
HIP, Versión:	
CI, Versión:	PDF

Y que considera que:

Se cumplen los requisitos necesarios de idoneidad del protocolo en relación con los objetivos del estudio y se ajusta a los principios éticos aplicables a este tipo de estudios.

La capacidad del/de la investigador/a y los medios disponibles son apropiados para llevar a cabo el estudio.

Están justificados los riesgos y molestias previsibles para los participantes.

Que los aspectos económicos involucrados en el proyecto, no interfieren con respecto a los postulados éticos.

Y que este Comité considera, que dicho estudio puede ser realizado en los Centros de la Comunidad Autónoma de Andalucía que se relacionan, para lo cual corresponde a la Dirección del Centro correspondiente determinar si la capacidad y los medios disponibles son apropiados para llevar a cabo el estudio.

Lo que firmo en SEVILLA a 24/06/2015

D/Dª. Jose Salas Turrents, como Secretario/a del CEI de los hospitales universitarios Vírgen Macarena-Virgen del Rocío

Código Seguro De Verificación:	5f2df9c0b7d26dc4712fbfaa47cdef336441277d	Fecha	24/06/2015
Normativa	Este documento incorpora firma electrónica reconocida de acuerdo a la Ley 59/2003, de 19 de diciembre, de firma electrónica.		
Firmado Por	Jose Salas Turrents		
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CERTIFICA

Que este Comitê ha ponderado y evaluado en sesión celebrada el 29/05/2015 y recogida en acta 05/2015 la propuesta del/de la Promotor/a (No hay promotor/a asociado/a), para realizar el estudio de investigación titulado:

TÍTULO DEL ESTUDIO:	Influencia de un programa de ejercicios de baja presión abdominal modificados para el embarazo para el fortalecimiento de la musculatura del suelo pélvico en la mujer embarazada
Protocolo, Versión:	PDF
HIP, Versión:	
CI, Versión:	PDF

Que a dicha sesión asistieron los siguientes integrantes del Comitê:

Presidente/a
D/Dª. Víctor Sánchez Margalet

Vicepresidente/a
D/Dª. Dolores Jiménez Hernández

Secretario/a
D/Dª. Jose Salas Turrents

Vocales
D/Dª. Enrique Calderón Sandubete
D/Dª. Amancio Carnero Moya
D/Dª. Enrique de Álava Casado
D/Dª. Antonio Hevia Alonso
D/Dª. Juan Ramón Lacalle Remigio
D/Dª. M LORENA LOPEZ CERERO
D/Dª. Luis Lopez Rodriguez
D/Dª. CRISTOBAL MORALES PORTILLO
D/Dª. Cristina Pichardo Guerrero
D/Dª. Joaquin Quiralte Enriquez
D/Dª. Gabriel Ramírez Soto
D/Dª. Clara María Rosso Fernández
D/Dª. Javier Vitorica Fernandez
D/Dª. MARIA EUGENIA ACOSTA MOSQUERA
D/Dª. ANGELA CEJUDO LOPEZ
D/Dª. Regina Sandra Benavente Cantalejo
D/Dª. EVA MARIA DELGADO CUESTA

Que dicho Comitê, está constituido y actua de acuerdo con la normativa vigente y las directrices de la Conferencia Internacional de Buena Práctica Clínica.

Lo que firmo en SEVILLA a 24/06/2015

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