Effectiveness of pelvic floor muscle exercises versus pelvic floor muscle exercises combined with biofeedback for stress urinary incontinence in postpartum: randomised clinical trial

Final Project

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ABSTRACT:

Background: In patients with stress urinary incontinence, most of the time during activities that increase intra-abdominal pressure their muscles surrounding the urethra cannot press together strongly and urine accidentally escapes the urethra. Vaginal delivery is one of the risk factors of this condition. To avoid it pelvic floor muscles exercises are recommended to postpartum womens.

Objectives: The goal of this study is to assess effectiveness of Biofeedback combinated with Pelvic Floor Muscle exercises compared with PFM exercises alone on women in postpartum with stress urinary incontinence regarding the severity of this condition.

Method : This study is a double-blind randomized controlled trial (RCT). In this study we will select womens aged between 18 and 35 years old, in postpartum diagnosed of stress urinary incontinence from 3 centers in Nîmes. Participants will be randomized and allocated to two groups. In both groups they will receive 4 rehabilitation sessions with a physiotherapist of 20 minutes monthly over 16 consecutive weeks and they will be asked to perform home exercises everyday. In the experimental group all exercises will be identical but they will perform them with the biofeedback "Emy". Participants will be assessed at 3 different periods, once before intervention, once post- treatment, one day after the last session and once follow-up, 10 weeks before the last session. The assessment will consist of the One-hour pad test in order to follow the severity of the stress urinary incontinence, the PERFECT Scheme in order to follow the changements on pelvic floor muscles strength and the Incontinence Quality of Life Scale in order to follow the impact on life (I-QOL). All data will be collected in an Excel document and finally analysed by a qualified statistician researcher.

Discussion: : Previous studies suggest that biofeedback can be an effective element adding to Pelvic Floor Muscles exercises used in urology rehabilitation. So, the intervention might produce better outcomes than the control group for stress urinary incontinence in women in postpartum.

Keywords: Stress Urinary Incontinence, Pelvic Floor Muscles Exercises, Biofeedback, Postpartum and Effectiveness

I. Hypothesis

For my **null hypothesis**, I expected that Pelvic Floor Muscles exercises and Pelvic Floor Muscles exercises in combination with biofeedback have the same effectiveness in the treatment of stress urinary incontinence in women in postpartum.

For my **alternative hypothesis**, I expected that Pelvic Floor Muscles exercises in combination with biofeedback are more effective than Pelvic Floor Muscles exercises only in the treatment of stress urinary incontinence in women in postpartum.

II. Objectives

The goal of this study is to assess effectiveness of Biofeedback combinated with Pelvic Floor Muscle (PFM) exercises compared with PFM exercises alone on women in postpartum with stress urinary incontinence regarding severity of this condition.

The secondary objective is to evaluate the effects of biofeedback combined with Pelvic Floor Muscles Exercises compared with PFM exercises alone on pelvic floor muscles strength.

Our last objective is to determine if a biofeedback combined with Pelvic Floor Muscles Exercises could increase the well being of women in postpartum with stress urinary incontinence.

III. Introduction

Pregnancy and delivery leave marks on the woman's body and Urinary Incontinence (UI) is part of it. Cross-sectional studies examining the prevalence rate of pregnant and postpartum women report having urinary incontinence show a large variability of the crude prevalence rate from 16.1 to 68.8% due to different methodologies and differences in study populations, which makes these studies difficult to compare [1]. Urinary Incontinence is a sensitive topic, few women tend to report on their condition, which underestimates studies of UI prevalence.

Urinary incontinence is defined by International Continence Society as an involuntary loss of urine, causing a social or hygiene problem [2]. It occurs most of the time starting at the 36th week of pregnancy and is still a problem 1 year after delivery, depending on type and severity of UI [3].

Postpartum is the period after childbirth until period returns. Most of the new mothers experience postpartum depression or "baby blues" which most of the time manifests by mood swings, persistent sad, anxious feelings and difficulty sleeping. This is due to physical and life changes. After childbirth, there is a big drop of hormones (estrogen and progesterone) in your body that contribute to postpartum depression [4].

Adding urinary incontinence to all of these sources of stress can be really hard to manage, all the more that is still a big taboo in our society. This points to the importance of research on factors that may help in this condition.

First of all, it is important to determine risk factors of urinary incontinence and try to limit them. Risk factors depend on different types of urinary incontinence. In research, three types of urinary incontinence are being described: Stress, Urge and Mixed. Stress is more common for postpartum women, followed by mixed and urge [1].

Stress Urinary incontinence (SUI) is more common in young women [5]. It happens when muscles surrounding the urethra do not press together strongly and urine accidentally escapes from the urethra. Most of the time, it occurs during activities that increase pressure inside of the abdomen, such as effort, laughing, sneezing, or coughing [6].

Risk factors of stress urinary incontinence are first respectively age followed by vaginal deliveries, diabetes and obesity [7]. In research it is also demonstrated that intensive exercises such as repeated heavy lifting may be a risk factor for stress urinary incontinence when it is poorly chosen or improperly performed. Some sports are more risky than others as they act on intra-abdominal hyperpressure that may affect the pelvic muscle function and excess capacity of sphincters [8].

Frequency and amount of urine leakage in stress urinary incontinence have been reported in previous researches. Most of the women have reported urine leakage several times a day in 44.2% of cases and in small amounts in 71.4% of cases. Regarding situations in which urine leakage occurs, most (57.1%) reported coughing or sneezing, followed by leakage when exercising. The same study has shown that in 70.1% of cases, SUI began during pregnancy and has persisted during the postpartum period [1].

Urge Urinary incontinence (UUI) is more frequent in women age [5]. Urge Incontinence occurs when a strong urge to urinate occurs at an unsuitable time or place. The cause can be neurologic, when the condition affects nerves that travel from the brain to the bladder [6]. It can be uninhibited detrusor muscle contractions (detrusor hyperreflexia) or an impaired sensory pathway at the bladder [5].

For UUI, age had the highest impact as a risk factor, as well as having at least one comorbidity (for example: obesity) [7].

Mixed Urinary Incontinence (MUI) is a combination of both stress and urge incontinence which means involuntary leakage associated with urgency and with effort, sneezing, and coughing. It is the most common type of urinary incontinence among older women [5].

For MUI, risk factors are first age and obesity which have similar impacts followed by having at least one comorbidity (for example: Chronic obstructive pulmonary disease) [7].

Urine is stored in the bladder. This organ has the capacity to adapt to large increases of urine volume with minimal increases in intravesical pressure. Continence is the ability to maintain urine storage with convenient and socially acceptable voluntary emptying. It is based on coordination of multiple components, muscle contraction and relaxation, appropriate connective tissue support, innervation and communication between these structures [9].

First, regarding filling, there is a coordination between urethral contraction that avoids urine leaking and bladder relaxation to store urine. Second, looking at voiding, the urethra relaxes and the bladder contracts. These mechanisms may be troubled by uninhibited detrusor contractions, increases in intra-abdominal pressures, and changes of anatomic components of the continence mechanism. Continence is based on transmission of pressure and urethral support [9].

Normally the urogenital tract supports an increase in intra-abdominal pressure and transmits it to the bladder, bladder base, and urethra. If there is an increase in downward-directed pressure from cough, laugh, or sneeze, pressure is countered by supportive tissue tone provided by the levator ani muscle and vaginal connective tissue. A loss of pelvic support causes an urethral hypermobility and in this case urethral pressure cannot be maintained if abdominal pressure increases. The bladder will descend and urinary leakage can occur (annex 1) [9].

Urethral support is based on ligaments (annex 1) along the lateral aspects of the urethra, pubourethral ligaments, the vagina and its lateral fascial condensation, the arcus tendineus fascia pelvic and levator ani muscles (annex 2). The diminution of urethral support creates reduced urethral closing pressures, inability to resist increases in bladder pressure and finally, incontinence [9].

In order to diagnose stress urinary incontinence, the health care professional must begin with a detailed medical history [6]. It has been proved with collected genetic data and detailed urinary incontinence that there is evidence of genetic associations for urinary incontinence and calls for further research to replicate our findings and identify additional risk variants [10].

The second step of diagnosis is a physical examination to assess the pelvic region [6]. The Valsalva or cough test can easily confirm a stress urinary incontinence. During the test, the therapist asks the patient to cough with a full bladder, if there is urine leaking from the urethra, SUI is confirmed (annex 1) [11]. The Pad test is used to quantify the urine leakage and classify in three grades of severity of stress urinary incontinence [12].

To avoid an adverse diagnosis, it is necessary to check urinalysis for evidence of infection [6]. If SUI is observed on examination, it is important to assess the pelvic floor muscle strength. It can be done with digital vaginal examination while asking the patient to

squeeze her pelvic floor, also known as a Kegel contraction. Patients with good proprioception and ability to contract their pelvic floor are candidates for home pelvic floor exercises [11].

In 1948, Kegel exercises were first described by Arnold Kegel for pelvic floor muscle strengthening. Dr. Kegel's study showed that the exercises could help to prevent stress urinary incontinence. Currently, there is no fixed protocol for Kegel exercises, but the fundamental rules are: to identify the appropriate muscles which stop or slow the urination, to contract the muscles as mentioned earlier in a correct manner and to repeat the cycle for several times [13].

If the diagnosis is uncertain after the first assessment, additional tests may be necessary depending on the evolution of symptoms after treatments [6].

Stress urinary incontinence is an uncomfortable condition that may isolate patients and limit their social life. Treatment is indispensable to manage this condition and improve the well-being of patients. The literature is vast regarding different procedure success rates for treating female SUI.

Surgical options are often indicated when conservative therapies fail. The most commonly known are burch colposuspension [14], midurethral slings (MUS) and pubovaginal slings (PVS) [15].

The burch colposuspension or the burch retropubic urethropexy, is a fixation to Cooper's ligament of bilateral urethrovaginal via the abdominal approach. Studies report that women with the Burch urethropexy surgery have an overall continence rate of 85–90% at 1 year and 70% at 5 years after the operation. The efficacy of Burch urethropexy for SUI has been demonstrated especially in the long term. However, the operating time and hospital stay are longer, which can increase risks of infection or nosocomial diseases. The Burch procedure was long regarded as the gold standard for SUI treatment prior to the emergence of MUS (annex 4) [16].

The second technique, MUS is a minimally invasive surgery. Studies report that this technique has symptom cure rates of 75–94% and objective cure rates of 57–92%. Generally, MUSs are the gold standard surgical treatment for female SUI. As it is an invasive

intervention, some patients do suffer from serious complications but most women experience subjective and objective improvement in SUI [16].

The last technique, pubovaginal Sling, consists of harvesting autologous fascia from the anterior abdominal wall (rectus fascia sling) or the thigh (tensor fascia lata sling). This surgery is used for women with recurrent SUI, severe SUI, a fixed urethra on examination, or previous complications with the MUS. This surgery is long and there is high blood loss, this is why it is used for women in last resort. It has been proved that PVS is an effective treatment for SUI. However as all surgical intervention there is no risk zero [16].

In order to avoid using surgery treatment directly, conservative treatments can be first used. As Pelvic Floor Muscle Therapy (PFMT). PFMT are individualized exercises, which aim to improve pelvic floor muscle strength, endurance, power, relaxation. Exercises are repeated muscle contractions and improved conscious muscle pre-contraction prior to anticipated increases in abdominal pressure such as coughing [16]. The fast contractions train the pelvic floor muscles to adapt to the increased intra-abdominal pressure during coughing and laughing. The slow contractions help with muscle strengthening [13].

It has been reported in a review of studies that assess the effects of PFMT for women with stress urinary incontinence (UI) in comparison to placebo treatment, that the PFMT group were eight times more likely to report being cured [17].

Even if studies remain uncertain because of very low-quality evidence, a meta-analysis examining PFMT and postpartum urinary incontinence by patient self-report symptoms demonstrated a 56% reduction in UI risk at 12 months postpartum in women with PFMT [18].

Currently, the National Institute of Health and Care Excellence (NICE) recommends a trial of supervised pelvic floor muscle training of at least 3 months as first-line treatment to women with stress or mixed UI. It is also recommended to start PFMT at the sixth week of postpartum [19].

Different PFMT can be assisted by accessories such as electrostimulation (EE), biofeedback (BF) and vaginal cones. BF uses an external device in which muscle activity, muscle contraction (pressure measurement), relaxation, strength of individual PFM contractions (electromyogram) and the way in which certain muscles contract, and the

direction of contraction (ultrasound) is monitored, amplified, and conveyed to the patient (feedback) as visual or acoustic signals [20, 21].

Anti-incontinence devices are also an option for conservative management of SUI. A vaginal pessary is an intra-vaginal device to support vaginal wall prolapse and provide urethral support. It is a tampon-like device that can easily be used at home after teaching on proper placement and removal [11]. In 70–90% of the cases, women with SUI which used a pessary reported a symptomatic relief [17].

Preventive treatment should be applied during pregnancy. In a study in which pregnant women without prior urinary incontinence were randomised to a group with intensive antenatal PFMT and an second group with no PFMT or usual antenatal care, it has been observed that group 1 was less likely than group 2 to report urinary incontinence up to six month after delivery [22].

There is already a study comparing PFM exercises to PFM exercises combinated to biofeedback for the treatment of stress urinary incontinence. In this study, the sample is women with 18 years of age or above, presenting with a new episode of stress or mixed UI but all women who are less than 6 months postnatal are excluded from the study [23]. There is another study that has been done concerning Pelvic Floor Muscle Exercise by Biofeedback and Electrical Stimulation to reinforce the Pelvic Floor Muscle for postpartum women but it is not about the treatment of stress urinary incontinence [24]. This research protocol could give us a better idea of the effectiveness of Biofeedback for postpartum women for the treatment of Stress Urinary Incontinence.

IV. Method

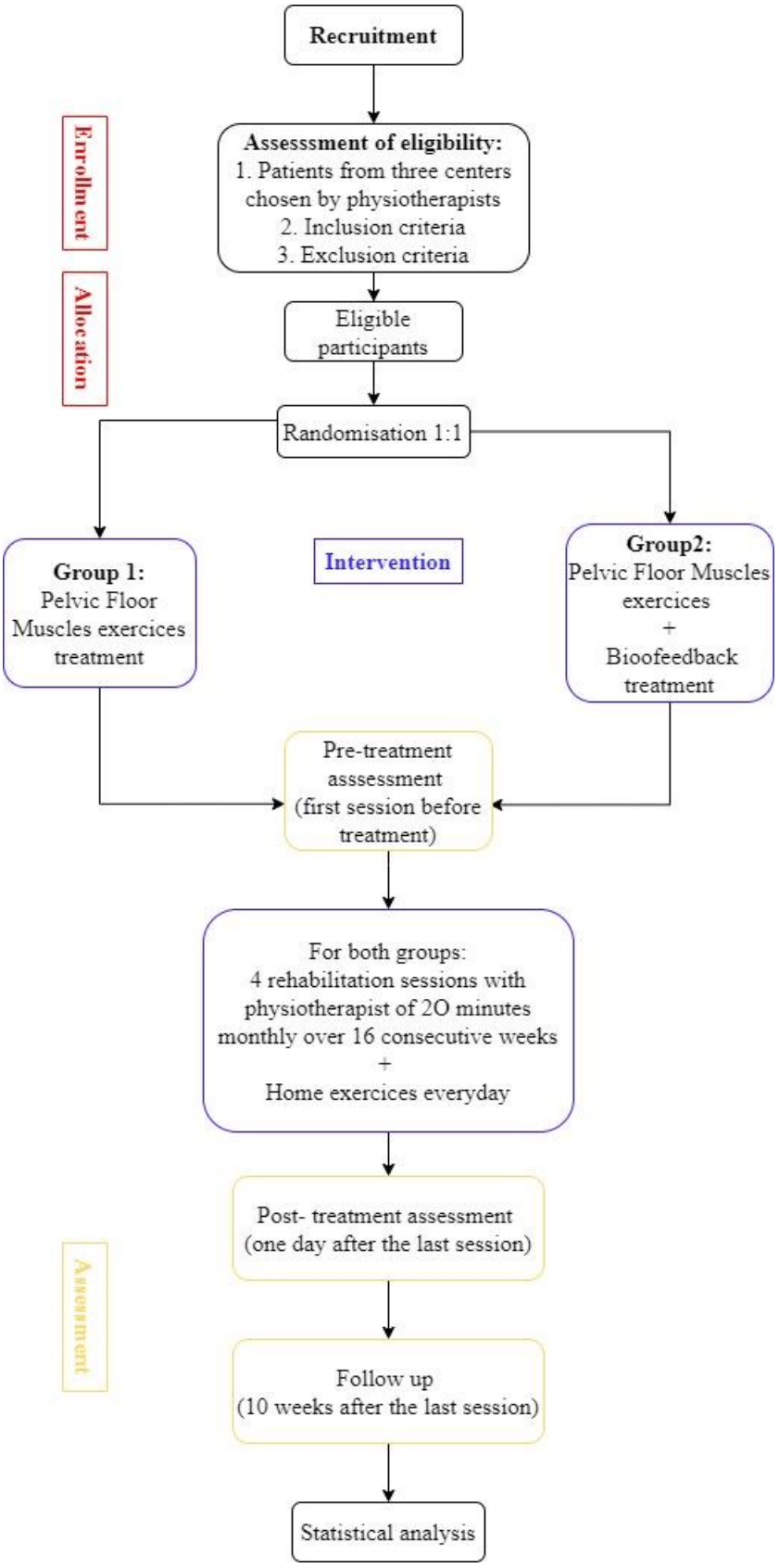
1. Study Design

This study will be a Randomised Controlled Trial (RCT). This kind of study design aims to find out which treatment is best by making a fair comparison between two treatments. We will follow the SPIRIT Guidelines to conduct this study.

In order to avoid bias and to have a bigger sample, this study will be multi-centered. We will first collect participants following inclusion and exclusion criterias from 3 different centers.

Participants which correspond to criterias of the study will be allocated randomly into two groups, one group will receive Pelvic Floor Muscle Exercises and the other Pelvic Floor Muscle Exercises combined with Biofeedback. It is important that these two groups of people are as similar as possible because in this case we are sure that any differences in outcomes between groups are only due to the treatment received. In order to avoid bias, this study will be a double-blind randomized meaning that neither participants, the investigator, assessors and the statistician researcher will know who is receiving a particular treatment.

Flow diagram



2. Study settings

In this study we will choose three different centers, one hospital, one clinic and one private cabinet. Different types of centers will be important to have a representative population of the general population. In order to be close to our patients and to follow the processus, all centers chosen will be in Nîmes, in the south of France.

First we will choose the "Centre Hospitalier Universitaire" located in Place du Professeur Robert Debré 30029 Nîmes, FRANCE. It is a large center in which there is an important department of Gynecology and Obstetrics, which is crucial for our subject.

The second center that we will choose is the " Clinique Kennedy" located at 7 Chemin de Pissevin, 30900 Nîmes. It is a private center, also with a department of Gynecology and Obstetrics.

The last one will be a private cabinet of physiotherapy, with physiotherapists specialized in urology. "Espace Human Physio" is located at 15 bis, boulevard Jean Jaurès 30000 Nîmes.

The treatment will be performed in the University Hospital Center of Nîmes. The center of the investigation is close to each center and there is enough space. Patients will be treated in a quiet, individual room. Every room will be decorated in the same way to avoid any differences to the perception of patients with different treatment.

3. Recruitment

The investigator will be in charge of the recruitment of therapists and participants. He will also manage the costs, the time needed for this recruitment, the agreement between clinics and the respect of ethical criteria. All the participants have to be recruited simultaneously to start the trial at the same time.

After the recruitment of centers and physiotherapists, physiotherapists responsible of interventions will provide a list to the investigator with current patients diagnosed of stress urinary incontinence in postpartum. The investigator will consult them to ask them if they are interested in taking part in the study.

These patients will be contacted by phone to ask them if they meet inclusion and exclusion criteria. If so, they will be asked if they want to take part in the study. Patients who agreed to participate will be received in an individual meeting with the investigator to give them an informed consent (annex 5). The informed consent contains the inclusion and exclusion criteria and provides all the study's information necessary for the participant. A certificate of consent (annex 6) will be attached to the informed consent, and participants will be asked to fill it. This meeting will also be the time to explain all the aspects of the two different programs, the whole protocol in order to encourage them and to be sure everyone is well informed about the progress of the study.

To minimize the giving up and increase the compliance during the study, it is also important to exclude patients without stable situations. Taking into consideration that the study could last a certain amount of time, it should avoid some people moving away. To avoid a loss of motivation for certain patients, participants should only be selected if they appear convinced by and are enthusiastic about the project.

Concerning the physiotherapist team, they will be selected voluntarily. Physiotherapists selected must be specialized in urology with at least 3 years of practice. They obviously have to be familiar with this kind of patient and pathology. They will have to be available during the all study and agree with the program and the rules. One part of physiotherapists will be assigned to the intervention part. Others part of physiotherapists will be assigned to the measurement of the outcomes. The number of physiotherapists will depend on the sample size.

Finally, the investigator will be also in charge of the recruitment of a qualified statistician researcher that will analyze all datas.

4. Sample size

The adequate number of patients required will be calculated by Minimally Clinically Important Difference (MCID). MCID is the smallest amount of change in an outcome that might be considered important by the patient or clinician.

Our first objective is to assess effectiveness of Biofeedback combinated with Pelvic Floor Muscle exercises compared with PFM exercises alone on women in postpartum with stress urinary incontinence regarding severity of this condition. To measure this outcome we

will use the 1 hour Pad test. According to previous studies, the MCID for urine loss reduction of 1 hour Pad test is around 9.5g to 12.6g [25].

5. Eligibility criteria

A randomized control trial requires patients to respect inclusion and exclusion criteria in order to increase the homogeneity of patients and strengthen the internal validity of the study.

Inclusion criteria
Woman. Aged between 18 and 35 years old. Mode of delivery: vaginal. First pregnancy. Healthy baby. 6 weeks of postpartum. **Stress urinary incontinence** diagnosed by: - the 1-hour pad with an increase between 1g and more (grade mild, moderate, severe). - a positive valsalva test. Pain scale less than 4. Fluent in english or french (all informations or papers will be given to participant in her langage, english or french).

Exclusion criteria

Urogenital :

- Mode of delivery: episiotomy, cesarean
- Previous pregnancy
- Previous urinary incontinence
- Any surgical treatment of gynecological and urological illnesses
- Urinary tract infection tract
- Diagnosed of urge urinary incontinence, mild urinary incontinence
- Currently participating in other research relating to their UI

Conditions :

- Progressive neurological disease
- Body mass index (BMI) greater than 30 (obese)
- Serious cardiac, or other internal medical condition
- Malignant disease
- Disease of respiratory
- Acute trauma
- Acute vascular accident
- Currently receiving pharmacological or physiotherapy treatment
- Allergy to component to biofeedback

Impairment:

- Women with visually impaired: because it is impossible for them to receive visual feedback.
- Women with intellectual impairment which are unable to use the application of biofeedback and perform exercises at home.
- Women who are unable to give informed consent.

6. Randomization

The randomization is a principle largely used in clinical trials, it avoids the selection bias and promotes the statistics and fate theory. It produces the comparable groups and eliminates the source of bias in treatment assignments [26].

Once participants have been selected and have given their consents to be part of the study, they will be randomly distributed between group 1 (control group, receiving only conventional treatment PFME) and group 2 (study group, receiving PFME combined to biofeedback).

To avoid bias, the investigator will manage randomization. The most common and basic method of simple randomization is flipping a coin. The side of the coin heads will determine the assignment to the group 1 and tails to the group 2 until having the same number of participants in each group [26].

7. Blinding

In order to increase the internal validity of the study, a double-blinding will perform which means neither participants nor assessors will know who is receiving the experimental treatment. Only therapists will know which treatment they apply.

First of all, during allocation, the investigator and participants will not be aware of which interventions correspond to which side of the coin. The investigator will allocate participants to group 1 and group 2. By this way, we avoid bias of selection and participants will not be aware of which intervention they will receive, if they are part of the controlled group or the experimental group. This avoids patients to act differently, and this increases the internal validity of the study.

During the assessment, assessors will be blinded. Assessors will come to the clinic only to do one pretreatment assessment (the day of the first session), one post treatment assessment (one day after the last session) and one follow up (10 weeks after the last session). They will not be aware of the treatment each participant received, they will only know the number of the group of participants. The assessor will just have to perform tests on participants and report results of group 1 and group 2 in an Excel document.

Finally, during statistical analysis, the statistician will interpret results from the document that the assessor will have filled previously without knowing which treatment corresponds to which group.

8. Intervention

Group 1: The controlled group

The Controlled group will receive Pelvic Floor Muscle Exercises. Pelvic Floor Muscle Exercises is the first line treatment for stress urinary incontinence. It is a program of muscle reinforcement with a series of repetitions of contractions of pelvic floor muscles. It has been proved in a previous study that PFME is effective for stress urinary incontinence. Indeed, it shall improve symptoms of SUI and all other types of UI by reducing the number of leakage episodes, the quantity of leakage on the short pad tests in the clinic and symptoms on UI‐specific symptom questionnaires [17].

Concerning the protocol of PFME there is not a precise description. Most studies are doing a different protocol. In this study we will perform our proper protocol following the National Institute for Health and Care Excellence (NICE). It is recommended by NICE that Pelvic floor muscle training programmes should comprise at least 8 contractions performed 3 times per day. It is also recommended to start PFMT at the sixth week of postpartum [27].

All participants of group 1 will follow this standardized pelvic floor muscle training protocol which consists of endurance and speed training. The participants will be treated individually by the physiotherapist in monthly sessions of 20 minutes for 16 weeks [28]. All sessions will be performed in a quiet, individual room face to face to a physiotherapist.

1st session:

In order for participants to be doing as better as possible exercises with a physiotherapist and at home, we will educate participants and we will provide comprehensive care [29]. During the first session, participants received verbal information about pelvic floor

anatomy, muscle localization, and function, with the use of anatomical models and illustrations.

In a decubitus position, they will learn how to contract the PFMs correctly without contracting the adjacent muscles, such as the abdominal, gluteal, and hip adductor muscles, with verbal instruction and physiotherapist digital palpation [30].

Participants will learn exercises that they will have to perform at home everyday explained by the physiotherapist.

- **Endurance training** involves slow velocity close to maximum contraction for 3-10 seconds, followed by relaxation for 3-10 seconds.
- **Speed training** involves quick, moderately strong contractions for 2 seconds followed by relaxation for 2 seconds.

They will receive a paper with exercise explanations that they have to do at home (annex 7).

<u>2nd session:</u>

During this session the physiotherapist will check that the participants are doing well exercises at home, give him advice and answer questions if it is necessary.

Participants will perform 3-5 sets of each type of training, 10 contractions in a row or until fatigue [28].

- **Endurance training** involves slow velocity close to maximum contraction for 3-10 seconds, followed by relaxation for 3-10 seconds.
- **Speed training** involves quick, moderately strong contractions for 2 seconds followed by relaxation for 2 seconds.

3rd session:

In this session, the physiotherapist will explain different positions to perform exercises of Endurance training and Speed training. Participants will perform one set of 10 contractions in lateral decubitus position, one set of 10 contractions in seated position and one set of 10 contractions in standing position.

4th session:

In the last session, the physiotherapist will show participants type of activities while they have to perform contraction of pelvic floor muscle.

- Walking on a treadmill for 15 minutes at 7km/h
- Jumping on a trampoline 10 repetitions
- Coughing 3 times

The goal of this session is to make these exercises more functional by working on "Knack". "Knack" is a strong contraction of pelvic floor muscle performed immediately during activities that increase downward pressure on the pelvic floor.

Group 2: The experimental group

The Experimental group will receive Pelvic Floor Muscle Exercises combined with biofeedback. Biofeedback (BF) is a device in which muscle activity, contraction, relaxation, and strength is monitored, amplified, and conveyed to the patient (feedback) as visual or acoustic signals. It provides instantaneous information to the patient about the status of the PFM. In this study we will use "Emy". It is a device connected with a free mobile app. We have chosen it because it allows participants to do it at home easily.

1st session:

In order for participants to be doing as better as possible exercises and to be the most familiar, comfortable with the biofeedback "Emy", as Group 1 during the first session,

participants will receive verbal information about pelvic floor anatomy, muscle localization, and function, with the use of anatomical models and illustrations. They will also receive an explanation about the functioning of the biofeedback and the application “Emy”. Insertion is similar to a tampon, it is better if participants relax themselves before introducing it.

Similar to group 1, they will learn how to contract the PFMs correctly with verbal instruction and physiotherapist digital palpation to begin. Then the participant will introduce the biofeedback in the vagina. The patient will be asked to relax herself to a point that we can see on the screen that there is no contraction or only a little. Then they will be asked to perform several quick contractions to be sure that the logiciel is working.

Participants will then learn the same exercises as group 1 as they will have to perform such exercises at home everyday explained by the physiotherapist but the participant will have to do them with the biofeedback.

- **Endurance training** involves slow velocity close to maximum contraction for 3-10 seconds, followed by relaxation for 3-10 seconds.
- **Speed training** involves quick, moderately strong contractions for 2 seconds followed by relaxation for 2 seconds.

They will receive the same paper as group 1 with exercise explanations that they have to do at home and in addition a paper with Emy explanations (annexes 7 and 8).

2nd session:

During this session, the physiotherapist will check that the participants are doing exercises at home in a satisfying way, give her advice and answer questions if it is necessary. He will check the results of the patients on Emy app.

Participants will perform 3-5 sets of each type of training, 10 contractions in a row or until fatigue [28].

- **Endurance training** involves slow velocity close to maximum contraction for 3-10 seconds, followed by relaxation for 3-10 seconds.
- **Speed training** involves quick, moderately strong contractions for 2 seconds followed by relaxation for 2 seconds.

3rd session:

Similar to group 1, in this session, the physiotherapist will explain different positions to perform exercises of Endurance training and Speed training. Participants will perform one set of 10 contractions in lateral decubitus position, one set of 10 contractions in seated position and one set of 10 contractions in standing position with the biofeedback.

4th session:

As in group 1 for the last session, the physiotherapist will show participants types of activities to conduct while they have to perform contraction of pelvic floor muscles with the biofeedback.

- Walking on a treadmill for 15 minutes at 7km/h
- Jumping on a trampoline 10 repetitions
- Coughing 3 times

V. Outcomes

The goal of this study is to determine effectiveness of Biofeedback combinated with Pelvic Floor Muscle exercises compared with PFM exercises alone on severity of stress urinary incontinence in women in postpartum. To assess this outcome, we will be using the Pad testing. This test could give us an idea of the evolution of the condition depending on which intervention they received. It is a non-invasive method of detecting and quantifying severity of urine leakage. We will perform the One-hour pad test [31].

The secondary objective is to evaluate the effect of biofeedback on pelvic floor muscles strength. To assess this outcome we will use the PERFECT Scheme. PERFECT means P= power (or pressure, a measure of strength using a manometric perineometer), E = endurance, R = repetitions, F = fast contractions, and ECT = every contraction timed. It is a technique to assess pelvic floor muscles strength [32].

Our last objective is to determine if a biofeedback could increase the well being of women in postpartum with stress urinary incontinence. To assess this outcome, we will use the Incontinence Quality of Life Scale (I-QOL). This is 22 questions evaluating the distress and impact of urinary incontinence on the patient's quality of life (annex 9) [33].

The same physiotherapist called by the assessor will undertake all measurements in the two groups to make sure there is no inter-rater bias. The assessor will measure the outcomes face to face for all the participants in the study. He will perform 3 assessment measurements, the first day of the study before the first treatment session, one post treatment assessment one day after the last session and one follow up assessment 10 weeks after the last treatment session. The assessor will fill results of group 1 and group 2 in an Excel document with a list of numbers corresponding to participants. He will have to report the participants' scores on One-hour pad test, PERFECT Scheme and Incontinence Quality of Life Scale (I-QOL) next to their associated number. At the end of the study, the assessor will transfer the Excel Document to the statistician to analyze them.

VI. Assessments

The assessor will perform the same assessment 3 times at different moments of the study to see the evolution. The first assessment will be pre-treatment, before the first session of rehabilitation. The second assessment will be post-treatment, one day after the last session of rehabilitation. The last assessment will be 10 weeks after the last session of rehabilitation to follow-up the impact of treatment on the longer term.

For the first objective, the assessor will use the One-hour pad test [31,34].

For the one-hour pad test, participants are given pre-weighed pads that they should wear. The assessor will ask participants to drink 500 ml of plain water over a 15 minutes period of time. The following 30 minutes include simple walking, including climbing one flight of stairs (up and down) and in the last 15 minutes womens are instructed to perform provocation exercises in a private area:

- standing up from sitting 10 repetitions
- coughing vigorously 10 repetitions
- running on the spot for 1 min
- bending to pick up an object from the floor 5 repetitions
- washing hands in running water for 1 min

The pad would then be re-weighed to determine the total amount of urine leaked. All the patients are instructed not to empty their bladder during that 1-hour period unless absolutely necessary.

Severity of stress urinary incontinence by Pad-test will be classified in three grades :

- Mild incontinence corresponding to an increase between 1g and 10g.
- Moderate incontinence corresponding to an increase between 11g and 50g moderate.
- Severe incontinence corresponding to an increase of 50g or more.

For the second objective, the assessor will use the PERFECT Scheme [32].

The PERFECT Scheme is a method of PFM evaluation of power, endurance, fast contractions, and every contraction timed. Participants will be in a supine position with their head on a pillow, hips flexed and abducted, and knees bent. The assessor will examine using the index finger placed approximately 4 cm to 6 cm inside the vagina and positioned at 4 o'clock and 8 o'clock.

First we will evaluate the **Power**. Power is measured on a modified Oxford scale (annex 10).

- **Grade 0**: corresponds to no discernible muscle contraction.
- **Grade 1**: corresponds to a flicker or pulsation is felt under the assessor's finger.
- **Grade 2**: corresponds to the detection of an increase in tension, without any discernible lift.
- **Grade 3**: corresponds to a muscle tension being further enhanced and characterised by lifting of the muscle belly and also elevation of the posterior vaginal wall.
- **Grade 4** corresponds to an increased tension and good contractions, which are capable of elevating the posterior vaginal wall against resistance (digital pressure applied to the posterior vaginal wall).
- **Grade 5** corresponds to a strong resistance that can be applied to the elevation of the posterior vaginal wall; the assessor finger is squeezed and drawn into the vagina.

Then, the assessor will assess the **Endurance**. The endurance is timed until the muscle starts to fatigue. The assessor will ask the participant to maintain as many contractions as possible with the grade maximum that the participant can perform (*Example 1: 3/10 = grade 3 hold for 10 seconds).*

The assessor will then evaluate the number of **Repetitions** (up to 10). The purpose of the PERFECT assessment is to determine the number of contractions necessary to overload the muscle. The assessor will ask the participant to maintain as many contractions as possible

with the grade maximum that the participant can perform and repeat this as much as possible with four seconds rest between each contraction. *(Example 2: 3/10/4 = grade 3 hold for 10 seconds, and repeated 4 times-with 4 seconds rest between each contraction).*

After one minute of rest, the assessor will assess the number (up to 10) of one-second maximum voluntary contraction corresponding to "**Fast**". Participants will be asked to 'contract-relax' as quickly and strongly as possible, in their own time, until the muscles fatigue *(Example 3: 3/10/4/9 = moderate contraction, hold for 10 seconds, repeated 4 times, followed by 9 fast contractions).*

"**Every Contraction Timed**" means that the assessor should report all results in the Excel document.

For the last objective the assessor will use the Incontinence Quality of Life Scale (I-QOL) [33].

The assessor will give a paper to participants with questions to answer and give them explanations about how to complete it (annex 9). The Incontinence Quality of Life Scale (I-QOL) is composed of 22 items about:

- ➔ Avoidance and Limiting Behavior: Items 1, 2, 3, 4, 10, 11, 13, and 20
- ➔ Psychosocial Impacts: Items 5, 6, 7, 9, 15, 16, 17, 21, and 22
- ➔ Social Embarrassment: Items 8, 12, 14, 18 and 19

Every item will be quantified on a scale from 1 corresponding to "extremely" to 5 corresponding to "not at all". Better is the score, better the quality of life is. The maximal score is 110 and the minimal score is 22.

VII. Statistical Analysis

All the data needed will be collected by the assessors during the different assessment periods and then will be analysed by one qualified statistician researcher.

All the outcomes of the One-hour pad test, the PERFECT Scheme and the I-QOL utilised to make the assessment of the evolution of the patient performances are numerical data which means that those are quantitative variables. To compare the results of these three tests between the two groups, we will perform a Student's t-test. The assessor will fill an Excel document with all measures of the three tests. The other thing we want to analyze is if there is a correlation or a relationship between two variables, so the statistician will use Pearson's Correlation test to do the statistical analysis. The level of significance will be set at $p \leq 0.05$.

Those data will help find which of the hypotheses are validated. If the results are the same for the control and the experimental group then the null hypothesis will be validated. If there is significant amelioration for the experimental group, the alternative hypothesis will be validated. The third solution will be that the control group have better outcomes which means biofeedback has a harmful effect for such patients.

VIII. Ethics

One of the most important preoccupations in this study is to respect the rules of good clinical practice, the principles set in the Helsinki Declaration (World Medical Association, 1989).

We engage ourselves to assure maximal safety and transparency for the participants during the whole study and to serve their best interest. The participation of the patient in the study is voluntary, and she has the right to withdraw from the study at any time. It is important to keep a balance between the interest of having more medical knowledge and the health and interests of the participants. Therefore, this study will present a well-free-informed consent form that includes clear and basic information about the study procedures to obtain the conviction that all participants are taking into consideration the informed consent (annex 5).

Finally, the study will be protective of the subjects by respecting them, a well-informed consent campaign will be conducted among participants, and the study will ensure having a positive risk-benefit ratio and a fair and equal selection.

IX. Calendar/Planning

<table>
<tr><td colspan="10">Study Period</td></tr>
<tr><td></td><td>Enrollment</td><td>Allocation</td><td>Baseline</td><td colspan="4">Intervention Period</td><td colspan="2">Follow-up</td></tr>
<tr><td>Time Point</td><td>-T1</td><td></td><td>T0 = Before the first session treatment</td><td>T1</td><td>T2</td><td>T3</td><td>T4</td><td>T5 = One day after the last session treatment</td><td>T6= 10 weeks after the last session treatment</td></tr>
<tr><td>ENROLLMENT</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Eligibility screen</td><td>×</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Informed consent</td><td>×</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Allocation</td><td></td><td>×</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>INTERVENTIONS</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Experimental Group</td><td></td><td></td><td></td><td colspan="4">Pelvic Floor Muscles Exercises with Biofeedback
(4 rehabilitation sessions + home exercises)</td><td></td><td></td></tr>
<tr><td>Control Group</td><td></td><td></td><td></td><td colspan="4">Pelvic Floor Muscles Exercises
(4 rehabilitation sessions + home exercises)</td><td></td><td></td></tr>
<tr><td>ASSESSMENTS</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>The One-hour pad test</td><td></td><td></td><td rowspan="3">×</td><td></td><td></td><td></td><td></td><td rowspan="3">×</td><td rowspan="3">×</td></tr>
<tr><td>The PERFECT scheme</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>The Incontinence Quality of Life Scale</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
</table>

X. Limitations

Concerning intervention that both groups will receive, home exercises depend on participants. Even if they engage themself to perform exercises at home, we will not be able to control it. Moreover, we can not control how they are doing their exercises. This is why the first session of rehabilitation is really important because it is during this session that the physiotherapist will give all explanations to the participant. With clear information, the participant will be more able to perform better as possible exercises at home. In addition, physiotherapists will also be here to motivate the participants, which will help them to keep doing home exercises.

The role of the physiotherapist is fundamental for the effectiveness of the home exercises. As the study includes different physiotherapists, they can have different ways to explain and motivate participants and this can lead to differences in effectiveness of home exercises. This is why we would like to standardize information given to participants on papers that we will give them (annexes 7 and 8).

The effectiveness of the intervention will be assessed at different periods until the follow-up, 10 weeks before the last session. In this case, we will have an idea of the effectiveness of Biofeedback combinated with Pelvic Floor Muscle exercises compared with PFM exercises alone on women in postpartum with stress urinary incontinence on short term but we are not be able to have a look at the effectiveness on long term.

XI. Role of the Investigators

To provide a good development of this study, it is important that roles of each member of the research team are defined clearly.

The investigator will have the principal role because he will supervise the whole study. His work will first manage the agreement between clinics. When clinics agree to be part of the study, the investigator will be in charge of the recruitment of therapists, statistician researchers and participants following criterias. The investigator must also take in account the management of the cost, the time needed for the recruitment and the respect of ethical criteria.

When recruitment is finished, the investigator will be in charge of the allocation of participants. In order to avoid biais, the investigator will be blind to the selection of participants. He will just allocate participants to group 1 or 2 by flipping a coin without knowing which intervention will be performed in which group. During the allocation, the investigator will complete an Excel document with a number allocated to each participant and the number of the participant's group. This document will be used to report data about each participant.

Interventions will be performed by physiotherapists. They will be recruited in the three centers following some criterias by the investigator. The number of physiotherapists will depend on the sample size. They will be responsible to provide a list to the investigator with current patients diagnosed of stress urinary incontinence in postpartum. They will have to perform 4 sessions of rehabilitation with participants. One physiotherapist will follow the same participant for the four sessions but the same physiotherapist could have different participants.

The measurements of the outcomes will be performed by other physiotherapists that will be assessors. In order to avoid biais, assessors will be blind, which means they will not be aware of the treatment received by the participant. They will just know from which group participants are. They will have to perform the same assessment 3 times at different moments of the study to see the evolution. During assessment, assessors will complete the Excel document with a number allocated to each participant, the number of his group and data collection.

Finally, a statistical analysis will be performed by a qualified statistician researcher. They will have to analyse data and determine if the interventions were effective or not.

XII. Resources

To conduct this study, we will need materials. Here is the list of what is required:

Fungible materials:

- Antibacterial gel
- Protective paper for the physiotherapy table
- A pen to complete the Incontinence Quality of Life Scale and sign the certificate of consent for each participant
- Paper with informed consent and certificate of consent for each participant (annexes 5 and 6)
- Paper with home exercises for both participants of each group (annex 7)
- Paper with biofeedback explanations for participant of group 2 (annex 8)

Non-fungible materials:

- A coin
- Physiotherapy table
- Computer with Excel
- Emy for each participant
- Phone with Emy application installed for each participant
- A treadmill
- A trampoline

Human resources:

- 1 investigator
- Physiotherapists specialized in urology with at least 3 years of practice (the number will depend on the sample size)
- Assessors, physiotherapists (the number will depend on the sample size)
- 1 qualified statistician researcher

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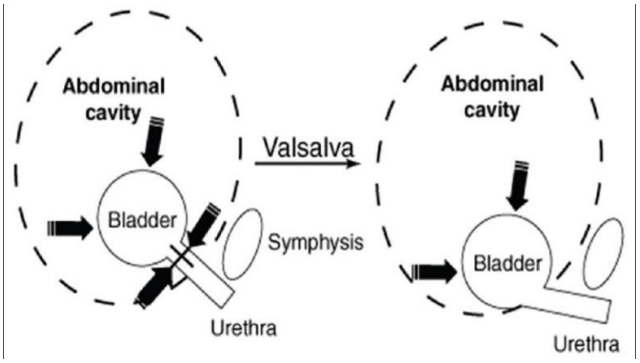
XIV. Annexes

Annex 1: Effects of Valsalva test on incontinent woman



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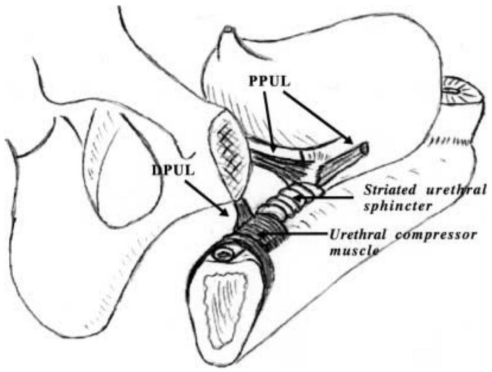
Annex 2: PPUL: proximal pubourethral ligament, DPUL: distal pubourethral ligament



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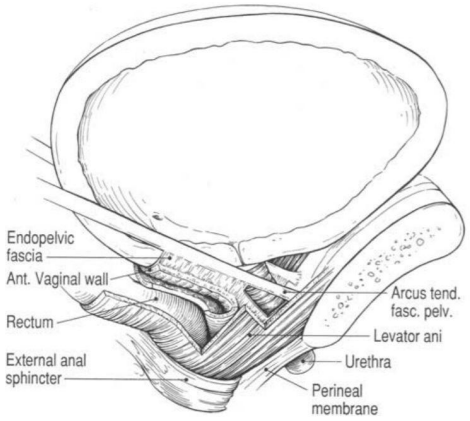
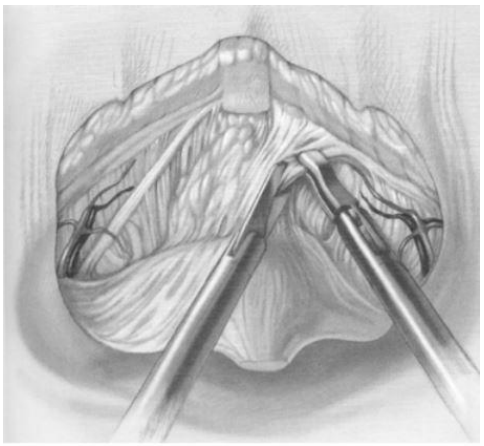
<u>Annex 3:</u> Lateral view of the components of the urethral support system



Ashton-Miller JA, DeLancey JOL. Functional anatomy of the female pelvic floor. Ann N Y Acad Sci. 2007;1101(1):266–96.

<u>Annex 4:</u> Suture placement during Burch colposuspension



Veit-Rubin N, Dubuisson J, Ford A, Dubuisson J-B, Mourad S, Digesu A. Burch colposuspension. Neurourol Urodyn. 2019;38(2):553–62.

Annex 5: Informed Consent (English version)

Informed Consent

Stress urinary incontinence in postpartum: randomised clinical trial

Here you can find the names of the principal members who manage the project:

- Principal Investigator: Mrs Ripart Coline
- Organisation: Centre Universitaire Hospitalier de Nîmes
- Sponsor: EUSES Physiotherapy Barcelona

This Informed Consent presents two parts:

- An Information Sheet that gives you all the information about the research project
- A Certificate of Consent that you have to sign if you agree to take part in the study

You will be given a copy of the full Informed Consent Form.

PART 1: Information Sheet

This paper does not engage in anything. You do not have to decide today whether or not you will participate in the research. The consent will not be received after the end of the enrollment process. If you have any questions, please contact us at coline.ripart@laposte.net or at the university hospital:

Place du Professeur Robert Debré 30029 Nîmes

Opening hours: every day 24h/24h

Introduction:

You are being invited to take part in a research study, a randomized clinical trial. This research will be about treatment of stress urinary incontinence. It is your choice to take part in said study or not. Research studies are ways of finding out new information that might help other people with similar conditions to yours, thereby being essential to make significant progress in the medical care proposed to our patients. In this paper you will find who is the investigator and why we choose to work on this study. It will explain the purpose of the study, interventions and the development of the study. It also tells you about inconvenience, discomfort or risk with this study. Our goal is to be totally transparent with you and to give you the maximum of information to help you to decide freely and fully knowingly if you want to be part of the study or not.

Who are we?

My name is Coline Ripart, I am a student in the fourth year of Physiotherapy at the University of Barcelona EUSES. I am the investigator of this study in collaboration with my school, EUSES Physiotherapy Barcelona and the Centre Universitaire Hospitalier of Nîmes. We are doing research on the treatment of women with stress urinary incontinence in postpartum, which is a phenomenon that has become more and more common in the world.

What is the purpose of the study?

We are doing this research to help women who became incontinent after giving birth. This condition limits their independence in life and doesn't give her the possibility to enjoy fully this period with their baby.

Type of research:

This research will be randomised controlled trial double-blind, which means that participants will not be aware of which treatment they are receiving and assessors will not know which treatment participants have received.

Who can take part in this study?

To take part in this study, you must have the diagnosis of a stress urinary incontinence by the 24-hour pad positive test and a positive valsalva test. You must be a woman aged between 18 and 35 years old. It must be the first pregnancy and your baby should be healthy. You have to be in the 6th week of postpartum. The investigator has discussed with you the requirements for being in this study. It is important that you are completely honest with the doctor and the staff about your health history, your feelings, your symptoms… Any misinformation might lead to the entire study being disproved.

You cannot participate in this study if:

- → You had an episiotomy or a cesarean.
- → You had a previous urinary incontinence or surgical treatment of gynecological and urological illnesses.
- → You have an urinary tract infection.
- → You have a body mass index greater than 30.
- → You have progressive neurological disease, serious cardiac, serious respiratory, or other internal medical conditions.
- → You are currently receiving pharmacological or physiotherapy treatment.

Voluntary participation:

Your participation in this study is based on voluntarism. Whether you choose to participate or not to the study, there will be no change in the services you receive at the hospital and you will be offered the treatment that is routinely offered. Please keep in mind that if you agree to be part of the study, you can stop participating at any time. Regardless of your decision, you will have access to classic cares at your respected medical centers if you decide so. However, if you decide to participate, we would kindly ask you to respect your engagements to be committed to the study and to finish it for its sake. Yet, in the case of a medical or social emergency or personal reason, you will be able to interrupt the study without. After 2 sessions missed, you will automatically be rejected from the study. In the case you refuse to enroll for the study, you retain the right to change your mind and join within the allocated time in order to begin one of our therapy.

Procedures and protocol:

Because we currently do not know if experimental treatments are better than conventional treatments, currently used in physical rehabilitation, we need to compare both.

To do this, we will split subjects that accept to take part in the research into two groups. Participants will be randomly divided into two groups. Participants of one group will receive experimental treatment while participants of the other group will receive conventional treatment. In order to increase internal validity of the study, you will not be aware of which group you have been assigned to.

During sessions, participants will be in a quiet room with a physiotherapist. He will show them some exercises that they would have to reproduce. The physiotherapist will be looking at patients carefully during each session and will help them. Before and after receiving the treatment, we will ask them to do some tests that assess physical ability and answer several questionnaires about your feeling and your sense of independence in different daily life activities. You will have to do some exercises that the physiotherapist will explain to you at home everyday. You have to be aware and have agreed that you will receive in both groups an intravaginal intervention.

Duration:

This study will involve 4 sessions with a physiotherapist of 20 minutes monthly and every day work at home over 16 consecutive weeks, one pretreatment assessment, one post treatment assessment (one day after the last session) and one follow up (10 weeks after the last session).

You will need to come to one of the 3 clinics we selected during the time of the study. We therefore kindly ask you, if you decide to enter the study, to make sure you have the possibility to come to the clinics for all the treatment sessions, assessment and for the follow up.

Confidentiality:

All the personal information collected from this research will be kept confidential. We certify to you that no one except the medical and research staff involved in the study are able to access your personal data collected during the study. Therefore, your name and any information about you will be replaced by a number to keep you anonymous, and no one except the medical and research staff will know the link between number and personal data.

Right to refuse or Withdraw:

Keep in mind that you have entirely the right to choose not to participate in the study if you do not want to. Your participation is voluntary and your refusal of taking part in the study will not reflect negatively on the care you will be provided during treatment. You can stop participating in the study at any moment without any justification.

Side effects:

There are almost no side effects during and after treatment in either groups. It can make you tired or have pain during the next days following each session because you are working on muscles that have been traumatized by delivery. As the 0% of risk does not exist, it is possible that an unexpected side effect that we are not aware of appears. In any cases, we will monitor you carefully, particularly with the presence of doctors, and take note of any unwanted effects or problems and make decisions such as stopping your participation in the study if a serious side effect is detected. Furthermore, you will always be consulted before moving to the next step, and talk together if necessary.

Risks:

There are no real risks with this study if all excluded criteria are respected. However, we are required to anticipate and provide you enough information in any event that can occur. Even if the room and the material will be disinfected after each session, there is still a risk of infection between subjects. If this happens, we will have doctors to take care of you and if needed we will give you a drug to stop the infection. Also, if any other more serious events occur, such as a fall, a high level of care will be available because of the hospital site.

While the possibility of this happening is very low, you have to be aware of the marginal possibility,.However, the research team would like to ensure you that everything will be done to decrease the chances of such an event occurring.

Benefits:

If you choose to participate in this study, you will observe several benefits: therapeutic, psychological and social. Also, if you fall sick during the study, you will be treated at no charge to you. Your participation can help us to respond to our research question. There may be benefits for society if the research has positive results because it can help to improve our rehabilitation for stress urinary incontinence.

Reimbursements:

As a result of your participation, if you choose to be part, we will reimburse your travel/parking payment to the hospital if you are not a patient from the hospital.

All the information that we will collect from the study will be kept confidential. Furthermore, before the publication of the final results, we will invite you to be part of a meeting to explain to you in detail all the information about the results. Finally, the final outcomes will be published without the communication of any personal information about you: it will be anonymous.

If you have any question or doubts about the study, you can ask the research team now or later or contact us at the : +33637259275 or by e-mail at the following address : coline.ripart@laposte.net.

This proposal has been reviewed and approved by the Ethic Review Committee of the World Health Organization (WHO), which is funding/sponsoring/supporting the study.

Annex 6: **Certificate of consent (English version)**

PART 2: Certificate of consent

Statement by the patient/participant:

I have carefully read all the foregoing information, or it has been read to me. I took time to ask any questions about the protocol I might have and any questions that I have asked have been answered to my complacency. I voluntarily consent to be part as a patient in this research about stress urinary incontinence treatment.

I agree to voluntary participate to this study, I understand all important terms and purpose of this study:

YES **NO**

I give the authorization of the researchers to use the anonymous data obtained in this study in the final research publication:

YES **NO**

Name, Surname of the Participant:

Date:

Signature of the Participant:

For illiterate participant:

I have witnessed the accurate reading of the Informed consent to the potential participant, and this person has had the opportunity to ask any questions concerning the protocol and solve any doubt about it. I confirm that the individual has taken time to decide about her/his participation, and has given an independant, informed and freely consent.

Name, Surname the witness participant:

Date:

Signature of the witness participant:

Thumb print of the participant:

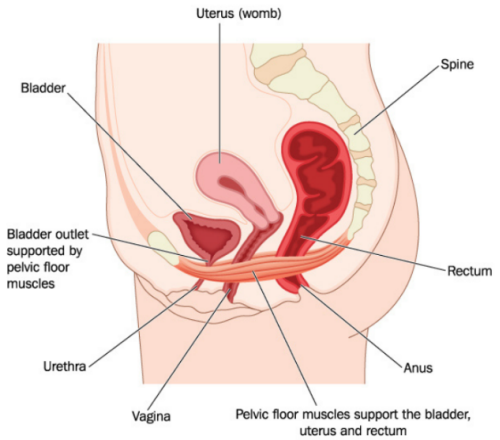
<u>Annex 7:</u> Paper of home work for group 1 and group 2 (English version)

PELVIC FLOOR MUSCLES EXERCISES

For stress urinary incontinence

E U S E S

ANATOMY



https://images.squarespace-cdn.com/content/v1/5678fd4a12f443593746 61d/1453337895298-VWMQL3HAEZUYA6VODURK/ke17ZwdGBTodd8pDm48kDHJ8dP32QNGD_G18fEWvZ12w-zPPgdn4jUwVcJE1ZvWQUxwkmyExglNqGp0IvTJZUJFbgE-7XRK3dMEBRBhUpxGGq000shC7D9tbDmzXzL_Ug-LKws-x5C8AHGCbO8BMCue0Tnn9N-oQxozEpS8dpGU/image-asset.jpeg?format=1500w

HOW TO LOCATED AND CONTRACTED PELVIC FLOOR MUSCLES?

- Try to stop the flow of urine when you are at the toilet to located correct muscles.
- Insert a finger in your vagina and try to squeeze it.
- Pretend you are try to keep a gas.

While performing try to remember this feeling and be aware to not tighten your abdominal, gluteal, and hip muscles.

HOME-WORK 1 AND 2

Lie on your back and start training !

Endurance training
- Slowly performed maximal contraction
- Maintain during 3-10second
- Relax 3-10 second
- Repeat for 10 contractions

Speed training
- Quickly performed moderte contraction
- Maintain during 2 seconds
- Relax for 2 seconds
- Repeat for 10 contactions

Repeat both exercises 3-5 times depending on your fatigue everyday

HOME-WORK 3

Performed **endurance training** and **speed training** one set of 10 contactions on each of these positions everyday:
- lying on the side
- seated
- standing

HOME-WORK 4

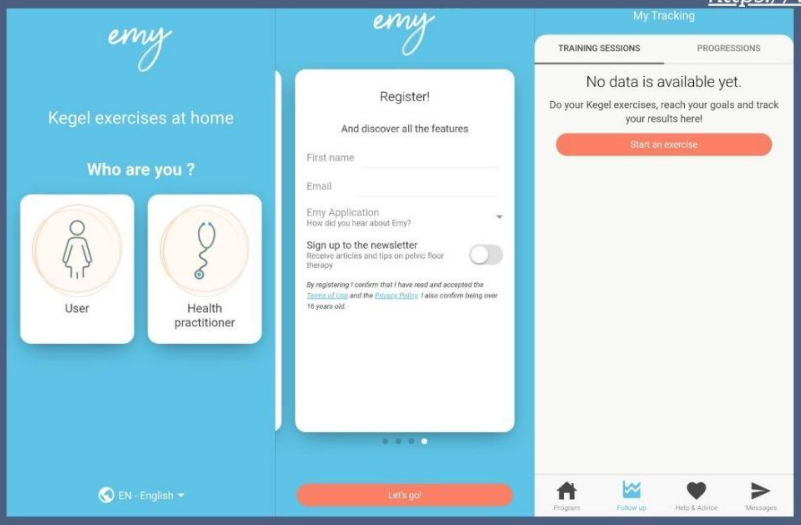
Now that you have better conscience of your pelvic floor muscles keep in mind what you learnt in daily life.
For this last part of the rehabiliation performed these exercises while **contacting your pelvic floor muscles** everyday:
- **Walking** for 15 minutes
- **Jumping** 10 repetitions
- **Coughing** 3 times

If you have any questions any doubts , please contact us at coline.ripart@laposte or at the university hospital:
Place du Professeur Robert Debré 30029 Nîmes
Opening hours: every day 24h/24h

<u>Annex 8</u>: Paper for group 2 (English version)

HOW TO USE EMY APPLICATION ?

https://www.fizimed.com/en



Don't forget to put it before doing your home work

HOW TO USE YOUR EMY ?

1) Clean your device
2) Turn on the bluetooth
3) Fill in your personnal informations
4) Turn on your device by shaking it
5) Inser the device

If you have any questions any doubts or any problem with Emy please contact us at coline.ripart@laposte or at the university hospital: Place du Professeur Robert Debré 30029 Nîmes Opening hours: every day 24h/24h

<u>Annex 9</u>: Incontinence quality of life scale (English version)

All items use the following response scale:
1 = EXTREMELY 2 = QUITE A BIT 3 = MODERATELY 4 = A LITTLE 5 = NOT AT ALL

Name and surname of the participant:
Group:
Date:

Questions:	Score:
Q1 : I worry about not being able to get to the toilet on time	
Q2 : I worry about coughing or sneezing because of my urinary problems or incontinence	
Q3 : I have to be careful standing up after I've been sitting down because of my urinary problems of incontinence	
Q4 : I worry about where toilets are in new places	
Q5 : I feel depressed because of my urinary problems or incontinence	
Q6 : Because of my urinary problems or incontinence, I don't feel free to leave my home for long periods of time	
Q7 : I feel frustrated because my urinary problems or incontinence prevents me from doing what I want	
Q8 : I worry about others smelling urine on me	
Q9 : My urinary problems or incontinence is always on my mind	
Q10 : It's important for me to make frequent trips to the toilet	
Q11 : Because of my urinary problems or incontinence , it's important to plan every detail in advance	
Q12 : I worry about my urinary problems or incontinence getting worse as I grow older	
Q13 : I have a hard time getting a good night of sleep because of my urinary problems or incontinence	
Q14 : I worry about being embarrassed or humiliated because of my urinary problems or incontinence	
Q15 : My urinary problems or incontinence makes me feel like I'm not a healthy person	
Q16 : My urinary problems or incontinence makes me feel helpless	
Q17 : I get less enjoyment out of life because of my urinary problems or incontinence	
Q18 : I worry about wetting myself III	
Q19 : I feel like I have no control over my bladder	
Q20 : I have to watch what or how much I drink because of my urinary problems or incontinence	
Q21 : My urinary problems or incontinence limit my choice of clothing	
Q22 : I worry about having sex because of my urinary problems or incontinence	
Overall score =	/110

https://kinedoc.org/work/kinedoc/64f0c8db-a3ca-4a98-8869-f33ff9871359.pdf

<u>Annex 10:</u> Proposed modified Oxford grading scheme (English version)

Grading	*Muscle response*
0	Nil
1	Flicker
2	Weak
3	Moderate
4	Good
5	Strong

Laycock J, Jerwood D. Pelvic floor muscle assessment: The PERFECT scheme. Physiotherapy. 2001;87(12):631–42.