

**The Effects of the Pilates Method on Pelvic Floor Injuries during  
Pregnancy and Childbirth: A Quasi-experimental Study**

**NCT:.....**

**Data: 10/10/2018**

## INTRODUCTION

It is well known that female pelvic floor weakness and/or pelvic floor dysfunction (PFD) can have both structural and functional effects, such as urinary incontinence, bowel incontinence, pelvic organ prolapse, and dyspareunia and/or sexual dysfunction (Bozkurt et al., 2014, Pierce et al., 2015, Hyakutake et al., 2016, Neels et al., 2016). One of the main risk factors associated with pelvic dysfunction is the reproductive process, including pregnancy and birth. During this process both modifiable and non-modifiable risk factors for PFD can be identified. Chief among the former are the pregestational and full-term body mass index (BMI), weight gain, smoking, the type of birth, the use of forceps, the duration of the first and second stages of birth, the practice of episiotomy and the use of epidural anaesthesia. Among the non-modifiable risk factors (also known as risk indicators), are age at maternity, position of the foetus and circumference of the newborn's head, the weight of the newborn, and the presence/existence of perineal injury, chiefly those which can affect the anal sphincter (Bozkurt et al., 2014, Hyakutake et al., 2016).

Of all these factors, vaginal birth is the chief modifiable risk factor for developing pelvic floor dysfunction, as women in this group are 2.8 times more likely to suffer stress urinary incontinence, and 5.5 times more likely to suffer a prolapse of the pelvic organs, in comparison with those who give birth via caesarean section. These risks increase with instrumental delivery, which seems to be related to the fact that the incidence of injury to the anal musculature is higher in this procedure (Howard & Makhoul, 2016).

Among the non-modifiable obstetric risk factors, chief is perineal trauma, whether spontaneous or induced (second degree tears or obstetric anal sphincter injuries), which represents one of the most frequent complications associated with birth (85% of puerperal women) (León-Larios et al., 2017), and has a clear influence in the subsequent appearance of PFD (Bose et al., 2017, León-Larios et al., 2017).

Although in recent years the practice of routine episiotomies has decreased in Spain, the percentage remains above the recommendations of the WHO (WHO 1999, Escuriet et al., 2015) at around 40.2% (León-Larios et al., 2017). Within this average there is a disparity between the public and private systems, whereby, according to Escuriet et al. (2015), there has been an increase in the number of

episiotomies in private hospitals. In a study carried out in the United Kingdom, Smith et al. (2013) found a difference in the frequency of episiotomies between primiparae and multiparae, and also in the different degrees of perineal tearing, with the most frequent being second degree tears in both uniparity and multiparity contexts (Smith et al., 2013, Zimmo et al., 2017).

In addition, the risk of suffering more serious perineal trauma, specifically fourth degree tears affecting the anal sphincter and recta mucosa is three times greater among primiparae than multiparae (León-Larios et al., 2017, López et al., 2014, OMS 1999).

Perineal wounds suffered during birth significantly increase the risk of PFD, with a consequent impact on the female population of physical and emotional discomfort, depression, social isolation, avoidance of healthy physical activity, and reduction in productivity and quality of life, and a resultant increase in the demands on the health service (Smith et al., 2013, Bozkurt et al., 2014, Pierce et al., 2015, Hyakutake et al., 2016).

Primary prevention of PFD is therefore essential, and the following interventions have been shown to be effective: (i) perineal massage during pregnancy (from week 34) ) (Oblasser et al., 2016), which has been found to diminish the number of episiotomies in primiparae, shorten the first and second stages of labour, and to reduce postpartum pain in multiparae (León-Larios et al., 2017); (ii) weight management and prevention of constipation through the promotion of a suitable diet and by doing physical exercise adapted to pregnancy (Davidson et al., 2000, Kyvernitakis et al., 2015); and (iii) pelvic floor strengthening exercises, which help to reduce discomfort (mainly among primiparae) and reduce the risk of urinary incontinence in the third trimester of the pregnancy and after childbirth (Hyakutake et al., 2016, León-Larios et al., 2017).

With respect to exercises for strengthening the pelvic floor, the most common are hypopressive abdominal exercises and the Pilates Method (PM), which focus on developing the musculature of the transverse abdominis and pelvis in order to decrease intra-abdominal pressure (Kyvernitakis et al., 2015). The latter method is an exercise programme holistically encompassing body and mind in a combination of eastern and western techniques, and incorporating movements drawn from traditional and Swedish gymnastics, rehabilitation techniques, martial arts, yoga and dance (Llewellyn et al., 2017).

## **Background**

Pilates is based on the six fundamental principles of breath, concentration, flow, precision, centring and control. It aims for an equilibrium in musculature by reinforcing weak muscles and stretching tight ones, with an emphasis on control, strength, and flexibility. It focuses particularly on the core – the abdominal muscles, vertebral column and pelvic floor, and is thus instrumental in improving body alignment and good posture across the range of movements habitually carried out in daily activities (Guzmán et al., 2013, Shaban et al., 2014, Llewellyn et al., 2017, Navarro & Luján, 2017). Advocates also note that practitioners gain a greater self-awareness of their body image, their range of motion and personal health (Almagiá, 2003), among other benefits (Culligan et al., 2010, Cruz-Ferreira et al., 2011, Shaban et al., 2014). For this reason, Pilates is often recommended generally as a treatment for alleviating back pain (Boix-Vilella et al., 2017).

Given the marked increase in practising Pilates during pregnancy (Wells et al., 2012, Shaban et al., 2014, Llewellyn et al., 2017), various studies have been carried out to evaluate its effectiveness. These include the effect of Pilates in antenatal classes for reducing anxiety about giving birth and in terms of its overall perinatal outcome and the benefits of a Pilates-based exercise programme during pregnancy and birth (Sarpkaya et al., 2018). Also notable in this regard are studies demonstrating the role of Pilates in reducing lumbar pain during the third trimester Maczka & Sass, 2017, Rogríguez-Díaz et al., 2017). With regard to the specific relation of Pilates with PFD, Dias et al. (2017) found a positive impact on the pelvic floor musculature during pregnancy (Oktaviani, 2017), while Muniz de Souza et al. (2017) concluded that the method was a valid means of helping to prevent the dysfunction (Dias et al., 2017).

The starting hypothesis of this study is that the incidence of perineal wounds during childbirth to be lower among those participating in a specially designed Pilates program.

## **THE STUDY**

### **Aim**

The aim of this study is to evaluate the influence of Pilates sessions during pregnancy on the incidence and degree of intrapartum perineal injuries.

### **Design**

A multicentre quasi-experimental study, will be carry out between November 2018 and December 2019 in health centres (HCs) pertaining to two distinct health districts

### **Participants**

A convenience sample of pregnant women attending antenatal classes at health centres in two distinct districts, and meeting the following inclusion criteria:

(i) being registered on an antenatal programme (AP); (ii) giving written consent of participation; (iii) the pregnancy being a singleton; (iv) the pregnancy being low risk; (v) there not being any contraindications for physical exercise (vi) being at least 18 years old.

Women who have missed antenatal appointments, had difficulty in speaking or understanding Spanish, had given birth by caesarean section or declined to participate will be excluded from the study.

### **Interventions**

The study will be carry out in two stages: the first involved finding Pilates trainers to deliver the sessions, while the second collated participant data from both the experimental and control groups. The first phase took place in November 2018, with the collaboration of two trainers in Huelva and one in Seville, all with the same training background. The second phase will be carried out between December 2018 and December 2019 in the corresponding health centres in Huelva and Seville.

In order to eliminate potential bias as a result of the antenatal classes being deliver by health professionals of different categories, only those health centres where classes are deliver by a midwife were selected for the study. The women participat in the corresponding antenatal classes at the respective centres were

then will be invited to participate in the study either to the experimental group (AC + PM) or in the control group (AC only).

#### Experimental group

The experimental group will be receiver two one-hour Pilates sessions per week over a period of 4 weeks (Table 1). In addition, the participants will be receiver their usual antenatal classes at their respective health centres in accordance with the Comprehensive Healthcare Programme for Pregnancy, Childbirth, and Postpartum (CHPPCP) from the Andalusian Regional Government (Aceituno et al. 2014).

#### Control group

The control group will be receiver solely the antenatal clases at their corresponding centres as programmed (Table 2).

#### Sample size

A minimum sample size of 36 women will be project, for a confidence level of 95% and a power of 80%, considering 49% avoiding episiotomy in the control group in comparison with 98% in the experimental group (Rodríguez et al., 2017), and divided according to a ratio of 2 women in the control group for every woman in the experimental group. This number will be increas in case any women dropped out, such that the final number of participants will be 72, of which 24 will be form the experimental group and 48 the control.

#### Data Collection

##### Outcomes

The dependent variables wwill be age (years), blood pressure (mmHg), weight (kg), BMI (kg/m<sup>2</sup>), starting level of physical activity, and tobacco use. These variables will be all measured by experienced personnel at the start of the experimental phase, at two weeks, and again at four weeks after the treatment for both groups had been completed.

Variable relating to childbirth will be measured between the eighth and tenth day after birth by telephone interview and review of hospital medical history. The number of weeks of pregnancy at birth will be measur on a discrete

quantitative scale. Labour onset (spontaneous, stimulated, induced), type of delivery (spontaneous, assisted delivery with forceps, Thierry's spatulas or vacuum extraction, caesarean section), the use of intrapartum pharmacological analgesia (none, epidural anaesthesia, sedatives, nitrous oxide), type of episiotomy (not required, median, lateral, medio-lateral) will be measured by nominal scales, while the degree of perineal tear will be evaluated on an ordinal scale (no injury, degree I: injury to perineal skin; degree II: injury to perineal skin and muscle; degree III: injury to perineal skin, muscle and anal sphincter; degree IV: injury to perineal skin, muscle, sphincter and anorectal mucosa). Weight (kg) and height (cm) will be recorded during the routine antenatal appointments at the health centres using stadiometers with weight scale function. The level of physical activity will be measured using the International Physical Activity Questionnaires (IPAQ) (Craig et al. 2003).

### *Ethical considerations*

The study will be carried out in keeping with the principles enshrined in the Declaration of Helsinki (1964), the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (1997), the Universal Declaration on the Human Genome and Human Rights (1997), and also complied with the requirements stipulated by Spanish Law 3/2018 of the 5th December in the area of biomedical research, data protection and bioethics. Approval from the bioethics committee of the Andalusia Health Service (SAS) will be also obtained. Only data for which informed consent had been given in writing will be used.

### **Data analysis**

The quantitative variables will be presented with the mean and standard deviation, while the qualitative data will be given in frequencies and percentages.

In order to measure the goodness of fit of the quantitative data to a normal distribution, a Lilliefors corrected Kolmogorov-Smirnov test will be used. Bivariate analysis will be carried out with Student's t-test for the comparison of two means. In the case of the qualitative data, the Chi-square test will be used, except when Fisher's exact test was required. Likewise, for the analysis of three or more means, a repeated measures ANOVA will be used to evaluate the effects of the

treatment in the two groups, at baseline, three and five weeks. Correlation between the quantitative variables will be verified using the Pearson coefficient correlation ( $r$ ). Finally, in order to allow for the possibility that the data did not meet the criterion of normality or homoscedasticity, non-parametric versions of the tests above will be also carry out.

Binary logistic regression models adjusted for various qualitative and quantitative predictive variables will be calculated in order to determine association of the variables with perineal trauma in childbirth.

The Odds Ratios (ORs) will be determined with a confidence interval of 95%. The goodness of fit tests ( $-2 \log$  likelihood, goodness of fit statistic, Cox and Snell  $R^2$ , Nagelkerke  $R^2$  and Hosmer–Lemeshow) will be calculated to evaluate the overall fit of the model.

In all statistical analyses, alpha will be set to below 5% / the significance level was established at 5% ( $p < 0.05$ ) and a confidence interval of 95% will be computed. All statistical calculations will be made using IBM SPSS Statistics version 25.0.

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