**Study protocol**

**Project Title:** The effect of pelvic floor muscle exercise on female sexual function during pregnancy and the first three months postpartum: A randomised controlled trial

**Trial registration** ACTRN12617001030369p

**Protocol version Version 2**

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**Roles and responsibility:** Dr Jenny King, Chief investigator

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**Introduction**

Sexual dysfunction is widespread and a major public health concern and can have an enormous effect on quality of life ([Weig, 2006](#_ENREF_65); [Zahra et al., 2014](#_ENREF_67)). Sexual dysfunction is defined as the disturbance in sexual desire and psychophysiological changes that characterize the sexual response and cause interpersonal difficulty and marked distress ([Ferreira et al., 2015](#_ENREF_25)) capable of adversely altering quality of life ([Running, Smith-Gagen, Wellhoner, & Mars, 2012](#_ENREF_52)). Several studies estimate that sexual dysfunction ranges from 19% to 50% of the population, with a higher incidence and prevalence in women (43%) than men (31%) ([Frank, Mistretta, & Will, 2008](#_ENREF_28); [Zakhari, 2009](#_ENREF_68)).

When it comes to pregnancy and birth, according to a study, the incidence of sexual dysfunction rises to approximately 63% to 93% of all pregnant women ([Ribeiro et al., 2014b](#_ENREF_49)). Pregnancy frequently results in a significant life stress that interrupts previous stages of physical and emotional coadaptation of couples, and many women experience changes about sexuality during pregnancy. ([Pauls, Occhino, & Dryfhout, 2008](#_ENREF_47)). Despite this, sexual function and sexual behaviour during pregnancy has received insufficient attention despite the significant gains in knowledge about female sexuality in recent years ([Erol et al., 2007](#_ENREF_24)). Approximately, 90% of women recommence sexual activity six weeks after childbirth ([Golmakani, Zare, Khadem, Shareh, & Shakeri, 2015](#_ENREF_30)). Of this total, 83% experience sexual problems (such as discomfort) in the first three months and 64% in the first six months following birth ([Golmakani, Zare, Khadem, Shareh, & Shakeri, 2015](#_ENREF_30)). Khajehei et al (2015) found that 64.3% of Australian women expressed sexual dysfunction during the first year after birth and 70.5% reported sexual dissatisfaction([Khajehei, Doherty, Tilley, & Sauer, 2015](#_ENREF_33)) .

Several factors have been associated with sexual dysfunction including maternal duties, sleep disorders, psychosocial changes, fatigue and changes in maternal body image as well as breastfeeding after birth. However, among them, reduced strength of pelvic floor muscles after birth is a major factor that negatively affects women’s sexual function ([Golmakani et al., 2015](#_ENREF_30)). Loss of pelvic muscle strength is one of the physical changes in the postpartum period, and even years afterwards, leading to complications such as pelvic pain, urinary incontinence, cystocele, rectocele and lack of sexual satisfaction ([Elbegway, Elshamy, & Hanfy, 2010](#_ENREF_23); [Golmakani et al., 2015](#_ENREF_30)). Healthy pelvic floor muscle tone in women has been found to be crucial for satisfactory genital arousal and attainment of orgasm and weak muscles may provide inadequate stimulation and arousal, thus hindering orgasmic potential ([Mohktar et al., 2013](#_ENREF_43)).

To date, there is an international consensus that pelvic floor muscle training (PFMT) should be the first-line treatment for stress urinary incontinence (SUI)and pelvic organ prolapse (POP). There is, however, no consensus on either prevention or treatment of symptoms related to female sexual dysfunction (FSD) ([C. Ferreira et al., 2015](#_ENREF_25); [M. K. Tennfjord et al., 2015b](#_ENREF_61)). Pauls et al (2008) suggested that pelvic floor muscle training (PFMT) should be the first line treatment for stress urinary incontinence and pelvic organ prolapse. However, the authors suggested that more high quality randomised controlled trials (RCTs) are warranted to test whether PFMT can reduce sexual dysfunction ([Pauls et al., 2008](#_ENREF_47)). Similarly, Ferreira et al (2015) proposed that many aspects of the effects of PFMT on sexual function remain understudied. They concluded that there is an urgent need for RCTs specifically designed to investigate the effect of PFMT on female sexual function (FSF) and treatment of sexual dysfunction as a primary aim ([Ferreira et al., 2015](#_ENREF_25)). A summarised systematic review of literature will be presented in the next section to provide a summary of relevant studies available on this topic.

**Systematic Review**

A systematic review of literature was conducted to investigate the effect of PFMT on female sexual function in pregnancy and postpartum and also on childbirth**.**

During the first search, 4033 papers were initially identified. However, after screening, thirteen papers were identified to be most relevant to the objectives of this study. Six out of thirteen articles examined the effect of postnatal pelvic floor muscle exercise on FSD and seven articles were related to the effect of PFMT on labour and childbirth. However, no article specifically discussed the effect of PFMT on FSD in pregnancy as a primary outcome.

Some studies ([Golmakani et al., 2015](#_ENREF_30); [Modarres et al., 2013](#_ENREF_40)) showed a significant increase in sexual efficacy ([Golmakani et al., 2015](#_ENREF_30)) and sexual satisfaction ([Modarres et al., 2013](#_ENREF_40)) after PFMT in primiparous women after 8-16 weeks ([Golmakani et al., 2015](#_ENREF_30)) and 6-12 months ([Modarres et al., 2013](#_ENREF_40)) following normal birth. Similarly, Citack et al ([Citak et al., 2010](#_ENREF_16)) reported that desire, pain and total FSFI scores were significantly higher in the seventh month compared with fourth month following birth in both intervention and control groups. Sexual arousal, lubrication, orgasm, and satisfaction scores were improved in the seventh month in the training group (p<0.001) after pelvic floor muscle exercise ([Citak et al., 2010](#_ENREF_16)). One study (non-RCT) reported an improvement in sexual function with improving pelvic floor, muscle strength (p<0.05) in 30 multiparous postnatal women ([Elbegway et al., 2010](#_ENREF_23)). In contrast, Tennjford et al identified no difference between training and control group after pelvic floor muscle training ([M. K. Tennfjord et al., 2015b](#_ENREF_61)). Baytur et al concluded that PFMS and mode of birth did not affect sexual function. They also found that PFMS was lower in group with normal birth compared with those who had a caesarean section, and in nulliparous women ([Baytur et al., 2005](#_ENREF_7)).

**The effect of PFMT on childbirth outcome**

Pregnancy and childbirth are among the primary factors leading to trauma of the pelvic floor. Unnecessary interventions during labour may cause perineal trauma and affect the health of women negatively ([Dönmez & Kavlak, 2015](#_ENREF_20)). Data regarding the effect of PFMT on the first stage of labour are limited ([Y. Du et al., 2015](#_ENREF_21)). In this review, some studies ([Y. Du et al., 2015](#_ENREF_21); [Salvesen & Mørkved, 2004b](#_ENREF_55)) showed that PFMT may be effective in reducing the duration of the first stage of labour. However, another study ([Wang et al., 2014](#_ENREF_64)) showed no difference between two groups. Likewise, three studies ([Y. Du et al., 2015](#_ENREF_21); [Salvesen & Mørkved, 2004b](#_ENREF_55); [Wang et al., 2014](#_ENREF_64)) reported that PFMT may be effective in shortening the second stage of labour. However, Dias et al, found no effect of PFMT on labour and newborn outcome ([Dias et al., 2011](#_ENREF_19)). Similarly, the current data on the effect of PFMT on episiotomy, laceration rate and instrumental birth are conflicting. There are studies ([Agur et al., 2008](#_ENREF_2); [Bø et al., 2009](#_ENREF_9); [Y. Du et al., 2015](#_ENREF_21)) which found no difference in treatment and control groups. In contrast, Donmez et al, concluded that PFMT is effective to reduce the laceration formation rate, perineal pain and also to accelerate the healing of wound after birth ([Dönmez & Kavlak, 2015](#_ENREF_20)).

**Conclusion**

Pelvic floor muscle exercise might improve some aspects of sexual function ([Citak et al., 2010](#_ENREF_16); [Dias et al., 2011](#_ENREF_19); [Modarres et al., 2013](#_ENREF_40)) and also childbirth outcomes ([Dönmez & Kavlak, 2015](#_ENREF_20); [Y. Du et al., 2015](#_ENREF_21); [Salvesen & Mørkved, 2004b](#_ENREF_55)); however, the current data on the effect of PFMT on FSD and childbirth are conflicting. There is a lack of evidence about the effectiveness of antenatal pelvic floor muscle program on FSD during pregnancy and the postpartum. More RCTs with larger sample size, and high quality methodology using a validated assessment tools considering the confounding variables in pregnancy, labour and postpartum are needed to assess the effect of PFMT on different aspects of sexual function in pregnancy and postpartum and also on labour and childbirth outcomes in both multiparous and primiparous women

**Objectives**

**Research aim:**

Toevaluate the effectiveness of antenatal PFMT on sexual function in primiparous women during pregnancy and at three months following birth by conducting a RCT on women receiving antenatal standard care compared with those receiving antenatal standard care plus antenatal PFMT.

**Research objectives:**

**Primary objective:**

1. to undertake a RCT to examine the impact of antenatal pelvic floor muscle exercise (PFMT) on sexual function in primiparous women three months following birth.
2. to conduct a RCT to examine the impact of antenatal pelvic floor exercise (PFMT) on sexual function in primiparous women during pregnancy.

**Secondary objective:**

1. to determine the impact of antenatal PFMT on urinary and faecal incontinence symptoms during pregnancy and at three months following birth.
2. to explore the impact of antenatal PFMT on childbirth outcomes.
3. to determine whether undertaking antenatal PFMT improves women’s specific quality of life during pregnancy and at three months following birth.

**Research hypothesis:**

 **Primary Hypothesis**:

* Women who perform antenatal PFMT have better sexual function three months following birth compared with women who receive antenatal standard care alone.
* Women who perform antenatal PFMT have better sexual function during pregnancy compared with women who receive antenatal standard care alone.

**Secondary Hypothesis**:

* Women who perform antenatal PFMT have improved childbirth outcomes compared with women who receive antenatal standard care alone.
* Women who perform antenatal PFMT have less urinary incontinence and faecal incontinence symptoms during pregnancy and three months following birth compared with those women who receive antenatal standard care alone.
* Women who perform antenatal PFMT have better specific quality of life compared with women who receive only antenatal standard care alone.

**Trial Design**

**Randomised controlled trial (RCT)**

In this study, a parallel RCT will be used in which control group will receive standard antenatal care with no intervention, and intervention group will receive intervention and standard antenatal care. The strength of proposed randomised controlled trial design is the capacity to determine causality between the outcome variables (dependent variables) and the exercise/no exercise program received by women in the two groups (independent variables). A RCT is the most rigorous way of determining whether a cause-effect relation exists between an intervention and an outcome and for assessing the casual link between PFMT and health outcomes of the intervention. Women not allocated to the PFMT group will be cared for as usual. Subjects will be analysed within the group to which they were allocated, irrespective of whether they experienced the intended intervention. All exclusions will be reported. The ratio of treatment/control is one.

**Methods (Participants, intervention and outcomes)**

Low risk prim-parous pregnant women less than 20 weeks gestation who present to the antenatal clinic at Westmead public hospital for prenatal care will be approached to participate in the study.

**Study Setting**

After ethical approval, recruitment will be undertaken at the antenatal clinics at Westmead public hospital (WPH) including; midwives’ clinic, GP shared care and the caseload midwife’s clinic. Discussions have been held with Dr Jenny King urogynaecologist and the head of Pelvic Floor Department in Westmead hospital, the chief Physiotherapist and Director of Women and Children’s Health at Westmead and verbal approval has been given for the study.

**Eligibility Criteria**

**Inclusion criteria:**

* Primiparous women over 18 years old and less than 20 weeks’ gestation
* Having a current sexual partner
* Being in a heterosexual relationship
* Singleton pregnancy
* Anticipating a vaginal birth
* No history of urinary incontinence or pelvic surgery or pelvic organ prolapse
* Able to read, understand and communicate in English
* No previous history of depression, mental illness, alcohol and drug use, domestic violence
* Women need to agree not to perform a PFME protocol other than what they are taught in this study

 **Exclusion criteria**

* Over 20 weeks’ gestation
* Planning to give birth via caesarean section at the time of booking
* Multiparous women
* Women with a multiple pregnancy
* Women with complicated pregnancies (type 1 and type 2 diabetic, vaginal bleeding) and those with known pelvic floor muscle dysfunction
* Women who are not able to read and understand English to answer the questionnaires

**Eligibility Criteria for Researcher who perform the intervention**

The researcher is a current PhD candidate of Western Sydney University and holds a Master of Science degree in midwifery and maternal and child health and is currently a registered midwife working in Birth unit of Westmead hospital. She has been working across all areas of midwifery scope of practice such as antenatal, birth unit and postnatal ward. She has been giving advice to women about pelvic floor muscle exercise as a part of the antenatal and postnatal care and as a primary health care provider with a focus on women’s centred care by providing women with evidence-based information. Moreover, the researcher has done previous research examining the relationship between pelvic floor muscle strength, urinary incontinence and dyspareunia in women of reproductive age during her Masters of Science degree. The researcher will provide the PFMT program to women according to the protocol design which will be explained in the next section in this study protocol. Additionally, the research design has been considered in collaboration with Dr Jenny King, the Urogynecologist and head of pelvic floor unit in Westmead hospital and also the physiotherapy department of Westmead Hospital in order develop the most feasible protocol and also to receive support including pamphlets on pelvic floor muscle exercises from physiotherapy department. The researcher also has attended discussion sessions with a physiotherapist in postnatal ward (team leader) in Westmead hospital in order to stay updated and consistent with the current education about pelvic floor muscle exercise being provided to the women. In addition, close supervision and support being provided by academic and onsite supervisors who are highly experienced and knowledgeable in this area of research as described in NEAF.

**Intervention**

The intervention being examined in this research project is the implementation of pelvic floor muscle exercise training, which is currently part of antenatal education in Westmead Hospital; However, the current antenatal education is only brief, consisting of verbal education by the midwife in one antenatal visit, with education being given in less than 20 minutes at the same time that the routine antenatal care is provided to the pregnant women. It appears that the advice being given by midwives is not consistent, is not sufficient enough to encourage women to comply with the exercise and there is no follow up or practical training advice on how to perform pelvic floor exercise correctly.

In this study, the pelvic floor muscle exercise program will be structured using an evidence-based protocol with regular follow up to increase women’s compliance. Women in the intervention group will receive routine antenatal care and education as well as training on how to perform pelvic floor muscle exercise. While women in the control group, will receive standard antenatal care only. There is no restriction or specific requirement needed from women while participating in this study. There is no plan to change the study protocol. If women raise any concern during research, they will be encouraged to discuss it with researcher or their health care provider.

**Antenatal PFMT protocol**

The first training session will be conducted by the researcher (PhD candidate) and is designed to take 30 minutes. All women in the intervention group will be provided with instructions on how to perform pelvic muscle exercises by the researcher. The pelvic floor muscle exercise program in this study has been extracted from two references including: effective functional motor activation patterns called “(The knack”) ([Miller, Ashton‐Miller, & DeLancey, 1998](#_ENREF_39)) and the study carried out by Elbegway et al (Elbegway et al., 2010).

Women will be instructed as follows:

Women will be individually trained as follows:

1. Squeeze the anal sphincter, the vaginal and urethral as tightly as possible.
2. To increase the intensity of their effort.
3. To hold the contraction as tightly as they can for 8-10 seconds.
4. To relax their effort, allowing their muscle to relax and rest for 8-10 seconds.
5. To repeat the sequence 8 times
6. To perform five fast pelvic floor muscle contractions after completing slow contractions.
7. To perform one set of 13 PFME (eight slow and five fast) three times a day.
8. 7. To do this daily. Do these daily (Table 1).

Women in the intervention group will be provided with a pamphlet including PFMT instruction as well as a compliance diary to record their exercises program. Red stick up spots will be used to remind women to do the exercises as this has been demonstrated to be effective ([Miller et al., 1998](#_ENREF_39)).

The women will be instructed how to lift up and inward around urethra, vagina, rectum, and squeeze as hard as they can and hold it for 8-10 seconds before relaxing the muscles gently. Women will be asked to keep breathing in and out during the contractions (Mørkved & Bø, 2014). Women will be instructed to perform PFME in different positions so they can choose the most comfortable position to practice PFME at home (Fig 3).

Table 1. PFMT Routine

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| Begin with assessed muscle function and aiming for 10 reps with 10 second hold three times a day (document in diary provided) |
| Triggers (red stick up dots): shower, teeth, meals, queues etc. |
| The Knack: functional bracing: grip up before cough, sneeze, lift, bend |
| Postnatally: as above and also incorporating good bladder habits |

In order to monitor the effect of PFMT, women will be provided with self-reported questionnaires to find out the effect of pelvic floor muscle exercise on their sexual symptoms, urinary and faecal incontinence and quality of life. The information about their birth will be collected via Obstetrix in order to find out the effect of pelvic floor muscle exercise on childbirth. Women can withdraw from study if they decide not to continue and no more information will be collected from them after their withdrawal. Women will be included or excluded according to the eligibility criteria as described above. There is no plan to change the study protocol during this research as it is already designed to be practical and feasible for women. There is no report of harm from pelvic floor exercise in literature. It is reported in literature that PFMT will be either beneficial or with no effect at all, but no harm effects have been reported in literature.

Follow up: women will be provided a diary and fortnightly text message assessing their compliance. Women will also be further followed up during next antenatal visits regarding data collection, their compliance with PFMT program and also if they need further support or advice.

**Outcomes**

**Primary outcome**

The primary outcome measure will be the female sexual function measurement by using the female Sexual Function Index Score which will be measured at the time of booking, at 36 weeks of pregnancy, and three months following birth.

**Secondary outcome**

* Maternal (childbirth outcome):Duration of the three stages of labour, fetal positions and presentation at birth, mode of birth (normal vaginal birth, caesarean section and instrumental birth), episiotomy and perineal trauma rate (1st, 2nd, 3rd and 4th degree).
* Fetal outcomes**:** APGAR score, head circumference, length, and weight**.**
* Urinary incontinence, faecal incontinence symptoms (assessed by UDI-6 and faecal incontinence questionnaire) and specific quality of life (assessed by IIQ-7).

Secondary outcomes will be measured at the time of booking, 36 weeks of pregnancy and three months following birth. Birth outcomes will be collected after birth via the Obstetrix data base.

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| * **Participant timeline**
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Figure 1. Post consent randomisation

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| Primiparous women booking for pregnancy care (under 20 weeks gestation) approached with information about PFMT |

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|  | Excluded: women booking for elective caesarean section and those who don’t meet inclusion criteria |
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| Included: women meet the inclusion criteria and who give written consent (N= 200) are randomised to antenatal PFMT or routine care |

**Intervention (N=100) Control (N=100)**

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| Women will receive routine care plus instruction from the researcher to perform pelvic floor muscle exercises as per PFMT protocol described above and will receive follow up from 20 weeks gestation up to birth and once at three months after birth. Women will be provided questionnaires to answer and diary. (Please see data collection section) |  | Women will receive routine pregnancy care and are not discouraged to conduct antenatal PFMT.Women in control group will need to answer questionnaires at 20 weeks of pregnancy, at 36 weeks’ gestation and at three months after birth. (Please see data collection section). |

**Participants Timeline**

Figure2. Timetable at the time of recruiting primiparous pregnant women at first visit in antenatal clinics

In total approximately 75 minutes needed for women who are allocated in intervention group and 45 minutes for women who are allocated to control group at first visit (Figure 2).

Women in the intervention group will receive fortnightly follow up by text messages to check for their compliance from 20 weeks’ gestation up to the birth. Women in the intervention group will also receive further follow up in next antenatal visit to provide them with more support or advice if they need, and also if there is missing information, change of their circumstances or if they need diary. The follow up contact will cease after birth. However, women in both control and study groups will be contacted once at three months after birth to complete the questionnaires and also to answer some questions regarding their postpartum history. Women in the control group will be contacted only twice during research process: once at 36 weeks’ gestation and once at three months after birth to complete questionnaires (through REDCAP or in paper) and answer some questions about their postpartum history as indicated in survey.

**Sample size**

There is a lack of information about the effect of PFMT on FSD in pregnancy. As a result, the sample size of this study was calculated based on the current research available on the impact of PFMT on FSD in postpartum period. There was only one study that provided detailed information about the total FSFI score in both the control and intervention groups using FSFI scale before and after PFMT in postpartum women ([Citak et al., 2010](#_ENREF_16)). Using the information from this study (Citak et al., 2010), considering a total FSFI score of 28.9 ± 4.54 in intervention group after PFMT and 26.6 ± 4.40 in control group and standard deviation of 4.54 in both groups, a sample size of minimum of 62 in each arm would be required with 80% power and alpha = 0.5, and a ratio of treatment/control participants=1. However, 200 will be randomized to allow for possible dropouts and loss to follow up. This sample size will allow detecting even the smallest statistical significant difference of 8% between two groups.

**Recruitment**

After ethical approval, recruitment will be undertaken at the antenatal clinics at Westmead public hospital (WPH) including; midwives’ clinic, GP shared care and the caseload midwife’s clinic. The researcher (PhD candidate) will attend any team or staff meetings; research forums or staff hands over where the discussion of the study would be appropriate. Women will be recruited at the time of booking or at their first antenatal visit before 20 weeks gestation. The administration desk will attach information sheets to the papers of all primiparous women. Midwives booking or providing routine antenatal care for women who are less than 20 weeks gestation will refer the women who are interested in the study to the researcher. The researcher will provide women with detailed information about the research and will ask them to consider consenting. The researcher will be available in the antenatal clinic during all booking and antenatal visits to provide the women with information, obtain consent and to randomise them. To avoid repeated approaches to women if they decline to participate, this would be documented in their notes. Women who are considering entering the trial or have been missed during booking visits will be contacted at subsequent antenatal visits (Figure 1).

**Methods (randomisation)**

A computer-generated randomiser will be used to generate the randomisation sequence after informed consent from women and randomisation will be remote to Westmead public hospital. Details of the woman’s consent and trial entry data will be recorded. The researcher will then be informed of the group (intervention or control group) to which the woman has been randomly allocated and the woman will be issued with a unique 4-digit study number. Group allocation will be recorded on the trial register. All women participating in the study will have a study sticker placed on the front of their case notes. To assess the comparability of the study groups, baseline demographic and medical information will be collected from the medical record at the time of entry into the study.

**Blinding**

There is no blinding in this research. Education and data collection will be conducted by the same researcher to enable continuity of care with the women when conducting the education and asking personal questions required for completion of the survey. However, in order to reduce the risk of bias, questionnaires are self-report questionnaires and the participant’s identity will be linked to a 4-digit number as a study code, so the researcher will not be able to identify participants when entering data into electronic system (REDCAP). In order to further reduce the risk of bias, women will be provided an electronic access to the questionnaires to answer the questions and to return them via REDCAP system (Harris et al., 2009). This system allows the information to be entered into system automatically so the assessors will be blind to the participant’s answers. This electronic system is different from email correspondence. However, only study code as a 4-digit number will identify participants. If women choose to answer questions in hardcopies, then the questionnaires will be de-identified and only a study code as identifier. So, the researcher will not be able to identify women when entering data into REDCAP manually. If women choose to receive or return their questionnaires via email, they will be provided with questionnaires that are linked to the study code (4-digit number). In this case, researcher will not be able to identify the participants when entering data manually into the electronic system. The email address which will be used for this purpose will be a temporary email address which can be destroyed after completion of study. Email correspondence will be kept only as a last option and as an alternative to hardcopies and REDCAP.

**Data collection methods**

All the questionnaires that will be used to collect data are outlined in Table 2. Female Sexual Function Index (FSFI) will be used to collect data to assess the primary outcome of this study. In order to collect data related to the secondary outcomes of this study, the urogenital distress inventory (UDI-6) ([Utomo et al., 2015](#_ENREF_63)), Faecal Incontinence Questionnaire Score (Sansoni et al., 2011) ([Jorge & Wexner, 1993](#_ENREF_32)) and specific quality of life questionnaire of incontinence impact questionnaire (IIQ-7)([Utomo et al., 2015](#_ENREF_63)) will be used to collect data related to urinary and faecal incontinence and specific quality of life respectively.

 FSFI is a multidimensional self-report valid instrument for the assessment of female sexual function, consists of 19 questions grouped into six domains: desire, arousal, lubrication, orgasm, satisfaction and pain. A value of 0 to 5 is attributed to each answer. The scores range from 2 to 36, and the lower the score, the worse the sexual function ([Rosen et al., 2000](#_ENREF_50)).

Short forms IIQ-7 and UDI-6, composed of 7 and 6 questions, respectively, are validated self-report questionnaires and have been shown to have a high degree of correlation with the longer forms of these questionnaires. Both questionnaires are recommended by the second international consultation on incontinence ([Cam, Sakalli, Ay, Cam, & Karateke, 2007](#_ENREF_13)). The short form of faecal incontinence questionnaire has been validated in Australia and will be used in this study (Sansoni et al., 2011).

The list of instruments and the time of data collection have been summarised in Table 1. Women’s demographic, medical, surgical, psychological history including mental illness or depression and family history including domestic violence, alcohol and drug abuse will be obtained from their antenatal history in Obstetrix. Birth outcomes and postpartum history will be obtained via Obsterix, and also three months following birth when women receive the questionnaires. In order to find the confounding variables that might diminish the effect of PFMT on FSD, women will be asked about depression symptoms (using the Edinburgh depression scale questionnaire) (Cox et al., 1987) and also about their relationship using a relationship questionnaire (Hendrick et al., 1988) at 36 weeks gestation and again at three months following birth.There is also an expectancy questionnaire (Devilly et al., 2000) that will be given to women in the intervention group at the first few weeks of PFMT program. This is a self-made questionnaire extracted from another study (Devilly et al., 2000). However, there is no standard expectancy questionnaire. This questionnaire will provide information on women’s expectation of treatment.

**Table 2. The list of data collection instruments and time of collection data**

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| **Questionnaires** | **Time of data collection** |
| FSFI (to assess the primary outcome of female sexual function) | At the time of booking, ≥36 weeks of pregnancy, three month following birth from both control and intervention groups |
| UDI-6 (to assess urinary incontinence symptoms as a secondary outcome) | At the time of booking, ≥36 weeks of pregnancy, three month following birth from both control and intervention groups |
| IIQ-7 (to assess specific quality of life as a secondary outcome) | At the time of booking, ≥ 36 weeks of pregnancy, three month following birth from both control and intervention groups |
| FI questionnaire (to assess fecal incontinence symptoms as a secondary outcome) | At the time of booking, ≥36 weeks of pregnancy, three month following birth from both control and intervention groups |
| Demographic, Obstetric and Medical, surgical and family history | At the time of booking via Obsterix database from both control and intervention groups |
| Childbirth outcomes (secondary outcome) |  After childbirth via Obsterix database from both intervention and control groups |
| Postpartum history  | Via Obstetrix and at three months following birth at the time of data collection |
| Edinburgh depression scale questionnaire  | Third trimester of pregnancy and three months following birth |
| Expectancy and relationship questions | During the third trimester of pregnancy and three months following birth |

Baseline data collected will include: name, address, contact number, maternal age, gestational age, household income, highest education level attained, ethnicity, pre- pregnancy weight, smoking status, medications, remedies, preparations or supplement used during pregnancy, medical and surgical, family and psychological history and any history of incontinence before, during or after the pregnancy.

Participants will be encouraged to adhere with study protocol via fortnightly follow up and their antenatal visits. If participants decide to drop out, their information will be kept secure and will be included in data analysis. However, they will not be contacted for further information collection after their withdrawal.

**Data Management**

All data will be collected by the same researcher to enable continuity of care with the women when conducting the education and asking personal questions required for completion of the questionnaires. The questionnaires are self-report questionnaires given to women via REDCAP system (Harris et al., 2009). This system allows the user to enter data into the databaseautomatically and the researcher will be kept blind to the subject’s information throughout the data entry. Data will be kept in this system securely and will be analysed using SPSS and will be discarded safely according to the NSW legislation policy in 5 years after completion of study. Participant’s identity will not be recorded or disclosed during data entry and analysing. All the hardcopies questionnaires will be linked to a 4-digit number. If women choose to answer questions in hard copies instead of electronically, data will be recorded manually into REDCAP system as soon as they are collected, and papers will be safely discarded.

**Statistical methods**

Analysis of the primary and secondary outcome will be based on intention-to-treat basis which will include withdrawal and losses to follow up. Odds ratios, percentage differences, confidence intervals, Chi-square and student’s t tests will be used to examine group differences in the primary and secondary outcomes. Data from REDCAP will be exported and SPSS will be used to analyse data.

**Data Monitoring**

An annual report will be given to Western Sydney University research department and ethics committee about the progress of research.

**Description of any interim analysis and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial harms**

The principle supervisors and the onsite researcher will have access to the data. If women raise any concerns about their health during recruitment and throughout the research process, they will be referred to their health care professionals to receive additional treatment and care. There are no known harms reported as a result of pelvic floor muscle exercise in the literature. However, there are few studies on the effect of pelvic floor muscle exercise on sexual function in the postpartum period. So, women will be notified to discuss their concerns with study researcher or their health care providers during and after trial, free of charge.

**Ethics and dissemination**

Study will be undertaken after ethical approval from Western Sydney University, Western Sydney Health District and Westmead Hospital. The findings of study will be published in seminars or peer reviewed journals after analysing of data without disclosing participant’s identity.

**Research ethics approval**

Application will be made to seek ethics approval from Western Sydney University, Westmead Public Hospital and Western Sydney Health District.

**Protocol amendments**

Any amendments to the protocol will be submitted to ethics.

**Consent or assent**

After ethical approval, recruitment will be undertaken at the antenatal clinics at Westmead public hospital including; midwives’ clinic, GP shared care and the caseload midwife’s clinic. Midwives booking or providing routine antenatal care for women who are less than 20 weeks gestation will refer the women who are interested in the study to the researcher. The researcher will provide women with detailed information about the research and will ask them to consider consenting. The researcher will be available in the antenatal clinic during all booking visits to provide the women with information, obtain consent and to randomise them. To avoid repeated approaches to women if they decline to participate, this would be documented in their notes. Women who are considering entering the trial or have been missed during booking visits will be contacted at subsequent antenatal visits. If participants agree to participate and meet the inclusion criteria, the patient information sheet and informed consent will be presented for review and signature.

**Confidentiality**

A study number only will identify participants in the trial, with a master code sheet linking names with numbers being held securely. Women will be assured that their information will be kept confidential and the consent form which outlines privacy of information will be signed by both the researcher and participants. If women raise any concerns about their health during recruitment and throughout the research process, they will be referred to their health care professionals to receive additional treatment and care.

**Declaration of interests**

There is no financial interest in this research for investigators

**Access to data**

The main investigators at this study will have access to data.

**Ancillary and post-trial care**

If any concern is raised by any of the participants during the trial, they will be referred to appropriate health care professional for counselling. Women will be given chance to discuss their ideas or concerns with researcher during and after research.

**Dissemination policy**

The findings of this research will be published as papers in peer reviewed journals, conferences and it will be open for public to study and read them**.**

**Model consent form and other related documentation given to participants and authorised surrogates.**

The NEAF, consent form, participant’s information sheet, NSW privacy form, advertisement/product information, surveys, questionnaires and diary have been attached to this study protocol for review in ethics committee.