**Clinical Educational Intervention Study**

**Protocol**

Effectiveness of a Pelvic Floor Muscle Exercises in Improving Knowledge, Attitude, Practice and Self-Efficacy among Pregnant Women in Malaysia.

# **PROTOCOL TITLE**

Effectiveness of an Education Program on Pelvic Floor Muscle Exercises Knowledge, Attitude, Practice and Self-Efficacy and Continence Status in Pregnant Women.

**NMRR ID: NMRR-16-2029-28782**

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# **SPONSOR**

There is no sponsor and funding for this study.

# **LIST OF ABBREVIATIONS**

UI urinary Incontinence

SUI stress urinary incontinence

UUI urge urinary incontinence

MUI mixed urinary incontinence

ICS International Continence Society

IUGA International Urogynecological Association

PFME pelvic floor muscle exercises

NICE National Institute for Health and Clinical Excellence

RCTs Randomized control trials

BPP Birth preparation program

HBM Health belief model

MI Motivational interviewing

MHKL Maternity Hospital of Kuala Lumpur

UPM University Putra Malaysia

MOH Ministry of Health

KAP knowledge, attitude and practice

SESPPFE Self-Efficacy Scale for Practicing PFEs

ICIQ-UI-SF International Consultation on Incontinence Questionnaire-Urinary

Incontinence-Short Form

BMI body mass index

WHO World Health Organization

GEE generalized estimating equations

NMRR National Medical Research Register

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# **1. INTRODUCTION: BACKGROUND INFORMATION AND STUDY RATIONALE**

## **1.1Background of Urinary Incontinence and Pelvic Floor Muscle Exercise**

Urinary incontinence (UI) is an important public health concern in women as it may impact on all aspect of women’s wellbeing from physical, social and psychological (Lukacz S.E.et al., 2010). UI can range from involuntary urinary leakage occurring on physical exertion or effort, coughing or sneezing, stress urinary incontinence (SUI); leakage associated with sudden urge to void or urgency, urge urinary incontinence (UUI); a mixture of these symptoms, mixed urinary incontinence (MUI) as defined by the International Continence Society (ICS) and International Urogynecological Association (IUGA) (Haylen B.et al., 2010).

UI is the most common bladder health problem in women which estimated to affect 423 million or 21.6% women globally in 2018 (Irwin D.E et al., 2011). The regional burden of this condition is projected to be greatest in Asia. In United State, the projection of total cost of UI is $76.2 billion in 2015 and $82.6 billion in 2020 (Coyne K. S. et al., 2014). Current evidence demonstrates the substantial economic burden of UI to patients and society increase overtime in parallel with the projected increase in UI prevalence worldwide (Milson I. et al., 2014; Irwin D.E. et al., 2011). Therefore, it is important to focus on preventive care at relevant phase of woman’s life stages at risk of developing UI.

Pregnancy was established to be the major predisposing factor in the development of UI among women (Fritel X. et al.,2012; Wenes S. L.et al., 2013). A large proportion of women ranged from 17-54% experience first urinary incontinence during pregnancy (Wesnes L S., 2013). Overall the prevalence of UI in pregnancy is reported between 32-64% regardless parity (Milson I. et al., 2009). The incidence of UI during pregnancy among primigravida and multiparous increased by gestation whereby 19% and 40 % respectively claimed UI during pregnancy at first and third trimester (Franco F.M.et al., 2014). Prevalence of UI increases from 10.8% in the 12 months before the index pregnancy to 17.0% in early pregnancy (mean gestation 15 weeks) and 55.9% in the third trimester (Brown S.J. et al.,2010). SUI (36.9%) and MUI (13.1%) were more common during pregnancy than UUI alone (5.9%).

UI during pregnancy is an important form of maternal morbidity but is often overlooked and neglected (Whitford H.M. et al., 2011). Indeed, UI during pregnancy can be considered as a silent maternal problem since many pregnant women perceived UI as a normal physiological pregnancy change and do not report it to their obstetrician or midwifes as a health problem (Bo K.et al., 2012; Adaji S.E.et al., 2010). Although UI during pregnancy can be transient in nature, but the symptoms can persist and fluctuate and type of UI may interchange from SUI to UUI or MUI during postpartum (Viktrup L.et al., 2008). At the same time, it may also recur and worsen during subsequent pregnancies (Hansen B.B. et al., 2012). Few studies revealed that, the onset of UI during pregnancy increased the risk of UI in the immediate postpartum whereby the symptoms could last up 6 months to 5 years (Liang C-C. et al., 2013; Gartland D. et al., 2012; Arrue M. et al., 2011, Solan- Domenech M. et al., 2010). A prospective pregnancy cohort study among 1507 continent nulliparous women revealed that UI had a seven-fold increase in odds of persistent UI at postpartum (aOR 7.4, 95% CI 5.1-10.7) (Gartland D. et al. 2012).

In order to avoid or delay UI onset, pregnant women are recommended to engage in preventive strategies specifically pelvic floor muscle exercises (PFME) even in the absence of incontinence as it is a safer preventive strategy option during pregnancy (Sievert K.D. et al., 2012). Current systematic reviews and Cochrane reviews established PFME as a first-line treatment and prevention of UI during pregnancy and postpartum (Boyle R.et al., 2012; Morkved S.et al., 2014). International Continence Society and the National Institute for Health and Clinical Excellence (NICE, 2006) guidelines also recommend antenatal PFME should be offered to all pregnant women as a preventive strategy for UI.

### **Pelvic Floor Muscle Exercises**

Pelvic floor muscles exercises (PFME) is a form of exercise targeting to strengthen and tone up the pelvic floor muscles specifically the levator ani. This muscle consists of 3 layers of muscle, puborectalis, pubococcygeus and illiococcygeus which form the muscular pelvic diaphragm to provide support for the pelvic viscera and maintain the bladder and bowel control and aid in sexual and spine stability function. Pelvic floor muscle exercise, often referred to as Kegel exercise was initiated by Dr Arnold Kegel in late 1940’s to help reduce urinary incontinence among postpartum women. Since then many randomized controlled trial were conducted among pregnant and postpartum women that produce a Grade A evidence in supporting the effectiveness of pelvic floor muscle exercises in preventing urinary incontinence during pregnancy and postpartum (Wesnes S.L. et al., 2013). Therefore, PFME should be a standard component of prenatal and postpartum care and women should advice and teach to perform PFME during pregnancy and postpartum (Wesnes S.L. et al., 2013).

Theoretically, it is hypothesized that strengthening of pelvic floor muscles help to reduce the impact of natural physiological and structural changes as well as mechanical impact on pelvic floor muscles throughout the pregnancy. Training the pelvic floor muscles might help to counteract the increased intra-abdominal pressure caused by the growing fetus, the hormonally mediated reduction in urethral pressure and the increased laxity of fascia and ligament in the pelvic area during pregnancy (Boyle R. et al., 2012). Trained pelvic floor muscles easier to retrain and regain pelvic floor muscle function in maintaining urinary and bowel continence and sexual function as well as prevent pelvic organ prolapse.

### **1.1.2 Pelvic Floor Muscle Exercise Intervention**

The prevention study in urinary incontinence can divide into antenatal prevention trials in women who continence when randomized and antenatal mixed prevention and treatment trials in women some of whom incontinence and continence during randomized (Boyle R.et al., 2012).

There is mixed conclusion in available systematic reviews and meta-analyses referred to antenatal prevention trials and antenatal mixed prevention and treatment trials. Two meta-analyses of studies concluded that antenatal PFME effective in reducing incontinence up to six months after delivery regardless of continence status (Boyle R. et al., 2012; Lemos A. et al., 2008). Combined of four randomized control trials (RCTs) with high methodological quality, indicated that perineal muscle exercise significantly reduced the development of urinary incontinence from 6 weeks to 3 months after delivery (odds ratio = 0.45; confidence interval: 0.3 to 0.66) (Lemos A. et al., 2008). Pregnant women without prior urinary incontinence (prevention) who were randomized into intensive antenatal PFME were less likely than women randomized to no PFME or usual antenatal care to report urinary incontinence up to six months after delivery (about 30% less; risk ratio (RR) 0.71, 95% CI 0.54 to 0.95, combined five RCTs (Boyle R. et al., 2012). However, both meta-analyses result not favoring the efficacy of PFME in antenatal at preventing UI in late pregnancy. At the same time, the results of seven studies showed a statistically significant result favoring PFME in a mixed population (women with and without incontinence symptoms) in late pregnancy (RR 0.74, 95%CI 0.58 to 0.94, random-effects model) (Boyle R. et al., 2012).

Hay-Smith et al. (2008) concluded that antenatal PFME reduce the likelihood of incontinence from late pregnancy (56% less likely) to 3–6 months postpartum (30% less likely) in pregnant women without UI. However, they were unable to comment on the possible benefits of PFME as a treatment for UI in pregnancy. Literature review by Cooper and Cook (2011) revealed that the evidence for the use of antenatal PFME to treat UI in pregnancy is inconclusive although majority of the reviews included were overlapping. However, a latest systematic review concluded that PFME during pregnancy and after delivery can prevent and treat UI (Morkved S. et al., 2014). The recent two randomized control trials enrolled women purely continent that was not included in latest systematic review showed that PFME training in early pregnancy effective in preventing UI in late pregnancy as well as in postpartum (Pelaez M.et al., 2014; Kocaoz S.et al., 2013).

Few studies revealed consistent results of effectiveness of PFME when taught in general fitness class or general birth preparation class. Study conducted in Brazil among 197 nulliparous women with or without UI, revealed that birth preparation program (BPP) comprised supervised exercises, educational activities and home physical activities significantly reduce the risk of UI at 30 weeks of pregnancy (BPP 42.7%, CG 62.2%; RR 0.69; 95% CI 0.51-0.93) and at 36 weeks of pregnancy (BPP 41.2%, CG 68.4%; RR 0.60; 95% CI 0.45-0.81) (Miquelutti M.A. et al., 2013). Supervised exercises in BPP includes 50 minutes non aerobic exercise includes back stretching, abdominal lower limb exercise, relaxation exercise which conducted every antenatal visit (approximately 10 visits) and PFME and home aerobic exercise 30 min and daily PFME.

Similarly, a study conducted in Norway found fewer pregnant women reported UI following PFME taught during low-impact aerobics classes (Stafne S. et al., 2012). PFME incorporated in general antenatal exercise found to be effective in preventing UI among continent healthy primiparous women at late pregnancy (Pelaez M.et al., 2014). However, study by Bo K et al (2011) found that PFME taught during general fitness class for twelve weeks of training comprising twice-weekly 1-hour fitness for healthy nulliparous pregnant showed non-significant difference of reporting UI between exercise and control group during pregnancy.

Most of the studies focus on supervised PEME training as preventive strategies for UI in pregnancy. Individual or group supervised PFME training showed positive result in reducing UI among pregnant women compared to usual care (Kocaoz S.et al., 2013; Ko P. et al., 2011; Dinc A. et al., 2009). It shows that the success of PFME depends on supervised training component of the program and adherence to the exercise protocol. In addition, supervised PFME might assist the pregnant women’s confidence and ensure correct PFME performance compare to usual method of care.

However, supervised clinical based intervention can be a challenging task when adherence concerns in pregnant women. Adherence to such supervised clinical based intervention was responsible for non-significant results compared to usual care or written instruction of PFME (Fritel X. et al., 2015; Mason L. et al., 2010). The latest randomized controlled study conducted in France 282 among nulliparous women showed that prenatal supervised pelvic floor muscle training was not superior to written instruction in reducing prevalence of UI, severity of UI and pelvic floor trouble related to bladder, bowel, prolapse and sexual (Fritel X. et al., 2015). UI at end of pregnancy CG: 49/112 (43.7%); IG: 50/112 (44.6%) p= 0.89; OR 1.0 (95% CI 0.6-1.8) and UI severity score reduction -0.2 (95% CI-1.2 to 0.8), CG: 2.9±4.0; IG: 2.7±3.7, p=0.99. This study explained that low adherence to PFME was responsible for non-significant result in PFME group compared to control group. Where by only 5% of women in the PFME group did daily exercise at the end of pregnancy out of 28% reported doing the exercise almost daily.

Mason et al (2010) highlighted pregnant women’s reluctance to attend a supervised PFME class possibly due to high proportion of women working and felt attending a class was too arduous or time-consuming. Furthermore, supervised training is costly, need staffing and time consuming not only for patient but also to healthcare provider. Thus, the key issue with supervised PFME training aimed at prevention and treatment of UI is whether such training could translate into clinical practice and able to reach many women in early pregnancy.

At the same time, it has been showed that providing adequate information and clue how to perform a correct PFME without former assessment via vaginal palpation can be effective method in teaching PFME (Peleaz M et al., 2014). In addition, not supervised PFME with called at home to motivate regular exercise and coordinated with visits at hospital to check the PFME performance record among pregnant women without UI showed significant reduction in risk of UI during pregnancy (Kocaoz S. et al., 2013). This particular study showed a certain level of evidence to show that structured education provided to pregnant women can reduce occurrence of UI during pregnancy.

### **1.1.3 Dosage of Effective PFME**

The dosage of PFME referred to the frequency repetition, intensity and the duration of the training period in addition to adherence to the training protocol are primary important. Although, there is no evidence regarding an optimal dosage of effective PFME, a training protocol following general strength-training principles, emphasizing close to maximum contractions for at least an 8-week training period was recommended includes daily three sets of 8-12 maximal contraction with each contraction holds for 6-8 seconds. (Morkved S. et al.,2014). Performance of PFME daily with sufficient intensity and duration while paying attention to the correct performance of the exercises and integrating the exercises into activities of daily life are recommended (Bernards A.et al., 2014).

## **1.2 Study Rationale**

In spite of the benefits of PFME in pregnancy, only few pregnant women practice PFME according to evidence based recommendation. Guerrero et al (2007) found that just 15% of women exercised their pelvic floor muscle on a daily basis during pregnancy although they think they should do this daily. Several studies reported that only 9.7 % to 17% pregnant women practice PFME during pregnancy at least once a week (Hilde G. et al., 2012; Whitford H. et al., 2007; Bo K. et al., 2007a).

The common reasons given for not practicing PFME during pregnancy were lack of knowledge about UI and PFME in term of its benefits, and the lack of understanding of how to contract the muscle correctly (Sangi-Haphpeykar H et al., 2008; Fine P et al., 2007; Whitford H.M. et al., 2007)). In line with knowledge, self-efficacy has been identified as a key predictor of PFME (Whitford H.M., 2011). Other reasons gave by pregnant women for not practicing PFME were lack of time, too busy, forgot and belief unnecessary in the absence of symptoms (Sangi-Haphpeykar H. et al.,2008; Fine P. et al., 2007).

Despite high prevalence of UI reported in Malaysia 19.6%, a study showed that the overall knowledge and practice of PFME was poor among pregnant women at 32 weeks gestation who did not received PFME information during antenatal clinic (Rosediani M. et al., 2014). In Malaysia, antenatal education offered in the final weeks of pregnancy by midwives, physiotherapists and other healthcare providers focuses more on topics related to labor preparation, postnatal care and early parenting.

Delay in providing accurate and timely information of preventive strategies of UI may inhibit pregnant women to take up preventive action and intervention during pregnancy. Hence, these can lead to early onset of UI during pregnancy, which may potentially increase the lifespan prevalence of UI. Therefore, in order for pregnant women to take initial steps in reducing and preventing UI during pregnancy, they are required to know about preventive strategies, PFME; and they also need precise instructions on how to perform the PFME to acquire skills and confidence in performing PFME.

While PFME intervention has been extensively studied in the western countries, not much data was available in Malaysia. The available studies conducted locally which containing information pertaining to UI and PFME in pregnant women is cross sectional studies (Daliah M.Y. et al., 2014; Rosediani M et al., 2014) whereas the studies conducted in other countries only focused on efficacy of supervised PFME program or intervention in preventing and reducing UI rather than on the PFME targeted behavior (Boyle R.et al., 2012; Morkved S.et al., 2014). Hence, a gap exits in the current literature in the exploration of educational interventions conducted in the context of PFME knowledge, attitude, practice and self-efficacy especially in Malaysia. Moreover, there are needs of a simple, easy and cost effective PFME education program that not only guides pregnant women but also guides local health care providers to teach antenatal women (Daliah M.Y. et al., 2014; Rosediani M et al., 2014).

In response to the above matter, this study proposes to develop, implement and evaluate the effectiveness of PFME education program on knowledge, attitude, practice and self-efficacy of PFME and continence status. This study differs from previous studies conducted locally and other countries in 3 ways. Firstly, this study will focus on efficacy of an education program in improving UI status as well as behavior changes on the PFME targeted behavior (Boyle R.et al., 2012; Morkved S.et al., 2014). Secondly, this study employs health belief model (HBM) and motivational interviewing(MI) based education program of PFME. Finally, PFME education program material will be tailored in 2 main languages, English and Malay.

## **1.3 Potential Benefits of the Study**

In line with the national effort to improve maternal health care (Millennium Development Goal 5, 2010), the present study would benefit pregnant women by improving their knowledge, self-efficacy and change their attitude and practice of PFME as well as preventing or reducing the incidence of UI during pregnancy and postnatal. Currently, there is no PFME module in Malaysia that can guide local health care providers to teach antenatal mothers (Rosediani M.et al., 2014). Therefore, the present study would benefit physiotherapists as they would be able to use the module as a guide during antenatal education classes since there is no existing guideline or module in this area. Additionally, the module will enable physiotherapists to disseminate evidence based information on UI and PFME to pregnant women and improve quality of antenatal care. Since there are limited numbers of studies assessing PFME intervention especially in Malaysia, it is hoped that the findings of this study may shed light on intervention to promote PFME in pregnant women and contribute to the body of knowledge.

# **2. STUDY OBJECTIVES AND HYPOTHESIS**

## **2.1 General Objective**

The general objective of this study is to develop, implement and evaluate the effectiveness of PFME Education Program in improving knowledge, attitude, practice and self-efficacy of PFME and continence status amongst pregnant women.

## **2.2 Specific Objectives**

1. To determine difference of the baseline socio-demographic characteristics, clinical and obstetric characteristics and baseline outcome measures of PFME knowledge, attitude, practice and self-efficacy, and UI status of respondents between the intervention and control group.
2. To determine each group’s changes in PFME knowledge, attitude, practice and self-efficacy of respondents over time at baseline, at early and late third trimester and early postnatal.
3. To determine each group’s changes in continence status of respondents over time at baseline, at early, late third trimester and early postnatal.
4. To evaluate effectiveness of the PFME education program compare to existing practice over time (baseline, early and late third trimester and early postnatal) in terms of:
5. Improving knowledge, attitude and practice of PFME amongst respondents.
6. Improving in self-efficacy of PFME amongst respondents.
7. Reducing the occurrence of UI and severity of UI amongst respondents.

## **2.3 Hypothesis**

It is hypothesized that:

1. There is no difference between intervention and control in terms of socio-demographic characteristics, clinical and obstetric characteristic and outcome measures of PFME knowledge, attitude, practice and self-efficacy, and UI status of respondents between the intervention and control group.
2. There are significant changes in each group’s in PFME knowledge, attitude, practice and self-efficacy scores of respondents over the time.
3. There is a significant change in each group’s changes in continence status of respondents over time.
4. There is a significant difference of respondents PFME knowledge, attitude and practice scores over time between the study group and control group.
5. There is a significant difference of respondents PFME self-efficacy scores over time between the study and control group.
6. There is a significant difference of respondents reporting the occurrence of UI and severity of UI over time between the study group and control group.

# **3. STUDY DESIGN**

A 2-armed randomized control trial, single blind study will be carried out. This study will be planned and designed based on the consort statement (Schulz, et al., 2010)

## **3.1 Study Location**

The study will be conducted in the Maternity Hospital of Kuala Lumpur (MHKL). MHKL located at central region in main city of the capital of Malaysia. MHKL is one of the largest and busiest maternity hospitals in Malaysia with more than 11,000 deliveries conducted yearly based on the National Obstetrics Registry 2nd Report 2010 (Ravichandran J. et al., 2011). It also serves as a tertiary referral center for numerous government antenatal clinics, private hospitals and also private clinics around Klang Valley. Furthermore, MHKL is the national referral center for obstetrical and gynecological service in the country that provides consultation and teaching services for a number of peripheral hospitals.

## **3.2 Study Duration**

The study duration will take a total of 3 years which will begin from the searching of relevant literature and development of PFME education program for pregnant women. Once developed the education program, it will be implemented and evaluated which will take about 9 months.

## **3.3 Study Population**

The study population is healthy pregnant women attending antenatal outpatient clinic at the time of the study in MHKL.

## **3.4 Sampling Frame**

The list of all pregnant women who met the inclusion criteria in MHKL will serve as the sampling frame of the present study. The patients will be recruited during every clinic day.

## **3.5 Sample Size**

The sample size was determined on a reduction of UI between the intervention group and control group. The minimum sample size for the study was calculated using a sample size formula for binary outcomes by Rosner (2006). Since there is no existing information of primary outcome, sample size was calculated based on the occurrence of UI in a previous study among pregnant women. The prevalence of urinary incontinence among pregnant women who attended the Patient Assessment Centre of a tertiary referral hospital in klang valley (Malaysia) during third trimester was 34.3% (95%CI:29.0,39.7) Abdullah B et al., 2016). Boyle R. et al 2004, in systematic review revealed that women who were randomized to antenatal PFMT had about 20% less risk of urinary incontinence in late pregnancy (RR 0.81, 95% CI 0.74-0.88).

n = [ Z₁₋√ pq (1+ 1/k) + Z₁₋ᵦ√ p₁q₁ + p₂ q₂ / k ]²/ ∆² (Rosner B., 2006)

1. **n**- required sample size
2. value of **α**, the probability of type I error (choose either one-sided test or two-sided test)
3. value of **β**, the probability of type II error, or (1-power) of the test
4. value of **P1**, proportion of characteristic present in arm 1 (**P1** = 0.143; **Q1** =0.857))
5. value of **P2**, proportion of characteristic present in arm 2 (**P2**,= 0.343; **Q2** = 0.657)
6. ∆ = **P1** – **P2** =0.343 – 0.143 = 0.20
7. **P**=0.343+0.143/2=0.243; **Q**=0.757

**n**=

= 71 (minimum sample size required in each group)

To allow a 20% attrition rate, the minimum required sample size will be 85 per group with a total sample size of 170 for both intervention and control group.

# **4. SELECTION AND ENROLLMENT**

The eligibility criteria for the trial are described below

## **4.1 Inclusion Criteria**

* Pregnant women at ≥18 weeks’ gestation.
* Pregnant women with a singleton pregnancy.
* Pregnant women who give informed consent.

## **4.2 Exclusion Criteria**

* Pregnant women aged ≤18.
* Non Malaysian pregnant women
* Pregnant women undergoing physiotherapy treatment for severe urinary incontinence
* Pregnant women with complicated pregnancy and chronic medical problem prior to pregnancy (diabetes, hypertension, HIV positive, neurological condition, pelvic organ prolapse); complicated pregnancy or contraindications to the practice of physical activity (preeclampsia, persistent bleeding, pre-term labor, incompetent cervix, acute febrile infection, and fetal growth restriction or placenta previa, cephalopelvic disproportion); previous urogenital surgery.

## **4.3 Withdrawal Criteria**

The respondents will be informed of their voluntary participation and their right to withdraw if they refused participation at any time without it affecting their usual health care. Respondents will be withdrawn from the study if consent is withdrawn. Some respondents who unable to complete all follow-up sessions and develop pregnancy complication (gestational diabetes, preeclampsia, persistent bleeding, pre-term labor, incompetent cervix, acute febrile infection, and fetal growth restriction or placenta previa, cephalopelvic disproportion and miscarriage) during study period will be terminated. However, they will be made aware that data collected before their withdrawal or termination cannot be destroyed and may still be used in analysis but no identification will be possible. Respondents who withdraw or terminate from the study will not be replaced, but withdrawal rates and reasons for withdrawal or termination will be recorded.

## **4.4 Suspending or terminating the study**

## The study will not be terminated unless instructed by the local Clinical Research Center (CRC) or ethics committee in case of violation of the signed protocol. Upon termination of the study, the hospital director, research teams and respondents will be notified.

## **4.5 Study Enrollment Procedures**

Flowchart of the study showing participant enrollment, randomization, allocation of interventions and follow-up (Figure 1). The list of pregnant women registers for antenatal visit will be obtained on clinic day. Staff nurses on duty will provide assistance in identifying potential study participants according to the eligibility criteria. Eligible pregnant women who met the inclusion and exclusion criteria will be approached by trained research assistant for recruitment while they are waiting to see the doctor. All eligible pregnant women will be explained about the objectives, importance, risks and benefits of the research before recruitment by research assistant. The consent and information sheets (Appendix 3-6) will be distributed to each respondent who agreed to participate in the study. All respondents will be given a copy of the consent form and contact details of the study coordinator for their future questions and concerns.

## **4.4 Treatment Assignment Procedures**

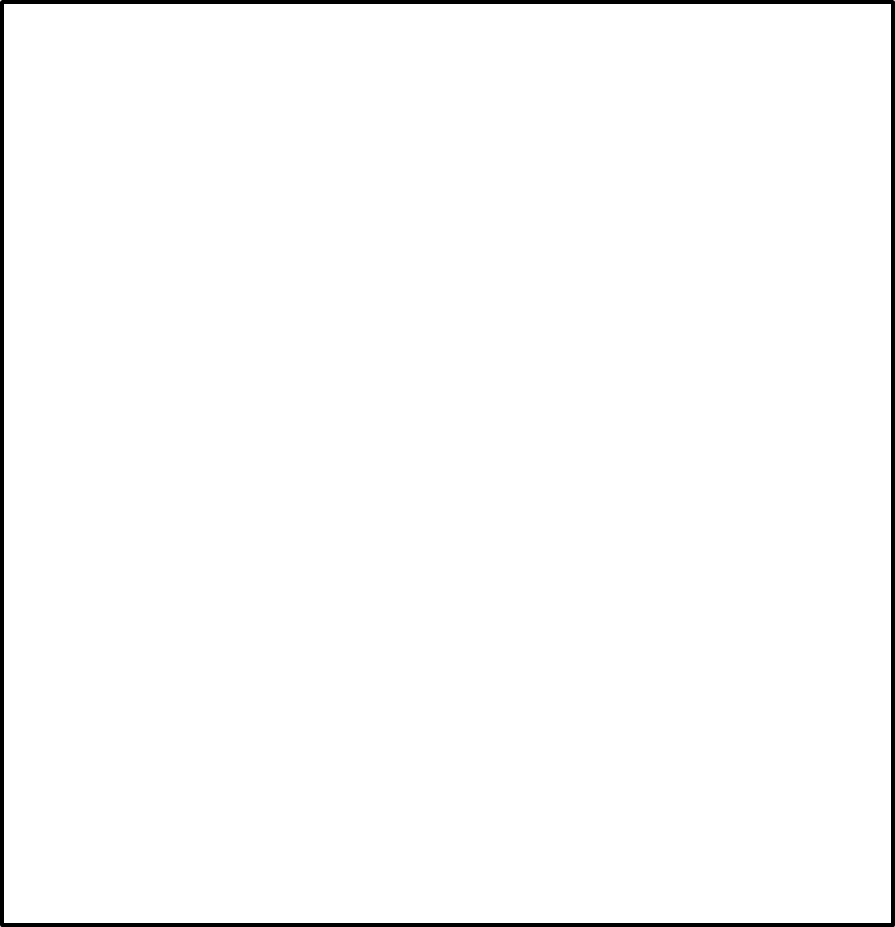
### **4.4.1 Randomization Procedures**

Following informed consent, the research assistant will allocate the recruited pregnant women to intervention or control groups on a 1:1 basis, using stratified randomization procedure. The randomization process will be prepared in consultations with study biostatistician using a computer-generated permuted block design with variable size permuted blocks of 6. Stratification will be undertaken according to treatment continence status and parity. Continence status will be assessed according to the answer for question: “how often do you leak urine”? Women are classification as continent if they answer “never’. Women in the first pregnancy will be classified nulliparous and other as multiparous.

To ensure allocation concealment, randomization to groups will be undertaken by using computer randomization and sealed opaque envelope technique. This process will ensure that the research assistant is unaware of the participant’s group assignment prior to allocation and thus allocation concealment is maintained. At the time of recruitment, the research assistant opens the sealed opaque enveloped that sequentially numbered within each block corresponding to the stratum (continence status and parity) to allocate the subject. New block will be selected after every "block" of specified size 6. This process will be continued until a total number of 170 pregnant women recruited.

### **4.4.2 Blinding Procedures**

A single blind method will be used, where respondents will not know which group they belong to. The consent and information sheets informed about the study in general but did not mention whether the pregnant women will be in the intervention or control groups. This is to maintain the blinding process throughout the study. However, due to the nature of the intervention, it is not possible to blind the research assistant or research staff to the treatment group. At the same time, it is also possible that women attending the antenatal clinic on the same day might interact with each other which can lead to potential contamination. Therefore, all the respondents will be requested not to share the information with others and the education intervention session will be scheduled and provided in a private room.

****

Analysis

Stratified Permuted block randomization (continence status and parity)

**Control Group**

Continence (n=?), Incontinence (n=?) Nulliparous (n=?), multiparous (n=?)

Total in control group**,** n=85

**Intervention Group** Continence (n=?), Incontinence (n=?), Nulliparous (n=?), multiparous (n=?

Total in intervention group, n=85

Recruited (n=170)

**4-6 weeks postnatal (Early Postnatal)**

n= ? loss of follow-up n=other reasons

**4-6 weeks postnatal (Early Postnatal)**

n= ? loss of follow-up n=other reasons

**28-30 weeks pregnancy (Early third trimester)**

n= ?loss of follow-up

n=? discontinue

**36-38 weeks pregnancy (Late third trimester)**

n= ? loss of follow-up n=other reasons

**28-30 weeks pregnancy (Early third trimester)**

n=? loss of follow-up

n= ?discontinue intervention

**36-38 weeks pregnancy (Late third trimester)**

n= ?loss of follow-up n= other reasons

**Excluded -** Refused consent (n=?) - Not met inclusion criteria (n=?)

Analysis n=85

Follow-up

Analysis n=85

Follow-up

Follow-up

Allocation

Enrolment

Eligible Pregnant women (n=?)

**4.4.3 Figure 1: Study Flow Chart- CONSORT STATEMENT**

# **5. STUDY INTERVENTIONS**

## **5.1 Interventions**

The intervention consists of usual prenatal care plus and a newly developed educational intervention of Pelvic Floor Muscles Exercise and follow-up booster sessions. This educational program design in an attempted to facilitate and maximize the opportunities for the participants actively engaged in the program.

### **5.1.1Development Pelvic Floor Muscles Exercise Program**

The education program development will involve 4 steps.

#### **(1) Extensive Literature Review and Theoretical Frameworks**

The development of initial PFME educational intervention involved identification of the relevant evidence based recommendation and clinical guideline related to PFME. Since the educational intervention is hypothesized to impact on behavior changes of pregnant women, therefore, the education program design based on behavior theoretical framework. Theoretical frameworks influenced the development of this educational intervention including: health belief model (HBM) and motivational interviewing (MI).

The intervention strategies based upon the important concepts of health belief model, includes that believe of susceptible to the incontinence (susceptible); that severity of present incontinence is likely to worsen or incontinence has negative impact on health (severity) and a particular behavior will improve continence status (benefit); believe that they are capable of performing these health behaviors (self-efficacy), and then overcoming barrier to action and activate readiness (cue to action) (Gillard S. & Shamley D., 2010; Bo K. et al., 2007b).

The information based on HBM will be delivered using motivational interviewing techniques to increase motivation to facilitate behavior change. Motivational interviewing is using collaborative conversation style, which create a conversation for strengthening a person’s own motivation and commitment to change (Miller W. R. et al., 2013). This approach may help in enhancing PFME adherence discussion among participant and educators (McClurg D et al., 2015). The idea behind this approach is to share information rather than delivering a chunk of information via directive advice-giving in which no strategies to enhance motivation for behavior change. In order to provide some standardization to the MI process, a semi-structured MI script will be developed and used to guide the interaction with the participants. In such a way it will motivate pregnant women in making their own decision regarding health behavior. The educational program incorporate with the health belief model and motivational interviewing will consist of:

1. Lecture with slide presentation on information and discussion about perceived susceptibility and severity of urinary incontinence and perceived benefit of PFME.
2. Educate on basic anatomy and function of PFME.
3. Practical and demonstration correct technique of PFME that can be integrated easily into daily activities.
4. Information on recommendation related to healthy bladder habit
5. Group discussion of perceived barrier of PFME and cue to action.

The components of the PFME intervention are designed for delivery in a single group session. A manual of content with MI script and teaching activities will be used to maintain consistency in delivery of the intervention. The education sessions will take approximately 30 to 40 minutes and limited for 5 to 10 number of participant. At end of the session, the respondents also will receive the “Pelvic Floor Muscle Exercises During Pregnancy and After Childbirth” educational manual which will be used to guide this session.

Three additional booster sessions at 4-week post-intervention, early and late third trimester will be provided to rein-force practice of PFME and support women through the pregnancy period. These booster sessions specifically will be focused on reinforcing skills and aims for targeted PFME, discussing experiences, challenges or barriers to practice PFME and facilitate continuous practice of PFME. Additionally, in the final booster session, information about the benefit of performing PFME and strategies to incorporate PFME into the daily routine of caring for a new baby during the postnatal period will be provided. Booster sessions will be conducted privately in a group of minimum 3 respondents before or after routine antenatal visits for an average 10 to 15 minutes.

The reminder in a form of text message and reminder card will be utilized as reinforcement strategies. The text message will be delivered weekly for 8 weeks to remind and prompt continues PFME. Since, 8 weeks of exercising pelvic floor muscles are important to notice of effectiveness in reducing severity of urinary incontinence and the risk of developing urinary incontinence, the reminder message continues for the first 8-weeks post intervention. The additional information provided at the final booster session will be summarized and included in the “New Baby congratulations cards” that specifically develop as a reminder message to remind respondents about the importance of PFME after childbirth. This card will be distributed to the respondents during the hospitalized postnatal period. Both text message and reminder card will be in English and Malay. The structure of intervention, administration and duration with time frame of data collection are illustrated in Figure 2.

**Data Collection**

3rd Follow-up (Early Postnatal)

2nd Follow-up (Late third trimester)

1st Follow-up (Early third trimester)

Baseline

18-20 weeks 21-27 weeks 28-30 weeks 36-38 weeks  Postnatal 4-6 weeks

3rd Booster session

2nd Booster session

Weekly telephone message reminder and 4th week 1st booster session

Group PFME Education

Usual postnatal education during hospitalization by hospital team similar as in control group

**Intervention**

**Figure 2: The structure of intervention, administration and duration with time frame of data collection**

#### **(2) Focus Group Discussion**

The initial draft on the PFME intervention will be discussed with a group of pregnant women and physiotherapist via focus group sessions. The focus group participants will be recruited from pregnant women and physiotherapists in MHKL. A group ranging from 6-8 nulliparous pregnant women and 6-8 multiparous pregnant women will be involved in this focus group discussion. Pregnant women who had recently received usual prenatal education will be invited for this focus group discussion. Focus group discussion aims were determined based on continence promotion that derived from health belief model (Bo K. et al., 2007b). The following questions were developed according to the aims of focus group to identify, knowledge about PFME in preventing UI in term of belief, perceived susceptibility and severity, to explore the attitude, perceived barrier, ability to perform PFME and cue to action:

1. What you know about urinary incontinence during pregnancy?
2. What you understand about pelvic floor muscle exercise?
3. What is your opinion about doing PFME during pregnancy?
4. What are the major problems you facing to perform pelvic floor muscle exercise?
5. What will motivate you to do the PFME?

Focus group transcripts will be examined to modify the education program which could fit the needs of pregnant women. All information collected from the focus group discussion will be incorporated into initial draft of education program to develop the module on ‘PFME Education Program”.

#### **(3) Expert Group**

The third part will involve thorough checking and reviewing by a group of expert. The panel of experts will consist of consultants and specialists in Family Medicine, Public Health and Clinical Psychology from University Putra Malaysia (UPM) Faculty of Medicine and Health Sciences as well as one experts in Obstetrics and Gynecology and Physiotherapy, from MHKL. The module will be checked for content validity in terms of suitable for use among pregnant women in Malaysia. The content validity will make sure that the module is sufficient in content and covered all important aspects.

#### **(4) Pilot study**

The final PFME intervention module will be piloted on 30 pregnant women attending the antenatal clinic in MHKL. Among the 30 patients recruited, 15 patients will be randomly recruited into the intervention group and 15 patients will be recruited into the control group. Detailed procedure of recruitment of patients for the pilot test will be similar to that of the data collection. The pilot participants will not be included in the main study. This pilot study will be used to evaluate the feasibility of recruitment, randomization, retention, assessment procedures, and implementation of the education program, the usability and acceptability of the program.

## **5.2 Usual Prenatal Care**

Usual perinatal care at MHKL compose of physical examination, health screening, case management and health education, based on the Ministry of Health (MOH) guidelines for pregnant women (MOH, 2013). Usual perinatal care at the study sites does not include routine UI assessment or follow-up of UI concerns. However, antenatal education at late third trimester offered to pregnant women and postnatal education during hospitalized postnatal period which includes brief advice on PFME by physiotherapist. The control group will receive usual prenatal care.

# **6. STUDY OUTCOME MEASURES**

## **6.1 Primary Outcome**

The primary outcome measure is PFME knowledge, attitude, practice and self-efficacy. The knowledge, attitude and practice (KAP) of PFME will be measured using a questionnaire that has been developed for local study population, which is available in English and Malay language (Rosediani M. et al., 2014). Cronbach’s alpha for KAP questionnaire were 0.949, 0.837 and 0.742 respectively. The higher score of KAP scale indicating positive knowledge, attitude and practice. A total of eighteen items included to assess women’s knowledge pertaining to pelvic floor muscle and benefit of PFME (11 items) and method in performing PFME (7 items). For knowledge items, categorical responses (true/false/don’t know) are applied. For items related to attitude, a total of 8 items are assessed using 5-point Likert scale (strongly agree/agree/neutral/not agree/strongly disagree). For items related to practice of PFME, 2 original questions are replaced with questions on intensity of PFME which is adapted from “An audit of NICE guidelines on antenatal pelvic floor exercises” study by Ismail (2009). A total of 4 items for practice questions ordinal responses are applied (never/seldom/neutral/ frequent/always). For the detection of self-efficacy effects of PFME education program, the Self-Efficacy Scale for Practicing PFEs (SESPPFE) will be used (Sacomori C. et al., 2013). The respondent responds to these items on a scale ranging from 0 to 100. The points allocated for each item will be summed to calculate the self-efficacy score for practicing PFME. Higher scores indicated highly confidence.

## **6.2 Secondary Outcome**

Secondary outcomes are continence status and severity of UI. UI status and severity measured by self-report using a validated questionnaire based on from International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form (ICIQ-UI-SF). Severity of UI will be assessed base on ICIQ scores (Klovning A. et al., 2009). ICIQ-UI-SF has been shown to have good construct validity, acceptable convergent validity and good reliability (Avery K. et al., 2004). ICIQ-UI-SF contained total of 4 items pertaining to continence status. Women will be assessed as continent if they answer “never’ to the question: “how often do you leak urine”? Severity of UI will be scored base on first 3 questions in ICIQ-UI-SF with overall score 0-21 which categories into; slight (1-5), moderate (6-12), severe (13-18) and very severe (19-21). Greater the values indicating increased severity.

## **6.3 Covariates**

Information on socio-demographic characteristic including age, ethnic, academic qualification, household income, occupation; clinical and obstetric characteristic includes history of pregnancy and delivery, health problem, pre-pregnancy UI, smoking status and constipation will be collected. Medical record abstraction from clinical notes will be recorded for data of interest in postnatal include gestation at delivery, delivery type, duration of labor, degree of perineum trauma and, infant birthweight and maternal weight.

Anthropometry measures will be taken, including body weight and height measurements. Anthropometric; standing height and body weight will be measured by using a stadiometer and a calibrated electronic scale. The height and body weight of each participant will be measured to the nearest 0.5 cm and 0.1 kg respectively. The measurement will be recorded three times in order to get accurate result. Body mass index (BMI) will be calculated as weight (kg) divided by height in meters² (m²) based on World Health Organization definitions for Asian populations (WHO, 2004).

## **6.4 Validation of the Questionnaire**

The questionnaire consist of Section A- 15 items of socio-demographic variable; Section B – ICIQ-UI-SF (4 items) ; Section C – PFME KAP (30 items) and Section D - Self-Efficacy Scale for Practicing PFEs (17 items), will be prepared in bilingual, English and the national language of Malaysia, Malay. The Malay version questionnaire is targeting for non-English speaking participants. Firstly, the questionnaire will be prepared in English and then followed by forward translation of Malay version will be performed by one physiotherapist and one native Malay speaker who are also fluent in English and Malay. Next, another pair of bilingual native speakers consists of trained translator will translate the forward-translated Malay version back into English. The backward translation processes are also will be done independently. Subsequently, the questionnaire will go through validation process starting with;

1. Content validation will be ensured by 2 experts in the field consisted of consultants and specialists in Family Medicine, Public Health and Psychology from UPM Faculty of Medicine and Health Sciences as well as 1 experts in Obstetrics and Gynecology, from MHKL.
2. The face validity will be assessed via pre-test procedure consists of testing a questionnaire in the field to make sure that participant have a good understanding of the questions and comments about the language. Terms or questions that are poorly understood or that do not match well the culture of the target population will be corrected. This pre-test will be conducted to a group of 30 pregnant women from each different ethnic and educational background.
3. Reliability will be determined using Cronbach's alpha for internal consistency. The Cronbach’s alpha measures how well individual items within particular sections of a questionnaire relate with one another and whether the items are all measuring the same thing. A Cronbach’s alpha value 0.7 and more reflects that the questionnaire is reliable (Dawson B, et al., 2001).

## **6.5 Data Collection**

The data collection schedules, measures or variables are summarized, with a timeline, in Table 1. Data collection involved the administration of self-administered questionnaire (Appendix 1-2); anthropometric measurements; and obstetrics data from clinical notes. In both study groups, the data collection will be carried out at baseline which is immediate after recruitment and three time points: at early (28-30 gestation weeks), late third trimester (36-38 gestation weeks) and postnatal period (4-6 weeks). The pregnant women are followed up at early third trimester, late third trimester and early postnatal period as prevalence of UI increased during this period. Moreover, theoretically muscular changes after specific pelvic floor muscle exercise to treat and prevent UI occur during the first 6 to 8 weeks (Dinc A. et al., 2009).

The trained research assistant will collect anthropometric measurement at baseline and the completed questionnaire by hand at each time point. The information on delivery and labour will be abstracted from the case note. The questionnaire either be collected by hand during postnatal clinic visit or during postnatal home visit. To enhance retention, respondents will be served meal after every time point of data collection and goodie bag after delivery (RM 10).

### **6.5.1 Intervention Group**

The respondent who allocate in the intervention group will be invited for single session of group education program according to their preferred date/time before 21 weeks of gestation. The education sessions scheduled twice weekly to ensure that every respondent in the intervention groups could join the education program. The participant will be followed up by the research assistant to remind them of the program and confirm their attendance. The principal researcher (physiotherapist) will conduct or facilitate this group session of “PFME Education’ intervention. This will be followed by periodic booster sessions at four weeks’ post intervention, early third trimester between 28-30 weeks of gestation, late third trimester between 36-38 weeks of gestation and hospitalized postnatal period.

The pregnant women will be followed-up at early and late third trimester and request to complete the same set of questionnaire except socio-demographic questions before booster session. The self-administrated questionnaires will be then distributed again at postnatal 4-6 weeks. The postnatal follow-up questionnaire is similar to the follow-up during pregnancy except in recording for updates on gestation at delivery, delivery type, perineum trauma, duration of labour and infant birth weight and maternal weight and height.

### **6.5.2 Control Group**

The respondent who allocate in the control group, will be followed-up by the researcher assistant (physiotherapist) of the study. A baseline evaluation will be also done for this group using similar self-administrated questionnaires used in the intervention group. Upon baseline data collection, respondents are requested to carry out the usual prenatal visit and maintain normal daily activities. The respondents will be followed-up at 28-30 gestation weeks, 36-38 gestation weeks and 4-6 weeks postnatal and the similar data will be collected as the intervention group.

**Table 1: Data collection schedule and measures**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Variable (measure)** | **Timing of Measures** | | | |
| **Baseline** | **Early third trimester (28-30 gestation weeks)** | **Late third trimester (36-38 gestation weeks)** | **Early postnatal (4-6 weeks)** |
| Demographic (age, ethnic, academic qualification, household income, occupation, history of pregnancy and delivery, health problem, pre-pregnancy UI, smoking status and constipation | X |  |  |  |
| Postnatal data – gestation at delivery, delivery type, duration of labor, degree of perineum trauma and infant birthweight (abstract from clinical notes) |  |  |  |  |
| Anthropometric – height and weight (pregnancy and postnatal) | X |  |  |  |
| PFME knowledge, attitude and practice (KAP) | X | X | X | X |
| Self-Efficacy Scale for Practicing Pelvic Floor Exercises (SESPPFE) | X | X | X | X |
| Status of continence, type and severity of urinary incontinence using ICIQ-UI-SF | X | X | X | X |

# **7. DATA ANALYSIS**

Data will be entered, cleaned, stored and analyzed using Statistical Package for Social Sciences Software, version 22.0. All analysis will be done on an intention-to-treat basis, and respondents will be analyzed in the group to which they were randomized. All statistical tests are based on two-tailed alternatives, and P < 0.05 will be considered significant. Following method will be used to analysis the data:

1. **Test for normality**

All continuous explanatory and outcome variables will be assessed for normality and the presence of outliers. The assumption of normality of distribution will be assessed by using histogram, p-p plots and Kolmogorov-Smirnov test for each continuous variable. Equal variances across the intervention and control will be also verified by Levene’s test.

1. **Descriptive Statistic**

Descriptive statistics will be used to summarize the baseline socio-demographics clinical or obstetric characteristics and continence status for both groups. Missing values at follow-up visits or drop-outs in the two groups will be assessed to identify any potential bias. Measures of central tendency and dispersion such as mean and standard deviation will be used to describe the continuous data while percentage and frequency will be used to describe the categories data for baseline data

1. **Inference Statistic**

* The education group and control group will be compared to determine the homogeneity of respondents in terms of socio-demographic, clinical or obstetric characteristic and continence status, by using Chi-square tests for categorical or discrete variables and independent t-tests for continuous variables.
* The effect of intervention across the four time points will be examined by conducting repeated measures analyses using generalized estimating equations. The reason for using these methods of analysis is considered the high correlations between individual respondents since data will be collected from respondents at four different time points (Meyer L.S.et al., 2013). Furthermore, this analysis method does not require complete data and can be fitted even when individuals do not have observations at all time points. For the continuous outcome measures, identifying the link function was used, while the logit link function was used for the binary outcome measure. Group differences in primary and secondary outcomes will be illustrated as estimated marginal mean differences or odds ratios with 95% confidence interval. All statistical tests are based on two-tailed test and the level of significance, alpha (α)is set at 0.05.

# **8. PARTICIPANT RIGHTS AND CONFIDENTIALITY**

## **8.1 Ethics**

The ethical approval will be sought it out from University Putra Malaysia Ethic Committee for Human Research and National Medical Research Register (NMRR) of Malaysia. Approval from the Director of the hospital also will be obtained before commencement of the study. The protocol, informed consent form(s), subject information sheet, and all other relevant materials will be submitted to the NMMR for review and approval. Approval of both the protocol and the consent form will be obtained before any subject is enrolled. Any amendment to the protocol will send to NMMR and approval will be obtained prior to implement the changes in the study.

## **8.2 Informed Consent Process**

Participants consent will be obtained by providing information sheet and inform consent form and asking their willingness to participate in the study. Patient information sheet and informed consent forms available in two most common languages, English and Malay. The consent form will describe the purpose of the study, the procedures to be followed, and the risks and benefits of participation.

Extensive discussion of risks and possible benefits of study participation will be provided to subjects and their families, if applicable. The pregnant women will be informed of their voluntary participation and their right to withdraw if they refused participation.

Beside asking their willingness, the respondents will be requested to sign a consent form prior to volunteering to participate in the study. For those who were unable to read any language the consent form and details of intervention were read and explained by bilingual staff, and then their agreement will be obtained. All respondents will be given a copy of the signed and dated consent form and contact details of the study coordinator for their future questions and concerns.

If any new information becomes available during the course of study, which relevant to the respondent’s willingness to continue participation in the study, the respondent will be informed in a timely manner and will be re-consent using the updated consent form. The respondent will be informed their right to withdraw or continue in the study before sign the updated informed consent.

## **8.3 Confidentiality**

The identity of respondents will be protected throughout the study and publication of results. Each respondent will receive code numbers consisting of a three-digit starting from 001 which would be used to identify themselves on the questionnaires in order to maintain confidentiality and to allow for combining of data sets of different time points.

All information will be handled with strict confidentiality by keeping all raw data in a locked secure area and computer. The access to these data will be limited to the researcher, research assistant and supervisory committee members. As the study, may be subject to inspection, review and audit by the hospital Clinical Research Center and ethic committee, direct access to the study data will be permitted for the purpose of verifying whether the study conducted according to the protocol and the data are recorded correctly.

Those participating in the research will be given access to their personal data or the results of their own analyses upon request for as long as the information available. However, this information will not be reviewed until after the research study has been completed. The results of the entire study will be made available to all respondents in summary form.

## **8.4 Storage and archival of study data**

All information relevant to the study, including electronic data will be archived and retained for a period of 3 years after completion of study. The principal researcher will be responsible for ensuring the security of archived data. The collected paper consent forms, questionnaires and other study data will be destroyed by shredding, whereas the electronic data will be deleted at the end of its retention period.

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