THE EFFECT OF ABDOMINAL EXERCISE ON DIASTASIS RECTI ABDOMINAL (DRA) AMONG POSTPARTUM PRIMIGRAVIDA MOTHER IN KUALA LUMPUR

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by

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LIST OF ABBREVIATIONS

DRA Diastasis abdominal muscle

PFM Pelvic floor muscle

UI Urinary incontinence

UDI-6 Urinary distress impact-6

IIQ-7 Impact index questionnaire-7

TrA Transverse abdominal muscle

RA Rectus abdominis muscle

PGP Pelvic girdle pain

EMG Electromyography

UUI Urinary urge incontinence

SUI Stress urinary incontinence

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KESAN SENAMAN OTOT PERUT TERHADAP DIASTASIS RECTI ABDOMINAL (DRA) DALAM KALANGAN WANITA SELEPAS BERSALIN ANAK SULUNG DI KUALA LUMPUR

ABSTRAK

Senaman otot perut untuk diastasis rekti abdominal (DRA) selepas bersalin masih belum diterokai dalam penyelidikan. Walaupun terdapat program senaman umum dalam program pemulihan dan senaman kekuatan, namun hanya terdapat beberapa kajian yang mengkaji pelaksanaan senaman perut secara berperingkat dan progresif, serta memberi manfaat. Objektif kajian ini adalah untuk mengetahui kesan program senaman perut yang dikenali sebagai Split Tummy Exercise Program (STEP) terhadap saiz DRA, kekuatan serta ketahanan otot lantai pelvis (PFM), dan hubungan kesemua pembolehubah tersebut. Program STEP dibina dikembangkan berdasarkan kajian literasi dan disahkan oleh pakar. Kajian rawak terkawal telah dijalankan di klinik Obstetrik dan Ginekologi, Pusat Perubatan Universiti Kebangsaan Malaysia (UKMMC), Kuala Lumpur untuk dan 41 wanita hamil dipilih. Kemudian, wanita ini dibahagikan secara rawak ke dalam kumpulan intervasi (21 peserta) dan kumpulan kawalan (20 peserta). Kriteria pemilihan peserta adalah wanita yang mengandung anak sulung, didiagnosa mempunyai DRA semasa kandungan 34 minggu ke atas dan seterusnya jika perbezaan antara otot perut pada bahagian pusat melebihi dua jari diukur dengan kaedah palpasi. Wanita hamil kembar, pernah menjalani pembedahan bahagian perut dan urogenital, bersalin secara pembedahan, dan menghidap penyakit yang boleh mengganggu kekuatan PFM seperti Ehlan Danlos Syndrome dikecualikan dari kajian. Kumpulan intervensi menerima modul STEP yang mengandungi sembilan jenis senaman perut dalam tiga fasa. Setiap fasa senaman dipertingkatkan setiap tiga minggu dan fasa tiga berakhir pada minggu ke lapan selepas bersalin. Saiz DRA

(menggunakan 2D ultrasound) dan tahap gejala inkontinen (menggunakan soal selidik Inventori Masalah Urogenital - UDI-6 dan soal selidik Impak Inkontinen - IIQ-7) yang dinilai pada awal saringan dan 8-minggu selepas bersalin, manakala kekuatan dan ketahanan PFM (menggunakan perineometer) dinilai pada 8 minggu selepas bersalin untuk kedua-dua kumpulan. Daripada 41 peserta, 87.8% adalah Melayu dengan purata umur 28 tahun (SD = 0.56) dan kebanyakannya bekerja (78%). Terdapat pengurangan saiz DRA pada kedua-dua kumpulan selepas 8 minggu tetapi tidak signifikan. Walaubagaimanapun, analisa perbezaaan min antara dua kumpulan menunjukkan pengurangan saiz DRA yang signifikan pada p<0.001 dimana kumpulan intervasi berkurang sehingga 27% (min: 6.2; 95% CI: 3.7, 8.7) berbanding dengan 8.2% (min: 1.66; 95% CI: -1.3, 4.6) dalam kumpulan kawalan. Begitu juga dengan kekuatan PFM kumpulan intervensi dimana terdapat perbezaan ketara dalam kekuatan PFM dengan perbezaan min 5.89 mmHg (95% CI: 2.10, 9.68; p = 0.003) dan ketahanan PFM dengan perbezaan min 1.11 saat (95% CI: 0.01, 2.22; p = 0.049) antara kumpulan. Sementara itu, untuk fungsi urinari, tidak terdapat perbezaan yang signifikan di antara kumpulan, namun kedua-dua kumpulan menunjukkan pengurangan dalam tanggapan gejala distres urinari selepas 8 minggu dengan p<0.001. Kesimpulannya, senaman otot perut menggunakan modul STEP selama lapan minngu berjaya mengurangkan saiz DRA dan dapat dilaksanakan untuk ibu selepas bersalin. Fungsi otot PFM lebih baik pada kumpulan STEP pada minggu ke lapan dan tiada perbezaan yang ketara dalam gejala kebocoran air kencing antara dua kumpulan. Seterusnya, tidak terdapat hubungan anatara saiz DRA dan fungsi PFM dan gejala kebocoran kencing. Kajian lanjut perlu memastikan keberkesanan latihan otot perut di kalangan populasi yang lebih besar.

KEYWORDS: diastasis recti abdominal, inkontinen, otot lantai pelvis, primigravida, senaman perut.

THE EFFECT OF ABDOMINAL EXERCISE ON DIASTASIS RECTI ABDOMINAL (DRA) AMONG POSTPARTUM PRIMIGRAVIDA MOTHER IN KUALA LUMPUR

ABSTRACT

Abdominal exercise for diastasis recti abdominal (DRA) during postpartum has yet to be explored in research. Despite general exercise programs in current rehabilitation, strength and conditioning programs, few studies have examined the implementation of gradual and progressions abdominal training, and the benefits therein. The objective of this study was to investigate the effects of a progressive abdominal exercise known as Split Tummy Exercise Program (STEP) on the DRA size, pelvic floor muscle (PFM) strength, endurance and perceived urinary distress symptoms and determine the correlation between these variables. STEP module was developed based on literature review and validated by the experts. A randomized control trial study design was carried out at Obstetric and Gynaecology clinic, University Kebangsaan Malaysia Medical Centre (UKMMC) Kuala Lumpur and 41 pregnant women were selected. Later the participants were randomly assigned to the intervention (21 subjects) and control group (20 subjects). The participants were selected among primigravida diagnosed with DRA at 34-week gestations onward if the gap between the abdominal muscle is more than two-finger width measured with finger palpation at the umbilicus. Those with multiple pregnancies, previous abdominal and urogenital surgery, lower caesarian section delivery, and disease that could interfere with PFM strength such as Ehlan Danlos Syndrome were excluded. The intervention group received STEP module consist of three phases of nine abdominal exercises. The progression from phase one to phase two was administered every three weeks and completed phase three at eight weeks postpartum. DRA size (using 2D ultrasound)

and urinary functions (using Urogenital Distress Inventory questionnaire - UDI-6 and Incontinence Impact questionnaire - IIQ-7) were assessed at baseline and 8-weeks postpartum, whereas the PFM strength and endurance (using perineometer) was evaluated at 8-weeks postpartum for both groups. Out of 41 participants, 87.8% were Malays with the mean age of 28 years old (SD=0.56), and most of them (78%) were working. After 8 weeks, both groups had a reduction of DRA size, but result between the group was not significant whereas within-group analysis, DRA size was reduced up to 27% (mean difference: 6.2; 95% CI: 3.7, 8.7) as compared to 8.2% (mean difference: 1.66; 95% CI: -1.3, 4.6) in the control group with significant intervention effect at p < 0.001. There is a significant difference in PFM strength with a mean difference of 5.89 mmHg (95% CI: 2.10, 9.68; p=0.003) and PFM endurance with the mean difference of 1.11 second (95% CI: 0.01, 2.22; p=0.049) between groups. On the other hand, for urinary function, there is no significant difference in urinary distress symptoms between-group however, within-group analysis, both groups show significant different (p<0.001). In conclusion, the abdominal exercise using eight weeks STEP module effectively reduce the DRA size and could be implemented for mothers with DRA. The strength and endurance of PFM are higher in the STEP group at 8 weeks postpartum and no significant difference in perceived urinary incontinence symptom between the group. Finally, no relationship was found between DRA size and PFM function and perceived urinary distress symptoms. Further research is warranted to ascertain the efficacy of abdominal exercise among a larger population. **KEYWORDS:** abdominal exercise, diastasis recti abdominal, pelvic floor muscle, primigravida, urinary incontinence

CHAPTER 1

INTRODUCTION

1.1 Background

Diastasis Recti Abdominal (DRA) is a condition that affects women during pregnancy. DRA affect the abdominal muscle and linea alba, particularly in which these structures are stretched and separated in the midline of the anterior wall of the abdomen. All the abdominal muscle are affected, mainly rectus abdominis (RA) muscle (Axer, von Keyserlingk, & Prescher, 2001). During pregnancy, hormone such as relaxin, progesterone and estrogens play a significant role in relaxation and soften the muscles around the trunk and pelvic for the accommodation of the growing fetus and also for easy delivery (Dehghan et al., 2014). These hormones are rising at first trimester and toward the last few weeks of pregnancy. The abdominal muscles will split in the middle of the trunk due to these hormonal influence and in the presence of gradual pressure arise from the growing fetus as the pregnancy progress (J. Boissonnault & Blaschak, 1988).

Few studies showed that DRA are expected to resolve spontaneously after delivery (J. S. Boissonnault & Blaschak, 1988; Coldron, Stokes, Newham, & Cook, 2008) but the prevalence of DRA in postpartum women are increasing and often overlooked by the clinician. The incidence of DRA in postpartum mother reported in few literatures (Bo et al., 2016; Boissonnault & Blaschak, 1988; Gilleard & Brown, 1996; Mota et al, 2015) showed more than half of women (53%) still have DRA at week 4 to week 8 postpartum and remaining 39% at 6 months postpartum. In fact, recent studies (Bo et al., 2016; Turan et al., 2011) indicated that high prevalence of DRA

ranging from 30% to 60% in postpartum mother up to 1 year after delivery. These data show that the condition of DRA is progressing through pregnancy which does not resolve spontaneously after delivery as it is expected. Thus, DRA is a condition that needs crucial attention during pregnancy and postpartum period by the clinician as well as the mother itself.

It is believed that the presence of DRA during the postpartum period may result in negative health consequences to the mother such as pelvic floor muscle (PFM) dysfunction, back pain, pelvic girdle pain and umbilical hernia (Sapsford, & Hodges, 2010; Lee & Hodges, 2016; Spitznagle et al., 2007). Furthermore, unresolved DRA during postpartum period was postulated to weaken and lengthen of abdominal muscle thus reduce the ability of abdominal muscle to generate force during functional activities (Coldron et al., 2008; Hernandez-Gascon et al., 2013). As consequences, it may predispose the trunk and pelvic region to pressure especially during functional activities such as lifting and bending, eventually contribute to pelvic instability and back pain (Lee, 2016; Spasford et al., 2013). Despite reducing the integrity and functional strength of abdominal wall, other supporting muscles around the pelvic girdle such as PFM may also be affected. Therefore, increase the probability and severity of the related conditions in subsequent pregnancy as well if left untreated (Tupler & Gauld, 2005; Sapsford & Hodges, 2012).

Conservative management was the preferred treatment compared to surgical procedure which consists of a combination of exercises including aerobic, strength training of upper and lower limb as well as the use of electrotherapy such as hot and cold modalities (Benjamin, Water, & Peiris, 2014; Keeler et al., 2012). Most countries include this treatment as part of an antenatal and postpartum program for mother. Nevertheless, the major concern in these antenatal and postnatal program is for

prevention of back pain and urinary incontinence rather than focusing on the DRA condition.

Currently, there is scarce evidence on the effect of exercise on the DRA. General exercise may help to reduce the DRA size among postpartum mother (Benjamin, 2014). In fact, by performing abdominal exercise alone is sufficient for DRA closure (Khandale & Hande, 2016; Walton et al., 2016) but none of these studies agrees on the type of abdominal exercise that is more customized in improving the DRA. It could be presumed that there is no specific protocol or regime to treat DRA in particular. Most of the abdominal exercise prescribed to the mothers in previous studies were focusing on the Transverse abdominal (TrA) muscle activation. The same exercise will be carried over by the mother up to six to eight-week duration. Even though the result showed improvement in the DRA size as well improve abdominal muscle strength, reduce waist and hip circumference, it is difficult to conclude the effect of abdominal training from the available evidence due to several limitations of these studies. First of all, the measurement tools were different between studies and only one study using reliable, valid and recommended research tool for DRA measurement (Walton et al., 2016). However, this study had a small sample size, and the DRA size at the baseline are smaller and could be considered normal (Beer et al., 2009). Other studies on abdominal exercise was a single group study with no comparison in which the changes in DRA probably was not due to the intervention instead natural recovery of the conditions (Acharry & Kutty, 2015; El-Mekawy et al., 2013; Khandale & Hande, 2016; Mahalaksmi et al., 2016). On the other hand, the studies did mention the use of PFM as part of the treatment for DRA (Khandale & Hande, 2016) however, no further evaluation is done on the PFM function.

It is known that disturbance and deficiency of PFM may not only cause stress urinary incontinence (SUI) but several conditions such as pelvic organ prolapse, frequent urination, urgency and urge incontinence (Sapsford, 2004; Sapsford & Hodges, 2001; Spitznagle et al., 2007). Spitznagle et al. (2007) studied the effect of DRA among women with the urogynaecology condition found that 66% women with DRA develop greater pelvic organ prolapse, urinary and faecal incontinence compared to women without DRA. Nevertheless, there is still limited study looking on the effects of DRA on the function of PFM and whether DRA directly contributes to the incidence of urinary incontinence (UI) among pregnant and postpartum mother. A recent study found a contradictory finding which revealed no differences in PFM function among women with or without DRA (Sperstad et al., 2016). These contradicting findings might be due to the different of the study population and method used in measuring the DRA. It is important to manage DRA as early as possible at the postpartum period to enhance the recovery process, eventually, prevent the worsening of this condition and other health sequelae.

1.2 Problem statement

The prevalence of unresolved DRA among postpartum women is higher. Therefore there is still little effort/attention among clinician and women itself about this condition. Currently, few developing countries are aware and thoroughly assess the presence of DRA during pregnancy however exercise program provided at postnatal period aims to prevent back pain by focusing on improving trunk and abdominal muscle rather specifically for DRA condition. There is no clear guideline and protocol developed for women with DRA. Secondly, there is also minimal quality studies that investigate the effect of abdominal exercise on the DRA. Even the results are positive, but only one study was RCT with the used of gold standard measurement, which

conclusive finding on the exercise effect is questionable. In addition, all studies used various type of abdominal exercises, different use of outcome measure and location of DRA measurement. Third, there is no studies investigate the effect of abdominal exercise on PFM function in women with DRA however there is already numerous finding on the effects of abdominal contraction on healthy subject and back pain patient which indicate abdominal muscle work in synergy with PFM.

Even though it is still inconclusive, but DRA has been linked to other physical problems such as lower back pain, urinary incontinence and pelvic organ prolapse in women. The risk of developing these problems is higher for women participating in activity daily living or any physical activity that required intense training or used of abdominal muscle. Hence, It is ideal to have an individual exercise program for women, specifically targeting not only TrA muscle but the whole abdominal muscle to treat and prevent DRA and its negative health consequences.

1.3 Research significant

To date, there is currently not enough quality evidence in the literature to guide clinical practice on the conservative management for the DRA in postpartum mother. This study is important to evaluate potential treatment for DRA in postpartum women as well as to educate them to manage the DRA as early as possible during their confinement period and speed up recovery, allowing them to return to their routine physical and social activities more quickly with less risk of having negative effects of DRA. A standardised, comprehensive and specific exercise protocol is required.

In Malaysia, the Ministry of Health had highlighted the DRA and list of exercises to perform. Similarly, the programs contain a variety of exercise that not specific for DRA. The outcomes of this study may also help to establish an effective

abdominal exercise program that feasible to be carried out by women in confinement period. This abdominal exercise programs not only can be used to treat women with DRA but also as one of the preventive methods for the development of DRA after delivery. Later, any interest agencies and government can utilise or promote this program to be used among postpartum women in the maternity hospital. The clinician as well would be able to use the outcome of this study as a reference for exercise prescription for postpartum women with DRA. It could be explored more in term of the benefit to other supporting structured around the pelvic girdle as well. The optimal strategies suggested in the literature is the combination of both TrA and RA training. This study attempt to develop abdominal exercise training consisted of activation of whole abdominal muscle progress gradually and to investigate the effect not only to DRA size but PFM strength and endurance as well.

1.4 Research question

Does the abdominal exercise program reduce the DRA size and improve pelvic floor muscle function in postpartum mother diagnosed with DRA?

1.5 Research objective

1.5.1 General objective

To study the effect of abdominal exercise on the DRA, PFM functions and perceived urinary stress symptoms in postpartum primigravida mother diagnosed with DRA.

1.5.2 Specific objectives

- i. To investigate the effect of abdominal exercise on DRA in postpartum primigravida mother diagnosed with DRA.
- To compare the PFM strength and endurance in postpartum primigravida mother diagnosed with DRA between groups.
- iii. To determine the effect of abdominal exercise on perceived urinary distress in postpartum mother diagnosed with DRA.
- iv. To determine the correlation of DRA, PFM strength, PFM endurance and perceived urinary distress in postpartum primigravida mother diagnosed with DRA.

1.6 Null hypothesis

- i. There is no significant difference in DRA size in postpartum primigravida mother following an abdominal exercise.
- ii. There is no significant difference of PFM function following an abdominal exercise in postpartum primigravida mother diagnosed with DRA.
- iii. There is no significant difference in the perceives urinary distress symptoms following an abdominal exercise in postpartum primigravida women diagnosed with DRA.
- iv. There is no significant correlation of DRA between PFM function and perceived urinary distress score in postpartum primigravida women diagnosed with DRA.

1.7 Conceptual framework

Figure 1.1 shows the conceptual framework of the physical changes and the presence of DRA during pregnancy. The physiological changes occurring during pregnancy have

detrimental effects on the structures and functions of the muscles, nerves and fascial tissue that make up the pelvic region especially on the two important muscles which are abdominal muscle and PFM. There is a multitude of factors that contribute to DRA such as hormonal changes, the weight of the uterus and baby and also mothers weight gain during pregnancy. Hormonal changes during pregnancy influence the ligaments and muscles and eventually soften and weaken the connective tissue of the linea alba. As a consequence, the linea alba becomes wider, and the rectus abdominis (RA) muscle that attaches at the linea alba may stretch apart, lengthen, weak and reduce the ability to generate strong contraction approximate each other in the midline of the body thus, creating DRA.

Despite linea alba and abdominal muscle, the influence of the pregnancy hormone similarly affect the PFM and lead to joint mobility in the pelvic organ that is stabilized by ligaments. These joint hypermobility in pelvic organ together with the presence of DRA may contribute to PFM weakness and subsequent development of UI symptoms. This study will investigate the effectiveness of the abdominal exercise programs in reducing the DRA and improvement of PFM function and UI symptoms in postpartum primigravida women. The primary outcome of this study was a DRA size. PFM strength and endurance, and urinary function are also measured as secondary outcomes.

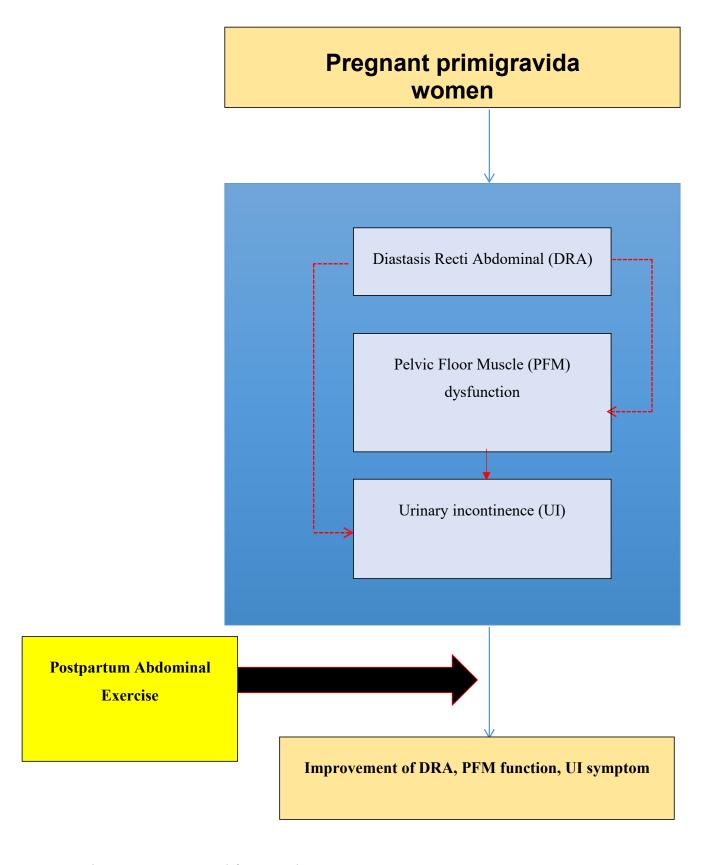


Figure 1.1: Conceptual framework

1.8 Operational definitions

Diastasis Recti			
abdominal (DRA)		

Any gap in between the RA muscle along the xiphoid process to the symphysis pubis. DRA was diagnosed when the gap is more than two-finger width measured with finger palpation at the umbilicus (Bo et al., 2016).

Lower urinary tract symptoms (LUTS)

Include storage symptoms, voiding symptoms and post micturition symptoms.

Pelvic floor muscle (PFM)

The layer of muscles that support the pelvic organ consists of puborectalis, iliococcygeus, pubococcygeus (levator ani).

Urinary incontinence (UI)

Refers to involuntary leakage of urine.

Stress urinary incontinence (SUI)

Define by the International Continence Society (ICS) as "a complaint of involuntary leakage of urine on effort or exertion or with sneezing, coughing, laughing, or physical exertion. (Abrams et al., 2003).

Frequency urinary incontinence (FUI)

Refers to voiding more frequently than previously thought as normal, or more than eight daytime voids per day (Koelbl et al., 2013).

Pelvic girdle pain (PGP)

Pain at the back and pelvis area (Sapsford et al., 2013).

CHAPTER 2

LITERATURE REVIEW

2.1 The Diastasis Recti Abdominal (DRA)

DRA is an impairment of anterior abdominal muscle which characterized by a widening of the linea alba or separation of two bellies of Rectus Abdominis (RA) muscle in the midline of the body along the xiphoid process to the pubis symphysis (Liaw et al., 2011). There is still no consensus among the researcher on the determination of the normal DRA width that consider being pathological or clinically harmful for women at both during pregnancy and the postpartum period. Earlier, it has been suggested in the literature that the normal width of DRA from the study of cadavers using abdominopelvic tomography should be less than 27mm (Rath et al., 1996). On the other hand, the norm was different in the study of nulliparous women measured by ultrasound at three reference point along the xiphoid to symphysis pubis which is between 15 mm to 22 mm (Beer et al., 2009). Latest, DRA exceeding 30 mm is considered clinically harmful and suggested to be repaired surgically (Emanuelsson et al., 2014). Several other studies classified the DRA according to severity, the largest the width, the severe the DRA (Candido et al., 2005; Sperstad et al., 2016). It is important for a clinician to be able to classify the DRA so that appropriate treatment can be delivered and the outcomes could be measured as well. Nevertheless, recent studies utilising ultrasound consider normal DRA was based on Rath et al., 1996 studies in which average to be 0.9 cm between the pubic symphysis and umbilicus, 2.7 cm just

above the umbilicus and 1.0 cm between the umbilicus and the xiphoid which can be reliably measured with ultrasound imaging (Coldron et al., 2008).

Next, there is also variability in the assessment method between studies. Most publish studies using finger palpation to assess the DRA size even it has been agreed that DRA should be measured using a tool that more objective such as callipers and ultrasound (Benjamin, 2016). Still, in most clinical setting, finger palpation is acceptable to be used to assess the presence of DRA. This variability in DRA width, unstandardized assessment methods and location of measurement hamper comparison between the results obtained.

2.2 Abdominal muscles

The abdominal muscle plays a crucial role in managing intra-abdominal pressure during movement and physical activity. The abdominal muscles consist of four layers of muscles: the rectus abdominis (RA), the external obliques (EO), the internal obliques (IO), and the TrA with each pair of muscles has its function within the body. Generally, abdominal muscle groups work in maintaining body posture in erect position, providing support of the trunk during functional and expiratory function such as coughing and sneezing, assist in defectation and moving the trunk in a variety of direction, stabilise the muscles of the lower back and pelvis region by controlling the angle of insertion (Neumann & Gill, 2002).

RA is the most superficial layer, which extends vertically down the body from the sternum to the pelvis. It is divided in the midline of the body by the linea alba, a connective tissue that binds with abdominal muscles to make up abdominal aponeurosis. The RA serves as a front wall of the trunk, and the main function is to bend the trunk forward. Whereas, the EO and IO attach to the pelvis and the linea alba

at the centre of the RA through the tendon-like aponeurosis at the end of each muscle. The obliques compress the viscera and work in conjunction with the TrA (Boissonnault & Blaschak, 1988). The deepest and most important muscle is the TrA which wrap around the body laterally before attaching to the RA (Richardson, 1999). The aponeuroses of the external and internal oblique and TrA create an anterior and a posterior sheath that encloses each half of the RA muscle. The enclosure of the viscera by the TrA provides a great contribution to the support of the abdominal contents and acts as a corset with the contribution of the obliques muscle that attaches to the abdominal aponeurosis. It is believed that TrA play a crucial role in optimising the function of lumbopelvic and contributes to intersegmental and intrapelvic stiffness thus maintaining the stability of the trunk (Richardson et al., 2002; Sapsford & Hodges, 2012), This is supported by the model known as the integrated system (Lee et al., 2007).

2.3 Lumbopelvic stability

Synergetic action of trunk muscle is needed for loads to be transferred effectively through the lumbopelvic region during multiple tasks of varying load. It was postulated that DRA is a possible component of a failed load transfer system in the lumbo pelvic core. Failed load transfer may lead to pain, incontinence and breathing disorder (lee et al., 2011). To optimize lumbopelvic load transfer, abdominal muscle particularly TrA should be optimally function. The presence of DRA eventually will weaken the abdominal muscles even more and influence their functions (Boissonnault & Blaschak, 1988). When the linea alba no longer attaches in the midline, the abdominal muscle no longer able to contract effectively which may result in the widening of the DRA thus reducing the ability of the muscle to generate force as described in a patient with DRA exceeding 30 mm at eight weeks postpartum (Coldron et al., 2008). Additional, repeated stretch on the abdominal wall in multiparous women will as well increase the risk of

developing DRA (Boissonnault & Blaschak, 1988) and in fact, the size of DRA in parous women are bigger than nulliparous (Chiarello & McAuley, 2013; Coldron et al., 2008). In pregnancy, apart from a weakening of soft tissue of the linea alba and abdominal muscles, the growing fetus may eventually stretch the abdominal wall and create an amount of tension on already weakening structured predisposed to the separation of the abdominal muscles (Boissonnault & Blaschak, 1988). Thus strengthening of TrA is important during pregnancy to maintain trunk stability for movement and activity (Benjamin et al., 2014; Richardson et al., 2002)

2.4 The synergy action of abdominal and pelvic floor muscle

During the functional activity, there is a rise in intraabdominal pressure in which abdominal muscle is controlling the forces affecting the lumbar spine hence preventing spine injury whereas PFM function is to elevate the bladder thus preventing descent of the bladder neck (Sapsford, 2004). This synergy activity of PFM and abdominal muscle were first investigated via EMG study, which demonstrated that maximum contraction of PFM was achieved with abdominal contraction (Sapsford, 2001). Several other studies support this finding (Neumann & Gill, 2002; Sapsford & Hodges, 2001) and recent systematic review conclude that this synergy exists and contraction of abdominal muscle particularly TrA and PFM are useful in optimizing pelvic stability and improve pelvic floor muscle dysfunction (Ferla et al., 2016).

Pelvic stability is very important and should be maintained throughout pregnancy to prevent other musculoskeletal problem such as pelvic girdle pain, hip and back pain (Axer et al., 2001; Candido et al., 2005; Parker et al., 2009). Not only that, as the pregnancy progress the insertion angle of pelvic to abdominal muscle may jeopardies and later affect the performance of PFM and lead to PFM dysfunction with

some of the women reported a high incidence of UI and pelvic organ prolapse (POP) (Spitznagle et al., 2007). Despite that, cosmetically DRA may affect body image as the diastasis between the abdominal muscles in the midline may cause bulging or protrusion of the abdomen (Beer et al., 2009). This usually happens during exertion on physical activity as the increase in intrabdominal pressure. It may be associated with epigastric and umbilical hernia, which usually need surgical correction (Cheesborough & Dumanian, 2015). Understanding the synergism between these muscle group may favour the development of strategies for the prevention and treatment of disorder related to abdominal and pelvic floor muscle.

2.5 PFM function

The PFM comprise of four layers of skeletal muscles. PFM function is to maintain continence and stabilise the trunk for movement and activity and contribute to sexual function (Sapsford, 2001). The strength of PFM is needed to maintain continence in the present of intra-abdominal pressure during an activity such as coughing, sneezing and laughing. When PFM contraction is not forceful enough or cannot be sustained, leakage may occur. Pregnancy is one of the factors that affects the PFM. As the pregnancy progress, there is increase intra-abdominal pressure in the trunk, which will eventually exert pressure on the PFM and bladder throughout pregnancy (Mørkved et al., 2003). Ultrasound studies have shown that there are morphological changes of PFM during pregnancy that induced weakening of PFM. This studies demonstrated a decreased in hiatus area as well as bladder neck elevation in pregnant women (Hong et al., 2011).

Decreased hiatus area has been associated with pelvic floor muscle dysfunction such as urinary incontinence and pelvic organ prolapse in pregnant women (Shek,

Kruger & Dietz, 2012). The present of DRA may perhaps worsen the PFM due to the synergy effect of PFM, and abdominal muscle as it is believed that women who have some impairment in abdominal wall and the local connective tissue such as DRA may present with mechanical changes of the fascia which form the rectus sheath and this may eventually cause PFM dysfunction (Sapsford & Hodges, 2001), however recent cohort study comparing women with and without DRA found that no difference in PFM function at postpartum women (Sperstad et al., 2016). Only one study related to the presence of DRA with PFM dysfunction in the population of menopause women (Spitznagle et al., 2007). It is somehow impossible to compare the results between these two studies as different in the population of study and also different in the use of outcome measure in measuring the DRA and PFM function. The study by Sperstad et al., (2016) warns the clinician to be caution to postulate association between abdominal muscle, PFM and Pelvic floor dysfunction until more research are available.

2.6 Urinary Incontinence symptoms

UI is defined as any involuntary leakage of urine and can be divided into three main types of incontinence. Firstly is SUI, define as involuntary urine leakage associated with coughing, sneezing, physical exertion, or other physical strain. Secondly is urgency urinary incontinence (UUI), in which there is a strong desire or urge to urinate with an inability to get to the toilet in time, and lastly mixed incontinence (MI), which is a combination of both SUI and UUI (Abrams et al., 2002). The prevalence of UI among pregnancy is well documented and relatively high, between 35% to 65% (Burgio, 2013). The commonest type of UI during pregnancy is SUI, which range from 18.6% to 75% (Sangsawang & Sangsawang, 2013). Few authors agree that this is a transient condition that would normally resolve within the first three months delivery (Burgio, 2013; Farrell, Allen, & Baskett, 2001). However, in the study by

Dariah et al. (2014) revealed that about 20% of the postpartum mother still experiencing UI three months after delivery.

Childbearing age women are susceptible to UI because of the many risk factors related to pregnancy and the delivery process. A prevalence study in Taiwan women during pregnancy and one year postpartum found that vaginal delivery was one of the risk factors for SUI at postpartum (Lin et al., 2018). There is only one study reported a close association between UI and the presence of DRA. A study by Spitzangel et al. (2007) showed that middle-aged women with DRA reported a higher incidence of UI symptoms. However, the population of the study was women that already been diagnosed with PFM dysfunction. It is stipulated that the effect of hormonal changes, as well as increasing abdominal loading, give direct pressure on the PFM. The inability of the PFM to sustained the load may eventually lead to UI.

2.7 Diastasis recti abdominal management

There is little known about the prevention and the management of DRA. Despite the fact that this condition is common and significant in clinical practice (Axer et al., 2001; Sancho et al., 2015; Sperstad et al., 2016). The management of DRA has been debated in the literature since at least 1990s. An extensive literature and research reports described a variety of interventions and methods to prevent and treat DRA during pregnancy and the postpartum period in women. DRA can be managed conservatively and surgically. Conservative management is defined as non-surgical treatment such as physical activity, muscular training or physiotherapy (Akram & Matzen, 2014). Evidence showed that conservative management was the choice of treatment which comprise of exercise, postural correction and education, therapeutic modalities such as

soft tissue mobilisation, hot and cold compression and the use of external support (Benjamin et al., 2014; Keeler et al., 2012).

The use of external support or abdominal binder is essential and a common confinement practice in all over the countries, including Malaysia. A systemic review on postpartum practice and rituals (Dennis et al., 2007) points out that the purpose of the binder is to hasten uterine involution and to flatten the stomach. Zamani (2001) in his review prescribe binder or 'barut' in Malays word as six main components involved during postpartum care despite body massage, 'tuku', 'salai', tonic drinks and diet. Binder is made of cloth and is tightly wrapped around the woman's waist. It is believed that the binder helps the woman to regain her slim body shape. It is usually worn in the morning after the body massage and during the night; it is seldom worn in the afternoon (Zamani, 2001). Abdominal binder has been proposed, but not scientifically studied especially in the DRA patients (Collie & Harris, 2004; Keeler et al., 2012). In fact, in a clinical setting worldwide, DRA managed during antenatal and postnatal follow up though the major concern is back pain and urinary incontinence symptoms. Most frequent training include general body exercise and abdominal strengthening programs (Chiarello et al., 2005). It is presumed that abdominal muscle exercise was taught as one of the exercises to be performed by the mother with the aims to prevent back pain and improves posture rather managing DRA. In Malaysia, National health education through web pages (http://www.myhealth.gov.my/senaman-posnatal-2/) highlighted DRA as one of the conditions that need to be addressed during antenatal and postnatal follow up, but it is perceived that this practice is not normally common in most maternity hospital. This is mainly due to the lack of awareness among the clinician and mother about this condition. Furthermore DRA is not directly associated with any pain

and discomfort. It could be concluded that there is no specific protocol or regime yet to treat DRA in particular.

2.7.1 Effect of abdominal exercise on the DRA size

DRA is characterised by the thinning and widening of the linea alba with a combination of laxity of the anterior wall of abdominal muscle (Liaw et al., 2011). In pregnant women, the abdominal muscle particularly RA split in the middle as the linea alba gradually widening in the presence of DRA. A recent study demonstrated that the linea alba aponeurosis or recti fascia is the most essential unit for the mechanical stability of the abdominal wall (Hernandez-Gascon et al., 2013). Abdominal exercises are encouraged during pregnancy, supported by the theory that abdominal strength during pregnancy may reduce the incidence of DRA (Boissonnault & Blaschak, 1988; Lee & McLaughlin, 2008). Exercise is also recommended in the postpartum period to counteract the effects of pregnancy on a woman's anterior abdominal wall and body posture. The rationale behind these strengthening training programmes is the assumption that contraction of all abdominal muscles will reduce the abdominal horizontal diameter in such a way that a horizontal force will be generated, producing the approximation of both rectus abdominis muscles, particularly at umbilical level (Sancho et al., 2015).

There are few studies with varies design investigated the effect of abdominal exercise only on the DRA size (Acharry & Kutty, 2015; El-Mekawy et al., 2013; Khandale & Hande, 2016; Mahalaksmi et al., 2016; Walton et al., 2016). The first study by El Mekawy et al. (2013) concluded that abdominal exercise starting at second day postpartum in six-week duration improve abdominal muscle as well as a greater

reduction in DRA size compared to mother that used abdominal binder. This study concluded that the use of abdominal binder was effective as exercise in reducing the DRA size in both groups. However, the exercise group had a significant reduction not only in DRA size but also in hip/waist measurement and improving abdominal muscle strength. This study shows that performing abdominal exercise is more superior and beneficial compared to the abdominal binder. A study by Acharry & Kutty, 2015 set off the abdominal exercise for DRA mother at one month after delivery which the mother performed the exercise for only two weeks. Even though only three abdominal exercises prescribed with a shorter duration, the result is promising with DRA size reduce significantly. In this study, abdominal exercises performed together with bracing of the abdominal using own hand to compress the DRA. The use of the hand as a bracing technique works as a harness to minimise the internal abdominal pressure while performing the abdominal exercise consist of crunch, TrA activation and pelvic clock exercise.

They claimed that these combination exercises and bracing able to facilitate, concentric activation and stabilisation the abdominal muscle thus effectively reduce the DRA. Both studies stated the positive effect of using exercise alone or in combination with a binder in reducing the DRA size. Similarly with other studies conclude that abdominal exercise benefited in reducing the DRA size not only on primiparous women (Walton et al., 2016; Khandale & Hande, 2016) but also multiparous women (Mahalaksmi et al., 2016). These studies used abdominal training to reduce DRA size (El-Mekawy et al., 2013), but there is no conclusive evidence suggest which type of abdominal exercise particularly resulted in DRA closure. Most of these studies focusing on the activation of TrA on their exercise programmed and claimed other abdominal exercises, especially crunch exercise should be avoided during the postpartum period.

Only one study recruited whole abdominal muscle activation through plank exercise and compared with the traditional method of abdominal exercise (Walton et al., 2016). Earlier 1993, studies showed that by activation of TrA may reduce the DRA among postpartum mother, and since then TrA activation was stimulated in various position (Sancho et al., 2015) such as supine, prone and kneeling. TrA activation is an isometric contraction of abdominal muscle involving draw in and pulling the abdomen inward. Activation of this muscle will improve the integrity of the linea alba, reduce DRA size and speed up recovery allowing the women to return to their activity daily living as soon (Benjamin, 2014). Keeler et al (2012) used survey monkey contains a questionnaire to 2200 physiotherapist on type of intervention used to address DRA in postpartum women. They found 89.2% physiotherapist in US used general training of TrA muscle activation for postpartum women and 69% reported a success rate of 41% - 100%. It could be concluded that re-education of deep stabilising muscle of the trunk including TrA are important in patient with DRA and it has been well documented (Acharry & Kutty, 2015; El-Mekawy et al., 2013)

Another type of abdominal training is crunch exercise which involves lifting the head to scapula level to initiated RA contraction was previously prohibited in DRA patients as it may increase the internal abdominal pressure and may have an impact on the PFM and jeopardise the lumbopelvic stability (Boissonnault & Blaschak, 1988). Opposing to the statement, Pascoal et al. (2014) found out that abdominal crunch could be effective in narrowing the DRA. The latest claimed that there is an approximation of linea able during crunch measured with the US at 3 cm above the umbilicus and claimed DRA is widened when performing TrA activation. This conflicting result indicates the lacking in knowledge of how different type of abdominal exercise affects the DRA. The fact that they used different evaluation instruments also limited the comparison between

studies. The most common instruments used to measure the DRA was finger palpation (Acharry & Kutty, 2015; Khandale & Hande, 2016; Mahalaksmi et al., 2016), calliper (El-Mekawy et al., 2013) and ultrasound (Walton et al., 2016). It is established that the use of ultrasound is more reliable in detecting the size of DRA and only one studies performed an ultrasound to assessed the changes in the DRA size (Walton et al., 2016). However, the baseline DRA size in this study was very small and could be consider normal compared to DRA size suggested by other ultrasound studies which is more than 22mm to be considered DRA (Beer et al., 2009; Emanuelsson et al., 2016). There is also lacking in the standardisation of the DRA location, but there is similar instruction given to assess the width of DRA. Patient was asked to lift the head in supine position prior to measurement as to performed crunch exercise, which means the abdominal muscle was in contraction position during the assessment and not in the resting state. This measurement position definitely the most commonly used practice for identifying DRA clinically (Boissonnault & Blaschak, 1988; Keeler et al., 2012) as the width of DRA are more wider. In summary, as shown in Table 2.1, there is no consensus regarding the ideal type of abdominal exercise in the management of DRA among the researchers even though, these studies stated that abdominal strengthening exercise was protective for the development and/or reduction of the DRA among pregnant and postpartum mother. It is important to identify the minimal interventions that may help promote rapid DRA closure that could be useful in the medical field.

Table 2.1: Literature on the effects of exercises in DRA closure

Author	Research design	Sample & Exercise protocol	Type of abdominal exercise	Duration of exercise	Findings
			1. Static abdominal		
El Mekawy et al. (2013)	RCT	n=30	contraction 2. Posterior pelvic tilt	30 minutes	Significant improvement in DRA size in the exercise group compared to the
	Did not mention	Exercise begins on	3. Reverse sit up	3 times a week	control group (used abdominal binder)
	randomisation procedure and blinding method	2 nd day	4. Trunk twist5. Reverse trunk twist	Duration: 6	- Improving muscle strength and
	5	Measure: callipers (cm)	or reverse traine on ast	weeks	- Hip and waist ratio
Khandale & Hande	Pre-post design	n=40	Static abdominal exercise	30 minutes	The abdominal exercise was effective in reducing the DRA and improved
		Exercise begins	2. Head lift with PPP	5 times a week	abdominal strength as well.
(2016)		Immediate delivery	3. Pelvic rock exercise	Duration: 8	
		Measure: finger	4. Double straight leg raising exercise	weeks	
		palpation	5. Plank		
			6. Superman exercise		
Acharry et al. (2015)	Descriptive	n=30	Static abdominal exercise	2 times a day at home	Improved DRA however, the subjects selection in term of weight and how
	Cross-sectional study	Subjects recruited	2. Head lift and pelvic	5	many children were not done
		one month or more after delivery	tilt with bracing 3. Pelvic clock exercise	Repeat 5-7	(inclusion/exclusion criteria were loose)
		and delivery	5. Pervic clock exercise	Duration: 2 week	
		Mix: primed and gravid (1-4 child)			

table 2 1 Literature on the effects of exercises in DRA closure

Table 2.1 : continue

Mahalaksmi (2016)	Quasi experimental study	SVD, n=36 Exercise begins on 3 rd day Review at 2 nd and 6 week postpartum LSCS, n= 32 Exercise begins at 2 nd week Review at 6 and 10 th week postpartum Measure: Finger palpation	1. 2. 3. 4. 5.	Pelvic tilt Heel drop with coactivation	30 minute 3 times a week Duration: 6 weeks	Exercise was effective if starting as early as possible
Watson, 2016	RCT	n=9 Subjects recruited at 3 month to 3 years postpartum. Measure: Ultrasound	1. 2. 3. 4.	Abdominal curl Kegel exercise xercise group Plank exercise Russian twist Abdominal curls	3 times a week Duration: 6 weeks Home exercise Follow up by telephone call every 2 week	Both group showed significant improvement in DRA size with control group exhibit more DRA reduction than the experimental group.

2.7.2 Other factor associated with DRA

Studies have shown that there is no different in term of age, ethnicity, height, weight gain during pregnancy, pregnancy weight and gestational age at delivery between women with and without DRA (Candido et al., 2005) however the risk of developing DRA is higher among multiparous women particularly strong relationship concerning the provision of childcare during pregnancy (Rett et al., 2009; Spitznagle et al., 2007)

2.8 Methods to measure diastasis recti abdominal, pelvic floor muscle functions and urinary incontinence

2.8.1 Diastasis recti abdominal measurement

At the moment, no agreement between researchers regarding the size of DRA that consider abnormal and clinically harmful to pregnant women. There is also disagreement in term of the most accurate location best to measure the DRA. CT scan study had shown that the biggest size of DRA located at the umbilicus (27 mm), followed by supraumbilical (10 mm) and the least is infraumbilical (9 mm) depending on the age (Rath, 1996). Since then, DRA is considered pathological if the size is more than 27mm at the umbilical area. A recent study using the US by Beer et al. (2009) concluded that DRA is considered present if the size is more than 22 mm at 3 cm above the umbilicus and 16mm 2 cm below the umbilicus. The widest DRA from this study was above the umbilicus. Similarly, other evidence showed that, regardless of parity, the prevalence and most occurrence of DRA is at supraumbilical region compared to infraumbilical (Demartini et al., 2016) and it is also no different on DRA occurrence

between the type of delivery, SVD or LSCS (Mota et al., 2015). In this study, palpation of more than two finger width at the umbilicus area was an indicator of DRA. It further assessed using 2D ultrasound to quantify the exact DRA size of pregnant women at 34-week pregnancy. Again, based on the ultrasound study, the best location that most relevant to quantify the DRA size was above the umbilicus (Mendes et al., 2007). The author used 7 locations to assess the most accurate location to diagnose DRA and concluded that the area above and at umbilicus was the most precise location to determine the DRA size using ultrasound.

2.8.2 Pelvic floor muscle function measurement

Mostly used method to measure PFM contraction in a clinical setting is a vaginal examination using finger palpation. Despite that, a medical appliance such as perineometer is also preferable as it can detect the pressure created by the PFM contraction (Alves et al., 2017). This study used perineometer as it had proven valid and reliable in measuring PFM contraction. In the pregnant population, few past studies used this medical device to measure the efficacy of PFM exercise (Oliveira et al., 2007). It provided as centimetres of water pressure (cmH20) as score (Bo et al., 2017).

2.8.3 Urinary incontinence measurement

Despite improving in the symptom of UI as an indicator, evaluation of treatments using symptom inventory for incontinence which asks women to report presence or degree of distress for symptoms associated with UI will provide efficient measures of symptom severity. The effectiveness of treatment should be assessed based on the improvement in the severity of symptoms and how they impact the quality of life

(QOL). This information can be used to identify other treatment solutions that may be more effective and more widely used by the target population. This study utilised two questionnaires which is IIQ-7 and UDI-6 to determine otherness UI symptoms and how they affect their QOL.

CHAPTER 3

METHODOLOGY

3.1 Study place

The study was done at the University Kebangsaan Malaysia Medical Centre (UKMMC), Kuala Lumpur. Data were collected at clinic Obstetrics and Gynaecology (O&G), which patients were coming for a maternal check-up, and pregnancy follow-up.

3.2 Research design

This study is a single-blinded, two arms randomised control trial (RCT) was used to compare the effects of abdominal exercise program in reducing the DRA size, change in PFM function and perceived distress urinary incontinence. Data collection occurred at two times intervals which is at 34-week pregnancy and after 8 weeks of exercise except for PFM function. The participating participants were divided into two groups. The intervention and the control group. Participants in the intervention group were instructed to perform abdominal exercises during the postpartum period starting immediately one day after delivery and those in the control group continued their routine standard postnatal care. Standard care consist of breathing exercise, active exercise of the upper and lower limb, isometric abdominal exercise and pelvic floor exercise (Mahalaksmi et al., 2016). Dependant variables and their measures are listed in Table 3.1.

Table 3.1: Dependent variables assessed based on measure tools and unit

Dependent Variable	Measure	Units
Main outcomes: DRA size	2D ultrasound	Millimetre (mm)
Secondary outcomes: PFM strength PFM endurance Urinary function assessmen	Perineometer Perineometer IIQ-6 & UDI-7	Score (mmHg) Second (s) Score

3.3 Participants criteria

The target population for this study was pregnant women with DRA. The presence of DRA was tested using finger width palpation, and the gap of more than two finger width were invited to participated in the study and consented. Women delivered via caesarean delivery or have previous abdominal surgery were excluded to avoid possible contraindicated consequence related to treatment effect. Women with a history of urogenital surgery also excluded to avoid the potential impact of pain on pelvic floor muscle activation. Women delivery at day one were also excluded for recruitment due to logistic problem on performing DRA assessment using ultrasound. Further details criteria, as listed below, were used for the selection of study participants.

3.3.1 Inclusion criteria

- i) All primigravida women aged > 18 years
- ii) All primigravida women diagnosed with DRA at 34 to 40-week pregnancy.
- iii) Delivered a singleton pregnancy via spontaneous vertex delivery, vaginal breech delivery or instrumental delivery.

3.3.2 Exclusion criteria

- i) Multiple pregnancies
- ii) Previous abdominal surgery
- iii) Lower section caesarean section (LSCS)
- iv) Previous urogenital surgery
- v) The disease that can interfere in PFM strength such as Ehlan Danlos syndrome
- vi) Uterine stretches due to any condition such as Polyhydramnios or fibroid

3.4 Sample size calculation

To compare the effect of abdominal exercises on the DRA, the sample size was determined using Power and Sample Size software for comparison of two means (independent-t). For the comparison between groups, a standard deviation (σ) of DRA in post-partum women was 0.72 (Liaw *et al.*, 2011). An estimated mean difference (δ) of DRA among post-partum women in the intervention and control groups was 0.5 mm based on mean DRA in post-partum women by Liaw *et al.* (2011) was 1.81. The power of the study was set at 0.8, type 1 error (α) at 0.05, and the ratio between intervention and control group (m) was set at 1. Then, the sample size calculated for each group (n) was 24. After considering 30% dropout, the required sample size was 31 per group.

3.5 Sampling method

Convenient sampling was used in this study which is targeted on pregnant women attended O&G clinic at the institution. Manual palpation was done to confirm the presence of DRA. Randomization took place once the participant safely delivered the baby via vaginal delivery. Participants were randomly assigned following simple randomization procedures (computerized random number) to 1 of 2 treatment groups. Detailed of the allocated group were

given in the sealed envelope containing a card with the number of treatment group, that was kept at the agreed location in the ward. This study included one researcher who is the primary investigator and one physical therapy who specialised in women's health. The primary researcher blinded to group assignment performed all the assessment procedure such as measurement of DRA using finger palpation and USI, assess PFM strength and endurance with perineometer and administered the urinary impact questionnaire. The allocation of participants into the groups was performed by a physiotherapist, who was not involved in the assessment or the teaching of the abdominal exercises. The process for the selection of respondents was summarised in a flow chart presented in Figure 3.1

3.6 Data collection

Figure 3.1 showed the flow of data collection. All pregnant women at 34 weeks onward and fulfil the inclusion criteria were invited to participate in this study. Participants who agreed to be included in this study were initially screened for DRA. Those who fulfilled the DRA diagnosis was given an explanation on the procedure and the benefit of the study (Appendix C) and then had to sign the consent form (Appendix D). Then, the women were given the date for baseline assessment using USI used to measure the DRA size. Later, participants who delivered via spontaneous delivery were continued in the study, whereas those delivered via caesarean section were excluded.

3.6.1 Screening for DRA

All the eligible pregnant mothers were screened for DRA using manual palpation by the researcher. Participants were tested in the hook lying position with both knee bend. Palpating fingertips identify the medial edge of the right and left RA and size of DRA was determined based on the number of fingers placed between the two RA. If the size of DRA is two and more

finger width, the patients were considered to have DRA and included in the study (Bursch, 1987). Then, the 2D ultrasound was performed by a trained physiotherapist to measure the DRA size. The participants' position was crook-lying supine with one pillow under the knee. The ultrasound probe was transversely placed on the location marked by the marker. To standardise the location of the transducer, an ink mark was drawn on the desired measurement location. Measured conducted at 2 points along the linea alba (Candido et al., 2005) which is at 2.5 cm above and below the umbilicus with the participant in the supine resting position, knees bent at 90°, feet resting on the plinth and arms alongside the trunk. The width of the DRA was measured and recorded from on-screen rulers within the software displaying the images.

3.6.2 Baseline data collection

During antepartum, baseline information was gathered. Then, participants were asked to answer the Incontinence Impact Questionnaire Short Form (IIQ-7) and Urogenital Inventory Form (UDI-6). The final questionnaire score is calculated by adding all the scores and divided to obtain a mean value. In the situation that there are left unanswered to, the mean is calculated only for answered questions.

3.6.3 Post-intervention data collection

Post-intervention data collection was done after 8 weeks postpartum. Participants need to come to the O&G clinic. Participants were assessed on the DRA size using 2D ultrasound. Then, the assessment of PFM strength and endurance was performed using perineometer. Patients were asked to squeeze her PFM as maximum and as long as they could. The pressure was recorded as PFM strength. Simultaneously, the PFM endurance time was assessed using a built-in endurance setting on the perineometer. Both tests were repeated three times with a 10-

second rest for the short holds, and 1-minute rest for endurance holds. A mean value was taken for the three tests. The peak or maximum contraction in mmHg as a measure of PFM strength, whereas the endurance was recorded in second.

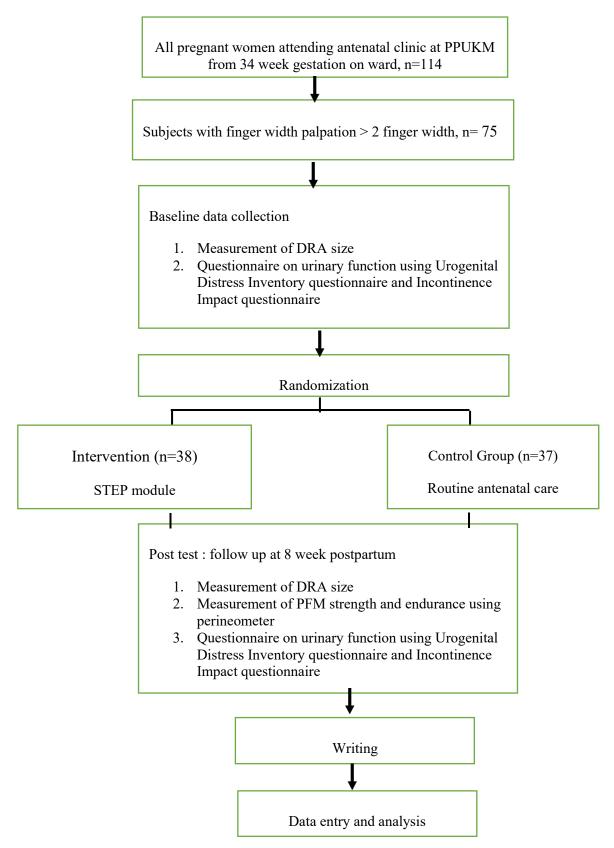


Figure 3.1: Process of participation selection

3.7 Study instrumentation

The size of DRA is quantified by the measurement of the distance between two bellies of RA muscle. It could be measured by one of several methods such as finger width, callipers, tape measurement and ultrasound imaging (USI) in clinical practise or clinical studies (Keeler, 2012; Benjamin, 2016). In this study, finger width palpation was used initially to identify the presence of DRA and later, USI was used to quantify the size of DRA.

3.7.1 Finger width palpation

Finger width palpation is one of the easiest and quickest method use in a clinical setting to determine the size of DRA. It is agreeable that the gap of more than two finger width is considered diastasis recti and the location usually at the umbilicus. It has good intra-rater reliability and moderate inter-rater reliability and can be used in clinical practice (Mota et al., 2013). Recent systemic review by Benjamin (2016), concluded that finger width palpation could be used as a screening method for the presence of DRA but not to evaluate the size of DRA. In this study, finger width palpation was used to screen for the presence of DRA on pregnant mother at the clinic.

3.7.2 2D Ultrasound imaging

Ultrasound Imaging (USI) is used in this study to determine the size of DRA at baseline and after treatment. It was found to have good reliability (Liaw et al., 2011; Mota et al., 2012). It was proven safe and non-invasive method that can be repeated several times during pregnancy (Mendes et al., 2007) despite very accurate in measuring DRA above and at the umbilicus compared to surgical compass during abdominoplasty. It was also a reliable method

to assessed DRA at any different location along the linea alba and any situation, whether at rest or during abdominal crunch (Benjamin, 2016).

The transabdominal ultrasound used in this study was an imaging unit set in B-mode (Ultrasonic APLIO 500, TOSHIBA) with a 7.5Mhz linear array transducer. Ultrasound images in brightness mode (B-mode) were collected from the superficial abdominal musculature, including the RA muscles and linea alba. Images were obtained with the abdominal muscles at rest (supine resting position). The ultrasound transducer was not moved during the testing procedure. USI is not a new method used for measuring the gap of DRA, and It had significant correlations with measurements obtained by manual finger width assessment and callipers (Mota et al., 2012) used in the most clinical setting. Further in his systemic review, Benjamin (2014) explained the importance of determining the method that has not only sound measurement properties but also clinically feasible. USI in this study is used to evaluate the treatment effects on the width of DRA.

3.7.3 Perineometer

In this study, perineometer (peritron 9300; cardio design Pty Ltd, Australia) (Appendix G) was used to measure the strength and endurance of the PFM on postpartum mother to evaluate the treatment effects at 8 weeks after delivery. Perineometer was used to measure vaginal pressure as a marker of pelvic muscle strength and was reported to be reliable and valid (Bo et al., 1990). For testing sessions, the woman emptied her bladder and laid supine on a plinth with 2 pillows under her knees. The lubricated sensor was inserted into the vaginal opening by the researcher. The pressure sensor was calibrated and zeroed according to manufacturer instructions.83 Each participant performed 3 to 5 slow contractions of the pelvic floor muscles to assure correct placement of the sensor probe and familiarity with the instrumentation. To assess strength, each

subject performed 3 maximum contractions with a 1-minute rest between contractions. Each contraction of the pelvic floor muscles was held for as long as the woman was able, up to a maximum of 10 seconds duration. The researcher recorded the maximum pressure produced during each contraction in mmHg. The highest reading of the 3 contractions for each period was used as the maximal strength pressure and used for data analysis. To test endurance of the pelvic floor muscles, the participant held 3 maximum contractions until peak force was observed on the recording. The patient were asked to sustain the contraction and the length of time (in seconds) the pelvic floor muscle contraction was recorded and repeated for 3 times. The average of these 3 contraction lengths was calculated and used for data analysis

3.7.4 Urinary function assessment

Participants were requested to answer two sets of questionnaires, i.e. Urogenital Distress Inventory (UDI-6) and Incontinence Impact Questionnaire (IIQ-7) (Uebersax, Wyman, Shumaker, & Mcclish, 1995). It has been validated in the Malaysian population (Nusee et al., 2016) and were used in all recruited women in this study. The questionnaire was given to the patient during pregnancy (baseline) and at 8 weeks postpartum during the second follow up. Diagnosis and severity of urinary incontinence such as stress incontinence (SUI), urge urinary incontinence (UUI) and mixed urinary incontinence (MUI) were assessed.

Participant's symptoms and quality of life were assessed by validated questionnaires IIQ-7 and UDI-6 (Table 3.I and Table 3.2). IIQ-7 is a seven-question form which analyses the impact of UI on physical activity, travel, social and emotional health. Whereas, UDS-6 is a 6-point questionnaire covering irritative, obstructive and stress symptoms (Table 2, Appendix B gives complete wording). Scoring system is the same as with the IIQ-7. Both questionnaires involved item responses with assigned values of 0 for "not at all," 1 for "slightly," 2 for "moderately," and 3 for "greatly." These provide a single number that indicates overall

symptom distress, combining information on irritative symptoms (items 1 and 2), stress symptoms (items 3 and 4), and obstructive/discomfort symptoms. A low score signifies a better quality of life compared to a high score. The urinary incontinence diagnosis was based on classification by the International Continence Society (ICS) (Abrams et al., 2003).

Table 3.2: Items in the Urogental Distress Inventory Short Forms (UDI-6)

Items in the Urogenital Distress Inventory Short Form (UDI-6)

- 1) Frequent urination
- 2) Leakage related to feeling of urgency
- 3) Leakage related to activity, coughing or sneezing
- 4) Small amount of leakage (drops)
- 5) Difficulty emptying bladder
- 6) Pain or discomfort in lower abdominal or genital area

Table 3.1: Item in the Incontinence Impact Questionnaire Short form (IIQ-7)

Item in the Incontinence Impact Questionnaire Short form (IIQ-7)

Has urinary leakage and/or prolapsed affected:

- 1) Household chores
- 2) Physical recreation
- 3) Entertainment activities
- 4) Travel > 30 minutes away from home
- 5) Social activities
- 6) Emotional health (nervousness, depression etc)
- 7) Feeling frustrated

3.7.5 Demographic and health status variables

The proforma (Appendix F) was used to gather the relevant information regarding demography variables and health status, which is antepartum history, intrapartum history, postpartum history, and objective assessment of DRA and PFM function. Reviewed in detail for each participant, and the following data were systemically abstracted: maternal demographic and reproductive characteristic including maternal age, parity, maternal weight (during pregnancy and postpartum), body mass index (BMI) at pregnancy and postpartum, health status during pregnancy (pre-eclampsia/eclampsia and gestational diabetes, insulindependent only). Postpartum history was gathered regarding confinement practice, the presence of any back pain post-delivery and the need for a helper. For the objective assessment, 2D ultrasound was measured at baseline after been confirmed the presence of DRA screened with finger palpation and again at 8 weeks postpartum together with PFM function using perincometer.

3.8 The development of the Split Tummy Exercise Programs (STEP)

3.8.1 STEP module

In Malaysia setting, the standard care for postpartum women following guidelines from Malaysian health ministry website consists of general body exercise such as upper and lower limb movement, back strengthening exercise, breathing exercise and encouraging early mobilization (Borhan, 2019) and no specific exercise program for postpartum women diagnosed with DRA. STEP module was an evidence-based physical activity intervention developed specifically for postpartum women with the diagnosis of DRA during pregnancy. It was based on literature reviews that proved abdominal exercise is beneficial in reducing the

gap of the DRA in postpartum women (Acharry & Kutty, 2015; El-Mekawy et al., 2013; Jung, Jung, Joo, & Song, 2016). An expert consensus on the module proposed was conducted to express whether this STEP module feasible and safe to practice for women after delivery. The feedback were recorded to extract a consensus from the various opinions, suggestion, and recommendations. The session was conducted with 6 respondents that have experienced in women health areas. This includes physiotherapist in charges in the Obstetric and Gynaecology, consultant involved in module development and health education, family medicine specialist and specialist doctor in women health. They were selected based on the related experienced dealing and treating women during pregnancy and postpartum and secondly they have more than 10 years experienced in their respected field. Finally, some wording issues were resolved without content-related issue was then submitted for final review through an e-mail to all respondents. STEP module consists of three phases of facilitation, integration and strengthening of abdominal muscle within 8 weeks confinement duration. The essential program components and activities are as shown in Table 3.4. The minimum recommended exercise was three times a week with 10 repetitions, and for each exercise should be performed at least three sets (ACSM guidelines, 2010). The drafted STEP module then was tested for face validity among five antenatal and five postnatal mothers to ensure the content is understood by which the participant able to execute and carry out the exercise seamlessly. During phase 1, participants in the intervention group received the initial one to one STEP education session with a physiotherapist within 24 hour after delivery. The purpose of this session was to educate the participant on DRA and facilitate them to perform gentle abdominal contraction through isometric contraction of TrA. Once participants were able to contract the TrA, they were educated on the upper limb movement and lower limb movement while simultaneously contract the TrA. Participants then were explained on the exercises they should perform during Phase 2 and Phase 3.

3.8.2 STEP pamphlet

The STEP module then was sent for graphic design to become health education pamphlet and colour printed. The pamphlet consists of 9 pictures of exercise (3 types of exercise for each phase) for the participant to perform from week 1 to week 8 at the postpartum period (Appendix H). The participants kept the STEP module pamphlet for their reference and guideline, especially during postpartum that need them to continue the STEP exercises at home. The pamphlet not only consists of pictures of exercise but also schedule exercise log as a guide for participants to records the frequency, repetition and set of exercise performed as part of monitoring and compliance assessment. They need to record all the exercise performed every day.

Table 3.2: The content of STEP module

Phase	Aims of exercise	Type of exercises	Repetition, set and duration
PHASE 1 The exercises start immediately at 24 hours after delivery. The participants have to do daily until the fourth week postpartum.	To facilitate abdominal muscle isometrically without any load on the pelvis and spine.	 Isometric abdominal exercise Upper Limb movement with isometric abdominal exercise Alternate lower limb movement 	All the exercise has to repeat ten times, three set and minimum three times a week.
PHASE 2 The exercises begin at the fifth week to week six postpartum.	To integrate the abdominal muscle work and pelvic muscle.	 Posterior pelvic tilt Pelvic Clock's Bridging 	All the exercise has to repeat ten times, three set and minimum three times a week.
PHASE 3 The exercises begin at week seven to week 8 postpartum.	To strengthen the abdominal muscle.	 Crunch Plank Russian Twist 	All the exercise has to repeat ten times, three set and minimum three times a week.

3.8.3 Video on STEP

Beside pamphlet, video on how to perform exercises was produced and given to the participants via WhatsApp. The video consists of threes part on how to perform the exercise according to phase. It was sent to the participant according to the postpartum week i.e. week 1 to week 4 first video consist of the first phase was sent and followed by the second video at week 4 to week 6 and lastly the third video of the phase 3 at week 7 and 8. The duration of each video is within 3 minutes.

3.8.4 STEP reminder

Telephone calls were made once a week to ask for problems facing on complying to exercise. This is part of the procedure to ensure compliance to exercise.

3.9 Data analysis

Data were entered and analysed using SPSS version 24. The mean difference of DRA size within the groups and between the intervention and control groups were analysed using paired t-test and independent t-test, respectively. The difference in PFM function post-intervention between groups was analysed using independent t-test. As the data of perceived urinary distress were not normally distributed, Mann Whitney U test and Wilcoxon Rank test was performed to analyse the mean differences between and within groups. Lastly, the correlation of DRA and PFM function and perceived urinary distress were analysed using Pearson correlation coefficient (r) and Spearman correlation.

3.10 Ethical issues

The study was approved by the institutional ethics committee both from University Sains Malaysia (USM/JEPeM/17090395) (Appendix A) and University Kebangsaan Malaysia Human Research Ethics Committee (FF-2018-051) (Appendix B) and registered at Thai clinical trial. The trial registration number was TCTR20190904005. Potential participants who met the study criteria were fully informed of the research purposes, intervention benefits and risks, procedures, and were asked to sign a consent form. During the informed consent process, participants were also be informed on the precautions that will be taken to protect the confidentiality of the data which only the researcher and team members had access to the data. Through out the process of data analysis, interpretation, reporting and presentation, the respondent were not been identified individually and the data were anonymous.

CHAPTER 4

RESULT

The purpose of this study was to investigate the effectiveness of abdominal exercise program (STEP) on the size of DRA. It is further examined the changes in PFM function, UI symptoms and the relationship of these with the size of DRA in postpartum mother.

4.1 Participants enrolment

A total of 114 participants primigravidae were identified, fulfilling the inclusion criteria and were invited to participate in the study. All participants were screened for the presence of DRA using finger width palpation. Out of them, 33 participants were excluded because they did meet the DRA criteria, and 6 participants did not get interested in participating. There were only 57 participants who met all study criteria and agreed to participate. Participants who agreed to participate in the study were provided with a complete description of the study procedure as well as signing the inform consent form. The participants then were randomly divided into two groups, the intervention and the control group. The intervention group consisted of 28 participants and control group 29 participants. However, some participants were excluded from the study for various reasons, including inaccessibility (n=6) at postnatal and refused to complete the study (n=10). The final number of participants completed this study was 41, 21 participants in the intervention group and 20 in control. Figure 4.1 shows the participants entry process into this study.

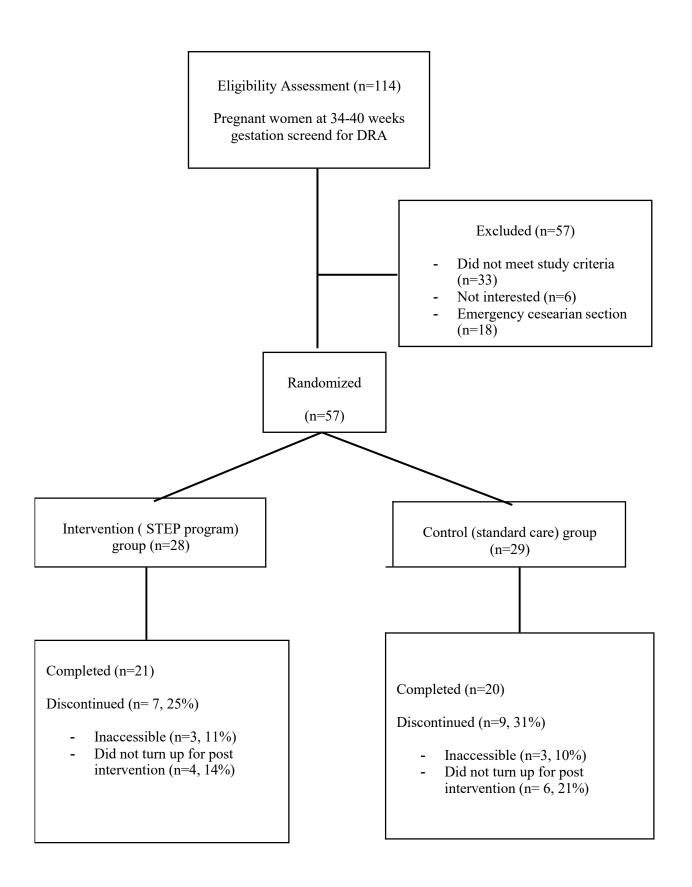


Figure 4.1: CONSORT diagram explaining the participants' enrolment

4.2 Participant enrolment and compliance

Overall the involvement of all participants was good with 76% of them present during data collection sessions. For intervention groups, all participants are committed and provide good cooperation. It is found that most participants are working hard to comply with the exercise regime provided. All participants in the intervention group completed the recruitment booklet. The booklet was given after a mother giving birth and returned during the next data collection session. Based on a booklet, all 90% of participants in the intervention group completed the 3 phases of exercise regime within 8 weeks confinement duration at minimum, performing the exercise 3 times a week. The reason for the participants did not comply with the exercise is due to the health status of their baby. It can, therefore, be concluded that the participants' compliance level on this intervention module was very good.

4.3 Demographic and characteristics of the study population

Majority of study participants were Malays, i.e. 36 (87.8%), followed by Chinese (7%) and others (5%). Their mean age was 28 (SD=3.6) years old, and the mean body mass index, BMI was 27.5 (SD=4.9) kg/m2. The highest level of education for most participants (80.5%) was tertiary education (college/university), and most of them were (78%) working mothers. In term of health status, most of them were healthy (85%), and only 15% have either diabetes or hypertension. In this study, pelvic girdle pain at the third trimester of pregnancy was complaint by 68% of the participants. There was no significant difference for the health status and demographic characteristics of the study participants between the intervention and the control groups (Table 4.1)

Table 4.1: Characteristic of primigravida mother with diastasis recti abdominal in Kuala Lumpur (n=41)

	Freque	ncy (%)		
	Control	Interventional		
	group	group	p-value	
Variable	(n=20)	(n=21)		
Maternal age (years)	29 (4.06) ^β	27 (2.96) ^β	0.185a	
Height (cm)	$156 (6.84)^{\beta}$	$158 (4.96)^{\beta}$	0.647^{a}	
Body weight (kg)	, ,	` ,		
Weight at pregnancy	$68 (17.36)^{\beta}$	$68 (9.53)^{\beta}$	0.465^{a}	
Weight at postpartum	$56(16.69)^{\beta}$	$58(9.15)^{\beta}$	0.267^{a}	
BMI (kg/m^2)	, ,	,		
BMI at pregnancy	$26 (9.52)^{\beta}$	$26 (6.77)^{\beta}$	0.676^{a}	
BMI at postnatal	$21 (8.91)^{\beta}$	$22(5.69)^{\beta}$	0.375^{a}	
Ethnicity	,	,		
Malay	17 (85.0)	19 (90.5)	0.810^{b}	
Chinese	2 (10.0)	1(4.8)		
Others	1 (5.0)	1(4.7)		
Education level				
Secondary	5 (25.0)	3 (14.3)	0.454^{c}	
Tertiary	15 (75.0)	18 (85.7)	0.151	
Work status	(, - : -)	()		
Working	17 (85.0)	15 (71.4)	0.454°	
Not working	3 (15.0)	6 (28.6)		
Antenatal health status				
Healthy	15 (75.0)	20 (95.0)	0.158^{b}	
Hypertension	2 (10.0)			
Diabetes	3 (15.0)	1 (5.0)		
Pelvic Girdle Pain at pregnancy, yes	13 (65.0)	15 (71.4)	0.658^{b}	
Pelvic Girdle Pain at postpartum, yes	7 (35.0)	10 (50.0)	0.412^{b}	
Intrapartum history				
Duration of second stage of labour (minute)	$24 (15.81)^{\beta}$	$26 (19.73)^{\beta}$	0.814^{a}	
Neonatal birth weight	$3(0.38)^{\beta}$	$3(0.27)^{\beta}$	0.273^{a}	
Episiotomy, yes	10 (50.0)	16 (76.0)	0.082^{b}	
Tear, yes	5 (25.0)	3 (14.0)	0.454^{c}	
Confinement practice				
Confinement massage, yes	8 (38.0)	6 (30.0)	0.796^{b}	
Confinement corset, yes	15 (71.4)	15 (75.0)	0.440^{b}	
Breastfeeding, yes	17 (80.9)	16 (80.0)	0.697^{c}	
Carer during confinement				
Husband	4 (19.0)	3 (15.0)	0.743^{b}	
Mother	12 (57.1)	15 (75.0)		
Mother in law	4 (19.0)	3 (15.0)		

β Mean (standard deviation)

The Mann Whitney-U test

Chi-square test

Fisher's exact test

4.4 Lower urinary tract symptoms among mothers with diastasis recti abdominal

Table 4.2 showed the presence of UI among participants at baseline or during antepartum. The result showed that more than half of participants reported nocturia and frequency in urination. Among those complaints of having nocturia, 35% of them wakes up more than twice at night to urinate. Mother having a urinary frequency, 58% urinate more than 8 times during the day. Meanwhile, only 32% of participants reported SUI, with almost 12% suffered urinary leakage weekly. The least reported UI symptom was urgency (24%) that appeared monthly toward the end of the trimester.

Table 4.2: Lower urinary tract symptoms (LUTS) among mothers with diastasis recti abdominal in Kuala Lumpur (n=41)

	Number (%)	Severity of symptoms Number (%)		
Stress urinary incontinence	13 (31.7)	Monthly 8 (19.5)	Weekly 5 (12.2)	Daily -
Urgency	10 (24.4)	10 (24.4)	-	-
Frequency	24 (58.5)	8 -12 / day 16 (39.0)	13 – 16/ day 7 (17.1)	>=17/ day 1 (2.4)
Nocturia	26 (63.4)	Twice/ night 12 (29.3)	3 -4 / night 13 (31.7)	>= 5 / night 1(2.4)

4.5 Perceived urinary distress among mothers with diastasis recti abdominal

At the baseline, the majority of the participants perceived frequent urination as the symptoms that troubling them the most during pregnancy (73.2%). Other urinary symptoms such as leaking urine on urgency and related to activity, coughing or sneezing only troubling 18% to 30% of the mothers. The least disturbing was difficulty emptying the bladder (<10%). Almost half (46.8%) of the mothers reported having pain and discomfort in lower abdominal

during pregnancy, which makes it the second-highest troubling symptoms complaint by the participants. Refer to Table 4.3.

Table 4.3: The severity of perceived urinary distress among mothers with diastasis recti abdominal in Kuala Lumpur (n=41)

Questions		Perceived urinary distress Frequency (%)				
	Not at all troubling	Slightly troubling	Moderately troubling	Greatly troubling		
	11 (26.8)	14 (34.1)	14 (34.1)	2 (4.9)		
d to feeling of	30 (73.2)	8 (19.5)	2 (4.9)	1 (2.4)		
	34 (82.9)	5 (12.2)	2 (4.9)			
of leakage (drops)	34 (82.9)	6 (14.6)	1 (2.4)			
tying bladder	37 (90.2)	4 (9.8)				
	22 (53.7)	13 (31.7)	4 (9.8)	2 (4.9)		
֡֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜	tion d to feeling of d to activity, eezing of leakage (drops) tying bladder fort in lower enital area	troubling tion d to feeling of 30 (73.2) d to activity, eezing of leakage (drops) tying bladder 37 (90.2)	Not at all troubling Slightly troubling	Not at all troubling Slightly troubling Troubling Troubling Troubling Troubling		

4.6 The impact of UI on quality of life in mothers with diastasis recti abdominal

Table 4.4 showed the results of QOL associated with UI based on IIQ-7 questionnaire. A small percentage of participants (17 out of 41) reported UI slightly affects their QOL participants. Majority of participants claimed that UI does not disturb them at all in performing their activity as listed, such as household chores, physical recreational, etc. Most of the questionnaire left untick, which make the form are not qualified for analysis.

Table 4.4: The impact of urinary incontinence on quality of life using the IIQ-7 questionnaire (n=17)

Activities	Not at all (0)	Slightly (1)	Moderately (2)	Greatly (3)
Household chores	39 (95.1)	2 (4.9)		
Physical recreation	37 (90.2)	4 (9.8)		
Entertainment activities	39 (95.1)	2 (4.9)		
Travel > 30 minutes away from home	39 (95.1)	2 (4.9)		
Social activities	38 (92.7)	3 (7.3)		
Emotional health (nervousness, depression, etc.)	40 (97.6)	1 (2.4)		
Feeling frustrated	39 (95.1)	2 (4.9)		

^{*}Data presented as frequency (%)

4.7 Baseline DRA size, perceived urinary distress and urinary incontinence impact on the quality of life

Table 4.5 shows the baseline results of the DRA size, the score for perceived urinary distress and the score for urinary incontinence impact on the QOL. Generally, pregnant women who participated in this study had a mean DRA size of 21.6 mm (SD=5.17) measured at the 2.5 above umbilical. The mean score for perceived urinary distress indicates that participants only had very minimal perceived urinary distress which is 7.59. In contrast, the mean score for the impact of UI on QOL was 0.85 based on 17 subjects that were filling all the questions in the form.

Table 4.5: Baseline DRA size, perceived urinary distress and urinary incontinence impact on the quality of life in primigravida mother with diastasis recti abdominal in Kuala Lumpur (n=41)

Clinical measurement	Mean (SD)
DRA size (mm)	21.61 (5.17)
Perceives urinary distress score	7.59 (3.59)
Urinary incontinence impact on QOL score (n=17)	0.85 (2.31)

4.8 The changes in DRA size following STEP intervention

The effect of the STEP intervention was assessed on the DRA changes between groups and within groups comparisons.

4.8.1 Between-group changes of DRA size

The difference in the DRA size between control and the intervention groups were presented in table 4.6. Results show that at the baseline, the DRA size was 2.54 mm larger in the intervention groups compared to the control group. However, the difference was not significant. Both groups had a reduction in the size of DRA at the post-intervention even though the difference was not statistically significant. Clearly, the DRA size in the intervention group was much reduced than the control group.

Table 4.6: Mean DRA size between control and intervention groups (n=41)

	Mean (SD)		Mean size	t-statistic	<i>p</i> -value*	
	Control n=20	Intervention n=21	difference (95% CI)	(df)		
Baseline	20.3 (4.82)	22.9 (5.31)	2.54 (-0.66, 5.75)	1.60 (39)	0.117	
Post- intervention	18.7 (5.35)	16.7 (3.55)	-1.96 (-4.82, 0.88)	-1.39 (39)	0.171	

^{*}Independent t-test

4.8.2 Within-group changes of DRA size

Further analysis comparing the mean size of DRA within groups at baseline and post-intervention was performed using paired t-test (Table 4.7). There was a significant intervention effect at p< 0.001 level in the intervention group. Following STEP intervention, DRA size reduced up to 27% as compared to 8.2% in the control group.

Table 4.7: Comparison of mean DRA size within each group (n=41)

Group	Mean (SD)		Mean difference	t-statistic (df)	<i>p</i> -value*	
	Baseline	Post- intervention	(95% CI)	(41)		
Intervention (n=21)	22.9 (5.30)	16.7 (3.55)	6.2 (3.7, 8.7)	5.2 (20)	<0.001	
Control (n=20)	20.3 (4.82)	18.7 (5.34)	1.66 (-1.3, 4.6)	1.2 (19)	0.260	

^{*}Paired t-test

4.9 The changes of PFM strength and endurance between intervention and control group

The PFM strength and endurance was assessed during postpartum in both groups. The intervention group shows a statistically significant difference in PFM strength (p=0.003) and PFM endurance, as presented in Table 4.8.

Table 4.8: Comparison of PFM strength and endurance between control and intervention groups (n=41)

	Mean (SD)				
variables	Control group (n=20)	Intervention group (n=21)	Mean diff (95% CI)	t-statistic (df)	<i>p</i> -value*
Pelvic floor muscle strength	15.25 (6.00)	21.14 (6.01)	5.89 (2.10,9.68)	3.15 (39)	0.003
Pelvic floor muscle endurance	3.60 (1.35)	4.71 (2.07)	1.11 (0.01, 2.22)	2.05 (34)	0.049

^{*}Independent t-test

4.10 The changes in perceived urinary distress following STEP intervention

4.10.1 Between-group changes in perceived urinary distress

As the data of perceived urinary distress were not normally distributed, the Mann Whitney U test was used to compare the difference in perceived urinary distress score between the intervention and control group before and after STEP intervention. There were no significant differences in perceived urinary distress score between groups (Table 4.9).

Table 4.9: Comparison of perceived urinary distress using the UDI-6 score between control and intervention groups (n=41)

	Median score (IQR)		_	
Measurement time	Control group n=20	Intervention group n=21	Z	<i>p</i> -value*
Baseline	8.50 (3)	8.00 (3)	168	0.272
Post-intervention	6.00 (1)	6.00(3)	198	0.597

^{*}Mann Whitney U-test

4.10.2 Within-group changes in perceived urinary distress

Table 4.10 shows significant improvement in perceived urinary distress in both intervention and control group (p<0.001). Wilcoxon test was used in this analysis as the data was not normally distributed.

Table 4.10: Comparison of perceived urinary distress using the UDI-6 score within each group (n=41)

Groups	Median			
	Baseline	Post- intervention	Z	<i>p</i> -value*
Intervention group (n=21)	8.00(3)	6.00(3)	-3.545	< 0.001
Control group (n=20)	8.50 (3)	6.00(1)	-3.854	< 0.001

^{*}Wilcoxon test

4.11 Correlation of DRA size between PFM function and perceived urinary distress

The measured DRA size and PFM function at postpartum were analysed using the Pearson correlation coefficient. Whereas the DRA size and perceived urinary distress at postpartum were analysed using Spearman correlation, as shown in Table 4.11. Results show an inverse correlation between DRA size and PFM strength and PFM endurance. There was a

positive correlation between DRA size and perceived urinary distress. However, all correlations were very weak and not significant. The three correlations were presented by the scatter plot (Figure 4.2, Figure 4.3 and Figure 4.4).

Table 4.11: Correlation of DRA size between PFM function (strength and endurance) and perceived urinary distress score at postpartum primigravida mother with DRA (n=41)

	Correlation coefficient, r (p-value)			
Variables	PFM strength score	PFM endurance score	Perceived urinary distress score	
Diastasis recti abdominal	-0.103 (0.520) ^a	-0.09 (0.575) ^a	0.101 (0.531) ^b	

^a Pearson correlation

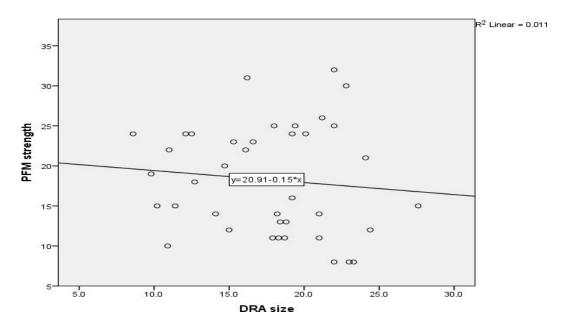


Figure 4.2: Scatterplot of correlation between DRA size and PFM strength

^b Spearman correlation

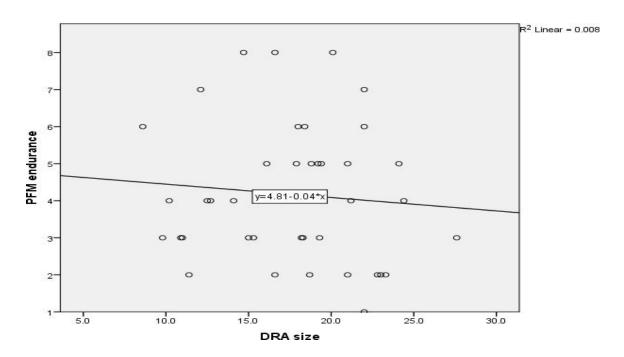


Figure 4.3: Scatterplot of correlation between DRA size and PFM endurance

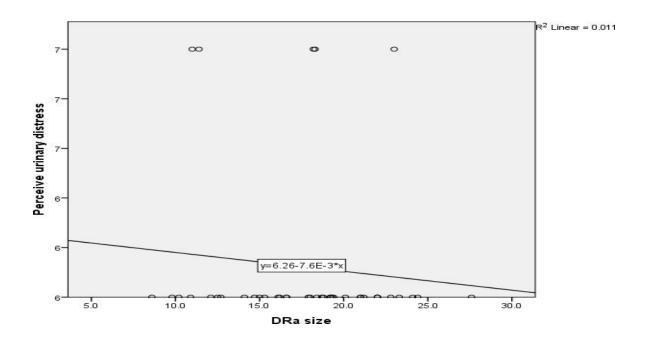


Figure 4.4: Scatterplot of correlation between DRA size and perceived urinary distress score

CHAPTER 5

DISCUSSION

5.1 Introduction

Generally, this research found STEP have positive effects on the reduction in DRA size. This chapter further discusses the findings, starts with a summary of the key findings, the theoretical support for the results, the quality of the study design and methods, and finally, the implications of the findings.

5.2 STEP Intervention for DRA management

The purpose of this study was to investigate the outcome of the abdominal exercise programs known as Split Tummy Exercise Programs (STEP) on the size of DRA and PFM functions in mothers diagnosed with DRA during pregnancy and also to determine the relationship between the size of DRA, PFM functions and perceived distress of UI.

The STEP program was explained via a face-to-face basis and instructed to be performed by mothers during the confinement period from week 1 to week 8. The study was conducted in a teaching hospital in Kuala Lumpur and was designed to measure the outcomes that are typically available and practicable for clinic use. Pregnant mothers who participated in this research were randomised into two groups. The intervention group received STEP module, and the control groups continued with routine postpartum care in the hospital setting. It was hypothesized that those participants in the STEP intervention would have significant improvement across all measured outcomes as compared to the control group.

5.3 Baseline characteristic

In this study, the sample size ended up smaller than the calculated number of sample. The estimated number of participants was 62 mothers using a power of 0.80. Throughout the study process, a significant number of mothers end up with caesarean delivery. Due to that, 75 mothers were recruited, that is more the calculated sample needed. However, the final number of mothers who participated was 41, with the attrition rate of 45% for the intervention group and 46% in the control group. Of those, 20 participants were in the STEP intervention group and another 21 in the control group. The small sample size partly was due to exclusion criteria which excluded women who delivered via caesarean section, and 30% of women in this study delivered their baby by caesarean section. Women who delivered via a caesarean need to be ambulated earlier to prevent post-operative complications, and the initial aims of treatment would be bed mobility and walking within the room (Kaur & Sikka, 2015). Thus, it is not a suitable time to start strength training of abdominal muscle immediate after delivery as its required a longer waiting period for proper recovery and healing of the incision site. STEP start at day one or 24 hours after birth and to control the bias, women delivered through caesarean were excluded from this study.

The LUTS questionnaire was administered to determine the presence of UI. Out of 41 participants, only 17 participants claimed to have an incidence of urine leaking throughout pregnancy. Results of the questionnaire were presented descriptively. At baseline, there were no significant differences among the two groups of participants, that is the STEP intervention and the control groups.

5.4 The effect of STEP intervention on DRA size

It is agreeable that DRA is one of impairment that affects the anterior abdominal wall, and the best method to restore it is by performing the abdominal exercise (Benjamin et al., 2014). Strong abdominal muscles associated with improvement in function and increasing the recruitment of muscle fibres (Boissonnault & Blaschak, 1988; Lee et al., 2008). By focusing on abdominal training as in STEP module, it is believed to shorten the anterior and lateral fibre of abdominal muscle, thus reducing the size of DRA. Therefore, in this study, it was hypothesised that the STEP group would show greater reduction in DRA size than the control group.

At the baseline, the size of DRA in the STEP intervention group was much bigger than the control group. Even though both groups show a reduction in the size after 8 weeks, but the changes in the control group (8.2% reduction) was not statistically significant between baseline and post-intervention. Whereas in the STEP intervention group showed a larger reduction (27%) in mean DRA size from 22.9 mm to 16.7 mm after 8 weeks, which was statistically significant. The result of this study is somewhat lower than what has been reported in a study done by El-Mekawy et al. (2013) reported a 33 % reduction in the mean DRA size. However, the reduction in DRA size in this study is considered larger compare to the study by Walton et al. (2016), showing only 0.2% mean DRA reduction. Different in the severity at baseline and the prescribed intervention may have contributed to the difference in results from the present study and Walton (2016) study. The baseline measurement of DRA size in Walton et al. (2016) study was very small, which is less than 15 mm somehow consider normal as stated by beer et al. (2009) classification of DRA. Subjects in both studies are parous women with more than one children (El-Mekawy et al., 2013; Walton et al., 2016).

At the moment, there is little evidence suggesting which abdominal exercises are most efficient in reducing DRA, and most of the study combined a few types of abdominal exercises to be completed at a particular duration. The present study, targeting and focusing on different abdominal muscles activation at different phases, starting with TrA activation and gradually progress it to RA activation and lastly whole abdominal muscle contraction. This might explain the significant reduction in the DRA observed in the current study. The first phases of STEP focusing on facilitation and engaging TrA. Engaging the TrA was achieved with isometric contraction of the abdominal muscle by pulling it in and then slowly moves the upper limb and lastly moving the lower limb alternately while keep engaging the TrA. This phase was performed for 3 weeks, minimum 3 times per week with 10 repetitions as included in the STEP module (Table 3.3).

Activation of TrA are effective yet crucial in the management of DRA and been well documented (Acharry & Kutty, 2015; El-Mekawy et al., 2013). It is believed that activation of the TrA bilaterally may eventually stabilise the ribs, linea alba and thoracolumbar fascia thus reduce the DRA gap as the RA shorten. It has been suggested as one of the abdominal exercises that able to protect the linea alba and may help to prevent and reduce the DRA as well as speed up recovery (Benjamin, 2014). There is one study that unagreeable with the current study (Mota et al., 2015). This study involves 84 primigravida women in which the measurement of DRA size was taken at 4 times, once during pregnancy at 35 weeks to 41 gestations and 3 more during the postpartum period at 6-8 weeks, 12-14 weeks and 24 – 26 weeks. The result showed that DRA size was slightly wider in the group that performing the TrA activation compared to the group that performed the abdominal crunch. Nevertheless, the participants in this study were randomly selected immediately after delivery in which there are not classified as having DRA.

STEP module is different compared to other abdominal exercise programs in the previous studies (Khandale & Hande, 2016; Walton et al., 2016). STEP module comprises of

progressive training as it is an essential safety element from isometric contraction to strengthening training. The progression of exercises from phase 1 to phase 3 allowed individual abdominal muscles to be trained and toward phase 3, it is expected the whole abdominal muscles were recruited in order to produce a maximal and strong abdominal contraction. In Phase 1, deep muscle activation was generated through TrA action. It was assumed that tension generated from deepest abdominal muscle would reduce the abdominal horizontal diameter in such a way that horizontal force will be generated wherein will improve RA approximation thus draw the belies of RA together, improve the integrity of the linea alba and increase fascia tension allowing efficient load (Khandale & Hande, 2016; Liaw et al., 2011).

To perform the exercise at phase two of STEP module, it is important to keep engaging the TrA for maximum and effective contraction. One of the effects of pregnancy is lengthening and weaken abdominal muscle with shortening of the lower back muscle, which explained back pain and discomfort during pregnancy (Candido et al., 2005). Thus it is crucial to integrate the pelvis movement, especially by performing the pelvic tilt and pelvic clock as this help to reverse the effect of pregnancy by shortenings the RA and lengthening the lower back muscle. Lastly, bridging will improve overall abdominal and hip muscle strength to support the body and preparation for strengthening exercise in phase 3.

Phase 3 aims to strengthen the abdominal muscles that involve abdominal crunch, plank and Russian twist. Phase 3 starts at week 7 after delivery and onward. For postpartum mothers, this is the best and safest time to start strengthening abdominal exercise as the uterus already healed and shrink to almost normal size. Almost all interventional studies on DRA (Pascoal et al., 2014; Walton et al., 2016) suggested abdominal crunch as an effective method to strengthen the abdominal muscle. Pascoal et al. (2014) indicated that crunch exercise is effective if performed in combination with isometric abdominal exercise in narrowing the DRA compared to isolation training. This study compared the postpartum to nulliparous women in which

postpartum women had larger DRA size, and both groups had a reduction in DRA size after adding isometric contraction while performing crunch exercise. It is believed that the gap of DRA closer much faster by performing crunch exercise, the same with plank and Russian twist. In addition, Walton et al. (2016) comparing traditional abdominal exercise and abdominal exercise with a plank, which revealed plank exercise adding to abdominal programs were more effective in restoring abdominal function and reducing the DRA size.

Despite the type of exercises, the timing of exercise also important criteria considered in the STEP module for its effectiveness. Most of the study started the exercise at 1 month or 6 weeks after delivery, but, the present study began within 24 hours after delivery. This suggests that in the early postpartum period, exercises seem to be effective, so this can be a nonsurgical solution for the DRA (Acharry & Kutty, 2015). As mentioned earlier, at the moment, intervention research on exercise program prescribed for DRA mother at the postpartum period was a combination of various exercise however present study focusing on different abdominal training which gradually progresses according to phases. In conclusion, STEP module performed regularly during the confinement period eventually improve the strength of the abdominal muscles thus support the spine and the back muscle during functional activity as commented by Mahalaksmi et al. (2016).

5.5 The effect of STEP intervention on PFM functions

PFM functions represent PFM strength and endurance. The result showed significant improvement in PFM strength and endurance in the STEP intervention group compared to the control group after 8 weeks of intervention. The changes in the experimental group verify that by training the abdominal muscles, it enhances the PFM function. Hence, the significant improvement in PFM strength and endurance in STEP group may be attributed by the type of exercise selected such as TrA activation at phase 1, pelvic tilt at phase 2 and crunch exercise at

phase 3 in which already proven to simultaneously activate PFM contraction. The results prove that activation of abdominal muscles particularly TrA simultaneously produce positive effects on the PFM.

These findings are consistent with previous research reported by Bo et al. (1990). They demonstrated that RA only contracts at maximum voluntary PFM contraction but not at submaximal contraction, measured using a surface electrode. Its was further confirmed by a few groups of researchers using concentric EMG which found that both PFM and abdominal muscle work in synergy not only during PFM contraction but also during straining, pelvic tilt, abdominal curl-ups, gluteal and hip abductor contraction in normal population (Bo and Stein, 1994). In addition, Sapsford (2012) further confirmed that TrA contracts during PFM contraction in healthy participants. Based on these studies, they recommended that PFM training could be conducted indirectly by contracting the TrA only. It could be concluded that DRA mothers who perform STEP program not only reduce the DRA size but would benefit their PFM as well. Ther is vast evident that improves PFM strength and endurance may enhance the quality of life in women (Radzimińska et al., 2018).

5.6 The effect of STEP intervention on perceived urinary distress

In this study, the most reported UI symptoms among mothers with DRA was nocturia and frequent urination. These findings in contrary to previous evidence that demonstrated SUI and UUI are the most reported symptoms among pregnant mothers (Rogers et al., 2017). Even though the result shows significant improvement in perceived urinary distress in the STEP intervention group, a similar result was also found in the control group. It indicates that UI symptoms in the study population could be a transient UI as the majority of the women reported subsiding in symptoms less than 8 weeks after delivery (Thom & Rortveit, 2010). The complaint of UI in this study possibly due to the result of the progression of pregnancy as the

weight of the baby and uterus pressed on the PFM subsequently contribute to the UI symptoms especially frequent urination as found in this study.

5.7 Correlation between DRA and PFM functions and perceived urinary distress

Correlational analysis was performed between DRA size, PFM strength and endurance as well as perceived UI distress score. The current study found a negative weak and non-significant correlation between PFM strength (r=-0.103, p=0.520) and DRA size as well as between PFM endurance and DRA size (r=-0-09, p=0.575). These indicate that the size of DRA does not correlate with the function of PFM, and the presence of DRA is independent that does not influence the PFM functions. This finding is similar to the recent cohort study by Bo et al. (2018), who reported that women with PFM dysfunction did not correlate with the size or the presence of DRA.

Similarly, the correlation between DRA size and perceived urinary distress symptoms demonstrated a weak positive and non-significant correlation. Again, the presence of DRA does not influence the perceived urinary distress symptoms among participants. It could be assumed that the presence of UI was due to pregnancy effects. Thus, the result of this study showed that pregnancy itself might affect PFM and UI symptoms. As proposed earlier (Figure 1.1), DRA may result in the incidence of PFM dysfunction and UI. However, this study showed otherwise which the presence of PFM dysfunction and UI are due to the direct effects of pregnancy. The presence of DRA during pregnancy is not the factor of developing PFM dysfunction and UI. Improvement in PFM function in the STEP group as a result of abdominal exercise may not have reflected as the changes in perceived stress UI as this symptoms may appear partly due to the loading of the uterus and abdominal content into the bladder which causes bothersome feeling among pregnant mother.

5.8 Strengths and limitations of the study

This study used RCT as study design. This is considered as the prime strength for this current research. This is important to determine the effects of STEP on DRA closure and also allow for a standardisation of STEP intervention. Bias in the study was eliminated by randomisation and blinding. In this study, two physiotherapists were trained and blinded to conduct the assessment of DRA and PFM function without knowledge of the group allocations.

The second strength is the use of responsive, reliable and valid measurement tools to assess DRA and PFM function. For instance, the use of US in which its already proven as a gold standard for DRA measurement. Furthermore, many previous studies using the US were-non-randomized, uncontrolled and unblinded. Another strength of this study is the stage of exercise been progress in STEP module, which can also be used in future studies. Each phase of the exercise programme was gradually progress from isometric muscle contraction to strength training of the muscle. The progression was not overly challenging to the patients, and the exercises were simple enough for the participants to complete successfully. Furthermore, STEP did not require the use of equipment thus, feasible to be performed in clinical setting.

The main limitation of this study is the small sample size. Our study examined first-time pregnant women at 34 weeks gestation onward in which the pregnant uterus is considerably enlarged. Based on the previous study, the incidence of DRA among women at third trimester was higher as much as 100% ((Boissonnault & Blaschak, 1988) however, out of 114 participants screening for DRA at baseline, only 81 (71%) participants had DRA more than 2 finger-width in which affect the number of participants despite 24% of participants were excluded immediately after caesarean delivery.

Another limitation was the exercise sessions performed at home could not be supervised, and the participants were only motivated to perform the exercises by explaining the

complications of DRA. Most of the participants have some difficulty to come for supervised training at the outpatients' clinic. Thus, monitoring was done through a telephone call and message through WhatsApp application as a reminder to ensure compliance toward STEP exercise at home but still no witness on the actual exercise practice among them. Part of that, an exercise diary filled by the participants was used to verify patients compliance toward exercise.

Apart from that, some of the participants missed and cancelled the follow-up assessment which was scheduled after 8 weeks postpartum due to so many reasons such as still in the confinement period and not allowed to go out from the house. The appointment sometimes extended to 10 weeks, and if not control may cause a threat to internal validity.

CHAPTER 6

CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

The effects of pregnancy on the abdominal muscles should not be ignored. As the tissue of linea alba softens due to the effects of the hormone, the point of attachment of the abdominal muscle is jeopardised and should be protected during pregnancy and the postpartum period. Even though exercise is proven benefited in DRA reduction, but the comparison between study is difficult due to the difference in outcome measure, cut point of value and measurement location of the DRA. There is minimal study investigate the effects of abdominal exercise on the reduction of the DRA size and this present study prove that by training the abdominal muscle is adequate to reduce the DRA size as well as improvement in the PFM function.

In this study, the STEP intervention group had a greater and significant reduction in DRA size. This indicates that the STEP module targeting an abdominal exercise results in TrA activation as well as improving the RA strength. Finally, it helps to reduce the DRA gap and improve PFM strength and endurance. This study also proposed that the presence of DRA will eventually lead to PFM dysfunction and worsening UI symptoms. However, the result of correlation indicates that PFM dysfunction and UI symptoms are not related to the presence of DRA but are mostly due to the effect of pregnancy and expected to diminish at the postpartum period.

6.2 Recommendations

The STEP module is proven effective to be used as part of the training program during postnatal class, which the effect not only for DRA closure but also improving in PFM function.

Some improvement in term of adding specific exercise focusing on PFM training can be made to further improve the perceived urinary distress symptoms.

The study revealed that DRA could be treated earlier thus, it is recommended to measure the presence of DRA immediate after delivery. This study used 2D ultrasound, which is considered to be one of the gold standards for DRA measurement, but it is big and immobile. If possible, mobile and the hand-carry US should be used widely in the clinical setting to ease the process of DRA measurement in which later the home supervision more comfortable to be conducted, not only for preventive measures but also for the research purposes. Indirectly, it could prevent high drop out among participant as the tool are handy and easy to carry for home use.

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APPENDICES

Jawatankuasa Etika

Universiti Sains Malaysia

: jepem@usm.my : www.jepem.kk.usm.my

Penyelidikan Manusia USM (JEPeM) Human Research Ethics Committee USM (HREC)

Universiti Sains Malaysia Kampus Kesihatan, 16150 Kubang Kerian, Kelantan, Malaysia T : (6)09-767-3000/2354/2362 F : (6)09-767-2351

APPENDIX A: USM Ethic form (JEPeM)



30th November 2017

Assoc. Prof. Dr. Nik Rosmawati Nik Husain Department of Community Medicine School of Medical Sciences Universiti Sains Malaysia 16150 Kubang Kerian, Kelantan.

JEPeM Code : USM/JEPeM/17090395

Protocol Title : The Effectiveness of Abdominal Exercise Program on Diastasis Rectai Abdominal

(DRA) and Pelvic Floor Muscle Function in Primipara with Antepartum DRA.

Dear Dr.,

We wish to inform you that your study protocol has been reviewed and is hereby granted approval for implementation by the Jawatankuasa Etika Penyelidikan Manusia Universiti Sains Malaysia (JEPeM-USM). Your study has been assigned study protocol code USM/JEPeM/17090395, which should be used for all communication to the JEPeM-USM related to this study. This ethical clearance is valid from 30th November 2017 until 29th November 2018.

Study Site: Pusat Perubatan Universiti Kebangsaan Malaysia (PPUKM).

The following researchers also involve in this study:

- 1. Dr. Ixora Kamisan Atan
- 2. Miss Suhaila Shohaimi

The following documents have been approved for use in the study.

1. Research Proposal

In addition to the abovementioned documents, the following technical document was included in the review on which this approval was based:

- 1. Participant Information Sheet and Consent Form (English version)
- 2. Participant Information Sheet and Consent Form (Malay version)
- 3. Data Collection Form
- The Incontinence Impact Questionnaire and the Urogenital Distress Inventory (IIQ-7 & UDI-6) Questionnaire

Attached document is the list of members of JEPeM-USM present during the full board meeting reviewing your protocol.

While the study is in progress, we request you to submit to us the following documents:

- Application for renewal of ethical approval 60 days before the expiration date of this
 approval through submission of JEPeM-USM FORM 3(B) 2017: Continuing Review
 Application Form. Subsequently this need to be done yearly as long as the research goes on.
- Any changes in the protocol, especially those that may adversely affect the safety of the
 participants during the conduct of the trial including changes in personnel, must be
 submitted or reported using JEPeM-USM FORM 3(A) 2017: Study Protocol Amendment
 Submission Form.

CERTIFIED BY:

National Pharmaceutical Regulatory Agency (NPRA) Forum for Ethical Review Committees in Asia & Western Pacific Region

- Revisions in the informed consent form using the JEPeM-USM FORM 3(A) 2017: Study Protocol Amendment Submission Form.
- 4. Reports of adverse events including from other study sites (national, international) using the **JEPeM-USM** FORM **3(G) 2017: Advene Events Report.**
- 5. Notice of early termination of the study and reasons for such using JEPeM-USM FORM 3(E) **2017.**
- 6. Any event which may have ethical significance.
- 7. Any information which is needed by the JEPeM-USM to do ongoing review.
- Notice of time of completion of the study using JEPeM-U5M FORM 3(C) 2017: Final Report Form.

Please note that forms may be downloaded from the JEPeM-USM website: ww -jepem.kk.usm.my

Jawatankuasa Etika Penyelidikan (Manusia), JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.

Thank you.

"ENSURING A SUSTAINABLE TOMORROW"

Very truly yours,

PROF. DIR. HANS AMIN VAN ROSYFINBERGHE

Chairperson

Jawatankuasa Etika Penyelidikan (Manusia) JEPeM

Universiti Sains Malaysia



Date of meeting

: 29th October 2017

Venue Time

: Meeting Room, Division of Research & Innovation, USM Kampus Kesihatan.

: 9.00 a.m - 2.00 p.m

Meeting No

: 373

Jawatankuasa Etika Penyelidikan Manusia USM (JEPeM) Human Research Ethics Committee USM (HREC)

Universiti Sains Malaysia Kampus Kesihatan, 16150 Kubang Kerian, Kelantan, Malaysia T: 16(39-767 3000/2354/2362 F: 16)09-767 2351 E: jepem@usm.my

jepem@usm.my www.jepem.kk.usm.my www.usm.my

Members of Committee of the Jawatankuasa Etika Penyelidikan (Manusia), JEPeM Universiti Sains Malaysia who reviewed the protocol/documents are as follows:

Member (Title and Name) Chairperson: Professor Dr. Hans Amin Van Rostenberghe		Occupation (Designation)	Male/ Female (M/F)	Tick (/) if present when above items, were reviewed / (Chairperson)	
		Chairperson of Jawatankuasa Etika Penyelidikan (Manusia), JEPeM USM	м		
Secret Mr. M	tary: lohd Bazlan Hafidz Mukrim	Science Officer	м	-	
Meml	bers :				
1.	Associate Professor Dr. Azlan Husin	Lecturer, School of Medical Sciences	М	~	
2,	Mr. Harry Mulder	Community Representative	M	~	
3.	Associate Professor Dr. Haslina Taib	Lecturer, School of Dental Sciences	F	~	
4.	Tn. Haji Ismail Hassan	Community Representative	М	~	
5.	Associate Professor Dr. Mohtar Ibrahim	Lecturer, School of Medical Sciences	М	~	
6.	Dr. Mujahid Bakar	Lecturer, School of Health Sciences	M	1	
7.	Professor Dr. Nik Hazlina Nik Hussain	Lecturer, School of Medical Sciences	F	7	
8.	Mrs. Norleha Mohd Noor	Executive Secretary, School of Dental Sciences	F	1	
9.	Associate Professor Oleksandr Krasilshchikov	Lecturer, School of Health Sciences	М	1	
10.	Associate Professor Dr. Sarimah Abdullah	Lecturer, School of Medical Sciences	F	~	

Jawatankuasa Etika Penyelidikan (Manusia), JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.

PROFESSOR DR. HANS AMIN VAN ROSTENBERGHE

Chairperson

Jawatankuasa Etika Penyelidikan (Manusia), JEPeM

Universiti Sains Malaysia

CERTIFIED BY:

National Pharmaceutical Regulatory Agency (NPRA)



Forum for Ethical Review Committees in Asia & Western Pacific Region





Pusat Perubatan UKM

UKM Medical Centre

Rujukan : UKM FPR.4/244/FF-2018-051
Tarikh : > Februari 2018

Dr. Ixora Kamisan @ Atan Jabatan Obstetrik & Ginekologi Pusat Perubatan UKM

YBhg. Profesor/Datuk/Dato'/Datin/Tuan/Puan,

Kelulusan Menjalankan Penyelidikan.

Tajuk Penyelidikan

The Effectiveness of Abdominal Exercise Program on Diastasis Recti Abdominal (DRA) and Pelvic Floor Muscle Function in Postpartum Primigravida Diagnosed

with DRA.

Kod Projek

: FF-2018-051

Dengan hormatnya merujuk kepada perkara di atas.

Adalah dimaklumkan bahawa Jawatankuasa Penyelidikan Perubatan, Pusat Perubatan UKM bersetuju meluluskan permohonan menjalankan penyelidikan YBhg. Profesor/Datuk/Dato//Datin/Tuan/Puan bagi tajuk di atas. Butiran kelulusan seperti berikut:

Tempoh Kajian Diluluskan

25 Januari 2018 - 24 Januari 2019

Bantuan Kewangan

Tanpa Bantuan

Sila kemukakan Laporan Kemajuan setiap 6 bulan dan Laporan Akhir dalam tempoh tiga (3) bulan selepas tamat tempoh kelulusan kepada pihak Sekretariat. Kegagalan mengemukakan laporan akhir penyelidikan akan menjejaskan permohonan penyelidikan serta bantuan kewangan pada masa akan dalang.

Permohonan tambahan masa/peruntukan/pertukaran penyelidik pertu dikemukakan kepada pihak Sekretariat selewat-lewatnya satu (1) bulan sebelum tamat tempoh kelulusan. Penyelidik juga perlu memaklumkan kepada pihak Sekretariat sekiranya Penyelidik Utama telah berhenti/bersara dalam tempoh kelulusan dan melantik Penyelidik Utama yang baru. Borang-borang boleh dimuat turun dari taman web Sekretariat (http://www.ppukm.ukm.my/sppi/muat-turun-borang-penyelidikan/).

Sila pastikan juga projek penyelidikan ini telah didaftarkan di *National Medical Research Register* (www.nmr.gov.my) sekiranya penyelidikan ini melibatkan sebarang penggunaan infrastruktur/organisasi/fasiliti/kakitangan/pelajar/pesakit di hospital/klinik/organisasi di bawah Kementerian Kesihatan Malaysia.

Untuk makluman YBhg. Profesor/Datuk/Dato'/Datin/Tuan/Puan juga, salinan surat kelulusan bagi penyelidik bersama serta pelajar akan dihantar secara salinan lembut (softcopy) sahaja melalui emel. Sukacita dingatkan projek penyelidikan ini hanya boleh dijalankan setelah mendapat surat ketulusan daripada Jawatankuasa Etika Penyelidikan UKM.

Sekian, terima kasih.

Sekretariat Penyelidikan Perubatan & Inovasi, Pusat Perubatan Universiti Kebangsaan Malaysia,
Tingkat 15, Bangunan Praklinikat, Jalan Yaacob Latif, Bandar Tun Razak, 56000 Cheras Kuala Lumpur, Malaysia,
Telefon: +603-9145 5002 / 5003 / 9480 / 9481 / 9496 / 9497 / 9498 / 9499 Faksimiti: +603-9145 6634
E-met: sppi@ppukm.ukm.edu.my Laman Web: http://www.onukm.edu.my Laman Web: http://www.onukm.edu

UNIVEFLSITI EBANGSAAN LAYSIA

The National University of Malaysia

Prisat Peilgurusan Peny eiidikan dan Instrumentasi

Centre for Research an d Instrumeniarion Management

Rujukan: UKM PPEJ11/8/JEP•2017•771 Tarikh: 30 Januarl 2018

Dr. koa Kamisan @ Atan Jabatan Obstetric 6 Ginekologi Hospitd Cariselor Tuanku Muhriz Pusat Perubatan tJKM

Y.8hg. Pofesor/Datuk/Data'/Datin/Tuan/Puan,

KELULU9AII ETIKA MENJALAI\IKAN PENYELIDIKAN DI UKM

Tajuk Penyelidikan: 7he E//ec/iwess 0/ébdomfia/ Exerc/se Program On 0/asfas/< Recti Abdominal

(DRA) And Pelvic Floor Musts Furx; Yion In Pastpalufn Pnm'qrav"da Diagnosed Witt

Perkara yang tersebut di atas adalah dirujuk.

2. Sukacita dimaklumkan, Jawaankuasa Etika Penyelidikan UkM melvluskm permohonan penyelidikan Y. Bhg. Profesor/Datuk/0ato'/Datin/Tuan/Puan bagi tajuk diatas. Terrpoh kelulusan penyelidikan addah daripada 25 Januarl 2018 -24 Januarl 2019. Sila kemukakan sebarang Laporan Kesan \$amplngan, **Laporan Kemajuan** Setiap 6 Bulan dan Laporan Akhir sebaik sahaja penyelidikan tamat kepada Jawatankuasa Etika Penyelidikan UKM.

3. Sukacita diingattan projek penyelidikan ini hanya boleh dijalanta/t setelah nendapat surat **kelulusan** menjalankan penyelidikan dari Timbalan Dekan Penyelidikan F-akulti atau Pengarah Pusat/Institut.

Sekian, terima kasih.

Yangdeenar,

PROFESOR DAYO DR. FUAD ISMAIL

Pengerusi

Jawatankuasa Haka enyelidikani Universiti Kebangsaan Malaysia

s.k. Pengarah

Pusat Pergurusan Penyetid dan Instrumentasi (CRtM)

Universiti Kebangsaan Malaysia

(Penyelldlkan & Inovasl) Secretariat Penyelidikan Perubatan 6 Inovasi Hospital Canselor Tuanku Muhriz Pusat Perubatan UKM

Ketua Jabatan ObsQtrik & Glnekologl Haspital Cansdor Tuwku Muhriz Pusat Perubahan UKM



NAIYIE OF ETHICS COMMITTEE/IRB:
Research Ethics Committee,
The National University of Malaysia

PROTOCOL TITLE:
The Effectiveness Of Abdomlnal Exercise Program On Diastasis Recti Abdominal (DRA) And Pelvic Floor Muscb Function In Postpartum Primigravida Diagnosed With DRA

PRINCIPAL INVESTIGATOR : Dr. Ixora Kamisan @ Atan

Oepattment of Obstetric & Gynecology HospItalCanselor Tuanku Muhriz

UKMMe kal Cents

The following items have been received and reviewed in connection with the above study to be conducted by the above investigabr.

Documents

X Research Application Form

X Resesrch Piopasal/ Potocd

X Publication Policy

X Non-Disclosure Agreement

Information Steel:-

Malay Engligh

Consent Fom:-

Malay English

Questionnaire:-

Malay English

GuWcWumV#aeotReseamher:-

Principal Co•researcher

X Good Clinical Practice Certifoate(GCP)

X Project Agreement

The Research Ethics Committee, The National University of Malaysia operat05 lh accodance to the InternationalConference of Harmonization Good Clinical Practice Guidelines.

Student

Comment(if any): The control oroiio should be taucht the exexises once the studY is complete for them,

§r. Ixora Kamisan @ Atan is the orinciPal Investigator for this studY and also member of Research Ethics Committee She stricfY was not involved in the decision of Research Ethics Committee to approve this study

Date of Approval: 25 January 2018

PROFESSOR R. FUAD ISMAIL Chairman Reseamh Ethics C méee Tie Naiond University of Makysia

Research E0sks Comldtta,ne National Unl¥erslty OfBaf4ycis, 1stFbaʻ, apical Bbck, Hospitsl C8nedix Tunkj Mdvtz, UKkl Medical Ce«be 3alan Yaaav b Latil, 88rdar Tun RazaK. 56000 Cfe/as. Kuala Mpur, Malaysia. Telefen: +603-9145 B48/SRI

APPENDIX C: Research information form

Research Title:

THE EFFECT OF ABDOMINAL EXERCISE PROGRAM ON DIASTASIS RECTI ABDOMINAL (DRA) AMONG POSTPARTUM PRIMIGRAVIDA MOTHER IN KUALA LUMPUR

Researcher's Name: ASSOC. PROF. DR NIK ROSMAWATI NIK HUSAIN

MMC Registration No.: 34746

Co-Researchers:

SUHAILA BINTI SHOHAIMI, DR IXORA KAMISAN @ ATAN (MMC 36488).

INTRODUCTION

You are invited to take part voluntarily in a research study: Effect of abdominal exercise in diastasis recti abdominal (DRA) and pelvic floor muscle function among postpartum primigravida diagnosed with DRA. It has been reported that pregnant women experienced of diastasis recti abdominal, weaker pelvic floor muscle and urinary incontinence. By participating in this study, you will be screened for RDA. The screening for RDA will be conducted at 34 weeks of your gestation. The screening will be done using abdominal ultrasound and abdominal examination. Before agreeing to participate in this research study, it is important that you read and understand this form. If you participate, you will receive a copy of this form to keep for your records.

PURPOSE OF THE STUDY

The purpose of this research is to study the burden of RDA among pregnant women and its association with the function pelvic floor muscle. This research also will determine the development of RDA and strength of pelvic floor muscle following postpartum abdominal exercise. Finally, this research want to study the factors that associate with RDA and pelvic floor muscle after child delivery.

QUALIFICATION TO PARTICIPATE

The doctor in charge of this study or a member of the study staff has discussed with you the requirements for participation in this study. It is important that you are completely truthful with the doctor and staff about you health history. You should not participate in this study if you do not meet all qualifications.

Some of the requirements to be in this study are:

- 1. Primigravida pregnant women
- 2. Diagnosed with DRA at third trimester
- 3. Delivered a singleton pregnancy via spontaneous vertex delivery, vaginal breech delivery or instrumental delivery.

Exclusion criteria

You will not be invited to participate in this study if:

- 1. Multiple pregnancies
- 2. Previous abdominal and urogenital surgery
- 3. Delivery via LSCS
- 4. Having disease that can interfere in pelvic floor muscle strength such as Ehlan Danlos syndrome

STUDY PROCEDURES

If you agree to participate in this study, you would be required to give information regarding personal particulars, occupation, household income, medical history and intrapartum history. A questionnaire regarding urinary incontinence also be handed to you to be filled. Then, you will be examined on the abdomen and assessed for the pelvic muscle function. Later, you are randomly divided into intervention and control groups. The intervention group will be teach on the abdominal exercise (training and notes). The exercises will be teach immediate after deliver, 4th week and at 6th week postpartum. The control group will be educated on healthy diet for postpartum mother. Both groups will be assessed on similar assessment after 8 weeks of delivery.

In the event of unforeseen circumstances, participation may be terminated.

RISKS

There are minimal health risks in taking part in this study. You may feel initial discomfort when being assessed for pelvic muscle function. If any important new information is found during this study that may affect you wanting to continue to be part of this study, you will be told about it right away.

REPORTING HEALTH EXPERIENCES.

If you have any injury, bad effect, or any other unusual health experience during this study, make sure that you immediately call Dr. Nik Rosmawati Nik Husain [MMC Registration No. 34746] at 09-7676621. You can call at anytime, day or night, to report such health experiences. Participants of this study will have treatment entitlements in the case of study related injury.

PARTICIPATION IN THE STUDY

Your taking part in this study is entirely voluntary. You may refuse to take part in the study or you may stop participation in the study at anytime, without a penalty or loss of benefits to which you are otherwise entitled. Your participation also may be stopped by the study researchers or sponsor without your consent. Participants will receive an honorarium as a sign of appreciation for taking the time and effort in the study. The research team shall serve as investigators and not healthcare providers. You shall be referred to a healthcare team if the need arises.

POSSIBLE BENEFITS [Benefit to Individual, Community, University]

Study procedures will be provided at no cost to you. You may receive the results of your DRA and pelvic floor muscle assessment and a abdominal exercise program, if chosen. The results from this study, would also enable us to produce recommendations in hope that it may help

more pregnant mothers from other districts and states as well. You will not receive any compensation to participating in this study.

QUESTIONS

If you have any question about this study or your rights, please contact; Assoc. Prof. Dr Nik Rosmawati Nik Husain (MMC No: 34746)

Department of Community Medicine School of Medical Sciences USM Health Campus Tel. No 01110018353 / 09-7676621 E-mail:rosmawati@usm.my

If you have any questions regarding the Ethical Approval or any issue / problem related to this study, please contact:

Mr. Mohd Bazlan Hafidz Mukrim
Secretary of Human Research Ethics Committee USM
Centre for Research Initiatives, Clinical & Health Sciences
USM Health Campus

Tel. No.: 09-767 2354 / 09-767 2362 Email: bazlan@usm.my/jepem@usm.my

CONFIDENTIALITY

Your medical information will be kept confidential by the study doctor and staff and will not be made publicly available unless disclosure is required by law. Data obtained from this study that does not identify you individually will be published for knowledge purposes. Your original medical records may be reviewed by the researcher, the Ethical Review Board for this study, and regulatory authorities for the purpose of verifying clinical trial procedures and/or data. Your medical information may be held and processed on a computer. You have the right to access your records at any time during the study period.

By signing this consent form, you authorize the record review, information storage and data transfer described above.

SIGNATURES

To be entered into the study, you or a legal representative must sign and data the signature page.

Patient/Subject Information and Consent Form (Signature Page)

Research Title:

THE EFFECTIVENESS OF ABDOMINAL EXERCISE PROGRAM ON DIASTASIS RECTAI ABDOMINAL AND PELVIC FLOOR MUSCLE FUNCTION IN PRIMIPARA WITH ANTEPARTUM DRA

Researcher's Name:

ASSOC. PROF. DR NIK ROSMAWATI NIK HUSAIN (MMC 34746)

Co-Researchers:

SUHAILA BINTI SHOHAIMI, DR IXORA KAMISAN @ ATAN (MMC 36488).

To become a part this study, you or your legal representative must sign this page. By signing this page, I am confirming the following:

I have read all of the information in this Patient Information and Consent Form including any information regarding the risk in this study and I have had time to think about it. All of my questions have been answered to my satisfaction. I voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested. I may freely choose to stop being a part of this study at anytime. I have received a copy of this Patient Information and Consent Form to keep for myself.

Participant Name	
Participant I.C No.	
Signature of Participant or Legal Representative (Add time if applicable)	Date (dd/MM/yy)
Name of Individual Conducting Consent Discussion	
Signature of Individual Conducting Consent Discussion	Date (dd/MM/yy)
Name & Signature of Witness	Date (dd/MM/yy)

Note: i) All subject/patients who are involved in this study will not be covered by insurance.

APPENDIX E: Proforma from

PRO	FORMA	

DATE	•	
DAIL	•	

Name	
MRN	
IC	
Date of delivery	
Ethnicity	
Height	
Pre-pregnancy weight	
Total weight gain in pregnancy	
Occupation	
Medical History	
Surgical History	
Antenatal problem	
Any antepartum exercise class attend? if yes,	
what type of exercise	
what type of exercise	
Intrapartum	
- PAO / POG at birth	
171071 00 41 51141	
- Any epidural	
- Mode of delivery	
·	
- Duration of	
labor 1 st stage	
2 nd stage	
3 rd stage	
- Type of perineal tear	
Catal weight (kg)	
- Fetal weight (kg)	
- Fetal head circumference? (cm)	
- Fetai flead circumerence! (ciri)	
Postnatal	
- Any musculoskeletal pain (pelvic	
pain / back pain)	
- Type of confinement	
practice Massage	
Corset /	
binder Others	
Llalman	
- Helper	
Alone	
Husban	
d Mathew / meeth on in levy	
Mother / mother in law	
other	

-	Breastfeeding (Y / N)			
SI	1/mth	1/wk	1/day	more	
UI	1/mth	1/wk	1/day	more	
F	<8	8-12	13-16	17+	
N	2	3-4	5+		
Drag	ging sensation	Absent	Present		
Lum	p	Absent	Present		
Chro	nic constipation	Absent	Present		
Straining stool		Absent	Present		
Incor	nplete emptying	Absent	Present		

OBJECTIVE ASSESSMENT

seline at 3rd trimester)	Da	nte:
2.5 cm above	umblical	2.5 cm below

Date

DRA Measurement (8 week postpartum)

	2 cm above	umblical	2 cm below
Finger palpation			
Calipers			
ultrasound			

PFM Assessment

Finger palpation ultrasound

Oxford scale	0	1	2	3	4	5
Perineometer (cmHg)						
PFM base elevation (cm)						
PFM endurance (sec)						

APPENDIX F : UDI-6 AND IIQ-7 questionnaire

Short Forms to Assess Life Quality and Symptom Distress for Urinary Incontinence in Women: The Incontinence Impact Questionnaire and the Urogenital Distress Inventory (UDI-6 IIQ-7)

Incon	tinence Impact Questionnaire-Shari Form IIQ-7	Not at all	Slightly	Moderate	Greatly
Has urine leakage and/or prolapse affected your:					
1	Ability to do household chores (cooking, housecleaning, laundry)?				
2	Physical recreation such as walking, swimming, or other exercise?				
3	Entertainment activities (movies, concerts, etc.)?				
4	Ability to travel by car or bus more than 30 minutes from home?				
5	Participation in social activities outside your home?				
6	Emotional health (nervousness, depression, etc.)?				
7	Feeling frustrated?				
Uroge	enital Distress /Inventory-Short Form (UDI-6)				
Do yo	ou experience, and, if so, how much are you bothered by:				
1	Frequent urination?				
2	Urine leakage related to the feeling of urgency?				
3	Urine leakage related to physical activity, coughing, or sneezing?				
4	Small amounts of urine leakage (drops)?				
5	Difficulty emptying your bladder?				
6	Pain or discomfort in the lower abdominal or genital area?				

APPENDIX G: Perineometer (Cardio design, Australia



