Study protocol

Research title: The effectiveness of a mHealth App on Pelvic Floor Muscle Exercises in improving compliance and continence status amongst pregnant women: Randomized control trial.

Trial registration: In progress

Protocol version 1

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CHAPTER 1: INTRODUCTION

1.0: Introduction
Urinary incontinence (UI) is the most common bladder health problem in women which estimated to affect 423 million or 21.6% women globally in 2018 (Irwin, Kopp, Agatp, Milsom, & Abrams, 2011). The regional burden of this condition is projected to be greatest in Asia (Irwin et al., 2011). In the United States, the projection of the total cost of UI was $76.2 billion in 2015 and estimated to cause $82.6 billion in 2020 (Coyne et al., 2014). Current evidence demonstrates the substantial economic burden of UI to patients, and society increases over time in parallel with the projected increase in UI prevalence worldwide (Irwin et al., 2011; Milsom et al., 2014). Pregnancy was established to be the major predisposing factor in the development of UI among women (Fritel, Ringa, Quiboeuf, & Fauconnier, 2012; Wesnes & Lose, 2013). A large proportion of women ranged from 17-54% experienced the first UI during pregnancy (Wesnes & Lose, 2013). Therefore, it is essential to focus on preventive care among pregnant women who are at risk of developing UI.

Pelvic floor muscle exercise (PFME) often referred to as Kegel exercise was initiated by Dr. Arnold Kegel in the late 1940s to help reduce UI among postpartum women. Since then many randomized controlled trials were conducted among pregnant and postpartum women that produced Grade A evidence in supporting the effectiveness of PFME in preventing UI during pregnancy and postpartum (Wesnes & Lose, 2013). Therefore, PFME should be a standard component of perinatal care, and women should be advised and taught to perform PFME during pregnancy and postpartum (Wesnes & Lose, 2013).

Adherence concerns in supervised clinical based interventions have always been an issue. Mason et al. (2010) highlighted pregnant women’s reluctance to attend a supervised PFME class as one of the issues especially when it involved working women and they felt attending a class was too arduous or time-consuming (Mason, Roe, Wong, Davies, & Bamber, 2010). Rosediani et al. (2011) reported only ten percent practices PFME even though half of them has PFME knowledge, in our local study (M., N.H, M., & D., 2012). The reluctance is not only for the patient but also to healthcare providers, the supervised training is costly and requires dedicated staffs and time (Fine et al., 2007; Sangi-Haphpeykar, Mozayeni, Young, & Fine, 2008).

Self-care requires self-monitoring for a consumer to pursue daily decisions to maintain functionality (Chodosh et al., 2005). There is growing evidence that health consumers are using mHealth (mobile Health) apps for self-monitoring (Gill Preetinder S, Kamath Ashwini, & Tejkaran, 2012). The success of implementing any mHealth apps intervention is highly dependent on its design. Therefore, a user-centric design philosophy needs to be applied to achieve an optimal design of any system. The user-centric design attempts to gather as much feedback throughout the system development to ensure that the users’ needs, wants, and abilities are considered into the resulting product. The users in the case of mHealth apps on PFME would be both patients and their healthcare providers.
“mHealth” (short for mobile Health) apps self-care system is currently being proposed because mobile phones have high computational power while being relatively inexpensive and own by many of our population. Mobile phones also have the added benefit of being portable, enabling patients to be monitored at any location with mobile phone reception. However, the feasibility and efficacy of mHealth apps self-care system especially among antenatal women and the health care providers are currently unknown.

1.1 Problem statement:
Urinary incontinence has been reported to increase considerably during pregnancy with prevalence ranges from 19.9% (Hvidman, Hvidman, Foldspang, Mommsen, & Bugge Nielsen, 2002b) to as high as 71% (Frederice, Amaral, & De Oliveira Ferreira, 2013). The recent local study reported that urinary incontinence during antenatal women at their third trimester was 34.3% with the most prevalent type is stress incontinence (64.8%) followed by mixed incontinence (24.8%) and urge incontinence (6.7%) (Abdullah et al., 2016). Hence, it is timely for the primary care providers to take actions in the management and prevention for UI management, teaching the correct technique of PFME that can be done anywhere, any position and at any time.

1.2 Significance of research
The results of this study may provide some value of the PFME among pregnant women in preventing UI and lead to better continent in future. This study will add the importance of PFME during antenatal and hence can be included in the guideline for antenatal care in our country. The results from this study will assist healthcare providers who are involved in managing antenatal care mothers or pregnant women, researchers in the field of UI, healthcare governance and policy makers in planning for future improvement, in order to effectively reduce health and economic burden of UI. This study will be a source of reference as it will be using mobile apps in preventing and managing UI among pregnant women.

There are no risks for subjects on placebo. However, there is little risk in getting miscommunication or misunderstood regarding the PFME. To overcome this issue, videos and Frequently Asked Question (FAQ) will be installed in the module to further assist the user.
1.3 Research Question(s)

1. To determine the prevalence of urinary incontinence and PFME practices during pregnancy in primary care clinics.

2. Does the introduction of a mHealth App on PFME ("pelvic floor muscle exercise") for pregnancy self-care increase compliance on the PFME among pregnant women?

3. What are specific design features of the mHealth App on PFME for pregnancy self-care that will significantly affect the rate of compliance with the clinical protocol among pregnant women?

4. Does the implementation of a mHealth App on PFME for pregnancy self-care improve continence status amongst pregnant women?

1.4 Research objectives

The main objective of this research is to investigate the optimal design of a mHealth app on PFME for pregnancy self-care and to determine the effects of the system on self-care, clinical management, and health outcomes.

The specific objectives of this study are:

1. To determine the prevalence of urinary incontinence and PFME practices during pregnancy in primary care clinics.

2. To develop a mHealth App on PFME for pregnancy self-care.

3. To assess the usability of the mHealth app on PFME for pregnancy self-care in improving clinical protocol compliance and success rate of pregnant women compliance with the clinical protocol.

4. To evaluate the effectiveness of a mHealth App on PFME for pregnancy self-care in reducing the occurrence of UI and severity of UI amongst pregnant women.

1.5 The hypotheses for this study:

H1: There is significant difference between the sociodemographic characteristics of UI among patients enrolled at primary care clinics and tertiary care center.

H2: The mHealth is user friendly in managing UI among pregnant women.

H3: The mHealth apps is effective in managing UI among pregnant women.

H4: The mHealth apps is effective in preventing UI during post-partum.

H5: The mHealth apps is effective in improving sexual function UI among pregnant women.
H6: The mHealth apps is effective in improving sexual function UI during post-partum
H7: The mHealth apps is effective in increasing PFME adherence among pregnant women.
H8: The mHealth apps plays role in improving quality of life among pregnant women with UI.
H9: The mHealth apps improve self-efficacy among pregnant women with UI.

1.6 Conceptual framework
Diagrammatic illustration of the study framework which provides a context to explain the study.

Figure 1: Conceptual Framework based from Social Cognitive Theory (Bandura, 1986)
CHAPTER 2 : LITERATURE REVIEW

2.0: Urinary incontinence and its epidemiology

Urinary incontinence has been a typical scenario during pregnancy and post-partum (post-delivery). This happens when the bladder pressure remains higher than the urethral closure pressure due to any impairment to the urethral or the bladder (Fritel et al., 2012). Urinary incontinence has three types; stress urinary incontinence (SUI), urge urinary incontinence (UUI) and mixed urinary incontinence (MUI), which associates the first two (Fritel et al., 2012). Stress urinary incontinence (SUI) is an involuntary loss of urine which is due to physical exertion or on sneezing or coughing (Haylen et al., 2010). The primary identified disorders with regards to SUI are impaired urethral support and sphincter deficiency (DeLancey, Trowbridge R Elisa, & Miller, Janis M., Morgan Daniel M, Guire Kenneth, Fenner Dee E., Weadock William J., 2009).

Urgency urinary incontinence (UUI) is when the involuntary loss of urine is associated with urgency (Haylen et al., 2010). The urgency in this situation is defined as a sudden and convincing desire to void urine, or that is truly difficult to defer or to hold. The pathophysiology of UUI has yet to be elucidated. It appears to be connected with poor transmission or processing of information between the bladder and the nervous system (De Groat, 2004).

Urinary incontinence has been reported to increase considerably during pregnancy with prevalence ranges from 19.9% (Hvidman et al., 2002b) to as high as 71% (De Oliveira et al., 2013). In our local studies reported that urinary incontinence during antenatal women at their third trimester was 34.3% and has been increased almost into double recently with 65.8% UI among pregnant women (Abdullah et al., 2016; Yusoff, Awang, & Kueh, 2019). The most prevalent type is stress incontinence (64.8%) followed by mixed incontinence (24.8%) and urge incontinence (6.7%) (Abdullah et al., 2016). Unfortunately, the numbers has been almost double to 65.8% in our latest study which include primigravida and multigravida (Yusoff et al., 2019).

Malaysia study has almost similar findings in Spain, in which this study was looking at the differences between UI during first trimester and third trimester (Abdullah et al., 2016; Martínez Franco, Parés, Lorente Colomé, Méndez Paredes, & Amat Tardiu, 2014)abd. They reported that 34.37% of the population of pregnant women has UI and is more common during the third trimester of pregnancy than during the first (Martínez Franco et al., 2014).

Unlike Malaysian and Spain, antenatal mothers in Brazil has almost doubled diagnosed with UI. Their reported prevalence of UI among antenatal mothers or during pregnancy was 71.0% (De Oliveira et al., 2013).

Table 1: Prevalence of UI study

<table>
<thead>
<tr>
<th>Country</th>
<th>Types (Primipara or multigravida)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malaysia</td>
<td>Primigravida: 34.4% (Abdullah et al., 2016)</td>
</tr>
<tr>
<td>Country</td>
<td>Status</td>
</tr>
<tr>
<td>--------------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>Denmark</td>
<td>Primigravida: 19.9%</td>
</tr>
<tr>
<td>Spain</td>
<td>Primigravida: 39.1%</td>
</tr>
<tr>
<td>Brazil</td>
<td>Mixed: 71.0%</td>
</tr>
<tr>
<td>Turkey</td>
<td>Mixed: 27.0%</td>
</tr>
<tr>
<td>Norway (multi-ethnicity)</td>
<td>Mixed: (Bo, Pauck Oglund, Sletner, Morkrid, &amp; Jenum, 2012)</td>
</tr>
</tbody>
</table>

2.1: Urinary incontinence and its risk factors

Findings from Brazil reported that it is among pregnant women who did not exercise regularly and having increased body weight (De Oliveira et al., 2013). Increased body weight during pregnancy is a risk factor of UI. Another study reported that SUI during pregnancy strongly related with Body Mass Index (BMI) at first visit (Martins, E.S., Pinheiro, A.K.B., Aquino, P.S., Oriá, M.O.B., Castro, R.C.M.B., Lima, D.J.M. & K.V., Sousa, C.S.P.de and Holanda, 2016).

A large multi-center study found that the (BMI) of the mother and heavier babies have a risk of incontinence first starting during the pregnancy. In addition to that, the maternal age was associated with new postnatal incontinence. They also reported that women after their first delivery by cesarean section have less urinary incontinence (Glazener et al., 2006). Supporting this finding is from another study has observed that at the-12 months postpartum, parity stood out as the risk factor of persistent SUI in the vaginal delivery group, but no significant risk factor was found in Caesarean group (Lin et al., 2018). Recent meta-analyses from 15 cross-sectional studies have reported that almost double increase in the risk of developing long-term SUI when comparing any vaginal delivery with cesarean section (Ta¨htinen Riikka M, Cartwright et al., 2016).

Therefore, antenatal and post-partum urinary incontinence causes are multifactorial. Risk factors listed are increased maternal age, increased fetal head circumference and position, traumatic birth, use of forceps, length of the second stage of labor, sphincter damage, obesity, and smoking (Bartling, Zito, Rph, & Frsph, 2016).

2.2 Urinary incontinence and its quality of life impact.

It is very troublesome when someone cannot hold their urine. Even more when they leak every time they sneeze or bouts of cough. This event can hinder the woman to
attend social events and difficulties when at works or traveling. The impact of urinary incontinence on the women can be divided into the quality of life, financial burden and psychologically impact. The woman needs to buy specially designed panty liners to protect their underpants for hygienic purposes.

A recent study reported that mothers with urinary incontinence affecting their life in social, behavioral, physical and emotionally. They even sometimes avoid themselves from the society and they self-doubting about their health (Martins, E.S., Pinheiro, A.K.B., Aquino, P.S., Oriá, M.O.B., Castro, R.C.M.B., Lima, D.J.M. & K.V., Sousa, C.S.P.de and Holanda, 2016). In Spain, a study recently found that the incontinent which was slight-moderate has not severely hamper mothers’ everyday life. Unfortunately, it did affect the physical, mental and social domains of their quality of life. (De Oliveira et al., 2013).

In a review stated that 15% of the women with genuine SUI in the United Kingdom, who were referred to a tertiary urogynaecology unit, scored with poor health on the King’s Health Questionnaire. Two-thirds of them scored “a lot” or “moderately” question asked on “how much do you think your bladder problems affect your life?” (Hampel et al., 2004). Another study demonstrated that the more severe the UI, the more influence on patients’ QOL (Siracusano et al., 2003).

2.3 Urinary incontinence and its burden cost

In the United States, a cost-analysis study reported that patients with UUI have the total national cost of $65.9 billion in which $49.1 billion direct medical costs, $2.3 billion direct nonmedical costs, and $14.6 billion indirect costs (Coyne et al., 2014). The total national cost has been projected to be $76.2 billion in 2015 and $82.6 billion in 2020 (Coyne et al., 2014).

Unfortunately, the cost of absorbent pads was not cheap either. It has been calculated that the cost of routine care, for example, the absorbent pads, was $3.4 billion, which denoted the primary contributor to the total annual direct cost of UUI and MUI (HuTeh-Wei, Wagner Todd H, Bentkover Judith D., Leblanc Kristi, Zhou Steve Z., Hunt, 2003).

Among women, the annual direct cost was $8.6 billion for those in the community with the annual direct cost was higher for women aged ≥ 65 years ($7.6 billion) than for those aged < 65 years ($3.6 billion). This study also reported that the highest direct cost category was from the routine care which has been costs of $11.3 billion; 70% of total direct costs and the complications costs of $1.0 billion (Coyne et al., 2014). It also demonstrated that the cost of routine care was higher for MUI than for SUI in a multivariate analysis model (Coyne et al., 2014).
2.4 Urinary incontinence and sexual dysfunction

The activity of an intimacy between couples and having sexual activity is very important and has been included in one of the aspects that need to be evaluated in assessing quality of life. The sexual activity been assessed under the domain of social relationship of questionnaires (“Development of the World Health Organization WHOQOL-BREF quality of life assessment. The WHOQOL Group,” 1998).

In pregnant women, they face with changes physiologically and emotionally. Evidence had demonstrated that pregnant women sexual function slightly declined in the first trimester with variable patterns during their second trimester (Yıldız, 2015). During their third trimester, their sexual function decreased tremendously (Yıldız, 2015). In a finding from a longitudinal study stated that only a third of pregnant women had orgasm and the number doubled at 12 weeks post-partum (Connolly, Thorp, & Pahel, 2005). In addition to this, a recent study among Turkish pregnant women, had demonstrated that majority of them had sexual dysfunction which was 91.08% (Aydin et al., 2015).

Therefore, evidence had stated that due to physiological changes, hormonal changes and this can affect the emotions of pregnant women and could lead to sexual dysfunction. Pregnant women whom experienced UI will have more risk having sexual dysfunction. This is due to leaking or urine during sexual intercourse and during orgasm (Felippe et al., 2017). Therefore, pregnant women with UI will experience sexual dysfunction and will affect their quality of life. However, one study found an interesting fact that when pregnant and non-pregnant women with and without urinary incontinence had similar sexual function. The study reported that the sexual dysfunction among pregnant women were associated with the higher gravidity and parity (Aydin et al., 2015).

Unfortunately, a very recent systematic review reported that there were no study looking at the effect of antenatal PFME on during pregnancy or the immediate postpartum period (Sobhgol, Priddis, Smith, & Dahlen, 2019). Hence, this study will fill the gap looking at the effectiveness of PFME during antenatal on the sexual function among UI pregnant women.

2.5 Urinary incontinence and its first line management

The first line management by the guideline is to do a pelvic muscle floor training to improve the sphincter strength (Marques et al., 2013). The recommendations by the International Continence Society (ICS) for continence promotion among pregnant mothers, is to educate and to encourage pelvic floor muscle training (PFMT) for primary prevention. It is a must to be one of the standard components of prenatal and postpartum care (P. Abrams , K.E. Andersson, L. Birder, L. Brubaker, L. Cardozo, C. Chapple, A. Cottenden, W. Davila, D. de Ridder, R. Dmochowski, M. Drake, C. DuBeau, C. Fry, P. Hanno, J. Hay Smith, G. Hosker, C. Kelleher, H. Koelbl, S. Khoury,* R. Madoff, I. Milsom, K. Moore, D. Newman, V. Nitti, C. Norton, I. Nygaard, C. Payne, A. Smith, D. Staskin, S. Tekgul, J. Thuroff, A. Tubaro, D. Vodusek, A. Wein, & Key, 2010). PFMT is very important for maintaining continence.
not just during the pregnancy or post-delivery but throughout their lifetime (Dumoulin, Glazener, & Jenkinson, 2011; Hay-Smith, Herderschee, Dumoulin, & Herbison, 2011). Evidence from the guideline showed that PFME is safe and effective.

An interesting systematic review stated that, historically, Hippocrates and Galen had described pelvic floor exercise regimens in the baths and gymnasiuems of ancient Greece and Rome to strengthening pelvic muscles to promote health, longevity, spiritual development and sexual health (Price, Dawood, & Jackson, 2010). In 1936, it was the year when PFMT first entered modern medicine by Margaret Morris. She reported on the tensing and relaxing of the pelvic floor muscle and stated that PFMT is preventive and treatment option for urinary and fecal incontinence (Price et al., 2010). Twelve years after that, in 1948, Arthur Kegel reported the exercise was successful in restoring the function of the perineal muscles’ among patients with UI (Kegel, 1948).

Antenatal mothers who do the intensive supervised PFMT during pregnancy was reported in a systematic review to have a reduction in their postpartum urinary leakage in the first year after childbirth (Price et al., 2010). Additional into this, primigravida mothers (first baby), and performed PFMT were found to have less risk of urinary incontinence in late pregnancy and also during early postpartum (Price et al., 2010). Hence, the evidence is keen to support PFMT for the prevention and treatment UI during pregnancy and post-partum.

Another issue is on the frequency of the PFMT. How frequent should the mother perform PFMT? Will once daily or three to four times daily resulted in increased PFM function in young women without any side effects? A study looking into the frequency of PFMT demonstrated that the adoption of simple daily exercises of ten minutes duration able to show an effective preventive strategy (Pereira-baldon et al., 2019). The study found that simple training of short duration might have similar results, with long duration PFMT. The advantage of short training can improve patient adherence, and this is very important to improve muscle strength (Pereira-baldon et al., 2019).

2.6 Adherence to exercise

A patient or person will be called adherence when their behaviour or their actions reaches as same as what has been prescribed or recommended by their health practitioner or prescriber (Horne & Weinman, 2002). A person needs to be highly motivated and continuously able to self-regulate himself or herself to adhere with the exercise. Self-regulatory process in a person operates through three principal subfunction: self-monitoring of his or her behaviour, judgement of his or her behaviour and whether has positive or negative self-reaction towards the exercise (Bandura, 1991).

To be consistently adhere to a certain exercise needs effort and hard work. This is because instructions from prescriber will not be able to affect one’s motivation and
actions easily. A person needs to have a good self-regulation which rely on the strictly obey the exercise, being consistent and being able to self-monitor himself or herself. This principles which has been discussed in the self-regulatory systems in social cognitive theory (Bandura, 1991). A study found that previous experience with exercise, motivation, social support, time and financial factors did contribute in the exercise adherence (Howard & Gosling, 2008).

2.7 Barriers to exercise

It is not uncommon to have non-adherence to certain exercise despite the easy type or the quick exercise. A person will not be able to comply despite has been explain the importance of exercise and even had previous experience on certain complications for example knee osteoarthritis in an obese patient. The reasons identified in non-adherence to PFME are symptoms persists, forget to do PFME, unable to remember the PFME, not achieving symptom relief, inability to remember the exercises, forgetting to do them, did perceive as UI is major concern, belief that PFME is not for curing UI and lack confidence to perform PFME (Hayn, Greco, Capuano, & Byrnes, 2000) The trouble in travel to the clinic, time constraints, taking too much time and not in a good relationship with the clinician were being stated in a systematic review findings (Paddison, 2002). Another study found that not exercising from the first trimester and no role model contributing to as the barrier of doing the exercise

2.8 The intervention and its theory

In order to have a better impact, PFMT should be designed via a theory-based intervention. PFMT is a behaviour modification and to ensure its adherence, the modification should be developed based from a theoretical model (McClurg et al., 2015). The adherence of PFMT in UI is the most important in managing UI. A person’s perception of their symptoms, the effectiveness of the intervention, their ability to incorporate it into everyday life and support from physiotherapists will affect their adherence of any intervention (R. Campbell et al., 2001).

Therefore, it is necessary to explore relevant theories to ensure best choice of a complex intervention (M. Campbell et al., 2000). There are six theories that related with behavioural modification which are few Health Belief Model (Strecher, Becker, & Rosenstock, 1988), Theory of Planned Behaviour (Ajzen, 2011), Social Cognitive Theory with Self Efficacy Beliefs (Bandura, 1986), Self-Regulatory Model (Leventhal, Meyer, Nerenz, & Rachman, 1980) and Health Action Process Approach (Schwarzer, 1992).

Previous interventional studies related to PFMT in managing UI which incorporating the theoretical models (McClurg et al., 2015) are for example, Health Belief Model (Sacomori, Berghmans, Mesters, de Bie, & Cardoso, 2015; Sacomori & Cardoso, 2012;), Theory of Planned Behaviour (Whitford & Jones, 2011), Social Cognitive Theory with Self Efficacy Beliefs (Messer et al., 2007), Transtheoretical Model
(Alewijnse, Metsemakers, Mesters, & van den Borne, 2003), Self-Regulatory Model (Alewijnse et al., 2003) and Health Action Process Approach (Schwarzer, 1992).

In addition to this, there are four models that has been suggested for PFME intervention by McClurg et al (2015) which are Information-Motivation-Behavioral Skills Model (Fisher, Fisher, Bryan, & Misovich, 2002), Behavior Change Techniques Taxonomy (Abraham & Michie, 2008), Capability, Opportunity, And Motivation Behaviour (Michie, van Stralen, & West, 2011), Normalization Process Theory And Information (May & Finch, 2009), Motivational Interviewing (Miller & Rose, 2009) and Information, Satisfaction and Recall Model (Ley, 1982).

The social cognitive theory states that when a person has a sense of autonomy, behavioral change is then possible (Bandura, 2004). Social cognitive theory specifies a core set of determinants, the mechanism through which they work, and the optimal ways of translating this knowledge into effective health practices. The core determinants include knowledge of health risks and benefits of different health practices and perceived self-efficacy in which a person able to manage himself or herself health habits. For the outcome expectation is about the expected costs and benefits for different health habits tailored with the health goals people set for themselves.

Self-efficacy is an essential and fundamental to the Social Cognitive Theory. It is pertaining on a person’s ability to perform specific behaviors and matching with their effectiveness. It has been proposed to be central determinants of health-related behaviors (Bandura, 1986). It involves four factors which are; belief in the ability to achieve the goals, to have a role model, social encouragement and physiological.

2.9. Pelvic Floor Muscle Training via Mobile applications.

Smartphone usage has been increasing its availability in Malaysia. It has been postulated, in 2019, about 20.71 million usages among Malaysian and 20.38 million users in 2020. The increment is about one percent every year. Hence, mobile health app is a rising field which able to offer new technology in improving our health quality and system. The mobile application has its ability to deliver health services (Peterson, Hamilton, & Hasvold, 2016). The advantage of these health apps is that it increases the people’s accessibility to health care for people with a barrier to access the care itself. A recent systematic review found that more than half of the randomized control trials showed favorable toward treatment adherence to chronic diseases management (Hamine, Gerth-Guyette, Faulx, Green, & Ginsburg, 2015). Another interesting finding that the effectiveness of mobile health apps is only positive for 40% of the trials. Hence there is a need to understand the methods to overcome the exact barriers to treatment adherence (Hamine et al., 2015).

There were few interventions via a mobile app (designed for iOS or Android devices) with a treatment program for SUI, focused on PFMT (Asklund et al., 2017; Pepper, Zhang, Li, & Wang, 2015). A free software app released, which was labeled as iDry® and developed by Touchdown Inc. in 2011-2012 (Pepper et al., 2015). iDry® enables individuals with UI (male and female) to document their incontinence
symptoms and evaluate the effectiveness of interventions and report status to health care providers. iDry’s database contains 48 interventions for managing UI. The examples of the intervention involved are lifestyle management, physical therapy, medications, holistic and alternative therapies, physical devices, and surgical and medical procedures. The patients can select their preferred intervention by clicking a hyperlink. They can read a summary via the hyperlink and do further research on the method/intervention chosen. Another unique criteria for iDry® in which it can separately monitor progress for each intervention, hence, patients can evaluate the effectiveness of each. (Pepper et al., 2015).

The results of non-randomized interventional study of iDry® found that patients who use iDry® more than 30 days was amongst those with more leakage and more frequent pad changes, but they did not show any improvement in daily pad use, and they improved less than others in the amount of leakage (Pepper et al., 2015). On the contrary, the short-term users did show signs of improvement, by using 20% fewer pads per day (Pepper et al., 2015).

Another app, called Tät®, is developed by a collaboration with software engineers at ICT Services and System Development, Umeå University (Asklund et al., 2017). The treatment program was based on experiences reported by researchers, clinicians, and users with our previous internet program. This mobile app focused on PFMT exercises with SUI information, the pelvic floor, and lifestyle factors related to incontinence (Asklund et al., 2017). The PFMT exercises were ordered by increasing difficulty (six necessary and six advanced levels and it includes different combinations and repetitions of commonly used contractions. The primary contraction is by using the correct muscles to improve its strength and endurance, quick contractions, and contractions before coughing (Asklund et al., 2017). The exercises prescribed was three times daily with the ability to set three reminders/day.

The apps show graphics to describe the duration and intensity of each contraction with concomitant relaxation and the woman able to save it in a statistics table post-exercise. The goal was to exercise regularly for three months, not to reach a particular exercise level (Asklund et al., 2017).

The result from a randomized controlled study using Tät® among female with UI aged 44.7-44.8 years old demonstrated positive results. There was a similar reduction of UI symptoms as reported in other RCT with different types of PFMT programs. This showed that the improvement by using Tät® was a real effect and not a placebo effect. This app lacked its face-to-face contact as it has a reminder is build-in with the system. A reminder is critical as in a randomized controlled trial highlighted that the most common barrier was poor remembering to do the exercises (Borello-France et al., 2013). Other than lack reminders, the barriers reported to interfere adherence with PFMT include poor exercise instruction from the provider; unconvincing with its effectiveness; unsure the exercises were performed correctly; lacking time, interest, self-motivation, and interference of daily activities or other illnesses (Milne & Moore, 2006). Thus, this app showed evidence that PFMT is effectively delivered via mobile app and it has benefited the middle-aged woman.
Therefore, urinary incontinence has a significance impact on pregnant mothers with strong evidence that it can be prevented with the correct technique of PFMT. Hence, this study is to determine the prevalence of urinary incontinence among pregnant mothers and during post-partum periods. Another aim of this study is to design a pelvic floor muscle training delivered via a mobile application version to prevent the urinary incontinence and to assess its effectiveness.

CHAPTER 3: METHODOLOGY

3.0 Description of methodology

Sequential Exploratory Mix Method approach will be used to develop a mHealth App on PFME for pregnancy self-care, and to assess the usability of the mHealth app on PFME for pregnancy self-care in improving clinical protocol compliance and success rate of pregnant women compliance to the clinical protocol. This method involves two phases; first phase is the prevalence study, then followed qualitative and intervention phase which is quantitative data. The results from all these phases are then will be merged during the interpretation phase (Creswell & Vicki L. Plano Clar, 2011).

3.1 Study stages/phases

3.1.1. Phase one

In the first phase, it is a cross-sectional study in which will be involving a few primary healthcare clinics as its study locations. The study population is the low risk of pregnant women at any gestation who presents to the antenatal clinic in Hulu Langat district for antenatal care. The inclusion criteria are pregnant mothers with a singleton pregnancy, anticipating vaginal delivery, able to communicate and read in Malay or English. The exclusion criteria for this study are mothers, those with a history of childhood enuresis, history of UI or pelvic surgery or pelvic organ prolapse, history of mental illness or psychosis and history of poorly controlled Diabetes Mellitus.

Using sampling formula \( N = \left( \frac{Z}{\alpha} \right)^2 \frac{P(1-P)}{D^2} \) by Kish L (1965) taking \( \alpha = 0.05 \) and 95% power of study, and the prevalence of urinary incontinence among pregnant women was 65.8% (Yusoff et al., 2019), the sample size estimation is 345 (Kish, 1965). The final sample size is 530 after considering 20% dropout or non-respondent.

The sampling method will be via simple random sampling. The patient will be invited to join this study when they register in the antenatal clinic at the primary care clinics by the researcher or researcher assistants. They will be informed regarding the study objectives and consent forms to be signed. The questionnaires will be involved the socio-demographic assessments with the specific questionnaires related to the PFME.

The questionnaire involves International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-SF), and Knowledge, Attitude and Practice (KAP) towards PFME. The ICIQ-SF assess the frequency of urinary
incontinence, amount of leakage, the overall impact of urinary incontinence and diagnosis of the type of incontinence. It is listed in the screening guideline to measure the symptoms and the quality of life (Lucas et al., 2015). The effect on the quality of life will be evaluated by the total score of three questions assessed by Likert scale. It has been validated and has Malay and Chinese version (Lim Renly, Liong Men Long, Lau Yong Khee, 2017).

The ICIQ-LUTS disease is for evaluating the quality of life (QoL) in urinary incontinent patients. It provides a detailed and vigorous measure to assess the impact of urinary incontinence on quality of life with specific reference to social effects. It explores in detail the effect on patients’ lives of urinary incontinence and can be used as an outcome measure to assess the impact of different treatment modalities. It has 20 items and will take 10-15 minutes. It has been validated in Malay and Chinese version (Lim Renly, Liong Men Long, Lau Yong Khee, 2017).

The KAP for PFME is to assess the knowledge, attitude, and practices towards PFME. It consists of 29 items in total. The knowledge (K) of PFME: regarding its methods has 5 items and 12 items regarding the benefits of performing it. The attitude (A) has 8 items with 4 items on the PFME practice (P) (M. et al., 2012). The Cronbach’s alpha for KAP questionnaires was good which was 0.949 for knowledge, 0.837 for attitude and 0.742 for practices. The knowledge has categorical responses of true, false and don't know used. The attitude has 5 likert scales for its response: strongly agree to strongly not agree. The practices PFME has a categorical response of never, seldom, frequent and always. The scoring will be reserved for the negative item. The total score will be categorized as good and poor which based on the mean of total score (M. et al., 2012).

The data will be entered and will be analysed using Statistical Package for Social Science (SPSS) version 25.0 (SPSS Inc., Chicago, IL). The significant level will be set at \( \alpha = 0.05 \). The categorical data will be presented in the form of a total number and their corresponding percentage values. The continuous data, the mean and standard deviation will be analysed.

For the inferential analysis, an independent t-test will be analysed to compare the means of the continuous variables between two groups and one-way ANOVA will be used to compare means of the continuous variables between four groups. The multivariate linear regression will be used to analyse the association of the study variables. The single linear regression will be used to analyse the association of the study variables. Multivariate linear regression will then be analysed to determine the predictors if available in this study.

3.1.1. Phase two

In phase two, Sequential Exploratory Mix Method approach will be used to develop a mHealth App on PFME for pregnancy self-care, and to assess the usability of the mHealth app on PFME for pregnancy self-care in improving clinical protocol compliance and success rate of pregnant women compliance to the clinical protocol.

A mHealth apps self-care system will be developed using a user-centric design process meaning the apps will be developed mainly based on the in-depth interview
conducted with the potential users (the pregnant women who attended the antenatal clinic in Hulu Langat district). The patient is the focus of the design process. The interview will use the semi-structure standardized interview to identify the end user context, needs, challenges and factors contributing to the intention to use the apps. Data will be collected, and followed-up interview via teleconference and mobile application (Whatsapp) to suit the needs of the study will be done (Baker, Brownson, Dreisinger, McIntosh, & Karamehic-Muratovic, 2009).

The interviews will be recorded, transcribed and analysed using a constant comparative method to develop categories and themes for the study (Wellington, 2000). Data will be managed by using NVIVO software. The findings will be validated through member checking method whereby each of the transcripts will be verified by each of the participants to ensure the credibility of the results (Harper & Cole, 2012). Results from the interview will be then transferred into developing the mHealth app which will meet the users’ needs.

Following this, the quantitative method will be used to determine the usability and effectiveness of the mHealth app. Usability assessment through the traditional surveys, log analysis, and clickstream analysis will be used to assess the benefit use and usage pattern of the mHealth app on PFME for pregnancy self-care. Surveys are primarily used to measure a user’s perception of the usability of the mHealth app. USE questionnaire is the instrument that comprises usability, satisfaction, and ease of use (Lund, 2016). It is to determine (i) mHealth app meets the needs and objectives, (ii) Users’ satisfaction in using the mHealth app, (iii) easiness in using the mHealth app and (iv) usefulness of using the mHealth app. In this survey, it is effective in determining the end user perception towards an app. Survey data in this research consists of the user feedback in the form of answers to the survey questionnaire.

3.2 Trial design

3.2.1 Randomised controlled trial (RCT)
A two-armed cluster randomized control trial, single-blind study will be carried out to evaluate the effectiveness of the mHealth App on PFME for pregnancy self-care in improving continence status amongst pregnant women. It is a parallel RCT in which the control group will receive standard antenatal care with no intervention, and the intervention group will receive the mHealth App on PFME as an intervention and standard antenatal care. RCT is the most accurate method to assess the cause-effect relation exists between an intervention and an outcome. RCT also can add value by comparing with a control group with usual standard care whereby pregnant women in the control group will receive standard antenatal care as following our Perinatal Care Manual by our Ministry of Health. All defaulters or exclusions will be reported. The recruited pregnant women will be allocated to the intervention or control groups on a 1:1 basis.

This study is a two-arm randomized clinical trial involving pregnant women who are eligible to the study from September 2019 until June 2020 at twelve primary care
clinics, Hulu Langat, Selangor, Malaysia. Random allocation of the clinics will consider and eliminate the possible cross contamination of the participants from both groups. The experimental group will receive mHealth apps with PFME module and in the controlled group will receive Prenatal Care Guideline (Ministry of Health, 2013) added to standard routine care and mHealth apps (only the questionnaire) for the assessment. Both groups will need to answer the assessments follow the same schedule. For standard routine and intervention group, patients need to attend their clinic and as usual based on their appointment date. A baseline measurement on UI severity, quality of life, self-efficacy, adherence and sexual function will be collected on respondents in both intervention and control group prior to the research. The efficacy endpoint will then be measured immediately, 8 weeks post intervention, 16 weeks post-intervention and six weeks after post-partum.

3.2.2 Methods
The study will be conducted in twelve primary care clinics in Selangor, Malaysia. The primary care clinics were chosen will be in the Hulu Langat district area which has high antenatal cases attendances or follow-up.

3.2.3 Sampling frame
Pregnant women attend the clinic of each recruitment site whom interested to join this study.

3.2.4 Sampling unit
Pregnant women attend the clinic of each recruitment site after being assessed and found to be eligible to the study based on inclusion and exclusion criteria.

3.2.5 Eligibility criteria:
Inclusion criteria: Pregnant women before 20 weeks’ gestation, with a singleton pregnancy, low-risk pregnancy and who give informed consent will be included in this study.

Exclusion criteria: Non-Malaysian pregnant women, pregnant women undergoing physiotherapy treatment for severe urinary incontinence, and with complicated pregnancy and chronic medical problems prior to pregnancy (diabetes, hypertension, HIV positive, neurological condition, pelvic organ prolapse); complicated pregnancy or contraindications to the practice of physical activity (preeclampsia, persistent bleeding, pre-term labor, incompetent cervix, acute febrile infection, and fetal growth restriction or placenta previa, cephalopelvic disproportion); previous urogenital surgery will be excluded from this study.

3.2.6 Eligibility Criteria for Researcher who perform the intervention
The researcher is a current Ph.D. candidate of Universiti Putra Malaysia. She has a Master-Degree in Family Medicine and has been registered as a Family Medicine Specialist since 2008. She has been specialist and medical lecturer since then. She
has been experienced working in multiple departments and has been posted across all areas of maternity units such as an antenatal clinic, birth unit, and postnatal ward. She has been exposed to the complications of UI and has exposure in advising pregnant women about pelvic floor muscle exercise. The researcher will provide the PFMT program to women according to the protocol design which will be explained in the next section in this study protocol.

Furthermore, this research design is a collaboration with Mrs. Parwathy Alagirisamy, who is the Head Department of Physiotherapist in a private hospital in Malaysia. She has a Master-Degree in Clinical Physiotherapy which Major in Continence and Women's Health from Australia. Recently, she has published a book “Pelvic Floor Muscle Exercises during and after Pregnancy.” The content of these mHealth apps has been closely monitored and used mostly from the book itself and other sources as its references.

3.2.7 Study variables
The main independent variable of this study is the PFME intervention. There are other independent or predictor variables which include socio- demographic factors (age, gender, ethnicity, income, education, gravida, marital status), physical factor (body mass index).

Dependent or primary outcome variable of this study will be UI severity. The secondary outcome will be self-efficacy, adherence PFME and ICIQ SF Quality of Life.

3.2.8 Operational definition of terms/variables
Urinary incontinence is the inability to control urination. Urinary incontinence is generally divided into three types (Lucas et al., 2015):

a. Stress Incontinence - involuntary leakage of urine on effort or exertion, such as sneezing or coughing
b. Urge Urinary Incontinence - involuntary leakage of urine, accompanied by or immediately preceded by a strong desire to pass urine.
c. Mixed Urinary Incontinence – a combination of both stress and urge incontinence symptom.

Pelvic floor muscle exercise (known as “Kegel” exercise) is a specific type of exercise which involved voluntary contraction and relaxation of pelvic floor muscles which involves “squeeze and inward lift” movement around urethra, vagina and anus (Kegel, 1948).

Self-efficacy is pertaining on a person’s ability to perform specific behaviors and matching with their effectiveness (Bandura, 1986).

Adherence is when their behaviour or their actions reaches as same as what has been prescribed or recommended by their health practitioner or prescriber (Horne & Weinman, 2002)
3.3 Intervention

The intervention being analyzed in this research project is the implementation of PFME via mHealth apps among pregnant women. Currently, our antenatal standard care does not include PFME. It has antenatal exercise but as general exercise. During the follow-up, it is not a routine to enquire with regards to UI among pregnant women. A recent study shows that majority of pregnant women want to be screened with UI (Yusoff et al., 2019).

Both the intervention and control group will receive standard antenatal care throughout the study. The control group will be provided with Perinatal Care 3rd Edition (Ministry of Health Malaysia (MOH), 2013) via mHealth Apps but without any PFME intervention component.

For our mHealth Apps, the PFME program will be derived using the social cognitive theory which stated that behavioral change is possible in a presence of patient’s autonomy (Bandura, 2004). The Social Cognitive Theory explains how people develop and sustain certain behavioral patterns, hence it is relevant for health education and health behavior programs.

Social cognitive theory specifies its core set of determinants which include patient’s self-efficacy and expectations on a certain healthy habit. It also stated that there is a dynamic interaction between behaviors, personal factors and the environment. Behavior is not due to the influence of the environment and the person alone but it does provide a template for the behaviour (Glanz, Rimer, & Viswanath, 2008).

The theory is based on two fundamental constructs which is self-efficacy and outcome expectancy. In this study, outcome expectancy is urinary continent and financial cost. Self-efficacy is fundamental to the Social Cognitive Theory and is about one’s ability to control or perform specific behaviors. Self-efficacy is the central determinants of health-related behaviors (Bandura, 1986) and has been shown to be an essential predictor of PFME adherence (Alewijnse et al., 2003; Messer et al., 2007). In addition, socio-structural factors act as facilitators or barriers to adherence and can indirectly affect behavior through their influence on goals (Bandura, 2001). It is very important for them to understand the health benefit and risk certain health habit.

3.3.1 The instrument

The instrument involves will be questionnaires assessing the severity of UI, the quality of life, self-efficacy, exercise adherence and sexual function among pregnant women.

3.3.1.1 Instrument testing

In the initial stage, the construct and items have been identified based on past literature. The questionnaire will be used are ICIQ-SF and ICIQ-QoL (has been
discussed earlier for phase 1 study). For the second phase, there will additional questionnaire which are self-efficacy scale for practicing pelvic floor exercise questionnaire (SESPPFE) (Sacomori, Cardoso, Porto, & Negri, 2013), adherence to exercise using exercise adherence rating scale (EARS) (Newman-Beinart et al., 2017) and sexual function using sexual female sexual function index (FSFI) (Rosen et al., 2000; Sidi, Abdullah, Puteh, & Midin, 2007).

The SESPPFE questionnaire is a valid and reliable tool in measuring self-efficacy among post-partum women to practice pelvic floor exercises (Sacomori et al., 2013). The study showed that Chronbach’s alpha was α=0.923. It has three factors which has been construct from social cognitive theory (Bandura, 1986, 2006). The construct are the performance expectation considering the action, performance expectation considering the preparation for action and outcome expectations (Sacomori et al., 2013). The validated and translated version of this questionnaire has not been available in our country. Hence, this questionnaire will be translated and validated for this study.

<table>
<thead>
<tr>
<th>SESPPFE constructs</th>
<th>Items</th>
<th>Total variance (%) and Chronbach’s alpha</th>
</tr>
</thead>
</table>
| 1. Expected performance regarding an action. (8 items) | Perform the exercises during vacation and while traveling.  
Perform the exercises in the sitting position.  
Perform the exercises in the standing position.  
Contract PF before coughing, sneezing, or strongly laughing to prevent leakage.  
Continue performing the exercises even when your personal and familial responsibilities are more demanding than usual.  
Continue performing the exercises even when you have more activities to do than usual.  
Continue performing the exercises even when you have another health problem that is more urgent.  
Perform the exercises even when other people say they are unnecessary (e.g., family and friends). | 48.25%  
α=0.840 |
| 2. Expected performance regarding action | Perform PFEs on your own.  
Remember to perform the exercises every | 10.25% |
For the adherence, in addition to considering participants will be considered as adherence to the PFME when they perform three times a week, EARS will enable the objective measurement of adherence (Newman-Beinart et al., 2017). It has been constructed for prescribed home exercise in managing and prevention of chronic conditions (Newman-Beinart et al., 2017). Therefore, EARS may able to facilitate the evaluation of PFME which promoting self-management for UI. EARS consists of six items with Chronbach’s alpha $\alpha = 0.810$. EARS has five response levels which are from completely agree to completely disagree. This validated and translated version of this questionnaire has not yet available in our country. Therefore, this questionnaire will need to be translated and validated to the population of this study.

### Table 3: EARS items

<table>
<thead>
<tr>
<th>Adherence items in EARS</th>
<th>$\alpha$</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I do my exercises as often as recommended</td>
<td>$\alpha = 0.889$</td>
</tr>
<tr>
<td>2. I forget to do my exercises</td>
<td>$\alpha = 0.862$</td>
</tr>
<tr>
<td>3. I do less exercise than recommended by my healthcare professional</td>
<td>6.81%</td>
</tr>
<tr>
<td>4. I fit my exercises into my regular routine</td>
<td></td>
</tr>
<tr>
<td>5. I don’t get around to doing my exercises</td>
<td></td>
</tr>
<tr>
<td>6. I do most, or all, of my exercises</td>
<td></td>
</tr>
</tbody>
</table>

The Female Sexual Function Index (FSFI) was consistent with the questionnaire correlated to sexual activity, intercourse, and stimulation (Rosen et al., 2000). The questionnaire comprised of 19 items and 6 subcategories (desire, arousal, lubrication, orgasm, satisfaction, and pain). It has been locally validated and translated from a primary care clinic based study (Sidi et al., 2007). The study found that there was a high test–retest correlation by respondent with good discriminant validity for each domain and as a whole. The cut-off points to distinguish between
women with sexual dysfunction and those without will be explained further by referring Table 2.

Table 4: Malay Version FSFI

<table>
<thead>
<tr>
<th>Malay Version FSFI</th>
<th>Cut-off point</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sexual dysfunction</td>
<td>≤ 55</td>
<td>99%</td>
<td>97%</td>
</tr>
<tr>
<td>Sexual desire disorder</td>
<td>≤5</td>
<td>95%</td>
<td>89%</td>
</tr>
<tr>
<td>Sexual arousal disorder</td>
<td>≤9</td>
<td>77%</td>
<td>95%</td>
</tr>
<tr>
<td>Disorder of lubrication</td>
<td>≤10</td>
<td>79%</td>
<td>87%</td>
</tr>
<tr>
<td>Orgasmic disorder</td>
<td>≤4</td>
<td>83%</td>
<td>85%</td>
</tr>
<tr>
<td>Sexual dissatisfaction</td>
<td>≤11</td>
<td>83%</td>
<td>85%</td>
</tr>
<tr>
<td>Sexual pain disorder</td>
<td>≤7</td>
<td>86%</td>
<td>95%</td>
</tr>
</tbody>
</table>

3.3.1.2 Preliminary validation of tools

For the preliminary validation of tools, 50 of other respondents with similar demographic backgrounds will be randomly selected to answer all items.

3.3.1.3 Reliability and validity

Confirmatory factor analysis and measurement model in structural equation modelling by Analysis of Moment Structures software will be used to assess the reliability and validity after the data collection.

3.3.2 mHealth apps PFME

For our mHealth Apps, the PFME program will be using based from the Intervention Mapping (IM) protocol (Eldredge et al., 2016). The apps will be designed for both Malay and English version. It is a pathway that describes from problem identification to problem solving. Each of the six steps of IM comprises several tasks each of which integrates theory and evidence. The IM process consists of six different steps; 1) performing needs assessment, 2) developing objectives of the program, 3) selection of intervention methods (based from theory-based intervention methods) 4) producing program components and materials (by integrate the methods and practical applications), 5) plan for adoption and implementation and, 6) constructing an evaluation plan for assessment.
As this research focus in the community, IM approach added benefit as it has a it includes community members commitment in identifying important and relevant areas. Therefore, by adding the input from the community regarding relevant factors in developing PFME mHealth Apps, it will be tailored to fit the local needs.

Table 5: Development mHealth using IM protocol

<table>
<thead>
<tr>
<th>Steps</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1: Needs assessment</td>
<td>In the initial steps of the IM process, literature will be reviewed pertaining studies assessing effectiveness in PFME among pregnant women. A cross-sectional study will be done in order to assess the pregnant women’s knowledge, attitude and practices on PFME. Additionally, we will embark on qualitative research using semi-structured interview guide, for in-depth interviews with pregnant women to understand more on their understanding and their hope in ways to disseminate knowledge on PFME practices via mHealth apps. From this information, we will derive specific program tailored to their needs and expectations. A semi-structured interview guide which has several open-ended questions will be used as a tool. The interview session will be held in the clinic, and the interviews were conducted in the clinic by the researcher. The interviews will be audio recorded, verbatim transcribed and analyzed using systematic text condensation (Malterud, 2012). There will be a pilot study including 5-10 pregnant women with the researcher and for them to understand the PFME protocol and assessing the friendly-user of the mHealth app.</td>
</tr>
<tr>
<td>Step 2: Development program objectives</td>
<td>The needs assessment results in set of four key behaviors, PFME, toilet habits, bowel habits and lifestyle changes</td>
</tr>
<tr>
<td>Step 3: Intervention methods</td>
<td>To link and incorporate the intervention method with a suitable theory-based method. In this intervention, social cognitive theory will be chosen as it has an evidence in community-based intervention.</td>
</tr>
<tr>
<td>Step 4: Producing program components and materials</td>
<td>mHealth apps which include informative program and step-by-step PFME.</td>
</tr>
<tr>
<td>Step 5: plan for adoption and implementation</td>
<td>Adherence plan by the exercise begin from introductory level into optimum level. Reminder will be also included in the mHealth apps.</td>
</tr>
<tr>
<td>Step 6: constructing an evaluation plan for assessment</td>
<td>A set of questionnaires will be pop out on three occasion after the intervention: 8 weeks, 16 weeks and 4 weeks during post-partum.</td>
</tr>
</tbody>
</table>
3.3.3 Antenatal PFME protocol

All pregnant women in the intervention group will receive a link to download mHealth Apps. This mHealth Apps will provide instructions on how to perform PFME. Participants will follow the instructions, and they can select the timing for their reminder to perform PFME. The information and instruction on the correct method on performing PFME are as below. (Adapted from Pelvic Floor Muscle Exercises during and after Pregnancy – accepted to be published)

3.3.3.1 How to do Pelvic Floor Muscle Exercises?

Pelvic floor muscle exercise involved “squeeze, lift upward and inward movement around urethra, vagina, and anus."

There are three common ways to visualize how to contract the pelvic floor muscles:

1. "Imagine trying to stop passing wind", by squeeze and lift inward and upward around anus or back passage.

   ![Arrow shows movement direction of “Squeeze and lift” around anus.]

2. "Imagine trying to slow the flow of urine" by squeeze, lift up and inward around your urethra and vagina.

   ![Arrow shows movement direction of “Squeeze and lift” around urethra or bladder tube and vagina.]

3. "Imagine trying to bring the tailbone and pubic bone close to each other by "squeeze and lift your muscles inside your pelvis”.

   ![Arrow shows movement direction of “Squeeze and lift” as bringing the pubic bone and tail bone closer.]

Figure 2: Ways on perform PFME
3.3.3.2 Targeted pelvic floor muscles exercise prescription:

Intensity

- “Squeeze and lift” as hard as possible during each contraction
- try to **hold it for 6–8 s** before gently release or relax the muscle and feel the “letting go”.
- After each contraction **rest for 6 seconds**.

Frequency

- Do **8–12 repetitions in a row for 3 times daily**.
- At least aims for **24 - 36 repetitions per day**.

Duration

- At least **8 weeks training period is recommended** to strengthen pelvic floor muscles during pregnancy and after childbirth.
- Good to practice pelvic floor muscles everyday throughout life.

*If this seems too difficult, start with fewer repetitions and hold for few seconds but aim for 24-36 repetitions per day.

For example, start with 2 second hold and 6 second rest, 5 repetitions (repeat this set 5 times throughout the day for a total of 25 repetitions) and gradually work towards target frequency and intensity.

![Example](image)

Progress progressively to ....................... **for example**, to 4 second hold and 6 second rest, 6 repetitions and repeat 5 times daily.

![Example](image)

Try to achieve target frequency and intensity...... **For example**, 6 second hold, 6 second rest, 7 repetitions and repeat 3 times daily.

![Example](image)

**Figure 3: PFME prescription**
The success of the exercise program takes doing the exercises the right way and regularly. The correct exercise can make the pelvic floor muscles stronger, thicker and firmer that can improve the muscle function.

3.3.3.3 When and where to do the exercise?

Pelvic floor muscle exercises can be performed anywhere and anytime. It is recommended to first try them while lying down or any prefer to relax position to identify and isolate the contraction.

Choose one or more of these starting positions.

Once the muscle group gets stronger, begin doing them sitting and then standing.

- Kneel on all fours with your knees out to the side and feet together. Lift the pelvic floor upwards and inwards.

- Sit with your legs apart and your back straight and avoid slumped posture. Lift upwards and inwards around the openings in the pelvic floor.

- Stand with your legs apart, and check that the buttock muscles are relaxed while you squeeze the pelvic floor muscles.

Paying attention to the correct performance of the exercises and integrating the exercises into activities of daily life.

Figure 4: PFME position and timing
3.3.4 Confidentiality and security of source documents and study data
All participants’ information will be protected and processed in a classified with full of confidentiality manner. It will be in accordance with applicable laws and/or regulations. Participants’ identity will not be revealed without participants’ expressed consent when publishing or presenting the study results. There will be few qualified monitors and auditors, the sponsor or its affiliates and governmental or regulatory authorities that may inspect and copy participants’ medical records only when necessary. Participants will be given the access code to their personal information and study data.

The study data will be destroyed after 2 years period of storage. However, data from the study will be archived for 10 years. This is for the purpose of analysis and discussion. There are possibilities the data may be transmitted outside the country for the research purposes, but the participants’ identity will be kept confidential at any time.

3.3.5 The mobile apps system and maintenance
The application support system is for two years and using the Azure server 1 core 1.75GB RAM 50 GB storage. The data storage is of single database. The warranty will be for two years including the supporting services for any breakdown and changes. All technical backup will be managed by the software team.

3.3.6 Study endpoints/Outcome
The primary outcome measure is the continence status. UI status and severity will be measured by self-report using a validated questionnaire based on the International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form (ICIQ UI-SF). The severity of UI will be assessed based on ICIQ scores (Lim Renly, Liong Men Long, Lau Yong Khee, 2017).

The secondary outcome measure is the self-efficacy and their adherence to the protocol. It is defined as exercising three days per week or more at moderate to high intensity and also form Exercise Adherence Rating Scale (EARS) (Newman-Beinart et al., 2017). The self-efficacy is looking at their belief that they are able to perform PFME correctly by using Self-Efficacy Scale for Practicing Pelvic Floor Exercises (SESPPFE) (Sacomori et al., 2013). Performing the exercise programme is strongly emphasized. Another outcome is the other associations the quality of life among the respondents. The questionnaire involves Incontinence Impact Questionnaire Quality of Life (ICIQ-LUTSqol) (Lim Renly, Liong Men Long, Lau Yong Khee, 2017). Final outcome will be sexual function among pregnant women by using FSFI (Sidi et al., 2007). To assess the improvement of their sexual function post intervention.
The effectiveness of a mHealth App on Pelvic Floor Muscle Exercises in improving compliance and continence status amongst pregnant women: Randomized control trial
3.2.9 Sample size

a. Using an assumed expected outcome of improvement of UI severity within 3 months intervention.

The sample size for this interventional phase is using comparison of means for cluster randomization design (Donner & Klar, 2000).

\[ n = \left( Z_{\alpha/2} + Z_{\beta} \right)^2 \left( 2\sigma^2 \right) \left[ 1 + (m-1)\rho \right] / (\mu_1 - \mu_2)^2 \]

\[ Z_{\alpha/2} = 1.96 \text{ at 95\% confidence interval,} \]
\[ Z_{\beta} = 0.84 \text{ corresponding for power of 80\%,} \]
\[ \sigma = 3.5 \text{ (estimated standard deviation),} \]
\[ \rho = 0.05 \text{ (intra-cluster correlation coefficient (ICC)),} \]
\[ \mu_1 - \mu_2 = 3.9 \text{ (mean difference) (Asklund et al., 2017),} \]
\[ m = 59 \text{ (cluster size) (Eldridge, Ashby, & Kerry, 2006)} \]

\[ n = (1.96 + 0.84)^2 2(3.5)^2 \left[ 1 + (59 - 1)(0.05) \right] / (3.9)^2 = 49 \]

By using the power of 80\%, a confidence interval of 95\%, ICC of 0.05, the cluster size of 49, an estimated standard deviation of 3.2 and mean difference of 3.5 the calculated sample size was estimated to be 68 participants in each group. (Asklund et al., 2017) The sample size is 265 for each group after the adjustment for the expected 20\% response rate attrition rate and design effect. Hence, the total sample size for this study will be **530 participants**.

b. Using an assumed expected outcome of improvement of UI severity within 3 months intervention.

The sample size for this interventional phase is using comparison of means for cluster randomization design (Donner & Klar, 2000).

\[ n = \left( Z_{\alpha/2} + Z_{\beta} \right)^2 \left( 2\sigma^2 \right) \left[ 1 + (m-1)\rho \right] / (\mu_1 - \mu_2)^2 \]

\[ Z_{\alpha/2} = 1.96 \text{ at 95\% confidence interval,} \]
\[ Z_{\beta} = 0.84 \text{ corresponding for power of 80\%,} \]
\[ \sigma = 6.4 \text{ (estimated standard deviation),} \]
\[ \rho = 0.05 \text{ (intra-cluster correlation coefficient (ICC)),} \]
\[ \mu_1 - \mu_2 = 5.3 \text{ (mean difference) (Asklund et al., 2017),} \]
\[ m = 59 \text{ (cluster size) (Eldridge, Ashby, & Kerry, 2006)} \]

\[ n = (1.96 + 0.84)^2 2(6.4)^2 \left[ 1 + (59 - 1)(0.05) \right] / (5.3)^2 = 88 \]
By using the power of 80%, a confidence interval of 95%, ICC of 0.05, the cluster size of 59, an estimated standard deviation of 6.4 and mean difference of 5.3 the calculated sample size was estimated to be 98 for the expected 90% response rate participants in each group. (Asklund et al., 2017) The sample size is 480 for each group after the adjustment for the expected 20% response rate attrition rate and design effect. Hence, the total sample size for this study will be 960 participants.

c. Using an assumed expected outcome of improvement adherence within 3 months intervention.

The sample size for this interventional phase is using comparison of means for cluster randomization design (Donner & Klar, 2000).

\[ n = \left( \frac{Z_{\alpha/2} + Z_{\beta}}{2} \right)^2 \left( \frac{2\sigma^2}{1+(m-1)\rho} \right) / (\mu_1-\mu_2)^2 \]

\[ Z_{\alpha/2} = 1.96 \text{ at 95\% confidence interval,} \]
\[ Z_{\beta} = 0.84 \text{ corresponding for power of 80\%,} \]
\[ \sigma = 3.9 \text{ (estimated standard deviation),} \]
\[ \rho = 0.05 \text{ (intra-cluster correlation coefficient (ICC)),} \]
\[ \mu_1-\mu_2 = 1.1 \text{ (mean difference) } (Sacomori et al., 2015) \]
\[ m = 59 \text{ (cluster size) } (Eldridge, Ashby, & Kerry, 2006) \]

\[ n = \left( \frac{1.96+0.84}{2} \right)^2 \left( \frac{2(3.9)^2}{1+(59-1)(0.05)} \right) / (1.1)^2 = 769 \]

By using the power of 80%, a confidence interval of 95%, ICC of 0.05, the cluster size of 769, an estimated standard deviation of 3.9 and mean difference of 1.1 the calculated sample size was estimated to be 854 for the expected 90% response rate (Sacomori et al., 2015). The sample size is 4165 for each group after the adjustment for the expected 20% response rate attrition rate and design effect. Hence, the total sample size for this study will be 8330 participants.

d. Using an assumed expected outcome of improvement of sexual function within 3 months intervention.

The sample size for this interventional phase is using comparison of means for cluster randomization design (Donner & Klar, 2000).

\[ n = \left( \frac{Z_{\alpha/2} + Z_{\beta}}{2} \right)^2 \left( \frac{2\sigma^2}{1+(m-1)\rho} \right) / (\mu_1-\mu_2)^2 \]

\[ Z_{\alpha/2} = 1.96 \text{ at 95\% confidence interval,} \]
\[ Z_{\beta} = 0.84 \text{ corresponding for power of 80\%,} \]
\[ \sigma = 4.2 \text{ (estimated standard deviation),} \]
\[ \rho = 0.05 \text{ (intra-cluster correlation coefficient (ICC)),} \]
\[ \mu_1-\mu_2 = 8.7 \text{ (mean difference) } (Pourkhiz, Mohammad-Alizadeh-Charandabi, Mirghafourvand, Haj-Ebrahimi, & Ghaderi, 2017) \]
\[ m = 59 \text{ (cluster size) } (Eldridge, Ashby, & Kerry, 2006) \]
\[ n = (1.96 + 0.84)^2 \frac{2(4.2)^2 [1+(59-1)(0.05)]}{(8.7)^2} = 7 \]

By using the power of 80%, a confidence interval of 95%, ICC of 0.05, the cluster size of 49, an estimated standard deviation of 4.2 and mean difference of 8.7 the calculated sample size was estimated to be 7 participants in each group (Pourkhiz et al., 2017). The sample size is 39 for each group after the adjustment for the expected 20% response rate attrition rate and design effect. Hence, the total sample size for this study will be 78 participants.

e. Using an assumed expected outcome of improvement of sexual function within 6 months intervention.

The sample size for this interventional phase is using comparison of means for cluster randomization design (Donner & Klar, 2000).

\[ n = (Z_{\alpha/2} + Z_{\beta})^2 \frac{(\sigma^2) [1+(m-1)\rho]}{(\mu_1-\mu_2)^2} \]

\[ Z_{\alpha/2} = 1.96 \text{ at 95\% confidence interval}, \]
\[ Z_{\beta} = 0.84 \text{ corresponding for power of 80\%}, \]
\[ \sigma = 1.8 \text{ (estimated standard deviation)}, \]
\[ \rho = 0.05 \text{ (intra-cluster correlation coefficient (ICC))}, \]
\[ \mu_1-\mu_2 = 8.1 \text{ (mean difference) (Pourkhiz et al., 2017)} \]
\[ m = 59 \text{ (cluster size) (Eldridge, Ashby, & Kerry, 2006)} \]

\[ n = (1.96 + 0.84)^2 \frac{2(1.8)^2 [1+(59-1)(0.05)]}{(8.1)^2} = 3 \]

By using the power of 80%, a confidence interval of 95%, ICC of 0.05, the cluster size of 3, an estimated standard deviation of 1.8 and mean difference of 8.1 the calculated sample size was estimated to be 4 participants in each group (Pourkhiz et al., 2017). The sample size is 20 for each group after the adjustment for the expected 20% response rate attrition rate and design effect. Hence, the total sample size for this study will be 40 participants.

From the sample size estimation of the outcomes, the outcome measure of adherence towards PFME provides the largest sample size \( n = 4165 \text{ per group} \) with total sample size for two groups is 8330 participants. Hence, this will be used as the sample size for this research study.

3.2.10 Recruitment

The recruited pregnant women will be allocated to the intervention or control groups on a 1:1 basis, cluster sampling method.

After attained the ethical approval, the recruitment will be undertaken at the antenatal clinics at twelve primary care clinics in Hulu Langat district, Selangor. The researcher (Ph.D. candidate) will attend the briefing sessions or staff meeting before
the recruitment process. Pregnant women will be recruited either during their antenatal visit before 20 weeks gestation. There will be an informative advertisement about this research with a registration link or QR code to join this research. The participants will sign e-consent to participate in this study.

After they agreed to participate, they will have to answer screening questions for the inclusion and exclusion criteria. Those who are eligible will be given a message stated that they are suitable to join this research and to click with the link given via the message or WhatsApp. This link will lead to the downloaded mHealth apps, and they will follow the instructions given via mHealth Apps. The participants will need to answer a few questions to assess their continence status, and the result will appear at their mHealth Apps.

### 3.2.11 Randomization
The randomization will be carried out at the clinic level. Simple randomization protocol will be conducted by the researcher assistant to randomized 12 randomly selected clinics into two groups; control and intervention groups. The random allocation will perform as below:

1. Numbers were assigned to the clinics.
2. Numbers were written in pieces of paper, folded and mixed up
3. The numbers were then picked at random.
4. First six clinics will be assigned as intervention clinics, and another six clinics will be assigned as control clinics.

Pregnant women in the intervention group will receive usual perinatal care and a newly developed mHealth App on PFME for pregnancy self-care. Usual perinatal care at primary care clinics composes of physical examination, health screening, case management, and health education, based on the Ministry of Health guidelines for pregnant women (Ministry of Health Malaysia (MOH), 2013). Usual perinatal care at the study sites does not include routine UI assessment or follow-up of UI concerns. The control groups in this study will receive the usual prenatal care and manual prenatal care guideline (Ministry of Health Malaysia (MOH), 2013) via whatsapp or email.

### 3.2.12 Blinding: Single-blinded RCT
Being as a single-blinded cluster randomized trial, only the researcher will be unaware of which group they were in. With regards to the blinding procedure, the consent and information sheets for respondents state general information about the study (mobile apps program). It will not mention about the program they were about to receive. It will be a method to maintain the blinding process throughout the study. The participants will receive a QR code or an activation code for them to log in the mobile apps program.
The group allocation is according to the clinic with an intention of reducing the cross contamination. Hence, participants will be unaware of which group they were in when discussing with other participants form the same clinics.

The data collection and information given to the participants will be conducted by the same researcher. This is to ensure the quality of care and to avoid miscommunication. There will Frequently Ask Questions (FAQ) available in the mHealth Apps to allow the participants more understating with regards to the common questions frequently asked on the PFME and UI.

The questionnaires are self-report questionnaires, and it will be entered automatically into the system for the analysis. Hence, the researchers will be blind to the participant’s answers and their group allocation.

3.2.13 Study duration
The study duration will take a total of two years which will begin from the searching of relevant literature and development of a mHealth App on PFME for pregnancy self-care. The pregnant women will participate in this study for 26-28 weeks in duration (from before 20 weeks gestation until six weeks post-partum). The study population is healthy pregnant women attending antenatal outpatient clinics at the time of the study in primary care clinics. The list of all pregnant women who meet the inclusion criteria will serve as the sampling frame of the present study. The patients will be recruited during every clinic day. A trained research assistant for recruitment will approach eligible pregnant women who meet the inclusion and exclusion criteria while they are waiting to see the doctor.

3.2.14 Data collection
In both intervention and control study groups, the data collection will be carried out at baseline which is immediately after recruitment and three-time points: at early (28-30 gestation weeks), late third trimester (36-38 gestation weeks) and postnatal period (4-6 weeks). The pregnant women will be followed up at early third trimester, late third trimester and early postnatal period as the prevalence of UI increases during this period. Moreover, theoretically muscular changes after specific pelvic floor muscle exercise to treat and prevent UI occur during the first 6 to 8 weeks (Dinc, Kizilkaya Beji, & Yalcin, 2009).

3.2.14.1 Data collection questionnaires:
For the primary outcome, this study will use a questionnaire based on the International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form (ICIQ-UI-SF). The severity of UI will be assessed based on ICIQ scores (Lim Renly, Liong Men Long, Lau Yong Khee, 2017). ICIQ-UI-SF has been shown to have good construct validity, acceptable convergent validity and good reliability internationally and also locally validated (Avery et al., 2004; Lim Renly, Liong Men Long, Lau Yong Khee, 2017). ICIQ-UI-SF contains a total of 4 items about continence status. Women will be assessed as a continent if they answer “never’’ to the question: “how often do you leak urine”? The severity of UI will be scored based on the first three questions in ICIQ-UI-SF with an overall score of 0-21 which
categories into; slight (1-5), moderate (6-12), severe (13-18) and very severe (19-21). The higher the values indicate increased severity.

Other secondary outcomes will be using four other sets of questionnaire. Quality of life among the respondents will also be scored. The questionnaire involves Incontinence Impact Questionnaire Quality of Life (ICIQ-LUTSqol). The ICIQ-LUTSqol is for evaluating the quality of life (QoL) in incontinent urinary patients. It provides a detailed and vigorous measure to assess the impact of urinary incontinence on quality of life with specific reference to social effects. It explores in detail the impact on patients’ lives of urinary incontinence and can be used as an outcome measure to assess the impact of different treatment modalities. It has 20 items and will take 10-15 minutes. It has been validated in Malay and Chinese version (Lim Renly, Lioong Men Long, Lau Yong Khee, 2017).

Self-efficacy questionnaire which will be using the SESPPFE questionnaire. It is a valid and reliable tool in measuring self-efficacy among post-partum women to practice pelvic floor exercises (Sacomori et al., 2013). The study showed that Chronbach’s alpha was α=0.923. The construct is on the performance expectation considering the action, performance expectation considering the preparation for action and outcome expectations (Sacomori et al., 2013). The validated and translated version of this questionnaire has not been available in our country. Hence, this questionnaire will be translated and validated for this study.

Another data on adherence to the protocol. It is defined as exercising three days per week or more at moderate to high intensity. Performing the exercise programme is strongly emphasized. In addition to this, a questionnaire on adherence to exercise will be used (EARS). EARS will enable the objective measurement of adherence (Newman-Beinart et al., 2017). It has been constructed for prescribed home exercise in managing and prevention of chronic conditions (Newman-Beinart et al., 2017). EARS consists of six items with Chronbach’s alpha α = 0.810. EARS has five response levels which are from completely agree to completely disagree. This validated and translated version of this questionnaire has not yet available in our country. Therefore, this questionnaire will need to be translated and validated to the population of this study.

Finally, Female Sexual Function Index (FSFI) was consistent with the questionnaire correlated to sexual activity, intercourse, and stimulation (Rosen et al., 2000). The questionnaire comprised of 19 items and 6 subcategories (desire, arousal, lubrication, orgasm, satisfaction, and pain). It has been locally validated and translated from a primary care clinic based study (Sidi et al., 2007). The study found that there was a high test–retest correlation by respondent with good discriminant validity for all domains.

3.3 Data Management

All data will be gathered from the system developed by the mHealth Apps. This system enables the participants and the researcher to the data accessibility. The
participants will be able to monitor their progression on the UI, and this will motivate them doing PFME. The data will be securely stored in this system. The participant’s identity will not be disclosed during data entry and analyses.

Log analysis consists of log data; a form of data representing interactions of the user with the mobile application. Log analysis in this research is used for measuring user task completion and to determine the important components in the compliance. Clickstream analysis is a method popular in web analytics that deals with identifying usage patterns in web pages. An application of this method from web analytics is used in this research to identify usage patterns from log data and to determine where users get “off track” (become non-compliant to a design intent). These patterns are used for task identification and interaction sequence mining. Together, these three methods give a better understanding of the impact of the mobile app design on clinical outcomes.

The data will be entered and will be analyzed using Statistical Package for Social Science (SPSS) version 25.0 (SPSS Inc., Chicago, IL). The significant level will be set at $a = 0.05$. The categorical data will be presented in the form of a total number and their corresponding percentage values. The continuous data, the mean and standard deviation will be analyzed.

3.4 Statistical method

Generalized Linear Mixed Model (GLMM) analysis was used to examine the effect of the intervention primary (UI) and secondary outcomes (PFME adherence and Quality of Life). Baseline data were adjusted in GLMM analysis. In this analysis, the clustering effect (clinic level effects) was also adjusted. The 95% confidence interval (95% CI) was set for means estimation, with a p-value at 0.05 for the level of significance for rejection of the null hypothesis.

Repeated measures logistic regression analysis using generalized estimating equations (GEE) will be used to evaluate the odds ratios of continence status UI between the intervention groups and control groups at four-time points. Group differences in primary outcome will be illustrated as odds ratios with 95% confidence interval. In the case of statistically significant results, Cohen’s d will be calculated for the effect size. The data will be analyzed according to the continence status and severity of UI. All statistical tests are based on two-tailed test and the level of significance, alpha ($\alpha$) is set at 0.05.

Analysis of outcomes will be by intention-to-treat where all participants who were randomized and entered the trial need to be included in the analysis in the condition to which they were assigned, regardless of whether they completed the trial, or may even have switched over to receive the incorrect treatment, per-protocol (complete case) analysis and chi square test.

3.5 Data Monitoring
The data will be given to the Universiti Putra Malaysia and ethical committee six-monthly to update the research progress. The data will be stored for two years and will be destroyed.

3.6 Description of any interim analysis and stopping guidelines (if any harm).

The onsite researcher will have access to the data. If any pregnant women have any health issues at the recruitment and during the research, they will be encouraged to seek help from their health care professionals during antenatal follow up or any primary care clinics to receive any treatment. Evidence has shown no harm to perform PFME among pregnant women. The participants will be given relevant information with regards to UI and PFME via mHealth Apps. The participants can request to withdraw from the study at any time.

3.7 Ethical consideration(s)

This research needs approval by the Ethics Committee for Research Involving Human Subjects, Universiti Putra Malaysia (JKEUPM: Jawatankuasa Etika Universiti Melibatkan Manusia), National Research Medical Registration (NMRR) and Medical Research and Ethics Committee (MREC) before its implementation.

This research will also be registered under Australia New Zealand Clinical Trial Registry (ANZRCT) with the request id number: 376963. This research has its own Universal Trial Number (UTN) by the World Health Organisation (WHO): U1111-1228-5103.

Free and voluntary informed consent will be obtained from participants. Participants have the right to withdraw from the study at any point. The mobile apps in this study is designed with unique features to ensure personal privacy and confidentiality at all time. The participant’s identification will be protected during any journal publications or proceedings.

3.8 Protocol amendments

The amended protocol will be submitted to the ethical committee if any.

3.9 Confidentiality

A code number will identify participants in the trial, with a master code data linked to the patient’s name. This is to ensure the issue of confidentiality. The researcher is responsible for ensuring data safety. The participants will have access to the results of their assessments. They will be able to monitor their UI progression via their apps.
4.0 Declaration of interests
There is none to declare.

5.0 Budget

Table 6: Details of the budget

<table>
<thead>
<tr>
<th>Budget details</th>
<th>Amount requested</th>
</tr>
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<tbody>
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<td></td>
<td>Year 1 (RM)</td>
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<tr>
<td>Salary and wages</td>
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</tr>
<tr>
<td>One Research Assistant: Pekerja Smabilan Harian (UPM)</td>
<td>3,000</td>
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<tr>
<td>Travelling and Transportation/ (Transportation costs to-and-from study site)</td>
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<tr>
<td>Rental</td>
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<td>Research Materials &amp; Supplies (Printing of Banners)</td>
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<td>Maintenance and Minor Repair</td>
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<td>Professional Services</td>
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<td>Accessories and Equipment</td>
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6.0 Gantt chart & milestone

Please refer to Table 7
7.0 References


https://doi.org/10.1016/j.urology.2003.10.037


Tahtinen Riikka M, Cartwright, R., Tsui, J. F., Aaltonen, R. L., El, R., Joronen, K. M.,


Table 7: Gantt Chart of Research Activities, Milestones and Dates

The effectiveness of a mHealth App on Pelvic Floor Muscle Exercises in improving compliance and continence status amongst pregnant women: a randomized controlled trial.

<table>
<thead>
<tr>
<th>Year</th>
<th>2019</th>
<th>2020</th>
</tr>
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<tbody>
<tr>
<td>Project implementation plan write up</td>
<td></td>
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<tr>
<td>Ethical Proposal</td>
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<tr>
<td>Phase 1</td>
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<tr>
<td>• Data collection</td>
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<tr>
<td>• Data entry and analysis</td>
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<tr>
<td>• Results and discussion</td>
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</tr>
<tr>
<td>Phase 2: Software development life cycle</td>
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<tr>
<td>• System integration testing (expert review)</td>
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<tr>
<td>• User acceptance testing (pilot test)</td>
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<tr>
<td>• Production – mHealth app release to the public</td>
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<tr>
<td>Phase 2: Clinical trial</td>
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<tr>
<td>• Patient recruitment</td>
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<td></td>
</tr>
<tr>
<td>• Data collection</td>
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<td></td>
</tr>
<tr>
<td>• Data analysis &amp; thesis writing</td>
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