UNIVERSITI PUTRA MALAYSIA

RANDOMISED CONTROLLED TRIAL IN PELVIC FLOOR MUSCLE EXERCISE INTERVENTION ON URINARY INCONTINENCE AMONG PREGNANT WOMEN

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Thesis Submitted to the School of Graduate Studies, Universiti Putra Malaysia, in Fulfilment of the Requirements for the Degree of Doctor of Philosophy

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Abstract of thesis presented to the Senate of Universiti Putra Malaysia in fulfilment of the requirement for the degree of Doctor of Philosophy

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Chairman : Professor Datin Sherina Mohd Sidik, MBBS, MMED, PhD
Faculty : Medicine and Health Sciences

Across Malaysia, despite an increased prevalence of urinary incontinence during pregnancy between 34% and 85% over the past five years, the awareness and practice of pelvic floor muscle exercise (PFME) in the prevention and reduction of urinary incontinence (UI) among pregnant women was considerably poor. This requires substantial, and urgent attention to promote continence health in the antenatal phase of a woman's life. The objective of this study was to develop, implement and evaluate the effectiveness of PFME intervention based on health belief models and motivational interviewing, focused on improving knowledge, attitude, practice and self-efficacy relating to PFME, continence status and severity of urinary symptoms amongst pregnant women. A single blinded two-armed randomised control trial was conducted in the Maternity Hospital of Kuala Lumpur. A hundred and seventy eligible pregnant women at 18-20 weeks gestation with or without urinary incontinence were randomly assigned into intervention and control group by using a computer-generated stratified permuted block size of 6 for each combination of the continence status and parity. In addition to usual perinatal care, the intervention group received PFME intervention which consists of one group session of PFME education followed by three booster sessions at 4 weeks post-intervention, early, and late third trimester of pregnancy together with weekly text message reminders for 8 weeks. Whereas, the control group received the usual perinatal care. The data were collected at 4 time points; baseline, post intervention at early third trimester, late third trimester and early postnatal. Socio-demographic and clinical characteristics as well as primary and secondary outcome measurements were taken using validated questionnaires; Knowledge Attitude Practice of PFME questionnaire, Self-Efficacy Scale for Practicing Pelvic Floor Exercises and the International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form.

Data were analyzed using SPSS Statistics 22 and the significant level set at alpha=0.05. The intervention effects were analyzed using a generalized estimating equation. The primary analysis was based on modified intention-to-treat including respondents with at least 1 follow-up, pursued with an intention-to-treat sensitivity analysis. Among the 170 respondents at baseline, 112 (65.9%) returned for their early third trimester follow-up visit, 82 (48.2%) returned for their late third trimester follow-up and only 21 (12.4%) returned for their early postnatal follow-up. At baseline, there were no significant differences in socio-demographics and characteristics of the respondents between intervention and control group. The results of primary analysis, which includes 122 respondents show that the intervention group had a significant improvement in knowledge (Wald X^2=59.571, p<0.001), attitude (Wald X^2=19.164, p<0.001), practice (Wald X^2 =58.113, p<0.001) and self-efficacy (Wald X^2=90.045, p<0.001) over time compared to the control. However, there was no significant improvement in self-reported urinary incontinence (Wald X^2=3.369, p=0.338) but the severity of urinary incontinence was significantly reduced over time among the intervention group compared to control group (Wald X^2=25.904 p<0.001). The results of this study indicate that PFME intervention could be considered as an initial offering in providing information about urinary incontinence prevention to pregnant women.

Key words: Pelvic Floor Muscle Exercises, urinary incontinence, knowledge, attitude practice, self-efficacy

Abstrak tesis yang dikemukakan kepada Senat Universiti Putra Malaysia sebagai memenuhi keperluan untuk ijazah Doktor Falsafah

PERCUBAAN KLINIKAL TERKAWAL RAWAK INTERVENSI SENAMAN OTOT LANTAI PELVIK TERHADAP INKONTINENS URINARI DI KALANGAN WANITA HAMIL

Oleh

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Di Malaysia, walaupun terdapat peningkatan prevalensi inkontinens urinari semasa kehamilan antara 34% dan 85% selama 5 tahun terakhir, kesedaran dan amalan senaman otot lantai pelvik dalam pencegahan dan pengurangan inkontinens urinari di kalangan wanita hamil sangat rendah. Ini memerlukan perhatian segera untuk mempromosikan kontinens urinari semasa peringkat kehamilan kehidupan seorang wanita. Objektif kajian ini adalah untuk membangun, melaksanakan dan menilai keberkesanan intervensi senaman otot lantai pelvik berdasarkan model kepercayaan dan wawancara motivasi, dengan memberi tumpuan kepada meningkatkan pengetahuan, sikap, amalan dan keyakinan dalam melaksanakan senaman serta status dan keterukan gejala inkontinens urinari di kalangan wanita hamil. Kajian percubaan kawalan rawak dua-kelompok telah dijalankan di Hospital Bersalin Kuala Lumpur. Seramai 170 wanita hamil yang layak pada 18-20 minggu kandungan dengan atau tanpa inkontinens urinari telah dimasukkan secara rawak samada ke dalam kelompok intervensi atau dalam kelompok kawalan dengan menggunakkan blok permakut yang dijana oleh computer sebanyak enam peserta bagi setiap kombinasi status kontinens urinari dan pariti. Di samping penjagaan perinatal yang biasa, kumpulan intervensi menerima intervensi senaman otot lantai pelvik yang terdiri daripada satu sesi pendidikan senaman otot lantai pelvik secara berkumpulan diikuti oleh tiga sesi penggalak pada empat minggu selepas intervensi dan, pada awal dan lewat trimester ketiga kehamilan. Manakala, kumpulan kawalan menerima penjagaan perinatal biasa. Data dikumpulkan pada empat titik masa; permulaan kajian, pada awal dan lewat trimester ketiga dan pada peringkat awal selepas bersalin. Data sosio-demografi dan ciri klinikal serta hasil kajian primer dan sekunder telah diambil dengan menggunakan borang soal selidik yang telah disahkan; Pengetahuan, Sikap dan Amalan senaman otot lantai pelvik soal selidik, sekala keyakinan diri

untuk mengamalakan senaman otot lantai pelvik (*Self-efficacy Scale for Practicing Pelvic Floor Exercises*) dan perundingan Antarabangsa mengenai soal selidik inkontinens urinari (*International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form*). Data dianalisis dengan menggunakan SPSS versi 22 dan tahap signifikan ditetapkan pada alfa 0.05. Kesan intervensi dianalisis dengan menggunakan ujian "*generalized estimating equation"*. Analisis utama dibuat berdasarkan niat-untuk-rawatan yang diubah termasuk responden dengan sekurang-kurangnya satu susulan, diikuti dengan analisis kepekaan mengikut niat-untuk-merawat. Antara 170 responden di peringkat awal, 112 (65.9%) kembali untuk lawatan susulan pada awal trimester ketiga, 82 (48.2%) kembali untuk susulan pada akhir trimester ketiga dan hanya 21 (12.4%) yang kembali untuk susulan selepas bersalin. Pada peringkat awal, tidak terdapat perbezaan yang signifikan dalam sosio-demografi dan ciri-ciri responden antara kumpulan intervensi dan kawalan. Keputusan analisis utama, yang merangkumi 122 responden menunjukkan bahawa kumpulan intervensi mempunyai peningkatan yang signifikan dalam pengetahuan (Wald X^2=59.571, p<0.001), sikap (Wald X^2=19.164, p<0.001), amalan (Wald X^2 =58.113, p<0.001) dan keyakinan diri (Wald X^2=90.045, p<0.001) dari masa ke masa berbanding dengan kumpulan kawalan. Walaupun, tiada perubahan yang ketara dalam status kontinens urinari (Wald X^2=3.369, p=0.338) tetapi keterukan gejala inkontinens urinari telah berkurangan dengan ketara di kalangan kumpulan intervensi berbanding dengan kumpulan kawalan (Wald X^2=25.904 p<0.001). Hasil kajian ini menunjukkan bahawa intervensi senaman otot lantai pelvik ini dapat dianggap sebagai penawaran awal dalam memberikan maklumat mengenai pencegahan inkontinens urinari kepada wanita hamil.

Kata kunci: Senaman otot lantai pelvik, inkontinens urinari, pengetahuan, amalan sikap, keyakinan diri

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LIST OF ABBREVIATIONS

BMI	Body Mass Index
FGD	Focus group discussion
GEE	Generalized estimating equations
HBM	Health Belief Model
HKL	Hospital Kuala Lumpur
ICIQ-UI-SF	International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form
ICS	International Continence Society
IUGA	International Urogynecological Association
ITT	Intention-to-treat
KAP	Knowledge, Attitude and Practice
LOCF	last observation carried forward
MHKL	Maternity Hospital of Kuala Lumpur
MI	Motivational interviewing
mITT	Modified “Intention to treat”
MOH	Ministry of Health
MUI	Mixed urinary incontinence
NICE	National Institute for Health and Clinical Excellence
NIH	National Institute of Health Quality Assessment
PFME	Pelvic Floor Muscle Exercises
QoL	Quality of life
RA	Research assistant
RCT	Randomized Control Trial
SESPPFE	Self-Efficacy Scale for Practicing Pelvic Floor Exercises

SPSS	Statistical package for the social science
SUI	Stress urinary incontinence
UI	Urinary incontinence
UUI	Urge urinary incontinence
WHO	World Health Organization

CHAPTER 1

INTRODUCTION

This chapter discusses the background of the study, defines the problem of interest and explains the significance of the study, research objectives, and hypothesis.

1.1 Background

Urinary incontinence (UI) is a significant public health concern found in women since it may impact all aspects of a woman's life and wellbeing from physical, social and psychological aspects (Lukacz et al., 2011). UI can be divided into stress urinary incontinence (SUI), urge urinary incontinence (UUI), and mixed urinary incontinence (MUI). SUI is involuntary urinary leakage that occurs through physical exertion or effort, coughing or sneezing while UUI is involuntary urinary leakage associated with a sudden urge to void or urgency and MUI is a mixture of all the ascribed symptoms (Haylen et al., 2010).

The UI is the most common bladder health problem diagnosed in women, estimated in 2018, to affect 423 million or 21.6% women globally (Irwin et al., 2011). Population studies from numerous countries have reported that the prevalence of UI has ranged approximately from 5% to 70% (Milsom & Gyhagen, 2019). The regional burden of this condition is projected to be the most significant in Asia. In the United States (US), the projected total cost of UI in 2015 was $76.2 billion and is predicted to be $82.6 billion in 2020 (Coyne et al., 2014). Current evidence suggests that the substantial economic burden of UI to patients and society increases over time in parallel with the projected increase in UI prevalence globally (Irwin et al., 2011; Milsom et al., 2014). Therefore, it is important to concentrate on preventive care at particular phases of a woman's life, which is predisposed to the risk of developing UI.

Pregnancy has been established as being the major predisposing factor in the development of UI among women (Fritel et al., 2012; Wesnes et al., 2012). A large proportion of women ranged from 17% to 54% experience first UI during pregnancy (Wesnes et al., 2012). Indeed, UI during pregnancy is an important form of maternal morbidity, which is often overlooked and ignored and can be considered to be a silent maternal problem since many pregnant women perceive UI as a normal physiological pregnancy change and failing to report it to their obstetricians or midwives as a potential health problem (Adaji et al, 2010; Bo et al., 2012; Hill et al., 2017). Moreover, UI is not disclosed voluntarily, nor is it explored by healthcare professionals during a woman's pregnancy (Barbosa et al., 2018c).

Although gradual remission can occur in postpartum for some women who experience UI during pregnancy, for the rest, UI tends to recur and gradually worsen during subsequent pregnancies or persist for longer periods or throughout lifetime (Pizzoferrato et al., 2014; Svare et al., 2012). The onset of UI during pregnancy increases the risk of UI in the immediate postpartum, whereby the symptoms could last up to 6 months to 12 years (Arrue et al., 2010; Gartland et al., 2012; Hansen et al., 2012; Liang et al., 2013; Lin et al., 2018; Pizzoferrato et al., 2014; Solan-Domenech et al., 2010;). In comparison to continental nulliparous women during pregnancy, incontinent women have a seven-fold increase in the odds of acquiring persistent UI (Gartland et al., 2012).

In light of this, the antenatal period provides an opportunity in the primary prevention of UI among women (Bo et al., 2012). Moreover, in order to avoid or delay UI onset, pregnant women are recommended to engage in preventive strategies specifically pelvic floor muscle exercises (PFME), even in the absence of incontinence given it is considered to be a safer preventive strategy option during pregnancy (Sievert et al., 2012). Current systematic reviews and Cochrane reviews have established PFME as a first-line treatment and prevention of UI during pregnancy and postpartum (Boyle et al., 2012; Morkved & Bo, 2014; Woodley et al., 2017). The International Continence Society (ICS) (Abram et al., 2010) and the National Institute for Health and Clinical Excellence (NICE, 2013) guidelines also recommend antenatal PFME should be offered to all pregnant women as a preventive strategy measure for UI.

Accordingly, training pelvic floor muscles during early pregnancy offers an opportunity to prevent and reduce UI and may reduce the need for further invasive intervention in future. Therefore, PFME should be a standard component of prenatal and postpartum care, and women should be well educated and instructed to perform PFME during pregnancy and postpartum (Wesnes & Lose, 2013). Specifically, all pregnant women at a minimum should be offered PFME information and education in the early stage of their pregnancy and also explore women's self-efficacy in performing PFME together with other reminders to regularly perform PFME (Daly et al., 2019).

1.2 Problem Statement

UI prevalence has been reported to increase significantly during pregnancy across Malaysia, with prevalence ranging from 34% to 85% over the past 5 (Abdullah et al., 2016; Jaafar et al., 2020; Yusoff et al., 2019). In addition to the higher prevalence, the onset of UI during pregnancy may potentially increase the persistent or later-life prevalence of UI among women (Abdullah et al., 2016; Dariah et al., 2014; Jaafar et al., 2020; Yusoff et al., 2019). Despite this, there are limited UI screenings during antenatal visits and not all women are informed about the implication of UI during pregnancy (Yusoff et al., 2019).

Nevertheless, this is of significant concern, especially for pregnant women who are not seeking help for any onset of UI during pregnancy due to their unawareness of the real fact that the condition is highly preventable and treatable (Hill et al., 2017; Liu et al., 2019). Moreover, the existing research has revealed that the overall knowledge and practice of PFME remained poor among pregnant women at the third trimester (Rosediani et al., 2012). This highlights the fact that the delay in providing accurate and timely information concerning preventive strategies of UI may inhibit women from adopting preventive action and intervention during their pregnancies.

In Malaysia, PFME are prescribed as part of antenatal exercise during antenatal educational classes which are generally offered to women and their partners in the third trimester of the woman's pregnancy and afford a wide variety of topics on labour, birth, parenthood, breastfeeding, postnatal care, exercises and healthy eating by a multidisciplinary team. With regards to the exercises, a physiotherapist conducts the classes according to the Antenatal and Postnatal Exercise Manual developed by the Family Health Development Division, Ministry of Health Malaysia, MOH (Ministry of Health, 2014).

Although PFME has become a standard component in the Antenatal and Postnatal Exercise Manual aside from postural care, breathing exercise, general stretching and strengthening exercise, less emphasis is placed on PFME related to UI prevention. The information regarding PFME in this manual is very brief with minimal focus on the details associated with pelvic floor muscles anatomy and function, the benefit of PFME exercise, PFME self-efficacy and healthy lifestyle behaviour related to UI prevention. Also, despite the availability of this manual, little is known concerning the continence promotion and its effectiveness in promoting behavioural changes among pregnant women in Malaysia.

At the same time, current public health initiatives or recommendations in Malaysia place less emphasis on UI prevention and control, even though the prevalence of UI among pregnant women is high. Given this situation, there needs to be a simple, easy and cost-effective PFME intervention or program that not only guides the local healthcare providers to educate antenatal women, but also help the pregnant women to make decisions regarding their continence health (Abdullah et al., 2016; Daliah et al., 2014; Rosediani et al., 2012).

Although many studies report the effectiveness of antenatal PFME intervention or training in preventing and reducing UI during pregnancy, there is limited evidence to support the PFME intervention in the Malaysian context. Moreover, the theoretical basis for PFME intervention is poorly defined in existing studies, given the importance of behavioural changes in the success of PFME intervention in the prevention and management of UI (McClurg et al., 2015). At the same time, only limited intervention studies explore and measure

the variables that are related to behavioral changes such as knowledge, attitude, practice and self-efficacy related to PFME on UI.

Therefore, in response to the previous studies gaps stated above, this study aims to develop, implement and evaluate the effectiveness of a PFME intervention on knowledge, attitude, practice and self-efficacy of PFME and to determine whether this intervention improves the continence status and severity of urinary symptom among pregnant women. Moreover, this study differs from previous studies conducted locally and in other countries in several ways. Firstly, this study focuses on the effectiveness of a PFME intervention on target behaviour changes, which may aid in improving continence status and severity of urinary symptoms. In addition, this study employs the health belief model (HBM) and motivational interviewing (MI) techniques to develop and implement the PFME intervention effectively. Finally, the PFME intervention material was developed and implemented in two languages, English and Bahasa Malaysia: the native language of Malaysia.

1.3 Significance of the Study

While PFME intervention has been extensively studied in western countries, the availability of data is limited in Malaysia. Hence, important information on the effectiveness of PFME in UI control strategies among pregnant women is deficient. As such, the findings of this study will extend and contribute to the body of knowledge on PFME and improve future interventions which may be integrated into local antenatal services within the country. At the same time, the present study may benefit pregnant women by improving their knowledge, attitude, practice and self-efficacy of PFME, and improve their continence status by preventing or reducing the occurrence of UI, and reducing the severity of UI during pregnancy and postnatally.

Notwithstanding, the development of this PFME intervention shall also benefit healthcare providers: especially physiotherapists in Malaysia, as they would be able to use the intervention manual as a guide during antenatal education classes. As mentioned earlier, there is a lack of specific guidelines, manuals, or modules in this area locally. Additionally, this intervention manual will enable physiotherapists to disseminate evidence-based information on UI and PFME to pregnant women and enhance the quality of antenatal care in line with our national efforts to improve maternal health care in Malaysia, Millennium Development Goal 5 (Malaysia Millennium Development, 2015).

1.4 Research questions

1. Is the PFME intervention effective in improving PFME knowledge, attitude, practice and self-efficacy among pregnant women in Malaysia?
2. Is the PFME intervention effective in improving continence status and severity of urinary symptom among pregnant women in Malaysia?

1.5 Objectives of the Study

1.5.1 General Objective

The general objective of this study is to develop, implement, and evaluate the effectiveness of a PFME intervention in improving knowledge, attitude, practice, and self-efficacy of PFME and continence status and severity of urinary symptom among the respondents.

1.5.2 Specific Objectives

The specific objectives of the study are:

1. To develop and implement the PFME intervention for pregnant women in a hospital in Kuala Lumpur, Malaysia.
2. To determine the difference in the baseline socio-demographic characteristics, clinical, and obstetric characteristics and baseline outcome measures of PFME knowledge, attitude, practice, self-efficacy, continence status, and severity of urinary symptom of the respondents between the intervention and control group.
3. To compare the PFME knowledge, attitude, practice and self-efficacy of the respondents at baseline, early third trimester, late third trimester and early postnatal between and within the intervention and control group.
4. To compare the continence status and severity of urinary symptom of the respondents at baseline, at early third trimester, late third trimester, and early postnatal between and within the intervention and control group.
5. To evaluate the effectiveness of the PFME intervention on PFME knowledge, attitude, practice and self-efficacy over time at early third trimester, late third trimester, and early postnatal between the intervention and control group among the respondents.
6. To evaluate the effectiveness of the PFME intervention on the continence status and severity of urinary symptom over time at early third trimester, late third trimester, and early postnatal between the intervention and control group among the respondents.

1.6 Research Hypotheses

It is hypothesised that:

1. There is no significant difference regarding the socio-demographic characteristics, clinical, and obstetric characteristics and outcome measures of PFME knowledge, attitude, practice and self-efficacy, continence status, and severity of a urinary symptom of the respondents between the intervention and control group.
2. There is a significant difference in PFME knowledge, attitude, practice, and self-efficacy scores at each time point between and within the intervention and control group among the respondents.
3. There is a significant difference in continence status and severity of the urinary symptom at each time point between and within the intervention and control group among the respondents.
4. There is a significant improvement in PFME knowledge, attitude, practice, and self-efficacy over time between the intervention and control group among the respondents.
5. There is a significant improvement in continence status and severity of urinary symptom over time between the intervention and control group among the respondents.

1.7 Definition of Terminology

In order to standardise the terms used in this study, the terminology is operationally defined as follows.

1.7.1 Urinary incontinence

Urinary incontinence (UI) is described as a complaint of involuntary leakage of urine (Haylen et al., 2010).

1.7.2 Continence status

Continence status refers to the presence of UI which is classified as incontinent or continent.

1.7.3 Gravidity

Gravidity refers to the number of times a woman was pregnant (Tidy & Payne., 2019). Primigravida refers to a first-time pregnant woman while multigravida refers to women who have been pregnant more than once.

1.7.4 Parity

Parity refers to the number of times that women has given birth to a fetus with a gestational age of 20 weeks or more, irrespective of whether the child was born alive or was stillborn (Tidy & Payne., 2019). In this study, pregnant women who never give birth were classified as nulliparous, and women were given birth once or more grouped as multiparous.

1.7.5 Severity of urinary symptom

Severity of urinary symptom refers to the frequency and amount of leakage, the impact of leakage on quality of life in women with urinary incontinence.

1.7.6 Pelvic Floor Muscles Exercise

Pelvic floor muscle exercises (PFME) refers to the exercise especially targeted to strengthen and tone up the pelvic floor muscles that involves an inward and upward lift and squeezes around the urethra, vagina, and anus (Bo et al., 2015).

1.7.7 Pelvic floor muscle exercise intervention

PFME intervention refers to a newly developed theory based intervention with three key components: group education session, text message and booster session that provides information on UI and PFME, teaches correct pelvic floor muscle contraction, prescribes an appropriate exercise dose (frequency, intensity, duration) together with integrating the exercise into daily activities and educating the person on healthy bladder habits and motivates continuing PFME practise during and after pregnancy.

1.7.8 Knowledge of Pelvic Floor Muscle Exercise

This referred to a pregnant woman's awareness and understanding of the perceived susceptibility and severity of UI, along with the benefits and methods of performing PFME in prevention and treatment of UI during and after pregnancy.

1.7.9 Attitude towards Pelvic Floor Muscle Exercise

This referred to the pregnant woman's beliefs and feelings about PFME in the prevention and treatment of UI.

1.7.10 Practice of Pelvic Floor Muscle Exercise

This referred to the action taken to perform PFME in terms of frequency, intensity, holding time of each contraction and integrating the exercise into daily activities especially activities that increase abdominal pressure such as coughing, sneezing, and lifting.

1.7.11 Self-Efficacy of Pelvic Floor Muscle Exercise

This referred to the pregnant woman's confidence in their ability to practice PFME in the context of overcoming the challenges or barriers and their confidence with the beneficial outcome expected (Sacomori et al., 2013).

1.7.12 Effectiveness

Effectiveness refers to the significant improvement in PFME knowledge, attitude, practice and self-efficacy scores, continence status and severity of urinary incontinence post-PFME intervention.

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