

UNIVERSITI PUTRA MALAYSIA

PRELIMINARY OUTCOMES OF A NEW PELVIC TRAINING APP AMONG INCONTINENT PREGNANT WOMEN ATTENDING CLINICS IN THE HULU LANGAT DISTRICT, SELANGOR, MALAYSIA

AIDA BINTI JAFFAR

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By

AIDA BINTI JAFFAR

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

July 2022

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DEDICATION

This dissertation is dedicated to all women who have experienced urinary incontinence during pregnancy, significantly affecting their quality of life.



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

PRELIMINARY OUTCOMES OF A NEW PELVIC TRAINING APP AMONG INCONTINENT PREGNANT WOMEN ATTENDING CLINICS IN THE HULU LANGAT DISTRICT, SELANGOR, MALAYSIA

Ву

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July 2022

Chairman : Professor Datin Sherina Mohd Sidik, PhD

Faculty: Medicine and Health Sciences

Pregnant women do experience difficulty controlling urine or urinary incontinence (UI). Kegel exercise or pelvic floor muscle training (PFMT) is recommended for its treatment. PFMT is when someone performs pelvic floor muscle exercise (PFME), according to the prescription by healthcare professionals. Despite advances in digital and mobile health apps, limited PFMT apps were evidence-based. Thus, this study proposed a PFMT mHealth app using the Capability, Opportunity, Motivational and Behaviour Model to assist in its adherence. This study aimed to develop and evaluate the preliminary outcomes of a PFMT app on knowledge, attitude, practice, self-efficacy, and adherence to PFMT among incontinent pregnant women attending a clinic in Hulu Langat district, Selangor.

The multiphase mixed methods design approach comprises three main phases were involved. In phase 1, two studies were conducted; (1) a cross-sectional study to determine the knowledge, attitude, and practices (KAP) of pelvic floor muscle exercise (PFME), the prevalence of UI and its quality of life (QOL) among pregnant women (N=440), through validated questionnaires (Knowledge, Attitude Practice on PFME, Incontinence Questionnaire-Urinary and Incontinence Short Form, and ICIQ-Lower Urinary Tract Symptoms Quality of Life, and (2) five focus group discussions (FGDs) to evaluate pregnant women's (N=24) preferred design for the app. In phase 2, two concurrent studies were performed to finalize the Kegel Exercise Pregnancy Training (KEPT) app prototype design. It consisted of usability studies from both incontinent pregnant women (N=5) and experts (N=4) using the Malay-mHealth App Usability Questionnaire (Malay-MAUQ), and mHealth App Usability Questionnaire (MAUQ). Finally, phase 3 involved a pilot randomized control trial (RCT) among incontinent pregnant women (N=26) to assess the preliminary outcomes of the

KEPT app, utilizing a few questionnaires, such as the Exercise Adherence Rating Scale, the Self-Efficacy Scale For Practicing Pelvic Floor Exercise Questionnaire, and the Malay-MAUQ, in addition to similar questionnaires as phase 1. The generalized estimating equation (GEE) was used to compare both groups' improvement scores.

Phase 1 indicated that the mean age of respondents was 29.8 years old (SD 4.69), with the prevalence of UI moderately high at 40.1% (95%CI: 2.04-2.70), and only 12.7% performed regular PFME. Stress UI, (OR 6.94, 95%CI 4.00–12.04) and urge UI (OR3.87, 95%CI 0.48–31.28) were significantly associated with negative QOL. Phase 2 demonstrated that the incontinent pregnant women evaluated the app's ease-of-use, interface and satisfaction, and usefulness with 5.52/7.0, 6.4/7.0, and 6.17/7.0, respectively, whereas the experts evaluated the app's ease-of-use, interface and satisfaction, and usefulness with 5.80/7.0, 5.57/7.0, and 5.83/7.0. Phase 3 reported a retention rate of 61.5%, and only attitude toward PFMT was significantly improved post-intervention (β = 5.884, P = 0.034), whilst the adherence towards PFMT scored with (β = -2.910, P = 0.312). They rated the KEPT app (interactive version) as being usable with system information arrangement (4.98/7.0), usefulness (4.89/7.0), and ease-of-use and satisfaction (5.03/7.0).

Therefore, the KEPT app has the potential to help pregnant women adhere to PFMT. Future research should identify the effectiveness of the KEPT app in achieving adherence to PFMT and improving its UI.

Keywords: Pelvic Floor Muscle Training, urinary incontinence, mHealth app, knowledge, attitude, practice, self-efficacy

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

PENGHASILAN AWAL APLIKASI LATIHAN PELVIK DI KALANGAN WANITA HAMIL MEMPUNYAI INKONTINEN URIN YANG MENGHADIRI KLINIK DI DAERAH HULU LANGAT, SELANGOR

Oleh

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Wanita hamil mengalami kesukaran mengawal air kencing atau inkontinen (UI) di mana senaman Kegel atau latihan otot lantai pelvik (PFMT) adalah disyorkan untuk merawatnya. PFMT ialah apabila seseorang melakukan senaman otot lantai pinggul (PFME), mengikut preskripsi oleh anggota kesihatan profesional. Walaupun terdapat kemajuan dalam aplikasi kesihatan digital dan mudah alih, aplikasi PFMT berasaskan bukti masih lagi terhad. Oleh itu, kajian ini mencadangkan aplikasi mHealth PFMT menggunakan model Keupayaan, Peluang, Motivasi dan Tingkah Laku (COM-B) untuk membantu pematuhannya. Kajian ini bertujuan untuk membangunkan dan menilai hasil awal prototaip aplikasi PFMT mengenai pengetahuan, sikap, amalan, efikasi kendiri, dan pematuhan kepada PFMT dalam kalangan wanita hamil yang mempunyai masalah inkontinen yang menghadiri klinik di daerah Hulu Langat, Selangor.

Pendekatan reka bentuk dengan menggunakan kaedah campuran berbilang fasa terdiri daripada tiga fasa yang terlibat. Dalam fasa 1, dua kajian telah dijalankan; (1) kajian keratan rentas untuk menentukan pengetahuan, sikap, dan amalan (KAP) senaman otot lantai pinggul (PFME), prevalens UI dan kualiti hidupnya di kalangan wanita hamil (N=440), melalui soal selidik yang disahkan (Pengetahuan, Sikap dan Amalan mengenai PFME, Soal Selidik Inkontinens-Inkontinens Kencing Bentuk Pendek, dan Kualiti Hidup Simptom Saluran Kencing Bawah ICIQ), dan (2) lima perbincangan kumpulan fokus (FGD) untuk menilai pilihan wanita hamil (N=24) berkenaan reka bentuk app tersebut. Dalam fasa 2, dua kajian serentak telah dilakukan untuk memastikan reka bentuk prototaip aplikasi Latihan Kehamilan Senaman Kegel (KEPT). Ia terdiri daripada kajian kebolehgunaan daripada wanita hamil yang mempunyai masalah inkontinen (N=5) dan pakar (N=4) menggunakan Soal Selidik Kebolehgunaan Aplikasi Malay-mHealth (Malay-MAUQ), dan Soal Selidik Kebolehgunaan

Aplikasi mHealth (MAUQ). Akhir sekali, fasa 3 melibatkan percubaan kawalan rawak perintis (RCT) dalam kalangan wanita hamil mempunyai masalah inkontinen (N=26) untuk menilai hasil awal daripada aplikasi KEPT, dengan menggunakan beberapa soal selidik, seperti Skala Penilaian Kepatuhan Latihan, Skala Keberkesanan Kendiri Untuk Mengamalkan Soal Selidik Latihan Lantai Pelvis, dan Malay-MAUQ, sebagai tambahan kepada soal selidik yang sama seperti fasa 1. Persamaan anggaran umum (GEE) digunakan untuk membuat perbandingan peningkatan skor dikedua-dua kumpulan.

Fasa 1 menunjukkan bahawa umur purata responden ialah 29.8 tahun dengan Standard Deviation (SD) = 4.69, dengan prevalens UI sederhana tinggi pada 40.1% (95%CI: 2.04,70), dan hanya 12.7% melakukan PFME biasa. Stress UI, (OR 6.94, 95%CI 4.00, 2.04) dan Urge UI (OR3.87, 95%CI 0.48, 1.28) dikaitkan secara signifikan dengan QOL yang negatif. Fasa 2 menunjukkan bahawa wanita hamil inkontinen menilai kemudahan penggunaan, antara muka dan kepuasan aplikasi serta kegunaan masing-masing dengan 5.52/7.0, 6.4/7.0 dan 6.17/7.0, manakala pakar menilai kemudahan penggunaan aplikasi itu, antara muka dan kepuasan, dan kegunaan dengan 5.80/7.0, 5.57/7.0 dan 5.83/7.0. Fasa 3 melaporkan kadar pengekalan sebanyak 61.5%, dan hanya sikap terhadap PFMT telah meningkat dengan ketara selepas intervensi β = 5.884, P = 0.034, manakala pematuhan terhadap PFMT mendapat skor dengan β = -2.910, P = 0.312. Mereka menilai aplikasi KEPT (versi interaktif) sebagai boleh digunakan dengan susunan maklumat sistem (4.98/7.0), kebergunaan (4.89/7.0), dan kemudahan penggunaan dan kepuasan (5.03/7.0).

Oleh itu, aplikasi KEPT berpotensi untuk membantu wanita hamil mematuhi PFMT. Penyelidikan masa depan perlu mengenal pasti keberkesanan aplikasi KEPT dalam mencapai pematuhan kepada PFMT dan menambah baik UI.

Kata kunci: Senaman otot lantai pelvik, inkontinens urin, aplikasi mobil, pengetahuan, amalan sikap, keyakinan diri

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I certify that a Thesis Examination Committee has met on 22 July 2022 to conduct the final examination of Aida Jaffar on her thesis entitled "Preliminary Outcomes of a New Pelvic Training App among Incontinent Pregnant Women Attending Clinics in the Hulu Langat District, Selangor, Malaysia" in accordance with the Universities and University Colleges Act 1971 and the Constitution of the Universiti Putra Malaysia [P.U.(A) 106] 15 March 1998. The Committee recommends that the student be awarded the Doctor of Philosophy.

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This is to confirm that:

- the research conducted and the writing of this thesis was under our supervision;
- supervision responsibilities as stated in the Universiti Putra Malaysia (Graduate Studies) Rules 2003 (Revision 2012-2013) are adhered to.

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LIST OF ABBREVIATIONS

BMI Body Mass Index

CI Confidence Interval

COM-B Capability, Opportunity, Motivation – Behaviour

FGD Focus group discussion

GEE Generalized Estimating Equations

HCP Healthcare provider

ICIQ-UI-SF International Consultation on Incontinence Questionnaire-

Urinary Incontinence-Short Form

ICS International Continence Society

IUGA International Urogynecological Association

KAP Knowledge, Attitude and Practice

KK Klinik Kesihatan

mHealth Mobile Health

mHealth app Mobile Health Application

MOH Ministry of Health

MUI Mixed urinary incontinence

MYR Malaysian Ringgit

NICE National Institute for Health and Clinical Excellence

NIH National Institute of Health Quality Assessment

PFME Pelvic Floor Muscle Exercise

PFMT Pelvic Floor Muscle Training

QOL Quality of life

RA Research assistant

RCT Randomized Control Trial

SD Standard Deviation

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 study background, states the study motivation, defines the study problems, and justifies the significance of the study, research objectives, and hypothesis.

1.1 Background

Urinary incontinence (UI) is a common bladder health problem in women where the sufferer cannot hold urine voluntarily. UI can be divided into three common types: stress urinary incontinence, urge urinary incontinence, and mixed urinary incontinence, which associates with the first two (Abrams et al., 2017). Stress urinary incontinence (SUI), the commonest form of UI, is characterized by an involuntary loss of urine due to physical exertion, such as sneezing or coughing (Abrams et al., 2017).

UI occurred during pregnancy and post-partum (post-delivery) (Moossdorff-Steinhauser et al., 2021c). Many women experienced UI even during their first pregnancy, as reported by 38.7% of 860 nulliparous pregnant women in a multistrand prospective cohort study (Daly et al., 2018). Another study demonstrated that primigravida with SUI has up to four-fold increased risks of developing SUI at 12 years postpartum (OR: 2.14; 95% CI: 1.29-3.55) (Arrue Gabilondo et al., 2021).

Several factors were involved, such as weakened pelvic floor muscles and hormonal changes. Stress UI occurs when the bladder pressure exceeds the urethral closure pressure due to the added weight of the gravid uterus (Sangsawang & Sangsawang, 2013). Pregnant women were inclined to keep their UI secret from the health care providers (HCP) since they perceived it as usually occurring during pregnancy and will disappear postpartum (Woodley & Hay-Smith, 2021). The HCP needs to correct their misperception and institute early management strategies to improve pelvic muscle strength. In order to strengthen the pelvic floor muscle, Kegel's exercise or pelvic floor muscle training (PFMT) was suggested by Dr Arnold Kegel (Kegel, 1948). Randomized controlled trials demonstrated that PFMT improved stress UI and mixed UI severity during pregnancy and postpartum and has been recommended in a few guidelines (Paul Abrams et al., 2018; NICE Guideline CG123, 2019; Woodley et al., 2020).

PFMT adherence implies performing voluntary contractions of the pelvic floor muscles (PFM) regularly, according to a prescribed protocol, and the duration of the training period. A Cochrane review highlighted that the PFMT programme usually comprises one or more daily exercises performed on at least several days of the week for at least eight weeks (Woodley et al., 2020). However, pregnant women must understand that UI is a medical problem, and PFMT can help them to prevent and improve their symptoms. After acquiring the correct information about UI, they will be able to have a positive attitude and correct practice in managing their symptoms. A systematic review was conducted to identify women's KAP related to urinary incontinence and reported that all articles (n=15) demonstrated misinformation about UI. Only one article (n=1/7) had a good attitude, and all articles (n=19) revealed low rates of seeking care (Bezerra et al., 2018). Hence, delayed help-seeking worsens their UI and affects their quality of life (Boutib et al., 2022) due to lack and interrupted nights of sleep and frequent urination.

In this country, the state healthcare system has been financed through government tax-based financing enabling public outpatient healthcare (primary care clinic) to provide MYR1 (estimated to be USD 0.22 in 2022) for each visit. However, a study reported that not all are willing to pay the cost per visit, even for acute or chronic illness, especially from the low socio-income group (Puteh et al., 2017). There are other added costs such as absent form work cost, transportation cost, in addition to the absorbent pad costs and costs of washing clothes. UI considerably impacted healthcare costs worldwide (Milsom et al., 2014; Milsom & Gyhagen, 2021). For example, the projected total healthcare cost for managing UI in the United States was \$76.2 billion in 2015 and was predicted to increase to \$82.6 billion in 2020, with 85% of the treatment cost for SUI (Coyne et al., 2014). Most of the patient's cost used pads with a mean cost of \$1.69 per week, and almost half of them used laundry with a mean cost of \$6.09 per week (L. L. Subak et al., 2006). They paid about \$900 per year for routine incontinence care, especially for those with severe incontinence (L. L. Subak et al., 2006). The financial burden was apparent for the health and the patient's cost in managing UI.

PFMT was a cost-effective and valuable prevention and management option for UI in pregnancy. Individual PFMT during pregnancy only costs \$768 to the health service to prevent one case of UI (Brennen et al., 2021) but needs an additional cost of \$1202 to cure it in the postnatal period (Brennen et al., 2021). Hence, it is cost-effective to focus on preventing and managing UI during pregnancy to reduce the risk of developing UI during postpartum and menopause. Despite evidence on the usefulness of PFMT, pregnant women fail to adhere for several reasons. These include personal factors (e.g. unawareness of the importance of PFMT), healthcare providers' factors (reluctance to promote PFMT due to human resource and time constraints), and the nature of PFMT itself as it is time-consuming and adherence is required (Terry et al., 2020; Woodley & Hay-Smith, 2021). Thus, to improve pregnant women's UI symptoms, there is a need to overcome these barriers to educate and promote PFMT adherence.

A report from a pilot study conducted at the antenatal clinic in the tertiary hospital stated that only 51.8% of pregnant women had good knowledge of performing the exercise, with only 10.7% practising it (Rosediani et al., 2012). Another study highlighted that pregnant women believed that by performing PFMT, vaginal trauma could be reduced and facilitate delivery (Temtanakitpaisan et al., 2020). However, there was a limited study looking at the knowledge, attitude, practices (KAP), and adherence of PFMT at primary care clinics which need to be studied. Pregnant women in tertiary care in our urban area preferred to be taught and briefed on the importance of exercise and performed UI screening during antenatal follow-up by healthcare providers (Mohd Yusoff et al., 2019).

Fortunately, this country's mobile phone and internet access have improved, reaching a saturation point of 98.7% of users in 2020. Patients can access internet technologies and reach health care professionals using smartphones using mHealth apps. Mobile health, also known as mHealth, uses mobile and wireless technologies to take advantage of the rapid uptake of information and communication technologies (ICT) to improve health system efficiency and health outcomes (Agarwal et al., 2016). A cross-sectional study in Selangor, Malaysia, reported that the most common mHealth apps used were the multipurpose, general health and fitness apps. Regarding the use pattern, about a third of the participants reported using their health apps daily to gain benefits by tracking health status (47%), receiving motivation (41%), and gaining knowledge about their health and fitness (9%). However, the main issues reported were the inaccuracy of the app (24%), inconvenience (20.7%), and not being user-friendly (18.5%) (Bhuvan et al., 2021).

As for pregnant women, there has been growing evidence for using mobile Health (mHealth) applications for self-monitoring, although evidence is still scarce (Asklund et al., 2017; Li et al., 2020; Wadensten et al., 2021). Intervention using mHealth apps was proposed for this study because smartphone ownership is very high among Malaysians due to its potential for improving accessibility and personalisation. According to the Tanahashi model, accessing the healthcare service is one of the determinants of ensuring the healthcare services reach the target population (Tanahashi, 1978).

1.2 Problem Statement

The prevalence of UI during pregnancy across Malaysia has been high, ranging from 34% to 65.8% over the past five years (Abdullah et al., 2016; Mohd Yusoff et al., 2019). This high prevalence is worrying as a longitudinal cohort study reported that SUI among primigravida doubled the risk (OR: 2.14; 95% CI: 1.29-3.55) of having UI in the subsequent 12 years (Arrue Gabilondo et al., 2021). Additionally, BMI (OR, 1.20; 95% CI, 1.14–1.27) and parity (OR, 1.46;95 % CI, 1.08–1.97) became significant factors for the cumulative incidence of UI. Unfortunately, despite this high prevalence, UI screening was not done during antenatal visits (Mohd Yusoff et al., 2019; Yeoh et al., 2016).

Hence, it is a public health concern that healthcare personnel does not screen pregnant women for UI. Furthermore, pregnant women are not seeking help for their UI due to their unawareness, although the condition is preventable and treatable (Soave et al., 2019; Woodley et al., 2020). The overall poor knowledge and practice of PFMT (Rosediani et al., 2012) warrant the emphasis on providing accurate PFMT information to prevent UI during their pregnancies and postpartum. The successful implementation of a PFMT awareness program has yet to be empirically studied in a primary care setting in Malaysia.

There are antenatal educational classes for pregnant women in Malaysia. A dedicated multidisciplinary team delivers various classes on labour, birth, parenthood, breastfeeding, postnatal care, exercises, and healthy eating. Before the COVID19 pandemic began, a physiotherapist regularly conducted weekend antenatal exercises among pregnant women from selected primary care clinics in Hulu Langat district, Selangor. PFMT was prescribed as part of the antenatal exercise. The physiotherapy team conducted the classes based on the Antenatal and Postnatal Exercise Manual developed by the Family Health Development Division, Ministry of Health Malaysia, MOH (Ministry of Health, 2014). However, during the pandemic COVID19, the antenatal exercise program had to be cancelled.

This further limits pregnant women's access to PFMT and its role in preventing and reducing UI symptoms (Woodley et al., 2020). Hence, pregnant women face various barriers, including time constraints, privacy concerns, and difficulty accessing the healthcare systems (Bayat et al., 2021; Mallett et al., 2018; Wagg et al., 2017). Mobile health technology may provide a potential solution for these barriers as they usually have handphones and internet accessibility.

Evidence in other countries has shown promising effects of using mobile applications to enable pregnant women to confidently perform daily PFMT with a reminder system, resulting in UI improvement (Araujo et al., 2020; Asklund et al., 2017; Nyström et al., 2018). Unfortunately, there is limited local evidence on the delivery of PFMT using mobile applications among pregnant women with UI in Malaysia. The available evidence from a systematic review of the available PFMT apps demonstrated poor credibility (Dantas et al., 2021) and quality (Ho et al., 2020) with a score of 2.9/5.0 by the Mobile Application Rating Scale (MARS), the quality. This could be due to the poorly-designed app without using the correct development framework. The behavioural change theories (Grace-Farfaglia, 2019; Kramer & Kowatsch, 2017), such as the Health Belief Model (Rosenstock, I. M., Strecher, V. J., & Becker, M. H., 1988), described that the ability to perceive the risk of untreated UI, and the Social Cognitive Theory whereby they had the ability in performing PFMT. These theories could guide the researchers and developers to tackle the specific behaviour changes in promoting PFMT adherence in pregnant women.

Additionally, usability features (Overdijkink et al., 2018) are essential to obtain the best possible results in ensuring user adherence and subsequent UI reduction. The persuasive systems design (Karppinen et al., 2016; Sporrel et al., 2021) is crucial to motivating patients to engage with the mHealth app. Therefore, the design and development process of a mHealth app would include needs assessment and its development and evaluation among target users, pregnant women. To the best knowledge, there is no local evidence on the delivery of PFMT using mobile applications among pregnant women with UI in Malaysia.

1.3 Significance of the Study

Although PFMT interventions were successfully implemented in developed countries, it is still limited in the primary care setting in Malaysia. With the current pandemic COVID19 situation, the restriction of movement and social distancing measures resulted in more barriers to meeting physiotherapists. Therefore, using mobile technology in the e-health era is much warranted. As such, the findings of this study will lead to the development of a theory-based mHealth app, which may be integrated into our local antenatal e-health services in future. Concurrently, the present study may benefit pregnant women by improving their PFMT knowledge, attitude, practice, and adherence to self-efficacy enhancement. Hopefully, this newly developed mHealth app will improve their continence status and quality of life.

The software development life cycle (SDLC) is a systematic software or system development method that aims to complete a project in a timely manner while producing a high-quality, reliable, and cost-effective product. SDLC provides activities or steps that primarily guide system architects and developers in software development (Mishra & Dubey, 2013). Iterative software development life cycle (SDLC) is one of the most preferred process models for developing an effective and high-quality software product (Sen et al., 2021) and mobile health app (Barra et al., 2017). The process carries on the specification, implementation, and validation activities concurrently to quickly produce an initial version of the software system that can then be refined through iterations.

The use of an iterative approach in conjunction with the mHealth development and evaluation process is recognized. Hence, mHealth Development and Evaluation Framework was introduced (Jacobs & Graham, 2016; Whittaker et al., 2012), stressing an iterative approach to refining mHealth interventions. The framework relies on concurrent and sequential qualitative and quantitative research with the target users and focuses on disseminating research findings throughout the development process. The iteration was intended to ensure the development of the app has its potential to be useful and acceptable to pregnant women

If successful, it is hoped the app can be expanded to provide other aspects of antenatal care, such as other antenatal exercises and nutrition advice. Pregnant women experiencing time limitations and social restrictions to attend their antenatal clinic physically may benefit from using this app. The app may enhance the sustainability of antenatal care according to our national strategies in achieving the second pillar of the 11th Malaysia Plan (Improving wellbeing for all) and the 3rd goal (Good health and wellbeing) from the Sustainable Development Goals by the United Nations (Economic Planning Unit, 2015; Nunes et al., 2016).

1.4 Research Questions

This study focuses on answering three research questions:

- 1. What is the quality of life of pregnant women with and without UI and their prevalence of knowledge, attitude, and practice of PFMT in a primary care clinic in Selangor?
- 2. How to design and develop a PFMT mHealth app prototype for incontinent pregnant women in the primary care setting?
- 3. Does the PFMT mHealth app prototype demonstrate preliminary outcomes in improving adherence, knowledge, attitude, practices and self-efficacy to PFMT and the severity of UI and quality of life among incontinent pregnant women?

1.5 Aims and Objectives

1.5.1 Aims of the Study

A1. Develop a mHealth application for pregnant women with UI A2. Assess the feasibility and its preliminary effectiveness of the newly developed app.

1.5.2 General Objective

The general objective of this study was to develop and evaluate the preliminary outcomes of a PFMT mHealth app prototype on knowledge, attitude, practice, self-efficacy, and adherence to PFMT among incontinent pregnant women attending a clinic in Hulu Langat district, Selangor.

1.5.3 Specific Objectives

The specific objectives of the study have been developed to achieve the aims stated above:

- To perform the need assessment for the mHealth app by studying the associations of urinary incontinence and its quality of life, PFMT knowledge, attitude, and practice, among pregnant women in health clinic Kajang, Hulu Langat, Selangor, Malaysia.
- 2. To design, develop and validate the PFMT mHealth app for pregnant women with urinary incontinence attending a health clinic in Hulu Langat, Selangor, Malaysia.
- To assess the feasibility and evaluate the preliminary outcomes of a PFMT app on knowledge, attitude, practice, self-efficacy, and adherence to PFMT among incontinent pregnant women attending a clinic in Hulu Langat district, Selangor

1.5.4 Research Hypotheses

- 1. There is no significant association between the quality of life, sociodemographics, and clinical and obstetric characteristics on the prevalence of UI among pregnant women attending a clinic in Hulu Langat district, Selangor.
- 2. There is no significant association in the knowledge, attitude, and practice of PFMT with the severity of UI symptoms and the quality of life of the respondents in the incontinent and continent groups.
- 3. There is no significant difference in the socio-demographic characteristics, clinical and obstetric characteristics, and outcome measures of PFMT knowledge, attitude, practice, self-efficacy, adherence, the severity of a urinary symptom, and the quality of life of the respondents between the intervention and control group.

1.6 Outline and Structure of the Thesis

This thesis is presented in eight chapters divided into six discrete sections: introduction, literature review, methodology, four published articles, and conclusions (Figure 1.1). Chapter 2 explore the literature review of urinary incontinence, pelvic floor muscle training facilitation and barriers among pregnant women. This review aimed to identify the interventions available to improve PFMT adherence and develop the conceptual framework to initiate and engage with mHealth as the research intervention. Chapter 3 presents the research process and the methodology of this thesis. A critical realist

epistemological orientation underpins this research and influences the research strategy.

Chapters 4 to 7 are presented in the form of published articles. Chapter 4 describes the needs assessment findings in the app development, such as the poor quality of life associated with certain types of UI. It was based on a crosssectional study which was conducted at a primary health care clinic. Findings from Chapter 4 motivate and justify the importance of PFMT mHealth app prototype development. Chapter 5 elaborates on the validation process in developing the PFMT mHealth app prototype. This validation process involved findings from a cross-sectional study and focus group discussion (FGDs), which assisted the developer and researcher in designing and developing the app, known as the Kegel Exercise Pregnancy Training app (KEPT app). It discussed the app's development process that was derived from initial requirement driven the user-centred incorporated in the iterative process model, from which the mHealth framework was developed, which include six stages: (1) conceptualization; (2) formative research; (3) pre-testing; (4) pilot testing; (5) randomized controlled trial; and (6) qualitative research, before escalating to more comprehensive intervention.

Chapter 6 highlights the usability evaluation of the app from the experts'. The expert usability evaluation consisted of four experts assessments using three evaluations; (1) cognitive walkthrough - which utilizes accurately detailed procedures to simulate a user's problem-solving process at each step, (2) heuristic evaluation - to detect user interface problems cost-effectively, and (3) usability testing (mHealth App Usability Questionnaire) - to assess the usability of a mHealth app which has three domains focusing on the ease of use, interface and satisfaction, and usefulness of the app. The findings from a pilot feasibility randomised controlled trials (RCT) designed to test the preliminary outcomes of the KEPT app prototype in a primary health care clinic in Hulu Langat district, Selangor, are reported in Chapter 7. Finally, Chapter 8 provides a synthesizing and summary discussion of various research components concerning the research aims and objectives. Additionally, the specific contributions to knowledge, the mHealth app development and tools for assessment, and future practice were highlighted.

1.7 Summary

The development of this PFMT mHealth app may benefit healthcare providers: especially primary care doctors, staff nurses, and physiotherapists in Malaysia. They can use this PFMT mHealth app to support and empower pregnant women to self-monitor and self-manage without attending PFMT antenatal education classes. Additionally, this intervention will enable physiotherapists to disseminate evidence-based PFMT information via this mHealth app designed from behavioural change theory.

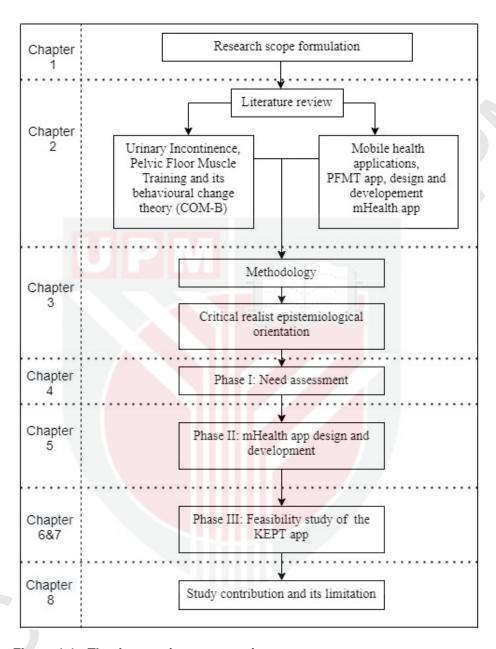


Figure 1.1: Thesis overview progression

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