Abstract of thesis entitled

“An Evidence-based Pelvic Floor Muscle Training Program to Prevent Urinary Incontinence During Pregnancy and After Delivery”

Submitted by

Tam Wai Yuen

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Urinary incontinence is a common problem in women who are pregnant and in postpartum period. It affects women in four aspects, physical activity, emotional health, social relationship and travel, which results in a lower quality of life. In addition, urinary incontinence will increase the economic burden to the public health system.
Pelvic floor muscle training is the first line intervention to manage urinary incontinence for women who are pregnant and after delivery. It is cost-effective and can be implemented by nurses. Therefore, it is important to develop an evidence-based guideline for preventing urinary incontinence and regaining urinary continence in pregnant women and women after delivery.

The objectives of this study are to systemically review the current literature on the effectiveness of pelvic floor muscle training in preventing urinary incontinence or regaining urinary continence of pregnant women and or women after delivery. Data from the selected studies are extracted for establishing table of evidence. Moreover, quality assessment of the selected articles is performed. An evidence-based guideline of pelvic floor muscle exercise for pregnant women and women after delivery is developed and its feasibility and transferability to the target setting and clients is determined.

In this study, a pelvic floor muscle exercise program is proposed. The target setting is one urology center of surgical department in a local public hospital and the target clients are pregnant women of 16 weeks of gestation. Data are extracted from 14 articles. The implementation potential of the proposed guideline is high because of its
transferability, feasibility and cost-effectiveness. Based on the evidence, an
evidence-based practice guideline is developed to decrease the urinary incontinence.

In order to improve the quality of life of the pregnant women, it is recommended to
establish the practice to all public hospitals.
An Evidence-based Pelvic Floor Muscle Training Program to Prevent Urinary Incontinence during Pregnancy and After Delivery

by

Tam Wai Yuen

BSc(Hons) NURS, R.N.

A dissertation submitted in partial fulfillment of the requirements for the Degree of Master of Nursing at The University of Hong Kong

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Declaration

I declare that this thesis thereof represents my own work, except where due acknowledgement is made, and that it has not been previously included in a thesis, dissertation or report submitted to this University or to any other institution for a degree, diploma or other qualifications.

Signed

Tam Wai Yuen
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Abbreviations

Activities of daily living (ADL)
Antegrade Pyleogram (AP)
Associate Consultant (AC)
Bristol Female Lower Urinary Tract Systems Questionnaire (BFLUTS)
Chief of Service (COS)
Continuous Nursing Education (CNE)
Department Operation Manager (DOM)
Flexible Cystoscopy (FC)
Incontinence Impact Questionnaire (IIQ-7)
International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF)
Medical Officer (MO)
National Guideline Clearinghouse (NGC)
National Institute for Clinical Excellence (NICE)
New Zealand Guideline Group (NGZZ)
Pelvic floor muscle exercise (PFME)
Quality of life (QoL)
Randomized Controlled Trial (RCT)
Retrograde Pyleogram (RP)
Scottish Intercollegiate Guideline Network (SIGN)
Urinary incontinence (UI)
Videocystometrogram (VCMG)
Wand Manager (WM)
Chapter 1: Introduction

According to Sangsawang and Sansawang (2013), urinary incontinence is common during pregnancy and postpartum. Pelvic floor muscle exercise is cost-effective which can be implemented by nurses. Therefore, pelvic floor muscle exercise is suggested to help women to prevent urinary incontinence or regain urinary continence during pregnancy and after delivery.

There are some articles stated that the effectiveness of Pelvic Floor Muscle Exercise (PFME) on treating and preventing urinary incontinence among pregnant women is insignificant (Hilde et al, 2013). It is important to provide evidence to support the effectiveness of pelvic floor muscle exercise on preventing and treating urinary incontinence among pregnant women before putting it into practice. Therefore, an integrative review of selected topic will be demonstrated in this paper.

Before performing critical appraisal of the chosen articles, the importance of translating the best evidence into practice will be discussed first in terms of background information, affirming need and significance.

1.1 Background

Urinary incontinence is a common problem in women who are in pregnant and in postpartum period. During pregnancy and postpartum period, pelvic floor muscle is weaker or damaged by the maternal weight, the uterus and the fetus, which leads to urethral sphincter incompetence. When the intra-abdominal pressure increases, for example, laugh, cough and sneeze, the pressure will transmit to bladder and when the pressure inside bladder is greater than urethral closure pressure with the effect of
weakened sphincter muscle, urinary incontinence occurs (Sangsawang, 2013). Urinary incontinence (UI) affects women in four aspects, physical activity, emotional health, social relationship and travel, which results in lower quality of life (Dolan, 2004).

There are several surgical and medical interventions to manage urinary incontinence, for example, medication and tension-free vaginal tape; however, they are not suggested during pregnancy and postpartum period. Pelvic floor muscle training is the first line intervention to manage urinary incontinence for women who are pregnant and after delivery (Kocaoz, 2013).

Pelvic floor muscle training can strengthen the pelvic floor muscle, and the trained muscle is less likely prone to be damaged by the maternal weight, the uterus and the fetus, also the strengthened muscle can help to counteract the increased intra-abdominal pressure. As a result, urinary incontinence can be prevented or treated (Boyle, Hay-Smith, Cody & Morkved, 2012).

1.2 Affirming the need
Urinary incontinence is a global problem among antenatal and postnatal women. Chan et al. (2013) claimed that the prevalence of Chinese pregnant women urinary incontinence is 58.5% and the prevalence of urinary incontinence during postpartum period is 25%. Sangsawang (2014) mentioned that the prevalence of urinary incontinence among western pregnant women is 18.6 to 75%. Wong et al. (2006) stated that the prevalence of urinary incontinence will decrease in Hong Kong. As the educational level of Hong Kong women increases, they will less likely feel
embarrassed to disclose their urinary problem and they will be more willing to seek medical help.

**Social cost**
Urinary incontinence is a costly public health problem. In Australia, urinary incontinence cost USD 710.44 million in 1998 and will increase to USD 1.27 billion in 2018 (Wu et al, 2011). In view of this, the urinary incontinence will also cost a heavy financial burden to the society in Hong Kong.

**Quality of life**
Urinary incontinence significantly decreases the quality of life (QoL) among pregnant women. Dolan et al (2004) stated that nearly all of the women who are urinary incontinence experience urinary frequency and nocturia. In addition, lower urinary tract symptoms are common in women with urinary incontinence. Urinary incontinence can negatively affect physical activity, travel, social relationship and emotional health among women with urinary incontinence during pregnancy and postpartum (Sangsawang, 2014)

**Pelvic floor muscle training protocol**
At this moment, the most effective pelvic floor muscle exercises protocol is still uncertain. In Hong Kong, different health care settings have different strategies to deal with pregnant women and or postpartum period urinary incontinence. Some healthcare setting will refer physiotherapist to manage this problem. Some healthcare setting will only give pelvic floor muscle exercise pamphlets to patients. Some healthcare setting will educate patients with pelvic floor muscle exercise during
nursing routine bedside work. In my setting, mothers will attend a small group workshop of pelvic floor muscle exercise after giving birth during the session a nurse will present a talk to them with pamphlet and demonstration of PFME and other information related to baby care and mother self-care, and there is no follow up for pelvic floor muscle exercise or urinary incontinence.

Lack of education

Wong et al (2006) stated that the urinary incontinence education is not adequate. Many of the respondents in Wong’s (2006) study had misconception or lack of knowledge on urinary incontinence. Many of them viewed urinary incontinence as a normal aging process or it is normal after giving birth. They thought urinary leakage was normal and did not seek any treatment or management. Also, they thought that their urinary leakage problem was not serious. Therefore, they did not seek advice from doctors. Obviously, lack of education prevents patient from urinary incontinence diagnosis and treatment.

Pelvic floor muscle training is one of the treatments for urinary incontinence during pregnancy and postpartum period. Dine et al (2009), Morkved (2000) and Kocaoz et al (2013) stated that pelvic floor muscle exercises can help urinary incontinence during pregnancy and postpartum period effectively. However, Hilde et al (2013) and Mason et al (2010) stated that pelvic floor muscle exercise cannot help solve pregnant women urinary incontinence problem. Different researches have different pelvic floor muscle exercise protocol and their results differ. It is necessary to propose a standardized and effective pelvic floor muscle exercise protocol for managing urinary incontinence during pregnancy and after give birth.
There are still many rooms for improving the current protocol of my setting, for example, the time for initiating pelvic floor muscle exercise, the exercise initiator (nurse or physiotherapist), the intensity, the duration, the follow up plan, the use of bio-feedback and the use of electrical stimulation. Last but not least, urinary incontinence decreases the quality of life of women during and or postpartum. Therefore, it is necessary to conduct a wide search of well-designed studies to standardize or to conclude the most effective pelvic floor muscle exercise protocol, in order to reduce the cost of urinary incontinence and increase quality of life of pregnant women and women after giving birth.

1.3 Objective and Significance

1.3.1 Research question

Does the use of pelvic floor muscle training decrease the rate of urinary incontinence during pregnancy and after giving birth compared with the group without pelvic floor muscle training?

P: pregnant women and women after giving birth

I: pelvic floor muscle training

C: routine care without pelvic floor muscle training

O: reduce the rate of urinary incontinence

1.3.2 Objectives

- To review the current literature systematically for the effectiveness of pelvic floor muscle exercise for pregnant women and women after delivery.

- To extract information from literatures and make a table of evidence.
- To perform a quality assessment of the implementation potential of the identified interventions from the selected literatures.
- To determine the feasibility and transferability of pelvic floor muscle training to the target mothers.
- To develop an evidence-based pelvic floor muscle exercise protocol for pregnant women during and after giving birth.

1.3.3 Significance
According to Tenfelde and Janusek (2014), women with urinary incontinence experience great psychological impact. They feel stigma and humiliation, which may ruin relationship and result in social isolation. In addition, women with urinary incontinence sometimes may experience reduced sexual desire; this may affect the intimacy and relationship with her partner. Nocturia may affect sleeping quality; this will affect women’s daytime career or household performance. Last but not least, urinary incontinence may lead to the reduction of the willingness to travel or exercise and finally result in depression. Apart from the quality of life of women with urinary incontinence, the social and economic burden is also a huge problem of urinary incontinence. Urinary incontinence costs United States $12 billion per year.

The proposed intervention provides clear and detailed information about the pelvic floor muscle training and the treatment regimen to the pregnant women. In general, an evidence-based pelvic floor muscle protocol can help pregnant women and women after giving birth to improve their quality of life. Also, it can help society to reduce the cost of urinary incontinence.
Chapter 2: Critical Appraisal

After the affirming needs and the emphasizing of the significance in the development of evidence based pelvic floor muscle training program. I am going to discuss the screening strategies, appraisal strategies and summarize the findings.

2.1 Search and appraisal strategies

2.1.1 Electronic databases/ search methodology

Search was performed in three electronic databases including Pubmed, ProQuest and Cochrane library. Apart from the three electronic databases, a clinical guideline search was conducted in the National Guideline Clearinghouse (NGC), CMA InfoBase, Scottish Intercollegiate Guideline Network (SIGN), National Institute for Clinical Excellence (NICE), New Zealand Guideline Group (NGZZ), Guideline International Network and the Registered Nurses Association of Ontario.

2.1.2 Keywords

The keywords used were guided by the PICO format. Without any restriction or limitation, searches were started by the keywords ”women”, “pregnancy”, “pregnant women”, “antenatal”, “postnatal”, “postpartum”, “pelvic floor muscle exercise”, “pelvic floor muscle training”, and “urinary incontinence”. The keywords were used individually and combined in order to search comprehensively without missing any relevant articles.

2.1.3 Selection criteria

In order to select the suitable and relevant articles, a number of selection criteria were established.
Inclusion criteria

- Pregnant women or women after delivery
- Over 18 years old
- No limitation on continence status
- The intervention must involve pelvic floor muscle training

Exclusion criteria

- Women with neurological disease
- Women with urine incontinence before pregnancy
- Mentally impaired patient
- Patient is under other treatment for urinary incontinence e.g. surgery, anti-incontinence device, medication, bio-feedback, behavior training, lifestyle modification or suppression techniques

2.1.4 Data extraction

Data from the selected studies were extracted into table of evidence according to SIGN 50 – A Guideline developer’s handbook ANNEX D: completed table (SIGN, 2012b) from Scottish Intercollegiate Guidelines Network.

2.1.5 Appraisal strategies

SIGN 50 – A Guideline developer’s handbook from Scottish Intercollegiate Guidelines Network (Appendix A Checklist randomized controlled trial and Appendix B Notes for randomized controlled trial) was used to interpret and evaluate the quality of selected studies (see Appendix C Appraisal table).
2.2 Searching Result

2.2.1 Date of search

From 1 June to 16 September 2014, an electronic search of published literature was conducted in the three databases: PubMed, ProQuest and The Cochrane Library.

2.2.2 Describe search history

Keywords: “pregnancy” or “pregnant women” or “antenatal” or “postnatal” or “postpartum” in combination with “pelvic floor muscle exercise” or “pelvic floor muscle training” and “urinary incontinence” were used for searching in the database.

The journals retrieved were screened by Randomized Controlled Trial (RCT) design study, then the studies remained were screened by language – English. After that the title and abstract of the retrieved paper were assessed. The passed journals were then selected by the availability of full text. Finally, the passed papers were screened by the inclusion and exclusion criteria which mentioned in the previous section.

There were 10 studies selected from PubMed, 6 studies selected from ProQuest and 12 studies selected from The Cochrane Library. For the 6 studies from ProQuest, 2 articles were duplicated with articles selected form PubMed. For the 12 studies from The Cochran Library, 4 were duplicated with ProQuest and 8 were duplicated with PubMed. As a result, there were 14 articles selected from 3 electronic databases.

Appendix N shows the PRISMA 2009 flow diagram of searching systematic review and meta-analysis.
2.2.3 Summary of level of evidence

There were 14 studies selected from PubMed, ProQuest and the Cochrane library. Relevant data were extracted into a table according to SIGN 50 (see Appendix D Table of evidence).

2.2.4 Summary of quality assessment of the studies

Location

The 14 RCTs were published from 1997 to 2013. These studies were conducted in Taiwan, United States of America, Turkey, Thailand, Norway, United Kingdom, Australia, New Zealand and Netherlands. There was only one article’s population from Asia (Taiwan), other articles’ populations were from foreign counties.

Sample size

The sample sizes of studies were ranged from 66 to 676.

Demographic characteristics

The differences in demographic characteristics such as age, educational level and body mass index in each article were insignificant between the intervention and control group.

Intervention and control group

Most of the intervention in selected studies was Pelvic floor muscle exercise (PFME) instructed by nurse or physiotherapist individually and a regular follow up was provided to the subjects. The control groups in selected articles were including group with regular perinatal care without any PFME training and group with PFME instruction given. Both control groups were without regular follow up.
Outcome measures

All the studies focused on the effect of PFME to reduce rate of urinary incontinence as primary outcome. Most of the studies achieved significant results in reducing rate of urinary incontinence after PFME at different periods. Apart from urinary incontinence rate, some articles measured strength of pelvic floor muscle, quality of life as the secondary outcomes.

2.2.5 Summarize methodological issues

In the 14 RCTs, the level of evidence according to the SIGN grading system ranged from low to high risk of bias (1+ to 1-). Six RCTs classified as 1+ and the remaining 8 RCTs classified as 1-. All of the selected studies stated the research question clearly.

For the randomization method, there are 8 articles (Sampselle et al., 1997; Hilde et al., 2013; Reilly et al., 2002; Chiarelli and Cockburn, 2002; Agur et al., 2008; Mason et al., 2010; Wilson and Herbison, 1998; and Woldringh et al., 2007) were used computerized randomization program. While there are 2 studies (Ko et al., 2011; and Dine et al., 2009) were used sealed envelopes to perform randomization. There are 3 articles (Sangsawang & Serisathien, 2011; Morkved & Bo, 2000, 1997) were used matching method for allocate intervention and control group. There is one study (Kocaoz et al., 2013) was used odd and even day to allocate intervention and control group.

For the blinding process, there is 1 study (Kocaoz et al., 2013) used double blind design and there are 6 studies (Sampselle et al., 1997; Hilde et al., 2013; Reilly et al., 2002; Chiarelli and Cockburn, 2002; Mason et al., 2010; and Dine et al., 2009) used...
single blind design to minimize bias. The remaining 7 studies did not mention the blinding method for minimizing bias.

Subjective measurement (questionnaire) for prevalence and severity of UI were used in most of the articles (Sampselle et al., 1997; Sangsawang & Serisathien, 2011; Morkved & Bo, 2000; Reilly et al., 2002; Chiarelli and Cockburn, 2002; Agur et al., 2008; Mason et al., 2010; Wilson and Herbison, 1998; Dine et al., 2009; Woldringh et al., 2007; and Morkved and Bo, 1997). Apart from subjective measurement, objective measurement (pad test) was also used in measuring the severity of urinary incontinence in some of the selected studies.

The dropout rates of articles were ranged from 0% (Ko wt al., 2011; and Sampselle et al., 1997) to 53.5% (Mason et al., 2010). The reason for discontinuing participation or withdrawal from studies were “moved to another location”, “lost to follow up”, “discontinues intervention”, “illness”, “no reason” and “pregnant again”.

For the location of the selected studies, there are 4 articles (Chiarelli and Cockburn, 2002; Mason et al., 2010; Woldringh et al., 2007; and Morkved and Bo, 1997) recruited subjects from more than one country. Furthermore, subjects in each of the 4 articles were from different hospitals in the same country. While there are 7 studies (Ko et al, 2011; Kocaoz et al, 2013; Sangsawang & Serisathien, 2011; Hilde et al, 2013; Reilly et al, 2002; Agur et al, 2008; and Wilson and Herbison, 1998) recruited subjects from one country. 3 articles (Sampselle et al, 1997; Morkved & Bo, 2000; and Dine et al, 2009) did not mention the location of recruited of subjects.
2.3 Summary and Synthesis

2.3.1 Summary of data

2.3.1.1 Assessment and outcome measures

Quality of life
- Incontinence Impact Questionnaire
- Leicester Impact Scale

Urinary incontinence rate
- Self-report of urinary incontinence
- Pad test
- Visual analog rating scale to measure urinary incontinence rate
- International Consultation on Incontinence Questionnaire- Urinary Incontinence Short Form (ICIQ-UI SF)
- Bristol Female Lower Urinary Tract Systems Questionnaire (BFLUTS)
- PRAFAB questionnaire
- Urogenital Distress Inventory

2.3.1.2 Training mode

Henderson et al. (2013) concluded that most of the women can perform pelvic floor muscle exercise (PFME) correctly under verbal instruction. In the selected studies, the pelvic floor muscle training was mainly verbal instruction with written materials, and the trainings were provided by either nurses or physiotherapists. The most important point was that the client knows how to perform pelvic floor muscle correctly.

The increased motivation of practicing PFME can increase the compliance of performing PFME, it helps to treat or prevent urinary incontinence during and after
give birth (Morkved et al., 2000; Wilson & Herbiso, 1998). It is recommended that encouragement of performing PFME should be given in every follow up.

2.3.1.3 Appropriate time schedule for pelvic floor muscle training

In the selected studies, the time for initiating of the pelvic floor training is ranged from 14 to 24 gestation weeks and the time for the last follow up is ranged from 3 days to 1 year. The follow up schedule commonly arranged 2 – 3 times before give birth (including the first follow up) and 1 to 3 times after delivery.

2.3.1.4 Patient education tool

For the intervention groups, the pelvic floor muscle exercise (PFME) was taught by verbal and written materials. For the control groups, the interventions were different in the selected articles. Clients received verbal instruction on PFME only or written materials on PFME only or no information on PFME.

2.3.1.5 Duration and time of exercise

In all selected articles, there were no fixed time and duration of performing pelvic floor muscle exercise.

2.3.2 Synthesis of data

10 out of 14 selected articles suggest that urinary incontinence (UI) is a common problem for pregnant women and women after delivery. More importantly, urinary incontinence among pregnant women and women after give birth is preventable. Pelvic floor muscle exercise (PFME) can significantly decrease the rate of urinary incontinence among pregnant women and women after delivery (Ko et al., 2001;
Sampselle et al., 1997; Kocaoz et al., 2013; Sangsawang & Serisathien, 2011; Morkved & Bo, 2000; Reilly et al., 2002; Chiarelli and Cockburn, 2002; Agur et al., 2008; Dine et al., 2009; Morkved and Bo, 1997). Pelvic floor muscle exercise can be taught by verbal instruction with written materials and the correctness of contacting pelvic floor muscle must be ensured. The compliance of performing PFME can be increased by increasing motivation of clients. Therefore, encouragement of self-practice of PFME by clients during follow up is recommended (Morkved et al., 2000; Wilson & Herbis, 1998). For the intervention, the target clients will be 14-24 gestation weeks (Ko et al., 2001; Sampselle et al., 1997; Kocaoz et al., 2013; Sangsawang & Serisathien, 2011; Reilly et al., 2002; Agur et al., 2008; Dine et al., 2009) and 2 more follow up will be arranged before delivery (Kocaoz et al., 2013; Dine et al., 2009) and 1 follow up will be arranged after give birth (Kocaoz et al., 2013; Reilly et al., 2002; Agur et al., 2008; Dine et al., 2009). During follow up, 2 outcomes will be measured; they are rate of urinary incontinence status and quality of life of client. The urinary incontinence status will be measured by pad test (Kocaoz et al., 2013; Morkved & Bo, 2000; Reilly et al., 2002; Morkved and Bo, 1997) and the quality of life of client will be measured by Incontinence Impact Questionnaire (Ko et al., 2001).
Chapter 3: Innovation

In the previous chapter, it is suggested that pelvic floor muscle training can manage urinary incontinence among pregnant women and women after delivery effectively. It is important to translate the evidences to an innovation in the local practice so that pregnant women and women after delivery can benefit from it. After performing the critical appraisal of the selected studies, an innovation of the pelvic floor muscle training intervention in the local setting is being generated.

3.1 Name of the training program

An Evidence-based Pelvic Floor Muscle Training Program (PFME) to prevent urinary incontinence during pregnancy and after delivery

3.2 Target audience

Women of 16th gestational week (fit the inclusion criteria) in the antenatal clinic will be invited to join this program.

3.3 Target setting

The innovation will be held in a urology center in a public hospital.

3.4 Target staff

Nurses work in the target urology department.

3.5 Length of follow up

The length of the innovation will be 9 months for a client. Women of 16th gestational weeks will be referred from antenatal clinic. Follow up will be arranged for them on 28th, 32th gestation week and 3 months postpartum.
3.6 Patient education tools

A leaflet will be designed for the program. All the information such as the anatomy and function of pelvic floor muscle, the cause of urinary incontinence, the benefit of pelvic floor muscle exercise and the instruction of the pelvic floor muscle exercise will be described in detail and clearly.

3.7 Activities schedule

In the program, the pelvic floor muscle training program will be divided into two phases, pre-delivery and post-delivery.

Pregnant women of 16 gestational weeks will be invited to join this program in the antenatal clinic if they fit the inclusion criteria that mentioned in the previous chapter. Consent will be signed before the first follow up of this pilot study.

In the first phase, nurse will explain the details of the innovation in the urology center. Education of the anatomy and function of pelvic floor muscle, the cause of urinary incontinence, the benefit of pelvic floor muscle exercise and the instruction of the pelvic floor muscle exercise will be given to client with the guidance of the information leaflet. After that, the correctness of performing pelvic floor muscle exercise will be assessed and pad test for urinary incontinence will be performed. Before the clients leave the center, they are encouraged to perform pelvic floor muscle exercise at home. Clients will come back for the follow up at 28th and 32th gestational week. During follow up, questionnaire of quality of life will be given to client, pad test will be performed and nurses will reinforce the importance of pelvic floor muscle exercise and encourage clients to practice pelvic floor muscle exercise at home. Also,
nurses will answer questions and difficulty encountered by the clients.

In the last follow up, the nurse will give the questionnaire of quality of life to clients, and nurse will perform pad test for clients. Moreover, the nurse will reinforce clients to practice PFME themselves. If the client cannot regain urinary continence, the client will be referred to incontinence clinic for further management.
Chapter 4: Implementation potential

In the previous chapter, pelvic floor muscle exercise has been proved that is effective to reduce the rate of urine incontinence during and after pregnancy. If urinary incontinence condition is controlled, the quality of life of mothers including physical activity, travelling, social relationship and emotional health will be improved. Also, the cost caused by urinary incontinence will be reduced. In order to implement the pelvic floor muscle exercise in the local clinical setting and gain support from hospital, the implementation potential, transferability, feasibility and the cost benefit ratio of the innovation are needed to analyze. All of these elements will be discussed in this chapter.

4.1 Target audience

The proposed target audience attending the pelvic floor muscle training program has to meet the following criteria.

Inclusion criteria:
The target audience must be aged 18 or above pregnant female with 16 gestational weeks. All of the participants must have a regular antenatal follow up in one of the Hong Kong public hospitals. They must be mentally fit and Activities of Daily Living (ADL) independent.

Exclusion criteria:
Participants suffered from neurological disease, urinary incontinence before pregnancy or under treatment for urinary incontinence.
4.2 Target setting

The target setting is located in the urology center which is part of the urology unit in a public hospital in Kowloon West Cluster. This hospital has a urology department with one ward, one extracorporeal shock wave lithotripsy center and one urology center. The urology center provides incontinence consultation and incontinence education (for post radical prostatectomy) by nurse specialist; flexible cystoscopy (FC), videocystometrogram (VCMG), retrograde pyleogram (RP) and antegrade pyleogram (AP) performed by Medical Officer (MO) or Associate Consultant (AC).

The nurses will be responsible for educating pelvic floor muscle exercise, assessing the correctness of performing pelvic floor muscle exercise one by one in the first visit, conducting pad test for assessing the urinary incontinence status and answering any difficulty encountered by client. Candidates need to sign consent before implementing this innovation, they can quit this innovation at any time.

4.3 Transferability of the findings

In this part, the finding from reviewed articles are generalized and transferred to the local clinical setting.

As mentioned in the previous chapter, 14 journals were selected and 10 of them concluded that pelvic floor muscle exercise can prevent urinary incontinence and regain urinary continence during pregnancy and after delivery. Those findings are transferable as they fit the target participants and setting.
4.3.1 Characteristics of setting and participants

Most of the reviewed studies were carried out in the hospital during the follow up session which is similar to the target setting. Interventions in all selected studies are same (instruction of pelvic floor muscle exercise). The interventions in five out of ten articles are performed by trained nurse and the interventions in the other five articles are carried out by physiotherapist.

In the target setting, all nurses are well trained. The clinical setting and nurses are fit for this innovation.

The characteristics of the target participants in the target hospital’s antenatal unit are similar to the subjects in the reviewed studies. All participants are pregnant women with around 16 gestational weeks, the mean age is not specified, the range of mean age of selected studies is 26-31 and all of them are having a regular antenatal follow up. Both of the target setting and population are similar. Therefore, it is fit for translating the findings from reviewed studies to the local clinical setting.

4.3.2 Philosophy of care

Mission:
This innovation commits to offer the best pelvic floor muscle exercise training to pregnant women.

Goals
Help pregnant women in preventing urinary incontinence and regaining urinary continence during and after pregnancy.
Principles:
- We strive for service excellence through continuous learning and improvement.
- We continually elevate our competence and advance ourselves professionally.
- We seek the best way to allocate department resource to provide the best services.
- We maximize the candidates’ benefit with our best services.

Pelvic floor muscle exercise can effectively prevent pregnant women from urinary incontinence or reduce the rate of pregnant women getting urinary incontinence; as a result, a better quality of life can be achieved. The philosophy of care of this program is similar to the mission of Hospital Authority. According to the Hospital Authority (2014) “The Hospital Authority appreciates that patients are usually the "leading actors" in our work, and that healthcare professionals merely play supporting roles. Sometimes it is our job to give them life-saving treatment, but more often than not we are simply partners who empower them to regain their health and stay healthy by offering them support in the forms of diagnosis, medication, exercises, information, encouragement and motivation” (Hospital Authority, 2014). There are no conflicts between the innovation and the clinical setting.

4.3.3 Time for implementation and evaluation

From the majority of the selected studies, the instruction of pelvic floor muscle exercise and assessment of the correctness of pelvic floor muscle exercise will be arranged in the first visit (at 16 gestation week), and have a follow up session for evaluation of the urinary incontinence problem on 28th, 32th gestational week and 3 months postpartum. Since this innovation is new to the target setting, the implementation and evaluation time frame of the majority of reviewed studies will be adopted.
4.4 Feasibility

For the current practice, pelvic floor muscle exercise will be introduced by nurse during antenatal follow up, and pregnant women will not have any follow up related to urinary incontinence. For the innovation, the education and assessment of pelvic floor muscle exercise will be conducted in urology center. Before attending the first follow up, nurse in the antenatal clinic will assess the patient to see whether they are fit in the inclusion criteria and unfit in the exclusion criteria, then client will be invited to join the program. Nurse in urology center will introduce the details of the program and obtain consent of joining this program. In the first follow up, the urology center nurse will educate patient with the pelvic floor muscle exercise and assess the correctness of performing PFME. Also, nurses will perform urinary incontinence and quality of life assessment for clients. In other follow up session, urology center nurse will assess the urinary incontinence status and quality of life of clients. During every follow up, candidates will be assessed to see whether they meet the inclusion criteria, and candidates are free to quit this program anytime.

This innovation is new to the target setting; a new post (program coordinator) should be added, in order to prevent extra workload of nurses in urology center. The program coordinator mainly works in urology center and is specific in launching this innovation. Other nurses in urology department will be trained for this innovation, so that all nurses in urology department are competent to substitute the position for any situation, for example, sick or annual leave of the responsible nurse. In 2012-2013, there were around 5000 new born in my hospital (Hospital Authority, 2014). For estimation, there are around 19 mothers (19 mothers * 5 working days * 52 weeks) of 16 gestational weeks come to the urology center for the one to one first visit of this
innovation every day (if this innovation is fully implemented). One nurse is enough for this one to one session. For the follow up (28\textsuperscript{th}, 32\textsuperscript{th} gestational week and 3 months postpartum), there are approximately 19 mothers will come to urology center every day (if this innovation is fully implemented). One nurse is enough for performing the 1 hour pad test, assessing quality of life of clients and answering questions from clients, all patients can start the pad test at the same time. By a better manpower arrangement, 2 nurses (including the coordinator) can be arranged to implement the innovation.

During the first visit, gloves for assessing the correctness of muscle is being contracted and leaflet for educating candidates is needed. While during the follow up session, pad, weighting scale, water jar and cup is needed for the 1 hour pad test (see 7.1.1, 1 hour pad test in patient outcomes), questionnaire is needed for the evaluation of the impact of the urinary incontinence (Appendix J). All the materials are available in the department.

Administrative support is very important. The administrative and managerial level staff is responsible for all nurses’ training, cost of all materials and non-material. They are also responsible for communicating with doctors and Chief of Service (COS) to get their support for this innovation. Although the operative cost will be increased (see the Appendix L), it is worth to launch this innovation. It is because the philosophy of this innovation is similar to the mission of Hospital Authority, and this innovation is in low risk, low cost and high benefit. This program can help the department to develop evidence based practice atmosphere. The managerial level staff of hospital will support this program.
For the consensus, all training for nurses, measuring tools and evaluation of candidates are standardized.

Before implementing innovation, all nurses are trained by a standardized training protocol. Program coordinator will give a two hours lecture to the ward nurses on the details of how to perform pelvic floor muscle exercise, etiology of urinary incontinence related to pregnancy, assessment of urinary incontinence (1 hour pad test) and quality of life (Incontinence Impact Questionnaire (IIQ-7) Short Form), digital vaginal palpation for the correctness of pelvic floor muscle contraction, teaching and documentation skills. At the end of the training session, a questionnaire (Appendix M) will be given to nurses for assessing their self-perceived skills and knowledge to conduct the program. All the content in the training session are standardized, so the education given by nurses to clients are standardized. In order to increase the acceptability of nurses, Continuous Nursing Education (CNE) point will be earned by staff after finishing this training.

For the equipment, no special or extra equipment is needed for this innovation, as gloves (for assessment of the correctness of pelvic floor muscle exercise), weight scale (for the pad test), questionnaire and information leaflet are already available in hospital.

For the evaluation of the effect of pelvic floor muscle exercise, the assessment tools are standardized to 1 hour pad test (for the continence status, a weight gain of pad >1gm will be considered as urinary incontinence) (Abdel-fattah, Barrington & Youssef, 2004), questionnaires and patient progress forms. For evaluation of the
correctness of pelvic floor muscle contraction, digital vaginal palpation (see 6.2) will be adopted (female nurse only).

It is feasible to implement this program. For the frontline staff, a short training is enough for reinforcing staff the detail and teaching skills. For the material, there are some low cost materials needed to buy (pad and paper cup for the pad test). For the managerial staff, ward manager will be responsible for duty roster and the program coordinator will be in charge of the program, therefore, no extra managerial staff is needed. Apart from the additional post (program coordinator), the managerial staff of the target setting has no reason to reject this innovation.

4.5 Cost-benefit Ratio of the Innovation

The transferability of the finding and the feasibility of the program had been assessed in the previous section. The following section will assess the cost-benefit ratio of the program.

4.5.1 Candidates’ potential risks

The potential risks of innovation are rare. This program is an educational intervention, which implements in a safe clinical environment. Candidates can terminate the intervention and quit anytime if they want. There are some medical officers in the urology center perform other procedures for other patients, they are also responsible for any unexpected or emergency situation of those program’s candidates.

4.5.2 Candidates’ potential benefits

The pelvic floor muscle exercise can reduce the risk of developing urinary
incontinence during and after pregnancy, or regain urinary continence if urinary incontinence developed during or after pregnancy. As a result, the quality of life (physical activity, social relationship and emotional health) of candidates can be improved (Sangsawang, 2014).

4.5.3 Staff and hospital’s potential risks
The implementation of this program will post a potential risks to staff and hospital. Since this program is newly introduced to the department, in order not to increase extra workload of nurses, adding a new post for this program is suggested and increasing manpower is recommended. If manpower cannot be increased, better arrangement of nurse duties during the implementation of the program can help to minimize the risks.

4.5.4 Hospital’s potential benefits
Wu (2011) stated that urinary incontinence cost USD 710.44 million to medical cost in Australia in 1998 and will increase to USD1.27 billion in 2018. It is believed that this innovation can help to decrease the medical cost of urinary incontinence.

4.5.5 The material and non-material cost of innovation
The essential materials for this program such as gloves and weighting scale are already available in the urology center and no additional equipment is needed to be purchased. The printing service of addition written materials such as information leaflet and questionnaire is currently available in the department. Therefore, the potential material costs are minimal.
For the non-material cost, a new post (program coordinator) for this innovation is suggested. The coordinator needs to design the information leaflet, evidence-based training protocol, consent forms, a training session for nurses who is responsible for the implementation of the program after obtaining the approval of starting the innovation from the managerial level.

It is concluded that the pelvic floor muscle exercise to pregnant women program is transferable, feasible and cost effective. Therefore, the program can be implemented in the target setting.
Chapter 5: Developing an Evidence Based Practice Guideline

Based on the evidence from the selected articles critically appraised in the previous chapter, an evidence-based guideline is developed. All the recommendations in the guideline are supported by the relevant supporting evidence accordingly.

5.1 Background of the guideline

Urinary incontinence is a common problem of pregnant and or post-partum women. However, in the current practice, no specific pelvic floor muscle exercise protocol is provided to the pregnant women in Hong Kong. This program is an evidence-based pelvic floor muscle training guideline to prevent urinary incontinence during and after pregnant. As discussed in the previous chapter, evidence from different journals supports that pelvic floor muscle exercise could help pregnant women and post-partum women prevent urinary incontinence or regain urinary continence.

Scottish Intercollegiate Guidelines Network (SIGN, 2012) is used to rate the level of evidence and grades of recommendation. The levels of evidence ranged from 1++ to 4 (see Appendix A), and the grades of recommendation ranged from A to E (see Appendix E).

5.2 Title of the evidence based practice guideline

An Evidence-based Pelvic Floor Muscle Training Program to prevent urinary incontinence during pregnancy and after delivery

5.3 Target population

Patients must fulfill the following criteria
- 18 years old or above
- 16 gestation week
- Without neurological disease
- Urinary continence before pregnant
- Mentally capable
- Do not perform pelvic floor muscle exercise before joining this program
- Have antenatal follow up (according to hospital’s antenatal follow up protocol)
- Able to understand Cantonese or English

5.4 Aim if the guideline

Help pregnant women and women after delivery to prevent urinary incontinence

5.5 Objectives of the guideline

1. To standardize the education protocol of pelvic floor muscle exercise provided to pregnant women in an evidence-based approach.
2. To educate pregnant women about pelvic floor muscle exercise.
3. To prevent urinary incontinence among pregnant women.
4. To improve quality of life of pregnant women.

5.6 Practice recommendations

“An Evidence-based Pelvic Floor Muscle Training Program to prevent urinary incontinence during pregnancy and after delivery” is an evidence based guideline. Based on the selected studies, some recommendations are suggested and followed the grades of recommendations of the Scottish Intercollegiate Guidelines Network (SIGN) (Scottish Intercollegiate Guidelines Network, 2012). Recommendation of pelvic floor
muscle training can be divided into five parts (Pelvic floor muscle exercise instruction; Assessment of the correctness of performing pelvic floor muscle; Education tool; Schedule of pelvic floor muscle exercise program; Evaluation tool). (see Appendix F Recommendation)
Chapter 6: Implementation Plan

Pelvic Floor Muscle Exercise (PFME) can help pregnant women and women after delivery to prevent urinary incontinence; however, PFME education is not a routine practice for pregnant women and women after delivery in Hong Kong. Therefore, the evidence-based practice guidelines are formulated to facilitate PFME education practice among pregnant women and women after delivery. In order to introduce PFME education practice smoothly, it is necessary to set up an implementation plan to make sure all stakeholders are familiar with the innovation through good communication. In addition, there is a pilot test to see the feasibility of PFME education practice before implementing.

6.1 Communication plan

In order to minimize obstacles and gain support, an effective communication needs to be established with stakeholders. Therefore, a communication plan plays an important role in implementing an innovation. The communication plan includes: 1. identifying the stakeholders, 2. the process of communication plan, and 3. initiating, guiding and sustaining the change.

6.1.1 Identifying the stakeholders

The first step in communication plan is to identify the potential stakeholders. The stakeholders in this program include administrators (Department Operation Manager (DOM) and Wand Manager (WM)), Doctor (Chief of Service (COS)) and registered nurses in urology unit.
Department Operation Manager (DOM)

The department operation manager has the authority and right to approve and review the implementation of the proposed evidence based guidelines. Besides, the budget of the proposed innovation needs DOM’s financial support before purchasing. Apart from this, without DOM’s support, the proposed innovation cannot be submitted to higher administrative level.

Ward Manager (WM)

Ward manager is responsible for assigning duty of nurses who plays an important role in communicating with DOM and frontline staff for their feedback of the innovation.

Doctor (Chief of Service (COS)) of surgery

It is needed to get approval and agreement from COS before implementing the proposed evidence based guideline. The COS will disseminate the newly proposed evidence based guideline to all surgical staff. The urologists are responsible for urology patient care (including the client) in the surgery unit. All the urologists will follow and execute the guidelines approved by the COS. Moreover, all urologists including COS can give their professional advice at any time.

Nurses

Nurses are the most important stakeholders; it is because they are the frontline staff to execute the evidence based guideline. Their stress and workload may increase because of the new routine and tasks. Therefore, they are the most affected group of people in the newly proposed innovation. In view of this, more effort should be put in communicating with nurses. In order to resolve uncertainty and to standardize the
innovation, all the details will be introduced and questions are welcome to ask, and a
training session will be arranged to all nurses in urology unit.

6.1.2 The process of communication plan

The process of communication with all stakeholders should be planned carefully.
Nurses should be contacted first to obtain some comments and feedback. Then WM
and DOM will be contacted for obtaining approval. After getting WM and DOM’s
approval, we will have a meeting with COS to obtain the final approval. Then nurses
will be contacted again for delivering the final program plan and to get their comment
and feedback.

Nurses, the most frontline staff, should be contacted first. Formal staff meeting for
this program will be held at the beginning and one month later, so that nurses have
time to think about the program and give comment and feedback. Informal discussion
and sharing will be held in anytime when they are free. Through meeting, discussion
and sharing, nurses can understand the benefits and the affirming needs of the
innovation. Also, the program coordinator can estimate staffs’ acceptance and
capacity to carry out the innovation. In addition, opinion (including doubt and
difficulty) will be gathered for adjusting the provided innovation before
implementation.

Then the administrators will be approached for obtaining approval and support for
executing the innovation. Department Operation Manager (DOM) and Ward Manager
(WM) will be contacted via Email. The current situation, affirming need, evidence
from literature, transferability, feasibility and the cost benefit ratio will be explained.
In addition, comment and concern from nurses will also be attached. After WM and DOM have a brief idea of the program, we will invite WM and DOM to have a formal meeting for a presentation of the innovation. All details of the innovation including the cost-effectiveness will be presented and all queries will be answered directly.

After getting the approval from DOM and WM, Chief of service (COS) will then be contacted for the final decision. COS will be contacted via Email by DOM for introducing the new innovation such as the current situation, affirming need, evidence from literature, transferability, feasibility and the cost benefit ratio. If COS showed interest in the innovation, a presentation session will be asked for presenting the innovation and answer questions from COS.

After getting approval and support from COS, a nursing staff meeting will be arranged to nurses for explaining the detailed intervention guideline and the implementation plan. All nurses are welcome to ask questions and give comments. After the nursing staff meeting, an innovation related training will be arranged to nurses.

6.1.3 Initiating, guiding and sustaining the change

A new post – coordinator, who is a urology nurse specialist, will be created for initiating the newly proposed change. The coordinator will invite an urologist who will act as an adviser for giving expert and professional opinion to the care of client. And the coordinator will train nurses in urology ward and urology center with pelvic floor muscle exercise and the assessment of urinary incontinence.
After getting approval from administrator, a pilot study will be conducted to review and evaluate the guideline. Detail of pilot will be discussed in the next section.

Pelvic floor muscle exercise is a non-invasive and effective intervention to reduce urinary incontinence during pregnancy and postpartum. From the client’s point of view, there is no point to object this innovation. However, from the point of view of nurses, the new innovation (new routine, new task) may increase the stress of nurses. They may show resistance to the innovation. To solve this, regular meeting (once per two weeks) to nursing staff who take part in the innovation is essential (when the innovation is fully implemented). It is because a regular meeting can act as a channel for nurses to voice out their opinion and problem encountered. The coordinator is responsible to provide support.

The coordinator will be responsible for preparing the user guidebook for clients, training notes for nurses, document and materials related to the innovation (consent, clinical progress form, assessment form, weighing equipment, and pad for pad test). Then ward clerk will help to prepare and ensure the stocks are always available.

The coordinator will then train the trainer. Coordinator will give a two hours lecture to the ward nurses (total 20 nurses) on the details of the urinary incontinence related to pregnancy and the treatment. The pelvic floor muscle exercise, assessment method, assessment form and documentation will be taught or refreshed. The 2 hours training session will be held on Saturday and Sunday after morning shift duty. All nurses are welcome to raise question or give comment at any time. After all nurses are trained, the pilot study can then be started.
All nurses in urology unit will be trained to implement the innovation and they are randomly assigned for the duty (ward or innovation) by ward manager. All nurses working hours are 44 hours per week (same contract condition). The working pattern will be A (07:00-14:00), P (14:00-21:00) and N (21:00-07:00) for ward duty, and 0900-17:00 for innovation.

The coordinator will monitor, review and evaluate the effectiveness of the innovation continuously. Patient’s progress of urinary incontinence, job satisfaction of nurses involved in innovation will be monitored for determining the feasibility of the innovation, and the guideline.

6.2 Pilot study

After developing the communication plan, a pilot study plan should be developed. It is important to provide the opportunity in revealing the limitations and modifications of the proposed innovation.

The objectives of the pilot study are:

1. To determine the feasibility of performing pelvic floor muscle exercise program for pregnant women.
2. To identify any obstacle and problem that experienced during carrying out the innovation.
3. To evaluate the acceptance and feedback from the guideline users and patients.
4. To evaluate the proposed changes and make any necessary modifications during the pilot study in order to revise the guideline accordingly.
The pilot study will be held in December 2015 and last for 1 month. And the pilot study will be held in the urology center, which is mainly used for flexible cystoscopy (FC), videocystometrogram (VCMG) and nursing consultation for cancerous bladder and urinary incontinence patient. The pilot study will be lasted for 1 month, the number of clients involved will be 93 (31 women of 16 gestation week, 31 women of 28-32th gestational week and 31 women of 3 months postpartum, number of clients please refer to 7.3). The first 2 weeks is the recruitment period. 3-4 pregnant women of 16th gestation weeks will be referred from antenatal clinic each day (2 weeks* 5working day per week * 3-4 clients each day, total max. 31 clients). Nurses will educate client with PFME, assess the clients’ correctness of performing PFME, assess quality of life (Incontinence Impact Questionnaire) of clients and perform pad test for clients.

The third week will be used for performing 1 hour pad test and Incontinence Impact Questionnaire for women of 28-32th gestation week. 6-7 pregnant women of 28-32th gestation weeks will be referred from antenatal clinic each day (2 weeks* 5working day per week * 6-7 clients each day, total max. 31 clients).

The fourth week will be used for performing 1 hour pad test and Incontinence Impact Questionnaire for women of 3 months after delivery. 6-7 pregnant women of 28-32th gestational weeks will be referred from postnatal clinic each day (2 weeks* 5working day per week * 6-7 clients each day, total max. 31 clients).

Convenience sampling will be used for the subject recruitment in this pilot study plan. In the antenatal and postnatal clients will be invited to join this program if they agree
to take part in this pilot study. They will then sign consent and make an appointment with the innovation coordinator.

Before the pilot study, all nurses in urology ward will be trained (mentioned in the previous chapter). All nurses needed to re-demonstrate the skill and knowledge of teaching pelvic floor muscle exercise. In order to evaluate the outcome of the intervention, familiarization of the measuring tool and evaluation tool will be included in the training.

The coordinator will be responsible for the logistical arrangement. All the materials and resources needed in pilot study such as guidebook, pad, weighting scale, gloves, tissue, progress form and assessment form will be prepared. The expense of the pilot study will be monitored for determining the budget of the full scale program.

Ward manager will assign coordinator and one nurse randomly in this pilot program. Trained nurses (including coordinator) will be responsible for the client education and follow up. Nurse in ward will replace nurses who are responsible for the innovation when they are on leave.

**Methodology**

A questionnaire (Appendices G and H) will be given to nurses and clients in this pilot study to assess their acceptability. Apart from the questionnaires, nurses and clients can voice out their opinion and comment in anytime. The coordinator can collect feedback by these two channels.

In the PFME education follow up, nurses will educate client with pelvic floor muscle
exercise and assess the correctness of performing pelvic floor muscle exercise. Clients will be ensured to perform pelvic floor muscle exercise correctly. Digital vaginal palpation will be used to assess the correctness of performing pelvic floor muscle exercise (Sartori, et al., 2015). The client will be instructed to lay in supine position with straight knees and abducted legs, the nurse will use her index and middle fingers to extend and insert into client’s vagina. Then nurse will ask client to contract the pelvic floor muscle, if nurse’s index and middle fingers sense the contract, that’s mean client performed pelvic floor muscle correctly. Then pad test and Incontinence Impact Questionnaire will be performed for the baseline data before leaving the clinic.

During other follow up (28th-32th gestational week and 3 months postpartum) the pad test and Incontinence Impact Questionnaire will be performed and nurses will reinforce the importance of pelvic floor muscle exercise and encourage clients to practice pelvic floor muscle exercise at home. During follow up, clients are encouraged to ask questions and voice out difficulties encountered.

To fully implement innovation, compliance will be assessed. The compliance of pelvic floor muscle exercise will be assessed by a daily record book (Appendices I). In every follow up, nurses will collect the used daily record book and a new book will be given to clients.

The coordinator will analyze all the collected data and discuss with nurses who take part in the innovation during monthly staff meeting. After each meeting, the guideline and details of the program will be modified if necessary. Approval from DOM, WM and COS will be asked for any modification.
Chapter 7: Evaluation plan

The main purpose of evaluation plan is to assess the effectiveness of pelvic floor muscle exercise in preventing urinary incontinence among the pregnant women. It is important to review and modify the program regularly and continuously. The final goal is promoting this program to all pregnant women in Hong Kong so that the incidence of urinary incontinence among pregnant women and postpartum women can be reduced.

7.1 Outcomes to be achieved

After developing the implementation plan, it is important to evaluate the effectiveness of the innovation. Based on the objectives, the outcomes of the evaluation plan will be categorized into patient outcomes, healthcare provider outcomes and system outcomes.

7.1.1 Patient outcomes

The effectiveness of pelvic floor muscle exercise guideline can be evaluated by assessing the clinical benefit of the program. The aim of pelvic floor muscle exercise is to prevent or treat urinary incontinence (UI) of women during pregnant (after 16 gestational week) and 3 months postpartum. The primary outcome is the continence rate. The secondary outcome is client’s quality of life affected by urinary incontinence.

One hour pad test will be used for measuring the incidence of urinary incontinence. One hour pad test is a reliable tool for evaluating the primary outcome of this program, since pad test can quantify the urine loss.
Clients will be instructed not to void for 2 hours before the one hour pad test and to wear a pad. The pad will be weighted before the test. Then the client will be asked to sit and drink 500ml of water. After that, client will be asked to walk for 30 minutes including go up and down 24 steps. After the 30 minutes walking, client will be instructed to stand and sit for ten times, cough vigorously ten times, run in a place for one minute, pick up object from ground five times, and put their hands under water for one minute. After all activities have finished, the pad will be weighted to measure the urine leakage. For the result, urine leakage larger than 1 gram will be classified as urinary incontinence (Wischnitzer et al., 2010). Data will be collected in every follow up (16th, 28th, 32th gestation week and 3 month postpartum).

As mentioned in the previous chapter, urinary incontinence decreases women quality of life. Therefore, quality of life (QoL) is the secondary outcome. The measuring tool of QoL is Incontinence Impact Questionnaire (IIQ-7) Short Form (Appendix J). The IIQ-7 consists of 7 questions which related to mental, physical, social and travel aspect, and the scored range from zero to one hundred, the higher score means greater impact from urinary incontinence (Uebersax et. al.,1995). Clients required completing IIQ-7 in every follow up (16th, 28th, 32th gestation week and 3 month postpartum).

7.1.2 Healthcare provider outcomes

Feedbacks from frontline staffs are important to evaluate the effectiveness of the program. The satisfactory level of implementing new program will be evaluated.

A questionnaire (Appendix K) will be designed for collecting their satisfaction and comment of the program. Likert scale and open end questions will be used in the
questionnaire. All nurses involved in the program will be required to complete the questionnaire in the 3th, 6th month after the training and at the end of pilot study. Apart from the questionnaire, nurses are welcome to voice out their opinion in anytime. The coordinator will interview and record nurses who give comment.

7.1.3 System outcomes

The budget and cost benefit ratio is very important to a new program. The hospitalization fee (bed charge, doctor’s fee, nurse care, meal, laboratory test) is $4,680 per day (Hospital Authority, 2015), incontinence pads is $12 per day ($2 * 6 pieces, every 4 hours), total $4,692 per day per head. The cost of the innovation is $8,248 (Appendix L) and the number of clients to be involved in the training program is 31. The cost of program includes materials cost and training cost. The materials cost (pad only) is $248 (each pad cost $2, 31 clients and 4 visits). The training cost (trainee) is $8,000, the average salary of registered nurse is around $200 per hour; a 2 hours training course and 20 nurses in urology will be trained. The coordinator held the course during her working hours; therefore the salary of coordinator is not being counted. However, the trainees will attend the course beyond their working hour, the 2 hours course time will be counted as compensating. Thus the trainees’ salary is needed to be counted.

The benefit increases if the number of hospitalization due to urinary incontinence is less than 2 out of the 31 clients. In addition, the out-patient clinic fee is $1,110 (Hospital Authority, 2015). The benefit increases if the number of clients attending out-patient clinic due to urinary incontinence is less than 8 out of the 31 clients.
The cost benefit ratio will affect the approval from the administrator. Therefore, the utilization rate, manpower and the cost will be assessed.

The utilization can be assessed by the patient progress form. During every follow up a new patient progress form will be used. Nurses will document all the interventions and result (e.g. reinforcement or education on pelvic floor muscle exercise, pad test, follow up arrangement and so on). All the patient progress forms will be collected at the end of the pilot study and fully implemented program for assessing the utilization.

For the manpower, all the urology center duty roster will be collected for assessing the manpower required for the pilot study and fully implemented program.

All the expense of the pilot study (mainly from photocopy of patient progress form, guidebook for client, daily record book for compliance and pad for pad test) will be recorded. The estimated cost of the pilot study will be calculated for granting funding. (Appendix L) and will be used for estimating cost for fully implemented program.

The coordinator is responsible for monitoring the actual cost continuously so that the cost will not exceed the budget. A final report will be made and submitted to administrator at the end of the pilot study.

7.2 Data analysis

Urinary incontinence refers to the result of the 1 hour pad test with result greater than 1 gram. The result of urinary incontinence rate will be presented in percentage (population of urinary incontinence over total population of clients). One size one
sample t-test with significance 5% will be used to assess the effectiveness of the program. The decrease of percentage reflects the effectiveness of the program.

The result of IIQ-7 short form will be calculated and analyzed as mean. One size one sample t-test with significance 5% will be used to assess the improvement of quality of life of clients.

Descriptive statistic will be used to analyze the result of the questionnaire for nurses and clients, the mean of the rating (satisfaction, assistance and support from coordinator, training sufficiency) will be calculated and presented. The comments of the open-ended questions will be extracted and coded into different themes.

For analyzing the outcome of system, all patient progress forms will be collected and counted for the valid progress form (all items had been completed and with signature of nurse), the total number of valid and invalid forms will be reported. The manpower of the program will be counted from the duty roster and will be reported in the final report. For the cost of the program, all expense will be recorded in a logbook and will be reported in the final report.

7.3 Nature and number of patients involved

As mentioned in the previous chapter, the inclusion criteria are: age over 18; pregnant women of 16 gestational week; receiving regular prenatal care in clinical setting; without history of genitourinary pathology or chronic disease; available for follow up; able to read and understand Chinese; and type of delivery: normal vaginal, forceps, vacuum. The exclusion criteria are: multiparity; multi-gestations; severe pregnancy
complication; high risk of preterm labor; pain during PFME; disease that interfere with participation; already received PFME or treatment of urinary incontinence; prior abortion and neurological disease.

For subject recruitment, convenience sampling is used. The primary outcome will be used to calculate the sample size. Ress Lenth’s power and sample size calculator are used. The primary outcome is urinary continence rate, which analyzed by one size one sample t-test. By setting sigma 2.32, true 1.06, power 0.8 and significant 0.05 (Mason et. al., 2010), the number of clients involved is 31.

7.4 Criteria for the considering an effective guideline intervention

The following criteria are used to determine the effectiveness of the guideline. The guideline is considered as effective if all the criteria are achieved.

The primary outcome, the continence rate, is measured by pad test. Effective guideline will be considered if the trend of continence rate before giving birth showed improvement in every follow up and the continence rate of 3 months postpartum is higher than the first visit.

The secondary outcome, the quality of life, is measured by IIQ-7. The guideline will be considered as effective if the trend of IIQ-7 scores show a decreasing trend throughout the follow up before giving birth and the IIQ-7 scores of 3 months postpartum is lower than the first follow up.

Lastly, the guideline will be considered as effective if the actual expense of the program does not exceed the budget of the funding.
Chapter 8: Conclusion

Urinary incontinence is a common problem among pregnant women and women after delivery. Urinary incontinence affects quality of life of pregnant women. It also posts an economic burden to health care system.

There are some surgical interventions to solve this problem. However, they are not suggested to pregnant women. Pelvic floor muscle exercise is a safe, non-invasive and cost effective intervention to prevent and treat urinary incontinence. Many studies suggested that pelvic floor muscle exercise is the first line management for urinary incontinence including pregnant women and women after delivery.

In this study, an evidence-based guideline on pelvic floor muscle exercise guideline is introduced to manage urinary incontinence in pregnant women and women after delivery.

After determining the transferability, feasibility and cost-benefit of the program, a well-designed communication plan will be established for communicating with all stakeholders. After getting support from stakeholders, a pilot study will be implemented. All comments and feedbacks will be collected for modifying the evidence-based guideline before it is put into full implementation.

The results of the evidence-based guideline for clients, healthcare providers and system will be evaluated. The guideline will be considered to be effective if the continence rate shows an increase before delivery, continence rate after deliver is higher than the first follow up and the actual expense of the program does not exceed
the budget of the funding. It is recommended to establish in all public hospitals as an usual practice in order to yield benefits to the target pregnant women.
Appendix A: Checklist RCT

**Methodology Checklist 2: Controlled Trials**

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<thead>
<tr>
<th>Guideline topic</th>
<th>Key Question No.</th>
<th>Reviewer</th>
</tr>
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</table>

Before completing this checklist consider:

1. Is the paper a randomised controlled trial or a controlled clinical trial? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a controlled clinical trial questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+.

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question □ 2. Other reason □ (please specify):

**SECTION 1: INTERNAL VALIDITY**

<table>
<thead>
<tr>
<th>In a well conducted RCT study...</th>
<th>Does this study do it?</th>
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<tbody>
<tr>
<td>1.1. The study addresses an appropriate and clearly focused question.</td>
<td>Yes □, No □, Can't say □</td>
</tr>
<tr>
<td>1.2. The assignment of subjects to treatment groups is randomised.</td>
<td>Yes □, No □, Can't say □</td>
</tr>
<tr>
<td>1.3. An adequate concealment method is used.</td>
<td>Yes □, No □, Can't say □</td>
</tr>
<tr>
<td>1.4. Subjects and investigators are kept blind about treatment allocation.</td>
<td>Yes □, No □, Can't say □</td>
</tr>
<tr>
<td>1.5. The treatment and control groups are similar at the start of the trial.</td>
<td>Yes □, No □, Can't say □</td>
</tr>
<tr>
<td>1.6. The only difference between groups is the treatment under investigation.</td>
<td>Yes □, No □, Can't say □</td>
</tr>
<tr>
<td>1.7. All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>Yes □, No □, Can't say □</td>
</tr>
<tr>
<td>1.8. What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>Yes □, No □, Can't say □</td>
</tr>
<tr>
<td>1.9. All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).</td>
<td>Yes □, No □, Does not apply □, Can't say □</td>
</tr>
<tr>
<td>1.10. Where the study is carried out at more than one site, results are comparable for all sites.</td>
<td>Yes □, No □, Can't say □, Does not apply □</td>
</tr>
</tbody>
</table>
###SECTION 2: OVERALL ASSESSMENT OF THE STUDY

| 2.1. How well was the study done to minimize bias? |
|---|---|
| Code as follows: harming bias. | High quality (++□), Acceptable (+□), Unacceptable (-□). |

| 2.2. Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? |

| 2.3. Are the results of this study directly applicable to the patient group targeted by this guideline? |

| 2.4. Notes. Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above. |

---

1. Unless a clear and well-defined question is specified, it will be difficult to assess how well the study has met its objectives or how relevant it is to the question you are trying to answer on the basis of its conclusions.

2. Random allocation of patients to receive one or other of the treatments under investigation, or to receive either treatment or placebo, is fundamental to this type of study.

3. Allocation concealment refers to the process used to ensure that researchers are unaware which group patients are being allocated to at the time they enter the study. Research has shown that where allocation concealment is inadequate, investigators can overestimate the effect of interventions by up to 40%.

4. Blinding refers to the process where study participants are kept unaware of which treatment an individual patient has been receiving when they are assessing the outcome for that patient. It can be carried out up to three levels. Single blinding is where patients are unaware of which treatment they are receiving. In double blind studies neither the clinician nor the patient knows which treatment is being given. In very rare cases studies may be triple blinded, where neither patients, clinicians, nor those conducting the analysis are aware of which patients received which treatment. The higher the levels of blinding, the lower the risk of bias in the study.

5. Patients selected for inclusion in a trial must be as similar as possible. The study should report any significant differences in the composition of the study groups in relation to gender mix, age, stage of disease (if applicable), social background, ethnic origin, or co-morbid conditions. These factors may be covered by inclusion and exclusion criteria, rather than being reported directly. Failure to address this question, or the use of inappropriate groups, should lead to the study being downgraded.

6. If some patients received additional treatment, even if of a minor nature or consisting of advice and counselling rather than a physical intervention, this treatment is a potential confounding factor that may invalidate the results. If groups were not treated equally, the study should be rejected unless no other evidence is available. If the study is used as evidence it should be treated with caution.

7. The primary outcome measures used should be clearly stated in the study. If the outcome measures are not stated, or the study bases its main conclusions on secondary outcomes, the study should be rejected. Where outcome measures require any degree of subjectivity, some evidence should be provided that the measures used are reliable and have been validated prior to their use in the study.
The number of patients that drop out of a study should give concern if the number is very high. Conventionally, a 20% drop-out rate is regarded as acceptable, but this may vary. Some regard should be paid to why patients dropped out, as well as how many. It should be noted that the drop-out rate may be expected to be higher in studies conducted over a long period of time. A higher drop-out rate will normally lead to downgrading, rather than rejection of a study.

In practice, it is rarely the case that all patients allocated to the intervention group receive the intervention throughout the trial, or that all those in the comparison group do not. Patients may refuse treatment, or contra-indications arise that lead them to be switched to the other group. If the comparability of groups through randomisation is to be maintained, however, patient outcomes must be analysed according to the group to which they were originally allocated irrespective of the treatment they actually received. (This is known as intention-to-treat analysis.) If it is clear that analysis was not on an intention-to-treat basis, the study may be rejected. If there is little other evidence available, the study may be included but should be evaluated as if it were a non-randomised cohort study.

In multi-site studies, confidence in the results should be increased if it can be shown that similar results were obtained at the different participating centres.

Rate the overall methodological quality of the study, using the following as a guide: High quality (++): Majority of criteria met, little or no risk of bias, results unlikely to be changed by further research. Acceptable (+): Most criteria met, some flaws in the study with an associated risk of bias. Conclusions may change in the light of further studies. Low quality (0): Either most criteria not met, or significant flaws relating to key aspects of study design. Conclusions likely to change in the light of further studies.
Appendix B: Notes on controlled trial checklist

Notes on Methodology Checklist 2: Controlled Trials

The top part of the form identifies the study and links it to the particular guideline and key question to which it relates. It includes reminders of factors you should consider before deciding whether it is worth progressing to a full appraisal of the paper concerned.

**Section 1**

This section makes a series of statements about aspects of the systematic review process that affect the **internal validity** of the review and asks you to assess how well the review addresses each issue. The objective is to assess how well the authors have dealt with the risk of **bias** in their methods.

If you would like more information on randomised controlled trials, their characteristics and weaknesses then please refer to Greenhalgh T. How to read a paper: the basics of evidence-based medicine. 3rd edition. Oxford: Blackwell;2006. Section 3.3 Page 44.

*Note that the “Response” column is for guidance only. You may opt for a different rating depending on how information is presented in any given review.*

<table>
<thead>
<tr>
<th>Statement 1.1</th>
<th>The study addresses an appropriate and clearly focused question</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What does this statement mean?</strong></td>
<td><strong>When does this statement apply?</strong></td>
</tr>
<tr>
<td>Unless a clear and well defined question is specified, it will be difficult to assess how well the study has met its objectives or how relevant it is to the question you are trying to answer on the basis of its conclusions.</td>
<td>Always applies</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<p>| Statement 1.2 | The assignment of subjects to treatment groups is randomised |</p>
<table>
<thead>
<tr>
<th>Statement 1.3</th>
<th>An adequate concealment method is used</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What does this statement mean?</strong></td>
<td>Random allocation of patients to receive one or other of the treatments under investigation, or to receive either treatment or placebo, is fundamental to this type of study.</td>
</tr>
<tr>
<td><strong>When does this statement apply?</strong></td>
<td>Always applies</td>
</tr>
</tbody>
</table>
| **Response:** | Yes - if a good randomisation method is used such as computer generated off-site allocation. If a poor randomisation method is used such as a coin-flip then mark as ‘yes’, but mention in notes that the randomisation method was poor.  
No - if deterministic methods such as day of the week, birth date, day of arrival at the clinic etc. These studies can then be assessed as controlled clinical trials instead of RCTs  
Can’t say - if randomisation is mentioned, but method not specified. |

<table>
<thead>
<tr>
<th>Statement 1.4</th>
<th>Subjects and investigators are kept ‘blind’ to treatment allocation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What does this statement mean?</strong></td>
<td>Allocation concealment refers to the process used to ensure that researchers are unaware which group patients are being allocated to at the time they enter the study. Research has shown that where allocation concealment is inadequate, investigators can overestimate the effect of interventions by up to 40%.</td>
</tr>
<tr>
<td><strong>When does this statement apply?</strong></td>
<td>Always applies</td>
</tr>
</tbody>
</table>
| **Response:** | Yes - if centralised allocation, computerised allocation systems, or the use of coded identical containers  
No - if method of concealment used is regarded as poor, or relatively easy to subvert. Mark as ‘no’ if no concealment method is reported.  
Can’t say - if concealment is mentioned, but not described. |
Blinding refers to the process whereby people are kept unaware of which treatment an individual patient has been receiving when they are assessing the outcome for that patient. It can be carried out up to three levels. Single blinding is where patients are unaware of which treatment they are receiving. In double blind studies neither the clinician nor the patient knows which treatment is being given. In very rare cases studies may be triple blinded, where neither patients, clinicians, nor those conducting the analysis are aware of which patients received which treatment. The higher the level of blinding, the lower the risk of bias in the study.

<table>
<thead>
<tr>
<th>Statement 1.5</th>
<th>The treatment and control groups were similar at the start of the trial</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What does this statement mean?</strong></td>
<td>Patients selected for inclusion in a trial must be as similar as possible. The study should report any significant differences in the composition of the study groups in relation to gender mix, age, stage of disease (if appropriate), social background, ethnic origin, or co-morbid conditions. These factors may be covered by inclusion and exclusion criteria, rather than being reported directly. Failure to address this question, or the use of inappropriate groups, should lead</td>
</tr>
<tr>
<td><strong>When does this statement apply?</strong></td>
<td>Always applies</td>
</tr>
</tbody>
</table>
| **Response:** | Yes - if the patient groups look reasonably similar. In some trials a p value will be given for each factor considered. These values should ideally all be >0.05. This is very good practice, but its absence should not affect your assessment of study quality.  
No - if the patient groups have important differences in factors that may influence the outcomes.  
Can’t say - if the patient groups have not been adequately described. |
to the study being downgraded.

<table>
<thead>
<tr>
<th>Statement 1.6</th>
<th>The only difference between the groups is the treatment under investigation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What does this statement mean?</strong></td>
<td>If some patients received additional treatment, even if of a minor nature or consisting of advice and counselling rather than a physical intervention, this treatment is a potential confounding factor that may invalidate the results. If groups were not treated equally, the study should be rejected unless no other evidence is available. If the study is used as evidence it should be treated with caution.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Statement 1.7</th>
<th>All relevant outcomes measured in a standard, valid and reliable way</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What does this statement mean?</strong></td>
<td>The primary outcome measures used should be clearly stated in the study. If the outcome measures are not stated, or the study bases its main conclusions on secondary outcomes, the study should be rejected. Where outcome measures require any degree of subjectivity, some evidence should be provided that the measures used are reliable and have been validated prior to their use in the study.</td>
</tr>
<tr>
<td>Statement 1.8</td>
<td>What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
</tr>
<tr>
<td>-------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>What does this statement mean?</strong></td>
<td>The number of patients that drop out of a study should give concern if the number is very high. Conventionally, a 20% drop out rate is regarded as acceptable, but this may vary. Some regard should be paid to why patients dropped out, as well as how many. It should be noted that the drop out rate may be expected to be higher in studies conducted over a long period of time. A higher drop out rate will normally lead to downgrading, rather than rejection of a study.</td>
</tr>
<tr>
<td><strong>When does this statement apply?</strong></td>
<td>Always applies</td>
</tr>
<tr>
<td><strong>Response:</strong></td>
<td>[Enter percentage]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Statement 1.9</th>
<th>All the subjects are analysed in the groups to which they were randomly allocated (intention to treat analysis)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What does this statement mean?</strong></td>
<td>In practice, it is rarely the case that all patients allocated to the intervention group receive the intervention throughout the trial, or that all those in the comparison group do not. Patients may refuse treatment, or contra-indications arise that lead them to be switched to the other group. If the comparability of groups through randomisation is to be maintained, however, patient outcomes must be analysed according</td>
</tr>
<tr>
<td><strong>When does this statement apply?</strong></td>
<td>Always applies</td>
</tr>
<tr>
<td><strong>Response:</strong></td>
<td>Yes - if ITT (intention to treat) is mentioned in the text. ‘modified’ ITT is acceptable if an explanation is provided. No - if ITT is not mentioned in the text. Can’t say if ‘modified’ ITT is indicated without any explanation Not applicable - if all participants are accounted for and none are lost to follow-up</td>
</tr>
</tbody>
</table>
to the group to which they were originally allocated irrespective of the treatment they actually received. (This is known as intention to treat analysis.) If it is clear that analysis was not on an intention to treat basis, the study may be rejected. If there is little other evidence available, the study may be included but should be evaluated as if it were a non-randomised cohort study.

<table>
<thead>
<tr>
<th>Statement 1.10</th>
<th>Where the study is carried out at more than one site, results are comparable for all sites.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What does this statement mean?</strong></td>
<td>In multi-site studies, confidence in the results should be increased if it can be shown that similar results were obtained at the different participating centres.</td>
</tr>
<tr>
<td><strong>When does this statement apply?</strong></td>
<td>In a multi-centre trial</td>
</tr>
</tbody>
</table>
| **Response:** | **Yes** - if there is no marked difference in the site data reported or if there is no difference in the centres that can be determined  
**No** - if there is one or more sites that have markedly worse or better data than the others. Or if the sites have different characteristics such as community treatment against hospital in-patient treatment.  
**Can’t say** - if no site specific data is given  
**Not applicable** - if there is only one site. |

**Section 2**

Section 2 relates to the overall assessment of the paper. It starts by rating the methodological quality of the study, based on your responses in Section 1 and using the following coding system. This section is very important and your rating will appear in the evidence table. PLEASE FILL IN.

<p>| Statement 2.1 | How well was the study done to minimise the risk of bias or confounding? |</p>
<table>
<thead>
<tr>
<th>Quality Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>++</td>
<td>High quality (++): Majority of criteria met. Little or no risk of bias. Results unlikely to be changed by further research.</td>
</tr>
<tr>
<td>+</td>
<td>Acceptable (+): Most criteria met. Some flaws in the study with an associated risk of bias. Conclusions may change in the light of further studies.</td>
</tr>
<tr>
<td>0</td>
<td>Low quality (0): Either most criteria not met, or significant flaws relating to key aspects of study design. Conclusions likely to change in the light of further studies.</td>
</tr>
</tbody>
</table>

**Statement 2.2**
Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?

This is your clinical judgement of the study.

**Statement 2.3**
Are the results of this study directly applicable to the patient group targeted by this guideline?

<table>
<thead>
<tr>
<th>What does this statement mean?</th>
<th>When does this statement apply?</th>
<th>Response:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does this study make sense in the Scottish context? Consider whether it is appropriate to extrapolate from other countries or health care systems.</td>
<td>Always applies</td>
<td>Yes □ No □</td>
</tr>
</tbody>
</table>

**Statement 2.4**
Notes. Summarise the author’s conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above. This is a very important part of the evaluation and will feature in the evidence table. PLEASE FILL IN.
### Appendix C: Appraisal Table

<table>
<thead>
<tr>
<th>1.1</th>
<th>The study addresses an appropriate and clearly focused question</th>
<th>Ko et al (2011)</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2</td>
<td>The assignment of subjects to treatment groups is randomized</td>
<td>Can’t say</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>1.3</td>
<td>An adequate concealment method is used</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Can’t say</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>1.4</td>
<td>Subjects and investigators are kept “blind” about treatment</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>1.5</td>
<td>The treatment and control groups are similar at the start of the trial</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>1.6</td>
<td>The only difference between group is the treatment under investigation</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>1.7</td>
<td>All relevant outcomes are measured in a standard, valid and reliable way</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>1.8</td>
<td>What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed</td>
<td>0%</td>
<td>0%</td>
<td>25%</td>
<td>5.7%</td>
<td>25%</td>
<td>8.6%</td>
<td>14.2%</td>
</tr>
<tr>
<td>1.9</td>
<td>All the subjects are analyzed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)</td>
<td>Can’t say</td>
<td>Can’t say</td>
<td>Can’t say</td>
<td>Can’t say</td>
<td>Can’t say</td>
<td>No</td>
<td>Can’t say</td>
</tr>
<tr>
<td>1.10</td>
<td>Where the study is carried out at more than one site, result are comparable for all sites</td>
<td>No</td>
<td>Can’t say</td>
<td>No</td>
<td>No</td>
<td>Can’t say</td>
<td>No</td>
<td>No</td>
</tr>
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<td>---</td>
<td>---</td>
</tr>
<tr>
<td>2.1</td>
<td>How well was the study done to minimise bias?</td>
<td>+</td>
<td>++</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>2.2</td>
<td>Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?</td>
<td>The randomization is not clear</td>
<td>/</td>
<td>No randomization</td>
<td>Dropout rate high</td>
<td>No randomization</td>
<td>No randomization</td>
<td>Dropout rate high</td>
</tr>
<tr>
<td>2.3</td>
<td>Are the results of this study directly applicable to the patient group targeted by this guideline?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

p.60
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>The study addresses an appropriate and clearly focused question</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>1.2</td>
<td>The assignment of subjects to treatment groups is randomized</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Can’t say</td>
<td>Yes</td>
</tr>
<tr>
<td>1.3</td>
<td>An adequate concealment method is used</td>
<td>Can’t say</td>
<td>Can’t say</td>
<td>Can’t say</td>
<td>Can’t say</td>
<td>Can’t say</td>
<td>Can’t say</td>
</tr>
<tr>
<td>1.4</td>
<td>Subjects and investigators are kept “blind” about treatment</td>
<td>No</td>
<td>Can’t say</td>
<td>Can’t say</td>
<td>No</td>
<td>Can’t say</td>
<td>Can’t say</td>
</tr>
<tr>
<td>1.5</td>
<td>The treatment and control groups are similar at the start of the trial</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>1.6</td>
<td>The only difference between group is the treatment under investigation</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>1.7</td>
<td>All relevant outcomes are measured in a standard, valid and reliable way</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>1.8</td>
<td>What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed</td>
<td>6.1%</td>
<td>38.8%</td>
<td>53.3%</td>
<td>36.9%</td>
<td>26%</td>
<td>20%</td>
</tr>
<tr>
<td>1.9</td>
<td>All the subjects are analyzed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)</td>
<td>No</td>
<td>Can’t say</td>
<td>Can’t say</td>
<td>Can’t say</td>
<td>Can’t say</td>
<td>Can’t say</td>
</tr>
<tr>
<td>1.10</td>
<td>Where the study is carried out at more than one site, result are comparable for all sites</td>
<td>Yes 3 hospital in Australia</td>
<td>No</td>
<td>Yes 2 hospitals in UK</td>
<td>No</td>
<td>Can’t say</td>
<td>Yes West, south and east of Netherlands</td>
</tr>
<tr>
<td>----------------------------</td>
<td>--------------------------------</td>
<td>------------------</td>
<td>-------------------</td>
<td>---------------------------</td>
<td>------------------</td>
<td>------------------------</td>
<td>------------------------</td>
</tr>
<tr>
<td>2.1 How well was the study done to minimise bias?</td>
<td>++</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>++</td>
<td>+</td>
</tr>
<tr>
<td>2.2 Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?</td>
<td>/</td>
<td>High dropout rate</td>
<td>High dropout rate</td>
<td>High dropout rate</td>
<td>High dropout rate</td>
<td>/</td>
<td>High dropout rate</td>
</tr>
<tr>
<td>2.3 Are the results of this study directly applicable to the patient group targeted by this guideline?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Appendix D: Table of Evidence


<table>
<thead>
<tr>
<th>Study</th>
<th>Author</th>
<th>Participants/Setting</th>
<th>Nos.</th>
<th>Intervention</th>
<th>Outcome Measure</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>RCT</td>
<td>Ko et al (2011)</td>
<td>Nulliparous women, at 16-24 gestational weeks</td>
<td>IG: 150, CG: 150</td>
<td>IG: Individually instructed about pelvic floor anatomy and how to contract PFM correctly Advice to practice PFME (3 repetitions of 8 contraction each held for 6s with 2mins rest between repetition) twice daily at home with additional training in group once a week for 45 mins, 12 weeks period. Strongly encourage PFME</td>
<td>(a) Incontinence Impact Questionnaire (QoL) (the lower score the higher QoL) (b) Urogenital Distress Inventory (the lower score the higher continence status) (c) Self-report UI</td>
<td>(a) IG lower score than CG at 36 pregnancy week, 6 weeks and 6 months postpartum (P&lt;0.01) (b) IG lower score than CG at 36 pregnancy week, 3 days, 6 weeks and 6 months postpartum (P&lt;0.01) IG lower incidence of self-report UI than CG (P&lt;0.05) at 36 pregnancy week and 6 months postpartum</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study</th>
<th>Author</th>
<th>Participants/Setting</th>
<th>Nos.</th>
<th>Intervention</th>
<th>Outcome Measure</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>RCT</td>
<td>Sampselle et al (1997)</td>
<td>Pregnant women at 20 gestational week</td>
<td>IG:34</td>
<td>IG: Standardized instruction in PFME</td>
<td>(a) Self-report UI symptom</td>
<td>(a) IG fewer UI symptoms than CG at 35 weeks gestation, 6 weeks and 6 months postpartum (P&lt;0.05)</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>CG:38</td>
<td>CG: Routine care with no systematic PFMT instruction</td>
<td>(b) Strength of PFM</td>
<td>(b) Not sign.</td>
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</tbody>
</table>


<table>
<thead>
<tr>
<th>Study</th>
<th>Author</th>
<th>Participants/Setting</th>
<th>Nos.</th>
<th>Intervention</th>
<th>Outcome Measure</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>RCT</td>
<td>Kocaoz et al (2013)</td>
<td>Pregnant women (14-20 gestational weeks)</td>
<td>IG:52, CG:50</td>
<td>IG: Individually instructed about pelvic floor anatomy and how to contract PFM correctly. Home practice (3 repetitions of 15 contraction each held for 10s and release for 10s then quick contraction held for 2s and release for 2s) three times daily at home. CG: Do not have any information on PFME provided.</td>
<td>(a) 1-hour pad test (&lt;2g) (the higher % the lower no. of UI)</td>
<td>(a) At 28 gestational week IG 24.2%&gt; CG (P=0.002) At 32 gestational week IG 30.7%&gt; CG (P=0.002) At 12 week postpartum IG 16.1%&gt; CG (P=0.007)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study</th>
<th>Author</th>
<th>Participants/ Setting</th>
<th>Nos.</th>
<th>Intervention</th>
<th>Outcome Measure</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>RCT</td>
<td>Sangsawang &amp; Serisathien (2011)</td>
<td>Pregnant women at 20-30 weeks gestational week</td>
<td>IG:31 CG:35</td>
<td>IG: Instruction on correct PFME, Attend a PFME programme (45 mins once per 2 weeks for 6 weeks) Encouraged to perform PFME with both slow and fast contractions. The slow contraction was performed by contracting the perivaginal and perianal muscles by holding a strong contraction for 10 seconds then slowly relaxing the muscle for 10 seconds. These exercises were followed by fast contractions which were performed by briefly</td>
<td>(a) Severity of UI (amount of urine leakage, UI frequency and self report of severity of UI by Visual Analogue Scale)</td>
<td>(a) IG had lower severity of UI than CG (P&lt;0.001)</td>
</tr>
</tbody>
</table>
contracting and relaxing the muscles rapidly for a total of 10 times wherein holding the initial contraction and relaxation of the pelvic floor muscle followed by rapid contraction and relaxation of these muscles equalled one set. (repeat 20 sets twice a day) 5 days per week for an overall period of 6 weeks.

CG: Received only usual nursing care with instruction on PFME (no training to support the performance of correct PFME).

<table>
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<tr>
<th>Study</th>
<th>Author</th>
<th>Participants/ Setting</th>
<th>Nos.</th>
<th>Intervention</th>
<th>Outcome Measure</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>RCT</td>
<td>Morkved &amp; Bo (2000)</td>
<td>Postpartum women (6 weeks after delivery)</td>
<td>IG: 81, CG: 81</td>
<td>IG: Attend PFME course (45 mins once a week) daily exercise for eight weeks Home exercise (two series of eight to twelve maximum contractions and to hold the contraction for 6-8 s. At the end of each contraction, three to four fast contractions were added) for the first 6 months after delivery. Motivation was strongly emphasised CG: Written postpartum instruction (did not mention included PFME information or not)</td>
<td>(a) Prevalence of UI (self-report &amp; pad test)</td>
<td>(a) IG had lower UI than CG (P&lt;0.01)</td>
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</table>

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<thead>
<tr>
<th>Study</th>
<th>Author</th>
<th>Participants/ Setting</th>
<th>Nos.</th>
<th>Intervention</th>
<th>Outcome Measure</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>RCT</td>
<td>Hilde et al (2013)</td>
<td>women 6 weeks after delivery</td>
<td>IG: 87, CG: 88</td>
<td>IG: Receive PFME with instruction on the correct contract then attend PFME program for 16 weeks (once a week) Home practice (three sets of 8 to 12 contractions close to maximum daily) CG: Receive PFME with instruction on the correct contract, without any follow up</td>
<td>(a) Urinary symptoms (ICIQ-UI SF) (b) Pad test</td>
<td>(a) Intervention did not decrease urinary symptoms (b) Not sign,</td>
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<tr>
<th>Study</th>
<th>Author</th>
<th>Participants/ Setting</th>
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<th>Intervention</th>
<th>Outcome Measure</th>
<th>Result</th>
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<tbody>
<tr>
<td>RCT</td>
<td>Reilly et al (2002)</td>
<td>Primigravidae (20 gestational weeks)</td>
<td>IC:139 CG:129</td>
<td>IG: Supervised PFME monthly Home practice (three repetitions of eight contractions each held for six seconds, with two minutes rest between repetitions. These were repeated twice daily)</td>
<td>(a) Prevalence of UI (self-report) (b) Strength of PFM</td>
<td>(a) IG fewer UI than CG (P=0.023) (b) Not sign.</td>
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</table>

CG: Receive PFME information verbally

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<th>Study</th>
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<th>Participants/ Setting</th>
<th>Nos.</th>
<th>Intervention</th>
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</table>
| RCT   | Chiarelli and Cockburn (2002) | Women who had forceps or ventouse deliveries or whose babies had a high birth weight (>=4000g) | IG:348 CG:328 | IG: Instruction on PFME once in hospital and 8 week postpartum with individual physiotherapist  
CG: Receive PFME information only with routine physiotherapy postnatal class | (a) Prevalence of UI (self-report)  
(b) Compliance of PFME (self-report) | (a) IG fewer UI then CG (-7.4%) (p=0.044) 3 month postpartum  
(b) IC higher than CE (+26%) (P=0.001) |

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<th>Study</th>
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<th>Result</th>
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</thead>
</table>
        CG: Received only verbal advice and/or a leaflet on PFME from their midwives | (a) Prevalence of UI (self-report) | (a) IG lower than CG (-13.5%) (P=0.02) at 3 months postpartum;  
          IG lower than CG (-3.4%) (P=0.7) (Not sign.) |

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<th>Study</th>
<th>Author</th>
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</table>
| RCT   | Mason et al (2010) | Pregnant women (11-14 gestational weeks) | IG:141 CG:145 | IG: Instruction on the correct PFME 45 mins physiotherapy class once a month for 4 months. 8–12 maximal pelvic floor muscle contractions repeated twice per day  
CG: Individual instruction on PFME or leaflet or a brief reminder or nothing | (a) Compliance of PFME (self-report)  
(b) Prevalence of UI (Bristol Female Lower Urinary Tract Symptoms Questionnaire – BFLUTS)  
(c) Impact of incontinence symptoms (Leicester Impact Scale) | (a) IG higher than CG (P=0.019 at 36 wks gestational week) and (0.022 at 3 months postpartum)  
(b) Not sign.  
(c) Not sign. |

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<th>Study</th>
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<th>Participants/ Setting</th>
<th>Nos.</th>
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<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>RCT</td>
<td>Wilson and Herbison (1998)</td>
<td>Women with UI 3 months postpartum</td>
<td>IG:117 CG:113</td>
<td>IG: PFME instruction by physiotherapist in the antenatal class and 3,4,6,9 months postpartum Home practice (fast and slow contractions, with the aim of 80-100 contractions Daily Motivation reinforced</td>
<td>(a) Prevalence of UI (self-report &amp; pad test) (b) Compliance of PFME (self-report)</td>
<td>(a) IG fewer than CG (-26%) (P=0.0003) (b) IG higher than CG (Sign.)</td>
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</table>

<table>
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<tr>
<th>Study</th>
<th>Author</th>
<th>Participants/ Setting</th>
<th>Nos.</th>
<th>Intervention</th>
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<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>RCT</td>
<td>Dine et al (2009)</td>
<td>Pregnant women with UI (20-34 gestational week)</td>
<td>IG:40 CG:40</td>
<td>IG: Trained on correct PFME then review 1 week after the instruction Re training is given for those who do PFME wrongly and re assess 1 week later Home practice (3 repetitions of 15 contraction each held for 10s and release for 10s then quick contraction held for 2s and release for 2s) three times daily at home CG: Instructed with correct PFM contraction then no follow up</td>
<td>(a) Prevalence of UI (self-report)</td>
<td>(a) IG fewer than CG (P=0.008 at 36-38 gestational weeks) (P=0.014 6-8 weeks postpartum);</td>
</tr>
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<th>Participants/ Setting</th>
<th>Nos.</th>
<th>Intervention</th>
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<th>Result</th>
</tr>
</thead>
</table>
| RCT   | Woldringh et al (2007) | Pregnant women with UI (17-20 gestational week) | IG:112, CG:152 | IG: Three sessions of PFMT between week 23 and 30 during pregnancy and one session 6 weeks after delivery, combined with written information Home practice  
CG: Routine care, some with instruction of PFME | (a) UI severity (Self-report; and PRAFAB) | (a) No effect of PFME |

<table>
<thead>
<tr>
<th>Study</th>
<th>Author</th>
<th>Participants/ Setting</th>
<th>Nos.</th>
<th>Intervention</th>
<th>Outcome Measure</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>RCT</td>
<td>Morkved and Bo (1997)</td>
<td>Pregnant women 8 weeks postpartum</td>
<td>IG:99 CG:99</td>
<td>IG: Instruction on the correct PFME PFME course 45 mins once a week for 8 weeks Home practice (8-12 maximum PFM contractions each held for 6-8s. at the end of each contraction 3-4 fast contractions were added twice a day) Encourage of PFME given</td>
<td>(a) Prevalence of UI (self-report; and pad test)</td>
<td>(a) IG fewer than CG (P&lt;0.01) at 16 weeks postpartum</td>
</tr>
</tbody>
</table>
### Appendix E: Grade of Recommendation

<table>
<thead>
<tr>
<th>Class</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>- At least one meta-analysis, systematic review, or RCT rated as 1+, and directly applicable to the target population, or  &lt;br&gt; - A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population and demonstrating overall consistency of results  &lt;br&gt; - Evidence drawn from a NICE technology appraisal</td>
</tr>
<tr>
<td>B</td>
<td>- A body of evidence including studies rated as 2++, directly applicable to the target population and demonstrating overall consistency of results, or  &lt;br&gt; - Extrapolated evidence from studies rated as 1++ or 1+</td>
</tr>
<tr>
<td>C</td>
<td>- A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results, or  &lt;br&gt; - Extrapolated evidence from studies rated as 2++</td>
</tr>
<tr>
<td>D</td>
<td>- Evidence level 3 or 4, or  &lt;br&gt; - Extrapolated evidence from studies rated as 2+, or  &lt;br&gt; - Formal consensus</td>
</tr>
<tr>
<td>D (GPP)</td>
<td>- A good practice point (GPP) is a recommendation for best practice based on the experience of the Guideline Development Group</td>
</tr>
</tbody>
</table>
**Appendix F: Recommendation**

Recommendation practices are divided into different parts:

1. Pelvic floor muscle exercise instruction
2. Assessment of the correctness of performing pelvic floor muscle
3. Education tool
4. Schedule of pelvic floor muscle exercise program
5. Evaluation tool

**Recommendation 1: Pelvic floor muscle exercise instruction**

**Recommendation 1.1**
Participants should be educated with anatomy of urinary tract and reproductive organ, the effect of pregnancy and vaginal delivery on urinary incontinence, how to perform pelvic floor muscle exercise and the benefits of performing pelvic floor muscle exercise. (Ko et al., 2011, 1+; Kocaoz et al., 2013, 1+) (Grade of recommendation: A).

**Recommendation 1.2**
The pelvic floor muscle exercise comprised 3 repetitions of 8 contractions each held for 6 seconds, with 2 minutes rest between repetitions. These were repeated twice daily at home. (Ko et al., 2011, 1+; Reilly et al., 2002, 1++) (Grade of recommendation: A).

**Recommendation 1.3**
Participants should be instructed with the method of assessing the correctness of pelvic floor muscle exercise. (Ko et al., 2011, 1+; Kocaoz et al., 2013, 1+) (Grade of recommendation: A)

**Recommendation 1.4**
The compliance of practicing pelvic floor muscle exercise can be increased by emphasizing the importance of performing pelvic floor muscle exercise during every follow up. (Ko et al., 2011, 1+; Sangsawang & Serisathien, 2011, 1+) (Grade of recommendation: A).

**Recommendation 2: Assessment of the correctness of performing pelvic floor muscle**

**Recommendation 2.1**
Observation of the inward movement of perineum during pelvic floor muscle contraction can assess the correctness of the pelvic floor muscle exercise. (Ko et al., 2011, 1+; Kocaoz et al., 2013, 1+) (Grade of recommendation: A).
Recommendation 2.2
Digital vaginal palpation by a trained nurse can be used to determine whether the correct muscle is contracting. (Kocaço et al., 2013, 1+) (Grade of recommendation: A) Stop test under a trained nurse’s supervision (trying to stop or slow urinary flow over a toilet for a second or two, then relax and finish emptying) is one of the methods for assessing the correctness of pelvic floor muscle exercise (Sangsawang & Serisathien, 2011, 1+) (Grade of recommendation: A)

Recommendation 3: Education tool
Recommendation 3.1
Pelvic floor muscle exercise should introduce to pregnant women individually (Ko et al., 2011, 1+) (Grade of recommendation: A) and with written materials (Sangsawang & Serisathien, 2011, 1+). (Grade of recommendation: A)

The written material (leaflet) contains the instruction of pelvic floor muscle exercise (see below):

How to perform the pelvic floor muscle exercise
Squeeze and hold
The exercise will build up your deep endurance muscle.
- Lie on your back with your knees bent and your feet slightly apart.
- Imagine you are trying to stop yourself from passing wind or trying to stop the flow or urine.
- The feeling is one of squeeze and lift, closing and drawing up the front and back passage.
- Hold the squeeze for 10 seconds.
- Gently let go allowing your pelvic floor muscle to relax completely.
- Progress the exercise by performing it sitting or standing up.

Fast contraction
This exercise will build up your superficial fast muscles.
- Quickly tighten and pull up your pelvic floor muscles.
- Relax immediately. Do not try to hold the contraction.
- Repeat quickly 10 times.
- Progress the exercise by repeating more times.
Recommendation 4: Schedule of pelvic floor muscle exercise program

Recommendation 4.1
The educational session should implement on 20 gestation weeks (Ko et al., 2011, 1+; Sampselle et al., 1997, 1++; Kocaoz et al., 2013, 1+; Dine et al., 2009, 1+) and follow up on 35 or 36 gestation weeks, 6 weeks and 6 months after delivery for evaluate the urinary continence status. (Ko et al., 2011, 1+; Sampselle et al., 1997, 1++) (Grade of recommendation: A)

Recommendation 5: Evaluation tool

Recommendation 5.1
The urinary continence status and severity will be evaluated by 1-hour pad test (Kocaoz et al., 2013, 1+; Reilly et al., 2002, 1++; Dine et al., 2009, 1+) (Grade of recommendation: A). For the 1-hour pad test, candidates will be asked to empty their bladder and wear a pre-weighted pad, then drink 500ml of plain water over 15 minutes, after that they will be asked to walk around for around 30 minutes and then they will be asked to do the following action: from seat stand up 10 times, hard coughing 10 times, place running 1 minute. After that, the pad will then be re-weighted. A pad gain >1gm will be considered as urinary incontinence (Abdel-fattah, Barrington & Youssef, 2004).

Recommendation 5.2
The quality of life can be measured by Incontinence Impact Questionnaire (IIQ-7) Short Form (Ko et al., 2011, 1+) (Grade of recommendation: A).
Appendix G: Patients' Evaluation Form for Pelvic Floor Muscle Training

Please comment on the following statements by ticking (✓) the appropriate boxes


<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
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</thead>
<tbody>
<tr>
<td>1. Nurses are competence for providing training</td>
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<tr>
<td>2. Nurses are always willing and available to answer questions</td>
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<tr>
<td>3. The instructions and explanations of the training are clear</td>
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<td>4. Relevant feedbacks are always given</td>
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<td>5. The learning materials are useful</td>
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<td>6. The objectives of the training program are clear</td>
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<td>7. The exercise are easy to follow</td>
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<td>8. The training schedule is appropriate</td>
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<td>9. You are willing to follow the schedule of program and home practice</td>
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<td>10. Generally the training program is satisfied</td>
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Other comment:

Appendix H: Nurses' Evaluation Form for Conducting Pelvic Floor Muscle Training

Please comment on the following statements by ticking (✓) the appropriate boxes


<table>
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<tbody>
<tr>
<td>1.</td>
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<td>Implementing the training program does not increase workload</td>
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<td>2.</td>
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<td>Resource are adequate</td>
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<td>3.</td>
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<td>Support from the coordinator are adequate</td>
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<td>4.</td>
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<tr>
<td>The training to nurses are adequate</td>
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<td>5.</td>
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<td>The guideline helps you educate urinary incontinence patient</td>
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<td>6.</td>
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<tr>
<td>Pelvic floor muscle exercise benefits the patients</td>
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<td>7.</td>
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<tr>
<td>You will recommend to implement this program</td>
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Other comments:

Appendix I: Pelvic floor muscle exercise daily record book

<table>
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<th>Month/Year</th>
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<th>Remark</th>
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**Appendix J: Incontinence Impact Questionnaire (IIQ-7) Short Form**

Please answer the following question by ticking (✓) the appropriate boxes.

0: Not at all 1: Slightly 2: Moderately 3: A great deal

<table>
<thead>
<tr>
<th>Has urine leakage affected your:</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
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</thead>
<tbody>
<tr>
<td>1 Ability to do household chores (cooking, cleaning, laundry etc)? (PA)</td>
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<td>2 Physical recreation such as walking, swimming or other forms of exercise? (PA)</td>
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<td>3 Entertainment activities (eg movies, concerts)? (T)</td>
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<td>4 Ability to travel by car or bus more than 30 minutes away from home? (T)</td>
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<td>5 Participation in social activities outside your home? (SH)</td>
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<td>6 Emotional health (nervousness, depression etc)? (EH)</td>
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<td>7 Feelings of frustration? (EH)</td>
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EH=Emotional Health; PA=Physical Activity; SH=Social Health; T=Travel

Scoring. Item responses are assigned values of 0 for "not at all," 1 for "slightly," 2 for "moderately," and 3 for "greatly." The average score of items responded to is calculated. The average, which ranges from 0 to 3, is multiplied by 33 1/3 to put scores on a scale of 0 to 100.

Appendix K: Nurses' Evaluation Form for the Satisfaction Levels

Please comment on the following statements by ticking (√) the appropriate boxes


<table>
<thead>
<tr>
<th>Nurses’ satisfaction levels</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
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</thead>
<tbody>
<tr>
<td>1  The workload of this program is acceptable</td>
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<td>2  The aim and objective of this program is clear</td>
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<td>3  The aim and objective are achievable</td>
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<td>4  The morale and job satisfaction are enhanced during this program</td>
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<td>5  The clients can benefit from the program</td>
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<td>6  The program is satisfied</td>
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<td>7  This program is recommended</td>
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Any difficulties encountered:

Other comment:

Appendix L: Cost of the pilot program

Materials:
Equipment or facility: $0 (no additional equipment needed)
Photocopying and printing: $0 (HA existing services)
Disposable material (incontinence pad): $248 ($2 * 31 clients * 4 visits)

Training:
Training by coordinator: $0 (working hours)
Training session for all staff: $8,000 ($200/hr * 2hrs * 20nurses)
(Registered nurse average salary is $200/hr)

Total: $8,248
Appendix M: Nurses' Evaluation Form for Self-perceived Skills and Knowledge and Satisfaction Levels

Please comment on the following statements by ticking the appropriate boxes.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
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<tbody>
<tr>
<td>1</td>
<td>You understand the potential complications (urinary incontinence) of pregnancy and postpartum</td>
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<td>2</td>
<td>You understand the benefits of pelvic floor muscle exercise during pregnant and postpartum</td>
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<td>3</td>
<td>You are clear about the selection criteria for target patients</td>
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<td>4</td>
<td>The time schedule of training is clear</td>
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<td>5</td>
<td>The skills, instruments and measuring tools for evaluation are well established</td>
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<td>6</td>
<td>You have the skills to conduct the program and make use of the instruments</td>
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<td>7</td>
<td>You understand the importance of conducting the program with the support of an evidence-based guideline</td>
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</table>

Appendix N PRISMA 2009 Flow Diagram

Records identified through database searching
Records after duplicates removed (n = 171)
Records screened (n = 42)
Full-text articles assessed for eligibility (n = 4)
Studies included in qualitative synthesis (n = 0)
Studies included in quantitative synthesis (meta-analysis) (n = 4)

Additional records identified through other sources
Records after duplicates removed (n = 171)
Records screened (n = 42)
Full-text articles assessed for eligibility (n = 4)
Studies included in qualitative synthesis (n = 0)
Studies included in quantitative synthesis (meta-analysis) (n = 4)

Records excluded (n = 129)
Full-text articles excluded, with reasons >10 years publication dates; Humans species (n = 0)


For more information, visit www.prisma-statement.org.
References


http://www.ha.org.hk/visitor/ha_visitor_index.asp?Content_ID=10009&Lang=EN&Dimension=100&Parent_ID=10004&Ver=HTML


http://www.ha.org.hk/visitor/ha_visitor_index.asp?Content_ID=10045&Lang=EN&Dimension=100&Parent_ID=10044&Ver=HTML


