

Development and validation of pelvic floor muscles exercise intervention for urinary incontinence among pregnant women

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ABSTRACT

Introduction: The prevalence of urinary incontinence among pregnant women is high in Malaysia. However, healthcare providers appear to pay little attention to it along with a limited local intervention that addresses the continence health during pregnancy. This study aims to develop and validate intervention with pelvic floor muscle exercise (PFME) for pregnant women.

Materials And Methods: The development of PFME intervention was guided by the Medical Research Council Framework for Developing and Evaluating Complex Intervention (MRC Framework). This involved four phases: identification of current research evidence, expert opinion, validation via focus group discussions with physiotherapists and pregnant women, and piloting the intervention using a single group pre-post design among 30 pregnant women at Maternity Hospital Kuala Lumpur to assess the feasibility of the intervention by evaluating changes in knowledge and attitude. The qualitative approach was used to analyse the first three phases, while non-parametric methods were used to analyse the pilot pre-post test results.

Results: Based on research evidence and guidelines found during the literature review, a PFME intervention was developed using a new paradigm incorporating two theories, the Health Belief Model and Motivational Interviewing that have been shown to be important in continence promotion and exercise adherence. The contribution of the panel of experts in refining the intervention to meet the local context, endorses the achievement of the intervention's content validity. While, the focus group discussion with pregnant women and physiotherapists revealed the face-validity of the intervention. The findings of the pilot pre-testing showed that PFME knowledge ($p < 0.001$) and attitude ($p = 0.011$) improved significantly immediately following the intervention.

Conclusions: Evidently, this is a pioneer study that illustrates the development of a Malaysian context-adapting PFME intervention on the basis of recommended steps using the MRC Framework. Incorporating a theory-based and rigorous validation approach into the development of

the PFME intervention brought novel perspectives to the intervention. Given the promising preliminary results of the pre-testing pilot study, the PFME intervention could be implemented in the planned randomised control trial to validate the robustness of the results.

KEYWORDS:

Urinary incontinence, Pelvic floor muscle exercise, Intervention, Pregnant women

INTRODUCTION

Urinary incontinence (UI) is defined as involuntary or uncontrolled urinary leakage, is the most common bladder problem diagnosed in women.¹ Women are at greater risk of developing UI during the pregnancy.^{2,3} The overall prevalence rate of UI during pregnancy revealed to be between 40% and 65% in the population of European, Asian and United States of America, regardless of parity and gestational age.² Onset of UI during pregnancy, tends to become an ongoing burden for most women, which may have an impact on all aspects of life of a woman and her wellbeing from the physical, social and psychological aspects.^{2,4} It may be considered to be a silent maternal problem as many pregnant women perceive UI as a normal physiological change during pregnancy and fail to report it to their obstetricians or midwives as a potential health problem.⁵⁻⁷

The physiological and anatomic changes that occur during pregnancy with additional risk factors such as maternal age, multiparity, pre-pregnancy UI, overweight and obesity, constipation, smoking and other risk factors associated with childbirth may result in the weakening of pelvic floor muscles.^{3,4,8-10} These changes may disrupt the normal mechanism of continence and increase the risk of UI during pregnancy.¹¹ UI, however is readily preventable and treatable where pelvic floor muscle exercise (PFME) or training in early pregnancy offers an opportunity to control the UI that can mitigate the need for more invasive intervention in the future.^{12,13}

In Malaysia, current public health initiatives or recommendations place less emphasis on the prevention of UI and control it specifically during pregnancy, despite the

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prevalence of UI among pregnant women increases significantly between 19% and 84.4%.^{5,7,14} Simultaneously, there are limited UI screenings during antenatal visits and not all women are informed about the implication of UI during pregnancy.^{5,7,14,15} This may be due to lack of awareness or empathy among healthcare providers along with a limited local intervention that addresses the continence health. Regardless of the availability of Antenatal and Postnatal Exercise Manual that informs PFME, the information regarding PFME in this manual is very brief with minimal focus on the details associated with PFME related to UI.¹⁶

There is a need for structural intervention that focuses on PFME in prevention and control of UI that not only guides the local healthcare provider to educate antenatal women, but also aid the pregnant women to make informed decisions regarding their continence health.^{5,7,14,16} A randomized controlled trial (RCT) was carried out to evaluate the effectiveness of the PFME intervention in terms of improving knowledge, attitude, practice and self-efficacy of PFME and continence status amongst the pregnant women. This study reports the development of PFME intervention on the basis of recommended steps using the Medical Research Council Framework for Developing and Evaluating Complex Intervention (MRC Framework).¹⁷

MATERIALS AND METHODS

This study is part of main RCT study, formal ethical approval for the main RCT was obtained from the Malaysia Ministry of Health Medical Research Ethics Committee (MREC) (NMRR-16-2029-28782) and the Universiti Putra Malaysia Ethic Committee for Research involving Human Subject (FPSK [MREC 17] P015).

The development of the PFME intervention was carried out in four phases which were guided by the MRC Framework.

Phase 1: Identifying the Evidence

The first phase was the integration of evidence and knowledge to draft the intervention through a literature review and clinical experience of the primary researcher in women's health and continence. In identifying the UI related antenatal PFME intervention components, theories, and relevant clinical guideline, a search was performed in several online databases: namely MedlinePlus, ScienceDirect, PubMed, Cumulative Index to Nursing, and Allied Health Literature (CINAHL), Scopus, Physiotherapy Evidence Database (PEDro) and Cochrane Central Register of Controlled Trials (CENTRAL).

The search was conducted from January of 2010 till January of 2017 with an extended search in 2019. To avoid the search being too restrictive, general search terms were used which included other synonyms, spelling variants and acronyms: ("pelvic floor muscle" or "pelvic floor" or "Kegel") AND ("exercise" or "training") AND ("pregnant women" or "pregnancy" or "antenatal" or "expectant mother" or maternal or gravida or gestation) AND (urinary incontinence or urinary leakage).

Phase 2: Expert Opinion

In the second phase, the opinions of experts were used to review and validate the initial draft of PFME intervention. Three senior consultants from UPM's Faculty of Medicine and Health Sciences, each with a speciality in Family Medicine, Public Health, Psychology, and one senior physiotherapist from Hospital Kuala Lumpur (HKL) formed a panel of experts which reviewed the initial draft of PFME intervention and provided qualitative suggestions and comments on a number of aspects such as the accuracy of the content, organisation of information, application of the theory and relevance of the intervention and comprehensibility. Two of the experts had experience in clinical counselling techniques. In response to the comments and suggestions by the experts, the content of the intervention was revised and modified to meet the Malaysian context.

Phase 3: Focus Group Discussion

The third phase involved validation of the PFME intervention through focus group discussion (FGD) to elicit and obtain feedback on the initial draft of PFME intervention. Two FGDs were conducted to evoke discussion among pregnant women and physiotherapists to gather more in-depth information, feedback and suggestions about PFME intervention following a "mock" PFME intervention that demonstrated the key elements of the intervention. In addition, the FGD with physiotherapists was used to explore the current practices and needs of the PFME intervention. The focus group participants, pregnant women, and physiotherapists were recruited using purposive sampling from the antenatal clinic, Maternity Hospital Kuala Lumpur (MHKL) and Physiotherapy Department, HKL respectively.

No specific inclusion criteria were applied in selecting participants as long as they voluntarily agreed to participate. Written consent was obtained from participants and separate demographic data was collected from participants in both groups. These FGDs were conducted and led by the primary researcher and two facilitators, one of whom documented the discussion and another one of whom tape-recorded the group discussion. A semi-structured, open-ended questions were used to facilitate discussion. Both FGDs took approximately an hour and they were audiotaped and transcribed. The results of each focus group were then summarized and these findings were used to revise the development of PFME intervention.

Phase 4: Pilot Pre-Testing

In the final phase, once the validation was completed, a pilot study was conducted using a single-group pre-test/post-test design among 30 pregnant women in MHKL using a convenience sampling method. The inclusion criteria of the study: pregnant women with a singleton pregnancy without complications or contraindications to practice the physical activity and has given consent to participate in this study. This pilot study aimed to assess the feasibility of the intervention by gauging the potential immediate effect of the PFME intervention in terms of changes in knowledge and attitude.

The PFME intervention was delivered in a single session that focused predominantly on the educational session of the PFME intervention. The participants were assessed at baseline

and immediately post-intervention using a validated and standardised questionnaire.¹⁴ The percentage of score of each 18 knowledge items with correct answers and 8 attitude items with positive response were computed. McNemar's test was used to estimate the significant difference in proportion of correct knowledge and positive attitude pre-test and post-test. The Wilcoxon matched-pairs signed-rank test was subsequently conducted to analyse changes in percentage score observed between pre-test and post-test. All the analysis performed using Statistical Package for Social Sciences (SPSS) Version 23 and a p-value of less than 0.05 were considered to be statistically significant.

RESULTS

Summary of findings from the literature review

Nine intervention studies focused on antenatal PFME linked to UI prevention and treatment were discovered through a literature search.¹⁸⁻²⁶ Despite the fact that existing PFME interventions have shown demonstrable effectiveness, the components that contributed to the observed effects of interventions in terms of improving continence status, behaviour or adherence were not clear. Notably, in each of the existing antenatal PFME studies, there are many variations in the intervention components with a lack of theoretical clarification. The key intervention component described in the existing antenatal PFME study includes strategies related to the transmission of UI-related PFME information or knowledge, the prescription of adequate exercise dosage (frequency, intensity, duration), the teaching of correct pelvic floor muscle contraction and adherence support to prescribed intervention.¹⁸⁻²⁶

There is, however, a lack of strategy targeting on healthy lifestyle behaviour or healthy bladder habits in existing PFME intervention. This is an important strategy for UI prevention and control during pregnancy and postpartum according to recommendations based on systematic review or expert consensus and international guidelines such as the European Association of Urology guideline, National Institute for Health and Clinical Excellence guideline, NICE, and the Continence Foundation of Australia pregnancy guideline on healthy bladder and bowel habits and Dutch Clinical practice guideline.^{3,8,27-32} Mostly all the intervention strategies were conveyed using traditional lecture-based approach or didactic approach which is a clinician centred approach with frequent supervision of practical sessions.

Although the effectiveness of PFME intervention depends on the component of supervised training, few studies have shown that poor compliance with such supervised clinical intervention is responsible for non-significant results in reducing UI prevalence and UI severity.^{18,19,24} In other words, clinical based supervised training may be perceived to be too intensive with frequent follow-up, costly and time-consuming not only for pregnant women, but also for health care providers.¹⁸

Despite this, three studies have shown that a combination of both short-term supervised pelvic floor muscles training and non-supervised home-based as well as provision of adequate information and skills training on PFME was likely to be more

effective, not only in the prevention and treatment of UI, but also in behavioural changes related to PFME.^{21,25,26} These approaches seem to demand less time, incur fewer costs, and possibly offer more motivation to adhere with PFME in real clinical practice.

Development of PFME intervention

All the findings and gaps identified from the literature review and clinical guidelines together with clinical experience were translated into the development of a PFME intervention. The development of PFME intervention involved developing the intervention manual which included an information booklet for pregnant women as a take-home guide. The PFME intervention was developed on the basis of a new paradigm incorporating two theories, the Health Belief Model (HBM) and Motivational Interviewing (MI), as proposed by McClurg et al.³³ HBM tends to be widely used in continence promotion primarily for preventive health behaviour and public programmes, while MI is the unexposed theory that could benefits in optimising commitment or adherence to intervention.³³ The content of the PFME intervention was guided by HBM that uses MI techniques as a tool for delivering information.

The PFME intervention content was structured on the basis of six HBM constructs that were proposed as motivating factors to commence and adhere to PFME.^{34,35} In this context, pregnant women are more likely to be motivated to practice PFME if they believe that they are susceptible to incontinence (perceived susceptibility), that severity of present incontinence is likely to worsen, or incontinence has a negative impact on their health (perceived severity) and that PFME is effective in improving continence status (perceived benefit). Moreover, pregnant women would be further motivated to practice PFME if they had experience of the actual practice of PFME by overcoming barriers to adherence (perceived barrier), feelings of competence in performing PFME correctly (perceived self-efficacy), and identifying appropriate cues or triggers in taking action in practicing PFME (cue to action).^{34,35}

With regards to the method of information delivery, the Elicit-Provide-Elicit ("Ask-tell-ask") approach of motivational interviewing was utilized, using five "core skills" to elicit change talk which consisted of asking open-ended questions, affirming, reflecting, summarizing, and informing and advising.³⁶ By employing this approach, the educator is immediately able to elicit the person's understanding and need for information, then provides information or feedback with permission.³⁷ Following that, questions about what this knowledge meant to clients and what else they needed were elicited. This client-centred approach may allow for a conversation for strengthening a person's motivation by fostering the individual's intrinsic motivation that addresses an individual's desire, opinions and feeling to modify behavioural changes.^{36,37}

The structure of PFME intervention was designed, according to the Hay Smith et al., recommendations which include education session, message reminders, and booster sessions.³⁸ All of the intervention schedules were planned to coincide with the schedule of antenatal clinical visits, so that no

Table 1: Summary of Findings from the Focus Group Discussion with Physiotherapists and Pregnant Women

Focus Group Discussion with Physiotherapists	
Topic	Physiotherapist's Responses and Feedback
Current practice	<ul style="list-style-type: none"> • Antenatal classes are held on every Tuesday • The class comprises midwife, physiotherapist and audiologist sessions focusing on preparation for labour, postnatal care, and early parenthood. • One-hour physiotherapy session includes a talk and practical session that specifically targets breathing exercise, relaxation during labour, back exercises, circulatory exercise and kegel exercise.
Needs of intervention	<ul style="list-style-type: none"> • We felt good to have a standard manual so that everyone communicates in the same language and using the same terms. • This manual ensured all the important information are shared to all the women. • Currently, we conduct the class in our own way and the information that is shared in the class may vary.
Intervention content	<ul style="list-style-type: none"> • Very informative and simple to understand, referring to the manual and information booklet. • Very systematic and the flow of content continuously links. • Comprehensive patient information booklets available in both Malay and English.
Intervention delivery and Implementation	<ul style="list-style-type: none"> • Feasible to implement, as it is group intervention. • Time constraint if it is an individual consultation in a busy clinical setting. • May need to assess the practicality of text messaging in current clinical practise.
Improvement or suggestion	<ul style="list-style-type: none"> • We require training for physiotherapists on how to use the therapist manual.
Focus Group Discussion with Pregnant Women	
Topic	Pregnant Women's Response and Feedback
Knowledge on urinary incontinence	<ul style="list-style-type: none"> • I felt it normal to have urinary incontinence during pregnancy. • I used to go to toilet very often during pregnancy "it is normal" during pregnancy. • I felt the baby pressing on the bladder. • I am not really bothered about it because I got it during every pregnancy and it subsided after delivery.
Knowledge on PFME	<ul style="list-style-type: none"> • Kegel exercise and squeeze around private area like stopping the urine. • It is like stop and start the urine. • I just learned the exercise during antenatal class "squeeze around private area while holding the breath". • I learned the exercise from a lady masseur during confinement "postnatal traditional massage".
Perceived susceptibility and severity of urinary incontinence	<ul style="list-style-type: none"> • I had urinary leakage in the first pregnancy but it doesn't bother me and disappeared after childbirth. • I only have it when I have a bad cough • I feel it is normal to have urinary leakage • It is normal to wee often during pregnancy • Growing baby presses on the bladder so its normal during pregnancy
Perceived benefit of PFME	<ul style="list-style-type: none"> • Yes, it is important because the Malay lady masseur told me to do this exercise to prevent womb from coming down or dropping. • To keep the private area stronger for the next pregnancy.
Perceived confident in performing PFME	<ul style="list-style-type: none"> • I know how to do but don't know whether I am doing the exercise correctly. • Confident level less than 5 out of 10.
Perceived barrier to adhere to PFME	<ul style="list-style-type: none"> • I never do it after my confinement. • I only do it when I remember. • I do it when urinating, stop and start the urine. • I more concern on abdominal exercise after delivery
Overview of the intervention, understandability and suggestion	<ul style="list-style-type: none"> • I am delighted to join this excellent programme. • I like the way we discuss and exchange opinions. • Very informative programme and the explanation is very simple and easy to understand. • I gained new knowledge about exercise and urinary leakage. • I never initially believed this muscle to be so important. I learned a lot. • I had urinary leakage in my first pregnancy, but it didn't bother me and disappeared after childbirth. Now I know the importance of doing the exercise • Good! Both Malay and English version brochures are available and easy to visualize and understand • We sincerely hope this program will be provided to all pregnant women

Table II: Participants' Correct Responses on Knowledge Based Questions

Knowledge Items	Participant's Correct Response		
	Pre-test	Post-test	p-value
	n (%)	n (%)	
Muscles involved in pelvic floor muscle exercises are situated at pubic region.	21 (70)	30 (100)	0.004*
Pelvic floor muscle exercises involve muscles at anal region.	13 (43.3)	30 (100)	<0.001*
Vagina muscles are not involved in the pelvic floor muscle exercises.	12 (40)	27 (90)	<0.001*
Muscles involved in pelvic floor muscle exercises are known as pelvic floor muscles.	13 (43.3)	30 (100)	<0.001*
Pelvic floor muscles are important in controlling urinary bladder function.	13 (43.3)	30 (100)	<0.001*
Pelvic floor muscles are not involved in controlling the anus.	5 (1.7)	25 (83.3)	<0.001*
Pelvic floor muscles are not involved in tightening the vagina	8 (26.7)	25 (83.3)	<0.001*
Pelvic floor muscles have a function in the sexual relationship between husband and wife.	12 (40)	16 (53.3)	0.481*
Buttock muscles may be tightened by performing pelvic floor exercises.	17 (56.7)	30 (100)	<0.001*
Pelvic floor muscle exercises may prevent urinary incontinence during laughing, sneezing or lifting weight.	7 (23.3)	23 (76.7)	<0.001*
Pelvic floor muscle exercises may also prevent or treat pelvic organ prolapse such as bladder prolapse.	13 (43.3)	29 (96.7)	0.001*
Pelvic floor muscle exercises may be done at anytime.	19 (63.3)	30 (100)	<0.001*
Perform pelvic floor muscle exercises can be done while holding the breath.	3 (10)	28 (93.3)	<0.001*
Pelvic floor muscle exercises involve squeezing inward in the vagina and anus.	17 (56.7)	30 (100)	<0.001*
Pelvic floor muscle exercises may be done during performing daily routine activities such as cooking and landing.	11(36.7)	30 (100)	<0.001*
Muscles involved in the pelvic floor muscle exercises should be contracted for 6 - 8 seconds before being released	14 (46.7)	30 (100)	<0.001*
Pelvic floor muscles should be contracted for 8 - 12 times in a row each time when performing the pelvic floor muscles exercise.	9 (30)	28 (93.3)	<0.001*
Pelvic floor muscle exercises should be done at least 3 times a day which are in the morning, afternoon and night.	5 (16.7)	29 (96.7)	<0.001*
Percentage of correct answers	38.4	92.6	<0.001‡

*McNemar's Test; ‡Wilcoxon Signed Rank Test; n (%) = number of participants (percentage); p-value<0.05 is significant

Table III: Participants' Positive Responses on Attitude Based Questions

Attitude Items	Participant's Positive Response		
	Pre-test	Post-test	p-value
	n (%)	n (%)	
Pelvic floor muscle exercises should be done by all females, especially pregnant women and postnatal women, regardless whether they have any urinary leakage symptoms or not.	22 (73.3)	30 (100)	0.008*
I should practice pelvic floor muscle exercises to prevent or treat urinary leakage.	23 (76.7)	30 (100)	0.016*
I should practice pelvic floor muscle exercises to prevent pelvic organ prolapse such as bladder prolapse.	26 (86.7)	30 (100)	0.125*
I feel that pelvic floor muscle exercises are boring.	22 (73.3)	30 (100)	0.008*
I believe that pelvic floor muscle exercises should be taught to all antenatal mothers at the antenatal clinic.	21 (70)	29 (96.7)	0.008*
I support those who want to perform pelvic floor muscle exercises.	24 (80)	29 (96.7)	0.125*
I believe that pelvic floor muscle exercises can increase sexual satisfaction.	21 (70)	29 (96.7)	0.008*
I will make the effort to search for information on pelvic floor muscle exercises.	23 (76.7)	29 (96.7)	0.031*
Percentage of positive responses	75.8%	98.4%	0.011‡

*McNemar's Test; ‡Wilcoxon Signed Rank Test; n (%) = number of participants (percentage); p-value<0.05 is significant

additional clinical attendance was necessary for pregnant women when participating in the study. As the first eight weeks of PFME is crucial for the prevention and reduction of UI symptom, the first eight weeks of the intervention were designed to deliver the main education session at one appointment.¹² This was followed by weekly exercise reminders and one booster session to keep motivating pregnant women to practice PFME. In addition, two booster sessions were added during routine antenatal clinical visits in the early third trimester and late third trimester to maintain the impact of the initial eight-week PFME intervention session.

Expert Opinion

A positive comment on the intervention was provided by all the experts in terms of relevance of the content, organisation of information, application of the theory and comprehensibility. Nevertheless, a few suggestions on the use of MI techniques, wording and terminologies used were given. In response to the experts' comments and suggestions, the content of the intervention was revised and modified to meet the Malaysian context. Following expert review, the information booklet and text messages that were prepared in English were translated into Bahasa Malaysia following a standard forward-backwards translation.

Focus Group Discussion

The detail of FGDs results is presented in Table I. A total of six nulliparous and multiparous pregnant women aged between 25 and 30 years old at 20 to 36 weeks of gestation participated in a FGD that evoked discussion from both experienced and first-time mothers. During the discussion in eliciting the participant's understanding about knowledge, belief, perceived benefit, perceived barrier and self-efficacy of PFME before sharing information during the mock intervention, most of the participants showed low general awareness of all these aspects. Majority of the participants demonstrated less details of prior knowledge of UI and PFME and about the benefit of the exercise. Moreover, only three pregnant women responded that they had some confidence in doing pelvic floor muscle exercises with rating range 4 to 5 out of 10 scale point. Following a mock PFME intervention, all pregnant women in the focus group held a favourable view of the PFME intervention. They also claimed that the information provided during the intervention and in the booklet was easily understood and helpful in increasing awareness of UI and practice of PFME. The participants also indicated that all pregnant women should in future be given this intervention during the antenatal visit.

The FGD, involved five physiotherapists with clinical experience ranging from 2 to 20 years, addressed the need for a standardised and structured PFME intervention. The physiotherapists claimed that the antenatal physiotherapy classes typically focussed on mat-based exercise sessions mainly aimed at breathing exercises and relaxation during labour, back exercises and circulatory exercises. They also highlighted that current antenatal education pertaining to PFME is less comprehensive and the information shared varied according to the education guided by traditional slide-based presentations.

Generally, the participants in the focus group agreed with the content, delivery method, and implementation of the PFME intervention. Despite the concerns of the physiotherapists about the feasibility of a weekly text message reminders, they all agreed that such a technique was crucial in empowering pregnant women to exercise and change their behaviours on a consistent basis. In addition, physiotherapists expressed their desire for training in using the manual. No further alterations were made following FGD with physiotherapists and pregnant women, as there were no contradictory comments on PFME intervention including the manual and information booklet.

Pilot Pre-Testing

A total of 30 healthy pregnant women age 22 to 39 years (mean age 29.7 ± 4.7) between 18 and 22 weeks gestation were included in this pilot pre-testing. The respondents were predominantly Malays (n=29, 96.7%), had completed high school and college/university (n=29, 96.7%), were employed (n=21, 70%), and were non-smokers. Regarding their parity, more than half of the respondents reported being multiparous or women who had given birth once or more times (53.3%). In relation to continence status, ten (33.3%) respondents reported having UI.

The results of the pilot test (shown in Table II and III) indicate that there was a significant improvement in the

PFME knowledge, and attitude immediately after the intervention. The scores on the knowledge items ranged from 38.4% correct at baseline to 92.6% at immediate post-intervention ($p < 0.001$). The results on the favourable attitude towards PFME ranged from 75.8% at baseline to 98.4% at immediate post-intervention ($p = 0.011$).

DISCUSSION

The development process results in pioneering intervention components that incorporate the best available evidence from international trials and clinical guidelines in combination with clinical experience and expert opinions. Integrating clinical experience with expert opinions strengthens the content validity of the PFME intervention. In particular, the participation of local experts ensures that the intervention includes elements that suit the local context and preferences. The findings of FGDs have shown that intervention users/physiotherapists and intervention recipients/pregnant women have acknowledged and accepted the intervention well. These FGDs findings demonstrated the face-validity of the intervention, which is an important criterion for the further implementation of the intervention. The FGD with physiotherapists has also addressed and verified the need for PFME intervention, which further reaffirms the rationale for developing a PFME intervention which indirectly expresses the physiotherapist's desire in providing quality care.

With regards to pilot pre-testing, only the knowledge and attitude of the participants were assessed at post-intervention, as other behavioural change outcomes such as practice and self-efficacy were not reliable at this juncture. Other behaviour changes need time to define the improvements and were accordingly, not assessed. The baseline data illustrate the need for intervention to enhance the awareness of these participants on UI and PFME as less than half of the participants were able to correctly answer each question. The immediate positive effect of PFME intervention on knowledge and attitude is considered to be the most important prerequisite for behavioural change relevant to the practise or adherence to PFME.^{33,38} While these findings indicated that the intervention could be viable in the proposed full-scale RCT, the effect of the intervention on other indicators of behavioural and clinical outcomes could not be verified. Therefore, the results from this pre-test pilot should be interpreted and generalised with caution.

The key strength of this research was the use of the evidence-based and rigorous methods to develop the PFME intervention. Beside using a robust method, the intervention schedules are defined on the basis of evidence and also on the basis of practicability that does not impose additional resource burden on healthcare providers and intervention recipients, including time and cost, to carry out and comply with the intervention.

Notwithstanding, there were some inherent limitations in spite of the strengths of this study. Firstly, only a single FGD was performed involving physiotherapists and pregnant women, which does not reflect the view of the target population as a whole. A second limitation related to the pilot testing. Using convenience sampling, the single arm

pre-post design with no control group can theoretically increase the risk of bias. The absence of a control group limits the interpretation of the potential for causal effects. The way the pilot pre-test was conducted in this study does not discuss the practicalities of the recruitment, randomization, fidelity, adherence and completeness of the evaluation which is necessary to inform the planned full-scale RCT study.³⁹ Moreover, not all sessions of the PFME intervention were introduced during the pilot pre-test due to budgetary, logistical, and time constraints. Therefore, all these limitations need to be considered when interpreting the results of the pilot study.

In spite of the limitations, the development of PFME intervention in this study may be considered as an initial step in continence health initiatives in the absence of specific guidelines, manuals, or modules in this field locally. If the intervention is found to be effective in main RCT study, the physiotherapist should be encouraged to use this manual as a guide for educating pregnant women during perinatal care. By using this manual, physiotherapists may enable the quality of care to pregnant women in line with Malaysian efforts to improve maternal health care according to the Millennium Development Goals 5.⁴⁰

CONCLUSION

As far as we know, this is a first study which illustrates the development in the Malaysian context-adapting PFME intervention on the basis of recommended steps using the MRC Framework. This paper describes the development of a PFME intervention based on current available evidence that combines clinical knowledge and clinical expert review with the intervention recipients/pregnant women and users/physiotherapists preference, along with assessment of the preliminary effect of the PFME intervention. Incorporating a theory-based and rigorous validation approach into the development of the PFME intervention brought novel perspectives to the intervention. Given the promising preliminary results of the pre-testing pilot study, the PFME intervention could be implemented in the planned randomised control trial to validate the results' robustness.

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