Development and validation of the pelvic floor muscle training video for pregnant women with urinary incontinence : subgroup analysis of pilot feasibility randomised controlled trial

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Abstract

Aim

Educational videos are essential in delivering pelvic floor muscle training (PFMT) educational videos to the targeted audience in primary care. This paper aims to describe the development and validation process of the PFMT video for managing urinary incontinence (UI).

Methodology

The video was developed based on the capability, opportunity, and motivation (COM-B) framework with the expert's input in the checklist development. Pregnant women with UI were invited to validate the video based on its understandability and actionability using the Patient Education Materials Assessment Tool (PEMAT) by pregnant women with urinary incontinence. This validation study was a subgroup analysis from a pilot randomised control trial (RCT) which aimed to evaluate the feasibility and preliminary effectiveness of a newly developed pelvic floor muscle training (PFMT) app among pregnant in Malaysia. This pilot study was a single-centre, single-blind, parallel, randomised controlled pilot feasibility study: the Kegel Exercise Pregnancy Training app (KEPT-app) trial. The participants were randomised using the randomisation app and the researchers were blinded to the study participants recruitment, allocation, and analysis.

Result

A total of twenty-six pregnant women with urinary incontinence from an urban healthcare clinic were recruited, with sixteen of them receiving the intervention. However, after one-month post-intervention, thirteen pregnant women with a mean (SD) age was 30.8 (3.4) years old, evaluated the video via the KEPT app. They

provided their feedback using PEMAT, with understandability 92.3%(1.8), and actionability was 96.2%(0.4).

Conclusion

Using the COM-B framework assisted in this newly developed video that may help pregnant women perform PFMT at home effectively.

Keyword: validation; development; patient educational video; pelvic floor muscle training; primary care; pregnant women; Patient Education Materials Assessment Tool; Capability, Opportunity, Motivation-Behaviour Model

1. Introduction

Pelvic floor muscle strength supports the bladder, rectum and uterus. Pregnant women have a high risk of urinary incontinence (UI) whereby they cannot hold their urination even after the first trimester of pregnancy (1). Unfortunately, most pregnant women were unaware of the pelvic floor disorder (2). They were uninformed that doing regular pelvic floor muscle training (PFMT) could reduce their symptoms (3) which, if untreated, may worsen their UI symptoms and quality of life (4).

There is no standard prescription on PFMT, leading to various exercise dosages, intensity, supervision, and adherence (5,6). This issue leads to non-standardised PFMT reporting in clinical trials limiting its replicability (6,7). However, a group of experts developed a checklist in reporting PFMT called Consensus on Exercise Reporting Template - Pelvic Floor Muscle Training or (CERT-PFMT) (8). It contains 19 items which are listed under seven headings about exercises and their delivery: (1) materials; (2) provider; (3) delivery; (4)setting; (5) dosage; (6) tailoring; and (7) fidelity to the protocol with some modification specifically to PFMT.

Several issues were highlighted in delivering antenatal PFMT lack of time from the healthcare providers and limited availability of standard guidelines (9,10). Healthcare providers felt a lack of confidence due to these limitations as they felt insufficient. Additionally, the anatomical parts of the pelvic floor muscles with several layers need to be more specific in their explanation to pregnant women.

Furthermore, they felt that having or experiencing UI was ‘normal’ or expected to occur. They felt that UI would disappear after delivery with no serious effects (11). They were reported to have limited PFMT information and felt overwhelmed to understand the anatomical parts of pelvic floor muscles layers (12). Therefore, despite

receiving training information, some experience difficulty comprehending and practising the exercise.

The study had acknowledged that seeking help for UI was an embarrassment to them, leading to unattended PFMT sessions in clinics and being unsupervised (9). Such embarrassment was an added barrier that may be resolved by other indirect educational platforms such as educational training videos. YouTube is the largest source of videos can become the reference point for them to close this gap. The recent analysis demonstrated that most YouTube videos on the PFMT were helpful as they were published by credible websites (13). However, half of the videos included in this analysis were not specifically for antenatal PFMT. The analysis was on the global quality scale from the experts' whether it has good quality, flow, information, and usefulness to the viewers.

Several current ineffective videos because of a few points need to be considered. Didactic videos presenting health information with or without graphics are ineffective in modifying the patient’s behaviour (14). A more pragmatic approach using real people performing the intended behaviour change was practical (14), especially for primary care patients (15). Secondly, it is essential to use the correct terminology to guide the users on the exact pelvic muscles to be contracted (16). Thirdly, there is a need for a clear explanation of each step involved in performing PFMT. Doing so boosts pregnant women's self-efficacy and confidence to perform the exercise (16).

However, there is minimal evidence on the development and validity of PFMT videos for pregnant women (17), especially in primary care settings. Thus, the primary objective of this study was to develop an educational PFMT video that can improve the self-efficacy of pregnant women in performing PFMT. Exclusively, this paper aims to describe the process of developing and validating a PFMT educational video for

pregnant women in primary care. The video was embedded in a mHealth app called Kegel Exercise Pregnancy Training app (KEPT app) (18).

2. Methodology

This study involved two main sections: PFMT video development and its quality assessment (Figure 1). The video was developed based on the capability, opportunity, motivation, and behaviour (COM-B) model. The COM-B model requires that an individual have the physical and psychological capability and physical and social opportunity, with automatic and reflective motivation to engage in a target behaviour and pelvic floor muscle training.

Figure 1. Study flowchart

Capability, opportunity, motivation- Behaviour Model (COM-B)

The “capability” component under the COM-B model indicates that pregnant women should acquire the necessary skills to perform a behaviour. Capability can be divided into the psychological and physical capacity of the behaviour. Capability means the pregnant women have the necessary knowledge and skills to perform the pelvic floor muscle training, and it can be further divided into psychological and physical capacity. However, having knowledge and skills are not enough as pregnant women involved must have the opportunity to correctly perform the exercise during their consultation with doctors or midwives. There are two categories for the opportunity, (1) physical opportunity such as during their visits to healthcare facilities, and (2) social opportunity like performing the PFMT without worrying about social stigma.

Simultaneously, the women need to be motivated to perform the PFMT. Knowledge without motivation is insufficient for them to adhere to the exercise (19). There is two types of motivation, (1) reflective motivation as they reflect the importance of

performing the exercise three times daily, and (2) automatic motivation is when pregnant women are habitually performing the pelvic exercise.

Woodley et al. (2021) suggested that it is vital to motivate pregnant women by (1) presenting positive modellings such as providing examples of women who have benefitted from the exercise and (2) adding an enabler that can assist the women in scheduling their schedule for the PFMT (19).

Cross-sectional study. Apart from the COM-B model, a cross-sectional study was conducted among 440 pregnant women to understand the knowledge (K), attitude (A), and practice (P) of pregnant women towards pelvic floor muscle exercise (20). All study respondents provided their informed consent via the written document. These study findings highlight the COM-B elements that need to be focused on when developing the PFMT video (Table 1).

Table 1. Correct responses on Knowledge (K), Attitude (A), and Practice (P) of pelvic floor muscle exercise (PFME) among pregnant women (N=440) based on COM-B

Capability	**Opportunity**	**Motivation**
Psychological	Physical	Reflective
K1. PFME muscles are situated at pubic region (51.8%)	A5. PFME should be taught to all antenatal mothers at antenatal clinics (25.2%)	A1. PFME should be done by all women (10.2%)
K2. PFME invloves muscles at anal region (44.5%)	A8. I will put in effort to search for info about PFME (18.9%)	A2. I should practice PFME to prevent/treat UI (19.5%).
K8. PFME can prevent UI during laughing/ sneezing/ weight bearing (66.4%)		A2. I should practice PFME to prevent uterine prolapse (16.4%)
K9. PFME can prevent/ treat uterine prolapse (55.5%)		P4.I have tried to search for info about PFME (2.7%)
Physical	Social	Automatic
P2. I have spent time to perform PFME (12.7%)	K10. PFME can be done at any time (71.6%)	K11. PFME can be done while performing daily activities (56.4%)
	P3. I have discussed PFME with friends (1.6%)	K12. Muscles involved should be contracted for 8 seconds. (41.8%)

	K14. PFME should be done at least 3x a day (morning ,afternoon,night) (35.9%)

Pre-development of PFMT video production.

Based on the meetings with experts (two physiotherapists, a family medicine specialist, and a public health specialist), we developed a checklist that consists of six main items; Script, Condition, “Real-patient” model, Instrument, Professional and Timing (SCRIPT) to assist the process of developing the video.

The storyboard was created with the SCRIPT checklist using the COM-B model and findings from the cross-sectional study. The video was developed by strictly adhering to the six elements of SCRIPT as summarized in Table 2. The link to this video is available at https://youtu.be/322WSBZVNgg. The video was narrated in the Malay language to cater to our target population. The video was then given to pregnant women with urinary incontinence for quality assessment.

Table 2: Checklist PFMT Video

Category	**Items**	**(Yes/No)**
Script	A script has been vetted by a committee (using layman words in an active voice). Content (layman words*) 1. Anatomy of pelvic floor muscle and its function. 2. PFMT exercise: Position, Technique and Frequency (contraction and relax period) 3. The common mistakes during exercise 4. How to check the technique is correct? 5. When to start the exercise after delivery?	
Condition	Condition: the room or location which has minimum disturbance from others, good lighting, well equipped with furniture and Pelvic model (3D)	

Real-patient or model	"Real-patient" situation to better illustrate the situation. For example, the model in the PFMT video should be a pregnant woman or wearing a "dummy uterus". Attire: Wearing pants for easy movement. Verbal cues: Intonation good, Enthusiastic, Curiosity Non-verbal cues: Forthcoming, accommodating	
Instrument	Instrument: Pelvis anatomy 3D model	
Professionals (Primary care providers, healthcare educators)	Professionals must participate actively as the instructor in the video. Verbal cues: Effective communication skills, Intonation good, Enthusiastic, compassion (21) Non-verbal cues: Forthcoming, supportive, encouraging.	
Timing	Timing (the duration must not be too long, making the audience lose focus and must not be too short of ensuring essential topics have been discussed). Duration: 5-8 min (22)	

Quality assessment among target users.

This was the sub-analysis from the pilot feasibility randomised control trial which the study protocol has been published elsewhere (23). All study participants provided their informed consent via the written document. The study duration was five months from June – November 2021 as it was enden due to the lockdown Covid-19 pandemic. This was a single-centre (Ampang health clinic) with the researcher-blind, parallel (1:1), randomised controlled pilot feasibility study. The intervention group received Kegel Exercise Pregnancy Training app (KEPT-app) whereby the control group received the KEPT app after they completed the study (waitlist control). Both groups received the antenatal care as usual (23).

The eligibility criteria for this study were age 18 years and above, pregnant with urinary incontinence, Malaysian citizen, has the internet access and smartphone, without contraindication to perform the PFMT. They were identified and recruited via the

WhatsApp after the nurses shared the e-poster of the study with them. The randomisation was done by applying stratification of parity and using the randomisation app (24) without any restriction of block size. The sealed envelop was used to conceal the allocation into either intervention or waitlist control group by the clinic staff. The participants were not blinded to the intervention but the researchers wer blinded to the group allocation. The KEPT app has undergone its validation study (18), usability study (25) and the detail of the KEPT app trial is currently undergone its publication process.

The participants in the intervention group, provided their feedback after using the app for one month. The videos' quality was evaluated using a Malay version of the Patient Education Materials Assessment Tool (PEMAT) questionnaire. PEMAT has 13 items on understandability and four items on actionability with choices of answer either “agree” (1 point) or “disagree” (0 points) (26). “Understandability” is the ability to comprehend and extract the critical message of the educational materials among people from various backgrounds and health literacy abilities (27). The education materials information with “actionability” when the people or the learners can identify the necessary actions to take after reading the information (27).

PEMAT has been translated into Malay and has undergone a validation process with a correlation coefficient of 0.852 (understandability) and 0.702 (actionability) (28). Pregnant women in this study had to respond to this set of questionnaires using an online form.

Statistical analysis. The descriptive data were analysed using the Statistical Package for Social Sciences (SPSS) version 25.0 (29) using the mean scores and standard deviation.

Results

Quality assessment of the PFMT video production

Two other physiotherapists assessed the video using the Malay version of the Patient Education Materials Assessment Tool (PEMAT) questionnaire. Both of them were agreed on all the items except for item No. 4 (Medical terms are used only to familiarize the audience) and item No. 14 (The material allows the user to hear the words clearly), where only one physiotherapy agreeable with the statement. Some of their suggestions were: (1) to add the background music; (2) to share further short information notes for the viewers; and (3) to visualise the palpated area more clearly.

Quality assessment of the PFMT video production

Thirteen participants were involved in the quality assessment (Figure 2). They watched the video via the KEPT app and expected to perform the PFMT according to the recommended schedules. All of them were Malays, and their mean (SD) age was 30.8 (3.4) years old. Only one participant in the middle-income groups with mean (SD) body mass index (BMI) during pregnancy was 28.8 (4.4) Kgm^2 and the characteristics of pregnant women are as in Table 3.

Table 3: Sociodemographic of the study participants

ID	Age	Gravida	Occupation
A	31	5	Administrative
B	27	1	Kindergarten teacher
C	30	5	Housewife
D	28	2	Engineer
E	32	2	Administrative
F	33	2	Customer service
G	27	2	Housewife
H	30	1	Staffnurse
I	29	2	Teacher
J	31	1	Customer service
K	35	3	Executive
L	39	3	Housewife
M	29	1	Housewife

Based on the Malay version of the PEMAT questionnaire, the understandability score was high of 93.7%, and the actionability was excellent of 100%, as tabulated in Table 4. However, the video was rated less than 50% on the logical sequence, which was markedly different from the other items.

Table 4: Malay PEMAT Tool for PFMT video

Malay PEMAT		**VIDEO**
Items		**Agree (n/%)**
Understandability		
1	Makes its purpose completely evident	12 (92.3)
3	Uses common, everyday language.	12 (92.3)
4	Medical terms are used only to familiarize audience	13 (100)
5	Uses active voice.	13 (100)
8	“Chunks” information into short sections	12 (92.3)
9	The material’s sections have informative headers.	11 (84.6)
10	The material presents information in a logical sequence.	13 (100)
11	The material provides a summary.	12 (92.3)
12	The material uses visual cues (e.g., arrows, boxes, bullets, bold, larger font, highlighting) to draw attention to key points.	11 (84.6)
13	Text on the screen is easy to read.	11 (84.6)
14	The material allows the user to hear the words clearly (e.g., not too fast, not garbled).	12 (92.3)
18	The material uses illustrations and photographs that are clear and uncluttered.	12 (92.3)
	Scores (Mean scores)	**92.3 (1.8)**
Actionability		
20	The material clearly identifies at least one action the user can take	12 (92.3)
21	The material addresses the user directly when describing actions.	12 (92.3)
22	The material breaks down any action into manageable, explicit steps.	13 (100)
25	The material explains how to use the charts, graphs, tables, or diagrams to take actions.	13 (100)
	Scores (Mean scores)	**96.2 (0.4)**

Discussion

Discussion on the study findings

The video in this study scored more than 90%, signifying acceptability in its understandability and actionability (26). The result was higher than a recent pilot study evaluating the quality of educational video for an overactive bladder (OAB) available from YouTube. The study highlighted that 78% of YouTube educational videos produced by a non-academician physician were scored with low acceptability, such as 74%±16% in understandability and 57%±39% for actionability (30).

This study scored similar in its actionability with the Urology Care Foundation videos produced by the urologist, and the duration videos were between 3 – 5 minutes in duration (30). The reason was most likely that both videos were produced by the field experts leading to their ability to practise. The PFMT video explained the correct method to perform PFMT, mainly using the active voice and showing the 3D model regarding the pelvic muscles' layers.

The importance of understandability is crucial to ensure that the patients correctly understand the theory behind specific exercises (26) and to improve and increase their self-efficacy and adherence in performing specific exercises. (31). Being able to explain in a stepwise method and using simple direct and explicit instruction in active voice may improve the comprehensiveness of the video.

This study was rated slightly lower on its logical sequence. Perhaps, the video demonstrated three different PFMT positions (sitting, standing, and lying) in one video, which may lead to difficulty comprehending each position's sequence. The sequence may be seen in its logical sequence when used in three separate videos. However, the logical order does not affect the actionability of the video, which may be because the other essential items of the understandability were not affected.

Finally, the physiotherapist summarised and recapitulated the PFMT steps, duration, and frequency to help antenatal mothers be confident in their daily PFMT. This explicit instruction is essential to ensure the actionability of the video can be developed from a few sessions in its construction among the experts and the relevant literature.

SCRIPT checklist assisted in the pre-development stage of the video production. The pelvic floor muscle anatomical model was selected to ensure the most appropriate model for better viewers' clarification. The room, lighting, and other necessary equipment have been prepared prior to the video recording. The production for this video took less than three hours compared to our previous video production without SCRIPT.

This study's reflections conclude that PFMT videos need to be meticulously planned during the pre-production stage. The experts must revise, improvise, and validate the script before the video shoot. The necessary equipment must also be available and arranged accordingly for better appreciation by viewers.

Clinical implications

Impact of the newly developed PFMT video

This video may bridge the practical-knowledge gap in disseminating PFMT education as there was no locally validated such video in this country. Despite the acquired results validating the developed PFMT video, it may be improved accordingly. The video will be then suitable to be shared with the stakeholder for its implementation in the healthcare clinics and the website.

Healthcare providers have an essential role in introducing and encouraging their antenatal patients to perform antenatal exercise, including pelvic exercise, with this video's help. Moreover, there is also a potential to use this video to educate on PFMT

and embedding in an app (32) for better accessibility among pregnant women for prevention and management UI.

Impact on the healthcare providers

Primary care providers and educators in primary care settings may use the SCRIPT checklist to guide them in developing an educational video for their patients for better understandability and actionability. Additionally, they must equip themselves with adequate and in-depth knowledge about every exercise taught to patients. Furthermore, they must demonstrate, give clear instructions and reassess the techniques they teach according to PEMAT. This guide must then be incorporated into educational exercise videos that they want to produce for their patients.

Furthermore, they should also anticipate and discern the many challenges that they may have to face from time to time. They should retain an open mind to the range of possible cognitive, behavioural, demographic (age, ethnicity with different languages, and educational backgrounds) factors that may contribute to a patient's lack of understanding and performance towards the exercises taught. Therefore, a creative approach in dealing with the needs of individual patients is paramount.

Finally, they should be aware of the broad range of possible strategies, such as using more verbal than non-verbal cues (vice versa) in dealing with certain types of patients, which may help them understand and perform better. Simplified but comprehensive instructions and demonstrations in educational exercise videos should ensure that the appropriate knowledge is transferred to the patients.

Impact on pregnant women

Pregnant women are at risk of UI, but many are still unaware or have little knowledge of PFMT. Since the exercises need to be done frequently with the correct techniques to ensure better clinical outcomes, an educational intervention, such as a video exercise, may help address this issue.

There are some great benefits to educational exercise videos for pregnant women. Firstly, these women will have some privacy in their own homes, without sitting in a treatment area or interacting with other patients. Secondly, they also have some independence by enabling themselves to self-manage their symptoms and the progression of therapeutic activities in their home environment's comfort. Ensuring adherence to the exercises in the video is paramount in order to get good clinical outcomes. Therefore, providing them with good quality, up to standard educational exercise video is very important.

Impact during COVID-19 pandemic

With the recent COVID-19 outbreak, many pregnant women underwent self-isolation or restricted movement due to total lockdown. Subsequently, they lost their accessibility to expert physiotherapy treatment and care (33,34). As a result, there was an increasing demand for virtual self-exercises at home, including educational exercise videos.

Educational exercise videos are valuable adjuncts for patient education, reinforce visual demonstration, and are a practical learning tool. It helps promote short and long-term patient adherence to treatment/exercise recommendations. However, a high standard, quality video must be produced by relevant, experienced and qualified health professionals to ensure better patient understanding and participation in PFMT, leading to better clinical outcomes.

The limitation of this study was the Malay language used in the video. We are unsure if the direct translation into English, Mandarin, or Tamil of the same video will be readily acceptable by other populations in this country. Future studies may need to be conducted to examine the direct translation of the video. A small sample size that occurred due to the lockdown may affect this study's actual results. Only two physiotherapists were evaluating the contents of the video, which may affect the low threshold in determining the medical accuracy of the video due to the limitation of PEMAT assessment (30).

This video will be used in a cluster randomized control study for future references (32), and approvals have been obtained from the Ethics Committee for Research Involving Human Subjects, Universiti Putra Malaysia (JKEUPM-2019-368) and Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia (NMRR-19-471-45606).

Conclusion

The newly developed PFMT educational video was shown to have a high understandability and actionability by the experts and the target audience. The contribution from the cross-sectional study expressed the autonomy of the target audience. The COM-B model underpinning the essential relationships intensified the video content. Consequently, this video was developed from the target audience, the target audience, and the target audience. This approach added the benchmark of its credibility in its development and validation of the newly-developed PFMT video.

We proposed this checklist SCRIPT to assist in the pre-development stage of the video production for better video quality. Considering SCRIPT as the pre-development step for other types of health education video may need future studies to validate its

process. Healthcare providers should enrich themselves in the digital realm to enable pregnant women to be self-empowered in upgrading their quality of life.

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Additional Information and Declarations

No personal information will be disclosed, and subjects will not be identified when the survey findings are published. The investigators declare they have no conflict of interest.

Author Contributions

A.J designed the study (conceptualization), applied for ethics approval, arranged for data collection, analyzed the data, data visualization, and writing original draft.

S.M.S is the primary investigator of the study, obtained the funding, and reviewed drafts of the paper. S.M.S and A.J., together wrote the final version of the paper.

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Conflict of interest

The authors declared no conflict of interest.

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