Original Article
Obstet Gynecol Sci 2024;67(3):323-334
https://doi.org/10.5468/ogs.23212
eISSN 2287-8580

Obstetrics & Gynecology Science

Analyze, design, develop, implement, and evaluate approach to develop a pelvic floor muscle training guidebook to treat stress urinary incontinence in women

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Objective
Stress urinary incontinence (SUI) is a common problem that affects the quality of life of women worldwide. Pelvic floor muscle training (PFMT) is an effective conservative first-line treatment for SUI. However, low compliance with PFMT is one of the main reasons for therapeutic failure. Indirect supervision using a guidebook may improve PFMT outcomes. To develop a PFMT guidebook using the analyze, design, development, implementation, and evaluation (ADDIE) method.

Methods
A guidebook was developed from July 2020 to April 2021 using the ADDIE method. This prospective study used mixed methods, namely qualitative analysis, focus group discussions, and in-depth interviews, and involved various experts from urogynecology, urology, medical rehabilitation, and physiotherapy departments. A pilot study was conducted on patients with SUI to evaluate the effectiveness of the guidebook.

Results
The ADDIE method was successfully implemented to develop the PFMT guidebook. The formative evaluation of the ADDIE steps mainly focused on the PFMT technique, content clarity, illustration, design, and color choice of the book. After the pilot study, the guidebook significantly improved Incontinence Impact Questionnaire, Short Form, 1-hour pad test, and perineometer scores. However, the pilot study showed no significant improvement in Urogenital Distress Inventory, Short Form scores.

Conclusion
The PFMT guidebook developed using the ADDIE method improved outcomes in patients with SUI.

Keywords: Urinary incontinence; Stress incontinence; Pelvic floor; Guidebook; Physical exercises

Received: 2023.08.21. Revised: 2023.12.09. Accepted: 2024.02.27.

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Introduction

Stress urinary incontinence (SUI) is a common problem in women, particularly elderly individuals. The prevalence of SUI is nearly 14% in Shanghai and 4% in Cipto Mangunkusumo Hospital (CMH), Jakarta [1,2]. With an aging population worldwide, SUI is likely to affect women's quality of life and increase the financial burden of healthcare [3]. SUI surgery, such as sling or suspension, is expensive and burdens the national healthcare budget [4,5]. This calls for a more intensive and extensive method to maximize conservative treatment in preventing and treating patients with SUI.

Kegel exercises are a conservative treatment with a decent cure rate and are relatively economical [6]. Kegel exercises were developed by Doctor Arnold Kegel to strengthen the pelvic floor muscle and reduce symptoms associated with weak pelvic floor muscles [7]. A systematic review found that Kegel exercises, known as pelvic floor muscle training (PFMT), were effective as a first-line treatment for patients with SUI along with some lifestyle modifications [8]. Although there are no best and effective regimens and intensity for PFMT, a minimum duration of 6 weeks and an optimal duration of 12 weeks are needed to achieve a significant cure rate [9].

However, the PFMT faces some challenges that need to be addressed. Patient compliance and correct understanding of the method to contract the pelvic floor muscle are essential for a successful therapy [10,11]. Furthermore, there are multiple regimens of PFMT across many health centers, and until now, there has been no consensus on the most effective PFMT regimen. Based on our observations, there are multiple variations in the PFMT regimens and techniques across Indonesian centers. Group sessions, supervised sessions, guidebooks, and reminders (in multiple forms) have been developed over the years to increase compliance and teach women to perform PFMT correctly [12-14]. However, with the persistence of the coronavirus pandemic, low socioeconomic status, health awareness, and limited access to healthcare facilities in developing countries have created a gap for women with SUI to learn PFMT correctly. Therefore, a method to resolve and adapt to these conditions is needed [15].

We aimed to develop a PFMT guidebook using the analyze, design, develop, implement, evaluate (ADDIE) method. This method facilitates building a learning design that is performance-based and personalized for the target population's language, culture, and beliefs. Furthermore, with this method, we can increase compliance and properly instruct patients to perform PFMT accurately [16]. A learning aid in the form of a guidebook was chosen because it is accessible to women in many situations. This could provide indirect supervision for patients. de Assis et al. [17] found that illustrated home exercises for PFMT effectively promoted urinary continence during pregnancy.

Materials and methods

This prospective study was conducted from July 2020 to April 2021 and adopted a mixed-method design, including qualitative analysis, focus group discussions (FGD), and in-depth interviews. All experts, clinicians, and patients involved in guidebook development signed the informed consent form and could withdraw from the study at any time without sanctions or coercion. This study consisted of two main ideas for guidebook development and a guidebook trial for patients with SUI.

ADDIE approach

ADDIE is an acronym for the analyze, design, develop, implement, and evaluate steps required to construct a curriculum or training for specific behavioral changes or techniques [15]. It provides learners with a systematic approach that includes studying concepts and the basics before the implementation and evaluation of outcomes. Although the US military system has developed this method, it has served as an effective technique for teaching medicine and improving health conditions or patient safety [18,19]. A simplified framework of the ADDIE approach is shown in Fig. 1.

The first step in ADDIE is analysis, which consists of situational and training-needs analyses. Situational analysis is the process of obtaining all information related to PFMT. The training needs analysis will identify the gap between PFMT information from the literature and the experts with the PFMT that patients with SUI and clinicians have practiced. We collected information about PFMT through qualitative analysis and in-depth interviews with experts, clinicians, and patients with SUI. A qualitative analysis was performed on literature published by a national health organization, an international organization, and experts involved in SUI/PFMT. In-depth interviews were conducted individually with

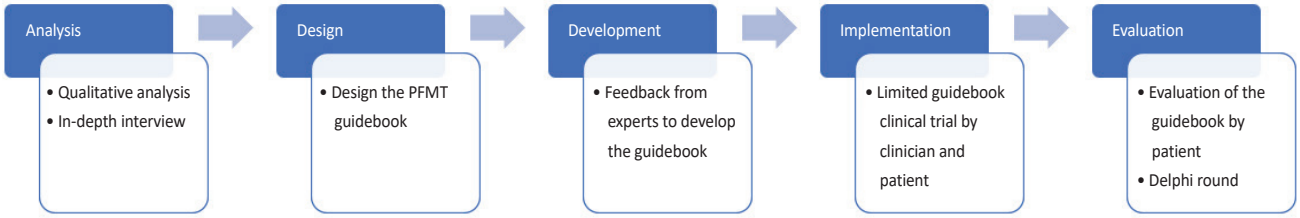

Fig. 1. ADDIE steps in developing the pelvic floor muscle training (PFMT) guidebook. ADDIE, analyze, design, development, implementation, and evaluation.

a minimum of one expert in the fields of urogynecology, physical therapy and rehabilitation, geriatric medicine, and urology. We defined the experts as urogynecologists, urologists, geriatrists, and physiatrists. Furthermore, the clinicians were urogynecology trainees or Obstetrics and Gynecology residents. We also interviewed patients with SUI directly or indirectly. All patients with SUI were consecutively recruited at the urogynecology clinic at CMH. During the in-depth interviews, we asked questions about the guidebook benefits and content, PFMT techniques and regimens, instruments, and methods to monitor and evaluate PFMT and guidebook design.

During the ADDIE design phase, we discussed and created a prototype of the PFMT guidebook based on information obtained during the analysis phase. We asked editors and an illustrator to design, illustrate, write, and edit information about the pelvic floor muscles, urinary incontinence, and instructions for PFMT. The design phase aims to obtain a prototype of the guidebook.

After the prototype guidebook was created, we started the development phase. We invited experts with experience in publishing guidebooks to evaluate our first guidebook prototype. As previously stated, the experts were urogynecologists, urologists, geriatrists, or physiatrists. A yes-no questionnaire was used to capture the overall impression of the guidebook and provide open feedback. We compiled and discussed the inputs provided by experts to further develop our prototype. The first revision of the PFMT guidebook was produced and prepared for use in clinical settings.

The implementation phase was conducted to evaluate the use of the guidebook by clinicians and patients to monitor, educate on, and evaluate SUI. We tested the guidebook on four clinicians and 30 patients. The inclusion criteria for SUI were based on the The Questionnaire for Urinary Incontinence Diagnosis (QUID) questionnaire and a 1-hour pad test, in addition to good cognitive function, residing in Jakarta, and having an active mobile phone. We used purposive sampling to select clinicians and patients in obstetrics and gynecology clinics at the CMH. After the initial examination of SUI (anamnesis, physical examination, Urogenital Distress Inventory, Short form [UDI-6] and Incontinence Impact Questionnaire, Short Form [IIQ-7] questionnaire, 1-hour pad test, and perineometer), patients were taught and instructed to perform PFMT for 1 week based on the prototype guidebook provided by the clinicians. The evaluation was conducted using a questionnaire consisting of 10 yes/no questions and open-ended questions to obtain responses from clinicians and patients. The clinicians who assessed and taught the patients had already agreed to participate in the current study. All clinicians and patients signed informed consent forms. A second revised guidebook was created based on the evaluation provided.

The objective of the evaluation phase was for the patients and experts to assess the second revision of the guidebook and its utility in different clinical settings, respectively. The evaluation consisted of two phases. The first phase included evaluation of the book 1 month after implementation by patients and later by experts in different health centers across Indonesia using two rounds of Delphi. First, we used a questionnaire consisting of 18 Likert-type questions, with responses rated on a 1-5 scale (with 1 representing strongly disagree and 5 representing strongly agree), and a column for open feedback. The questions were related to utility, content, graphics, PFMT technique, and book design. We also conducted a 30-minute online FGD with the patients. An interview was conducted via mobile phone if someone could not attend the FGD. The researcher was the moderator of the FGD and asked about the utility, graphic design, information included, difficulty, and benefits of the guidebook. We recorded conversations during the FGD for further verifica-

tion.

The next step was a content evaluation by experts from other Indonesian provinces. The experts evaluated the second prototype guidebook after receiving input from the patients. The primary purpose of this step was to determine the utility of this guidebook in different cultures and clinical settings and to obtain more insight. Purposive sampling was used to select experts who participated in this research. Our team decided on 15 experts to call and ask for their availability and approval to evaluate the guidebook; if the experts approved, verbal consent was obtained. A similar questionnaire consisting of 18 Likert scale questions with open feedback for each question was used. Based on Kittell-Limerick [20] and Giannarou and Zervas [21], a consensus of agreement is achieved when the standard deviation value is <1.5 or the interquartile range is <2.5. A consensus on the contract should be reached for every point on the questionnaire, to be assumed as requiring no further revisions. Corrections were made after the first round of applying the Delphi method. The second round of the Delphi method was conducted until a consensus was reached. Finally, the latest version of the guidebook should be regularly used by patients with SUI. Fig. 1 illustrates the steps involved.

Data analysis in ADDIE

Because the data collected were primarily in the form of audio/video records, we processed them for verbatim transcription. The first draft of the verbatim transcription was edited and checked based on recordings. Finally, another research team member conducted a cross-check of the verbatim transcription for finalization. To analyze the content, we used coding to categorize the main points/ideas of the verbatim transcription by listening to keywords implied by the speaker. We then grouped the same codes and concluded with all given inputs.

Preliminary study

We conducted a 1-month preliminary study with 30 patients to evaluate the utility and efficacy of the guidebook. This study was registered at clinicaltrials.gov (ID: NCT05304312). The clinical trial lasted from September 2020 to April 2021 at the urogynecology clinic in the CMH. The study population included women with SUI who had never undergone anti-incontinence surgery or received any therapy for incontinence. We included patients aged 25-65 years, with a QUID score ≥4, with good cognitive function (Montreal Cognitive Assessment-Indonesian translated ≥26), who were able and willing to perform PFMT, and who had signed an informed consent form. We excluded patients with a poor general condition, mixed urinary incontinence, abnormal uterine bleeding, higher than stage two pelvic organ prolapse, neuromuscular diseases, active urinary tract infection, a history of pelvic organ malignancy, and other risk factors that may cause persistent high abdominal pressure.

Consecutive sampling was used to recruit patients for the clinic. A general practitioner with a urogynecology fellow trained in SUI examined the patient and recorded the initial UDI-6, IIQ-7, 1-hour pad test, and perineometer scores. Clinicians also taught the patients how to use the guidebook and reminded them to bring the guidebook for follow-up. Kegel regimen training was based on the guidebook; three sessions of contractions consisted of 5-10 slow and fast twitch contractions daily. The patients were asked to record the number of contractions in every session of the guidebook.

The UDI-6 and IIQ-7 questionnaires that were used had been validated and translated into Indonesian. For perineometer examination, we used Peritron© (Cardio-Design, Oakleigh, Australia) with the cmH_2O scale. Perineometer measurements were taken when the patient's pelvic floor muscles were fully contracted, and the average pressure was noted within three trials. The 1-hour pad test protocol was based on the CMH protocol. The 1-hour test steps were as follows: first, we asked the patient to wear a pad and drink 500 mL of water for under 15 minutes. For the next 30 minutes, the patient was required to walk up and down stairs; in the last 15 minutes, the patient had to sit and stand 10 times, cough 10 times, and bow down 10 times before washing their hands under running water for 1 minute. After all the exercises, the patient removed the pad and weighed it.

The patient was asked to return after 4 weeks for monitoring and evaluation. To reduce bias, we assigned a different general practitioner who had been trained previously to assess UDI-6 and IIQ-7 improvements, 1-hour pad test results, pelvic floor muscle strength with a perineometer, and patients' adherence to PFMT according to the PFMT guidebook. We encouraged the patients and addressed their issues with PFMT accordingly whenever possible during the study. Patients were provided with an incentive of 50,000 rupiahs for completing the preliminary study.

Data analysis was performed using SPSS version 23.0 (IBM,

Table 1. ADDIE steps to develop the pelvic floor muscle training guidebook

ADDIE step	Input	Process description	Subjects participated	Instrument	Output
Qualitative analysis	Seven sources of the PFMT guidebook from 1) National Institutes of Health US [22] 2) Oxford University Hospitals (NHS UK) [23] 3) Lianne McCabe, Kelli Young, Sarah Ferguson. UHN [24] 4) Pelvic, Obstetric and Gynaecological Physiotherapy [25] 5) Pelvic floor first, Australia [26] 6) Inside out, Michelle Kenway [27] 7) IUGA [28]	Qualitative analysis to compile information about the pelvic floor, PFMT training regiment, monitoring and evaluation	All of the authors	N/A	1) Several training regiments and methods to do effective PFMT 2) Information about pelvic floor dysfunction that women need to know 3) A daily form of PFMT 4) Monitoring and evaluation form
In depth interview	Literature compilation from PFMT review	In-depth head-to-head interview about SUI and PFMT regiment	Thirteen interviewee consisted of: two urogynecologist, two urologist, one geriatrist, one physiatrist, two urogynecology fellows, one physical rehabilitation resident, and four SUI patients	Questions about four aspects of guidebook development 1) Guidebook benefits and content 2) PFMT technique and regiment 3) Monitoring and evaluation of PFMT 4) Design of the book	1) The guidebook is essential for clinicians and patients to educate, monitor, evaluate, and increase compliance with PFMT 2) There are two regiments of PFMT, slow twitch (5-10 seconds contract) and fast twitch (2 seconds contraction). Both were done 10 times per session with three sessions per day 3) A PFMT diary could monitor the compliance 4) Evaluation could be done by pad test, perineometer, and questionnaire 5) The guidebook size should be around a regular notebook with an interesting design
Design	Information collected during the analysis phase	Creating the prototype of the guidebook with the help of the editors and an illustrator	All of the authors, editors, and an illustrator	N/A	First PFMT guidebook prototype

Table 1. ADDIE steps to develop the pelvic floor muscle training guidebook (Continued)

ADDIE step	Input	Process description	Subjects participated	Instrument	Output
Development	Guidebook prototype	We ask for feedback and evaluation for developing the guidebook before the implementation	Four experts that had published a guidebook	Yes-no questionnaire with an open answer feedback	Based on the questionnaire and feedback, some input given by the experts were 1) More pictures to illustrate the Kegel movement 2) The questionnaire for evaluation was not clear enough 3) Insert a contact number or referral for the patient that had trouble during PFMT
Implementation	PFMT guidebook 1st revision	Implement the guidebook in a clinical situation to obtain feedback regarding the utility of the guidebook	Thirty patients and four clinicians	A feedback questionnaire was used with 10 yes/no questions and four open questions	1) Based on the feedback questionnaire, the guidebook information and pictures about PFMT were good. Critics were given to add more details for the PFMT technique, more infographics, and a link for an animated video 2) The 2nd revision guidebook based on the feedback was made
Evaluation of the guidebook by the patient	The 2nd revision of the guidebook	Thirty minutes focus group discussion with the patients	Thirty patients	1) A questionnaire consisted of eighteen questions with Likert scale answers (1-5) 2) Open feedback session	A low score was given by the patient for design. Most of them complained about a better design and better color choice
Evaluation of the guidebook by the clinicians	The 2nd revision of the guidebook	An indirect interview with eight urogynecologist from a different hospital in Indonesia using two-round Delphi. All eight urogynecologist should reach a convergence of agreement for the book to pass	Eight experts	1) A questionnaire consisted of 18 questions with Likert scale answers (1-5) 2) Open feedback session	1) At the first round of Delphie, the guidebook has obtained convergence in all aspects by the urogynecologist 2) Some feedback was given about the book's better design and color 3) The final edition of the guidebook

ADDIE, analyze, design, development, implementation, and evaluation; PFMT, pelvic floor muscle training; NHS UK, National Health Service, United Kingdom; UHN, University Health Network; IUGA, International Urogynecological Association; N/A, not available; SUI, stress urinary incontinence.

Obstetrics & Gynecology Science
Vol. 67, No. 3, 2024

Chicago, IL, USA). Demographic and patient characteristic data are presented as percentages or means/medians according to distribution. Bivariate analysis using a paired *t*-test or Wilcoxon test was performed to analyze the differences compared with baseline. Statistical significance was set at $P<0.05$.

Results

ADDIE approach

A summary of the ADDIE processes is presented in Table 1. The analysis, design, and development phases were straightforward, and basic steps were required to create the prototype and first revision of the guidebook. The formative evaluation began during the implementation and evaluation phases. The implementation phase was performed by four clinicians and 30 patients with SUI who were evaluated 1 week after implementing the guidebook. The questionnaire included 10 yes and no questions and an open feedback form. Overall, positive feedback was obtained from both clinicians and patients. However, certain aspects required improvement, such as medical terms, detailed explanations of the PFMT technique, and more pictures and videos related to the technique.

After the implementation phase, a second revision of the guidebook was created based on feedback from patients and clinicians. A second formative evaluation was conducted during the evaluation step. A Likert-scale questionnaire consisting of 18 questions was used to evaluate the guidebook. The questionnaire evaluated aspects such as understandability, ease of use, helpful information on SUI conditions, explicit instruction on PFMT, addressing the issue of communication between patients and clinicians, monitoring improvement, and book aspects (design, size, picture, font, and color choice). The first phase of evaluation was implemented by the patients, and most of them gave low scores on the guidebook design and color choice. Details of the first phase of the evaluation are presented in Table 2. Another evaluation was performed by experts in Indonesia using the Delphi method to determine the utility of the guidebook in different cultures and clinical settings. Of the 15 experts, only eight

Table 2. First phase of evaluation of the guidebook by patients with SUI

Item	Value
The guidebook helps you to obtain SUI condition and information	4.5±0.53 (1.0)
The guidebook contained examples, pictures, and illustrations that helped me to understand PFMT	4.25±0.53 (1.0)
The guidebook helps you to monitor PFMT independently	4.5±0.53 (1.0)
The guidebook evaluation is presented comprehensively and can be used as a reminder to do PFMT	4.5±0.53 (1.0)
The guidebook helps you to monitor the improvement of SUI symptoms independently	4.0±0.76 (1.5)
The guidebook exercise regiment is suitable for the condition you had	4.37±0.52 (1.0)
The guidebook fulfil the need to exercise PFMT	4.25±0.71 (1.0)
The guidebook has an interesting cover and pictures	3.88±0.99 (1.5)
The guidebook facilitates us in giving feedback to the clinician about our PFMT training	4.25±0.71 (1.0)
The guidebook color of choice is suitable for your liking	3.75±1.17 (2.25)
The guidebook facilitates us to give feedback to the clinician about SUI symptoms improvement	4.25±0.71 (1.0)
The guidebook has suitable illustrations and pictures of PFMT	4.0±1.07 (1.75)
The guidebook instruction is easy to follow and clear	4.5±0.53 (1.0)
The fonts model and size are comfortable to read	4.25±1.04 (1.0)
The PFMT steps given are clear and easy to follow	4.5±0.53 (1.0)
The guidebook size is appropriate	4.0±0.76 (1.5)
The guidebook has clear, appropriate and communicative language	4.5±0.53 (1.0)
The graphic, visual and verbal illustrations used in this manual are in sync	4.0±1.07 (1.75)

Values are presented as mean±standard deviation (interquartile range).
SUI, stress urinary incontinence; PFMT, pelvic floor muscle training.

Table 3. Second phase of evaluation (Delphi round) of the guidebook by clinicians

Clinician	Value	Decision	Comment
Clinician 1	4.0±0.0 (0.0)	Agree	Good
Clinician 2	4.0±0.8 (0.75)	Agree	Good
Clinician 3	5.0±0.0 (0.0)	Agree	Monitor UDI-6 and IIQ-7 improvement at 4-week, 8-week, and 12-week
Clinician 4	3.2±0.89 (1.75)	Agree	The book cover and design are not interesting
Clinician 5	4.0±0.54 (0.0)	Agree	Word of choice improvement
Clinician 6	4.2±0.38 (0.0)	Agree	Make an e-book version of it
Clinician 7	5.0±0.0 (0.0)	Agree	Suggest creating a pocket-book version
Clinician 8	4.5±0.71 (1.0)	Agree	Suggest the involvement of a physical rehabilitation's

Values are presented as mean±standard deviation (interquartile range).
UDI-6, Urinary Distress Inventory, Short Form; IIQ-7, Incontinence Impact Questionnaire, Short Form.

Table 4. Characteristics of the study participants

Variable	Value
Last education	
Below elementary school	1 (3.3)
Middle school	10 (33.3)
Highschool or higher education	19 (63.3)
Income (Rupiah)	
<3.9 million	10 (33.3)
3.9-10 million	13 (43.3)
Above 10 million	7 (23.3)
Profession	
Civil servant	11 (36.7)
Housewife	9 (30.0)
Health workers (nurses, midwives, and health analysts)	6 (20.0)
Others (employees' private sector, teachers, entrepreneurs)	4 (13.3)
Age (yr)	
Mean±SD	45.80±10.36
Median (min-max)	45-50 (20-68)
Parity	
Nullipara	4 (13.3)
1-3	21 (70.0)
4	5 (16.7)
Method of delivery	
Cesarean section	0 (0.0)
Spontaneous vaginal delivery	28 (93.3)
Instrumental delivery (forceps/vacuum)	2 (6.7)
Baby birthweight (g)	
Mean±SD	3,101.0±538.7
Median (min-max)	3,170 (1,675-4,000)

Values are presented as number (%) unless otherwise indicated.
SD, standard deviation.

agreed to evaluate the guidebook. To pass the evaluation phase, the guidebook had to achieve convergent agreement from all experts (standard deviation=1.5 or interquartile range=2.5). Fortunately, after the first round of evaluation, the book achieved consensus; therefore, no further evaluation was required. Table 3 presents the results. The final revision of the guidebook was concluded after the ADDIE steps and used in the pilot study.

Pilot study

A pilot book clinical trial was conducted with 30 female patients with SUI. No dropouts were observed within 1 month of follow-up. The demographic characteristics of the patients are shown in Table 4. Most women had spontaneous vaginal deliveries and had normal birth weight. Only 40% of the women in our trial had menopause and none had a history of pelvic surgery or other neurological disabilities.

Within 1 month, we significantly improved the IIQ-7, pad test, and perineometer scores. There was an increase of 4.3 cmH_2O in the perineometer (P=0.002), an improvement of 7.14 IIQ-7 score (P=0.019), and a 1 g decrease in the pad test (P<0.001). However, there was no significant improvement in the UDI-6 score, although the mean UDI-6 decreased by 4.44. The details of the UDI-6, IIQ-7, pad test, and perineometer results and calculations are presented in Table 5.

Discussion

SUI is a growing problem in Indonesia, and the number of older women is expected to increase with increased life expectancy. Thus, the prevalence of SUI is expected to increase [22]. This study should help women address the issue of SUI with conservative treatments, such as the PFMT. Until now, the use of a guidebook or application for PFMT has not been common and is not stated in the second edition of the Indonesia urinary incontinence guideline by PERKINA [23]. Supervision is essential in PFMT; thus, we utilize the guidebook to provide indirect supervision for the patient and improve treatment effectiveness and accessibility [24-26]. The guidebook also could spread awareness of SUI. The ADDIE approach helped us develop a guidebook for national use to maintain women's compliance with PFMT and treat patients with SUI. This is the first study in Indonesia to develop a guidebook and implement a standardized PFMT regimen.

The guidebook's objectives were to provide indirect supervision, reminders, and instructions for performing PFMT. According to Hoff Brækken et al. [27], Kegel exercises with direct supervision increase muscle volume, reduce the levator hiatus distance, shorten muscle length, and elevate the bladder's resting position. The study was conducted over 6 months, with good adherence (79%) and low dropout rates (n=2). A similar study by Leme Nagib et al. [28] that attempted to replace human supervision with a smartphone application, found that this application could help reduce the severity of SUI symptoms. Furthermore, in our setting, we could enhance and ensure that the women implemented PFMT correctly using biofeedback, such as a perineometer. To ensure perineometer use and role, we added pelvic floor muscle strength parameters for monitoring women with SUI. In a meta-analysis conducted by Moroni et al. [29], they found that by utilizing biofeedback, there was an improvement in clinical outcomes, quality of life using the King's Health Questionnaire, the number of daily urinary incontinences, and a decrease in the pad test score. Thus, biofeedback and books may help reduce SUI symptoms while maintaining reasonable patient compliance rates.

In the analysis phase, we aimed to compile information

Table 5. Perineometer, IIQ-7, UDI-6, and pad test results

Variable	Initial examination	1-month follow-up	*P*-value
Perineometer (cmH_2O)	23.37±8.36	27.67±9.24	0.002[a]
UDI-6	41.11±12.22	36.67±16.82	0.072[a]
IIQ-7	41.42±20.01	34.28±21.09	0.019[a]
1-hour pad test (g)	4.00 (3-90)	3.00 (1-23)	<0.001[b]

Values are presented as mean±standard deviation or median (min-max).
IIQ-7, Incontinence Impact Questionnaire, Short Form; UDI-6, Urinary Distress Inventory, Short Form.
[a]Paired *t*-test.
[b]Wilcoxon Mann-Whitney test.

about PFMT from the literature and from the experiences of experts, clinicians, and patients who had already undergone PFMT. We were unsure that the qualitative analysis from the literature was not suitable for practice. Therefore, we conducted a situational analysis of experts, clinicians, and patients to strengthen and integrate the theories obtained from daily practice. However, the design and development phases were straightforward. During the implementation and evaluation phases, some revisions needed to be adjusted for the book because PFMT failure could be attributed to factors such as compliance and the inability of women to perform Kegel exercises [30,31]. We needed to ensure that the instructions in the book were explicit. However, in the implementation phase, we found that some women did not understand the instructions for PFMT thoroughly and required an illustration to describe PFMT. We provided some illustrations of the PFMT and its position during PFMT. Thus, in the evaluation phase, there was a significant revision of the content. However, some clinicians and patients provided feedback on design, color choice, font, and diction. To improve the design, we redesigned the book cover (Supplementary Fig. 1), color palette, and combination and increased the number of illustrations in the book. The guidebook's design and content focused on capturing patients' attention and encouraging them to fill in worksheets and evaluation forms.

A clinical trial was conducted in 30 patients. During the 1 month trial, there was a significant increase in the perineometer, IIQ-7, and pad test scores. The IIQ-7 score improvement observed was 7.14 (P=0.019), and the UDI-6 improved by 4.44 (P=0.07). Our results were still below those achieved by Kaya et al. [32] which found an improvement in UDI-6 and IIQ-7 by 27.1 and 19.6 points, respectively, after 6 weeks of PFMT. Moreover, the decrease in the 1-hour pad test in this study was 1 g for 4 weeks, which was lesser than that reported by Celiker Tosun et al. [33] who reported a decrease of 3.4 points within 12 weeks. Despite the low value of improvement, an improvement in SUI was observed. Since the optimum duration of PFMT is 6 weeks, the improvement of IIQ-7, UDI-6, and 1-hour pad test parameters was lower than in other studies, and UDI-6 improvement remained non-significant [34]. If this preliminary study is continued for longer, it may experience the same level of decline or lower than that recorded by previous studies.

We measured the pelvic floor muscle strength using a perineometer and found a significant increase of 4.3 cmH_2O in the perineometer (P=0.002). This increase was similar to that reported by Sun et al. [35], with a significant increase of 1 cmH_2O (P<0.05), and from the Dinc et al. [36] study, with a significant increase of 15.8 cmH_2O (P=0.000) in postpartum women during 6-8 weeks of therapy. Conversely, Al Belushi et al. [26] found no increase in pelvic floor muscle strength in women with SUI after 12 weeks of PFMT with 0.1 cmH_2O increments (P=0.624). Proper PFMT techniques and regimens are believed to increase levator muscle strength and reflex activation.

The study was limited by our inability to analyze the available PFMT regimens and guidebooks. We focused our literature review on widely used international and national health organizations. Due to the extensive project involving multiple CMH departments, blinding interviewees and experts from the guidebook developers was unfeasible. To mitigate bias, we consulted external experts and clinicians, and shared the guidebook with the development department. The perineometer only assessed pelvic floor muscle strength and neglected other crucial aspects such as endurance and coordination. Consequently, we lacked the necessary parameters to measure these variables. However, this study was the first in Indonesia to use a robust method to develop a guidebook for PFMT. It involved experts from various fields to create the most suitable regimens and evaluation parameters for PFMT. Furthermore, we are still progressing on the controlled trials to compare the effectiveness of the guidebooks. We hope that the guidebook will provide a significant improvement and can soon be used widely in Indonesia to help patients with SUI undergo PFMT.

The ADDIE method is an effective and systematic approach for guidebook development. The pilot study showed that the guidebook might help patients achieve significant improvements in the IIQ-7, 1-hour pad test, and perineometer scores. However, the UDI-6 score did not improve significantly after four weeks of PFMT.

Conflict of interest

The authors declare no conflict of interest.

Ethical approval

This study was approved by Faculty of Medicine, University of Indonesia.

Patient consent

The study procedures were explained to all participants in advance, and written informed consent was obtained from all participants.

Funding information

None.

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