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CLINICAL TRIAL REPORT

A Pelvic Floor Muscle Training-Based Complex Intervention for Community-Dwelling Older Women with Urinary Incontinence: A Feasibility Study and Process Evaluation

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Purpose: Urinary incontinence is a common health issue among older women, negatively affecting quality of life. Although pelvic floor muscle training (PFMT) is recommended as the first-line treatment, its uptake remains low. We previously developed a PFMT-based complex intervention to improved adherence and implementation fidelity among community-dwelling older women. This study aimed to test its acceptability and feasibility.

Patients and Methods: This study consisted of two parts. First, a cluster randomized controlled pilot trial was conducted in Changsha, China. Four community daycare centers were randomly assigned to the intervention arm (receiving the PFMT-based complex intervention) or the control arm (receiving health education). Primary outcomes were the acceptability, appropriateness and feasibility of the complex intervention. Additionally, a mixed-method process evaluation was conducted to assess the implementation fidelity and the contextual factors influencing the implementation outcomes, with quantitative data collected from research logs and qualitative data from interviews, respectively.

Results: From October 2023 to January 2024, the pilot trial enrolled 36 eligible older women, with 22 in the intervention arm and 14 in the control arm. Compared with health education, the complex intervention demonstrated greater acceptability, appropriateness, and feasibility, with mean differences and corresponding 95% confidence intervals being 1.25 (0.19, 2.31), 1.25 (−0.02, 2.53) and 2.29 (0.78, 3.81), respectively. The process evaluation revealed that the complex intervention was implemented successfully, with 48% of the approached older women enrolled and intervention content delivered as planned. However, low motivation, monotonous content, limited promotion and inadequate attention were identified as barriers requiring further improvement.

Conclusion: Our preliminary findings indicate that the PFMT-based complex intervention, developed with consideration of participants' preferences and implementation influence factors, is acceptable and feasible. These findings support a larger confirmatory trial and indicate that future research should further improve data collection strategies, adopt objective outcome measures, and optimize intervention components.

Keywords: urinary incontinence, older women, community, complex intervention, pilot trial, process evaluation

Introduction

Urinary incontinence (UI) is any involuntary leakage of urine,[1] with a higher prevalence observed among older women.[2] Globally, the prevalence of UI in older women ranged from 22% to 80%,[3] with more than 25% of Chinese women aged ≥ 60

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years affected.[4] Beyond physical discomfort, UI can also lead to anxiety or depression, reduced daily activities, and loss of self-confidence.[5] The economic burden of UI is substantial, with the annual costs estimated at €69.2 billion in the European Union (in 2023) and $82.6 billion in the United States (in 2020).[6,7] Clinical practice guidelines recommend pelvic floor muscle training (PFMT) as the first-line treatment for its accessibility, cost-effectiveness, and limited risks.[8] However, patients are reluctant to seek help and more than half of older women with UI fail to perform PFMT.[9] Notably, over 80% of Chinese older women with UI primarily exhibit mild to moderate symptoms,[10] which could be effectively managed with PFMT.[8] Therefore, improving patient uptake of PFMT and maximizing its benefits remain important challenges.

Although the effectiveness of PFMT has been well demonstrated, its practical effectiveness is often limited by inadequate implementation and poor participant compliance.[11,12] Moreover, given the low treatment rate and limited healthcare resources in China, interventions that solely aim to improve pelvic floor function are insufficient to achieve effective management of UI.[4] Therefore, complex interventions involving multiple interacting components have been proposed to improve the implementation fidelity of PFMT and increase adherence among older women, ultimately optimizing the treatment effect.[13,14] Thus, we have developed a complex intervention for community-dwelling older women with UI following the Medical Research Council guidance.[8,15] The developed complex intervention was designed with PFMT as the core component based on older women' preferences, and integrated six supporting components systematically derived from qualitative interviews to address barriers and facilitators of PFMT adherence and implementation in community settings. This evidenced-based complex intervention was refined and finalized through multidisciplinary expert consensus.[16]

A feasibility study is a preliminary research conducted to inform the design and conduct of a subsequent main trial.[17] Before initiating a full-scale trial for evaluating effectiveness or implementation, a small-scale feasibility study is essential to identify methodological uncertainties and to assess the acceptability, appropriateness and feasibility of the complex intervention among the target population.[18] In addition, the process evaluation within a feasibility study serves to evaluate whether the intervention was implemented as intended and identify factors affecting the implementation process, thereby contributing to the refinement of the complex intervention and informing future implementations. This study aimed to assess the feasibility of implementing a PFMT-based complex intervention in the community setting and to identify factors facilitating or hindering its implementation.

Material and Methods

This study consists of two parts. First, a cluster randomized controlled pilot trial was conducted to evaluate the implementation feasibility of the complex intervention, enrolling 36 participants who received either a six-week PFMT-based complex intervention or health education. The primary outcomes were the acceptability, appropriateness, and feasibility of the complex intervention. This part was reported following the Consolidated Standards of Reporting Trials 2010 statement: extension to randomized pilot and feasibility trials.[19,20] Second, guided by a process evaluation design and reporting framework, a mixed-methods process evaluation was conducted. Quantitative data were collected via research logs during the intervention period to assess implementation fidelity, while qualitative data were obtained through post-intervention interviews to identify factors influencing the implementation process.[21] The pilot trial was registered in the Chinese Clinical Trial Registry (identifier: ChiCTR2300076166).

The Cluster Randomized Controlled Pilot Trial

Participants and Recruitment

Setting

The community daycare centers were selected as the study sites, because they offer easily accessible and familiar environments that align with older women's preferences, as well as provide appropriate space for organizing group-based PFMT sessions.[22] As an essential component of China's elderly care system, these government-funded and community-oriented facilities provide daytime services such as health rehabilitation, social engagement and health education for community-dwelling older adults.[23] In recent years, community daycare centers have become increasingly widespread and relatively well-established across China. The eligibility criteria for daycare centers included: (i) the availability of a suitable space for group-based PFMT, and (ii) approval from the center manager.

Participants

Eligible women were required to meet the following criteria: (i) aged ≥ 60 years and capable of walking into the daycare centers independently; (ii) experiencing mild to moderate UI, as assessed by International Consultation on Incontinence Questionnaire-short form (ICIQ-SF), with scores ranging from 1 to 14;[24,25] and (iii) willing to participate in the study. Women were excluded if they (i) exhibited severe functional deficits in vision, hearing, and comprehension that would hinder participation; (ii) were currently receiving treatment for UI; (iii) were involved in any other intervention programs, regardless of their focus.

Recruitment Process

Four community daycare centers that met the eligibility criteria were recruited in Changsha, Hunan, China. After obtaining consent from the center managers, the daycare centers were randomly assigned to either the intervention or control arm. Participant recruitment and informed consent were conducted after community daycare centers randomization, using a combination of on-site presentations and online announcements, with assistance from the daycare center managers.[26] Community-dwelling older women who fulfilled the eligibility criteria were enrolled in this study.

Randomization and Masking

The unit of randomization was the community daycare center, with all participants in a daycare center assigned to the same arm. Randomization was performed based on the random number table by a researcher not involved in the study. The randomization assignments were concealed using sequentially numbered opaque envelopes until a daycare center was included. Participants and intervention implementers were aware of their arm allocation due to the features of the interventions, data collectors were not blinded, as the outcomes were self-reported by the older women.

Interventions

The primary objective of a pilot study is to assess feasibility rather than effectiveness. Accordingly, a 6-week intervention period was considered sufficient to assess the intervention's acceptability, appropriateness, and feasibility.[27,28] Participants in the intervention arm received a 6-week complex intervention developed previously, with PFMT as the core component and six supplementary components: symptom and quality of life assessment, health education, reminder and supervision, group discussion, reward system, and flexible schedule. The intervention was delivered by trained researchers with a medical background. The details of the complex intervention are shown in Table 1.

The control arm received a 6-week health education, consisting of the "health education" component from the complex intervention. Health education is a commonly used strategy for community-dwelling older women with UI in China.

Outcomes

Data were collected at baseline, week 3 (mid-point) and week 6 (end-point) (Supplemental Table 1). Socio-demographic characteristics such as age, marital status and education level were collected at baseline using a self-developed questionnaire.

The primary outcomes were acceptability, appropriateness, and feasibility of two interventions (the complex intervention or the health education), measured using the Chinese versions of the Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and Feasibility of Intervention Measure (FIM).[29] Each questionnaire consists of four items rated on a 5-point scale ranging from "completely disagree" to "completely agree", with a maximum total score of 20 points. Higher scores indicate better acceptability, appropriateness and feasibility of the intervention.

The secondary outcomes included improvement in UI symptoms, quality of life, and safety. The ICIQ-SF, a brief patient-reported questionnaire, was used to assess UI symptoms. The total score ranges from 0 to 21 points, with higher scores indicating more severe symptoms. Quality of life was assessed using the self-reported Incontinence Quality of Life Questionnaire (I-QOL), which consists of 22 items.[30] The questionnaire is organized into three domains: behavioral restrictions, psychological impact, and social embarrassment. The final score is converted to a scale of 0 to 100, where a higher score indicates a better quality of life. Safety information was assessed using a self-developed adverse events questionnaire, including details on specific adverse events, as well as their onset and duration.

Table 1 Details of the Pelvic Floor Muscle Training-Based Complex Intervention

Components	Description
Symptom and quality of life assessment	Assessment: UI symptom severity and UI-related quality of life were assessed using the ICIQ-SF and I-QOL questionnaires, respectively. Procedure: using self-reported paper-based surveys on baseline, mid-intervention (week 3), and post-intervention (week 6).
Health education	Content: health education materials were selected and organized from online popular science resources by the research team to facilitate participants' understanding, including: (i) knowledge regarding UI: prevalence of UI in older women, anatomy of pelvic floor muscles, etiology, hazards, clinical symptoms, diagnosis, misconceptions, prevention strategies, existing treatment strategies and related pros and cons. (ii) knowledge regarding PFMT: techniques, benefits, and potential economic costs. Procedure: health education were delivered by the intervention implementer, including: (i) a community-based health knowledge lecture delivered once following the first week group-based PFMT training session; (ii) a health education manual distributed after the health knowledge lecture; (iii) popular science works disseminated via WeChat at least twice weekly.
PFMT	Content: the PFMT program comprised group-based and self-directed home training. The research team produced a PFMT instructional video based on the techniques for older women with UI developed by Xiangya School of Nursing, Central South University. Procedure: group-based training sessions were conducted in the activity rooms of community daycare centers, with around ten participants per group. Each session began with a 5-minute warm-up, followed by 15–30 minutes of PFMT, held twice weekly. Trained implementers with medical backgrounds (e.g., gynecology or geriatrics) instructed and led older women on-site throughout the group training sessions. Self-directed home training: Participants were encouraged to perform PFMT at home at least once a week, following the same techniques introduced during the group sessions.
Reminder and supervision	Supervisors: intervention implementers, managers of the daycare centers, and highly organized and motivated older women were selected to assist with supervision. Strategies: (i) sending reminders via WeChat or phone calls before each group-based PFMT session; (ii) recording attendance by clocking in and signing out at each session; (iii) sending daily WeChat reminders for self-directed home PFMT on days without group training sessions.
Group discussion	During the first two weeks of the intervention, the implementer organized weekly group discussion to collect participants' experiences about the training, problems encountered, and provide suggestions for improvement.
Reward system	After the intervention, participants were awarded prizes based on their attendance in the group-based PFMT sessions (articles for daily use such as paper towels, dishwashing liquid, laundry detergent, etc.).
Flexible schedule	If necessary, adjusting the schedule or performing home training alternatively when unavoidable factors (e.g., the bad weather) prevent group training sessions.

Abbreviations: ICIQ-SF, International Consultation on Incontinence Questionnaire-Short Form; I-QOL, Incontinence Quality of Life Questionnaire; PFMT, pelvic floor muscle training; UI, urinary incontinence.

Statistical Analysis

A sample size of no less than 12 older women with UI per arm was estimated based on the literature recommendation for sample size in pilot studies.[31]

For the socio-demographic characteristics, categorical data (calculated as frequency and percentage) were analyzed using Fisher's Exact test due to the sample size of less than 40. Normality of all continuous variables was assessed using the Shapiro–Wilk test. All continuous data were normally distributed (calculated as mean and standard deviation [SD]) and Student's *t*-test was used for analysis.

The analysis of primary outcomes (acceptability, appropriateness, and feasibility) and secondary outcomes (improvement in UI symptoms and quality of life) utilized a linear mixed model. Effect size was quantified using the Mean Difference (MD) along with its 95% confidence interval (CI). For primary outcomes, a scale-constant covariance structure was assumed to account for the clustering effect, given our consideration that the measured results at each time point are independent. For secondary outcomes, a first-order autoregressive covariance structure was assumed to account for the clustering effect, acknowledging the inherent correlation between the repeated measures data. The model included fixed effects for treatment arm (PFMT-based complex intervention or health education) and

time to repeated-measure, while random effects accounted for variations among different community daycare centers and participants. Safety related information, including the specific adverse events, occurrence time and duration were described in detail.

The data analyses were carried out on the principle of intention to treat, in which outcomes were compared between participants according to their community daycare centers randomization assignment, regardless of their actual adherence to the intervention. All the analyses were conducted using SPSS 21.0, with $P < 0.05$ being considered statistically significant.

Process Evaluation

Study Design

A mixed-methods approach was used to collect both quantitative and qualitative data for the process evaluation. The main aspects assessed are shown in Supplemental Table 2.

Quantitative Data Collection

Quantitative data on the implementation of the complex intervention were collected during the 6-week intervention period. Research logs served as the primary tool to document: (i) recruitment, including the strategies adopted to recruit both community daycare centers and older women, as well as the total number who consented to participate; (ii) reach, which recorded the attendance of older women at each group-based training session; (iii) delivery, detailing the content delivered to both the community daycare centers and the older women, along with the duration of each session; (iv) unintended consequences, captured as adverse events occurring during the intervention period, which were reported as secondary outcomes of the pilot trial.

Qualitative Data Collection

Qualitative interviews were conducted to obtain feedback from daycare center managers and older women, as well as to explore the contextual elements during the implementation of the complex intervention. These components are collectively referred to as the influencing factors in the implementation process. Purposive sampling was adopted to select the participants and managers from the community daycare centers in the intervention arm.[32] After the 6-week intervention period, interviewees were invited to participate in face-to-face interviews. All interviews were conducted in a quiet and private room by the intervention implementer, who was familiar with the interview content and had established rapport with the interviewees. The interview was audio recorded with the oral consent of the interviewees. The sample size was determined according to the principle of data saturation, and sampling was discontinued when no new information emerged from the consecutive interviews.[32,33]

Two versions of the interview guide were developed to capture perspectives from both participants and daycare center managers. The interview guide was developed based on the Consolidated Framework for Implementation Research (CFIR) to identify factors influencing the implementation of the PFMT-based complex intervention. The interview content covered five areas of the CFIR framework: (i) Innovation, the advantages and costs of the complex intervention; (ii) External factors, external pressure to implement the complex intervention; (iii) Internal factors, such as the availability of resources; (iv) Individuals, the needs and opportunities of the participants; and (v) Implementation process, feedback on the content and implementation of the complex intervention. The complete list of questions is provided in Supplemental Figures 1 and 2.

Due to the poor adherence to home practice of the complex intervention, questions about home practice were added to the interview guides for participants to explore the compliance of participants at home practice and related reasons.

Data Analysis

In the process evaluation, both quantitative and qualitative data were collected. The quantitative data contained only categorical variables, which were summarized using frequencies and percentages for descriptive analysis.

Regarding to qualitative data, the audio recordings were transcribed within 24 hours after each interview, and the interviewer organized and checked the transcriptions. Qualitative data were analyzed using content analysis with the assistance of NVivo 12.0 software (QSR International). First, a coding manual was formed based on the CFIR framework by assigning one or more categories to meaningful statements from the transcriptions. The coding manual was then

modified and refined as needed. Second, the meaningful statements in the transcriptions were coded and classified according to the coding manual. Finally, the categories were assessed as facilitators, barriers, or neutral factors. Two researchers independently analyzed the data, with disagreements being resolved through discussion or consultation with a third researcher. A final list of factors influencing the implementation was established through group discussion.

Results

Results of the Pilot Trial

Basic Information of Participants

From October 2023 to January 2024, four community daycare centers were enrolled in the pilot trial. Two daycare centers were randomized into the intervention arm, while the remaining two were assigned to the control arm. A total of 36 eligible older women participated in the intervention program, with 22 in the intervention arm and 14 in the control arm. The detailed recruitment process for both the daycare centers and the older women is described in the results of the process evaluation. The flow of participants through the study is shown in Figure 1.

As shown in Table 2, baseline characteristics of the participants were similar between arms. Overall, participants had a mean age (SD) of 65.00 (4.98) years. Most of the participants had mild UI symptoms (77.78%), with a mean (SD) ICIQ-SF score of 5.75 (3.05).

Acceptability, Appropriateness and Feasibility Between the Two Arms

The distribution of scores for acceptability, appropriateness and feasibility scales for the two interventions (complex intervention or health education) is shown in Supplemental Table 3. The intervention arm exhibited higher AIM, IAM and FIM scores compared to the control arm, with MDs and their corresponding 95% CIs being 1.25 (0.19, 2.31), 1.25 (−0.02, 2.53) and 2.29 (0.78, 3.81), respectively. However, no significant difference was observed in the appropriateness score. The results of the main effect are shown in Table 3, while the detailed results are in Supplemental Table 4.

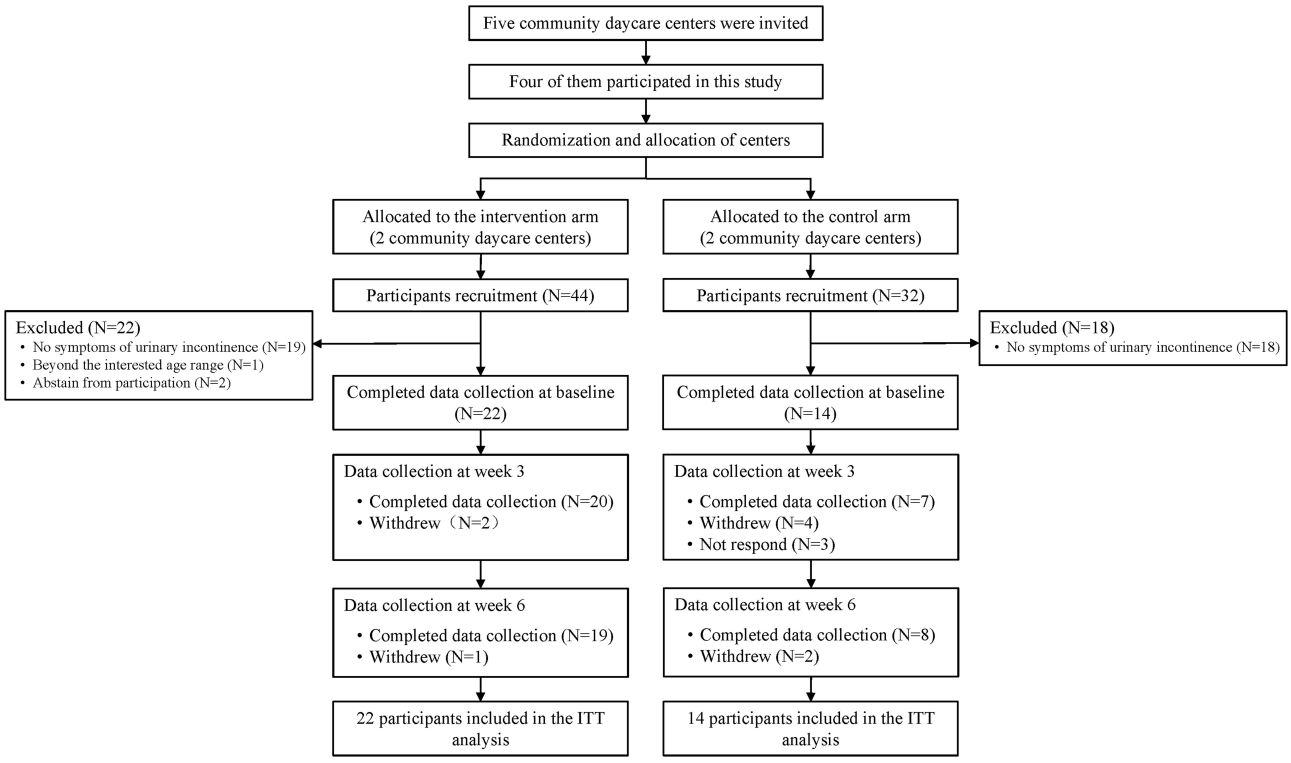

Figure 1 Flow of participants through the pilot trial.
Note: ITT: the principle of intention to treat.

Table 2 Baseline Characteristics of the Participants

Participant Characteristics	Intervention Arm (N = 22)	Control Arm (N = 14)	*P* Value
Age (years) (Mean±SD)	65.05±4.85	64.93±5.37	0.946
BMI (Mean±SD)	24.21±5.69	24.10±2.75	0.948
Residential location (N [%])			0.547
Towns and cities	21 (95.4)	12 (85.7)	
Countryside	1 (4.6)	2 (14.3)	
Education level (N [%])			0.884
Primary school	4 (18.2)	4 (28.6)	
Middle school	7 (31.8)	5 (35.7)	
High school	8 (36.4)	3 (21.4)	
College (Junior college) or above	3 (13.6)	2 (14.3)	
Occupation before retirement (N [%])			0.440
Peasantry	3 (13.6)	4 (28.6)	
Worker	8 (36.4)	3 (21.4)	
Company employee	3 (13.6)	0 (0.0)	
Administrator	1 (4.6)	0 (0.0)	
Salesperson or service personnel	1 (4.6)	0 (0.0)	
Self-employment venture	0 (0.0)	1 (7.1)	
Technical and professional worker (e.g., teacher, doctor, lawyer)	3 (13.6)	4 (28.6)	
Inoccupation	3 (13.6)	2 (14.3)	
Monthly income level (CNY) (N [%])			>0.999
≤ 3000	15 (68.1)	10 (71.4)	
3001 ~ 6000	6 (27.3)	4 (28.6)	
≥ 6001	1 (4.6)	0 (0.0)	
Number of deliveries (N [%])			0.565
1	12 (54.5)	6 (42.9)	
2	6 (27.3)	7 (50.0)	
3	3 (13.6)	1 (7.1)	
4	1 (4.6)	0 (0.0)	
Have learned about PFMT (N [%])			0.441
Yes	6 (27.3)	2 (14.3)	
No	16 (72.7)	12 (85.7)	
ICIQ-SF score (Mean±SD)	5.68±3.17	5.85±2.96	0.869
I-QOL score (Mean±SD)	68.23±16.38	76.38±18.18	0.172

Abbreviations: BMI, Body Mass Index; ICIQ-SF, International Consultation on Incontinence Questionnaire-short form; I-QOL, Incontinence Quality of Life Questionnaire; PFMT, pelvic floor muscle training; SD, standard deviation.

Effects for Urinary Incontinence Symptoms and Quality of Life

Regarding to UI symptoms, the intervention arm exhibited a lower ICIQ-SF score compared to the control arm, with a MD and a 95% CI of −1.10 (−2.73, 0.52), however, no significant difference was observed.

Regarding to quality of life, the intervention arm exhibited a higher I-QOL score compared to control arm, with a MD and a 95% CI of 13.88 (6.11, 21.65). The results for all three domains of the I-QOL showed that the complex intervention led to higher scores in behavioral limitation (MD: 5.07, 95% CI: 2.39–7.76), psychological influence (MD: 4.04, 95% CI: 1.28–6.80) and social embarrassment (MD: 2.75, 95% CI: 0.10–5.40). The results of the main effect are shown in Table 3, while the detailed results are in Supplemental Table 5.

Adverse Events

During the intervention period, the intervention arm reported a total of two adverse events, each occurring in a separate training group. Specifically, two older women experienced lumbar and abdominal soreness during the first week of group-based training. These symptoms were relieved by rest and subsequently resolved as the training progressed. In contrast, no adverse events were reported in the control arm.

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Table 3 Main Effect of the Primary Outcomes and Secondary Outcomes

	Baseline		Week 3		Week 6		Main Effect MD (95% CI)
	Intervention Arm (Mean±SD)	Control Arm (Mean±SD)	Intervention Arm (Mean±SD)	Control Arm (Mean±SD)	Intervention Arm (Mean±SD)	Control Arm (Mean±SD)	
Primary outcomes							
Acceptability	–	–	18.90 ± 1.65	18.71 ± 2.36	19.47±1.12	17.25±1.28	1.25 (0.19, 2.31)
Appropriateness	–	–	18.30 ± 1.81	17.86 ± 2.04	19.16±1.71	17.38±2.20	1.25 (−0.02, 2.53)
Feasibility	–	–	18.40 ± 2.19	16.29 ± 1.70	19.42±1.22	17.00±2.83	2.29 (0.78, 3.81)
Secondary outcomes							
Symptom	5.68±3.17	5.85±2.96	5.50±1.90	7.14 ± 3.63	4.11±3.13	5.63±4.50	−1.10 (−2.73, 0.52)
Quality of life	68.23±16.38	76.38±18.18	75.40±14.08	67.21 ± 12.80	83.33±9.83	70.31±17.53	13.88 (6.11, 21.65)
Behavioral limitation	27.05±5.70	30.36±7.04	29.80±4.53	26.29 ± 1.38	30.15±8.17	26.88±5.87	5.07 (2.39, 7.76)
Psychological influence	37.18±6.00	39.36±7.16	39.3±5.03	36.71 ± 7.99	41.84±2.81	38.63±5.34	4.04 (1.28, 6.80)
Social embarrassment	17.82±4.09	19.50±4.07	19.25±4.55	18.14 ± 3.76	21.37±3.58	18.38±5.40	2.75 (0.10, 5.40)

Notes: SD: standard deviation; MD (95% CI): mean difference and 95% confidence interval; a 95% CI excluding zero indicated a statistically significant difference.

Results of Process Evaluation

Recruitment of Community Daycare Centers

Five community daycare centers were initially invited to participate in our study. Four of these daycare centers consented and were subsequently enrolled, while one daycare center manager declined participation, citing concerns that the training room's location on a relatively high floor might hinder accessibility for older women.

Recruitment and Reach in Older Women

Following the randomization of the included daycare centers, recruitment of older women was initiated at each center. With the assistance of the center managers, a combination of online and offline invitations was sent to community-dwelling older women. In total, 75 older women across all four daycare centers expressed a willingness to participate in our intervention program, and 36 of them met the eligibility criteria and were enrolled.

Intervention Delivery

At the community daycare center level, each daycare center formed a distinct intervention group based on the number of participants enrolled. All intervention content, including both the complex intervention and the health education, was delivered by an implementation team consistently at each daycare center. This team adhered to the established protocol to ensure consistency and uniformity in the delivery of the intervention content.

In the intervention arm with 22 older women, the complex intervention comprised 12 sessions of group-based PFMT. Specifically, eight of these older women (36%) had an 100% attendance rate (all 12 sessions); 14 (64%) had an attendance rate of over 80% (10 or more sessions); 18 (82%) had an attendance rate of over 67% (eight or more sessions). Details on the implementation of the complex intervention are shown in Supplemental Table 6.

In the control arm with 14 older women, four withdrew during the third week of data collection, and two withdrew in the sixth week, with no reasons provided for their withdrawals. In addition, three older women were absent from data collection in the third week due to scheduling conflicts; however, they participated in the sixth week of data collection.

Influencing Factors in Implementing the Complex Intervention

Eight older women (denoted as C01 to C08) and all the two daycare center managers (denoted as X01 to X02) in the intervention arm were interviewed after the intervention period. The interview duration ranged from 10 to 30 minutes, reflecting differences in participants' willingness or ability to express their thoughts.

A total of 23 influencing factors were identified, including 18 facilitators, four barriers and one neutral factor. These factors cover five domains and 14 constructs of the CFIR, mainly distributed in the innovation, individual and implementation process domains. Both daycare center managers and older women expressed positive responses to the complex intervention. However, four barriers affecting the implementation and adherence of the complex intervention were identified. First, low motivation was identified because the lack of supervision resulted in reduced willingness to engage in home-based PFMT, which was often deprioritized relative to daily activities. Second, monotonous content of PFMT led to decreased interest and negatively affected adherence. Third, limited promotion hindered participation due to insufficient awareness of the intervention. Fourth, many older women perceived UI as a normal part of aging, and this misconception further impeded engagement. Details about the influencing factors are shown in Figure 2, while the interviewee quotes are shown in Supplemental Table 7.

Home Training for Older Women with Urinary Incontinence

Results from the interviews revealed that the reasons for the low attendance rate of home training during the intervention period was that the majority of older women persisted unstructured home training at their discretion. They lacked a fixed training schedule, consistent frequency and clearly defined intensity. Further details are shown in Supplemental Table 8.

Discussion

This pilot trial assessed the practical feasibility of implementing a previously developed PFMT-based complex intervention. The preliminary results indicated that the PFMT-based complex intervention was feasible and acceptable in a community setting, as reflected by positive findings in the primary outcomes and feedback from interviews. The

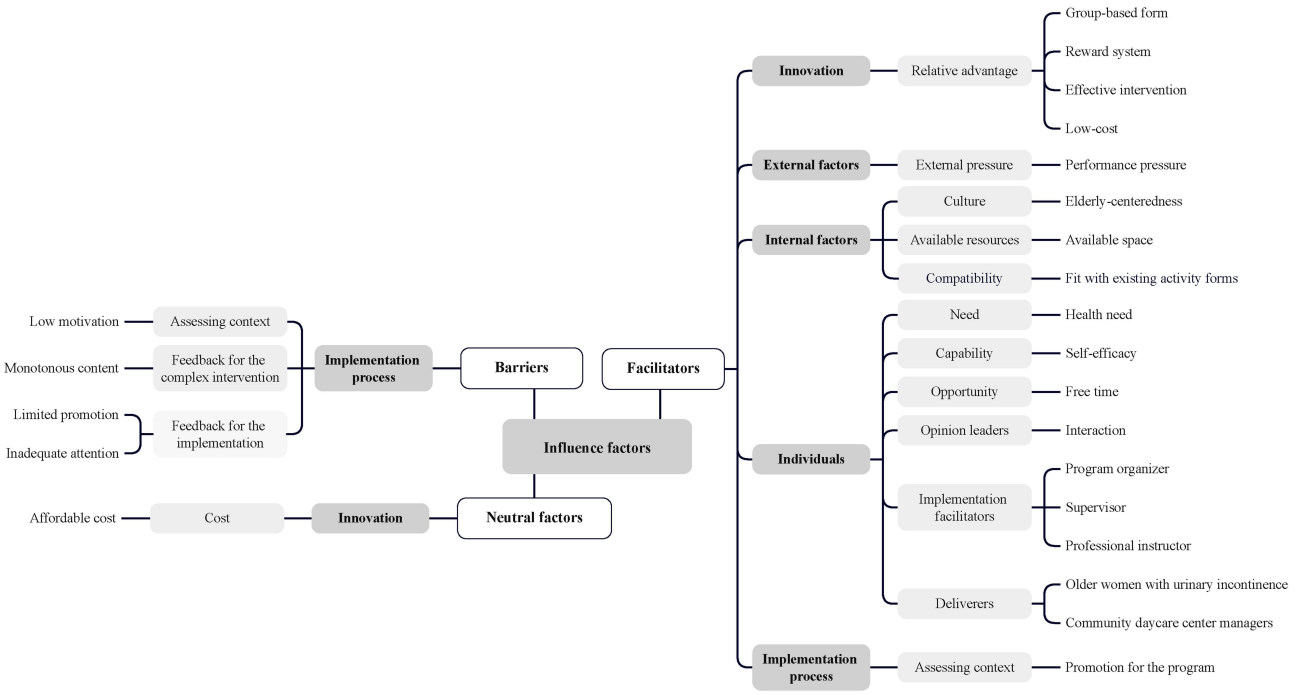

Figure 2 The influencing factors for the complex intervention implementation.
Notes: Factors identified from the qualitative interviews are categorized as facilitators, barriers, or neutral factors. Text in bold with a background color represents domains of CFIR framework; text with background color only represents components of CFIR framework; text without bolding or background color represents the specific factors identified in this study.

process evaluation identified 23 factors influencing the implementation of the complex intervention, providing valuable insights for the refinement and future implementation of the complex intervention.

Although the implementation outcomes are preliminary due to the small sample size, they suggest meaningful potential and support further evaluation in a larger confirmatory trial. First, the complex intervention exhibited significantly higher acceptability than health education, which may be attributed to the group-based PFMT component that aligns with older women's preferences. This format not only enhanced peer support and reduced stigma but also conserved human and financial resources.[34,35] Additionally, components targeting factors affecting implementation likely contributed to the higher feasibility observed. Delivering the complex intervention in community daycare centers, which align with both the elderly-centered institutional values and older women's preferences, further enhanced adherence and may promote long-term sustainability.[36] However, differences in appropriateness were not statistically significant, which may be due to the limited sample size or may indicate that both interventions are practically relevant for addressing older women with UI.

Notably, the high withdrawal rate in the control arm (43%) may reduce the reliability of our findings. This is because selective retention of participants more positively inclined toward health education could lead to a lack of statistical significance and an underestimation of implementation outcomes. On the other hand, the high withdrawal rate may also support our results, as it probably reflects health education failing to engage older women effectively and reducing their commitment to longitudinal data collection.[37] Nonetheless, future studies should incorporate strategies such as incentive measures and clearer communication to minimize withdrawal while maintaining comparability and data quality during study design.

We conducted a preliminary exploration of the effects of the complex intervention on UI symptoms and quality of life, as the study was designed primarily to assess its feasibility and acceptability and a small sample size was used. Although the intervention showed a positive trend in symptom improvement, the lack of statistical significance may be due to the short intervention duration and limited sample size. Moreover, the complex intervention significantly improved participants' activity limitations, psychological impact, and social restrictions, contributing to enhanced quality of life, which aligns with previous evidence.[38] Despite these results being preliminary, they suggest the potential effects, supported by the observed positive trends and the well-established benefits of PFMT. In addition, two cases of mild

discomfort during the PFMT were reported, consistent with previous reports.[34,39] These findings provide guidance for refining the intervention, indicating that stepwise training techniques should be adopted in future implementations.

The process evaluation indicated that the complex intervention could be implemented in the community as planned, while also identifying barriers for future optimization. Notably, 36% of older women in the intervention arm attended fewer than 80% of the group training sessions (fewer than 10 out of 12), possibly due to scheduling conflicts with competing priorities.[40] To mitigate this anticipated challenge, home-based training was included as a supplementary component. However, unstructured home training was reported in practice, that may compromise the PFMT effectiveness.[41] Qualitative interviews revealed facilitators to implementation including innovation (e.g., group-based PFMT, low cost), internal factors (e.g., availability of space), and individual factors (e.g., capability and opportunity), which ensured successful delivery and enhanced participants' adherence.[42] Conversely, given the observed barriers, future studies could explore task-shifting approaches, such as training peer leaders among older women or community daycare center managers to organize supervised group training sessions.[43,44] The monotonous training content could be addressed by integrating diverse forms of exercise, such as yoga or tai chi.[45]

Strengths and Limitations

One of the main strengths of this study was the use of reliable and validated tools to assess the implementation outcomes of the complex intervention, which is essential for evaluating the success of implementation efforts. Additionally, a process evaluation was conducted to understand the influencing factors of the implementation. The involvement of both recipients of the complex intervention and managers of the implementation setting provided multiple perspectives about the complex intervention, hence, it provides the basis for the complex intervention optimization and promotion in future studies.

Several limitations of this study should be acknowledged. First, participation was restricted to older women who were able to access community daycare centers, thereby excluding those who faced stigma or had mobility issues. Even so, the findings of this study hold important implications for older women experiencing mild to moderate UI symptoms. Second, blinding was not implemented due to the nature of the intervention, and the use of patient-reported outcomes may have led to underestimation of the outcomes, particularly among participants assigned to the less engaging control arm. Future studies could consider using objective outcome measures, such as pad tests or urodynamic assessments. Third, while we included the two managers from both community daycare centers of the intervention arm in the qualitative interview for the process evaluation, this limited number of interviewees may not capture the perspectives of all daycare center managers.

Conclusion

The preliminary findings indicate that the PFMT-based complex intervention, developed with consideration of participants' preferences and implementation influence factors, is acceptable and feasible, thereby supporting a subsequent larger-scale confirmatory trial. These results will help refine the design of future trials and inform broader implementation of the complex intervention, including improving data collection strategies, adopting objective outcome measures, and optimizing intervention components based on process evaluation findings.

Data Sharing Statement

The data for this study are available from the corresponding author (Irene XY Wu) on reasonable request.

Ethics Approval and Informed Consent

Approval of the regional ethics committee has been obtained from the ethics committee of Xiangya School of Public Health, Central South University [No. XYGW-2023-65]. The study was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from participants in the pilot trial, and verbal consent was obtained from interviewees.

Consent for Publication

This manuscript does not contain any identifiable personal data, such as personal names or telephone numbers. All participants and interviewees agreed to the use of their anonymized data and anonymized interview quotes in publication.

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In the writing of this paper, the ChatGPT-5 mini AI tool was used to improve the clarity and fluency of the language. After using this tool, the authors reviewed and revised the text as needed and take full responsibility for the content of the manuscript.

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Disclosure

The authors report no conflicts of interest in this work.

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