UNSUPERVISED BEHAVIORAL AND PELVIC FLOOR MUSCLE TRAINING PROGRAMS THAT TARGET WOMEN'S STORAGE-TYPE LOWER URINARY TRACT SYMPTOMS

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ABSTRACT

Chen Wu: Unsupervised Behavioral and Pelvic Floor Muscle Training Programs That Target Women's Storage-Type Lower Urinary Tract Symptoms
(Under the direction of Mary H. Palmer)

Background: Storage-type lower urinary tract symptoms (LUTS), including urinary incontinence (UI), nocturia, urinary urgency, and urinary frequency, are prevalent and impactful burdens for women that should be addressed by population-level interventions. Unsupervised behavioral and pelvic floor muscle training (B-PFMT) programs are feasible for population-level applications, but evidence for their effectiveness is limited.

Methods: This dissertation comprises three manuscripts based on symptom management theory (SMT). In Manuscript 1, the narrative synthesis is employed to synthesize the effects of unsupervised B-PFMT programs on storage-type LUTS among women. The other manuscripts present secondary analyses of data collected over 24 months from the Translating Unique Learning for Incontinence Prevention (TULIP) study. In Manuscript 2, mixed-effects modeling is used to identify and compare the effects of unsupervised B-PFMT programs on nocturia, urinary urgency, and urinary frequency among postmenopausal women who were assigned to attend a face-to-face class that lasted approximately two hours (*2-hrClass*) or view a 20-minute DVD-delivered video that presented the same information (*20-minVideo*). In Manuscript 3, *k*-means cluster analysis is used to explore women's adherence to pelvic floor muscle exercises (PFME), which constitutes the key component of unsupervised B-PFMT programs. Frequency is

used to describe within- and between-pattern changes over time, and logistic regression models are used to identify theory-derived factors influencing identified patterns.

Results: Unsupervised B-PFMT programs are effective in treating women's UI, but the effect sizes could not be synthesized. Secondary analyses show that unsupervised B-PFMT programs are effective in mitigating nocturia, urinary urgency, and urinary frequency. No significant between-group differences were found except for nocturia at 24 months when the effectiveness favored women in the *20-minVideo* group. Four PFME adherence patterns were identified, and adherence pattern at a later point was associated with the previous pattern. Regulatory self-efficacy and task self-efficacy predicted both short- and long-term PFME adherence.

Conclusions: Unsupervised B-PFMT programs are effective in improving women's storage-type LUTS. SMT is useful in guiding the analyses of intervention effects and factors that can be modified to facilitate program adherence. Future studies should optimize unsupervised B-PFMT programs and expand their application to treat and prevent storage-type LUTS across women's life course.

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CHAPTER 1: INTRODUCTION

Introduction to The Problems

Storage-type lower urinary tract symptoms

Lower urinary tract symptoms (LUTS) are indicators of diseases or changes that affect the structure and/or the function of the bladder and/or urethra, which are the main components of the lower urinary tract (Abrams et al., 2003; Abrams, Cardozo, Wagg & Wein, 2017). LUTS can be divided into three types of symptoms: storage, voiding, and post micturition. Storage-type LUTS, defined as symptoms that are experienced during the storage phase of the bladder, include urinary incontinence (UI), nocturia, urinary urgency, and urinary frequency and constitute the most prevalent type of LUTS, especially in women (Abrams et al., 2003; Milsom et al., 2017). Storage-type LUTS thus are the focus of this dissertation.

'Urinary incontinence' (UI) is defined as "the complaint of any involuntary leakage of urine" and includes three subtypes: stress urinary incontinence (SUI), urgency urinary incontinence (UUI), and mixed urinary incontinence (MUI) (Abrams et al., 2003; Abrams et al., 2017). SUI is defined as "the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing", UUI is defined as "the complaint of involuntary leakage accompanied by or immediately preceded by urgency", and MUI is defined as "the complaint of involuntary leakage associated with urgency and also with exertion, effort, sneezing or coughing" (Abrams et al., 2003; Abrams et al., 2017). The other storage-type LUTS are nocturia, defined as waking at night one or more times to urinate, urinary urgency, defined as the perception of a sudden

compelling desire to urinate that is hard to defer, and urinary frequency, defined as the perception of urinating too often during the day (Abrams et al., 2003; Abrams et al., 2017).

The etiology of storage-type LUTS is not entirely clear. The literature reports that SUI is caused mainly by decreased urethral closure pressure and urethral support (DeLancey, 2010) whereas UUI is commonly attributed to detrusor overactivity during bladder filling (Abrams et al., 2017; Nygaard, 2010). Researchers regard nocturia as caused by nocturnal polyuria, reduced nocturnal bladder capacity (e.g., detrusor overactivity), and polyuria (Bosch & Weiss, 2010; Van Kerrebroeck & Andersson, 2014). Urinary urgency is thought to be controlled primarily by the central nervous system and detrusor myogenic functions (i.e., overt detrusor contractions, myofibroblast abnormalities, and micromotions) (Brubaker, 2004; Michel & Chapple, 2009).

Storage-type LUTS are prevalent conditions in women worldwide. Over the past two decades, evidence from multinational studies shows that the prevalence of any storage-type LUTS is well above 50 percent (Irwin et al., 2006; Sexton et al., 2009; Zhang et al., 2015). In 2018, the number of women aged 20 years and over with any storage-type LUTS was estimated to be 1.7 billion globally (Milsom et al., 2017). Aoki et al. (2017) found that pooled UI prevalence in adult women is approximately 30%, and Milsom et al. (2017) found that UI prevalence increases with age. Melville, Katon, Delaney, and Newton (2005) reported that the UI prevalence for 3,536 women is 28%, 48%, and 53% in age groups of 30 to 39 years, 50 to 59 years, and 70 to 79 years, respectively.

Researchers have found that nocturia prevalence for women aged between 20 and 40 years ranges from 20.4% to 43.9% and for women older than 40 years exceeds 40 percent (Bosch & Weiss, 2010). For example, empirical evidence indicates that 50% of women aged 50 to 59 years reported at least one void per night (Tikkinen, Tammela, Huhtala, & Auvinen, 2006) and

pooled evidence indicates that 77% of women aged 70 years or older reported at least one void per night (Bosch & Weiss, 2010). The prevalence of urinary urgency is reported to be around 20% (Agarwal et al., 2014; Robinson et al., 2018; Zhang et al., 2015) and is associated with aging (Suskind, 2017). Specifically, before the age of 60 years, a gradual increase in urinary urgency occurs, with a leveling off around 70 years and gradual increase in prevalence thereafter (Eapen & Radomski, 2016). For unexplained reasons, of all the storage-type LUTS, urinary frequency is the least studied symptom. One multinational study reported that 3.2% of women reported experiencing urinary frequency (Irwin et al., 2006). No data-based evidence supports the association of the prevalence of urinary frequency with aging or its changes over time.

Storage-type LUTS also create burdens for women and for society in general. Researchers have found that UI directly affects women's quality of life (Abrams, Smith, & Cotterill, 2015; Akkus & Pinar, 2016). Further, UI brings substantial economic burden. The annual cost estimate for UUI management (e.g., diagnosis and treatment costs, and costs associated with comorbid conditions) in the United States was 66 billion United States dollars (USD) in 2007, and in Canada, Germany, Italy, Spain, Sweden, and the United Kingdom was €7 billion (1 € = 1.11 USD) in 2005 (Milsom et al., 2014).

Nocturia disrupts sleep, decreases quality of life, increases falls and fracture incidence, and increases mortality (Fung et al., 2017; Hsu et al., 2015; Kupelian et al., 2012). Nocturia also is associated with substantial economic burden. Using the criterion of waking up at night two or more times to urinate, the annual total cost of nocturia management (e.g., hospitalizations and outpatient visits) in the United States was estimated to be 214.5 billion USD, equivalent to the per-person per-year cost of 3,491 USD (Jhaveri, Gauthier-Loiselle, Gagnon-Sanschagrin, & Wu, 2019). The annual total cost was estimated to be approximately €2.32 billion (1 € = 1.11 USD) in

Germany, €1.77 billion in the United Kingdom, and €0.54 billion in Sweden (Weidlich et al., 2017).

Urinary urgency also has been associated with decreased quality of life among women (Agarwal et al., 2014; Coyne et al., 2004; Robinson et al., 2018). Although direct evidence for the economic cost of urinary urgency management is lacking, the cost of overactive bladder (OAB) management is substantial. OAB is the symptom entity of urinary urgency, urinary frequency, and nocturia with or without UUI, and the core symptom is urinary urgency (Abrams et al., 2003). The annual total cost of OAB management (e.g., medical and non-medical costs and lost productivity) in the United States was estimated at 65.9 billion USD in 2007, 76.2 billion USD in 2015, and 82.6 billion USD in 2020 (Reynolds, Fowke, & Dmochowski, 2016). Limited evidence is available regarding the impact of urinary frequency. One study reported that an inter-void interval that is shorter than every two hours is more bothersome than that of every three to four hours (Lukacz, Whitcomb, Lawrence, Nager, & Luber, 2009). No cost information on urinary frequency is available.

In summary, storage-type LUTS encompass symptoms that are experienced by a large number of women worldwide and have considerable negative impacts on women's lives and society. Global aging may exacerbate problems brought on by these symptoms. Although conservative, pharmacological and surgical treatment options are available for storage-type LUTS, guidelines call for conservative therapies as the first lines of treatment and include physical therapy and behavioral therapies (Gormley et al., 2012; Gormley, Lightner, Faraday, & Vasavada, 2015; Sussman, Syan, & Brucker, 2020). Interventions are needed that target the etiology of storage-type LUTS and are available for population-level applications.

Behavioral and pelvic floor muscle training (B-PFMT) programs: A population-level intervention option

Behavioral therapies such as pelvic floor muscle exercises (PFME), bladder training with urge suppression, the so-called 'Knack', and lifestyle modifications are considered conservative strategies and often are prescribed in combination (Newman & Burgio, 2020; Newman & Wein, 2013); **Table 1.1** provides descriptions of these therapies. They are grouped into multiple component interventions referred to as behavioral and pelvic floor muscle training (B-PFMT) programs.

B-PFMT programs can be delivered in either a supervised or unsupervised format. Supervised B-PFMT programs are conducted under conditions where women travel to a location outside their homes to participate in a program that is offered either as a one-to-one or group-coached intervention, typically provided by pelvic floor specialists (i.e., physical therapists, nurse specialists) for multiple sessions (Pereira, Correia, & Driusso, 2011). Dumoulin et al. conducted a parallel trial with older women to compare the effects of a group-supervised B-PFMT program with a one-to-one supervised B-PFMT program. Women in each group completed a 12-week, 1 hour/week PFME program coached by an experienced pelvic floor physiotherapist (Dumoulin et al., 2020). In contrast to supervised programs, unsupervised B-PFMT programs are conducted under conditions where women participate in a one-time one-to-one or group-delivered education session followed by an independently administered B-PFMT program. Sampselle et al. conducted a parallel trial to compare the effects of unsupervised B-PFMT programs delivered in two formats among women aged 55 years and older. Women received similar one-time education sessions of B-PFMT programs that were delivered by a

trained healthcare provider or via DVD, after which women started self-administration of the B-PFMT program at home (Sampselle et al., 2017).

PFME constitutes the fixed component of B-PFMT programs (Newman & Wein, 2013) but often is operationalized differently across studies, i.e., based on various combinations of short and long muscle contractions and the number of contractions prescribed (Frawley, Dean, Slade, & Hay-Smith, 2017). For example, in one study, women were prescribed ten sets of ten contractions per day (Cavkaytar, Kokanali, Topcu, Aksakal, & Doganay, 2015) whereas women in other studies were prescribed three sets of thirty contractions or three sets of six contractions per day (Diokno et al., 2010; Hung, Chih, Lin, & Tsauo, 2012). In addition to variations in PFME elements, variation across studies is evident in prescribed behavioral therapies that are focused primarily on storage-type LUTS. The 'Knack' often is prescribed with PFME for women with SUI (Asklund et al., 2017; Sjostrom et al., 2013). Bladder training with urge suppression and lifestyle modification with or without the Knack often are prescribed for women with UUI, MUI, and OAB (Fan, Chan, Law, Cheung, & Chung, 2013; Newman & Wein, 2013; Sampselle et al., 2017).

The criterion for population-level applications of interventions is scalability. The transfer of a research intervention that was designed originally for a limited number of participants to a population-level application involves a change of scale, or 'scaling up', which has been defined as "deliberate efforts to increase the impact of successfully tested health innovations so as to benefit more people and to foster policy and programme development on a lasting basis" (World Health Organization & Department of Reproductive Health and Research-ExpandNet, 2010). Prior to any scaling up, the suitability of an intervention for scaling up, i.e., the scalability of the intervention, should be evaluated (Milat, King, Bauman, & Redman, 2013). The effectiveness of

the intervention and the so-called ‘filter criterion’, i.e., feasibility, provide the cornerstone for scalability (Vos et al., 2010; World Health Organization & Department of Reproductive Health and Research-ExpandNet, 2010). An effective intervention may not be scalable due to its lack of feasibility, which is at the heart of scalability (Milat et al., 2013). Therefore, for this dissertation, the scalability potential of both supervised and unsupervised B-PFMT programs was investigated.

Research has consistently corroborated the effectiveness of supervised B-PFMT programs, especially with regard to treatment for women with UI. For example, one systematic review analyzed 31 randomized and quasi-experimental trials and corroborated the effectiveness of supervised B-PFMT programs as UI treatment (i.e., the programs mitigated UI and symptom perceptions and improved quality of life) for women (Cacciari, Dumoulin, & Hay-Smith, 2019). As to UI prevention for women, one review concluded that evidence to support the effectiveness of supervised B-PFMT programs was limited (Palmer et al., 2020). Another review reported that evidence to support the effectiveness of supervised B-PFMT programs to treat OAB in women was inconclusive (Monteiro et al., 2018).

As designed, supervised B-PFMT programs are not feasible for population-level applications. First, an adequate professional workforce is not available in numerous regions and countries to provide the intense level of supervision that is needed for supervised B-PFMT programs. For example, data collected from 69 member organizations of the World Confederation for Physical Therapy revealed that the reported ratio of physical therapists to patients was between 0.02 and 28.2 per 10,000 population (Sykes, Bury, & Myers, 2014). In Japan, the prevalence of UI in women was reported to be 21.7% (Ohta, Hatta, Ota, Yoshikata, & Salvatore, 2020), yet very few of the 2,302 wound, ostomy, and continence nurses had expertise

in incontinence care (Ostaszkiewicz et al., 2018). Second, frequent and possibly long-distance commutes bring challenges to women who participate (or want to participate) in supervised B-PFMT programs. These challenges may hinder women from sustaining their participation in such programs (Valenzuela, Okubo, Woodbury, Lord, & Delbaere, 2018) and may burden women living in rural areas who experience financial stress. Third, repeated tasks, such as scheduling and preparation, that must be undertaken by the workforce in the settings where the programs are conducted create additional work. In addition, dedicated and private space reserved for women to participate in group programs can create logistic difficulties in clinical or community settings. In sum, despite evidence that supports the effectiveness of supervised B-PFMT programs, the feasibility to scale up such programs for population-level applications is lacking.

By contrast, unsupervised B-PFMT programs appear to be feasible for scaling up primarily because they do not rely solely on pelvic floor specialists or physical space to be effective. They can be delivered via DVD, the internet, or mobile apps (Asklund et al., 2017; Sampselle et al., 2017; Sjostrom et al., 2013). Therefore, women who are interested in participating in these programs have no need to travel to clinic and community settings, thus reducing physical barriers to participation. Some empirical studies have identified the effectiveness of unsupervised B-PFMT programs for UI prevention or treatment. One study reported that unsupervised B-PFMT programs can mitigate UI and improve symptom perception and quality of life for women aged 55 years or older within a timeframe of one year (Diokno et al., 2018). The other empirical study reported that unsupervised B-PFMT programs can maintain the continent status of women aged 55 years or older within a timeframe of two years (Sampselle et al., 2017). Evidence is scant for the effectiveness of unsupervised B-PFMT programs for nocturia, urinary urgency, and urinary frequency among women.

In order to scale up unsupervised B-PFMT programs to the population level, more studies are needed to investigate their effectiveness for storage-type LUTS among women. To this end, this dissertation reports the findings of three separate studies that relate to the effectiveness of unsupervised B-PFMT programs for storage-type LUTS in groups of women. These investigations will contribute new knowledge to the scientific literature and will assist with scaling up unsupervised B-PFMT programs to the population level.

Symptom Management Theory

Symptom management theory (SMT) (Dodd et al., 2001; Humphreys et al., 2008) provides the theoretical underpinning for this dissertation; see **Figure 1.1**. SMT is a deductive, middle-range theory that builds on empirical studies of adult patients and is applicable for healthy people. SMT posits that troublesome symptoms can be managed and prevented and that symptom management is a multidimensional process that occurs in the three domains of nursing science: person, health and illness, and environment (Dodd et al., 2001; Humphreys et al., 2008). In SMT, the three domains of nursing science are comprised of variables that may influence individuals' adherence to PFME. The person domain includes demographic, psychological, sociological, and psychological variables that are intrinsic to an individual as well as to the level of development or maturation of an individual. The health and illness domain encompasses variables that are unique to the health or illness state of an individual and includes risk factors, health status, and disease and injury. The environment domain is comprised of contextual variables within which symptom occur and includes physical, social, and cultural variables (Dodd et al., 2001; Humphreys et al., 2008).

The multidimensional symptom management process includes the dimensions of symptom experience, symptom management strategies, adherence, and outcomes. The dimension

of symptom experience (i.e., the perception of symptoms, evaluation of symptoms, and response to symptoms) is not necessary in SMT because interventions may be initiated before the development of the symptom(s). The dimension of symptom management strategies describes interventions in terms of components of who (delivers), what, where, when, why, how much, to whom, and how. These components of symptom management strategies will influence individuals' adherence to the strategy, e.g., the characteristics of the healthcare provider (who) can influence individuals' adherence. 'Adherence' is defined in SMT as "whether the intended recipient of the strategy actually receives or uses the strategy prescribed". The World Health Organization updated the definition of 'adherence' as "the extent to which a person's behavior corresponds with agreed recommendations from a healthcare provider" (Sabaté, 2003). Symptom management strategies influence outcomes, with adherence as the mediator, and the components of symptom management strategies moderate the effects of the strategies on the outcomes. The dimension of outcomes includes symptom status, functional status, emotional status, mortality, morbidity/co-morbidity, quality of life, costs, and self-care (Dodd et al., 2001; Humphreys et al., 2008).

The framework presented in **Figure 1.2** is based on SMT. In Chapter 2 (Manuscript 1), *Unsupervised Behavioral and Pelvic Floor Muscle Training Programs for Storage Lower Urinary Tract Symptoms in Women: A Systematic Review*, the framework is applied with a focus on the relationships among storage-type LUTS, components of unsupervised B-PFMT programs, and outcomes related to storage-type LUTS. Chapter 3 (Manuscript 2), *Effects of Unsupervised Behavioral and Pelvic Floor Muscle Training Programs on Nocturia, Urinary Urgency, and Urinary Frequency in Postmenopausal Women: A Secondary Analysis of the TULIP Study*, addresses the relationships among nocturia, urinary urgency, and urinary frequency (storage-type

LUTS), components of unsupervised B-PFMT programs, and the symptoms status of these three outcomes (i.e., outcomes relevant to storage-type LUTS). In Chapter 4 (Manuscript 3), *Adherence to Pelvic Muscle Exercises among Postmenopausal Women Participating in Unsupervised Behavioral and Pelvic Floor Muscle Training Programs: Preliminary Results*, the framework is applied with a focus on the relationships between variables in the person and health and illness domains and PFME adherence. The reason for the selection of these two domains only (and exclusion of the environment domain) is that adherence to PFME in supervised B-PFMT programs is influenced mainly by the variables within the person domain and the health and illness domain (Borello-France et al., 2013; Dumoulin, Alewijnse, et al., 2015; Frawley, McClurg, Mahfooza, Hay-Smith, & Dumoulin, 2015).

The Three Dissertation Manuscripts

The format of this dissertation is three published/publishable manuscripts preceded by an introductory chapter and followed by a conclusions chapter. Chapter 1 provides an overview of the prevalent and impactful burdens for women who have storage-type LUTS. This chapter reflects on the social significance of employing strategies through B-PFMT programs at the population level. Extending interventions to population-level applications requires the assessment of their scalability, of which feasibility and effectiveness are two key criteria. B-PFMT programs are commonly used interventions to manage storage-type LUTS and are offered in either a supervised format or unsupervised format. Evidence against the feasibility of supervised B-PFMT programs for population-level applications is provided. The focus of this dissertation is thus on unsupervised B-PFMT programs that demonstrate feasibility for scaling up. However, evidence regarding their effectiveness currently is limited. Chapters 2, 3, and 4

(the three separate manuscripts) are designed to explore evidence for the effectiveness of unsupervised B-PFMT programs for storage-type LUTS in women.

Chapter 2 is a published manuscript, *Unsupervised Behavioral and Pelvic Floor Muscle Training Programs for Storage Lower Urinary Tract Symptoms in Women: A Systematic Review*. The aim of this manuscript is to synthesize the effects of unsupervised B-PFMT programs on outcomes that are relevant to women's storage-type LUTS. Data retrieval was completed in consultation with a librarian at the Health Science Library at the University of North Carolina at Chapel Hill (UNC-CH) on August 6th, 2019. The protocol for this review was submitted for registration in the International Prospective Register of Systematic Reviews (PROSPERO) in September 2019; approval was obtained in January 2020 with the registration number CRD42020149503. By pooling evidence for the effectiveness of unsupervised B-PFMT programs on short- and long-term outcomes of storage-type LUTS as defined by the authors of the retrieved articles, the findings from this manuscript enhance the understanding of unsupervised B-PFMT programs to prevent/treat storage-type LUTS among women. This manuscript was accepted for publication by the *International Urogynecology Journal* in August 2020.

Chapter 3 and Chapter 4 report and discuss the findings from secondary analyses using data collected from women aged 55 years and older who did not have UI and were enrolled in a study, *Translating Unique Learning for Incontinence Prevention* (TULIP), funded by a National Institute of Nursing Research Grant (R01NR012011). In order to access the data collected in the TULIP study, the Data Transfer and Use Agreement was signed between the Trustees of the University of Pennsylvania and the UNC-CH. The ethical oversight and approval of the secondary analyses were obtained from the UNC-CH (19-0645) in August 2019 and renewed in

May 2020. The women who enrolled in the TULIP study were provided unsupervised B-PFMT programs. Specifically, each woman was randomly assigned either to attend a face-to-face class that was approximately two hours long (*2-hrClass*) or to view a 20-minute DVD-delivered video that provided the same information (*20-minVideo*) and started self-administration of the program thereafter. Follow-up assessments of nocturia, urinary urgency, urinary frequency, and adherence to PFME were set at 3 months, 12 months, and 24 months after program initiation.

Chapter 3 is a publishable manuscript titled, *Effects of Unsupervised Behavioral and Pelvic Floor Muscle Training Programs on Nocturia, Urinary Urgency, and Urinary Frequency in Postmenopausal Women: A Secondary Analysis of the TULIP Study*. The aims of this manuscript are to determine and compare the effects of the 2-*hrClass* and *20-minVideo* unsupervised B-PFMT programs on the symptom status of nocturia, urinary urgency, and urinary frequency of postmenopausal women with no UI who were enrolled in the TULIP study at the three follow-up time points. Given the current lack of research into the effectiveness of unsupervised B-PFTM programs to mitigate these three symptoms among women, findings from this manuscript will add important evidence to the literature.

Chapter 4 is a publishable manuscript titled, *Adherence to Pelvic Muscle Exercises among Postmenopausal Women Participating in Unsupervised Behavioral and Pelvic Floor Muscle Training Programs: Preliminary Results*. The aims of this manuscript are (1) to explore the patterns of adherence to PFME of women who participated in unsupervised B-PFTM programs delivered in the *2-hrClass* format or *20-minVideo* format at each follow-up time point and the within- and between-pattern changes over time, and (2) to determine the theory-driven factors that influenced the identified adherence patterns. Findings from this manuscript provide evidence with regard to women's adherence to PFME in unsupervised B-PFMT programs.

Importantly, the identified significant factors will help practitioners adopt strategies to facilitate women's adherence to PFME.

Chapter 5 provides a brief review of the research background of the three published/publishable manuscripts followed by a summary of the main findings from these manuscripts, overall discussion of the theoretical framework, and implications for future research and practice.

Table 1.1

Descriptions of Pelvic Floor Muscle Exercises and Behavioral Therapies for Storage-Type Lower Urinary Tract Symptoms

Strategies	Description
Pelvic floor muscle exercises	Repeated voluntary pelvic floor muscle contractions performed by individuals to improve the structural support of the pelvic organs, increase urethral closure pressure, inhibit detrusor muscle contraction, and suppress the micturition reflex (Frawley et al., 2017; Newman & Burgio, 2020; Shafik & Shafik, 2003).
Bladder training with urge suppression	The scheduled voiding prescribed with progressive increases in the intervals between voids until the 3-4 hours voiding interval is achieved. Meanwhile, individuals are recommended to adopt urge suppression strategies like 'squeeze pelvic muscles', 'distract yourself' to control bladder urgency (Newman & Burgio, 2020).
The 'Knack'	Quick pelvic floor muscle contractions that are performed by individuals prior to an event that triggers urine leakage to obtain immediate reduction in the volume of urine leakage and that are theorized to inhibit detrusor muscle contraction (Miller, Ashton-Miller, & DeLancey, 1998; Miller, Sampselle, Ashton-Miller, Hong, & DeLancey, 2008).
Lifestyle modifications	Strategies adopted by individuals that include weight loss, modifications of fluid intake or diet, management of bowel regularity, etc. (Gormley et al., 2012; Sussman et al., 2020; Tse et al., 2016). Weight loss is hypothesized to decrease the intra-abdominal pressure that is increased by obesity and leads to chronic stress on the pelvic floor. Modifications to fluid intake or diet work to decrease irritation on the bladder. Management of bowel regularity can help avoid the denervation of the external anal sphincter and pelvic floor muscles (Wyman, Burgio, & Newman, 2009).

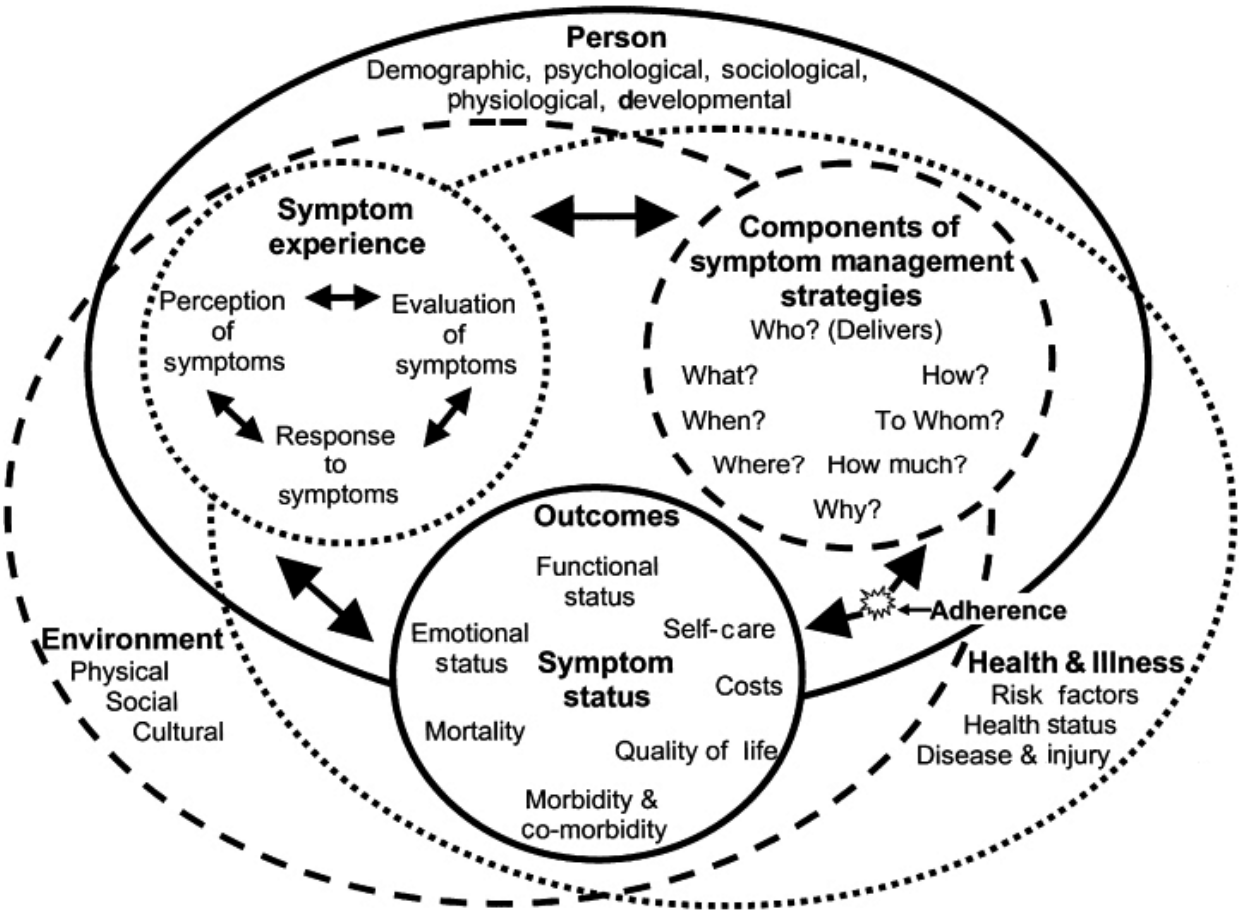

Figure 1.1

Revised UCSF Symptom Management Model. Source: Dodd, Janson, et al. (2001). Reprinted with Permission from Wiley-Blackwell (#4931971428698). The Model Was Renamed 'Symptom Management Theory' in 2008 (Humphrey Et Al., 2008).

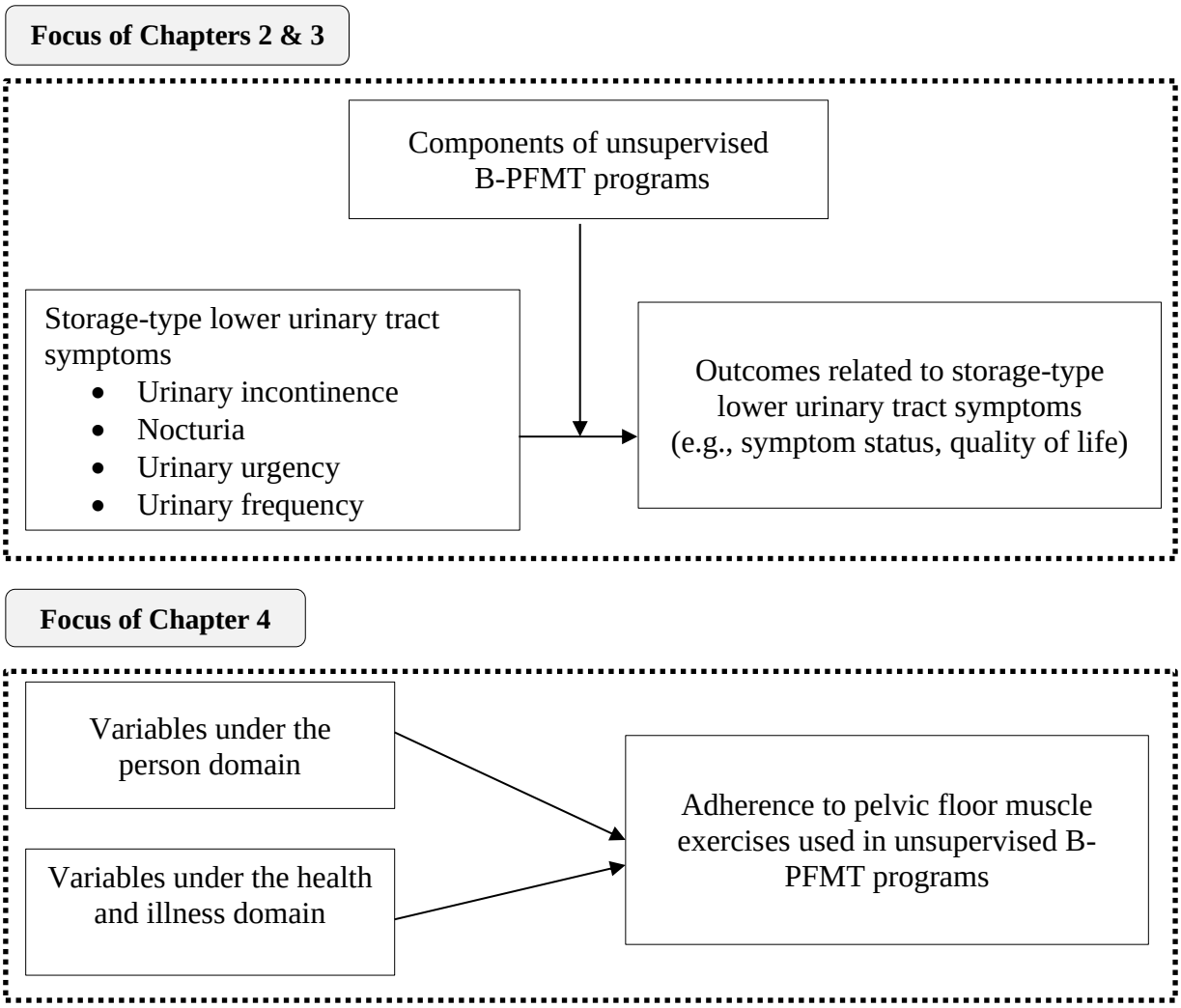

Figure 1.2

Framework of Effectiveness of Unsupervised Behavioral and Pelvic Floor Muscle Training Programs on Storage-Type Lower Urinary Tract Symptoms among Women

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CHAPTER 2: UNSUPERVISED BEHAVIORAL AND PELVIC FLOOR MUSCLE TRAINING PROGRAMS FOR STORAGE LOWER URINARY TRACT SYMPTOMS IN WOMEN: A SYSTEMATIC REVIEW [1]

Introduction

Approximately 2.3 billion of the adult world population experience lower urinary tract symptoms (LUTS), and of those, 1.7 billion are women with storage LUTS (Abrams, Cardozo, Wagg. A., & Wein, 2017). Storage LUTS, i.e., stress urinary incontinence (SUI), urgency urinary incontinence (UUI) and mixed urinary incontinence (MUI), urinary urgency, urinary frequency, and nocturia, have a detrimental impact on women's health-related quality of life (Abrams et al., 2017).To improve women's bladder health, an urgent need exists to disseminate evidence-based programs for storage LUTS to large groups or populations of women. This process, scaling up of interventions, is complex. The World Health Organization (WHO) noted the core components for any scaling-up attempt, where an intervention's effectiveness for representative samples and its scaling-up feasibility are considered (World Health Organization & Department of Reproductive Health and Research-ExpandNet, 2010).

Behavioral and pelvic floor muscle training (B-PFMT) programs are commonly used interventions to prevent and treat storage LUTS in women (Lamin, Parrillo, Newman, & Smith, 2016; Newman & Wein, 2013; Newman & Wein, 2009), specifically SUI. A core component of these programs is pelvic floor muscle exercise (PFME) with quick pelvic floor muscle

[1] Adapted by permission from Springer Nature Customer Service Centre GmbH: Springer Nature. International Urogynecology Journal. Unsupervised behavioral and pelvic floor muscle training programs for storage lower urinary tract symptoms in women: a systematic review, Wu, C., Newman, D.K. & Palmer, M.H., 2020.

contractions prior to an event triggering urine leakage, also known as the Knack, to prevent UI by inhibiting detrusor contraction (Newman, Borello-France, & Sung, 2018; Newman & Burgio, 2016). In women who have UUI and MUI, behavioral components including lifestyle modification, bladder training with urge suppression strategies are often combined with PFME as part of an multi-component B-PFMT program (Newman, et al., 2018; Newman & Burgio, 2016). These programs can be categorized as either supervised or unsupervised.

Supervised B-PFMT programs are conducted under conditions where women come to medical offices or clinics according to specified training intervals and participate in either individualized or group coached intervention that are typically provided by pelvic floor specialists (i.e., nurse specialists, physical therapists) (Pereira, Correia, & Driusso, 2011). A body of evidence exists for the effectiveness of supervised programs that aim to prevent and treat female storage LUTS in different age cohorts and stages of life (Cacciari, Dumoulin, & Hay-Smith, 2019; Monteiro et al., 2018; Palmer et al., 2020). Although supervised programs are highly recommended (Bo et al., 2017), they, by their nature, have limited feasibility to scale up to large groups or populations.

An inadequate number of qualified providers in clinical or community settings globally is a significant barrier to providing the intense level of supervision required by the program. As an example, the ratio of physical therapists to patients is lower than 1:1000 in Australia, the UK, the USA, and Canada, and the ratio is 1:100,000 in China (Jones & Skinner, 2013). The limited number of continence nurse specialists available in many countries is also concerning. Approximately 250 and 100 registered nurses specialize in continence nursing in Australia and Canada, respectively. Although 2,302 nurses in Japan were certified as the wound, ostomy, and

continence nurses in 2016, few had specialist knowledge and skills in the management of incontinence (Ostaszkiewicz et al., 2018).

Besides workforce implications, women enrolled in supervised programs can face challenges. Because women need to travel to and from clinical locations, travel can act as a barrier to accessing care over time, especially for women living in rural areas. Frequent and long-distance transportations are reported as the barriers for sustaining exercise programs for individuals (Valenzuela, Okubo, Woodbury, Lord, & Delbaere, 2018), and challenges women who live in rural areas may lead to increased physical, psychological, and/or financial stress (Field, 2019). Because women are required to return for repeated visits to the setting where supervised programs are delivered, ancillary tasks of scheduling, preparing for, and following up from appointments can create additional work for the staff. When offering supervised programs to large numbers of women, dedicated and private space is needed which can create logistic difficulties for clinic and community settings.

Unsupervised B-PFMT programs have been reported in the literature, and they are implicitly defined and typically reported to have two components: (1) provision of a single education session offered in face-to-face or non-face-to-face modalities to introduce participants to the programs and provide them with necessary information and materials and (2) participants' active self-administration of all aspects of the B-PFMT programs (Newman & Wein, 2013).

Because of the participants' independent role in these programs, they could avoid the aforementioned issues of feasibility posed by supervised programs. Moreover, unsupervised B-PFMT programs are acceptable to women. Qualitative evidence demonstrated that women who participated in unsupervised B-PFMT programs felt confident about self-training and thought it enabled them to assume responsibility for their symptom management (Asklund, Samuelsson,

Hamberg, Umefjord, & Sjostrom, 2019). Evidence of effectiveness is an important criterion for assessing the scalability of interventions. Therefore, we conducted this review to synthesize evidence of the effectiveness of unsupervised B-PFMT programs on improving storage LUTS outcomes including symptoms, severity, impact, self-reported symptom improvement, and pelvic floor muscle strength (PFMS) among adult community-dwelling women. Findings from this study may provide evidence for scaling up these programs in women living in the community.

Methods

Search strategy

The systematic review was registered in PROSPERO (CRD42020149503). The report of this systematic review was guided by the Preferred Reporting Items for Systematic Review and Meta-analysis (PRISMA) statement (Moher, Liberati, Tetzlaff, & Altman, 2009). Articles with women aged ≥ 18 years as participants were deemed eligible; other inclusion criteria for articles were: (1) ≥ 2 arm randomized controlled trials (RCTs) comparing effects of unsupervised B-PFMT intervention group(s) with control group(s) or with parallel intervention group(s); (2) quasi-experimental articles (i.e. articles using nonequivalent control group designs, pretest-posttest design, or interrupted time series design) reporting the effects of unsupervised B-PFMT programs; (3) short- and long-term outcomes relevant to storage LUTS, as defined by authors of retrieved studies, including symptoms, severity, impact, self-reported symptoms' improvement, and PFMS. Exclusion criteria for articles were: (1) case study/series, commentary, intervention protocol, and all type of review articles; (2) trials that combined B-PFMT programs with surgery or drug therapy; (3) women who were athletes, soldiers, described as frail, pregnant, and had cognitive impairment, multiple sclerosis, stroke, or lung disease; (4) women who were performing biofeedback-assisted PFME or PFME using vaginal cones or electrical stimulation.

In consultation with a Health Sciences Library librarian, four databases-PubMed, CINAHL, Web of Science, and PsycINFO-were retrieved using search strings listed in **Table S2.1**. We searched the databases from their dates of inception through the last search date of August 6, 2019, and the language filter used for all databases was English.

Data extraction

The data extraction process was predominantly completed by two independent researchers. The titles and abstracts of the articles retrieved were assessed via Covidence (www.covidence.org) by rating the relevance of each article with "yes", "maybe", or "no" following the inclusion and exclusion criteria. The full texts for all articles rated as "yes" and "maybe" were further reviewed and assessed under the same criteria, and the final set of articles was determined by the reviewers. The data extraction form was developed by referring to the Data Collection Form for Intervention Review-Randomized Trials and Non-randomized trials from the Cochrane Collaboration (https://airways.cochrane.org/data-collection). After pilot testing this form with eligible articles, it was then used to extract data. Any inconsistent rating arising between two researchers during the above steps was resolved by discussion and consensus. No direct contact with the authors of retrieved articles to gather additional or undisclosed information was made.

Risk of bias

The risk of bias for eligible articles was independently assessed by two researchers. The results were judged as "low", "some concerns", or "high" for RCTs by summarizing rating categories under five domains included in the tool of assessing risk of bias in randomized trials (RoB2) (Sterne et al., 2019). The risk of bias for quasi-experimental articles was evaluated as "the least risk of bias", "some risk of bias", or "significant risk of bias" by using 12-item

"Quality Assessment Tool for Before-After (Pre-Post) Articles With No Control Group" developed by National Heart, Lung, and Blood Institute and Research Triangle Institute International (www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools). Two researchers discussed their ratings to reach consensus. If consensus could not be achieved, quality adjudication was forwarded to a methodologist external to the study whose expertise was in design and statistical methods.

Data synthesis

Variations existed in the: (1) methods used and providers recruited to deliver information or provide educational resource materials to participants, (2) information delivered in the education session and included in the PFME elements, and (3) primary and secondary outcomes measures and their grading systems as well as analytic plans used. Because of these heterogeneities, pooling evidence to obtain an average number for effect size using meta-analysis was not applicable for this study (Fletcher, 2007). Therefore, we used Popay et al. narrative synthesis approach which demonstrated comparable synthesis power as meta-analysis to synthesize quantitative evidence in this review (Popay et al., 2006).

Results

Identification of articles

Our initial search strategy yielded 1,388 articles including 368 duplicates across 4 databases. After title and abstract screening, 41 articles were moved to full-text screening. After the full-text screening, 13 articles remained eligible for this systematic review. **Figure 2.1** depicts the selection process.

Summary of included articles

Table 2.1 outlines the overall characteristics of 13 eligible articles. Ten of the 13 articles were randomized controlled trials (RCTs) (Asklund et al., 2017; Diokno et al., 2018; Diokno et al., 2010; Diokno et al., 2004; Hoffman, Söderström, & Samuelsson, 2017; Pereira-Baldon, Avila, Dalarmi, de Oliveira, & Driusso, 2019; Sampselle et al., 2017; Sari & Khorshid, 2009; Sjostrom et al., 2013, 2015) and 3 used pretest-posttest designs (Cavkaytar, Kokanali, Topcu, Aksakal, & Doganay, 2015; Fan, Chan, Law, Cheung, & Chung, 2013; Hung, Chih, Lin, & Tsauo, 2012). Most of the studies (8/13) were from western countries, including the USA (n = 4) (Diokno et al., 2018; Diokno et al., 2010; Diokno et al., 2004; Sampselle et al., 2017) and Sweden (n = 4) (Asklund et al., 2017; Hoffman et al., 2017; Sjostrom et al., 2013, 2015); three articles were from Turkey (n = 2) (Cavkaytar et al., 2015; Sari & Khorshid, 2009) and Brazil (n = 1) (Pereira-Baldon et al., 2019), and two articles were from developed regions of China, i.e., Taiwan (Hung et al., 2012) and Hong Kong (Fan et al., 2013).

UI was the sole targeted storage LUTS identified in all the articles. In ten articles, the aim was to treat UI (Asklund et al., 2017; Cavkaytar et al., 2015; Diokno et al., 2018; Diokno et al., 2010; Fan et al., 2013; Hoffman et al., 2017; Hung et al., 2012; Sari & Khorshid, 2009; Sjostrom et al., 2013, 2015), while the aim was to prevent UI in two articles (Diokno et al., 2004; Sampselle et al., 2017). The aim of one article was to investigate the relationship between the frequency of PFME per day and pelvic floor muscle function (Pereira-Baldon et al., 2019) [32]. In ten articles that reported UI treatment: women with unspecified UI, i.e., no UI type described, were enrolled in three articles (Diokno et al., 2010; Fan et al., 2013; Hung et al., 2012), women with SUI were enrolled in four articles (Asklund et al., 2017; Hoffman et al., 2017; Sjostrom et al., 2013, 2015), women with either SUI or MUI were enrolled in two articles (Cavkaytar et al.,

2015; Sari & Khorshid, 2009), and in one article women with either SUI or UUI were enrolled (Diokno et al., 2018). In one article, women without pelvic floor muscle dysfunction were enrolled (Pereira-Baldon et al., 2019).

There were 2,469 participants in the eligible articles. Women's ages ranged between 41 and 67 years in 12 articles, and between 24 and 26 years old in 1 article (Pereira-Baldon et al., 2019). The methodological evaluation demonstrated some concerns for bias in five of the ten RCTs (Diokno et al., 2018; Diokno et al., 2010; Diokno et al., 2004; Pereira-Baldon et al., 2019; Sampselle et al., 2017), and high risk of bias for the remaining five RCTs (Asklund et al., 2017; Hoffman et al., 2017; Sari & Khorshid, 2009; Sjostrom et al., 2013, 2015). Of three pretest-posttest articles, one article had the least risk of bias (Hung et al., 2012) and two articles had some risk of bias (Cavkaytar et al., 2015; Fan et al., 2013).

Components of unsupervised B-PFMT programs

Table S2.2 summarizes components of unsupervised B-PFMT programs reported in the eligible articles.

Education session

The method of delivery. Eight of 13 articles described face-to-face education sessions including group delivery (n = 4) (Diokno et al., 2018; Diokno et al., 2010; Diokno et al., 2004; Sampselle et al., 2017) and one-on-one delivery (n = 4) (Fan et al., 2013; Hung et al., 2012; Pereira-Baldon et al., 2019; Sari & Khorshid, 2009). Five articles described non face-to-face interactions including the use of emails, mailed materials, mobile App, and DVDs to deliver information (Asklund et al., 2017; Hoffman et al., 2017; Sampselle et al., 2017; Sjostrom et al., 2013, 2015), and one article did not report the method used to deliver information (Cavkaytar et al., 2015).

Provider(s). Those who provided face-to-face education sessions included a urologist (n = 1) (Diokno et al., 2004), (trained) nurses specialist (n = 3) (Diokno et al., 2010; Diokno et al., 2004; Sampselle et al., 2017), physical therapist (n = 2) (Hung et al., 2012; Pereira-Baldon et al., 2019), trained interventionist (n = 1) (Diokno et al., 2018), and continence advisor (n = 1) (Fan et al., 2013). One article did not describe background or discipline of the provider(s) (Sari & Khorshid, 2009).

Information provided. PFME instructions were provided to all of the women; however, there was variation in the other information women received. Researchers in 12 articles reported that participants were taught how to locate and contract their pelvic floor muscle (Asklund et al., 2017; Cavkaytar et al., 2015; Diokno et al., 2018; Diokno et al., 2010; Diokno et al., 2004; Fan et al., 2013; Hoffman et al., 2017; Hung et al., 2012; Pereira-Baldon et al., 2019; Sari & Khorshid, 2009; Sjostrom et al., 2013, 2015), in seven articles researchers used either vaginal palpation (n = 6) (Cavkaytar et al., 2015; Diokno et al., 2010; Diokno et al., 2004; Hung et al., 2012; Pereira-Baldon et al., 2019; Sari & Khorshid, 2009) or having women draw-in their perineum or anus and contract their perineal muscles (n = 1) (Cavkaytar et al., 2015) as safeguards against incorrect practice. Ten articles reported that researchers provided information to increase participants UI knowledge (Asklund et al., 2017; Diokno et al., 2018; Diokno et al., 2010; Diokno et al., 2004; Hoffman et al., 2017; Hung et al., 2012; Sampselle et al., 2017; Sari & Khorshid, 2009; Sjostrom et al., 2013, 2015); nine articles reported that researchers provided participants information about lifestyle modifications (Asklund et al., 2017; Diokno et al., 2018; Diokno et al., 2010; Diokno et al., 2004; Fan et al., 2013; Hoffman et al., 2017; Sampselle et al., 2017; Sjostrom et al., 2013, 2015); five articles reported that researchers provided participants with anatomical information for both the pelvis/pelvic floor and the lower urinary tract (Diokno

et al., 2018; Diokno et al., 2010; Diokno et al., 2004; Hung et al., 2012; Sari & Khorshid, 2009); three articles reported that researchers provided participants anatomical information about the pelvis/pelvic floor only (Asklund et al., 2017; Hoffman et al., 2017; Sampselle et al., 2017). Two articles reported researchers taught participants the "Knack" and bladder training (Diokno et al., 2018; Sampselle et al., 2017), five articles reported researchers taught participants the "Knack" only (Asklund et al., 2017; Hoffman et al., 2017; Sari & Khorshid, 2009; Sjostrom et al., 2013, 2015), and two articles reported researchers taught participants the bladder training only (Diokno et al., 2010; Diokno et al., 2004). One article reported researchers provided participants with information about neural control of the lower urinary tract (Diokno et al., 2004).

Self-administered training

Elements of PFME. Elements of PFME were reported in 9 of 13 articles (Asklund et al., 2017; Cavkaytar et al., 2015; Fan et al., 2013; Hoffman et al., 2017; Hung et al., 2012; Pereira-Baldon et al., 2019; Sari & Khorshid, 2009; Sjostrom et al., 2013, 2015) and included repetition, frequency of exercises, and duration of exercises. Information covered by these elements varied across articles except for the frequency of exercises: 3 sets per day was reported in seven articles (Asklund et al., 2017; Cavkaytar et al., 2015; Hoffman et al., 2017; Hung et al., 2012; Sari & Khorshid, 2009; Sjostrom et al., 2013, 2015).

Reinforcement strategies. Ten articles reported the reinforcement strategies researchers used in their programs (Asklund et al., 2017; Cavkaytar et al., 2015; Diokno et al., 2018; Diokno et al., 2010; Diokno et al., 2004; Fan et al., 2013; Hoffman et al., 2017; Sari & Khorshid, 2009; Sjostrom et al., 2013, 2015). Specifically, four articles reported that face-to-face contacts with participants were used for re-assessing the correct contraction of pelvic floor muscle at 10 days (n = 1) (Cavkaytar et al., 2015), at 2 to 4 weeks (n = 2) (Diokno et al., 2010; Diokno et al., 2004)

[23, 25], at 3 months, and 6 to 9 months (n = 1) (Fan et al., 2013) after the intervention initiation. Researchers in four articles applied strategies to promote adherence (Asklund et al., 2017; Diokno et al., 2018; Hoffman et al., 2017; Sari & Khorshid, 2009), by either providing weekly telephone contacts or a magnetized reminder that displayed the project logo to serve as a discrete reminder to follow the program (n = 2) (Diokno et al., 2018; Sari & Khorshid, 2009), or contacting participants through an email at 4 weeks, or allowing participants to create three reminders per day in a mobile App after the intervention initiation (n = 2) (Asklund et al., 2017; Hoffman et al., 2017). Two articles reported that researchers provided participants timely support and answered questions initiated by participants through email (Sjostrom et al., 2013, 2015), and one study reported that researchers initiated telephone contact with the participants on a weekly basis to answer questions participants raised (Sari & Khorshid, 2009).

Outcome assessment tools

Table 2.2 describes all the measures used to assess outcomes.

(1) Symptoms diagnostic/screening tools (n = 8) included 2- or 3-day bladder diary (n = 7) (Asklund et al., 2017; Diokno et al., 2018; Diokno et al., 2010; Diokno et al., 2004; Hung et al., 2012; Sari & Khorshid, 2009; Sjostrom et al., 2013), 1-h or 24-h pad test (n = 3) (Diokno et al., 2018; Diokno et al., 2010; Sari & Khorshid, 2009), and paper towel test (n = 3) (Diokno et al., 2018; Diokno et al., 2010; Sampselle et al., 2017); two articles included all three tools (Diokno et al., 2018; Diokno et al., 2010), and one article included the first two tools (Sari & Khorshid, 2009).

(2) Symptom severity assessment tools (n = 9) included the standardized Medical Epidemiologic and Social aspects of Aging questionnaire (MESA) (n = 2) (Diokno et al., 2018; Diokno et al., 2004), the Sandvik Severity Index (n = 1) (Diokno et al., 2010), Severity Index

Score (n = 1) (Hung et al., 2012), the Indevus Urgency Severity Scale (IUSS) (n = 1) (Sampselle et al., 2017), and the International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form (ICIQ-UI SF) (n = 6) (Asklund et al., 2017; Diokno et al., 2018; Hoffman et al., 2017; Sampselle et al., 2017; Sjostrom et al., 2013, 2015). Two articles included two tools, i.e., the IUSS and ICIQ-UI SF (Sampselle et al., 2017) and MESA and ICIQ-UI SF (Diokno et al., 2018), respectively.

(3) PFMS assessment tools (n = 7) included digital palpation (n = 6) (Cavkaytar et al., 2015; Diokno et al., 2018; Diokno et al., 2010; Diokno et al., 2004; Hung et al., 2012; Pereira-Baldon et al., 2019) and pressure perineometer (n = 1) (Sari & Khorshid, 2009).

(4) Perceived symptom improvement assessment tools (n = 7) included one self-reported improvement question (n = 1) (Hung et al., 2012) and the Patient Global Impression of Improvement (PGI-I) (n = 6) (Asklund et al., 2017; Cavkaytar et al., 2015; Diokno et al., 2018; Hoffman et al., 2017; Sjostrom et al., 2013, 2015).

(5) Symptom impacts assessment tools (n = 9) included the Symptom Impact Index (n = 1) (Hung et al., 2012), the Incontinence of Quality of Life (I-QOL) (n = 2) (Diokno et al., 2018; Sari & Khorshid, 2009), the Urogenital Distress Inventory-6 (UDI-6) (n = 2) (Cavkaytar et al., 2015; Fan et al., 2013), the Incontinence Impact Questionnaire short form (IIQ-7) (n = 2) (Cavkaytar et al., 2015; Fan et al., 2013), the International Consultation on Incontinence Questionnaire-Lower Urinary Tract Symptoms Quality of Life (ICIQ-LUTSqol) (n = 4) (Asklund et al., 2017; Hoffman et al., 2017; Sjostrom et al., 2013, 2015), and the EuroQol 5D-Visual Analogue Scale (EQ5D-VAS) (n = 2) (Sjostrom et al., 2013, 2015). Two articles included both the UDI-6 and IIQ-7 (Cavkaytar et al., 2015; Fan et al., 2013), and two articles included both the ICIQ-LUTSqol and EQ5D-VAS (Sjostrom et al., 2013, 2015).

Outcome synthesis of studies

Table S2.3 describes outcomes assessed by symptom diagnosis/screening tools.

Bladder diary

UI treatment. Two articles reported significant reduction of number of voids for the intervention group (at least 6-8 weeks post intervention) compared to the control group (Diokno et al., 2018; Diokno et al., 2010).Three articles reported the significant reduction of the number of UI episodes after at least 2 months' intervention for the intervention group compared to the control group (Asklund et al., 2017; Diokno et al., 2018; Sari & Khorshid, 2009); one article reported a comparably significant reduction of the number of UI episodes for two parallel groups (i.e., an internet intervention administered group and a postal intervention administered group) after 4 months' intervention (Sjostrom et al., 2013). One pretest-posttest article reported significant reduction in the number of voids and the number of UI episodes after 4 months' intervention (Hung et al., 2012).

UI prevention. One article reported that continent participants had a significant reduction of the number of voids at 12 months after intervention for the intervention group compared to the control group (Diokno et al., 2004).

Pad test

UI treatment. Two articles reported no significant advantages of the intervention group over the control group on urine leakage reduction in grams assessed by 24-hour pad test after 6 to 8 weeks' intervention, but significantly fewer grams of urine leakage in the intervention group versus that in the control group at 3 months and 12 months (Diokno et al., 2018; Diokno et al., 2010). One article reported a significantly greater reduction in grams of urinary leakage assessed

by the 1-h pad test for the intervention group than that in the control group from baseline to 2 months (Sari & Khorshid, 2009).

Paper towel test

UI treatment. Two articles reported a significant reduction in mean leak diameter (i.e., the sum of orthogonal diameters of the wet area divided by two) after 6 to 8 weeks' intervention or lower percentage of participants having a positive paper towel test at 3 months and 12 months in the intervention group versus that in the control group (Diokno et al., 2018; Diokno et al., 2010).

UI prevention. One article enrolled continent participants in two parallel groups (i.e., a class intervention administered group and a DVD intervention administered group) and reported neglectable changes in the paper towel test results between baseline and each of three follow-up time points for each group (Sampselle et al., 2017).

Table S2.4 provides outcomes measured by symptom severity assessment tools.

ICIQ-UI SF

UI treatment. Four articles reported significant reductions in post-intervention scores, with the mean differences (MD) ranging from 2.9 to 3.9 from baseline (with the score rated 10 and above) to 3 months, 12 months and 24 months (Asklund et al., 2017; Hoffman et al., 2017; Sjostrom et al., 2013, 2015), but the differences in the intervention effect across time points were not presented by these data. One article reported that the ICIQ-UI SF scores decreased 1.96 points on average every 3 months for the intervention group, which was significantly larger than that for the control group; the average reduction was 0.98 (Diokno et al., 2018). Two articles reported comparably significant reductions in scores between two parallel groups (i.e., an internet intervention administered group and a postal intervention administered group) of

participants at the following measurement intervals: from baseline to 3 months, 12 months, and 24 months (Sjostrom et al., 2013, 2015).

UI prevention. One article reported comparable reductions in scores between two parallel groups (i.e., a class intervention administered group and a DVD intervention administered group) of participants at the following measurement intervals: baseline to 3 months, 12 months, and 24 months (Sampselle et al., 2017).

MESA

UI treatment. For participants who had SUI and those who had UUI, one article reported the median sum scores of all items of MESA were significantly lower for the intervention group than those for the control group at 3 months and 12 months (Diokno et al., 2018).

UI prevention. Instead of addressing all items in MESA, researchers in one article enrolled continent participants and operationalized continence as both having no leakage and having leakages no more than 5 days in the past 12 months. They reported the odds of having no leakage at 12 months for participants in the intervention group was 2.03 times (95% CI 1.04-3.98, $p = 0.04$) that for participants in the control group. They also reported that the odds of continence status remaining unchanged and transitioning from no more than 5 days to no leakage from baseline to 12 months for participants in the intervention group was 1.97 times (95% CI 1.15-3.98, $p = 0.01$) that for participants in the control group (Diokno et al., 2004).

Other severity tools

UI treatment. One article used the Sandvik Severity Index to classify UI into three severity categories, i.e., slight, moderate, and severe based on frequency and amount of urine leakage at baseline and 6 to 8 weeks post-intervention. There was a significant decrease in the percentage of participants in the moderate cluster (47.8% to 21.7%, $p = 0.03$), and there was a

significant increase in the percentage of participants in the slight cluster (17.4% to 56.5%, p = 0.036). There were no significant changes for participants in the control group in each severity category (Diokno et al., 2010). One article reported a significant decrease in UI severity assessed by Severity Index Score after a 4-month intervention, i.e., the median score changed from six at baseline to three at 4- months, with $p < 0.001$ (Hung et al., 2012).

UI prevention. One article reported there was not significantly different amelioration in urinary urgency severity assessed by IUSS between two parallel groups (i.e., class intervention administered group and the DVD intervention administered group) of participants from baseline to 3 months, 12 months, and 24 months (Sampselle et al., 2017).

Table S2.5 describes PFMS assessed by digital palpation and pressure perineometer.

Digital palpation

UI treatment. Using grading on the Brink scoring system, one article reported a significant increase in scores for pressure, displacement, and duration after 6 to 8 weeks of intervention while in the control group, a significant increase was found for displacement (Diokno et al., 2010). One article reported no significant differences between the intervention group and the control group at baseline, 3 months, and 12 months in percentages of participants who were graded 4, 5, or 6 for pressure and who were graded 4 or 5 for displacement and in median scores for duration (Diokno et al., 2018). Using grading on the Modified Oxford Scale, two pretest-posttest articles reported significant increases in PFMS at 2- and 4-month post-intervention (Cavkaytar et al., 2015; Hung et al., 2012).

UI prevention. Using grading on the Brink scoring system, one article reported there were significantly higher scores of pressure and displacement at 12 months and significantly higher increases in these scores from baseline to 12 months for continent participants in the

intervention group versus those in the control group (Diokno et al., 2004). Using grading on the Modified Oxford Scale, one article reported a significant increase in PFMS for participants doing PFME once daily and those doing PFME three times daily when assessed at 2 months after the intervention initiation. There were no significant differences in PFMS between the two groups at baseline and at 2 months (Pereira-Baldon et al., 2019).

Pressure perineometer

UI treatment. One article reported the increases in the mean contraction pressure and maximum contraction pressure of pelvic floor muscle were significantly greater for participants in the intervention group than for those in the control group (Sari & Khorshid, 2009).

Table S2.6 describes outcomes assessed by perceived symptom improvement assessment tools.

PGI-I

UI treatment. Grading on a 7-point Likert scale from "very much better" to "very much worse", two articles reported that the percentages of participants with their UI getting much better or very much better were significantly higher in the internet group than those in the postal group at 4 months (40.9% versus 26.5%, $p = 0.01$) and at 24 months (39.2% versus 23.8%, $p = 0.03$), but the significant difference was not observed at 12 months (Sjostrom et al., 2013, 2015). One article reported that significantly more participants in the intervention group said their UI was much better or very much better than those in the control group (Asklund et al., 2017). One article reported the percentage of participants who said that their UI was much better or very much better was significantly higher in the intervention group than that in the control group at 3 months (46.9% versus 8.1%, $p < 0.001$) and at 12 months (64.3% versus 11.3%, $p < 0.001$) (Diokno et al., 2018). Another article reported that 66.7% of participants in the intervention

group reported their leakages were much better or very much better assessed at 24 months (Hoffman et al., 2017). Grading on yes/no improvement responses, an article reported findings from a pretest-posttest study in which the percentage of participants with SUI who graded on "yes" was significantly higher than those with MUI (68.4% versus 41.2%, $p = 0.01$) at 2 months (Cavkaytar et al., 2015).

One self-reported improvement question

UI treatment. One pretest-posttest article reported that 75% of participants reported their UI "improved" and "cured" at 4 months (Hung et al., 2012).

Table S2.7 describes outcomes evaluated by symptom impacts assessment tools.

ICIQ-LUTSqol

UI treatment. Two articles reported significant reductions in scores for both the internet group and postal group from baseline to 4 months ($MD_{internet} = 5.8$; $MD_{postal} = 4.8$), to 12 months ($MD_{internet} = 6.1$; $MD_{postal} = 5.8$), and to 24 months ($MD_{internet} = 7.1$; $MD_{postal} = 6.4$) (Sjostrom et al., 2013, 2015), but there were no significant differences in reductions between groups; two articles reported significant reductions in scores for the intervention group from baseline to 3 months (MD = 4.8) and to 24 months (MD = 4.0), and participants in the intervention group had a significantly lower score than those in the control group at 3 months (Asklund et al., 2017; Hoffman et al., 2017).

I-QOL

UI treatment. One article reported the increases of total scores and scores for each of three domains (i.e., avoidance and limiting behavior, psychosocial impacts, and social embarrassment) were significantly higher for the intervention group than those for the control group from baseline to 2 months (23.19 ± 11.43 versus -5.74 ± 6.26, $p < 0.01$) (Sari & Khorshid,

2009). One article reported the total scores were significantly higher for the intervention group than those for the control group at 3 months (median: 86 versus 83, $p < 0.001$) and at 12 months (median: 92 versus 85, $p < 0.001$) (Diokno et al., 2018).

UDI-6 and IIQ-7

UI treatment. Two pretest-posttest articles reported significant reduction in UDI-6 and IIQ-7 scores for participants with UI (MD $_{UDI-6}$ = 8.6, MD $_{IIQ-7}$ = 7.3), with SUI (MD $_{UDI-6}$ = 26.1, MD $_{IIQ-7}$ = 21.9) and with MUI (MD $_{UDI-6}$ = 13.1, MD $_{IIQ-7}$ = 15.2) (Fan et al., 2013; Hung et al., 2012). One of them also reported the reduction in UDI-6 and IIQ-7 scores were significantly larger for participants with SUI than for those with MUI (Cavkaytar et al., 2015).

EQ5D-VAS

UI treatment. Two articles reported a significant increase in scores for participants in the internet group from baseline to 4 months (MD = 4.2) and to 24 months (MD = 4.2), but there were no significant differences in score increases between participants in the internet group and those in the postal group (Sjostrom et al., 2013, 2015).

Symptom impact index

UI treatment. One article reported significant reductions in scores for four items (i.e., the number of worries, the number of activities affected, avoiding activities because of worrying about leakages, and avoiding activities because of needing a toilet) from baseline to 4 months (Hung et al., 2012).

Discussion

This review provides evidence that unsupervised B-PFMT programs for middle-aged women who have UI are appropriate for scaling up to the population level. With the high prevalence and impact burden of storage LUTS, especially UI, efforts to provide population-

based interventions are needed. Synthesized evidence resulting from this study identifies characteristics of women most often studied, unpacks unsupervised B-PFMT programs into their components, describes outcome assessment modules, and provides accumulated evidence supporting the effectiveness of these programs on treating women's UI. This evidence also indicates that unsupervised B-PFMT programs appear to be a promising scaling up approach while providing important guidance for scaling up attempts with unsupervised B-PFMT programs.

Women with UI represented the majority of participants in the eligible articles (n = 10) and were mostly middle-aged (i.e., 40 to 60 years old); three articles describe prevention-focused unsupervised B-PFMT programs, i.e., women who did not have UI (n = 2) or pelvic floor muscle dysfunction (n = 1). Few articles were located that primarily enrolled women < 40 or > 60 years old. Unsupervised B-PFMT programs have not been tested in the prevention or treatment of storage LUTS other than UI. These include nocturia, urinary urgency, and urinary frequency in women across the life course. Future studies are recommended to address these gaps to advance science of preventing and treating storage LUTS among women.

Unsupervised B-PFMT programs are conceptually defined as having a one-time education session followed by a long-term self-administered training program. There are, however, variations in how some researchers operationalize such programs. First, multiple modalities for information delivery were used in the education session, including group and individual delivered, face-to-face and non-face-to-face delivered (i.e., mailing materials and adopting DVD, internet, and mobile Apps). Second, although the information delivered in education session generally adhered to UI conservative behavioral management guidelines, including PFME, bladder training, and lifestyle modification, variations exist with the inclusion

of other information, e.g., teaching information about female anatomy of the lower urinary tract, UI, and/or nervous system controlling the lower urinary tract. It remains unknown if the type of information delivered in an education session influences the quality and quantity of subsequent self-administered training. Third, information about the elements of PFME in the published articles included repetition, frequency of exercises, and duration of exercise. Except for exercise frequency in the form of three sets per day, information for the other elements differed dramatically across articles. This variation makes replicating and building on research findings challenging. The use of checklists in publications, such as consensus on exercise reporting template (CERT) (Slade, Dionne, Underwood, & Buchbinder, 2016) and template for intervention description and replication (TIDieR) (Hoffmann et al., 2014), are recommended for future studies.

Unfortunately, little information was reported about participants' practice of lifestyle modification, bladder training, urge suppression strategies and the "Knack" during self-administered training, thus, the magnitude of the effects of these behavioral components on storage LUTS are underexplored. Monitoring participants' performance and adherence to these behavioral components and testing their effects on outcomes are recommended before scaling-up attempts.

Another observation from this review is the lack of core outcomes and core measurement tools. Researchers used multiple assessment tools in an attempt to capture parameters indicating UI changes. They can be categorized into the following modules: symptom diagnostic/ screening tools, symptom severity assessment tools, perceived symptom improvement tools, and PFMS assessment tools.

Researchers also used either symptom-specific or generic symptom impact assessment tools to quantify the changes in quality of life and disturbances of UI on individuals' activities, relationships, and feelings after the intervention. Two methodological strategies are recommended for future scaling up programs. First, careful selection of tools from each assessment module is needed by giving comprehensive consideration of their relevance to participants in the study (i.e., tools used for individuals with specific symptoms or without specific symptoms) (Sussman, Syan, & Brucker, 2020), their psychometric characteristics (i.e., reliability and validity tested under the classic test theory, or difficulty and discrimination tested under the item response theory) (DeVellis, 2016), participants' characteristics, which might influence their understanding (e.g., literacy), and the feasibility for application to large groups or populations. Second, preplanning approaches to adjust *p*-value for multiple comparisons to avoid the inflation of the type I error and monitoring data presentation to avoid selective reporting and p-hacking are also important (Vidgen & Yasseri, 2016).

This review found the amelioration of UI symptoms, severity, and impact, subjective improvement of UI, and improvement of PFMS were evident at 6 to 8 weeks after program initiation. Cumulative effectiveness however was limited to specific outcomes, i.e., reduction in the number of UI episodes as evidence from bladder diary entries, reduction of ICIQ-UI SF and ICIQ-LUTqol scores, improvement of symptoms assessed by PGI-I, and improvement of PFMS assessed by vaginal palpation.

The reduction in the number of UI episodes after ≥ 2 months was evident from this review despite the various descriptive statistics reported in articles, i.e., percentage, median, and mean. Conclusions about the effect size and its change over time remain limited.

The significant reduction in ICIQ-SF scores after 3 months or longer, indicating improvement of UI, was evident from this review, but the effect size described in mean difference might not be influenced by the time variable. This change reflects clinically meaningful differences given the significant improvement of ICIQ-LUTSqol and subjective perception of symptom improvement assessed by PGI-I, which were collected from women with their ICIQ-SF responses. It remains unclear however if the effect size for objective and subjective improvement could be influenced by using different combinations of the unsupervised B-PFMT programs components.

As the only 'sign', significant improvement of PFMS was evident 6 to 8 weeks after starting the programs, and this finding was not altered by the type of statistic (i.e., median, percentage and mean) or grading systems used. Neither the pooled effect size of this outcome nor its changes over time can be concluded from this review. In addition, this outcome cannot be assessed without face-to-face contact with women which limits its application in scaling up programs.

Despite the promising findings of applying unsupervised B-PFMT programs to prevent UI among postmenopausal women, no cumulative effectiveness can be obtained in this review. More UI prevention studies of women across the life course are warranted to determine their effectiveness in promoting bladder health and inclusion in scaling-up efforts.

Limitations

This systematic review has several limitations. There were concerns about quality (i.e., 5 RCTs had high risk of bias, 2 pretest-posttest articles had some risk of bias) of eligible articles in this review may compromise some conclusions we made. Rigorous studies applying unsupervised B-PFMT programs are required to provide high level of evidence. No contact with

the authors in retrieved articles was made during this study. Therefore, some detailed information about the intervention protocols and findings may not have been included in this review. Effect sizes for most significant findings cannot be synthesized from this review, and it remains unclear if they are influenced by time or various combinations in the components of the unsupervised B-PFMT programs. Specific populations, e.g., pregnant, and postpartum women, were not represented in this review because variance of data from these groups could compromise the precision of effectiveness synthesis for the majority of women. Therefore, the findings from this review can be extrapolated only to UI treatment of women in their 40s to 60s who live in the community. Initial scaling up attempts may have to be situated within this limitation.

Conclusions

Evidence from this review indicates that unsupervised B-PFMT programs can be scaled up to women in their 40s to 60s who have UI. More studies are needed across the life course to investigate potential effects of unsupervised B-PFMT programs with women who do not have UI and with women who have storage LUTS other than UI.

No optimal composition of unsupervised B-PFMT programs can be concluded from this review, but researchers can use this information to address the identified gaps in knowledge. Unsupervised B-PFMT programs have the potential to be scaled up to improve women's access to B-PFMT programs and improve their bladder health.

Table S2.1

Search Strategy Used on August 6, 2019

Set #	Database: PubMed (MEDLINE)	Results
1	"Urinary Incontinence"[Mesh] OR "Nocturia"[Mesh] OR "Urinary Bladder, Overactive"[Mesh] OR “overactive bladder”[tiab] OR (("Urination"[Mesh] OR urinary[tiab] OR urination[tiab]) AND (incontinence[tiab] OR urgency[tiab] OR frequency[tiab]))	58693
2	"Women"[Mesh] OR "Female"[Mesh] OR women[tiab] OR woman[tiab] OR female[tiab] OR females[tiab]	8665565
3	"Behavior Therapy"[Mesh] OR "Physical Therapy Modalities"[Mesh] OR “Behavior Therapy”[tiab] OR “Behaviour Therapy”[tiab] OR “Behavior Therapies”[tiab] OR “Behaviour Therapies”[tiab] OR “behavioral therapy”[tiab] OR “behavioural therapy”[tiab] OR “behavioral therapies”[tiab] OR “behavioural therapies”[tiab] OR “behavioral treatment”[tiab] OR “behavioural treatment”[tiab] OR “behavioral treatments”[tiab] OR “behavioural treatments”[tiab] OR “behavioral intervention”[tiab] OR “behavioural intervention”[tiab] OR “behavioral interventions”[tiab] OR “behavioural interventions”[tiab] OR “Behavior Modification”[tiab] OR “Behavior Modifications”[tiab] OR “Behaviour Modification”[tiab] OR “Behaviour Modifications”[tiab] OR physiotherapy[tiab] OR physiotherapies[tiab] OR “physical therapy”[tiab] OR “physical therapies”[tiab]	246788
4	("Pelvic Floor"[Mesh] AND ("Muscles"[Mesh] OR muscles[tiab] OR muscles[tiab])) OR “pelvic floor muscle” [tiab] OR “pelvic floor muscles” [tiab]	5980
5	#1 AND #2 AND #3 AND #4	960
6	#5 NOT (pregnant OR pregnancy OR prenatal OR postnatal OR postpartum)	794
7	#6 AND English[lang]	696

Set #	Database: Cumulative index to nursing and allied health literature (CINAHL)	Results
1	MH "Urination Disorders+" OR TI (“overactive bladder”) OR AB (“overactive bladder”) OR ((MH "Urination" OR TI (urinary OR urination) OR AB (urinary OR urination)) AND (TI (incontinence OR urgency OR frequency) OR AB (incontinence OR urgency OR frequency)))	27070
2	MH "Women+" OR MH "Female" OR TI (women OR woman OR female OR females) OR AB (women OR woman OR female OR females)	1816160
3	MH "Behavior Therapy+" OR MH "Physical Therapy+" OR TI (“Behavior Therapy” OR “Behaviour Therapy” OR “Behavior Therapies” OR “Behaviour Therapies” OR “behavioral therapy” OR “behavioural therapy” OR “behavioral therapies” OR “behavioural therapies” OR “behavioral treatment” OR “behavioural treatment” OR “behavioral treatments” OR “behavioural treatments” OR “behavioral intervention” OR “behavioural intervention” OR “behavioral interventions” OR “behavioural interventions” OR “Behavior Modification” OR “Behavior Modifications” OR “Behaviour Modification” OR “Behaviour Modifications” OR physiotherapy OR physiotherapies OR “physical therapy” OR “physical therapies”) OR AB (“Behavior Therapy” OR “Behaviour Therapy” OR “Behavior Therapies” OR “Behaviour Therapies” OR “behavioral therapy” OR “behavioural therapy” OR “behavioral therapies” OR “behavioural therapies” OR “behavioral treatment” OR “behavioural treatment” OR “behavioral treatments” OR “behavioural treatments” OR “behavioral intervention” OR “behavioural intervention” OR “behavioral interventions” OR “behavioural interventions” OR “Behavior Modification” OR “Behavior Modifications” OR “Behaviour Modification” OR “Behaviour Modifications” OR physiotherapy OR physiotherapies OR “physical therapy” OR “physical therapies”)	174753

4	MH "Pelvic Floor Muscles" OR TI (“pelvic floor muscle” OR “pelvic floor muscles”) OR AB (“pelvic floor muscle” OR “pelvic floor muscles”)	2698
5	#1 AND #2 AND #3 AND #4	593
6	#5 NOT (pregnant OR pregnancy OR prenatal OR postnatal OR postpartum)	451
7	#6 AND English	422
Set #	Database: PsycINFO	Results
1	DE "Urinary Function Disorders" OR DE "Urinary Incontinence" OR TI (“overactive bladder”) OR AB (“overactive bladder”) OR ((DE "Urination" OR DE "Diuresis" OR TI (urinary OR urination) OR AB (urinary OR urination)) AND (TI (incontinence OR urgency OR frequency) OR AB (incontinence OR urgency OR frequency)))	3921
2	DE "Human Females" OR DE "Battered Females" OR DE "Daughters" OR DE "Female Criminal Offenders" OR DE "Mothers" OR DE "Sisters" OR DE "Widows" OR DE "Wives" OR DE "Working Women" OR TI (women OR woman OR female OR females) OR AB (women OR woman OR female OR females)	583328
3	DE "Behavior Therapy" OR DE "Aversion Therapy" OR DE "Conversion Therapy" OR DE "Dialectical Behavior Therapy" OR DE "Exposure Therapy" OR DE "Implosive Therapy" OR DE "Reciprocal Inhibition Therapy" OR DE "Response Cost" OR DE "Systematic Desensitization Therapy" OR DE "Physical Therapy" OR TI (“Behavior Therapy” OR “Behaviour Therapy” OR “Behavior Therapies” OR “Behaviour Therapies” OR “behavioral therapy” OR “behavioural therapy” OR “behavioral therapies” OR “behavioural therapies” OR “behavioral treatment” OR “behavioural treatment” OR “behavioral treatments” OR “behavioural treatments” OR “behavioral intervention” OR “behavioural intervention” OR “behavioral interventions” OR “behavioural interventions” OR “Behavior Modification” OR “Behavior Modifications” OR “Behaviour Modification” OR “Behaviour	71046

	Modifications" OR physiotherapy OR physiotherapies OR "physical therapy" OR "physical therapies") OR AB ("Behavior Therapy" OR "Behaviour Therapy" OR "Behavior Therapies" OR "Behaviour Therapies" OR "behavioral therapy" OR "behavioural therapy" OR "behavioral therapies" OR "behavioural therapies" OR "behavioral treatment" OR "behavioural treatment" OR "behavioral treatments" OR "behavioural treatments" OR "behavioral intervention" OR "behavioural intervention" OR "behavioral interventions" OR "behavioural interventions" OR "Behavior Modification" OR "Behavior Modifications" OR "Behaviour Modification" OR "Behaviour Modifications" OR physiotherapy OR physiotherapies OR "physical therapy" OR "physical therapies")	
4	TI ("pelvic floor muscle" OR "pelvic floor muscles") OR AB ("pelvic floor muscle" OR "pelvic floor muscles")	153
5	#1 AND #2 AND #3 AND #4	15
6	#5 NOT (pregnant OR pregnancy OR prenatal OR postnatal OR postpartum)	13
7	#6 AND English	13
Set #	Database: Web of Science	Results
1	TS = ("overactive bladder" OR ((urinary OR urination) AND (incontinence OR urgency OR frequency)))	51074
2	TS = (women OR woman OR female OR females)	2170387
3	TS = ("Behavior Therapy" OR "Behaviour Therapy" OR "Behavior Therapies" OR "Behaviour Therapies" OR "behavioral therapy" OR "behavioural therapy" OR "behavioral therapies" OR "behavioural therapies" OR "behavioral treatment" OR "behavioural treatment" OR "behavioral treatments" OR "behavioural treatments" OR "behavioral intervention" OR "behavioural intervention" OR "behavioral interventions" OR "behavioural interventions" OR "Behavior Modification" OR "Behavior Modifications" OR "Behaviour	95221

	Modification" OR "Behaviour Modifications" OR physiotherapy OR physiotherapies OR "physical therapy" OR "physical therapies")	
4	TS = ("pelvic floor muscle" OR "pelvic floor muscles")	2738
5	#1 AND #2 AND #3 AND #4	304
6	#5 NOT TS = (pregnant OR pregnancy OR prenatal OR postnatal OR postpartum)	272
7	#6 AND English	257

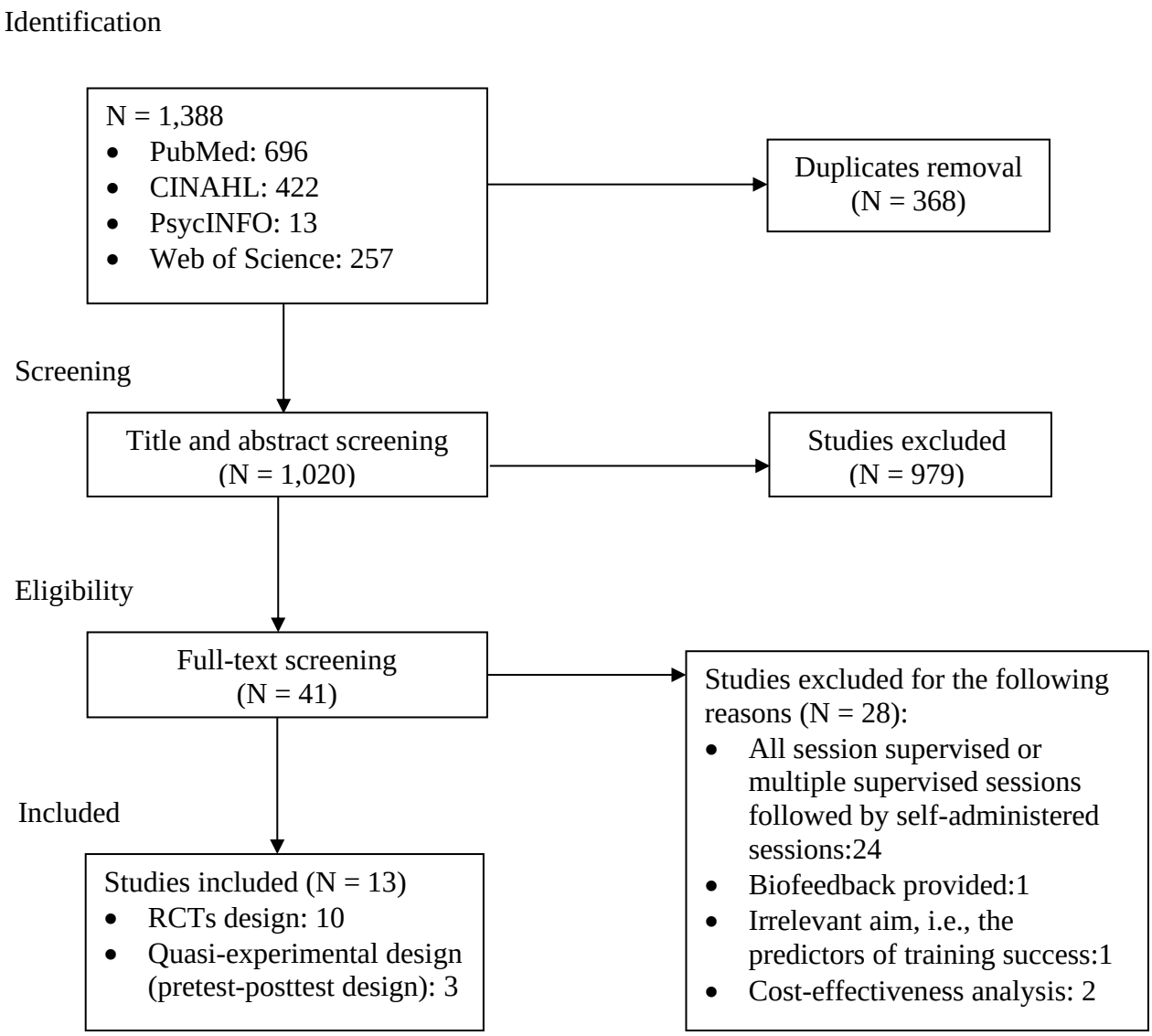

Figure 2.1

PRISMA Flow Diagram for Inclusion of Articles in The Systematic Review

Table 2.1

Overall Characteristics of Eligible Articles (N = 13)

First author name, Year, Country	Design	Female participants	Risk of bias*
Diokno et al., 2004 USA	RCT	Having no urinary incontinence Intervention group: n = 164, age: 66.2 ± 6.4 years Control group: n = 195, age: 65.4 ± 6.7 years	Some concerns
Sarı et al., 2009 Turkey	RCT	Having stress or mixed urinary incontinence Intervention group: n = 19 (17 for analysis), age: 41.82 ± 8.65 years Control group: n = 22 (17 for analysis), age: 44.64 ± 6.90 years	High risk of bias
Diokno et al., 2010 USA	RCT	Having urinary incontinence Intervention group: n = 23, age: 60.6 ± 14.4 years Control group: n = 21 (18 for analysis), age: 52.2 ± 12.6 years	Some concerns
Hung et al., 2012 Taiwan, China	Pretest-posttest design	Having urinary incontinence (n = 68), age: 50.5 ± 6.0 years	Least risk of bias

Fan et al., 2013 Hongkong, China	Pretest-posttest design	Having urinary incontinence (n = 372), age: 52.3 ± 10.8 years	Some risk of bias
Sjöström et al., 2013 Sweden	RCT	Having stress urinary incontinence Internet group: n = 124 (107 for analysis), age: 47.9 ± 10.6 years Postal group: n = 126 (113 for analysis), age: 49.4 ± 9.8 years	High risk of bias
Cavkaytar et al., 2015 Turkey	Pretest-posttest design	Having stress urinary incontinence (n = 38), age: 49.6 ± 8.1 years Having mixed urinary incontinence (n = 34), age: 48.9 ± 8.8 years	Some risk of bias
Sjöström et al., 2015 Sweden	RCT	Having stress urinary incontinence Internet group: n = 124 (87 for analysis at 1-year follow-up; 75 for analysis at 2-year follow-up), age: 47.9 ± 10.6 years Postal group: n = 126 (80 for analysis at 1-year follow-up; 79 for analysis at 2-year follow-up), age: 49.4 ± 9.8 years	High risk of bias
Asklund et al., 2017 Sweden	RCT	Having stress urinary incontinence Mobile App group: n = 62 (61 for analysis), age: 44.8 ± 9.7 years Control group: n = 61 (60 for analysis), age: 44.7 ± 9.1 years	High risk of bias

Hoffman et al., 2017 Sweden	RCT	Having stress urinary incontinence Mobile App group: n = 62 (46 for analysis at follow-up), age: 44.8 ± 9.7 years	High risk of bias**
Sampselle et al., 2017 USA	RCT	Having no urinary incontinence 2-hour class group: n = 332 (298 for analysis at 3-month follow-up; 291 for analysis at 12-month follow-up; 276 for analysis at 24-month follow-up), age: 63.03 ± 5.43 years 20-minute DVD group: n = 315 (290 for analysis at 3-month follow-up; 280 for analysis at 12-month follow-up; 268 for analysis at 24-month follow-up), age: 62.79 ± 5.91 years	Some concerns
Diokno et al., 2018 USA	RCT	Having stress or urgency urinary incontinence Intervention group: n = 232 (209 for analysis at 3-month follow-up; 192 for analysis at 6-month follow-up; 184 for analysis at 9-month follow-up; 195 for analysis at 12-month follow-up), age:64 ± 7 years Control group: n = 231 (212 for analysis at 3-month follow-up; 205 for analysis at 6-month follow-up; 202 for analysis at 9-month follow-up; 203 for analysis at 12-month follow-up), age:65 ± 8 years	Some concerns
Pereira-Baldon et al., 2019 Brazil	RCT	Having no reported pelvic floor muscle dysfunction	Some concerns

		Intervention group 1 (frequency: once daily): n = 15 (13 for analysis), age: 25.08 ± 2.79 years Intervention group 2 (frequency: 3 times daily): n = 15 (12 for analysis), age: 24.26 ± 3.82 years	

Notes:

(1) RCT: randomized controlled trial

(2) * Risk of bias for RCT was judged on “low risk of bias”, “some concerns”, and “high risk of bias” by using the Cochrane tool of assessing risk of bias in randomized trials (RoB2), while risk of bias for pretest-posttest design was graded on “least risk of bias”, ”some risk of bias” and “significant risk of bias” by using 12-item tool of “Quality Assessment Tool for Before-After (Pre-Post) Studies With No Control Group” developed by National Heart, Lung, and Blood Institute and Research Triangle Institute International

(3) **Although the article only used the intervention group to answer research aim(s), data were derived from the RCT reported by Asklund et al., 2017, therefore, the design and risk of bias were assessed based on this information

Table S2.2

Components of Unsupervised B-PFMT Programs in The Eligible Studies (N = 13)

First author name, Year Country	Education session		Self-administered training part	
	Method of delivery (Providers)	Overview of information provided to participants (Strategies used to ensure correct performance of pelvic floor muscle contraction)	Elements of pelvic floor muscle exercises	Reinforcement used in intervention group(s) (Timing)
Diokno et al., 2004 USA	Face-to-face, group delivered (Urologist and nurse specialist)	Anatomy of the lower urinary tract and pelvis Central and peripheral nervous system controlling the lower urinary tract Knowledge of the urinary incontinence (i.e., etiology and impacts) Voiding frequency and bladder capacity Lifestyle modification Health habit and self-care Personal voiding interval assessment Instruction in practicing bladder training and locating and exercising pelvic floor muscles	NR	One face-to-face contact for reassessing the correct contraction (2-4 weeks after intervention initiation)

		Prescription of the pelvic floor muscle exercise dose Integrate bladder training and pelvic floor muscle exercise into daily activities (Vaginal palpation)		
Sarı, et al., 2009 Turkey	Face-to-face, one-on-one delivered (Unclear)	Anatomy of the lower urinary tract and pelvis Knowledge of the urinary incontinence (i.e., continence mechanisms) Locating the position of the levator ani Prescription of the pelvic floor muscle exercise dose Description of the "Knack" (Vaginal palpation)	*Repetition* -one quick contraction with relaxation, followed by one sustained contraction with relaxation *Frequency of exercises* -three sets of 30 repetitions per day *Duration of exercises* -quick contraction:1-2 seconds -sustained contraction: starting from 5 seconds and then increasing by 1 second for each week until reaching the maximum of 10 seconds	Telephone contacts initiated by providers for adherence reinforcement and answer any questions (weekly)

			-relaxation: the time is the same as that for the contraction it follows	
Diokno et al., 2010 USA	Face-to-face, group delivered (Trained nurse specialists)	Anatomy of the lower urinary tract and pelvis Central and peripheral nervous system controlling the lower urinary tract Knowledge of the urinary incontinence (i.e., etiology and impacts) Voiding frequency and bladder capacity Lifestyle modification Health habit and self-care Personal voiding interval assessment Instruction in practicing bladder training and locating and exercising pelvic floor muscles Prescription of the pelvic floor muscle exercise dose Integrate bladder training and pelvic floor muscle exercise into daily activities (Vaginal palpation)	NR	One face-to-face contact for reassessing the correct contraction (2-4 weeks after intervention initiation)

Hung et al., 2012 Taiwan, China	Face-to-face, one-on-one delivered (Physical therapist)	Anatomy of the lower urinary tract and pelvis Knowledge of the urinary incontinence (i.e., continence mechanisms) The bladder hygiene Instruction in locating and exercising pelvic floor muscles Prescription of the pelvic floor muscle exercise dose (Vaginal palpation)	*Repetition* -high-intensity contraction with relaxation *Frequency of exercises* -three sets of 6 repetition per day *Duration of exercises* -high-intensity contraction: 10 seconds -relaxation: at least 10 seconds	NR
Fan et al., 2013 Hongkong, China	Face-to-face, one-on-one delivered (Continence advisor)	Anatomy of perineal or anus and perineal muscles contraction Lifestyle modification Instruction in locating and practicing the pelvic floor muscles Prescription of the pelvic floor muscle exercise dose (In-drawing topography)	*Repetition* -contraction with relaxation *Frequency of exercises* -three sets of 10 repetitions per day *Duration of exercises* -contraction with relaxation: 10 seconds -three months' training was suggested.	Two face-to-face contacts for reassessing the correct contraction (3 months and 6-9 months after intervention initiation)

Cavkaytar et al., 2015 Turkey	Unclear (Unclear)	Instruction on how to contract pelvic floor muscles Prescription of the pelvic floor muscle exercise dose (Vaginal palpation)	*Repetition* -contraction(s) *Frequency of exercises* -ten sets of 10 contractions per day *Duration of exercises* -at least 2 months was suggested	One face-to-face contact for reassessing the correct contraction (10 days after intervention initiation)
Sjöström, et al., 2013 Sjöström, et al., 2015 Sweden *	Email and postal delivered (N/A)	Knowledge of the stress urinary incontinence Lifestyle modification Instruction in practicing pelvic floor muscle exercise Prescription of the pelvic floor muscle exercise dose Description of the “Knack” (NR)	*Repetition* -maximum contractions -submaximal contractions -quick contractions *Frequency of exercises* -three sets of 8-10 repetitions of maximum contraction per day -three sets of 1 repetition of submaximal contraction -2-3 sets of 8-10 repetitions of quick contractions *Duration of exercises*	Encrypted e-mail contacts initiated by participants in the internet group for asking supports and answering questions (timely)

			-maximum contractions: 8 seconds -submaximal contractions: 15-90 seconds -quick contractions: 3 seconds	
Asklund, et al., 2017 Hoffman et al., 2017 Sweden **	App delivered (N/A)	Anatomy of the pelvic floor Knowledge of the stress urinary incontinence Lifestyle modification Prescription of the pelvic floor muscle exercise dose Instruction in locating and exercising the pelvic floor muscles Description of the "Knack" (NR)	*Repetition* -different combination of commonly used contractions: a basic contraction to identify the correct muscles, contractions to improve the strength and endurance, and quick contractions *Frequency of exercises* -three sets of repetition per day *Duration of exercises* -regularly exercises for 3 weeks were suggested	The app's 3 reminders/day function for adherence reinforcement (at the start of intervention) One email contact initiated by providers for adherence reinforcement and providing support (4 weeks after intervention initiation)

Sampselle et al., 2017 USA	Face-to-face, group delivered (Trained nurse specialists) DVD delivered (N/A)	Anatomy of the pelvis Knowledge of the urinary incontinence and its impacts Knowledge of pelvic floor muscle exercise Instruction in practicing bladder training, urge suppression, the "Knack" and pelvic floor muscle exercise Lifestyle modification (NR)	NR	NR
Diokno, et al., 2018 USA	Face-to-face, group delivered (Trained interventionists)	Anatomy of the lower urinary tract and pelvic floor muscle Knowledge of urinary incontinence and its impact, and continence mechanism Bladder and pelvic floor muscle function Instruction in practicing bladder training, urge suppression, the "Knack", and locating and exercising pelvic floor muscle (NR)	NR	A magnet with the project logo to serve as a discrete reminder for adherence enforcement (at the start of intervention)
Pereira-Baldon, et al., 2019 Brazil	Face-to-face, one-on-one delivered	Instruction in locating and exercising pelvic floor muscle Prescription of the pelvic floor muscle exercise dose	*Repetition* -one maximum contraction followed by 6-8 fast contraction with relaxation	NR

	(Physical therapist)	(Vaginal palpation)	*Frequency of exercises* -group 1: one set of 8-12 repetitions per day -group 2: three sets of 8-12 repetitions per day *Duration of exercises* -maximum contraction: 6-8 seconds -quick contraction -relaxation: 6-8 seconds	

Notes:

(1) NR indicated “not reported”; N/A indicated “not applicable”.

(2) * two articles used data from the same study but focused on either the short-term or long-term effects of the intervention.

(3) ** two articles used data from the same study, Asklund et al. reported the short-term effects, while Hoffman et al. reported the long-term effects of the intervention group.

Table 2.2

Tools for Assessing Outcomes of Interest (N = 13)

First author name, Year, Country	Symptom diagnostic/screening tools			Symptom severity assessment tools					Pelvic floor muscle strength assessment tools		Perceived symptom improvement assessment tools		Symptom impact assessment tools					
	2-day /3-day bladder diary	1-hour /24-hour pad test	Paper towel test	MESA	Sandvik Severity Index	Severity Index Score	IUSS	ICIQ-UI SF	Digital palpation	Pressure perineometer	Self-reported improvement	PGI-I	Symptom Impact Index	I-QOL	UDI-6	IIQ-7	ICIQ-LUTSqol	EQ5D-VAS
Diokno et al., 2004, USA	√			√					√									
Sarı et al., 2009, Turkey	√	√*								√				√				

Diokno et al., 2010, USA	√	√	√		√				√								
Hung et al., 2012, Taiwan, China	√					√			√		√		√				
Fan et al., 2013, Hongkong, China															√	√		
Sjöström, et al., 2013, Sweden	√**							√				√					√	√
Cavkaytar et al., 2015, Turkey									√			√			√	√		
Sjöström et al.,								√				√					√	√

2015, Sweden																	
Asklund, et al., 2017, Sweden	√**							√				√					√	
Hoffman et al., 2017, Sweden								√				√					√	
Sampselle et al., 2017, USA			√				√	√										
Diokno, et al., 2018, USA	√	√	√	√				√	√			√		√				
Pereira-Baldon, et al., 2019, Brazil									√									

Notes:

(1) * 1-hour pad test

(2) ** 2-day bladder diary

(3) Abbreviations

MESA: the standardized Medical Epidemiologic and Social aspects of Aging questionnaire

IUSS: Indevus Urgency Severity Scale

ICIQ-UI SF: International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form

PGI-I: Patient Global Impression of Improvement

I-QOL: Incontinence of Quality of Life

UDI-6: Urogenital Distress Inventory

IIQ-7: Incontinence Impact Questionnaire short form

ICIQ-LUTSqol: International Consultation on Incontinence Questionnaire-Lower Urinary Tract Symptoms Quality of Life

EQ5D-VAS: EuroQol 5D-Visual Analogue Scale

Table S2.3

Outcomes Assessed by Symptom Diagnostic/Screening Tools (N = 8)

Tools	First author name, year	Time of assessments	Grading criteria	Outcomes
2-day/3-day bladder diary	Diokno et al., 2004*	Baseline and 12 months after intervention	The number of voids	Intervention group versus control group Significantly more reduction in number of voids in intervention group compared with that in control group (24 hours, $p < 0.0001$; awake hours, $p < 0.0001$; sleep hours, $p = 0.004$)
			Intervoid interval	Significantly more increase of intervoid interval in intervention group compared with that in control group (33 minutes versus 2 minutes, $p = 0.01$)
	Sari et al., 2009	Baseline and 2 months after intervention	The number of leakages	Intervention group versus control group Significant reduction in number of leakages in intervention group compared with that in control group (-3.23 ± 2.19 versus 0.82 ± 2.81, $p < 0.01$)
	Diokno et al., 2010	Baseline and 6~8 weeks after intervention	The number of voids	Intervention group versus control group *At baseline* Both groups reported the similar number of daily voids Intervention group: there was significant reduction in number of voids (24 hours, 9.9 to 6.8, $p < 0.001$; during the day, 8.7 to 6.1, $p = 0.001$; night hours, 1.3 to 0.8, $p = 0.018$)

				Control group: there was no significant reduction in number of voids (24 hours, 8.8 to 9.2, $p = 0.715$; during the day, 7.8 to 8.2, $p = 0.699$; during the night, 0.9 to 0.9, $p = 0.999$)
	Hung et al., 2012	Baseline and 4 months after intervention	The number of voids	Pre-intervention versus post-intervention Significant reduction in number of voids after intervention (median: 8.9 versus 7.9, $p < 0.001$)
			The number of leakages	Significant reduction in number of leakages after intervention (median: 0.3 versus 0, $p < 0.001$)
	Sjöström et al., 2013**	Baseline and 4 months after intervention	Multiply the number of leakages by 3.5 to obtain the number of leakages per week	Internet group versus postal group Internet group: there was significant reduction in number of leakages per week (12.7 ± 12.0 to 4.8 ± 7.7, $p < 0.001$) Postal group: there was significant reduction in number of leakages per week (9.4 ± 8.6 to 4.4 ± 6.7, $p < 0.001$) No significant between-group difference on reductions in number of leakages per week ($p = 0.23$)
	Asklund et al., 2017***	Baseline and 3 months after intervention	Multiply the number of leakages by 3.5 to obtain the number of leakages per week	Intervention group versus control group *At 3 months* Significantly smaller number of leakages per week in intervention group compared with that in control group (median: 7 versus 14, $p = 0.001$)

	Diokno et al., 2018	Baseline, 3, 6, 9, and 12 months after intervention	The number of leakages	Intervention group versus control group The percentage of participants demonstrated reduction in number of leakages in intervention group was significantly higher than that in control group (41.1% versus 5.7%, $p < 0.001$) Operationalizing 70% reduction in leakages as successful results, the percentage of participants demonstrated successful results in intervention group was significantly higher than that in control group (35.3% versus 22.1%, $p = 0.005$) The medium number of leakages were significantly smaller in intervention group compared with that in control group at 3,6,9,12 months (no reported data and the *p*-value)
			The number of voids	The medium number of voids were significantly smaller in intervention group compared with that in control group at 3, 6, 9, 12 months (no reported data and the *p*-value)
1-hour or 24-hour pad test	Sari et al., 2009†	Baseline and 2 months after intervention	Grams of urine leakages	Intervention group versus control group Significant reduction in grams in intervention group compared with that in control group (-5.11 ± 7.29 versus 8.88 ± 12.52, $p < 0.01$)
	Diokno et al., 2010	Baseline and 6-8 weeks	Grams of urine leakages	Intervention group versus control group Intervention group: No significant reduction in grams of urine leakages (33.9 ± 87.2 versus 12.5 ± 27.5, $p = 0.097$)

		after intervention		Control group: No significant reduction in grams of urine leakages (14.4 ± 17.9 versus 13.7 ± 18.2, $p = 0.906$)
	Diokno et al., 2018	Baseline, 3, 6, 9, and 12 months after intervention	Grams of urine leakages	Intervention group versus control group *At baseline* No significant between-group difference in grams of urine leakages (median: 3.8 versus 4.8, $p = 0.08$) *At 3 months* Significantly fewer grams of urine leakages in intervention group compared with that in control group (median: 2.3 versus 4.2, $p = 0.002$) *At 12 months* Significantly fewer grams of urine leakages in intervention group compared with that in control group (median: 1.9 versus 3.7, $p < 0.001$)
Paper towel test	Diokno et al., 2010	Baseline and 6-8 weeks after intervention	Leak diameter by dividing the sum of orthogonal diameters of the wet area by two (unit: centimeter)	Intervention group versus control group Intervention group: there was significant reduction in leak diameter (31.2 ± 53.4 to 12.6 ± 41.6, $p = 0.012$) Control group: there was no significant reduction in leak diameter (22.5 ±49.1 to 19.6 ±48.4, $p = 0.854$)
	Sampselle et al., 2017 *	Baseline, 3, 12, and 24	Orthogonal diameters of the wetted area were measured, and	Two-hour class group versus 20-minute DVD group *From baseline to 3 months*

		months after intervention	its area was calculated using the formula for an ellipse	2-hour class group, the reduction in score (0.09 ±0.03), no reported *p*-value 20-minute DVD group, the reduction in score (0.06 ± 0.03), no reported *p*-value *From baseline to 12 months* 2-hour class group, the reduction in score (0.09 ±0.03), no reported *p*-value 20-minute DVD group, the reduction in score (0.05 ± 0.03), no reported *p*-value *From baseline to 24 months* 2-hour class group, the reduction in score (0.06 ±0.04), no reported *p*-value 20-minute DVD group, the reduction in score (0.06 ± 0.04), no reported *p*-value No reported p-values for score reductions between two groups from baselines to 3 months, from baseline to 12 months, and from baseline to 24 months
	Diokno et al., 2018	Baseline, 3, 6, 9, and 12 months after intervention	Number of positive cases /total number of positive cases	Intervention group versus control group At 3 months: Significantly lower percentages of positive cases in intervention group compared with that in control group (31.1% versus 47.6%, $p < 0.001$)

				At 12 months: Significantly lower percentages of positive cases in intervention group compared with that in control group (26.3% versus 42.3%, $p < 0.001$)

Notes:

(1) * Participants enrolled had no urinary incontinence

(2) **The duration of the intervention was 3 months, and the assessment tool was the 2-day bladder diary

(3) ***The assessment tool was the 2-day bladder diary

(4) †The assessment tool was the 1-hour pad test

Table S2.4

Outcomes Assessed by Symptom Severity Assessment Tools (N = 9)

Tools	First author, year	Time of assessments	Grading system	Outcomes
MESA*	Diokno et al., 2004**	Baseline and 12 months after intervention	Continence was operationalized as both the absolute continence and having leakages no more than 5 days in the past 12 months	Intervention group versus control group Participants in the intervention group was 2.03 times (95% CI 1.04-3.98, $p = 0.04$) as likely to remain 0 leakage and transit from 1-5 days of leakages to 0 leakage as those in control group Participants in the intervention group was 1.97 times (95% CI 1.15-3.98, $p = 0.01$) as likely to remain 0 leakage or 1-5 days of leakage and transit from 1-5 days of leakages to 0 leakages as those in control group
	Diokno et al., 2018	Baseline, 3, 6, 9, and 12 months after intervention	Six questions for urgency urinary incontinence and nine for stress urinary incontinence. Each question was grading on 0 to 3 for responses to never,	Intervention group versus control group *At baseline* For participants with urgency urinary incontinence, there was no significant between-group difference in scores (median: 33 versus 39, $p = 0.22$) For participants with stress urinary incontinence, there was no significant between-group difference in scores (median: 44 versus 44, $p = 0.83$)

			rarely, sometimes, and often, and scoring is additive	*At 3 months* For participants with urgency urinary incontinence, there was significant between-group difference in scores (median: 28 versus 33, $p < 0.001$) For participants with stress urinary incontinence, there was significant between-group difference in scores (median: 33 versus 41, $p < 0.001$) *At 12 months* For participants with urgency urinary incontinence, there was significant between-group difference in scores (median: 20 versus 28, $p < 0.001$) For participants with stress urinary incontinence, there was significant between-group difference in scores (median: 26 versus 41, $p < 0.001$)
Sandvik Severity Index	Diokno et al., 2010	Baseline and 6~8 weeks after intervention	Three response options after multiplying results of two questions: slight (1-2), moderate (3-4), and severe (6-8)	Intervention group versus control group Intervention group: there was no significant reduction in the percentage of participants in the severe cluster (34.8% to 21.7%, $p = 0.375$); there was significant reduction in the percentage of participants in the moderate cluster (47.8% to 21.7%, $p = 0.03$); there was significant increase in the percentage of participants in the slight cluster (17.4% to 56.5%, $p = 0.036$)

				Control group: there was no significant changes in percentages of participants in any of these three severity levels
Severity Index Score*	Hung et al., 2012	Baseline and 4 months after intervention	Range from 1 to 12	Pre-intervention versus post-intervention Significant reduction in severity index score after intervention (median: 6 versus 3, $p < 0.001$)
IUSS	Sampselle et al., 2017 **	Baseline, 3, 12, and 24 months after intervention	One question was grading on 0 to 3 for responses to: no urgency, mild, moderate, and severe	Two-hour class group versus 20-minute DVD group In each group, no significant difference in score from baseline to each follow-up time point No significant between-group differences in scores from baselines to 3 months, from baseline to 12 months, and from baseline to 24 months (no reported *p*-value)
ICIQ-UI SF *	Sjöström, et al., 2013	Baseline and 4 months after intervention ***	Three questions with the sum score of 0-21, with higher scores indicating increased severity	Internet group versus postal group Internet group: there was significant reduction in score (10.4 ± 3.1 to 6.9 ± 3.1, the difference was 3.4 ± 3.4, $p < 0.001$), Postal group, there was significant reduction in score (10.3 ±3.5 to 7.3 ± 3.9, the difference was 2.9 ± 3.1, $p < 0.001$) The comparison of score reductions between two groups was not significant ($p = 0.27$)
	Sjöström, et al., 2015	Baseline, 12 and 24	Three questions with the sum score of 0-21, with higher scores	Internet group versus postal group *From baseline to 12 months*

		months after intervention	indicating increased severity	Internet group: there was significant reduction in score (10.4 ± 3.1 to 6.6 ± 3.1, the difference was 3.7 ± 3.3, $p < 0.001$) Postal group: there was significant reduction in score (10.3 ±3.5 to 6.7 ± 3.2, the difference was 3.2 ± 3.4, $p < 0.001$) The comparison of score reductions between two groups was not significant ($p = 0.47$) *From baseline to 24 months* Internet group: there was significant reduction in score (10.4 ± 3.1 to 6.5 ± 3.0, the difference was 3.6 ± 3.5, $p < 0.001$) Postal group: there was significant reduction in score (10.3 ±3.5 to 6.4 ± 3.5, the difference was 3.4 ± 3.3, $p < 0.001$) The comparison of score reductions between two groups was not significant ($p = 0.79$)
	Asklund et al., 2017	Baseline and 3 months after intervention	Three questions with the sum score of 0-21, with higher scores indicating increased severity	Intervention group versus control group Intervention group: there was significant reduction in score (the reduction was 3.9, 95% CI 3.0-4.7, no reported *p*-value) Control group: there was no significant reduction in score (the reduction was 0.9, 95% CI 0.1-1.6, no reported *p*-value) *At 3 months* Significantly smaller score in intervention group compared with that in control group (7.0 ± 3.5 versus 10.2 ± 3.2, $p < 0.001$)

	Hoffman et al., 2017	Baseline and 24 months after intervention	Three questions with the sum score of 0-21, with higher scores indicating increased severity	Intervention group There was significant reduction in score after intervention (the reduction was 3.1, 95% CI 2.0-4.2, $p < 0.001$)
	Sampselle et al., 2017*	Baseline, 3, 12, and 24 months after intervention	Three questions with the sum score of 0-21, with higher scores indicating increased severity	2-hour class group versus 20-minute DVD group *From baseline to 3 months* 2-hour class group, there was no significant reduction in score (0.39 ±0.45), no reported *p*-value 20-minute DVD group, there was no significant reduction in score (-0.44 ± 0.2), no reported *p*-value *From baseline to 12 months* 2-hour class group, there was no significant reduction in score (-0.23 ±0.2), no reported *p*-value 20-minute DVD group, there was no significant reduction in score (-0.3 ± 0.19), no reported *p*-value *From baseline to 24 months* 2-hour class group, there was no significant reduction in score (-0.05 ±0.31), no reported *p*-value 20-minute DVD group, there was no significant reduction in score (-0.37 ± 0.23), no reported *p*-value

				The comparisons of score reductions between two groups were not significant from baselines to 3 months, from baseline to 12 months, and from baseline to 24 months (no reported *p*-value)
	Diokno et al., 2018	Baseline, 3, 6, 9, and 12 months after intervention	Three questions with the sum score of 0-21, with higher scores indicating increased severity	Intervention group versus control group Intervention group: for each 3 months, the mean reduction was 1.94, 95% CI -2.33 to -1.55 Control group: for each 3 months, the mean reduction was 0.98, 95% CI -1.37 to -0.59 The difference of the average score reductions between two group was 0.96, 95% CI -1.51 to -0.41, significant with no reported *p*-value

Notes:

(1) * Higher scores indicate higher severity, when applicable

(2) ** Participants enrolled had no urinary incontinence

(3) *** The duration of the intervention was 3 months

(4) Abbreviations

MESA: The standardized Medical Epidemiologic and Social aspects of Aging questionnaire

IUSS: Indevus Urgency Severity Scale

ICIQ-UI SF: International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form

Table S2.5

Pelvic Floor Muscle Strength Assessment Tools (N = 7)

Tools	First author, year	Time of assessments	Grading criteria	Outcomes
Digital palpation	Diokno et al., 2004*	Baseline and 12 months after intervention	Brink scoring system: pressure, and displacement	Intervention group versus control group *At 12 months* Significantly higher "pressure" score ($p = 0.003$) and "displacement" score ($p < 0.0001$) in treatment group compared with those in control group *From baseline to 12 months* More participants in intervention group demonstrated significantly higher increase in "pressure" ($p = 0.0008$) and "displacement" ($p < 0.0001$) scores compared with those in control group
	Diokno et al., 2010	Baseline and 6~8 weeks after intervention	Brink scoring system: pressure, displacement, and duration	Intervention group versus control group Intervention group: there was significant increase in in "pressure" (3.7 to 4.1, $p = 0.047$), "displacement" (1.3 to 2.3, $p = 0.001$), and "duration" (4.8 to 7.1, $p = 0.001$) scores Control group: there was no significant increase in "pressure" (3.4 to 3.8, $p = 0.228$) and "duration" (5.7 to 5.9, $p = 0.851$) scores, but significant increase in "displacement" score (1.4 to 2.1, $p = 0.016$)

	Hung et al., 2012	Baseline and 4 months after intervention	Modified Oxford Scale: 6-point scale from 0 to 5 grading on responses to zero, flicker, weak, moderate, good and strong	Pre-intervention versus post-intervention Significant increase in score after intervention (p = 0.001)
	Cavkavtar et al., 2015	Baseline and 2 months after intervention	Modified Oxford Scale: 6-point scale from 0 to 5 grading on responses to zero, flicker, weak, moderate, good and strong	Pre-intervention versus post-intervention For participants with stress urinary incontinence, there was significant increase in score after intervention (median: 2 versus 3, p < 0.001) For participants with mixed urinary incontinence, there was significant increase in score after intervention (median: 2 versus 3, p < 0.001) The comparison of score increases between participants stress urinary incontinence and those with mixed urinary incontinence was not significant (p = 0.724)
	Diokno et al., 2018	Baseline, 3, 6, 9, and 12 months after intervention	Brink scoring system: pressure, % (No./total No.) scoring 4 to 6 out	Intervention group versus control group *At baseline* No significant differences in percentages of participants who were graded 4, 5 or 6 for "pressure" (49.3% versus 48.0%, p = 0.78) and of participants who were graded 4 or 5 for "displacement" (9.7%

			of the maximum score of 6; displacement, % (No./total No.) 4 or 5 out of the maximum score of 5; duration	versus 11.8%, $p = 0.45$), and no significant difference in duration scores (median: 4 versus 4, $p = 0.91$) *At 3 months* No significant differences in percentages of participants who were graded 4, 5 or 6 for "pressure" (52.0% versus 54.3%, $p = 0.63$) and of participants who were graded 4 or 5 for "displacement" (10.8% versus 14.8%, $p = 0.23$), and no significant difference in duration scores (median: 4 versus 5, $p = 0.66$) *At 12 months* No significant differences in percentages of participants who were graded 4, 5 or 6 for "pressure" (56.3% versus 52.5%, $p = 0.46$) and of participants who were graded 4 or 5 for "displacement" (17.3% versus 11.5%, $p = 0.10$), and no significant difference in duration scores (median: 6 versus 5, $p = 0.09$)
	Pereira-Baldon, et al., 2019 **	Baseline and 2 months after intervention	Modified Oxford Scale: 6-point scale from 0 to 5 grading on responses to zero, flicker, weak, moderate, good and strong	Intervention group 1 (the frequency: once daily) versus intervention group 2 (the frequency: three times daily) Intervention group 1: there was significant increase in score (2.5 ± 1.1 to 3.0 ± 1.0, $p = 0.03$) Intervention group 2: there was significant increase in score (2.2 ± 0.8 to 3.0 ± 0.6, $p < 0.01$) No significant between-group differences in scores at baseline ($p = 0.61$) and at 2 months ($p = 0.85$)

			Maximum voluntary contraction (in cmH_2O)	Intervention group 1: there was significant increase in score (48.8 ± 32.6 to 56.1 ± 30.4, $p = 0.03$) Intervention group 2: there was significant increase in score (41.5 ± 19.0 to 55.4 ± 15.3, $p < 0.01$) No significant between-group differences in scores at baseline ($p = 0.81$) and at 2 months ($p = 0.85$)
Pressure perineometer	Sari et al., 2009	Baseline and 2 months after intervention	Use the perineometer to test the average and peak contraction pressure	Intervention group versus control group The increase in the mean contraction pressure in intervention group was significantly larger than that in control group (9.49 ± 6.53 versus -2.23 ± 4.43, $p < 0.01$) The increase in the maximum contraction pressure in intervention group was significantly larger compared with that in control group (11.23 ± 7.60 versus -3.70 ± 4.71, $p < 0.01$)

Notes:

(1) * Participants enrolled had no urinary incontinence

(2) ** Participants in this article has no reported pelvic floor muscle dysfunction

Table S2.6

Outcomes Assessed by Perceived Symptom Improvement Assessment Tools (N = 7)

Tools	First author name, year	Time of assessments	Grading system	Outcomes
Self-reported improvement	Hung et al., 2012	Baseline and 4 months after intervention	One question with responses of worse, unchanged, improved and cured	Pre-intervention versus post-intervention There was 75% of participants reported symptom improvement or cured after intervention
PGI-I	Sjöström, et al., 2013	Baseline and 4 months after intervention	One question with 7-Likert scaling format from "very much better" to "very much worse"	Internet group versus postal group *At 4 months* Significantly higher percentages of participants in internet group reported their leakages got much better or very much better compared with those in postal group (40.9% versus 26.5%, $p = 0.01$)
	Cavkavtar et al., 2014	Baseline and 2 months after intervention	One question with binary responses of yes and no improvement	Pre-intervention versus post-intervention For participants with stress urinary incontinence, 68.4% of them reported symptom improvement For participants with mixed urinary incontinence, 41.2% of them reported symptom improvement The comparison of symptom improvement percentages between participants with stress urinary

				incontinence and those with mixed urinary incontinence was significant (p = 0.02)
	Sjöström, et al., 2015	Baseline, 12 and 24 months after intervention	One question with 7-Likert scaling format from “very much better” to “very much worse”	Internet group versus postal group *At 12 months* No significant between-group difference in symptom improvement (p = 0.82) *At 24 months* The percentage of participants reporting their leakages got much better or very much better was significantly higher in internet group compared with that in postal group (39.2% versus 23.8%, p = 0.03)
	Asklund et al., 2017	Baseline and 3 months after intervention	One question with 7-Likert scaling format from “very much better” to “very much worse”	App group versus control group Participants in app group more often reported their leakages got much better or very much better compared with those in control group (p < 0.001)
	Hoffman et al., 2017	Baseline and 24 months after intervention	One question with 7-Likert scaling format from “very much better” to “very much worse”	Intervention group There was 66.7% of participants reported their leakages got much or very much better after intervention
	Diokno et al., 2018	Baseline, 3, 6, 9, and 12	One question with 7-Likert scaling format from “very	Intervention group versus control group *At 3 months*

		months after intervention	much better" to "very much worse"	The percentage of participants reporting their leakages got much better or very much better was significantly higher in intervention group compared with that in control group (46.9% versus 8.1%, $p < 0.001$) *At 12 months* The percentage of participants reporting their leakages got much better or very much better was significantly higher in intervention group compared with that in control group (64.3% versus 11.3%, $p < 0.001$)

Note:

PGI-I, Patient Global Impression of Improvement

Table S2.7

Outcomes Assessed by Symptom Impacts Assessment Tools (N = 9)

Tools	First author, year	Time of assessments	Grading system	Outcomes
Symptom Impact Index	Hung et al., 2012	Baseline and 4 months after intervention	The number of worries	Pre-intervention versus post-intervention Significant reduction in score after intervention (median: 2 versus1, $p < 0.001$)
			The number of activities affected	Significant reduction in score after intervention (median: 1 versus 0, $p = 0.001$)
			Avoiding activities because of worrying about leakages, responses to this question are never, sometimes, often, always, and missing	Significant improvement after intervention ($p < 0.001$)
			Avoiding activities because of needing a toilet, responses to this question are never, sometimes, often, always, and missing	Significant improvement after intervention ($p = 0.020$)

I-QOL	Sari et al., 2009	Baseline and 2 months after intervention	The 22-item scale has 3 domains: avoidance and limiting behavior, psychosocial impacts, and social embarrassment. All items were graded on 5-points scaling format, the sum scores for each domain and for the total scale are transformed into a 0 to 100 scale	Intervention group versus control group *At baseline* No significant between-group difference in "avoidance and limiting behavior" scores (74.26 ± 14.42 versus 65.44 ± 13.27, $p > 0.05$) *From baseline to 2 months* The increase in "avoidance and limiting behavior" score was significantly larger in intervention group compared with that in control group (18.01 ± 9.47 versus -5.88 ± 6.52, no reported *p*-value) *At baseline* No significant between-group difference in "psychosocial impact" scores (65.84 ± 20.82 versus 64.86 ± 17.83, $p > 0.05$) *From baseline to 2 months* The increase in "psychosocial impact" score was significantly larger in intervention group compared with that in control group (25.16 ± 16.38 versus -6.37 ± 0.09, no reported *p*-value)

				At baseline No significant between-group difference in "social embarrassment" scores (57.94 ± 21.06 versus 45.88 ± 20.63, $p > 0.05$) *From baseline to 2 months* The increase in "social embarrassment" score was significantly larger in intervention group compared with that in control group (27.94 ± 15.81 versus -4.41 ± 7.47, no reported *p*-value) *At baseline* No significant between-group difference in the total scores (67.11 ± 16.22 versus 60.76 ± 14.63, $p > 0.05$) *From baseline to 2 months* The increase in the total score was significantly larger in intervention group compared with that in control group (23.19 ± 11.43 versus -5.74 ± 6.26, $p < 0.01$)
	Diokno et al., 2018	Baseline, 3, 6, 9, and 12 months after intervention	The 22-item scale has 3 domains: avoidance and limiting behavior, psychosocial impacts, and	Intervention group versus control group *At 3 months*

			social embarrassment. All items were graded on 5-points scaling scheme, the sum scores for each domain and for the total scale are transformed into a 0 to 100 scale	The score was significantly larger in intervention group compared with that in control group (median: 86 versus 83, $p < 0.001$) *At 12 months* The score was significantly larger in intervention group compared with that in control group (median: 92 versus 85, $p < 0.001$)
UDI-6	Fan et al., 2013	Baseline and 3 months plus after intervention initiation *	The 6-item scale was graded on 0-3 scaling scheme, the score is transformed into to 0 to 100 scale	Pre-intervention versus post-intervention Significant reduction in score after intervention (30.7 ± 14.2 versus 22.1 ± 15.3, $p = 0.005$)
	Cavkavtar et al., 2014	Baseline and 2 months after intervention	The 6-item scale was graded on 0-3 scaling scheme, the score is transformed into to 0 to 100 scale	Pre-intervention versus post-intervention For participants with stress urinary incontinence, there was significant reduction in score after intervention (68.6 ± 17 versus 42.5 ± 16, $p < 0.001$) For participant with mixed urinary incontinence, there was significant reduction in score after intervention (66.3 ± 20 versus 53.2 ± 18, $p < 0.001$) The score reduction for participants with stress urinary incontinence was significantly larger compared with that

				for participants with mixed urinary incontinence (median: 27 versus 11, $p = 0.003$)
IIQ-7	Fan et al., 2013	Baseline and 3 months plus after intervention initiation*	The 7-item scale was graded on 0-3 scaling scheme, the score is transformed into to 0 to 100 scale	Pre-intervention versus post-intervention Significant reduction in score after intervention (29.2 ± 23.5 versus 21.9 ± 22.5, $p = 0.005$)
	Cavkavtar et al., 2014	Baseline and 2 months after intervention	The 7-item scale was graded on 0-3 scaling scheme, the score is transformed into to 0 to 100 scale	Pre-intervention versus post-intervention For participants with stress urinary incontinence, there was significant reduction in score after intervention (63.1 ± 21 versus 41.2 ± 13, $p < 0.001$) For participants with mixed urinary incontinence, there was significant reduction in score after intervention (62.8 ± 21 versus 47.6 ± 22, $p < 0.001$) The score reduction for participants with stress urinary incontinence was significantly larger compared with that for participants with mixed urinary incontinence (median: 24 versus 9, $p = 0.023$)
ICIQ-LUTqol	Sjöström et al., 2013	Baseline and 4 months after intervention	The 19-item scale was graded on 1-4 scaling scheme	Internet group versus postal group Internet group: there was significant reduction in score (33.6 ± 6.8 to 27.8 ± 6.0, $p < 0.001$)

				Postal group: there was significant reduction in score (33.6 ± 8.2 to 28.8 ± 7.3, $p < 0.001$) The comparison of score reductions between two groups was not significant (no reported p-value)
	Sjöström, et al., 2015	Baseline, 12 and 24 months after intervention	The 19-item scale was graded on 1-4 scaling scheme	Internet group versus postal group *From baseline to 12 months* Internet group: there was significant reduction in score (33.6 ± 6.8 to 27.5 ± 6.1, $p < 0.001$) Postal group: there was significant reduction in score (33.6 ± 8.2 to 27.8 ± 5.7, $p < 0.001$) The comparison of score reductions between two groups was not significant ($p = 0.55$) *From baseline to 24 months* Internet group: there was significant reduction in score (33.6 ± 6.8 to 26.5 ± 5.2, $p < 0.001$) Postal group, there was significant reduction in score (33.6 ± 8.2 to 27.2 ± 6.4, $p < 0.001$) The comparison of score reductions between two groups was not significant ($p = 0.28$)
	Asklund et al., 2017	Baseline and 3 months after intervention	The 19-item scale was graded on 1-4 scaling scheme	App group versus control group App group: there was significant reduction in score (the reduction was 4.8, 95% CI 3.4-6.2

				Control group: there was no significant reduction in score (the reduction was 0.7, 95% CI -0.5-1.8) The comparison of score reductions between two groups was significant (28.8 ± 6.4 versus 34.1 ± 6.7, $p = 0.005$)
	Hoffman et al., 2017	Baseline and 24 months after intervention	The 19-item scale was graded on 1-4 scaling scheme	App group Significant reduction in score after intervention (the reduction was 4.0, 95% CI 2.1-5.9, $p < 0.001$)
EQ5D-VAS	Sjöström et al., 2013	Baseline and 4 months after intervention	A vertical visual analogue scale with the endpoints of 0 and 100	Internet group versus postal group Interne group: there was significant increase in score (79.1 ± 13.6 to 83.3 ± 10.3, $p = 0.001$) Postal group: there was no significant increase in score (79.2 ± 14.0 to 81.8 ± 13.9, $p = 0.13$) The comparison of score increases between two groups was not significant ($p = 0.30$)
	Sjöström, et al., 2015	Baseline, 12 and 24 months after intervention	A vertical visual analogue scale with the endpoints of 0 and 100	Internet group versus postal group *From baseline to 12 months* Internet group: there was no significant increase in score (79.1 ± 13.6 to 80.4 ± 13.7, $p = 0.17$) Postal group: there was no significant increase in score (79.2 ± 14.0 to 83.4 ± 12.3, $p = 0.25$)

				The comparison of score increases between two group was not significant (p = 0.56) *From baseline to 24 months* Internet group: there was significant increase in score (79.1 ± 13. 6 to 83.3 ± 13.2, p = 0.005) Postal group: there was no significant increase in score (79.2 ± 14.0 to 83.5 ± 12.2, p = 0.09) The comparison of score increases between two groups was not significant (p = 0.81)

Notes:

(1) * At least 3-month exercises were prescribed in this article, and the reported duration of training was 9.9 ± 7.3 months when completing the final assessment

(2) Abbreviations

I-QOL: Incontinence of Quality of Life; higher scores present good quality of life

UDI-6: Urogenital Distress Inventory; higher scores present higher impacts

IIQ-7: Incontinence Impact Questionnaire short forms; higher scores present higher impacts

ICIQ-LUTSqol: International Consultation on Incontinence Questionnaire-Lower Urinary Tract Symptoms Quality of Life; higher scores present higher impacts

EQ5D-VAS: EuroQol 5D-Visual Analogue Scale; higher scores present good quality of life

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CHAPTER 3: EFFECTS OF UNSUPERVISED BEHAVIORAL AND PELVIC FLOOR MUSCLE TRAINING PROGRAMS ON NOCTURIA, URINARY URGENCY, AND URINARY FREQUENCY IN POSTMENOPAUSAL WOMEN: A SECONDARY ANALYSIS OF THE TULIP STUDY

Introduction

Nocturia, urinary urgency, and urinary frequency are prevalent and bothersome storage-type lower urinary tract symptoms (LUTS) among women. In 2018, the number of women aged 20 years and older with any storage-type LUTS was estimated to be 1.7 billion globally (Milsom et al., 2017). Specifically, the estimated number of nocturia (frequency ≥1), urinary urgency and frequency among women was 1.3 billion, 297 million, and 186 million, respectively (Milsom et al., 2017). Nocturia and urinary urgency are the most bothersome LUTS both at the individual and population levels (Agarwal et al., 2014). Women aged 25 to 84 years reported that an average inter-void interval that was shorter than or equal to every two hours was more bothersome than an interval of three to four hours (Lukacz, Whitcomb, Lawrence, Nager, & Luber, 2009). Nocturia and urinary urgency are associated with aging (Agarwal et al., 2014; Losada et al., 2016), and their population burden (i.e., prevalence and significant bothersome impact) is likely to increase with the challenge of the global aging population. Thus, providing effective interventions to large numbers of women through scaled-up strategies that can help mitigate the substantial burden of these symptoms and maintain women's lower urinary tract health is an important women's health priority.

Behavioral and pelvic floor muscle training (B-PFMT) programs that target bladder storage issues usually consist of several components: pelvic floor muscle exercises (PFME), the

'Knack' (i.e., quick pelvic floor muscle contractions prior to an event that is known to trigger urine leakage or urgency sensations), bladder training with urge suppression as an intentional effort to extend the inter-void interval to three to four hours, and lifestyle modifications such as fluid intake (Miller, Sampselle, Ashton-Miller, Hong, & DeLancey, 2008; Newman, Borello-France, & Sung, 2018; Newman & Burgio, 2020). B-PFMT programs that are conducted under the direction of trained continence specialists (e.g. nurse practitioners, physical therapists) over time are referred to as supervised B-PFMT programs (Burgio, 2013). Empirical evidence shows that supervised B-PFMT programs are effective in treating nocturia and urinary urgency in women by inhibiting involuntary detrusor muscle contractions (Burgio, 2013; Furtado-Albanezi, Jurgensen, Avila, Correia, & Driusso, 2019; Price, Dawood, & Jackson, 2010). Detrusor muscle contraction inhibition is theorized to occur with quick pelvic floor muscle contraction (Miller, et al, 2008; Newman, et al., 2018) and the long-term practice of PFME is thought to stimulate the automatic inhibition response to detrusor muscle contraction owing to changes in muscle morphology and neurologic function (Bo, Berghmans, Morkved, & Van Kampen, 2014; Shafik & Shafik, 2003). Supervised B-PFMT programs also have been shown to successfully treat urinary frequency of women through bladder training to extend void intervals (Burgio, 2013).

Despite favorable findings, the nature of supervised B-PFMT programs limits the number and the scope of women who can benefit from them due to the required sustained involvement of trained continence specialists during the intervention. In addition, the provision of multiple face-to-face supervised sessions that include PFME, behavioral skills training, and lifestyle modifications is not a feasible healthcare strategy, especially in countries with large female populations and an insufficient health care workforce to provide the required supervision. Thus,

B-PFMT programs that can be administered to large groups and across multiple geographic locations without intense healthcare provider supervision are needed.

Unsupervised B-PFMT programs, i.e., those that employ a one-time face-to-face or non-face-to-face education sessions and materials followed by unsupervised self-administration of the interventions, appear to be feasible for scaling up to large populations. At present, few studies have tested the effectiveness of unsupervised B-PFMT programs to improve nocturia, urinary urgency, and urinary frequency among women. As proposed in symptom management theory (SMT), symptom status can be improved by symptom management strategies. Also, the components of symptom management strategies, e.g., how to deliver strategies, will moderate the effects of such strategies on symptom status (Dodd et al., 2001; Humphreys et al., 2008). Therefore, we conducted secondary analysis using existing data from a randomized clinical trial that delivered unsupervised B-PFMT programs in one of two formats, either a face-to-face class that was about two hours long (2-hrClass) or a 20-minute video on DVD that provided essentially the same information (20-minVideo) (Sampselle et al., 2017) to test the following hypotheses:

Hypothesis 1: Women who participated in the 2-hrClass unsupervised B-PFMT program will have significant decreases in nocturia and urinary urgency episodes and significantly longer inter-void intervals at each follow-up time point from baseline.

Hypothesis 2: Women who participated in the 20-minVideo unsupervised B-PFMT program will have significant decreases in nocturia and urinary urgency episodes and significantly longer inter-void intervals at each follow-up time point from baseline.

Hypothesis 3: At each follow-up time point, women who participated in the 2-hrClass will present significant differences in nocturia and urinary urgency episodes and inter-void intervals compared with women who participated in the 20-minVideo program.

Methods

Design

This research effort is a secondary data analysis that employed existing data from a randomized, two-arm, parallel design superiority trial. The parent study, Translating Unique Learning for Incontinence Prevention (TULIP), was supported by funding from a National Institute of Nursing Research Grant (R01NR012011). The primary aim of the TULIP study was to compare the effects of unsupervised B-PFMT programs delivered in a 2-hrClass format and 20-minVideo format on urinary incontinence (UI) prevention. The primary findings have been published (Sampselle et al., 2017). The Consolidated Standard of Reporting Trials (CONSORT) flow diagram of the TULIP study is shown in **Figure 3.1**. The ethical oversight and approval of this secondary data analysis were obtained from the University of North Carolina at Chapel Hill (#19-0645).

Participants

Women aged 55 years or older were recruited at two sites (the University of Pennsylvania and the University of Michigan) for the TULIP study. These women were sent an invitation letter using a commercial mailing list. Those who wanted further information returned the postage-paid tear-off notice. Project staff contacted the respondents and determined their probable eligibility. Women with probable eligibility and having the willingness to be enrolled were scheduled for a clinical screening based on prespecified inclusion and exclusion criteria. Briefly, women with UI were excluded, but other symptoms, including nocturia, urinary urgency, and

urinary frequency of women, were not screened. Detailed descriptions of the recruitment process and the inclusion and exclusion criteria can be found elsewhere (Sampselle et al., 2017).

Randomization, allocation concealment, and blindness

In TULIP, eligible participants at each of the two sites were randomly assigned to one of two parallel groups of the trial using computer-generated random numbers. The site coordinator at each site randomized the eligible participants; trained interventionists were not blinded to group assignments; evaluators who independently conducted assessments at baseline, 3 months, 12 months, and 24 months remained blinded to the group assignment.

Intervention

Women assigned to the *2-hrClass* group (group size ≥5) attended one two-hour-face-to-face B-PFMT class taught by a trained health care provider. This session also included time for group discussions and questions and answers. Each participant received written descriptions of PFME, the 'Knack', and bladder training, as well as a PFME compact disc to use at home. Following a baseline evaluation at the clinical site, women who were assigned to the *20-minVideo* group individually viewed the video on DVD in a private office setting. No interaction between participants and interventionists was allowed. Each woman was given the DVD in order to have the opportunity to view the information at home.

The education session, which was delivered to both groups, provided specific components of the B-PFMT program including an array of non-invasive prevention practices—PFME to increase pelvic floor muscle strength, bladder training to optimize the inter-void interval, the 'Knack' to suppress both stress and urgency UI with anticipatory preemptive contraction and lifestyle modifications to include fluid and dietary modification (Arya, Banks, Gopal, & Northington, 2008). To assist with the self-administration of the interventions, women

in both groups received a magnet with the TULIP study logo to serve as a discrete reminder of the strategies they had been encouraged to adopt.

Measures

Sample characteristics

After providing their verbal and written consent, women in the TULIP study completed a questionnaire that included sociodemographic characteristics, presence of comorbidities, and health behaviors/conditions.

Outcome variables

Three outcome variables (nocturia, urinary urgency, and urinary frequency) were assessed at baseline, 3 months, 12 months, and 24 months.

Nocturia. The item, "How often do you have to get up in the night to urinate after you have fallen asleep?" on a question-based voiding diary, was used to assess nocturia. Response options were: 1 = never, 2 = one time, 3 = two times, 4 = three times, and 5 = four or more times (Arya et al., 2008).

Urinary urgency. The item, "Do you have to rush to the toilet to urinate?" on a question-based voiding diary, was used to assess urinary urgency. Response options were: 1 = never, 2 = occasionally, 3 = sometimes, 4 = most of the time, and 5 = all of the time (Arya et al., 2008).

Urinary frequency. Women's urinary frequency during their awake hours was assessed using a the 3-day bladder diary (Wyman, 2007). The inter-void interval was calculated by averaging three days' sum score of women's self-reported awake hours/urination number and was categorized into 1 = < 2 hours, 2 = ≥ 2 to < 3 hours, 3 = ≥ 3 to ≤ 4 hours, or 4 = > 4 hours.

Statistical analysis

This secondary analysis was a modified intent-to-treat analysis; missing data remained missing and were not imputed. Women's characteristics and the three urinary outcomes (nocturia, urinary urgency, and urinary frequency) at baseline were described in terms of mean ± standard deviation (SD) or frequencies and percentages, as appropriate, and the between-group differences of these variables were tested for random imbalance. Response to the three urinary outcomes at each follow-up time point are presented in frequency and percentage capture the overall group changes from baseline to 24-month follow up.

To test Hypotheses 1 and 2, we used a cumulative logit mixed-effects model, with time, site, and the time-by-site interaction as the fixed effect terms, and a random intercept term with a flexible threshold. The interaction term was added as a goodness-of-fit assessment and, if found non-significant, it was dropped from the model. To test Hypothesis 3, we used a cumulative logit mixed-effects model, with time, site, group, and the group-by-time interaction as the fixed effect terms, and a random intercept term with a flexible threshold. In addition, when sparse categories in the within- and between-group comparisons were evident for the urinary outcomes, we conducted sensitivity analysis by merging adjacent categories to validate the findings.

We performed all statistical analyses using the SPSS 26.0 software package (Armonk, NY: IBM Corp.). We used cumulative odds ratios (cOR) with their corresponding 95% confidence interval (95% CI) to quantify the effect size and considered a two-sided p-value <0.05 to be statistically significant without adjustment for multiple testing.

Results

Sample characteristics

The mean age of the 647 women enrolled in the TULIP study was (62.9 ± 5.7) years; 67.9% were non-Hispanic white and 90.3% had received at least some college education. The majority, 69.1%, reported annual household income ≤ 100,000 USD. Approximately 45% of the women reported that they were employed or retired/disabled, respectively. More than 60% of the women reported no comorbidities. Most of the women in the TULIP study were overweight or obese, had a history of pregnancy, and had no history of psychological disorder or bowel problems. Detailed information about sample and group characteristics is presented in **Table 3.1**. No significant between-group differences were evident.

Baseline characteristics of urinary outcomes

Women's responses for frequency of nocturia were 16.1% (104/644) never, 56.5% (364/644) 1 time, 20.7% (133/644) 2 times, 5.4% (35/644) 3 times, and 1.2% (8/644) 4 or more times. Women's responses for urinary urgency were 19.2% (124/646) never, 54.5% (352/646) occasionally, 23.2% (150/646) sometimes, 2.9% (19/646) most of the time, and 0.2% (1/646) all of the time. Women's responses for urinary frequency were: 21.7% (140/645) equal to or less than 2 hours, 47.0% (303/645) 2 to 3 hours, 20.8% (134/645) 3 to 4 hours, and 10.5% (68/645) greater than 4 hours of urinary frequency. Baseline outcome variables for both groups are presented in **Figure 3.2**; no significant between-group differences are evident.

Within-group changes for urinary outcomes

In the *2-hrClass* group, women's self-report of frequency for each outcome at each time point is provided in **Figure 3.2**. Women were more likely to have fewer nocturia episodes at 3 months (cOR = 2.1, 95% CI 1.6-2.9, $p < 0.001$), 12 months (cOR = 2.1, 95% CI 1.6-3.0, $p <$

0.001), and 24 months (cOR = 1.7, 95% CI 1.2-2.3, $p = 0.005$). They were also more likely to have fewer urinary urgency episodes at 12 months (cOR = 1.7, 95% CI 1.2-2.3, $p = 0.002$) and have longer average inter-void intervals (i.e., 3-4 hours and greater than 4 hours) at 3 months (cOR = 4.8, 95% CI 3.5-6.7, $p < 0.001$), 12 months (cOR = 4.5, 95% CI 3.2-6.3, $p < 0.001$), and 24 months (cOR = 5.7, 95% CI 4.0-8.1, $p < 0.001$); see **Table 3.2**.

In the *20-minVideo* group, women's self-report of frequency for each outcome at each time point also is provided in **Figure 3.2.** Women were more likely to have fewer nocturia episodes at 3 months (cOR = 2.7, 95% CI 2.0-3.8, $p < 0.001$), 12 months (cOR = 3.5, 95% CI 2.4-4.9, $p < 0.001$), and 24 months (cOR = 3.6, 95% CI 2.6-5.2, $p < 0.001$). They were more likely to have fewer urinary urgency episodes at 3 months (cOR = 1.8, 95% CI 1.4-2.4, $p < 0.001$), 12 months (cOR = 1.5, 95% CI 1.1-2.0, $p = 0.032$), and 24 months (cOR = 1.6, 95% CI 1.1-2.2, $p = 0.013$). They were also more likely to have longer average inter-void intervals (i.e., 3-4 hours and greater than 4 hours) at 3 months (cOR = 4.7, 95% CI 3.3-6.5, $p < 0.001$), 12 months (cOR = 5.3, 95% CI 3.8-7.4, $p < 0.001$), and 24 months (cOR = 5.3, 95% CI 3.8-7.5, $p < 0.001$); see **Table 3.2**.

Between-group differences for urinary outcomes

No significant between-group differences of nocturia were observed at 3 months and 12 months, however, at 24 months, women in the *2-hrClass* group were less likely to have fewer nocturia episodes (cOR = 0.5, 95% CI 0.3-0.7, $p = 0.005$) that women in the *20-minVideo* group. No significant between-group differences for urinary urgency and urinary frequency were observed at any follow-up time point; see **Table 3.3**.

Discussion

Researchers and clinicians have used multiple strategies (i.e., internet, mobile apps, and 20-minutes Video) to deliver effective unsupervised B-PFMT programs to treat or prevent UI in large samples of women (Asklund et al., 2017; Sampselle et al., 2017; Sjostrom et al., 2013).

This secondary analysis found evidence that postmenopausal women were more likely to have fewer episodes of nocturia and urinary urgency and longer average inter-void intervals after receiving unsupervised B-PFMT programs. These results complement those of Sampselle et al. and Diokno et al., who found that the *2-hrClass* unsupervised B-PFMT programs could be used to treat and prevent UI and maintain the original, negligible severity of urinary urgency in postmenopausal women 24 months later (Diokno et al., 2018; Diokno et al., 2004; Sampselle et al., 2017). In addition, Sampselle et al. (2017) found that the *20-minVideo* programs could be used to prevent UI and maintain the original, negligible severity of urinary urgency in postmenopausal women 24 months later (Sampselle et al., 2017). Hence, unsupervised B-PFMT programs are promising interventions that can be scaled up to large numbers of postmenopausal women to reduce the incidence and prevalence and impactful burdens of storage-type LUTS.

In this secondary analysis, the beneficial impacts of the unsupervised B-PFMT programs did not differ significantly between the two groups except for the nocturia at 24 months when the impact favored the *20-minVideo* group over the *2-hrClass* group. Despite non-significant findings from the between-group comparisons, the intervention delivery formats did appear to affect the effect sizes and their changing trends over time. For example, B-PFMT program delivered in *20-minVideo* format had a greater effect on symptom status of nocturia than that delivered in the *2-hrClass* format at each follow-up time point. Moreover, the effect size for the *20-minVideo* format showed a steady increasing trend, which differed from the *2-hrClass* format

for which the effect size remained unchanged through 12 months and declined thereafter. This difference indicates that women assigned to the *20-minVideo* group had a higher and more sustained probability of experiencing fewer nocturia episodes over time compared to their *2-hrClass* group counterparts. In addition, women assigned to the *20-minVideo* group showed greater sustained probability of experiencing fewer urinary urgency episodes over time compared to their *2-hrClass* group counterparts who experienced a significant decrease in episodes only at 12 months. Although no obvious advantage of one format over the other was found for urinary frequency, differences were found in the magnitude of their effects. These findings regarding effectiveness imply that the *20-minVideo* format likely is the better option for a scaled-up B-PFMT programs.

Another advantage of using the *20-minVideo* format over the *2-hrClass* format to deliver the intervention is its lower cost. For example, a cost analysis previously conducted using the data from the TULIP study indicated that the average operating cost (i.e., the labor fee) of the *2-hrClass* format was 38 USD and noted that most women were willing to pay only 30 USD or less. However, women indicated that they would be willing to pay 26 USD or 28 USD to receive the *20-minVideo* format programs for which the operating cost of this format was close to 0 USD (Wagner et al., 2018). Therefore, the expectation is that more women would participate in the *20-minVideo* unsupervised B-PFMT program than the *2-hrClass* program.

Further, the *20-minVideo* format used in TULIP study is similar to other patient learning opportunities in many clinical settings where women often view content-rich video without clinician involvement. This potential flexibility increases the feasibility of scaling up unsupervised B-PFMT programs to large groups of women using the 20-minVideo format.

This secondary data analysis has two specific strengths. First, the women who participated in the TULIP study were recruited initially to try to prevent incidence of UI within a two-year timeframe (Sampselle et al., 2017). It is likely, then, when compared to UI, women's social desirability response bias would be less for reporting nocturia, urinary urgency and urinary frequency. Second, the women enrolled in the TULIP study were homogeneous in many characteristics, which served to strengthen the internal validity of our findings.

This secondary analysis also has limitations. First, this analysis used data from a trial that did not specifically recruit women based on nocturia, urinary urgency, and urinary frequency. Thus, the sample size was not set *a priori* to power these analyses. Second, although the multiplicity of testing is an issue in this secondary analysis, no subgroup analyses for nocturia, urinary urgency, and urinary frequency were conducted because such analyses were not predefined in TULIP study, and the selective reporting of subgroups analyses could also lead to bias (Assmann, Pocock, Enos, & Kasten, 2000). Third, women recruited in the TULIP study had no UI, and therefore, translating these findings to postmenopausal women who have UI is a concern. Given the homogeneity of the sample, external validity that is applicable to other groups of women is limited. Fourth, urinary frequency is conceptualized as individual's complaint of urination too often (Milsom et al., 2017), and the goal of bladder training is to help women extend their inter-void interval to three to four hours (Newman & Burgio, 2020), which adheres to the definition of normal bladder function (Wyman et al., 2020). We observed that many women had inter-void intervals longer than four hours after the intervention, which could increase the risk of urinary tract infections (Wu, Xue, & Palmer, 2019; Zhu et al., 2019). The reason that these intervals exceeded current norms after the intervention is unclear, and future research is needed to address this issue.

Conclusions

Unsupervised B-PFMT programs, regardless of format (face-to-face or video instruction), significantly decrease nocturia and urinary urgency episodes and extend the average inter-void intervals among postmenopausal women. In terms of feasibility and acceptability, using the 20-minVideo format appears to be promising for scaling up unsupervised B-PFMT programs to manage storage-type LUTS for large groups of postmenopausal women. Because the original TULIP data were collected from older women who did not have UI, generalizing the findings to women with UI, especially those at younger ages may be problematic. Future studies are needed to address these concerns before scaling up this intervention.

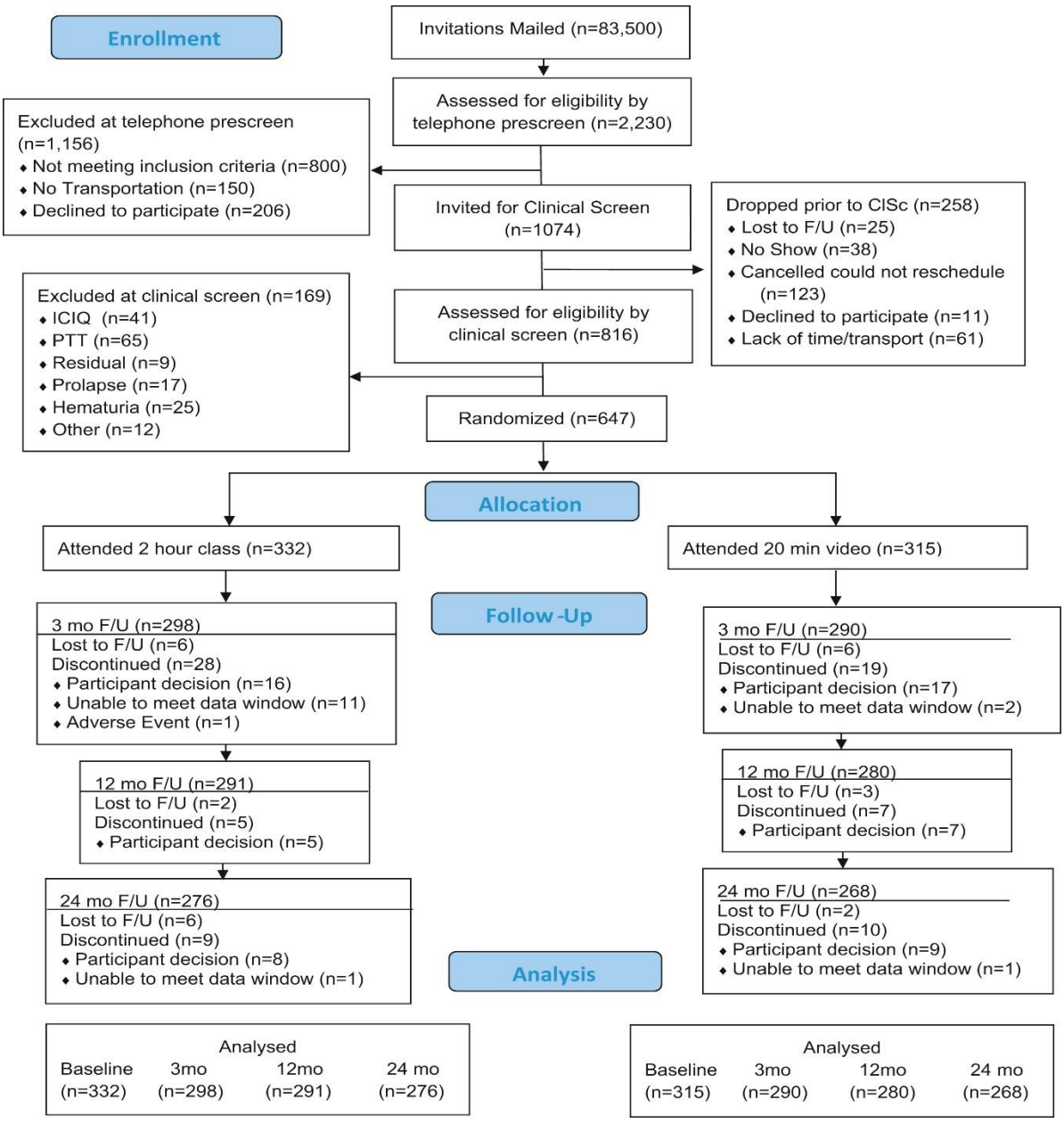

Figure 3.1

TULIP CONSORT Flow Diagram. Cisc, Clinical Screen. F/U, Follow Up. ICIQ, ICIQ-SF. PTT, Paper Towel Test. Source: Sampselle, Carolyn M, et al.(2017). Reprinted with Permission from Wolters Kluwer (#4915140347232).

Table 3.1

Characteristics of Postmenopausal Women Who Participated in TULIP Study

Variables	Overall sample n (%) or mean ± SD	2-hrClass group n (%) or mean ± SD	20-minVideo group n (%) or mean ± SD	*p*-value
Sociodemographic characteristics				
Age	62.9 ± 5.7	63.0 ± 5.4	62.8 ± 5.9	0.616
Race	647	332	315	0.130
Non-Hispanic white	439 (67.9)	214 (64.5)	225 (71.4)	
Non-Hispanic black	181 (27.9)	101 (30.4)	80 (25.4)	
Hispanic and others	27 (4.2)	17 (5.1)	10 (3.2)	
Educational background	647	332	315	0.553
High school and below	63 (9.7)	31(9.3)	32 (10.2)	
Some college	182 (28.1)	96 (28.9)	86 (27.3)	
Bachelor/post-baccalaureate	185 (28.6)	100 (30.1)	85 (37.0)	
Graduate level	217 (33.5)	105 (31.6)	112 (35.5)	
Employment	646	332	314	0.653
Employed (full-time & part-time)	292 (45.2)	144 (43.4)	148 (47.1)	
Unemployed/disabled	53 (8.2)	28 (8.4)	25 (8.0)	
Others (retired, disabled)	301 (46.6)	160 (48.2)	141 (44.9)	
Annual household income	645	331	314	0.550
< US$50,000	246 (38.1)	124 (37.5)	122 (38.9)	
US$50,000 - US$100,000	200 (31.0)	104 (31.4)	96 (30.6)	
> US$100,000	128 (19.8)	71 (21.4)	57 (18.1)	
Not reported	71 (11.0)	32 (9.7)	39 (12.4)	
Comorbidities				
Hypertension	642	330	312	0.306
Yes	233 (36.3)	126 (38.2)	107 (34.3)	

No	409 (63.7)	204 (61.8)	205 (65.7)	
Diabetes	643	329	314	0.438
Yes	74 (11.5)	41 (12.5)	33 (10.5)	
No	569 (88.5)	288 (87.5)	281 (89.5)	
Hyperlipidemia	645	331	314	0.747
Yes	224 (34.7)	113 (34.1)	111 (35.4)	
No	421 (65.3)	218 (65.9)	203 (64.6)	
Health behaviors/conditions				
BMI	642	328	314	0.199
Underweight (< 18.5)	8 (1.3)	4 (1.2)	4 (1.3)	
Normal weight (≤ 18.5 - ≤ 25)	173 (26.9)	81 (24.7)	92 (29.3)	
Overweight (< 25 - < 30)	222 (34.6)	115 (35.1)	107 (34.1)	
Obese (≥ 30)	239 (37.2)	128 (39.0)	111 (35.4)	
Smoking history	642	328	314	0.324
Yes	41 (6.4)	24 (7.3)	17 (5.4)	
No	601 (93.6)	304 (92.7)	297 (94.7)	
History of psychological disorder	641	330	311	0.442
Yes	126 (19.7)	61 (18.5)	65 (20.9)	
No	515 (80.3)	269 (81.5)	246 (79.1)	
Bowel problems (constipation, diarrhea)	640	330	310	0.743
Yes	94 (14.7)	47 (14.2)	47 (15.2)	
No	546 (85.3)	283 (85.8)	263 (84.8)	
Previous pregnancy history	642	330	312	0.637
Yes	545 (84.9)	278 (84.2)	267 (85.6)	
No	97 (15.1)	52 (15.8)	45 (14.4)	

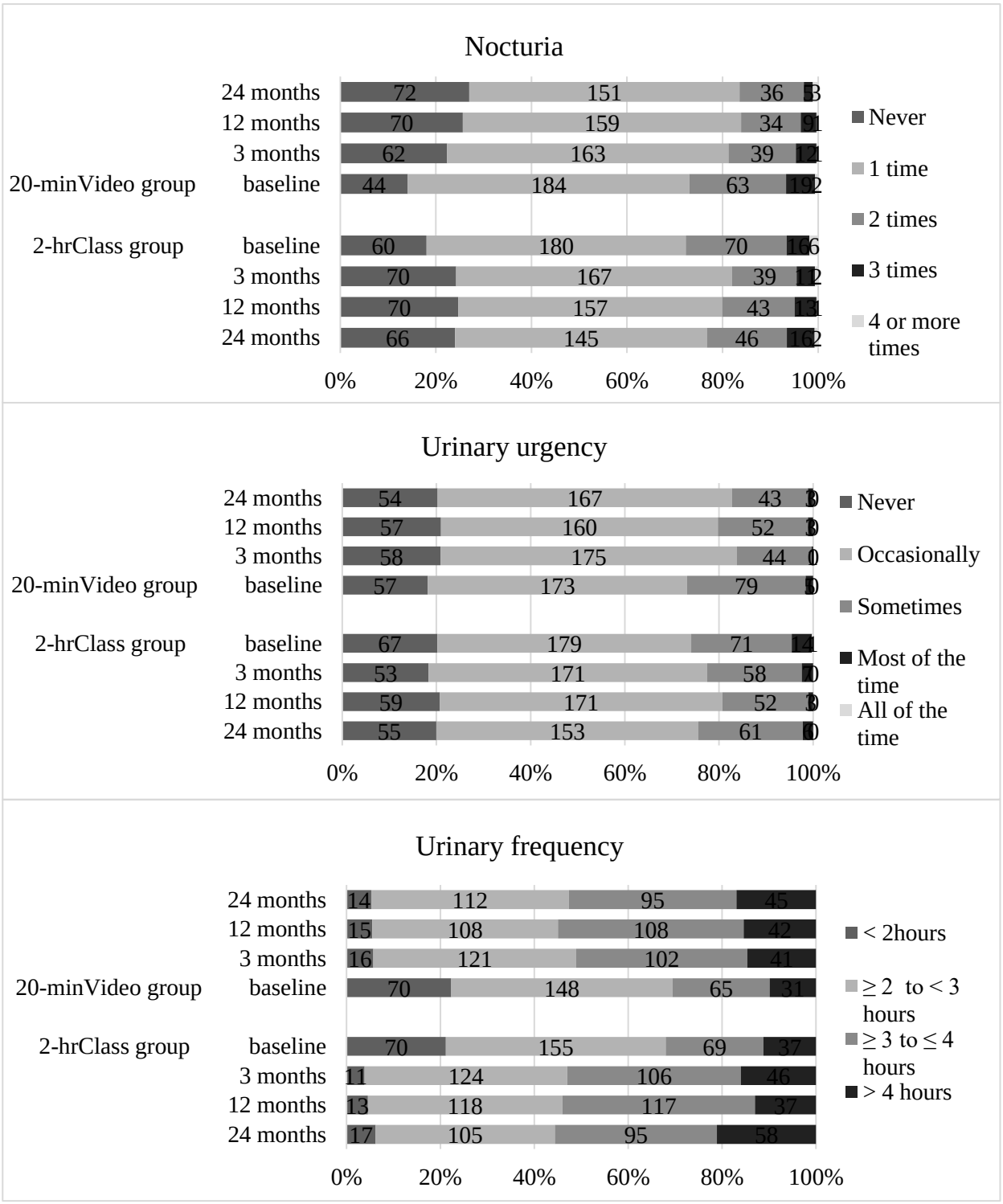

Figure 3.2

Distribution of Nocturia, Urinary Urgency and Urinary Frequency among Postmenopausal Women at Each Time Point

Table 3.2

Within Group Changes in Nocturia, Urinary Urgency and Urinary Frequency among Postmenopausal Women

Variables	2-hrClass group			20-minVideo group		
	cOR	95% CI	*p*-value	cOR	95% CI	*p*-value
Nocturia*						
Time (ref. baseline)						
3 months	2.1	(1.6, 2.9)	<0.001	2.7	(2.0, 3.8)	<0.001
12 months	2.1	(1.6, 3.0)	<0.001	3.5	(2.4, 4.9)	<0.001
24 months	1.7	(1.2, 2.3)	0.005	3.6	(2.6, 5.2)	<0.001
Urinary urgency*						
Time (ref. baseline)						
3 months	1.2	(0.9, 1.6)	0.224	1.8	(1.4, 2.4)	<0.001
12 months	1.7	(1.2, 2.3)	0.002	1.5	(1.1, 2.0)	0.032
24 months	1.2	(0.9, 1.7)	0.241	1.6	(1.1, 2.2)	0.013
Urinary frequency						
Time (ref. baseline)						
3 months	4.8	(3.5, 6.7)	<0.001	4.7	(3.3, 6.5)	<0.001
12 months	4.5	(3.2, 6.3)	<0.001	5.3	(3.8, 7.4)	<0.001
24 months	5.7	(4.0, 8.1)	<0.001	5.3	(3.8, 7.5)	<0.001

Notes:

(1) *Sensitivity analysis did not change conclusion reached using the raw data.

(2) Abbreviations

cOR: cumulative odds ratio

CI: confidence interval

Table 3.3

Between-Group Differences in Nocturia, Urinary Urgency and Urinary Frequency among Postmenopausal Women

Between-group comparisons	Nocturia*			Urinary urgency*			Urinary frequency		
	cOR	95% CI	*p*-value	cOR	95% CI	*p*-value	cOR	95% CI	*p*-value
2-hrClass versus 20-minVideo at 3 months	0.8	(0.6, 1.2)	0.392	0.7	(0.5, 1.0)	0.073	1.1	(0.7, 1.6)	0.852
2-hrClass versus 20-minVideo at 12 months	0.7	(0.4, 1.0)	0.089	1.1	(0.8, 1.8)	0.597	0.9	(0.6, 1.3)	0.496
2-hrClass versus 20-minVideo at 24 months	0.5	(0.3, 0.7)	0.005	0.8	(0.5, 1.3)	0.354	1.1	(0.7, 1.7)	0.756

Notes:

(1) * Sensitivity analysis did not change conclusion reached using raw data.

(2) Abbreviations

cOR: cumulative odds ratio

CI: confidence interval

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CHAPTER 4: ADHERENCE TO PELVIC MUSCLE EXERCISES AMONG POSTMENOPAUSAL WOMEN PARTICIPATING IN UNSUPERVISED BEHAVIORAL AND PELVIC FLOOR MUSCLE TRAINING PROGRAMS: PRELIMINARY RESULTS

Introduction

A review of the literature indicates that behavioral and pelvic floor muscle training (B-PFMT) programs are effective in treating urinary incontinence (UI), which is a very prevalent condition and creates substantial burden for women globally (Cacciari, Dumoulin, & Hay-Smith, 2019; Wu, Newman, & Palmer, 2020). The effectiveness of B-PFMT programs to prevent UI among women is supported by empirical studies (Diokno et al., 2004; Sampselle et al., 2017). 'Adherence', defined as "the extent to which a person's behavior corresponds with agreed recommendations from a health care provider", is crucial for ensuring and maintaining the effectiveness of any B-PFMT program (Dumoulin, Hay-Smith, et al., 2015; Sabaté, 2003).

Adherence to B-PFMT programs is a complex issue because such programs include a fixed component, i.e., pelvic floor muscle exercises (PFME), combined with other components including bladder training with urge suppression, the 'Knack', and lifestyle modifications (Newman, Borello-France, & Sung, 2018; Newman & Burgio, 2020). Further, B-PFMT programs can be delivered either in a supervised format or unsupervised format. Supervised B-PFMT programs are conducted under the direction of a trained continence specialist (e.g., a physical therapist or nurse practitioner) for multiple times or sessions (Burgio, 2013). Unsupervised B-PFMT programs start with either a one-time face-to-face or non-face-to-face education session about the B-PFMT program followed by self-administration of the program's

components (Newman & Wein, 2013). Discussion of adherence to B-PFMT programs, therefore, is expected to address both the components of the programs and the delivery format.

Most evidence for adherence by women who participate in supervised B-PFMT programs addresses one component, i.e., PFME (Dumoulin, Hay-Smith, et al., 2015). Because no standard protocol for the required elements of and dose for optimal PFME is currently available, researchers often have developed their own questionnaires to monitor women's adherence to a program's prescribed PFME. For example, one study used a questionnaire to assess the number of days women performed various PFME and the total count of their daily practice of muscle contractions and reported adherence using predefined rules (Borello-France et al., 2013). Another study used a questionnaire to evaluate the total daily minutes, daily repetition of exercise sets, and daily contractions of women and reported that higher sum scores of the three items indicated greater adherence to PFME (Sacomori, Berghmans, de Bie, Mesters, & Cardoso, 2020). In addition, studies that applied supervised B-PFMT programs identified several person-specific factors that could be associated with women's adherence to PFME, such as age, race/ethnicity, educational background, employment status, self-efficacy, and the type/severity of lower urinary tract symptoms (LUTS) (e.g., UI, nocturia, urinary urgency, and urinary frequency) (Dumoulin, Alewijnse, et al., 2015; Frawley, McClurg, Mahfooza, Hay-Smith, & Dumoulin, 2015).

Due to the high prevalence of UI, the prevention and treatment of UI should be studied closely and consider the delivery format of B-PFMT programs. However, limited evidence is available about the adherence to PFME of women who participate in unsupervised B-PFMT programs, which are feasible for the population-level applications. Unlike supervised B-PFMT programs, unsupervised B-PFMT programs are not restricted by the fact that the number of

continence specialists is insufficient globally (Bury, Skinner, & Stokes, 2015; Ostaszkiewicz et al., 2018) because unsupervised B-PFMT programs are less dependent on specialists to deliver the intervention. Furthermore, unsupervised B-PFMT programs are not dependent on scheduling and attending appointments, and frequent or long-distance travel to clinics or other venues for participants.

Therefore, this secondary analysis, under the guidance of symptom management theory (SMT) (Dodd et al., 2001; Humphreys et al., 2008), seeks to understand adherence to PFME of women who participate in unsupervised B-PFMT programs. We analyzed data collected from postmenopausal women who participated in unsupervised B-PFMT programs for two years to develop preliminary information about adherence to PFME in an unsupervised delivery format. The first aim was to explore women's adherence to PFME at 3, 12, and 24 months and the within- and between- pattern changes over time. The second aim was to test the hypothesis that women's PFME adherence at each follow-up time point was predicted by factors in the two domains of (1) person and (2) health and illness. This hypothesis is congruent with the proposition in SMT (Dodd et al., 2001; Humphreys et al., 2008) whereby adherence is influenced by person-related factors, such as demographic, psychological, sociological, and developmental variables, as well as by health and illness-related factors, such as risk factors, health status, disease, and injury (Dodd et al., 2001; Humphreys et al., 2008). We selected these factors for this study based on evidence for adherence to PFME in supervised B-PFMT programs (Dumoulin, Alewijnse, et al., 2015; Frawley et al., 2015).

Methods

Study design and participants

This secondary data analysis used data collected from the "Translating Unique Learning for Incontinence Prevention (TULIP)" study that was funded by a National Institute of Nursing Research Grant (R01NR012011). **Figure 4.1** presents the Consolidated Standard of Reporting Trials (CONSORT) flow diagram of the TULIP study. The primary aim of the TULIP study was to compare the effects of unsupervised B-PFMT programs delivered in two formats to prevent UI among women aged 55 years and older (Sampselle et al., 2017). In order to use TULIP data for this secondary data analysis, we signed a data use agreement and obtained ethical oversight and approval from the University of North Carolina at Chapel Hill (# 19-0645).

Researchers at two research centers, the University of Michigan and the University of Pennsylvania, recruited women for the TULIP study. The inclusion and exclusion criteria used in the recruitment process can be found in Sampselle et al. (2017). The total number of women who were eligible for the study was 647; women was randomly assigned into one of two intervention groups to participate in an unsupervised B-PFMT program: (1) a two-hour class (*2-hrClass*) group, with educational information taught by a trained health care provider and a PFME compact disc provided to each woman for her own practice, and (2) a 20-minute video on DVD (*20-minVideo*) group that received essentially the same educational information as women in the *2hrClass* group, as well as the DVD to view the information at home. The information delivered in the one-time education session for each group covered PFME, bladder training, the 'Knack', and lifestyle modifications. Detailed descriptions of the information delivered in the two groups are published elsewhere (Sampselle et al., 2017).

Pelvic floor muscles (PFM) consist of 70% slow-twitch and 30% fast-twitch muscle fibers (Laycock & Jerwood, 2001). The PFME prescribed in the TULIP study included three commonly used parameters (Wu et al., 2020): long contractions (i.e., sustained muscle contractions generated by the PFM), short contractions (i.e., short bursts of the maximum force generated by the PFM), and frequency of PFME (i.e., the number of days that PFME are performed within a certain timeframe). Together, these three parameters make each type of muscle fiber work as efficiently as possible.

Strategies that included verbal persuasion, emotional arousal, vicarious experience, and performance accomplishment, as originally recommended by Bandura (2002), were employed in the education session to increase women's self-efficacy. After the one-time education session, each woman was given a magnet having the logo of the TULIP study and was recommended to put it in a conspicuous location at home. The magnet served as a visual cue to remind each woman to perform PFME from the beginning of the program to its conclusion. Follow-up assessments of the TULIP study were set at 3 months, 12 months, and 24 months.

Measures

Person-related factors

The person-related factors collected in the TULIP study included age, race, employment status, educational background, and annual household income. Women self-reported these factors on a written questionnaire at baseline.

An additional person-related factor, self-efficacy, is a multi-dimensional concept; a modified version of self-efficacy for PFME questionnaire was used in the TULIP study (Messer et al., 2007). This 9-item questionnaire consisted of the knowledge dimension (4 items), regulatory dimension (2 items), and task dimension (3 items). The knowledge dimension was

designed to elicit women's knowledge about managing UI, e.g., "How confident are you that you can do things that will avoid urine loss?" The regulatory dimension was aimed to assess women's ability to embed PME into their daily life, e.g., "How confident are you that you can fit the exercise program into your weekly life?" The task dimension included items to assess women's ability to engage in PME consistently and correctly, e.g., "How confident are you that you can achieve the contractions for the full duration?". Self-efficacy was assessed immediately after the education session and prior to the self-administration of the program in the TULIP study. All items were graded on a 5-point scoring scale from 1 = not at all confident to 5 = a great deal confident. The average score was calculated for each dimension, with the higher score representing greater self-efficacy. The Cronbach's alpha coefficients for the three dimensions in this study ranged from 0.777 to 0.864.

Health and illness-related factors

The health and illness-related factors collected in the TULIP study included body mass index (BMI), smoking history, hypertension, diabetes mellitus, hyperlipidemia, bowel problems (e.g., constipation, diarrhea), and history of psychological disorder. Women self-reported these factors at baseline.

Nocturia and urinary urgency was assessed separately by a single item on a question-based voiding diary (Arya, Banks, Gopal, & Northington, 2008). The item, "How often do you have to get up in the night to urinate after you have fallen asleep?", was graded as 1 = never, 2 = one time, 3 = two times, 4 = three times, and 5 = four or more times to assess nocturia. The item, "Do you have to rush to the toilet to urinate?", was graded as 1 = never, 2 = occasionally, 3 = sometimes, 4 = most of the time, and 5 = all of the time to assess urinary urgency. Nocturia and urinary urgency were assessed at baseline, 3 months, and 12 months in the TULIP study.

'Urinary frequency' is defined as the perception of urinating too often during the day and was assessed via a 3-day bladder diary (Wyman, 2007). The inter-void interval was calculated by averaging three days' sum scores of self-reported awake hours/urination number in categories of 1 = < 2 hours, 2 = ≥ 2 to < 3 hours, 3 = ≥ 3 to ≤ 4 hours, or 4 = > 4 hours. The rationales for this categorization are (1) an inter-void interval that is shorter than every two hours is more bothersome than an interval of every three to four hours (Lukacz, Whitcomb, Lawrence, Nager, & Luber, 2009); (2) an inter-void interval of three to four hours adheres to the definition of normal bladder function (Wyman et al., 2020); and (3) an extended inter-void interval would increase the risk of urinary tract infections (Wu, Xue, & Palmer, 2019). Urinary frequency was assessed at baseline, 3 months, and 12 months in the TULIP study.

Adherence

Researchers of the TULIP study developed three items to assess women's adherence to PFME. The first item addressed short contractions of PFM by asking, "Each time you did the exercise, how many of the short contractions have you been able to complete?" The second item addressed long contractions of PFM by asking, "Each time you did the exercises, how many of the long contractions have you been able to complete?" Both items were graded as 1 = none, 2 = some, 3 = most, and 4 = all. The third item addressed the frequency of PFME by asking, "How often have you done the pelvic floor muscle exercises?" Responses were graded as 1 = never, 2 = less than once a week, 3 = once a week, 4 = twice most weeks, 5 = twice each week, 6 = three times most week, 7 = three times each week, and 8 = every day. PFME adherence was assessed at 3 months, 12 months, and 24 months in the TULIP study.

Statistical analysis

We used descriptive statistics to analyze all the variables and *k*-means clustering approach to obtain patterns in women's adherence to PFME at each follow-up time point. Starting from the number of clusters, $k = 2$, we determined the optimal value for *k* using three stopping rules: (1) the convergency attained within 10 iterations, (2) significant differences for all between-cluster comparisons of the standardized values of items by running one-way analysis of variance with Tukey's test, and (3) the clinical interpretability of the clusters. We subsequently renamed the identified clusters as 'adherence patterns' and described the characteristics of the within- and between-pattern changes from 3 months to 12 months and from 12 months to 24 months.

Depending on the number of adherence patterns identified, we used either binary or multinomial generalized logit models to identify the influencing person-related and health and illness-related factors of the adherence patterns at each follow-up time point. Each logit model included all the person-related and health and illness-related factors. The effectiveness of the unsupervised B-PFMT program to mitigate nocturia, urinary urgency, and urinary frequency already has been shown; therefore, we regressed the values of these three symptoms at baseline, 3 months and 12 months for the adherence patterns at 3 months, 12 months, and 24 months, respectively. Each logistic model was adjusted for variables indicating the two intervention groups and two research centers. Adjusted odds ratios (*aOR*) with corresponding 95% confidence interval (CI) were calculated. We performed all analyses using the IBM® SPSS® Statistics (version 26, IBM Corp., Armonk, NY). The familywise *p*- value < 0.05 was considered to be statistically significant and the reported *p*-value for each comparison was adjusted for multiple comparisons in the adherence pattens.

Results

Sample characteristics

The women enrolled in the TULIP study (n = 647) were aged 62.91 ± 5.68 years; 67.85% were non-Hispanic white, 45.20% were employed, 90.26% reported having at least some college education, and 69.15% reported their annual household income ≤ 100,000 USD. **Table 4.1** presents details of the sample characteristics. The self-efficacy scores for the knowledge, regulatory, and task dimensions were 4.53 ± 0.60, 4.56 ± 0.56, and 4.43 ± 0.59, respectively.

Most of the women in the TULIP study were overweight or obese (71.80%) and were non-cigarette smokers (93.61%) and did not have hypertension (63.71%), diabetes mellitus (88.49%), hyperlipidemia (65.27%), bowel problems (86.31%), or a history of psychological disorders (80.34%); see details in **Table 4.1**. At baseline, most women had experienced at least one-time nocturia episode (83.85%) and has experienced at least an occasional urinary urgency episode (80.80%). The percentages of women who had an average inter-void interval of shorter than two hours and within three to four hours were 21.71% and 20.78%, respectively. **Table 4.2** presents detailed statistics for nocturia, urinary urgency, and urinary frequency at 3 months and 12 months.

Adherence scores that corresponded to short contractions of PFM, long contractions of PFM, and the frequency of PFME at 3 months were 3.49 ± 0.78, 3.16 ± 0.88, and 5.58 ± 1.92, respectively; at 12 months were 3.26 ± 0.93, 3.05 ± 0.97, and 4.97 ± 2.09, respectively; and at 24 months were 3.28 ± 0.93, 3.09 ± 0.96, and 4.80 ± 2.10, respectively.

Adherence patterns at each follow-up time point

Four clusters were identified at each of 3 months, 12 months, and 24 months, respectively. According to the scores for the three adherence items under each cluster, as shown

in **Table 4.3**, we renamed the four clusters as adherence patterns A, B, C, and D, respectively, at each follow-up time point; see **Figure 4.2**. Adherence pattern A represented that women's adherence scores for PFM contractions and frequency were all above the group averages; adherence pattern B represented that women's adherence scores for contractions and frequency were all below the group averages; adherence pattern C represented that women's adherence scores for contractions were above the group averages, but the frequency score was below the group average; adherence pattern D represented that the adherence scores for contractions were below the group averages, but the frequency score was above the group average.

Within- and between-adherence pattern changes over time

At 3 months, 267 (47.76%), 63 (11.27%), 109 (19.50%), and 120 (21.47%) women were classified as having adherence patterns A, B, C, and D, respectively. **Figure 4.3 (a)** presents the within- and between-adherence pattern changes from 3 months to 12 months. At 12 months, of the women classified under adherence pattern A (199/530, 37.55%), 160 (80.40%) moved from adherence pattern A at 3 months. Of the women classified under adherence pattern B (115/530, 21.70%), 43 (37.39%), 26 (22.61%), and 31 (26.96%) moved from adherence patterns B, C, and D at 3 months, respectively. Of the women classified under adherence pattern C (133/530, 25.09%), 57 (42.86%) and 50 (37.59%) moved from adherence patterns C and A at 3 months, respectively. Of the women classified under adherence pattern D (83/530, 15.66%), 39 (46.99%) and 26 (31.33%) moved from adherence patterns D and A at 3 months, respectively.

Figure 4.3 (b) presents the within-and between-adherence pattern changes from 12 months to 24 months. At 24 months, of the women classified under adherence pattern A (185/517, 35.78%), 141 (76.22%) moved from adherence pattern A at 12 months. Of the women classified under adherence pattern B (104/517, 20.12%), 67 (64.42%) moved from adherence

pattern B at 12 months. Of the women classified under adherence pattern C (152/517, 29.40%), 74 (48.68%) and 34 (22.37%) moved from adherence patterns C and A at 12 months, respectively. Of the women classified under adherence pattern D (76/517, 14.70%), 34 (44.74%) and 16 (21.05%) moved from adherence patterns D and A at 12 months, respectively.

Factors that influenced adherence patterns at each follow-up time point

Based on the assumption that individuals who show more adherence to prescribed interventions are more likely to benefit from the interventions, adherence pattern B was selected as the reference group for all models (i.e., *ref.* B), as shown in **Table 4.4**.

For a one-unit increase in regulatory self-efficacy and task self-efficacy, the *aOR* of adherence pattern A (*ref.* B) at 3 months was 1.42 (95% CI 1.29-4.54, $p = 0.006$) and 1.94 (95% CI 1.56-5.52, $p = 0.001$), respectively; at 12 months was 1.61 (95% CI 1.37-4.97, $p = 0.004$) and 3.67 (95% CI 2.40-9.09, $p < 0.001$), respectively; at 24 months was 1.41 (95% CI 1.26-4.81, $p = 0.009$) and 4.19 (95% CI 2.67-10.08, $p < 0.001$) , respectively.

At 12 months, the *adjusted odds* of adherence pattern A (*ref.* B) for women of normal weight was 3.12 times (95% CI 1.35-7.19, $p = 0.008$) for those who were obese, and for women who reported an annual household income > 100,000 USD was 4.06 times (95% CI 1.44-11.47, $p = 0.008$) for those who reported an income ≤ 100,000 USD. At 24 months, the *adjusted odds* of adherence pattern A (*ref.* B) for women who reported no psychological disorder history was 2.77 times (95% CI 1.23-6.24, $p = 0.014$) for those who reported having a psychological disorder history, and for women of normal weight was 3.46 times (95% CI 1.41-8.55, $p = 0.007$) for those who were obese.

At 12 months, the *adjusted odds* adherence pattern C (*ref.* B) for women who reported an annual household income > 100,000 USD was 4.26 times (95% CI 1.48-12.27, $p = 0.007$) for

those who reported an income ≤ 100,000 USD. At 24 months, for a one-unit increase in task self-efficacy, the *aOR* of adherence pattern C (*ref.* B) was 1.93 (95% CI 1.53-5.62, $p = 0.001$).

At 12 months, the *adjusted odds* of adherence pattern D (*ref.* B) for women who had high school and below was 0.15 times (95% CI 0.04-0.65, $p = 0.012$) for those who received graduate level education, and for women of normal weight was 3.63 times (95% CI 1.38-9.51, $p = 0.009$) for those who were obese. At 24 months, for a one-unit increase in task self-efficacy, the *aOR* of adherence pattern D (*ref.* B) was 1.37 (95% CI 1.19-4.70, $p = 0.014$).

Discussion

Adherence to PFME is an important determinant for the effectiveness of a B-PFMT program (Dumoulin, Hay-Smith, et al., 2015), but such adherence is a significant challenge for many women. Once women who participate in unsupervised B-PFMT programs complete a one-time education session, they must rely on themselves to perform and adopt PFME into their daily life.

The present study was guided by SMT and identified four adherence patterns to PFME at each of three follow-up time points among women who participated in unsupervised B-PFMT programs. At each time point, scores for adherence pattern A, i.e., scores on the three adherence items, were all above the group averages, which approximated the level of adherence expected by the researchers and formed the largest proportion (i.e., above 35%) of participants. This finding may be the result of the two approaches employed in the TULIP study. First, each woman received a magnet with the TULIP study logo on it to serve as a visual cue to remind them to perform PFME. The use of pairing actions (e.g., exercises, behavioral changes) with frequently encountered salient cues may promote engagement in these actions (Gardner & Rebar, 2019; McDaniel & Einstein, 1993). Second, four strategies were adopted in the TULIP study to

improve women's self-efficacy for PFME. Empirical studies have shown that self-efficacy is associated with women's adherence to PFME (Messer et al., 2007; Sacomori et al., 2020). Through the lens of the absolute value, the proportion of adherence pattern A, which was between 35.78% and 47.76% at three follow-up time points, might be lower than we expected. The large proportion of women whose adherence level was not satisfactory may indicate the existence of moderators that buffered the effects of the two approaches.

The present study demonstrates that the PFME adherence pattern that is established early in the B-PFMT program is important to predict women's subsequent adoption of the same adherence pattern, specifically for adherence pattern A. The good practice of prescribed exercises at the beginning of a program has the greatest impact on gains in terms of maintenance (Gardner & Rebar, 2019). Women in adherence pattern A at 3 months consisted of 80.40% of women in adherence pattern A at 12 months, and women in adherence pattern A at 12 months consisted of 76.22% of women in adherence pattern A at 24 months. These findings are consistent with previous evidence that short-term adherence to PFME can significantly predict long-term adherence to PFME (Alewijnse, Mesters, Metsemakers, & van den Borne, 2003). These findings therefore support the importance of exploring strategies to promote short-term adherence to PFME for women. Further, these findings indicate that the prediction ability may decrease over time, and thus, the mechanism(s) of prediction ability should be addressed in future studies to gain a better understanding of ways that adherence to PFME is maintained among women.

In this secondary analysis, regulatory self-efficacy and task self-efficacy are significant predictors of adherence to PFME, which is consistent with previous findings (Messer et al., 2007). However, the novel contribution of this study is that the women with higher scores for

regulatory self-efficacy and task self-efficacy, which were assessed immediately after the education session, were more likely to display adherence pattern A, and this relationship was sustained at all three follow-up time points. This information provides empirical support for developing strategies to improve women's initial regulatory self-efficacy and task self-efficacy to obtain both short- and long-term adherence to PFME.

Despite being able to predict adherence patterns using BMI, educational background, annual household income, and psychological history, the roles of these factors are not consistent. In this secondary analysis, these factors did not influence women's adherence patterns at 3 months, but they did influence women's adherence patterns A, C, and D at 12 months or 24 months or at both time points. These findings align with previous evidence that the factors that influence adherence to PFME, excluding self-efficacy, vary considerably across studies (Dumoulin, Hay-Smith, et al., 2015; Hay-Smith et al., 2015). We propose that the relationship between these variables and adherence patterns may be related to the transition of the adherence patterns over time and the time of the evaluation. However, the exact mechanism remains unclear, and more studies are needed.

This secondary data analysis has several limitations. First, the factors we used to model the adherence patterns were limited primarily to those that are intrinsic to women. As purported in SMT, environmental factors also influence individuals' adherence (Dodd et al., 2001; Humphreys et al., 2008). Therefore, researchers should extend their work to explore the influences of extrinsic variables on women's adherence to PFME. Second, we failed to capture any variables that could predict women's adoption of adherence pattern C or D throughout multiple follow-up time points. This limitation suggests the need for researchers to target those women, understand the reasons behind their actions, and develop strategies to optimize their

adherence to PFME. Future studies are expected to address these gaps. Last, unsupervised B-PFMT programs consisted of multiple components, and we were unable to evaluate women's adherence to all of them in this study. Adherence to all components in B-PFMT programs will be beneficial to unleash the full potential of these programs, and thus, adherence to all components should be addressed in future research.

Conclusions

Adopting prescribed exercises into one's daily life over time is not a simple process. Although two approaches were employed in the TULIP study to promote postmenopausal women's adherence to PFME, only 35.78% to 47.76% of women had adherence scores that were all above group averages at the follow-up time points. The adherence pattern adopted by women at an early time point predicted their adoption of the same adherence pattern at the next time point, specifically for adherence pattern A. Regulatory self-efficacy and task self-efficacy, which were assessed immediately after the education session, predicted women's adoption of adherence pattern A at all three follow-up time points. Therefore, strategies that target facilitating regulatory self-efficacy and task self-efficacy in tandem with unsupervised B-PFMT programs are recommended to ensure women's short-and long-term adherence to PFME.

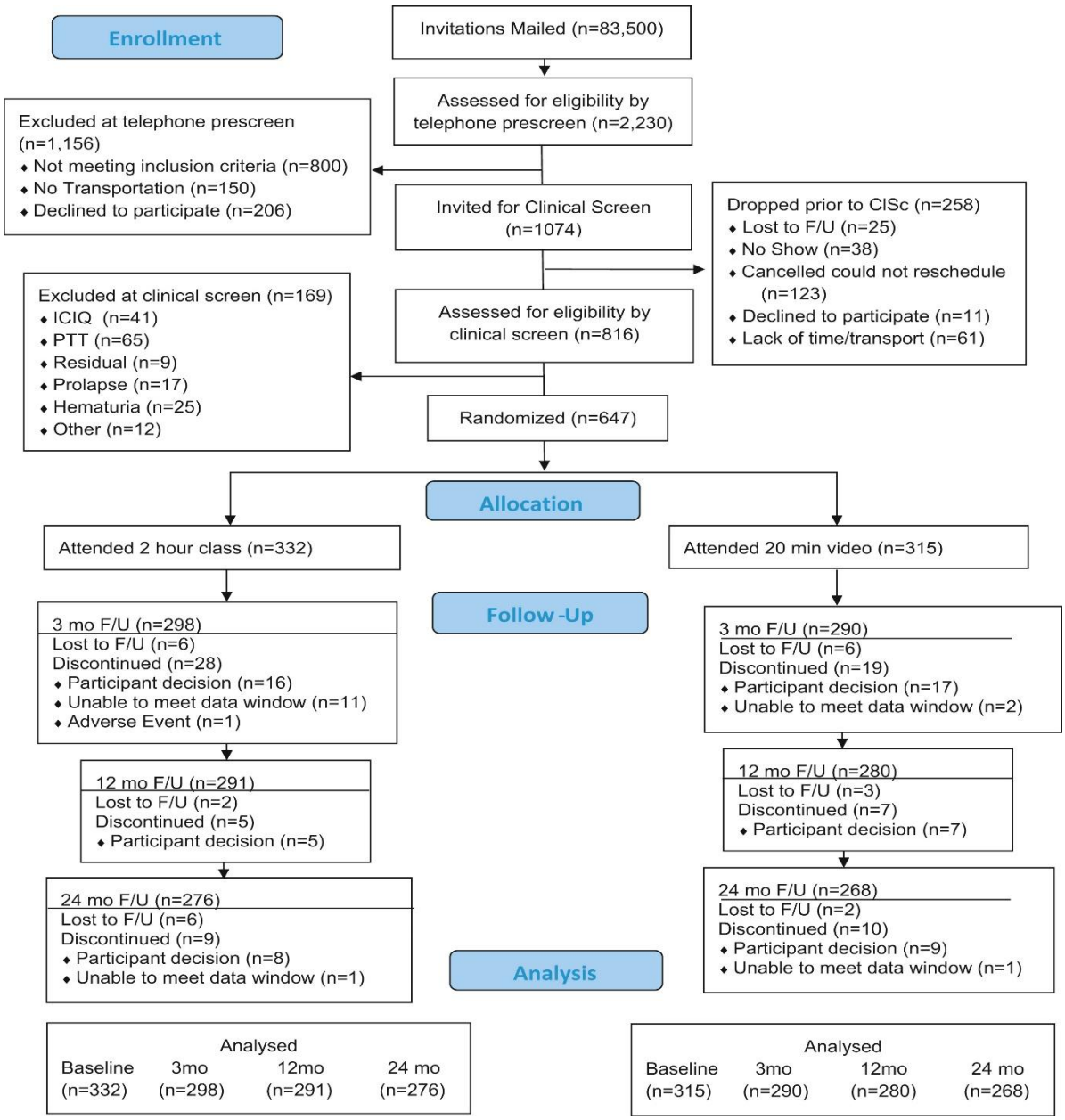


Figure 4.1

TULIP CONSORT Flow Diagram. Cisc, Clinical Screen. F/U, Follow Up. ICIQ, ICIQ-SF. PTT, Paper Towel Test. Source: Sampselle, Carolyn M, et al.(2017). Reprinted with Permission from Wolters Kluwer (#4915140347232).

Table 4.1

Characteristics of Postmenopausal Women in TULIP Study

Variables	Sample size n (%) or mean ± standardized deviation
Sociodemographic variables	
Age	62.91 ± 5.68
Race	647
Non-Hispanic black	181 (27.98)
Non-Hispanic white	439 (67.85)
Hispanic and others	27 (4.17)
Employment status	646
Employed (full-time and part-time)	292 (45.20)
Unemployed	53 (8.20)
Others (retired, disabled)	301 (46.59)
Education background	647
High school and below	63 (9.74)
Some college	182 (28.13)
Bachelor/post-baccalaureate	185 (28.59)
Graduate level	217 (33.54)
Annual household income (USD)	645
≤ 100,000	446 (69.15)
> 100,000	128 (19.84)
Prefer not to report	71 (11.01)
Psychological variable	
Self-efficacy	-
Knowledge self-efficacy	4.53 ± 0.60
Regulatory self-efficacy	4.56 ± 0.56
Task self-efficacy	4.43 ± 0.59
Risk factors	

Body mass index	642
Underweight (< 18.5)	8 (1.25)
Normal weight (≤ 18.5 - ≤ 25)	173 (26.95)
Overweight (< 25 - < 30)	222 (34.58)
Obese (≥ 30)	239 (37.22)
Smoking history	642
Yes	41 (6.39)
No	601 (93.61)
Disease status	
Hypertension	642
Yes	233 (36.29)
No	409 (63.71)
Diabetes mellitus	643
Yes	74 (11.51)
No	569 (88.49)
Hyperlipidemia	645
Yes	224 (34.73)
No	421 (65.27)
Health conditions	
Bowel problems (constipation, diarrhea)	640
Yes	94 (14.69)
No	546 (85.31)
History of psychological disorder	641
Yes	126 (19.66)
No	515 (80.34)

Notes:

(1) Knowledge self-efficacy is designed to address women's knowledge about managing urinary incontinence.

(2) Regulatory self-efficacy is designed to address women's ability to embed pelvic floor muscle exercises into their daily life.

(3) Task self-efficacy is designed to address women's ability to do pelvic floor muscle exercises consistently and correctly.

(4) Abbreviations

USD: US dollars

Table 4.2

Characteristics of Nocturia, Urinary Urgency, and Urinary Frequency among Postmenopausal Women at Baseline, 3 Months, and 12 Months

Variables	Baseline n (%)	3 months n (%)	12 months n (%)
Nocturia	644	566	557
Never	104 (16.15)	132 (23.32)	140 (25.13)
1 time	364 (56.52)	330 (58.30)	316 (56.73)
2 times	133 (20.65)	78 (13.78)	77 (13.82)
3 times	35 (5.43)	23 (4.06)	22 (3.95)
4 or more times	8 (1.24)	3 (0.53)	2 (0.36)
Urinary urgency	646	567	557
Never	124 (19.20)	111 (19.58)	116 (20.83)
Occasionally	352 (54.49)	346 (61.02)	331 (59.43)
Sometimes	150 (23.22)	102 (17.99)	104 (18.67)
Most of the time	19 (2.94)	8 (1.41)	6 (1.08)
All of the time	1 (0.15)	0 (0.00)	0 (0.00)
Urinary frequency	645	567	558
< 2 hours	140 (21.71)	27 (4.76)	28 (5.02)
≥ 2 to < 3 hours	303 (46.98)	245(43.21)	226 (40.40)
≥ 3 to ≤ 4 hours	134 (20.78)	208 (36.68)	225 (40.32)
> 4 hours	68 (10.54)	87 (15.34)	79 (14.16)

Table 4.3

Adherence Scores of Short and Long Contractions, and The Frequency of Pelvic Floor Muscle Exercises among Postmenopausal Women

Adherence patterns	Three items that assess adherence to pelvic muscle exercises (score range)	At 3 months (mean ± SD)	At 12 months (mean ± SD)	At 24 months (mean ± SD)
Adherence pattern A	Short contractions (1-4)	3.99 ± 0.12	3.96 ± 0.19	3.97 ± 0.18
	Long contractions (1-4)	3.75 ± 0.43	3.82 ± 0.39	3.80 ± 0.40
	Frequency (1-8)	6.84 ± 0.74	6.79 ± 0.87	6.75 ± 0.95
Adherence pattern B	Short contractions (1-4)	1.89 ± 0.48	1.94 ± 0.63	1.89 ± 0.68
	Long contractions (1-4)	1.83 ± 0.56	1.77 ± 0.51	1.75 ± 0.57
	Frequency (1-8)	2.75 ± 1.11	2.82 ± 1.21	2.37 ± 1.03
Adherence pattern C	Short contractions (1-4)	3.74 ± 0.44	3.65 ± 0.51	3.64 ± 0.52
	Long contractions (1-4)	3.27 ± 0.72	3.41 ± 0.61	3.51 ± 0.55
	Frequency (1-8)	3.26 ± 0.88	3.25 ± 0.84	3.45 ± 0.74
Adherence pattern D	Short contractions (1-4)	3.00 ± 0.57	2.94 ± 0.59	2.84 ± 0.59
	Long contractions (1-4)	2.46 ± 0.56	2.49 ± 0.57	2.42 ± 0.60
	Frequency (1-8)	6.35 ± 1.11	6.51 ± 0.89	6.32 ± 1.06

Notes:

(1) Adherence pattern A indicates that the adherence scores for muscle contractions and the frequency of pelvic muscle exercises are all above group averages.

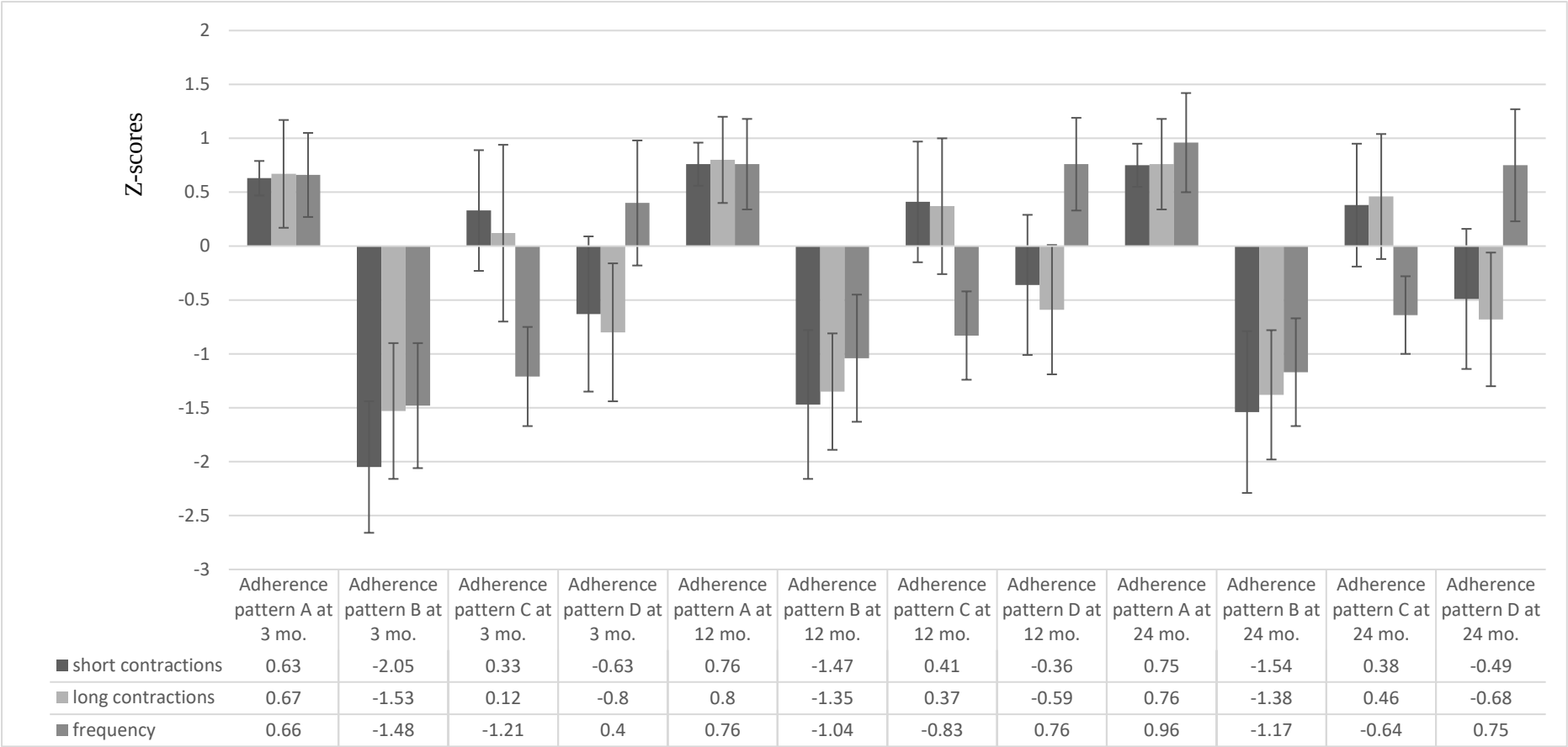
(2) Adherence pattern B indicates that the adherence scores for muscle contractions and the frequency of pelvic floor muscle exercises are all below group averages.

(3) Adherence pattern C indicates that the adherence scores for muscle contractions are above group averages, but the adherence score for frequency is below the group average.

(4) Adherence pattern D indicates that the adherence score for frequency is above the group average, but the adherence scores for muscle contractions are below group averages.

(5) Abbreviation

SD: standardized deviation



	Adherence pattern A at 3 mo.	Adherence pattern B at 3 mo.	Adherence pattern C at 3 mo.	Adherence pattern D at 3 mo.	Adherence pattern A at 12 mo.	Adherence pattern B at 12 mo.	Adherence pattern C at 12 mo.	Adherence pattern D at 12 mo.	Adherence pattern A at 24 mo.	Adherence pattern B at 24 mo.	Adherence pattern C at 24 mo.	Adherence pattern D at 24 mo.
short contractions	0.63	-2.05	0.33	-0.63	0.76	-1.47	0.41	-0.36	0.75	-1.54	0.38	-0.49
long contractions	0.67	-1.53	0.12	-0.8	0.8	-1.35	0.37	-0.59	0.76	-1.38	0.46	-0.68
frequency	0.66	-1.48	-1.21	0.4	0.76	-1.04	-0.83	0.76	0.96	-1.17	-0.64	0.75

Figure 4.2

Postmenopausal Women's Adherence Patterns to Pelvic Floor Muscle Exercises at 3 Months, 12 Months, and 24 Months

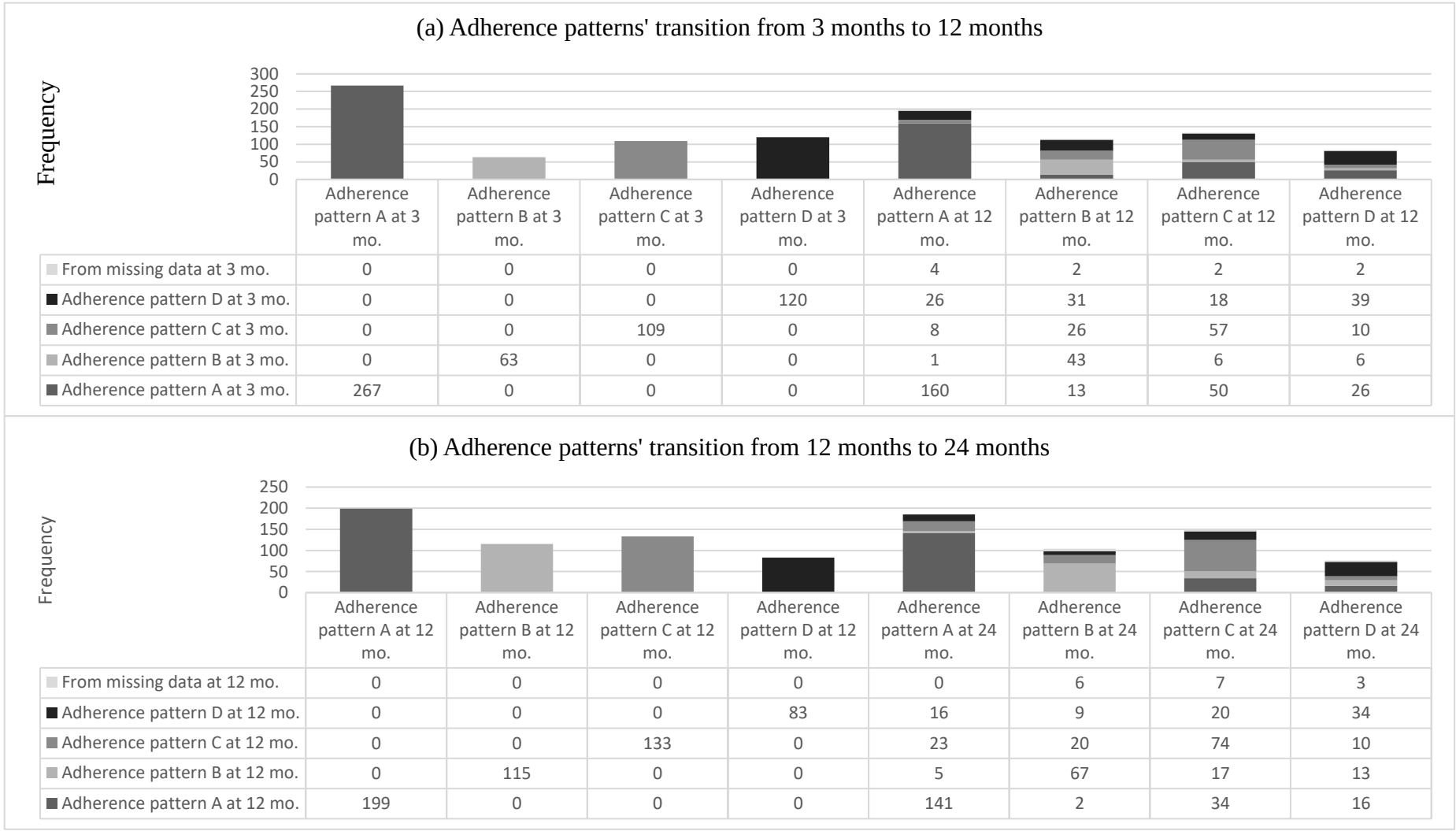
Notes:

(1) Adherence pattern A indicates that the adherence scores for muscle contractions and the frequency of pelvic floor muscle exercises are all above group averages.

(2) Adherence pattern B indicates that the adherence scores for muscle contractions and the frequency of pelvic floor muscle exercises are all below group averages.

(3) Adherence pattern C indicates that the adherence scores for muscle contractions are above group averages, but the adherence score for frequency is below the group average.

(4) Adherence pattern D indicates that the adherence score for frequency is above the group average, but the adherence scores for muscle contractions are below group averages.



	Adherence pattern A at 3 mo.	Adherence pattern B at 3 mo.	Adherence pattern C at 3 mo.	Adherence pattern D at 3 mo.	Adherence pattern A at 12 mo.	Adherence pattern B at 12 mo.	Adherence pattern C at 12 mo.	Adherence pattern D at 12 mo.
From missing data at 3 mo.	0	0	0	0	4	2	2	2
Adherence pattern D at 3 mo.	0	0	0	120	26	31	18	39
Adherence pattern C at 3 mo.	0	0	109	0	8	26	57	10
Adherence pattern B at 3 mo.	0	63	0	0	1	43	6	6
Adherence pattern A at 3 mo.	267	0	0	0	160	13	50	26

	Adherence pattern A at 12 mo.	Adherence pattern B at 12 mo.	Adherence pattern C at 12 mo.	Adherence pattern D at 12 mo.	Adherence pattern A at 24 mo.	Adherence pattern B at 24 mo.	Adherence pattern C at 24 mo.	Adherence pattern D at 24 mo.
From missing data at 12 mo.	0	0	0	0	0	6	7	3
Adherence pattern D at 12 mo.	0	0	0	83	16	9	20	34
Adherence pattern C at 12 mo.	0	0	133	0	23	20	74	10
Adherence pattern B at 12 mo.	0	115	0	0	5	67	17	13
Adherence pattern A at 12 mo.	199	0	0	0	141	2	34	16

Figure 4.3

Changes of Adherence Patterns to Pelvic Floor Muscle Exercises between Adjacent Follow-Up Time Points

Notes:

(1) Adherence pattern A indicates that the adherence scores for muscle contractions and the frequency of pelvic floor muscle exercises are all above group averages.

(2) Adherence pattern B indicates that the adherence scores for muscle contractions and the frequency of pelvic floor muscle exercises are all below group averages.

(3) Adherence pattern C indicates that the adherence scores for muscle contractions are above group averages, but the adherence score for frequency is below the group average.

(4) Adherence pattern D indicates that the adherence score for frequency is above the group average, but the adherence scores for muscle contractions are below group averages.

Table 4.4

Significant Influencing Factors of Adherence Patterns to Pelvic Floor Muscle Exercises among Postmenopausal Women at 3 Months, 12 Months, and 24 Months

	3 months		12 months		24 months	
	aOR (95% CI)	*p-value*	*aOR* (95% CI)	*p-value*	*aOR* (95% CI)	*p-value*
Self-efficacy						
Regulatory self-efficacy	Adherence pattern A 2.42 (1.29, 4.54)	0.006	Adherence pattern A 2.61 (1.37,4.97)	0.004	Adherence pattern A 2.46 (1.26, 4.81)	0.009
Task self-efficacy	Adherence pattern A 2.94 (1.56, 5.52)	0.001	Adherence pattern A 4.67 (2.40, 9.09)	< 0.001	Adherence pattern A 5.19 (2.67, 10.08)	< 0.001
					Adherence pattern C 2.93 (1.53, 5.62)	0.001
					Adherence pattern D 2.37 (1.19, 4.70)	0.014
Body mass index (*ref*. obese)						
Normal weight			Adherence pattern A 3.12 (1.35, 7.19)	0.008	Adherence pattern A 3.47 (1.41, 8.55)	0.007
			Adherence pattern D 3.63 (1.38, 9.51)	0.009		

Annual household Income (*ref*. ≤ 100,000 USD)						
> 100,000 USD			Adherence pattern A 4.06 (1.44, 11.47)	0.008		
			Adherence pattern C 4.26 (1.48,12.27)	0.007		
Education background (*ref*. graduate degree)						
High school and below			Adherence pattern D 0.15 (0.04, 0.65)	0.012		
History of psychological disorder (*ref*. yes)						
No (0)					Adherence pattern A 2.77 (1.23, 6.24)	0.014

Notes:

(1) All models used adherence pattern B, i.e., the adherence scores for muscle contractions and the frequency of pelvic floor muscle exercises are all below group averages, as the reference group.

(2) Adherence pattern A indicates the adherence scores for muscle contractions and the frequency of pelvic floor muscle exercises are all above group averages.

(3) Adherence pattern C indicates that the adherence scores for muscle contractions are above group averages, but the adherence score for the frequency is below the group average.

(4) Adherence pattern D indicates that the adherence score for frequency is above the group average, but the adherence scores for muscle contractions are below group averages.

(5) Abbreviations

aOR: adjusted odds ratio

CI: confidence interval

USD: US dollars

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CHAPTER 5: DISCUSSION

Overview of Research Background

Storage-type lower urinary tract symptoms (LUTS), urinary incontinence (UI), nocturia, urinary urgency, and urinary frequency are prevalent in women and can add substantial burden, such as decreased quality of life and significant economic costs (Abrams, Cardozo, Wagg. A., & Wein, 2017). The prevalence of most storage-type LUTS is positively associated with aging (Bower, Whishaw, & Khan, 2017; Milsom et al., 2017; Suskind, 2017; Tikkinen, Tammela, Huhtala, & Auvinen, 2006) and, therefore, the global trend of demographic aging will exacerbate the burden caused by storage-type LUTS in women. To address the high prevalence of storage-type LUTS and bolster the efforts of the Prevention of Lower Urinary Tract Symptoms (PLUS) research consortium that focuses on LUTS prevention across women's life course (Harlow et al., 2018), theory-driven efforts are needed to scale up interventions to population-level applications. The potential suitability of interventions for scaling up, i.e., their scalability, is based on two key criteria: the feasibility to reach a large group of individuals who are eligible to receive the intervention and the intervention's effectiveness (Milat, King, Bauman, & Redman, 2013).

Conservative strategies, defined as nonsurgical, nonpharmacological approaches, are the first treatment choices for storage-type LUTS. Such strategies include pelvic floor muscle exercises (PFME) and behavioral therapies (Gormley et al., 2012; Sussman, Syan, & Brucker, 2020) that often are prescribed in tandem as the behavioral and pelvic floor muscle training (B-PFMT) programs (Newman & Burgio, 2020; Newman & Wein, 2013). B-PFMT programs can

be delivered in two formats, supervised or unsupervised. Supervised B-PFMT programs are supported by a body of evidence that points to their effectiveness in treating UI (Cacciari, Dumoulin, & Hay-Smith, 2019; Palmer et al., 2020). However, researchers have drawn no conclusions about their effectiveness in treating other storage-type LUTS (Monteiro et al., 2018). In addition, despite their reported effectiveness in treating UI, supervised B-PFMT programs are not feasible for scaling up because of the intense time and human effort that are needed to schedule, prepare, and monitor/attend multiple program sessions for both healthcare providers and participants. By contrast, unsupervised B-PFMT programs, e.g., programs delivered via DVDs and mobile apps, can circumvent some of the challenges associated with supervised programs and reach large numbers of women. However, the effectiveness of unsupervised B-PFMT programs in mitigating storage-type LUTS has not yet been fully explored. As such, the studies discussed in Chapter 2, Chapter 3, and Chapter 4 of this dissertation were designed to address issues that relate to the effectiveness of unsupervised B-PFMT programs in mitigating storage-type LUTS in women. Each study was guided by a framework adapted from symptom management theory (SMT), as depicted in **Figure 1.2** in Chapter 1.

Summary of Findings

Findings from this dissertation add to the knowledge about the effectiveness of unsupervised B-PFMT programs in mitigating storage-type LUTS among women. In Chapter 2, the systematic review provides synthesized evidence that corroborates the effectiveness of unsupervised B-PFMT programs to treat UI among women in their 40s through 60s. Participation in unsupervised B-PFMT programs is shown to improve the quality of life of women with UI and UI/LUTS, their symptom perception, and their pelvic floor muscle strength, all of which were assessed two months after program initiation. The review also confirms the

variations and inconsistency in the components of unsupervised B-PFMT programs, e.g., that providers are from different disciplines (i.e., the 'who' in SMT) and that different information is delivered in the education sessions (i.e., the 'what' in SMT), as found in 13 eligible articles.

In Chapter 3, findings from secondary analyses are reported using data originally collected from women aged 55 years and older who participated in the Translating Unique Learning for Incontinence Prevention (TULIP) study for UI prevention. All of the women in the TULIP study participated in unsupervised B-PFMT programs. Each woman was randomly assigned to a group that received educational information about PFME, bladder training, the 'Knack', and lifestyle modifications either by attending a face-to-face class that was approximately two hours long (*2-hrClass*) or watching a 20-minute educational video (*20-minVideo*) (Sampselle et al., 2017). The within-group analyses of both groups revealed that the women experienced significantly fewer nocturia and urinary urgency episodes and extended inter-void intervals after program initiation. The between-group differences for nocturia did not reach statistical significance at 3 months and 12 months, but at 24 months, the effectiveness favored women in the *20-minVideo* group. The between-group differences for urinary urgency and urinary frequency did not reach statistical significance at any of the three follow-up time points.

In Chapter 4, findings from secondary analyses are reported using the data collected in the TULIP study in which women's adherence to PFME in a B-PFMT program was measured using three adherence items: short contractions (i.e., the number of short bursts of the maximum force generated by the pelvic floor muscles in an exercise set), long contractions (i.e., the number of sustained muscle contractions generated by the pelvic floor muscles in an exercise set), and frequency (i.e., the number of days that PFME are performed within a week). Four adherence

patterns were identified via *k*-means cluster analysis at 3 months, 12 months, and 24 months. These four patterns are referred to as A, B, C, and D, respectively, and each pattern had similar scores for three items over time. Adherence pattern A represents that all the scores for the three adherence items were higher than the group averages. At the three follow-up time points, the percentages of women who demonstrated adherence pattern A was between 35.78% and 47.76 percent. The PFME adherence pattern at a previous time point was able to predict the same adherence pattern at a later time point, especially for adherence pattern A. That is, women who exhibited adherence pattern A at 3 months represented 80.40% of women with adherence pattern A at 12 months, and 76.22% of women with adherence pattern A at 24 months had the same adherence pattern at 12 months.

Regulatory self-efficacy and task self-efficacy were assessed after the initial education session of the unsupervised B-PFMT program and were used to predict women's adherence pattern A (adherence pattern B served as the reference) at each follow-up time point. Specifically, the odds ratios for one unit increase in regulatory self-efficacy were 1.42 (95% confidence interval [CI] 1.29-4.54, $p = 0.006$) at 3 months, 1.61 (95% CI 1.37-4.97, $p = 0.004$) at 12 months, and 1.41 (95% CI 1.26-4.81, $p = 0.009$) at 24 months. The odds ratios for one unit increase in task self-efficacy were 1.94 (95% CI 1.56-5.52, $p = 0.001$) at 3 months, 3.67 (95% CI 2.40-9.09, $p < 0.001$) at 12 months, and 4.19 (95% C9I 2.67-10.08, $p < 0.001$) at 24 months. The variables that were able to predict adherence pattern A, C, or D at 12 months or 24 months were no psychological disorder history (history as the reference), body mass index (normal weight using obesity as the reference), educational background (high school and below using graduate-level education as the reference), and annual household income (income > 100,000 USD using income ≤ 100,000 USD as the reference).

Overall Discussion

Many women worldwide experience or are at risk of experiencing storage-type LUTS and, therefore, the global need for effective programs is urgent. The overall aim of this dissertation, guided by SMT, is to address the effectiveness of unsupervised B-PFMT programs that are feasible for population-level applications.

Chapter 2 presents a systematic review of the literature that targets the effects of unsupervised B-PFMT programs on storage-type LUTS and the cumulative evidence for these programs' effectiveness in improving outcomes related to UI among women in their 40s and 60s. The findings align with a proposition of SMT, i.e., symptom management strategies change symptom-related outcomes (Dodd et al., 2001), and add supporting evidence to the literature that unsupervised B-PFMT programs can be scaled up to treat UI among women in midlife. Evidence to support this proposition of SMT, i.e., that the components of symptom management strategies moderate the effects of these strategies, could not be pooled, however (Dodd et al., 2001). Of the 13 articles retrieved, only four adopted parallel studies with two treatment groups and delivered PFME either in different formats (i.e., the 'how' in SMT) or in different doses (i.e., the 'how much' in SMT).

The study described in Chapter 3 provides evidence for the effectiveness of unsupervised B-PFMT programs to improve the symptom status of nocturia, urinary urgency, and urinary frequency among postmenopausal women. The study adds fundamental evidence to the literature that unsupervised B-PFMT programs can be scaled up to decrease nocturia and urinary urgency episodes and to extend inter-void intervals among postmenopausal women. This finding supports the proposition of SMT that symptom management strategies change symptom status (i.e., one aspect of symptom-related outcomes). Two delivery formats (*2-hrClass* and *20-minVideo*) were

able to moderate the effects of unsupervised B-PFMT programs on nocturia only at 24 months. This evidence may not be sufficient to support the proposition in SMT that components of symptom management strategies moderate the effects of symptom management strategies. However, it may indicate the need to develop more studies to examine the optimal delivery format (i.e., the 'how' in SMT) of unsupervised B-PFMT programs in terms of effectiveness.

The study described in Chapter 4 addresses the important but often overlooked issue of women's adherence to PFME. The effectiveness of a B-PFMT program will be compromised without adherence to its core component, PFME. Of the four adherence patterns (A, B, C, and D) identified, the 3-item scores of adherence pattern A were all higher than the group averages, which might approximate the level of adherence expected by the researchers. The ratios of adherence pattern A, i.e., 35.78% and 47.76%, however, might be lower than the researchers' expectations. This outcome suggests that understanding the reasons for a below-par adherence level and developing strategies to improve women's PFME adherence are important considerations for the success of B-PFMT programs. In addition, the adherence pattern adopted earliest in the program was able to predict women's subsequent adoption of the same adherence pattern. This finding implies that strategies to help women achieve the highest level of adherence early in the program will be beneficial for maintaining that high level.

This study also found that regulatory self-efficacy and task self-efficacy could predict women's adoption of adherence pattern A at each follow-up time point. Other variables under the person domain and the health and illness domain predicted a certain adherence pattern at 12 months or 24 months. These findings align with the proposition in SMT that variables under the person and the health and illness domains influence individuals' adherence to symptom management strategies. These findings also suggest that the variables can influence adherence in

different ways and that the time variable is critical when applying SMT. Moreover, findings from this study provide two targets, regulatory self-efficacy and task self-efficacy, for future intervention studies to facilitate women's adherence to PFME.

Taken together, and guided by SMT, the three studies in this dissertation reveal that: (1) unsupervised B-PFMT programs are effective in treating UI among women in mid-life and that prevention-oriented evidence is limited in the literature; (2) unsupervised B-PFMT programs are effective in mitigating the symptom status of nocturia, urinary urgency, and urinary frequency among postmenopausal women; and (3) the level of adherence to PFME is not satisfactory and regulatory self-efficacy and task self-efficacy are two targets that can facilitate women's adherence to PFME in the short and long terms.

This dissertation, while providing new knowledge, could not discern the effect sizes of unsupervised B-PFMT programs designed to treat UI in women in their 40s and 60s. The effects of unsupervised B-PFMT programs on other symptom-related outcomes as described in SMT (except symptom status in terms of nocturia, urinary urgency, and urinary frequency) remain unclear. This dissertation could not ascertain the moderating effects of the components of unsupervised B-PFMT programs on the relationship between the programs and outcomes that relate to storage-type LUTS. In addition, women's adherence to behavioral components, i.e., bladder training with urge suppression, the Knack, and lifestyle modifications that are included in unsupervised B-PFMT programs, could not be monitored or assessed, which limits the understanding of the maximum potential for these programs' effectiveness. Optimal protocols for unsupervised B-PFMT programs therefore remain unknown.

The gaps in knowledge revealed by this dissertation point to several implications for future research. Future studies are recommended to design and describe each component of

unsupervised B-PFMT programs using a ‘consensus on exercise reporting template’ (CERT) (Slade, Dionne, Underwood, & Buchbinder, 2016) or the ‘template for intervention description and replication’ (TIDieR) (Hoffmann et al., 2014). Also, SMT should continue to guide the selection and design of symptom management strategies (Dodd et al., 2001). More research is needed to identify the effects of unsupervised B-PFMT programs on the symptom status of storage-type LUTS and other outcomes identified by SMT. Future research is expected to employ strategies such as verbal persuasion, emotional arousal, vicarious experience, and performance accomplishment (Bandura, 2002) to target improvements in regulatory self-efficacy and task self-efficacy to ensure and maintain women’s adherence to PFME. The development of tools to assess and monitor women’s adherence to behavioral components that are included in unsupervised B-PFMT programs is critical and will provide fundamental evidence to promote women’s overall adherence to PFME and assist in maximizing the effects of unsupervised B-PFMT programs.

The findings discussed in this dissertation also have several implications for public health and women’s healthcare providers. Given the prevalence of storage-type LUTS and the status of science, providers are recommended to address women’s storage-type LUTS through the lens of prevention and treatment instead of focusing solely on treatment-oriented approaches. Unsupervised B-PFMT programs are effective in managing storage-type LUTS among certain groups of women. Providers should extend these programs’ applications to treat and prevent storage-type LUTS in a more representative population. However, the effectiveness of such programs can be compromised by participants’ nonadherence to PFME. Findings from this dissertation provide some evidence regarding the less than optimal adherence to prescribed

PFME among women. Therefore, providers are recommended to build into such programs the adherence monitoring and promotion of PFME and other behavioral components.

In conclusion, findings from this dissertation provide promising evidence for scaling up unsupervised B-PFTM programs. Scaling up these programs to treat and prevent storage-type LUTS among women at the population level, however, is in its nascent stages, given the limited theory-driven evidence and substantial research gaps. This dissertation suggests that future studies should combine (1) the complete reporting of all the components of unsupervised B-PFMT programs with (2) the design of parallel studies of treatment groups that exhibit differences in certain components of unsupervised B-PFMT programs as described in SMT, e.g., different doses or a different delivery format, with (3) adherence promotion strategies and monitoring systems. Together, these three innovative efforts will provide useful evidence for future scale-up efforts to improve unsupervised B-PFMT programs and, consequently, women's health.

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