# BMJ Open Multifaceted self-management interventions for older women with urinary incontinence: a systematic review and narrative synthesis

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# **ABSTRACT**

Objective To synthesise the evidence for the multifaceted self-management interventions for older women with urinary incontinence (UI) and to understand the outcomes associated with these interventions.

**Design** A systematic review and narrative synthesis to identify randomised controlled trials that investigated the effect of multifaceted self-management interventions for older women with UI.

Methods MEDLINE, PsycINFO, EMBASE, The Cochrane Library, CINAHL and Applied Social Sciences Index and Abstracts databases were searched (January 1990 to May 2019) using a systematic search strategy, complemented by manually screening the reference lists and citation indexes. Study selection, data extraction and risk of bias assessment were undertaken independently. A narrative synthesis was undertaken in which studies, interventions and outcomes were examined based on the intervention components. The effect size and 95% CI were estimated from each study.

Results A total of 13147 citations were identified and 16 studies were included. There was no study rated as of high quality. Three types of multifaceted interventions were found: those that had an element of pelvic floor muscle exercises (PFME), those with bladder retraining and some with combination behavioural interventions. Outcome measures varied across studies. A statistically significant improvement in incontinence symptoms was reported in the intervention group compared with the control in 15 studies.

Conclusion Multifaceted interventions that included PFME, bladder retraining or combination behavioural techniques appear to be useful in some settings for UI management in older women, but the quality of the evidence was poor and unclear. There was insufficient evidence to determine whether any of the combination of components is superior to others in improving UI symptoms. There is a need for high-quality studies to confirm the effectiveness of these interventions and to identify comparative effectiveness.

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# **BACKGROUND**

Urinary incontinence (UI) is 'the complaint of any involuntary leakage of urine'. It has been estimated that, in the UK, over 14 million

# Strengths and limitations of this study

- Comprehensive searching using a sensitive search strategy identified a large number of potentially relevant reports.
- Tailored self-management intervention comprising multicomponent is needed for older women with incontinence.
- Multifaceted interventions that included pelvic floor muscle exercises, bladder retraining or combination techniques appear to be useful in Urinary incontinence management.
- No study was rated as of high quality on multifaceted self-management interventions for older women with incontinence, hence we have low confidence in the robustness of these findings.
- Insufficient evidence to determine whether any of the combination of components is superior to others in improving symptoms.

people are affected by bladder control problems.<sup>2</sup> UI is more common in women aged 55 or above,<sup>3</sup> and estimates of the point prevalence range from 35% to 60%, increasing with age. 4-6 While not life-threatening, UI has physical, psychosocial and emotional consequences for individuals and their families, with considerable impacts on society. 7-9 There is limited up-to-date information on the cost of managing UI in the UK, the estimated annual cost (related to 1999/2000) to the UK National Health Service of treating clinically significant UI is £536 million (£233 million for women).<sup>10</sup>

Despite the substantial impact on individual's quality of life, UI remains under-reported and undertreated due to stigma and embarrassment. 11 12 Evidence has suggested that one-third of women with UI consult a doctor in European countries such as France, Germany, Spain and the UK, and only 20%-25% of those experiencing significant clinical symptoms seek care and less than half of them receive treatment. 13 14 Untreated UI



is not only an unmet health need but is also associated with falls and fractures (associated with needing to get to a bathroom frequently or urgently) as well as depression in older people. The main reasons for not accessing medical care are feeling embarrassed, poor awareness or low expectations of treatments, and perceiving UI as an inevitable consequence of ageing. Many individuals try to cope and self-manage on their own with variable success. 21–24

Since the advent of systematically developed chronic disease self-management programmes, 25 many self-management interventions have been developed to support people with long-term conditions. Participants report a range of positive outcomes including a high degree of self-efficacy, improved ability to undertake daily activities and reduced fatigue and depression. 26-36 Self-management is considered to be a multidimensional construct<sup>37</sup> and defined as an intervention designed to develop individuals' knowledge, skills or psychological and social resources and their ability to manage their health condition and consequences, through education, training and support.<sup>38-40</sup> However, older women living with UI remain a neglected group, because it is a hidden health problem, 41 42 and the high risk of having multiple comorbidities in older people. 43 This highlights the potential benefit of tailored self-management advice and support for older women living with UI.

Self-management interventions for UI are often complex and no single procedure or intervention is optimal for all people. For example, systematic reviews of single faceted interventions can only make tentative conclusions that pelvic floor muscle exercises (PFME) or bladder training may be helpful for women with UI. 44 45 A multifaceted intervention comprising management of physical and psychological impact offers the possibility of tailoring treatment to the desires and needs of the individual. 46 The success of self-management requires the development of skills that allow individuals to effectively manage their symptoms, behaviours and emotions simultaneously. Also, considering the potential comorbidities in older people, 47 a multifaceted self-management intervention is likely to be more effective than a single component for older women living with UI. 48 49 Although certain self-management strategies seem effective in addressing frequency and amount of women's leakage when compared with controls, for example, PFME, timed voiding and toilet habit training, 23 24 50 51 there is no synthesis of randomised controlled trials (RCTs) of multifaceted self-management interventions for older women (aged 55 or over) with UI in a systematic manner, hence this review. The aim of this review was, therefore, to synthesise multifaceted self-management interventions for older women living with UI and to understand the outcomes associated with these interventions.

#### **METHODS**

This systematic review was undertaken following the Centre for Reviews and Dissemination's (CRD's) guidance<sup>52</sup> and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.<sup>53</sup> <sup>54</sup>

# **Criteria for considering studies for this review**Type of studies

In evaluating the extent to which self-management interventions are effective in this group, RCTs will provide high-quality evidence and allow estimation of effect sizes. <sup>55</sup> RCTs were considered that included self-management interventions for managing urine leakage compared with any other form of treatment such as other self-management interventions, pharmacological treatment, usual care and/or waiting list controls.

#### Type of participants

Women 55 years of age or over who are cognitively intact with a symptom of any involuntary leakage of urine that is not caused by neurological diseases affecting the brain and spinal cord, such as Parkinson's disease, or requires cancer treatment, such as bladder cancer.

# Type of interventions

Multifaceted self-management interventions, such as exercises and education, delivered to older women with UI with an aim to develop individual's ability to manage the symptoms, treatment, physical and psychosocial consequences, and lifestyle changes. Trials were eligible for inclusion if the intervention involved at least two self-management methods, such as PFME and general exercise, delivered to women with an aim to help them manage their UI and associated problems.

# Type of outcome measures

There are inconsistent recommendations on core outcome domains in studies of interventions for UI.  $^{56}$  No core outcome sets were identified in Core Outcome Measures in Effectiveness Trials. For this review, therefore, trials were eligible for inclusion regardless of outcomes measured or reported.

### Search methods for identification of studies

Six databases (MEDLINE, PsycINFO, EMBASE, The Cochrane Library, CINAHL and Applied Social Sciences Index and Abstracts) were searched from January 1990 to May 2019. Detailed search strategies were developed for each database. These were based on the search strategy developed for MEDLINE (OVID) (see online supplementary 1) and refined in consultation with the research team and an information scientist. A range of keywords and subject headings representing self-management and UI were used, aiming to maximise the retrieval of relevant records. The Cochrane Highly Sensitive Search Strategy for identifying RCTs was also linked to the search as a means of retrieving RCTs. Fraference lists and citation indexes of relevant articles were scrutinised. Only records published after 1990 (the prototype for the chronic

disease self-management programme was completed in 1996) and in the English language (no resource available for translation) were searched.

# **Selection of studies**

Identified citations were exported to EndNote V.X6<sup>58</sup> for deduplication and review. Record titles and abstracts were screened independently by two review authors. Full paper copies of studies were retrieved where citations appeared to meet the eligibility criteria or where a decision to exclude could not be made on the information provided. Whenever there was a disagreement between two researchers (YF and LM) relating to the inclusion of a given study, a third researcher (EAN) was consulted until consensus was reached.

#### **Data extraction**

Data were extracted on the characteristics of study participants, intervention details, control groups, outcome measures and results, using a data extraction sheet piloted on two retrieved study reports. All review authors were involved in the piloting and modification process. Accuracy and consistency were monitored through random double-extraction of trials by LM. Any differences were resolved by discussion. Where a trial appeared to have multiple citations then original authors were contacted for clarification. With no replies received, a decision was made to use all information from multiple citations as from one trial.

#### Assessment of risk of bias

Risk of bias assessment was undertaken in accordance with the Cochrane Handbook for Systematic Review of Interventions.<sup>59</sup> A summary of the risk of bias across studies was given, where a low risk of bias was rated when all domains were at low risk, an unclear risk of bias when one or more domains were at unclear risk, and a high risk of bias when one or more domains were at high risk. Risk of bias assessment was undertaken independently by two review researchers (YF and LM). Whenever there was a disagreement, a third researcher (EAN) was consulted until consensus was reached.

# **Data synthesis**

The data synthesis was undertaken following CRD's guidance. 60 The effect size and 95% CI were estimated for the primary outcome of each study. 57 A narrative synthesis was undertaken following Popay et als approach to conducting narrative synthesis in a systematic and transparent manner, 61 which focuses on the effects of the interventions and how these interventions could lead to outcomes. Studies, interventions and associated outcomes were examined and regrouped based on the components of the self-management interventions. Shared themes and tabulated summaries were presented in which results and significance reported were indicated.

# Patient and public involvement

A project advisory group comprising three older women (aged 55 or over) living with UI and one nurse working in the community continence clinic had been set up prior to the commencement of this review, to ensure their valuable input on the study design. YF led the meeting that was facilitated by LM/EAN every 6 months. Group members were provided with background information and clinical guideline in the UI assessment and management and consulted for their current experiences and expectations of managing the UI. They all highlighted the need for evidence-based practice for older women and perceived synthesis of existing RCTs being necessary to inform such evidence. Process of conducting systematic reviews was clearly presented to all group members. As this study progressed, they were also invited to review and comment on results of study selection, risk of bias assessment and data synthesis.

#### **RESULTS**

#### Selection of studies

A total of 13561 citations were yielded by the initial search. Following the screening of titles and abstracts, 64 records were retrieved in full text, and 45 were further excluded as they only included single component interventions and/or involved participants who were not women aged 55 or above. In total, 19 citations were included representing 16 RCTs, as three trials had multiple citations (see figure 1).

#### Risk of bias

Risk of bias figure was completed for each included study (figure 2). Eleven studies were rated as high risk of bias, five were at unclear risk of bias and one was at low risk of bias. Most studies reported adequate information on methods used to generate the randomisation sequence, but commonly did not report on allocation concealment and blinding, leading to their being assessed as unclear risk of bias. For incomplete outcome data, a high risk of bias was noted if the last observation was carried forward was used to handle missing data. Selective outcome reporting bias was identified in four studies meaning that not all measured outcomes were reported. High and unclear risk of bias in most of the included studies was identified as the main barrier to the evaluation of the effectiveness of self-management interventions for women with UI.

# **Study characteristics**

The 16 included studies were conducted in the USA, Japan, UK, Canada, France, Hong Kong and Turkey. Of 16 studies, nine were undertaken in community centres<sup>22 49 62-68</sup> and seven in clinics<sup>69-74</sup> or nursing homes.<sup>75</sup> A total of 3237 women aged 55 or over with stress UI, urge UI, mixed UI and overactive bladder were recruited to component trials. Multifaceted self-management interventions comprised education, information

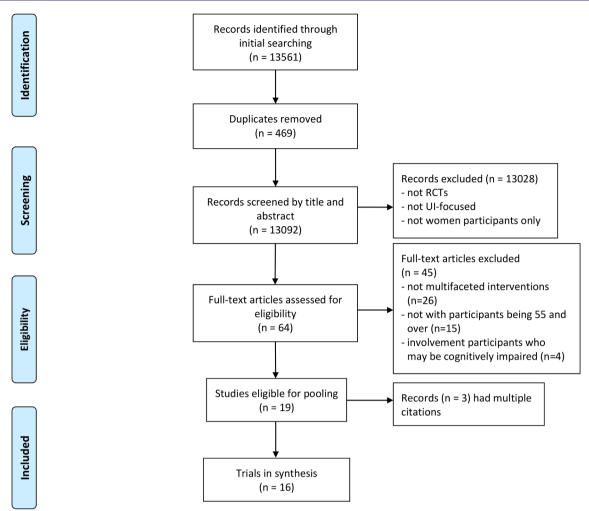


Figure 1 PRISMA flowchart. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; RCT, randomised controlled trial; UI, urinary incontinence.

provision, PFME, bladder retraining, lifestyle modification and behavioural training that aimed to improve UI symptoms by changing peoples' behaviour and by teaching skills for preventing urine loss. A total of 11 studies<sup>22 49 62 64 65 68-72 75</sup> had a conventional control treatment, including education, general lectures on health promotion, provision of general feedback, usual care, placebo and identical behavioural training without professional support or equipment, and five<sup>63 66 67 73 74</sup> designed a waiting list control group. Most interventions were delivered face to face; two were delivered in the format of internet based<sup>69</sup> or via video conferencing.<sup>62</sup> Length of the intervention varied from 60 min to 24 weeks with 12 weeks being the most common time period for intervention delivery (n=5).

A variety of outcome measures were used, including urine leakage frequency (by self-reported diary, n=14) and volume (by pad weight test or measuring loss in ml, n=5), pelvic floor muscle strength (n=3), psychological effect (n=4), quality of life (n=5), self-efficacy (n=1) and perceived improvement (n=10). Measures were regrouped into UI-specific items, physical functioning, emotional functioning, social functioning, pelvic floor

muscle functioning, general health, self-management ability and subjective perceptions of change. However, not all measures used were reported by studies included, and the impact of UI on psychological health measured was identified as the most poorly reported domain, which was not reported by any studies. All except four studies 62 66 72 75 defined their primary outcomes in the manuscript, but there was insufficient detail provided for study protocols to allow us to determine whether the reported primary outcome was that specified in the original study protocol. The characteristics of the included studies are presented in table 1.

# Interventions and associated outcomes

Three broad types of multifaceted self-management interventions were identified: PFME-related interventions, bladder retraining related interventions and combination behavioural interventions.

A meta-analysis was not conducted due to the level of heterogeneity of intervention components, outcome measures, settings and participants. Effect size and 95% CI were estimated for the primary outcome from each study based on information reported at the end of the

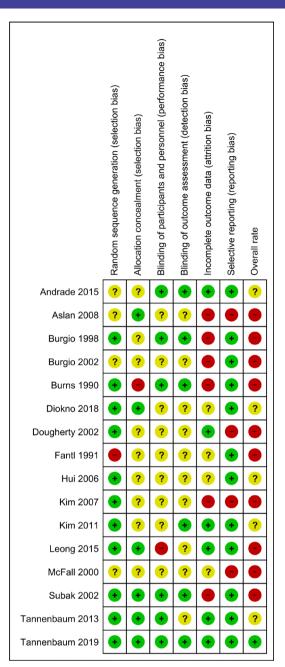


Figure 2 Risk of bias summary.

intervention. Where no primary outcome was defined, the outcome reflecting UI symptoms was estimated. The risk ratio (RR) was reported for dichotomous variables and the mean difference (MD) was reported for continuous variables (table 2).

Two studies reported no detailed description of the control intervention. Four studies had not defined their primary outcomes but all of them observed a significant difference in UI symptoms in women in the intervention groups compared with the control groups. A total of 12 studies had the primary outcome clearly defined, and significant differences in UI symptoms were reported in the intervention groups compared with the control groups in 11 studies. These are described in more detail below.

# PFME-related interventions

Three<sup>63 64 72</sup> studies reported the effect of PFME as an element of a multifaceted intervention. PFME and general fitness exercises were delivered in two studies, 63 64 and PFME with biofeedback using a vaginal probe was delivered in one study.<sup>72</sup> In these studies, PFME interventions were delivered as a group and participants were instructed in two formats: slow and quick contractions. Women were asked to contract the muscles and hold for seconds before relaxation in slow mode, whereas they were asked to tighten and relax as rapidly as they could in quick mode. Women were encouraged to practise both contractions together in different positions and record progress on a daily diary. Exercise frequency and duration reported varied. Women were instructed to perform up to 60 min general fitness exercise two times per week for 12 weeks<sup>63 64</sup> and 20 min PFME four times a day for 8 weeks.<sup>72</sup>

The first study<sup>63</sup> reported a higher 'UI cure rate' in the PFME and fitness group versus general education and exercises (54.4% vs 9.4%, RR 5.82, 95%CI 1.90 to 17.86). The second study<sup>64</sup> reported a higher UI cure rate' in the PFME and fitness group versus general education classes (44.1% vs 1.6%, RR 26.88, 95%CI 3.77 to 191.79). The third study reported more women experiencing zero UI episodes in the PFME and biofeedback group than control (no description of the control intervention) (9 vs 1, RR 8.55, 95%CI 1.14 to 63.31).<sup>72</sup>

Two studies evaluated the pelvic floor muscle by measuring adductor muscle in Newton-meters (Nm), 63 64 and one study evaluated it by measuring quick contraction in microvolts and urethral closure pressure.<sup>72</sup> The first study<sup>63</sup> reported higher adductor muscle strength in the PFME and fitness group versus general education and exercises (59.4 vs 51.5, MD 7.90, 95%CI 1.14 to 14.66). The second study<sup>64</sup> reported a small increase in adductor muscle strength in the PFME and fitness group versus general education class (24.1 vs 22.1, MD 2.00, 95%CI -0.30 to 4.30). Women in the PFME and biofeedback group in the third study<sup>72</sup> experienced stronger quick contractions than the control (5.96 vs 3.49, MD 2.47, 95%CI 0.38 to 4.56) but only a small increase in urethral closure pressure compared with the control (28.73 vs 28.06, MD 0.67, 95%CI -5.36 to 6.70).

# Bladder retraining related interventions

One studies<sup>73</sup> reported the effect of bladder retraining based interventions that compared with no treatment.<sup>73</sup> Bladder retraining is designed to help the bladder become less overactive or sensitive, developed based on the principles of behaviour modification, aimed to alter one's desire to void and cut down the frequency of passing urine.<sup>73</sup> Education was delivered together with bladder retraining interventions to support women to adapt the bladder retraining into their lifestyle. Women were instructed and encouraged to void at regularly scheduled intervals. Voiding intervals used varied ranging from 30 to 60 min based on their progress and tolerance, but the

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Table 1 Characteristics	Characteristics of included studies (n=16)	lies (n=16)			
		Ul type; baseline sample	Intervention characteristics		
Shidy year	Settings	size; mean age (year); UI duration (year)	ar); UI	Duration	Control characteristics
Andrade <i>et al</i> (2015) <sup>69</sup>	US clinic		the role of the urinary bladder, a changes; and information ar diary, urge suppression PFME; and a test contained by information delivered.	12 weeks	Identical online programme with voice only
Aslan <i>et al</i> (2008) <sup>75</sup>	Turkey nursing home	SUI, UUI, MUI  =25; age: 78.9; 8.76  C=25; age: 79.4; 6.4	and an call and and an call and	8 weeks	General education on UI without PFME and bladder retraining
Burgio <i>et al</i> (1998) <sup>71</sup>	US clinic	UUU, MUI 11=65; age: 67.3; 9.4 12=67; age: 68.2; 9.8 C=65; age: 67.6; 12.7	I: behavioural training that focused on teaching skills and strategies for preventing UI and provided with instructions for daily home practice; and anorectal biofeedback; toilet training; and pelvic muscle biofeedback; and combined bladder-sphincter biofeedback  12: Oxybutynin initiated at 2.5 mg of oxybutynin chloride three times daily.	8 weeks	Placebo control
Burgio <i>et al</i> (2002) <sup>70</sup>	US clinic	UUI, MUI 11=73; age: 64.8; 7.1 12=74; age: 65.8; 6.6 C=75; age: 65.8; 6.6	I1: behavioural training that focused on teaching skills and strategies for preventing UI and provided with instructions for daily home practice; and anorectal biofeedback; toilet training; and pelvic muscle biofeedback; and combined bladder-sphincter biofeedback	8 weeks	Self-administered behavioural treatment using a booklet
Burns <i>et al</i> (1990) <sup>72</sup>	US clinic	SUI, MUI total n=135, the sample size in each arm and age were not reported	11: performed PFME on a progressive basis four times a day day  12: received therapy on a weekly basis, where subjects were taught to contract and relax the pubococcygeus muscle using a vaginal probe and while observing a computer screen display of their contractions.	8 weeks	No description
					1000

Continued

Table 1 Continued					
Study, year	Settings	Ul type; baseline sample size; mean age (year); Ul duration (year) (I: intervention; C: control)	UI type; baseline sample Intervention characteristics size; mean age (year); UI duration (year) (I: intervention; C: control) Description of intervention	Duration	Control characteristics
Diokno <i>et al</i> (2018) <sup>74</sup>	US outpatient practice	SUI, UUI, MUI  =232; age: 64; NA C=231; age: 65;NA	I: bladder health and self-management session, with slide presentations and a booklet including: anatomy of the lower urinary tract; bladder and PFM function; anatomic and physiologic basis for UI; types, causes and effect of UI on quality of life; PFM identification and exercise; bladder training; instruction in evidence-based behavioural strategies, including active PFM contraction during activities that precipitate stress UI and urge suppression strategies; and coaching to facilitate incorporation of the strategies into their personal routines. After the class, participants were given materials for home use, including a booklet summarising the bladder health class, a magnet that served as a reminder to continue adherence, an audio CD with a PMFE session; and an individualised voiding interval prescription.	2 hours	No treatment
Dougherty <i>et al</i> (2002) <sup>22</sup>	US residence home	SUI, UUI, MUI l=94; age: 67.7; 12.6 C=84; age: 68.1; 12.0	I: self-monitoring using bladder diary; and bladder training (daytime voiding interval >4 hours); and PFEM (45 contractions per day 3 times a week for 12 weeks).	20-24 weeks	General feedback obtained at the baseline visit
Fantl <i>et al</i> (1991) <sup>73</sup>	US clinic	SUI, UUI I=60; age: 66; 13 C=63; age: 68; 8	I: an audiovisual programme followed by verbal and written instructions on how to adapt the programme to the personal lifestyle; and bladder training to establish the voiding schedule every 30 or 60 min voiding intervals and increase by 30 min each week, aiming to reach a 2.5–3 hours interval; and weekly clinic visits, each lasting approximately 15–20 min.	6 weeks	No treatment
Hui <i>et al</i> (2006) <sup>62</sup>	US community	/ SUI, UUI  =27; age: 73.5; NA C=31; age: 73.6; NA	I: talks covering an overview of the anatomy and physiology causes the treatment options; and behavioural training technique via videoconferencing in a group involving suppression, PFME, fluid management; and booklet on UI management; and sharing experiences with group members.	8 weeks	Usual care by the conventional continence service
Kim <i>et al</i> (2007) <sup>63</sup>	Japan community	SUI  =35; age: 76.6; 7.0 C=35; age: 76.6; 9.2	I: an exercise treatment session twice a week including warm up and stretching exercises, PFME and fitness exercises to strength training of the thigh and abdominal muscles; and a pamphlet illustrating the PFME and strengthening exercises and a recording sheet.	12 weeks	General education and exercises

Table 1 Continued					
		Ul type; baseline sample	Intervention characteristics		
Study, year	Settings	size; mean age (year); UI duration (year) (I: intervention; C: control)	Description of intervention	Duration	Control characteristics
Kim <i>et al</i> (2011) <sup>64</sup>	Japan, community	SUI, UUI, MUI  =63; age: 76.1; 4.8 C=64; age:75.7; 4.6	I: an exercise treatment session twice a week including warm up and stretching exercises, PFME and fitness exercises to strength training of the thigh and abdominal muscles; and a pamphlet illustrating the PFME and strengthening exercises and a recording sheet.	12 weeks	General education classes
Leong and Mok (2015) <sup>65</sup>	Hong Kong, community health centre	SUI, UUI, MUI I=27; age: 73.0;<2 years=15, 2–5 years=8, >5 years=4 C=28; age: 75.4;<2 years=18, 2–5 years=9,>5 years=1	I: education, including the anatomy of the PFM and urinary tract, UI mechanism, and bladder care; and PFME with the aid of vaginal palpation; and bladder training to increase the time interval between voids by a combination of progressive void schedules, urge suppression, distraction, self-monitoring, and reinforcement.	12 weeks	Information pamphlet on Ul
McFall <i>et al</i> (2000) <sup>66</sup>	US community	SUI, UUI  =56; age: 73.9;>5 years=34% C=61; age: 75.6; >5 years=28%	I: information and skill building in relation to bladder training, managing the urge to urinate, and performing pelvic muscle exercises; and group support.	5 weeks	No description
Subak <i>et al</i> (2002) <sup>67</sup>	US community	SUI, UUI, MUI I=77; age: 70.0; NA C=75; age: 68.5; NA	I: education and development of individualised voluntary voiding schedules based on baseline daytime voiding frequency recorded on the voiding diary; and verbal and written instructions on PFME; and feedback session and reflection.	6 weeks	No treatment
Tannenbaum <i>et al</i> (2013) <sup>49</sup>	UK community	SUI, UUI, MUI 11=64; age: 70.8; NA 12=70; age: 71.0; NA 13=61; age: 70.4; NA C=64; age: 74.1; NA	11: Ul education on different types, aetiology, risk factors and treatment options for urine loss 12: self-management programme using an evidence-based risk factor reduction tool for incontinence. 13: Ul education and self-management programme.	12 weeks	Lecture on health promotion
Tannenbaum <i>et al</i> (2019) <sup>68</sup>	UK, Canada, France community	SUI, UUI, MUI  =461; age: 77.4; NA C=448; age: 78.6; NA	I: a facilitated interactive discussion to address myths surrounding involuntary urine loss and possible causes; descriptions of self-management techniques such as PFME and lifestyle interventions; a self-management brochure.	60 min	Healthy ageing workshop

C, control group; I, intervention group; MUI, mixed urinary incontinence; NA, not applicable; OAB, over active bladder; PFME, pelvic floor muscle exercises; SUI, stress urinary incontinence; UUI, urge urinary incontinence.

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Table 2 Effect size of	Effect size of the intervention for the primary outcome (grouped by intervention type)	d by intervention type)	
Study, year	Intervention type	Primary outcome	Effect size (intervention vs control), 95% CI
Burns <i>et al</i> (1990) <sup>72</sup>	PFME related	Cure of UI episodes*	Biofeedback RR=8.55, (1.14 to 63.31)†‡ Without biofeedback RR=6.19, (0.80 to 48.02)†
Kim $et$ al (2007) $^{63}$	PFME related	The number of UI episodes in 3 days; cured defined as episodes disappeared	RR=5.82, (1.90 to 17.86)†‡
Kim et al (2011) <sup>64</sup>	PFME related	The cure rate of UI episodes	RR=26.88, (3.77 to 191.79)†‡
Fantl <i>et al</i> (1991) <sup>73</sup>	Bladder retraining related	The number of UI episodes in 7 days	MD=-10.00, (-13.89 to 6.11)†‡
Dougherty <i>et al</i> (2002) <sup>22</sup>	Combination interventions (PFME, lifestyle modification, bladder retraining)	Urine loss (g) per pad test	MD=1.00, (-28.91 to 30.91)§
Hui <i>et al</i> (2006) <sup>62</sup>	Combination interventions (PFME, lifestyle modification, education)	The number of UI episodes daily*	MD=0.10, (-0.09 to 029)†
Tannenbaum et al (2013) <sup>49</sup>	Combination interventions (PFME, lifestyle modification, education)	Self-reported improvement in incontinence	RR=5.40, (2.66 to 10.97)†† RR=6.00, (2.91 to 12.35)†‡
Tannenbaum et al (2019) <sup>68</sup>	Combination interventions (PFME, lifestyle modification, education)	self-reported improvement in incontinence at 1 year	RR=1.81, (1.44 to 2.27)†§
Aslan <i>et al</i> (2008) <sup>75</sup>	Combination interventions (PFME, bladder retraining, education)	Reduction in the number of UI episodes in 7 days*	RR=5.33, (1.77 to 16.05)†‡
Diokno <i>et al</i> (2018) <sup>74</sup>	Combination interventions (PFME, bladder retraining, education)	UI symptoms (measured by the International Consultation on Incontinence Questionnaire-short form)	MD=-0.91, (-1.59 to 0.23)§
Leong and Mok (2015) <sup>65</sup>	Combination interventions (PFME, bladder retraining, education)	The number of UI episodes in 7 days	MD=-6.40, (-8.81 to 3.99)†‡§
Andrade <i>et al</i> (2015) <sup>69</sup>	Combination interventions (PFME, bladder retraining, review session, education)	Health-related quality of life (measured by the overactive bladder health-related quality of life)	MD=11.38, (1.78 to 20.98)†‡§
Burgio <i>et al</i> (1998) <sup>71</sup>	Combination interventions (PFME, bladder retraining, review session, education)	Reduction per cent in the number of UI episodes	MD=41.30, (20.47 to 62.13)†§
Burgio <i>et al (</i> 2002) <sup>70</sup>	Combination interventions (PFME, bladder retraining, review session, education)	Reduction per cent in the number of UI episodes	Biofeedback: MD=4.50, (-8.66 to 17.66)§ Verbal feedback: MD=10.80, (-0.94 to 22.54)§
McFall <i>et al</i> (2000) <sup>66</sup>	Combination interventions (PFME, bladder retraining, review session, education)	The number of UI episodes in 7 days*	MD=-2.35, (-5.30 to 0.60)‡
Subak e <i>t al</i> (2002) <sup>67</sup>	Combination interventions (PFME, bladder retraining, review session, education)	The number of UI episodes in 7 days	MD=-5.80, (-10.61 to 0.99)†‡

<sup>#:</sup> primary outcome was not defined; \*: significance at 95%; +: per protocolanalysis; ‡: intention to treat; +‡: no loss to follow-up or dropout MD, mean difference; PFME, pelvic floor muscle exercises; RR, risk ratio; UI, urinary incontinence.

key was to suppress the urge as long as possible using relaxation and distraction techniques and not to void off the schedule.

This study reported a reduction in the number of UI episodes per week in the intervention group compared with the no treatment<sup>73</sup> (MD –10.00, 95% CI –13.89 to –6.11, or 1.4 fewer UI episodes per day). Women in the intervention group also experienced a reduction in urine loss (g) (MD –30.00, (95% CI –53.33 to –6.67).

# Combination behavioural interventions

# Interventions comprising PFME, lifestyle modification and bladder retraining

One study<sup>22</sup> reported the effect of behavioural training intervention comprising PFME, lifestyle modification and bladder retraining compared with general feedback. Women in the intervention group were supported to self-monitor their caffeine consumption, the amount and timing of fluid intake, voiding intervals, dietary and bowel function, to practise bladder retraining, and to perform PFME with biofeedback. Interventions lasted 20–24 weeks facilitated by a nurse.

Although urine loss measured on (gram/24hours) was not significantly different from a control group that received feedback alone (MD  $1.00\,\mathrm{g}/24\,\mathrm{hours},\ 95\%\,\mathrm{CI}-28.91$  to 30.91), the number of UI episodes did differ with the intervention group experiencing 0.8 fewer episodes per day compared with the control group (MD -0.80, 95% CI -1.42 to -0.18). Self-reported quality of life was lower (lower scores reflecting higher quality of life) (MD -5.80, 95% CI -9.81 to -1.79) and subjective assessment of UI severity (higher scores reflecting less UI severity) (MD 1.22, 95% CI 0.89 to 1.55) were better for the intervention compared with the control.

# Interventions comprising PFME, lifestyle modification and education

Three studies 49 62 68 reported the effect of a behavioural training intervention comprising PFME, lifestyle modification and education. Tannenbaum et al<sup>49</sup> performed a cluster randomised trial lasting 12 weeks, where the intervention delivered to 8-16 participants by a single facilitator was compared with a group lecture on health promotion. Hui et al<sup>62</sup> compared a telemedicine continence programme with conventional outpatient UI service. Women in the intervention group attended a videoconference class where they received information on anatomy and physiology of the urinary system, causes of UI, treatment options, behavioural management techniques including PFME, fluid management and dietary. Interventions lasted 8 weeks and the videoconference class was facilitated by the nurse specialist and a researcher for the behavioural training. The other study by Tannenbaum et al<sup>68</sup> compared an in-person 60 min UI self-management workshop with a control healthy ageing workshop involving older women recruited from multicommunities in the UK, Canada and France.

In Tannenbaum et al, 49 more women in the intervention group reported improvement in UI symptoms than the control group (RR 5.40, (95% CI 2.66 to 10.97). Compared with controls, the participants in the combined intervention reported an adjusted mean 2.05 points (95% CI 0.87 to 3.24) greater improvement on the International Consultation on Incontinence Questionnaire (ICIQ) from baseline to 3-month follow-up. In Hui et al, 62 no primary outcome was defined. There was only a small reduction observed in both intervention and control groups for the number of UI daily episodes (0.20 vs 0.10, MD 0.10, 95% CI -0.09 to 029), and for the frequency of daily voiding (8.50 vs 9.00, MD -0.50, 95% CI –1.92 to 0.92). However, there was a greater reduction in the volume of urine loss (mL) at each micturition in the intervention compared with the control group (MD 39.00, 95% CI 19.21 to 58.79). In the second study by Tannenbaum et al, 68 the primary outcome was self-reported UI improvement at 1 year. There were 15% of the intervention group versus 6.9% of controls reported significant improvements in UI (RR 2.16, 95% CI 1.45 to 3.24), and 35% vs 19% reported any improvement (RR 1.81, 95% CI 1.44 to 2.27). Compared with controls, women in the intervention group also reported a mean 1.3 point greater improvement on the quality of life score at 1 year (95% CI 1.2 to 1.4).

# Interventions comprising PFME, bladder retraining and education

Three studies 65 74 75 reported the effect of a behavioural training intervention comprising PFME, bladder retraining and education. These behavioural training based interventions were compared with an information pamphlet on UI, 65 no treatment 74 and general education on UI without PFME and bladder retraining, 75 respectively. Women in the intervention groups received information on structure and mechanism of the lower urinary system and UI, the structure of the pelvic floor muscles, together with bladder retraining and PFME techniques. Interventions lasted varied ranging from 2 hours to 12 weeks and were facilitated by an a physiotherapist, 65 a trained health professional 74 or a urogynaecology nurse.

Leong and Mok<sup>65</sup> observed a lower frequency of UI episodes (over 1 week) in the intervention group compared with the control (MD -6.40, 95% CI -8.81 to -3.99). An improvement was also observed in self-reported quality of life (measured by the Incontinence Impact Questionnaire Short Form with lower scores reflecting higher quality of life) (MD -3.90, 95% CI -5.03 to -2.77) and perception of improvement reported at the end of trial by the patient (measured by a 10 cm Visual Analogue Scale) (MD 7.30, 95% CI 6.84 to 7.76). Diokno et  $al^{74}$  reported that the intervention group had lower estimates of UI symptoms (MD -0.91, 95% CI -1.59 to -0.23), and that a higher proportion of intervention group patients rated themselves as 'much/very much better' (RR 5.82, 95% CI 3.61 to 9.39) compared with the control. Women in the intervention group also reported significantly higher scores on quality of life measured by the Incontinence

Ouality of Life Ouestionnaire (MD 5.11, 95% CI 2.37 to 7.85) compared with the control group. The number of daily voids (MD -1.26, 95% CI -1.62 to -0.90) and UI episodes per day (MD -0.45, 95%CI -0.67 to -0.23) were significantly lower for the intervention group than for the control group when estimated using a 3-day void diary. The urine volume loss (g) in 24 hours (MD -4.53, 95% CI - 6.34 to -2.72) was lower in the intervention than the control group. The Medical, Epidemiologic and Social Aspects of Ageing urge (MD -5.53, 95\% CI -9.34 to -1.36) and stress UI (MD -6.25, 95% CI -10.75 to -1.75) scores were significantly lower for the intervention group than for the control group, but there were no differences between the groups on the pelvic floor muscle strength (RR 0.96, 95% CI 0.80 to 1.15). No primary outcome was defined in Aslan et al, 75 but there were fewer complaints of frequency (RR 5.33, 95% CI 1.77 to 16.05), nocturia (RR 17.00, 95% CI 1.03 to 279.53) and urgency (RR 3.25, 95% CI 1.23 to 8.61) in the intervention group compared with the control.

# Interventions comprising PFME, bladder retraining, education and feedback

Five studies 66 67 69-71 reported the effect of a behavioural training intervention comprising PFME, bladder retraining, education and feedback compared with a control group with no description, 66 no treatment, 67 online audio programme, 69 stand-alone self-management booklet<sup>76</sup> and placebo.<sup>71</sup> Interventions studied included information on the condition, instructions on completing a bladder diary, skills and strategies needed for PFME and bladder retraining, and feedback session and reflection used for reviewing progress, setting new goals and encouraging persistence. PFME with biofeedback was delivered to women in two studies, 70 71 and in one study PFME with biofeedback was compared against PFME with verbal feedback and against control. <sup>70</sup> Interventions lasted from 5 to 12 weeks. Two studies 70 71 delivered interventions face to face, two were in small groups facilitated by trained instructors<sup>66</sup> and nurse educators,<sup>67</sup> and one provided an online education programme using a generic avatar coach.<sup>69</sup>

No primary outcome was defined in McFall *et al.*<sup>66</sup> There was a small reduction in the intervention in the number of UI episodes (MD –2.35, 95% CI –5.30 to 0.60), and a slight increase frequency of nocturnal urine loss per week (MD 0.30, 95% CI –2.70 to 3.30) compared with the control group. However, women in the intervention group experienced a lower frequency of diurnal micturition per week (MD –12.33, 95% CI –18.87 to –5.79) than the control group.

In Subak *et al*,<sup>67</sup> women in the intervention group experienced fewer 'total UI episodes per week' (MD –5.80, 95% CI –10.61 to –0.99), fewer 'diurnal UI episodes per week' (MD –5.40, 95% CI –9.76 to –1.04) and less 'diurnal micturitions per week' (MD –8.70, 95% CI –15.24 to 2.16) compared with the control group. There was only a small reduction in the intervention in the number of nocturnal

UI episodes per week (MD -0.30, 95% CI -1.11 to 0.51) or in total micturitions per week (MD -6.00, 95% CI -13.91 to 1.09) compared with the control.

In Andrade et al, 69 women reported higher scores in their quality of life (measured by the Overactive bladder Health-related Quality of Life) (MD 11.38, 95% CI 1.78 to 20.98), less daily frequency (MD -3.31, (95% CI -4.26 to 2.36), less daily urgency (MD -2.14, 95% CI -2.92 to -1.36 and less daily urge UI episodes (MD -2.12, 95% CI -3.13 to -1.1) in the intervention group compared with the control group. There was a significantly lower caffeine intake per 24 hours (Fl. Oz.) (MD -2.21, 95% CI -4.23 to -0.18) in the intervention group compared with the control group. No differences were observed in urge self-efficacy (measured by the Geriatric Self-efficacy Index for UI with higher scores reflecting a higher level of efficacy) (MD 0.86, 95% CI -0.21 to 1.95) or PFME self-efficacy (measured by a Visual Analogue Scale with higher scores reflecting higher level of efficacy) (MD 0.004, 95% CI -1.57 to 1.57). There were no differences between groups on the measure of perception of bladder condition (MD 0.22, 95% CI -0.60 to 1.04).

In Burgio et al, 70 interventions with biofeedback resulted in a mean 63.1% reduction in the frequency of UI episodes (MD 4.50, 95% CI -8.66 to 17.66) and 69.4% reduction in interventions with verbal feedback (MD 10.80, 95% CI -0.94 to 22.54). However, these were not significantly differences compared with the control. Women in the biofeedback group reported having 'fewer accidents' than control group participants (RR 1.12, (95% CI 1.02 to 1.22), 'smaller accidents' (RR 1.33, (95% CI 1.08 to 1.64), and were 'able to wear less protection' (RR 1.34, 95% CI 1.01 to 1.79). A higher proportion of women in the verbal feedback group, compared with the control group, described that they felt they had better progress (RR 1.14, (95% CI 1.03 to 1.26). No difference was observed across groups in terms of women being satisfied with treatment progress (biofeedback vs control: RR 1.03, 95% CI 0.96 to 1.10; verbal feedback vs control: RR 1.05, 95% CI 0.98 to 1.12).

In Burgio *et al*,<sup>71</sup> there was a large reduction in the number of UI episodes (reported as per cent reduction) in the intervention group versus the control group (MD 41.30, 95% CI 20.47 to 62.13). Compared with the control, women in the intervention group experienced 'fewer accidents' (RR 1.52, 95% CI 1.25 to 1.86) and fewer had 'smaller accidents' (RR 1.62, 95% CI 1.23 to 2.13). Unsurprisingly, therefore, more women in the intervention group felt 'able to wear less protection' (RR 1.76, 95% CI 1.24 to 2.50). A higher proportion of women in the intervention group than the control group reported that the frequency of UI had completely reduced (RR 2.34, 95% CI 1.11 to 4.94) and were satisfied with treatment progress (RR 1.52, 95% CI 1.25 to 1.86).

# **DISCUSSION**

This review synthesised the outcomes from 16 RCTs that evaluated the multifaceted self-management interventions for women with UI aged 55 or over. Three types of multifaceted interventions that included PFME related, bladder retraining related and combination behavioural interventions were developed. These multifaceted interventions are potentially useful approaches to the UI management, however, there was insufficient evidence to determine whether any of the combination of components is superior to others in improving UI symptoms.

Most of the studies included were of poor or unclear quality, although a statistically significant difference in UI symptoms was reported across all three types of multifaceted self-management interventions. In addition, no information in studies of poor or unclear quality reported on whether these outcome differences were also clinically significant. With only limited work undertaken determining the clinically relevant reference points for certain UI outcome measures, <sup>76</sup> future research is needed to clarify the meaning of clinical significance. Given the lack of core outcomes for use in this area, the absence of trial registration, and the very wide range of outcomes reported, it is highly likely that there is selective reporting of outcomes, which is commonly related to the size and direction of effect sizes. <sup>77</sup>

Interventions were categorised into three types to reflect the key components, however, the effects of those key components were not always evidenced by measures chosen or outcomes reported. For instance, although PFME-related interventions improved women's urine leakage, the strength of pelvic floor muscle was not simultaneously significantly changed. This may be related to study power or the fact that some women were unable to perform correctly or adhere to the PFME, or there was a lack of follow-up support. PFME is recommended as a first-line treatment for good clinical practice, however, research suggested that many women cannot initially contract their muscles correctly if they are only provided with a simple verbal instruction.<sup>78</sup> Improvement may be achieved by providing more detailed education on contraction technique and frequent appointments during the training programme.<sup>79 80</sup> Similarly, the number of UI episodes was significantly lower for the intervention group in the study using bladder retraining related interventions. Unfortunately, there were no outcome measures chosen relating to voiding intervals.<sup>73</sup> No conclusion can be drawn in terms of the most effective combination of components in practice. These identified components are often referred to as a group of behavioural treatments, which need to be tailored to the individual needs and the characteristics of the symptoms.

Unlike other chronic conditions such as chronic pain, <sup>81</sup> there is a lack of core outcome sets developed for women with UI. Leading organisations, for example, the ICIQ and the US Food and Drug Administration recommended patient-centred outcomes to be included in trials <sup>82</sup> <sup>83</sup> for women with UI. However, the fact that no

standard core outcome sets are available raises concern for outcome selection bias, which also makes it difficult to undertake a meaningful comparison between trials. While much attention has been paid to standardising the methods and procedures, the collection and reporting of outcomes have been neglected in RCTs in the area of UI. Without supporting evidence, a range of outcomes measures used in clinical trials may also be burdensome to participants, researchers and health professionals. It is also possible to have conflicting results reported when many measures are used without clear rationale. Future research is needed to develop core outcome sets with recommended measures to be used in trials investigating interventions for women with UI.

In estimating the effectiveness of multifaceted self-management interventions of UI, it would also be helpful to have the information on adherence. In these studies, unfortunately, adherence to self-management components was inconsistently monitored or reported. Continued adherence might be important to maintain the effectiveness of treatment and therefore to improve quality of life, but it is estimated that less than two-thirds of patients (64%) adhere to PFME and other advice during the treatment period when being supervised, and less than one-third (23%) remain adherent without supervision.<sup>87</sup> Evidence suggests positive adherence intentions, self-efficacy, attitudes towards and perceived benefits of treatment, and social pressure may impact adherence and might be amenable to health professional intervention, for example, by setting personalised self-management goals and adopting patient-centred adherence strategies. 88 89 More evidence is needed to develop and further test adherence strategies as an added intervention to self-management.

Self-reported improvement in UI severity increased significantly compared with the control in some studies using behavioural training interventions. Patients' subjective evaluation of outcomes including satisfaction with treatment progress has been recognised as an important aspect of healthcare outcomes and a quality indicator for many health services. 90 Patients' modified behaviours and lifestyles have also been found to be associated with self-management ability in people living with chronic conditions.<sup>37</sup> Self-management ability is an important indicator to be assessed, and it reflects the extent to which participants engage with the interventions and develop skills to control their symptoms. Rather than solely focusing on clinical indicators such as wet episodes or volume of leakage, subjective ratings can provide empirical evidence on the effectiveness, feasibility and acceptability of the intervention. 91 92

The majority of the included studies were conducted in local communities where women were identified and recruited. This may reflect the reluctance of women to present with the condition or the fact that little attention has been given by health professionals, <sup>93</sup> although the guideline by National Institute for Health and Care Excellence recommends that all women should be asked

about bladder and bowel health. It is a particular issue for older people who frequently visit health professionals but do not actively seek medical help for their UI. Given the fact that care pathways for older women with UI can be complex involving consultants, urologist or urogynae-cologist, physiotherapists and nurses, identifying those with higher risks and providing timely medical care and support at early stages would be of benefit in primary care settings.

#### **Implications**

Given the fact that most of the studies were of poor or unclear quality, there is a need for high-quality studies with a rigorous design and high methodological quality to evaluate the effectiveness of multifaceted interventions, and subsequently the comparative effectiveness. Most of the included studies were conducted in local communities, future studies are also needed to explore whether self-management interventions can improve outcomes for patients in clinical settings. To establish solid conclusions for all the other comparisons, there is a need to develop core outcome sets and to identify the clinically relevant reference points for women with UI. Although this review suggested the potential associations between these self-management interventions and identified outcomes, the optimal components of effective interventions and their mechanism remain unclear. 94 More research is needed to identify the active components and determine the effect size of self-management for UI management.

This review found that the group of multifaceted behavioural techniques, including PFME, bladder retraining and combination interventions, are potentially useful approaches to the UI management. The findings of this review also highlight the tailored support for individuals with an aim to improve their physical, psychological and social functioning may be useful to be implemented in multidisciplinary continence services in primary care. Our confidence in these findings is low as the RCTs most were at high or unclear risk of bias. Also, it would be useful to understand patients' satisfaction on treatment received for UI management in practice.

#### Limitations

There were potential weaknesses in this review. It was limited by the fact that only studies published in English were included. No study was considered of high quality. Publication bias may exist, as the majority of studies published reporting significant results. Given that most of the multifaceted interventions were delivered by providers who were either researchers or health professionals, theoretical bias arising from therapeutic alliance related to the quality of provider–participant relationship may exist which may lead to the placebo effect. Due to analysis in the included studies being conducted with mixed samples, subgroup analysis was impossible to be carried out in this review in order to examine whether effects of interventions differ across subgroups according to the type of UI.

#### Conclusion

This review found that PFME, bladder retraining and combination behavioural based, multifaceted interventions are potentially useful approaches to the UI management. There was insufficient evidence to determine whether any of the combination of components is superior to others in improving UI symptoms. It is likely that behavioural interventions comprising multiple components targeting symptom management, emotional and social functioning would be candidates for the future development of tailored self-management interventions.

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