
Adult conservative management.


Copyright:

Copyright © ICS 2017. This book chapter may be downloaded for personal use only. Any other use requires prior permission of the author and the publisher.

URL link to article:

https://www.ics.org/education/icspublications/icibooks/6thicibook

Date deposited:

31/10/2017

Embargo release date:

01 November 2018
Committee 12

ADULT CONSERVATIVE MANAGEMENT

Chair
C. DUMOULIN (CANADA)

Members
T. ADEWUYI (UK)
J. BOOTH (UK)
C. BRADLEY (USA)
K. BURGIO (USA)
S. HAGEN (UK)
K. HUNTER (CANADA)
M. IMAMURA (UK)
M. MORIN (CANADA)
S. MORKVED (NORWAY)
R. THAKAR (UK)
S. WALLACE (UK)
K. WILLIAMS (UK)

The present chapter would not have been possible without the work of the previous editors, Katherine Moore [2013], Jean hay Smith [2008] and don Wilson [2000, 2004]. They produced the remarkable framework for the present review. In addition, we would like to acknowledge the indispensable contribution of Pauline Campbell to the reviewing, analysis and reporting of POP section. Finally, this chapter would not have been possible without the untiring dedication of Yvonne Ruella.
## CONTENTS

### I. INTRODUCTION

#### 1. Lifestyle Modification Interventions
   - 1.1. Prevention
   - 1.2. Treatment
   - 1.2.1 Weight Loss by Obese or Overweight Women
   - 1.2.2 Physical Activity
   - 1.2.3 Strenuous Physical Activity
   - 1.2.4 Smoking
   - 1.2.5 Dietary Modification (Elimination Diet)
   - 1.2.6 Constipation
   - 1.3. Other LUTS
   - 1.4. Factors Affecting Outcome

#### 2. Pelvic Floor Muscle Training (PFMT)
   - 2.1. Prevention and Treatment (Pregnant and Postnatal Women Only)
   - 2.1.1 Is PFMT Effective in the Prevention of UI in Childbearing Women?
   - 2.1.2 Is PFMT Effective in the Treatment of UI in Childbearing Women?
   - 2.1.3 Is PFMT Effective in the Mixed Prevention and Treatment of UI in Childbearing Women?
   - 2.2. Prevention (Other Women)
   - 2.3. Treatment (Other Women)
   - 2.3.1 Is PFMT Better than No Treatment, a Placebo, or a Control Group Treatment?
   - 2.3.2 Is One Type of PFMT Programme Better than Another?
   - 2.3.3 Is PFMT Better than Other Treatments?

#### 2.4 Does the Addition of PFMT to Other Treatments Add Benefit?

### II. URINARY INCONTINENCE IN WOMEN

- 3. Weighted Vaginal Cones (VC)
  - 3.1. Prevention
  - 3.2. Treatment
  - 3.2.1 Are VC Better than No Treatment, Placebo or Control Treatments?

- 4. Magnetic Stimulation (MStim)
  - 4.1. Prevention
  - 4.2. Treatment

- 5. Posterior Tibial Nerve Stimulation (PTNS)
  - 5.1. Prevention
  - 5.2. Treatment

- 6. Electrical Stimulation (EStim)
  - 6.1. Prevention
  - 6.2. Treatment

- 6.2.1 Is MStim Better Than no Active Treatment (Placebo, Control or no Treatment)?
6.2.2 Is One Approach to MStim Better than Another? .......................... 87
6.2.3 Is MStim Better than Other Treatments? .......................... 85
6.2.4 Does the Addition of MStim to Other Treatments Add Any Benefit in the Treatment of UI? .......................... 85
6.3. Other LUTS ................................................. 85
6.4. Factors Affecting Outcome ................................................. 85
7. Scheduled Voiding Regimens ................................................. 85
7.1. Prevention ................................................. 87
7.2. Treatment ................................................. 87
7.2.1 What Is the Most Appropriate Bladder Training (BT) Protocol? .......................... 87
7.2.2 Is BT Better than No Treatment, Placebo or Control Treatments? .......................... 89
7.2.3 Is BT Better than Other Treatments? .......................... 89
7.2.4 Can Any Other Treatment Be Added to BT to Add Benefit? .......................... 90
7.2.5 Does the Addition of BT to Other Treatment Add Benefit? .......................... 90
7.2.6 Is Timed Voiding Effective at Treating UI? .......................... 91
7.3. Other LUTS ................................................. 91
7.4. Factors Affecting Outcome ................................................. 92
8. Complementary and Alternative Medicines ................................................. 92
8.1. Prevention ................................................. 93
8.2. Treatment ................................................. 93
8.2.1 Acupuncture for Treatment of SUI ................................................. 93
8.2.2 Acupuncture for Treatment of OAB, UUI and Mixed UI ................................................. 93
9. Future Research Directions ................................................. 95
9.1. Summary ................................................. 95
9.2. Recommendations for practice ................................................. 95
9.2.1 Lifestyle Intervention ................................................. 95
9.2.2 PFMT (Principal Recommendation) ................................................. 95
9.2.3 Cones ................................................. 96
9.2.4 EStim ................................................. 96
9.2.5 PTNS ................................................. 96
9.2.6 Magnetic Stimulation ................................................. 96
9.2.7 Bladder Training ................................................. 97
9.2.8 Complementary and Alternative Medicine ................................................. 97
9.3. Future Research Direction ................................................. 97
9.3.1 Lifestyle Modification Intervention ................................................. 97
9.3.2 PFMT in Antenatal and Postnatal women ................................................. 97
9.3.3 PFMT in Women (Others) ................................................. 97
9.3.4 Vaginal Cones ................................................. 98
9.3.5 EStim/PTNS/MStim ................................................. 98
9.3.6 Scheduled Voiding Regimen ................................................. 98

III. PELVIC ORGAN PROLAPSE (POP) ................................................. 98
1. Lifestyle Modification Intervention ................................................. 98
1.1. Prevention ................................................. 98
1.1.1 Quality of Data ................................................. 98
1.1.1.1 Association Between POP and Occupation and Physical Activity ................................................. 98
1.1.1.2 Association Between POP and Body Weight ................................................. 99
1.1.1.3 Association Between POP and Smoking ................................................. 99
1.1.1.4 Association Between POP and Bowel Function ................................................. 105
1.1.1.5 Association Between POP and Nutrition ................................................. 105
1.1.2 Results ................................................. 105
1.1.2.1 Association Between POP and Occupation and Physical Activity ................................................. 105
1.1.2.2 Association Between POP and Body Weight ................................................. 106
1.1.2.3 Association Between POP and Smoking ................................................. 106
1.1.2.4 Association Between POP and Bowel Function ................................................. 106
1.1.2.5 Association Between POP and Nutrition ................................................. 107
1.2. Treatment ................................................. 107
2. Pelvic Floor Muscle Training ................................................. 108
2.1. Prevention ................................................. 108
2.2. Treatment ................................................. 109
2.2.1 PFMT Alone ................................................. 109
2.2.2 PFMT and Surgery ................................................. 121
2.2.3 PFMT and Pessary ................................................. 124
3. Pessaries ................................................. 126
3.1. Prevention of POP with Pessaries ................................................. 127
3.2. Treatment of POP with Pessaries ................................................. 127
3.2.1 Pessary Alone ................................................. 127
7. Complementary and Alternative Medicines
   7.1. Prevention of UI.......................... 161
   7.2. Treatment UI............................ 161
   7.2.1 What Is the Most Effective Acupuncture Protocol? ............... 161
   7.2.2 Acupuncture Versus No Treatment, Sham Acupuncture or Any Other Treatment ... 161
   7.3. Other LUTS.............................. 161
   7.4. Factors Affecting Outcome................. 161
   8. Summary.................................. 161
   8.1. Recommendations for Practice.............. 161
   8.2. Future Research Directions............... 162
   8.2.1 Lifestyle Interventions.................. 162
   8.2.2 Pelvic Floor Muscle Training (PFMT).... 162
   8.2.3 Electrical Stimulation (EStim) and Magnetic Stimulation (MStim) ................. 162
   8.2.4 Scheduled Voiding Regimens............. 163

   V. URINARY INCONTINENCE IN MEN AND WOMEN 163
      1. Posterior Tibial Nerve Stimulation (PTNS)
         ........................................................................ 163
      1.1. Prevention of UI........................ 163
      1.2. Treatment of UI......................... 163
      1.2.1 Is PTNS Better Than No Treatment,
            Placebo or Control Treatments for UI?.. 163
      1.2.2 Is PTNS Better Than Other Treatments for
            UI?.................................................. 164
      1.2.3 Does the Addition of PTNS to Other UI
            Treatment Add Any Benefit?................. 165
      1.2.4 What is the Best PTNS Protocol for UI in
            Adults?............................................ 166
      1.3. What is the Effect of PTNS on LUTS Other Than UI?......................... 166
      1.4. Factors Affecting Outcomes.............. 170

   REFERENCES 172
ADULT CONSERVATIVE MANAGEMENT

C. DUMOULIN (CANADA)
T. ADEWUYI (UK), J. BOOTH (UK), C. BRADLEY (USA), K. BURGIO (USA), S. HAGEN (UK), K. HUNTER (CANADA), M. IMAMURA (UK), M. MORIN (CANADA), S. MORKVED (NORWAY), R. THAKAR (UK), S. WALLACE (UK), K. WILLIAMS (UK)

I. INTRODUCTION

Conservative management of urinary incontinence (UI) or pelvic organ prolapse (POP) is defined as any intervention not involving surgical or pharmacological approaches (1). These comprise lifestyle modification, pelvic floor muscle training (PFMT) (either alone or with the addition of biofeedback), vaginal cones, electrical stimulation, magnetic stimulation, posterior tibial nerve stimulation, scheduled voiding regimens, complementary/alternative medicines and supportive rings/pessaries. In this chapter, we cover studies that provide comparative data between a conservative management approach and the absence of treatment or placebo, between two conservative management approaches or between a conservative management approach and medications or surgery.

Conservative management approaches are considered relatively low cost and non-invasive, with minimal adverse effects that are typically guided by a healthcare professional and depend on user participation. It is generally accepted that conservative interventions are part of initial management at the primary care level for individuals suffering from either UI or POP. Conservative intervention is also indicated for those for whom other treatments are inappropriate, for example, those unwilling to undergo or unfit for surgery and women who plan future pregnancies. Other indications include individuals awaiting surgery or who wish to delay surgery and those whose symptoms are not severe enough for surgical intervention.

The research base on which to judge the effectiveness of conservative interventions is growing although some aspects, such as lifestyle modification interventions and alternative and complementary medicines in particular, require considerably more well-designed trials. In this chapter we add to the 2013 5th Edition ICI chapter on conservative management (2), integrate the evidence and upgrade the recommendations from the 5th ICI. We also add a new section on posterior tibial nerve stimulation with its levels of evidence and recommendation.

The updated literature search covered publications from July 1st, 2011 to September 9th, 2015 according to the following search strategy:

- Cochrane Incontinence systematic reviews

Relevant Cochrane systematic reviews were identified, for each section of this Chapter, by two of the authors (CD, SW) assessing the full list of reviews (Cochrane Incontinence (3) or on request). The leads for each section were given lists of these relevant reviews. Additional searches of the Cochrane Incontinence Specialised Register were provided to each section author to bring the searches up to date or, if there was a gap in review coverage, a full search of the Register was conducted (search date: September 9th, 2015).

- Additional searches for this ICI Chapter

Electronic searches

We identified relevant trials from the Cochrane Incontinence Specialised Register. For more details of the search methods used to build the Register please see the Group's module in the Cochrane Library (4). The Register contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, MEDLINE In-Process, ClinicalTrials.gov, WHO ICTRP, UK Clinical Research Network Portfolio and hand searching of journals and conference proceedings. The search covered:

- For sections covered by existing Cochrane reviews – from the date of last search for the published version of the review to September 9th, 2015.
- For sections not covered by existing Cochrane reviews – complete search of all contents of the Register on September 9th, 2015.
- Searching other sources

We searched the reference lists of relevant articles for other relevant trials.

We did not impose any language or other limitations on any of the searches described above.
In continuity with the last edition of the ICI chapter on conservative management and to ensure consistency throughout the chapter, the primary outcomes to be reported were patient-reported outcomes: cure and cure and improvement, UI-specific or POP-specific quality of life or symptoms-validated questionnaire and/or number of leakages (as per the diary). Cure and improvement were based on patients’ self-report when available; if not, cure and improvement based on quantifiable measures such as a diary and pad tests were reported.

Secondary outcomes were clinician-reported outcomes (pad test, POPQ score, etc.). These were chosen in relation to each subsection’s specificity and in continuity with our previous chapter.

Each subsection concludes with the level of evidence, grade of recommendations and factors affecting outcome. Separate chapters in this 6th Edition address incontinence in the frail older person, children, pessaries and products for continence, those with neurological conditions and those suffering from faecal incontinence.

Where summary statistics are presented, the raw data from which these are derived can be found in the tables within each subsection, in trial reports and systematic reviews cited in the chapter. The Chapter is intended as a stand-alone document and adds to the comprehensive reports from previous ICI editions.

### 1. LIFESTYLE MODIFICATION INTERVENTIONS

**Lifestyle modification Interventions for women**

A number of lifestyle factors may play a role in either the development or resolution of UI. Lifestyle modification interventions are defined as application of interventions in management of lifestyle-related health problems (1). They are low cost, non-invasive alterations in lifestyle such as weight loss; dietary changes; fluid intake modification; reduction in caffeinated, carbonated and alcoholic drinks; avoidance of constipation; stopping smoking; and physical activity.

As reported in the 5th ICI (2013) evidence for the efficacy of lifestyle modification interventions for urinary incontinence is lacking, there are few lifestyle modification interventions that have received scrutiny in randomised controlled trials, although weight loss and dietary factors have been examined and prospective studies and observational studies have been undertaken for diet, smoking and constipation. For more details, refer to ICI 5th Edition (2).

This review section updates the evidence on the use of lifestyle modification interventions to improve incontinence and related symptoms in females. It revealed 10 potentially eligible new trials. Table 1 illustrates the number of studies included in the 5th ICI edition as well as the new studies identified in the current update. Characteristics of each new trial are presented in subsequent tables for each lifestyle modification intervention for which there is new data.

#### Table 1 Studies included in the updated review 2016

<table>
<thead>
<tr>
<th>Lifestyle modification Interventions</th>
<th>ICI 2013</th>
<th>ICI 2016</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight loss</td>
<td>3 RCT 4 prospective cohort 7 cross sectional cohort 1 retrospective cohort 1 case control study</td>
<td>2 RCT 1 cohort study 1 meta-analysis 1 prospective longitudinal study</td>
<td>5 RCT 13 cohort studies 1 case control study 1 meta-analysis 1 prospective longitudinal study</td>
</tr>
<tr>
<td>Physical activity</td>
<td>2 prospective cohort 2 observational cohort</td>
<td>1 prospective cohort study 1 case control study</td>
<td>3 prospective cohort studies 2 observational cohort study 1 case control study</td>
</tr>
<tr>
<td>Smoking</td>
<td>2 case control studies</td>
<td>1 RCT (pilot, secondary analysis)</td>
<td>1 RCT pilot 2 case control studies</td>
</tr>
<tr>
<td>Dietary factors</td>
<td>3 observational studies</td>
<td>1 case control study 1 prospective cohort study 1 cross sectional cohort study</td>
<td>3 observational studies 1 case control study 1 prospective cohort study 1 cross sectional cohort study</td>
</tr>
</tbody>
</table>
Questions addressed are:

- Are lifestyle modification interventions (e.g. weight loss, increased/decreased physical activity/ smoking cessation/ dietary or fluid change) effective in the prevention of UI?
- Are lifestyle modification interventions (e.g. weight loss, increased/decreased physical activity/ smoking cessation/ dietary or fluid change) better than no treatment, placebo or control in the treatment of UI?
- Is one lifestyle modification intervention (e.g. weight loss, increased/decreased physical activity/ smoking cessation/ dietary or fluid change) better than another?

In 2015 a Cochrane review was published (5) which included all available trials of lifestyle modification interventions for urinary incontinence. These trials are included in this review, along with new trial data since the Cochrane search was undertaken (October 27th, 2014) as well as other cohort evidence where no trial data are available.

1.1. Prevention

Are lifestyle modification interventions (e.g. weight loss, increased/decreased physical activity/ smoking cessation/ dietary or fluid change) effective in the prevention of UI?

In the last ICI chapter (5th ICI, 2013), there were no trials on prevention of UI. No new trials have been published.

Based on the clear lack of evidence in the literature of RCTs or observational studies of lifestyle modification interventions to prevent UI, no evidence based recommendations can be made.

Prevention should be an area for future research investment and comprise robust economic evaluation to determine the benefits of prevention strategies in specific age groups.

1.2. Treatment

1.2.1 Weight Loss by Obese or Overweight Women

Urinary incontinence and obesity are both common problems for women. It is recognised that obese women have higher intra-abdominal pressures than non-obese women, and it has been suggested that this chronically elevated pressure may predispose to incontinence by weakening pelvic floor support structures (6).

One new trial was identified which examined weight loss in overweight/obese women (7) (Table 2). The study was conducted to determine the effect of an intensive weight loss programme over 4 years on a subset of female participants (n=2739), previously outlined in the Look AHEAD trial(7). All participants were randomised to an intensive weight loss programme or a diabetes support and education group. Self-report of incontinence, nocturia and daytime voiding frequency were recorded at baseline and 1 year. Each kilogramme of weight loss reduced the odds of developing UI at one year by 3% (OR 0.97, 95% CI (0.95–0.99); p=0.1). There was uncertainty over the risk of selection bias for several key parameters, including; random sequence generation and allocation concealment. Performance bias was unclear as the blinding of participants and staff was not undertaken. The study ensured the blinding of outcome assessment but did not provide complete outcome data and provided only selective reporting indicating possible reporting bias.

A single study not identified in our previous searches from 2008 was discovered (8). This prospective longitudinal study examined the effect of weight loss offered as part of a weight reduction programme which included low calorie diet and exercise, 64 obese continent women were included. Weight loss of ≥5% of baseline weight was associated with significant reduction in pad test loss (median difference, 19 g; 95% confidence interval, 13–28 g; p < 0.001). They also report a statistically significant improvement in quality of life measures. They suggest that weight reduction of 5% of initial body weight can improve UI severity and its effects on quality of life in obese women. There was uncertainty over the risk of bias in all parameters for this study due to the poor reporting style.

Further analysis on the effect of weight loss on changes in health-related quality of life are reported by Pinto et al. 2012 (9). In a study conducted for the Programme to Reduce Incontinence by Diet and Exercise (PRIDE), a longitudinal cohort analysis was undertaken of 338 obese and overweight women with UI and health related quality of life assessed at baseline, 6 and 18 months. They concluded that weight loss and increased physical activity but not reduction in frequency of UI were strongly associated with improvements in QoL.

More recently in 2014 a systematic review and meta-analysis of non-surgical weight loss interventions in overweight women was published by Vissers et al. (10) drawing on the studies from the ICI 2013 chapter and the more recent Cochrane review (2015); this concluded that whilst few (n=6) studies were available, non-surgical weight loss should be considered standard practice for overweight women with UI. This review did not identify any additional studies for inclusion here. It is important to note that this review sought to determine the effect of non-surgical weight loss interventions on urinary incontinence in overweight women, but, in fact, included studies of both obese and overweight women.
<table>
<thead>
<tr>
<th>Author, year</th>
<th>Comparator</th>
<th>N</th>
<th>Study population</th>
<th>Age</th>
<th>Outcomes/results</th>
<th>Follow up</th>
<th>Notes (side effects, loss of follow up, risk of bias)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phelan 2012(1)</td>
<td>Intensive weight-loss vs a structured education programme on weight loss</td>
<td>2994</td>
<td>Women in a diabetes trial</td>
<td>Group 1 57.8 Group 2 58.1</td>
<td>Decrease of at least 2 incontinence episodes a week assessed by a validated self report questionnaire. Mean weight loss at 1 year Group 1 : 7.7 group 2 0.7; p value&lt;0.0001</td>
<td>12 months</td>
<td>Random sequence generation: unclear Allocation concealment – unclear Blinding of participants – high risk Blinding of outcome assessment – low risk Incomplete outcome data – unclear risk Selective reporting – unclear risk</td>
</tr>
<tr>
<td>Breyer 2014(2)</td>
<td>Intensive weight loss versus a structured education programme on weight loss</td>
<td>1910</td>
<td>Men in a diabetes trial</td>
<td>59.9</td>
<td>Decrease in incontinence episodes or cure assessed by a validated self-report questionnaire</td>
<td>12 months</td>
<td>Random sequence generation : unclear Allocation concealment – unclear Blinding of participants – high risk Blinding of outcome assessment – low risk Incomplete outcome data – unclear risk Selective reporting – unclear risk</td>
</tr>
<tr>
<td>Auwad 2008(3)</td>
<td>Commercial programme of diet and exercise versus no control group</td>
<td>64</td>
<td>Obese women with urodynamically proved urinary incontinence</td>
<td>52.2</td>
<td>Decrease in pad test loss</td>
<td>18 months</td>
<td>Blinding of outcome assessment – unclear risk Incomplete outcome data – unclear risk Selective reporting – unclear risk</td>
</tr>
<tr>
<td>Pinto 2012(4)</td>
<td>Behavioural weight loss intervention versus a structured education programme on weight loss</td>
<td>338</td>
<td>Overweight and obese women with UI</td>
<td>53 -+ 11 years (SD)</td>
<td>Health related QoL</td>
<td>18 months</td>
<td>Secondary analysis of data: Random sequence generation : low risk Allocation concealment – low risk Blinding of participants – high risk Blinding of outcome assessment – low risk Incomplete outcome data – low risk Selective reporting – unclear risk</td>
</tr>
</tbody>
</table>

Summary

Evidence from 1 RCT, 2 cohort studies and one meta-analysis support lifestyle modification interventions promoting weight loss as a tool to reduce urinary incontinence in women who are overweight or obese. Weight loss of 5% of initial body weight has an impact on the reduction of urinary incontinence symptoms and the odds of developing UI at one year can be reduced by 3% for every kilogram lost by overweight and obese women. (Level of Evidence: 1)

Recommendations

Weight loss as a non-surgical intervention, should be recommended to obese and overweight women with UI. (Grade of Recommendation: A)

1.2.2 Physical Activity

No new RCT data have been published on either the benefits of moderate physical activity or the adverse effect of strenuous activity on UI in women. One relevant prospective cohort study (11) and one case control study have been reported since the last review Table 3.

The prospective cohort study (11) determined that low physical activity may be a causal factor in the development of overactive bladder. This study developed a hypothetical causative model for OAB involving secondary analysis from the Leicestershire UK MRC Incontinence study and included 3411 women free from OAB and 277 incident cases aged 40+. The study used graphical chain modelling to ESTimate the associations between variables and identify the likely causal pathways. Low physical activity was a direct risk factor linked to the development of over active bladder (OAB) with incontinence (RR 2.47;95% CI 1.82, 3.36). They identified the need for further research to demonstrate a causal link between lifestyle and OAB. This study was difficult to combine as it used sophisticated statistical modelling to determine a causative model for use in future research. This research indicated that poor lifestyle factors causally linked to diabetes and obesity and suggest that this may contribute to the onset of OAB. The authors identify that low physical activity could be an important modifiable causal factor for OAB operating via pathways involving obesity or diabetes.

Summary

Non RCT evidence is building which suggests that moderate exercise decreases the incidence of UI although the level of evidence remains low (Level of Evidence: 3).

Recommendations:

In the absence of robust randomised controlled trials (Grade of Recommendation: C)

1.2.3 Strenuous Physical Activity

The previous ICI identified no research evidence which suggested that strenuous exercise causes UI. Minimal uncontrolled data did suggest that women engaged in occupations which involved heavy lifting may be predisposed to genital prolapse or UI (12). A case control study conducted by Nygaard et al. (13) to determine lifetime physical activity and stress incontinence enrolled 1528 women between the ages of 39-65. Each participant underwent a Pelvic Organ Prolapse Quantification examination, 213 cases were identified and matched 1:1 to controls. Physical activity was measured using the Lifetime Physical Activity Questionnaire in which women recall their past physical activity. Lifetime strenuous activity was not associated with SUI (OR, 1.11; 95% CI, 0.99-1.25) and increased lifetime activity did not affect the odds of developing SUI (OR, 1.11; 0.99-1.25; p=0.06) (Table 3).

Summary

Evidence for the association between strenuous physical activity and incontinence need to be replicated using larger populations and more robust design before recommendations can be made. No further data was identified. (Level of Evidence: 3)

Recommendations:

In the absence of robust randomised controlled trials (Grade of Recommendation: C)

1.2.4 Smoking

In 2014, a pilot study investigated the effect of smoking cessation on overactive bladder symptoms (14). The authors explored the hypothesis that smoking abstinence would be associated with improvements in OAB symptoms. The sample was randomised to one of three arms: 1) very low nicotine cigarettes; 2) very low nicotine cigarettes and a 21g nicotine patch; 3) patch alone. All participants had at least one OAB symptom including urinary frequency, urgency, nocturia or urgency urinary incontinence, smoked 10-40 cigarettes a day for a year and were in good physical and mental health. The ICIQ-OAB was used at baseline and 12 weeks, 6 weeks after completion of the trial intervention. Outcomes included self-report of smoking cessation and OAB symptoms and score. 96 (47%) of the 202 participants met the inclusion criteria for this secondary analysis and 57 (59%) (37 women and 20 men) completed the study and were included in the analysis. Data was not presented separately for women and men. Those who were abstinent from smoking at 12 weeks were more likely to have a reduction in urinary frequency (p=0.042) and the ICIQ-OAB score showed no change for those who were abstinent or those who resumed smoking (4.6±0.5 vs 4.3±0.3, respectively, p=n.s). The authors conclude that smoking cessation and its effect on OAB would need to undergo more rigorous evaluation in further trials with larger sample size to determine the effect of smoking abstinence on OAB symptoms (Table 4).

Table 3
Summary
Data suggest that smoking increases the risk of more severe UI. This small new study indicates that urinary frequency may be improved by smoking abstinence. (Level of Evidence: 3)

Recommendations
There remains a need for further prospective studies of smoking cessation for urinary symptoms (Grade of Recommendation: C)

1.2.5 DietaryModification (Elimination Diet)
Dietary factors can be divided into three groups: Diet; Fluid Intake and Caffeine. There have been no new published RCTs evaluating the effect of diet or fluid intake on urinary incontinence, but one small new RCT (15), three new observational studies (1 case control study, 1 prospective cohort study, 1 cross sectional cohort study) examining the effect of caffeine on urinary incontinence, one in men presented in section IV (16), one in women (17) and one in both men and women (18) (Table 5).

A small double blind randomised crossover study by Wells et al. of 14 patients with OAB was conducted in which women were allocated to one of two groups. Group A were allocated to a 14 day caffeinated drink period followed by a 14 day de-caffeinated period. Groups B were allocated to a 14 day de-caffeinated period followed by a 14 day caffeinated period. Both were preceded by a 14 day run-in period. The primary outcome was reported episodes of urgency, frequency and volume per void recorded in a 3 day diary. Secondary outcomes included OAB symptom severity and health related quality of life (QOL). Of the eleven women who completed the study, a significant reduction of urgency (p<0.1) and frequency (p<0.5) were reported. Risk of bias was minimised using a double blind design, but conclusions must be cautious due to the very small sample size (15).

Three studies examined the association between caffeine and UI, Gleason et al. (2013) (17) examined the association in women in the US and Hyrayama et al. (2012)(18) in men and women in Japan and Davis et al. (2012)(16) in a male sample in the US.

In the cross sectional female US survey study, UI status was collected using the Incontinence Severity Index and food diaries were used to collect data on caffeine intake in 4309 women aged 20 or over. This study found an association between caffeine consumption in the highest quartile (>204mg day) was associated with any UI (prevalence odds ratio 1.47, 95% CI 1.07, 2.01), but not moderate or severe. Caffeine consumption at the very highest level was found to be associated with UI in a very large sample of US women. All parameters in terms of risk of bias reporting were unclear or high risk. The binding of participants and personnel and blinding of outcome assessment were at high risk of bias and the likelihood of incomplete outcome data and selective reporting was also high.

Hirayama and Lees study comprised a sample of 683 men and 298 women (results for men are reported separately) aged 40-75 who completed a food frequency questionnaire and the Consultation on Incontinence short Form (ICi-SF). The data showed a slight increase in the risk of UI at the highest level of caffeine consumption (similar to the US data), but this was not significant after adjusting for confounding factors with OR: 95% CI, 1.12 (0.57-2.22) for women. The risk of bias reporting was largely unclear in this study with binding of participants and personnel and binding of outcome assessment, incomplete outcome data and selective reporting all of high risk. The sample of women did not show an association between caffeine and UI, they suggest the need for further larger samples to explore any association further.

Summary
There have been no new data on dietary content modification and UI since 2013, the existing evidence suggests that dietary content may play a role in urinary incontinence (Level of Evidence: 3).

Minimal evidence exists on the role of macronutrient intake and reduction of UI. Fluid intake may play a minor role in the pathogenesis of UI (Level of Evidence: 2).

Caffeine consumption is likely to play a role in exacerbating UI and related symptoms such as urgency and frequency. Small clinical trials suggest that decreasing caffeine intake improves continence. (Level of Evidence: 2), new epidemiological evidence from a large cross sectional study supports this conclusion however it does not change the Level of Evidence: Level 2.

Recommendations
Recommendations for fluid intake and dietary intake have not changed (Grade of Recommendation: B). Further RCTs to assess the role of diet in UI are warranted.

A reduction in caffeine intake is recommended for those with incontinence and related symptoms (Grade of Recommendation: B) Larger RCTs to assess the effect of caffeine and other dietary factors are feasible and important.
Table 3 Summary of data on physical activity

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Comparator</th>
<th>N</th>
<th>Study population</th>
<th>Age</th>
<th>Assessment</th>
<th>Follow up</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>McGrother 2012(1)</td>
<td>Development of a Causative model for OAB</td>
<td>3411</td>
<td>Women in a UK epidemiological study of UI free from OAB at baseline</td>
<td>40+</td>
<td>Food frequency questionnaire and OAB recorded in a postal questionnaire</td>
<td>no</td>
<td>Low physical activity linked to the onset of OAB. Older women reporting less activity than their peers had more than double the risk of developing OAB.</td>
</tr>
<tr>
<td>Nygaard 2015 (2)</td>
<td>Case control study</td>
<td>1538</td>
<td>Women seeking gynaecological primary care</td>
<td>39-65</td>
<td>POP assessment, severity index score (indicating SUI), Lifetime physical activity questionnaire</td>
<td>no</td>
<td>SUI odds increased with overall lifetime activity (OR 1.20 per 70 additional metabolic equivalent of task-h/wk; 95% CI, 1.02-1.41.</td>
</tr>
</tbody>
</table>


Table 4 Summary of data on smoking cessation

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Comparator</th>
<th>N</th>
<th>Study population</th>
<th>Age</th>
<th>Outcomes/results</th>
<th>Follow up</th>
<th>Notes (side effects, loss of follow up, risk of bias)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wyman et al. 2014 (1)</td>
<td>Low nicotine cigarette alone vs low nicotine cigarette combined with 21mg nicotine patch vs patch alone</td>
<td>202</td>
<td>Subset of adult participants in a smoking cessation trial</td>
<td>18-70</td>
<td>ICIQ-OAB Self-reported smoking status and cessation</td>
<td>12 weeks</td>
<td>Subset of participants: Random sequence generation: uncertain Allocation concealment – uncertain Blinding of participants – uncertain Blinding of outcome assessment – uncertain Incomplete outcome data – low risk Selective reporting – unclear risk</td>
</tr>
</tbody>
</table>


Table 5 Summary of data on caffeine consumption

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Comparator</th>
<th>N</th>
<th>Study population</th>
<th>age</th>
<th>Outcomes/results</th>
<th>Follow up</th>
<th>Notes (limitations)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Davis 2013 (1)</td>
<td>Association between caffeine and UI in US men</td>
<td>3960</td>
<td>Publically available data from the National Health and Nutrition</td>
<td>20+</td>
<td>Incontinence Severity Index (ISI)</td>
<td>no</td>
<td>Cross sectional design means that no causation can be determined. The ISI needs additional validation for use in men. 25% of</td>
</tr>
<tr>
<td>Author, year</td>
<td>Comparator</td>
<td>N</td>
<td>Study population</td>
<td>age</td>
<td>Outcomes/results</td>
<td>Follow up</td>
<td>Notes (limitations)</td>
</tr>
<tr>
<td>-------------</td>
<td>------------</td>
<td>---</td>
<td>------------------</td>
<td>-----</td>
<td>-----------------</td>
<td>----------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Examination Surveys 2005-2006 and 2007-2008 in men</td>
<td>Structured dietary recall</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>the sample was excluded due to missing UI and dietary data.</td>
<td></td>
</tr>
<tr>
<td>Gleason 2013 (2)</td>
<td>Association between caffeine and UI in US women</td>
<td>4309</td>
<td>Publically available data from the National Health and Nutrition Examination Surveys 2005-2006 and 2007-2008 in women</td>
<td>20+</td>
<td>Incontinence Severity Index (ISI) Structured dietary recall</td>
<td>no</td>
<td>The cross sectional design means that no causation can be determined. Analysis depended on self report. Questions for UI type were not validated and data was not analysed according to UI type or severity.</td>
</tr>
<tr>
<td>Hirayama 2012(3)</td>
<td>Association between caffeine use and UI in Japanese adults</td>
<td>981</td>
<td>Community dwelling Japanese men and women</td>
<td>40-75</td>
<td>ICIQ-SF</td>
<td>18 months</td>
<td>Cross sectional study: No cause-effect relationship could be established due to the study design. Classification of urine loss was based on self report</td>
</tr>
<tr>
<td>Wells 2014 (4)</td>
<td>Group A were allocated to a 14 day caffeinated drink period followed by a 14 day de-caffeinated period. Groups B were allocated to a 14 day de-caffeinated period followed by a 14 day caffeinated period. 14 community dwelling women</td>
<td>Women patient with OAB</td>
<td>18+</td>
<td>Reported episodes of urgency, frequency and volume per voids recorded in a 3 day diary</td>
<td>no</td>
<td>Small double blind randomised crossover study</td>
<td></td>
</tr>
</tbody>
</table>

1.2.6 Constipation
No new trials on constipation were found. Therefore, the evidence remains the same (small observational studies) suggesting that chronic straining may be a risk factor for the development of UI (Level of Evidence: 3).

Recommendation
Further research is needed to define the role of straining in the pathogenesis of UI.

1.3. Other LUTS
No data were found.

1.4. Factors Affecting Outcome
No data were found.

2. PELVIC FLOOR MUSCLE TRAINING (PFMT)

Pelvic floor muscle training (PFMT) is defined as exercise to improve PFM strength, endurance, power, relaxation or a combination of these parameters (1). PFMT remains a key factor in the treatment of UI. Because pelvic floor muscle (PFM) integrity appears to play an important role in the continence mechanism (see report from Chapter 4: Pathophysiology), there is a biological rationale to support the use of PFMT in preventing and treating SUI in women (19-21). The role of PFMT in the treatment of UI came later, when it was recognized that PFM contraction can also be used to occlude the urethra to prevent leakage during detrusor contraction, as well as inhibit and suppress detrusor contraction (22, 23). More details about the biological rationale regarding PFMT for SUI and UI can be found in the last edition of this chapter (2).

PFMT is an intervention that involves the understanding of PFM activation and the pursuit of a repeated PFM exercise programme over time. Because effectiveness depends on the participant’s adherence during the intervention and afterwards (in the maintenance phase), a better understanding of adherence mechanisms and how they can be promoted is of major importance. The 2011 International Continence Society State of the Science Seminar on Adherence produced 4 papers and a Consensus Statement reviewing present literature and making recommendations to increase PFMT adherence that could be useful, both in the clinical and research settings UI (24-28).

This section presents evidence for the use of PFMT in the prevention and treatment of UI in women. Questions addressed are:

- Is PFMT effective in the prevention of UI?
- Is PFMT better than no treatment, placebo or control treatments in the treatment of UI?
- Is one type of PFMT programme better than another in the treatment of UI?
- Is PFMT better than other treatments in the treatment of UI?
- Does the addition of PFMT to other treatments add any benefit in the treatment of UI?
- What factors might affect the outcome of PFMT in the treatment of UI?
- What is the effect of PFMT on other lower urinary tract symptoms (LUTS)?

2.1. Prevention and Treatment (Pregnant and Postnatal Women Only)

This subsection specifically considers PFMT for the prevention and treatment of UI in pregnant and postnatal women (called childbearing women). As the physiological changes of childbearing can affect PFM function, it is possible that the effect of PFMT might differ in this group compared to non-childbearing women; therefore, this group is treated separately.

Since the last ICI (2013), 11 randomised controlled trials aiming at prevention and/or treatment of UI were identified and reviewed for this subsection (29) (30) (31) (32) (33) (34) (35) (36) (37) (38) (39) (Table 6). An updated Cochrane review was published in 2012, analysing data from 22 trials involving 8485 women (40). Trials in this section have been grouped in 3 areas: 1) trials of PFMT for prevention of UI (performed in women without UI symptoms when randomised); 2) trials of PFMT for treatment of UI; and 3) trials of PFMT for the prevention and treatment of UI (participants with and without UI symptoms enrolled). Trials were further separated into those beginning during pregnancy (antenatal) or postnatal.

The primary outcome of interest was self-reported UI (cure, improvement, number of leakage episodes). Other outcomes of interest included adherence measures.

2.1.1 Is PFMT Effective in the Prevention of UI in Childbearing Women?

This section addresses the question of PFMT effectiveness for primary and secondary prevention of UI in childbearing women. Clinically it can be difficult to effectively screen trial participants to ensure that a disease process is altogether absent (for primary prevention studies) or present, although asymptomatic (for secondary prevention). Trials investigating prevention of UI usually enrol people purely on the basis of the absence of symptoms. Thus, the trials in this section likely represent a combination of primary and secondary prevention effects.

Since last chapter edition three new prevention trials were found (30, 36, 38) (Table 6) adding to the six previously existing trials.

Two studies (30) (38) recruited nulliparous or primiparous women during pregnancy, and one recruited...
"pregnant women" (36). Primigravidae were recruited at weeks 6-9 (30), 10-14 (38) and 14-20 (36). In all trials, PFMT began during pregnancy while controls received usual antenatal care, which may have included advice on PFMT, from their maternity caregivers (30) (36) (38). There were some variations in the PFMT parameters (intensity and supervision) (Table 6).

Quality of data

Two were RCTs (30, 38), while one was a quasi-randomized trial (36). Allocation concealment appeared adequate only in the trial by Palaz (2014) (38). The outcome assessors were not blinded in the trials by Kocaoz (2013) (36) and Palaz (2014) (38), while Barakat (2011) (30) gives no information about blinding of evaluators. Dropout rates were 16% (30), 10-14% (38) and 22% (36), and quite similar in both study groups. Outcomes were measured at various times: outcome in late pregnancy was measured only after delivery (30), 36 weeks of pregnancy (38); and 28 and 32 weeks of pregnancy then at three months postpartum (36). None of the trials applied intention-to-treat analysis.

Results

- Late pregnancy (34 weeks or later): Palaz (38) found a statistically significantly lower frequency of UI (p<0.001) in the intervention group compared to the control group between 36 and 40 weeks of pregnancy, and concluded that PFMT was effective in primary prevention of UI in primiparous pregnant women, while Barakat (30) reported no difference in frequency of urine loss between the exercise (supervised moderate physical exercise including PFMT) and control groups in late pregnancy.

- Mid postpartum (three to six month postpartum): Kocaoz (36) reported a statistically significant difference between the intervention and control groups in terms of development of stress urinary incontinence at the 28th and 32nd weeks of pregnancy and the 12th postpartum week (p<0.05).

Summary

Two studies documented the effectiveness of PFMT on primary prevention of UI during pregnancy (36, 38). One study included only nulliparous women and reported UI in late pregnancy (38). The other study also included multiparous women and reported UI in late pregnancy and 12 weeks postpartum (36). (Level of Evidence: 1)

Recommendations

Offer continent, pregnant women a supervised (including regular health professional contact) and intensive strengthening PFMT programme to prevent antepartum and postpartum UI (Grade of Recommendation: A)

Research recommendation

Additional trials with long-term follow-up (more than 12 months postnatal) are needed to determine long-term benefits of antenatal PFMT.

The only study including multiparous women is a quasi-randomized trial. Thus, large and good-quality RCTs are needed to investigate the effect of antepartum PFMT on preventing postpartum UI in multiparous women.

2.1.2 Is PFMT Effective in the Treatment of UI in Childbearing Women?

Since last chapter edition two trials assessing the treatment effect of postnatal PFMT were found (29) (34) (Table 6) adding to the four previously existing trials.

Kim (2012) recruited a mix of primiparous and multiparous incontinent women less than six weeks (34) after delivery, while Åhlund (2013) recruited only primiparous women 10-16 weeks after delivery (29). The control group in the trial by Åhlund received standard care, which included ante and postpartum advice on PFMT (1), whereas the control group/unsupervised training group in Kim’s study were instructed in PFMT and followed the same PFMT programme as the supervised training group (34). The PFMT interventions varied (Table 6).

Quality of data

Both studies were RCTs, but random allocation concealment was inadequate. In one trial (34) evaluators were blinded to group allocation. Åhlund (2013) and Kim (2012) reported an 8% and 1% loss to follow up, respectively. Similar dropout rates were found in both study groups in both trials. Outcomes were measured, before, 3 months after delivery (34) and 6 months after delivery (29). Kim did not report analysis by intention-to-treat, while information is lacking in the trial by Åhlund.

Results

In the trial by Åhlund the results showed significantly improved continence in both groups, however there was no between group comparison. Kim reported significant difference in UI symptoms in favour of the supervised PFMT group.

Summary

Data from one trial showed significantly better treatment effect of supervised PFMT compared to unsupervised PFMT. The other trial did not compare difference in treatment effect between groups. The addition of the new trials does not change the level of evidence. (Level of Evidence: 1)

Recommendations

PFMT should be offered as first line conservative therapy to women with persistent UI symptoms three
2.1.3 Is PFMT Effective in the Mixed Prevention and Treatment of UI in Childbearing Women?

Since last chapter edition six mixed prevention and treatment trials were found adding to the ten previously existing trials. Five trials assessed the effect of antenatal PFMT (31) (35) (37) (39) (32), and one the effect of postnatal PFMT (33) (Table 6).

In five trials, nulliparous, primiparous or multiparous women were randomised to either supervised antepartum PFMT or usual antepartum care (31) (32) (35) (37) (39). One study randomised nulliparous women to supervised postpartum PFMT or usual postpartum care (33). Ko (2011) and Miguelutti (2013) recruited nulliparous women and Stafne (2012) multiparous women between 16-24 weeks’ gestation. Be’s study (2011) differed in that the primary aim was to assess the effect of regular exercise on weight gain in pregnancy. Primiparous, sedentary women within the first 24 weeks of pregnancy were recruited. Fritel (2015) included nulliparous women between 20-28 weeks of gestation.

i) Antepartum PFMT versus usual care

The PFMT interventions varied (Table 6).

Quality of data

- Antepartum PFMT versus usual care: The four RCTs had adequate random allocation generation and concealment and thus had a low risk of bias (31) (32) (37) (39). In two of the trials a blinded method of collecting patient-reported incontinence symptom data was used (32) (39). Sample sizes varied between 105 and 855 women (31) (39), and the proportions of lost to follow up were 20%, 2%, 33% and 11% respectively (31) (37) (32) (39). Losses to follow up in intervention and control groups were quite similar in all trials. Intention-to-treat analysis was performed by all, except for Bø (2011).

- Postpartum PFMT versus usual care or no PFMT: Random allocation generation and concealment was adequate and a blinded method of collecting patient-reported incontinence symptom data was used in the trial by Hilde (2013) (33). Lost to follow up was 9%, in the control 14% and in the exercise group 3%. Analysis was by intention-to-treat.

Results

i) Antepartum PFMT versus usual care

Ko (2011), Miguelutti (2013) and Stafne (2012) showed that women who were randomised to antepartum PFMT had significantly less risk of UI in late pregnancy compared to a group receiving usual care in late pregnancy.

Three of the new five new mixed prevention and treatment trials assessing the effect of antenatal PFMT (35) (37) (39), reported a significant effect of PFMT during pregnancy, and 3 months after delivery (35). Bø (2011) found no difference in late pregnancy and 3 months postpartum, between a group following an aerobic fitness class including PFMT and a control group. While Fritel (2015) showed no difference in prevalence or severity of UI between a group receiving written instructions and a group receiving an additional eight PFMT sessions with a midwife or physiotherapist in late pregnancy, 2 and 12 months postpartum.

Some adherence outcomes were included for four antepartum (31) (35) (32) (39) trials; >80% of the PFMT women attended every group session, and at 36 gestational weeks, 87% reported PFMT practice at least 75% of the time (35); 40% of the exercise group attended >80% of the weekly exercise classes (31); 67% of the women in the intervention group and 40% in the control group performed PFMT three times per week or more (39); 54% in the intervention and 63% in the control group performed postpartum PFMT (32).

ii) Postpartum PFMT versus usual care or no PFMT

The only new mixed prevention and treatment trial assessing the effect of postnatal PFMT (33), found no differences in the prevalence of UI between a supervised PFMT group and a control group receiving instructions in correct PFM contractions and written information. Adherence was 96% in the intervention group (33).
Table 6 Summary of PFMT data on prevention and treatment (pregnant and postnatal women)

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Comparator</th>
<th>N</th>
<th>Study population</th>
<th>Modality details or parameters</th>
<th>Outcomes/results</th>
<th>Follow up</th>
<th>Notes (side effects, loss of follow up...)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ahlund 2013(1)</td>
<td>Control group (n=49): instructions and control of correct PFM contractions and written information about PFMT. Intervention group (n=49): instructions and control of correct PFM contractions, written information about PFMT and follow up by midwife</td>
<td>N=98</td>
<td>Primiparous women with SUI, 10-16 weeks after delivery Multi centre Sweden</td>
<td>Three visits with midwife during the intervention period. A 6 months home PFM program including three fast contractions, three times 8-12 slow velocity (6 seconds), close to maximum contractions</td>
<td>Significantly (p&lt;0.05) improved continence score (0-20) in both groups at 6 months postpartum. Difference between groups was not reported.</td>
<td>no</td>
<td>Loss to follow up: 16% CG: 7/49 IG: 9/49</td>
</tr>
<tr>
<td>Bo 2011 (2)</td>
<td>Control (n=53): standard care Intervention (n=52): 12-16 wk' aerobic fitness class including PFMT</td>
<td>N= 105</td>
<td>Nulliparous, sedentary women within the first 24 weeks of pregnancy With and without UI at inclusion. Single centre Norway</td>
<td>12 -16 weeks of aerobic exercise classes twice per week during pregnancy, including intensive PFMT (in a group) led by aerobic instructor. Additional home exercises 10 max contractions (each held for six seconds) and to the last 4 were 3-4 fast contractions added x 3, per day. Correct VPFMC was not checked at enrolment.</td>
<td>No significant difference between groups: Self reported UI at 36-38 weeks of pregnancy: Control: 7/53 Intervention: 9/52 Self reported UI at 3 months postpartum: Control: 6/53 Intervention: 5/52</td>
<td>no</td>
<td>Loss to follow up: 20% CG: 11/53 IG: 10/52</td>
</tr>
<tr>
<td>Barakat 2011 (3)</td>
<td>Control group (n=40): standard care Intervention group (n=40): Physical conditioning program 45 minutes 3 times per week from inclusion to week 38-39. PFMT included during the last trimester.</td>
<td>N= 80</td>
<td>Sedentary women within 6-9 weeks of pregnancy. Without UI at inclusion. Single centre Spain</td>
<td>Exercises to strengthen the PFM included in a general exercise program with 45 minutes sessions x 3 per week, during the last trimester. No further details about the PFMT program.</td>
<td>No significant difference in frequency of urine loss (CIQ-SF Incontinence classification) in late pregnancy. (Questionnaire answered after delivery).</td>
<td>no</td>
<td>Loss to follow up: 16% CG: 6/40 IG: 7/40</td>
</tr>
<tr>
<td>Author, year</td>
<td>Comparator</td>
<td>N</td>
<td>Study population</td>
<td>Modality details or parameters</td>
<td>Outcomes/results</td>
<td>Follow up</td>
<td>Notes (side effects, loss of follow up…)</td>
</tr>
<tr>
<td>-------------</td>
<td>------------</td>
<td>---</td>
<td>------------------</td>
<td>--------------------------------</td>
<td>-------------------</td>
<td>----------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td>Fritel 2015 (4)</td>
<td>Control group (n=142): standard care including written instructions about PFMT</td>
<td>N=282</td>
<td>Nulliparous women between 20-28 weeks of gestation. With and without UI at inclusion. Multicentre France</td>
<td>The PFMT group received eight individual training sessions supervised by a midwife or a physiotherapist, once per week between the sixth and eight month of pregnancy. Each session lasted 20-30 minutes and included evaluation of pelvic floor muscle contraction. Sessions consisted of standing contractions (5 minutes), lying contractions (10 minutes) and learning how to start a pelvic floor muscle contraction just before exerting intraabdominal pressure (the Knack). Women were encouraged to perform daily PFMT. No specific instructions on the number or intensity of the contractions were given.</td>
<td>No significant difference between groups in UI severity (ICIQ-UI SF score) and prevalence at 2 and 12 months postpartum: UI severity at 2 months postpartum (mean, SD): Control: 2.3 (±3.4) Intervention: 1.7 (±2.9) UI severity at 12 months postpartum: Control: 2.1 (±3.3) Intervention: 1.9 (±3.7)</td>
<td>Yes 12 months</td>
<td>Loss to follow up: 33% CG: 45/142 IG: 47/140</td>
</tr>
<tr>
<td>Hilde 2013 (5)</td>
<td>Control group (n=88): receiving instructions in correct PFM contractions and written information</td>
<td>N=175</td>
<td>Singleton primiparous women Who delivered vaginally after more than 32 weeks of gestation Single centre Norway</td>
<td>PFMT in groups supervised by physiotherapist once per week in 16 weeks (starting 6-8 weeks after delivery) and daily home training with three sets of 8 to 12 contractions close to maximum</td>
<td>No significant differences in the percentage of women with UI at six months postpartum between a supervised PFMT group and a control group receiving instructions in correct PFM contractions and written information. UI 6 months postpartum: Control: 39% Intervention: 35%</td>
<td>no</td>
<td>Loss to follow up: 9% CG: 3/88 IG: 12/87</td>
</tr>
<tr>
<td>Kim 2012 (6)</td>
<td>Control (n=10): unsupervised PRMT</td>
<td>N=18, Mix of primiparous and multiparous incontinent women less than six weeks after delivery. All with UI at inclusion. Single centre Korea</td>
<td>PFMT in various positions (20 repetitions with 10 second holding), abdominal strengthening exercises and trunk stabilisation using a therapeutic ball. Twenty three one-hour sessions of training with physiotherapist, three times per week in an 8 week period. Additional daily home training program</td>
<td>Significant difference (p=0.001) in change in values for UI symptoms ((BFLUTS) between groups, in favour of the IG (mean, SD): Control: -18 (± 5.5) Intervention: -27 (± 6.2)</td>
<td>no</td>
<td>Loss to follow up: 10% CG: 9/10 IG: 9/10</td>
<td></td>
</tr>
<tr>
<td>Author,year</td>
<td>Comparator</td>
<td>N</td>
<td>Study population</td>
<td>Modality details or parameters</td>
<td>Outcomes/results</td>
<td>Follow up</td>
<td>Notes (side effects, loss of follow up…)</td>
</tr>
<tr>
<td>------------</td>
<td>------------</td>
<td>---</td>
<td>------------------</td>
<td>--------------------------------</td>
<td>------------------</td>
<td>-----------</td>
<td>-----------------------------------------</td>
</tr>
<tr>
<td>Ko 2011 (7)</td>
<td>Control: Routine antenatal care. Intervention: Individual PFMT with physiotherapist once per week between 20-36 weeks pregnancy with additional home exercises 3 sets of 8 contractions (each held for 6 seconds) repeated twice daily. Instructed to contract the PFM when coughing or sneezing.</td>
<td>N=300</td>
<td>Nulliparous women recruited at 16-24 weeks of pregnancy. With and without UI at inclusion. Single centre, Taiwan</td>
<td>The PFMT group met individually with a physical therapist for instruction and assessment of correct contraction. The PFMT included three sets of eight contractions repeated twice daily. Additional group therapy occurred weekly in 45 minute sessions over a 12 week period.</td>
<td>Self reported UI at 36 wk' pregnancy p&lt;0.01: Control: 76/150 (51%) Intervention: 52/150 (34%) Self reported UI at 3days postpartum p=0.06: Control:62/150 (41%) Intervention:46/150 (30%) Self reported UI at 6 weeks postpartum p=0.06: Control: 53/150 (35%) Intervention: 38/150 (25%) Self reported UI at 6 months postpartum p=0.04: Control: 42/150 (27%) Intervention: 25/150 (16%)</td>
<td>Yes 6 months</td>
<td>Loss to follow up: 0%</td>
</tr>
<tr>
<td>Kocaoz 2013 (8)</td>
<td>Quasi randomized trial Control group (n=68): ? Intervention group (n=68): Instructions in PFMT and information.</td>
<td>N=136</td>
<td>Continent, pregnant women at week 14-20 of pregnancy. Without UI at inclusion. Single centre Turkey</td>
<td>Correct voluntary PFM contraction was checked prior to training Daily PFMT, three sets of 10 contractions. Maximal contraction of the PFM and hold for 10 seconds, and quick contractions</td>
<td>A statistically significant difference was found between control and intervention group in SUI development at 28th and 32nd weeks of gestation and the 12th week postpartum.</td>
<td>yes 12th week postpartum</td>
<td>Loss to follow up: 25% CG: 18/68 IG: 16/68</td>
</tr>
<tr>
<td>Author, year</td>
<td>Comparator</td>
<td>N</td>
<td>Study population</td>
<td>Modality details or parameters</td>
<td>Outcomes/results</td>
<td>Follow up</td>
<td>Notes (side effects, loss of follow up...)</td>
</tr>
<tr>
<td>--------------</td>
<td>------------</td>
<td>---</td>
<td>------------------</td>
<td>-----------------------------</td>
<td>----------------</td>
<td>----------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>Miquelutti 2013 (9)</td>
<td>Control group (n=100): standard care</td>
<td>N=205</td>
<td>Nulliparous low risk women at 18 weeks of gestation. With and without UI at inclusion. Multi centre Brazil</td>
<td>On the days of prenatal visits; consisted of physical exercises, educational activities and instructions on exercises to be performed at home. The PFMT should be performed daily at home and included rapid (30 times) and sustained maximal contractions (20 times holding for 10 seconds) in sitting and standing positions.</td>
<td>The risk of UI was significantly lower in the intervention group at 30 weeks of pregnancy: CG 62% IG 43% RR 0.69 (95% CI 0.51-0.93) and 36 weeks of pregnancy: CG 68% IG 41% RR 0.60 (95% CI 0.45-0.81)</td>
<td>no</td>
<td>Loss to follow up: 2% CG: 2/102 IG: 6/103</td>
</tr>
<tr>
<td>Pelaez 2014 (10)</td>
<td>Control group (n=96)</td>
<td>N=169</td>
<td>Healthy, primiparous pregnant women in gestational week 10-14. Without UI at inclusion. Single centre Spain</td>
<td>Correct voluntary PFM contraction was checked prior to training. The intervention consisted of 70-78 group sessions; 10 minutes of PFMT three times per week in 22 weeks</td>
<td>At 36 weeks of pregnancy there was statistically significant (p=0.001) difference in frequency of UI and in ICIQ-UI SF score in favour of the intervention group. CG 2.7 (SD4.1) IG 0.2 (SD 1.2)</td>
<td>no</td>
<td>Loss to follow up: 16% CG: 7/96 IG: 10/73</td>
</tr>
<tr>
<td>Stafne 2012 (11)</td>
<td>Control group (n=426): standard care</td>
<td>N=855</td>
<td>Multiparous women between 16-24 weeks gestation. With and without UI at inclusion. Multi centre Norway</td>
<td>The PFMT group met individually with a physical therapist for instruction and assessment of correct contraction, and PFMT protocol was similar to that described previously by Mørkved (1997, 2003), including three sets of eight contractions repeated twice daily. Additional group therapy occurred weekly in 45 minute sessions over a 12 week period.</td>
<td>Self-reported UI at 34-38 weeks of pregnancy: Any UI (p=004): CG 192/365 (53%) IG 166/397 (42%) UI once per week or more (p=0.004): CG 68/365 (19%) IG 44/397 (11%)</td>
<td>no</td>
<td>Loss to follow up: 11% CG: 61/426 IG: 32/429</td>
</tr>
</tbody>
</table>


Summary

The effect of antepartum PFMT or postpartum PFMT, in groups of women where some did and some did not have prior UI symptoms, varied by study with some showing a benefit on UI prevalence whereas others did not. The characteristics of the new trials, all methodologically robust, that demonstrated reduced UI prevalence in late pregnancy (35) (37) (39) and six months postpartum (35), were high adherence to a supervised PFMT strength training program and home exercises. (Level of Evidence: 2)

However, a similar training protocol in postpartum women by Hilde (2013) did not show any difference between groups. Even if the combined results from the published trials still are not conclusive, the benefit of PFMT in the majority of the studies and the lack of adverse effects of PFMT should be taken into account.

Recommendations

Health providers should carefully consider the cost/benefit of population-based approaches to health professional taught antepartum or postpartum PFMT, that is, health professional instruction to all pregnant or postpartum women regardless of their current or prior continence status

(Grade of Recommendation antepartum PFMT: A)
(Grade of Recommendation postpartum PFMT: B)

Where a population approach is used, the ‘best’ evidence to date suggests the following: (a) an intervention comprising of a daily home PFMT and weekly physiotherapist-led exercise classes for 12 weeks, starting at 16-24 weeks’ gestation for pregnant women, and (b) an individually taught strengthening PFMT programme that incorporates adherence strategies for postpartum women who have had a forceps delivery or a vaginal delivery of a large baby (4000g or more). (Grade of Recommendation: C)

2.2. Prevention (Other Women)

Although there are multiple trials of PFMT for prevention of UI in peri-partum women (see section II.2.1) and in men undergoing prostatectomy (see section IV.2), there is little research on prevention of UI in non-childbearing women. A single randomised trial (41) was found that investigated the preventive effects of a multi-component behavioural modification program, including PFMT, Bladder Training (BT), and other behavioural skills, compared to no intervention in 359 older women who were essentially continent (0-5 days of incontinent episodes in previous year). The intervention was a 2-hour class followed 2-4 weeks later with an individualized session to test PFMT technique and reinforce adherence. After 12 months, continence status was the same or better in 56% of the prevention group compared to 41% of the control (p=0.01).

In this trial, randomisation was conducted prior to eligibility assessment, leading to a relatively high rate of non-completion (97/238 in the treatment group and 65/242 in the control group; 162/480 overall). Analysis was not ITT. The method of randomisation was not described but the randomization block size was set at 16 to minimize the chance of prior recruiter knowledge of subject assignment. The assessors were not blinded.

Summary

There is preliminary evidence that PFMT may help prevent UI in older women. (Level of Evidence: 2)

However, more definitive trials are needed to clarify the effects of this multi-component program or other approaches to using PFMT as a prevention strategy in older women.

Recommendations

Without robust randomised controlled trials on the preventive effect of PFMT on UI the Grade of Recommendation is Grade C (New).

With limited new data on the effects of preventive PFMT on UI in older women, this association should be investigated further.

2.3. Treatment (Other Women)

2.3.1 Is PFMT Better than No Treatment, a Placebo, or a Control Group Treatment?

This updated literature review identified 19 new trials that compared PFMT to no treatment, sham treatment, or control treatment. Six trials were excluded from this summary because they selected women with “OAB,” “lower urinary tract symptoms,” or “pelvic floor dysfunction,” thereby including women without urinary incontinence (42-47). Some included continent women, while others did not provide sufficient information to determine the continence status of participants. One additional trial was excluded due to insufficient detail about the intervention needed to discern whether PFMT was part of the treatment (48), and one was not considered because the sample consisted of residents in long-term care facilities (49). The 11 additional trials included in the analysis were diverse and included studies from 10 countries (See Table 7). Samples included young, nulliparous volleyball athletes, older women, peri-and post-menopausal women, obese women, and gynaecological cancer survivors. Most samples were drawn from community-dwelling populations.

PFMT Details

Most trials involved 12 weeks (3 months) of intervention, but some were of 6 weeks (50) or 8 weeks duration (51). Most involved supervised PFMT accompanied by a regimen of home-based exercises by a physiotherapist or nurse. One study tested a new smart phone application (52) with no face-to-face
contact. In several trials, PFMT was delivered on an individual basis (50, 53-57), while others were conducted in a group class (51, 58). Some trials were restricted to PFMT with or without functional PFM contraction to prevent SUI episodes (stress strategies, the Knack) (50, 57), while in others, PFMT was embedded in a multi-component programme with other behavioural or exercise components (Table 7). One trial included PFMT in a broader programme of general physical exercise (58).

**Risk of Bias**

Some of these 11 trials may have been limited by small sample size. Only 3 included more than 100 women, 3 included 50-100 women, and 5 had fewer than 50 participants. Two trials reported intent-to-treat analysis (52, 55). Three reported the method of randomisation (54, 55, 58); five reported concealment (52, 55, 58-60); and two reported using blinded outcome assessors (55, 58). Two studies were reported as abstracts making it difficult to assess some aspects of the methods and data quality (52, 55).

**Results**

A variety of outcome measures were used, including bladder diaries, validated questionnaires, global patient ratings, and pad test. Most trials used multiple measurements to evaluate outcomes.

Bladder diaries were used in 7 studies to assess change in incontinent episode frequency (52, 54-59). In all studies, reductions in incontinence episode frequency were significantly greater in the treatment group.

The UDI or UDI-6 was used in 4 trials to report change in urinary symptoms (54, 55, 57, 60). Significant differences were found in the two larger trials (54, 55). The ICIQ-UI was used as an outcome measure in two trials (51, 52), both demonstrating greater benefit for PFMT compared to control.

In 4 trials, the ILQ-7 was used to assess change in impact of UI. Two found significant between group differences (54, 59); one found significant change in the treatment group, but not in the control group; and the third did not observe improvement on this condition-specific quality of life measure (60).

The PGI-I was the primary outcome in one study that found 80% of women in the treatment group and 40% in the control group were “much better” or “very much better” (60). Similarly, in another trial, 55.7% of women in the treatment group were “better” compared to 5% in the control group (52).

Urine loss, assessed by 1-hour pad test (with provocation), was the primary outcome for one trial (50). Reductions in urine loss were greater in both treatment groups (individualized PFMT and group administered PFMT) compared to the control group. In four other studies that used a pad test as a secondary outcome, significant reduction and group differences were reported in two (54, 56), no differences in a third (55), the within and between group differences did not reach statistical significance (57).

**Summary**

PFMT is effective as a stand-alone therapy, as part of multi-component therapies embedding PFMT with concomitant behavioural strategies, lifestyle changes, and as part of more general physical exercise programmes to improve physical function in older women.

Results expand the evidence base to include PFMT implemented by mobile technology, with a potentially broader reach, cost savings, and impact on rural health.

Benefits are shown across age cohorts and UI type, in various cultural contexts, using several different training regimens, and assessed by multiple outcome measures. (Level of Evidence: 1)

**Recommendations**

Supervised PFMT should be offered as a first-line conservative therapy for women of all ages with urinary incontinence (Grade of Recommendation: A).

2.3.2 Is One Type of PFMT Programme Better than Another?

A number of factors can influence the outcome of a PFMT programme such as the way it is taught and/or supervised, the parameters of the actual exercises, and adherence to the training regimen. What, therefore, is the most effective PFMT programme?

This updated search revealed 24 new potentially eligible RCTs to address this question. Of them, one was excluded due to insufficient information on the incontinence outcome and inter-group comparison (61) and three because they did not report any incontinence outcomes but focused on PFM outcomes (62-64). Table 8 shows the studies included in the previous edition as well as those identified in this update. Characteristics of each new RCT are presented in Table 9.
<table>
<thead>
<tr>
<th>Study</th>
<th>Comparator</th>
<th>N</th>
<th>Study Population</th>
<th>Intervention</th>
<th>Outcomes/Results</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdulaziz 2012 (1)</td>
<td>No therapy</td>
<td>N=56</td>
<td>Obese, older, perimenopausal Saudi women with SUI (40-50 years)</td>
<td>3 months of supervised PFMT taught at physio clinic; 10 repetitions of 8 maximal contractions each, progressed to 12; 36 sessions</td>
<td>Fewer UI episodes on self-report (not BD) and better score on VAS (but p&gt;0.05 for group diff) Tx group: significant change and 90% cured CG: no change and 19% cured</td>
<td>Small N may have affected results</td>
</tr>
<tr>
<td>Asklund 2015 Abstract (2)</td>
<td>Delayed treatment</td>
<td>N=123</td>
<td>Women with weekly SUI (&gt;18 years; mean 45 years)</td>
<td>3 months of Smart phone app; PFMT exercises at different levels (6 basic and 6 advanced); graphic support and functions for statistics and reminders. No face-to-face contact</td>
<td>Web-based questionnaires and 2-day leakage diary; ICIQ-UI-SF, PGII, IEF, ICIQ-LUTSqol, use of incontinence aids, patient satisfaction (Tx group only). Tx group showed greater improvements on all outcomes (p&lt;0.001).</td>
<td>ITT analysis Allocation concealment with sequentially numbered envelopes</td>
</tr>
<tr>
<td>Celiker 2015 (3)</td>
<td>Wait-list</td>
<td>N=130</td>
<td>Women with SUI/MUI Excluded weak muscles</td>
<td>12-weeks of PFMT, 30 min sessions, supervised by physiotherapist, X3 per week initially, taught by perineal palpation, individually prescribed, home-based exercise. Included advice on bladder hygiene</td>
<td>UDI-6, IIQ-7, 3-day bladder diary, stop test, pad test. Tx group showed significant improvement on all outcomes and greater improvements than CG (p&lt;0.0001).</td>
<td>Not ITT; randomization computer generated; allocation concealment Tx included behavioral/lifestyle advice.</td>
</tr>
<tr>
<td>Dumoulin 2011 (4) Abstract</td>
<td>Education program on osteoporosis (3 hours) and follow-up phone calls</td>
<td>N=48</td>
<td>Postmenopausal women with osteoporosis and SUI, UUI, or MUI (55+ years)</td>
<td>12 weeks of Individualized PFMT, weekly 30-min PT sessions; daily home exercise; BF, urge control, dietary advice and constipation advice</td>
<td>7-day BD, 24-hour pad test, UDI. Post-treatment, Tx group had greater improvements on IEF (p=0.04) and UDI (p=0.04), but not pad test. At 1-year follow up, there were significant differences on IEF (p=0.04), UDI (p=0.03) and pad test (p=0.01).</td>
<td>Randomization computer generated Allocation concealment ITT analysis Blinded assessors No adverse events Tx included behavioral/lifestyle advice.</td>
</tr>
<tr>
<td>Ferreira 2014 (5)</td>
<td>Summary of PFMR education program via pamphlet</td>
<td>N=32</td>
<td>Nulliparous, female volleyball athletes with SUI (13-30 years)</td>
<td>3 months of PFMR; “educational action,” awareness of PFM, and informational pamphlet; weekly visits; home exercise - 30 sustained contractions and 4 quick contractions daily; daily bladder diary for awareness</td>
<td>7-day BD and pad test (15 min during practice). Tx group showed greater reductions on IEF (p&lt;0.001) and pad test (P&lt;0.001).</td>
<td>Randomization by lottery (participant drawing paper from a box) Small N</td>
</tr>
<tr>
<td>Study</td>
<td>Comparator</td>
<td>N</td>
<td>Study Population</td>
<td>Intervention</td>
<td>Outcomes/Results</td>
<td>Notes</td>
</tr>
<tr>
<td>-------</td>
<td>------------</td>
<td>----</td>
<td>------------------</td>
<td>--------------</td>
<td>------------------</td>
<td>-------</td>
</tr>
<tr>
<td>Karger 2015 (6)</td>
<td>No Tx</td>
<td>N=50</td>
<td>Elderly women with SUI (60-74 years)</td>
<td>Two months; eight 45-min group training classes taught by a nurse; 8-12 contractions in each of 3 positions, 6-8 second contractions with 3-4 fast contractions added; home exercise: 8-12 high intensity contractions, X3 daily. Strength, awareness, and relaxation training for other muscle groups.</td>
<td>ICIQ-UI and self-esteem. Group differences observed on ICIQ-UI (p=0.001), and on individual items of frequency, amount of leakage, and QoL.</td>
<td>Tx included other types of exercise.</td>
</tr>
<tr>
<td>Kim 2011 (7)</td>
<td>General health class monthly for 3 months</td>
<td>N=127</td>
<td>Elderly Japanese women with SUI, UUI, or MUI (70+ years)</td>
<td>3 months, multi-dimensional exercise Tx; twice weekly group classes, PFM and general strength exercise. PFMT: 10 fast contractions (3 sec), 10 sustained contractions (8-10 sec); lying, sitting, and standing positions. One-hour class X1/month during 7-month follow-up. Home exercise: 2-3 sets as learned in class, at least X3/week for 30 min/day</td>
<td>Primary outcome was cure based on 7-day BD and ratings on 5-point scale (in BD); ICIQ Tx group showed greater change in urine leak score (p=0.007) and cure. Tx group 44.1% cure rate post-Tx and 39.3% at 7-month follow up vs 1.6% and 1.6% in CG (p&lt;0.001).</td>
<td>Not ITT Computer generated randomization Randomization procedure blinded Blinded assessors</td>
</tr>
<tr>
<td>Leong 2015 (8)</td>
<td>Advice and pamphlet on management of UI</td>
<td>N=56</td>
<td>Older Chinese women with SUI, UUI, or MUI (55+ years)</td>
<td>12-week PT program, 30-min individual training sessions, 8 sessions taught with manual palpation and verbal feedback; progressive exercise program starting with 10 slow submaximal contractions (5 sec) increasing to 25 per session; urge suppression + bladder training (BT).</td>
<td>7-day BD, IIQ-SF-7, 11-point VAS for perception of improvement and satisfaction. Tx group showed greater improvement in IEF (p&lt;0.001) and IIQ-7 (p=0.001) and greater perception of improvement (p=0.004) and satisfaction (p=0.001). Reductions significant in Tx group only.</td>
<td>Computer generated randomization and allocation concealment Tx accompanied by urge suppression and bladder training</td>
</tr>
<tr>
<td>McLean 2013 (9)</td>
<td>No treatment</td>
<td>N=40</td>
<td>Women with predominant SUI (18+ years)</td>
<td>12-week individualized PFMT program with weekly 30-min sessions; PFMT taught by manual palpation; home exercise: 3 sets of 12 PFM contractions daily</td>
<td>3-day BD, pad test, IIQ-7, UDI-6. Tx group showed greater changes on IEF (intragroup p=0.007) and IIQ-7 (intragroup p=0.0003); Neither group had significant change on pad test or UDI-6</td>
<td>Randomization by automated computer algorithm. Primary purpose of the study was to examine urethral morphology and mobility. Measures of UI were secondary outcomes.</td>
</tr>
<tr>
<td>Study</td>
<td>Comparator</td>
<td>N</td>
<td>Study Population</td>
<td>Intervention</td>
<td>Outcomes/Results</td>
<td>Notes</td>
</tr>
<tr>
<td>-------</td>
<td>------------</td>
<td>-----</td>
<td>------------------</td>
<td>--------------</td>
<td>------------------</td>
<td>-------</td>
</tr>
<tr>
<td>Pereira 2011 (10)</td>
<td>No treatment</td>
<td>N=49</td>
<td>Women with SUI only (18+ years)</td>
<td>6 weeks PFMT in group or individual sessions; two 1-hour sessions weekly (12 sessions); taught by vaginal palpation in both Tx groups; 3 s and 5-10 s contractions; repetitions and duration progressed; average of 100 contractions per session.</td>
<td>Primary outcome: pad test; secondary King’s questionnaire and satisfaction. Both Tx groups showed greater improvement on pad test than CG (p&lt;0.0001). Improvements shown in both Tx groups but not CG.</td>
<td>Randomization was by participants drawing envelope from a box; assessments not blinded; not ITT. Purpose of the study was to examine group vs individual. No adverse events. Small N.</td>
</tr>
<tr>
<td>Rutledge 2014 (11)</td>
<td>Usual care (no handout)</td>
<td>N=40</td>
<td>Gyn cancer survivors with UI (37-79 years)</td>
<td>12 weeks; single 15-min training session; taught using levator ani palpation; 10 contractions 5 s duration; handout on behavioral management tips: fluid intake, reduction of caffeine and bladder irritants; constipation management; Home exercise: 3 sets of exercises daily for 12 weeks.</td>
<td>PGI-I and UDI-6 PGII: 80% in Tx group vs 40% in CG were “much better” or “very much better” (p=0.02). UDI-6: Groups not significantly different: Tx 70% vs CG 50% reported lack of bother (p=0.62).</td>
<td>Randomization generated by random number table. Allocation concealment Not ITT analysis. Treatment included behavioral/lifestyle advice.</td>
</tr>
</tbody>
</table>


Table 8 Studies comparing different PFMT programs included in the previous review (5th ICI) and current update (6th ICI)

<table>
<thead>
<tr>
<th>Studies included in the previous review (5th ICI)</th>
<th>New studies identified in this update (6th ICI)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Supervision of training: amount of contact with health professionals</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>2. Supervision of training: individual versus group supervision</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>3. Exercise program: direct versus indirect exercises</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>4. Exercise program: generic versus individualized exercises</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>5. Exercise program: submaximal versus near maximal contractions</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>6. Exercise program: daily versus three times per week</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>7. Exercise program: addition of upright exercise position</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>8. Exercise program: addition of strength training to motor learning</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>9. Exercise program: addition of abdominal or hip muscle exercises</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>10. Exercise program: addition of intravaginal resistance device</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>11. Exercise program: addition of adherence strategy</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>12. Exercise program: addition of biofeedback</td>
<td>9</td>
<td>6</td>
</tr>
<tr>
<td>Author, year</td>
<td>Comparator</td>
<td>N</td>
</tr>
<tr>
<td>-------------</td>
<td>------------</td>
<td>---</td>
</tr>
<tr>
<td>Cruz et al. 2014 (1) - Abstract</td>
<td>Supervised PFMT (43) vs Unsupervised (36)</td>
<td>79</td>
</tr>
<tr>
<td>Delgado et al. 2013 (2) Abstract was included in the ICI 5th edition</td>
<td>PFMT (24) vs PFMT + resistance device (28)</td>
<td>52</td>
</tr>
<tr>
<td>Author, year</td>
<td>Comparator</td>
<td>N</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>------------</td>
<td>----</td>
</tr>
<tr>
<td>Donahoe-Filmore et al. 2011 (3)</td>
<td>PFMT (5) vs PFMT + hip muscle training (6)</td>
<td>11</td>
</tr>
<tr>
<td>Ferreira et al. 2012(4) (pilot RCT)</td>
<td>Supervised PFMT (20) vs Unsupervised (home) PFMT (18)</td>
<td>38</td>
</tr>
<tr>
<td>Author, year</td>
<td>Comparator</td>
<td>N</td>
</tr>
<tr>
<td>----------------------</td>
<td>--------------------------------------</td>
<td>-----</td>
</tr>
<tr>
<td>Fitz et al. 2015</td>
<td>Supervised (25) vs Unsupervised (25)</td>
<td>63</td>
</tr>
<tr>
<td>Galea et al. 2013</td>
<td>PFMT (11) vs PFMT+BF (clinic) (12)</td>
<td>23</td>
</tr>
<tr>
<td>Author, year</td>
<td>Comparator</td>
<td>N</td>
</tr>
<tr>
<td>-------------</td>
<td>------------</td>
<td>----</td>
</tr>
<tr>
<td>Hirakawa et al. 2013 (7)</td>
<td>PFMT (23) vs PFMT +BF (home and clinic) (23)</td>
<td>46</td>
</tr>
<tr>
<td>Author, year</td>
<td>Comparator</td>
<td>N</td>
</tr>
<tr>
<td>-------------</td>
<td>------------</td>
<td>----</td>
</tr>
<tr>
<td>Jordre et al. 2014 (8)</td>
<td>Resisted hip rotation training (14) vs PFMT (16)</td>
<td>30</td>
</tr>
<tr>
<td>Jungin et al. 2014 (9)</td>
<td>PFMT with bladder neck effective relearning (42) vs PFMT (38)</td>
<td>80</td>
</tr>
<tr>
<td>Author, year</td>
<td>Comparator</td>
<td>N</td>
</tr>
<tr>
<td>-------------------------</td>
<td>----------------------------------------------------------------------------</td>
<td>-----</td>
</tr>
</tbody>
</table>
| Kashanian et al. 2011 (10) | PFMT (50) vs PFMT + resistance device (41)                                     | 91  | Women with SUI or MUI                 | PFMT: 6-8s contraction/6s rest Twice daily for 15 min  
PFMT + resistance device: twice daily for 15 min | Number of UI (self-reported)  
The data were categorized in ranges of different frequencies.  
Sign. changes in both groups (p<0.0001)  
Non-sign. difference btw groups  
UDI:  
PFMT pre-Tx 45.1±15.5 to post-Tx 71.8±11.2 (p<0.0001)  
PFMT + resistance pre-Tx 39.9±13.5 to post-Tx 69.9±10.1 (p<0.0001)  
Non-sign. difference btw groups (p=0.418)  
IIQ:  
PFMT pre-Tx 44.7±23.0 to post-Tx 67.7±20.20 (p<0.0001)  
PFMT + resistance pre-Tx 37.2±12.10 to post-Tx 62.52±12.13 (p<0.0001)  
Non-sign. difference btw groups (p=0.162) | 12 weeks of treatment, outcomes assessed 3 month post-Tx                       | Dropouts: PFMT 4/50  
PFMT + resistance device 2/41                                                                 |
| Kim et al. 2012 (11)    | Supervised PFMT + trunk stabilization (10) vs Unsupervised PFMT + trunk stabilization (10) | 20  | Women with postpartum UI              | Supervised PFMT and trunk stabilization: 23 1-h sessions, 3x/ week, for eight weeks; PFM contractions in different positions  
Unsupervised: same protocol but only one demonstration session | Bristol Female Lower Urinary Tract Symptom questionnaire –  
Urinary symptoms (changes)  
Supervised –27.22±6.20  
Unsupervised –18.22±5.49  
Quality of life  
Supervised –5.33±2.96  
Unsupervised –1.78±3.93)  
Total score  
Supervised –32.56±8.17  
Unsupervised –20.00±6.67  
All outcomes favored the supervised group (P<0.05) | 8 weeks of treatment, outcomes assessed post-Tx                               | Dropout: Supervised 1/10  
Unsupervised 1/10                                                                 |
<table>
<thead>
<tr>
<th>Author, year</th>
<th>Comparator</th>
<th>N</th>
<th>Study population</th>
<th>Modality details or parameters</th>
<th>Outcomes/Results</th>
<th>Follow-up</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Konstantinidou et al. 2013 (12)- abstract</td>
<td>PFMT (25) vs PFMT + transverse abdominis exercises (21)</td>
<td>46</td>
<td>Women with SUI or MUI (stress predominant) (minimum of 7 episodes per week and a 3-4 score at the Oxford scale)</td>
<td>PFMT monotherapy Transverse abdominis exercises combined with PFMT Limited information was provided about the training protocol</td>
<td>KHQ PFMT: pre-Tx 342.9±28.2 to post-Tx 198.3±18.4 (p&lt;0.0001) PFMT+TrA : pre-Tx 327.1±38.4 to post-Tx 193.1±24.7 (p=0.0003) Non-sign. difference btw the two groups (p=0.76) Bladder diary PFMT: pre-Tx 4.36±0.6 to post-Tx 1.8±0.3. (p&lt;0.0001) PFMT+TrA : pre-Tx 3.4±0.4 to post-Tx 1.2±0.2 (p&lt;0.0001) Non-sign. difference btw groups</td>
<td>3 months of treatment, outcomes assessed post-Tx</td>
<td>Dropouts are not reported</td>
</tr>
<tr>
<td>Lamb et al. 2009 (15)</td>
<td>Group PFMT (111) vs Individual PFMT (63)</td>
<td>174</td>
<td>Women with SUI and/or UUI</td>
<td>Group PFMT: Three 1h session for 3 weeks, average of 10 women per class, individual assessment with PFM examination if required Individual PFMT: Same as group intervention but individually supervised</td>
<td>Symptoms severity index Group changes from baseline 2.34±0.44 Individual changes from baseline 1.71±0.57 Non-sign. difference btw groups (p=0.38) Self-rated assessment of treatment benefit Group changes from baseline 5.37±0.29 Individual changes from baseline - 6.34±0.38 Higher perceived benefit for individual treatment (p=.0462) Incontinence related QoL Group changes from baseline - 14.40±1.75 Individual changes from baseline - 14.81±2.50 Non-sign. difference btw groups (p=.89)</td>
<td>3 weeks of treatment, outcomes assessed 6 months after randomisation</td>
<td>Dropout: Group PFMT 13/111 Individual PFMT 3/63</td>
</tr>
<tr>
<td>Author, year</td>
<td>Comparator</td>
<td>N</td>
<td>Study population</td>
<td>Modality details or parameters</td>
<td>Outcomes/Results</td>
<td>Follow-up</td>
<td>Notes</td>
</tr>
<tr>
<td>------------------------------</td>
<td>-----------------------------------</td>
<td>-----</td>
<td>------------------------------</td>
<td>-----------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Liebergall-Wischnitzer et al. 2013 (16) (This is a follow-up of the 2009 study)</td>
<td>Paula method (119) vs PFMT (126)</td>
<td>245</td>
<td>Women with SUI</td>
<td>Paula: 12 individual 45-min session</td>
<td>Frequency of UI (low or high) No sign. deterioration of UI in 6 months in both groups Paula method: 25 (39.7%) reported a low frequency rate of UI episodes PFMT: 18 (22.8%) in the PFMT group reported a low frequency Sign. difference btw groups (p=0.03)</td>
<td>12 weeks of treatment, follow-up at 6-month post-Tx</td>
<td>Dropout Paula 55/119 PFMT 47/126 The two groups differed according to the amount of supervision received (PFMT had group supervision and less sessions).</td>
</tr>
<tr>
<td>Manonai 2013 (17) - abstract</td>
<td>PFMT vs PFMT +BF (home)</td>
<td>61</td>
<td>Women with SUI</td>
<td>PFMT: verbal instruction about PFM contraction, 15 min of PFM exercises, three times a day for 16 weeks PFMT+BF: same as above but with pressure BF</td>
<td>Incontinence related QoL PFMT pre-Tx 51.1±15.9 to post-Tx 70.6±15.5 (sign.) PFMT+BF: pre-Tx 53.9±18.3 to post-Tx 72.6±10.81 (sign.) Non-sign. difference btw groups</td>
<td>16 weeks of treatment, outcomes assessed post-Tx</td>
<td>Dropouts: one in each groups</td>
</tr>
<tr>
<td>Marques et al. 2014 (18) - abstract (19) protocol</td>
<td>PFMT (15) vs PFMT + hip muscle training (20)</td>
<td>35</td>
<td>Women with SUI (urodynamic diagnosis)</td>
<td>Both groups received 20 individually supervised sessions, twice a week PFMT: PFM contraction verified by vaginal palpation in the first 8 sessions PFMT: same PFMT program with the addition of hip muscle strengthening (with progressive increases in loads)</td>
<td>Bladder diary (5 days) Non-sign difference btw the two groups (p=0.172)</td>
<td>10 weeks of treatment, outcomes assessed post-Tx</td>
<td>Dropout not reported</td>
</tr>
<tr>
<td>Author, year</td>
<td>Comparator</td>
<td>N</td>
<td>Study population</td>
<td>Modality details or parameters</td>
<td>Outcomes/Results</td>
<td>Follow-up</td>
<td>Notes</td>
</tr>
<tr>
<td>-------------</td>
<td>------------</td>
<td>----</td>
<td>------------------</td>
<td>-------------------------------</td>
<td>------------------</td>
<td>-----------</td>
<td>-------</td>
</tr>
<tr>
<td>Pereira et al. 2011 (20)</td>
<td>Group PFMT (17) vs Individual PFMT (17) vs Control (15)</td>
<td>49</td>
<td>Women with SUI</td>
<td>Group PFMT: Two 1h weekly sessions for 6 weeks. Approximately 100 contractions (3s contraction/6s rest and 5-10 s contraction/10-20 rest). Contraction taught individually at baseline Individual PFMT Same as above but individually supervised Control (15) No treatment</td>
<td>1-h pad test: Group: pre-Tx 1.88±2.85 to post-Tx 0.46±0.45 (p=0.05) Individual: pre-Tx 4.22±5.21 to post-Tx 0.45±0.90 (p=.0006) Non-sign. difference btw groups King health questionnaire Only the personal relationships and emotion differed btw the two groups and favored individual PFMT (p.043)</td>
<td>6 weeks of treatment, outcomes assessed post-Tx</td>
<td>Dropout: Group PFMT 2/17 Individual PFMT 2/17 Control 0/15 No adverse effects reported</td>
</tr>
<tr>
<td>Ong et al. 2015 (21)</td>
<td>PFMT (19) vs PFMT+ BF (home and clinic) (21)</td>
<td>40</td>
<td>Women with SUI</td>
<td>PFMT: 4 sessions individually supervised (20-min), 3-5 sets of 10 repetitions (3-10s contraction/3-10s rest). 3-5 sets of 10 repetitions (2s contraction/2s rest) PFMT + biofeedback: Same as above but with use of the Vibrance device at home and in the clinic</td>
<td>Subjective cure (based on the Q6 of the Australian pelvic floor questionnaire) PFMT 10/16 PFMT+BF 12/21 Non-sign. difference btw groups (p=.742) Australian pelvic floor questionnaire (total score) PFMT post-Tx 7.8±5.1 PFMT+BF post-Tx 11.3±8.3 Non-sign. difference btw groups (p=0.157)</td>
<td>16 weeks of treatment, outcomes assessed at 4 weeks of treatment and post-Tx</td>
<td>Dropouts: PFMT 3/19 PFMT+ biofeedback 0/21</td>
</tr>
<tr>
<td>Author, year</td>
<td>Comparator</td>
<td>N</td>
<td>Study population</td>
<td>Modality details or parameters</td>
<td>Outcomes/Results</td>
<td>Follow-up</td>
<td>Notes</td>
</tr>
<tr>
<td>-------------</td>
<td>------------</td>
<td>----</td>
<td>-----------------------------</td>
<td>------------------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>-----------</td>
<td>---------------------</td>
</tr>
<tr>
<td>Prudencio 2014 (24) abstract</td>
<td>PFMT (51) Vs PFMT+VC (55) Vs PFMT+BF (clinic) (50)</td>
<td>156</td>
<td>SUI women</td>
<td>The 3 groups received 20 sessions of 45 min (twice a week for 3 months). PFMT included isolated rapid and sustained contractions of the PFM and at the end functional exercises with contraction of the same muscle group by differentiating just the use or not of associated instruments. (No further information was provided on treatment in the abstract)</td>
<td>Cure of SUI Non-sign. difference btw groups (p=0.267) PFMT 39.2% (20/51continent) PFMT+BF 44% (22/50continent) KHQ: The 3 groups significantly improved from baseline (p&lt;0.001) PFMT preTx74±18 to postTx43±17 (p&lt;0.001) PFMT+BF preTx70±21 to postTx50±15 Sign. Difference btw groups (p&lt;0.001). It is not specified which groups differ</td>
<td>3 months</td>
<td>Dropout not specified</td>
</tr>
<tr>
<td>Shin et al. 2012 (25)</td>
<td>PFMT (30) vs PFMT+BF (home) (30)</td>
<td>60</td>
<td>Women with UI (type not specified)</td>
<td>PFMT: 20 min, twice a day, 5x/week for 6 months PFMT +BF: same as above but with the pressure device</td>
<td>ICIQ-SF: PFMT pre-Tx 8.8±4.7 to post-Tx 8.2±5.1 (non-sign.) PFMT+BF: pre-Tx 9.0±3.9 to post-Tx 7.0±2.7 (p&lt;0.05) KHQ PFMT pre-Tx 6.84±15.9 to post-Tx 59.2±19.2 (non-sign.) PFMT+BF: pre-Tx 69.5±14.2 to post-Tx 48.7±12.3 (p&lt;0.001) Bladder diary PFMT pre-Tx 9.7±3.3 to post-Tx 8.0±3.2 (non-sign.) PFMT+BF: pre-Tx 8.6±4.0 to post-Tx 5.1±4.6 (p&lt;0.001) Comparison btw groups not reported. Sign. reduction of leakage frequency, KHQ and ICIQ occurred in BF group but not in PFMT group</td>
<td>6 months of treatment, outcomes assessed at 6 weeks and 6 months</td>
<td>Dropouts: PFMT 6/30 vs PFMT+BF (home) 0/30</td>
</tr>
</tbody>
</table>


Quality of data

Of the 20 RCTs, 12 provided sufficient detail supporting adequate randomisation and allocation concealment methods (34, 50, 65-74). Of these, seven RCTs stated that the outcome assessors were blinded (34, 65-70). Pereira et al. (50) reported adequate randomisation and concealment but the evaluators were not blinded. Of the remaining eight RCTs, seven did not report sufficient information on allocation concealment methods and had unblinded assessors (75-81).

None of the included trials was large and half (10/20) included only 20 to 51 participants per group (65, 68, 69, 72, 74, 75, 77, 79-81). Eight had fewer than 20 participants per comparison group (34, 50, 70, 71, 73, 76, 78, 82). Six of the eight were reported as a pilot study (70-73, 76, 78). Only two RCTs had a larger sample size involving a total of 174 (66) and 245 women (67).

In four RCTs, a dropout rate of more than 46% in one study arm was reported. For instance, Dohanhoe et al. (78) reported 60% dropout in the PFMT combined with hip training and 20% in the PFMT group. Delgado et al. (72) had 37% and 57% in the PFMT group and PFMT combined with resistance, respectively. Liebergall-Wischnitzer et al. (67) reported a 46% and 37% dropout rate in the Paula and PFMT group, respectively while Cruz et al. (65) had 42-53% dropout in the supervised and unsupervised PFMT group. The results of these RCTs should therefore be interpreted with extreme caution (65, 67, 72, 78).

Ongoing RCTs

Based on a research on protocol registry database, there is currently one ongoing large non-inferiority RCT comparing group versus individual supervised PFMT (83) (comparison 2). Involving 364 elderly women with SUI or MUI, this study is expected to be completed by March 2017. Moreover, the study of Buen et al. (84) is also ongoing and will compare the efficacy of PFMT and Pilates in preventing and treating UI (N=80) (comparison 3). The study of Navarro et al. (85) will evaluate the efficacy of hypopressive exercises in 78 women with various pelvic floor disorders including UI (comparison 3). Expected in July 2017, the study of Radlinger et al. (51) will assess the benefit of adding motor learning to PFMT in 96 women suffering from SUI or MUI (Comparison 8). Rao et al. (86) undertook a study comparing the addition of abdominal muscle training to PFMT in 300 women (Comparison 9). Three upcoming RCTs will assess the benefit of adding clinic-based BF to PFMT (87-89).

Results

- Comparison 1. Supervision of training: amount of contact with health professionals?

Subgroup 1.1: additional group supervision

No further studies investigated the effect of adding an additional supervised group exercise session.

Subgroup 1.2: additional phone calls

No new studies investigated the effect of adding supervisory phone calls to PFMT programmes.

Subgroup 1.3: individual supervision versus no supervision

Four new RCTs were included in this comparison (34, 65, 71, 75). The PFMT programmes evaluated differed with regard to the amount of health-professional contact but were similar in type and quantity of PFM exercises.

Self-reported cure: Women in the supervised group were more likely to report cure in comparison with women following unsupervised PFMT (71). Although non-statistically significant, Cruz et al. (65) also reported a higher cure rate in the supervised group.

Improvement: Two RCTs reported improvement in UI symptoms as assessed with validated questionnaires (34, 65). Both showed that women receiving supervised treatment reduced their UI symptoms significantly more than women in the unsupervised arm (34, 65).

Leakage episodes: There was no statistically significant difference in the number of leakage episodes when comparing supervised and unsupervised PFMT in women (71, 75).

Pad tests: Two of the four RCTs measured UI severity with pad testing (71, 75). Fitz et al. (13) showed that supervised treatment resulted in a more significant reduction of leakage than unsupervised PFMT while Ferreira et al. (71) reported a non-significant difference.

- Comparison 2. Supervision of training: individual versus group

Two new RCTs were included in this comparison; both studies used the same PFMT program and differed only according to the type of supervision (group vs individual). It should also be underlined that Pereira et al. (50) conducted an individual assessment of the PFMT to teach active PFM contraction to all women prior to class training while Lamb al. (66) included this assessment only when required.

Self-reported cure: No data were reported.

Improvement: Non-significant differences in the symptom severity index were found between group and individual PFMT in the study of Lamb et al. (66) However, both Lamb et al. (66) and Pereira et al. (50) favoured individual treatment with regard to self-rated treatment benefits and the impact of UI (personal relationships and emotion domains), respectively. The study of Pereira et al. (50) involving 17 women per group, may be insufficiently powered to detect significant difference between groups. In the study of Lamb et al. (66), a large sample was included (n=174). However, the information was limited in regard to...
whether this sample was sufficient to conclude treatment equivalence (as per sample size calculation in non-inferiority design).

Leakage episodes: No data were reported.

Pad test: Only the study of Pereira et al. (50) used the pad test and reported a non-significant difference between the two groups.

- Comparison 3. Exercise programme: direct versus indirect exercises

This comparison encompassed six subgroups evaluating direct versus indirect training. In "direct" PFMT, women specifically performed voluntary contractions of the pelvic floor muscles while in the "indirect" PFMT, women focused on other muscle groups in order to facilitate or stimulate pelvic floor muscle contractions.

Subgroup 3.1: PFMT versus sham/imitation

No new studies were found comparing PFMT to sham or imitation PFMT treatments (e.g. crossing the ankles and pulling the legs apart).

Subgroup 3.2: PFMT versus the 'Paula method'

The previous ICI chapter on conservative management included the study of Liebergall-Wischnitzer et al. (90) comparing PFMT to the Paula method. The 6-month follow-up of this study was included in the current review (67). It should be emphasized that the two groups did not receive the same amount of supervision by a health professional because the Paula group was individually supervised and the PFMT group had group teaching.

Subgroup 3.3: PFMT versus the 'Sapsford' approach

Our search revealed no new RCTs evaluating incontinence outcomes for this subgroup.

Subgroup 3.4: PFMT versus Pilates

No new RCT were found evaluating Pilates treatment in comparison to PFMT.

Subgroup 3.5: PFMT versus hip rotator training

One RCT was included in this subgroup evaluating the effectiveness of hip external and internal rotator training compared to PFMT (76).

Subgroup 3.6: PFMT versus hypopressive training

Our search revealed no RCT including hypopressive training conducted in women with UI.

Self-reported cure: No data were reported in the different sub-groups.

Improvement: Liebergall-Wischnitzer et al. (67) in subgroup 3.2 showed that UI results were maintained at the 6-month follow-up in both the Paula method and the PFMT groups. Women who received the Paula method intervention were more likely to report a lower rate of UI than women after PFMT. In subgroup 3.5, non-significant differences were found between hip rotator training and PFMT with regard to subjective UI improvement and UI symptoms and related impact (76).

Leakage episodes: Jordre et al. (76), subgroup 3.5, reported that women who received hip training had significantly fewer UI episodes than women in the PFMT group.

Pad test: Neither of the two new RCTs used pad-testing measurements.

- Comparison 4. Exercise programme: generic versus individualized exercises

No further evidence was available.

- Comparison 5. Exercise programme: submaximal versus near maximal contractions

No further evidence was available.

- Comparison 6. Exercise programme: daily versus three times per week

No further evidence was available.

- Comparison 7. Exercise programme: addition of upright exercise position

No further evidence was available.

- Comparison 8. Exercise programme: addition of strength training to motor learning

Junginger et al. (68) evaluated PFMT and motor re-learning taught with ultrasound imaging in comparison to regular PFMT using EMG biofeedback in women with SUI or MUI. Both groups had the same amount of contact with health professionals.

Self-reported cure: No data were reported.

Improvement: There was no difference between the two groups in the number who reported 'some' or 'great' improvement. However, women in the PFMT group were more likely to switch to the motor relearning group at RCT completion.

Leakage episodes: No data reported.

Pad tests: The pad-testing measure was not included (68).

- Comparison 9. Exercise programme: addition of abdominal or hip muscle exercises

This comparison encompassed two subgroups evaluating the addition of either abdominal muscle (subgroup 9.1) or hip muscle (subgroup 9.2) training to PFMT.

Subgroup 9.1: PFMT vs PFMT+ abdominal muscle exercises

One new RCT evaluates the effectiveness of adding transverse abdominis exercises to PFMT (77). Limited information was available about the training protocol in this abstract report.
Subgroup 9.2: PFMT vs PFMT + hip muscle exercises

Two RCTs investigated the addition of hip muscle exercises to PFMT in women with SUI (78, 82). The same amount of health-professional supervision was given to each group (78, 82).

Self-reported cure: No trial reported this outcome.

Improvement: There was no significant benefit of adding abdominal muscle exercises to PFMT in the study of Konstantinidou et al. (77) (subgroup 9.1). Likewise, Donahoe-Fillmore et al. (78) showed a non-significant difference between adding hip muscle exercises to PFMT training as assessed with the King’s health question and the Incontinence Severity Index (sub-group 9.2). Results from the UDI-6 questionnaire, favoured the combined treatment (78). These findings should be interpreted with caution given the small sample size of Donahoe-Fillmore et al.’s study (78) (n=11).

Leakage episodes: Non-significant differences in leakage episodes were found when adding abdominal muscle (77) or hip muscle exercises (82).

Pad and paper towel tests: No data were reported.

- Comparison 10. Exercise programme: Addition of intravaginal resistance device

The study of Delgado et al. (2009) (91), presented as an abstract, was included in the previous ICI edition. The complete published manuscript has now been included in the current review (72) along with a new study evaluating the addition of an intravaginal resistance device to PFMT in women with SUI or MUI (69). Both RCTs were the same in all aspects except that one group used an intravaginal device designed to increase resistance to the PFM contraction. In both RCTs, the resistance device was composed of a spring-loaded device with two limbs (69, 72).

Self-reported cure: There was no statistically significant difference between the groups in terms of the number of women who indicated they were ‘cured’ (72).

Improvement: There was no statistically significant difference between the groups in terms of self-reported improvement and reduction of symptoms as assessed with standardised questionnaires (69, 72).

Leakage episodes: No data were reported for this outcome.

Pad and paper towel tests: No data reported.

- Comparison 11. Exercise programme: Addition of adherence strategy

No new RCTs investigated the efficacy of adding adherence strategies to PFMT.

- Comparison 12 Teaching programme: Addition of biofeedback (BF)

Six new RCTs compared PFMT alone to PFMT assisted with BF (70, 73, 74, 79-81). In these RCTs, the comparison groups were similar according to the amount of supervision and the intensity of training; they differed only with regard to the addition of biofeedback.

Two RCTs investigated clinic-based BF using pressure perineometry (79) and ultrasound imaging (70). Prudencio et al. (79) included women with SUI while Galea et al. (70) also evaluated women with UUI. Duration of treatment varied from 10 weeks (70) to 3 months (79).

Four RCTs evaluated home-based biofeedback using a Vibrance device (73), EMG BF (74) and pressure BF (80, 81). Of these, three were conducted in women with SUI (73, 74, 81) and one did not specify the type of UI of women included (80). In all RCTs, the same PFMT program was used in the comparison groups and differed only with regards to the addition of BF. Treatment duration varied from 12 weeks (74), 16 weeks (73, 81) and 6 months (80).

Self-reported cure: There was no statistically significant difference in terms of the number of women who indicated they were ‘cured’ between PFMT alone or combined with home-based (73) or clinic-based BF (79).

Improvement: Galea et al. (70) reported a non-significant benefit of adding clinic-based BF as assessed with the King’s health questionnaire. Using the same questionnaire, Prudencio et al. (79) conversely reported a significant difference between groups but did not reveal which of the three treatment arms differed. With regard to home-based BF, three of the four RCTs reported a non-significant difference between PFMT combined or not with BF. Shin et al. (44) did not conduct any inter-group comparisons but reported a significant reduction of incontinence only in the group which received BF.

Leakage episodes: Galea et al. (70) found a non-significant difference in leakage episodes in women receiving or not clinic-based BF. Likewise, non-significant benefits were found when adding home-based BF to PFMT (74).

Pad and paper towel tests: Galea et al. (70) reported a non-significant benefit of adding clinic-based BF to PFMT as assessed with pad-testing measurements. Also, Hirakawa et al. (74) found a non-significant difference between women receiving or not home-based BF.
Summary

Based on current evidence, PFMT with regular (e.g. weekly) supervision is better than PFMT with little or no supervision (Level of Evidence: 1). However, data were unclear as to whether supervision was more effective in individual or group settings. Sufficiently powered studies using appropriate design should be undertaken to investigate this comparison.

Based on limited evidence (6 previous RCTs and 2 new RCTs), ‘indirect’ methods of PFMT (e.g. the ‘Paula method’ or ‘Sapsford’ approach) are not better than direct PFMT. However, some data were confounded by differences in the amount of contact time with health professionals or the small sample size, which made it difficult to detect clinically significant differences (Level of Evidence 2: unchanged).

No robust recommendation can be made with regard to the type or specification of training (i.e. generic versus individualized exercises, submaximal versus near maximal contractions, daily versus three times per week, addition of upright exercise position).

There remains insufficient evidence as to whether the combination of PFMT with other treatment modalities (i.e. motor learning, abdominal- or hip-muscle training, intra-vaginal resistance device) could increase its efficacy.

With regard to clinic-based BF, new evidence (2 studies) reported no statistically significant differences between BF-assisted and non-BF groups for self-reported cure, improvement, or frequency of leakage episodes (Level of Evidence: 1).

Likewise, there is no statistically significant differences between home BF and non-BF groups for self-reported cure, improvement, frequency of leakage episodes and pad-test measures in women with SUI (Level of Evidence: 2).

Recommendations

Clinicians should offer and provide the most intensive health professional-led PFMT programme possible within service constraints. (Grade of Recommendation: A).

Although studies are limited, there does not appear to be clear benefit for adding other modalities (i.e. motor learning, abdominal- or hip-muscle training, intra-vaginal resistance device) to PFMT (Grade of Recommendation: B).

There is no clear benefit from adding clinic- (Grade of Recommendation: A) or home-based BF (Grade of Recommendation: B) to a PFMT program.

Implications for research

Comparisons of PFMT approaches are, de facto, comparisons of two active treatments. It is therefore difficult to determine which approach is best unless (a) the differences in outcome are large or (b) the RCTs are designed with sufficient sample size to find small to moderate differences. Finding the best approach to PFMT remains among the highest research priorities. Future studies should be sufficiently powered to detect clinically important differences.

2.3.3 Is PFMT Better than Other Treatments?

Trials were considered for inclusion in this section if they compared PFMT with another stand-alone intervention, e.g. vaginal cones, bladder training, drug therapy. The 2013 ICI review concluded that PFMT is better than EStim, BT, or vaginal cones for women with SUI and better than duloxetine because of its side-effects. PFMT and surgery were both effective, but PFMT was recommended as first-line therapy because it is less invasive. For women with UUI or MUI, PFMT and BT were both deemed effective, with some evidence to suggest an advantage for PFMT. Evidence was sparse for a comparison between PFMT and drug therapies.

Seven new trials were found that compared PFMT to another stand-alone treatment.

PFMT was compared to vaginal cones (92-94), surgery (95), continence pessary, (96, 97), drug therapy (98), and bladder training (98). One trial was a head-to-head comparison of PFMT to surgery (95). The other trials had more than two arms. They included PFMT alone and another treatment alone, but were also designed to evaluate combinations of treatments (See Tables 10 and 13).

Trials addressed the following comparisons:

i) PFMT versus vaginal cones (VC):

One recent Cochrane review compared PFMT to VC (92). This review considered the eleven studies included in this consultation along with two other RCTs (93, 94). Moreover, our literature search revealed the study of Golmakani et al. (60). Details of these new trials are presented in Table 13.

ii) PFMT versus EStim:

No new trials have been published.

iii) PFMT versus Bladder training (BT):

The Kafri trial examined the effects of PFMT alone and BT alone in the context of its 4-arm design (98). All groups had significant improvement at 3 and 12 months on all parameters, including UUI episodes. But, no significant time X group interactions were found that would indicate a difference between PFMT and BT (Table 10).

iv) PFMT versus drug therapy:

The trial by Kafri and colleagues examined the effects of PFMT alone compared to anticholinergic drug therapy alone in the context of a 4-arm design (98). All groups had significant improvement at 3 and 12 months on all parameters, including UUI episodes but, no significant time X group interactions were found that would indicate a difference between PFMT and drug therapy (Table 10).
v) PFMT versus surgery:
The single trial of surgery compared PFMT to mid-urethral sling in women with stress predominant UI (95). It was a multi-site trial involving 23 medical centres and 83 physiotherapists (Table 10).

vi) PFMT vs continence pessary:
A single new trial compared PFMT to continence pessary in women with stress predominant UI (96, 97). It was a multi-site trial conducted by the Pelvic Floor Disorders Network of the National Institute on Child Health and Human Development (NICHD) (Table 10).

Quality of data
i) PFMT versus VC:
Randomization and adequate allocation concealment were reported in the three new RCTs (93, 94, 99). Of these, two indicated that outcome assessors were blinded (93, 99). In the third study, the evaluator was unblinded (94). Sample sizes were small ranging from 15 to 30 women with SUI per group (93, 94, 99). Dropout rates were higher in the VC groups in two studies (93, 99); no loss to follow up was reported in the study of Pereira et al. (94). Substantial attrition occurred in the study of Harvey et al. (93) with drop-outs reaching 41% in the PFMT group and 72% in the VC group. Follow-up beyond the post-treatment evaluation was reported by Pereira et al. (94) in a subsequent publication with a 12-month post-treatment assessment (100).

ii) PFMT versus EStim: Not applicable.

iii) PFMT versus BT:
Risk of Bias - This trial was not a head-to-head comparison of PFMT and drug therapy, but rather a comparison of four treatment approaches including BT and combined therapy. Randomization method and allocation concealment were described. Analysis was conducted by ITT. It was not clear whether assessors were blinded.

iv) PFMT versus drug therapy:
This trial was not a head-to-head comparison of PFMT and drug therapy, but rather a comparison of four treatment approaches including BT and combined therapy. Randomization method and allocation concealment were described. Analysis was conducted by ITT. It was not clear whether assessors were blinded.

v) PFMT versus surgery:
Randomization method and allocation concealment were reported. Analysis included ITT and other approaches. It was not clear whether assessors were blinded. Fifteen women in the surgery group and 28 in the PFMT group did not start treatment after randomization. The ITT analyses did not include these individuals. Nineteen women in the surgery group and 28 in the PFMT group were lost to follow-up after starting treatment.

vi) PFMT vs continence pessary:
Randomization method and allocation concealment were reported. Analyses were performed by ITT.

Results and Summary
i) PFMT versus VCs:
As underlined in Herbison et al.’s meta-analysis (92) comprising 13 RCTs, most studies had a small sample size and differed according to the PFMT regimen (92). There was also limited overlap between outcomes. No statistically significant differences between PFMT and VC were found in subjective improvement or cure (reported in six RCTs) (Risk ratio (RR) for failure 0.97, 95% CI 0.75 to 1.24) (92). There were no significant differences in subjective cure (reported in five RCTs) (RR for failure 1.01, 95% CI 0.91 to 1.13) (92). Pooled data from these RCTs showed substantial heterogeneity. Likewise, inconsistency between RCTs was noted in relation to leakage episodes whereas a non-significant difference between treatments was observed (mean difference 0.00, 95% CI -0.20 to 0.20) (92). With regard to improvement in pad test, non-significant differences were found in the meta-analysis based on six RCTs (RR for failure 1.00, 95% CI 0.76 to 1.31). However, the new study of Golmakani et al. (60) favoured PFMT when using the 1-h pad test and the leakage index. With regard to quality of life improvement, the three new RCTs found a non-significant difference between PFMT and VC treatments (93, 94, 99). Three RCTs included in the Herbison review as well as the study of Golmakani et al. (60) reported the inability for some women to use VCs and adverse effects such as pain, vaginitis, bleeding and a sense of unpleasantness or inconvenience.

In the 14 RCTs (13 from the new Cochrane review, 11 of which were discussed in the previous ICI chapter edition and 1 additional RCT) that compared PFMT with VC in women with SUI, limited evidence suggests that VC appear to have similar effects or are not superior to PFMT (Level of Evidence: 1). There were no statistically significant differences between interventions in subjective improvement or cure (reported in six RCTs), subjective cure (reported in five RCTs), or leakage episodes per day (reported in four RCTs), and no improvement in the pad test (reported in six RCTs). The additional RCT favoured PFMT using both the 1-h pad test and the leakage index. VC treatment may be inappropriate in some cases due to the inability to use and potential side effects as reported in four RCTs (i.e., pain, vaginitis, bleeding and a sense of unpleasantness or inconvenience).

ii) PFMT versus EStim:
No new trials were found. Previous pooled data demonstrated that self-reported cure and cure/improvement were more likely in PFMT than in EStim groups (Level of Evidence: 1).
iii) PFMT versus BT:
There is evidence for an advantage of PFMT over BT for women with SUI (Level of Evidence: 2).
There does not appear to be a significant difference between PFMT and BT in UUI and MUI women (Level of Evidence: 2).

iv) PFMT versus drug therapy:
There is weak evidence that PFMT is more beneficial than drug therapy, but not enough evidence to change previous recommendations (Level of Evidence: 2).

v) PFMT versus surgery:
On the primary outcome, PGI-I at 12 months, perceived improvement was significantly greater in the surgery group compared to the PFMT group: 90.8% of women in the surgery group reported being "much better" or "very much better" compared to 64.6% in the PFMT group. Change in the UDI UI domain and OAB domain were also significantly greater with surgery and a higher proportion of women in the surgery group had subjective and objective cure.
The one new trial of PFMT compared to surgery appeared well-designed and adequately powered, providing evidence that mid-urethral sling may be more effective than PFMT for treatment of SUI in women (Level of Evidence: 2).

vi) PFMT vs continence pessary:
The PFMT/behavioural group had better outcomes on the PFDI SUI subscale and greater patient satisfaction. The groups were not significantly different on the PGI-I, UI episode frequency, or outcome measures, including domains of the PFDI and PFIQ.
There may be some benefit for PFMT over continence pessary alone, the evidence is not strong enough to recommend one treatment over the other (Level of Evidence: 2; Grade of Recommendation: D).

**Recommendations**

For women with SUI:
- PFMT and VC are both effective as conservative therapy, although PFMT is better because inability of use and side effects are experienced with VC in some women (Grade of Recommendation: B).
- PFMT is better than EStim as first line conservative therapy (Grade of Recommendation: B).
- PFMT is better than BT as first line conservative therapy (Grade of Recommendation: B).
- PFMT and drug therapy are both effective as first line therapy, although PFMT is better because of side effects experienced with drug therapy (Grade of Recommendation: B).
- Surgery is more effective than PFMT, but potential benefit should be weighed against potential adverse events. PFMT should be offered as first line therapy due to its being less invasive. (Grade of Recommendation: B New).
- PFMT and continence pessary are both effective in first line conservative therapy (Grade of Recommendation: B New).

For women with SUI or MUI:
- VC do not appear to be better than PFMT in the treatment of UI. PFMT should be recommended as first-line conservative therapy (Grade of Recommendation: B).

VC with supervised training sessions by a trained health professional can be offered to women who can and are prepared to use them (Grade of Recommendation: B).
VC may be inappropriate for some women due to inability to insert or retain the cone or because of side effects and discomfort.

For women with UUI or MUI:
- PFMT and BT are effective first-line conservative therapy (Grade of Recommendation: B).
- PFMT is better than oxybutynin as first line therapy (Grade of Recommendation: B).

For women with UUI
- PFMT and BT are effective first line conservative therapy (Grade of Recommendation: B).

**Research recommendation**

Larger, good quality trials are needed to address each of the above comparisons if these are of interest to women. In planning comparisons researchers should consider carefully the potential impact of different levels of supervisory intensity between groups, particularly in comparisons of conservative therapies.
<table>
<thead>
<tr>
<th>Author, year</th>
<th>Comparator</th>
<th>N</th>
<th>Study Population</th>
<th>Intervention</th>
<th>Outcomes/Results</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kafri 2013 (1)</td>
<td>Drug therapy (anticholinergic) BT</td>
<td>N=164</td>
<td>Women with UUI, No SUI (45-75 years)</td>
<td>PFMT based on National Institute for Health and Clinical Excellence (NICE) recommendations. Included behavioral guidance 3 sets of 8-12 slow maximal contractions sustained for 6-8 s in different positions. Daily home-based exercise prescribed.</td>
<td>Number of voids and UUI episodes, QOL-ruI, Urogyn VAS. All groups had significant improvement at 3 and 12 months on all parameters (p&lt;0.001). No significant timeXgroup interactions (except favoring combination group)</td>
<td>Comparison was in context of 4-arm trial, including arm for combined Tx. Randomization method and allocation concealment described. ITT analysis Not clear whether assessors were blinded</td>
</tr>
<tr>
<td>Richter 2010 (2) Kenton 2012 (3)</td>
<td>Intravaginal pessary</td>
<td>N=446</td>
<td>Women with predominant SUI (18+ years)</td>
<td>12 weeks of supervised PFMT and behavioral strategies (PFM pre-contraction for SUI; urge suppression for concomitant UUI). Implemented in 4 visits at 2-week intervals. Home exercise: written prescriptions X3 daily exercise between visits.</td>
<td>Primary: PGI-I and SUI subscale of the PFDI at 3 months (FU 6 &amp; 12 months) Secondary: Satisfaction, PFDI, PFIQ PFMT/behavioral group had better outcomes on the PFDI SUI subscale (49% vs 33% reporting no bothersome SUI symptoms, p=0.006) and greater satisfaction (75% vs 63%, p=0.02). Groups not significantly different on the PGI-I (49% vs 40% &quot;much better&quot; or &quot;very much better,&quot; (p=0.09), UI episodes on bladder diary, or other outcome measures including other domains of the PFDI and PFIQ.</td>
<td>Comparison was in context of 3-arm trial, including arm for combined Tx Multi-site trial Randomization method and allocation concealment reported ITT analysis</td>
</tr>
<tr>
<td>Author, year</td>
<td>Comparator</td>
<td>N</td>
<td>Study Population</td>
<td>Intervention</td>
<td>Outcomes/Results</td>
<td>Notes</td>
</tr>
<tr>
<td>--------------</td>
<td>------------</td>
<td>---</td>
<td>------------------</td>
<td>--------------</td>
<td>------------------</td>
<td>-------</td>
</tr>
<tr>
<td>Labrie 2013 (4)</td>
<td>Mid-urethral sling</td>
<td>N=460 PFMT: 230 Surgery: 230</td>
<td>Women with predominant SUI (35-80 years)</td>
<td>Supervised, somewhat individualized program conducted by 83 PTs according to Dutch guidelines. Treatments given at 1-week or 2-week intervals with an intended 9 sessions in 9-18 weeks. Goal to build up to 8 to 12 maximal contractions X3 per day. Use of touch, tapping, massage, BF, or functional electrical stimulation allowed to increase muscle awareness as needed.</td>
<td>Assessed at 12 months Primary: PGI-I, 90.8% in surgery group were “much better” or “very much better” vs 64.4% in PFMT. Secondary: UDI, IIQ, PGI-S Both groups had significant improvement in UDI and IIQ domain scores. Change in UDI greater for surgery than PFMT on UI and OAB domains (P&lt;0.001-.02) Subjective cure: (single question) 85.2% in surgery vs 53.4% in PFMT Objective cure: (cough test) 76.5% in surgery vs 58.8% in PFMT After 12 months, 99 women (49.0%) had crossed over to surgery after a mean 31.7 weeks.</td>
<td>Multi-site trial (23) Randomization computerized on central server Allocation not concealed Not clear whether assessors were blinded. 65 adverse events reported - all in surgery group. Analysis included modified ITT and other approaches. 15 in surgery group and 28 in PFMT group did not start treatment after randomization. 19 in surgery group and 28 in PFMT group were lost to follow-up after starting Tx.</td>
</tr>
</tbody>
</table>

2.3.4 Does the Addition of PFMT to Other Treatments Add Benefit?

Six trials addressed the following comparisons (Table 11):

i) PFMT+VC vs VC: Both the Herbison et al. meta-analysis (92) and the ICI 5th edition (2) included two studies comparing combined PFMT/VC versus VC. No new RCTs with the same comparators were identified.

ii) PFMT + EStim vs EStim: A single trial examined the effects of adding PFMT to vaginal EStim in 48 women with SUI (101). No significant differences were found between the groups.

iii) PFMT + BT vs BT: Two trials examined the effects of adding PFMT to BT, one in 108 women with SUI, UUI, or MUI (102), the other in 164 women with UUI (no SUI) (98). In the first, significantly more patients in the combined therapy group reported cure or improvement and greater improvements on several secondary outcomes. In the second trial, all groups had significant improvement, but there were no significant interactions indicating differential group effects.

iv) PFMT + drug therapy vs drug therapy alone: A single trial examined the effects of adding PFMT to intravaginal oestriol in 206 postmenopausal women with SUI and vaginal atrophy (103). Combined therapy resulted in significantly greater improvement than oestriol only.

v) PFMT + continence pessary vs continence pessary: A single trial examined combined pessary + PFMT to pessary alone in 446 women with stress predominant UI (97). The combined therapy group had significantly better outcomes on the PGI-I and the PFDI and reported greater satisfaction with treatment.

vi) PFMT + surgery vs surgery:

A single, multi-centre trial examined the effects of perioperative behavioural and pelvic floor muscle training (BPMT) in 374 women undergoing surgery to treat both apical prolapse and SUI (104). The group receiving BPMT resulted in no greater improvements in urinary symptoms compared to usual peri-operative care at 6 or 24-month follow up.

Summary

The literature on the effect of adding PFMT to another stand-alone therapy remains relatively small.

There is no evidence of benefit in adding PFMT to VC in women with SUI (Level of Evidence: 2).

There may be some benefit for adding PFMT when using a continence pessary (Level of Evidence: 2).

PFMT may add benefit in terms of reducing SUI over intravaginal estrogen alone when treating women with vaginal atrophy (Level of Evidence: 2).
Table 11 Summary of data on PFMT + another treatment vs the other treatment

<table>
<thead>
<tr>
<th>Study</th>
<th>Comparator</th>
<th>N</th>
<th>Study Population</th>
<th>Intervention</th>
<th>Outcomes/Results</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Richter 2010 (1)</td>
<td>Continence pessary alone</td>
<td>N=446</td>
<td>Women with stress predominant UI</td>
<td>Pessary + behavioral training Behavior training program - supervised PFMT +</td>
<td>Primary: PGI-I and SUI subscale of UDI at 3 months Results - Combined therapy</td>
<td>Multi-site trial conducted by the NICHD Pelvic Floor Disorders Network with randomization to 3 arms: pessary alone, behavioral training alone, combined Tx Data quality – Randomization method and allocation concealment were reported. Analysis conducted by ITT</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>behavioral strategies: PFMT pre-contraction for SUI and urge suppression for</td>
<td>group had significantly better outcomes on the PGI-I (53.3% vs 39.6% reporting</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>concomitant UUI. Treatment implemented in 4 visits at 2-week intervals and</td>
<td>”much better” or “very much better,” p=.02) and the PFDI (44.0% vs 32.9%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>included written prescriptions for home exercise X3 daily between visits.</td>
<td>reporting no bothersome SUI symptoms (p=.05). Combined group also reported</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>greater satisfaction with treatment (78.7% vs 63.1%, p=.003). The groups were</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>not significantly different on number of UI episodes on bladder diary. Group</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>differences not sustained to the 12-month follow up.</td>
<td></td>
</tr>
<tr>
<td>Barber 2014 (2)</td>
<td>Surgery alone for prolapse</td>
<td>N=374</td>
<td>Women undergoing surgery to treat both apical vaginal</td>
<td>Surgery + perioperative behavioral and pelvic floor muscle training (BPMT)</td>
<td>Primary: UDI at 6 months Results – Perioperative BPMT not associated with</td>
<td>Multi-center 2X2 factorial trial with 2 distinct randomizations: First: to perioperative BPMT or usual care Second: to one of 2 surgical approaches for prolapse, each with concomitant retropubic midurethral sling for SUI. Data quality – Randomization method and allocation concealment reported.</td>
</tr>
<tr>
<td></td>
<td>and SUI</td>
<td></td>
<td>prolapse and SUI</td>
<td>PFMT program - Single session 2-4 weeks prior to surgery; 4 postoperative</td>
<td>greater improvements in urinary symptoms at 6 months or 24-month follow-up</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>visits (2, 4-6, 8, &amp; 12 weeks) Individualized, supervised program of</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>progressive home PFME, education on healthy bladder and bowel habits, and</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>behavioral strategies to reduce UI episodes (PFM pre-contraction for SUI, urge</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>suppression for UUI) Home PFME prescribed for X3 daily with duration</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>increasing to 10 sec.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Capobianco 2012 (3)</td>
<td>Intravaginal estrogen alone</td>
<td>N=206</td>
<td>Postmenopausal women with SUI and</td>
<td>Estrogen + PFMT with EStim (per Castro, 25)</td>
<td>Outcome based on change in patient rating of SUI as none, mild,</td>
<td>Data quality - Randomization method not described.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Comparator</td>
<td>N</td>
<td>Study Population</td>
<td>Intervention</td>
<td>Outcomes/Results</td>
<td>Notes</td>
</tr>
<tr>
<td>-------</td>
<td>------------</td>
<td>-------</td>
<td>-----------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Study Population</strong></td>
<td>PFMT was for 6 months and included EStim. Further details lacking, but per reference to a previous article, PFMT was conducted in 45-minute group sessions X3 per week under the supervision of a physiotherapist.</td>
<td>moderate, or severe before and after 6 months of treatment. Results - Combined therapy resulted in significantly greater improvement than estril only. 73.5% (61/83) of treated and 9.7% (10/103) showed improvement in UI (p&lt;.01)</td>
<td>Group allocation was concealed. Analysis was by ITT AEs were reported Not clear all women actually had SUI.</td>
</tr>
<tr>
<td>Kafri 2013 (4)</td>
<td>BT alone</td>
<td>164</td>
<td>Women with UUI, no SUI (ages 45-75)</td>
<td>Bladder training + PF rehab and behavioral. PFMT program based on the National Institute for Health and Clinical Excellence (NICE) recommendations. Women practiced 3 sets of 8-12 slow maximal contractions sustained for 6-8 s in different positions. Daily home-based exercise was prescribed, and urge suppression using PFM contraction was taught.</td>
<td>Number of voids and UUI episodes, voids/24 hours, QoL-rUI, Urogyn VAS, number of pads Results - analysis was by repeated measures ANOVA with all four groups, including tests for main effects and group X time interactions. However, statistical analysis did not include comparisons between individual groups. All groups had significant improvement at 3 and 12 months on all parameters, (p&lt;.001) but there were no significant interactions. UI episodes decreased by 1.7/day in BT and 4.0/day in combined therapy, but a test of this difference was not conducted. Only CPFR showed significant reduction in voids/24 hours.</td>
<td>Comparison was in context of 4-arm trial: BT alone, PFMT alone, drug therapy alone, and combined Tx. Data quality –Randomization method and allocation concealment described. Analysis conducted by ITT. Not clear whether assessors were blinded.</td>
</tr>
<tr>
<td>Kaya 2015 (5)</td>
<td>BT alone</td>
<td>108</td>
<td>Women with SUI, UUI, MUI</td>
<td>BT + PFMT for 6 weeks High-intensity PFMT program conducted in 4 visits across 6 weeks by an experienced physical therapist. Home-based exercise regimen initiated with 5 sets of exercises per day and progressed to 30</td>
<td>Primary: global rating of improvement on a 4-point scale (worse, unchanged, improved, cured). Secondary: UI severity, symptom distress, QOL, UI episodes, voids/day. Results – Significantly more patients in the combined therapy group reported cure or improvement (100% vs 82.7%, p=.001). Greater</td>
<td>Data quality –Randomization method and allocation concealment described. Analysis conducted by ITT. Not clear whether assessors were blinded.</td>
</tr>
</tbody>
</table>
Study | Comparator | N | Study Population | Intervention | Outcomes/Results | Notes |
--- | --- | --- | --- | --- | --- | --- |
Furst 2014 (6) | EStim alone Vaginal probe; two 30-min sessions per week; frequencies of 4Hz and 50Hz; fixed intensity (20mA); 4 s stimulation/rest cycles | N=48 | Women with SUI (Mean age 49.6) | EStim + PFMT for 3 months PFMT program – individually designed by PT, 2 30-min sessions per week. PFMT and EStim conducted on alternate days. No home PFME program | Improvements in urinary symptoms, IEF per bladder diary, satisfaction (perception of need or not to repeat or change Tx); assessments at 3, 12 and 96 months. Results – Both groups showed improvement in leakage episodes and voiding intervals. No significant between group differences. | Data quality – Randomization method described; allocation concealed. Analysis not conducted by ITT (only included patients who had not received any additional therapy) |

3. WEIGHTED VAGINAL CONES (VC)

Weighted vaginal cones (VC) were developed as a method for testing PFM function and to provide progressive muscular overload during PFM strengthening exercises (105). In theory, when a cone is inserted into the vagina, the sensation of ‘losing the cone’ provides strong sensory feedback that prompts the PFM to contract to prevent the cone from slipping out. Women start in a standing position with a weighted cone held inside the vagina for at least one minute, incrementally adding time and increased cone weight whilst standing or walking. The goal is to walk around for 20 minutes without losing the cone; the gradual increase in cone weight maintains muscle overload over the course of the exercise programme.

There are various cone weights and sizes (Figure 1). However, the effectiveness of the VC training method is unclear. Because orientation of the vagina is not completely vertical, some women can retain the cone without actually contracting the pelvic floor. Radiology has also demonstrated that the cones can rest in a transverse position (106). Depending on the axis of the vagina, women need to produce different force intensities to retain the cone. Thus, using VC as a measure of PFM function may not be a valid method. Finally, some women may find it impossible to insert the cones due to a narrowed vaginal opening or, conversely, to retain it due to an enlarged vaginal opening, prolapse, or an insufficient PFM contraction, one incapable of holding even the lightest cone.

This section examines the evidence for VC in the prevention and treatment of UI in women. Questions addressed:

- Are VC better than no treatment, placebo or control for the prevention of UI?
- Are VC as effective as other treatments for the treatment of UI?
- Are VC combined with PFMT better than PFMT alone for the treatment of UI?

3.1. Prevention

No previous (prior to last Consultation) or new RCT investigating either the primary or secondary prevention effects of training with VC for women with UI were found.

3.2. Treatment

A Cochrane review specifically addressing the effectiveness of VC in the treatment of UI was updated in March 2013 (92) This meta-analysis and four new studies form the basis of this subsection (79, 99, 107, 108). Table 12 illustrates the number of studies included in the 5th ICI and in the Cochrane review of Herbison et al. (92) as well as the new studies identified in the current update. Characteristics of each RCT not included in the previous ICI are presented in Table 13.
Table 12: Studies of VC included in the previous review (5th ICI), in the Cochrane meta-analysis of Herbison et al. and current update (6th ICI)

<table>
<thead>
<tr>
<th>Category</th>
<th>Studies included in the previous review (5th ICI)</th>
<th>Studies included in the Cochrane review of Herbison et al.</th>
<th>New studies identified in this update (6th ICI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFMT vs VCs (section II.2.3.3i)</td>
<td>11</td>
<td>13</td>
<td>1</td>
</tr>
<tr>
<td>PFMT/VCs vs VCs (section II.2.3.4i)</td>
<td>2</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>VCs vs no treatment, placebo or control treatments</td>
<td>4</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>VCs vs EStim</td>
<td>5</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>PFMT/VCs vs PFMT</td>
<td>2</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Author, year</td>
<td>Comparator</td>
<td>N</td>
<td>Study population</td>
</tr>
<tr>
<td>-------------</td>
<td>------------</td>
<td>---</td>
<td>------------------</td>
</tr>
<tr>
<td>Golmakani 2014 (1)</td>
<td>PFMT (30) vs VCs (30)</td>
<td>60</td>
<td>Women with SUI (at least 3 episodes per week)</td>
</tr>
<tr>
<td>Author, year</td>
<td>Comparator</td>
<td>N</td>
<td>Study population</td>
</tr>
<tr>
<td>-------------</td>
<td>------------</td>
<td>---</td>
<td>------------------</td>
</tr>
<tr>
<td>Harvey 2006 (2) - abstract</td>
<td>PFMT (19) vs VCs (25)</td>
<td>44</td>
<td>Women with urodynamically proven SUI</td>
</tr>
<tr>
<td>Author, year</td>
<td>Comparator</td>
<td>N</td>
<td>Study population</td>
</tr>
<tr>
<td>-------------</td>
<td>------------</td>
<td>----</td>
<td>------------------</td>
</tr>
<tr>
<td>Pereira 2012 (3)</td>
<td>VCs (15) vs PFMT (15) vs Control (15)</td>
<td>45</td>
<td>Postmenopausal women with SUI (at least 1 episode of urinary leakage in the previous month)</td>
</tr>
<tr>
<td>Author, year</td>
<td>Comparator</td>
<td>N</td>
<td>Study population</td>
</tr>
<tr>
<td>--------------</td>
<td>------------</td>
<td>---</td>
<td>------------------</td>
</tr>
<tr>
<td>Porta Roda 2013 (4) abstract and poster</td>
<td>VC+PFMT (37) vs PFMT (33)</td>
<td>70</td>
<td>SUI or stress predominant MUI in parous women</td>
</tr>
<tr>
<td>Author, year</td>
<td>Comparator</td>
<td>N</td>
<td>Study population</td>
</tr>
<tr>
<td>-------------</td>
<td>------------</td>
<td>---</td>
<td>------------------</td>
</tr>
<tr>
<td>Prudencio 2014 (5) abstract</td>
<td>PFMT (51) vs PFMT+VCs (55) vs PFMT+BF (50)</td>
<td>156</td>
<td>SUI women</td>
</tr>
<tr>
<td>Santos 2009 (6)</td>
<td>VCs (21) vs EStim (24)</td>
<td>45</td>
<td>Women with SUI (urodynamic diagnosis)</td>
</tr>
<tr>
<td>Author, year</td>
<td>Comparator</td>
<td>N</td>
<td>Study population</td>
</tr>
<tr>
<td>-------------</td>
<td>------------</td>
<td>---</td>
<td>------------------</td>
</tr>
<tr>
<td>Stupp 2011 (7) abstract</td>
<td>PFMT (22) vs PFMT + proprioception and awareness training (including VC) (22)</td>
<td>44</td>
<td>Women with SUI or MUI</td>
</tr>
</tbody>
</table>

3.2.1 Are VC Better than No Treatment, Placebo or Control Treatments?

The meta-analysis published by Herbison et al. (92) comprised 5 RCTs comparing VC to a control treatment. Except for Pereira et al. (94) (presented in Table 13), these studies were part of the ICI previous edition. Our literature search identified no further RCT.

Quality of data

In the study of Pereira et al. (94), adequate allocation concealment and randomisation was reported. The evaluator was however not blinded to patient assignment. No attrition was reported in the VC group while 13% dropped out from the control group. No adverse effects were reported in this RCT.

Results

As discussed in Herbison et al.’s meta-analysis (92), women in the VC groups were more likely to report they were cured than the controls (RR for failure 0.84, 95%CI 0.76 to 0.94). VCs were also better than control treatment in the subjective reporting of cure or improvement (RR for failure 0.72, 95%CI 0.52 to 0.99). Further, Pereira et al. (94) reported better incontinence-related QOL and a significant reduction in the 1-h pad test for women in the VC group compared to the control treatment.

Summary

VCs with supervised training sessions by a trained health professional are better than control treatments for subjective reporting of cure or cure/improvement and the QOL impact on the treatment of SUI (Level of Evidence: 1).

However, VC treatment may be inappropriate in some cases due to potential reported side effects (92).

Recommendations

For women with SUI, VCs with supervised training sessions by a trained health professional may be offered as a first-line conservative therapy to those who can and are prepared to use them (Grade of Recommendation: B)

Trained health professional assessment is recommended. VC may be inappropriate in some cases due to inability to insert or retain the cone or because of side effects and discomfort. (Grade of Recommendation: D).

3.2.2 Are VC As Effective as Other Treatments?

VC have been compared with PFMT and EStim, but not with other therapies such as drug treatment, BT or surgery.

i) VC versus PFMT

This comparison is addressed in Section II.2.3.3. Details of the VC and PFMT programs for each trial are presented in Table 13.

ii) VC versus EStim

Since the last ICI edition, a meta-analysis update was published. (92) It comprised the same trials as in the ICI 5th edition as well as the study of Santos et al. (109) (presented in Table 13). Our literature search revealed no further trials.

Quality of data

i) VC versus PFMT: See Section II.2.3.3.

ii) VC versus EStim

In the study of Santos et al. (109), participants were randomly assigned to treatments while blinding of assessors and allocation concealment were not clearly reported. No losses to follow-up were reported (109).

Results

i) VC versus PFMT: See Section II.2.3.3.

ii) VC versus EStim

As reported in the Herbison et al. meta-analysis (92), there was no statistically significant difference between VC and EStim in the pooled data of three trials with regard to self-reported cure (RR for failure 1.26 95% CI 0.85 to 1.87). Non-significant differences also emerged from the pooled data of three RCTs with respect to improvement in pad test (RR 1.21 95%CI 0.90 to 1.63) and leakage episodes (Mean difference -0.27 to 0.17). Herbison et al. (92) reported discomfort or side effects associated to both EStim and VC (VC: abdominal pain, vaginitis, bleeding, motivational problems and difficulties using the VC, EStim: tenderness and bleeding, discomfort or motivational and other difficulties in using the EStim).

Summary

The meta-analysis of Herbison et al. (92) including six RCTs revealed no significant difference between VCs and EStim in terms of self-reported cure, cure/improvement, improvement in pad test or the number of leakage episodes; both the VC and EStim groups reported adverse events.

VC and EStim seem equally effective in the treatment of SUI and MUI. (Level of Evidence: 1). Side effects and discomfort appear to limit their utility in clinical practice. (Grade of Recommendation: D).

3.2.3 Are VC Combined with PFMT Better than PFMT Alone?

Both Herbison et al.’s meta-analysis(92) and the ICI 5th edition relied on two RCTs comparing combined PFMT/VC to PFMT alone. Our search revealed three additional studies presented as published abstracts (79, 107, 108). Details of the PFMT/VC and PFMT are presented in Table 13.
Quality of data

Limited information on method and results were available from these published abstracts (79, 107, 108). Although participants were randomly assigned, no information on allocation concealment and blinding of assessors was provided. The sample sizes were relatively small with no more than 39 patients per treatment arm. Dropouts ranged from 0 (79) to 13% (108) in the PFMT group and 0% (79, 108) to 5% (107) in the combined treatment.

Results

Including two RCTs, Herbison’s meta-analysis reported no significant differences between PFMT/VC and PFMT alone for either cure or cure/improvement. Likewise, the results from the three additional RCT failed to show any significant difference between treatments in terms of subjective cure (79, 108) and subjective cure/improvement (107). Porta Roda et al. reported that improvement occurred earlier in the combined group (after 3 months of treatment) but this was not maintained at the end of the treatment (6 months of treatment) (107).

Summary

Limited evidence suggests no benefit from adding VCs to PFMT for women with SUI (Level of Evidence: 2).

Recommendations

No recommendation is possible for combination intervention. Adequately powered studies are needed to confirm or refute the advantages of adding VCs to PFMT (No Recommendation).

3.3. Other Lower Urinary Tract Symptoms (LUTS)

In the previous ICI, two RCTs reported data on the efficacy of VC on urgency and nocturia (Williams et al. 2006) and nocturia (Gameiro et al. 2010). Our search revealed no new RCTs on other lower urinary tract symptoms.

3.4. Factors Affecting Outcome

None of the RCTs above addressed the effect of age or other factors on the outcome of VC training. Nonetheless, in the 22 RCTs included here, on average, 22% of the women being treated with VCs (range 0 to 63%) withdrew from the study or dropped out. Although few RCTs examined the causes of attrition, among those that reported causal factors low compliance, motivational problems, unpleasantness, aesthetic dislike, discomfort, and bleeding were implicated although no one reason predominated.

4. ELECTRICAL STIMULATION (ESTIM)

The theoretical basis of neuromuscular electrical stimulation (ESTim) interventions has emerged with increasing understanding of the neuroanatomy and physiology of the central and peripheral nervous systems. The mechanisms of action vary depending on the cause(s) of UI and the structure(s) being targeted e.g. PFM or detrusor, peripheral or central nervous system. In general, the aim of ESTim for SUI appears to be to increase proprioception and/or to improve the muscle function of an atrophied or weak PFM, while for UUI the objective seems to be to inhibit detrusor overactivity (DO) (1).

ESTim is provided by clinic-based mains powered machines or portable battery powered stimulators (Figure 2) with a seemingly infinite combination of current types, waveforms, frequencies, intensities, electrode types and placements (Figure 3). Without a clear biological rationale, it is difficult to make choices about different ways of delivering ESTim. Additional confusion is created by the relatively rapid developments in the area of ESTim, and a wide variety of stimulation devices and protocols that have been developed even for the same condition.

Finally, the nomenclature used to describe ESTim remains inconsistent. ESTim has not only been described based on the type of current being used (e.g. faradic, interferential), but also on the structures targeted (e.g. neuromuscular), the current intensity (e.g. 61.

Figure 2 Neuromuscular electrical stimulation equipment

Figure 3 Neuromuscular electrical stimulation electrodes
low-intensity, or maximal stimulation), and the pro-
posed mechanism of action (e.g. neuromodulation).
In this section, EStim type and parameters are re-
ported in line with International Continence Society
definitions (1).

This section presents the evidence for the use of EStim in the prevention and treatment of UI in women. Questions addressed are:

- Is EStim effective in the prevention of UI?
- Is EStim better than no active treatment (placebo, sham, control or no treatment) for treatment of UI?
- Is one type of EStim better than another in the treatment of UI?
- Is EStim better than other treatments in the treatment of UI?
- Does the addition of EStim to other treatments add any benefit in the treatment of UI?
- What is the effect of EStim on other LUTS?
- What factors might affect the outcome of EStim in the treatment of UI?

Eligible interventions were non-invasive EStim without implanted electrodes. (Magnetic stimulation and posterior tibial nerve stimulation are described in Sections II.5 and II.6). Other criteria for inclusion were (1) randomised or quasi-randomised (alternate allocation) trial design, (2) women with UI or other LUTS, (3) no participants with incontinence due to neurological or cognitive impairment and (4) no pregnant or postpartum women (within 12 months of childbirth). Trial data reported in conference abstracts as well as full-text papers were included. EStim compared with PFMT and vaginal cones are covered in previous sections (sections II.2.3.3 and II.3.2.2). This section focuses on EStim compared with no active treatment or other conservative treatments.

The primary outcomes were cure rates (the number of women with no urinary incontinence episode at time of assessment) and improvement rates (the number of women improved, including cure). There was considerable variability in the way these outcomes were measured. Women’s self-report was given priority but for studies in which it was not reported, the rate based on diaries was used as a proxy; where diary data were also not reported, the rate based on pad tests or any other definitions chosen by the trialists was used (110). Data on health-related quality of life and adverse effects were also extracted. Data at the end of the prescribed treatment phase, or at the first outcome measurement, if later, were used in the analysis. Any treatment effects shown are likely to reflect maximum effect of each intervention. Data from further follow-up were also recorded.

Due to the small number of available studies per intervention, data were sub-grouped by dominant type or pattern of incontinence: (1) studies with all or at least 50% of participants having SUI alone or a predominant symptom of SUI (as defined by trial investigators), (2) studies with all or >50% of participants having UUI alone or a predominant symptom of UUI (as defined by trial investigators), (3) other studies of participants with UI in which neither stress- or urgency-UI represented a predominant symptom in the study population (‘UI all types’ hereafter), and (4) studies of overactive bladder (OAB) or DO in which it was unclear whether all participants had UI.

Single EStimates with 95% confidence intervals (CI) were derived for each study comparison using odds ratios (OR) for dichotomous variables or mean difference (MD) for continuous variables. Summary EStimates were calculated using random effects models if there was more than one study reporting the same outcome (meta-analysis).

‘Risk of bias’ in the included studies was assessed for allocation concealment (selection bias) and completeness of outcome data (attrition bias), using relevant items in a standard tool developed by the Cochrane Urinary Incontinence Group (111). Risk of bias regarding blinding to the allocated intervention was high in most included studies: blinding of participants and care providers is not always feasible (other than the use of sham EStim), and blinding of outcome assessors is equally difficult for self-reported outcomes such as cure, improvement and quality of life.

**Description of intervention in included studies of EStim**

Nine new trials were identified for this update, making a total of 42 trials included in this section. All new trials targeted women with SUI or predominant SUI. No new studies for predominant UUI, DO or OAB (incontinent or not) were found for this update. Findings for UUI, UI all types, DO and OAB are therefore unchanged from 5th CI. The number of included studies by dominant type or pattern of incontinence is summarised in Table 14.

In addition, there was one study, published in Portuguese, which was a three-arm trial comparing EStim and PFMT (N = 24), PFMT (N = 25) and control (N = 22) (112). This trial could not be incorporated here, as an English translation was not available.

The EStim parameters and protocols in this section are summarised in Table 15. Some approaches to treatment are now less common, such as the use of interferential current or external electrodes. There was considerable variation in the intervention protocol. Although the biological rationale and purpose of EStim might be different depending on diagnosis, there was no consistency in the EStim protocols used for women with SUI, UUI, UI all types, or DO.

**4.1. Prevention**

No published trials were found.
Table 14 Studies of EStim included in the previous review (5th ICI) and current update (6th ICI)

<table>
<thead>
<tr>
<th>Studies included in the previous review (5th ICI)</th>
<th>New studies identified in this update (6th ICI)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>EStim vs No active treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SUI or predominant SUI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UUI or predominant UUI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UI all types</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DO/OAB (dry or wet)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>4</td>
<td>13</td>
</tr>
<tr>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>One type of EStim vs another</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SUI or predominant SUI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UUI or predominant UUI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DO/OAB (dry or wet)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>EStim vs other treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SUI or predominant SUI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UUI or predominant UUI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DO/OAB (wet or dry)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>No study found</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>EStim+PFMT vs PFMT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SUI or predominant SUI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UUI or predominant UUI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UI all types</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8 (no BF)</td>
<td>2 (no BF)</td>
<td>10</td>
</tr>
<tr>
<td>2 (with BF)</td>
<td>1 (with BF)</td>
<td>3</td>
</tr>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2 (no BF)</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>BF = biofeedback</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 15 Summary of EStim protocols

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Current</th>
<th>Current Intensity</th>
<th>Pulse Shape &amp; Duration</th>
<th>Frequency (Hz)</th>
<th>Duty Cycle</th>
<th>Electrodes</th>
<th>Treatment Duration</th>
<th>Target UI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alves 2011 (1)</td>
<td>Biphasic</td>
<td>Max tolerable intensity</td>
<td>Study arm 1: 100ms; Study arm 2: 700ms</td>
<td>Study arm 1: medium frequency 2000Hz; Study arm 2: low frequency 50Hz</td>
<td>Single ratio: 1:2 (4s on, 8s off)</td>
<td>Single vaginal electrode</td>
<td>20min session, 2x a week: 6wks</td>
<td>SUI</td>
</tr>
<tr>
<td>Author, year</td>
<td>Current</td>
<td>Current Intensity</td>
<td>Pulse Shape &amp; Duration</td>
<td>Frequency (Hz)</td>
<td>Duty Cycle</td>
<td>Electrodes</td>
<td>Treatment Duration</td>
<td>Target UI</td>
</tr>
<tr>
<td>-------------</td>
<td>---------</td>
<td>-------------------</td>
<td>------------------------</td>
<td>---------------</td>
<td>------------</td>
<td>------------</td>
<td>--------------------</td>
<td>-----------</td>
</tr>
<tr>
<td>Correia 2014 (2)</td>
<td>Biphasic</td>
<td>Max tolerable intensity</td>
<td>Duration: 700µsec</td>
<td>Single freq: 50Hz</td>
<td>Single ratio: 1:2 (4s on, 8s off) + 2s rise, 2s fall</td>
<td>Study arm 1: 4 electrodes (2 in the suprapubic region and 2 medial to the ischial tuberosity); Study arm 2: Single vaginal electrode</td>
<td>20min session, 2x a week, by physiotherapist: 6wks</td>
<td></td>
</tr>
<tr>
<td>Huebner 2011 (3)</td>
<td>NR</td>
<td>Range 20-80mA</td>
<td>NR</td>
<td>Single freq: 50Hz</td>
<td>Study arm 1: Active contracting of PFM 8s. After reaching the maximum contraction, electrical stimulation was added for 8s. Resting 15s; Study arm 2: Stimulation 8s. Resting 15s. Active contracting of PFM 8s. Resting 15s.</td>
<td>Single vaginal electrode</td>
<td>15min session, 2x a day, home treatment with 5 clinic visits: 12wks</td>
<td></td>
</tr>
<tr>
<td>Jeyaseelan 2003* (4)</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>Range not defined</td>
<td>A longer duty cycle than is traditionally used</td>
<td>NR</td>
<td>NR</td>
<td>SUI</td>
</tr>
<tr>
<td>Lopès 2014 (5)</td>
<td>Rectangular biphasic</td>
<td>NR</td>
<td>Duration: 400µsec</td>
<td>3 frequencies available: 50Hz for SUI, 20Hz for MUI, 12.5Hz for pure urgency</td>
<td>NR</td>
<td>Vaginal electrode</td>
<td>20min session, 3x a day, home treatment: 6mths</td>
<td>SUI</td>
</tr>
<tr>
<td>Maher 2009* (6)</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>Study arm 1: external electrodes; Study arm 2: single vaginal electrode</td>
<td>Study arm 1: external electrodes; Study arm 2: single vaginal electrode</td>
<td>30min session, 4x a week, home treatment: 8wks (outcome reported at 4wks)</td>
<td>SUI</td>
</tr>
<tr>
<td>Author, year</td>
<td>Current</td>
<td>Current Intensity</td>
<td>Pulse Shape &amp; Duration</td>
<td>Frequency (Hz)</td>
<td>Duty Cycle</td>
<td>Electrodes</td>
<td>Treatment Duration</td>
<td>Target UI</td>
</tr>
<tr>
<td>-------------</td>
<td>---------</td>
<td>------------------</td>
<td>------------------------</td>
<td>----------------</td>
<td>------------</td>
<td>------------</td>
<td>-------------------</td>
<td>----------</td>
</tr>
<tr>
<td>Patil 2010 (7)</td>
<td>Interferential</td>
<td>Max tolerable intensity</td>
<td>NR</td>
<td>Freq range: 0-100Hz</td>
<td>NR</td>
<td>4 electrodes (2 flat electrodes placed anteriorly over the obturator foramen, and 2 electrodes placed posteriorly medial to ischial tuberosity on either side of the anus)</td>
<td>First session 15min, other sessions 30min, 3x a week, by physiotherapist: 4wks.</td>
<td>SUI</td>
</tr>
<tr>
<td>Pereira 2012 (8)</td>
<td>NR</td>
<td>Max tolerable intensity</td>
<td>Duration: 700µsec</td>
<td>Single freq: 50Hz</td>
<td>Single ratio: 1:2 (4s on, 8s off)</td>
<td>4 electrodes (2 in the suprapubic region and 2 medial to the ischial tuberosity)</td>
<td>20min session, 2x a week, by physiotherapist: 6wks</td>
<td>SUI</td>
</tr>
<tr>
<td>Terlikowski 2013 (9)</td>
<td>NR</td>
<td>NR</td>
<td>200 to 250µsec</td>
<td>Freq range: 10-40Hz</td>
<td>Single ratio: 1:2 (15s on, 30s off)</td>
<td>Single vaginal electrode</td>
<td>20min session, 2x a day, home treatment: 8 weeks</td>
<td>SUI</td>
</tr>
</tbody>
</table>

*abstract only.*

Footnotes: EStim = electrical stimulation, freq= current frequency, PFM = Pelvic floor muscle, PFMC= Pelvic floor muscle contraction, VPFMC= voluntary Pelvic floor muscle contraction


Table 16 Summary of data on EStim vs no active treatment

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Comparator</th>
<th>N randomised</th>
<th>Study population</th>
<th>Duration (months)</th>
<th>Outcome**</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SUI or predominantly SUI</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correia 2014 (1)</td>
<td>ES (31) vs No treatment (17)</td>
<td>48</td>
<td>SUI alone</td>
<td>1.5</td>
<td>Cure: NR Improvement: NR QoL via KHQ Surface ES vs no treatment, N = 32, mean difference 54.45 lower, 95% CI 73.44 to 35.46 lower; Vaginal ES vs no treatment, N = 32, mean difference 56.67 points lower, 95% CI 75.30 to 38.04 lower Adverse effects: NR</td>
</tr>
<tr>
<td>Lopès 2014 (2)</td>
<td>ES (78) vs No treatment (86)</td>
<td>164</td>
<td>SUI or SUI-predominant MUI</td>
<td>6</td>
<td>Cure: NR Self-reported improvement: 63/76 vs 58/85 QoL via ICIQ: N = 161, mean difference in change from baseline 3.10 lower, 95% CI 4.39 to 1.81 lower Adverse effects: reported with no detail</td>
</tr>
<tr>
<td>Pereira 2012 (3)</td>
<td>ES (7) vs No treatment (7)</td>
<td>14</td>
<td>SUI alone</td>
<td>1.5</td>
<td>Cure: NR Improvement: NR QoL via KHQ: N = 14, mean difference 42.95 lower, 95% CI 70.74 to 15.16 lower Adverse effects: no events noted</td>
</tr>
<tr>
<td>Terlikowski 2013 (4)</td>
<td>ES + BF† (68) vs Sham ES + BF† (34)</td>
<td>102</td>
<td>USI alone</td>
<td>2</td>
<td>Self-reported cure: 29/64 vs. 2/29 Self-reported improvement: 41/64 vs 6/29 QoL via I-QoL: N = 93 at 8 weeks (end of treatment), mean difference 22.3 higher, 95% CI 15.52 to 29.08 higher; N = 93 at 16 weeks (8 weeks after treatment), mean difference 30.20 higher, 95% CI 22.18 to 38.22 higher Adverse effects: smarting and discomfort</td>
</tr>
</tbody>
</table>

Note: For modality details or parameters, see Table 14.
NR = not reported; ICIQ = International Consultation of Incontinence Questionnaire (higher scores indicate greater impact on QoL, i.e. a higher score indicates a lower QoL); I-QoL = Incontinence Quality of Life Questionnaire (higher scores indicate higher QoL); KHQ = King’s Health Questionnaire (higher scores indicate greater impairment);

**Source of cure and improvement outcome: women’s self-report was given priority but for studies in which it was not reported, quantification of outcomes based on diaries, pad tests or any other definitions chosen by trialists were used as a proxy.**

† Electromyography-assisted biofeedback


4.2. Treatment

4.2.1 Is EStim Better than No Active Treatment (Placebo, Sham, Control or No Treatment) for Treatment of UI?

Four new studies including 267 women with SUI or predominant SUI (113-116). Participants in one of these studies were women who had responded positively to physiotherapy treatment for their UI (10-15 sessions), with EStim used to maintain the benefit of initial physiotherapy (114). One study (115) was a pilot study for a newly identified study (113).

Characteristics of the new studies comparing EStim with no active treatment are presented in Table 16. No active treatment consisted of no treatment (113, 115), sham EStim (116) or usual care (114). One study was a three-arm trial. Two of the arms using surface and intravaginal EStim (N = 31) were combined and compared with the ‘no treatment’ arm (N = 17) (113).

Quality of data

Three studies reported adequate methods of allocation concealment, namely third party involvement (113, 116) or opaque (and sealed) envelopes with third party involvement (115) in the allocation procedure. One study did not describe methods used for allocation concealment (116). Trial results were reported for everyone who entered the trial in one study (115) but this was not done in the others. One study is funded by the manufacturer of the study stimulator (114).

Results

SUI or predominant SUI. When adding new studies to those previously reported, pooled data suggest that cure rates were, on average, higher for EStim compared with no active treatment but the difference was not statistically significant (N = 434, 22% vs 5%, OR 2.43, 95% CI 0.89 to 6.60) (116-123). Improvement rates were statistically significantly higher for EStim compared with no active treatment (N = 613, 53% vs 30%, OR 3.64, 95% CI 1.82 to 7.27) (114, 116-118, 120-124), although there was some evidence of statistical heterogeneity for the improvement rate (I-squared = 45%). The result of this meta-analysis using additional data from newly identified studies remained similar to the analysis performed in the 5th ICI, except that effect size was larger and confidence interval for cure was wider, and effect size was smaller and confidence interval was narrower for improvement.

Quality of life was reported in seven studies, using diverse measures. Six studies, including 4 new studies, found statistically significant differences favouring EStim compared with no active treatment (113-116, 118, 119), and one previous study found no significant differences between the groups (125). All new studies that reported this outcome favoured EStim: one (114) used the International Consultation on Incontinence Questionnaire (ICIQ), one (116) used the Incontinence Quality of life (I-QoL) questionnaire, and two used the King’s Health Questionnaire (KHQ) (113, 115).

Adverse effects appeared uncommon. One new study reported bleeding in one and discomfort in three of 64 participants using the active EStim device and none of 29 participants in the sham EStim device (116). This is in line with two previous studies that reported tenderness and bleeding (118), and vaginal irritation, pain or infection (123) associated with the device. Another study reported that one participant each in the treatment (N = 78) and control (usual care; N = 86) groups was lost to follow-up due to adverse effects (no further detail was provided) (114).

Summary

A total of 21 studies assessed the effect of EStim compared with no active treatment, including 13 in women with SUI or predominant SUI, three in UUI or predominant UUI, two in all types of UI, and three in DO/OAB (incontinent or no).

Findings from update analysis using the additional data from newly identified studies were broadly similar to those from the 5th ICI. Included studies were generally assessed as having a high risk of bias. EStim might be more effective than no treatment in improving symptoms and quality of life in women with SUI and improving symptoms in women with UUI, although this may not result in cure (Level of Evidence: 2).

Information on quality of life was sparsely reported particularly for UUI or DO, and the limited data that were available were not consistent. Adverse effects appear uncommon but some women experienced discomfort with the treatment device. Scant data were available on long-term performance.

Recommendations

EStim might be better than no treatment to improve symptoms and quality of life in SUI women (Grade of Recommendation: B).

EStim may be considered for treatment to improve symptoms for UUI (Grade of Recommendation: B).

However, this recommendation should be viewed with caution until the findings are supported or refuted in further trials; it would be particularly useful if further trials used validated and reliable quality life measures as a primary outcome indicator particularly for UUI.

4.2.2 Is One Type of EStim Better than Another in the Treatment of UI?

Four new studies including 145 women with SUI and predominant SUI (113, 126-128) were found. The characteristics of the new studies comparing one type of EStim with another are presented in Table 17. Different variants of EStim were assessed, either alone (113, 126, 128) or as an adjunct to PFMT and biofeedback (127).
Table 17 Summary of data on different types of ESTim comparisons

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Comparator</th>
<th>N randomised</th>
<th>Study population</th>
<th>Duration (months)</th>
<th>Outcome**</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUI or predominantly SUI</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alves 2011 (1)</td>
<td>Medium frequency ES vs Low frequency ES (number per group not reported)</td>
<td>24</td>
<td>SUI alone</td>
<td>1.5</td>
<td>Cure based on pad test: 10/10 vs 10/10 Improvement: NR QoL: NR Adverse effects: NR</td>
</tr>
<tr>
<td>Correia 2014 (2)</td>
<td>Surface ES (15) vs Vaginal ES (16)</td>
<td>31</td>
<td>SUI alone</td>
<td>1.5</td>
<td>Cure: NR Improvement: NR QoL via KHQ: N = 30, mean difference 2.22 higher, 95% CI 6.95 lower to 11.39 higher Adverse effects: NR</td>
</tr>
<tr>
<td>Huebner 2011 (3)</td>
<td>Dynamic ES + PFMT + BF† vs Conventional ES + PFMT + BF† (36)</td>
<td>72</td>
<td>SUI or SUI-predominant MUI</td>
<td>3</td>
<td>Cure: NR Improvement: NR QoL via KHQ: N = 61, mean difference in change from baseline 4.10 lower, 95% CI 6.77 to 1.43 lower Adverse effects: allergic reaction to lubricant</td>
</tr>
<tr>
<td>Maher 2009* (4) (ongoing)</td>
<td>External ES vs Vaginal ES (number per group not reported)</td>
<td>18</td>
<td>SUI alone</td>
<td>2 (outcome measured at 1 month)</td>
<td>Cure: NR Improvement: NR QoL: NR Adverse effects: NR</td>
</tr>
</tbody>
</table>

Note: For modality details or parameters, see Table 14.
NR = not reported; KHQ = King's Health Questionnaire (higher scores indicate greater impairment);
* abstract only;
**Source of cure and improvement outcomes: women’s self-report was given priority but for studies in which it was not reported, quantification of outcomes based on diaries, pad tests or any other definitions chosen by trialists was used as a proxy.
† Electromyography-assisted biofeedback

One study comparing external and vaginal EStim for women with SUI, available only as an abstract, did not report any of the specified outcomes and thus did not contribute to the analysis (128). Since there is little duplication of EStim interventions, it was not thought appropriate to combine study findings.

Quality of data

Allocation concealment was adequate in one study which involved a third party in the allocation procedure (113). The other three studies did not mention allocation concealment (126-128). Data were reported only for those who completed the trial in two studies (126, 127) but it was unclear in the other two studies if trial results were reported for everyone who entered the trial (113, 128).

Results

SUI or predominant SUI. One new small study comparing medium and low frequency EStim found no difference for cure rates (126). The results for improvement rates are as reported in two previous studies (129, 130).

While no information was available on quality of life and adverse effects in the 5th ICI, two new studies reported quality of life using the KHQ. The first study comparing ‘dynamic’ EStim (contract pelvic floor muscles, and then add stimulation at maximal contraction) with ‘conventional’ EStim (perform stimulation, rest, and contract pelvic floor muscles) found a statistically significant difference favouring ‘dynamic’ ES, although study authors considered the difference to be small and not clinically important (127). The second study comparing surface and vaginal EStim found no statistically significant difference between the groups (113).

One new study in which EStim was performed as an adjunct to PFMT and biofeedback reported that one of 72 participants had an allergic reaction to biofeedback lubricant and withdrew from the study, although it was unclear in which group these adverse effects occurred (127).

Summary

A total of eight studies assessed the effect of one approach of EStim compared with another, with six in women with SUI and predominant SUI and two in women with DO. No study focusing on UUI or predominant UUI was identified.

Findings from an updated analysis using the additional data from newly identified studies were broadly similar to those from the 5th ICI. Included studies generally had a high risk of bias. There were eight small trials comparing different EStim protocols; the clinical heterogeneity between studies meant it was not appropriate to pool the data.

Based on a single trial (130) for women with SUI, maximal clinic-based stimulation may be more effective than low-intensity home-based stimulation in improving symptoms, although no data were available on cure rates, quality of life and adverse effects (Level of Evidence: 2).

The other studies did not find clinically important differences between stimulation groups for the specified outcomes; the studies were small and may have been underpowered. Further comparisons of EStim protocols are needed.

Recommendations

For women with SUI maximal clinic-based EStim might be better than daily low-intensity home-based EStim in improving symptoms (Grade of Recommendation: B).

There is a need for studies to elucidate the purpose and biological rationale for EStim in different diagnostic groups, so these can then be tested and compared in clinical trials.

4.2.3 Is EStim Better than Other Treatments for UI?

No new study was found that investigated whether EStim is better than other treatments for UI. The level of evidence and recommendations remains unchanged from the previous review (5th ICI) formed on the basis of six studies (124, 131-135).

Summary

The 5th ICI included six studies, including one in women with SUI, one in women with predominant UUI, and four in women with OAB/DO (wet or dry). Included studies were generally assessed as having a high risk of bias. With small numbers per comparison group available, there is insufficient evidence to determine if EStim is better than vaginal oestrogens in women with SUI, propantheline bromide in women with UUI, or oxybutynin and tolterodine for DO (Level of Evidence: 2).

Recommendation

Based on current limited evidence, EStim could be considered as an alternative to medical treatment. Medical treatments (drugs) appear to be no more effective than EStim (Grade of Recommendation: B). These findings need to be investigated further with high quality trials, if it is a clinical question of interest to women.

4.2.4 Does the Addition of EStim to Other Treatments Add Any Benefit in the Treatment of UI?

Three new studies including 52 women including women with SUI and predominant SUI were found (127, 136, 137). The characteristics of these new studies are presented in Table 18. Two studies (136, 137) combined EStim with PFMT (EStim + PFMT vs PFMT), while the other (127) combined EStim with PFMT and biofeedback (EStim + PFMT + BF vs PFMT + BF).
<table>
<thead>
<tr>
<th>Author</th>
<th>Comparator</th>
<th>N randomised</th>
<th>Study population</th>
<th>Duration (months)</th>
<th>Outcome**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jeyaseelan 2003* (1)</td>
<td>ES + PFMT (6?) vs PFMT (7?)</td>
<td>13?</td>
<td>SUI alone</td>
<td>2</td>
<td>Cure: NR</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Improvement: NR</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>QoL via IIQ (% change from baseline): N = 6, median -27%, range -63 to 0, vs. N = 7, median 0%, range -67 to 200</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>QoL via UDI (% change from baseline): N = 6, median -32%, range -50 to -18, vs. N = 7, median 0%, range -43 to 180</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Adverse effects: NR</td>
</tr>
<tr>
<td>Patil 2010 (2)</td>
<td>ES + PFMT (55) vs PFMT (55)</td>
<td>13</td>
<td>USI alone</td>
<td>1</td>
<td>Cure: NR</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Improvement: NR</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>QoL via IIQ: N = 102, mean difference 12.53 lower, 95% CI 19.45 to 5.61 lower</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Adverse effects: NR</td>
</tr>
<tr>
<td>Huebner 2011 (3)</td>
<td>ES + PFMT + BF† (72) vs PFMT + BF† (36)</td>
<td>26</td>
<td>SUI or SUI-predominant MUI</td>
<td>3</td>
<td>Cure: NR</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Improvement: NR</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>QoL via KHQ Dynamic ES+PFMT+BF vs PFMT+BF: N = 55, mean difference in change from baseline 4.60 lower, 95% CI 7.43 to 1.77 lower; Conventional ES+PFMT+BF vs PFMT+BF: N = 60, mean difference in change from baseline 0.50 lower, 95% CI 3.22 lower to 2.22 higher</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Adverse effects: allergic reaction to lubricant</td>
</tr>
</tbody>
</table>

Note: For modality details or parameters, see Table 14.

NR = not reported; IIQ = Incontinence Impact Questionnaire (lower scores indicate better QoL); KHQ = King’s Health Questionnaire (higher scores indicate greater impairment); UDI = Urogenital Distress Inventory (higher scores indicate greater discomfort);

**Source of cure and improvement outcome: women’s self-report was given priority but for studies in which it was not reported, quantification of outcomes based on diaries, pad tests or any other definitions chosen by trialists were used as a proxy.

† Electromyography-assisted biofeedback


One study was a three-arm trial that included both ‘dynamic’ EStim (stimulation added at maximum contraction of pelvic floor muscles) and ‘conventional’ EStim (stimulation followed by rest and pelvic floor muscle contraction) as two of the study arms (127). These arms were combined in the analysis. One study is a pilot study, available only as abstract, with limited information (136).

Quality of data

Allocation concealment was inadequate in one study which used opaque sealed envelopes but with no indication of third party involvement in the allocation procedure (137). The other two studies did not mention allocation concealment (127, 136). In two studies, data were reported only for those who completed the trial (127, 137) and it was unclear in the other study if trial results were reported for everyone who entered the trial (136).

Results

i) EStim + PFMT vs PFMT

SUI or predominant SUI. Two new studies assessing EStim as an adjunct to PFMT compared with PFMT alone, contributed no additional data in terms of cure, improvement and adverse effects. The 5th ICI previous analysis for these outcomes therefore remains unchanged.

Three studies reported data on quality of life with inconsistent results. One previous study found no statistically significant differences between the group (138), whereas one new study using the Incontinence Impact Questionnaire (IIQ) found a statistically significant difference favouring the group which combined EStim with PFMT (137). The results from another new study based on either the IIQ or the Urogenital Distress Inventory were inconclusive, due to the pilot nature of the study and small sample size (N = 13) (136).

ii) EStim + PFMT with biofeedback vs PFMT with biofeedback

SUI. One new study assessed EStim as an adjunct to PFMT and biofeedback compared with PFMT and biofeedback alone. This was a three-arm trial, assessing a combination of either ‘dynamic’ or ‘conventional’ EStim with PFMT and biofeedback, compared with PFMT and biofeedback alone (127).

This study did not provide any data on cure and improvement rates (127). Thus, the 5th ICI analysis of improvement rates based on two studies (129, 130) remains unchanged, with no available information on cure rates.

While no information was available on quality of life and adverse effects for this comparison in the 5th ICI, the new study (127) reported that quality of life scores based on the King’s Health Questionnaire improved statistically significantly for the group which combined ‘dynamic’ EStim with PFMT and biofeedback, compared with PFMT and biofeedback alone, although study authors did not consider the difference to be clinically important. No significant difference was found for the group combining ‘conventional’ EStim with PFMT and biofeedback, compared with PFMT and biofeedback alone.

In the same study (127), one of 72 participants had an allergic reaction to biofeedback lubricant and withdrew from the study, although it was unclear in which group this occurred.

Summary

A total of 15 studies assessed the effect of EStim as an adjunct to another treatment, compared with the other treatment alone. All but two studies included women with SUI or predominant SUI. No study focusing on UUI or predominant UUI was identified.

Findings from update analysis using the additional data from newly identified studies were broadly similar to those from the 5th ICI. For comparisons of EStim with PFMT versus PFMT alone, there was no clear evidence of a difference between the groups in women with SUI or predominantly SUI in terms of cure and improvement. Evidence for quality of life outcomes was not consistent across studies (Level of Evidence: 2). There was also no evidence to suggest that the addition of EStim to a BF-assisted PFMT was more effective than BF-assisted PFMT in women with SUI (Level of Evidence: 2). A few women experienced adverse effects with EStim. There is no evidence to draw any conclusion about the effect of adding EStim to PFMT for women with UUI.

Recommendations

The addition of EStim to PFMT or BF-assisted PFMT programmes does not appear to add benefit (Grade of Recommendation: B); combinations of techniques need to be investigated further with high quality trials if this is a clinical/research question of interest to women.

4.3. Other LUTS

In the 5th ICI, there were no trials that analysed the effect of EStim in women with other LUTS alone. No new published trials were found.

4.4. Factors Affecting Outcome

None of the included trials addressed the effect of age, or any other factor, on outcomes of EStim. There was no clear indication from the included trials that EStim could not be tolerated by elderly. There is no reason, therefore, to either exclude older women from studies of EStim, or not to offer EStim as part of a conservative management programme, except where recognised precaution with use of intra-vaginal electrodes in women with vaginal atrophy and contraindications such as a cardiac pacemaker are present.

One newly identified study including elderly women (over 60 years old) highlighted the potential embarrassment perceived by the elderly with regard to conventional intra-vaginal stimulation and suggested that
surface EStim may be a more acceptable method for this population (115).

Of note, in a prospective cohort of 3,198 women treated with home-managed EStim in Norway during 1992-1994, there was no association between self-reported improvement and age (139). In the same cohort, success rates as defined by clinicians were higher in younger individuals but this effect was not significant after controlling for other factors.

Aside from age, other factors may have the potential to mitigate treatment outcome. On the basis of trial reports to date, it appeared that there was considerable variation in EStim protocols with no consistent pattern emerging. EStim protocols are also often poorly reported, lacking detail of stimulation parameters, devices and methods of delivery. The wide range of protocols that have been tested may have affected the effect EStimates reported in this section. ICS/IUGA has produced a physiotherapy interventions terminology paper in the last year, and authors are encouraged to refer to this paper when reporting EStim parameters in a publication (1).

It is not clear whether one diagnostic group may benefit more than another from EStim. It has been hypothesised that, in women with SUI who cannot voluntarily contract the PFM to begin a PFMT programme, EStim might help initiate or substitute for a voluntary contraction. However, most studies focusing on the efficacy of EStim do use EStim to initiate or substitute for a voluntary PFM contraction (140). To date, there has been no trial addressing this hypothesis.

As with all conservative therapy modalities, one of the key factors to the success or failure of EStim is treatment adherence. Some authors commented on adherence or reported adherence data. Of the new studies identified for this 6th ICI update, one study reported that adherence to EStim was satisfactory (116) and another reported that the EStim regimen was adhered to by over >75% of participants (114). However, adherence measures were highly variable, making comparison across studies difficult.

5. POSTERIOR TIBIAL NERVE STIMULATION (PTNS)

Posterior tibial nerve stimulation (PTNS) is a form of peripheral neurostimulation targeted towards symptom relief of OAB and UUI (141). Indirect access to the sacral plexus is achieved by intermittent, electrical stimulation of the posterior tibial nerve, which lies behind the medial malleolus. PTNS may be minimally invasive, involving insertion of a fine needle close to the nerve (Percutaneous PTNS), or non-invasive, using skin surface electrodes applied to the medial malleolar area (Transcutaneous PTNS)(141).

PTNS aims to stimulate the sacral nerve plexus through the afferent fibres of the posterior tibial nerve, a mixed nerve containing L5-S3 fibres (142). The S3 nerve root contains sensory fibres from the pelvic floor and parasympathetic motor efferent fibres to the detrusor as well as the pelvic sphincters and the pelvic floor muscles. Afferent nerve stimulation can therefore lead to activation of inhibitory sympathetic neurons and suppression of detrusor contraction through a direct sacral route. Urodynamic studies have shown that electrical stimulation of the posterior tibial nerve increases cystometric capacity and suppresses detrusor contraction (143-145). The full mechanism of action of treatment effect for PTNS is not yet understood, however it is thought that the observed effects may be related to a neuroplastic reorganisation of sacral spinal reflexes and regulation of cortical excitability (146, 147).

Percutaneous PTNS is performed as an outpatient procedure. It involves inserting a 34-gauge needle 3–5 cm cephalad to the medial malleolus. The needle is connected to a low-voltage stimulator device, and a grounding pad is placed on the bottom of the foot just below the smallest toe. Transcutaneous PTNS may be delivered either in clinic or self-administered at home. Self-adhesive electrodes are placed behind the medial malleolus and 10cm proximal to this. The positive lead is connected to the proximal electrode and the negative to the distal electrode and both are connected to a portable battery-powered stimulator. The intensity level of the stimulation current for percutaneous PTNS and transcutaneous PTNS is determined once correct positioning has been established by noting sensory and motor (hallux) reaction (Figure 4).

This section presents the evidence for the use of PTNS in the prevention and treatment of UI in women. Since this is a new section for the Conservative Management chapter, the same search strategy as EStim section was used although no date restrictions have been applied to the literature search.

Figure 4 PTNS equipment
### Table 19 Summary of PTNS protocols

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Current</th>
<th>Current Intensity</th>
<th>Pulse Shape &amp; Duration</th>
<th>Frequency (Hz)</th>
<th>Duty Cycle</th>
<th>Electrodes</th>
<th>Treatment Duration</th>
<th>Target UI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bellette 2009 (1)</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>2 months</td>
<td>OAB</td>
</tr>
<tr>
<td>Finazzi-Agrò 2010 (2)</td>
<td>NR</td>
<td>0 – 10 mA; increased until flexion of big toe or fanning of all toes become noticeable</td>
<td>200 microseconds</td>
<td>20 Hz</td>
<td>NR</td>
<td>One surface electrode on the medial aspect of the calcaneous</td>
<td>3 months</td>
<td>UUI</td>
</tr>
<tr>
<td>Manriquez 2013* (3)</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>3 months</td>
<td>OAB</td>
</tr>
<tr>
<td>Marques 2008* (4)</td>
<td>Biphasic</td>
<td>VIF (variation of intensity and frequency)</td>
<td>200 microseconds</td>
<td>10 Hz</td>
<td>NR</td>
<td>Two transcutaneous electrodes</td>
<td>1 month</td>
<td>OAB</td>
</tr>
<tr>
<td>Peters 2010* (5)</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>3 months</td>
<td>OAB</td>
</tr>
<tr>
<td>Preyer 2007* (6)</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>3 months</td>
<td>UUI</td>
</tr>
<tr>
<td>Preyer 2015 (7)</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>3 months</td>
<td>OAB</td>
</tr>
<tr>
<td>Sancaktar 2010 (8)</td>
<td>NR</td>
<td>0.5 – 10Ma; adjusted in accordance to patient’s tolerance</td>
<td>0.2 milliseconds</td>
<td>20 Hz</td>
<td>NR</td>
<td>NR</td>
<td>3 months</td>
<td>OAB</td>
</tr>
<tr>
<td>Schreiner 2010 (9)</td>
<td>Continuou s mode</td>
<td>10 – 50mA; according to sensitivity and hallux mobilisation</td>
<td>200 milliseconds</td>
<td>10 Hz</td>
<td>NR</td>
<td>Negative electrode on medial malleolus and the positive electrode was 10cm proximal to this on the right leg along the nerve path</td>
<td>3 months</td>
<td>UUI</td>
</tr>
<tr>
<td>Souto 2014 (10)</td>
<td>NR</td>
<td>NR</td>
<td>250 microseconds</td>
<td>10 Hz</td>
<td>NR</td>
<td>Negative surface electrode placed behind medial malleolus and positive electrode placed 10cm above it</td>
<td>3 months</td>
<td>OAB</td>
</tr>
<tr>
<td>Author, year</td>
<td>Current</td>
<td>Current Intensity</td>
<td>Pulse Shape &amp; Duration</td>
<td>Frequency (Hz)</td>
<td>Duty Cycle</td>
<td>Electrodes</td>
<td>Treatment Duration</td>
<td>Target UI</td>
</tr>
<tr>
<td>-------------</td>
<td>---------</td>
<td>------------------</td>
<td>-----------------------</td>
<td>---------------</td>
<td>------------</td>
<td>------------</td>
<td>-------------------</td>
<td>----------</td>
</tr>
<tr>
<td>Vecchioli-Scaldazza 2013 (11)</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>1.5 months</td>
<td>OAB</td>
</tr>
</tbody>
</table>

* abstract only.

NR = not reported


<table>
<thead>
<tr>
<th>Author, year</th>
<th>Intervention</th>
<th>N randomised</th>
<th>Study population</th>
<th>Duration (months)</th>
<th>Outcome**</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>UUI</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Finazzi-Agrò 2010 (1)</td>
<td>Percutaneous PTNS (18) vs Sham percutaneous PTNS (17)</td>
<td>35</td>
<td>UUI</td>
<td>3</td>
<td>Cure: NR Improvement based on diary: 12/17 vs. 0/15 QoL via I-QoL (mean): N = 17, change from pre 69.6 to post 81.3, p = 0.025 vs. N = 15, change from pre 69.5 to post 70.6, p = 0.619 Adverse effects: no serious events</td>
</tr>
<tr>
<td></td>
<td><strong>DO/OAB</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bellette 2009† (2)</td>
<td>Transcutaneous PTNS (21) vs Sham transcutaneous PTNS (16)</td>
<td>37</td>
<td>OAB</td>
<td>2</td>
<td>Not available†</td>
</tr>
<tr>
<td>Marques 2008* (3)</td>
<td>Transcutaneous PTNS vs Sham transcutaneous PTNS (number per group not reported)</td>
<td>43</td>
<td>OAB (some had SUI and UUI)</td>
<td>1</td>
<td>Cure: NR Improvement: NR QoL: NR Adverse effects: NR</td>
</tr>
</tbody>
</table>

Note: For modality details or parameters, see Table 19.

NR = Not reported; I-QoL = Incontinence Quality of Life Questionnaire (higher scores indicate higher QoL); OAB-q = Overactive Bladder Questionnaire (higher scores indicating worse condition);

* abstract only

**Source of cure and improvement outcome: women’s self-report was given priority but for studies in which it was not reported, quantification of outcomes based on diaries, pad tests or any other definitions chosen by trialists were used as a proxy.

† Publication in Spanish with English abstract. English translation of the main text was not available at the time of writing.


Questions addressed are:
- Is PTNS effective in the prevention of UI?
- Is PTNS better than no active treatment (placebo, sham, control or no treatment) for treatment of UI?
- Is one type of PTNS better than another in the treatment of UI?
- Is PTNS better than other treatments in the treatment of UI?
- Does the addition of PTNS to other treatments add any benefit in the treatment of UI?
- What is the effect of PTNS on other LUTS?
- What factors might affect the outcome of PTNS in the treatment of UI?

Eligible interventions were PTNS/neurostimulation/neuromodulation, percutaneous or transcutaneous. Eligibility criteria for study participants and outcomes, as well as criteria used to assess ‘risk of bias’ in the included studies, were identical to those used in the previous section on EStim (Section II.4).

Description of intervention in included studies of PTNS

A total of 11 studies were eligible and are summarised in Table 19 (148-158).

5.1. Prevention

No studies that investigated either primary or secondary prevention of UI or LUTS were identified.

5.2. Treatment

5.2.1 Is PTNS Better than No Active Treatment (Placebo, Sham, Control or No Treatment) for Treatment of UI?

Three studies compared PTNS with no active treatment (Table 20) (148, 149, 151). One study included women with UUI (149) and two included women with OAB where some but not all participants had UI. No study focusing on SUI or predominant SUI was found.

A placebo or a sham procedure was employed as a comparator in all three studies. In two studies, the sham procedure was described as having electrodes placed without turning on the electrical generator (148, 151). In another study (149), the electrical generator was turned on only for a few seconds to allow the patient to experience a mild sensation; prior to treatment, patients in both groups had been counselled that the subsequent absence of the sensation was due to adaptation. The choice of a different needle position in the sham group was to eliminate any presumed response that could arise from the acupuncture effect from piercing the skin cephalad to the medial malleolus (149).

Quality of data

One study described using a computer generated randomisation list (149); other studies did not report randomisation techniques (148, 151). No study reported information on allocation concealment. Results were reported for everyone who entered the trial in one study (148), and another study reported 5% attrition rate from PTNS group and 13% from the sham group and that the reasons for drop out from each group were unrelated to the treatment (149), however it was unclear whether the other study had missing data (151).

Results

(a) UUI. No included studies reported information on cure rates. One study (149) reported that improvement rates were significantly higher for PTNS compared with no active treatment (reported p value <0.001). I-Qol scores found a significant difference between the groups which was due to a lack of significant change after the sham procedure and to the significant increase (improved quality of life) after PTNS (149). No serious adverse effects were reported in either group but patients in both groups reported occasional transient pain at the stimulation site (149).

(b) DO/OAB. There was no information on cure rates.

Summary

The three included studies were small (35-43 participants). All were generally assessed as having a high risk of bias. Data pooling was not possible. Data available from two studies on women with UUI or OAB suggests PTNS may be more effective than no active treatment in improving symptoms and quality of life, although no data were available on cure (Level of Evidence: 2). The included studies reported no serious adverse effects associated with either active or sham treatment (Level of Evidence: 2). No evidence was available for women with SUI or predominant SUI.

Recommendations

For women with UUI or OAB, PTNS may be more effective than no active treatment in symptom control (Grade of Recommendation: C New).

More studies with larger sample sizes and consistent and clear reporting of core outcomes would be beneficial in reaching a conclusion on the effectiveness of PTNS over no active treatment.

5.2.2 Is One Type of PTNS Better than Another in the Treatment of UI?

No study was found for this comparison.

5.2.3 Is PTNS Better than Other Treatments for Treatment of UI?

Five studies compared PTNS with drug treatment (Table 21).
### Table 21 Summary of data on PTNS vs other treatments

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Comparator</th>
<th>N randomised</th>
<th>Study population</th>
<th>Duration (months)</th>
<th>Source of outcome**</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>UUI</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preyer 2007* (1)</td>
<td>Percutaneous PTNS (16) vs Tolterodine (15)</td>
<td>31</td>
<td>UUI</td>
<td>3</td>
<td>Cure: NR Improvement: NR QoL via unspecified tool (higher scores indicate improvement): mean 4.4 higher, 95% CI 1.7 to 7.1 higher vs mean 4.6 higher, 95% CI 2.1 to 7.0 higher, reported p value = 0.93 Adverse effects: unspecified events noted</td>
</tr>
<tr>
<td><strong>DO/OAB</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manriquez 2013* (2)</td>
<td>Transcutaneous PTNS vs Oxybutynin (number per group not reported)</td>
<td>56</td>
<td>OAB</td>
<td>3</td>
<td>Cure: NR Improvement: NR QoL via OAB-q: no significant difference, no data Adverse effects: NR</td>
</tr>
<tr>
<td>Preyer 2015 (3)</td>
<td>Percutaneous PTNS (18) vs Tolterodine (18)</td>
<td>36</td>
<td>OAB (wet or dry)</td>
<td>3</td>
<td>Cure: NR Improvement: NR QoL via VAS, change from baseline, median [range]: N = 18, 1.9 [0 to 8] vs N = 18, 2.7 [0 to 8.5], reported p-value = 0.07 Adverse effects: pain, dry mouth, dizziness</td>
</tr>
<tr>
<td>Souto 2014 (4)</td>
<td>Transcutaneous PTNS (25) vs Oxybutynin (25)</td>
<td>50</td>
<td>OAB</td>
<td>3</td>
<td>Cure: NR Improvement: NR QoL via ICIQ-SF, mean [range]: 7.2 [0 to 18] vs 9.8 [0 to 18] at 3 months (treatment end), 8.3 [0 to 20] vs 13.3 [8 to 20] at 6 months (i.e. 3 month after treatment) QoL via ICIQ-OAB, mean [range]: 5.9 [1 to 11] vs 4.6 [0 to 10] at 3 months, 6.1 [1 to 20] vs 9.2 [4 to 13] at 6 months Adverse effects: NR</td>
</tr>
<tr>
<td>Vecchioli-Scaldazza 2013† (5)</td>
<td>Percutaneous PTNS (20) vs Solifenacin Succinate (SS) (20)</td>
<td>40</td>
<td>OAB (some had UUI)</td>
<td>1.5</td>
<td>Cure: NR Improvement: NR QoL via PGI-I (Wilcoxon test for paired sample, mean, SD): Group A (SS→PTNS): post SS 2.9 (1.1), post PTNS 2.1 (0.7); Group B (PTNS→SS): post SS 3.1 (1.0), post PTNS 2.3 (0.7) QoL via OAB-q: significant improvement in all groups both with SS and PTNS Adverse effects: NR</td>
</tr>
</tbody>
</table>

Note: For modality details or parameters, see Table 19.

NR = not reported; ICIQ-SF = International Consultation on Incontinence-Short Form (higher scores indicate increased severity); ICIQ-OAB = International Consultation on Incontinence-OAB (higher scores indicate increased severity); OAB-q = Overactive Bladder Questionnaire (higher scores indicating worse condition); PGI-I = Patient Global Impression of Improvement Questionnaire (lower scores indicate greater improvement); VAS = Global response assessment on visual analogue scale (higher scores indicate greater impact on QoL);

* abstract only

**Source of outcome: women's self-report was given priority but for studies in which it was not reported, quantification of outcomes based on diaries, pad tests or any other definitions chosen by trialists was used as a proxy.
PTNS was compared with solifenacin succinate in one (158), tolterodine in two (153, 154) and oxybutynin in two (150, 157). The target population had OAB (with UI in some but not all of the participants) except for one study (153) where it was UUI. No study focusing on SUI or predominant SUI was found. One study used a cross-over design (158). Another study was a three-arm trial comparing PTNS versus oxybutynin versus PTNS and oxybutynin; only the findings for PTNS vs oxybutynin are reported here (157).

Quality of data

One study described using a computer generated sequence using adaptive randomisation, where allocation was centralised using telephone (154). Permuted blocks were used in one study but it was unclear whether there was allocation concealment (150). Other studies did not report such information on allocation concealment nor provided details on the randomisation process (153, 157, 158). In one study there was a dropout rate of 11% in both groups (154). In another study (158), a two-arm crossover trial of PTNS and Solifenacin where group A had Solifenacin then PTNS after a washout period and group B had PTNS then Solifenacin, there was a dropout rate of 30% from the group A and 20% from group B; the reasons were refusal of further treatment (10% vs 5%), no indication for starting treatment (10% vs 15%). A further 10% dropped out from group A as a result of adverse effects of treatment. Twenty-six percent of participants were excluded from analysis in one study (157) because they failed to comply with 12 weeks of treatment and/or did not attend follow up at six months; the reasons for non-compliance or missing data were not reported. In one study (150), it was unclear whether results were reported for everyone who entered the trial, while in another (153) the authors did not account for all drop-outs.

Results

(a) UUI. There was no information on cure and improvement (153). Quality of life outcomes, measured using an unspecified tool, improved in both groups, although there was no statistically significant difference between them (153). One study reported unspecified adverse events in one of 16 participants and six of 15 participants in the PTNS and Tolterodine groups respectively; authors did not specify the nature of these adverse events (153).

(b) OAB. Data on cure or improvement were not reported. Quality of life outcomes were reported in four studies. Three of these found no significant difference between the groups, based on the Overactive Bladder Questionnaire in one study (150), OAB-q and the Patient Global Impression of Improvement (PGI-I) in another (158) and a visual analogue scale in the third (154). One study using ICIQ-SF and ICIQ-OAB reported that post-treatment scores decreased (indicating symptom reduction) in both groups at 12 weeks of treatment, although the score increased (indicating symptoms worsened) significantly for the oxybutynin group in contrast to the PTNS group. The PTNS group maintained their scores at 6 months follow-up (12 weeks after the cessation of treatment) (157). One study reported that adverse events were observed in three of 18 (17%) participants in the PTNS group (mainly pain at the puncture site) and nine of 18 (50%) participants in the tolterodine group (mainly dry mouth and dizziness) (154).
Summary

Five studies were included. These were small (36-56 participants) and generally assessed as having a high risk of bias. There were limited and widely heterogeneous data. Two studies (one for UUI, one for OAB) reported that quality of life improved over time for both PTNS and drug treatment groups with no significant difference between them, while two other studies (for OAB) found no significant difference in quality of life between PTNS and drug treatment post-intervention (Level of Evidence: 2). However, one study on women with OAB found that the improvement in quality of life was longer lasting following the cessation of treatment with PTNS than after tolterodine (Level of Evidence: 2). Data available from two studies on women with UUI or OAB suggests that PTNS is associated with a lower rate of adverse events than tolterodine and when they occurred, there were not as bothersome as those associated with tolterodine (Level of Evidence: 2). No evidence was available for women with SUI or predominant SUI.

Recommendations

There is no significant difference between PTNS and tolterodine in terms of quality of life, however PTNS may be considered as both may improve quality of life (Grade of Recommendation: B New).

PTNS may considered for women as it is associated with fewer and less bothersome adverse effects than those from drug treatment (Grade of Recommendation: B New).

Recommendations

More randomised controlled trials with large sample sizes and clear and consistent reporting of core outcome data would be beneficial in reaching a firm conclusion on the effectiveness of PTNS over other treatments.

5.2.4 Does the Addition of PTNS to Other Treatments Add Any Benefit in the Treatment of UI?

Three studies assessed the effect of PTNS as an adjunct to another treatment, compared with the other treatment alone or with PTNS alone (Table 22). One study included women with UUI (reported as OAB incontinent) and combined PTNS with PFMT and bladder training (PTNS plus PFMT plus bladder training vs PFMT plus bladder training) (156). Two other studies included women with OAB (where some but not all participants had UI) and combined PTNS with a drug. One study combined PTNS using the Stoller afferent neuro-stimulation (SANS) protocol with Tolterodine (PTNS plus Tolterodine vs Tolterodine) (155). The other study was a three-arm trial of PTNS versus Oxybutynin versus PTNS plus Oxybutynin; only the findings for PTNS plus Oxybutynin versus Oxybutynin are reported here (157). No study focusing on SUI or predominant SUI was found.

Quality of data

All studies reported adequate methods of randomisation, including the use of a list of random numbers (155), simple random number generator (156) and online randomisation (157). Allocation concealment was not mentioned in any of the study reports. In one study, there was 10% missing data from the group who had tolterodine alone, while there were no missing data in the combination therapy group (155). In another study, there was 5% missing data from the PTNS group only; the reported reason for the attrition was due to health problems unrelated to therapy (156). In the third study, 24% dropped out of the oxybutynin group while 16% were excluded from the analysis in the combination therapy group. The reasons patients failed to complete the trial were not reported and it is unclear whether they were related to treatment (157).

Results

(a) UUI. No information was available on cure rates. One study reported that improvement rates were statistically significantly higher for the group combining PTNS with PFMT and bladder training compared with PFMT and bladder training alone (156). None of the participants reported significant adverse effects (156). ICIQ-SF scores improved for both groups but the combination treatment group had a significantly greater improvement (156). Similar results were found for KHQ; the combination treatment group showed a significantly greater improvement (156).

(b) OAB. No information was available on cure and improvement. Two studies reported quality of life outcomes. One study using the short form of Incontinence Impact Questionnaire (IIQ-7) reported that post-treatment scores decreased (indicating less impact of UI on daily living) in both groups but this decrease in the group combining PTNS and drug was greater that the group using drug alone (155). Another study reported that ICIQ-SF scores decreased (indicating symptom reduction) in both groups at 12 weeks of treatment, although the score increased (indicating symptoms worsened) significantly for the group using drug alone compared with the group combining PTNS and drug at 6 month follow-up (157). ICIQ-OAB results from the same study found that the combination treatment group had a greater improvement in OAB symptoms compared with the group using drug alone at 12 weeks of treatment; ICIQ-OAB scores increased (worsening in symptoms) for the group using drug alone in contrast to the other group that maintained their scores at 6-month follow-up (157). No information was available on cure and improvement.
<table>
<thead>
<tr>
<th>Author, year</th>
<th>Comparator</th>
<th>N randomised</th>
<th>Study population</th>
<th>Duration (months)</th>
<th>Outcome**</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>UUI</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Schreiner 2010 (1) | Transcutaneous PTNS + PFMT + bladder training (26) vs PFMT + bladder training (26) | 52 | UUI | 3 | Cure: NR
Improvement based on diary: 19/25 vs 7/26
QoL via ICIQ-SF, change from baseline, mean (SD): 7.2 (4.3) vs. 2.6 (3.3), reported p-value <0.001
QoL via KHQ: reported p-value <0.05 favouring the combination treatment group; no data
Adverse effects: no events noted |
| **OAB**     |            |              |                  |                  |           |
| Sancaktar 2010 (2) | SANS (Percutaneous) + Tolterodine (20) vs Tolterodine (20) | 40 | OAB (some had UUI) | 3 | Cure: NR
Improvement: NR
QoL via IIQ-7, mean (SD): SANS + Tolterodine, change from pre 19.0 (2.0) to post 9.0 (0.8), p <0.001;
Tolterodine, change from pre 18.1 (2.5) to post 11.2 (2.7), p <0.001
Adverse effects: dry mouth, constipation, headache, local irritation of puncture site |
| Souto 2014 (3) | TENS (Transcutaneous) + Oxybutynin (25) vs Oxybutynin (25) | 50 | OAB | 3 | Cure: NR
Improvement: NR
QoL via ICIQ-SF, mean [range]: 7.9 [0 to 14] vs 9.8 [0 to 18] at 3 months (treatment end), 7.4 [0 to 14] vs 13.3 [8 to 20] at 6 months (i.e. 3 month after treatment)
QoL via ICIQ-OAB, mean [range]: 2.9 [0 to 5] vs 4.6 [0 to 10] at 3 months, 3.0 [0 to 5] vs 9.2 [4 to 13] at 6 months
Adverse effects: NR |

Note: For modality details or parameters, see Table 19.
NR = not reported; ICIQ-SF = International Consultation on Incontinence-Short Form (higher scores indicate increased severity); ICIQ-OAB = International Consultation on Incontinence-OAB (higher scores indicate increased severity); IIQ-7 = short form of Incontinence Impact Questionnaire (lower scores indicate better QoL); KHQ = King’s Health Questionnaire (higher scores indicate greater impairment);
SANS = Stoller Afferent Nerve Stimulation of the posterior tibial nerve;
TENS = Transcutaneous Electrical Nerve Stimulation of the posterior tibial nerve;
TTNS = Transcutaneous Tibial Nerve Stimulation;
**Source of cure and improvement outcome: women’s self-report was given priority but for studies in which it was not reported, quantification of outcomes based on diaries, pad tests or any other definitions chosen by trialists was used as a proxy.

Adverse events were reported by one study comparing PTNS plus tolterodine with tolterodine alone (155). In this study, severe dry mouth, severe constipation, headache and local irritation at puncture site were reported in both treatment groups, and skin irritation for the group using PTNS. Two of 18 participants (11%) experienced more than one adverse event in the tolterodine group compared with one of 20 participants (5%) in the group combining PTNS with tolterodine.

Summary

Three small studies were included (40-52 participants). The included studies were assessed as having a high risk of bias. No data were available on cure and improvement rates for this comparison. Data from one study suggests that the addition of PTNS to PFMT and bladder training was more effective in improving symptoms and quality of life than PFMT and bladder training alone in women with UUI (Level of Evidence: 2).

Data from two studies suggest that adding PTNS to drug treatment resulted in a greater improvement in quality of life than the drug treatment alone in women with OAB, and this effect was sustained for a longer term (6 months) for the treatment with PTNS than the treatment without PTNS (Level of Evidence: 2). Adverse events appear uncommon for either group in the same study. No evidence was available for women with SUI or predominant SUI.

Recommendations

PTNS may be considered for symptom control when chosen in combination interventions by women with UUI or OAB (Grade of Recommendation: B New).

This recommendation should be viewed with caution until these findings are supported or refuted in further trials.

5.3. Other LUTS

No trials were identified that analysed the effect of PTNS in women with other LUTS alone, e.g. frequency of voiding, urgency and/or nocturia.

5.4. Factors Affecting Outcome

The included studies did not address the effect of factors that could potentially affect the response to treatment with PTNS. A greater discussion of the factors that affect outcome is provided in the section on urinary incontinence in men and women (see section V.1.4).

6. MAGNETIC STIMULATION (MSTIM)

MStim has been developed for “non-invasive” stimulation of both central and peripheral nervous systems (159). MStim for the treatment of UI was reported for the first time in 1999 by Galloway (160). In contrast to EStim, extracorporeal magnetic innervation (more commonly called magnetic stimulation) stimulates the PFM and sacral nerve roots without insertion of an anal or vaginal probe (161). For treatment, the individual is positioned in a chair. Within the seat is a magnetic field generator (therapy head) that is powered and controlled by an external power unit (Figure 5). A concentrated steep gradient magnetic field is directed vertically through the seat of the chair. When seated, the individual’s perineum is centred in the middle of the seat, which places the PFM and sphincters directly on the primary axis of the pulsing magnetic field (Figure 6). Because of their anatomical location, it is thought that all tissues of the perineum can be penetrated by the magnetic field. According to Galloway (1999) no electricity, but only magnetic flux enters the body from the device. Goldberg (2000) has suggested that, in contrast to electrical current, the conduction of magnetic energy is unaffected by tissue impedance, creating a theoretical advantage in its
clinical application compared to EStim. Conventional magnetic stimulators deliver, at frequencies of 10 to 50 Hz, repetitive pulses of current lasting less than 100 µsec (161) and 275 µsec (160) in duration. Size and strength of the magnetic field is determined by adjustments of this amplitude by the therapist (160).

Possible advantages of MStim are that it is performed through clothing, needs no probes, skin preparation, or contact with the skin surface. On the other hand, the need for repeated clinic based treatment sessions is a potential disadvantage. In contrast to EStim, MStim lacks portability, although a study by But in 2003 (162) reported the development of a portable small electromagnetic device (Pulsegen) for home use that fit into the underwear and was designed for continuous use for up to 8 weeks.

The mechanism of action of MStim is not fully understood (163). Some authors have suggested that in SUI stimulation of the PFM causes external sphincter contraction (164), acts as a passive PFMT exercise (165), and increases maximal urethral closure pressure (162). In UUI, MStim might suppress DO through activation of pudendal nerve afferents blocking parasymptomatic detrusor motor fibres at the spinal reflex arc, activation of inhibitory hypogastric sympathetic neurons, or a combination of both mechanisms (166). Stimulation of sympathetic fibres maintaining smooth muscle tone within the intrinsic urethral sphincter and modulation of pudendal nerve afferent branches stimulating an inhibitory spinal reflex at the S3 nerve root, are also suggested to play a role in this mechanism of action (166).

In this section the evidence is considered for the use of MStim for the prevention and treatment of UI in women. Questions addressed are:

- Is MStim effective in the prevention of UI?
- Is MStim better than no active treatment (placebo, sham, control or no treatment) for the treatment of UI?
- Is one type of MStim better than another in the treatment of UI?
- Is MStim better than other treatments in the treatment of UI?
- Does the addition of MStim to other treatments add any benefit in the treatment of UI?
- What is the effect of MStim on other LUTS?
- What factors might affect the outcome of MStim in the treatment of UI?

Eligible interventions were non-invasive magnetic stimulations. Eligibility criteria for study participants and outcomes, as well as criteria used to assess ‘risk of bias’ in the included studies, were identical to those described in the previous sections on EStim and PTNS (Sections II.4 and II.5).

**Description of intervention**

In addition to eleven studies included in the 5th ICI, two new trials were identified for this update. The number of included studies by dominant type or pattern of incontinence is summarised in Table 23. Table 24 illustrates the intervention characteristics of the two new trials.

6.1. **Prevention**

In the last ICI chapter, there were no trials on prevention of UI or LUTS. No new published trials were found.

6.2. **Treatment**

6.2.1 Is MStim Better Than no Active Treatment (Placebo, Control or no Treatment)?

Two new studies including 162 women were identified (167, 168). In one study the majority of female participants had SUI (refractory to first-line management) (167). The other study included all types of UI (168).

Characteristics of the two new studies comparing magnetic stimulation with no active treatment are presented in Table 25. In both studies the no active treatment consisted of sham treatment. One study assessed the efficacy of a magnetic stimulator developed for home use (168), whereas in the other study treatment was provided in the outpatient clinic setting (167). Since there was little duplication of MStim interventions, or sample populations, in the eleven trials, it was inappropriate to combine study findings.

**Quality of data**

Allocation concealment was considered to be adequate in one study that used an independent research assistant in the randomisation process (168). The other study did not describe methods used for allocation concealment (167). In both studies, data were reported only for those participants who completed the study (167, 168). In particular, in the study by Wallis (2012), 19% (12/62) of participants from the intervention group and 15% (9/60) in the control group withdrew from the study (168).

**Results**

i) SUI. No additional data on cure and improvement were available for this update. The results for cure and improvement rates are as reported in two previous studies (169, 170).

Information on quality of life was provided in three studies, including one new study (167), but the results were not consistent. Two previously reported studies found no significant differences between the groups (169, 170), whereas the new study reported better quality of life at 18 weeks after active treatment compared with sham treatment, based on the Urge-Urinary Distress Inventory and the Overactive Bladder Questionnaire (167).
### Table 23 Studies of MStim included in the previous review (5th ICI) and current update (6th ICI)

<table>
<thead>
<tr>
<th>Study Description</th>
<th>Studies included in the previous review (5th ICI)</th>
<th>New studies identified in this update (6th ICI)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>MStim vs No active treatment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SUI or predominant SUI</td>
<td>3</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>UUI or predominant UUI</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>MUI</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>UI all types</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>DO/OAB (wet or dry)</td>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>One type of MStim vs another</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SUI or predominant SUI</td>
<td>0</td>
<td>No study found</td>
<td>0</td>
</tr>
<tr>
<td>UUI or predominant UUI</td>
<td>0</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>UI all types</td>
<td>1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>MStim vs other treatment</td>
<td>No study found</td>
<td>No study found</td>
<td>0</td>
</tr>
<tr>
<td>MStim+PFMT vs PFMT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SUI or predominant SUI</td>
<td>1</td>
<td>No study found</td>
<td>1</td>
</tr>
<tr>
<td>UUI or predominant UUI</td>
<td>0</td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>

### Table 24 Summary of data on MStim

<table>
<thead>
<tr>
<th>Study</th>
<th>Intervention description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tsai 2014 (1)</td>
<td>A Magstim Rapid2 with a 70-mm figure-8 coil. Treatment administered over the bilateral third sacral roots, with the maximal tolerable intensity, which was typically 70% to 80% of the maximal stimulator output, for 20 minutes each day for 12 consecutive weekdays. The stimulation frequency and the stimulation-on time and -off time were fixed at 5Hz, 10 seconds, and 20 seconds, respectively.</td>
</tr>
<tr>
<td>Wallis 2012 (2)</td>
<td>A commercially available undergarment incorporating 15 static magnets of 800-1200 Gauss arranged anterior, posterior, and inferior to the pelvis. Women were asked to wear it for a minimum of 6 consecutive hours during the day and at least 6 hours overnight for 3 months.</td>
</tr>
</tbody>
</table>


Two studies (one new) reported no adverse effects (167, 169).

i) All types of UI. One new study that provided stimulation using an undergarment with embedded magnets reported that improvement rates were statistically significantly higher for active compared with no treatment, although the result did not hold in sensitivity analysis (168). No information was available regarding cure rates.

With respect to quality of life measures, no statistically significant difference was found based on the Bristol Female Lower Urinary Tract Symptoms (BFLUTS) questionnaire (168).

In the same study, participants reported problems with comfort and wearability of the garment, which were considered by study authors to have contributed to a relatively high attrition rate of 20%. Commonly cited problems include the attraction to metal objects; embedded magnets sticking to each other and making it difficult to put on; and also the garment being bulky and very warm to wear, especially in the subtropical climate of the study area (168).

### Summary

A total of 11 studies assessed the effect of MStim compared with no active treatment, including four focusing on SUI or predominant SUI, one on UUI, one on MUI, two on all types of UI, and three on OAB/DO (where only some but not all had UI).

Findings, using the additional data from newly identified studies were broadly similar to those in the 5th ICI.

For women with SUI, MStim might be more effective than sham in improving (not necessarily curing) symptoms (Level of Evidence: 2).

Data from two small trials of MStim (12 and 6 sessions) examining the effect on quality of life were conflicting (Level of Evidence: 2).

For women with UUI, evidence from a small trial (171) suggests that active MStim might result in better quality of life than sham (Level of Evidence: 2), although there is some uncertainty surrounding this, as data was limited and no statistical test was performed.
Active MStim was associated with higher cure rates than sham in a small trial (172) with women with MUI (Level of Evidence: 2), and also higher cure and improvement rates in another small trial (162) with women with all types of UI (Level of Evidence: 2) but no such difference was observed for women with DO (wet or dry) (Level of Evidence: 2). In general, adverse effects appear uncommon.

**Recommendations**

No recommendation is possible based on current conflicting evidence (Grade of recommendation D).

### 6.2.2 Is One Approach to MStim Better than Another?

No new study comparing one approach of MStim with another was found for this update. The level of evidence and recommendations remains unchanged from the 5th ICI.

**Summary and Recommendation**

The 5th ICI included one study with women presenting UI symptoms (173). There is insufficient evidence to determine if one type of MStim is better than another (Level of Evidence: 2). No recommendation is possible (Grade of Recommendation: D).

### 6.2.3 Is MStim Better than Other Treatments?

There were no trials for this comparison in the 5th ICI chapter. No new published trials were found for this update.

### 6.2.4 Does the Addition of MStim to Other Treatments Add Any Benefit in the Treatment of UI?

No new study was found investigating the effect of adding MStim to other treatments compared with the other treatments alone. The level of evidence and recommendations remains unchanged.

**Summary and Recommendation**

The previous 5th ICI included one study in women with SUI (174). The addition of MStim to PFMT does not appear to be beneficial (Level of Evidence: 2).

Adding MStim to PFMT does not appear to be beneficial (Grade of Recommendation: C). This hypothesis needs to be investigated further with high quality trials, if it is a clinical question of interest to women.

### 6.3 Other LUTS

No trials were identified that analysed the effect of MStim in women with other LUTS alone, i.e., frequency of voiding, urgency and/or nocturia.

### 6.4 Factors Affecting Outcome

None of the included trials addressed the effect of age, or any other factor, on outcome of MStim. In one early prospective multi-centre study, factors predicting success of MStim were included (160). Treatment success was associated with no prior hysterectomy, no prior anti-incontinence operations, UI symptoms for fewer than 10 years, and no use of medications known to cause UI. Brodak has suggested that detrusor response to MStim might be better in ‘thin’ individuals (presumably due to a shorter distance between the stimulating coil and the sacral nerve roots) and at low bladder volumes (175). Overall, little is known about the factors affecting the outcome of MStim.

### 7. SCHEDULED VOIDING REGIMENS

**Scheduled voiding regimens**

This section examines the evidence on use of scheduled voiding regimens in cognitively intact, non-institutionalized women with UUI, SUI, and MUI and provides recommendations for their use in clinical practice. A summary of the search strategy and inclusion/exclusion criteria for selecting studies for review is provided (see section I). The chapters on the Frail Elderly and Neurogenic Incontinence provide detailed review of scheduled voiding regimens that are used in those with cognitive impairment, or UI secondary to central nervous system or spinal cord disease (see chapter 11).

**Types of Scheduled Voiding Regimens**

Bladder training is a broad term often used to describe any type of a scheduled toileting intervention. This has created conceptual confusion in interpreting research reports where few details are provided other than the statement that bladder training was used. The types of scheduled voiding regimens can be categorised as: bladder training, timed voiding, habit training, and prompted voiding (176). Although these regimens share a common feature of a toileting schedule, they differ on the basis of adjustments to the voiding schedule, the active or passive involvement of the patient, the nature of patient education including the teaching of strategies to control urgency and prevent stress leakage, the use of reinforcement techniques, and the nature of the interactions between clinicians and patients. In practice, however, scheduled voiding regimens may share aspects of one or more of these features.
### Table 25 Summary of data on MStim vs no active treatment

<table>
<thead>
<tr>
<th>Author</th>
<th>Comparator</th>
<th>N randomised</th>
<th>Study population</th>
<th>Duration (months)</th>
<th>Outcome**</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Predominantly SUI</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tsai 2014 (1)</td>
<td>MStim (20) vs Sham MStim (20)</td>
<td>40</td>
<td>&gt;50% of study sample had SUI alone</td>
<td>outcome measured at 4.5 months</td>
<td>Cure: NR Improvement: NR QoL: OQB-q: N = 30, mean difference 23.80 lower, 95% CI 36.28 to 11.32 lower QoL via Urge-UDI: N = 30, mean difference 1.80 lower, 95% CI 2.64 to 0.96 lower Adverse effects: no events observed</td>
</tr>
<tr>
<td>All types of UI</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wallis 2012 (2)</td>
<td>MStim (62) vs Sham MStim (60)</td>
<td>122</td>
<td>SUI, UUI or MUI</td>
<td>3</td>
<td>Cure: NR Self-reported improvement: 26/46 vs 18/50 QoL via BFLUTS (median change in score, IQR): UI symptoms, N = 101, 1.5 (3.0) vs 1.5 (3.0), p = 0.80; Sexual function, N = 101, 0 (0.75) vs 0 (0), p = 0.80; Quality of life, N = 101, 1.0 (5.0) vs 0 (5.0), p = 0.28 Adverse effects: discomfort of the garment</td>
</tr>
</tbody>
</table>

Note: For modality details or parameters, see Table 24.

NR = not reported; BFLUTS = Bristol Female Lower Urinary Tract Symptoms (higher scores indicate more severe complaints); OAB-q = Overactive Bladder Questionnaire (higher scores indicating worse condition); Urge-UDI = Urge-Urinary Distress Inventory (higher scores indicate worse condition);

**Source of cure and improvement outcome: women’s self-report was given priority but for studies in which it was not reported, quantification of outcomes based on diaries, pad tests or any other definitions chosen by trialists was used as a proxy.


### Bladder training

Bladder training (also referred to as bladder drill, bladder discipline, bladder re-education, and bladder retraining) involves a programme of patient education along with a scheduled voiding regimen with gradually progressive voiding intervals. Specific goals of bladder training are to correct faulty habit patterns of frequent urination (if present), improve control over bladder urgency, prolong voiding intervals, increase bladder capacity, reduce incontinent episodes, and restore patient confidence in controlling bladder function. The underlying mechanism of how bladder training achieves its effect is poorly understood. Several hypotheses have been proposed including improved cortical inhibition over detrusor contractions; improved cortical facilitation over urethral closure during bladder filling; improved central modulation of afferent sensory impulses; altered behaviour resulting from better individual awareness of the lower urinary tract function and circumstances that cause UI, and increasing the “reserve capacity” of the lower urinary tract system (177-179).

### Timed voiding

Timed voiding is a fixed voiding schedule that remains unchanged over the course of treatment (176). The goal is to prevent UI by providing regular opportunities for bladder emptying prior to exceeding bladder capacity. Timed voiding has been recommended for patients who cannot participate in independent toileting (180). It also has applicability for use in outpatient settings with incontinent women who have infrequent or irregular voiding patterns (181) and men who are independent in their voiding function (182).

### Habit training

Habit training is a toileting schedule matched to the individual’s voiding pattern based on their voiding diary. The toileting schedule is assigned to fit a time interval that is shorter than the person’s normal voiding
pattern and precedes the time when incontinent episodes are expected. Thus, the voiding interval may be lengthened or shortened throughout the day depending on the participant’s voiding pattern with the goal to pre-empt UI. Habit training is usually implemented by caregivers in institutional settings with cognitively and/or physically impaired adults, but it has also been tested in homebound older adults (183). It is potentially useful for adults without cognitive or physical impairment, who have a consistent pattern of UI (181).

**Prompted voiding**

Prompted voiding refers to a caregiver education programme in combination with a scheduled voiding regimen, typically every two hours. It is used to teach people with or without cognitive impairment to initiate their own toileting through requests for help and positive reinforcement from caregivers when they do so (184). It has been used primarily in institutionalized settings with cognitively and physically impaired older adults.

**Section Overview**

This section examines evidence for the use of bladder training and timed voiding for the prevention and treatment of UI in non-institutionalised women of all ages without cognitive or mobility impairment. However, the majority of evidence available pertains to the effects of bladder training, thus this is the focus of this section.

Previously, no trials were identified that tested habit training or prompted voiding for UI in independent-living women without cognitive or physical impairment, and no new trials meeting these criteria were identified in this update. Therefore, evidence for use of habit training and prompted voiding is not included in this section.

Questions addressed in this section include:

- Can scheduled voiding regimens prevent UI?
- What is the most appropriate bladder training protocol?
- Is bladder training better than no treatment, placebo or control treatments?
- Is bladder training better than other treatments?
- Can any other treatment be added to bladder training to add benefit?
- Does the addition of bladder training to other treatments add any benefit?
- Is timed voiding effective at treating UI?
- What is the effect of bladder training on other LUTS?
- What factors might affect the outcome of bladder training?

### 7.1. Prevention

Previously no trials had examined scheduled voiding regimens as a sole intervention in the prevention of UI. In this update, no further trial was identified.

### 7.2. Treatment

Previous recommendations related to bladder training as treatment for UI were based on review of individual published trials and three systematic reviews that provided descriptive synthesis with evidence grading (180, 185, 186), including a published Cochrane review last updated in 2006 (185). In this ICI update, 5 additional trials were identified and are described in the relevant sections below (98, 102, 156, 187, 188).

#### 7.2.1 What Is the Most Appropriate Bladder Training (BT) Protocol?

Previously no trials were identified that compared two or more methods of bladder training (BT), and none were identified for this update. In the absence of trials comparing two or more approaches, a content analysis was performed looking at the protocols used in trials investigating the effects of BT. It has been updated for this edition. Twenty-two trials on BT involving a total of 3194 women have been identified, including 5 trials involving 732 women added since the last update (98, 102, 156, 187, 188). Several of the trials previously reviewed (189-194) and 2 of the new trials identified for this update (156, 187) provided no or minimal details regarding the specific BT protocol used. In trials that did provide some description, BT protocols were implemented in differing ways. In the following review of BT protocols, information from studies added in this update are integrated with information from previously reviewed studies.

All protocols involved some type of patient education, namely:

- Brief verbal (191, 192) or written instructions (195, 196)
- Verbal, written, and audio-visual instruction (177, 179, 197)
- Introduction to an individual who successfully completed BT (193)

If specified, the education was provided by nurses (177, 179, 189, 190, 198, 199), general practitioners (200), or physiotherapists (98, 102, 188).

Scheduling of voids varied in the following ways:

- Assignment of the initial voiding interval varied from 30 minutes to two hours, with one hour being the most common interval based upon the participant’s voiding pattern or 30 minutes beyond the participant’s average (195, 201) or longest (102) voiding interval.
- Adjustments to the voiding interval varied from 15 to 30 minutes, with 30 minutes the most com-
mon interval. Increases were made daily for inpatient regimens (193), after 48 hours of dryness (202), every four to five days (201), or weekly if schedule was well-tolerated (102, 177, 179).

- Goals for optimal voiding interval varied from three to four hours.
- Voiding was ‘mandatory’ with restriction of voiding in between assigned toileting times even if UI occurred (193), a scheduled voiding regimen that allowed interruptions in the schedule if urgency became unbearable (177, 179, 199), or self-scheduling of voiding with a target goal to reach (195).
- Voids were not scheduled (allowed) during sleeping hours (193); none of the other protocols identified how voids were handled during sleeping hours.

In some protocols the scheduled voiding regimen was supplemented by specific strategies to control urgency and/or stress leakage, including distraction and relaxation (102, 177, 179, 188, 195, 199), and pelvic floor muscle contraction (102, 177, 190, 196). In other studies there was encouragement to suppress urge but it was not clear what strategies were used (192, 200, 203). Feedback techniques included self-monitoring (177, 179, 191, 194, 199), goal setting with feedback of progress (198), and positive reinforcement (177, 179, 201).

Several protocols included use of adjunctive treatments:
- Fluid and caffeine adjustments (197, 199, 203)
- Fluids allowed up to a certain level (1,500 ml) (202)
- No fluid modifications (102, 177, 179, 195, 200)
- Advice on constipation prevention (199)

Both in and outpatient BT programmes have been used. Early inpatient BT programmes involved five to 13 days of hospitalisation to ensure strict protocol adherence (193). Outpatient programmes are more commonly described and the amount of health professional contact ranged from weekly visits for six weeks with fortnightly telephone calls for six additional weeks (177), to weekly visits (179, 188, 189), fortnightly visits (102, 201), and monthly visits (202). A “simplified” BT treatment with minimal to no health professional contact (instructions given to patients on a one page instruction sheet) has also been tested (195, 196).

Overall, there is a lack of consistency in BT protocols. Based on the protocols described, a reasonable outpatient BT protocol, based on expert opinion is shown in Figure 7.

### Typical Bladder Training Regimen

- An initial voiding interval typically beginning at one hour during waking hours, which is increased by 15 to 30 minutes per week depending on tolerance of the schedule (such as fewer incontinent episodes than the previous week, minimal interruptions to the schedule, and the patient’s feeling of control over urgency and confidence to expand the voiding interval), until a two to three hour voiding interval is achieved. A shorter initial voiding interval, e.g. 30 minutes or less, may be necessary for patient whose baseline micturition patterns reveal an average daytime voiding interval of less than one hour.
- Education about normal bladder control and methods to control urgency such as distraction and relaxation techniques and PFMT contraction.
- Self-monitoring of voiding behaviour using diaries or logs in order to determine adherence to the schedule, enhance self-awareness, evaluate progress, and determine whether the voiding interval should be changed (for example, see Figure 7).
- A supervising health care professional to monitor progress, suggest adjustments to the voiding interval, and provide positive reinforcement to patient undergoing BT at least weekly during the training period.
- If there is no improvement after three weeks of BT, re-evaluation is warranted and other treatment options would be considered. Inpatient BT programmes may follow a more rigid scheduling regimen with progression of the voiding interval on a daily basis.

### Summary

There is still no trial evidence to suggest the most effective method or specific BT parameters. For those undertaking BT it is likely that more health professional contact will be better than less, based on the developing evidence for PFMT, which like BT, requires behavioural change (Level of Evidence: 4). The literature suggests several areas that could be investigated in future trials, including the instructional approach, supervisory intensity, strategies for controlling urgency, scheduling parameters, frequency of schedule adjustments, length of treatment, and use of adjunctive treatments.

### Recommendations

Clinicians and researchers are advised to refer to the operant conditioning and educational literature to provide a rationale for their choice of their approach to BT. The ICS Consensus statement and review pa-
7.2.2 Is BT Better than No Treatment, Placebo or Control Treatments?

BT as sole therapy has been used in the treatment of DO, urodynamic SUI, MUI, UUI, UUI with a stable bladder, and OAB (also called urgency-frequency syndrome).

No new trials were identified that addressed this question. Previously 5 RCTs reporting on 515 women were identified that compared the effect of BT to no treatment or control (179, 189, 194, 199, 200). Of 4 trials with relevant analysable data (179, 189, 194, 200), 3 reported improvements in the BT group compared to the control group (179, 194, 200). The trial quality and detailed results were presented in previous editions of this chapter.

Summary

The few available trials (reviewed previously) were small and of variable quality. No new trials were identified in this update.

There is limited Level 1 evidence that BT may be an effective treatment for women with UUI, SUI, and MUI (Level of Evidence: 1).

Recommendations

BT should be recommended as first line conservative therapy for UI in women (Grade of Recommendation: A).

Additional high quality studies are needed that examine the effect of BT versus no treatment in treatment of women with UUI, SUI, and MUI.

7.2.3 Is BT Better than Other Treatments?

This section, considered trials which compared BT alone versus another active therapy.

For the comparison of BT versus PFMT see II.2.3.3.

The only other comparison for which trials were found was BT versus drug therapy. One additional trial was identified for this update (98). Previously, two small trials were identified that randomized 131 women with UUI to BT or drug treatment (193, 201).

Kafri et al. (98) randomized 184 women with UUI to one of four groups: BT, PFMT, tolterodine extended release 4 mg or combined behavioural therapy (BT and PFMT). Results from the BT and drug treatment group comparison are included here, while results of
the BT vs PFMT comparison are included in section II.2.3.3.

Quality of data

Kafri et al. (98, 201) was a single-blinded trial in which 83 women were randomized to drug treatment or BT and followed up for 12 months. A power calculation and adequate random allocation concealment were reported. Drug tolerability and adverse events were assessed, but side effects were reported in a composite outcome only. Intent-to-treat principles were followed. Drop out at 3 months was higher in the drug treatment compared to BT group (36% vs 5%) (98).

Results

In Kafri (98), the number of self-reported UUI episodes in the past week significantly decreased at 3 and 12 months in both the BT and drug treatment groups. Between group comparisons suggested no difference in outcomes. Differential dropout suggested drug treatment was associated with more adverse effects, but this was not clearly reported. These results were similar to one previously reviewed trial in short-term outcomes (201), but in that trial symptoms recurred more often after drug treatment than after BT at 6 months follow-up. Another older trial found BT superior to drug treatment at 3 months follow-up (193). Both previously reviewed trials found adverse effects common in the drug treatment groups, but not in BT groups.

Summary

Despite an additional trial, it remains unclear whether BT or drug therapy is more effective for women with DO or UUI (Level of Evidence: 1).

This result is consistent with the findings of the Cochrane review (185), which concluded that there was not enough evidence to determine whether first line therapy should be BT or anticholinergic drugs.

Recommendations

When considering BT and anticholinergic drug for women with DO or UUI, either may be effective (Grade of Recommendation: B).

BT may be preferred by women and clinicians because it is not associated with the drug related side effects (Grade of Recommendation: D).

7.2.4 Can Any Other Treatment Be Added to BT to Add Benefit?

To be included here, trials needed to investigate the effects of BT versus BT plus therapy A to address the additive benefit of therapy. Three new trials were identified that tested the additional benefit of PFMT, drug therapy and tibial nerve transcutaneous electrical stimulation when added to BT (102, 156, 187). One trial addressed the added benefit of PFMT to BT (102) and is considered in the section on PFMT (II.2.3.4). A 2010 randomized trial tested the additive effects of tibial nerve transcutaneous electrical stimulation in 51 older women undergoing “routines of care” which included BT and Kegel exercises (156). As BT was combined with pelvic floor exercise treatment in both groups and no details were provided about the BT protocol, it was not possible to determine the effects of BT alone, and it is not considered further here. The third trial tested the addition of oxybutynin, imipramine or placebo to BT in 282 men and women with DO who had failed at least 8 weeks treatment of BT alone (187). However, very limited information is available on the methods and results (abstract only). This trial was also not considered further.

Prior editions of this chapter identified trials addressing the additional benefit of caffeine reduction, PFMT, and drug therapy when combined with BT. The caffeine reduction trial was included in the Lifestyle Interventions (II.1) section (203), and the trial addressing additional benefit of PFMT when added to BT was included in the PFMT section (II.2.3.4) (177). Three trials previously identified tested the added benefit of drug therapy to BT treatment. One of these tested a drug that is no longer available (terodiline), and is not considered further (192). The remaining trials included one that randomized 34 women and men with DO to BT or BT plus imipramine therapy (202), and another that randomized 60 women and men to BT and placebo or BT plus immediate release oxybutynin (191). No difference was seen in incontinence outcomes between the groups in either trial, although subjective improvement was greater with addition of a drug in one (191). Data quality and detailed results from these trials were reviewed in past editions of this chapter.

Summary

No new trials contributed evidence in this area. In two small trials (reviewed in previous editions) comparing BT (or BT plus placebo) versus BT plus drug in DO, there was a suggestion that the effect of BT might be enhanced by active drug (Level of Evidence: 2). However, both trials were small, conducted in gender-mixed sample populations, and outcomes were not common to both trials. Thus, there is insufficient evidence to derive a conclusion related to the effectiveness of augmenting BT with drug therapy.

Recommendations

Direct comparisons of BT versus BT with drug for UI treatment are needed to address the question of whether the effect of BT can be augmented by drug therapy. No recommendation is possible (Grade of recommendation D).

7.2.5 Does the Addition of BT to Other Treatment Add Benefit?

To be included here, trials needed to investigate the effects of Therapy A versus Therapy A plus BT to assess the added benefit of BT over Therapy A alone. A search for trials that investigated the effects of PFMT alone versus PFMT plus BT, and drug therapy...
alone versus drug therapy plus BT was performed. No new trials focused on this question were identified.

Three trials were reviewed in previous editions of this chapter, including one older study that compared BT, PFMT and combination therapy in 204 community-dwelling women with SUI and/or DO (177). Two larger RCTs compared a “simplified” BT (administered by providing participants with a 1 page written instructions on BT) plus drug therapy (tollerodine (2mg twice daily) (190, 195) and solifenacin (5/10mg daily)(195)) to drug therapy alone in women and men with OAB with or without UUI. UI outcomes were secondary endpoints in these trials.

Summary
A single trial found combining BT with PFMT improved short-term outcomes compared to PFMT alone, but the added benefit did not persist three months later (Level of Evidence: 2).

There is no evidence for an added benefit of combining brief written BT instructions with tolterodine (2mg twice daily) or solifenacin (5/10mg daily) compared to drug therapy alone for urgency incontinence (Level of Evidence: 2), although these trials were likely underpowered to study UI outcomes.

Recommendations
With no new trials contributing evidence in this update, the available evidence (single trial) supports the use of BT as a supplement to PFMT in improving short-term outcomes, but not longer-term results (Grade of Recommendation: B).

Limited evidence suggests the addition of written information on BT for women with OAB taking an antimuscarinic drug does not further improve UI (Grade of Recommendation: B).

More research is needed using an appropriately supervised BT programme combined with drug therapy versus drug alone.

7.2.6 Is Timed Voiding Effective at Treating UI?

The Cochrane review on timed voiding for management of UI in adults was last updated in 2010 (204). Ostaszkiewicz (2010) considered randomized and quasi-randomised trials only and identified two trials comparing timed voiding combined with additional interventions (including medications) to usual care. Both trials were conducted in nursing homes and most participants were elderly women with cognitive impairment. Neither study recruited participants that met criteria for inclusion here.

No new trials were identified that tested timed voiding for UI in women without cognitive or physical disability. Previously, two older non-randomised studies, excluded from the Cochrane review, reported findings on the effects of timed voiding in women with UUI, stable bladders with UUI, and MUI (205, 206). One of these, a small, double-blind crossover study compared timed voiding plus anticholinergic drug therapy (terodiline) to timed voiding plus placebo (205). As terodiline is no longer available, this study was not considered further. The second study was a small case series of 20 women with mild UI treated with timed voiding and followed from 6 weeks to 8 months after treatment (206). A successful outcome (not objectively quantified) was reported in 79% of participants.

Summary
There are no RCTs, or high quality observational studies, providing evidence on the effects of timed voiding for UI in cognitively intact, community-dwelling women, and no new trials considering this were identified. Based upon the data from one small uncontrolled study, it seems a two-hour timed voiding schedule may be beneficial in treating women with mild UI, infrequent voiding patterns, and stable bladder function (Level of Evidence: 3).

Recommendations
Timed voiding with a two-hour voiding interval may be considered as a sole intervention for women with mild UI or infrequent voiding patterns (Grade of Recommendation: C) Timed voiding may also be considered as an adjunct to other treatment.

7.3. Other LUTS

Two new trials were identified that reported frequency outcomes. Kafri et al. (98) compared BT to drug treatment and reported on frequency outcomes (others reviewed in section II.7.2 above). A second trial addressed the added benefit of PFMT to BT (102) and reported frequency as a secondary outcome. This trial is considered in the section on PFMT (II.2.3.4).

Older trials (from past editions of this chapter), which also contributed evidence related to other LUTS outcomes, compared BT to drug therapy (190, 193, 201), BT to no treatment (179, 189, 194), BT plus placebo to BT and drug treatment (191), and additive effects of a simplified BT program to drug treatment (195, 196).

Quality of data
The quality of data in the new trial that tested BT vs drug treatment was described earlier (II.VII.2c).

Results
i) Urgency: No new trials reported on urgency outcomes. In previously reviewed trials, urgency results were conflicting. An older trial suggested BT was superior to drug treatment (193), but another reported greater improvement in urgency after drug treatment or combined drug and BT treatment compared to BT alone (190). Two larger trials found no additional improvement in urgency when a simplified BT treatment was added to drug treatment for OAB (195, 196).
ii) Daytime (diurnal) frequency:
A newly identified trial found frequency improved at 3 and 12 months after treatment with BT, drug treatment (tolterodine extended release 4 mg), or a combined BT and PFMT group (98). On average, subjects reported 2 to 4 fewer voids per 24 hours after treatment. Between group differences were not reported.

In previously reviewed trials, frequency improved to a greater extent in BT groups compared to no treatment (179, 189, 194). In trials testing BT compared to drug treatment, frequency improved in both groups similarly (190, 201), or to a greater extent in the BT group (193). In one trial testing the additive effect of drug treatment to BT, a greater reduction in frequency was reported in the BT plus drug treatment group compared to BT plus placebo group (191). Lastly, two trials found that “simplified” BT significantly augmented the effect of drug alone. BT with tolterodine had greater improvement in voiding frequency compared to drug alone (33% versus 25% improvement, respectively; p<0.001) and BT with solifenacin reduced the number of voids in 24 hours to a greater extent compared to drug alone (2.8 versus 2.1 fewer voids in 24 hours; p<0.001) (195, 196).

iii) Nocturia: No new trials were identified reporting on nocturia. Three previously reviewed trials reported data in comparisons of BT with no treatment, and found reductions in nocturia after BT but not in the control group (179, 189, 194). Four previously reviewed trials compared BT with drug therapy. Two smaller trials found BT superior compared to drug treatment in treating nocturia (193, 201). Another trial compared BT plus placebo versus BT plus drug (191) and found no difference in nocturnal micturition frequency. Song (2006) reported that nocturia improved similarly in women with OAB treated with BT (56.1%), tolterodine (65.4%), and combined treatment (66.3%) (190).

Summary
No trials were identified which tested the effectiveness of BT compared to no treatment or a control for urgency. It remains unclear whether BT or drug treatment is more effective in treating urgency (Level of Evidence: 2).

Several trials, including one newer study, suggest BT is effective at improving frequency, (Level of Evidence: 1), but it is unclear whether BT or drug treatment is more effective (Level of Evidence: 2). Two larger, higher quality trials show that the addition of “simplified” BT to drug treatment does not provide additional benefit in treating urgency, but does improve frequency (Level of Evidence: 1). A few small, randomized trials of variable quality suggest BT is effective at treating nocturia (Level of Evidence: 2). Additional small trials do not find that BT (or BT added to drug treatment) is more effective at treatment of nocturia than drug treatment, but evidence is limited (Level of Evidence: 2).

Recommendations
Insufficient evidence exists to support either the use of BT to treat urgency in women with UI and/or OAB, or to guide the choice of BT vs drug treatment as initial treatment aimed at urgency (Grade of Recommendation: D).

Routine addition of a “simplified” BT to drug therapy does not provide additional improvement in urgency, but should be considered in treatment of voiding frequency in women with UI and OAB (Grade of Recommendation: B).

BT should be offered as treatment for urinary frequency and nocturia (Grade of recommendation: B), but in choosing between BT and an anticholinergic drug for women with frequency, either may be effective (Grade of Recommendation: B).

7.4. Factors Affecting Outcome
Few trials on BT have examined predictors of treatment response. New trials reviewed for this update did not contribute additional information related to predictors of timed voiding or BT treatment response.

8. COMPLEMENTARY AND ALTERNATIVE MEDICINES
There is limited, but growing evidence that complementary and alternative medicines (CAMs) may influence physiological function and/or health outcomes. CAMs include those therapies that are not part of the traditional biomedical model, such as meditation, imagery, hypnosis, acupuncture and naturopathic and herbal remedies.

This section reviews the current evidence for the effects of CAMs on UI in cognitively intact, community-dwelling women. Studies focused on UI in women with neurogenic aetiologies (for example, UI associated with stroke or multiple sclerosis) have been excluded. A summary of the search strategy used for selecting studies for review is provided in section I.

In the 5th ICI, a single RCT focused on hand acupuncture therapy was reviewed here. Given the lack of evidence, no recommendations related to CAMs were made for women with UI. Since then, additional RCTs and a Cochrane review have been published. Many of these trials tested various acupuncture techniques for UI; these are reviewed and summarized below.

Small individual trials testing other types of CAM therapy (for example, meditation and relaxation therapies and natural supplements) for UI were identified in the current search, many labelled as pilot trials. As recommendations cannot be made based on the minimal evidence available for any individual type of CAM therapy, these are not formally reviewed here. As interest in CAM therapies grows and more evidence accrues, additional types of non-traditional therapies may be reviewed in future editions.
Acupuncture and UI

Acupuncture and related techniques have been performed as part of Eastern medicine for thousands of years. Related therapies may include body acupuncture, hand acupuncture, electroacupuncture and acupuncture, amongst others. Their mechanisms of action are not fully understood, but discussions of these mechanisms related to treatment of UI from traditional Chinese medicine and other perspectives are available (207, 208).

8.1. Prevention

In the 5th ICI, no trials examined acupuncture for the prevention of UI. In this update, no new trials were identified.

8.2. Treatment

8.2.1 Acupuncture for Treatment of SUI

Previously, one low-quality RCT that studied the effect of hand acupuncture vs control (no treatment) for female SUI in 52 women (203) was identified. In this update, a recently-published Cochrane review of acupuncture and SUI was reviewed (207), which included one trial of acupuncture vs drug treatment for SUI (210). An additional trial of acupuncture for the treatment of is included in this update (211).

The 2013 Cochrane review considered evidence for acupuncture interventions from traditional Chinese medicine (body acupuncture, scalp acupuncture, electroacupuncture, warm acupuncture, fire needle and elongated needle), and did not consider trials of other interventions, such as hand acupuncture and acupressure (207). The authors searched and reviewed English and Chinese language publications. Only 1 trial was included (many were excluded because they combined acupuncture with other treatments or compared different types of acupuncture). The single eligible trial randomized 60 women to acupuncture vs a drug treatment (midrodine) and reported subjective improvement and cure and adverse effects at 6 to 12 weeks (207).

Chang et al. completed an RCT of 81 women with urodynamic SUI, randomized to 3 groups including acupuncture, sham acupuncture and “usual care” including PFMT (taught at baseline) (211). The treatment and sham groups underwent 3 weekly treatment sessions for 10 weeks. No information was provided on performance of PMFT (or other treatments) in the “usual care” group (or the other treatment groups). Outcomes were assessed after the 10-week treatment period. The primary outcome was pelvic floor muscle strength. Numbers of urine leak episodes from a 4-day diary and a subjective assessment of urine incontinence severity were also assessed.

Quality of data

Randomization concealment was inadequate in both trials (207, 211). No blinding or partial blinding was performed. Few participants withdrew from the trials (<5%). Adverse effects were reported in 1 reviewed trial (207).

Results

More women reported improvement in the acupuncture group (73% vs 33%; risk ratio 2.2 (95% CI 1.3-3.8)) compared to drug treatment (207). Cure rates were low and not different between the groups (13% vs 7%; risk ratio 2.0 (95% CI 0.4, 10.1)). Adverse effects were reported in the drug group only (including headache, dizziness, and thirst).

In the trial comparing acupressure, sham acupressure vs PFMT alone, numbers of incontinence episodes were unchanged and did not differ between groups, although self-reported severity of leakage improved to a greater extent in the acupressure compared to the sham acupressure group (p=0.04) and to PFMT alone (p=0.01) (211). Adverse effects were not reported.

Summary

A single trial suggests acupuncture may be better than drug treatment in SUI (Level of Evidence: 2), but the low quality and atypical comparator group limits the impact of these results.

A single trial suggests mixed results for acupressure compared to sham treatment or usual care in treatment of SUI (Level of Evidence: 2), but the low quality and small numbers limit these findings. There is inadequate evidence to know if acupuncture or acupressure treatments are effective for SUI in women.

Recommendations

No recommendations can be made regarding the use of acupuncture or acupressure for SUI in women. High-quality RCTs are needed.

8.2.2 Acupuncture for Treatment of OAB, UUI and Mixed UI

In this update, two recently-published reviews were identified which focused on acupuncture for women with OAB, UUI or Mixed UI, as well as an additional trial (not included in the reviews) (208, 212, 213). Paik et al. (208) performed a systematic review of RCTs published in English or Korean language journals testing acupuncture and acupressure treatments for UI. Four small RCTs were found eligible for that review. One of these studied acupressure for SUI and is discussed in the section above (211), but 3 are considered in this section, all published before 2010 (214-216). A second review focused on acupuncture and OAB in non-comparative and comparative trials (212). This review identified 4 RCTs relevant to this section (comparative trials of acupuncture for women with UI), 3 of which were also included in the review by Paik et al. (214-217). Thus, in total 5 RCTs (four included in the recently published reviews and 1 additional trial) are included in this edition. Study populations included women with OAB and UUI (214,
Two trials compared acupuncture to sham or placebo acupuncture (215, 216). One was a pilot RCT which tested acupuncture vs sham acupuncture (sham needles which didn't puncture the skin were used) in 9 women with mixed or urgency UI (216). The second trial randomised 74 women with OAB including UUI to acupuncture vs acupuncture performed at relaxation points (215). Two trials compared acupuncture to drug treatment, including an older trial that tested acupuncture vs oxybutynin 5 mg twice daily in 39 women with OAB with UUI (214). A recent, larger trial randomized 272 women with OAB with or without UUI to acupuncture or tolterodine 2 mg twice daily (217). Last, Jin et al. studied combination therapy with electroacupuncture plus tolterodine 2 mg twice daily versus electroacupuncture alone in 71 women with MUI (213).

Acupuncture techniques and regimens differed widely among the studies, including different acupuncture points treated. Treatments occurred 1 to 3 times weekly, lasted 4 to 8 weeks and outcomes were assessed immediately after treatment or 2 to 12 weeks later.

**Quality of data**

Randomization concealment was considered adequate in 2 of 5 trials (215, 217), one testing acupuncture vs placebo acupuncture and one comparing acupuncture to drug treatment (tolterodine). Blinding of participants and assessors was done in the trials testing acupuncture with a sham or placebo treatment (215, 216). Participants were not blinded in the 3 trials involving acupuncture and drug treatments (213, 214, 217), and assessors were blinded in only 1 of these (217). Sample size calculations were reported in only one trial (215). Adverse effects were described in 4 of 5 trials (214-217).

**Results**

Overall, no differences were seen in primary outcomes when comparing acupuncture with sham or placebo treatment and when comparing acupuncture with drug treatment. One small trial comparing acupuncture vs sham acupuncture in women with MUI reported greater reductions in overall incontinence episodes and urgency incontinence episodes in the acupuncture group after 4 weeks of treatment (67.5% vs 16.7% and 75.2% vs 24.9%, respectively), but statistical significance was not reached (216). Another trial of acupuncture vs sham acupuncture (relaxation points) in women with OAB and with UUI found a non-significant reduction in incontinence episodes (59 and 40% in the treatment and placebo groups) (215). For acupuncture treatment compared to drug therapy (oxybutynin or tolterodine) in women with OAB, no difference was seen in improvement in UUI episodes between treatment groups (214, 217). In one, frequency and urgency improved but UUI was unchanged and in the other, frequency, urgency and UUI improved, but no between group differences were reported (214). In the trial comparing combination treatment with electroacupuncture and tolterodine to electroacupuncture alone for MUI, both groups had significant reductions in overall UI episodes and in urine leakage volume on pad test, but these outcomes did not differ between groups. Significantly more women in the combination treatment group had a more than 50% improvement in number of UI episodes (76 vs 59%, p<0.05) (213).

No serious adverse effects occurred. Minor bruising and bleeding as well as some discomfort with needle placement were described (214-217).

**Summary**

Two trials (small to medium size) of varying quality found no or limited benefit in testing acupuncture to various sham treatments for MUI and OAB/UUI in women (Level of Evidence: 2).

Several factors limit these results, including small sample size, risk of bias and heterogeneity of active and sham treatments. Two trials comparing acupuncture to drug therapy in women with OAB, UUI and MUI found no difference between treatments (Level of Evidence: 2). One low quality trial suggested combination therapy of electroacupuncture plus drug for MUI was superior to electroacupuncture alone (Level of Evidence: 2).

**Recommendations**

When choosing between acupuncture and anticholinergic drug for women with OAB, UUI and MUI, either may be effective (Grade of Recommendation: B).

There is insufficient evidence to make a recommendation related to the effectiveness of augmenting electroacupuncture with drug therapy (Grade of Recommendation: D). High-quality RCTs are needed, including standardized acupuncture treatment regimens.

**Conclusions**

Limited evidence is available for the use of acupuncture techniques for the treatment of UI in women. Challenges in this area (in performing research as well as in interpreting the literature) include a lack of consistency in acupuncture techniques and regimens and controversy regarding the best comparator (sham or placebo acupuncture) (218). Also, much of the literature is not published in English language journals. Given the limitations to the quality and the heterogeneous nature of evidence available, few formal recommendations are possible related to use of acupuncture for SUI, UUI, MUI or overall UI in women. More rigorously-conducted RCTs are needed in this area.
9. FUTURE RESEARCH DIRECTIONS

9.1. Summary

Even with the number of reasonable trials on conservative management of UI in women, the standards of trial conduct and reporting varied considerably. It is strongly recommended that future RCTs on conservative management include power and sample size calculation, account for potential risk of bias, intervention content and intensity, and choose of outcome measures prior to conducting the trial.

9.2. Recommendations for practice

While some recommendations are underpinned by good and consistent evidence of effects, there remains a need for further testing because of insufficient Level 1 and Level 2 evidence.

9.2.1 Lifestyle Intervention

Treatment:

Nonsurgical weight loss should be considered a first line treatment to reduce UI in obese and overweight women (Grade of Recommendation: A).

Moderate exercise may help in decreasing the incidence of UI: this effect may be mediated by weight control (Grade of Recommendation: C).

Caffeine reduction may help in improving incontinence symptoms (Grade of Recommendation: B).

Minor decrease of fluid intake (by 25%) may be recommended provided baseline consumption is not less than 30 ml/Kg a day (Grade of Recommendation: B).

9.2.2 PFMT (Principal Recommendation)

PFMT in the prevention of UI in childbearing women: Continental, pregnant women should be offered a supervised (including regular health professional contact) and intensive strengthening antepartum PFMT programme to prevent antepartum and postpartum UI (Grade of Recommendation: A).

PFMT in the treatment of UI in childbearing women: PFMT should be offered as first line conservative therapy to women with persistent UI symptoms three months after delivery (Grade of Recommendation: A).

An ‘intensive’ PFMT programme (in terms of supervision and exercise content) is likely to increase the treatment effect (Grade of Recommendation: B).

PFMT in the prevention/treatment of UI in childbearing women: Health providers should carefully consider the cost/benefit of population based approaches to health professional taught antepartum or postpartum PFMT, that is, health professional instruction to all pregnant or postpartum women regardless of their current or prior continence status (Grade of Recommendation antepartum PFMT: A). (Grade of Recommendation postpartum PFMT: B).

Where a population approach is used, the ‘best’ evidence to date suggests the following: (a) an intervention comprising of a daily home PFMT and weekly physiotherapist-led exercise classes for 12 weeks, starting at 16-24 weeks’ gestation for pregnant women, and (b) an individually taught strengthening PFMT programme that incorporates adherence strategies for postpartum women who have had a forceps delivery or a vaginal delivery of a large baby (4000g or more) (Grade of recommendation: C).

i) Other women PFMT

Prevention:

There is preliminary evidence that PFMT may help prevent UI in older women. (Grade of Recommendation: C New).

Treatment:

Supervised PFMT should be offered as first line conservative therapy to women urinary incontinence (Grade of Recommendation: A).

Clinicians should provide the most intensive health professional-led PFMT program possible within service constraints because programs that are taught and supervised by health-professionals are better than those with little or no supervision (Grade of Recommendation A).

Although studies are limited, there does not appear to be clear benefit for adding other modalities (i.e. motor learning, abdominal- or hip-muscle training, intra-vaginal resistance device) to PFMT (Grade of Recommendation: B).

There is no clear benefit from adding clinic- (Grade of Recommendation B) or home-based BF (Grade of Recommendation B) to a PFMT program. The use of clinic or home-based BF should remain a therapist/individual decision based on individual’s needs and service constraints.

ii) Other women PFMT vs other intervention

For women with SUI:

- PFMT and VC are both effective as conservative therapy, although PFMT is superior (Grade of Recommendation: B).
- PFMT is better than EStim as first line conservative therapy (Grade of Recommendation: B).
- PFMT is better than BT as first line conservative therapy (Grade of Recommendation: B).
- PFMT and drug therapy are both effective as first line therapy, PFMT avoids the adverse effects experienced with drug therapy (Grade of Recommendation: B).
- Surgery is more effective than PFMT, but potential benefit should be weighed against potential adverse events. PFMT should be offered as first line conservative therapy (Grade of Recommendation: B New).
• PFMT and continence pessary are both effective as first line conservative therapy (Grade of Recommendation: B New).

For women with SUI or MUI:

• VC does not appear to be better than PFMT in the treatment of UI. PFMT should be recommended as first-line conservative therapy (Grade of Recommendation: B).

VCs with supervised training sessions by a trained health professional can be offered to women who can and are prepared to use them (Grade of Recommendation: B).

VC may be inappropriate for some women due to inability to insert or retain the cone or because of side effects and discomfort.

For women with UUI or MUI:

• PFMT and BT should be offered as effective first-line conservative therapies (Grade of Recommendation: B).

• PFMT is better than oxybutynin as first line therapy (Grade of Recommendation: B).

For women with UUI

PFMT and BT should be offered as effective first line conservative therapy (Grade of Recommendation: B).

iii) Other women PFMT + other intervention vs PFMT

In women using VC, it does not appear to help to add PFMT (Grade of Recommendation: C).

For the treatment of SUI, UUI, or MUI in women, consider a combination of PFMT and BT rather then BT alone (Grade of Recommendation: C).

For treatment of UUI (tolterodine) but not for SUI (duloxetine), consider adding PFMT to drug therapy (Grade of Recommendation: B),

When treating women with SUI and vaginal atrophy, consider combining PFMT and intravaginal oestrogen over estrogen alone may be better than estrogen alone (Grade of Recommendation: C New).

9.2.3 Cones

For women with SUI, VC with supervised training sessions by a trained health professional may be offered as a first-line conservative therapy to those who can and are prepared to use them (Grade of Recommendation: B).

VC may be inappropriate in some cases due to inability to insert or retain the cone or because of side effects and discomfort. Trained health professional assessment is recommended (Grade of Recommendation: D).

VC and EStim seem equally effective in the treatment of SUI and MUI. Side effects and discomfort caused by both VC and EStim appears to limit their utility in clinical practice (Grade of Recommendation: B).

If this combined intervention proves to be of interest to women, then adequately powered studies are needed to confirm or refute the advantages of adding VCs to PFMT (No Recommendation).

9.2.4 EStim

EStim might be better than no treatment to improve symptoms and quality of life in SUI women (Grade of Recommendation: B).

EStim may be considered for treatment to improve symptoms for UUI (Grade of Recommendation: B).

For women with SUI maximal clinic-based EStim might be better than daily low-intensity home-based EStim in improving symptoms (Grade of Recommendation: B).

Based on current limited evidence, EStim could be considered as an alternative to medical treatment. (Grade of Recommendation: B).

The addition of EStim to PFMT or BF-assisted PFMT programmes does not appear to add benefit (Grade of Recommendation: B)

9.2.5 PTNS

For women with UUI or OAB, PTNS may be more effective than no active treatment in symptom control (Grade of Recommendation: C New).

There is no significant difference between PTNS and tolterodine in terms of quality of life, however PTNS may be considered as both may improve quality of life and PTNS is less invasive (Grade of Recommendation: B New).

PTNS may be considered for women as it is associated with fewer and less bothersome adverse effects than those from drug treatment (Grade of Recommendation: B New).

PTNS may be considered for symptom control when chosen in combination interventions such as with PFMT plus bladder training, or drug treatment by women with UUI or OAB (Grade of Recommendation: B New).

9.2.6 Magnetic Stimulation

No recommendation is possible based on current conflicting evidence (Grade of recommendation: D).

No recommendation is possible regarding optimum type of MSlim (Grade of Recommendation: D).

The addition of MSlim to PFMT in treatment of SUI does not appear to be beneficial (Grade of Recommendation: C).
9.2.7 Bladder Training

BT should be recommended as first line conservative therapy for UI in women (Grade of Recommendation: A).

Clinicians should provide the most intensive BT supervision that is possible within service constraints (Grade of Recommendation: D).

Clinicians and researchers are advised to refer to the operant conditioning and educational literature to provide a rationale for their choice of their approach to BT. (Grade of Recommendation: D).

When considering BT and anticholinergic drug for women with DO or UUI, either may be effective (Grade of Recommendation: B).

BT may be preferred by women and clinicians because it is not associated with the drug related side effects (Grade of Recommendation: D).

The available evidence (single trial) supports the use of BT as a supplement to PFMT in improving short-term outcomes, but not longer-term results (Grade of Recommendation: C).

Limited evidence suggests the addition of written information on BT for women with OAB taking an antimuscarinic drug does not further improve UI (Grade of Recommendation: B).

Timed voiding with a two-hour voiding interval may be considered as a sole intervention for women with mild UI or infrequent voiding patterns (Grade of Recommendation: C). Timed voiding may also be considered as an adjunct to other treatment.

Insufficient evidence exists to support the use of BT to treat urgency in women with UI and/or OAB, or to guide the choice of BT vs. drug treatment as initial treatment aimed at urgency (Grade of Recommendation: D).

Routine addition of a “simplified” BT to drug therapy does not provide additional improvement in urgency, but should be considered in treatment of voiding frequency in women with UI and OAB (Grade of Recommendation: B).

BT should be offered as treatment for urinary frequency and nocturia (Grade of recommendation: B), but in choosing between BT and an anticholinergic drug for women with frequency, either may be effective (Grade of Recommendation: B).

9.2.8 Complementary and Alternative Medicine

Acupuncture:

The limited evidence available to date does not support the use of acupuncture when compared to sham or placebo treatment for women with OAB, UUI and MUI.

When choosing between acupuncture and anticholinergic drug for women with OAB, UUI and MUI, either may be effective (Grade of Recommendation: B).

There is insufficient evidence to make a recommendation related to the effectiveness of augmenting electroacupuncture with drug therapy (Grade of Recommendation: D).

High-quality RCTs are needed, including standardized acupuncture treatment regimens.

9.3. Future Research Direction

All future trials must be designed, implemented and reported in ways that maximise their usefulness in practice; this includes being well powered, with longer term follow up, with evaluation of cost-effectiveness and planned secondary analysis of trial data to investigate predictors of effectiveness. Readers are referred to the revised CONSORT statement for guidance (219).

9.3.1 Lifestyle Modification Intervention

Prevention should be an area for future research investment and comprise robust economic evaluation to determine the benefits of lifestyle modification strategies in women with UI.

With limited new data on the effects of physical activity (moderate or strenuous), smoking cessation, diet modification and constipation, their association with UI development or symptom reduction should be investigated further.

Separate investigation of the impact of lifestyle modification interventions on nocturia, diurnal frequency, urgency and UI should be undertaken.

9.3.2 PFMT in Antenatal and Postnatal Women

- Additional trials with longer-term follow-up (greater than 12 months postnatal) are needed to determine long-term benefits of antenatal PFMT.
- Large and good-quality RCTs are needed to investigate the effect of antepartum PFMT on preventing postpartum UI in multiparous women.
- Large and good-quality RCTs are needed to investigate the effect of intensive post-partum PFMT on preventing postpartum UI in women. Attention must be given to high risk subgroups.
- There is a need for at least one large, pragmatic, well-conducted and explicitly reported trial with long term follow-up (five plus years) of postpartum PFMT that investigates the long term effect of ‘intensive’ PFMT for persistent postnatal UI.

9.3.3 PFMT in Women (Others)

The effect of PFMT in the prevention of UI in women should be studied further.
Larger, good quality trials are needed to address comparisons between PFMT regimens, PFMT and other modalities or PFMT + another modality and PFMT alone, if these are of interest to women. In planning comparisons, researchers should consider carefully power calculation, intervention intensity and the potential impact of different levels of supervisory intensity between groups, particularly in comparisons of conservative therapies.

9.3.4 Vaginal Cones

Larger, good quality trials are needed to address comparisons between VC and other modalities, and VC+ other modalities compared to VC, if these are of interest to women. In planning comparisons researchers should consider carefully power calculation, intervention intensity and the potential impact of different levels of supervisory intensity between groups, particularly in comparisons of conservative therapies.

9.3.5 EStim/PTNS/MStim

Larger, good quality trials are needed to address comparisons between EStim/PTNS/MStim and no treatment, EStim/PTNS/MStim and other modalities, EStim/PTNS/MStim + other modalities and EStim/PTNS/MStim, if these are of interest to women. In planning comparisons researchers should consider carefully power calculation, intervention intensity and the potential impact of different levels of supervisory intensity between groups, particularly in comparisons of conservative therapies.

9.3.6 Scheduled Voiding Regimen

Larger, good quality trials are needed to address comparisons between BT and no treatment, BT and other modalities, BT + other modalities and BT, if these are of interest to women. In planning comparisons researchers should consider carefully power calculation, intervention intensity and the potential impact of different levels of supervisory intensity between groups, particularly in comparisons of conservative therapies.

1. LIFESTYLE MODIFICATION INTERVENTION

Lifestyle modification interventions include weight loss, reducing exacerbating activities (e.g. lifting, coughing) and treating constipation, and are intended to avoid worsening of the prolapse by decreasing intra-abdominal pressure.

1.1. Prevention

1.1.1 Quality of Data

No trials of lifestyle modification interventions to prevent prolapse were identified in this update. However, 12 observational studies (retrospective reviews, prospective surveys and case-control studies) that examined the association between modifiable lifestyle factors such as occupation (involving heavy lifting/strenuous physical activity), bodyweight, smoking, constipation, nutrition and the development of prolapse have been published since last review, which add to the 33 previously described (9 in 5th edition, 15 in 4th edition and 9 in 3rd edition). These are reported and summarised in Table 26. Studies often examined multiple risk factors and contribute evidence to more than one section below. If modifiable lifestyle factors are established as risk factors for prolapse these could be targeted with a view to prevention.

1.1.1.1 Association Between POP and Occupation and Physical Activity

To date, the potential relationship between occupation and physical activity on prolapse has received scant attention (5 studies in 3rd edition (225), 5 in 4th edition (226), 3 in 5th edition (2)). A recent narrative lit-
Literature review (227) investigated the effect of physical activity and occupation on the development of prolapse. The review authors identified 10 studies, all of which have been reviewed in-depth in previous editions of this chapter. They concluded that the evidence linking physical activity and occupation with an increased risk for POP was weak and inconclusive.

Our systematic search identified a further 5 additional studies, included (228-232). The key characteristics of these studies are described in Table 26.

Akmel et al. (2012) conducted a retrospective study of women in one Ethiopian hospital treated surgically for prolapse over three years (230). Medical interns extracted data from the women’s medical records on demographics, medical, surgical and obstetric history, symptoms and risk factors. Only univariate analysis was performed and therefore the study was judged to be at high risk of bias (Table 26).

Bathla et al. 2014 (232) carried out a retrospective review of case notes for women who presented with prolapse at mobile surgical camps in a remote village of Himachal Pradesh between 2009-2013. Women underwent POP-Q assessment prior to surgery. The aim was to study the epidemiological risk factors for prolapse, including occupation and nutrition (see below). The analysis was mainly descriptive although the authors report they did “correlation regression”, but it was not clear what this was, and therefore the results were difficult to interpret and at high risk of bias (Table 26).

Gumanga et al. (2014) undertook a prospective study of women presenting with prolapse at gynaecological outpatients at a hospital in Ghana over two years (2010-2011), describing occupational, socio-cultural practices and obstetric characteristics and how they related to severity of prolapse (231). Data collected included demographics, reproductive history and pelvic examination findings. Women were included if they complained of a mass in the vagina and had demonstrable descent on pelvic examination. There was no control group so analysis of risk factors was not possible, thus the study was at high risk of bias (Table 26).

Lonnée-Hoffmann et al. (2015) recently reported on a cross-sectional study they undertook in women 30 years or older in one Nordic county in the Nord-Trøndelag Health Study (228). Outcome measures examined were self-reported prolapse surgery, age at survey, socio-demographic factors, and information on risk factors for prolapse (smoking, chronic obstructive pulmonary disease, asthma, constipation a decade previously, and measured body mass index) (see Table 26). Multivariable logistic regression was used for analysis thus the study was judged to be at low risk of bias.

Nygaard et al. (2014) conducted a retrospective case-control study of women with prolapse (descent ≥ 1 cm beyond the hymen) and without prolapse (descent ≤ 1 cm above the hymen), age and site matched, to assess the impact of lifetime physical activity on the risk of prolapse (229). Women were recruited from primary care or community advertisements, and were not seeking treatment for prolapse. Physical activity was measured using the Lifetime Physical Activity Questionnaire (LPAQ), which assesses physical activity over four periods (start of menstruation to age 21, 22–34, 35–50, and 51–65 years), and includes leisure activity, outdoor work, and housework. The Occupation Questionnaire (OQ), part of the LPAQ, was also used. Multivariable models were fitted to assess the effect of physical activity on prolapse indicating a low risk of bias for this study (Table 26).

1.1.1.2 Association Between POP and Body Weight

There has been little agreement on whether an increase in weight (or increased waist circumference or higher BMI) is linked with an increased risk of POP. Seventeen studies have evaluated the effects of body weight on POP since the previous editions (4 in 5th edition, 5 in 4th edition, 6 in 3rd edition) (228, 233-248). In addition, two reviews have recently been published on this topic (249, 250) (Table 26). The former literature review included a study by Kudish and colleagues (2009) – which had not previously been included in earlier editions of this chapter – it is therefore included here (251).

1.1.1.3 Association Between POP and Smoking

Three studies on the relationship between smoking and prolapse were identified (228, 232, 252). In addition, Kudish (2009) investigated smoking as a risk factor (251).

Estanol and colleagues (252) studied female smokers and non-smokers with and without prolapse in a cross-sectional study in one centre. Smokers and non-smokers without prolapse were age matched to smokers and non-smokers with prolapse. The aim was to examine the impact of smoking on collagen markers (MMP-9) and vitamin C, in those with and without prolapse. Women with prolapse had a bulge at or beyond the hymen on examination, and answered positively to two Pelvic Floor Distress Inventory (PFDI) questions on the feeling of a bulge or a visible bulge in the last 12 months. A univariate analysis of the associations was carried out, thus a high risk of bias was assumed (Table 26).

A significant association between POP and smoking has also been reported in 2 studies above (228, 251). Bathla et al., (2014) also noted that 30-57% of their sample were smokers; collectively these studies suggest that smoking is a risk factor for POP.
| Author, year | Study design/ Comparator | N   | Study population                                                                 | Modality details/methods employed | Outcomes/results                                                                 | Follow up | Notes (side effects, loss of follow up…)
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>POP and Occupation/Physical activity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Akmel 2012 (1)</td>
<td>Retrospective descriptive case note analysis</td>
<td>129</td>
<td>Patients who were admitted and operated on in the gynaecology ward in one hospital in Ethiopia. All the women with POP who were admitted and treated during the study period were included; no sampling technique was employed.</td>
<td>Demographic and medical characteristics were extracted based on the initial medical history and physical examination documentation in the case records.</td>
<td>Type of occupation was strongly associated with stage of prolapse. Housewives were more likely to have stage IV (vs stage III) prolapse compared to farmers.</td>
<td>None</td>
<td>Data was available for 129 out of a possible 143 women. No multivariate analysis to allow for other confounding variables.</td>
</tr>
<tr>
<td>Bathla 2014(2)</td>
<td>Retrospective descriptive case note analysis</td>
<td>157</td>
<td>157 women who had POP surgery conducted in 5 mobile surgical camps in Shillai, Himachal Pradesh from 2009 to 2013 (“Project Prolapse”).</td>
<td>Epidemiological data and POP-Q data were collected.</td>
<td>Factors contributing to POP believed to be “poor nutritional status (mean weight 41.1 kg), multiparity (mean 3.5), early marriage (mean age 18.2 years), unassisted home deliveries (100%), premature bearing down (23.8%), early postpartum resumption of strenuous activity (54.7%) and smoking (33%)” This was not based on statistical analysis.</td>
<td>None</td>
<td>“Statistical analysis was performed using correlation regression analysis”, but limited data presented. No multivariable analysis performed.</td>
</tr>
<tr>
<td>Gumanga 2014 (3)</td>
<td>Prospective observational study</td>
<td>118</td>
<td>POP cases, out-patients seen over 2-year study period at a teaching hospital in Ghana.</td>
<td>Questionnaires and physical exam in patients whose main complaints included “a mass falling from the vagina” or “bulging mass” or “sensation of mass in the vagina”.</td>
<td>Main occupations were trading of produce 66/118 (55.9%) and farming 44/118 (37.3%)</td>
<td>None</td>
<td>Authors report that occupational factors might contribute to the severity of POP in this sample. Analysis undertaken is unclear but appears not to be multivariable analysis.</td>
</tr>
<tr>
<td>Author, year</td>
<td>Study design/ Comparator</td>
<td>N</td>
<td>Study population</td>
<td>Modality details/methods employed</td>
<td>Outcomes/results</td>
<td>Follow up</td>
<td>Notes (side effects, loss of follow up…)</td>
</tr>
<tr>
<td>--------------</td>
<td>--------------------------</td>
<td>-----</td>
<td>------------------</td>
<td>----------------------------------</td>
<td>------------------</td>
<td>----------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td>Lonnee-Hoffmann 2015 (4)</td>
<td>Cross-sectional survey</td>
<td>20,285</td>
<td>All women aged ≥ 30 years in one Nordic county invited to take part</td>
<td>Women were sent questionnaires and attended screening stations. Risk factors assessed: smoking, chronic obstructive pulmonary disease, asthma, constipation a decade previously, and measured BMI</td>
<td>POP surgery was reported by 1,123 (5.3%). Only women reporting more lifting in addition to walking had significantly higher odds of reporting POP surgery compared with women with sedentary occupation in the age-adjusted model</td>
<td>None</td>
<td>Authors also report that constipation reported a decade prior, above-normal BMI, and COPD were significant non-obstetric risks for prolapse surgery. Multivariable analysis performed.</td>
</tr>
<tr>
<td>Nygaard 2014 (5)</td>
<td>Retrospective case-control study</td>
<td>382</td>
<td>191 POP cases and 191 age and recruitment-site matched controls, aged between 39-65 years, not seeking prolapse treatment</td>
<td>Women were asked to complete Lifetime Physical Activity and Occupation Questionnaires based on self-reported activities</td>
<td>No associations between odds of POP and overall lifetime physical activity, lifetime leisure activity, or lifetime strenuous activity</td>
<td>None</td>
<td>Authors suggest that strenuous activity during teenage years may have an association with POP, and recommend further prospective research in this area Multivariable analysis??</td>
</tr>
<tr>
<td>Estanol 2015 (6)</td>
<td>Cross-sectional study</td>
<td>96</td>
<td>4 groups of women: smokers with POP (n=16), non-smokers with POP (n=16), smokers without POP (n=32) and non-smokers without POP (n=32)</td>
<td>Fasting blood panel, including plasma procollagen 1-N propeptide (P1NP), matrix metalloproteinase 9 (MMP-9), and vitamin C. These are markers of collagen metabolism. Smokers were defined as smoking 1 pack or more a day for at least 1 year; non-smokers were defined as not having smoked for at least 7 years</td>
<td>Comparing women with POP and without, there were no significant differences in vitamin C, P1NP and MMP-9 levels, independent of smoking status. MMP-9 levels were higher and vitamin C lower in smokers compared to non-smokers.</td>
<td>None</td>
<td>Small sample size; was not sufficiently large to detect a true difference, particularly in those with prolapse. No multivariable analysis</td>
</tr>
</tbody>
</table>

**POP and Smoking (see also entries for Bathla 2014, Kudish 2009 and Lonnee-Hoffmann 2015)**
<table>
<thead>
<tr>
<th>Author, year</th>
<th>Study design/ Comparator</th>
<th>N</th>
<th>Study population</th>
<th>Modality details/methods employed</th>
<th>Outcomes/results</th>
<th>Follow up</th>
<th>Notes (side effects, loss of follow up…)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bezerra 2014 (7)</td>
<td>Cross-sectional survey</td>
<td>172</td>
<td>Participants referred to one tertiary urogynecology outpatient clinic with self-reported symptoms of PFD: POP [POP-Q ≥ stage II and/or UI]</td>
<td>Medical history, series of questionnaires (ICIQ-SF; KHQ; PISQ-12), Cleveland Constipation Scale and physical exam using the PERFECT scheme.</td>
<td>No differences in prolapse status between patients with and without anal incontinence and/or bowel disorders.</td>
<td>None</td>
<td>No multivariable analysis</td>
</tr>
<tr>
<td>Elbiss 2015 (8)</td>
<td>Cross-sectional</td>
<td>429</td>
<td>Women attending family development centres in United Arab Emirates, 29.6% reported POP symptoms</td>
<td>Questionnaire included items for details of socio-demographic, obstetrics, medical and surgical history. Presence of a lump in/out of vagina was taken as presence of POP.</td>
<td>Chronic constipation and chest disease, level of education, occupation birth weight and BMI were independent risk factors for having POP symptoms.</td>
<td>None</td>
<td>Multivariable analysis was performed. Authors recommended additional healthcare campaigns to raise awareness about risk factors for POP</td>
</tr>
<tr>
<td>Navaneethan 2015 (9)</td>
<td>Prospective case-control study</td>
<td>120</td>
<td>Women with (n=51) or without (n=69) PFD on examination when attending outpatient clinic at one tertiary care centre in South India</td>
<td>Medical history and clinical examination (POP-Q) were performed. Serum 25-hydroxy vitamin D levels were measured in all participants</td>
<td>23/51 had POP alone, 9/51 had POP+SUI; vitamin D levels were not significantly associated with POP</td>
<td>None</td>
<td>Multivariable analysis performed to adjust for age.</td>
</tr>
<tr>
<td>Parker-Autrey 2012 (10)</td>
<td>Retrospective chart review</td>
<td>394</td>
<td>Women over 19 years old attending a Urogynecology Care Clinic from 2008 to 2010 who had vitamin D measured.</td>
<td>Diagnosis categorized as PDF (SUI, UUI, FI, POP) (n=268) or general GYN (n=126). Demographic and medical characteristics were extracted. PFDI-SF 20, IIQ-7, Medical, Epidemiologic, and Social Aspects of Aging (MESA) questionnaire.</td>
<td>Only higher IIQ-7 scores were significantly related to having insufficient vitamin D.</td>
<td>None</td>
<td>Multivariable logistic regression model used to adjust for age, BMI, ethnicity, and use of vit. D supplementation</td>
</tr>
<tr>
<td>Author, year</td>
<td>Study design/ Comparator</td>
<td>N</td>
<td>Study population</td>
<td>Modality details/methods employed</td>
<td>Outcomes/results</td>
<td>Follow up</td>
<td>Notes (side effects, loss of follow up…)</td>
</tr>
<tr>
<td>------------------------------</td>
<td>------------------------------------------</td>
<td>-------</td>
<td>----------------------------------</td>
<td>---------------------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>Myers et al., 2012(11)</td>
<td>Secondary data analysis of RCT</td>
<td>338</td>
<td>Overweight and obese women with UI</td>
<td>Women were randomised either into an intensive 6-month weight loss or to the control group (educational program) Symptomatic prolapse was defined as a positive response to at least 1 prolapse subscale question of the UDI. &quot;Bother&quot; was defined as responses of slight, moderate, or great.</td>
<td>Increasing BMI was associated with only &quot;feeling&quot; a vaginal bulge. (13% of obese women reported feeling vaginal bulging compared with overweight women (0%).</td>
<td>6 months</td>
<td>At 6 months, there were no significant differences in improvement of self-reported bothersome prolapse symptoms in women in the weight loss or the control group Multivariable analysis was performed.</td>
</tr>
<tr>
<td>Kudish 2009 (12)</td>
<td>Secondary analysis of a 5-yr clinical trial</td>
<td>16608</td>
<td>Post-menopausal women aged 50-79 yrs</td>
<td>Degree of prolapse assessed using the WHI Prolapse Classification System</td>
<td>Prolapse risk in overweight and obese women (compared with the women with healthy BMI) increased by 32% and 48% for cystocele, by 37% and 58% for rectocele, and by 43% and 69% for uterine prolapse, respectively</td>
<td>Annual pelvic exam over a 5 year interval</td>
<td>Being overweight or obese is associated with progression of POP. Authors reported that &quot;weight loss was not significantly associated with regression of POP&quot;, and argued that pelvic floor damage related to weight gain could be irreversible Multivariable analysis was performed.</td>
</tr>
</tbody>
</table>

Abbreviations: PFDI-20: pelvic floor distress inventory short form 20, PFIQ-7: pelvic floor impact questionnaire short form; PFM: pelvic floor muscles; PFMT: pelvic floor muscle training; POP-Q: Pelvic Organ Prolapse Quantification system; PISQ-12: Pelvic organ prolapse/urinary incontinence sexual questionnaire’ POP-SS: pelvic organ prolapse symptom score; QoL: quality of life; RCT: randomized controlled trial; sEMG: surface electromyography; SR: systematic review; UI: urinary incontinence


1.1.1.4 Association Between POP and Bowel Function

Previously there were 8 studies that had examined the potential impact of bowel disorders/ or bowel dysfunction on prolapse (4 in 5th edition, 4 in 4th edition). This update adds a further 4 studies. Two are described below; two have been described above (Lonnee-Hoffman et al., 2012; Kudish et al., 2009).

Bezerra et al. (2014) undertook a cross-sectional study of women with pelvic floor disorders (POP-Q ≥ stage II and/or urinary incontinence) presenting at a tertiary urogynaecology clinic in Brazil (253). The aim was to report the prevalence, bother, and impact on quality of life (QoL) of unreported bowel symptoms, to improve the patient care. Those with and without defaecatory or anal continence problems were compared. A number of measures were used depending on the presence/absence of bowel and urinary incontinence symptoms: ICIQ-SF, King’s Health Questionnaire, PISQ-12, the Wexner score, Cleveland Clinic Florida Incontinence Scale, Cleveland Clinic Florida Constipation Scale (mild, moderate or severe). All women completed the SF-36 and had their pelvic floor assessed by a physiotherapist using the PERFECT scheme. Only univariate analysis was performed, putting the study at a high risk of bias (Table 26).

Elbiss and colleagues (238) carried out a cross-sectional study of parous Emirati women 30 years or older attending three family development centres in Al-Ain in one year. The objective was to ESTimate the prevalence of prolapse and its risk factors. The study used a self-developed questionnaire, which was piloted and revised before use. The questionnaire covered demographic, obstetrics, and medical history, prolapse symptoms (lump coming down in the vagina, lump coming out of vagina or lump felt or seen outside vagina), other vaginal symptoms and the need to digitate to empty bladder or bowel. Following univariate analysis, multivariable binary logistic regression analysis (prolapse symptoms versus no prolapse symptoms) was performed including all significant variables to determine which were independent risk factors for prolapse (Table 26). This study was judged as having a low risk of bias.

1.1.1.5 Association Between POP and Nutrition

Two studies were identified in previous editions of the chapter that examined the effects of anaemia (4th edition) and vitamin D (5th edition) on prolapse. A further 2 studies relating to vitamin D are included in this update (Table 26).

Navaneethan et al (2015) conducted a case-control study of postmenopausal women with and without pelvic floor disorders, in particular, symptoms of urinary incontinence or prolapse. It was not clear how the women were selected but the study took place in a department of obstetrics and gynaecology in South India. A clinical and obstetric history was taken, examination performed (POP-Q and stress test) and vitamin D measured in all women. A multivariable logistic regression analysis was undertaken to assess the relationship between vitamin D and PFD adjusting for other variables (254). A low risk of bias was assumed (Table 26).

Parker-Autry et al. (2012) in Alabama, US, undertook a retrospective review of women who were new urogynaecology outpatients presenting over a two-year period (2008 to 2010) and who then had vitamin D measured within one year of that visit. 25(OH)D < 15 ng/ml was defined as being deficient in vitamin D, and 15 to 29 ng/ml as having insufficient vitamin D. Women were classified into two groups, either PFD (having SUI, UUI, FI or POP) or general gynaecology (no PFD) (Table 26). Demographic, medical, and laboratory data were extracted from the initial history and physical examination notes. Questionnaire responses from the clinic visit were also available (PFDI-SF 20 (including the UDI, CRADI, POPDI) and IIQ-7). Multivariable logistic regression was used to examine the association between vitamin D status and pelvic floor disorder symptoms, with adjustment for age, BMI, race/ethnicity, and the use of vitamin D supplementation. This study was judged to be at low risk of bias.

1.1.2 Results

1.1.2.1 Association Between POP and Occupation and Physical Activity

In the Akmel et al. (2012) study, 143 prolapse cases were examined and complete data retrieved for 129 cases. The mean age of the women was 42 years (range 22 to 72 years), mean parity was 6.5 (range 1 to 14) and all had stage III (56%) or IV (44%) prolapse. Significant univariate associations were found between age, parity and rurality and stage of prolapse. Occupation was significantly associated with prolapse stage in that farmers were more likely to have a lower stage and housewives a higher stage of prolapse (230).

In the retrospective case analysis described by Bathla et al. (2014), 192/490 surgical case presentations were gynaecological and 82% of these were prolapse (99% involving the anterior compartment). These women were aged between 30 and 70 (mean 47 years), had mean parity of 3.5, and all had unassisted home deliveries. Premature bearing down during delivery was reported for 24%. Women on average resumed strenuous physical work and sexual activity 20 days after giving birth. 33% were smokers and 55% lifted heavy weights uphill. The authors reported non-significant correlations between POP-Q stage and parity, resumption of physical activity and weight (232).

Out of 4403 outpatients, 118 cases (2.7%) of prolapse were seen over the study period in the Gumanga (2014) paper, with a mean age of 46 years (SD 15 years) and mean parity 4.4 (SD 1.7). For 57%
of women their deliveries had been exclusively at home. Women were predominantly farmers (37%) or traders (56%) (231).

Of all women in the county 30 years or older, 20,285 (50.3%) were included in the Lonnee-Hoffman (2012) study; of which 1,123 (5.5%) reported having undergone prolapse surgery. In the multivariable models, the odds of having prolapse surgery were shown to be significantly greater for women with BMI of 25 or greater, and for those who reported “marked” constipation (as compared to no or mild constipation). There was no relationship with smoking, asthma or occupation (228).

One hundred and ninety-one cases and an equal amount of matched controls were recruited in the Nygaard et al. (2014) study. The mean age of women was 50 years (SD 7). Cases tended to have a higher BMI than controls, and had significantly greater parity and more vaginal deliveries. Vaginal bulge was more prevalent in the cases than controls, but there was no difference in other pelvic floor symptoms. The authors found no evidence that physical activity (lifelong overall activity, leisure or strenuous physical activity) was associated with risk of prolapse in multivariable models. The exception was that strenuous physical activity in the teenage years showed a significant relationship with the odds of prolapse, indicating an increased risk of prolapse for those reporting 21 hours/week or more of strenuous physical activity when a teenager (229).

Elbiss (2015) found nature of occupation to be a significant predictor of prolapse symptoms (see below); women with non-physical jobs were more likely to report symptoms.

1.1.2.2 Association Between POP and Body Weight

Vergeldt et al. (2015) systematically identified 8 studies that examined the association of higher BMI and POP and presented the results in a narrative synthesis. The authors reported that 4/8 studies identified that higher BMI was a significant risk factor for POP; 3/8 found no relationship between high BMI and the development of primary POP and 1/8 study found that a “higher BMI slightly protective”. The authors reported that the relationship between weight and POP was inconsistent; thus no conclusions can be reliably drawn (250). This well-conducted review was judged to be at low risk of bias.

Kudish and colleagues (2009) explored the relationship between prolapse progression (or regression) and weight change in 16,608 post-menopausal women (Table 26). This second primary analysis study was based on longitudinal data from the WHI E+P trial; a double-blinded RCT. Women aged between 50 and 79 years received annual pelvic examinations over a 5-year interval. The majority of women enrolled in the study gained weight, and the overall prolapse prevalence (stage I-III) increased from 40.9% at baseline to 43.8% by year 5. The risk of all types of prolapse increased in overweight and obese women compared to post-menopausal women with normal BMIs (Table 26). When the data was adjusted for women diagnosed with prolapse at baseline and baseline BMI, a 10% weight loss was associated with minimal change in overall POP (251). This study was judged to be at low risk of bias.

1.1.2.3 Association Between POP and Smoking

In the Estanol (2015) study, a total of 96 women were recruited: 32 with prolapse (16 smokers, 16 non-smokers) and 64 without prolapse (32 smokers, 32 non-smokers) (252). Smokers with prolapse had lower levels of vitamin C and higher levels of MMP-9, compared to non-smokers with prolapse, but this relationship was not statistically significant. However, comparing smokers without prolapse to non-smokers without prolapse, there were significant differences in both vitamin C and MMP-9, suggesting an impact of smoking on these collagen markers. Ignoring smoking status, vitamin C and MMP-9 levels in women with prolapse were similar to those without prolapse. The authors suggest that the damage to connective tissue that leads to prolapse may be different from the harm caused by cigarette smoking.

Lonnee-Hoffman et al. (2015) found no association between smoking and whether a woman reported having had prolapse surgery or not (228). Bathla et al. (2104) commented that 33% of the women having prolapse surgery were smokers (232).

1.1.2.4 Association Between POP and Bowel Function

Bezerra and colleagues reported that a total of 172 women with prolapse and/or urinary incontinence participated and initially none of them reported defecatory problems or anal incontinence, although 54.6% reported one or both on interview. Those with AI/defecatory problems were no more likely to report prolapse (sensation of a ball in the vagina) than those without these problems (68% versus 65%). Stage of prolapse was not associated with AI/defecatory problems either (253).

Of the 482 eligible women in the Elbiss (2015) study, 429 (89%) participated, of which 127 (29.6%) reported prolapse symptoms. Those women with and without prolapse symptoms did not differ in terms of age. Of the factors significantly associated with prolapse in the univariate analysis (BMI, education level, nature of occupation, history of chronic chest disease, constipation, diabetes, previous instrumental delivery, maximum birth weight, history of urinary incontinence and previous surgery for urinary incontinence) six were independent risk factors in the multivariable analysis: history of constipation, education level, chronic chest disease, nature of occupation, maximum birth weight and BMI. Women were more likely to have prolapse symptoms if they had chronic
chest disease or constipation, higher BMI or maximum birth weight, lower education level, and were a housewife or had a non-physical job (238).

Lonnee-Hoffman et al. (2015) found that marked constipation (as compared to no or mild constipation) was significantly associated with having prolapse surgery (228).

1.1.2.5 Association Between POP and Nutrition

Navaneethan et al. (2015) reported that of the 120 women who participated: 42.5% had PFD (54.9% prolapse alone, 27.4% SUI alone, 17.6% SUI and prolapse) and 57.5% had no PFD. Multivariable analysis showed that, after adjustment for age, having any PFD was associated with having lower vitamin D levels and being five years or more post-menopausal. However having prolapse was only associated with the latter, and there was no significant relationship with vitamin D (254).

Of 550 women potentially eligible to participate in the Parker-Autry (2012b) study, 394 were included (268 in the PFD group and 126 in the no PFD group). The prevalence of vitamin D insufficiency was 51% in the PFD group. Vitamin D insufficiency was independently associated only with IIC-7 score. That is, there was no relationship with prolapse symptoms (255).

Summary

- There remain no trials of lifestyle modification interventions to prevent prolapse. Some new observational studies have added to our knowledge of potentially helpful ways to modify lifestyle risk factors.
- Two new good quality observational studies (228, 229) suggested occupation and physical activity are not risk factors for prolapse surgery or prolapse 1cm or more beyond the hymen on examination. A third study however found women who were housewives or in a non-physical occupation were more likely to report prolapse symptoms (238). The vast majority of studies reported in previous editions supported an association between current heavy occupational lifting and prolapse, overall therefore the evidence seems to be conflicting, and this may be due to different ways of defining prolapse (Level of Evidence: 3; Grade of Recommendation: D Conflicting therefore no recommendation).
- Recent evidence on the relationship between prolapse and bodyweight is conflicting. (Level of Evidence: 3; Grade of Recommendation: D Conflicting therefore no recommendation).
- Smoking was found not to be associated with prolapse in two studies: a matched case control study (Estandol) (high risk) and large cross-sectional survey with multivariable analysis (Lonnee-Hoffman) (low risk). No studies were found in earlier editions (Level of Evidence: 3; No recommendation).
- Evidence from previous editions regarding the association between constipation or straining at stool and prolapse was conflicting. Two new, low risk studies, which adjusted for covariates, concluded that constipation was associated with both prolapse symptoms and having prolapse surgery, contributing more evidence of an association (Level of Evidence: 3; Grade of Recommendation: C New; Majority evidence of an association).
- Two new, low risk studies on vitamin D supported previous findings (1 study, 5th Edition) of no association with prolapse (Level of Evidence: 3; Grade of Recommendation: C Majority evidence of no association).

1.2. Treatment

Previously no studies that evaluated the effectiveness of lifestyle modification interventions in the treatment of women with POP had been identified. Subsequently we have identified one trial, which measured prolapse outcomes after weight loss programmes (243). Not all trial participants had prolapse however, which limits the usefulness of this evidence (see Table 26).

Quality of Data

Myers and colleagues (2012) performed a secondary analysis of data from the PRIDE trial of an intensive weight loss programme versus an educational programme for urinary incontinence in overweight and obese women (243). Prolapse symptoms were measured at baseline and six months (post-intervention) using the prolapse items from the UDI. Any positive response to any questionnaire items indicated the presence of prolapse symptoms. A subgroup of women agreed to have urodynamics and POP-Q assessment before and after intervention. Women were classified as overweight, obese or severely obese according to their BMI. Women who had prolapse symptoms at baseline were analysed at 6 months for differences between the randomised groups. The risk of bias was judged as low in relation to selection, detection and attrition for the original PRIDE trial (6) in a recent Cochrane review (5).

Results

Myers et al. (2012) reported that 338 women were randomised and 110 had urodynamics and POP-Q (243). Of the women randomised, 16% were overweight, 58% obese and 26% severely obese. At baseline 53% reported at least one prolapse symptom, but this did not differ across BMI groups. A significantly greater proportion of obese women reported feeling vaginal bulge compared to overweight women (10% severely obese vs 14% obese vs 0% overweight), but the mean number of prolapse symptoms did not differ across the BMI groups. The proportion with prolapse beyond the hymen was 17% overall but
did not differ across the BMI groups (24% overweight group, 17% obese group, 13% severely obese group). Post-intervention the intensive weight loss group had lost significantly more weight than the control group (mean 7.8kg vs 1.5kg). Over 70% reported cure or improvement in prolapse symptoms, although this was no different between the intensive weight loss group and the educational group. There was also no significant difference in prolapse beyond the hymen between weight loss intervention and educational groups. The findings would suggest a lack of relationship between weight loss and improvements in prolapse. However, the trial was designed for women with urinary incontinence rather than prolapse, and the post-intervention comparison was not randomised.

**Summary**

Currently, there is evidence from secondary analysis of one robust trial regarding the role of weight loss in the treatment of POP. The trial however was in overweight and obese women with UI, some of whom had prolapse. It would appear that weight loss in both groups led to an improvement in prolapse, however there was no relationship between degree of weight loss (intensive vs normal weight loss programme). Any weight loss may improve prolapse in overweight or obese women and UI. (Level of Evidence: 2; Grade of Recommendation: D).

### 2. PELVIC FLOOR MUSCLE TRAINING

The pelvic floor muscles play a critical role in giving structural support to the pelvic organs and pelvic openings. It is hypothesized that improving pelvic floor muscle function may improve this structural support for the pelvic organs.

A programme of supervised PFMT includes assessment of the woman’s pelvic floor muscles and her ability to contract these muscles; education about the pelvic floor muscles and how they support the pelvic organs; instruction in how to correctly perform pelvic floor muscle exercises and “the Knack” (pelvic floor muscle bracing against increased intra-abdominal pressure, for example when coughing and sneezing) (256). An individualised exercise programme is prescribed for the woman to follow. Adjuncts to PFMT (such as biofeedback) or other physical therapies (such as neuromuscular EStim) may be used. These therapies aim to improve PFM strength, endurance, coordination and function. Other forms of physical therapy involving diaphragmatic aspiration are emerging.

#### 2.1. Prevention

**Quality of data**

Previously there were no trials of PFMT for prevention of prolapse, only evidence from cross-sectional studies of a possible association between pelvic floor muscle function and risk of prolapse. Two RCTs have now been identified that evaluate the role of PFMT in prevention of prolapse (257, 258). A summary of the setting, design and study population of prevention trials is presented in Table 27. Blinding of patients is generally not possible in trials of PFMT so this is not taken into consideration in the risk of bias analysis.

Bo et al (2013) (258) carried out a trial in primiparous women after vaginal delivery of a singleton infant after 32 weeks gestation, comparing supervised PFMT with written advice to do PFMT (control), to prevent and treat prolapse. All women had received written recommendations to perform PFMT in the delivery ward. The PFMT group attended a weekly PFMT class for 4 months starting at 6-8 weeks postpartum, and performed home-based exercise. The control group had no further supervision or follow-up. Outcomes measured at 6 weeks and 6 months post-partum included POP-Q stage, bladder neck position (transperineal ultrasound) and symptom of vaginal bulge (ICIQ-VS). The trial was judged as low risk for selection bias, performance and detection bias, attrition bias and reporting bias. However, the trial was judged as unclear for other types of bias (Table 27).

The PREVPROL trial, undertaken by Hagen and colleagues, compared PFMT versus lifestyle advice leaflet as secondary prevention for women with pre-clinical signs of prolapse (257). Participants were women originally enrolled in a longitudinal follow-up of postnatal incontinence (at 3 months, 6 and 12 years) after giving birth in 1993/94. Those, who had not sought treatment for prolapse, but who showed early signs of prolapse (POP-Q stage I, II or III) were invited to take part. They were randomised to receive either a programme of PFMT (individualised physiotherapy appointments, maintenance via Pilates-based classes (progressive Pilates-based exercises, pelvic floor muscle training as given in the one-to-one intervention, core exercises from the “Pelvicore Technique with Kari Bo” DVD) and annual one-to-one check-ups) or a prolapse prevention lifestyle advice leaflet. Women were followed up at 1 and 2 years in terms of their prolapse symptoms (POP-SS), prolapse-related QoL, uptake of prolapse treatment, symptoms of urinary incontinence (ICIQ-UI SF), anorectal or sexual dysfunction (PISQ-12), perceived health benefit, and cost-effectiveness.

The trial was judged as low risk for selection bias, performance and detection bias, attrition bias, reporting bias and other types of bias (Table 27).

**Results**

One hundred and seventy-five primiparous women were randomised in the Bo (2013) study, 87 to PFMT and 88 to control, mean age 30. At 6 months post-
partum there was no difference between groups in the prevalence of symptoms of bulging either inside or outside the vagina. There was no difference between groups in the prevalence of stage II prolapse at 6 months, or in any of the individual POP-Q measurements, or the bladder neck position (258).

In the PREVPROL trial 414 women were randomised, 207 to PFMT and 207 to control, mean age 46 years (257). There was a significantly lower POP-SS score at 2 years in the PFMT group compared to the control group, indicating fewer symptoms. Women in the control group were significantly more likely to have sought treatment for prolapse symptoms by 2 years. No significant difference was found between the groups in the percentage who experienced any urine leakage at 2 years, although there was a significant difference in favour of the intervention group in the ICIQ-UI short form score. Faecal urgency and leakage, and sexual function were not significantly different between the groups at 2 years. Women in the intervention group were more likely to say they felt a health-related benefit from the study compared to the control women.

Summary

Currently, there is evidence from two robust trials regarding the role of PFMT in the prevention of POP. The trials were in different populations of women however (postnatal women, 13% of whom had stage II prolapse, and middle-aged women with mild prolapse, 55% with stage II or greater, who had not sought treatment) and drew differing conclusions. It would appear that in younger post-natal women PFMT does not influence the development of prolapse by 6 months, whereas in older women, more than 12 years after giving birth, there was a significant benefit of PFMT in terms of fewer prolapse symptoms after 2 years and less uptake of treatment. PFMT can prevent symptoms of prolapse which develop in the longer term after childbirth but not immediately after giving birth.

Postnatal: Level of Evidence: 1; Grade of Recommendation: B New; majority evidence from RCT of no effect for postnatal.
12 years post-childbirth: Level of Evidence 1; Grade of Recommendation: B New; Majority evidence from RCT of effect in the long term after childbirth.

2.2. Treatment

Quality of data

Evidence from trials now exists relating to the role of PFMT in the treatment of prolapse. The role of PFMT as an adjunct to surgery or pessary has also been the subject of randomised studies. A Cochrane review specifically addressing this question was first published in 2004 (259), and updated in 2011 (220) and 2016 (in preparation) (221).

2.2.1 PFMT Alone

Thirteen trials now exist in this area, six of which were previously reported in previous consultations. Key characteristics of the seven new trials, and new published information about two earlier trials, are summarised in Table 28. Narrative descriptions of these trials are reported below.

Alves and colleagues carried out a trial in post-menopausal women in which they compared a general fitness programme (control) with a PFMT programme (intervention) (47). Both groups performed a fitness programme twice weekly for 6 weeks including global muscle stretching, endurance and functional exercises. In addition, the intervention group took part in a physiotherapist-supervised PFMT programme in groups of seven, 30 minutes twice weekly for 6 weeks. The control group women were taught about pelvic floor muscles and how to contract them correctly, but without any training. Outcomes were assessed after the intervention at 6 weeks. The trial was generally judged as low risk for performance and detection bias, attrition bias, reporting bias and other types of bias. However it was unclear if opaque envelopes were used in the allocation process, and an intention to treat analysis was not performed (Table 28).

Culligan and colleagues compared a standardised PFMT programme with a standardised Pilates programme in community women with POP-Q stage I prolapse to see if they provided similar improvements in PFM strength (260). The PFMT programme, made up of twice weekly 1-hour sessions for 12 weeks, included computerized biofeedback, vaginal manipulation, neuromuscular re-education, and manual therapy. Participants completing 20 or more of the 24 possible sessions were defined as “successful”. The control group attended a Pilates programme with the same pattern of sessions where they were taught full-body exercises focusing on the “core muscles”, and the pelvic floor in particular. Women were assessed at baseline and after the intervention at 12 weeks in terms of PFM strength and pelvic floor symptoms and impact (PFDI-20), Short Form Pelvic Floor Impact Questionnaire (PFIQ-7). The trial was judged as low risk for selection bias, attrition bias, reporting bias and other types of bias. However, performance and detection bias was judged as unclear risk of bias as it was unclear if outcome assessors were blinded (see Table 28).

Due et al. (2016) undertook a trial in women with symptomatic prolapse of stage II or greater, comparing a structured lifestyle advice programme plus PFMT (combined group) with lifestyle programme alone (lifestyle group) (261). The PFMT included both group PFMT (6 sessions over 12 weeks) and individual home training after an assessment and individual instruction. Women were assessed using the Patient Global Index of Improvement scale (PGI-I), POP-Q, PFDI-20, PFIQ-7 and PISQ-12 at baseline, immediately post-intervention (3 months) and at 6 months.
The trial was judged as low risk for selection bias, performance and detection bias, attrition bias, reporting bias and other types of bias (261) (Table 28).

Frawley et al. (2012) carried out a trial in four Australian centres involving women with symptomatic prolapse stage I to III, randomised to PFMT or a lifestyle advice leaflet (control) (262). This trial protocol was based on that of the UK POPPY trial (263) described below with some slight adjustments and additional measurements. Women were assessed at baseline, 6 and 12-month follow-up for PFM function (manometric and digitally-assessed strength and endurance (ICS scale)), prolapse symptoms (POP-SS) and severity/type (POP-Q). The trial was judged as low risk for selection bias, performance and detection bias, reporting bias and other types of bias. However, the trial was considered to have high risk of attrition bias. Communication with the author provided explanations about the dropout observed (Table 28).

Giraudo et al.'s (2011) trial compared PFMT plus negative pressure abdominal work (intervention group) with PFMT plus abdominal hollowing exercise (control group) in women with untreated stage I or II prolapse (264). Both groups were taught correct contraction of the pelvic floor muscles and given tailored lifestyle advice on ways of reducing intra-abdominal pressure, as well as a standardised lifestyle advice sheet. There was no description of 1) the negative pressure abdominal work or 2) abdominal hollowing exercises but they are described elsewhere as 1) hypopressive exercises, which are thought to result in negative pressure in the thoracic cavity and involuntary contraction of the pelvic floor and abdominal wall, and 2) pulling the belly button in towards the spine. The intervention duration was 24 weeks, with individual supervision twice weekly for one hour each session during the first 3 months, followed by once a week for the last 3 months. Women were assessed at baseline and at 24 weeks for prolapse symptom severity (P-QOL), prolapse severity (POP-Q) and PFMT strength (Oxford scale). The trial was judged as low risk for selection bias (randomisation only), performance and detection bias and reporting bias. The trial was judged as unclear risk of bias for selection bias (allocation concealment), attrition bias, and other types of bias (264) (Table 28).

Hagen and colleagues carried out a multicentre trial (POPPY trial) comparing an individualised PFMT programme (including lifestyle advice) with a lifestyle advice leaflet (control group) (263). Participants were outpatients attending with newly-diagnosed, symptomatic stage I, II, or III prolapse. The PFMT intervention which was delivered by a specialist women's health physiotherapist over 16 weeks in 5 sessions included teaching of anatomy and function of pelvic floor muscles, the correct exercise technique and 'the Knack', and a prescription of a home exercise programme. A standardised lifestyle advice leaflet and tailored lifestyle advice were given. The control group received the lifestyle advice leaflet by post. Outcomes measured at 6 and 12 months were prolapse symptoms (POP-SS), prolapse-related QoL, need for further prolapse treatment, bladder, bowel and sexual symptoms. POP-Q was measured at baseline and 6 months. The trial was judged as low risk for selection bias, performance and detection bias, attrition bias, reporting bias and other types of bias (Table 28).

Kashyap and colleagues reported a single-centre trial in parous women with stage I to III prolapse, which compared taught pelvic floor muscle training plus a self-instruction manual (SIM) with the SIM alone as the control intervention (265). One person delivered the training to all intervention women. This included explanation of anatomy and function of pelvic floor muscles, PFMT training, plus exercise practice and checking for correct PFMT contractions by vaginal examination. Pressure manometry was included for biofeedback and motivation. A home exercise programme was prescribed for 3 times daily. Women were instructed to perform the intervention for 24 weeks. After the initial training session, there were 6 follow up visits (at weeks 1, 3, 6, 12, 18 and 24). The content of the manual was not described and therefore what written instruction the control group received is unclear. Women were assessed at baseline and at 1, 3, 6, 12, 18 and 24 weeks using the POP-SS, a visual analogue scale and the PFIRQ-7. The trial was judged as low risk for selection bias. However, the trial was judged as high risk for performance and detection bias, attrition bias, reporting bias and other types of bias (see Table 28).

Stupp/Resende carried out a three-arm trial comparing PFMT versus hypopressive exercises (diaphragmatic breathing) plus voluntary pelvic floor muscle contraction (PFMT+HE) versus lifestyle advice only (266, 267). Participating women were attending a urogynaecology service in Sao Paulo, Brazil, and had untreated stage II anterior or posterior prolapse. The PFMT intervention involved three physiotherapy appointments to learn how to perform PFMT correctly (weeks 0, 1, 2). Then a 12-week home exercise programme was prescribed consisting of three sets of exercises daily. The PFMT+HE group had three appointments (weeks 0, 1, 2) during which they had instruction in correctly performing hypopressive exercises and pelvic floor muscle contractions, and how to do these simultaneously. They practiced the exercises for 12 weeks. Both of these groups completed an exercise diary, had a telephone call from the physiotherapist every two weeks and a monthly appointment (weeks 6, 10, 14). The control group received one appointment, were given lifestyle advice and were instructed how to perform PFMT contractions. However, it was unclear with whom the appointment was held, or whether the instruction was verbal or included a digital assessment. A standardised lifestyle advice sheet was given to all women containing global stretching exercises and advice on weight loss, constipation, coughing and avoidance of heavy lifting.
<table>
<thead>
<tr>
<th>Author, year</th>
<th>Comparator</th>
<th>N</th>
<th>Study population</th>
<th>Modality details or parameters</th>
<th>Outcomes/results</th>
<th>Follow up</th>
<th>Notes (side effects, loss of follow up...)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bø 2013 (1)</td>
<td>Parallel group RCT; 2 groups, PFMT vs control</td>
<td>175</td>
<td>Primiparous women, vaginal delivery, singleton infant, ≥ 32 weeks</td>
<td>All women: written advice in delivery ward to perform PFMT. 2 trained physiotherapists taught PFM contraction and assessed PFM function before randomisation by observation of the perineum and vaginal palpation. PFMT group: weekly PFMT classes delivered by trained physiotherapists for 4 months starting at 6-8 weeks postpartum. Performed home-based exercise, 3 sets of 8-12 close to maximum PFM contractions per day. Control group: no further supervision or follow-up during the intervention period.</td>
<td>Stage of POP and bladder neck position. Secondary outcomes: symptoms of POP (sensation of bulging) using International Consultation on Incontinence Vaginal Symptoms questionnaire</td>
<td>Assessed at 6 weeks (pre-test) and 6 months’ (post-test) postpartum</td>
<td>Randomisation was computer generated and opaque sealed envelopes were used. Outcome assessors were blinded and the groups were comparable at baseline. Intention-to-treat analysis was employed and dropouts were clearly reported. The trial was judged as potentially having an unclear risk of bias as the authors noted that &quot;because of ethical reasons the control group was not discouraged from performing PFMT on their own, but they were asked to follow the prescription for the group they were randomised to.&quot;</td>
</tr>
<tr>
<td>Hagen 2014 (2)</td>
<td>Parallel group RCT; 2 groups, PFMT versus control (lifestyle advice leaflet)</td>
<td>407</td>
<td>Primiparous women assessed for pelvic floor dysfunction 12 years after an index birth; women involved in the ProLong cohort study (3) who have POP-Q stage I, II or III); no previous treatment for prolapse (surgery, pessary, PFMT)</td>
<td>Intervention: 1:1 PFMT taught using digital palpation delivered in 5 physiotherapy appointments over 16 weeks, followed by Pilates-based classes, including PFMT. Classes were carried out in 6-week block (one class per week) and each woman was offered two 6-week blocks. Exercise DVD was provided for home use. Women offered a 1:1 physiotherapy annual review appointment at 1 and 2 years after randomisation. Control group: sent a lifestyle advice leaflet containing advice on weight loss, and avoidance of constipation, heavy lifting, coughing and high impact exercise.</td>
<td>POP-SS, Prolapse-related QoL, uptake of prolapse treatment, symptoms of urinary incontinence, anorectal or sexual dysfunction, women’s perceived health benefit, and cost-effectiveness</td>
<td>Data collected at baseline, 1 and 2 years post randomisation</td>
<td>Randomisation was generated using a computer program located at the Trial Office on a password-protected PC. Outcome assessors were blinded and the groups were comparable at baseline. Intention-to-treat analysis was employed and dropouts were adequately reported. Questionnaire response rate: 81% year 1, 86% year 2 follow-up. Attendance at annual review appointments: 52% and 46% at year 1 and year 2 respectively, and uptake of classes in the UK was 33% and 17% at 1st and 2nd block respectively. By year 2, 77% in the intervention group reported they had done PFM exercises in the last 4 weeks</td>
</tr>
</tbody>
</table>
Abbreviations: PFM: pelvic floor muscles; PFMT: pelvic floor muscle training; POP-SS: pelvic organ prolapse symptom score; QoL: quality of life; RCT: randomised controlled trial


Table 28 Summary of data on PFMT vs no active treatment for POP

| Author, year | Study design/ Comparator | N | Study population | Modality details or parameters | Outcomes/results | Follow up | Notes (side effects, loss of follow up…)
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Alves 2015 (1)</td>
<td>Parallel group RCT, 2 groups, PFMT vs control</td>
<td>30</td>
<td>Women ≥5 years postmenopausal, with urogynecological complaints</td>
<td>Intervention: PFMT taught using digital palpation. Groups of 7 women: 12 sessions, twice weekly for 30 minutes, over six weeks. Include pelvic mobility exercises, stretching, strengthening and relaxation in supine, sitting, on Gym Ball, squatting and standing, along with PFM contractions, consisting of 4 sets of 10 fast contractions and 4 sets of 10 sustained contractions, 8 seconds hold followed 16 seconds relaxation All women: performed a Fitness Program based on global muscle stretching, endurance and functional exercises for the elderly</td>
<td>POP-Q, ICIQ-VS, ICIQ-UI SF, ICIQ-OAB, PFM assessment (digital palpation, sEMG), treatment satisfaction (VAS, 0-10)</td>
<td>Assessed at baseline and post intervention (6 weeks).</td>
<td>Generally low ROB. Randomisation by draw, with each participant blindly drawing a sealed envelope containing a pre-printed card; however it was unclear whether opaque envelopes were used. Outcome assessors were blinded. Sample size calculation was reported and the groups were comparable at baseline. ITT not employed but dropouts were adequately reported. High attrition rate for the intervention group; 30/42 women completed the trial.</td>
</tr>
<tr>
<td>Culligan 2010(2)</td>
<td>Parallel group RCT; 2 groups, standardised PFMT program vs standardised</td>
<td>62</td>
<td>Non pregnant community women with POP-Q stage I, with or without complaint of pelvic floor dysfunction</td>
<td>Intervention: 1:1 PFMT, 24 1-hour sessions, twice weekly for 12 weeks. Included computerized biofeedback, vaginal manipulation, neuromuscular re-education, and manual therapy. Authors imply women taught contraction used digital palpation.</td>
<td>PFDI-20; PFIQ-7, PFM strength (vaginal pressure)</td>
<td>Assessed at baseline and post-intervention at 12 weeks</td>
<td>Generally low ROB. Randomised using blocked random assignment, and allocation concealment used sequentially numbered opaque sealed envelopes. Unclear whether participants and outcome assessors were blinded. Groups were comparable at baseline.</td>
</tr>
<tr>
<td>Author, year</td>
<td>Study design/ Comparator</td>
<td>N</td>
<td>Study population</td>
<td>Modality details or parameters</td>
<td>Outcomes/results</td>
<td>Follow up</td>
<td>Notes (side effects, loss of follow up…)</td>
</tr>
<tr>
<td>--------------</td>
<td>--------------------------</td>
<td>---</td>
<td>------------------</td>
<td>--------------------------------</td>
<td>------------------</td>
<td>----------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td>Due 2016 (3)</td>
<td>Parallel group RCT; 2 groups, Combined group (PFMT plus structured lifestyle advice program) and lifestyle group (structured lifestyle advice program alone)</td>
<td>109</td>
<td>Women ≥18 years with POP symptoms and a POP-Q ≥ stage II</td>
<td>Intervention: group PFMT and home training after a digital assessment and individual instruction. 6 group sessions delivered over 12 weeks. Include the Knack, home exercise 5 days a week (3 sets of up to 10, 10 second contractions). Plus lifestyle advice program as below. Control group: Lifestyle advice program, 6 1-hour group teaching sessions including information on POP-promoting factors, reducing pelvic floor pressure, bladder and bowel function, diet, body image and physical activity. No PFMT.</td>
<td>POP-Q; POP-Q; POP-Q; PFDI-20; PFIQ-7; PISQ-12; Patient Global Index of Improvement scale (PGI-I)</td>
<td>Assessed at baseline, immediately post-intervention (3 months) and 6 months</td>
<td>Low ROB for selection bias, performance and detection bias, attrition bias, reporting bias and other types of bias “Majority of the women in the lifestyle advice group (p≤0.001) had sought further treatment at six months follow-up, mainly as PFMT”</td>
</tr>
<tr>
<td>Frawley 2012 (4)</td>
<td>Parallel group RCT; 2 groups, PFMT vs control (lifestyle</td>
<td>168</td>
<td>Women with symptomatic POP of stage I, II or III</td>
<td>This trial used the same protocol as the UK POPPY trial with some slight adjustments and additional measurements (see Hagen 2010 below)</td>
<td>POP-Q; POP-SS; PFM manometric strength and endurance; digitally assessed PFM strength/endurance (ICS scale)</td>
<td>Data collected at baseline and 6 and 12 month follow up</td>
<td>Generally low ROB. Randomisation was computer generated and participants were allocated to the trial using a remote randomisation service. Outcome assessors were blinded. Potentially high risk for attrition</td>
</tr>
<tr>
<td>Author, year</td>
<td>Study design/ Comparator</td>
<td>N</td>
<td>Study population</td>
<td>Modality details or parameters</td>
<td>Outcomes/results</td>
<td>Follow up</td>
<td>Notes (side effects, loss of follow up…)</td>
</tr>
<tr>
<td>--------------</td>
<td>--------------------------</td>
<td>---</td>
<td>------------------</td>
<td>--------------------------------</td>
<td>------------------</td>
<td>-----------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td>Hagen 2014(6)</td>
<td>Parallel group RCT; 2 groups, individualised programme of PFMT vs prolapse lifestyle advice leaflet</td>
<td>447</td>
<td>Female outpatients with newly-diagnosed, symptomatic stage I, II, or III POP</td>
<td>Intervention: Anatomy/function of PFMs explained, taught to correctly contract PFMs (vaginal palpation, PERFECT) and pre-contracting against increases in abdominal pressure. 5 physiotherapy appointments delivered over 16 week period (weeks 0, 2, 6, 11 &amp; 16). Home exercise prescribed - 3 sets of exercises per day: 10 maximum voluntary contractions held for up to 10s, with POP-SS; POP-Q; women’s perceived change in prolapse; interference due to prolapse; days of symptoms; uptake of prolapse treatment; ICIQ UI-SF; PISQ; SF-12</td>
<td>Assessed at 12 months, except POP-Q assessed at 6 months</td>
<td>Low ROB. Randomisation was computer generated, and university-based trial coordinator accessed the web-based application and then informed the woman, and the physiotherapist as necessary, of the allocated group. Outcome assessors and investigators (who were gynaecologists at trial sites), were...</td>
<td></td>
</tr>
<tr>
<td>Giraudo 2011 (5)</td>
<td>Parallel group RCT; 2 groups, PFMT plus negative pressure abdominal work vs PFMT plus abdominal hollowing exercise</td>
<td>44</td>
<td>Women with untreated stage I or II prolapse. No mention of whether women had symptoms.</td>
<td>Both interventions: PFMT delivered over 24 weeks, 1:1 supervised sessions twice-weekly for 1 hour for 3 months, once a week for last 3 months. Women taught to contract the PFMs correctly by vaginal palpation. Tailored lifestyle advice given on reducing intra-abdominal pressure plus standardised lifestyle advice sheet (advice on weight loss, constipation, avoidance of heavy lifting, coughing and high-impact exercise). Groups: individualised PFM contraction with either abdominal hollowing exercises or negative pressure abdominal work.</td>
<td>Prolapse symptom severity measured via P-QOL Questionnaire. Prolapse severity (POP-Q) and PFM strength (Oxford scale). ICIQ-UI SF also used but not reported.</td>
<td>Assessed at baseline and at 24 weeks</td>
<td>bias. Dropouts were accounted for but no explanations given for high attrition rates at 6 and 12 month follow up. Attrition was greater in the PFMT group at 6 months (14.3% vs 10.7%) but greater in the lifestyle group at 12 months (5.6% vs 21.3%).</td>
</tr>
<tr>
<td>Author, year</td>
<td>Study design/ Comparator</td>
<td>N</td>
<td>Study population</td>
<td>Modality details or parameters</td>
<td>Outcomes/results</td>
<td>Follow up</td>
<td>Notes (side effects, loss of follow up…)</td>
</tr>
<tr>
<td>--------------</td>
<td>--------------------------</td>
<td>---</td>
<td>------------------</td>
<td>-------------------------------</td>
<td>----------------</td>
<td>----------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4srest between; after 1 minute rest, up to 50 rapid contractions. Standardised lifestyle advice leaflet and tailored lifestyle advice given. Control group: received the same lifestyle advice leaflet by post.</td>
<td></td>
<td></td>
<td>masked to group allocation; the statistician was masked until after data analysis. ITT analysis was employed and dropouts were adequately reported.</td>
</tr>
<tr>
<td>Author, year</td>
<td>Study design/ Comparator</td>
<td>N</td>
<td>Study population</td>
<td>Modality details or parameters</td>
<td>Outcomes/results</td>
<td>Follow up</td>
<td>Notes (side effects, loss of follow up…)</td>
</tr>
<tr>
<td>-------------</td>
<td>--------------------------</td>
<td>----</td>
<td>------------------</td>
<td>--------------------------------</td>
<td>------------------</td>
<td>----------</td>
<td>-----------------------------------------</td>
</tr>
<tr>
<td>Kashyap 2013 (7)</td>
<td>Parallel group RCT; 2 groups, PFMT and a self-instruction manual (SIM) vs SIM alone</td>
<td>140</td>
<td>Parous women attending gynaecology outpatient department, aged 20–70 years, who were willing to attend follow-up visits</td>
<td>Intervention: anatomy/function of PFMs explained. 1:1 PFMT training, plus exercise practice and checking for correct contractions of PFM by vaginal examination. Pressure manometry for biofeedback and motivation. Given SIM. After training session, 6 follow up visits (weeks 1, 3, 6, 12, 18 and 24). Home exercise programme of 3 times/daily set of exercises comprising 10 voluntary contractions, held for 10s each with 10s rest in between. Participants performed the intervention as described for 24 weeks. Control: SIM plus 3 follow-up visits (weeks 6, 18 and 24). Home exercise prescribed as above.</td>
<td>POP-SS; symptoms measured by visual analog scale (VAS), PFIQ-7, POP-Q</td>
<td>Assessed at baseline and at 1, 3, 6, 12, 18 and 24 weeks</td>
<td>Low risk for selection bias as the trialists had used a block randomisation method for randomisation, and a physician, who was not involved in the study, performed the patient allocation. Potential for high risk of bias, as “the study design did not include blinding”. There was a crossover of 4 participants from group B to group A after randomisation. Details of attrition were not well reported: it was indicated that analysis was performed on all 140 participants however there was also reference to individuals “missing” and “lost to follow-up”. Self-completed exercise diary but unclear how well adherence was actually delivered as planned.</td>
</tr>
<tr>
<td>Resende 2008/ Stupp 2011 (8, 9)</td>
<td>3-arm RCT; PFMT training vs hypopressive</td>
<td>58</td>
<td>Women with stage II POP and not undergoing surgery to correct it during</td>
<td>PFMT: Session 1 (week 0), anatomy/function of PFMs explained, training on PFM contractions, observation on correct performance. Follow up sessions</td>
<td>POP-Q; symptom severity (Prolapse Quality of Life (P-QoL)); PFM</td>
<td>Baseline evaluation and immediately</td>
<td>Low or unclear ROB. Randomisation was computer generated, but allocation concealment was not described.</td>
</tr>
<tr>
<td>Author, year</td>
<td>Study design/ Comparator</td>
<td>N</td>
<td>Study population</td>
<td>Modality details or parameters</td>
<td>Outcomes/results</td>
<td>Follow up</td>
<td>Notes (side effects, loss of follow up...)</td>
</tr>
<tr>
<td>-------------</td>
<td>--------------------------</td>
<td>----</td>
<td>------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>-------------------------------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>Wiegersma 2014 (10)</td>
<td>Two parallel RCTs. POPPS 1 (described here) 2 groups; PFMT vs watchful waiting</td>
<td>287</td>
<td>Women aged at least 55 years with symptomatic mild POP identified via screening survey in 15 GP practices</td>
<td>Intervention: Explanation of the function of pelvis/pelvic floor/ pelvic floor dysfunctions, taught “the Knack”. Weekly visits to pelvic physiotherapist until able to correctly contract and relax PFMs (assessed by digital palpation), then 2-3 weeks intervals. Home exercise 3-5 times a week, 2 or 3 times a day. Advice on lifestyle (diet, body weight) and toilet habits. Control: no treatment or recommendations</td>
<td>Assessed 3 months from the start of treatment (or from randomisation for control group): PFDI-20, PFIQ-7, POP-Q, SF-12, PISQ-12, patients’ perceived change in symptoms (VAS), PFM function (ICS method)</td>
<td>after intervention (at 3 months)</td>
<td>The main investigator was blind to the study groups and not involved in delivering the intervention. Groups were comparable at baseline and dropouts were accounted for. Attrition was evident only in the control group where 16/21 (76%) were analysed. Single trial reported over multiple papers (confirmed by author). Reports do not agree about number of participants, age. Authors state: “The women who took part in the present study also participated in a randomized, controlled trial on PFMT to reduce POP, the results of which are not available yet. Therefore, in this study, we considered only the results regarding PFM function.”</td>
</tr>
</tbody>
</table>

exercises plus PFMT vs lifestyle advice & instruction on PFM contraction (1 appointment)
Abbreviations: PFDI-20: pelvic floor distress inventory short form 20, PFIQ-7: pelvic floor impact questionnaire short form; PFM: pelvic floor muscles; PFMT: pelvic floor muscle training; POP-Q: Pelvic Organ Prolapse Quantification system; PISQ-12: Pelvic organ prolapse/urinary incontinence sexual questionnaire; POP-SS: pelvic organ prolapse symptom score; QoL: quality of life; RCT: randomized controlled trial; sEMG: surface electromyography


Women were assessed at baseline and immediately after intervention (at 3 months) using POP-Q (blinded assessment); PFM strength and endurance (Oxford scale), electrical activity (sEMG) and symptom severity and impact (P-QoL). The trial was judged as low risk for selection bias (randomisation) and unclear risk for allocation concealment. The trial was also judged at low risk for performance and detection bias, attrition bias, reporting bias and other types of bias (266, 267) (Table 28).

Wiegersma and team conducted a trial in primary care (POPP1) of women aged ≥55 years with symptomatic mild prolapse (above the hymen) (268). Women in the trial were randomised to either PFMT or watchful waiting. Women in the PFMT group were given an explanation of pelvic floor anatomy and pelvic floor dysfunction, were taught “the Knack”, and given lifestyle advice. They had weekly visits with the pelvic physiotherapist initially. The intervals between appointments were extended when they could correctly contract and relax their PFMs. Home exercise was recommended three to five times a week, twice or three times each day. Data were collected at baseline and at 3, 12, and 24 months after the start of treatment. The primary outcomes were change in bladder, bowel, and pelvic floor symptoms, as measured by the PFDI-20, assessed at three months. Secondary outcomes were condition specific and general quality of life, sexual functioning, and degree of prolapse, PFM function, and patients’ perceived change in symptoms from the start of the study. The POPP1 trial was judged as low risk for selection bias, performance and detection bias, attrition bias, reporting bias and other types of bias (Table 28).

**Results**

In the Alves (2015) trial, 42 women were randomised, 21 in each group, however there was high attrition and only data from 18 and 12 women in the intervention and control group respectively were analysed. Two in the intervention group did not complete the treatment due to health or family problems, while 9 in the control group refused to complete the final physiotherapy appointment. The Alves trial was judged as low risk for selection bias, performance and detection bias, attrition bias, reporting bias and other types of bias (Table 28).

In the Due (2016) trial, 109 women were randomised, 56 to the combined group and 53 to the lifestyle group (261). Of these 43% had POP stage III and 57% had POP stage II. Follow-up at 3 and 6 months was 82% and 78% complete respectively. Significantly more women in the combined group indicated improvement in the PGI-I at 3 and 6 months. There was no difference between groups in any PFDI-20 or PFIQ-7 scores at 3 months. Both groups improved significantly in the total PFDI-20 score and its subscores by 3 months, except the lifestyle group had no improvement in the POPDI sub-score. Significant improvement in PFIQ-7 could only be found in the lifestyle advice group. It was unclear if there were any differences between groups in PFDI/PFIQ at 6 months. The PISQ-12 and objective prolapse stage did not improve significantly. Significantly more women (68% vs 28%) in the lifestyle advice group had sought further treatment (mainly PFMT) at 6 months follow-up. The authors concluded that there was a small benefit of both lifestyle advices alone or combined with PFMT for women with stage II or III prolapse. There was a significant difference in the primary outcome (PGI-I) in favour of the combined group, but this was not really highlighted.

In the Frawley (2012) trial, 168 women were randomised to either the PFMT group (n=84) or the control group (n=84), with 12 and 9 lost to follow-up by 6 months and a further 4 and 16 by 12 months respectively, 19% and 30% in total (262). 82% of women in the PFMT group attended 4 or 5 of the 5 physiotherapist appointments. The POP-SS score was significantly lower, indicating fewer symptoms, in the PFMT group compared to the control group at both 6 and 12 months. There was no difference in POP-Q stage between groups at 6 or 12 months, although there was some evidence of a difference at 12 months between groups, in the posterior wall POP-Q measurements, A1 and B1, in favour of the PFMT group. Digital muscle strength was significantly stronger in the PFMT group compared to the control group at 6 months but not at 12 months. There were no significant differences between groups in manometry outcomes, except total work performed was higher in the PFMT group at 6 months. The intervention was concluded to be beneficial immediately following the intervention, and after a further 6 months.

In a conference abstract, Giraudo and colleagues reported 47 women were randomised but 3 were excluded because they could not contract their pelvic
floor muscles, leaving 44, 23 intervention (PFMT + negative pressure abdominal work) and 21 control (PFMT + abdominal hollowing) (264). Improvement in prolapse symptoms and POP-Q values from baseline to 24 weeks was significantly greater in the intervention group compared with the control group. There was evidence of an improvement in PFM strength and endurance in both groups, but no significant difference between the groups. The authors concluded there may be benefit of adding negative pressure core exercises to PFMT for women with stage I and II prolapse.

Of the 447 women enrolled in the POPPY trial, 225 women were randomised to intervention and 222 to control (263). 84% and 66% of women completed questionnaires at 6 and 12 months respectively, with no differential drop-out. POP-Q re-assessments at 6 months were obtained for 75% (168) and 77% (171) of women respectively. 80% in the intervention group attended 4 or 5 of the 5 appointments. Women in the intervention group had a significantly greater reduction in prolapse symptoms at 6 and 12 months than those in the control group, although they were no more likely than control women to have a reduced severity of prolapse at 6 months. At 12 months, significantly more women in the control group than the intervention group had received further treatment. In particular significantly more women in the control group (27% vs 1%) had had a referral for PFMT. At 6 months, all aspects of daily life, and sexual, bladder, and bowel function (except for faecal incontinence), were significantly better in the intervention group compared to the control group. This was not sustained at 12 months. It was concluded that one-to-one PFMT is effective for improving symptoms in women with stage I to III prolapse in the medium term.

In the Kashyap trial, 140 women were randomised, 70 per group, although four women transferred from the control group to the training plus manual group and the group in which these women were analysed was unclear (265). Improvements were reported in POP-SS, VAS and PFIQ-7 scores in both groups from baseline to week 24. There were significant differences between groups in the change in POP-SS with the intervention group reporting greater symptom improvement. There was also significantly more improvement in the intervention group in terms of the VAS scores and the PFIQ-7 scores. Five women in the intervention group had an improved POP-Q stage compared to one woman in the control group. The authors concluded that one-to-one PFMT plus the SIM led to more symptom improvement than the SIM alone.

The Stuppe-Resende trial was reported over multiple publications (4 conference abstracts, 2 papers and a trial register entry) (confirmed by personal communication with an author), reporting on different comparisons amongst the three trial groups, and not all reports agreed on participant details (e.g. the number of participants, age) making it difficult to interpret the findings. 63 women were randomised in the trial: 21 to PFMT, 21 to PFMT plus hypopressive exercise, 21 to lifestyle group. Five women in the lifestyle group discontinued leaving 58 women at follow-up. The PFMT group women were more likely than the control group to have an improvement in their POP-Q stage of prolapse, both anterior and posterior. The domains and symptoms scores from the P-QoL were compared before and after in each group separately, but no between-group comparisons were made. However, the authors concluded erroneously that since the PFMT group scores improved significantly and the control groups did not, the PFMT group had benefitted more. Pelvic floor muscle assessment outcomes were compared between the three groups (266). Significant differences were found between the PFMT and PFMT+HE groups when compared to the control group, in favour of the PFMT groups, in terms of Oxford score, contraction endurance and muscle activity (SEMG). No significant difference was found between the PFMT and PFMT+HE groups in terms of Oxford score and muscle activity (SEMG), however PFMT group did significantly better than PFMT+HE in terms of contraction endurance.

Wiegersma trialists screened 4,465 women to identify those with mild prolapse (n=365) (268). Of these, 287 women were randomised, 145 to PFMT and 142 to watchful waiting, of which 250 (87%) completed the trial follow-up. Women in the intervention group improved their PFDI-20 score significantly more than those in the watchful waiting group, and were also more likely to report overall symptom improvement (57% vs 13%). There were no other significant differences between the trial groups including improvement in POP-Q stage. The authors concluded that the difference in PFDI-20 may not be clinically significant and that more studies are needed to examine the factors affecting success.

Summary

Results from an additional seven new trials are now available and more complete reports for two of the six earlier trials.

There have been different types of control groups used in the trials to date: minimal intervention control e.g. lifestyle leaflet or watchful waiting; other type of exercise as control e.g. Pilates or general fitness; lifestyle intervention as control; other form of delivery of PFMT as control e.g. self-instruction PFMT manual. One small trial compared PFMT of two different types (PFMT with negative pressure abdominal work and PFMT with abdominal hollowing). Most evidence (8 trials) exists for PFMT versus a minimal intervention control, and it can now be concluded more confidently that PFMT significantly reduces pelvic floor symptoms in women with stage I to III prolapse. Evidence of effectiveness for PFMT relating to the specific symptom of a vaginal bulge or something coming down associated with prolapse was Level 1, but less consistent.
Six of these trials reported change in POP-Q stage, but a beneficial effect on the stage was reported in only 1 of these, and thus there was evidence of no effect of PFMT on prolapse stage.

In the other categories, four out of six trials providing data were small and very likely underpowered although they were otherwise at low risk of bias (Alves n=42, Culligan n=62, Giraudo n=47, Stupp n=63).

Of the remaining two, Due (n=109) found PFMT plus lifestyle advice to be superior to a lifestyle advice programme in terms of overall improvement on the Patient Global Index of Improvement Scale, but not prolapse symptoms or POP-Q severity, where both groups improved [46]. Kashyap (n=140) found a taught course of PFMT plus self-instruction manual was better than a self-instruction manual alone in improving prolapse symptoms [50]. The difference in findings might in part be due to different PFMT interventions: group PFMT delivered in the Due trial versus one-to-one PFMT in the Kashyap trial.

Based on previous studies and new evidence there is now evidence of benefit that PFMT is effective in reducing pelvic floor symptoms in women with prolapse (Consistent Level of Evidence: 1, Grade of recommendation: A). There is some evidence of benefit showing that PFMT is effective in alleviating specific prolapse symptoms (e.g. vaginal bulge) (Majority Level of Evidence: 1, Grade of recommendation: C). There is no evidence that PFMT is effective in reducing severity of prolapse based on POP-Q stage (Consistent Level of Evidence: 1, Grade of recommendation: B).

2.2.2 PFMT and Surgery

Two trials have been reported in previous editions of this chapter (269, 270). There have been an additional 4 trials published since the last edition (104, 271-274). Three trials compared surgery plus PFMT with surgery alone, and one trial compared surgery with PFMT (275). The latter did not report on prolapse outcomes and is therefore not discussed further. Salient features of each trial are described in Table 29.

Quality of data

Barber and colleagues carried out the OPTIMAL 2x2 factorial trial of PFMT as an adjunct to vault prolapse surgery (104). This trial compared two methods of suspending the vaginal vault in women undergoing surgery for prolapse. Additionally, participants were randomised either to adjunctive post-operative PFMT or routine care, to assess whether such adjunct therapy improves both anatomical and symptomatic outcomes two years after surgery.

The adjunct intervention consisted of one pre-operative visit and four post-operative visits with a behavioural interventionist for PFMT and education in behavioural strategies. Routine care was usual peri-operative teaching and post-operative instructions. The authors’ primary outcomes were urinary symptoms at 6 months (PFDI-UDI), and prolapse symptoms (PFDI-POPDI) and anatomical failure (descent on the POP-Q or retreatment) at 24 months after surgery (Table 29).

The OPTIMAL trial was judged as low risk for selection bias, performance and detection bias, attrition bias, reporting bias and other types of bias (104) (Table 29).

McClurg and colleagues undertook a pilot trial of pre-and post-operative PFMT for women undergoing a primary prolapse repair (274). Women were randomised to either the intervention group receiving PFMT or the control group receiving usual care. Prior to surgery all women were seen by a physiotherapist to complete baseline outcome measures. Those in the intervention group were also seen once pre-operatively by another physiotherapist to be taught pelvic floor muscle exercises and the Knack. Women were advised to do three sets of exercise per day. After 6 weeks the intervention group women were seen for 5 visits over 16 weeks and an individualised home exercise programme was prescribed and advice given. Control group women received a lifestyle advice leaflet. Both groups completed outcome measures at 6 and 12 months post-surgery: POP-SS (primary), ICIQ-UI SF, ICIQ-BS, PISQ-12, SF-12, and PFM assessment (PERFECT and modified Oxford scale) (Table 29). The feasibility trial was generally judged as low risk for selection bias, attrition bias, reporting bias and other types of bias. However, there was potential for performance and detection bias (see Table 29) (274).

Pauls et al. (2011) (271, 272) undertook a trial in women undergoing vaginal reconstruction, comparing PFMT as an adjunct to surgery with standard care. Women were having planned surgical correction, including a native tissue vaginal repair with or without a vaginal hysterectomy or suburethral sling. PFMT consisted of one appointment 2 weeks before their scheduled surgery date, and five post-operatively, each with a specialist pelvic floor physiotherapist. The control group attended appointments with physician assessment alone at all the same post-operative intervals. There was a final follow-up assessment at 24 weeks (Table 29). The primary outcome was quality of life measured using the WHOQOL-Bref. Secondary outcomes included PFDI-20, PFIQ-7, POP-Q assessment, the Female Sexual Function Index (FSFI), PISQ-12, a modified Oxford scale for pelvic floor strength and contraction, short form General Health Survey (SF-12), and a 24-hour voiding diary (271, 272). The trial was judged as low risk for selection bias, performance and detection bias, attrition bias, reporting bias and all other types of bias (Table 29).
<table>
<thead>
<tr>
<th>Author, year</th>
<th>Comparator</th>
<th>N</th>
<th>Study population</th>
<th>Modality details or parameters</th>
<th>Outcomes/results</th>
<th>Follow up</th>
<th>Notes (side effects, loss of follow up)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barber 2014 (1)</td>
<td>2 x 2 factorial RCT: comparing to surgery types +/- PFMT</td>
<td>374</td>
<td>Women having surgical repair for apical or uterine POP of stage II or greater, who also have SUI</td>
<td>Women were randomised to both surgery type and PFMT. Surgery: 1) sacrospinous ligament fixation, or 2) uterosacral vaginal vault suspension. Perioperative PFMT: 1) 1:1 PFMT (1 pre-operative + 4 post-operative visits for PFMT (2,4,6,8 and 12 weeks), examination at each visit, and exercise and education in behavioural strategies), or 2) usual care (usual peri-operative teaching and post-operative instructions)</td>
<td>Outcomes for PFMT: long-term improvement in anatomic outcomes (POP-Q) and prolapse symptoms (POPD1 subscale of the PFDI); short term (6 months) improvement in urinary symptoms (UDI subscale of PFDI).</td>
<td>6, 12 and 24 months</td>
<td>Low ROB for selection bias, performance and detection bias, attrition bias, reporting bias and other types of bias</td>
</tr>
<tr>
<td>McClurg 2010 (2)</td>
<td>Parallel group RCT; 2 groups, treatment group (surgery and PFMT sessions) vs a control group (usual care)</td>
<td>57</td>
<td>Women attending the gynaecological clinic and for whom primary surgery was recommended due to their POP symptoms</td>
<td>Intervention: 1 pre-operative + 5 post-operative appointments within a period of 12 weeks. Pre-operatively, anatomy and function of PFMs, types of prolapse and the surgical procedure discussed with information about recovery/return to normal activities. Women taught by digital palpation to contract PFMs and ‘the Knack’. Home exercise, 3 sets per day of 10 maximum contractions (up to 10s hold) with 4s rest between, 1-min rest followed by 10 fast contractions. Control: received the same lifestyle advice leaflet.</td>
<td>POP-SS; ICIQ-UI SF; ICIQ-BS; PISQ-12; SF-12; PFM assessment (PERFECT, modified Oxford scale).</td>
<td>All outcomes were measured at baseline, 6 and 12 months</td>
<td>Generally judged as low ROB. Randomisation generation and allocation concealment were judged as adequate. Outcome assessors reported as being blinded but researchers involved in the trial were not blinded and it is unclear what direct involvement they may have had with each participant. Groups were comparable at baseline, but there were more complaints of bowel dysfunction in the treatment group. Dropouts were clearly accounted for and all pre-specified outcomes were adequately reported.</td>
</tr>
<tr>
<td>Author, year</td>
<td>Comparator</td>
<td>N</td>
<td>Study population</td>
<td>Modality details or parameters</td>
<td>Outcomes/results</td>
<td>Follow up</td>
<td>Notes (side effects, loss of follow up)</td>
</tr>
<tr>
<td>-------------</td>
<td>------------</td>
<td>---</td>
<td>-----------------</td>
<td>-------------------------------</td>
<td>-----------------</td>
<td>----------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td>Pauls 2013 (3)</td>
<td>Parallel group RCT; 2 groups, PFMT vs standard care in women undergoing vaginal reconstruction</td>
<td>49</td>
<td>Women aged &gt; 18 years having surgical correction to include a native tissue vaginal repair +/- a vaginal hysterectomy or suburethral sling</td>
<td>Intervention: physiotherapy appointment 2 weeks before surgery, and 2, 4, 6, 8, and 12 weeks postoperatively, in conjunction with a physician assessment. Sessions covered bladder and bowel function, pain management, breathing and relaxation, core exercises, scar tissue mobilization, increased strengthening and training over time. Control: attended appointments (biweekly until 12 weeks postoperatively) with physician assessment alone at intervals as above.</td>
<td>PFDI-20, PFIQ-7, POP-Q, Female Sexual Function Index (FSFI), PISQ-12, SF-12, WHO-QOL Bref, modified Oxford scale for PFM strength and contraction, 24-hour voiding diary</td>
<td>Assessments undertaken at baseline (some limited assessment at appointments occurred at 2, 4, 6, 8 weeks), and follow-up assessments at 12 and 24 weeks</td>
<td>Low ROB. Randomisation generation and allocation concealment were judged as adequate. Outcome assessors were blinded appropriately. Groups were comparable at baseline, dropouts were all accounted for and all pre-specified outcomes were reported. The trial is fully reported in two main papers.</td>
</tr>
</tbody>
</table>

Abbreviations: PFM: pelvic floor muscles; PFMT: pelvic floor muscle training; POP: pelvic organ prolapse; POP-SS: pelvic organ prolapse symptom score; QoL: quality of life; RCT: randomized controlled trial; ROB: risk of bias; SUI: stress urinary incontinence; UI: urinary incontinence

**Results**

In the OPTIMAL trial, 408 women were randomised, 34 withdrew prior to surgery leaving 374 women randomised to PFMT (n=186) or usual care (n=188). There was no significant difference at 6 months or 24 months between the PFMT and usual care groups in the prolapse scores or POP-Q. The routine use of PFMT was concluded to be unnecessary (104).

McClurg (2010) randomised 57 women from three sites, 28 to PFMT and 29 to control, with the majority of women (n=27, 47%) coming from one site. By 6 months there was significant improvement in both groups on prolapse, bladder, bowel and general health measures, but no difference between groups. Analysing 12 month data from the highest recruiting site where longer follow-up was possible (there were significant recruitment and logistical issues at other sites which caused delays and limited the follow-up), there were significant differences between groups in POP-SS and SF-12: prolapse symptoms and general health were more improved in the PFMT groups (274).

In Pauls (2013) trial, a total of 57 women were randomised, 29 to physiotherapy and 28 to control, and 49 completed the study (24 and 25 respectively). Improvement over baseline was found in both groups in quality of life, PFDI and PFQI measures, but there were no differences between groups. The PFMT group had better muscle strength after 12 weeks, but at 24 weeks this was no longer evident. (271, 272).

**Summary**

Although there were three new randomised studies reporting prolapse outcomes, only one trial (OPTIMAL) was both at low risk of bias and of adequate size (104). It found no evidence of an effect on prolapse symptoms or stage at 2 years of adding PFMT to surgery in women having vault prolapse repair (Level of Evidence: 1). The other two small trials provided no evidence of an effect of PFMT.

Peri-operative PFMT does not improve prolapse symptoms in women undergoing surgery for vault prolapse (Grade of Recommendation: B New).

### 2.2.3 PFMT and Pessary

Three RCTs have been published since the 5th Edition when previously there had been none. Details of the categories and treatment components of the active interventions are provided in Table 30.

i) Pessary + PFMT vs pessary

Hagen and colleagues carried out a pilot trial in which women with stage I to IV prolapse of any type who had successfully been fitted with a pessary were randomised to have PFMT or not. PFMT was delivered by a specialist women’s health physiotherapist in 5 appointments over 16 weeks (276) (Table 30). The pessary was removed at 6 months and outcomes (POP-SS, prolapse-related quality of life, prolapse severity (POP-Q), and perceived change in prolapse since pessary fitted) measured at 7 months. The authors aimed to randomise 50 women from 4 centres to inform the development of a larger trial. The PEPPY trial was judged as low risk for selection bias, performance and detection bias, attrition bias, reporting bias and all other types of bias (276, 277).

ii) PFMT vs PFMT + pessary

Cheung and colleagues carried out a trial in women with symptomatic stage I to III prolapse with no previous treatment for prolapse, who were randomised to either a vaginal ring pessary+ PFMT, or PFMT alone (278). Both groups were taught and encouraged to do PFMT standardized pelvic floor exercise training course which included a teaching session within 2 weeks after the first consultation and three individual training sessions at 4, 8, and 16 weeks. Women were advised to practice daily with at least two sets of 8–12 preset exercise repetitions per day, with 8–10 exercises per session at least two times per week. Change in urinary symptoms was measured using the PFDI (including PFDI-UDI) before, 6 months and 12 months after the treatment. The PFQI was also completed at 12 months. The trial was judged as low risk for selection bias, performance and detection bias, attrition bias, reporting bias and other types of bias (Table 30).

iii) Colpexin sphere + PFMT vs PFMT

Manonai and colleagues (2012) studied the use of the Colpexin sphere in women with Stage I or II prolapse (279). The Colpexin sphere is an intra-vaginal device similar to a pessary except it requires the woman to actively contract her pelvic floor muscles to keep the device in place. Women were randomised to either PFMT alone (control) or PFMT along with a Colpexin sphere (study group). All women were instructed to perform three sets of exercises daily. Those in the Colpexin group exercised with the device in situ. The intervention duration was 16 weeks. Pelvic floor muscle strength was measured using the Colpexin pull test and digitally using the Brink scale, at baseline, 4, 8, 12 and 16 weeks after treatment. There were no specific prolapse outcomes reported. Participants were excluded if compliance with the daily pelvic floor exercise was less than 80%. The trial was judged as low risk for selection bias, performance and detection bias, attrition bias, reporting bias and other types of bias (Table 30).

**Results**

Of the 31 eligible women recruited to the PEPPY trial, 16 were randomised, eight to the pessary alone group and eight to the pessary plus PFMT group. The mean age of women was 63 years (SD 14); 25% had stage I prolapse, 50% stage II, and 25% stage III. Compliance with the intervention was good: 75% of intervention women attended 4 or 5 appointments. With such a small sample size statistical analysis was not carried out.
<table>
<thead>
<tr>
<th>Author, year</th>
<th>Comparator</th>
<th>N</th>
<th>Study population</th>
<th>Modality details or parameters</th>
<th>Outcomes/results</th>
<th>Follow up</th>
<th>Notes (side effects, loss of follow up…)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cheung 2016(1)</td>
<td>Parallel group RCT; 2 groups, Vaginal ring pessary + PFMT vs PFMT</td>
<td>276</td>
<td>Women had symptomatic prolapse (Stage I-III), had received no previous treatment</td>
<td>Intervention: vaginal pessary, (ring pessary was used). Women also received regular PFMT. Home exercise performed at least 3 times a week and 2 times each day. Control: PFMT alone.</td>
<td>Total scores on PFDI and PFQ. Change of urinary symptoms measured by PFDI-UDI and subscales (obstructive, irritative, stress).</td>
<td>Data collected at baseline and 6 months (PFDI-UDI only) and 12 months after treatment.</td>
<td>Low ROB for selection bias, performance and detection bias, attrition bias, reporting bias and other types of bias</td>
</tr>
<tr>
<td>Hagen 2010(2)</td>
<td>Feasibility pilot RCT; 2 groups, PFMT in conjunction with pessary management vs pessary management alone</td>
<td>16</td>
<td>Women with prolapse of any type, of stage I to IV, with a pessary newly successfully fitted (still in place after 2 weeks)</td>
<td>PFMT was delivered at 5 appointments over 16 weeks (as per Hagen 2010 in Table 28) with the pessary in place. Control: pessary management alone.</td>
<td>POP-SS, prolapse-related quality of life, prolapse severity (POP-Q), and perceived change in prolapse since pessary fitted.</td>
<td>Data collected at baseline (after pessary fitted but before randomization), 6 months post-randomization (with pessary in situ, then pessary removed), and 7 months post-randomization without pessary.</td>
<td>Low ROB for performance and detection bias, attrition bias, reporting bias and all other types of bias. Poor recruitment was a key issue within the trial – target was to randomise 50 women</td>
</tr>
<tr>
<td>Manonai 2012(3)</td>
<td>Parallel group RCT; 2 groups, Colpexin sphere with PFMT vs PFMT alone</td>
<td>91</td>
<td>Women aged 20 years+, prolapse stage I or II</td>
<td>All participants: taught about home-based practice with booklet of PFM. Visual inspection of contraction. Home exercise involved tightening the PFMs, holding for 10s, relaxing 10s and doing 10 repetitions 3 times a day for a period of 16 weeks. Colpexin+PFMT: exercised as above with the Colpexin sphere in situ.</td>
<td>ICIQ-VS (Thai version), POP-Q, PFM strength (Colpexin pull test, digital test using Brink scale)</td>
<td>POP-Q and ICIQ- VS at baseline and 16 weeks. PFM data collected at baseline, 4, 8, 12 and 16-week after starting treatment.</td>
<td>Low ROB. Random sequence generation was computer generated and information for decoding randomisation was kept secure and opaque sealed envelopes were used during the allocation process. Although ITT analysis was not employed, all dropouts were clearly accounted for. The groups were comparable at baseline and the authors reported a sample size calculation.</td>
</tr>
</tbody>
</table>

**Abbreviations:** PFM: pelvic floor muscles; PFMT: pelvic floor muscle training; POP-SS: pelvic organ prolapse symptom score; RCT: randomized controlled trial

However, from observing the mean scores it was apparent that symptoms in both groups were worse a month after the pessary had been removed (month 7) compared to baseline (when the pessary had been in place for 2 weeks), and there was no indication of a symptom or objective benefit for those women who had received PFMT on any of the outcomes. In both groups 2 out of 7 women said their prolapse was the same or worse at 6 months after the pessary had been inserted. Recruitment was problematic in the trial, and it was concluded that this would need to be addressed before moving to a larger trial (276, 277).

Of the initial 311 women recruited to the Cheung trial, 276 were randomised, 137 to PFMT treatment and 139 to vaginal pessary plus PFMT. Authors reported in one abstract an intention-to-treat analysis of the difference between the groups in PFDI-UDI and its subscores, and on the prevalence of women with SUI, UUI and voiding difficulties (278). Prolapse outcomes were not reported. Although there was significant improvement on all outcomes at 12 months, there was no significant difference between the groups. In a second abstract the authors reported a non-randomised comparison of those women who continued successfully with their pessary until 12 months (n=78) and those who continued successfully with pelvic floor exercises only (n=118) (278). At 12 months the pessary group had significantly better scores that the PFMT group on all the PFDI and PFIOQ scores and subscores. This would seem to suggest that generally pessary and pelvic floor exercises are equally effective at improving urinary symptoms in women with prolapse, however in the select subgroup of women who adhere to treatment, the pessary provides extra benefit in reducing pelvic floor symptoms (278).

A total of 91 women were randomised in the Manonai (2012) trial, 45 in the study group and 46 in the control group. Eighty-five women (93%, equal in both groups) completed the 16-week assessment with 80% compliance to daily exercise. There was no significant difference in improvement in pelvic floor muscle strength between the groups at 16 weeks; either measured using the pull test or the digital assessment (279).

### Summary

Three new trials were found, one comparing pessary alone versus pessary plus PFMT and two comparing pessary plus PFMT versus PFMT alone. The first was a pilot trial with recruitment difficulties and a very small sample, which did not contribute to the evidence (278). The other two trials were larger and concluded no difference between pessary plus PFMT and PFMT alone in terms of muscle strength at 4 months (279) or prolapse symptoms at 12 months (non-randomised comparison) (278). Combined pessary and PFMT and PFMT alone can be equally effective (Level of Evidence: 1)

**PFMT + pessary may be as effective as PFMT alone in reducing symptoms. (Grade of Recommendation: B New; however; some caution since the two trials considered two very different devices).**

### 3. PESSARIES

A pessary is defined as a device that is inserted into the vagina to provide structural support to one or more of descending vaginal compartments, i.e., the uterus, anterior vaginal wall (and bladder), posterior vaginal wall (and rectum) and/or vaginal apex (with or without small intestine after a prior hysterectomy) (280). They offer a non-surgical option for the treatment of urinary incontinence and pelvic organ prolapse (POP). This section, discusses evidences for use of pessary to prevent or treat POP; evidence for use of pessaries to prevent or treat UI will be covered in chapter 20.

A range of vaginal pessaries (Figure 8) exist which can be broadly divided into two types: support and space-filling pessaries. Support pessaries lie along the vaginal axis, with the posterior component sitting in the posterior fornix and the anterior component coming to rest just under the symphysis pubis, thus providing a supportive shelf for the descending pelvic organs. As there is no evidence to support the use of a specific type of pessary, choice is based on clinical experience and trial and error. It is generally accepted that the ring pessary should be tried first because of ease of insertion and removal, and if this fails, other pessaries can be used (281).

A recent review of data obtained from public use files from the Centres for Medicare and Medicaid Services in the United States over a 10-year period from 1999 to 2009 showed that the rates of pessary insertion were consistent at 11-13% over the period (282). In the United Kingdom, a postal survey demonstrated that 87% of consultants use vaginal pessaries for management of POP (283). The likely candidates for vaginal pessaries are those with co-morbid medical conditions, those who still wish to bear children, as interim relief prior to surgery and for those who prefer...
non-surgical treatment (284). Other indications include vaginal laxity, neonatal prolapse mainly seen in association with neural tube defects such as spina bifida and prolapse during pregnancy (285).

Factors that predict the type of treatment chosen for POP have been evaluated in various studies. Younger women (286) and those with a higher incidence of stress incontinence (286) are more likely to refuse pessary use. Age greater than 65 years at the time of pessary insertion and more severe prolapse (Stage III-IV) were more predictive for pessary discontinuation at one year (287-289). Ko et al. (2011) found that substantially older women or post menopausal women opted for a pessary rather than surgery, and more sexually active women expressed a significantly greater preference for surgery. In addition to opting for surgery over pessary use, younger sexually active women are more likely to change from conservative to surgical treatment over a one-year period (290).

3.1. Prevention of POP with Pessaries

Previously no trials had examined pessaries as an intervention in the prevention of POP. In this update, no further trials were identified.

3.2. Treatment of POP with Pessaries

3.2.1 Pessary Alone

Three new studies were included. Study details are presented in table 31. Ding et al. (291) evaluated 81 women with stage 3 and 4 prolapse who were successfully fitted with a ring pessary with support after 3 months. Subjective evaluation was carried out using non-validated questions and prolapse was objectively assessed using POP-Q.

To evaluate if the cube pessary can be used as a first line treatment, Nemeth et al. (292) prospectively evaluated 78% of women who had a cube pessary inserted after one year. Subjective outcome was established by using a non-validated questionnaire as a validated questionnaire was not available in Hungarian. As one of the aims of the study was to evaluate if it was well tolerated, the authors rated the process of pessary insertion and general wellbeing on a numeric rating scale and also on a patient global improvement scale.

Brazell et al (293) reported findings from a secondary analysis of a study that sought to evaluate if pessary use was associated with improvement in bulge symptoms and improvement in body image (294). They focused on bowel symptoms using the Colorectal Anal Distress Inventory, a subscale of PFDI-20 and Colorectal Anal Impact Questionnaire, a subscale of PFIQ-7. The study had a high attrition rate as only 43 women of the initial 104 had complete data at 12 months.

Results

The study by Ding et al. (295) found improvement in prolapse and bladder symptoms 3 months after use of a ring pessary with support in women with stage 3 and 4 prolapse. Of the 74% who were initially successfully fitted with the pessary, 10% failed to retain the pessary at 3 months. Their findings contradict the manufacturer's recommendations regarding use of this type of pessary in early prolapse. Of interest, 82.7% women who were of the median age of 70 years were able to manage the pessary themselves indicating that with proper counselling and encouragement hospital care can be minimised.

The cube pessary seemed to be a viable option for sexually active women to self-manage their pessary as Nemeth et al. (292), were able to demonstrate a significant improvement in general wellbeing in the 78% women who were still using the pessary at 12 months, 85% rated pessary care use as easy or very easy.

Brazell et al. (293) demonstrated a significant improvement in both bowel related symptoms and quality of life. Patients who completed the 12-month follow-up were significantly older and more likely to have stage 3 and 4 prolapse compared to stage 2.

3.2.2 Pessary Versus no Treatment

No new studies were identified.

3.2.3 Pessary and PFMT

- Pessary versus PFMT

One new study was identified. A RCT comparing PFMT to pessary treatment in 160 women (PFMT n=79, pessary n=81) aged ≥55 years with advanced POP. A pessary was fitted successfully in 47/81 (58 %)women (296). Only those women in whom a pessary was fitted successfully, were compared. Risks of bias were high as both participant and evaluator were not blinded and an ITT analysis was not performed.

In women aged ≥55 years with an advanced symptomatic POP, PFMT resulted in a significant but not clinically relevant improvement of pelvic floor symptoms after 3 months (PFDI-20). There was no difference between PFMT and pessary treatment. PFMT was more effective in improving anterior wall POP than pessary treatment on POP-Q (Table 31).

- Pessary plus PFMT versus PFMT

Refer to section III.2.3.2

- Pessary plus PFMT versus Pessary

Refer to section III.2.3.2

3.2.4 Pessary Versus Surgery

One new study was identified (297), making a total of three studies comparing pessary versus surgery (Table 32). All were prospective, observational cohort case controlled. The new study by Lone et al. (297) evaluated 133 women who opted for surgery and 154 who opted for surgery one year after pessary treatment using the ICIQ-VS and ICIQ-UI (297). Women
who had surgery were older with no difference in characteristics like body mass index, parity, ethnicity, history of hysterectomy and prolapse surgery. 69% women who used pessary and 67% women who had surgery completed the questionnaire at one year. The non-randomised design of the study with approximately 30% attrition rate suggested a high risk of bias.

Three studies (285, 297, 298) compared patient related outcomes after pessary use and surgery. Abdool demonstrated a significant improvement in prolapse, urinary, bowel and sexual function in both treatment arms but no difference between the two groups. Using the ICIQ-VS and ICIQ-UI, Lone et al. found a statistically significant vaginal, sex, QOL and urinary symptoms score improvement in both groups but no statistically significant difference was noted between the surgery and pessary groups. However, Barber (2006) found that subjects in the surgery group had significantly greater improvement in all of the scales of the PFDI and the prolapse and urinary scales of the PFQI than did the pessary group.

3.2.5 Comparison of One Pessary to Another

No new trial was identified for this update, making a total of one trial included in this section comparing pessary to another device. Cundiff (299) conducted the largest multi-centre crossover trial, comparing a ring with support and a Gellhorn pessary for the treatment of symptomatic stage II or greater symptomatic prolapse in 134 women. There were no significant differences between groups in baseline characteristics. Participants were fitted with one of the pessaries for three months, and with the second for a further three months. During each three-month period, data was collected at one, six and twelve weeks from women who had a successful fit. Outcomes were measured at enrolment, three and 12 months, and included objective assessment using POP-Q and subjective assessment using PFDI, PFQI, and a sexual function questionnaire. Allocation was by computer-generated random numbers using permuted blocks of variable size. Opaque, sealed envelopes were used to store the random allocation. Participants and clinicians were not blind to the allocation, but data was coded such that the analysis was conducted blind. Those women who were successfully fitted were asked to wear the pessary for three months, but if they discontinued prior to three months’ data collection was accelerated. Attrition rates in the study were high with only 85 of the 134 women completing the study leading to high risk of bias. However, the trial was not underpowered due to the cross over design.

Cundiff et al. (299) found a statistically and clinically significant improvement in the majority of the PFDI scales and many of the PDIQ scales with both pessaries but no difference between the ring or Gellhorn pessary. Approximately 60% of women offered a pessary continued treatment in the long term irrespective of the type of device.

Success rates

There is no agreement as to what constitutes a successful fitting of a pessary. Some consider success if a pessary was perceived comfortable by a patient when retained during Valsalva and voiding at the initial visit, while others consider it success if a patient continues to use the pessary until the following visit to the doctor. Thus quoted rates of successful fitting vary widely with differing follow-up times. (Table 33). Reasons for failure range from expulsion due to complications such as vaginal discharge, erosion, de novo SUI, pain, voiding difficulty and constipation (Table 33). The risk factors for failure also vary, making it difficult to draw conclusions.

Complications

Minor complications after pessary insertion range from vaginal discharge, erosion, de novo SUI, bleeding, pain and constipation (Table 33). A recent study by Collins (300) has shown that women who have a pessary are more likely to be bothered by discharge (30.0% vs 2.1%, p < .001) and this develops early and may be due to an inflammatory process in the vagina (300). Using the cube pessary appears to be complication free, probably because it has to be removed on a regular basis.

Rarely major complications may occur. Neglected pessaries present with more serious complications namely fistula formation and peritonitis. Erosion into the bowel or bladder and dense adhesions to other pelvic structures have been reported. Unusual complications of cervical entrapment, small bowel incarceration, and hydronephrosis have also been reported (301).

Conclusion

As in the most recent Cochrane review (222) and 1 recent RCT, there is no good quality evidence from randomised controlled trials on which to base the management of POP using pessaries.

Prospective case controlled cohort studies suggest that pessaries are a viable option for women who complain of symptomatic prolapse. (Level of Evidence: 3).

There appears to be no advantage of pessary use over PFMT, from one high risk of bias RCT (Level of Evidence: 3).

One single randomised study, with a high attrition rate of 40% found no significant difference between ring pessaries with support and the Gellhorn pessary in PFDI and PFQI scores (Level of Evidence: 2).
### Table 31 Summary of data on PFMT vs pessary for POP

<table>
<thead>
<tr>
<th>Author/year</th>
<th>Study design</th>
<th>Comparison group</th>
<th>Participants</th>
<th>Type of pessary</th>
<th>Subjective assessment</th>
<th>Objective assessment</th>
<th>Length of follow-up</th>
<th>Improvement in symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Panman CM, 2014</td>
<td>RCT</td>
<td>PFMT (n=79): No standard protocol – individual adaptation in line with normal practice (included being able to use electrical stimulation) vs PESSARY (n=81): Fitting – opted for 2 week try of pessary with refit at 2 weeks if necessary and max of 3 refits. Fitted by ‘trained research physician’</td>
<td>160 women aged ≥ 55 years with self identified POP symptoms (on screening) POP at or beyond hymen (POPQ)</td>
<td>First ring, then ring with support and then Shaatz or Gellhorn</td>
<td>Primary outcome: PFDI-20</td>
<td>Secondary: change in POP-Q stage</td>
<td>3 months</td>
<td>No sign diff. in PFDI POP-Q Anterior compartment: 26.5% &gt;=1 stage change in PFMT v 7.1% pessary p=0.013 * No ITT, only 47 of 81 (58%) with successful fitting included in analysis</td>
</tr>
</tbody>
</table>

Foot notes: RCT- Randomised Controlled study, PFDI- Pelvic Floor Distress Inventory, PFMT- Pelvic floor muscle training, POP- pelvic organ prolapse

### Table 32 Summary of data on pessary for POP

<table>
<thead>
<tr>
<th>Author/year</th>
<th>Study design</th>
<th>Comparison group</th>
<th>Participants</th>
<th>Type of pessary</th>
<th>Subjective and Objective assessment</th>
<th>Objective assessment</th>
<th>Length of follow-up</th>
<th>Improvement in symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdool et al. 2011 (1)</td>
<td>Prospective observational cohort case controlled</td>
<td>Pessary treatment compared to surgery</td>
<td>359</td>
<td>Ring, Gellhorn, Cube, Donut</td>
<td>Sheffield prolapse questionnaire</td>
<td>Baden-Walker</td>
<td>12 months</td>
<td>Awareness of lump, prolapse coming out of vagina, dragging pain in lower abdomen, low back pain, voiding difficulty, need to push prolapse to void, urinary urgency, fecal urgency, sexual satisfaction, interference with physical activity and quality of life</td>
</tr>
<tr>
<td>Author/year</td>
<td>Study design</td>
<td>Comparison group</td>
<td>Participants</td>
<td>Type of pessary</td>
<td>Subjective and Objective assessment</td>
<td>Objective assessment</td>
<td>Length of follow-up</td>
<td>Improvement in symptoms</td>
</tr>
<tr>
<td>---------------------</td>
<td>-----------------------------------</td>
<td>-------------------------------------------------------</td>
<td>-------------------------</td>
<td>-----------------</td>
<td>-------------------------------------</td>
<td>----------------------</td>
<td>---------------------</td>
<td>-------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Barber et al. 2006 (2)</td>
<td>Prospective observational cohort case controlled</td>
<td>Pessary treatment (3 months) compared to surgery (6 months) for pelvic organ prolapse</td>
<td>Pessary (n=42) Surgery (n=64)</td>
<td>Ring and Gellhorn</td>
<td>PFDI and PFQ</td>
<td>POP-Q</td>
<td>3 months for pessary</td>
<td>Significant improvement in prolapse and urinary scales of the PFDI. No change in the colorectal scale. No change in the PFQ scales</td>
</tr>
<tr>
<td>Brazell et al. 2014 (3)</td>
<td>Prospective observational cohort</td>
<td>N/A</td>
<td>43</td>
<td>Ring with support and Gellhorn</td>
<td>PFDI-20 PFQ-7</td>
<td>POP-Q</td>
<td>12 months</td>
<td>CRADI-8 mean scores decreased by 6.9 and CRAIQ-7 decreased by 8.1</td>
</tr>
<tr>
<td>Clemons et al. 2004 (4)</td>
<td>Prospective observational cohort</td>
<td>N/A</td>
<td>100</td>
<td>Ring and Gellhorn</td>
<td>Not validated</td>
<td>POP-Q</td>
<td>2 months</td>
<td>Bulge (90% to 3%) Pressure (49% to 3%) Discharge (12% to 0%) Splinting (14% to 0%) SII 45% UI 46% Voiding difficulty 53%</td>
</tr>
<tr>
<td>Cundiff et al. 2007 (5)</td>
<td>Randomised cross-over</td>
<td>Ring with support to Gellhorn</td>
<td>134</td>
<td>Ring with support to Gellhorn</td>
<td>PFDI,PFIQ, Sexual Function Questionnaire</td>
<td>POP-Q</td>
<td>6 months</td>
<td>Statistically and clinically significant improvements in majority of the PFDI and many PFQ scales in both pessaries, but no clinically significant differences between the two pessaries</td>
</tr>
<tr>
<td>Ding et al. 2015 and 2016 (6, 7)</td>
<td>Prospective observational study</td>
<td>N/A</td>
<td>81 with Stage III and IV</td>
<td>Ring with support</td>
<td>Not validated</td>
<td>POP-Q</td>
<td>3 months</td>
<td>Improved bulging (90.4% to 23.3%) Decreased pelvic pressure (64.4% to 13.7%) Improved urinary symptoms as follows Voiding – 97.8% Splinting- 100% Urge urinary incontinence- 76.9% Stress urinary incontinence- 58.1%</td>
</tr>
<tr>
<td>Author/ year</td>
<td>Study design</td>
<td>Comparison group</td>
<td>Participants</td>
<td>Type of pessary</td>
<td>Subjective and Objective assessment</td>
<td>Objective assessment</td>
<td>Length of follow-up</td>
<td>Improvement in symptoms</td>
</tr>
<tr>
<td>--------------</td>
<td>--------------</td>
<td>------------------</td>
<td>--------------</td>
<td>-----------------</td>
<td>-------------------------------------</td>
<td>---------------------</td>
<td>---------------------</td>
<td>------------------------</td>
</tr>
<tr>
<td>Fernando et al. 2006 (8)</td>
<td>Prospective observational cohort</td>
<td>N/A</td>
<td>203</td>
<td>Ring, Gellhorn, Cube, Donut</td>
<td>Sheffield prolapse questionnaire</td>
<td>Baden Walker</td>
<td>4 months</td>
<td>Awareness of lump (71%), prolapse coming out of vagina (52%), vaginal soreness (21%), dragging sensation in lower abdomen (24%), lower back ache (30%), difficulty emptying bladder (40%), push prolapse to void (29%), urinary urgency (38%), urge urinary incontinence (29%), stress urinary incontinence (40%), incomplete emptying of bowels (28%), rectal digitation to empty bowels (12%), vaginal digitation to empty bowels (7%), faecal urgency (30%), urge faecal incontinence (20%), frequency of sexual intercourse (16%), sexual satisfaction (11%)</td>
</tr>
<tr>
<td>Jones et al. 2008 (9)</td>
<td>Prospective observational cohort</td>
<td>N/A</td>
<td>90</td>
<td>Ring, Incontinence ring, Gellhorn, Oval</td>
<td>PFDI</td>
<td>POP-Q</td>
<td>3 months</td>
<td>Improvement in the overall PFDI scale and all subscales with the exception of colorectal distress inventory</td>
</tr>
<tr>
<td>Komesu et al. 2007 (10)</td>
<td>Prospective observational cohort</td>
<td>Compare PF symptoms in patients who continue and discontinue pessary use</td>
<td>64</td>
<td>Choice of pessary left to discretion of the provider</td>
<td>PFDI-20</td>
<td>POP-Q</td>
<td>6-12 months</td>
<td>In the continuation group final PFDI-20 total, bladder and prolapse scale scores were better than the discontinuation group.</td>
</tr>
<tr>
<td>Kuhn et al. 2009 (11)</td>
<td>Prospective observational cohort</td>
<td>N/A</td>
<td>73</td>
<td>Cube</td>
<td>Female Sexual Function Index, Sheffield questionnaire, Kings Health Questionnaire</td>
<td>POP-Q</td>
<td>3 months</td>
<td>Improvement in feeling of bulge, improvement in stool outlet problems, overactive bladder symptoms. Improvement in sexual desire, orgasm, lubrication and satisfaction after therapy</td>
</tr>
<tr>
<td>Author/year</td>
<td>Study design</td>
<td>Comparison group</td>
<td>Participants</td>
<td>Type of pessary</td>
<td>Subjective and Objective assessment</td>
<td>Objective assessment</td>
<td>Length of follow-up</td>
<td>Improvement in symptoms</td>
</tr>
<tr>
<td>-------------</td>
<td>--------------</td>
<td>------------------</td>
<td>--------------</td>
<td>----------------</td>
<td>-------------------------------------</td>
<td>---------------------</td>
<td>--------------------</td>
<td>------------------------</td>
</tr>
<tr>
<td>Lone et al. 2015 (12)</td>
<td>Prospective observational study</td>
<td>Pessary treatment versus surgery</td>
<td>269</td>
<td>Ring, Gellhorn, Cube, Donut</td>
<td>ICIQ-VS ICIQ-UI</td>
<td>POP-Q</td>
<td>12 months</td>
<td>Statistically significant vaginal, sex, QOL and urinary symptoms score improvement in both groups. There was no statistically significant difference was noted between the surgery and pessary groups.</td>
</tr>
<tr>
<td>Nemeth et al. 2013 (13)</td>
<td>Prospective observational study</td>
<td>N/A</td>
<td>78</td>
<td>Cube pessary</td>
<td>Non-validated questionnaire (Hungarian)</td>
<td>POP-Q</td>
<td>12 months</td>
<td>Improved general wellbeing score</td>
</tr>
<tr>
<td>Patel et al. 2010 (14)</td>
<td>Prospective observational cohort</td>
<td>N/A</td>
<td>75</td>
<td>Ring, Ring with support, Gellhorn</td>
<td>Body Image Scale (BIS) and PFDI-20, PFIQ, Prolapse subscale of PFIQ</td>
<td>POP-Q</td>
<td>3 months</td>
<td>Improvement in body image scale scores, PFDI-20 scores, PFIQ scores</td>
</tr>
</tbody>
</table>

Foot notes: N/A-Not applicable, SUI- Stress Urinary Incontinence, UUI-Urge urinary incontinence, RCT- Randomised Controlled study, P- Prospective Observational study, PFDI- Pelvic Floor Distress Inventory, UDI -Urinary Distress Inventory, ICIQ-VS- International Consultation on Incontinence- Vaginal Symptoms, ICIQ- UI- International Consultation on Incontinence- Urinary Incontinence, CES-D – The center for Epidemiological Depression Measures, MOS Scores- Medical Outcome Study (MOS) Social Support Survey


**Table 33 Summary of data on pessary success rates and risk factors for failure**

<table>
<thead>
<tr>
<th>Author/ year</th>
<th>Number</th>
<th>Types of pessaries</th>
<th>Study design</th>
<th>Follow-up period</th>
<th>Success rate n (%)</th>
<th>Reason for failure</th>
<th>Risk factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdool et al. 2011 (1)</td>
<td>554</td>
<td>Ring, Gellhorn, Cube, Donut</td>
<td>Prospective observational case controlled cohort</td>
<td>12 months</td>
<td>243 (68%)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Brazell et al. 2014 (2)</td>
<td>104</td>
<td>Ring with</td>
<td>Prospective observational study</td>
<td>12 months</td>
<td>34(41%)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Ding et al. 2015 and 2016 (3, 4)</td>
<td>81</td>
<td>Ring with support</td>
<td>Prospective observational cohort</td>
<td>3 months</td>
<td>73 (67%)</td>
<td>Feeling of discomfort and pressure, a desire for surgical correction, extrusion of pessary, bothersome de novo stress incontinence</td>
<td>No specific risk factors like stage or type of prolapse identified</td>
</tr>
<tr>
<td>Fernando et al. 2006 (5)</td>
<td>203</td>
<td>Ring, Gellhorn, Cube, Donut</td>
<td>Prospective observational cohort</td>
<td>2 weeks</td>
<td>153 (75%)</td>
<td>Failure to retain pessary, pain/bleeding/discomfort, worsening symptoms</td>
<td>Increasing parity, previous hysterectomy</td>
</tr>
<tr>
<td>Author/ year</td>
<td>Number</td>
<td>Types of pessaries</td>
<td>Study design</td>
<td>Follow-up period</td>
<td>Success rate n (%)</td>
<td>Reason for failure</td>
<td>Risk factors</td>
</tr>
<tr>
<td>--------------</td>
<td>--------</td>
<td>-------------------</td>
<td>--------------</td>
<td>-----------------</td>
<td>-------------------</td>
<td>-------------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Handa et al. 2002 (6)</td>
<td>56</td>
<td>Ring, Donut, Gellhorn, Cube</td>
<td>Prospective observational cohort</td>
<td>3 months</td>
<td>36 (64.3%)</td>
<td>Discomfort, expulsion</td>
<td>-</td>
</tr>
<tr>
<td>Jones et al. 2008 (7)</td>
<td>90</td>
<td>Ring, Incontinence ring, Gellhorn, Oval</td>
<td>Prospective observational cohort</td>
<td>3 months</td>
<td>42 (47%)</td>
<td>Failure to retain, Inadequate relief of symptoms</td>
<td>Large baseline measurement of the perineal body at rest Large levator hiatus</td>
</tr>
<tr>
<td>Komesu et al. 2007 (8)</td>
<td>64*</td>
<td>Choice of pessary left to discretion of the provider</td>
<td>Prospective observational cohort</td>
<td>6-12 months</td>
<td>64 (56%)</td>
<td>failure to retain, uncomfortable</td>
<td>Prolapse score decrease to 77% of baseline</td>
</tr>
<tr>
<td>Kuhn et al. 2009 (9)</td>
<td>73</td>
<td>Cube</td>
<td>Prospective observational cohort</td>
<td>12 months</td>
<td>32 (44%)</td>
<td>Pessary expulsion, desire for surgery, bothersome de novo SUI, inability to remove or insert pessary, pain or feeling of discomfort, unspecified</td>
<td>N/A</td>
</tr>
<tr>
<td>Lone et al. 2011 (10)</td>
<td>246</td>
<td>Ring, Gellhorn, Cube, Donut</td>
<td>Prospective observational cohort</td>
<td>5 years</td>
<td>53 (28.3%)</td>
<td>Expulsion, excoriation/bleeding, pain/discomfort, constipation</td>
<td>N/A</td>
</tr>
<tr>
<td>Patel et al. 2010 (11)</td>
<td>75</td>
<td>Ring, Ring with support, Gellhorn</td>
<td>Prospective observational cohort</td>
<td>3 months</td>
<td>54 (79%)</td>
<td>Failure to retain, ineffective</td>
<td>N/A</td>
</tr>
<tr>
<td>Nemeth et al. 2012 (12)</td>
<td>78</td>
<td>Cube</td>
<td>Prospective observational cohort</td>
<td>12 months</td>
<td>62 (79%)</td>
<td>Stress incontinence Vaginal discomfort</td>
<td>Parity, previous hysterectomy and/or colpoperineorrhaphy, Difficult insertion</td>
</tr>
<tr>
<td>Wu et al. 1997 (13)</td>
<td>110</td>
<td>Ring with and without diaphragm, Cube</td>
<td>Prospective observational cohort</td>
<td>Initial visit</td>
<td>81 (74%)</td>
<td>Failure to sustain support of the prolapse, intolerable urinary incontinence, vaginal discharge, pelvic pain, vaginal abrasions and erosions</td>
<td>Younger women, previous pelvic surgery, history of stress incontinence prior to pessary insertion</td>
</tr>
</tbody>
</table>

Foot notes: N/A = not applicable; N/R = not reported,*Includes patients with incontinence and/or prolapse


4. RECOMMENDATIONS

There is growing attention being paid to the effectiveness of conservative interventions for POP. There are encouraging signs of more rigorous research in the area.

4.1. Recommendations for Practice

4.1.1 Lifestyle Modification

1. Constipation is associated with development of prolapse (Grade of Recommendation: C New).
2. Smoking cessation, while generally recommended, cannot be recommended specifically for the avoidance of prolapse development (Grade of Recommendation: D).
3. Vitamin D deficiency is not associated with development of prolapse (Grade of Recommendation: C New).

4.1.2 Pelvic Floor Muscle Training (PFMT)

1. PFMT does not influence the development of prolapse post-natally (Grade of Recommendation: B New).
2. PFMT intervention delivered 12 years+ after childbirth can reduce symptoms of prolapse which develop in the longer term (Grade of Recommendation: B New).
3. There is evidence of benefit that PFMT is effective in reducing pelvic floor symptoms (Grade of Recommendation: A New)
4. There is some evidence of benefit showing that PFMT is effective in alleviating specific prolapse symptoms (e.g. vaginal bulge) (Grade of Recommendation: C New)
5. There is no evidence that PFMT is effective in reducing severity of prolapse based on POP-Q stage (Grade of recommendation: B New).
6. Peri-operative PFMT does not improve prolapse symptoms in women undergoing surgery for vault prolapse (Grade of Recommendation: B New).
7. Combined pessary and PFMT and PFMT alone can be equally effective in reducing symptoms and increasing muscle strength and should be considered for treatment (Grade of Recommendation: B New).

4.1.3 Pessaries

1. In a choice between the Gellhorn pessary and a ring with support, offer either to improve prolapse symptoms and reduce their impact (Grade of Recommendation: B).

4.2. Future Research Directions

4.2.1 Lifestyle Interventions

1. Trials of interventions for constipation are needed to assess their effectiveness in preventing/treating prolapse.
2. Studies to fully investigate the association between occupation/heavy lifting, and bodyweight and prolapse are needed as current evidence is conflicting. These studies should ensure that:
   i. Occupation, physical activity and diet are assessed rigorously, using instruments with sound psychometric properties.
   ii. Potential confounding variables are considered. Attempts are made to overcome recall bias inherent in assessing lifetime occupational history, and healthy worker bias, which is a problem when attempting to compare prolapse in women currently employed in heavy labour type jobs versus others.
   iii. Outcome measures used are valid and reliable, and are consistent across studies; prolapse symptoms should be the primary outcome within studies, followed by prolapse anatomical severity.

4.2.2 Pelvic Floor Muscle Training (PFMT)

1. Further studies are needed to confirm the role of physical therapies in the prevention of POP.
2. Further trials are needed to add to the evidence regarding:
   i) The effectiveness of PFMT for different stages and types of prolapse.
   ii) The role of PFMT as an adjunct to surgery for anterior and posterior prolapse.
3. More trials needed to improve the evidence relating to the following comparisons:
   i) Low versus high intensity supervision of PFMT (taught PFMT vs self-instruction manual already trialled)
   ii) Individual versus group PFMT (group PFMT vs group lifestyle already trialled)
   iii) PFMT versus surgery (anterior/posterior repair vs PFMT already trialled)
   iv) PFMT versus pessary. (PFMT vs PFMT plus pessary already trialled)

The assessment and measurement of POP and the assessment of prolapse symptoms need to be made in a standardised fashion using a validated outcome measure (such as the POP-Q examination). A single validated symptom tool was not apparent in new studies, but the PFDI, PFIQ and POP-SS tools were most commonly used and may provide a useful basis for comparisons across trials in future.
4.2.3 Pessarie for Prolapse

Although the use of pessaries has been common clinical practice and has been used for many centuries robust evidence of their use is lacking. There is a pressing need for well-designed randomised studies using validated measures for subjective and objective assessment. Areas that need focus are:

- Pessary versus no treatment
- Pessary versus PFMT
- Pessary versus surgery
- Risk benefit of the use of local oestrogen in conjunction with a pessary
- Progression or regression of prolapse using in women using pessaries
- Optimal management protocols for pessary usage e.g. indications, interval between pessary changes, complications and their treatment and which pessary is indicated for a specific type of prolapse.

IV. URINARY INCONTINENCE IN MEN

As in earlier consultations, UI in men remains under-reported and under-studied in comparison to studies of women. Pooled prevalence of UI in community based men ranges from 4.81-32.17%. (302) UI and other LUTS in men increase with age, with variation in prevalence rates reflecting different study populations, definitions of incontinence and methods (303). Despite the prevalence of UI and LUTS in older men, the only aspect which continues to receive systematic consideration with respect to conservative management is post-prostatectomy urinary incontinence after radical prostatectomy (RP). The primary conservative approach for prevention and treatment of UI after RP, or transurethral resection (TURP), remains PFMT, with or without some form of biofeedback (BF). PFMT, in combination with anal EStim, BF or transcutaneous electrical nerve stimulation (TENS), MStim, and novel therapies such as dyadic planning and concentration have been utilised for UI in men.

The PFMT, EStim, MStim and PTNS interventions, and other combinations of PFMT with general exercise and other approaches, in the current review were kept in the same organizational format as the previous consultation to reflect evolving evidence and emerging directions of research. All new studies of EStim and MStim in men undergoing or post prostatectomy combined these modalities with PFMT and thus were included under the PFMT section. Penile vibratory stimulation (PVS) was added as a novel technology category. The study on PVS involved men incontinent after RP, but did not include PFMT, so was kept in a separate section, as were studies of EStim and MStim for non-prostatectomy related incontinence or other LUTS. Studies on PTNS are presented in section V.1.

A literature search of relevant systematic reviews and reports of RCTs and quasi-RCTs was updated. No other types of study designs were considered. One systematic review, an update of the Cochrane systematic review on conservative management of post-prostatectomy incontinence, was identified (304). For this review, 14 new published trials (305-318) and eight abstracts (319-326) were identified. Table 34 provides summary information on the 22 trials added in this review. One study previously included only as an abstract (327) is now included as a full publication (328). This study is included in the table as in the full publication with additional information that was not previously included in the abstract. The published peer reviewed journal publication (329) of a previously included report of two parallel trials (RP and TURP arms) was added to the references which previously included an abstract and health technology report (330, 331). One study previously excluded as it was a study in progress (332) was included this time as a peer reviewed publication of a completed trial (307). Nine ongoing trials were identified from trial registries, but not included in this review.

1. LIFESTYLE

Lifestyle recommendations such as smoking cessation, healthy eating, appropriate body weight, avoiding excessive caffeine or alcohol are all part of a primary care approach and are intended to be preventative in the onset of obesity, cardiovascular disease, diabetes. Up until the last ICI edition, no trial had addressed the topic of lifestyle interventions alone in men with UI. In this edition, a few new trials have been added.

1.1. Weight Loss by Obese or Overweight Men

One new trial was identified on weight loss in overweight/obese men (7, 333) and has been added in this update. This was the partner study to Phelan, Kanaya et al. (2012) conducted to determine the effect of an intensive weight loss programme over 4 years previously outlined in the look AHEAD trial - on a subset of male participants (n=1910). Men were randomised to an intensive weight loss programme or diabetes support and education group. Self-report of incontinence, nocturia and daytime voiding frequency were recorded at baseline and 1 year. The odds of prevalent UI at one year were reduced by 38% in the intensive lifestyle modification intervention group compared to the support and education group, with UI decreasing from 11% to 9% in men. As reported for women there was uncertainty over the risk of selection bias for a number of key parameters including: random sequence generation and allocation concealment. Performance bias was unclear as the blinding of participants and staff was not undertaken. Both
studies did ensure the blinding of outcome assessment but neither provided complete outcome data and both provided only selective reporting indicating possible reporting bias (Table 2).

1.2. Smoking

One new trial was found however data was not presented separately for women and men. (Refer to section II.1.2.4 for more details)

1.3. Dietary Modification in Men

In a separate sample (from the study by Davis, Vaughan et al. 2013 presented in Lifestyle intervention in women’s section II.1.2.5) 3960 men over 20 were included (16).

The authors found that the highest level of caffeine intake was associated with having moderate to severe UI (1.72, 95% 1.18-2.49 and 2.08, 95% 1.15-3.77) respectively. All parameters in terms of risk of bias reporting were unclear or high risk. The blinding of participants and personnel and blinding of outcome assessment were at high risk of bias and the likelihood of incomplete outcome data and selective reporting was also high.

A sample of 683 men aged 40-75 who completed a food frequency questionnaire and the Consultation on Incontinence short Form (ICI-SF) as part of the Hirayama study (18). The data showed a slight increase in the risk of UI at the highest level of caffeine consumption (similar to the US data), but this was not significant after adjusting for confounding factors with OR: 95% CI, 1.36 (0.65-2.88) in the male participants. The risk of bias reporting was largely unclear in this study with blindness of participants and personnel and blinding of outcome assessment, incomplete outcome data and selective reporting all of high risk. Results of sex stratified analysis of the data from the sample of Japanese men and women did not show an association between caffeine and UI, the authors suggest the need for further larger samples to explore any association further (Table 5).

Summary

Evidence from 1 RCT supports lifestyle modification interventions promoting weight loss as a tool to reduce urinary incontinence in men who are overweight or obese. (Level of Evidence: 2; 1 new RCT).

Evidence from a small new RCT indicates that urinary frequency may be improved by smoking abstinence, (Level of Evidence: 3).

Caffeine consumption is likely to play a role in exacerbating UI in men. New epidemiological evidence from a large cross sectional study supports this conclusion (Level of Evidence: 3).

Recommendations

Weight loss: Where weight loss through lifestyle changes should be recommended to obese and overweight men with UI, particularly those with type 2 diabetes. (Grade of Recommendation: B New)

Smoking abstinence should be recommended for men with UI. (Grade of Recommendation: C New)

A reduction in caffeine intake is recommended for those with incontinence symptoms; evidence suggest the equivalent of 2 cups of coffee a day (250mg) is associated with urinary incontinence in both men and women. (Grade of Recommendation: C)

Larger RCTs to assess effect of lifestyle modification interventions are important.
Table 34 Summary of data on conservative management in male urinary incontinence

| Author, year | Comparator | N | Study population | Modality details or parameters | Outcomes/results | Follow up | Notes (side effects, loss of follow up…)
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pelvic Floor Muscle Training (PFMT)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ahmed et al. 2012 (1)</strong></td>
<td>3 group comparison PFME vs PFMT plus EStim vs PFMT plus EStim plus biofeedback</td>
<td>N= 90 men randomized, N=80 completed trial Group 1 n= 26 Group 2 n=26 Group 3 n= 28 Randomization by computer generated random number list in sealed envelopes. Surgeons blinded to randomization. Blinding of outcomes assessor not indicated.</td>
<td>Men undergoing RP for clinically localized prostate cancer</td>
<td>Treatments started one week after catheter removal, twice weekly for 12 weeks Group 1 PFME (control) Group 2 PFMT plus EStim starting one week after catheter removal, twice weekly for 12 weeks Group 3 PFMT plus EStim plus biofeedback starting one week after catheter removal, twice weekly for 12 weeks EStim – electrodes on skin over sacrum Biofeedback - surface electrodes on abdomen and perineum</td>
<td>Primary outcome 24 hour pad test, secondary was quality of life assessed with IIQ-7. Mean leakage significantly lower in Group 3 (EStim plus biofeedback) at 6 through 24 weeks (p &lt; 0.05) Significant differences in continence at weeks 12 and 24 with Group 3 having more continent patients, followed by Group 2. Concluded early EStim and biofeedback decrease duration and degree of postprostatectomy UI</td>
<td>Continenence assessed at baseline, 6, 12 and 24 weeks</td>
<td>Continence assessed at baseline, 6, 12 and 24 weeks</td>
</tr>
<tr>
<td><strong>Baroni et al. 2013(2)</strong></td>
<td>Intervention (individual PFMT and group treatment) vs control (individual PFMT)</td>
<td>N= 40 men Divided into two groups (randomization not described). Intervention: n = 16 patients mean age 61.8 years Control n = 24 mean age 67.5 Assessor blind to allocation until assignment.</td>
<td>Men with SUI or mixed UI after RP (time after surgery not reported)</td>
<td>Intervention: 5 individual training sessions with a physical therapist followed by small groups sessions (total 15 sessions at the rehabilitation centre), home exercises. Control: individual training sessions with physical therapist.</td>
<td>Outcomes included adherence to training program (exercise at home), self report of change in continence using VAS scale and number of pads, quality of life ICIQ-SF, cost effectiveness (therapist time). Non significant difference in home practice (intervention 69% vs 58% controls). No</td>
<td>Initial briefing by therapist, final evaluation one month after rehabilitation.</td>
<td>Initial briefing by therapist, final evaluation one month after rehabilitation.</td>
</tr>
<tr>
<td>Author, year</td>
<td>Comparator</td>
<td>N</td>
<td>Study population</td>
<td>Modality details or parameters</td>
<td>Outcomes/results</td>
<td>Follow up</td>
<td>Notes (side effects, loss of follow up…)</td>
</tr>
<tr>
<td>-------------</td>
<td>------------</td>
<td>---</td>
<td>------------------</td>
<td>--------------------------------</td>
<td>------------------</td>
<td>-----------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>Burkert et al. 2011(3)</td>
<td>Intervention (dyadic PFME planning) vs one of three controls</td>
<td>N = 112 prostatectomy patients and their partner (dyads). 2x2 mixed design. Couples randomized in blocks of four to one of four groups Intervention n= 28, Controls n= 29, 29 and 26 Research assistants blinded to allocation Mean age of patients 62.8 years, partners 59.3 years. Men undergoing laprascopic RP who had a partner willing to participate</td>
<td>All patients received standard care including written information on PFME 1 day post surgery (PFME 3x day for 10 minutes), physical therapist introduced PFME on day 3 or 4. Discharge day all participated in single 30 minute planning session intervention with completion of planning sheet for health behaviours (in dyad or individually). Intervention: dyad PFME planning Control: (dyadic nutrition planning, Control: individual PFME planning, Control: individual nutrition planning</td>
<td>Main outcome: self reported dyadic planning and PFME. Self reported dyadic PFME planning increased with both the dyadic and individual PFME planning session. No effect on PFME was found. Continence was not an outcome.</td>
<td>Questionnaires at 2 d, 2 weeks, 1, 3 and 6 months post-surgery.</td>
<td>Dropouts Intervention n=5 Control: dyadic nutrition planning n=2 Control individual PFME planning n=7 Control: individual nutrition planning n= 4 Sample size analysis required 112 couples (dyads). Intention-to-treat analysis completed.</td>
<td></td>
</tr>
<tr>
<td>Collado, Serra 2013 (4)</td>
<td>Abstract only</td>
<td>N= 193 patients recruited Randomization and blinding detail not provided. Men with localized prostate cancer scheduled for RP</td>
<td>Intervention: starting 3 weeks before surgery included weekly assisted BF sessions (surface electrodes) with periodic, rapid,</td>
<td>Primary outcome: Degree of continence improvement compared to week 1 during followup (continence not defined)</td>
<td>No detailed description. Pad tests reported for week 1, week 6, month 3, month 6 and 1 year.</td>
<td>Dropouts –detail only for intervention group n=5 (2 perineal pain, 2 post RP complication, 1 left treatment.</td>
<td></td>
</tr>
</tbody>
</table>
| Author, year | Comparator | N | Study population | Modality details or parameters | Outcomes/results | Follow up | Notes (side effects, loss of follow up…)
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Dijkstra-Eshuis et al. 2015 (5)</td>
<td>Intervention PFMT plus biofeedback pre-op vs Control PFME post-op</td>
<td>N=122 patients recruited, N= 121 randomized. Pre-operatively. Mean age 63.7 years. Randomization by computer generated random numbers (block randomization, variable block size). Therapists and participants blinded to randomization until first visit. Intervention n= 65 Control n= 56</td>
<td>Men undergoing laparoscopic RP (one surgeon), prostate cancer state T1 or T2.</td>
<td>All participants assessed pre-op by physical therapist Intervention: once weekly 30 minute session of PFMT with biofeedback pre-op x 4 weeks provided by physical therapist with twice daily practice at home. Told to restart immediately after catheter removal. Written instructions for 2 sets of 30 contractions. Control: standard care of written PFME instructions on catheter removal (7-10 days post surgery)</td>
<td>Primary outcome: urinary continence defined as no leakage on 24 hour pad test and self report by KHQ, IPSS and PeLFI (pelvic floor inventories) 20.8% of patients continent at 6 weeks, 43.6% at 3 months, 61.5% at 6 months, 72.3 % at 9 months, 77.2% at one year. No difference in SUI or QoL between intervention and control at any time points. Authors suggested that post-prostatectomy UI likely due to intrinsic sphincter deficiency that</td>
<td>Questionaires, 24 hour diary and pad test at 6 weeks, 3, 6, 9 and 12 months post-operatively. PeLFT and examination of the pelvic floor pre-operatively and 1 year post-operatively.</td>
<td>Dropouts Intervention: language barrier (1), lost to followup (4), discontinued intervention (4) Control: Lost to followup (4), discontinued intervention (6) Sample size analysis was 124 patients in each group (n=248), interim analysis planned at 122 patients. Trial halted as interim analysis showed no benefit.</td>
</tr>
</tbody>
</table>
| Author, year | Comparator | N | Study population | Modality details or parameters | Outcomes/results | Follow up | Notes (side effects, loss of follow up…)
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Geraerts et al. 2013 (6)</td>
<td>Intervention PFMT plus biofeedback pre-op vs Control PFMT post-op</td>
<td>N= 180 men</td>
<td>Men undergoing open or robot assisted laparoscopic RP (3 surgeons)</td>
<td>Intervention: 30 minute session of therapist guided PFMT with biofeedback weekly starting 3 weeks prior to surgery plus home program of 60 contractions per day. Restarted PFME day 4 post-op with catheter <em>in situ</em>. Control: PFMT after catheter removal. Both groups: Post-op weekly session to discuss bladder diary and have guided session with digital or EMG biofeedback plus home program. PFMT continued until continent</td>
<td>Primary outcome: incidence of continence and time to continence. Continence defined as 3 consecutive days of 0gm urine loss on 24 hour pad test. Other measures were: 1 hour pad test, VAS, IPSS, KHQ (QoL). No difference between groups on duration of UI, pad test, VAS or IPSS. Median time continence was 30 (control) and 31 (intervention) days. Intervention group scored better on impact of incontinence at 3 and 6 months</td>
<td>Pre-operative baseline and 1, 3, 6 and 12 months post-operatively</td>
<td>Dropouts: Intervention n=6 died (1), stroke (1), transport problems (3), refused further participation (1) Control n= 4 transport problems (2), refused further participation (2) Sample size analysis required 166 for power.</td>
</tr>
<tr>
<td>Ghanem et al. 2013 (7) Abstract only</td>
<td>Intervention PFME pre-op vs Control PFME post-op</td>
<td>N=100 men randomized. Randomization technique not described. Intervention N=50 Control N=50</td>
<td>Men with localized prostate cancer undergoing radical prostatectomy</td>
<td>Intervention: PFME protocol for 2 weeks prior to surgery (detail not provided) with post-operative PFME program. Control: postoperative PFME program only</td>
<td>Continence defined as using 0-1 pads. Also completed the ICIQ SF male. More intervention patients continent at 14 weeks than controls (p&lt; 0.05). 70% of patients in both groups continent at 18 weeks, 85% by 54 weeks.</td>
<td>Timepoints for measurement not clear, last dated reported at 54 weeks post-op.</td>
<td>Dropouts: not described Sample size analysis not described.</td>
</tr>
<tr>
<td>Hou et al 2013 (8)</td>
<td>Intervention post-op PFME vs control</td>
<td>N= 66 randomized. Randomization</td>
<td>Men undergoing TURP for benign</td>
<td>Intervention: PFME after removal of catheter day 2 post-op.</td>
<td>Outcome: early recovery of bladder function post TURP using the IPSS and Baseline and 1, 4 and 12 weeks post-op</td>
<td>Dropouts n= 5 (group assignment not identified) delay in</td>
<td></td>
</tr>
<tr>
<td>Author, year</td>
<td>Comparator</td>
<td>N</td>
<td>Study population</td>
<td>Modality details or parameters</td>
<td>Outcomes/results</td>
<td>Follow up</td>
<td>Notes (side effects, loss of follow up…)</td>
</tr>
<tr>
<td>-------------</td>
<td>------------</td>
<td>---</td>
<td>------------------</td>
<td>-----------------------------</td>
<td>------------------</td>
<td>-----------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td>Kakihara et al. 2007 (9)</td>
<td>Intervention (PFMT with EStim) vs PFME only</td>
<td>N=20 men from a single urology clinic, mean age 64.3 years Randomly divided into two groups (detail on randomization technique not provided) Intervention group n=10, control n=10 N=18 in final analysis for pad test and visual analogue data : intervention n=8, control n=10</td>
<td>Men with urinary incontinence post RP (minimum of 6 months post-op, had undergone urodynamic testing)</td>
<td>Intervention: Physical therapy taught functional PFMT with EStim. PFME started with 2s contractions increasing daily by 1s until 10s reached. Patients were instructed to do 90 contractions/day at home (divided equally into 3 times per day). Also had EStim with endo-anal electrode weekly. UUI – 8 Hz increasing to 10 Hz after 3 months, for SUI 35Hz increasing to 50 Hz after 3 months. Control: Physical therapy taught functional PFMT only</td>
<td>UI measured with 1 hour pad test (incontinence &lt; 2 gm), visual analogue scales for incontinence, patient perception of the problem, and pad use Intervention group: 4 patients UUI, 6 had SUI, mean time post surgery 12.3 months. Control group: 5 had UUI, 5 SUI, meantime post surgery 16.8 months Significant decrease in urine loss on pad test and self report baseline to 12 months in both groups. No difference between groups</td>
<td>Measures at baseline, visit 2, and 3, 6 and 12 months.</td>
<td>Dropouts Intervention n=2 discharged at 3rd and 6th months, reason not provided. Control n=3 discharged at 3rd, 6th and 12th as regained continence Length of time EStim continued for the intervention group unclear. No sample size or intention-to-treat analysis reported.</td>
</tr>
</tbody>
</table>
| Author, year | Comparator | N | Study population | Modality details or parameters | Outcomes/results | Follow up | Notes (side effects, loss of follow up…)
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Kongtragul et al. 2014 (10)</td>
<td>Intervention (PFME with concentration therapy) vs control (PFME only)</td>
<td>N= 138 men recruited from a single hospital N= 135 cases in final analysis (n= 68 intervention, n= 67 control) Randomization technique not given. Sample stratified for time of catheter removal (prior to or after discharge) and type of surgery (no further detail provided).</td>
<td>Men 17-80 years of age with prostate cancer who had no incontinence prior to radical prostatectomy surgery</td>
<td>Intervention: Starting 3 weeks post-operatively, PFME with concentration therapy (concentrating on the exercise and eliminating other issues or use of the rehabilitation health spa rock - not clearly described). PFME was practiced 240 times daily by holding and relaxing muscle tension around the anus. Control: PFME only</td>
<td>Primary outcome was urinary incontinence (incontinence ≥ 2 gm urine on 1 hour pad test) 65/68 in intervention group compared to 48/67 controls achieved continence (p&lt; 0.001 More men in intervention group 66/68 practiced regularly than in control group 34/67 (p&lt;0.001)</td>
<td>Measurements at baseline (3 weeks post surgery) and weekly for up to 3 months</td>
<td>Dropouts Intervention n=1 (refused treatment Control n=2 (refused treatment) Needed 69 cases in each group for power. No intention-to-treat analysis.</td>
</tr>
</tbody>
</table>
| Laurienzo et al. 2013 (11) | 3 groups Pre-op PFMT plus EStim vs pre-op PFMT vs control | N= 58 men recruited. Randomization by computer generated list. All intervention provided by a single therapist N= 49 completed study (n= 17 PFME plus EStim, n= 17 PFME, n= 15 control) | Men with prostate cancer stage T2 waiting RP | Intervention Group 1: 10 pre-op physiotherapy sessions of EStim using rectal probe. Tonic fibers – 20HZ, 700 microseconds, work time 6s, rest 6s. Phasic fibers – 65 HZ, 150 microseconds, work time 6s, rest 18s. Five exercises for PFM contraction. Group 2: 10 pre-op physiotherapy sessions with only the PFME. Control Pre-op information on prostate anatomy only | Primary outcome: continence assessed by 1 hour pad test (> 2 gm incontinence). Secondary outcomes: ICIQ-SF, SF-36 No significant differences between groups on pad test at any time points. No differences in QoL (SF-36) | Measurements at 1, 3 and 6 months post surgery. | Dropouts N=9 (detail on group not provided). Desistance (sic)(2), adjuvant radiotherapy (1), urethral stenosis (1), urinary fistula (1), surgical risk (1), inadequate followup (1) No sample size analysis described. No intention-to-treat analysis.
<table>
<thead>
<tr>
<th>Author, year</th>
<th>Comparator</th>
<th>N</th>
<th>Study population</th>
<th>Modality details or parameters</th>
<th>Outcomes/results</th>
<th>Follow up</th>
<th>Notes (side effects, loss of follow up…)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laurienzo et al 2015 (12) Abstract only</td>
<td>3 groups PFMT plus EStim vs PFMT vs control</td>
<td>N=123 men incontinent after RP Randomization by computer, sealed envelopes. Group 1 n=40 control, no treatment Group 2 n=41 assisted PFMT Group 3 n=42 EStim with assisted PFME No details on blinding.</td>
<td>Men with more than 3 gram loss of urine on a 1 hour pad test one month after RP</td>
<td>Assisted PFMT described as two series of ten exercises taught by verbal command EStim protocol was 20 minute sessions twice weekly over 7 weeks. Frequency 35 HZ</td>
<td>Outcomes Incontinence and quality of life using the ICQ-SF, erectile dysfunction by IIEF-5, IPSS, 1 hour pad test, evaluation of pelvic floor with perineometer. No differences between groups in quality of life, erectile dysfunction or PFM strength at any time point post-surgery. Pad test data not provided.</td>
<td></td>
<td>Patients evaluated pre-operatively and then at 1, 3, and 6 months post RP</td>
</tr>
<tr>
<td>Martini et al 2011 (13) Abstract only</td>
<td>Intervention pre-op PFMT vs control</td>
<td>N= 70 men recruited N= 49 with pelvic floor impairment identified on exam randomized to intervention or control. Intervention n=24 Control n=25 Randomization details not provided.</td>
<td>Men undergoing laparoscopic RP for localised prostate cancer T1-T3</td>
<td>Intervention: 5 sessions of physical therapist guided PFMT 2-3 weeks before surgery, PFME continued post-op Control: usual care – written instruction on PFME provided post-operatively</td>
<td>Outcome: focus on PFI as a potential factor in post RP UI. Continence defined by not wearing a pad. Other: 24 hour pad test, pad use, 7 day bladder diary, QoL. Patients with PFI used more pads and had more SUI episodes. PFI independent predictor of UI at 3 and 6 months. For those with PFI, UI on getting up and squatting was significantly lower in intervention group at 1 month (p=0.006) but not other time points.</td>
<td>Measurement pre-op baseline, and 1, 3 and 6 months post-op.</td>
<td>Dropouts: not identified. Sample size analysis not provided.</td>
</tr>
<tr>
<td>Morihoro et al 2011 (14) Abstract only</td>
<td>Intervention post-operative PFME with EStim</td>
<td>N= 34 men Randomized post-operatively to 2 groups.</td>
<td>Men who had undergone laparoscopic RP</td>
<td>Intervention: PFME and EStim 2x daily for 15 minutes for one</td>
<td>Outcome UI, defined as not needing a pad to keep clothing dry.</td>
<td>Measurement at 1, 3, 6, and 12 months.</td>
<td>Dropouts: not described.</td>
</tr>
</tbody>
</table>
| Author, year | Comparator | N | Study population | Modality details or parameters | Outcomes/results | Follow up | Notes (side effects, loss of follow up…)
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ng 2014 (15) Abstract only</td>
<td>Intervention pre-op PFMT vs control</td>
<td>N=66 men</td>
<td>Men undergoing radical prostatectomy</td>
<td>Intervention: PFMT started 3 weeks pre-operatively from advanced practice nurse. Control: Standard care (no detail provided).</td>
<td>Primary outcome: urine loss on 24 hour pad test. Secondary outcomes: incontinence impact and potency satisfaction. Earlier return to continence in intervention group at 3 months compared to controls (p= 0.002). Intervention group also had higher score on potency at 3 months (p = 0.005).</td>
<td>Measures at 1, 2, 3 and 6 months</td>
<td>Dropouts: no information provided.</td>
</tr>
<tr>
<td>Ocampo-Trujillo et al. 2014 (16)</td>
<td>Intervention (pre-op PFMT with biofeedback) vs control (standard pre-op teaching only)</td>
<td>N=16 men, mean age 58 years Randomized to 2 groups Intervention n=8, control n=8 Randomization – single blind, centralized. Researchers blind to group assignment prior to enrollment.</td>
<td>Men &gt; 40 years waiting RP for prostate cancer (T&lt;3 N0M0 PSA&lt;20)</td>
<td>Intervention: Intensive PFMT 3 times daily for 4 weeks prior to surgery. Biofeedback audible and visual signals, anal pressure probe. Control: standard pre-operative diet and general health teaching</td>
<td>24 hour pad test for continence, histological analysis of muscle tissue from external sphincter of urethra. Health related quality of life assessed with UCLA-PCI and SF 12. Continence defined as 3 consecutive days of no urine loss on 24 hour pad test, results not reported. 6/8 intervention vs 4/8 of controls did not need pads at 8 weeks. Self report of symptoms favoured improvement in intervention group (no p</td>
<td>Measurements (pad test, health related quality of life) at week 0 prior to surgery and week 8 post-op. Histology samples taken at the end of the intervention and on day of surgery.</td>
<td>Dropouts: none No histology samples taken prior to start of intervention.</td>
</tr>
<tr>
<td>Author, year</td>
<td>Comparator</td>
<td>N</td>
<td>Study population</td>
<td>Modality details or parameters</td>
<td>Outcomes/results</td>
<td>Follow up</td>
<td>Notes (side effects, loss of follow up...)</td>
</tr>
<tr>
<td>-------------</td>
<td>------------</td>
<td>---</td>
<td>------------------</td>
<td>-------------------------------</td>
<td>-----------------</td>
<td>----------</td>
<td>--------------------------------------------</td>
</tr>
<tr>
<td>Park et al. 2012 (17)</td>
<td>Intervention (combined exercise with PFME vs control (PFME only))</td>
<td>N= 66 men 65 years or older recruited. Random allocation by random number generator, sealed envelopes N= 39 completed study. (n= 26 in intervention group, n= 25 in control) Participants not blinded; surgeons and research assistant completing evaluation questionnaires not blinded.</td>
<td>Men who had undergone laparoscopic RP.</td>
<td>Intervention: Exercise (resistance, pelvic flexibility and Kegel exercises) initiated post-op week 3 for 12 weeks (twice weekly). Control : Kegel exercises only. Detail of Kegal (PFME) exercises not provided. Exercise program developed by sport science experts, detail of who supervised the intervention not provided.</td>
<td>Continence a secondary outcome Measured by 24 hour pad test. Urinary continence was &lt; 1 gm Significant improvement (p= 0.033) in favour of intervention group at time of last visit (15 weeks post-op). Concluded intervention group had an earlier return to continence.</td>
<td>Measurements at 1 week prior to surgery, 3 weeks post-op and after the intervention (15 weeks post-op)</td>
<td>Dropouts Intervention: n=7 (other unrelated surgery, TURP for urethral stricture, non compliance, new employment) Control: n=8 (other unrelated surgery, adjuvant radiotherapy, non compliance, new employment) No intention-to-treat.</td>
</tr>
<tr>
<td>Pedriali et al. 2014 (18)</td>
<td>Intervention post-op pilates vs control PFME plus EStim</td>
<td>N= 69</td>
<td>Men one month after RP</td>
<td>Intervention: 10 sessions mat Pilates exercises with certified Pilates physical therapist. Control: 10 sessions of PFME plus EStim with physical therapist. Both: Written instructions for home exercises corresponding to treatment.</td>
<td>Outcomes: continence on 24 hour pad test, number of pads used, ICIQ-SF Significant reduction in urine loss/24 hours and pads used, improvement in QoL in both groups. 58% of intervention and 50% of controls achieved continence as measured by no pad use (p=0.57) Authors concluded Pilates as efficacious as control condition and may reduce health care costs.</td>
<td>Time points of measurement not provided, 3 months of treatment mentioned.</td>
<td>Dropouts: no details provided. No information on sample size calculation provided.</td>
</tr>
<tr>
<td>Author, year</td>
<td>Comparator</td>
<td>N</td>
<td>Study population</td>
<td>Modality details or parameters</td>
<td>Outcomes/results</td>
<td>Follow up</td>
<td>Notes (side effects, loss of follow up…)</td>
</tr>
<tr>
<td>--------------</td>
<td>------------</td>
<td>---</td>
<td>------------------</td>
<td>--------------------------------</td>
<td>-----------------</td>
<td>----------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>Serda et al. 2014 (19)</td>
<td>Intervention post-op combined exercise with PFME vs control no intervention</td>
<td>N= 69 men with prostate cancer (any stage) who had undergone prostatectomy +/- hormone or hormone and radiotherapy randomized to 2 groups. n= 36 intervention n= 33 control Mean age 71 in both groups. N=66 completed</td>
<td>Men with no prior incontinence recruited after treatment for prostate cancer (time period not identified). Details of randomization approach not provided.</td>
<td>Intervention: Progressive strength program in 3 consecutive stages: global posture re-education, PFMT, exercises to radiate muscle strength. Duration 24 weeks, 16 weeks of supervised work, 8 of autonomous exercise. PFMT performed with music, focus on biofeedback (sense of awareness). Slow twitch (≤1 s) and fast twitch (5 s) contractions. Control group: watchful waiting by telephone contact</td>
<td>UI assessed by 20 minutes pad test. Type of incontinence measured by UI-4, intensity and frequency of urine loss by Sandvik scale and VAS/UI and FACT-P (urinary related QoL). Also included data on obesity, muscle resistance, constipation and activity. 33.33% of intervention group had stress UI compared to 36.36% controls. The rest had urgency UI or mixed UI. Significant improvement on VAS/UI scale regarding intensity UI symptoms favouring intervention group. QoL improvement greater in those with greater improvement in UI. Pad test dated/number achieving continence not reported.</td>
<td>Data collected at baseline and 24 weeks. Calculated sample size achieved.</td>
<td>Dropouts Intervention: n=3 (medical reason, cognitive problem, metastasis) Control: None No intention-to-treat.</td>
</tr>
<tr>
<td>Tienforti et al. 2012 (20)</td>
<td>Intervention (pre-operative and post-operative PFMT with biofeedback) vs control group (post-op PFME only)</td>
<td>N= 34 men screened and recruited pre-op, computer generated randomization schedule. N= 32 men in the final analysis (n= 16 in intervention, age 60-74; n= 16 in control age 52-74). No significant differences between</td>
<td>Men undergoing standard open retropubic RP for localized prostate cancer at one centre.</td>
<td>Intervention: Pre-operative biofeedback (anal probe, reference electrode on anterior superior iliac spine) with teaching on PFM the day prior to surgery. After catheter removal, oral and written PFME with structured exercise program (3 daily 10</td>
<td>Recovery of continence (self report on ICIQ-UI) primary outcome. Significant difference in achievement of continence favoring intervention group at 1, 3 and 6 month followups. 10/16 intervention vs 1/16 control patients continent at 6 months.</td>
<td>Measurements at baseline, 1, 3 and 6 months.</td>
<td>Dropouts Intervention: n=1 (intolerance to rectal probe insertion) Control: n=1 (intraoperative surgical complications) No intention-to-treat.</td>
</tr>
<tr>
<td>Author, year</td>
<td>Comparator</td>
<td>N</td>
<td>Study population</td>
<td>Modality details or parameters</td>
<td>Outcomes/results</td>
<td>Follow up</td>
<td>Notes (side effects, loss of follow up…)</td>
</tr>
<tr>
<td>-------------</td>
<td>------------</td>
<td>----------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Zopf et al. 2015 (21)</td>
<td>Intervention (combined exercise with PFME vs control (no intervention))</td>
<td>N = 85 men who had undergone prostatectomy for prostate cancer. n= 56 in intervention group n= 29 in control group N= 70 (50 intervention, 20 control) completed followup</td>
<td>Men recruited 6-12 weeks after prostatectomy +/- radiation. Multicentre, partially randomized controlled trial. Patients who consented to randomization were to be randomized, patients who refused randomization were to receive intervention of their choice. As all patients</td>
<td>Intervention: 15 month supervised multimodal exercise program (aerobic, resistance and PFME) with one of 4 community sports groups. Exercise 60 minutes per week Details of PFME not provided. Control: No intervention</td>
<td>Multiple secondary outcomes including urinary incontinence as measured by 20 minute pad test. Primary endpoint was physical fitness. Significant improvement in UI for intervention group between baseline and post testing (p= 0.005). No significant difference between intervention and control. Significant improvement of self reported urinary symptoms (EORTC-QLQ PR 25) in favour of intervention group.</td>
<td>Measures for UI at 3 time points, detail not provided. Authors identify poor compliance with pad testing was a limitation. Calculated sample size not achieved, limited power to detect differences between groups.</td>
<td>Dropouts&lt;br&gt;Intervention: n=6, reasons not related to intervention&lt;br&gt;Control: dropouts not described.&lt;br&gt;Intention-to-treat analysis performed.</td>
</tr>
</tbody>
</table>
| Author, year | Comparator | N | Study population | Modality details or parameters | Outcomes/results | Follow up | Notes (side effects, loss of follow up…)
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Fode 2015 (22)</td>
<td>Intervention PVS vs control delayed PVS</td>
<td>N= 39 randomized by computer generated list 1 :1 ratio N= 31 in analysis (Group 1 early intervention n= 19; Group 2 delayed intervention n=20</td>
<td>Men with UI &gt; 1 year post RP. All patients had previously received PFMT with RP.</td>
<td>12 week study. Intervention: PVS for first 6 weeks of study. Stimulation of ventral surface of glans once daily; 10 seconds of stimulation followed by 10 second pause repeated 10 times. Control: delayed intervention – no intervention in first 6 weeks, PVS in second 6 weeks</td>
<td>Primary outcome: difference in leakage measured by 24 hour pad test and 72 hour voiding diary. Subjective assessment by ICIQ-SF, IPSS and satisfaction questionnaire. Early intervention group: 12/15 had reduction in leakage on pad test baseline to 6 weeks (p = 0.021); maintained in 8/12 at 12 weeks (p= 0.04) Delayed intervention group: reduction (not significant) with treatment weeks 6-12. No significant difference between groups at 6 weeks. Pooled analysis: Significant overall median decline in urine loss on 24 hour pad test (p= 0.07) Authors suggest sufficient evidence to move to larger trial.</td>
<td>Measures at baseline prior to inclusion and 6 and 12 weeks.</td>
<td>Drop outs: Group 1 early intervention n=4 lung infection (1), pain on stimulation (2), non compliance (1) Group 2 delayed intervention n= 5 untreated diabetes (1), urinary tract infection (2), change in drinking habit (1) discontinued after 6 weeks non compliance (kept in analysis) (1) Sample size calculation was n=50, enrollment stopped early as sample size deemed adequate for purpose (pilot)</td>
</tr>
<tr>
<td>Author, year</td>
<td>Comparator</td>
<td>N</td>
<td>Study population</td>
<td>Modality details or parameters</td>
<td>Outcomes/results</td>
<td>Follow up</td>
<td>Notes (side effects, loss of follow up...)</td>
</tr>
<tr>
<td>-------------</td>
<td>------------</td>
<td>---</td>
<td>------------------</td>
<td>-------------------------------</td>
<td>------------------</td>
<td>----------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>treatment (PFME, urge suppression, delayed voiding) vs drug therapy</td>
<td>Randomized using sealed envelopes after stratification for voiding frequency</td>
<td>Behaviour treatment n=73</td>
<td>symptoms after treatment with an alpha blocker for prostatic obstruction.</td>
<td>combined behavioural treatment composed of elements of bladder training (PFME, urge suppression techniques and delayed voiding). Verbal instruction by nurse practitioners, and PFME guided practice using verbal feedback based on anal palpation. Daily practice of 45 exercises (3 sessions of 15 exercises). Also used fluid management. Control: drug therapy with oxybutynin 5-30mg.</td>
<td>frequency on 7 day bladder diary. Other OAB symptoms (nocturia, urgency, incontinence) also collected on bladder diary. Secondary outcomes: global perception of improvement and patient satisfaction. Results Frequency: both groups had statistically significant improvement from baseline to after treatment. Equivalence analysis showed post treatment voiding frequency equivalent between behaviour and drug therapy groups (p&lt; 0.001) Behaviour therapy group had greater reduction of nocturia episodes, but urgency scores were lower in the drug therapy group. No difference in reduction in incontinence episodes.</td>
<td>measure, post treatment measures.</td>
<td>Dropouts reported: n=9 in behavioural therapy group, n= 10 in drug therapy group.</td>
</tr>
</tbody>
</table>

BF – biofeedback; RP – radical prostatectomy; TURP – transuretheral prostatectomy; PFME – pelvic floor muscle exercises; PFMT – Pelvic floor muscle training; PVS – Penile vibratory stimulation; ICIQ-SF – International Consultation on Incontinence Questionnaire Short Form; IPSS – International Prostate Symptom Score


2. PELVIC FLOOR MUSCLE TRAINING (PFMT)

Almost all studies of PFMT in men focused on UI associated with prostate surgery. In the 5th ICI, improvement in the quality of trials included was found when compared to earlier reports, although heterogeneity and varying outcomes continued to affect the ability to compare trial findings. Studies in the first part of this section remain grouped into three types: pre-operative interventions, mixed pre- and post-operative studies of all men undergoing prostatectomy and studies of post-operative interventions for men with established incontinence. A total of 20 new RCTs of PFMT alone or combined with other conservative interventions focused on prostate surgery were added to the 38 studies from the previous ICI reports. Nineteen of the new trials involved men pre or post RP (N= 1597 randomized), one trial involved men post TURP (N= 66 randomized). Recommendations are at the end of the section.

2.1. Pre-Operative RP PFMT

Trials in this section compared pre-operative interventions. Three new trials of pre-operative PFMT intervention (313, 314, 320) were identified and added to the two previously included trials. Ocampo-Trujillo (314) compared pre-operative PFMT with BF (n=8) to standard pre-operative teaching (n=8). Laurienzo (313) randomized to three groups, reporting group numbers for only the 49 of 58 men that completed the study; pre-operative PFME program plus EStim (n=17), pre-operative PFME (n=17) and control which received only pre-operative information on prostate anatomy (n=15). Collado-Serra (320) also reported group numbers for those completing (179 or 193) and compared an intervention group receiving pre-operative PFMT plus BF (n=87) to a control group (n=92) receiving only oral PFME program post-surgery followed by PFMT plus BF 3 months later.

Quality of data

Ocampo-Trujillo (2013) used a centrally randomised, single blind approach, with researchers blind to the group assignment prior to enrolment. No information on sample size analysis or post hoc power analysis was provided. This was a very small study that was likely underpowered. There were no dropouts from the study. Laurienzo (2013) described randomization using a computer-generated list. Detail of blinding was not provided and a single therapist provided all interventions. There was no report of sample size calculation, post hoc power analysis or intention-to-treat analysis. Nine dropouts were reported, but the group from which they withdrew was not given. Collado Serra (2013) study was available only as an abstract and did not report how participants were randomized or if there was any blinding. There was no information on sample size, and no intention-to-treat analysis reported. Only dropouts from the intervention group (n=5) were described.

Results

Ocampo-Trujillo and colleagues (2013) did not report the results of the 24-hour pad test data but did report that 6/8 (75%) of the intervention group compared to 4/8 (50%) of the control did not require pads at 8 weeks. The authors also report a statistically significant difference in objective measures of muscle tissue from the external sphincter of the urethra favouring the intervention group. As no histology samples were taken prior to the intervention, the claim that the difference is due to the intervention cannot be supported. Subjective report of symptoms reportedly favoured improvement in the intervention group. Laurienzo (2013) reported no differences between intervention and control groups at any time point (1, 3 and 6 months post-surgery) on objective measure of incontinence (one-hour pad test). There were no differences between the two interventions and one control group on subjective report of quality of life. Collado Serra (2013) reported improvement in continence at week 6, month 3, month 6 and 1-year favouring intervention group, but did not clearly define its primary outcome. Significant difference on objective 24-hour pad test was only at 3 months favouring the intervention group.

2.2. Pre-Operative and/or Post-Operative RP PFMT, Post RP Continence Status Not Established Prior to Intervention

Trials in this section addressed the effect of PFMT initiated pre-operatively and/or post-operatively but before post-op continence/incontinence was established. In these studies, men were recruited pre-operatively or immediately post-operatively and the investigators compared a treatment group that received the intervention pre-operatively and/or post-operatively to a group receiving an intervention only post-operatively. Nine new studies (305-307, 309, 315, 321, 323, 324, 326) were added to the 10 previously included trials, for a total of 19 trials in the category, over three subsections.

2.2.1 Pre-Operative PFMT Instruction with Post-Operative Home PFMT Versus Control

Four new trials (307, 321, 323, 326) were added to three previously included studies. In the previous consultation, studies varied in support of an earlier return to continence with PFME plus or minus biofeedback. Dijkstra-Eshuis (2015) compared an intervention group that received preo-operative PFMT plus BF with home practice and post-operative home PFME (n=65) to a control group that received written post-operative PFME instruction (n=56). Ghanem (2013), available only in abstract, compared an intervention group with a PFME programme two weeks pre-operatively and continued post-operatively (n=50) to a control group that received only a postoperative PFME programme (n=50). Detail of the PFME programme was not provided. Ng (2014), also only available in abstract, compared an intervention (of PFMT starting 3 weeks pre-operatively to a control group
that received standard care. A total of 66 men participated, but numbers randomized to each group and details of the standard care were not provided. Martini (2011), again in abstract only, described an intervention group (n=24) that received five physiotherapy guided PFMT sessions 2-3 weeks pre-operatively, with continued PFME post-operatively. The control group (n=25) received post-operative written instruction on PFME.

Quality of data

Dijkstra-Eshuis and colleagues (2015) reported adequate random allocation concealment. Participants and therapists were blinded to randomisation until first visit. They also reported results of follow up were sent to clinic of the single surgeon performing the RP, but blinding of outcome assessment is not made explicit. Sample size analysis was provided, intention-to-treat was not addressed. Dropouts in both intervention (n=9/65, 13.6%) and control groups (n=10/56, 18%) were described. Three studies (321, 323, 326) were available only as abstracts with randomisation, blinding, sample size calculation and dropouts not described.

Results

In all new studies, the primary outcome was continence measured by either the pad test or number of pads used; secondary outcomes were self-report of symptoms and/or quality of life on standardised questionnaires. Dijkstra-Eshuis et al. (2015) found no differences between intervention and control at any time points on the primary objective outcome (24-hour pad test) or on secondary self-reported symptom and quality of life measures but the trial was stopped prior to full recruitment after a planned interim analysis showed no demonstrated benefit, with the authors concluding that post RP UI is likely due to intrinsic sphincter injury and not treatable with exercise. Two other studies (321, 326) reported an earlier postoperative return to continence (at 14 weeks and 3 months respectively) favouring the intervention group, but the effect was not demonstrated later time points. Similarly, Martini (2011), who included only men with demonstrated pelvic floor impairment prior to surgery, reported significantly less UI on getting up and squatting (no quantification provided) in the intervention group at 1 month but not at later time points.

2.2.2 Pre-Operative PFMT Instruction Followed by supervised Post-Operative PFMT Versus Post-Operative PFMT

Two new trials (309, 315) were added to the previous four studies in this subsection, making a total of six studies included. Tienforti (2012) randomized 34 men undergoing RP, but reported only on group assignment for those completing the study. The intervention (n=16) was pre-operative and post-operative PFMT with BF, started the day before surgery and continuing monthly, with daily home practice, during follow-up. The control group (n=16) received oral and written instructions post-operatively with no monthly follow-up. Geraerts (2013) compared the intervention (n=91) of PFME plus BF and a home program starting 3 weeks prior to surgery with PFME starting 4 days post-operatively to a control group (n=89) that started PFMT post-operatively. Both groups received weekly post-operative treatment that included BF and bladder diary review, with PFMT continuing until continence achieved.

Quality of data

Tienforti (2012) used a computer-generated randomisation schedule. Information on blinding to group assignment and outcome assessment was not provided. In this small study, no sample size calculation or intention-to-treat was reported. Dropouts in each group, one in each intervention and control (6% from each group) were described. Geraerts (2013) used computer generated randomisation using stratification for age and surgical approach, blinding to group assignment and outcome assessment was not provided. In this large trial, sample size calculation recruited an adequate sample to power the study. Intention-to-treat analysis was not discussed. There were n=6/91 (7%) dropouts in the intervention group, and n=4/89 (5%) in the control, reasons were provided.

Results

The newer studies continue to report variable results. Tienforti (2012) found a significant difference in achieving continence at one, three and six months favouring the intervention group, but this was by self-report of symptoms, with no objective measure of continence included as an outcome. In the Geraerts (2013) study, which was larger and of good quality, there were no differences between the groups with regards to objective duration of UI measured by 24-hour pad test or self-reported symptoms at any time point. The intervention group scored better on impact of incontinence at 3 and 6 months, but not at 12 months follow up.

2.2.3 Post-Operative PFMT Immediately Before or After Catheter Removal (No Pre-Operative Instruction)

Three new trials (305, 306, 324) were found comparing post-operative PFMT immediately before or after catheter removal, bringing the total to six. In the previous consultation, there was considerable heterogeneity in intervention and findings. Ahmed (2012), compared three groups, reporting on group assignment only for those completing the trial. Group 1, the control group (n=26), received PFME post-operatively. Group 2 (intervention, n=26) started PFME plus ESTim after catheter removal for 12 weeks, and Group 3 (intervention, n=28) started PFME plus ESTim and BF after catheter removal for 12 weeks. Morihor (2011) was available only in abstract form, and compared an intervention group (n=20) that received PFMT with ESTim for one month after catheter removal to a control group (n=14) assigned to PFME.
alone. Burkert (2011), using a 2x2 mixed design, randomized patients and their partners to one intervention group (n=28) that received dyadic PFME planning or to 3 control groups (n=29, 29 and 26) that received dyadic nutrition planning, individual PFME planning or individual nutrition planning.

Quality of data
Morohiro (2011) available only as an abstract, did not describe randomisation, blinding, sample size calculation or dropouts. Ahmed (2012) randomised using computer generated random numbers in sealed envelopes. Surgeons were blinded to randomisation but blinding of the outcomes assessor was not clear. Sample size was met, and dropouts from each group described: control n= 4/26+4 (13%), intervention Group 2 n= 2/26+2 (7%) and intervention Group 3 n=4/28+4 (12.5%). No intention-to-treat analysis was undertaken. In the Burkert (2011) study, research assistants were blinded to allocation. Sample size calculation and intention-to-treat were not discussed. Dropouts for the intervention group n=5/28 (18%) and three control groups (n=2/29 (7%), 7/29 (24%), 4/26 (15%) were presented but no reasons for withdrawal were provided.

Results
Ahmed (2012) reported more men continent at 12 and 24 weeks post RP in the two intervention groups (PFMT plus EStim and PFMT plus EStim and BF) compared to PFMT alone using the objective 24-hour pad test as primary outcome. Mean leakage was significantly lower in intervention Group 3 at 6 through 24 weeks. Morohiro (2012) found recovery of urinary continence favoured the intervention group (PFMT with EStim) at 12 months. Incontinence was measured by subject report of requiring a pad to keep clothing dry. Burkert reported only adherence to PFMT with no continence data provided. There were no differences between the groups.

Summary
A total of 9 new trials are now included which apply a variety of pre- or immediately post-operative or post-catheter removal PFMT based interventions (or a combination of both, plus or minus BF and EStim). As in earlier consultations, differences between intervention and control groups were modest and short term, and often reflect self-reported but not objective data such as the pad test. Few differences were sustained up to 12 months post-surgery. Many of the studies reviewed were small, varied in design and quality, and had different outcome measures. The two larger studies that were of better quality (307, 309) found no difference between intervention and control groups. The authors of one of larger study (307) suggested post RP UI is likely often due to a mechanism such as intrinsic sphincter deficiency that is not amenable to exercise based treatment. It is possible that this is true for some men with persistent UI post RP, and they may require surgical rather than conservative intervention. Studies that include evaluation of the extent of sphincter function using imaging techniques would be helpful in understanding the subpopulations where conservative treatments are most helpful. There is modest evidence but inconsistent evidence that therapist delivered PFMT with or without BF or EStim before or after surgery may support an earlier return of continence after RP in some men up to 3-6 months post-surgery, however this difference is not significant at 12 months post-surgery (Level of Evidence: 2).

Variation in outcomes measurement remains problematic. As concluded in the previous consultation, it is possible that the emphasis on quantitative outcomes (i.e. pad test) is not meaningful to participants as men appear to find therapy helpful and value the direction provided by a therapist. Studies comparing the effectiveness of pre- versus post-operative PFMT, and the number of sessions required, are needed so that practitioners may advise men about pre-operative preparation and budget conscious health services can make informed decisions on programme funding. In designing such studies, the natural history of UI after radical prostatectomy must be considered because the spontaneous recovery rate means that sample sizes must be large to detect any differences between protocols. As well, attempts to identify which men might benefit more, such as in the study by Martini (2011) who focused the intervention on those with identified pelvic floor impairment, need to be undertaken.

Recommendations
Some pre-operative instruction or immediate post-operative instruction in PFMT for men undergoing RP may be helpful in earlier recovery of continence (Grade of Recommendation: B Clarified).

Use of BF to assist PFMT should remain a therapist/patient decision based on economics and preference. (Grade of Recommendation B).

2.3. Post-Operative RP PFMT for Incontinent Men
Trials in this section addressed the effect of PFMT post-operatively after incontinence was established. In these studies, incontinent men were recruited at variable lengths of time after surgery.

2.3.1 PFMT with Digital Rectal Feedback (DRE) After Radical Prostatectomy
No new trials were identified to add to the previous five trials in which PFMT was taught using digital rectal feedback (DRE) to men incontinent after RP.
Summary
There are no new trials to clarify whether PFMT taught by DRE offers any benefit over and above verbal or written instruction. (Level of Evidence: 2).

Recommendations
The recommendation is unchanged (Grade of Recommendation: B).

2.3.2 PFMT with BF After Radical Prostatectomy
No new trials were found under this category to add to the six previously included trials.

Recommendations
The use of BF in clinic, over and above home PFMT, should remain a therapist/individual decision based on economics and preference. (Grade of Recommendation: B).

2.3.3 PFMT Plus or minus BF with EStim or MStim after Radical Prostatectomy
Three new trials (311, 322, 325) were added to the eight previously included in this section. As in the earlier consultation, a problem of heterogeneity of study samples in this category was noted. Kakihara (2007) compared an intervention of physiotherapy lead PFMT with EStim (n=10) to PFMT alone (n=10) in men a minimum 6 months post-surgery (mean 12.3 months for intervention group, 16.8 months for control). Pedriali (2014) recruited incontinent men one-month post RP and assigned them to post-operative pilates (n=26) versus PFMT plus EStim (n=28), but reported group assignment in only the 54/69 (78%) of men completing the study. Laurienzo (2015), available only in abstract, also included men incontinent one-month post RP, randomising to three groups: Group 1 control (no treatment) (n=40), Group 2 PFMT (n=41) and Group 3 PFMT plus EStim (n=42).

Quality of data
Kakihara (2007) did not provide information on randomisation or blinding. No sample size calculation was given. Dropout numbers for each group were given, but the reasons for dropping out of the intervention group were not provided. Three participants were discharged from the control group at 3, 6 and 12 months as continence was achieved and were included in the final analysis. Pedriali (2014), available only as an abstract, did not provide details of randomisation, blinding, sample size calculation or dropouts. Laurienzo (2015) was only available in abstract, but did describe randomisation approach, but not blinding, sample size calculation or dropouts.

Results
In the Kakihara (2007) trial, there was improvement in urine loss on 1-hour pad test in both groups between baseline and 12 months, but no difference in men receiving PFMT with EStim compared to those who received only PFMT. Men had undergone urodynamic testing, and both those with UI and SU were included. Pedriali (2014) reported 58% of the Pilates group and 50% of the EStim plus PFME achieved continence, as measured by use of no pads. The difference was not statistically significant and the authors concluded that Pilates, which includes pelvic floor strengthening, is as efficacious as EStim plus PFME. Laurienzo (2015) reported no differences between controls and two intervention groups (PFMT, PFMT with EStim) at any time points, objective pad test results not provided, subjective reports of quality of life and symptoms only.

Summary
Data suggest no further benefit of EStim when added to PFMT over PFMT alone for men with incontinence post RP (Level of Evidence: 2).

Recommendations
There does not appear to be any benefit of adding EStim to a PFMT programme for men with persistent post-prostatectomy incontinence. (Grade of Recommendation: B).

2.3.4 PFMT Compared to or Plus Other Interventions After Radical Prostatectomy
Four new trials (312, 316, 318, 319) were identified that combined PFMT post-operatively with other novel interventions in men with post-prostatectomy incontinence, adding to the two previously included studies. The previous consultation found variation in intervention and time since surgery. Zopf (2015) recruited men 6-12 weeks post RP, and assigned them to either an intervention of a multimodal exercise programme with PFME (n=50) or a control group that received no intervention (n=20). Serda (2014), using a two group design, randomised men post RP to a combined exercise and PFME intervention group (n=36) or control with no intervention (n=33). Time after surgery was not reported. Kongtragul (2014) randomised 138 incontinent men recruited in hospital after RP. Group assignment was reported only for those completing the study; 68 men were in the intervention group with PFME and concentration therapy (no detail provided) starting 3 weeks post-surgery. The control group (n=67) received only PFME. Baroni (2013) was available only in abstract. Men with SU or mixed UI after RP (time after surgery not reported) were assigned to an intervention of individual PFMT and group treatment (n=16). Controls (n=24) received only individual PFMT.

Quality of data
The Zopf (2015) study had intended to randomise those who consented, but as all participants refused randomisation and gave a group preference, blinding of outcome measurement was not described. The authors indicated intention-to-treat analysis was undertaken but the study did not achieve the calculated
sample size and was thus underpowered. Dropouts from the intervention group only (n=6/50 12%) were described, but reasons were not provided. Serda (2014) randomised participants but did describe how this was done. Blinding to outcome assessment was not reported. Calculated sample size was achieved, number of dropouts (intervention group (n=3/36 8%; control 0/33) and reason for withdrawal was provided. Baroni (2013) was available only in abstract and had no detail on randomisation but reported the assessor was blinded until assignment. Sample size calculation and dropouts were not described. Kongtragul (2014) did not describe the approach to randomisation or blinding, but dropouts (intervention n=1/68+1, 1%; control n=2/67+2, 3%) were described. The study did not achieve the number in each group required for power to detect a difference between groups.

Results
Zopf (2015) reported a significant improvement in UI, as measured by the 20-minute pad test, from baseline to post testing, but no significant difference between intervention (exercise plus PFMT) and controls (no intervention). However, a significant difference between the groups on reported urinary symptoms was found. Serda (2014) reported a significant improvement in favour of the intervention group (combined exercise and PFME) on self-report of the intensity of urinary symptoms, but did not report the results of the 20-minute pad test. Baroni (2013) reported no significant difference between intervention and control on the VAS, number of pads used or home practice. In the study of concentration exercises plus PFME (Kongtragul 2014), significant differences were found between intervention and control groups on achieving continence measured by the 1-hour pad test.

Summary
Interventions were varied: general exercise plus PFME (316, 318) PFME with concentration therapy (not defined by author) (312) and individual PFMT compared to individual and group therapy (319). There was also heterogeneity of samples in terms of time since surgery. There is some early evidence that novel interventions, such as general exercise programmes, use of support groups and concentration exercises added to PFME after RP for incontinent men may be beneficial, but this is very limited. Some of the trials are small and of low quality. Larger studies of high quality are needed to determine the benefits of these adjuncts to PFME.

2.4. Pre-Operative TURP PFMT
No new trials were identified. Little research has been dedicated to UI after TURP as the incidence of UI after TURP is reported to be very low.

2.5. Pre-Operative and/or Post-Operative TURP PFMT
No new trials were identified.

Summary
In the absence of sufficient data from rigorous and well-reported trials it is not known if PFMT reduces UI following TURP. More systematic investigation of the natural history of UI after TURP is probably needed, to establish the potential cost/benefit of intervention, before further trials are initiated.

2.6. Post-Operative TURP PFMT for Incontinent Men
One new study (310) was added. The previous consultation reported limited evidence in this area. The larger well designed study previously included showed no benefit in terms of objective measures of incontinence. Hou (2013) reported group assignment only for those completing the study. The intervention group (n=32) was given instruction in PFME two days after surgery when the catheter was removed, and instructed to practice daily at home, with weekly telephone reminders. The control group (n=29) activity was not described.

Quality of data
Approach to randomisation, blinding, sample size calculation and dropouts in the smaller, newly included trial (Hou 2013) were not described.

Results
Hou (2013) found a statistically significant difference in self-report of symptom severity favouring the intervention group at 12 weeks. No objective measure of incontinence, such as the pad test, was reported.

Summary
There continues to be limited evidence on the benefit of PFME post TURP. The new smaller trial suggests a potential benefit on perception of symptom severity of UI, but no objective data were reported.

2.7. Factors Affecting Outcome
Based on the current evidence, it appears that time from surgery to implementation of exercises does affect outcome and that by three months after surgery less improvement is noted. Future trials should consider analysis to evaluate the effect of sphincter insufficiency, pelvic floor dysfunction, urethral length, length of time from prostatectomy, co-morbid conditions, prior pelvic surgery, medications, other risk factors (including smoking and alcohol use) on treatment outcome.
2.8. PFMT for Other LUTS
2.8.1 PFMT for Post-Micturition Dribble (PMD)

No new trials were identified to add to the two previously included trials.

Recommendations
Offer men with PMD instruction to do a strong PFM contraction immediately after voiding, or urethral massage to empty the urethra (Grade of Recommendation: C).

### 3. ELECTRICAL STIMULATION (ESTIM)

An extensive overview of EStim in men is reported in the 5th consultation(2). Rectal or surface electrodes are most common; surface electrodes are positioned over the perineal region. EStim can also be applied via the posterior tibialis nerve (PTN). Trials of EStim in men post-prostatectomy combined this treatment with PFME, and are included in the sections on post-prostatectomy treatment above.

#### 3.1. Prevention of UI

No new trials were identified. There remain no studies on the effect of EStim for prevention of non-post prostatectomy UI or SUI in men.

#### 3.2. Treatment of UI

No new trials were added to the nine previously included RCTs, four of which included PFME plus EStim post prostatectomy. New trials that combined EStim with PFME were reported in the PFMT section above as the separate effects of EStim alone cannot be assessed.

##### 3.2.1 Is EStim Better than No Treatment, Placebo or Control Treatments?

No new trials were identified to add to the two previously included trials. Both previously included trials did not separate male and female results. In the continued absence of sufficient data from rigorous and well-reported trials it is not known if EStim, as a standalone treatment for male UI (PMD), is better than no treatment, placebo or control treatments.

##### 3.2.2 Is One Approach to EStim Better Than Another?

No new trial was identified. No studies comparing EStim protocols were included in previous consultations.

##### 3.2.3 Is EStim Better Than Other Treatments?

No new trials were identified. Three studies, two comparing EStim to Mstim and one EStim to medication, had been included in previous consultations. Details of these were provided in the 5th consultation (Moore 2013): insufficient data exist to establish if EStim is better than either intervention. Both studies combined male and female data.

#### 3.2.4 Does the Addition of EStim to Other Treatments Add Benefit?

All of the studies combining EStim with other treatments included the PFMT plus EStim combination, and are reviewed under the Pelvic Floor Muscle Training section.

#### 3.3. Other LUTS

No new studies were identified. No previous studies of EStim alone for other LUTS were included in previous consultations.

#### 3.4. Factors Affecting Outcome

The previous consultation identified age, type of incontinence (SUI post prostatectomy versus OAB and UUI) and other factors (types of electrodes, frequency and duration of treatment) as potentially affecting outcomes. No trials have investigated these factors in males.

### 4. MAGNETIC STIMULATION (MSTIM)

Although MStim has been used to treat UI after RP and to inhibit DO, no new studies were identified.

#### 4.1. Prevention of UI

No trials investigating the primary or secondary prevention effects of MStim for men with UI were found.

#### 4.2. Treatment of UI

No new trials to add to the three trials (two published, one abstract without data) identified and described in the 5th consultation were found. Only the two published trials were included in the previous consultation.

##### 4.2.1 Is MStim Better Than No Treatment, Placebo or Control Treatment?

No studies were found addressing this question.

##### 4.2.2 Is One Approach to MStim Better Than Another?

No studies were found addressing this question.

##### 4.2.3 Is MStim Better Than Other Treatments?

No new studies were identified.

#### 4.3. Other LUTS

No studies were found.

#### 4.4. Factors Affecting Outcome

The relationship between age (or any other factor, such as treatment parameters, treatment adherence,
or diagnosis) and the outcome of MStim has yet to be determined.

5. PENILE VIBRATORY STIMULATION (PVS)

This is a novel conservative treatment, based on the stimulation of the pudendal nerve via penile vibratory stimulation (PVS) to treat SUI in men post prostatectomy.

PVS has been shown to increase external sphincter pressure in men with spinal cord injury (334, 335), and vibratory stimulation applied to the perineum in healthy women also increased external urethral pressure (336).

5.1. Prevention of UI

No trials of prevention were identified.

5.2. Treatment of UI

One new trial was identified (308). Fode (2015) randomised 39 men with UI over one-year post RP to two groups. Group 1 (n= 19) was the early intervention group who received PVS using a commercially available hand held personal vibrator for 6 weeks. Stimulation was performed on the ventral surface of the penis once daily with 10 seconds of stimulation followed by a ten second pause, repeated 10 times. Group 2 was the delayed treatment control group, who had no intervention the first 6 weeks, but performed PVS in the second 6 weeks.

Quality of data

Computer generated randomisation technique was described, but blinding of outcome measurement was not (308). A sample size calculation was provided, but the authors report stopping recruitment early as the study was a pilot and the sample achieved was thought to be adequate. Drop outs in both early (n=4/19, 21%) and delayed (n=5/20, 25%) intervention groups were described, with one of five dropouts in the delayed intervention group kept in the analysis, although others were not. The participant kept in had a pattern of non-compliance over the study, and discontinued after 6 weeks.

Results

Primary outcome was difference in leakage measured by 24 pad test. Participants also completed voiding diary. Results showed a significant improvement in the early intervention group from baseline to 6 weeks, but not in the delayed intervention group. Pooled analysis results from both early and delayed intervention groups showed significant overall median decline in urine loss on 24-hour pad test (p= 0.07).

Conclusion

This was a small pilot study of a novel intervention. Further well designed studies are needed to understand the place for PVS in treatment of male UI. No recommendation can be made.

5.3. Other LUTS

No trials were identified.

6. SCHEDULED VOIDING REGIMENS

Scheduled voiding regimens include bladder training, timed voiding, habit training and prompted voiding. They are frequently combined to achieve maximum benefits. Although there is evidence to suggest that scheduled voiding regimens, especially bladder training and timed voiding, are commonly used in the treatment of men with UI and other LUTS, there has been substantially less research that addresses their use in men compared to the literature on their use in women, leaving insufficient evidence to comment on effectiveness.

6.1. Prevention of UI

No trials investigating the preventive effects of scheduled voiding regimens for men with UI were found.

6.2. Treatment of UI

6.2.1 Bladder Training

One new trial of a mixed behavioural treatment approach composed of elements of bladder training compared to drug therapy in men with OAB was identified (317) and added to the five previously included trials of bladder training that have included men. Burgio (2011) compared a combined behavioural treatment (PFME, urgency suppression, delayed voiding) to drug therapy (n=73) with drug therapy (individually titrated extended release oxybutynin) for OAB (n = 70). This category previously included studies that have included BT plus caffeine reduction, BT plus placebo or anticholinergic drug therapy

Quality of data

Burgio and colleagues (2011) used sealed envelopes to randomise, blinding of person(s) gathering data on outcomes was not described. Sample size analysis was not given, but intention-to-treat analysis was undertaken. Dropouts from each group (combined behavioural therapy n=9/73, 12%; drug therapy n=10/70, 14%) were reported, reasons were not provided.

Results

Primary outcome was 24-hour voiding frequency recorded on a seven-day bladder diary. Secondary outcomes were other OAB symptoms, perception of improvement and satisfaction.

Results showed that treatment with behavioural strategies (bladder training) compared to pharmacological treatment was equivalent. There was no significant
difference between incontinence episodes between the behaviour and drug therapy groups.

6.2.2 Timed Voiding
No new trials were identified.

6.3. Other LUTS
One new study was identified for treatment of other LUTS in men. The newly included study, described above (317) also measured OAB symptoms, with the primary outcome being frequency of voiding.

Quality of data
Refer to C.VI.2a above.

Results
Primary outcome was 24-hour voiding frequency recorded on a seven-day bladder diary. Secondary outcomes were other (non UUI) OAB symptoms including nocturia and urinary urgency; perception of improvement and satisfaction. Treatment with behavioural strategies (bladder training) compared to pharmacological treatment was equivalent. The behaviour therapy group had greater reduction in nocturia episodes, but urgency scores were lower in the drug therapy group.

Summary
In men, behavioural treatment may be just as effective for some LUTS, including UI, as pharmacological therapy. Further studies of high quality are needed before a recommendation for practice can be supported.

6.4. Factors Affecting Outcome
Age: No new trials were found addressing age as a factor affecting outcome.
Other: No studies were identified on other factors affecting outcome of BT or prompted voiding in men.

7. COMPLEMENTARY AND ALTERNATIVE MEDICINES
Therapies include acupuncture, relaxation, meditation, imagery, hypnosis, naturopathic and herbal remedies. In previous consultations, only trials of acupuncture therapy were found in men with UI. Studies were small, objective measured of UI were missing and long-term follow-up was lacking, leaving only limited evidence on the effectiveness of acupuncture for men with UI.

7.1. Prevention of UI
No new trials were identified on the preventative role of complementary therapies in men.

7.2. Treatment UI
No new trials were identified.

7.2.1 What Is the Most Effective Acupuncture Protocol?
No new trials were identified.

7.2.2 Acupuncture Versus No Treatment, Sham Acupuncture or Any Other Treatment
No new trials were identified.

7.3. Other LUTS
No new trials were identified.

7.4. Factors Affecting Outcome
No new trials were identified.

8. SUMMARY
Despite the prevalence of UI and LUTS in older men, research continues to focus mainly on men following radical prostatectomy. Overall, the effect of conservative treatment (lifestyle interventions, physical therapies, schedule voiding regimes, complementary therapies) for men has received much less research attention compared to women.

8.1. Recommendations for Practice
There is generally insufficient Level 1 or 2 evidence on which to base recommendations for practice, and most recommendations are, in effect hypotheses, that need further testing in research.

Lifestyle interventions
Weight loss through lifestyle changes should be recommended to obese and overweight men with UI, particularly those with type 2 diabetes. (Grade of Recommendation: Grade B New)
Smoking abstinence should be recommended for men with UI (Grade of Recommendation: C New)
A reduction in caffeine intake is recommended for those with incontinence symptoms. (Grade of Recommendation: C New)

Pelvic floor muscle training (PFMT)

- Some pre-operative or immediate post-operative instruction in PFMT for men undergoing radical prostatectomy may be helpful in earlier recovery of continence. (Grade of Recommendation: B Clarified).
- In men with persistent post-prostatectomy incontinence, PFMT taught by digital rectal examination (DRE) may be undertaken but it is unclear whether this offers any benefit over and above verbal or written instruction in PFMT (Grade of Recommendation: B Clarified).
- Use of BF in clinic, over and above home PFMT should remain a therapist/patient decision based on economics and preference (Grade of Recommendation: B).
• There does not appear to be any benefit of adding EStim to a PFMT programme for men with persistent post-prostatectomy incontinence (Grade of Recommendation: B).

• Use of a strong pelvic floor muscle contraction immediately after voiding, or urethral massage to empty the urethra, should be offered for symptoms of post-micturition dribble (Grade of Recommendation: C).

Electrical Stimulation (EStim)

For men with persistent post-prostatectomy incontinence there does not appear to be any benefit of adding EStim to a PFMT programme (Grade of Recommendation: B).

8.2. Future Research Directions

Despite recognition that there is much scope for research on the effects of conservative therapies for UI and LUTS in men in the 6th consultation, this remains largely unexplored. Research that is urgently needed, in the opinion of committee members, is highlighted with the use of italics. The committee continues to support the recommendations that apply to all future studies in men, namely:

• All future intervention studies must be designed to allow standardised and comprehensive reporting of results based on the ICS and CONSORT recommendations.

• The natural history of UI after radical prostatectomy must be considered in study design as the spontaneous recovery rate means that sample sizes must be large to detect any differences between protocols.

• More research is needed to find out what are the most important outcomes for men with UI, so such measures can be incorporated as the primary outcome measures in further trials.

• Data is needed to establish the cost, and cost effectiveness, of conservative therapies in men with UI.

• Surgical approaches with laparoscopy or robotics offer promising improvements in visualisation for nerve-sparing procedures; further research should address continence and erectile function after these newer surgical procedures.

8.2.1 Lifestyle Interventions

• The effects of interventions such as weight, caffeine reduction, constipation and physical activity are priorities for future research.

8.2.2 Pelvic Floor Muscle Training (PFMT)

• Further studies to test the hypothesis that pre-operative proprioceptive training plus PFMT is more effective than PFMT alone to prevent UI in men undergoing radical prostatectomy.

• A comparison of pre-operative versus post-operative PFMT verbal and written feedback to reduce prevalence and severity of UI following radical prostatectomy is needed.

• Methods of PFMT instruction and supervision require further investigation. Two areas of research interest are:
  o Whether PFMT taught by DRE offers any benefit over and above verbal or written instruction.
  o The effect of group exercise as peer support may be helpful to a healthy recovery.

• Future studies should focus on identification of men more likely to benefit from conservative interventions, such as those with pelvic floor dysfunction, and screening those with potential intrinsic sphincter deficiency post-surgery. This might be established using imaging. Men with extensive sphincter deficiency should be referred for urological intervention. Studies of conservative measures including PFMT should include those with milder damage in order to determine efficacy in this group.

• More systematic investigation of the natural history of UI after TURP is needed, to establish the potential cost/benefit of intervention, before further trials are initiated.

• The relationship between age, or any other factor (urethral length, PFM function), and the outcome of PFMT for UI in men, and predictors of success needs to be investigated.

8.2.3 Electrical Stimulation (EStim) and Magnetic Stimulation (MStim)

• It is not known if pre- or post-operative EStim or MStim has a role in reducing UI after radical prostatectomy.

• RCTs in larger samples, with long-term follow up, are needed to investigate all aspects of the effectiveness of EStim and MStim as a treatment for UI in men, including:
  o Either type of stimulation versus no treatment, sham stimulation or other control conditions.
  o Comparisons of both EStim and MStim protocols.
  o EStim versus MStim.
  o Either type of stimulation versus medication.
  o Whether the addition of either type of stimulation to other treatments adds benefit, in particular, the addition of stimulation to PFMT.
  o The effect of age, and other factors, on outcome of stimulation. Older men may have more co-morbid conditions than young men.
and a more pragmatic approach to inclusion in EStim studies is needed.

8.2.4 Scheduled Voiding Regimens

- RCTs of voiding regimens and combinations of conservative treatments in men with OAB and UUI are needed. Further comparison of these conservative approaches to drug therapy would be helpful for clinicians in recommending treatment to patients.

V. URINARY INCONTINENCE IN MEN AND WOMEN

1. POSTERIOR TIBIAL NERVE STIMULATION (PTNS)

Posterior tibial nerve stimulation (PTNS) is a form of peripheral neuromodulation targeted towards symptom relief of OAB and UUI (141). Evidence for the use of PTNS for the prevention and treatment of UI in men or in adults (study with men and women with results combined) is presented below.

Questions addressed are:

- Can PTNS prevent UI?
- Is PTNS better than no treatment, placebo or control treatments for UI?
- Is PTNS better than other treatments for UI?
- Does the addition of PTNS to other treatments add any benefit?
- What is the best programme of PTNS for UI in adults?
- What is the effect of PTNS on LUTS other than UI?
- What factors might affect the outcome of PTNS?

A literature search for reports of relevant systematic reviews and reports of RCTs and quasi-RCTs was performed (see section I). Trial data reported in conference abstracts as well as full text papers were included. Since this is a new section for the Conservative Management chapter no date restrictions were applied.

Eligibility criteria:

1. Reports of RCTs or quasi-randomised trials of PTNS, percutaneous or transcutaneous.
2. Adult men and women with UI and/or OAB (with or without urgency incontinence) presentation of data for men only or combined for men and women. Trials including women only are presented in section II.5.

Evidence overview

A total of 7 RCTs of posterior tibial nerve stimulation (PTNS) in adults were identified (337-343) and one Cochrane systematic review of anticholinergic drugs versus non-drug active therapies for non-neurogenic overactive bladder syndrome in adults (141), in which PTNS trials with adults of both sexes and men only were included. Only one randomised trial of PTNS in men has been reported (344), which addressed post-stroke neurogenic bladder dysfunction and therefore did not meet the inclusion criteria for the conservative management chapter. No trials of non-neurogenic bladder dysfunction have been reported for men only.

The trial data is summarised in tables 35 to 38.

Three randomised trials compared PTNS with a sham intervention (337-339).

Four trials were comparative:

- Two compared different anticholinergics (340, 341)
- Two compared different stimulation protocols (342, 343)

Percutaneous PTNS was used in 5 randomised trials (337, 339-342)

Transcutaneous PTNS was used in 2 (338, 343).

No direct comparisons of percutaneous and transcutaneous PTNS for treatment of UI have been undertaken in the adult population or in men only.

On the basis of the included studies, percutaneous PTNS seems to involve a standard protocol with regard to stimulation parameters of frequency and session-duration using the Urgent PC™ stimulator. However, the number of individual sessions, overall duration of programme and timing of delivery protocols may vary. There is also variation between percutaneous and transcutaneous stimulation parameters and one transcutaneous device study (343) did not report stimulation parameters, preventing comparison with other results. This variability reflects the limited understanding of the mechanisms of PTNS, which cannot be assumed to be identical for both percutaneous and transcutaneous routes. Further investigation is required for both percutaneous and transcutaneous PTNS to determine the most effective type of stimulation and treatment protocols.

1.1. Prevention of UI

There have been no studies on the effect of PTNS for prevention of UUI/OAB in adults or in men only.

1.2. Treatment of UI

1.2.1 Is PTNS Better Than No Treatment, Placebo or Control Treatments for UI?

Three randomised controlled trials address this question in adult men and women. One RCT (337) is adequately powered whereas Vohra (339) and Booth (338) are both pilot RCTs.
Quality of evidence

Computerised randomisation was used in all three studies with adequate allocation concealment reported in two (337, 338) and unclear in one (339). Subjects and outcome assessors were blinded throughout in two studies (337, 338), with blinding unclear in one (339). Two studies reported intention-to-treat analysis (337, 338); the type of analysis was not reported in one (339). There was no apparent inequality in loss to follow-up across the groups: in one trial (345) seven subjects were lost to follow-up in the PTNS group and 5 in the sham group thus 94% and 95% respectively were analysed. Two of the 30 subjects (6.6%), both from the sham group, discontinued in one trial (338) and one subject (4.5%) from the control group discontinued in the other trial (339). Mild or moderate treatment related adverse events were reported by 6 PTNS subjects in one trial (337). They included ankle bruising (1 of 110, 0.9%) discomfort at needle site (2 of 110, 1.8%) bleeding at the needle site (3 of 110, 2.7%) and tingling in the leg (1 of 110, 0.9%). No subjects in the transcutaneous PTNS trial (338) reported adverse events and presence of adverse events was unclear in one study (339). Two trials were reported as pilots with no sample size calculation (338, 339) and one was adequately powered (337) however the payment of subjects for time and expense was a potential limitation and the efficacy achieved may not be equivalently reflected in translating to real world practice. Long term follow-up to 3 years post-initial treatment was reported by Peters (345). Overall risk of bias was low in two trials (337, 338) and high in one (339).

Results

No study reported cure rates for UI, however all three trials reported improvements. In the SUMiT trial (337) 37.9% PTNS subjects reported moderate or markedly improved urgency incontinence compared to 22.1% sham subjects (p=0.02). Voiding diary analysis showed PTNS to be statistically superior to sham in reducing urge incontinence episodes (p=0.002) from a median of 3.0 episodes accompanied by moderate to severe urgency per day at baseline, to a median of 0.3 episodes at 13 weeks (p<0.0001). In the two pilot trials Booth (338) reported improved ICIQ-U1 SF in 10 of 15 (67%) transcutaneous PTNS group and 6 of 13 (46%) sham group (p=0.132, NS); Vohra reported significantly reduced UI in 7 of 11 PTNS subjects but no estimates of effect size were provided; data was not differentiated for men and women. In one large trial (337) PTNS subjects reported statistically significant improvements in overall bladder symptoms with 54.5% reporting moderate or markedly improved Global Response Assessment (GRA) from baseline compared to 20.9% of sham subjects (p<0.001). A significant difference between the groups in favour of PTNS was found for the OAB-q quality of life scores (p=0.006) and the SF-36 general health survey quality of life scores significantly improved between baseline and 13 weeks for the PTNS group in the physical (p=0.002) and mental (p=0.049) domain scales. One pilot trial (339) reported significant improvements in quality of life (QoL questionnaires not specified and SF-36) but provided no data or figures to support this.

A prospective study to assess long-term outcomes and determine frequency of top-up stimulation sessions required was reported (345). Fifty responders to the original trial underwent a fixed 14-week tapered stimulation protocol, followed by a personal treatment plan aimed at maintaining improvements. Twenty-nine of 50 (58%) completed the outcomes. 77% of these maintained moderate or marked improvement in OAB symptoms at three years with a median 1.1 treatments each month.

Summary

The results of two trials, one rigorous, well-reported trial and one low quality pilot trial, showed that percutaneous PTNS is a safe and more effective intervention than a sham treatment for improving urgency incontinence in adults with OAB/UI.

There is evidence that, with regular treatment, effects are sustained for up to 3 years. (Level of Evidence: 1).

One small high quality pilot trial indicates that transcutaneous PTNS is safe and may be more effective than sham stimulation for reducing UI and urinary symptoms in older adults in institutional care. Further studies are needed to determine the effectiveness of transcutaneous PTNS. (Level of Evidence: 2).

Recommendation

Percutaneous PTNS can be offered to men and women (adults) with UI/OAB who do not achieve satisfactory results from first line lifestyle and behavioural intervention and pharmacological therapy. (Grade of Recommendation: B New).

In this population, Transcutaneous PTNS may be a useful option to test in the adult with UI/OAB earlier in the algorithm, following lifestyle and behavioural interventions and before more invasive therapies are considered.

1.2.2 Is PTNS Better Than Other Treatments for UI?

One RCT compared PTNS with another treatment for UI. The other treatment was extended release tolterodine 4mg daily (341). There are no trials comparing transcutaneous PTNS with other treatments.

Quality of evidence

1:1 randomisation to percutaneous PTNS or tolterodine was implemented using a random block design stratified by investigational site however the success of allocation concealment was unclear. Blinding of subjects, clinicians or assessors was not possible given the different nature of the interventions. An intention to treat analysis was not undertaken. Seven subjects (14%) withdrew from the drug group and 9 (18%) from the percutaneous PTNS group; none due
to adverse effects. Adverse effects were mild or moderate in both groups with 14.3% (7 subjects) from the tolterodine arm reporting moderate adverse effects and 16.3% (8 subjects) from the percutaneous PTNS group. Percutaneous PTNS related adverse events included leg cramps, intermittent foot/toe pain, generalised swelling, headache, haematuria, inability to tolerate stimulation, worsening incontinence and vaso-vagal response to needle placement. A sample size calculation was provided and the study was adequately powered for a non-inferiority margin of 20% in number of voids per 24 hours. Long-term follow-up of percutaneous PTNS subjects for nine months after initial treatment completion was reported (346). The overall risk of bias was high.

**Results**

Data was reported for the whole group with no differentiation by sex. The global response assessment (GRA) demonstrated that subjective assessment of bladder symptom change compared to baseline was statistically significant with 79.5% (35) of the percutaneous PTNS group reporting cure (1) or improvement (34) and 54.8% (23) of the tolterodine group reporting cure (2) or improvement (21) (p=0.01). Both groups had improved significantly. Symptoms of UI reported in the voiding diaries improved significantly in both groups however there was no significant difference between the groups for these measures. Quality of life scores showed statistically significant improvements for both treatment groups (P<0.001) but between group differences were not statistically significant. The percutaneous PTNS group reported statistically significantly less dry mouth than the tolterodine group (p=0.01) and a non-significant lower rate of constipation.

Follow-up to determine duration of effect up to 12 months from baseline was offered to percutaneous PTNS responders (those who reported a successful response to GRA after 12 weeks) (346). Thirty-three of the 35 responders chose to continue. The GRA showed sustained improvements in 96% at 12 months with a mean of 21 days between treatment sessions.

**Summary**

Evidence from a single RCT indicates that percutaneous PTNS may be as effective as tolterodine for urgency UI with an improved side effect profile; however, design limitations suggest caution and further studies are recommended to establish the effects of percutaneous PTNS and transcutaneous PTNS in comparison to other pharmacological treatments (Level of Evidence: 2).

As there were no trials comparing transcutaneous PTNS with another active treatment trials are also needed to determine the effects of transcutaneous PTNS compared to common anticholinergic drugs used to treat UUI/OAB in adults.

---

**Recommendation**

Percutaneous PTNS can be offered as an alternative to tolterodine for OAB/UUI in adult men and women. (Grade of Recommendation: B New).

1.2.3 Does the Addition of PTNS to Other UI Treatment Add Any Benefit?

One RCT was identified (340) that compared percutaneous PTNS with percutaneous PTNS and oxybutynin for treatment of patients with overactive bladder (with or without incontinence) and urodynamically diagnosed detrusor overactivity (DO).

**Quality of evidence**

Randomisation following urodynamic studies into percutaneous PTNS group or percutaneous PTNS plus 5mg daily oxybutynin hydrochloride was reported but no description of method of randomisation. Adequacy of allocation concealment and blinding of subjects, clinicians or assessors was not reported nor was type of analysis, which was unclear. It appears that no subject dropped out and reported adverse events were mild: percutaneous PTNS plus drug group - seven reported dry mouth, one blurred vision; percutaneous PTNS group – one reported a small haematoma, one local tenderness. There was no sample size calculation, no long-term follow-up and overall risk of bias was high.

**Results**

Four of five subjects receiving percutaneous PTNS only and all five subjects receiving percutaneous PTNS and oxybutynin, with urgency UI reported cure on voiding diary. The numbers were too small for statistical analysis. Overall treatment response was defined as patient-reported improvement in OAB symptoms of frequency, urgency and urge incontinence by > 35% and occurred in 61.6% percutaneous PTNS group and 83.2% percutaneous PTNS plus oxybutynin group. The between group difference was not statistically significant.

**Summary**

The evidence is limited to a single low quality trial (Level of Evidence: 2) which indicates there may be additional effects if oxybutynin is added to a programme of percutaneous PTNS. Further trials are needed to establish whether the addition of an anticholinergic drug enhances the effectiveness of percutaneous PTNS in adults with UUI/OAB and which drugs provide the greatest effect.

As there were no trials comparing transcutaneous PTNS added to another active treatment with the active treatment alone studies are also needed to determine the effects of adding transcutaneous PTNS to first line lifestyle and behavioural treatments for OAB and UUI including bladder training and percutaneous PFMT, with these first line lifestyle and behavioural treatments alone.
1.2.4 What is the Best PTNS Protocol for UI in Adults?

Two RCTs compared different stimulation protocols (342, 343). Details are provided in table 38.

Quality of the evidence

Randomisation methods were not described for either study. Allocation concealment could not be determined from the reports and blinding of subjects or clinicians was not possible with this design. Neither study reported the type of analysis undertaken. Primary outcomes were reported at the end of the (342) treatment protocol. No long-term follow up was reported. Withdrawals were high (29.2%) in the Seth (343) pilot trial, with 8 of the 14 withdrawals being device related, although no significant adverse events occurred. There were no withdrawals in the Finazzi-Agro trial and no adverse events reported.

Results

In the Finazzi-Agro (342) trial 4 of 11 (36%) subjects with UI in the weekly percutaneous PTNS group and 5 of 11 (45%) subjects with UI in the 3 X weekly percutaneous PTNS group reported complete cure after treatment. Overall success of >50% reduction in micturition episodes/24 hours or (if incontinent) UI episodes/24 hours was confirmed for 11 of 17 (63%) subjects in the weekly percutaneous PTNS group and 12 of 18 (67%) subjects in the 3 times weekly percutaneous PTNS group. Subjective improvement was reported after 6-8 sessions, regardless of frequency of delivery. In the Seth (343) trial 18 of 34 (54%) subjects who completed the 12 week protocol were responders, who rated their improvement as moderate to significant on the General Response Assessment (GRA). Statistically significant improvements in ICIQ-OAB (p=0.001) and ICIQ LUTS-qol (p=0.000) were reported for both daily and weekly stimulation groups. There were no statistically significant differences in ICIQ or bladder diary parameters between those with idiopathic and OAB of neurogenic origin.

Summary

Two small trials indicate that no additional benefit is conferred by a more than once weekly stimulation protocol for percutaneous or transcutaneous PTNS. However, it is possible that symptom improvement may be more rapid with a more frequent delivery protocol (Level of Evidence: 2).

Further rigorous and well-reported trials are needed to establish the most effective timing and duration of PTNS protocols.

Recommendation

Oxybutynin may be considered in addition to percutaneous PTNS in adults with DO. (Grade of Recommendation: B New).

This hypothesis needs to be investigated further with high quality trials.

Recommendation

Percutaneous or transcutaneous PTNS should be delivered at least once weekly and the protocol determined by patient preference. (Grade of Recommendation: B New).

1.3. What is the Effect of PTNS on LUTS Other Than UI?

No trials were identified that analysed the effect of PTNS in adults or men with other LUTS alone i.e. frequency of voiding, urgency, nocturia and integrated reporting of UI and other LUTS was a feature of all studies. For percutaneous PTNS compared with sham percutaneous PTNS, in one large well reported trial, the percutaneous PTNS group reported statistically significant improvements in voiding diary symptoms of frequency, night-time voids and voids with moderate to severe urgency, compared to the sham group (337). A small pilot trial reported reduced day and night time frequency and urgency after 12 weekly 30 minute percutaneous PTNS sessions by 63% of percutaneous PTNS subjects, although no ES
timates of effect size were provided. The elimination of detrusor overactivity on repeat urodynamic testing was also shown (339).

For transcutaneous PTNS compared with sham transcutaneous PTNS one trial in care home residents (338) reported statistically significantly improved total American Urological Association Symptom Index AUASI urinary symptom scores for 87% of the transcutaneous PTNS group compared to 31% sham group (p<0.001).

When comparing percutaneous PTNS with another treatment one trial (341) reported significant reduction in bladder diary reports of void frequency, nocturia, moderate to severe urgency episodes in both groups and no between group differences.

One trial comparing two percutaneous PTNS protocols (342) reported a statistically significant reduction in frequency (p=0.01) for both once and three times weekly treatment regimes.
<table>
<thead>
<tr>
<th>Study</th>
<th>Comparator groups</th>
<th>N</th>
<th>Study population</th>
<th>Modality details or parameters</th>
<th>Outcomes</th>
<th>Follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Percutaneous posterior tibial nerve stimulation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peters (2010) (1)</td>
<td>Treatment group: Percutaneous PTNS  &lt;br&gt; Active electrode: 34 gauge needle provides sensation.  &lt;br&gt; Inactive electrode: calcaneal surface electrode.  &lt;br&gt; Control group: Sham Percutaneous PTNS  &lt;br&gt; Placebo needle with sensation of insertion. Inactive</td>
<td>220</td>
<td>Adults (≥18) with OAB symptoms  &lt;br&gt; Males: 46  &lt;br&gt; Females: 174  &lt;br&gt; Results reported together</td>
<td>Pulse width: not reported  &lt;br&gt; Frequency: 20 Hz  &lt;br&gt; Intensity: 0.5-9mA according to sensory &amp; motor response.  &lt;br&gt; Duration: 30 minutes  &lt;br&gt; Number sessions: 12  &lt;br&gt; Programme length: 12 weeks</td>
<td>Primary outcome:  &lt;br&gt; Moderate/marked improvement in 7 level GRA at week 13  &lt;br&gt; Secondary outcomes:  &lt;br&gt; Change in individual GRA symptoms  &lt;br&gt; 3-day voiding diary parameters OABq scores  &lt;br&gt; SF-36 QoL scores</td>
<td>Week 13</td>
</tr>
<tr>
<td>Vohra (2002) (2)</td>
<td>Treatment group: Percutaneous PTNS  &lt;br&gt; Active electrode: 34 gauge needle provides sensation.  &lt;br&gt; Inactive electrode: calcaneal surface electrode.  &lt;br&gt; Control group: Sham Percutaneous PTNS  &lt;br&gt; Described as ‘PTNS treatment without nerve stimulation’</td>
<td>22</td>
<td>Adults with urgency frequency syndrome of &gt; 6 months and urodynamic detrusor overactivity  &lt;br&gt; Males: not reported  &lt;br&gt; Females: not reported  &lt;br&gt; Results reported together</td>
<td>Pulse width: not reported  &lt;br&gt; Frequency: 20 Hz  &lt;br&gt; Intensity: 0.5-10mA according to sensory &amp; motor response.  &lt;br&gt; Duration: 30 minutes  &lt;br&gt; Number sessions: 12  &lt;br&gt; Programme length: 12 weeks</td>
<td>Micturition diary  &lt;br&gt; QOL questionnaires  &lt;br&gt; Repeat urodynamics  &lt;br&gt; SF-36  &lt;br&gt; .</td>
<td>12 weeks</td>
</tr>
<tr>
<td><strong>Transcutaneous posterior tibial nerve stimulation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Booth 2013 (3)</td>
<td>Treatment group: Transcutaneous PTNS  &lt;br&gt; Active: Surface electrode medial malleolus provides sensation.  &lt;br&gt; Inactive: surface electrode 10cm proximal to medial malleolus,  &lt;br&gt; Control group: Sham Transcutaneous PTNS  &lt;br&gt; Surface electrodes X2 positioned below lateral malleolus and 10cm</td>
<td>30</td>
<td>Older adults (≥65) resident in care homes with urinary symptoms and/or incontinence  &lt;br&gt; Males: 6  &lt;br&gt; Females: 24  &lt;br&gt; Results reported together</td>
<td>Pulse width: 200 μS  &lt;br&gt; Frequency: 10 Hz  &lt;br&gt; Intensity: 1-50mA according to sensory &amp; motor threshold and subject comfort.  &lt;br&gt; Duration: 30 minutes  &lt;br&gt; Number sessions: 12  &lt;br&gt; Programme length: 6 weeks</td>
<td>AUASI  &lt;br&gt; ICIQ-UI  &lt;br&gt; SF  &lt;br&gt; PVR</td>
<td>Week 6</td>
</tr>
</tbody>
</table>
Table 36 Summary of data on PTNS vs other active treatments in men and women

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Comparator groups</th>
<th>N</th>
<th>Study population</th>
<th>Modality details or parameters</th>
<th>Outcomes/results</th>
<th>Follow up</th>
</tr>
</thead>
</table>


### Table 37 Summary of data on PTNS + another active vs PTNS

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Comparator groups</th>
<th>N</th>
<th>Study population</th>
<th>Modality details or parameters</th>
<th>Outcomes/results</th>
<th>Follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Karademir 2005 (1)</td>
<td>Treatment group: Percutaneous PTNS plus oral oxybutynin hydrochloride 5mg daily Active electrode: 34 gauge needle provides sensation. Inactive electrode: calcaneal surface electrode. Comparator treatment group: Percutaneous PTNS Active electrode: 34 gauge needle provides sensation. Inactive electrode: calcaneal surface electrode.</td>
<td>43</td>
<td>Adults with &gt; 6 month history of OAB symptoms and DO on UDS Males: 5 Females: 38 Results reported together</td>
<td>Pulse width: 200 μS Frequency: 20 Hz Intensity: 0.5-9mA according to sensory &amp; motor response. Duration: 60 minutes Number sessions: 8 Programme length: 8 weeks</td>
<td>Outcomes measured with Bristol Urinary Questionnaire and voiding diary. Improvements in symptoms by &gt;70%, 35-70% and &lt;35% represented complete remission, partial remission and no response.</td>
<td>8 weeks</td>
</tr>
</tbody>
</table>

Posterior tibial nerve stimulation: PTNS

1.4. Factors Affecting Outcomes

None of the included percutaneous PTNS trials addressed the effect of age or any other factor on prediction of outcome of PTNS. Effectiveness of transcutaneous PTNS in older adults resident in care homes was the focus of one study where the mean age was 84.2 years (338). The adherence to the transcutaneous PTNS was 100% for all participants, with no adverse effects reported and a response to therapy similar to that found with younger groups. A prospective study (347) of prognostic factors for successful percutaneous PTNS showed that gender, age, weight, body mass index, indication for percutaneous PTNS, duration of symptoms, number and type of previous treatments, number of UI episodes/24 hours, voiding frequency/24 hours and total IQoL scores were all unrelated to the success or not of percutaneous PTNS in men and women with OAB, non-obstructive urinary retention or chronic pelvic pain. A low Mental Component Summary Score on the SF-36 was a negative predictive factor for success of percutaneous PTNS, both subjectively and objectively. Additionally patients with detrusor overactivity had poorer outcomes than those without, as did those with low bladder capacity at baseline (143). This means that there is no reason to exclude older adults, those with a long symptom history, weight difficulties, severe symptoms or failure of previous treatments and they should be offered PTNS where indicated, except where recognised contraindications to PTNS, such as a cardiac pacemaker are present. Only in those patients with poor mental health and/or DO and/or low capacity bladders at baseline should the possibility of limited success be considered.

New factors are emerging which may influence understanding of potential effects for different diagnostic groups. In one pilot study (343) urinary neurotrophin levels (nerve growth factor and brain derived neurotrophic factor) were measured. Results indicated that for idiopathic OAB higher levels of nerve growth factor at baseline may predict poor response to transcutaneous PTNS. Level of brain derived neurotrophic factor significantly reduced over the treatment course in those who responded to transcutaneous PTNS, which suggests a potential biomarker for response in idiopathic OAB but the reduction was not seen in responders with neurological disease. Further investigation is required to fully understand the influence of these patient factors.

Summary

The evidence on which to base recommendations for best practice in the use of PTNS to treat OAB/UUI in men and women is sparse, for both percutaneous and transcutaneous PTNS. However it is sufficiently robust to support the use of percutaneous PTNS when less intensive and invasive behavioral treatment options have failed (Level of Evidence: 1) and there is the suggestion that percutaneous PTNS may be as effective as some drug therapy, making it a viable alternative (Level of Evidence: 2).

Only two small trials investigated transcutaneous PTNS but the promising results indicate that further well-designed and reported trials would allow decisions to be made about the place of transcutaneous PTNS in the treatment algorithms for OAB/UUI in men and women.

Health economic information is required to establish the cost effectiveness of the different forms of PTNS, particularly in comparison to pharmacotherapy.

Recommendations for practice:

In adults with OAB/UUI percutaneous PTNS is better for improving UUI than no treatment or sham and should be offered to adults with UUI/OAB who do not achieve satisfactory results from first-line lifestyle and behavioral interventions or drug therapy. (Grade of Recommendation: B New)

At least weekly PTNS sessions should be offered during an active treatment program with regular top-ups provided to sustain benefits for up to three years. (Grade of Recommendation: B New)

Transcutaneous PTNS is a safe treatment option and may be offered to frail older adults with UI or urinary symptoms however definitive evidence of effectiveness is needed. (Grade of Recommendation: C New)

Percutaneous PTNS can be offered as an alternative to tolterodine for OAB/UUI in adult men and women. (Grade of Recommendation: B New).

Oxybutynin may be considered in addition to percutaneous PTNS in adults with DO. (Grade of Recommendation: B New).

Future research directions:

Currently available evidence compares percutaneous PTNS with older antimuscarinics. Future rigorous trials should compare percutaneous PTNS with other commonly used antimuscarinics and beta 3 adrenergic agonists for efficacy and adverse effect profiles, in men and women with OAB/UUI.

The effectiveness of adding drug therapy to percutaneous PTNS should be investigated in high quality trials with adults with OAB/UUI.

Definitive evidence of the effectiveness of transcutaneous PTNS to treat OAB/UUI in adults is needed and its place in the treatment algorithm defined.

Research comparing transcutaneous PTNS with all types of drug therapy is required.

Direct comparison of percutaneous PTNS and transcutaneous PTNS to treat OAB/UUI in adults should be investigated.

Further rigorous and well-reported trials are needed to establish the most effective dose of percutaneous PTNS and transcutaneous PTNS, including the timing and duration of PTNS protocols.
### Table 38 Summary of data PTNS protocols comparisons

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Comparator</th>
<th>N</th>
<th>Study population</th>
<th>Modality details or parameters</th>
<th>Outcomes</th>
<th>Follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Percutaneous posterior tibial nerve stimulation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Finazzi-Agro 2005 (1)</td>
<td>Treatment group A: weekly Percutaneous PTNS&lt;br&gt;Active electrode: 34 gauge needle provides sensation. Inactive electrode: calcaneal surface electrode. Comparator treatment group B: 3 x weekly Percutaneous PTNS&lt;br&gt;Active electrode: 34 gauge needle provides sensation. Inactive electrode: calcaneal surface electrode.</td>
<td>35</td>
<td>Adults with refractory OAB syndrome&lt;br&gt;Males : 7&lt;br&gt;Females: 28 Results reported together</td>
<td>Pulse width: not reported&lt;br&gt;Frequency: 20 Hz&lt;br&gt;Intensity: 0.5-9mA according to sensory &amp; motor response.&lt;br&gt;Duration: 30 minutes&lt;br&gt;Number sessions: 12&lt;br&gt;Programme length: 12 weeks (Group A); 4 weeks (Group B)</td>
<td>24 hour BD IQoL&lt;br&gt;SF36&lt;br&gt;UDS&lt;br&gt;Success defined as those who reported micturition episodes/24 hours or incontinence episodes/24 hours reduced by ≥50%</td>
<td>4 weeks (3X weekly PTNS)&lt;br&gt;12 weeks (1 X weekly PTNS)</td>
</tr>
<tr>
<td><strong>Transcutaneous posterior tibial nerve stimulation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Seth 2014 (2)</td>
<td>Treatment group Transcutaneous PTNS using Geko™ device weekly&lt;br&gt;Comparator treatment group Transcutaneous PTNS using Geko™ device daily</td>
<td>48</td>
<td>Adults with idiopathic (24 subjects) or neuropathic (24 subjects) OAB&lt;br&gt;Males NR&lt;br&gt;Females NR Results reported together</td>
<td>Pulse width: not reported&lt;br&gt;Frequency: not reported&lt;br&gt;Intensity: not reported&lt;br&gt;Duration: 30 minutes&lt;br&gt;Number sessions: 12 (weekly group), 84 (daily group)&lt;br&gt;Programme length: 12 weeks</td>
<td>Outcomes: Responder defined as those rating moderate to significant improvement on GRA at 12 weeks&lt;br&gt;Change in individual GRA symptoms&lt;br&gt;ICIQ-OAB, ICIQ-LUTSqol&lt;br&gt;BD parameters</td>
<td>12 weeks</td>
</tr>
</tbody>
</table>

Footnotes; GRA : Global Response Assessment, UDS : Urodynamic studies; SF-36 :36-Item Short Form Health Survey; ICIQ-OAB : International Consultation on Incontinence Questionnaire on Overactive Bladder; ICIQ-LUTSqol : International Consultation on Incontinence Quality of Life questionnaire; BD parameters : bladder diary parameters; PTNS: Posterior tibial nerve stimulation


REFERENCES


57. Leong B, Mok N. Effectiveness of a new standardised Urinary Continence Physiotherapy Programme for community dwelling older women in Hong Kong. Hong Kong Medical Journal 2015;21(1):30-7.


60. Siva Priya R, Kokila V, Malai K, Kumar S. Effectiveness of Antenatal Motor Relearning Approach ofDiaphragm, Deep Abdominal and Pelvic Floor MusclesVersus Kegels Exercises


83. Dumoulin C. Physiotherapy compared to individual physiotherapy to treat urinary incontinence in aging women: A randomized controlled trial. Ref ID: 60909 Trials registry number(s): NCT02039830. 2012.


87. Hagen S. OPAL: A multicentre randomised trial of the effectiveness and cost effectiveness of basic versus bio feedback mediated intensive pelvic floor muscle training for female stress or mixed urinary incontinence. Ref ID: 64519 Trials registry number(s): ISRCTN57746448; UKCRN15841 2014.

88. Haruna M, Asai Y. Effect of postpartum pelvic floor muscle training with ultrasound biofeedback on recovery of pelvic floor muscle function: a randomized controlled trial. Ref ID: 66324 Trials registry number(s): JPRN-UMIN000015878. 2014.


119. Castro RA, Arruda RM, Zanetti MR, Santos PD, Sartori MG, Girao MJ. Single-blind,


incontinence in adults. Cochrane Database of Systematic Reviews. 2004(1).


231. Gumanga SK, Munkaila A, Malechi H. Social demographic characteristics of women with


297. Lone F, Thakar R, Sultan AH. One-year prospective comparison of vaginal pessaries and surgery for pelvic organ prolapse using the validated ICIQ-VS and ICIQ-UI (SF)


