National Institute for Health and Care Excellence

Final

Urinary incontinence and pelvic organ prolapse in women: management

[H] Evidence reviews for lifestyle and conservative management options for pelvic organ prolapse

NICE guideline NG123

Evidence reviews

April 2019

Final

These evidence reviews were developed by the National Guideline Alliance hosted by the Royal College of Obstetricians and Gynaecologists

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Contents

Lifestyle and conservative management options for women with pelvic organ prolapse

Review questions

This evidence report covers several reviews within subsections. The following are the three review questions that are going to be covered in this document:

- What lifestyle interventions are effective for managing pelvic organ prolapse?
- What is the effectiveness of topical oestrogen for managing pelvic organ prolapse with vaginal atrophy?
- What are the most effective conservative management options (for example, pelvic floor exercises and pessaries) for pelvic organ prolapse?

Management of pelvic organ prolapse

Lifestyle interventions

What lifestyle interventions are effective for managing pelvic organ prolapse (POP)?

Introduction

Pelvic organ prolapse is a common condition and the woman's symptoms can vary. Decisions about treatment choice depend on the woman's symptoms, severity of the prolapse and the woman's general health. Lifestyle interventions are an aspect of conservative management generally used by women with a mild prolapse or who do not wish to have more invasive treatment. These interventions aim to improve the woman's general health or to avoid exacerbation of the prolapse by decreasing intra-abdominal pressure.

This review will examine the effectiveness of lifestyle interventions in the management of POP.

Summary of the protocol

See Table 1 for a summary of the population, intervention, comparison and outcome (PICO) characteristics of this review.

Table 1: Summary of protocol (PICO table)

Population	Women over 18 years of age with pelvic organ prolapse who may be eligible for lifestyle interventions.
Intervention	• Weight loss • Smoking cessation • Exercise (high impact, low impact) • Avoiding heavy lifting • Constipation prevention.
Comparison	• No lifestyle interventions
Outcome	**Critical** • Improvement in symptoms: o Self-reported symptoms o Questionnaires: POP-SS, ICIQ-VS, EPAQ, PFIQ-7/PFDI-21 • Patient satisfaction (measured by PFDI, or patient reported) • Health-related quality of life (measured by EQ-5D). **Important** • Sexual function (PISQ) • Adverse events • Anatomical assessment of POP (assessed by POP-Q).

EPAQ: Electronic Personal Assessment Questionnaires; EQ-5D: EuroQuol-5D; ICIQ-VS: International Consultation on Incontinence Questionnaire – Vaginal Symptoms; PFIQ-7/PFDI-21: Pelvic Floor Distress Inventory; PISQ: pelvic Organ Prolapse/Incontinence Sexual Questionnaire; POP: Pelvic Organ Prolapse; POP-Q: Pelvic Organ Prolapse Questionnaire; POP-SS: Pelvic Organ Prolapse Symptom Score.

For full details see the review protocol in appendix A.

Methods and process

This evidence review was developed using the methods and process described in Developing NICE guidelines: the manual 2014. Methods specific to this review question are described in the review protocol in appendix A and for a full description of the methods see supplementary material C.

Declarations of interest were recorded according to NICE's 2014 conflicts of interest policy until 31 March 2018. From 1 April 2018, declarations of interest were recorded according to NICE's 2018 conflicts of interest policy. Those interests declared until April 2018 were reclassified according to NICE's 2018 conflicts of interest policy (see Register of Interests).

Clinical evidence

Included studies

A systematic review of the clinical literature was conducted but no relevant studies were identified which were applicable to this review question.

See the literature search strategy in appendix B and study selection flow chart in appendix C.

Excluded studies

Studies not included in this review with reasons for their exclusions are provided in appendix K.

Summary of clinical studies included in the evidence review

No studies were identified which were applicable to this review question.

Quality assessment of clinical studies included in the evidence review

No studies were identified which were applicable to this review question.

Economic evidence

Included studies

A systematic review of the economic literature was conducted but no studies were identified which were applicable to this review question. See supplementary material D for further information.

Excluded studies

No studies were identified which were applicable to this review question.

Summary of studies included in the economic evidence review

No economic evaluations were identified which were applicable to this review question.

Economic model

This question was not prioritised for economic modelling because the evidence to base this on was anticipated to be limited.

Clinical evidence statements

No evidence was identified which was applicable to this review question.

Economic evidence statements

No economic evidence on the cost effectiveness of lifestyle interventions for managing pelvic organ prolapse was available.

The committee's discussion of the evidence

Interpreting the evidence

The outcomes that matter most

The committee identified improvement in symptoms, health-related quality of life and patient satisfaction as critical outcomes as they considered these to have the greatest impact on the woman. The committee prioritised sexual function, adverse events and anatomical assessment of POP as important outcomes. No evidence was identified for any of the critical or important outcomes.

The quality of the evidence

The committee found no clinical evidence on lifestyle interventions on pelvic organ prolapse.

Benefits and harms

There was no evidence on the effectiveness or cost effectiveness of lifestyle interventions for pelvic organ prolapse in women. As a result, the committee could not draw conclusions as to the effectiveness of such interventions and made a recommendation based on the committee's experience and expertise.

The committee agreed that lifestyle advice is valued by women with the condition and is likely to improve their experience and is unlikely to generate significant harm. Based on their knowledge they highlighted advice on lifestyle choices that directly impact on pelvic organs.

The committee were aware that there is one study that did not match the inclusions criteria specified in the protocol which showed that weight loss as a result of bariatric surgery resulted in short-term improvement in pelvic organ prolapse. They therefore recommended that advice on weight loss should be given. This study was outside of the scope of the evidence review as the intervention was bariatric surgery.

Based on their expertise the committee acknowledged that chronic constipation and obstructive defecation can be directly linked to posterior vaginal wall prolapse. The committee also knew that obesity, heavy lifting and constipation increase intra-abdominal pressure and therefore are all likely to affect symptoms of prolapse. They therefore decided that it was reasonable to encourage advice on all of these to increase women's awareness about these issues.

The committee considered the subgroups identified in the scope but decided not to make different recommendations because the advice that they recommended would be useful for all of the subgroups.

Even though there was a lack of evidence the committee decided not to make a research recommendation because lifestyle interventions have to be individualised and tailored to the needs of each woman. They therefore decided that other topics would take priority for research recommendations, particularly those where recommendations may change current practice.

Cost effectiveness and resource use

No economic evidence on lifestyle interventions for women with pelvic organ prolapse was identified. The committee was aware of the overall economic benefits of weight management in general. Lifestyle advice on weight loss has the potential to reduce weight-related diseases and the associated morbidity, mortality and costs incurred by the NHS. For example, weight management reduces future healthcare expenditure by preventing costly conditions such as diabetes and coronary heart disease. Similarly, the committee noted that there is evidence that treatments for constipation are cost-effective in the general population. These treatments are inexpensive and not only improve symptoms but also patient satisfaction and health related quality of life. The committee noted that since time is being spent giving women advice anyway, there is not expected to be an increase in NHS costs by giving advice on weight loss, heavy lifting, constipation prevention, and exercise and its effects on pelvic organ prolapse symptoms.

Other factors the committee took into account

After considering the evidence from the three separate reviews presented in this report, the committee agreed that a general recommendation was warranted regarding what should be discussed with women who have pelvic organ prolapse and who are considering medical intervention. The committee emphasised that it was important that the available treatment options be fully discussed – including no treatment, conservative treatment, and surgery – and that such factors women's age, comorbidities, surgical history, preferences and lifestyle, the location of prolapse, and the benefits and risk associated with the relevant interventions, should be taken into account.

References

No studies were identified which were applicable to this review question.

The effectiveness of topical oestrogen for managing pelvic organ prolapse with vaginal atrophy

Review question

What is the effectiveness of topical oestrogen for managing pelvic organ prolapse (POP) with vaginal atrophy?

Introduction

The reduction in available oestrogen following menopause contributes to vaginal atrophy and therefore it may contribute to pelvic organ prolapse. Treatment with topical oestrogens have proven to be effective for the symptoms associated with vaginal atrophy (Weber 2015). Treatment with oestrogens may help in the treatment of pelvic organ prolapse by increasing synthesis of collagen and improving the strength of the vaginal epithelium (Weber 2015).

Summary of the protocol

Please see Table 2 for a summary of the population, intervention, comparison and outcome (PICO) characteristics of this review.

Table 2: Summary of the protocol (PICO table)

Population	Women (18 years of age or older) with pelvic organ prolapse and vaginal atrophy.
Intervention	Topical oestrogen: • Cream • Vaginal tablets/pessaries • E-string
Comparisons	• No topical oestrogen use • Placebo

Outcome	**Critical**
	• Improvement in symptoms
	  ○ Self-reported symptoms
	  ○ Questionnaires: POP-SS, EPAQ, PFDI-20
	• Patient satisfaction (measured by PFDI, patient reported)
	• Health-related quality of life (measured by EQ-5D, ICIQ-VS, PFIQ-7)
	
	Important
	• Sexual functioning (PIS-Q)
	• Adverse events
	  ○ Post-menopausal bleeding
	  ○ Breast symptoms pain/tenderness
	  ○ Pelvic discomfort and pain
	  ○ Discharge
	  ○ Allergic reaction
	• Anatomical assessment of POP (assessed by POP-Q)

EPAQ: Electronic Personal Assessment Questionnaire; EQ-5D: EuroQuol-5D; ICIQ-VS: International Consultation on Incontinence Questionnaire – Vaginal Symptoms; PFDI-20: Pelvic Floor Distress Inventory; PFIQ-7: Pelvic Floor Impact Questionnaire – Short Form; PIS-Q: Pelvic Organ Prolapse Incontinence Sexual Questionnaire; POP: pelvic organ prolapse; POP-Q: Pelvic Organ Prolapse Quantification System; POP-SS: Pelvic Organ Prolapse Symptom Score.

For full details see the review protocol in appendix A.

Methods and process

This evidence review was developed using the methods and process described in Developing NICE guidelines: the manual 2014. Methods specific to this review question are described in the review protocol in appendix A and for a full description of the methods see supplementary material C.

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Clinical evidence

Included studies

A systematic review of the clinical literature was conducted but no studies were identified which were applicable to this review question.

See the literature search strategy in appendix B and study selection flow chart in appendix C.

Excluded studies

Studies not included in this review with reasons for their exclusions are provided in appendix K.

Summary of clinical studies included in the evidence review

No studies were identified which were applicable to this review question.

Quality assessment of clinical studies included in the evidence review

No studies were identified which were applicable to this review question.

Economic evidence

Included studies

A systematic review of the economic literature was conducted but no studies were identified which were applicable to this review question. See supplementary material D for further information.

Excluded studies

No studies were identified which were applicable to this review question.

Summary of studies included in the economic evidence review

No economic evaluations were identified which were applicable to this review question.

Economic model

No economic modelling was undertaken for this review because the committee agreed that other topics were higher priorities for economic evaluation.

Clinical evidence statements

No studies were identified which were applicable to this review question.

Economic evidence statements

No economic evidence on the cost effectiveness of topical oestrogen for managing pelvic organ prolapse with vaginal atrophy was available.

The committee's discussion of the evidence

Interpreting the evidence

The outcomes that matter most

The committee prioritised improvement in symptoms, patient satisfaction and health-related quality of life as critical outcomes because these were seen as the best indicators of effectiveness to the patient. Sexual function, adverse events such as post-menopausal bleeding, breast symptoms of pain/tenderness, pelvic discomfort and pain, discharge, allergic reaction, and anatomical assessment of POP were prioritised as important because improvement in the critical outcomes would outweigh individual important outcomes that were listed. No evidence was identified for any of the critical or important outcomes.

The quality of the evidence

No studies were identified which were applicable to this review question.

Benefits and harms

The committee recognised that pelvic organ prolapse and vaginal atrophy are common problems in women. They also acknowledged the impact that these problems can have on women who wish to be physically and sexually active. Therefore, despite the lack of evidence, the committee agreed that it was important to make a recommendation on the use of vaginal oestrogen in women affected by these conditions. They also agreed to refer to the NICE Menopause guideline (2015) as they thought the guideline covered relevant recommendations on the use of vaginal oestrogen in women with urogenital atrophy. When making their recommendation the committee was aware of the fact that the NICE Menopause guideline was specific to women in menopause. In addition, the committee highlighted that vaginal oestrogen has a low probability of causing harm. The committee were aware that women may be less likely to be prescribed systemic hormone replacement therapy because of the potential for adverse events; however, they agreed that systemic absorption was very low from vaginal preparations.

Due to the lack of evidence the committee discussed whether or not to make a research recommendation. However, they decided not to make a research recommendation for this topic and that other topics would take priority for research recommendations.

Cost effectiveness and resource use

There was no economic evidence on the cost effectiveness of topical oestrogen for managing pelvic organ prolapse with vaginal atrophy.

The committee noted that recommending the use of vaginal oestrogen in women with pelvic organ prolapse and signs of vaginal atrophy may increase the awareness of the subject in primary care and, if GPs were more likely to prescribe vaginal oestrogen, there would be fewer referrals into secondary care which may result in substantial cost savings to the NHS given that pelvic organ prolapse and vaginal atrophy are common problems and affect a large proportion of women.

The committee discussed that there was unlikely to be a significant cost impact to the NHS associated with the use of a vaginal ring for women with cognitive and/or physical impairments as an alternative to vaginal pessaries or creams. The committee noted that the acquisition cost of a vaginal ring is likely to be similar to that of a vaginal pessary, and likely to be less than the cost of vaginal creams. Also, the use of an alternative form of a treatment i.e. vaginal ring in this sub-group of women is likely to result in improvements in health outcomes as otherwise these women would be incapable of self-administering vaginal oestrogen. An inappropriate form of treatment could potentially exacerbate symptoms that may need expensive specialist care at a later stage.

Therefore the recommendations may lead to greater prescription of topical vaginal products, but the committee believed that this increased cost would be offset by reductions in specialist care.

Other factors the committee took into account

After considering the evidence from the three separate reviews presented in this report, the committee agreed that a general recommendation was warranted regarding what should be discussed with women who have pelvic organ prolapse and who are considering medical intervention. The committee emphasised that it was important that the available treatment options be fully discussed – including no treatment, conservative treatment, and surgery – and that such factors women's age, comorbidities, surgical history, preferences and lifestyle, the location of prolapse, and the benefits and risk associated with the relevant interventions, should be taken into account.

The committee also took into account equalities considerations to address the needs of women with cognitive and/or physical impairments. They recognised the need to make a specific recommendation about women with cognitive and/or physical impairment because they were aware that sometimes these women may struggle to self-administer vaginal oestrogen.

References

Weber 2015

Weber, M.A., Kleijn, M. H., Langendam, M., Limpens, J., Heineman, M.J., Roovers, J. P. Local Oestrogen for Pelvic Floor Disorders: A Systematic Review, PLoS ONE 10 (9) e0136265 2015

Effectiveness of conservative interventions in the management of pelvic organ prolapse

Review question

What are the most effective conservative management options (for example, pelvic floor exercises and pessaries) for pelvic organ prolapse (POP)?

Introduction

Pelvic organ prolapse (POP) is a common condition and the woman's symptoms can vary. Decisions about treatment choice depend on the woman's symptoms, severity of the prolapse and the woman's general health. Women with a mild or moderate prolapse, or who do not wish to have more invasive treatment, or are unsuitable to undergo surgery for pelvic organ prolapse, are typically managed using conservative measures including pelvic floor muscle training and vaginal pessaries. Guidance is required to inform which conservative options are appropriate to be offered to women.

This review examines the effectiveness of conservative interventions in the management of POP.

Summary of the protocol

See Table 3 for a summary of the population, intervention, comparison and outcome (PICO) characteristics of this review.

Table 3: Summary of protocol (PICO table)

Population	Women over 18 years of age with pelvic organ prolapse who may be eligible for conservative management.

Intervention	• Pelvic floor muscle exercises:
	  ○ Bio feedback (digital/manual, use of cones, intravaginal devices)
	  ○ Supervised (including group learning)
	  ○ Self-directed
	  ○ Self-directed plus app
	  ○ With electrical stimulation
	  ○ With manual therapy/myofascial techniques.
	• Pessaries
	• V-brace (pants/underwear).

Comparison	• Pelvic floor muscle exercises versus no conservative treatment • Supervised pelvic floor muscle exercises versus self-directed pelvic floor muscle exercises • Pelvic floor muscle exercises plus bio feedback versus pelvic floor muscle exercises • Pelvic floor muscle exercises plus electrical stimulation versus pelvic floor muscle exercises • Pelvic floor muscle exercises plus manual therapy/myofascial techniques versus pelvic floor muscle exercises • Pessary versus no pessary use • Pessary use versus pelvic floor muscle exercises

	• V-brace (pants) versus no conservative treatment.

Outcomes	**Critical**
	• Improvement in symptoms:
	  ○ Self-reported symptoms
	  ○ Questionnaires: PFDI-20, POP-SS, EPAQ.
	• Patient satisfaction (measured by PFDI, patient reported)
	• Health-related quality of life (measured by EQ-5D, ICIQ-VS, PFIQ-7).
	
	Important
	• Anatomical assessment of POP (assessed by POP-Q)
	• Sexual function (PISQ)
	• Adverse events

EPAQ: Electronic Personal Assessment Questionnaires; EQ5D: EuroQuol-5D; ICIQ-VS: International Consultation on Incontinence Questionnaire – Vaginal Symptoms; PFIQ-7/PFDI-21: Pelvic Floor Distress Inventory; PISQ: Pelvic Organ Prolapse/Urinary incontinence sexual questionnaire; POP: Pelvic Organ Prolapse; POP-Q: Pelvic Organ Prolapse Questionnaire; POP-SS: Pelvic Organ Prolapse Symptom Score.

For full details see the review protocol in appendix A.

Methods and process

This evidence review was developed using the methods and process described in Developing NICE guidelines: the manual 2014. Methods specific to this review question are described in the review protocol in appendix A and for a full description of the methods see supplementary material C.

Declarations of interest were recorded according to NICE's 2014 conflicts of interest policy until 31 March 2018. From 1 April 2018, declarations of interest were recorded according to NICE's 2018 conflicts of interest policy. Those interests declared until April 2018 were reclassified according to NICE's 2018 conflicts of interest policy (see Register of Interests).

Clinical evidence

Included studies

Thirteen reports of 10 RCTs were included in the review (Braekken 2010; Braekken 2015; Cheung 2016; Due 2016a; Due 2016b; Hagen 2009; Hagen 2014; Hagen 2017; Kashyap 2013; Panman 2016; Panman 2017; Stupp 2016; Wiegersma 2014).

Braekken 2010 was an assessor-blinded RCT that assessed whether pelvic floor muscle training can: 1) reverse and prevent further development of POP, and 2) reduce symptoms related to POP. Braekken 2015 was a secondary publication to Braekken 2010.

Cheung 2016 was a single-blinded RCT that compared pelvic floor symptoms, quality of life, and complications in women with symptomatic POP, with or without vaginal pessaries, in addition to pelvic floor exercises for 12 months.

Due 2016a was an investigator-blinded RCT that examined whether pelvic floor muscle training in combination with a structured lifestyle advice programme would have better effect on a global improvement scale than a structured lifestyle advice programme alone in women with symptomatic POP stage II or greater. Due 2016b was a 12-month follow-up of Due 2016b.

Hagen 2009 was a multicentre RCT that assessed the effectiveness of pelvic floor muscle training for women with stage I or II POP of any type. Hagen 2014 was a multicentre RCT that assessed whether one-to-one pelvic floor muscle training reduces the symptoms of

prolapse and the need for further prolapse treatment in women with stage I to III prolapse, and whether it is cost-effective compared with a prolapse lifestyle advice leaflet. Hagen 2017 was a multicentre RCT that assessed the clinical and cost-effectiveness of pelvic floor muscle training in the secondary prevention of prolapse symptoms, worsening of prolapse severity, and uptake of prolapse treatment.

Kashyap 2013 was a RCT comparing the effect of two packages of pelvic floor muscle training on the clinical course of stage I-III POP among women attending a gynaecology outpatient department at a single centre in India.

Panman 2016 was a RCT that compared the clinical and cost-effectiveness of pessary treatment and pelvic floor muscle training in a primary care population of women aged at least 55 years with a symptomatic POP at or beyond the hymen.

Stupp 2016 was a single-blinded RCT that investigated the effectiveness of pelvic floor muscle training for the treatment of early stage POP.

Wiegersma 2014 was a RCT that compared the effects of pelvic floor muscle training and watchful waiting on pelvic floor symptoms in a primary care population of women aged 55 years or over with symptomatic mild prolapse. Panman 2017 was a 2-year follow-up publication to Wiegersma 2014.

The included studies are summarised in Table 4.

See also literature search strategies in appendix B, study selection flow chart in appendix C, study evidence tables in appendix D, forest plots in appendix E and GRADE tables in appendix F.

Excluded studies

Studies not included in this review with reasons for their exclusions are provided in appendix K.

Summary of clinical studies included in the evidence review

Table 4 provides a brief summary of the included studies. See appendix D for full evidence tables.

Table 4: Summary of included studies

Study	Population	Intervention	Comparison	Outcomes	Comments
Braekken (2010) Partially blinded RCT N=109 Norway	Women with POP stages 1, 2 and 3 as determined by the POP-Q. <u>POP stage:</u> 1: n=19 2: n=65 3: n=24 With positive POP-Q value: n=40 (PFMT: 25 (41.3%); Controls: 15 (30%)).	Women 'advised to avoid straining and taught how to contract their PFM before and during increases in abdominal pressure ("the Knack").' Physiotherapist supervised individuals' once/week in first 3m and once/fortnight in last 3m.	Women 'advised to avoid straining and taught how to contract their PFM before and during increases in abdominal pressure ("the Knack").' Women 'asked not to change frequency of, or to start, PFMT during	Change in stage of POP (POP-Q) Self-reported improvement in prolapse symptoms (reduced frequency and reduced bother) at 6 months Adverse events during study period	Differences between groups in prolapse symptoms at baseline

Study	Population	Intervention	Comparison	Outcomes	Comments
		Women 'advised to do 3 sets of 8 to 12 close to maximum PFM contractions per day and record home training adherence in an exercise diary.' Booklet and DVD of exercise program also provided	intervention period.'		
Braekken (2015) Secondary analysis of partially blinded RCT (Braekken, 2010) N=109 Norway	See Braekken (2010)	See Braekken (2010)	See Braekken (2010)	Change in sexual function compared to 6 months previously Adverse events	
Cheung (2016) Parallel-group, investigator-blind, randomised controlled trial with 12 months follow-up. N=276 Hong Kong	Women with dominant symptoms of prolapse stage 1 to 3 POP using POP-Q system, and no previous treatment received.	Standardised PFMT course offered by registered nurse specialist including a teaching session within 2 weeks of first consultation and '3 individual training sessions at 4, 8 and 16 weeks.' Daily practice of at least 2 sets of 8-12 exercise repetitions per day, with 8-10 exercises per session at least twice per week. Plus fitting of a vaginal pessary. Oestrogen cream was offered if there	Standardised PFMT course offered by registered nurse specialist including a teaching session within 2 weeks of first consultation and '3 individual training sessions at 4, 8 and 16 weeks.' Daily practice of at least 2 sets of 8-12 exercise repetitions per day, with 8-10 exercises per session at least twice per week.	POPDI at 6 and 12 months follow-up UDI at 6 and 12 months follow-up CRADI at 6 and 12 months follow-up POPIQ at 6 and 12 months follow-up UIQ at 6 and 12 months follow-up CRAIQ at 6 and 12 months follow-up	Only ring pessaries used. At 12 months, high rates of cross over to receive different treatment.

Study	Population	Intervention	Comparison	Outcomes	Comments
		was a vaginal ulcer. Phone consultation 2 weeks later.	Phone consultation 2 weeks later.	Adverse events through study period.	
Due (2016a) Randomised controlled trial. N=109 Denmark	Women with POP-Q stage 2 or more who had not received more than one surgical treatment for POP or urinary incontinence.	At least one appointment with specialised physiotherapist to ensure proper PFM contraction and correct performance of PFMT prior to 6 lifestyle teaching modules (with handouts on POP-related symptoms) and PFMT (the Knack) group sessions over 12 weeks, and home training 5 days/week of 3 x10 sustained PFM contractions with progression to PFMT requiring more effort.	6 PowerPoint teaching modules lasting 45-60 mins each (e.g. straining, constipation, being overweight, and heavy lifting) over 12 week period and handouts on POP-related symptoms.	Self-reported symptoms and bother at 3 and 6 months follow-up POPDI-6 at 3 and 6 months follow-up CRADI-8 at 3 and 6 months follow-up UDI-6 at 3 and 6 months follow-up PFDI-20 at 3 and 6 months follow-up UIQ-7 at 3 and 6 months follow-up CRAIQ-7 at 3 and 6 months follow-up POPIQ-7 at 3 and 6 months follow-up PFIQ-7 at 3 and 6 months follow-up	
Due (2016b) Follow-up study to Due (2016a) randomised controlled trial. N=109	See Due (2016a)	See Due (2016a)	See Due (2016a)	See Due (2016a) – 12 months follow-up	

Study	Population	Intervention	Comparison	Outcomes	Comments
Denmark					
Hagen (2009) Pilot study for multicentre, randomised controlled trial. N=47 UK	Women with POP-Q stage 1 or 2 pelvic organ prolapse.	Five appointments with a trained specialist physiotherapist over 16 weeks to ensure correct PFM contraction and how to perform, 'the Knack', individualized home exercise programme (6 sets daily). Lifestyle advice sheet (e.g. weight loss, constipation, avoidance of heavy lifting etc.) tailored to patient.	Lifestyle advice sheet (e.g. weight loss, constipation, avoidance of heavy lifting etc.) tailored to patient	Change in prolapse symptom score at 20 and 26 weeks Self-reported change in prolapse symptoms at 20 and 26 weeks Change in ICIQ score at 20 and 26 weeks Change in POP-Q at 20 weeks	Pilot study
Hagen (2014) Multicentre, parallel-group, randomised controlled trial. N=447 UK, New Zealand and Australia	Women with POP-Q stage 1-3 pelvic organ prolapse. <u>POP stage:</u> 1: n=41 (above hymen): n=95 2 (at or below the hymen): n=243 3: n=67 4: n=1	Five appointments with a trained specialist physiotherapist over 16 weeks to ensure correct PFM contraction and how to perform, 'the Knack', individualised home exercise programme (10 x 10s maximum holds and 50 fast contractions 3 times/day) Lifestyle advice sheet (e.g. weight loss, constipation, avoidance of heavy lifting etc.) given at first appointment	Lifestyle advice sheet (e.g. weight loss, constipation, avoidance of heavy lifting etc.) was posted to women	POP-SS at 6 and 12 months Self-reported prolapse symptoms at 6 and 12 months POP-Q stage at 6months Further treatment received by 12 months Self-reported effect of prolapse symptoms at 6 and 12 months Impact of prolapse symptoms on sex life at 6 and 12 months	Women in the control group increased uptake of supplementary treatments (mainly pelvic floor muscle training) after 6 months.

Study	Population	Intervention	Comparison	Outcomes	Comments
				Bladder symptoms at 6 and 12 months ICIQ-UI SF score at 6 and 12 months Bowel symptoms at 6 and 12 months Adverse events	
Hagen (2017) Multicentre, parallel-group, randomised controlled trial. N=412 UK and New Zealand	Women with POP-Q stage 1-3 pelvic organ prolapse. <u>POP stage:</u> 1 or 2 above or at the hymen: n=399 1:n=186 2 above or at hymen: n=213 3: n=1	Phase 1: Five appointments with a trained specialist physiotherapist over 16 weeks to ensure correct PFM training, individualised home exercise programme (3 sets of exercises daily). Lifestyle advice sheet (e.g. weight loss, constipation, avoidance of heavy lifting etc.) and advice tailored to patient Phase 2: Offered modified, supervised Pilates classes in 2 x 6 week block with PFMT, exercise DVD and 1-to-1 physiotherapy appointment at years 1 and 2.	Lifestyle advice sheet (e.g. weight loss, constipation, avoidance of heavy lifting etc.) was posted to women	POP-SS at year 1 and 2 Prolapse related quality-of-life scores at 2-years Self-reported sexual symptoms at 2-years PISQ-12 at 2-years Adverse events	
Kashyap (2013) RCT with no blinding	Women with POP-Q stage 1 to 3 pelvic organ prolapse.	1-to-1 PFMT instruction, self-instruction manual and home	Self-instruction manual and home programme including 10	POP-SS at weeks 12, 18 and 24	

Study	Population	Intervention	Comparison	Outcomes	Comments
N=140 India	POP stage: 1: n=89 2: n=37 3: n=14	programme including 10 voluntary contractions held for 10 seconds with 10 second rest in-between – 3 times daily. 6 follow up visits over 24weeks	voluntary contractions held for 10 seconds with 10 second rest in-between – 3 times daily. 3 follow up visits over 24weeks	PFIQ-7 score at weeks 12, 18 and 24 VAS score at weeks 18 and 24	
Panman (2016) RCT with no blinding N=162 The Netherlands	Women aged at least 55 years. <u>POP stage:</u> 2: 120 3: 42	Pessary – pessary fitted by trained research physician, including visits to clean pessary, evaluate treatment and monitor side effects. Topical oestrogen suggested in cases of discharge or ulceration due to vaginal atrophy.	PFMT instructions, received feedback during digital palpation, or applying myofeedback or electrical stimulation. Supervised and home PFMT (3-5 times per week, 2 or 3 times per day – tailored to individuals. Taught the Knack, plus information on toilet habits and lifestyle (e.g. diet, body weight).	PFDI-20 at 2 and 12 months POPDI-6 at 3 and 12 months CRADI-8 at 3 and 12 months UDI-6 at 3 and 12 months PFIQ-7 at 3 and 12 months PISQ-12 at 3 and 12 months. PCS-2 (SF-12) at 3 and 12 months Self-reported change of symptoms from start of study Adverse events through study period	PFMT: Myofeedback used in 14 women (22%) and electric stimulation in 9 women (14%).
Panman (2017)	See Wiegersma (2014)	See Wiiegersma (2014)	See Wiegersma (2014)	PFDI-20 at 12 and 24 months	

Study	Population	Intervention	Comparison	Outcomes	Comments
See Wiegersma (2014)				POPDI-6 at 12 and 24 months CRADI-8 at 12 and 24 months UDI-6 at 12 and 24 months PFIQ-7 at 12 and 24 months PSIQ-12 at baseline, 12 and 24 months PCS-12 at 12 and 24 months MCS-12 at 12 and 24 months Improvement of POP-Q stages at 24 months Adverse events through study period	
Stupp (2011) Investigator-blinded RCT N=37 Brazil	Women with untreated stage 2 anterior or posterior vaginal wall prolapse.	Supervised PFMT – 7 appointments with physiotherapist (protocol - instructions on PFMT; PFMT session using vaginal cone; Knack technique), 12-week home exercise programme (3 sets of exercises; 1 set of 8-12 contractions	Unsupervised PFMT – instructions on PFM contractions without protocol. Lifestyle advice containing global stretching, advice on weight loss, fluid intake etc	Change in POP-Q at 14 weeks P-QoL at 14 weeks Self-reported symptoms at 14 weeks	

Study	Population	Intervention	Comparison	Outcomes	Comments
		held for 6 to 10 seconds. Lifestyle advice containing global stretching, advice on weight loss, fluid intake etc.			
Wiegersma (2014) RCT N=287 The Netherlands	Women aged at least 55 years with POP. <u>POP stage</u> 1: 155 2: 132	PFMT – face-to-face PFMT (weekly basis, then every 2 to 3 weeks) with home exercises (3 to 5 times per week, 2 or 3 times per day) + digital palpation, myofeedback or electrical stimulation.	Watchful waiting (no treatment and no recommendations).	PFDI-20 at 3 months POPDI-6 at 3 months CRADI-8 at 3 months UDI-6 at 3 months PFIQ-7 at 3 months PSIQ-12 at 3 months PCS-12 at 3 months MCS-12 at 3 months Self-reported change in symptoms at 3 months. Improvement of 1 or more POP-Q stages Adverse events through study period	Myofeedback was used in 23 (16%) participants, and electric stimulation was used in 11 (8%) women in PFMT group.

CRADI: Colorectal anal distress inventory; CRAIQ: Colorectal anal impact questionnaire; MCS-12: Mental component scores; N: number; PCS-12: physical component scores; PFDI-20: Pelvic Floor Distress Inventory-short form; PFIQ-7: Pelvic Floor Impact Questionnaire – short form; PFM: Pelvic Floor Muscle; PFMT: Pelvic Floor Muscle Training; PIS-Q: Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire; POP: Pelvic Organ Prolapse; POPDI: Pelvic Organ Prolapse Distress Inventory; POP-Q: Pelvic Organ Prolapse Questionnaire; POP-SS: Pelvic Organ Prolapse Symptom Score; POP-SS: Pelvic Organ Prolapse Symptom Score; PSIQ: Pelvic Incontinence Sexual Questionnaire; POPIQ-7:Pelvic Organ Impact Questionnaire – short form 7; QoL: Quality of life; RCT: Randomised Controlled Trial; UDI: Urogenital Distress Inventory; UIQ: Urinary Impact Questionnaire.

Also see clinical evidence tables in appendix D.

Quality assessment of clinical studies included in the evidence review

GRADE analysis was conducted on critical and important outcomes and clinical evidence profiles can be found in appendix F.

Economic evidence

Included studies

The systematic search of the economic literature undertaken for the guideline identified:

- One UK study on the cost effectiveness and cost-utility of supervised PFMT plus lifestyle advice versus lifestyle advice only (Hagen 2017);
- One UK study on the cost-utility of supervised pelvic floor muscle training (PFMT) plus lifestyle advice versus lifestyle advice only (Hagen 2014);
- One Dutch study on the cost effectiveness and cost-utility of pessary treatment versus PFMT (Panman 2016);
- One Dutch study on the cost effectiveness and cost-utility of PFMT versus watchful waiting (Panman 2017).

Evidence tables for all economic evaluations included in the systematic literature review are provided in appendix H. Completed methodology checklists of the studies are provided in appendix M. Economic evidence profiles of studies considered during guideline development (that is, studies that fully or partly met the applicability and quality criteria) are presented in appendix I.

Excluded studies

No studies were identified which were applicable to this review question. See supplementary material D for further information.

Summary of studies included in the economic evidence review

Hagen (2017) evaluated the cost-utility of a supervised PFMT plus lifestyle advice compared with lifestyle advice only in adult women alongside an RCT (Hagen 2017) (n=412 baseline; n=323 at 12 months; and n= 341 at 24 months) conducted in the UK. The study population comprised of adult women with POP-Q stage 1-3 pelvic organ prolapse including anterior, posterior, and apical or a combination.

Supervised PFMT included five one-to-one appointments over 16 weeks with a women's health physiotherapist. Women were also offered Pilates classes and an exercise DVD for home use; plus review appointments at years 1 and 2. Women receiving supervised PFMT also received a lifestyle advice leaflet that was given to them during the face-to-face consultation. Women in the control group received a lifestyle advice leaflet only. The leaflet gave advice about weight loss, constipation, avoidance of heavy lifting, coughing, and high-impact exercise. Women received this leaflet by post.

The analysis was conducted from the UK NHS perspective. The study considered a range of direct healthcare costs including physiotherapy appointments, the initial appointment letter, the prolapse lifestyle advice leaflet, six Pilates-based classes, physiotherapy review appointment, and GP visits. The resource use estimates were based on the RCT. The unit costs were obtained from national sources. The measures of outcome for the economic analysis was quality adjusted-life years (QALYs). To obtain the utility weights SF-12 data collected from trial participants was converted to Short-Form Six-Dimension (SF-6D) utility

index using an algorithm. The UK population norms were used. The time horizon of the analysis was 12 and 24 months. No discounting was applied.

The supervised PFMT plus lifestyle advice when compared with lifestyle advice only resulted in an incremental QALYs of 0.02 and 0.01 in year 1 and year 2, respectively. Over 2 years supervised PFMT plus lifestyle advice when compared with lifestyle advice only resulted in an incremental QALYs of 0.03. The supervised PFMT plus lifestyle advice resulted in an incremental cost of £519 and £329 at year 1 and 2, respectively (2011/12 prices). Over 2 years supervised PFMT plus lifestyle advice when compared with lifestyle advice only resulted in an incremental cost of £848.

Based on the above costs and outcomes the incremental cost-effectiveness ratio (ICER) of supervised PFMT plus lifestyle advice (versus lifestyle advice only) was £21,996 per QALY gained which is above the lower NICE cost-effectiveness threshold of £20,000 per QALY gained. Similarly, at 2 years the ICER of supervised PFMT plus lifestyle advice (versus lifestyle advice only) was £28,267 which is also above the lower NICE cost-effectiveness threshold.

The analysis was directly applicable to the NICE decision-making context and had minor methodological limitations.

Hagen (2014) evaluated the cost-effectiveness of a supervised PFMT plus lifestyle advice compared with lifestyle advice only in adult women alongside an RCT (Hagen 2014) (n=477 baseline; n=295 at 12 months) conducted in the UK. The study population comprised of adult women with POP-Q stage 1-3 pelvic organ prolapse (anterior, posterior, or a combination).

Supervised PFMT included five one-to-one appointments over 16 weeks with a women's health physiotherapist. Women receiving supervised PFMT also received a lifestyle advice leaflet that was given to them during the face-to-face consultation. Women in the control group received a lifestyle advice leaflet only. The leaflet gave advice about weight loss, constipation, avoidance of heavy lifting, coughing, and high-impact exercise. Women received this leaflet by post

The analysis was conducted from the UK NHS perspective. The study considered a range of direct healthcare costs including physiotherapy appointments, costs associated with the clinic space, consultations with a family doctor or a practice nurse, and any further prolapse treatment including surgery, pessary, physiotherapy, oestrogen or hormone replacement therapy (HRT). The resource use estimates were based on the RCT (n= 295). The unit costs were obtained from national sources. The measures of outcome for the economic analysis was improvement measured on the POP-SS scale. The time horizon of the analysis was 12 months.

The supervised PFMT plus lifestyle advice group and lifestyle advice only group resulted in the reduction of 2.09 (SD: 5.39) points and 3.77 (SD: 5.62) points on POP-SS scale, respectively. The adjusted difference for baseline score, POP-Q stage, centre (since this RCT was conducted over multiple centres), and whether or not the woman was motivated to have surgery was 1.52 (95% CI: 0.46; 2.59), p = 0.0053 (in favour of a supervised PFMT plus lifestyle advice group). Based on the above costs and outcomes the ICER of a supervised PFMT plus lifestyle advice (versus lifestyle advice only) was £86.59 per additional point improvement on the POP-SS scale.

The analysis was partially applicable to the NICE decision-making context and had minor methodological limitations.

Panman (2016) evaluated the cost-effectiveness and cost-utility of treatment with pessary compared with PFMT in women with advanced stage (grade 2 or 3) pelvic organ prolapse alongside an RCT (Panman 2016, n=162) conducted in the Netherlands. In the pessary treatment group the first choice was an open ring pessary, followed by a ring pessary with support; if a ring pessary could not be fitted a Shaatz or Gellhorn pessary was tried. PFMT

training involved face to face contact and practising at home 3-5 times a week for 2-3 times each day.

The analysis was conducted from a healthcare payer perspective. The study considered a range of direct healthcare costs including pessaries and pessary-related visits, physical therapy, consultations with GPs and medical specialists, absorbent pads, medication, and operative procedures. The resource use estimates were based on the RCT. The source of unit costs was unclear. The measures of outcome for the economic analysis included the change in PFDI-20 scores and QALYs. PFDI-20 scores ranged from 0 to 300 with a higher score indicating higher distress. Utility weights for QALY estimation were derived using EQ-5D-3L, the UK general population norms. The time horizon of the analysis was 2 years. No discounting was undertaken.

Treatment with pessary resulted in lower distress measured using PFDI-20 compared with PFMT (50.5 versus 62.6, respectively; the difference adjusted for baseline PFDI-20 score and POP stage -3.7 in favour of the pessary (95% CI: -12.8 to 5.3), p=0.42. Both treatments resulted in a QALY loss, with pessary resulting in fewer QALYs lost when compared with PFMT (0.024 in the pessary group and 0.065 in the PFMT group, the difference of 0.041 in favour of pessary). The mean costs per woman were $437 for the PFMT and $309 for the pessary, the difference of $128 (95% CI: $27 to $236), in 2014 US dollars. Based on the above costs and outcomes treatment with pessary was dominant using both PFDI-20 and QALYs as an outcome measure (that is, treatment with pessary resulted in lower costs, lower distress as measured using PFDI-20 and also fewer QALYs lost).

According to bootstrapping, where costs and outcomes where randomly sampled with replacement to capture the uncertainty in costs and outcomes, treatment with pessary was preferred in 71% and 95% of the replications when using PFDI-20 and QALYs as outcome measures, respectively.

The analysis was partially applicable to the NICE decision-making context and had minor methodological limitations.

Panman (2017) evaluated the cost-effectiveness and cost-utility of PFMT compared with watchful waiting (WL) in older women (≥55 years) with a symptomatic mild pelvic organ prolapse alongside an RCT (Panman 2016) (n=287) conducted in the Netherlands. The PFMT training involved face to face contact and practising at home 3-5 times a week for 2-3 times each day. Women in the WL group received information on pelvic anatomy and pelvic floor muscle function by illustrated leaflets, they were also informed about the degree of their prolapse and the function of their pelvic floor muscles.

The analysis was conducted from a healthcare payer perspective. The study considered a range of direct healthcare costs including physical therapy, consultations with GPs and medical specialists, absorbent pads, other prolapse-related treatments (pessaries, pelvic floor muscle training and prolapse surgery). The resource use estimates were based on the RCT. The source of unit costs was unclear. The measures of outcome for the economic analysis included the change in PFDI-20 scores and QALYs. PFDI-20 scores ranged from 0 to 300 with a higher score indicating higher distress. Utility weights for QALY estimation were derived using EQ-5D-3L, the UK general population norms. The time horizon of the analysis was 2 years. No discounting was undertaken.

Treatment with PFMT resulted in a greater reduction on the PFDI-20 scale compared with the WL group (19 versus 5.4 point reduction, respectively); the difference adjusted for baseline PFDI-20 score and POP stage of 12.2 was in favour of PFMT (95% CI: 7.2 to 17.2). Both alternatives resulted in a QALY loss, with PFMT resulting in fewer QALYs lost when compared with WL (0.067 in the WL group and 0.061 in the PFMT group, the difference of 0.006 in favour of PFMT). The mean costs per woman were $437 for PFMT and $309 for pessary, a difference of $128 (95% CI: $27 to $236), in 2014 US dollars. Based on the above

costs and outcomes the ICER of PFMT (versus WL) was €43 per additional point improvement on PFDI-20 and €31,983 per QALY gained.

According to bootstrapping, where costs and outcomes where randomly sampled with replacement to capture the uncertainty in costs and outcomes, PFMT resulted in better outcomes and higher costs in 98% and 55% of the replications when using PFDI-20 and QALYs as an outcome measure, respectively.

The analysis was partially applicable to the NICE decision-making context and had minor methodological limitations.

Economic model

The cost-effectiveness of conservative management options (for example, pelvic floor exercises and pessaries) for pelvic organ prolapse was prioritised for de novo economic modelling. However, the clinical data identified was insufficient to populate an economic model in this area.

Clinical evidence statements

Pelvic floor muscle exercises versus no conservative treatment

Improvement in symptoms (self-reported symptoms)

- Very low quality evidence from one RCT (n=287) showed a clinically important difference favouring PFMT over no conservative treatment on self-reported improvement in symptoms at 3 months in women with POP: RR 4.46 (95% CI 2.83 to 7.03).

Improvement in symptoms (questionnaires)

- Low quality evidence from one RCT showed a clinically important difference favouring PFMT over no conservative treatment on the change in symptoms in women with POP, measured using PFDI-20 at 3 months (n=244, MD -10.60 [95% CI -17.07 to -4.13]), 12 months (n=239, MD -15.90 [95% CI -22.47 to -9.33]) and 24 months (n=251, MD -13.60 [95% CI -19.96 to -7.24]); POPDI-6 at 3 months (n= 247, MD -2.80 [95% CI -5.09 to -0.51]), 12 months (n=246, MD -4.10 [95% CI -6.39 to -1.81]) and 24 months (n=261, MD -4.10 [95% CI -6.32 to -1.88]); UDI-6 at 3 months (n=247, MD -6.50 [95% CI -9.67 to -3.33]), 12 months (n=243, MD -7.70 [95% CI -10.90 to -4.50]), and 24 months (n=259, MD -6.60 [95% CI -9.68 to -3.52]) .
- Low or very low quality evidence from one RCT showed a clinically important difference favouring PFMT over no conservative treatment on the change in symptoms in women with POP, measured using CRADI-8, at 12 months (n=241, MD -3.70 [95% CI -6.36 to -1.04]) and 24 months (n=254, MD -2.80 [95% CI -5.39 to -0.21]); however, low quality evidence from the same RCT showed no clinically important difference between PFMT and no conservative treatment on the change in symptoms measured using CRADI-8 at 3 months in women with POP (n=246, MD -0.90 [95% CI -3.52 to 1.72]).

Improvement in symptoms – Health-related Quality of Life (HRQoL)

- Low or very low quality evidence from one RCT showed a clinically important difference favouring PFMT over no conservative treatment on change in QoL scores in women with POP, measured using PFIQ-7 at 12 months (n = 234, MD -9.50 [95% CI -15.20 to -3.80]) and 24 months (n=250, MD -6.90 [95% CI -12.37 to -1.43]). However very low quality evidence from the same RCT showed no clinically important difference between PFMT and no conservative treatment on change in HRQoL scores in women with POP at 3 months (n=230, MD -3.70 [95% CI -9.43 to 2.03]).

Sexual function

- Low quality evidence from one RCT showed that there may be a clinically important difference favouring PFMT over no conservative treatment on sexual function, measured using PISQ-12 at 3 months, in women with POP (n=101, MD -0.70 [95% CI -2.32 to 0.92]), but there is uncertainty around the estimate. Low quality evidence from the same RCT showed no clinically important difference between PFMT and no conservative treatment on sexual function in women with POP, at 12 months (n=233, MD -0.20 [95% CI -1.17 to 0.77]) and 24 months (n = 96, MD 0.00 [95% CI -1.52 to 1.52]).

Anatomical assessment of POP

- Very low quality evidence from one RCT (n=287) showed a clinically important difference favouring PFMT over no conservative treatment on anterior vaginal prolapse, of one or more POP-Q stages at 3 months (MD 1.59 [95% CI 1.01 to 2.50]), but no clinically important difference on posterior prolapse (MD 0.91 [95% CI 0.44 to 1.87]) or apical prolapse at 3 months (MD 1.02 [95% CI 0.60 to 1.75]) in women with POP.

Supervised PFMT versus lifestyle advice

Improvement in symptoms

- Very low quality evidence from one RCT (n=69) showed a clinically important difference favouring supervised PFMT over lifestyle advice alone on frequency of prolapse symptoms (daily, weekly, monthly, or less than once per month) at 6 months in women with POP (RR 2.42 [95% CI 1.32 to 4.42]). Very low quality evidence from the same RCT showed that there may be a clinically important difference favouring supervised PFMT over lifestyle advice alone on bother of prolapse symptoms (feeling of vaginal bulging and/or heaviness) at 6 months in women with POP (RR 1.59 [95% CI 0.97 to 2.61]), but there is uncertainty around the estimate.

Sexual function

- Very low quality evidence from one RCT (n=90) showed a clinically important difference favouring supervised PFMT over lifestyle advice alone on self-reported sexual function at 6 months in women with POP (RR 7.95 [95% CI 1.97 to 32.13]).

Supervised PFMT + lifestyle advice versus lifestyle advice alone

Improvement in symptoms (self-reported symptoms)

- Very low quality evidence from one RCT (n=40) showed a clinically important difference favouring supervised PFMT + lifestyle advice over lifestyle advice alone on self-reported improvement in symptoms at 20 weeks in women with POP (RR 11.01 [95% CI 2.3 to 18.96)
- Very low quality evidence from two RCTs (n=416) showed a clinically important difference favouring supervised PFMT + lifestyle advice over lifestyle advice alone on self-reported improvement in symptoms at 6 months in women with POP (RR 3.03 [95% CI 2.20 to 4.16]).
- Very low quality evidence from one RCT (n=286) showed a clinically important difference favouring supervised PFMT + lifestyle advice over lifestyle advice alone on self-reported improvement in symptoms at 12 months in women with POP (RR 1.28 [95% CI 1.02 to 1.61]).

Improvement in symptoms

- Very low quality evidence from one RCT showed no clinically important difference between supervised PFMT + lifestyle advice and lifestyle advice alone in women with

POP, on PFDI-20 scores at 3 months (n=109, MD -3.20 [95% CI -17.33 to 10.93]) and 6 months (n=95, MD 3.60 [95% CI -12.60 to 19.80]); UDI-6 scores at 3 months (n=109, MD 1.00 (-5.08 to 7.08]) and 6 months (n=95, MD 5.70 [95% CI -1.21 to 12.61]); and CRADI-8 scores at 3 months (n=109, MD 1.10 [95% CI -4.20 to 6.40]) and 6 months (n=95, MD 2.30 [95% CI -3.75 to 8.35]).

- Very low quality evidence from the same RCT showed that there may be a clinically important difference favouring supervised PFMT + lifestyle advice over lifestyle advice alone in women with POP on POPDI-6 at 3 months (n=109, MD -5.60 [95% CI -11.48 to 0.28]) and 6 months (n=95, MD -6.70 [95% CI -13.43 to 0.03]), but there is uncertainty around the estimate.
- Very low quality evidence from one RCT showed that there may be a clinically important difference favouring supervised PFMT + lifestyle advice over lifestyle advice alone on POP-SS questions at 20 weeks in women with POP (n=37, MD -2.34 [95% CI -4.97 to 0.29]), but there is uncertainty around the estimate.
- Very low quality evidence from two RCTs (n=414) showed no clinically important difference between supervised PFMT + lifestyle advice and lifestyle advice alone on POP-SS at 26 weeks in women with POP (MD -3.07 [95% CI -3.91 to -2.23]).
- Very low quality evidence from two RCT (n=607) also showed no clinically important difference between supervised PFMT + lifestyle advice and lifestyle advice alone on POP-SS at 12 months in women with POP (MD -1.31 [95% CI -1.94 to -0.69]).
- Very low quality evidence from one RCT (n=341) showed no clinically important difference between supervised PFMT + lifestyle advice and lifestyle advice alone on POP-SS at 24 months in women with POP (MD -1.50 [95% CI -2.12 to -0.88]).

Health-related Quality of Life (HRQoL)

- Very low quality evidence from one RCT showed no clinically important difference between supervised PFMT + lifestyle advice and lifestyle advice alone on PFIQ-7 at 3 months (n=109, MD 6.50 [95% CI -5.72 to 18.72]) and 6 months (n=95, MD 9.70 [95% CI -4.18 to 23.58]); UIQ-7 at 3 months (n=109, MD 3.40 [95% CI -1.78 to 8.58]) and 6 months (n=95, MD -0.60 [95% CI -6.41 to 5.21]); and CRAIQ-7 scores at 3 months (n=109, MD 2.65 [95% CI -1.96 to 7.26]) and 6 months (n=95, MD 3.45 [95% CI -1.81 to 8.71]) in women with POP. The same RCT found a clinically significant difference favouring supervised PFMT + lifestyle advice over lifestyle advice alone on POPIQ-7 at 6 months in women with POP (n=95, MD 7.10 [95% CI 1.25 to 12.95]), but showed no clinically important difference between supervised PFMT + lifestyle advice and lifestyle advice alone at 3 months (n=109, MD 1.10 [95% CI -4.03 to 6.23]).

Sexual function

- Low quality evidence from one RCT (n=262) showed no clinically important difference between supervised PFMT + lifestyle and lifestyle advice alone on PISQ-12 sexual function score at 24 months in women with POP (MD 0.30 [95% CI -0.84 to 1.44]).

Anatomical assessment of POP

- Low quality evidence from one RCT showed no clinically important difference between supervised PFMT + lifestyle advice and lifestyle advice alone on improvement in POP-Q stage by 1 stage at 20 weeks (n=20, RR 0.20 [95% CI 0.02 to 2.39]).
- Low quality evidence from one RCT showed no clinically important difference between supervised PFMT + lifestyle advice and lifestyle advice alone on improvement in POP-Q stage by 2 stages at 20 weeks (n=20, RR not estimable, as zero events occurred) in women with POP.

- Very low quality evidence from one RCT showed no clinically important difference between supervised PFMT + lifestyle and lifestyle advice alone on improvement in POP-Q stage by 1 stage at 6 months (n=339, MD 0.90 [95% CI 0.50 to 1.60]).
- Very low quality evidence from one RCT showed no clinically important difference between supervised PFMT + lifestyle and lifestyle advice alone on improvement in POP-Q stage by 2 stages at 6 months (n=339, OR 0.44 [95% CI 0.13 to 1.45]) in women with POP .

Adverse events of treatment

- Very low quality evidence from one RCT (n=412) showed no clinically important difference between supervised PFMT + lifestyle and lifestyle advice alone on adverse events at 24 months in women with POP (RR 7.00 [95% CI 0.36 to 134.67]).

PFMT + self-instruction manual (SIM) versus SIM alone

Improvement in symptoms

- Low quality evidence from one RCT (n=140) showed a clinically important difference favouring supervised PFMT + SIM over SIM alone on change in the mean POP-SS from baseline to 24 weeks in women with POP (MD not estimable).

Health-related Quality of Life (HRQoL)

- Very low quality evidence from one RCT (n=140) showed a clinically important difference favouring supervised PFMT + SIM over SIM alone on the mean PFIQ-7 score at 24 weeks in women with POP (MD not estimable).

Supervised PFMT + Lifestyle advice versus Unsupervised PFMT + Lifestyle advice

Anatomical assessment of POP

- Low quality evidence from one RCT (n=37) showed no clinically important difference between supervised PFMT + lifestyle advice and unsupervised PFMT + lifestyle advice on improvement in POP-Q for anterior prolapse by one stage (RR not estimable) or two stages (RR not estimable) at 14 weeks in women with POP. Low quality evidence from one RCT (n=37) showed no clinically important difference between supervised PFMT + lifestyle advice and unsupervised PFMT + lifestyle advice on improvement in POP-Q for posterior prolapse by one stage (RR not estimable) at 14 weeks in women with POP. Very low quality evidence from one RCT (n=37) showed no clinically important difference between supervised PFMT + lifestyle advice and unsupervised PFMT + lifestyle advice on improvement in POP-Q for posterior prolapse by two stages (RR 2.32 [95% CI 0.10 to 53.42]) at 14 weeks in women with POP.

Vaginal pessary + PFMT versus PFMT alone

Improvement in symptoms (questionnaires)

- Very low quality evidence from one RCT (n=276) showed a clinically important difference favouring PFMT + vaginal pessary over PFMT alone on POPDI at 6 months and 12 months in women with POP (MD not estimable). The same RCT showed no clinically important difference between PFMT + vaginal pessary and PFMT alone on UDI and CRADI scores at 6 and 12 months in women with POP (MD not estimable).
- Very low quality evidence from the same RCT showed a clinically important difference favouring PFMT + vaginal pessary over PFMT alone on POPIQ scores at 12 months, but not at 6 months in women with POP (MD not estimable). The same RCT showed no clinically important difference between PFMT + vaginal pessary and PFMT alone on UIQ and CRAIQ scores at 6 and 12 months in women with POP (MD not estimable).

Adverse events of treatment

- Very low quality evidence from one RCT showed no clinically important difference between PFMT + vaginal pessary and PFMT alone on abnormal vaginal bleeding at 12 months (n=260, RR 2.18 [95% CI 0.69 to 6.91]) and significant vaginal discharge at 12 months (n=260, RR 2.91 [95% CI 0.60 to 14.15]) in women with POP.

Pessary versus PFMT + Feedback/electrical stimulation/lifestyle advice

Improvement in symptoms

- Low quality evidence from one RCT showed no clinically important difference between pessary and PFMT + Feedback/electrical stimulation/lifestyle advice on PFDI-20 scores at 3 months (n=112, MD 0.50 [95% CI -8.79 to 9.79]) in women with POP.
- Low quality evidence from one RCT showed no clinically important difference between pessary and PFMT + Feedback/electrical stimulation/lifestyle advice on PFDI-20 scores at 12 months (n=111, MD 4.40 [95% CI -4.86 to 13.66]), and 24 months (n=138, MD 6.90 [95% CI -1.31 to 15.11]).
- Very low quality evidence from one RCT showed no clinically important difference between pessary and PFMT + Feedback/electrical stimulation/lifestyle advice on CRADI-8 scores at 3 months (n=113, MD 2.00 [95% CI -1.83 to 5.83]). Low quality evidence from the same RCT showed no clinically important difference between pessary and PFTM + Feedback/electrical stimulation/lifestyle advice on CRADI-8 scores at 12 months (n=114, MD 1.10 [95% CI -2.67 to 4.87]) and 24 months (n=141, MD 2.10 [95% CI -1.27 to 5.47]).
- Low quality evidence from one RCT showed no clinically important difference between pessary and PFMT + Feedback/electrical stimulation/lifestyle advice on UDI-6 scores at 3 months (n=114, MD -3.60 [95% CI -8.21 to 1.01]), 12 months (n=115, MD -0.50 [95% CI -5.05 to 4.05]) and 24 months (n=140, MD -1.00 [95% CI -5.04 to 3.04]) in women with POP.
- Low quality evidence from the same RCT showed no clinically important difference between pessary and PFMT + Feedback/electrical stimulation/lifestyle advice on POPDI-6 at 3 months (n=115, MD 2.90 [95% CI -0.62 to 6.42]) in women with POP, but showed a clinically important difference favouring pessary use over PFMT + Feedback/electrical stimulation/lifestyle advice at 12 months (n=117, MD 4.10 [95% CI 0.64 to 7.56]) and 24 months (n=141, MD 4.70 [95% CI 1.61 to 7.79]) in women with POP.

Health-related Quality of Life (HRQoL)

- Low quality evidence from one RCT showed no clinically important difference between pessary and PFMT + Feedback/electrical stimulation/lifestyle advice on PFIQ-7 scores at 3 months (n=106, MD 1.30 [95% CI -6.25 to 8.85]), at 12 months (n=116, MD -4.20 [95% CI -11.28 to 2.88 and 24 months (n=130, MD 2.10 [95% CI -4.48 to 8.68]) in women with POP.

Sexual function

- Low quality evidence from one RCT showed a clinically important difference favouring pessary over PFMT + Feedback/electrical stimulation/lifestyle advice on PISQ-12 scores at 3 months (n=44, MD 2.70 [95% CI 0.87 to 4.53]), 12 months (n=48, MD 2.60 [95% CI 0.88 to 4.32]) and 24 months (n=130, MD 1.30 [95% CI 0.25 to 2.35]) in women with POP.

Adverse events of treatment

- Very low quality evidence from one RCT showed a clinically important difference favouring PFMT + Feedback/electrical stimulation/lifestyle advice over pessary use on adverse events at 24 months in women with POP(n=70, RR 0.02 (95% CI 0.00 to 0.37).

Economic evidence statements

- There was evidence from one UK study (n=412) showing that supported PFMT with lifestyle advice (plus Pilates) was cost ineffective when compared with lifestyle advice only in women with pelvic organ prolapse. The ICER of supervised PFMT and lifestyle advice (plus Pilates) versus lifestyle advice only was £21,996 and £28,267 per QALY gained at year 1 and year 2, respectively, which was above the lower NICE cost-effectiveness threshold of £20,000 per QALY. This evidence came from a directly applicable study that was characterised by minor methodological limitations.
- There was evidence from one UK study (n=477) showing that supported PFMT with lifestyle advice was potentially cost effective when compared with lifestyle advice only in women with pelvic organ prolapse. The ICER of supervised PFMT and lifestyle advice versus lifestyle advice only was £86.59 per additional point improvement on the POP-SS scale. This evidence came from a partially applicable study that was characterised by minor methodological limitations.
- There was evidence from one Dutch study (n=162) showing that pessary was dominant (that is, it was more effective and resulted in lower PFDI-20 scores and fewer QALYs lost) when compared with PFMT in women with pelvic organ prolapse. This evidence came from a partially applicable study that was characterised by minor methodological limitations.
- There was evidence from one Dutch study (n=287) showing that PFMT was cost ineffective when compared with watchful waiting in women with pelvic organ prolapse. The ICER of PFMT (versus watchful waiting) of €31,983 per QALY gained was above the upper NICE cost-effectiveness threshold of £30,000 per QALY. Also, it was unclear whether the ICER of PFMT (versus watchful waiting) of €43 per additional point improvement on PFDI-20 represented a good value for money. This evidence came from a partially applicable study that was characterised by minor methodological limitations.

The committee's discussion of the evidence

Interpreting the evidence

The outcomes that matter most

The committee identified improvement in symptoms, patient satisfaction and health-related quality of life as critical outcomes as they considered these to have the greatest impact on the woman's quality of life and overall satisfaction with treatment options. Women often seek non-surgical treatment for their prolapse symptoms and the majority of women who experience an improvement in their symptoms following PFMT or pessary insertion wish to continue with these treatments. Therefore the committee identified that improvement in symptoms, patient satisfaction and health-related quality of life were the critical determinants of success of these interventions. The committee identified anatomical assessment of POP, sexual function, and adverse events as important outcomes. The committee identified that resolution or improvement of prolapse on examination was less important than symptom improvement as need for further treatment is dependent on symptom resolution rather than examination findings. PFMT and pessary use can affect sexual function and pessary use is associated with adverse events such as vaginal discharge and bleeding and therefore these were identified as important outcomes.

Data were available for the outcomes improvements in symptoms, health related quality of life, sexual function and anatomical assessment of POP for the comparison PFMT versus no

treatment. Data were available for improvements in symptoms and sexual function for the comparison PFMT versus lifestyle advice alone. Data were available for the outcomes improvements in symptoms, health related quality of life and anatomical assessment of POP for the comparison supervised PFMT plus lifestyle advice versus lifestyle advice alone. Data were available for the outcomes improvements in symptoms and health related quality of life for the comparison PFMT plus SIM versus SIM alone. Data were available for anatomical assessment of POP for the comparison supervised PFMT plus lifestyle advice versus unsupervised PFMT plus lifestyle advice. Data were available for the outcomes improvement in symptoms and adverse events for the comparison vaginal pessary plus PFMT versus PFMT alone. Data were also available for the outcomes improvements in symptoms, health related quality of life, sexual function and adverse events for the comparison pessary versus PFMT plus feedback/electrical stimulation/lifestyle.

The quality of the evidence

The quality of the evidence was assessed using GRADE. The quality of the evidence for all outcomes ranged from very low to low. This was mainly related to risks of bias such as poor reporting of adherence to the exercise programme, high dropout rates and lack of blinding. The confidence in the evidence was further reduced by large uncertainties around the effect sizes.

Benefits and harms

The current review provides low and very low quality evidence to support supervised pelvic floor muscle training as the first line conservative management. The committee highlighted that all management options should be discussed with the woman to ensure that she can make an informed choice based on her preferences and personal views. Pelvic floor muscle training may not be the preferred choice for women who are not regularly exercising or have other reasons why they would not prefer to take part in such a programme. The committee also noted that for women with cognitive impairment there may be difficulties in following pelvic floor muscle training instructions, tolerating pessaries or surgical interventions. Based on their knowledge the committee agreed that complications from surgery may affect fertility and therefore future childbearing plans should also be considered. The committee discussed that comorbidities may also affect the ability to take part in exercise programmes and therefore should also feature in the discussion about treatment options. The committee agreed that a discussion of all these issues would facilitate the shared decision-making process about conservative treatment options.

Due to the evidence in favour of pelvic floor muscle training being only of very low or low quality, the committee decided that that pelvic floor muscle training can be considered as a long-term option and should last for at least 16 weeks with the woman continuing it, if it was beneficial. It was noted that the evidence of benefit of PFMT mainly related to stage I-2 prolapse and that there was insufficient evidence to recommend PFMT for prolapse stages 3 and 4.

Similarly, the current review provides very low quality evidence for the use of pessary and pelvic floor muscle training; however adverse effects are more common with pessary use. The committee discussed that pessary use remains an important alternative to surgical intervention for women with all stages of prolapse including advanced prolapse and decided that pessary management should be considered as an option for treatment of prolapse symptoms despite the low quality evidence.

The committee agreed that it was important for women with physical or cognitive impairment that might make it difficult for them to manage their ongoing pessary care, to have an appointment in a pessary clinic every 6 months.

Cost effectiveness and resource use

There was evidence from two Dutch studies showing that pelvic floor muscle training was potentially cost ineffective when compared to both watchful waiting and treatment with pessary. However, the committee questioned the generalisability of the findings to clinical practice in the UK. One of the main concerns was that both studies included women only at the age of 55 and above. The committee noted that in their clinical practice a large proportion of women with pelvic organ prolapse symptoms are in their late 20s and 30s. The committee expressed their view that effectiveness and cost effectiveness of pelvic floor muscle training may be more favourable in these younger age groups and they could not draw firm conclusions on the cost effectiveness of pelvic floor muscle training from these two studies. The committee discussed the observed QALY loss in both arms in the Dutch studies. In their view, this QALY loss was nothing to do with the intervention per se. It was more likely to be age related.

There was indirect evidence from 2 UK studies that examined the cost effectiveness of supervised pelvic floor muscle training plus lifestyle advice. However, no firm conclusions could be drawn from these studies either. One study indicated that the ICER of pelvic floor muscle training plus lifestyle advice (versus lifestyle advice only) was above NICE's lower cost-effectiveness threshold of £20,000 per QALY. The other study found that supervised pelvic floor muscle training plus lifestyle advice (versus lifestyle advice only) was potentially cost effective when using POP-SS as an outcome measure (that is, given that a total score on POP-SS scale ranges from 0 to 28 the committee were of a view that £86.59 per additional point improvement on the POP-SS scale represented a good value for money).

Overall, the clinical and economic evidence was scarce. However, the committee noted that pelvic floor muscle training showed improvement on various POP symptom scales when compared with other conservative treatment options. Hagen and colleagues (2014) estimated the cost of the physiotherapy intervention to be £192 (in 2016/17 prices) and the committee was of a view that for pelvic floor muscle training to be considered cost effective a required QALY gain of approximately 0.009 was small (that is, for the ICER of pelvic floor muscle training to be below the lower NICE cost-effectiveness threshold of £20,000 per QALY). A QALY gain of 0.009 is equivalent to spending 3 days in full health.

The committee discussed the limitations of the analysis comparing pelvic floor muscle training and pessary treatment and noted that the time horizon of 2 years may not be sufficiently long enough to capture all important differences in costs and outcomes. According to the committee, a pelvic floor muscle training intervention lasts only a few months with ongoing top-ups during follow-up, whereas pessary needs to be changed every six months and treatment usually continues for many years. Also, there is an increased risk of infections and other complications such as fistula associated with pessary that may incur additional NHS costs. The committee were of the view that the existing UK economic evaluation may have potentially underestimated the cost effectiveness of pelvic floor muscle training and as such pelvic floor muscle training should be considered as the first-line conservative management and that the addition of a pessary should remain an option.

Other factors the committee took into account

After considering the evidence from the three separate reviews presented in this report, the committee agreed that a general recommendation was warranted regarding what should be discussed with women who have pelvic organ prolapse and who are considering medical intervention. The committee emphasised that it was important that the available treatment options be fully discussed – including no treatment, conservative treatment, and surgery – and that such factors women's age, comorbidities, surgical history, preferences and lifestyle, the location of prolapse, and the benefits and risk associated with the relevant interventions, should be taken into account.

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Appendices

Appendix A – Review protocols

Review protocol for review question: What lifestyle interventions are effective for managing pelvic organ prolapse (POP)?

Table 5: Review protocol for lifestyle interventions for managing pelvic organ prolapse

Field (based on PRISMA-P	Content
Review question	What lifestyle interventions are effective for managing pelvic organ prolapse?
Type of review question	Intervention
Objective of the review	Pelvic organ prolapse is a common condition and the woman's symptoms can vary. Decisions about treatment choice depend on the woman's symptoms, severity of the prolapse and the woman's general health. Lifestyle interventions are an aspect of conservative management generally used by women with a mild prolapse or who do not wish to have more invasive treatment. These interventions aim to improve the woman's general health or to avoid exacerbation of the prolapse by decreasing intra-abdominal pressure. This review will examine the effectiveness of lifestyle interventions in the management of POP.
Eligibility criteria – population/disease/condition/issue/domain	Women over 18 years of age with pelvic organ prolapse who may be eligible for lifestyle interventions. We will consider women who are treatment naïve and those who are receiving another conservative management option (as long as the additional conservative management option is balanced at baseline between the groups).
Eligibility criteria – intervention(s)/exposure(s)/prognostic factor(s)	We will consider the following lifestyle interventions: • Weight loss • Smoking cessation • Exercise (high impact, low impact) • Avoiding heavy lifting

Field (based on PRISMA-P	Content
	• Constipation prevention
Eligibility criteria – comparator(s)/control or reference (gold) standard	• No lifestyle interventions

Outcomes and prioritisation	**Critical**
	• Improvement in symptoms:
	  ○ Self-reported symptoms
	  ○ Questionnaires: POP-SS, ICIQ-VS, EPAQ, PFIQ-7/PFDI-21
	• Patient satisfaction (measured by PFDI, or patient reported)
	• Health-related quality of life (measured by EQ-5D).
	
	Important
	• Sexual function (PIS-Q)
	• Adverse events
	• Anatomical assessment of POP (assessed by POP-Q).

Eligibility criteria – study design	Systematic reviews of RCT RCT Where no full-text are available, conference abstracts of RCTs will be considered In the absence of any RCT evidence, comparative cohort studies will be considered.
Other inclusion exclusion criteria	Inclusion: • English language Exclusion: • Pregnant women • Women who have had previous surgery for POP.
Proposed sensitivity/sub-group analysis, or meta-regression	Population subgroups: • Severity/grade of POP • Type of POP (anterior, apical, posterior).

Field (based on PRISMA-P	Content
Selection process – duplicate screening/selection/analysis	Sifting, data extraction, appraisal of methodological quality and GRADE assessment will be performed by the systematic reviewer. Quality control will be performed by the senior systematic reviewer. Dual sifting and data extraction will not be undertaken for this question.
Data management (software)	Pairwise meta-analyses, if possible, will be performed using Cochrane Review Manager (RevMan5). 'GRADEpro' will be used to assess the quality of evidence for each outcome. NGA STAR software will be used for generating bibliographies/citations, study sifting, data extraction and recording quality assessment using checklists (AMSTAR – Systematic reviews, Cochrane RoB – RCTs, NOS – Cohort studies)
Information sources – databases and dates	Sources to be searched: Medline, Medline In-Process, CCTR, CDSR, DARE, HTA, Embase. Limits (e.g. date, study design): For details see appendix B.
Identify if an update	This is a new topic for the guideline and is not an update.
Author contacts	Developer: The National Guideline Alliance https://www.nice.org.uk/guidance/indevelopment/gid-ng10035.
Highlight if amendment to previous protocol	For details please see section 4.5 of Developing NICE guidelines: the manual 2014.
Search strategy – for one database	For details please see appendix B.
Data collection process – forms/duplicate	A standardised evidence table format will be used, and published as appendix D (clinical evidence tables) or H (economic evidence tables).
Data items – define all variables to be collected	For details please see evidence tables in appendix D (clinical evidence tables) or H (economic evidence tables).
Methods for assessing bias at outcome/study level	Standard study checklists were used to critically appraise individual studies. For details please see section 6.2 of Developing NICE guidelines: the manual 2014. The risk of bias across all available evidence was evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group http://www.gradeworkinggroup.org/

Field (based on PRISMA-P	Content
Criteria for quantitative synthesis (where suitable)	For details please see section 6.4 of Developing NICE guidelines: the manual 2014.
Methods for analysis – combining studies and exploring (in)consistency	For details of the methods please see supplementary material C.
Meta-bias assessment – publication bias, selective reporting bias	For details please see section 6.2 of Developing NICE guidelines: the manual 2014. If sufficient relevant RCT evidence is available, publication bias will be explored using RevMan software to examine funnel plots. Trial registries will be examined to identify missing evidence: Clinical trials.gov, NIHR Clinical Trials Gateway.
Assessment of confidence in cumulative evidence	For details please see sections 6.4 and 9.1 of Developing NICE guidelines: the manual 2014.
Rationale/context – Current management	For details please see the introduction to the evidence review.
Describe contributions of authors and guarantor	A multidisciplinary committee developed the guideline. The committee was convened by the National Guideline Alliance and chaired by Dr Fergus Macbeth in line with section 3 of Developing NICE guidelines: the manual 2014. Staff from the National Guideline Alliance undertook systematic literature searches, appraised the evidence, conducted meta-analysis and cost-effectiveness analysis where appropriate, and drafted the guideline in collaboration with the committee. For details of the methods please see supplementary material C.
Sources of funding/support	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists.
Name of sponsor	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists.
Roles of sponsor	NICE funds the National Guideline Alliance to develop guidelines for those working in the NHS, public health, and social care in England.
PROSPERO registration number	Not registered with PROSPERO.

CDSR: Cochrane Database of Systematic Reviews; CENTRAL: Cochrane Central Register of Controlled Trials; DARE: Database of Abstracts of Reviews of Effects; EPAQ: Electronic Personal Assessment Questionnaires; EQ-5D: European Quality of Life Questionnaire; GRADE: Grading of Recommendations Assessment, Development and Evaluation; ICIQ-VS: International Consultation on Incontinence Questionnaire – Vaginal Symptoms; NHS: National Health Service; NICE: National Institute for Health and

Care Excellence; NIHR: National Institute of Health Research; PFIQ-7/PFDI-21: Pelvic Floor Distress Inventory; POP: Pelvic Organ Prolapse; POP-Q: Pelvic Organ Prolapse Questionnaire; POP-SS: Pelvic Organ Prolapse Symptom Score; RCT: Randomised Controlled Trial; RoB: Risk of Bias; RR: Risk Ratio; SD: Standard Deviation.

Review protocol for review question: What is the effectiveness of topical oestrogen for managing pelvic organ prolapse (POP) with vaginal atrophy?

Table 6: Review protocol for the effectiveness of topical oestrogen

Field (based on PRISMA-P	Content
Review question	What is the effectiveness of topical oestrogen for managing pelvic organ prolapse with vaginal atrophy?
Type of review question	Intervention
Objective of the review	It is believed that the reduction in available oestrogen following menopause may contribute to vaginal atrophy (VA) and pelvic organ prolapse (POP). The aim of this review is to examine the effectiveness of topical oestrogen therapy in the management of POP and VA.
Eligibility criteria – population/disease/condition/issue/domain	Women (18 years of age or older) with pelvic organ prolapse and vaginal atrophy.
Eligibility criteria – intervention(s)/exposure(s)/prognostic factor(s)	Topical oestrogen: • Cream • Vaginal tablets/pessaries • E-string. We will consider women who are treatment naïve or those receiving another conservative management or lifestyle intervention (as long as the additional management option is balanced at baseline between the groups).
Eligibility criteria – comparator(s)/control or reference (gold) standard	• No topical oestrogen use • Placebo

Outcomes and prioritisation	**Critical**
	• Improvement in symptoms
	  ○ Self-reported symptoms
	  ○ Questionnaires: POP-SS, EPAQ, PFDI-20

Field (based on PRISMA-P	Content

	• Patient satisfaction (measured by PFDI, patient reported)
	• Health-related quality of life (measured by EQ-5D, ICIQ-VS, PFIQ-7).
	
	Important
	• Sexual functioning (PIS-Q)
	• Adverse events
	  ○ Post-menopausal bleeding
	  ○ Breast symptoms pain/tenderness
	  ○ Pelvic discomfort and pain
	  ○ Discharge
	  ○ Allergic reaction
	• Anatomical assessment of POP (assessed by POP-Q).

Eligibility criteria – study design	Systematic reviews of RCT RCT Where no full-text reports are available, conference abstracts of RCTs will be considered. In the absence of any RCT evidence, comparative cohort studies will be considered.
Other inclusion exclusion criteria	Inclusion: • English language
Proposed sensitivity/sub-group analysis, or meta-regression	Population subgroups: • Stage/grade of POP • Type of POP (anterior, apical, posterior) • Women who are breastfeeding • Peri-menopausal women.
Selection process – duplicate screening/selection/analysis	Sifting, data extraction, appraisal of methodological quality and GRADE assessment will be performed by the systematic reviewer. Quality control will be performed by the senior systematic reviewer. Dual sifting and data extraction will not be undertaken for this question.

Field (based on PRISMA-P	Content
Data management (software)	Pairwise meta-analyses, if possible, will be performed using Cochrane Review Manager (RevMan 5). GRADEpro will be used to assess the quality of evidence for each review outcome. NGA STAR software will be used for generating bibliographies/citations, study sifting, data extraction and recording quality assessment using checklists (AMSTAR – systematic reviews, Cochrane RoB – RCTs, NOS – cohort studies).
Information sources – databases and dates	Sources to be searched: Medline, Medline In-Process, CCTR, CDSR, DARE, HTA, Embase. No limits will be applied. For details please see appendix B.
Identify if an update	This is a new topic for the guideline and is not an update.
Author contacts	Developer: The National Guideline Alliance. https://www.nice.org.uk/guidance/indevelopment/gid-ng10035.
Highlight if amendment to previous protocol	For details please see section 4.5 of Developing NICE guidelines: the manual 2014.
Search strategy – for one database	For details please see appendix B.
Data collection process – forms/duplicate	A standardised evidence table format will be used, and published as appendix D (clinical evidence tables) or H (economic evidence tables).
Data items – define all variables to be collected	For details please see evidence tables in appendix D (clinical evidence tables) or H (economic evidence tables).
Methods for assessing bias at outcome/study level	Standard study checklists were used to critically appraise individual studies. For details please see section 6.2 of Developing NICE guidelines: the manual 2014. The risk of bias across all available evidence was evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group http://www.gradeworkinggroup.org/
Criteria for quantitative synthesis	For details please see section 6.4 of Developing NICE guidelines: the manual 2014.
Methods for quantitative analysis – combining studies and exploring (in)consistency	For details of the methods please see supplementary material C.
Meta-bias assessment – publication bias, selective reporting bias	For details please see section 6.2 of Developing NICE guidelines: the manual 2014.

Field (based on PRISMA-P	Content
	If sufficient relevant RCT evidence is available, publication bias will be explored using RevMan software to examine funnel plots. Trial registries will be examined to identify missing evidence: ClinicalTrials.gov, NIHR Clinical Trials Gateway
Confidence in cumulative evidence	For details please see sections 6.4 and 9.1 of Developing NICE guidelines: the manual 2014.
Rationale/context – what is known	For details please see the introduction to the evidence review.
Describe contributions of authors and guarantor	A multidisciplinary committee developed the guideline. The committee was convened by the National Guideline Alliance and chaired by Dr Fergus Macbeth in line with section 3 of Developing NICE guidelines: the manual 2014. Staff from the National Guideline Alliance undertook systematic literature searches, appraised the evidence, conducted meta-analysis and cost-effectiveness analysis where appropriate, and drafted the evidence review in collaboration with the committee. For details of the methods please see supplementary material C
Sources of funding/support	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists.
Name of sponsor	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists.
Roles of sponsor	NICE funds the National Guideline Alliance to develop guidelines for those working in the NHS, public health and social care in England.
PROSPERO registration number	Not registered with PROSPERO.

CDSR: Cochrane Database of Systematic Reviews; CENTRAL: Cochrane Central Register of Controlled Trials; DARE: Database of Abstracts of Reviews of Effects; EPAQ: Electronic Personal Assessment Questionnaire; EQ-5D: European Quality of Life Questionnaire; ICIQ-VS: International Consultation on Incontinence Questionnaire-Vaginal Symptoms; PFIQ-7: Pelvic Floor Impact Questionnaire; PFDI-20: Pelvic Floor Distress Inventory; PIS-Q: Pelvic Organ Prolapse Incontinence Sexual Questionnaire; POP: Pelvic Organ Prolapse; POP-SS: Pelvic Organ Prolapse Symptom Score; POP-Q: Pelvic Organ Prolapse Quantification System.

Review protocol for review question: What are the most effective conservative management options (for example, pelvic floor exercises and pessaries) for pelvic organ prolapse (POP)?

Table 7: Review protocol for conservative management options for pelvic organ prolapse

Field (based on PRISMA-P	Content
Review question	What are the most effective conservative management options (for example, pelvic floor exercises and pessaries) for pelvic organ prolapse?
Type of review question	Intervention
Objective of the review	Pelvic organ prolapse is a common condition and the woman's symptoms can vary. Decisions about treatment choice depend on the woman's symptoms, severity of the prolapse and the woman's general health. Conservative management techniques are generally used by women with a mild or moderate prolapse or who do not wish to have more invasive treatment. This review will examine the effectiveness of conservative interventions in the management of POP.
Eligibility criteria – population/disease/condition/issue/domain	Women over 18 years of age with pelvic organ prolapse who may be eligible for conservative management.
Eligibility criteria – intervention(s)/exposure(s)/prognostic factor(s)	1. Pelvic floor muscle exercises • bio feedback (digital/manual, use of cones, intravaginal devices) • supervised (including group learning) • self-directed • self-directed plus app • with electrical stimulation • with manual therapy/myofascial techniques 2. Pessaries 3. V-brace (pants/underwear)
Eligibility criteria – comparator(s)/control or reference (gold) standard	• Pelvic floor muscle exercises versus no conservative treatment • Supervised pelvic floor muscle exercises versus self-directed pelvic floor muscle exercises

Field (based on PRISMA-P	Content
	• Pelvic floor muscle exercises plus bio feedback versus pelvic floor muscle exercises • Pelvic floor muscle exercises plus electrical stimulation versus pelvic floor muscle exercises • Pelvic floor muscle exercises plus manual therapy/myofascial techniques versus pelvic floor muscle exercises • Pessary versus no pessary use • Pessary use versus pelvic floor muscle exercises; • V-brace (pants) versus no conservative treatment.

Outcomes and prioritisation	**Critical**
	• Improvement in symptoms:
	  ○ Self-reported symptoms
	  ○ Questionnaires: PFDI-20, POP-SS, EPAQ.
	• Patient satisfaction (measured by PFDI, patient reported)
	• Health-related quality of life (measured by EQ-5D, ICIQ-VS, PFIQ-7).
	
	Important
	• Anatomical assessment of POP (assessed by POP-Q)
	• Sexual function (PIS-Q)
	• Adverse events

Eligibility criteria – study design	Systematic reviews of RCT RCT In the absence of any RCT evidence, comparative cohort studies will be considered.
Other inclusion exclusion criteria	Inclusion: • English language Exclusions:

Field (based on PRISMA-P	Content
	• pregnant women • rectal prolapse alone
Proposed sensitivity/sub-group analysis, or meta-regression	Population subgroups: • stage/grade of POP • Type of POP (anterior, apical, posterior) • type of pessaries Special consideration will be given to the following groups for which data will be reviewed and analysed separately if available: • older women • women with physical disabilities Special consideration of women with cognitive impairment and women who are considering future pregnancy was not prioritised for this question.
Selection process – duplicate screening/selection/analysis	Sifting, data extraction, appraisal of methodological quality and GRADE assessment will be performed by the systematic reviewer. Quality control will be performed by the senior systematic reviewer. Dual sifting and data extraction will not be undertaken for this question.
Data management (software)	Pairwise meta-analyses, if possible, will be performed using Cochrane Review Manager (RevMan5). 'GRADEpro' will be used to assess the quality of evidence for each outcome. NGA STAR software will be used for generating bibliographies/citations, study sifting, data extraction and recording quality assessment using checklists (AMSTAR – Systematic reviews, Cochrane RoB – RCTs, NOS – Cohort studies)
Information sources – databases and dates	Sources to be searched: Medline, Medline In-Process, CCTR, CDSR, DARE, HTA, Embase. Limits (e.g. date, study design): No limits as new question For details please see appendix B.
Identify if an update	This is a new topic for the guideline and is not an update.
Author contacts	Developer: The National Guideline Alliance https://www.nice.org.uk/guidance/indevelopment/gid-ng10035.

Field (based on PRISMA-P	Content
Highlight if amendment to previous protocol	For details please see section 4.5 of Developing NICE guidelines: the manual.
Search strategy – for one database	For details please see appendix B.
Data collection process – forms/duplicate	A standardised evidence table format will be used, and published as appendix D (clinical evidence tables) or H (economic evidence tables).
Data items – define all variables to be collected	For details please see evidence tables in appendix D (clinical evidence tables) or H (economic evidence tables).
Methods for assessing bias at outcome/study level	Standard study checklists were used to critically appraise individual studies. For details please see section 6.2 of Developing NICE guidelines: the manual. The risk of bias across all available evidence was evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group http://www.gradeworkinggroup.org/.
Criteria for quantitative synthesis (where suitable)	For details please see section 6.4 of Developing NICE guidelines: the manual 2014.
Methods for analysis – combining studies and exploring (in)consistency	For details of the methods please see supplementary material C.
Meta-bias assessment – publication bias, selective reporting bias	For details please see section 6.2 of Developing NICE guidelines: the manual 2014. If sufficient relevant RCT evidence is available, publication bias will be explored using RevMan software to examine funnel plots. Trial registries will be examined to identify missing evidence: Clinical trials.gov, NIHR Clinical Trials Gateway.
Assessment of confidence in cumulative evidence	For details please see sections 6.4 and 9.1 of Developing NICE guidelines: the manual 2014.
Rationale/context – Current management	For details please see the introduction to the evidence review in the full guideline.
Describe contributions of authors and guarantor	A multidisciplinary committee developed the guideline. The committee was convened by the National Guideline Alliance and chaired by Dr Fergus Macbeth in line with section 3 of Developing NICE guidelines: the manual 2014. Staff from the National Guideline Alliance undertook systematic literature searches, appraised the evidence, conducted meta-analysis and cost-effectiveness analysis where appropriate, and drafted the guideline in collaboration with the committee. For details of the methods please see supplementary material C.

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Sources of funding/support	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists.
Name of sponsor	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists.
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Appendix B – Literature search strategies

Literature search strategy for review question: What lifestyle interventions are effective for managing pelvic organ prolapse (POP)?

Database: Medline & Embase (Multifile)
Last searched on Embase Classic+Embase 1947 to 2017 June 26, Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 to Present.

Date of last search: 28th June 2017.

#	Searches
1	exp Pelvic Organ Prolapse/ use ppez
2	exp pelvic organ prolapse/ use emczd
3	(pelvic$ adj3 organ$ adj3 prolaps$).tw.
4	(urinary adj3 bladder adj3 prolaps$).tw.
5	((vagin$ or urogenital$ or genit$ or uter$ or viscer$ or anterior$ or posterior$ or apical or pelvi$ or vault$ or urethr$ or bladder$) adj3 prolaps$).tw.
6	(splanchnoptos$ or visceroptos$).tw.
7	Rectocele/ use ppez
8	rectocele/ use emczd
9	(hernia$ adj3 (pelvi$ or vagin$ or urogenital$ or uter$ or bladder$ or urethr$ or viscer$)).tw.
10	(urethroc?ele$ or enteroc?ele$ or sigmoidoc?ele$ or proctoc?ele$ or rectoc?ele$ or cystoc?ele$ or rectoenteroc?ele$ or cystourethroc?ele$).tw.
11	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
12	exp Smoking Cessation/ use ppez
13	exp "Tobacco Use Cessation"/ use ppez
14	exp "Tobacco Use Cessation Products"/ use ppez
15	exp "Tobacco Use Disorder"/ use ppez
16	Smoking/pc, th use ppez
17	exp smoking cessation/ use emczd
18	exp nicotine gum/ use emczd
19	exp smoking/pc, th use emczd
20	(smoking adj3 (cessation or ceas$ or intervention or withdrawal or quit$ or stop$)).tw.
21	Weight Loss/ use ppez
22	weight reduction/ use emczd
23	exp Diet Therapy/ use ppez
24	exp diet therapy/ use emczd
25	Weight Reduction Programs/ use ppez
26	weight loss program/ use emczd
27	(weight adj2 (los$ or reduc$)).tw.
28	((caloric or hypocaloric) adj2 (restrict* or diet*)).tw.
29	exp Life Style/ use ppez
30	exp lifestyle/ use emczd
31	lifestyle modification/ use emczd
32	((lifestyle$ or life-style$) adj3 (advice$ or intervention$ or modif$ or change$)).tw.
33	Drinking/ use ppez
34	drinking/ use emczd
35	fluid intake/ use emczd
36	((fluid$ or water) adj3 (supplement$ or increase$ or intake$)).tw.
37	Dietary Fiber/ use ppez
38	dietary fiber/ use emczd
39	((fibre or fiber) adj3 (supplement$ or increase$ or intake$)).tw.
40	((high-fibre high-fiber or high fibre or high fiber or fibre-rich or fiber-rich or fibre rich or fiber rich) adj diet$).tw.
41	(stool adj3 softener$).tw.
42	(bowel adj3 (re-train$ or retrain$ or train$ or re-educat$ or reeducat$ or educat$)).tw.
43	Laxatives/ use ppez
44	laxative/ use emczd
45	laxative$.tw.
46	(constipat$ adj3 prevent$).tw.
47	"Activities of Daily Living"/ use ppez

#	Searches
8	Physical Exertion/ use ppez
49	exp Physical Endurance/ use ppez
50	daily life activity/ use emczd
51	exp physical activity/ use emczd
52	endurance/ use emczd
53	((heavy or repetitive) adj3 lift$).tw.
54	(activit$ adj3 (restrict$ or recommend$ or avoid$ or modif$ or change$)).tw.
55	Health Behavior/ use ppez
56	health behavior/ use emczd
57	exp Exercise/ use ppez
58	exp Sports/ use ppez
59	exp exercise/ use emczd
60	exp sport/ use emczd
61	((high adj impact) or (low adj impact)).tw.
62	(strong adj effort).tw.
63	((exercis$ or activit$) adj3 (advice$ or intervention$ or modif$ or change$)).tw.
64	exp Cognitive Therapy/ use ppez
65	*Behavior Therapy/ use ppez
66	exp cognitive behavioral therapy/ use emczd
67	*behavior therapy/ use emczd
68	((behaviour$ or behavior$) adj3 (advice$ or intervention$ or modif$ or change$)).tw.
69	or/12-68
70	11 and 69
71	remove duplicates from 70
72	limit 71 to english language
73	letter/
74	editorial/
75	news/
76	exp historical article/
77	Anecdotes as Topic/
78	comment/
79	case report/
80	(letter or comment*).ti.
81	73 or 74 or 75 or 76 or 77 or 78 or 79 or 80
82	randomized controlled trial/ or random*.ti,ab.
83	81 not 82
84	animals/ not humans/
85	exp Animals, Laboratory/
86	exp Animal Experimentation/
87	exp Models, Animal/
88	exp Rodentia/
89	(rat or rats or mouse or mice).ti.
90	83 or 84 or 85 or 86 or 87 or 88 or 89
91	letter.pt. or letter/
92	note.pt.
93	editorial.pt.
94	case report/ or case study/
95	(letter or comment*).ti.
96	91 or 92 or 93 or 94 or 95
97	randomized controlled trial/ or random*.ti,ab.
98	96 not 97
99	animal/ not human/
100	nonhuman/
101	exp Animal Experiment/
102	exp Experimental Animal/
103	animal model/
104	exp Rodent/
105	(rat or rats or mouse or mice).ti.
106	98 or 99 or 100 or 101 or 102 or 103 or 104 or 105
107	90 use ppez
108	106 use emczd
109	107 or 108
110	72 and 109

#	Searches
111	72 not 110

Database: Cochrane Library via Wiley Online

Date of last search: 28th June 2017.

ID	Search
#1	MeSH descriptor: [Pelvic Organ Prolapse] explode all trees
#2	(pelvic* near/3 organ* near/3 prolaps*):ti,ab,kw (Word variations have been searched)
#3	(urinary near/3 bladder near/3 prolaps*):ti,ab,kw (Word variations have been searched)
#4	((vagin* or urogenital* or genit* or uter* or viscer* or anterior* or posterior* or apical or pelvi* or vault* or urethr* or bladder*) near/3 prolaps*):ti,ab,kw (Word variations have been searched)
#5	(splanchnoptos* or visceroptos*):ti,ab,kw (Word variations have been searched)
#6	MeSH descriptor: [Rectocele] explode all trees
#7	(hernia* near/3 (pelvi* or vagin* or urogenital* or uter* or bladder* or urethr* or viscer*)):ti,ab,kw (Word variations have been searched)
#8	(urethrocele* or urethrocoele* or enterocele* or enterocoele* or sigmoidocoele* or sigmoidocele* or proctocele* or proctocoele* or rectocele* or rectocoele* or cystocele* or cystocoele* or rectoenterocele* or rectoenterocoele* or cystourethrocele* or cystourethrocoele*):ti,ab,kw (Word variations have been searched)
#9	#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8
#10	MeSH descriptor: [Smoking Cessation] explode all trees
#11	MeSH descriptor: [Tobacco Use Cessation] explode all trees
#12	MeSH descriptor: [Tobacco Use Cessation Products] explode all trees
#13	MeSH descriptor: [Tobacco Use Disorder] explode all trees
#14	(smoking near/3 (cessation or ceas* or intervention or withdrawal or quit* or stop*)):ti,ab,kw (Word variations have been searched)
#15	MeSH descriptor: [Weight Loss] explode all trees
#16	MeSH descriptor: [Diet Therapy] explode all trees
#17	MeSH descriptor: [Weight Reduction Programs] explode all trees
#18	(weight near/2 (los* or reduc*)):ti,ab,kw (Word variations have been searched)
#19	((caloric or hypocaloric) near/2 (restrict* or diet*)):ti,ab,kw (Word variations have been searched)
#20	MeSH descriptor: [Life Style] explode all trees
#21	((lifestyle* or life-style*) near/3 (advice* or intervention* or modif* or change*)):ti,ab,kw (Word variations have been searched)
#22	MeSH descriptor: [Health Behavior] explode all trees
#23	MeSH descriptor: [Cognitive Therapy] explode all trees
#24	MeSH descriptor: [Behavior Therapy] explode all trees
#25	((behaviour* or behavior*) near/3 (advice* or intervention* or modif* or change*)):ti,ab,kw (Word variations have been searched)
#26	MeSH descriptor: [Drinking] explode all trees
#27	((fluid* or water) near/3 (supplement* or increase* or intake*)):ti,ab,kw (Word variations have been searched)
#28	MeSH descriptor: [Dietary Fiber] explode all trees
#29	((fibre or fiber) near/3 (supplement* or increase* or intake*)):ti,ab,kw (Word variations have been searched)
#30	((high-fibre high-fiber or high fibre or high fiber or fibre-rich or fiber-rich or fibre rich or fiber rich) next diet*):ti,ab,kw (Word variations have been searched)
#31	(stool near/3 softener*):ti,ab,kw (Word variations have been searched)
#32	(bowel near/3 (re-train* or retrain* or train* or re-educat* or reeducat* or educat*)):ti,ab,kw (Word variations have been searched)
#33	MeSH descriptor: [Laxatives] explode all trees
#34	laxative*:ti,ab,kw (Word variations have been searched)
#35	(constipat* near/3 prevent*):ti,ab,kw (Word variations have been searched)
#36	MeSH descriptor: [Activities of Daily Living] explode all trees
#37	MeSH descriptor: [Physical Exertion] explode all trees
#38	MeSH descriptor: [Physical Endurance] explode all trees
#39	((heavy or repetitive) near/3 lift*):ti,ab,kw (Word variations have been searched)
#40	(activit* near/3 (restrict* or recommend* or avoid* or modif* or change*)):ti,ab,kw (Word variations have been searched)
#41	MeSH descriptor: [Exercise] explode all trees
#42	MeSH descriptor: [Sports] explode all trees
#43	((high next impact) or (low next impact)):ti,ab,kw (Word variations have been searched)
#44	(strong next effort):ti,ab,kw (Word variations have been searched)
#45	((exercise* or activit*) near/3 (advice* or intervention* or modif* or change*)):ti,ab,kw (Word variations have been searched)

ID	Search
#46	#10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #29 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43 or #44 or #45
#47	#9 and #46

Database: Cinahl Plus

Date of last search: 28th June 2017.

#	Searches
S46	S9 AND S45
S45	S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43 OR S44
S44	TI ((exercis* or activit*) N3 (advice* or intervention* or modif* or change*)) or AB ((exercis* or activit*) N3 (advice* or intervention* or modif* or change*))
S43	TI (strong N1 effort) or AB (strong N1 effort)
S42	TI ((high N1 impact) or (low N1 impact)) or AB ((high N1 impact) or (low N1 impact))
S41	(MH "Sports")
S40	(MH "Exercise")
S39	TI ((behaviour* or behavior*) N3 (advice* or intervention* or modif* or change*)) or AB ((behaviour* or behavior*) N3 (advice* or intervention* or modif* or change*))
S38	(MH "Behavior Therapy")
S37	(MH "Cognitive Therapy")
S36	(MH "Health Behavior")
S35	TI (activit* N3 (restrict* or recommend* or avoid* or modif* or change*)) or AB (activit* N3 (restrict* or recommend* or avoid* or modif* or change*))
S34	TI ((heavy or repetitive) N3 lift*) or AB ((heavy or repetitive) N3 lift*)
S33	(MH "Physical Endurance")
S32	(MH "Exertion")
S31	(MH "Activities of Daily Living")
S30	TI (laxative*) or AB (laxative*)
S29	(MH "Cathartics")
S28	TI (bowel N3 (re-train* or retrain* or train* or re-educat* or reeducat* or educat*)) or AB (bowel N3 (re-train* or retrain* or train* or re-educat* or reeducat* or educat*))
S27	TI (stool N3 softener*) or AB (stool N3 softener*)
S26	TI ((fibre or fiber) N3 (supplement* or increase* or intake*)) or AB ((fibre or fiber) N3 (supplement* or increase* or intake*))
S25	(MH "Dietary Fiber")
S24	TI ((fluid* or water) N3 (supplement* or increase* or intake*)) or AB ((fluid* or water) N3 (supplement* or increase* or intake*))
S23	(MH "Fluid Intake")
S22	TI ((lifestyle* or life-style*) N3 (advice* or intervention* or modif* or change*)) or AB ((lifestyle* or life-style*) N3 (advice* or intervention* or modif* or change*))
S21	(MH "Life Style Changes")
S20	(MH "Life Style")
S19	TI ((caloric or hypocaloric) N2 (restrict* or diet*)) or AB ((caloric or hypocaloric) N2 (restrict* or diet*))
S18	TI (weight N2 (los* or reduc*)) or AB (weight N2 (los* or reduc*))
S17	(MH "Diet Therapy")
S16	(MH "Weight Reduction Programs")
S15	(MH "Weight Loss")
S14	TI (smoking N3 (cessation or ceas* or intervention or withdrawal or quit* or stop*)) or AB (smoking N3 (cessation or ceas* or intervention or withdrawal or quit* or stop*))
S13	(MH "Smoking/PC/TH")
S12	(MH "Smoking Cessation Programs")
S11	(MH "Tobacco Use Cessation Products")
S10	(MH "Smoking Cessation")
S9	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8
S8	TI (urethrocele* or enterocele* or sigmoidocele* or proctocele* or rectocele* or cystocele* or rectoenterocele* or cystourethrocele* or urethrocoele* or enterocoele* or sigmoidocoele* or proctocoele* or rectocoele* or cystocoele* or rectoenterocoele* or cystourethrocoele*) or AB (urethrocele* or enterocele* or sigmoidocele* or proctocele* or rectocele* or cystocele* or rectoenterocele* or cystourethrocele* or urethrocoele* or enterocoele* or sigmoidocoele* or proctocoele* or rectocoele* or cystocoele* or rectoenterocoele* or cystourethrocoele*)
S7	TI (hernia* N3 (pelvi* or vagin* or urogenital* or uter* or bladder* or urethr* or viscer*)) or AB (hernia* N3 (pelvi* or vagin* or urogenital* or uter* or bladder* or urethr* or viscer*))
S6	(MH "Rectocele")
S5	(splanchnoptos* or visceroptos*)
S4	TI ((vagin* or urogenital* or genit* or uter* or viscer* or anterior* or posterior* or apical or pelvi* or vault* or urethr* or bladder*) N3 prolaps*) or AB ((vagin* or urogenital* or genit* or uter* or viscer* or anterior* or posterior* or apical or pelvi* or vault* or urethr* or bladder*) N3 prolaps*)
S3	TI (urinary N3 bladder N3 prolaps*) or AB (urinary N3 bladder N3 prolaps*)

#	Searches
S2	TI (pelvic* N3 organ* N3 prolaps*) or AB (pelvic* N3 organ* N3 prolaps*)
S1	(MH "Pelvic Organ Prolapse+")

Literature search strategies for review question 8.2: What is the effectiveness of topical oestrogen for managing pelvic organ prolapse (POP) with vaginal atrophy?

Database: Medline & Embase (Multifile)
Last searched on Embase Classic+Embase 1947 to 2017 June 13, Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 to Present.

Date of last search: 14th June 2017.

#	Searches	
1	exp Pelvic Organ Prolapse/ use ppez	
2	exp pelvic organ prolapse/ use emczd	
3	(pelvic$ adj3 organ$ adj3 prolaps$).tw.	
4	(urinary adj3 bladder adj3 prolaps$).tw.	
5	((vagin$ or urogenital$ or genit$ or uter$ or viscer$ or anterior$ or posterior$ or apical or pelvi$ or vault$ or urethr$ or bladder$) adj3 prolaps$).tw.	
6	(splanchnoptos$ or visceroptos$).tw.	
7	Rectocele/ use ppez	
8	rectocele/ use emczd	
9	(hernia$ adj3 (pelvi$ or vagin$ or urogenital$ or uter$ or bladder$ or urethr$ or viscer$)).tw.	
10	(urethroc?ele$ or enteroc?ele$ or sigmoidoc?ele$ or proctoc?ele$ or rectoc?ele$ or cystoc?ele$ or rectoenteroc?ele$ or cystourethroc?ele$).tw.	
11	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10	
12	exp Estrogens/ use ppez	
13	exp Estrogen Antagonists/ use ppez	
14	"Estrogens, Conjugated (USP)"/ use ppez	
15	Estradiol/ use ppez	
16	Estriol/ use ppez	
17	Estrone/ use ppez	
18	exp estrogen/ use emczd	
19	exp antiestrogen/ use emczd	
20	conjugated estrogen/ use emczd	
21	estradiol/ use emczd	
22	estriol/ use emczd	
23	estrone/ use emczd	
24	(oestrogen$ or estrogen$ or oestradiol$ or estradiol$ or oestriol$ or estriol$ or oestron$ or estron$ or Vagiferm$ or estring$ or e-string$).tw.	
25	12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24	
26	11 and 25	
27	remove duplicates from 26	
28	vagina atrophy/ use emczd	
29	Atrophic vaginitis/ use ppez	
30	((vagin$ or urogenital$) adj2 atroph$).tw.	
31	28 or 29 or 30	
32	25 and 31	
33	remove duplicates from 32	
34	meta-analysis/	
35	meta-analysis as topic/	
36	systematic review/	
37	meta-analysis/	
38	(meta analy* or metanaly* or metaanaly*).ti,ab.	
39	((systematic or evidence) adj2 (review* or overview*)).ti,ab.	
40	((systematic* or evidence*) adj2 (review* or overview*)).ti,ab.	
41	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.	
42	(search strategy or search criteria or systematic search or study selection or data extraction).ab.	
43	(search* adj4 literature).ab.	
44	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.	
45	cochrane.jw.	
46	((pool* or combined) adj2 (data or trials or studies or results)).ab.	
47	letter/	

#	Searches	
48	editorial/	
49	news/	
50	exp historical article/	
51	Anecdotes as Topic/	
52	comment/	
53	case report/	
54	(letter or comment*).ti.	
55	47 or 48 or 49 or 50 or 51 or 52 or 53 or 54	
56	randomized controlled trial/ or random*.ti,ab.	
57	55 not 56	
58	animals/ not humans/	
59	exp Animals, Laboratory/	
60	exp Animal Experimentation/	
61	exp Models, Animal/	
62	exp Rodentia/	
63	(rat or rats or mouse or mice).ti.	
64	57 or 58 or 59 or 60 or 61 or 62 or 63	
65	letter.pt. or letter/	
66	note.pt.	
67	editorial.pt.	
68	case report/ or case study/	
69	(letter or comment*).ti.	
70	65 or 66 or 67 or 68 or 69	
71	randomized controlled trial/ or random*.ti,ab.	
72	70 not 71	
73	animal/ not human/	
74	nonhuman/	
75	exp Animal Experiment/	
76	exp Experimental Animal/	
77	animal model/	
78	exp Rodent/	
79	(rat or rats or mouse or mice).ti.	
80	72 or 73 or 74 or 75 or 76 or 77 or 78 or 79	
81	64 use ppez	
82	80 use emczd	
83	81 or 82	
84	or/34-35,38,40-45 use ppez	
85	or/36-39,41-46 use emczd	
86	84 or 85	
87	33 and 83	
88	33 not 87	
89	27 and 83	
90	27 not 89	
91	86 and 88	
92	90 or 91	
93	remove duplicates from 92	
94	limit 93 to english language	

Database: Cochrane Library via Wiley Online

Date of last search: 14th June 2017.

ID	Search
#1	MeSH descriptor: [Pelvic Organ Prolapse] explode all trees
#2	(pelvic* near/3 organ* near/3 prolaps*):ti,ab,kw (Word variations have been searched)
#3	(urinary near/3 bladder near/3 prolaps*):ti,ab,kw (Word variations have been searched)
#4	((vagin* or urogenital* or genit* or uter* or viscer* or anterior* or posterior* or apical or pelvi* or vault* or urethr* or bladder*) near/3 prolaps*):ti,ab,kw (Word variations have been searched)
#5	(splanchnoptos* or visceroptos*):ti,ab,kw (Word variations have been searched)
#6	MeSH descriptor: [Rectocele] explode all trees
#7	(hernia* near/3 (pelvi* or vagin* or urogenital* or uter* or bladder* or urethr* or viscer*)):ti,ab,kw (Word variations have been searched)

ID	Search
#8	(urethrocele* or urethrocoele* or enterocele* or enterocoele* or sigmoidocoele* or sigmoidocele* or proctocele* or proctocoele* or rectocele* or rectocoele* or cystocele* or cystocoele* or rectoenterocele* or rectoenterocoele* or cystourethrocele* or cystourethrocoele*):ti,ab,kw (Word variations have been searched)
#9	#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8
#10	MeSH descriptor: [Estrogens] explode all trees
#11	MeSH descriptor: [Estrogen Antagonists] explode all trees
#12	MeSH descriptor: [Estrogens, Conjugated (USP)] explode all trees
#13	MeSH descriptor: [Estradiol] explode all trees
#14	MeSH descriptor: [Estriol] explode all trees
#15	MeSH descriptor: [Estrone] explode all trees
#16	(oestrogen* or estrogen* or oestradiol* or estradiol* or oestriol* or estriol* or oestron* or estron* or Vagiferm* or estring* or e-string*):ti,ab,kw (Word variations have been searched)
#17	#10 or #11 or #12 or #13 or #14 or #15 or #16
#18	#9 and #17
#19	MeSH descriptor: [Atrophic Vaginitis] explode all trees
#20	((vagin* or urogenital*) near/2 atroph*):ti,ab,kw (Word variations have been searched)
#21	#19 or #20
#22	#17 and #21 in Cochrane Reviews (Reviews and Protocols), Other Reviews, Technology Assessments and Economic Evaluations
#23	#18 or #22

Literature search strategies for the review question: What are the most effective conservative management options (for example, pelvic floor exercises and pessaries) for pelvic organ prolapse (POP)?

Database: Medline & Embase (Multifile)
Last searched on Embase Classic+Embase 1947 to 2017 June 20, Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 to Present.

Date of last search: 21st June 2017.

#	Searches	
1	exp Pelvic Organ Prolapse/ use ppez	
3	(pelvic$ adj3 organ$ adj3 prolaps$).tw.	
4	(urinary adj3 bladder adj3 prolaps$).tw.	
5	((vagin$ or urogenital$ or genit$ or uter$ or viscer$ or anterior$ or posterior$ or apical or pelvi$ or vault$ or urethr$ or bladder$) adj3 prolaps$).tw.	
6	(splanchnoptos$ or visceroptos$).tw.	
7	Rectocele/ use ppez	
8	rectocele/ use emczd	
9	(hernia$ adj3 (pelvi$ or vagin$ or urogenital$ or uter$ or bladder$ or urethr$ or viscer$)).tw.	
10	(urethroc?ele$ or enteroc?ele$ or sigmoidoc?ele$ or proctoc?ele$ or rectoc?ele$ or cystoc?ele$ or rectoenteroc?ele$ or cystourethroc?ele$).tw.	
11	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10	
12	Conservative Treatment/ use ppez	
13	*conservative treatment/ use emczd	
14	(conservativ$ adj3 (manage$ or treat$ or prevent$ or interven$)).tw.	
15	((non-surg$ or nonsurg$) adj3 (manage$ or treat$ or prevent$ or interven$)).tw.	
16	Pessaries/ use ppez	
17	vagina pessary/ use emczd	
18	pessar$.tw.	
19	*clothing/ use ppez	
20	protective clothing/ use emczd	
21	protective equipment/ use emczd	
22	(support adj (pant$ or garment$ or underwear)).tw.	
23	(v-brace$ or vbrace$ or fembrace$).tw.	
24	pro-portare.tw.	
25	Self Care/ use ppez	
26	self care/ use emczd	

#	Searches
27	exp Exercise Therapy/ use ppez
28	*Physical Therapy Modalities/ use ppez
29	exercise/ use emczd
30	pelvic floor muscle training/ use emczd
31	kinesiotherapy/ use emczd
32	muscle training/ use emczd
33	((pelvic floor or PFM) adj5 (training or exercise$ or physiotherap$ or physical or therap$ or rehabilitat$)).tw.
34	(PFPT or PFME).tw.
35	Biofeedback, Psychology/ use ppez
36	feedback system/ use emczd
37	(biofeedback or bio-feedback).tw.
38	(vagin$ adj3 (cone$ or ball)).tw.
39	((intra-vagin$ or intravagin) adj3 device$).tw.
40	((digital$ or manual$) adj3 (feedback$ or palpat$ or assess$ or contract$)).tw.
41	exp Electric Stimulation Therapy/ use ppez
42	electrostimulation/ use emczd
43	(electrostimulat$ or electro-stimulat$).tw.
44	(electr$ adj3 stimulat$).tw.
45	(myofascia$ adj3 (release$ or therap$ or technique$)).tw.
46	(manual adj3 therap$).tw.
47	Resistance Training/ use ppez
48	resistance training/ use emczd
49	physiotherapy/ use emczd
50	physiotherap$.tw.
51	((strength$ or resistan$) adj3 (training or exercise$ or physiotherap$)).tw.
52	((pelvic floor or PFM or pelvic muscle$) adj3 strengthen$).tw.
53	or/12-52
54	11 and 53
55	remove duplicates from 54
56	limit 55 to english language
57	letter/
58	editorial/
59	news/
60	exp historical article/
61	Anecdotes as Topic/
62	comment/
63	case report/
64	(letter or comment*).ti.
65	57 or 58 or 59 or 60 or 61 or 62 or 63 or 64
66	randomized controlled trial/ or random*.ti,ab.
67	65 not 66
68	animals/ not humans/
69	exp Animals, Laboratory/
70	exp Animal Experimentation/
71	exp Models, Animal/
72	exp Rodentia/
73	(rat or rats or mouse or mice).ti.
74	67 or 68 or 69 or 70 or 71 or 72 or 73
75	letter.pt. or letter/
76	note.pt.
77	editorial.pt.
78	case report/ or case study/
79	(letter or comment*).ti.
80	75 or 76 or 77 or 78 or 79
81	randomized controlled trial/ or random*.ti,ab.
82	80 not 81
83	animal/ not human/
84	nonhuman/
85	exp Animal Experiment/
86	exp Experimental Animal/
87	animal model/
88	exp Rodent/
89	(rat or rats or mouse or mice).ti.

#	Searches
90	82 or 83 or 84 or 85 or 86 or 87 or 88 or 89
91	74 use ppez
92	90 use emczd
93	91 or 92
94	56 and 93
95	56 not 94

Database: Cochrane Library via Wiley Online

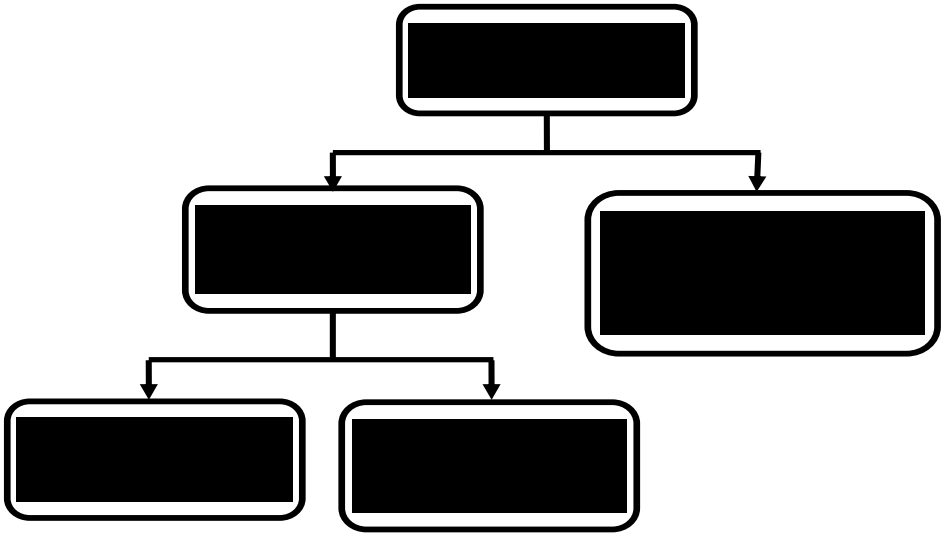
Date of last search: 21st June 2017.

ID	Search
#1	MeSH descriptor: [Pelvic Organ Prolapse] explode all trees
#2	(pelvic* near/3 organ* near/3 prolaps*):ti,ab,kw (Word variations have been searched)
#3	(urinary near/3 bladder near/3 prolaps*):ti,ab,kw (Word variations have been searched)
#4	((vagin* or urogenital* or genit* or uter* or viscer* or anterior* or posterior* or apical or pelvi* or vault* or urethr* or bladder*) near/3 prolaps*):ti,ab,kw (Word variations have been searched)
#5	(splanchnoptos* or visceroptos*):ti,ab,kw (Word variations have been searched)
#6	MeSH descriptor: [Rectocele] explode all trees
#7	(hernia* near/3 (pelvi* or vagin* or urogenital* or uter* or bladder* or urethr* or viscer*)):ti,ab,kw (Word variations have been searched)
#8	(urethrocele* or urethrocoele* or enterocele* or enterocoele* or sigmoidocoele* or sigmoidocele* or proctocele* or proctocoele* or rectocele* or rectocoele* or cystocele* or cystocoele* or rectoenterocele* or rectoenterocoele* or cystourethrocele* or cystourethrocoele*):ti,ab,kw (Word variations have been searched)
#9	#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8
#10	MeSH descriptor: [Conservative Treatment] explode all trees
#11	(conservativ* near/3 (manage* or treat* or prevent* or interven*)):ti,ab,kw (Word variations have been searched)
#12	((non-surg* or nonsurg*) near/3 (manage* or treat* or prevent* or interven*)):ti,ab,kw (Word variations have been searched)
#13	MeSH descriptor: [Pessaries] explode all trees
#14	pessar*:ti,ab,kw (Word variations have been searched)
#15	MeSH descriptor: [Clothing] explode all trees
#16	(support next (pant* or garment* or underwear)):ti,ab,kw (Word variations have been searched)
#17	(v-brace* or vbrace* or fembrace*):ti,ab,kw (Word variations have been searched)
#18	pro-portare:ti,ab,kw (Word variations have been searched)
#19	MeSH descriptor: [Self Care] explode all trees
#20	MeSH descriptor: [Exercise Therapy] explode all trees
#21	MeSH descriptor: [Physical Therapy Modalities] explode all trees
#22	MeSH descriptor: [Resistance Training] explode all trees
#23	((pelvic floor or PFM) near/5 (training or exercise* or physiotherap* or physical or therap* or rehabilitat*)):ti,ab,kw (Word variations have been searched)
#24	(PFPT or PFME):ti,ab,kw (Word variations have been searched)
#25	((strength* or resistan*) near/3 (training or exercise* or physiotherap*)):ti,ab,kw (Word variations have been searched)
#26	((pelvic floor or PFM or pelvic muscle*) near/3 strengthen*):ti,ab,kw (Word variations have been searched)
#27	physiotherap*:ti,ab,kw (Word variations have been searched)
#28	MeSH descriptor: [Biofeedback, Psychology] explode all trees
#29	(biofeedback or bio-feedback):ti,ab,kw (Word variations have been searched)
#30	(vagin* near/3 (cone* or ball)):ti,ab,kw (Word variations have been searched)
#31	((intra-vagin* or intravagin) near/3 device*):ti,ab,kw (Word variations have been searched)
#32	((digital* or manual*) near/3 (feedback* or palpat* or assess* or contract*)):ti,ab,kw (Word variations have been searched)
#33	MeSH descriptor: [Electric Stimulation Therapy] explode all trees
#34	(electrostimulat* or electro-stimulat*):ti,ab,kw (Word variations have been searched)
#35	(electr* near/3 stimulat*):ti,ab,kw (Word variations have been searched)
#36	(myofascia* near/3 (release* or therap* or technique*)):ti,ab,kw (Word variations have been searched)
#37	(manual near/3 therap*):ti,ab,kw (Word variations have been searched)
#38	#10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37
#39	#9 and #38

Appendix C – Clinical evidence study selection

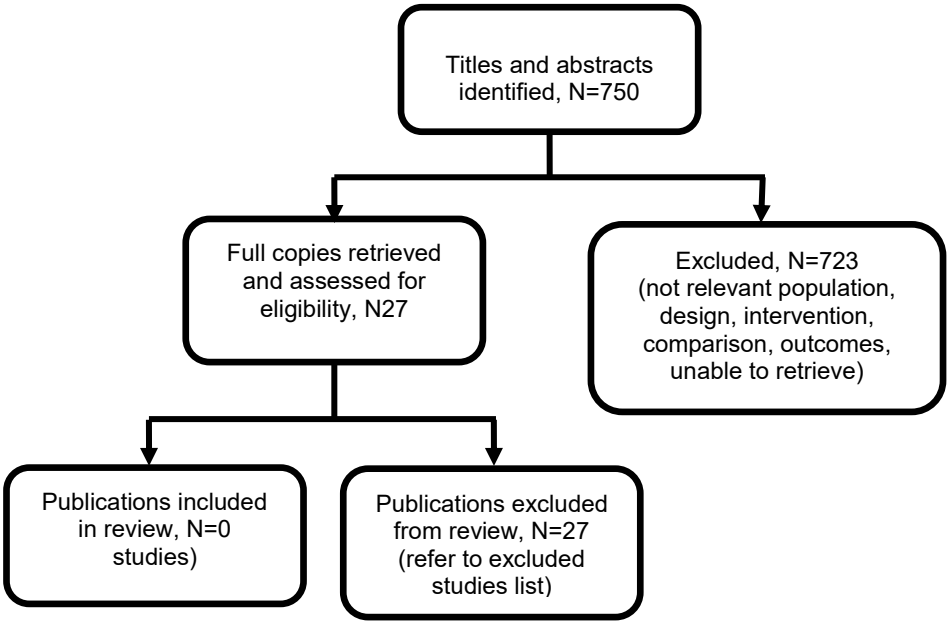
Clinical evidence study selection for review question: What lifestyle interventions are effective for managing pelvic organ prolapse (POP)?

Figure 1: PRISMA flow chart for review question: what lifestyle interventions are effective for managing pelvic organ prolapse (POP)?



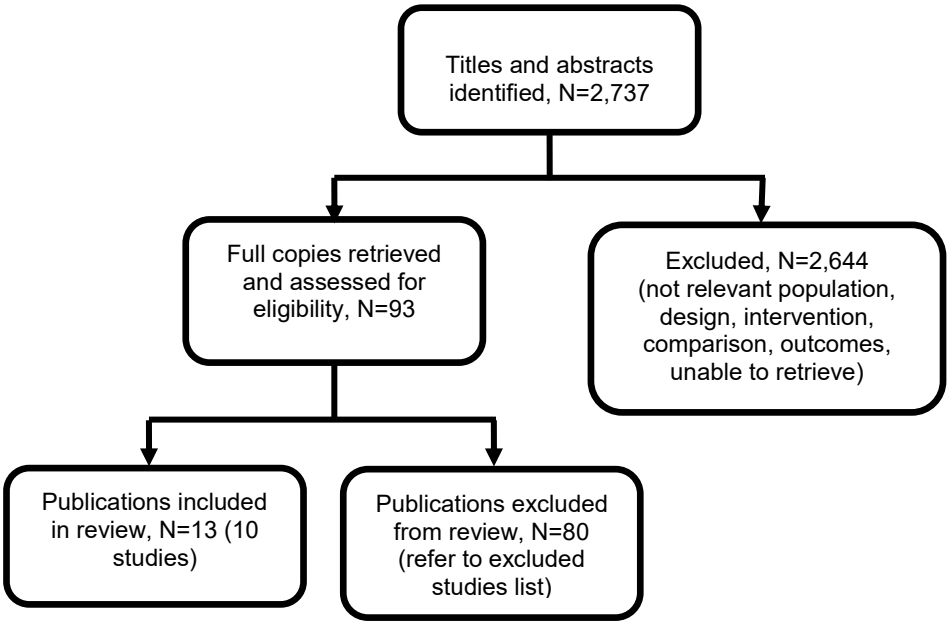
Clinical evidence study selection chart for review question: What is the effectiveness of topical oestrogen for managing pelvic organ prolapse (POP) with vaginal atrophy?

Figure 2: PRISMA flow chart for review question: what is the effectiveness of topical oestrogen for managing pelvic organ prolapse (POP) with vaginal atrophy?



Clinical evidence study selection for the review question: What are the most effective conservative management options (for example, pelvic floor exercises and pessaries) for pelvic organ prolapse (POP)?

Figure 3: PRISMA flow chart for review question: what are the most effective conservative management options for pelvic organ prolapse (POP)?



Appendix D – Clinical evidence tables

Clinical evidence tables for review question: What lifestyle interventions are effective for managing pelvic organ prolapse (POP)?

No studies were identified which were applicable to this review question.

Clinical evidence tables for review question: What is the effectiveness of topical oestrogen for managing pelvic organ prolapse (POP) with vaginal atrophy?

No studies were identified which were applicable to this review question.

Clinical evidence tables for the review question: What are the most effective conservative management options (for example, pelvic floor exercises and pessaries) for pelvic organ prolapse (POP)?

Table 8: Clinical evidence tables

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Due, U., Brostrom, S., Lose, G., The 12-month effects of structured lifestyle advice and pelvic floor muscle training for pelvic organ prolapse, Acta Obstetricia et Gynecologica Scandinavica, 95, 811-9, 2016 Ref Id 541390	Sample size N = 83/109 (76%) at 12-month follow-up Lifestyle advice alone: 43 (no further treatment: N = 13) Supervised PFMT+lifestyle: 40 (no further treatment: N = 21) Characteristics See Due 2016 for Lifestyle advice data	Interventions See Due (2016) Lifestyle advice	Details See Due 2016 Lifestyle advice All women completed the same questionnaires at baseline, 3, 6 and 12 months after inclusion. Statistical analysis Categorical data were analysed using the chi-squared test. Logistic regression analyses were performed to identify possible explanatory factors related to seeking	Results Pelvic organ prolapse distress inventory-6 (POPDI-6) - Mean ± SD (mean difference (± SD) 95% CI) Lifestyle advice alone (n = 13) Baseline: 27.9 (14.1) 12 months: 22.4 (14.0) Mean difference: 5.4 (9.7) (-0.4 to 11.3); p=0.07 Supervised PFMT + lifestyle (n = 21) Baseline: 33.7 (21.6) 12 months: 26.0 (16.8)	Limitations See Due 2016 Lifestyle advice Other information The authors stated that all but one of the 30 women in the control group had sought further treatment before the 6-month follow-up; the majority had sought PFMT. By contrast, women in the supervised PFMT group waited

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Country/ies where the study was carried out Denmark Study type 12-month follow-up of single-blinded, randomised controlled trial Aim of the study To evaluate the medium-term effects of adding pelvic floor muscle training (PFMT) to a structured lifestyle advice programme in women with symptomatic pelvic organ prolapse (POP), stage II-III and to explore factors possibly related to seeking further treatment. Study dates See Due 2016 Source of funding Researchers received various grants from the Association of Danish	Additional treatment - n/N (%) Lifestyle advice alone: 30/43 (70) Supervised PFMT + lifestyle: 19/40 (48) Inclusion criteria See Due 2016 Lifestyle advice Exclusion criteria See Due 2016 Lifestyle advice		further treatment before the 12-month follow-up for the total population: univariable logistic regression analyses performed in variables with ≥80% data completeness and variables included in the forward multivariable logistic regression if a p-value of ≤0.20 achieved. Intention-to-treat Per protocol. The primary investigator remained blinded throughout the study.	Mean difference: 7.7 (14.5) (1.1 to 14.3); p=0.02 Between group differences at 12 months follow-up - mean ± SD Lifestyle advice alone: 22.4 (14.0) Supervised PFMT + lifestyle: 26.0 (16.8); p=0.53 Pelvic floor distress inventory - short form 20 (PFDI-20) - mean ± SD, mean difference (± SD) 95% CI Lifestyle advice alone: Baseline: 71.6 (34.8) 12 months: 47.3 (34.4) Mean difference: 24.3 (29.0) (6.3 to 42.2); p=0.01 Supervised PFMT + lifestyle: Baseline: 81.8 (47.4) 12 months: 67.0 (43.1) Mean difference: 14.8 (26.2) (2.9 to 26.7); p=0.02 Between group differences at 12 months follow-up - mean ± SD Lifestyle advice alone: 47.3 (34.4) Supervised PFMT + lifestyle: 67.0 (43.0); p=0.17	until after the 6-month follow-up before seeking further treatment. The authors acknowledged the following limitations of the study: 1] Large dropout, especially in the supervised PFMT group before the 3-month follow-up. 2] Small sample size.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Physiotherapists, Svenska Cellulosa Aktiebolaget (SCA), Astellas Pharma, and Contura				Pelvic organ prolapse impact questionnaire 7 (POPIQ-7) - mean ± SD, mean difference (± SD) (95% CI) Lifestyle advice alone: Baseline: 4.4 (5.7) 12 months: 5.2 (7.4) Mean difference: -0.7 (7.5) (-5.2 to 3.8); p=0.73 Supervised PFMT + lifestyle: Baseline: 9.1 (10.7) 12 months: 5.9 (8.8) Mean difference: 3.2 (10.7) (-1.7 to 8.0); p=0.19 Between group differences at 12 months follow-up - mean ± SD Lifestyle advice alone: 5.2 (7.4) Supervised PFMT + lifestyle: 5.9 (8.8); p=0.79 Pelvic floor impact questionnaire - short form - mean ± SD, mean difference ± SD, 95% CI Lifestyle advice alone: Baseline: 17.2 (16.7) 12 months: 13.6 (17.5) Mean difference: 2.6 (22.8) (6.3 to 10.1); p=0.57	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Supervised PFMT + lifestyle: Baseline: 24.0 (24.0) 12 months: 17.2 (22.2) Mean difference: 6.8 (16.9) (-0.9 to 14.5); p=0.08 Between group differences at 12 months follow-up - mean ± SD Lifestyle advice alone: 13.6 (17.5) Supervised PFMT + lifestyle: 17.2 (22.2); p=0.62 In the PISQ-12 scores, no significant differences between treatment groups at 12-month follow-up or between women who had received further treatment or not (data not shown). No significant differences between post-intervention symptom scores at 3-month follow-up in either treatment group, comparing women who later sought further treatment with women who did not (data not shown). No significant differences in HRQoL scores between women in the control group who sought further treatment compared with women in the	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				supervised PFMT group who had not sought further treatment. Women in the supervised PFMT group who had sought further treatment did show statistically significant greater impact of their POP-related quality of life compared with women who did not (p=0.03; data not shown). Adverse events - n (%) Not reported.	
Full citation Braekken, I. H., Majida, M., Ellstrom Engh, M., Bo, K., Can pelvic floor muscle training improve sexual function in women with pelvic organ prolapse? A randomized controlled trial, Journal of Sexual Medicine, 12, 470-80, 2015 Ref Id 541296	Sample size See Braekken 2010 Characteristics See Braekken 2010 Inclusion criteria See Braekken 2010 Exclusion criteria See Braekken 2010	Interventions See Braekken 2010	Details See Braekken 2010	Results <u>Change in sexual function (compared to 6 months previously) - n (%)</u> <u>Unchanged/worsened</u> Supervised PFMT: 30 (61.2) Lifestyle advice: 39 (95.1) <u>Improvement</u> Supervised PFMT: 19 (38.7) Lifestyle advice: 2 (4.8) <u>Cured</u> Supervised PFMT: 0 Lifestyle advice: 0 <u>Adverse events - n (%)</u> Supervised PFMT: 0	Limitations See Braekken 2010 Other information See Braekken 2010

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Country/ies where the study was carried out Norway Study type Secondary analysis of partially blind RCT (Braekken 2010) Aim of the study To evaluate the effect of PFMT on sexual function in women with POP, including frequency of sexual intercourse, sexual satisfaction, ability to orgasm, and other issues women reported as affecting their sex life. To determine if any improvements in sexual function were related to increases in PFM function (strength, endurance, and vaginal resting pressure). Study dates				Lifestyle advice: 0	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
November 2005 and April 2008 Source of funding Norwegian Foundation for Health and Rehabilitation, the Norwegian Women's Public Health Association and The Norwegian Fund for Post-graduate Training in Physiotherapy.					
Full citation Braekken,I.H., Majida,M., Engh,M.E., Bo,K., Can pelvic floor muscle training reverse pelvic organ prolapse and reduce prolapse symptoms? An assessor-blinded, randomized, controlled trial, American Journal of Obstetrics and Gynecology, 203, 170-177, 2010 Ref Id 109863	Sample size N = 109 Supervised PFMT: 59 Lifestyle advice: 50 Characteristics <u>Age - mean ± SD (years)</u> Supervised PFMT: 49.4 (12.2) Lifestyle advice: 48.3 (11.4) <u>BMI - mean ± SD (kg/m²)</u> Supervised PFMT: 25.8 (3.8) Lifestyle advice: 26.18 (5.3)	Interventions Supervised PFMT: Women advised to avoid straining and taught how to contract their PFM before and during increases in abdominal pressure ("the Knack"). Women advised to do 3 sets of 8 to 12 close to maximum PFM contractions per day and record home training adherence in an exercise diary. Women received a booklet and a DVD showing the exercise programme, and	Details Participants completed postal questionnaires before baseline assessment and were examined on their ability to contract the PFM and measured on PFM function. Participants were stratified by severity of prolapse: • Maximal vaginal descent at or above the hymen • Maximal vaginal descent below the hymen Randomisation	Results <u>Change in stage of POP (POP-Q) - n/N (%)</u> <u>Stage I</u> Supervised PFMT: 0/8 (0) Lifestyle advice: 0/11 (0) <u>Stage II</u> Supervised PFMT: 6/36 (16.7) Lifestyle advice: 1/29 (3.4) <u>Stage III</u> Supervised PFMT: 5/14 (35.7) Lifestyle advice: 3/10 (30.0) Improvement in prolapse symptoms; vaginal bulging and/or heaviness - n (%) - mean difference (%) and ORs (95% CIs) <u>Reduced frequency</u>	Limitations Random sequence: Low risk of bias Allocation concealment: Low risk of bias Blinding: High risk of bias (assessor blinded only) Incomplete outcome data: High risk of bias (>10% dropout) Selective reporting: Low risk of bias

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Country/ies where the study was carried out Norway Study type Assessor blinded, randomised, controlled, parallel trial with stratification on severity of POP Aim of the study To evaluate whether PFMT can 1] reverse and prevent further development of POP, and 2] reduce symptoms related to POP Study dates November 2005 to April 2008 Source of funding Norwegian Foundation for Health and Rehabilitation and the Norwegian Women's Public Health Association.	Parity - mean ± SD Supervised PFMT: 2.4 (0.8) Lifestyle advice: 2.4 (0.7) With anterior wall POP - n (%) Supervised PFMT: 54 (93.1) Lifestyle advice: 49 (98.0) With posterior wall POP - n (%) Supervised PFMT: 46 (79.3) Lifestyle advice: 42 (84.0) With apical POP - n (%) Supervised PFMT: 47 (81.0) Lifestyle advice: 41 (82.0) Stage of POP (POP-Q) - n (%) Stage I Supervised PFMT: 8 (13.8) Lifestyle advice: 11 (22.0) Stage II Supervised PFMT: 36 (63.8) Lifestyle advice: 29 (58.0)	individually supervised by a physical therapist. Lifestyle advice: Women advised to avoid straining and taught how to contract their PFM before and during increases in abdominal pressure ("the Knack"). Women were asked not to change frequency of, or to start, PFMT during the intervention period. Women were individually supervised by a physical therapist.	Within each strata, a computer-generated random number system with concealed envelopes, randomly assigned women to either treatment group. Statistical analysis Continuous data (means, 95% CIs) checked for normality by Kolmogorov-Smirnov and Shapiro-Wilk tests. Between and within groups comparisons tested with Student *t* test (normally distributed data), Wilcoxon signed rank test, and Mann-Whitney *U* test (not normally distributed data. Treatment effect calculated using effect sizes. Differences between groups in baseline categorical data analysed by X^2. Treatment effect calculated for differences between groups with 95% CI and odds ratios (ORs) with 95% CI. Power calculation With power of 80%, a sample size of 45 per group was required. Intention-to-treat (ITT)	Supervised PFMT: 32 (74) Lifestyle advice: 8 (31) Mean difference: 43.6 (21.6 to 65.7); p=0.000 OR: 6.55 (2.23 to 19.24) Reduced bother Supervised PFMT: 29 (67) Lifestyle advice: 11 (42) Mean difference: 25.1 (1.5 to 48.7); p=0.000 OR: 2.82 (1.03 to 7.73) Adverse events Supervised PFMT: 0 Lifestyle advice: 0 Subgroup analyses 40 women with prolapse below the hymen demonstrated a reduction in frequency of prolapse symptoms in 56% (14/25) of the supervised PFMT group compared with 15% in the lifestyle advice group (p=0.008;X^2).	Other bias: Unclear risk of bias (PFMT adherence unclear; potential for controls to perform exercises). Other information The authors acknowledged the following limitations of the study: • Differences between groups in prolapse symptoms at baseline. • Small sample size. • Differences in amount of time spent by the physical therapist between groups. • Results may not be generalisable to women with more

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Stage III Supervised PFMT: 14 (22.4) Lifestyle advice: 10 (20.0) With positive POP-Q value - n (%) Supervised PFMT: 25 (41.3) Lifestyle advice: 25 (30.0) Prolapse symptoms - n (%) Supervised PFMT: 43 (72.9) Lifestyle advice: 26 (52.0) Inclusion criteria • Women with POP stages I, II and III as determined by the POP-Q • Women were at least 1 year post-partum Exclusion criteria • POP stage 0 or IV		ITT analyses used and baseline values carried forward for the 1 woman who dropped out in each treatment group.		severe POP. • Study not powered to do subgroup analyses.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• Inability to contract the PFM • Breastfeeding • Previous POP surgery • Radiating back pain • Pelvic cancer • Neurologic disorders • Psychiatric disorders • Untreated urinary tract infection • Planning to become pregnant during the next 6 months • Planning to be away for more than 4 weeks of the intervention period				
Full citation Kashyap, R., Jain, V., Singh, A., Comparative effect of 2 packages of pelvic floor muscle training on the clinical course of stage I-III pelvic	Sample size N = 140 PFMT + self instruction manual (SIM): 70 SIM: 70 Characteristics Age - mean (range) (years), SD not reported	Interventions PFMT + SIM: 1-to-1 PFMT given by principal investigator; participants demonstrated exercises and checked for correct positioning. + self-instruction manual which included a set of exercises repeated 3	Details Standardised history taken at baseline for both groups. PFMT + SIM group followed up at weeks 1, 3, 6, 12, 18 and 24. controls followed up at weeks 6, 18, and 24.	Results POP-SS score - mean, SD not reported Baseline: PFMT + SIM: 6.03 SIM: 7.11 12 weeks follow-up PFMT + SIM: 3.57 SIM: NA 18 weeks follow-up	Limitations Random sequence: Low risk of bias Allocation concealment: Low risk of bias

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
organ prolapse, International Journal of Gynaecology & Obstetrics, 121, 69-73, 2013 Ref Id 541483 Country/ies where the study was carried out India Study type Randomised controlled trial (not blinded) Aim of the study To compare the effect of two packages of PFMT on the clinical course of stage I-III POP among women attending a gynaecology outpatient department at a single centre in India Study dates August 2010 to October 2011	PFMT + SIM: 46 (23-70) SIM: 47 (25-70) <u>Postmenopausal - n (%)</u> PFMT + SIM: 33 (47.1) SIM: 27 (38.5) <u>Parity - mean ± SD</u> PFMT + SIM: 3 (1.23) SIM: 3 (1.44) <u>Co-morbidities - n (%)</u> PFMT + SIM: 23 (32.8) SIM: 16 (22.8) <u>POP-ss score - mean ± SD</u> PFMT + SIM: 6.03 (5.52) SIM: 7.11 (5.00) <u>VAS score - mean ± SD</u> PFMT + SIM: 32.19 (27.24) SIM: 37.81 (24.01) <u>PFIQ-7 score - mean ± SD</u> PFMT + SIM: 11.57 (5.20) SIM: 12.91 (5.77) <u>POP - n (%)</u> <u>Stage I</u> PFMT + SIM: 37 (52.9) SIM: 52 (74.3)	times daily at home (each set comprised up to 10 voluntary contractions, each held for 10 seconds with 10-second rest in between). SIM: Identical self instruction manual to supervised PFMT group.	Randomisation Block randomisation with sequence allocation generated by a physician not involved in the study. Statistical analysis Baseline and follow-up comparisons conducted using the Wilcoxon signed rank test. Between-group differences evaluated by the Mann-Whitney *U* test. Power calculation 65 women required for 90% power, but 70 recruited to each treatment arm to allow for drop-out. Intention-to-treat ITT analysis followed.	PFMT + SIM: 3.23 SIM: 5.89 <u>Change from baseline at week 18</u> PFMT + SIM: -2.80 SIM: -1.22; p=0.001 <u>24 weeks follow-up</u> PFMT + SIM: 3.04 SIM: 5.86 <u>Change from baseline at week 24</u> PFMT + SIM: -2.99 SIM: -1.25; p=0.002 <u>PFIQ-7 score - mean</u> <u>Baseline:</u> PFMT + SIM: 11.57 SIM: 12.91; p=0.115 <u>12 weeks follow-up</u> PFMT + SIM: 8.83 SIM: NA <u>18 weeks follow-up</u> PFMT + SIM: 8.46 SIM: 11.33, p<0.001 <u>24 weeks follow-up</u> PFMT + SIM: 8.30 SIM: 11.01, p<0.001 <u>VAS score - mean</u> <u>Baseline:</u> PFMT + SIM: 32.19 SIM: 37.81, p=0.140 <u>18 weeks follow-up</u> PFMT + SIM: 17.84 SIM: 27.03, p=0.009 <u>24 weeks follow-up</u> PFMT + SIM: 16.21 SIM: 24.97, p=0.005	Blinding: High risk of bias (not blinded) Incomplete outcome data: High risk of bias (>10% dropout) Selective reporting: Low risk of bias Other bias: Unclear risk of bias (unclear adherence to exercise) Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding None stated	<u>Stage II</u> PFMT + SIM: 26 (37.1) SIM: 11 (15.7) <u>Stage III</u> PFMT + SIM: 7 (10.0) SIM: 7 (10.0) Inclusion criteria • Parous women aged 20 to 70 years • Willing to attend follow-up visits Exclusion criteria • Women with POP stage IV disease • Women with other diseases likely to affect the ability to train (i.e. radiating back pain, neurologic disorders, previous pelvic cancer, psychiatric disease, or asthma) • Pregnancy • Breastfeeding			<u>Adverse events - n (%)</u> Not reported.	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• Planned absence of more than 4 weeks				
Full citation Panman, C. M. C. R., Wiegersma, M., Kollen, B. J., Berger, M. Y., Lisman-Van Leeuwen, Y., Vermeulen, K. M., Dekker, J. H., Effectiveness and cost-effectiveness of pessary treatment compared with pelvic floor muscle training in older women with pelvic organ prolapse: 2-year follow-up of a randomized controlled trial in primary care, Menopause, 23, 1307-1318, 2016 Ref Id 642845 Country/ies where the study was carried out	Sample size N = 162 PFMT: N=80 Pessary treatment: N=82 Characteristics <u>Age - mean ± SD (years)</u> PFMT: 65.6 (6.4) Pessary: 64.9 (7.4) <u>BMI - mean ± SD (kg/m²)</u> PFMT: 26.6 (4.3) Pessary: 26.1 (3.8) <u>Parity - mean ± SD</u> PFMT: 2.6 (1.1) Pessary: 2.4 (0.9) <u>Postmenopausal - n (%)</u> PFMT: 80 (100) Pessary: 81 (98.8) <u>Surgical history - n (%)</u> <u>Hysterectomy</u> PFMT: 10 (12.5) Pessary: 15 (18.3) <u>Pelvic floor surgery</u>	Interventions PFMT: Treatment with pelvic physiotherapist, and feedback during digital palpation or, if necessary, by applying myofeedback or electrical stimulation. Pessary treatment: Pessaries fitted by a trained research physician. The first choice was an open ring pessary, followed by a ring pessary with support.	Details PFMT: Exercises during face-to-face and at home (3-5 times a week, 2 or 3 times each day). All patients started with the same exercise regimen, which was later tailored to the needs of each participants. For women with an overactive pelvic floor, relaxation exercises were used rather than contraction. All women were taught 'the knack' - how to contract their pelvic floor muscles before and during any increase in abdominal pressure. Attention paid to toilet habits and lifestyle (e.g. diet, smoking, and body weight). Pessary treatment: Participants in whom the pessary fell out or who experienced discomfort within the first 2 weeks were refitted with a different type or size of	Results <u>PFDI-20 - mean ± SD</u> <u>Baseline</u> PFMT (n=75): 65.0 (35.8) Pessary (n=79): 59.8 (33.7) <u>3 months follow-up</u> PFMT (n=69): 55.8 (37.4) Pessary (n=43): 50.1 (30.6) <u>12 months follow-up</u> PFMT (n=66): 60.2 (40.9) Pessary (n=45): 50.6 (35.9) Difference at 24 months follow-up - mean, 95% CI (ITT adjusted): -3.7 (-12.8 to 5.3); p=0.42 <u>POPDI-6 - mean ± SD</u> <u>Baseline</u> PFMT (n=78): 16.9 (13.00) Pessary (n=81): 17.4 (13.50) <u>3 months follow-up</u> PFMT (n=70): 15.6 (13.6) Pessary (n=45): 13.2 (12.5) <u>12 months follow-up</u> PFMT (n=69): 16.4 (15.4) Pessary (n=48): 12.8 (12.8) Difference at 24 months follow-up - mean, 95% CI (ITT adjusted): -3.2 (-6.3 to -0.0); p=0.047 <u>CRADI-8 - mean ± SD</u>	Limitations Random sequence: Low risk of bias Allocation concealment: Low risk of bias Blinding: High risk of bias (not blinded) Incomplete outcome data: High risk of bias (>10% dropout) Selective reporting: Low risk of bias Other bias: Unclear risk of bias (PFMT adherence unclear) Other information PFMT: Myofeedback used in 14 women (22%)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
The Netherlands Study type Randomised controlled trial (not blinded) Aim of the study To compare the effectiveness (defined as improvement of pelvic floor symptoms) and the cost-effectiveness of pessary treatment and PFMT in a primary care population of women aged at least 55 years with a symptomatic POP at or beyond the hymen. Study dates October 2009 to December 2012 Source of funding Funded by the Netherlands Organisation for Health Research and Development (ZonMw)	PFMT: 7 (8.8) Pessary: 8 (9.8) Prior prolapse treatment PFMT: 21 (26.3) Pessary: 18 (22.0) Stage of prolapse - n (%) Stage II PFMT: 62 (77.5) Pessary: 58 (70.7) Stage III PFMT: 18 (22.5) Pessary: 24 (29.3) Type of prolapse - n (%) Anterior PFMT: 25 (31.3) Pessary: 20 (24.7) Posterior PFMT: 3 (3.8) Pessary: 0 Apical PFMT: 0 Pessary: 0 Anterior and posterior PFMT: 26 (32.5) Pessary: 23 (28.4) Anterior and apical PFMT: 8 (10.0) Pessary: 19 (23.5) Posterior and apical PFMT: 2 (2.5) Pessary: 0 Anterior and posterior and apical		pessary and reviewed again after another 2 weeks. If a pessary was not fitted successfully after 3 attempts, pessary fitting was regarded as unsuccessful. When a pessary led to vaginal discharge, irritation, or erosions, women were advised not to wear the pessary for 2 weeks. Topical oestrogen was suggested in cases of discharge or ulceration due to vaginal atrophy. Randomisation Random allocation in a 1:1 ratio using an external computer system with an interactive void response system (accessible by telephone). Block randomisation with variable block sizes used. Statistical analysis Linear multilevel analysis using both a fixed effect and random effects model, conducted to test the longitudinal difference between treatment groups for primary and secondary outcomes. Missing data were not imputed . Normal	Baseline PFMT (n=75): 18.1 (15.0) Pessary (n=81): 15.7 (13.8) 3 months follow-up PFMT (n=70): 16.8 (16.4) Pessary (n=43): 12.4 (10.5) 12 months follow-up PFMT (n=66): 17.7 (15.5) Pessary (n=48): 14.2 (12.3) Difference at 24 months follow-up - mean, 95% CI (ITT adjusted): -2.0 (-5.3 to 1.2); p=0.22 UDI-6 - mean ± SD Baseline PFMT (n=76): 30.4 (17.0) Pessary (n=81): 27.2 (17.5) 3 months follow-up PFMT (n=70): 23.3 (16.6) Pessary (n=44): 23.7 (16.3) 12 months follow-up PFMT (n=68): 25.0 (18.5) Pessary (n=47): 22.3 (17.9) Difference at 24 months follow-up - mean, 95% CI (ITT adjusted): 1.1 (-3.3 to 5.5); p=0.63 PFIQ-7 - mean ± SD Baseline PFMT (n=74): 19.4 (25.9) Pessary (n=79): 18.5 (28.2) 3 months follow-up PFMT (n=65): 15.3 (20.1) Pessary (n=41): 13.1 (26.1) 12 months follow-up PFMT (n=66): 15.8 (26.0)	and electric stimulation in 9 women (14%). The authors acknowledged the following limitations: • Conclusions can only be drawn in women who completed pessary treatment or PFMT, and not in women with unsuccessful pessary fitting • Large proportion of pessary fitting failures • High attrition rates • Lack of blinding

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	PFMT: 16 (20.0) Pessary: 19 (23.5) Inclusion criteria All women aged at least 55 years registered in a participating primary care practice. Exclusion criteria • Women who had undergone prolapse treatment in the previous year • Currently undergoing treatment for another urogynaecological disorder • Women with a pelvic organ malignancy • Impaired mobility • Severe or terminal illness • Cognitive impairment • Insufficient Dutch language comprehension		probability plots and plots of standardised residual versus predicted values were inspected to assess if they met the assumptions of normality and homogeneity of the variance. In the event of non-compliance, a square root transformation of one of the baseline variables was performed. Power calculation For power of 80%, successful pessary fitting in 70%, and a dropout rate of 15% after 2 years, 148 women were required. Intention-to-treat ITT and per protocol analyses conducted.	Pessary (n=50): 19.1 (36.9) Difference at 24 months follow-up - mean, 95% CI (ITT adjusted); 1.2 (-5.3 to 7.7); p=0.72 <u>PISQ-12 - mean ± SD</u> <u>Baseline</u> PFMT (n=29): 37.4 (4.1) Pessary (n=41): 35.5 (5.1) <u>3 months follow-up</u> PFMT (n=25): 37.7 (4.7) Pessary (n=19): 37.7 (4.5) <u>12 months follow-up</u> PFMT (n=24): 37.6 (4.2) Pessary (n=24): 35.3 (5.9) Difference at 24 months follow-up - mean, 95% CI (ITT adjusted): 0.2 (-1.2 to 1.5); p=0.83 <u>PCS-12 (SF-12) - mean ± SD</u> <u>Baseline</u> PFMT (n=70): 46.9 (11.4) Pessary (n=73): 45.4 (9.9) <u>3 month follow-up</u> PFMT (n=64): 46.4 (10.0) Pessary (n=44): 46.7 (9.5) <u>12 months follow-up</u> PFMT (n=65): 46.0 (10.4) Pessary (n=43): 47.2 (8.8) Difference at 24 months follow-up - mean, 95% CI (ITT adjusted): 2.1 (0.0 to 4.1); p=0.05	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				MCS-12 (SF-12) - mean ± SD Baseline PFMT (n=70): 51.9 (8.9) Pessary (n=73): 52.2 (10.1) 3 months follow-up PFMT (n=64): 52.3 (8.7) Pessary (n=44): 52.1 (10.4) 12 months follow-up PFMT (n=65): 53.5 (8.3) Pessary (n=43): 51.6 (10.3) Difference at 24 months follow-up - mean, 95% CI (ITT adjusted): -1.2 (-3.3 to 0.8); p=0.24 Self-reported change of symptoms from start of study - n (%) (ITT) Much better/better PFMT: 24 (35) Pessary treatment: 25 (34) Same PFMT: 35 (50) Pessary treatment: 41 (57) Worse/much worse PFMT: 11 (16) Pessary treatment: 6 (8) Adverse events at 24 months - n/N (%) PFMT: 0 Pessary: 21/35 (60): Increased vaginal discharge: n=14 Irritation or erosions of the vaginal walls: n=10 Urinary incontinence: n=5	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Due, U., Brostrom, S., Lose, G., Lifestyle advice with or without pelvic floor muscle training for pelvic organ prolapse: a randomized controlled trial, International Urogynecology Journal, 27, 555-63, 2016 Ref Id 541389 Country/ies where the study was carried out Denmark Study type Single-blinded, randomised controlled trial Aim of the study To examine whether pelvic floor muscle training (PFMT) in combination with a structured lifestyle	Sample size N = 109 Lifestyle advice alone: N = 53 Lifestyle advice + PFMT (supervised PFMT): N = 56 Characteristics <u>Age - Mean (range) (years), SD not reported</u> Lifestyle advice alone: 58 (34-79) Supervised PFMT: 60 (33-79) <u>BMI - Mean (range) (kg/m²), SD not reported</u> Lifestyle advice alone: 25 (20-36) Supervised PFMT: 24 (19-37) <u>Parity - Mean, range</u> Lifestyle advice alone: 2 (1-4) Supervised PFMT: 2 (1-9) <u>Surgery - N (%)</u> Lifestyle advice alone: 7 (13)	Interventions Lifestyle advice alone: 6 PowerPoint teaching modules lasting 45-60 minutes each, including: • Introduction to POP and how to reduce pressure on the pelvic floor • Bladder function and POP • Bowel function and POP and how to improve micturition and defecation technique • Diet, weight loss, and POP • Quality of life and POP and impact of POP on body image and sexuality • Sports and POP an how to increase level of activity without increasing pressure on the pelvic floor • Offered handouts during sessions, bladder and	Details All participants received 6 group sessions within 12 weeks. Only participants from the supervised PFMT group received an appointment with a specialised pelvic floor physical therapist for visual and digital assessment of their pelvic floor muscle function and an individual instruction in PFMT before starting group sessions. Women unable to contract their pelvic floor muscles correctly were offered more individual sessions before starting group training. Lifestyle advice alone sessions and sessions with PFMT were held on separate days and the 2 groups never met. Postmenopausal women with signs of vaginal atrophy were routinely offered vaginal oestrogen. Randomisation	Results <u>Symptom and bother - mean ± SD</u> <u>POPDI-6</u> Lifestyle advice alone: Baseline: 30.3 (19.6) 3-months follow-up:29.3 (17.0) 6 months follow-up: 27.3 (15.4) Supervised PFMT: Baseline: 37.2 (24.4); p=0.11 3-months follow-up: 30.6 (23.0); p=0.74 6-months follow-up: 27.5 (21.3); p=0.96 <u>CRADI-8</u> Lifestyle advice alone: Baseline: 24.2 (18.5) 3-months follow-up: 19.0 (16.7) 6-months follow-up: 17.0 (13.6) Supervised PFMT: Baseline: 24.6 (21.3); p=0.93 3-months follow-up: 20.5 (18.0); p=0.65 6-months follow-up: 21.7 (19.6); p=0.20 <u>UDI-6</u> Lifestyle advice alone: Baseline: 32.3 (22.6) 3-months follow-up: 26.4 (21.0)	Limitations Random sequence: Low risk of bias (computer-generated random numbers with stratification for age groups ≥60 years Allocation concealment: Low risk of bias (randomised closed envelopes) Blinding: High risk of bias (single primary investigator blinded) Incomplete outcome data: Low risk of bias (reasons for discontinuing stated and do not appear to be related to treatment) Selective reporting: Low risk of bias Other bias: Unclear risk of bias (authors

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
advice programme would have better effect on a global improvement scale than a structured lifestyle advice programme alone in women with symptomatic pelvic organ prolapse (POP) stage II or greater. Study dates October 2012 to December 2013 Source of funding Grants from Astellas Pharma, Coloplast, and SCA	Supervised PFMT: 9 (16) <u>Objective POP at baseline - n (%)</u> <u>POP-Q stage II/III</u> Lifestyle advice alone: 29/24 (55/45) Supervised PFMT: 33/23 (59/41) <u>Anterior</u> Lifestyle advice alone: 47 (89) Supervised PFMT: 49 (88) <u>Posterior</u> Lifestyle advice alone: 34 (64) Supervised PFMT: 36 (64) <u>Anterior 0cm or greater</u> Lifestyle advice alone: 38 (71) Supervised PFMT: 40 (71) <u>Posterior 0cm or greater</u> Lifestyle advice alone: 28 (53) Supervised PFMT: 30 (54) Inclusion criteria • Women aged at least 18 years with Pelvic	bowel diaries, and encouraged to try out any lifestyle advice relevant for their specific POP-related symptoms Supervised PFMT: • Identical lifestyle advice sessions as controls. • Group PFMT with focus on conscious pre-contractions before an increased intra-abdominal pressure (Knack training). • Home training based on generally accepted training principles, performed 5 days a week: 3 sets of 10 sustained (10 second) pelvic floor muscle contractions and knack training	Statistician provided computer-generated random numbers with stratification for age groups 60 years or older. Participants drew one closed envelope each. Statistical analysis Categorical data analysed using chi-square test, and relative risk (RR) was calculated for improvement on the Patient Global Index of Improvement Scale (PGI-I). Power calculation Power of 80% at a 5% significance level needed to enrol 45 women in each arm. Intention-to-treat analysis 3 and 6 month follow-up analyses performed using intention-to-treat (ITT) and last observation carried forward (LOCF). Univariate and multivariate forward logistic regression analyses (p value 0.20 or less, 80% or greater data completeness) performed to find possible baseline predictors of improvement at 3 month follow-up.	6-months follow-up: 20.4 (17.5) Supervised PFMT: Baseline: 29.6 (23.2); p=0.53 3-months follow-up: 24.7 (22.0); p=0.68 6-months follow-up: 23.4 (20.9); p=0.47 <u>PFDI-20</u> Lifestyle advice alone: Baseline: 87.0 (46.3) 3-months follow-up: 74.6 (39.5) 6-months follow-up: 64.7 (32.7) Supervised PFMT: Baseline: 91.3 (59.7) p=0.67 3-months follow-up: 75.7 (55.2); p=0.90 6-months follow-up: 72.6 (51.8); p=0.40 <u>Quality of life - mean ± SD</u> <u>UIQ-7</u> Lifestyle advice alone: Baseline: 18.3 (20.6) 3-months follow-up: 13.7 (18.0) 6-months follow-up: 9.6 (15.5) Supervised PFMT: Baseline: 12.7 (18.3); p=0.13 3-months follow-up: 11.5 (17.9); p=0.52 6-months follow-up: 11.1 (17.1); p=0.68	acknowledge potential for selection bias - only 11% of women contacted from hospital referral lists accepted recruitment; PFMT adherence unclear; potential for controls to perform exercises) Other information The authors acknowledged the following limitations: • Over optimistic sample size calculation as both groups reached predefined smallest relevant change of 15% • Potential that a larger sample would have given a

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Organ Prolapse Quantification system (POP-Q) of stage II of more. • At least one of three symptoms: seeing or feeling a bulge in the vaginal opening; voiding dysfunctions or defecation problems; feeling vaginal heaviness. • Fluency of Danish language. Exclusion criteria • Dementia • Symptomatic neurological disease, including serious back problems • PFMT within the last 2 years • Childbirth within the last year	during everyday activities	Level of significance set at p=0.05.	<u>CRAIQ-7</u> Lifestyle advice alone: Baseline: 8.15 (16.0) 3-months follow-up: 5.7 (14.8) 6-months follow-up: 2.0 (4.8) Supervised PFMT: Baseline: 10.0 (18.6); p=0.59 3-months follow-up: 10.2 (18.5); p=0.16 6-months follow-up: 7.3 (14.7); p=0.037 <u>POPIQ-7</u> Lifestyle advice alone: Baseline 12.2 (19.8) 3-months follow-up: 9.3 (17.4) 6-months follow-up: 9.0 (17.8) Supervised PFMT: Baseline: 13.8 (18.8) p=0.67 3-months follow-up: 12.0 (18.9); p=0.45 6-months follow-up: 10.0 (17.6); p=0.79 <u>PFIQ-7</u> Lifestyle advice alone: Baseline: 37.8 (45.1) 3-months follow-up: 28.7 (38.3) 6-months follow-up: 20.7 (30.3) Supervised PFMT: Baseline: 36.4 (47.0); p=0.87	different result

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	• More than one surgical treatment for POP or urinary incontinence • Women with POP stage I			3-months follow-up: 33.8 (48.0); p=0.55 6-months follow-up: 29.0 (43.2); p=0.31 <u>Adverse events - n (%)</u> Not reported.	
Full citation Hagen, S., Glazener, C., McClurg, D., Macarthur, C., Elders, A., Herbison, P., Wilson, D., Toozs-Hobson, P., Hemming, C., Hay-Smith, J., Collins, M., Dickson, S., Logan, J., Pelvic floor muscle training for secondary prevention of pelvic organ prolapse (PREVPROL): a multicentre randomised controlled trial, LancetLancet, 389, 393-402, 2017 Ref Id 619344	Sample size N = 412 Supervised PFMT: n=206 Lifestyle advice alone: n=206 Characteristics <u>Age - mean ± SD (years)</u> Supervised PFMT: 46.4 (4.7) Lifestyle advice alone: 46.6 (4.6) <u>Parity -median (range)</u> Supervised PFMT: 2 (1 to 11) Lifestyle advice alone: 2 (1 to 8) <u>Stage of prolapse - n (%)</u> <u>Stage I or II above or at the hymen</u> Supervised PFMT: 199 (97)	Interventions Supervised PFMT: 1-to-1 sessions and in a class setting. 5 appointments with specialist women's health physiotherapist over 16 weeks Lifestyle advice alone: Received by post, the same prolapse lifestyle advice leaflet as intervention group.	Details Supervised PFMT: Taught correct exercise technique, prescribed an individualised home PFMT programme (3 sets of exercises daily), prolapse lifestyle advice leaflet (focus on weight loss, avoidance of heavy lifting, constipation, coughing, and high-impact exercise), and tailored lifestyle advice (phase I). Offered modified Pilates classes (with pelvic floor muscle exercises and exercise DVD for home use) in 2 x 6 week blocks, and 1-to-1 physiotherapy review appointment at years 1 and 2 (phase II). Randomisation Women randomly assigned on 1:1 ratio (minimised by centre, parity (3 or less vs more	Results <u>POP-SS - mean ± SD</u> <u>Baseline</u> Supervised PFMT (n=206): 4.4 (4.5) Lifestyle advice alone (n=206): 3.9 (3.7) <u>1-year follow-up</u> Supervised PFMT (n=159): 3.2 (3.5) Lifestyle advice alone (n=164): 3.9 (3.7) Effect size (95% CI): -0.98 (-1.61 to -0.35); p=0.002 <u>2-year follow-up</u> Supervised PFMT (n=161): 3.2 (3.4) Lifestyle advice alone (n=180): 4.2 (4.4) Effect size (95% CI): -1.01 (-1.70 to -0.33); p=0.004 <u>POP-SS of 0 - n (%)</u> <u>Baseline</u> Supervised PFMT (n=206): 41 (20)	Limitations Random sequence: Low risk of bias (computer-generated) Allocation concealment: Low risk of bias Blinding: High risk of bias (participants and physiotherapists not blinded) Incomplete outcome data: Unclear risk of bias (reasons for discontinuing over 2 years not stated) Selective reporting: Low risk of bias

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Country/ies where the study was carried out UK and New Zealand Study type Multicentre, parallel-group, randomised controlled trial Aim of the study To identify the clinical and cost-effectiveness of PFMT in the secondary prevention of prolapse symptoms, worsening of prolapse severity, and uptake of prolapse treatment. Study dates December 2008 to February 2010 (New Zealand); October 2010 to September 2011 (UK) Source of funding Wellbeing of Women charity, the New Zealand Continence Association, and the	Lifestyle advice alone: 200 (97) <u>Stage I</u> Supervised PFMT: 90 (44) Lifestyle advice alone: 96 (47) <u>Stage II above or at the hymen</u> Supervised PFMT: 109 (53) Lifestyle advice alone: 104 (50) <u>Stage II beyond the hymen</u> Supervised PFMT: 6 (3) Lifestyle advice alone: 6 (3) <u>Stage III</u> Supervised PFMT: 1 (<1) Lifestyle advice alone: 0 <u>Leading edge of prolapse - n (%)</u> <u>Anterior only</u> Supervised PFMT: 101 (49) Lifestyle advice alone: 97 (47) <u>Posterior only</u> Supervised PFMT: 41 (20) Lifestyle advice alone: 44 (21) <u>Anterior and posterior</u> Supervised PFMT: 64 (31)		than 3 deliveries), prolapse stage (above hymen vs at or beyond the hymen), and delivery method (any vaginal vs all caesarean sections). Statistical analyses POP-SS scores compared with repeated measures mixed models with compound symmetry covariance matrices. Other continuous outcomes analysed with ANCOVA, and binary and ordinal outcomes analysed with binary and ordinal logistic regression, respectively. All adjusted for age, minimisation variables, and baseline measurements. Pre-specified sensitivity analyses to examine effect of missing POP-SS data under various assumptions (data missing at random by use of multiple imputation, with subsequent assumptions that data were missing not at random). Missing data assumed to be better than expected (1 point lower than the imputed value assuming missing at	Lifestyle advice alone (n=206):40 (19) <u>1-year follow-up</u> Supervised PFMT (n=159): 41 (26) Lifestyle advice alone (n=164): 27 (16) <u>2-year follow-up</u> Supervised PFMT (n=161): 35 (22) Lifestyle advice alone (n=180): 36 (20) <u>Prolapse related quality-of-life scores - mean ± SD</u> <u>Prolapse interferes with physical activity - baseline</u> Supervised PFMT (n=194): 0.8 (2.1) Lifestyle advice alone (n=194): 0.6 (1.7) <u>2-year follow-up</u> Supervised PFMT (166): 0.6 (1.6) Lifestyle advice alone (n=178): 0.8 (1.9) Adjusted mean difference at 2 years (95% CI): -0.18 (-0.51 to 0.15); p=0.286 <u>Prolapse interferes with social activity - baseline</u> Supervised PFMT (n=191): 0.5 (1.6) Lifestyle advice alone (n=195): 0.5 (1.6) <u>2-year follow-up</u>	Other bias: Unclear risk of bias (PFMT adherence unclear; potential for controls to perform exercises). Other information The authors acknowledged the following limitations: • Difference between UK and New Zealand timings of pretrial prolapse assessment • Unmasked study Participants had been involved in a longitudinal study of women after an index birth occurring between October (1993) and September (1994)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Dean's Bequest Fund of Dunedin School of Medicine.	Lifestyle advice alone: 63 (31) <u>Anterior, posterior, and vault</u> Supervised PFMT: 0 Lifestyle advice alone: 1 (<1) <u>Not known</u> Supervised PFMT: 0 Lifestyle advice alone: 1 <u>Duration of prolapse symptoms - mean ± SD (months)</u> Supervised PFMT: 33.3 (52.9) Lifestyle advice alone: 36.2 (54.3) <u>Baseline POP-SS</u> Supervised PFMT: 4.4 (4.5) Lifestyle advice alone: 3.9 (3.7) <u>Baseline POP-SS of 0</u> Supervised PFMT: 41 (20) Lifestyle advice alone: 40 (19) Inclusion criteria • Women of any age with anatomical evidence of prolapse (POP-Q stage ≥1)		random, and similarly 1 point worse than expected). Pre-specified subgroup analyses of treatment interactions with age (<50 vs ≥50 years), prolapse stage (above or at the hymen vs beyond the hymen), leading edge of prolapse (anterior vs posterior vs both). Power calculation 200 women per group required to achieve more than 99% power. Intention-to-treat ITT conducted.	Supervised PFMT (166): 0.4 (1.4) Lifestyle advice alone (n=178): 0.5 (1.6) Adjusted mean difference at 2 years (95% CI): 0.01 (-0.25 to 0.28); p=0.915 <u>Prolapse interferes with personal hygiene - baseline</u> Supervised PFMT (n=192): 0.6 (1.8) Lifestyle advice alone (n=195): 0.7 (1.9) <u>2-years follow-up</u> Supervised PFMT (n=166): 0.5 (1.3) Lifestyle advice alone (n=178): 0.6 (1.7) Adjusted mean difference at 2 years (95% CI): -0.06 (-0.35 to 0.23); p=0.679 <u>Prolapse interferes with every day life - baseline</u> Supervised PFMT (n=193): 0.8 (1.9) Lifestyle advice alone (n=195): 0.6 (1.6) <u>2-years follow-up</u> Supervised PFMT (n=166): 0.5 (1.4) Lifestyle advice alone (n=178): 0.7 (1.7) Adjusted mean difference at 2 years (95% CI): -0.13 (-0.41 to 0.14); p=0.344	(ProLong). At 12 year follow-up, these women were invited to have a POP-Q examination to assess for prolapse.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• No previous prolapse treatment sought Exclusion criteria • Women with State 0 or 4 prolapse • Previous incontinence surgery (except mid-urethral sling operation) • Previous formal instruction on PFMT for any diagnosis in the preceding 5 years • Planning pregnancy, pregnant, or had delivered a baby in the past 6 months • Unable to give informed consent			Self-reported sexual symptoms Sexually inactive due to prolapse - n/N (%) Baseline Supervised PFMT: 1/205 (0.5) Lifestyle advice alone: 1/199 (0.5) 2-year follow-up Supervised PFMT: 5/162 (3.1) Lifestyle advice alone: 9/177 (5.1) OR=0.71 PISQ-12 - mean ± SD Baseline Supervised PFMT (n=168): 36.4 (5.9) Lifestyle advice alone (n=158): 36.6 (6.1) 2-year follow-up Supervised PFMT (n=128): 38.7 (4.4) Lifestyle advice alone (n=134): 38.4 (5.0) Mean difference (95% CI): 0.38 (-0.44 to 1.20); p=0.363 Prolapse symptoms interfere with sex life - n/N (%) Baseline Supervised PFMT: 26/159 (16.4) Lifestyle advice alone: 24/152 (15.8) 2-year follow-up Supervised PFMT: 25/148 (16.7)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Lifestyle advice alone: 32/162 (19.8) OR (95% CI): 0.66 (0.31 to 1.41); p=0.283 Adverse events - n Supervised PFMT: 3 (1 fall, 1 pain in tail bone during PFMT, 1 shortness of breath and chest pain during PFMT). Lifestyle advice alone: 0	
Full citation Stupp, L., Magalhaes Resende, A. P., Oliveira, E., Castro, R. A., Castello Girao, M. J. B., Ferreira Sartori, M. G., Pelvic floor muscle training for treatment of pelvic organ prolapse: An assessor-blinded randomized controlled trial, International urogynecology journal, 22, 1233-1239, 2011 Ref Id 651083	Sample size N = 37 Supervised PFMT + lifestyle advice: n=21 Unsupervised PFMT + lifestyle advice: n=16 Characteristics Age - mean ± SD (years) Supervised PFMT: 58.12 (9) Unsupervised PFMT: 52.95 (6.4) BMI - mean ± SD (kg/m²) Supervised PFMT: 29.7 (2.7) Unsupervised PFMT: 29.9 (3.5) Post menopause - n (%)	Interventions Supervised PFMT: 7 appointments with physiotherapist over a 14-week period. Lifestyle advice containing global stretching, weight loss, fluid intake, constipation, and avoidance of heavy lifting. Unsupervised PFMT: Instructions on PFM contractions without a defined protocol and standardised lifestyle advice sheet identical to intervention group.	Details Supervised PFMT: including knack manoeuver, 12-week home exercise programme (8 to 12 voluntary contractions held for 6 to 10 seconds, with double time rest between each contraction, followed by 3 to 5 fast contractions. Randomisation Computer-generated randomisation. Statistical analyses Wilcoxon signed rank test. Numerical data compared using the paired non-parametric Mann-Whitney *U* test and McNemar's test for nominal data.	Results Change in POP-Q at 14 weeks - n (%) +2 stages Supervised PFMT: Anterior: 0 (0); Posterior: 1 (8.3) Unsupervised PFMT: Anterior 0 (0); Posterior: 0 (0) +1 stage Supervised PFMT: Anterior: 0 (0); Posterior: 0 (0) Unsupervised PFMT: Anterior: 0 (0); Posterior: 0 (0) No change in stage Supervised PFMT: Anterior: 6 (31.6); Posterior: 5 (41.7) Unsupervised PFMT: Anterior: 11 (78.6); Posterior: 4 (80) -1 stage Supervised PFMT: Anterior: 13 (68.4); Posterior: 4 (33.3)	Limitations Random sequence: Low risk of bias (computer-generated) Allocation concealment: Unclear risk of bias Blinding: High risk of bias (single blinded) Incomplete outcome data: Low risk of bias Selective reporting: Low risk of bias Other bias: Unclear risk of

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Country/ies where the study was carried out Brazil Study type Single-blinded randomised controlled trial Aim of the study To investigate the effectiveness of PFMT for the treatment of early stage POP Study dates September 2008 to February 2010 Source of funding State of Sao Paulo Research Foundation	Supervised PFMT: 11 (68.7) Unsupervised PFMT: 15 (71.4) Inclusion criteria Women with untreated stage II anterior or posterior vaginal wall prolapse Exclusion criteria • Women with apical prolapse • Chronic degenerative diseases affecting muscular and nerve tissues • Diabetes • Cardiovascular disease • Overt neurological conditions • Pregnancy • Autoimmune connective tissue disease • Previous pelvic floor re-education programmes and/or pelvic floor surgery		Power calculation Post hoc analysis revealed the final sample size was sufficient to provide a power of at least 90%. Intention-to-treat Not stated.	Unsupervised PFMT: Anterior: 3 (21.4); Posterior: 1 (20) <u>-2 stages</u> Supervised PFMT: Anterior: 0 (0); Posterior: 2 (16.7) Unsupervised PFMT: Anterior: 0 (0); Posterior: 0 (0) <u>P-QoL at 14 weeks - medians (min and max)</u> <u>General health - baseline</u> Supervised PFMT: 50 (25 to 100) Unsupervised PFMT: 50 (25 to 100) <u>14 weeks follow-up</u> Supervised PFMT: 50 (25 to 100) Unsupervised PFMT: 50 (25 to 100) <u>Prolapse impact - baseline</u> Supervised PFMT: 66.6 (0 to 100) Unsupervised PFMT: 50 (0 to 100) <u>14 weeks follow-up</u> Supervised PFMT: 33.3 (0 to 100) Unsupervised PFMT: 50 (0 to 100) <u>Role limitations - baseline</u> Supervised PFMT: 50 (0 to 100)	bias (potential for selection bias as patients with apical prolapse were excluded from the study; PFMT adherence unclear). Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Unsupervised PFMT: 41.6 (0 to 100) 14 week follow-up Supervised PFMT: 33.3 (0 to 66.6) Unsupervised PFMT: 41.6 (0 to 100) Physical limitations - baseline Supervised PFMT: 16.6 (0 to 66.6) Unsupervised PFMT: 16.6 (0 to 50) 14 week follow-up Supervised PFMT: 0 (0 to 33.3) Unsupervised PFMT: 16.6 (0 to 50) Social limitations - baseline Supervised PFMT: 22.2 (0 to 55.5) Unsupervised PFMT: 11.1 (11.1 to 33.3) 14 weeks follow-up Supervised PFMT: 22.2 (0 to 55.5) Unsupervised PFMT: 11.1 (11.1 to 33.3) Personal limitations - baseline Supervised PFMT: 16.6 (0 to 100) Unsupervised PFMT: 0 (0 to 100) 14 week follow-up	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Supervised PFMT: 16.6 (0 to 83.3) Unsupervised PFMT: 0 (0 to 100) <u>Emotions - baseline</u> Supervised PFMT: 0 (0 to 100) Unsupervised PFMT: 33.3 (0 to 88.8) <u>14 week follow-up</u> Supervised PFMT: 0 (0 to 66.6) Unsupervised PFMT: 33.3 (0 to 88.8) <u>Sleep - baseline</u> Supervised PFMT: 33.3 (16.6 to 50) Unsupervised PFMT: 33.3 (0 to 66.6) <u>14 week follow-up</u> Supervised PFMT: 33.3 (16.6 to 50) Unsupervised PFMT: 33.3 (0 to 66.6) <u>Severity measures - baseline</u> Supervised PFMT: 25 (0 to 50) Unsupervised PFMT: 12.5 (0 to 33.3) <u>14 week follow-up</u> Supervised PFMT: 8.3 (0 to 25) Unsupervised PFMT: 8.3 (0 to 33.3)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Self reported symptoms at 14 weeks - n (%) Bulge/lump from or in the vagina - baseline Supervised PFMT: 17 (80.9) Unsupervised PFMT: 14 (87.5) 14 week follow-up Supervised PFMT: 2 (9.5) Unsupervised PFMT: 13 (81.2) Heaviness or dragging on the lower abdomen - baseline Supervised PFMT: 13 (61.9) Unsupervised PFMT: 10 (62.5) 14 week follow-up Supervised PFMT: 3 (14.3) Unsupervised PFMT: 11 (68.7) Lower backache worsens with vaginal discomfort - baseline Supervised PFMT: 14 (66.7) Unsupervised PFMT: 13 (81.2) 14 week follow-up Supervised PFMT: 11 (52.4) Unsupervised PFMT: 7 (43.7) Urge incontinence - baseline Supervised PFMT: 6 (28.6) Unsupervised PFMT: 4 (25) 14 week follow-up	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Supervised PFMT: 4 (19) Unsupervised PFMT: 2 (12.5) <u>Stress incontinence - baseline</u> Supervised PFMT: 15 (71.4) Unsupervised PFMT: 6 (37.5) <u>14 week follow-up</u> Supervised PFMT: 5 (23.8) Unsupervised PFMT: 6 (37.5) <u>Straining to empty the bladder - baseline</u> Supervised PFMT: 11 (52.4) Unsupervised PFMT: 8 (50) <u>14 week follow-up</u> Supervised PFMT: 5 (23.8) Unsupervised PFMT: 10 (62.5) <u>Vaginal bulge interfering with the emptying bowel - baseline</u> Supervised PFMT: 8 (38.1) Unsupervised PFMT: 7 (43.7) <u>14 week follow-up</u> Supervised PFMT: 5 (23.8) Unsupervised PFMT: 5 (31.3) <u>Adverse events - n (%)</u> Not reported.	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Hagen,S., Stark,D., Glazener,C., Sinclair,L., Ramsay,I., A randomized controlled trial of pelvic floor muscle training for stages I and II pelvic organ prolapse, International Urogynecology Journal, 20, 45-51, 2009 Ref Id 109903 Country/ies where the study was carried out UK Study type Pilot study for multicentre, investigator-blinded, randomised controlled trial Aim of the study To assess the effectiveness of a PFMT intervention for women with	Sample size N = 47 Supervised PFMT + lifestyle: n=23 Lifestyle advice alone: n=24 Characteristics All women had experienced at least one vaginal delivery, with the largest group (40%) having had 2 deliveries. The most common type of prolapse was cystocele (85%) followed by rectocele (40%). 47% had one type of prolapse only, 45% had 2, and 8% had 3; the most common combination being cystocele and rectocele (30%). There were no significant differences with respect to age, parity, method of delivery, type or duration of prolapse, or prevalence of prolapse symptoms between the treatment groups at baseline.	Interventions Supervised PFMT: 5 appointments with health physiotherapist over 16 week period; taught the 'knack' technique; individualised home exercise programme prescribed. Standardised lifestyle advice (weight loss, constipation, avoidance of heavy lifting, coughing and high-impact exercise). Lifestyle advice: Standardised lifestyle advice identical to intervention group.	Details Supervised PFMT: Home exercise programme (6 sets of exercises daily (1 set of up to 10 voluntary contractions held for up to 10 seconds, with 4 seconds rest between each contraction and, after a 1 minute rest, 10 or more fast contractions in a row). Randomisation Remote telephone randomisation system (trial centre and number of births (none vs one or more) applied as minimisation criteria). Statistical analyses Chi square (for women's subjective assessment of change in their prolapse), Fisher's exact (for POP-Q stage), Mann-Whitney *U* (for POP-Q individual measurements) and Student's unpaired t tests (for prolapse, urinary, bowel and sexual symptoms, prolapse-related QoL and pelvic floor muscle strength). Power calculation Not stated.	Results <u>Change in prolapse symptom score (sum of 7 symptom questions) - mean ± SD</u> <u>20 weeks follow-up</u> Supervised PFMT (n=17): -1.94 (4.8); unpaired t p value: 0.080 Lifestyle advice (n=20): 0.40 (3.0) <u>26 weeks follow-up</u> Supervised PFMT (n=17): -3.47 (5.4); unpaired t p value: 0.021 Lifestyle advice (n=20): -0.10 (2.9) <u>Self-reported change in prolapse from baseline - frequency (%)</u> <u>The same or worse - 20 weeks</u> Supervised PFMT (n=19): 9 (47) Lifestyle advice (n=21): 20 (95) <u>26 weeks</u> Supervised PFMT: (n=19): 7 (37) Lifestyle advice (n=21): 16 (76) <u>Better - 20 weeks</u> Supervised PFMT: 10 (53) Lifestyle advice: 1 (5) <u>26 weeks</u> Supervised PFMT: 12 (63) Lifestyle advice: 5 (24)	Limitations Random sequence: Low risk of bias (computer-generated) Allocation concealment: Unclear risk of bias Blinding: High risk of bias Incomplete outcome data: Low risk of bias Selective reporting: Low risk of bias Other bias: Unclear risk of bias (PFMT adherence unclear; potential for controls to perform exercises) Other information The authors acknowledged the following limitations: • This was a pilot study, therefore

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
stage I or II POP of any type, measured by the POP-Q system Study dates September 2003 to November 2004 Source of funding Chief Scientist Office, Scottish Government	Inclusion criteria • Women attending outpatient gynaecology, urogynaecology and prolapse clinics at 2 Scottish teaching hospitals • Previously untreated prolapse of stage I or II (confirmed by their gynaecologist using POP-Q Exclusion criteria None stated		Intention-to-treat Not stated.	<u>Change in ICIQ short-form scores at 20 weeks - mean ± SD</u> Supervised PFMT (n=19): -0.21 (3.2); unpaired t p value: 0.494 Lifestyle advice (n=21): 0.48 (3.0) <u>26 weeks</u> Supervised PFMT: -1.79 (3.2); unpaired t p value: 0.070 Lifestyle advice: 0.00 (2.8) <u>Change in severity stage POP-Q data - n (%) at 20 week follow-up</u> <u>+2 stages</u> Supervised PFMT (n=11): 0 (0) Lifestyle advice (n=9): 0 (0) <u>+1 stage</u> Supervised PFMT: 1 (9) Lifestyle advice: 3 (33) <u>No change in stage</u> Supervised PFMT: 5 (45) Lifestyle advice: 6 (67) <u>-1 stage</u> Supervised PFMT: 4 (36) Lifestyle advice: 0 (0) <u>-2 stages</u> Supervised PFMT: 1 (9) Lifestyle advice: 0 (0) <u>Difference in site-specific points at 20 week for women</u>	sample size was small and follow-up short • Pelvic floor muscle strength was not measured in controls • High proportion of incomplete POP-Q data

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				with complete POP-Q data - mean difference (cm) Aa (anterior vaginal wall) Supervised PFMT: -0.36 Lifestyle advice: 0.67 Ba (anterior vaginal wall) Supervised PFMT: -1.09 Lifestyle advice: 0.56 Ap (posterior vaginal wall) Supervised PFMT: 0.18 Lifestyle advice: 1.44 Bp (posterior vaginal wall) Supervised PFMT: -0.18 Lifestyle advice: 1.11 C (superior vagina) Supervised PFMT: 0.10 Lifestyle advice: 0.75 D (superior vagina) Supervised PFMT: 0.20 Lifestyle advice: 0.75 Adverse events - n (%) Not reported.	
Full citation Panman, C. M. C. R., Wiegersma, M., Kollen, B. J., Berger, M. Y., Lisman-Van Leeuwen, Y., Vermeulen, K. M., Dekker, J. H., Two-year effects and cost-effectiveness of pelvic floor muscle training in mild pelvic organ	Sample size See Wiegersma 2014 Characteristics See Wiegersma 2014 Inclusion criteria See Wiegersma 2014 Exclusion criteria See Wiegersma 2014	Interventions See Wiegersma 2014	Details See Wiegersma 2014	Results Change in questionnaire scores - mean ± SD PFDI-20 Baseline Supervised PFMT (n=140): 65.2 (39.9) No conservative treatment (n=138): 59.0 (32.2) 12-month follow-up Supervised PFMT (n=111): 45.5 (42.1)	Limitations See Wiegersma 2014 Other information See Wiegersma 2014

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
prolapse: a randomised controlled trial in primary care, BJOG: An International Journal of Obstetrics and Gynaecology, 124, 511-520, 2017 Ref Id 651410 Country/ies where the study was carried out The Netherlands Study type Randomised controlled trial in 15 general practices (follow-up to Wiegersma, 2014) Aim of the study To compare the effects and cost-effectiveness of PFMT and watchful waiting in older women with a symptomatic mild prolapse in primary care during a 2-year follow up.				No conservative treatment (n=128): 55.2 (34.4) 24-month follow-up Supervised PFMT (n=122): 46.2 (35.4) No conservative treatment (n=129): 53.6 (35.2) Difference (95% CI) in mean change from baseline (adjusted): 12.2 (7.2 to 17.2); p<0.001 POPDI-6 - mean ± SD Baseline Supervised PFMT (n=145): 15.5 (13.4) No conservative treatment (n=141): 13.6 (12.4) 12-month follow-up Supervised PFMT (n=115): 9.5 (13.2) No conservative treatment (n=131): 11.7 (12.3) 24-month follow-up Supervised PFMT (n=127): 9.2 (11.4) No conservative treatment (n=134): 11.4 (11.5) Difference (95% CI) in mean change from baseline	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates October 2009 to October 2012 Source of funding The Netherlands Organisation for Health Research and Development (ZonMw).				(imputed): 2.9 (2.7 to 3.1); p<0.001 CRADI-8 Baseline Supervised PFMT (n=144): 17.2 (15.3) No conservative treatment (n=140): 16.2 (14.4) 12-month follow-up Supervised PFMT (n=112): 13.1 (16.4) No conservative treatment (n=129): 15.8 (13.2) 24-month follow-up Supervised PFMT (n=124): 13.8 (14.0) No conservative treatment (n=130): 15.6 (14.3) Difference (95% CI) in mean change from baseline (imputed): 2.2 (0.3 to 4.2); p=0.027 UDI-6 Baseline Supervised PFMT (n=141): 32.4 (19.7) No conservative treatment (n=140): 29.4 (15.8) 12-month follow-up	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Supervised PFMT (n=114): 22.6 (19.0) No conservative treatment (n=129): 27.3 (17.5) 24-month follow-up Supervised PFMT (n=127): 23.3 (17.2) No conservative treatment (n=132): 26.9 (18.2) Difference (95% CI) in mean change from baseline (imputed): 5.7 (3.2 to 8.2); p<0.001 PFIQ-7 Baseline Supervised PFMT (n=139): 22.1 (39.9) No conservative treatment (n=131): 12.1 (17.9) 12-month follow-up Supervised PFMT (n=111): 13.4 (29.2) No conservative treatment (n=123): 12.9 (24.2) 24-month follow-up Supervised PFMT (n=122): 15.7 (30.9) No conservative treatment (n=128): 12.6 (22.5)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Difference (95% CI) in mean change from baseline (imputed): -0.9 (-5.4 to 3.5); p=0.68 PSIQ-12 Baseline Supervised PFMT (n=64): 35.5 (5.3) No conservative treatment (n=70): 36.4 (5.4) 12-month follow-up Supervised PFMT (n=39): 35.5 (6.4) No conservative treatment (n=52): 36.6 (4.8) 24-month follow-up Supervised PFMT (n=44): 35.6 (5.1) No conservative treatment (n=52): 35.6 (4.7) Difference (95% CI) in change from baseline (imputed): -0.2 (-1.2 to 0.8); p=0.75 PCS-12 Baseline Supervised PFMT (n=122): 45.1 (10.5) No conservative treatment (n=130): 46.8 (9.7) 12-month follow-up Supervised PFMT (n=110): 45.8 (10.5)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				No conservative treatment (n=123): 46.5 (9.6) 24-month follow-up Supervised PFMT (n=118): 45.9 (10.7) No conservative treatment (n=114): 46.7 (10.9) Difference (95% CI) in mean change from baseline (imputed): -0.2 (-1.8 to 1.3); p=0.78 MCS-12 Baseline Supervised PFMT (n=122): 52.7 (8.5) No conservative treatment (n=130): 52.8 (8.5) 12-month follow-up Supervised PFMT (n=110): 53.1 (9.1) No conservative treatment (n=123): 53.2 (7.9) 24-month follow-up Supervised PFMT (n=118): 52.1 (9.3) No conservative treatment (n=114): 51.9 (8.0) Difference (95% CI) in mean change from baseline (imputed): 0.1 (-1.2 to 1.5); p=0.85	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Self-reported change in symptoms at 24 months - n/N (%) Much better/Better Supervised PFMT: 55/129 (43) No conservative treatment (n=142): 19/130 (14) Same Supervised PFMT: 67/129 (52) No conservative treatment: 91/130 (70); p<0.001 Worse/Much worse Supervised PFMT: 7/129 (5) No conservative treatment: 20/130 (15) Improvement of POP-Q stages - n/N (%) Improvement (≥1 POP-Q stage) Supervised PFMT: 28/101 (28) No conservative treatment: 20/116 (17) Same Supervised PFMT: 58/101 (57) No conservative treatment: 72/116 (62); p=0.14	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Deterioration (≥1 POP-Q stage) Supervised PFMT: 15/101 (15) No conservative treatment: 24/116 (21) Adverse events - n (%) No adverse events reported in the PFMT group.	
Full citation Cheung, R. Y., Lee, J. H., Lee, L. L., Chung, T. K., Chan, S. S., Vaginal Pessary in Women With Symptomatic Pelvic Organ Prolapse: A Randomized Controlled Trial, Obstetrics & Gynecology, 128, 73-80, 2016 Ref Id 541320 Country/ies where the study was carried out Hong Kong Study type Parallel-group, single-blind, randomised	Sample size N = 276 PFMT: n=137 PFMT + Vaginal Pessary: n=139 Characteristics Age - mean ± SD (years) PFMT: 62.7 (10.2) Pessary: 62.5 (9.1) BMI - mean ± SD (kg/m²) PFMT: 25.1 (3.9) Pessary: 25.6 (3.8) Parity - median (interquartile range) PFMT: 3 (2 to 4) Controls: 3 (2 to 3)	Interventions PFMT: Standardised PFMT course offered by registered nurse specialist. Pessary: Standardised PFMT course plus fitting of a vaginal pessary. Oestrogen cream was offered if there was a vaginal ulcer.	Details All women received PFMT (teaching session within 2 weeks after first consultation, and 3 individual training sessions at 4, 8 and 16 weeks. Advised to practice daily with at least 2 sets of 8 to 12 preset exercise repetitions per day, with 8 to 10 exercises per session at least 2 times per week. Both groups received a phone consultation 2 weeks later. If vaginal pessary slipped out, women were offered a reassessment and replacement. If a vaginal pessary was not able to be fitted, conservative	Results POPDI - median (IQR) - baseline Pessary: 73.8 (39.2 to 118.5) PFMT: 60.1 (25 to 101.2) 6 months follow-up Pessary: 40.7 (11.3 to 100); p=0.02 PFMT: 54.8 (22.6 to 103.6) 12 months follow-up Pessary: 32.1 (12.5 to 78.6); p=0.04 PFMT: 49.4 (21.4 to 95.2) UDI - median (IQR) - baseline Pessary: 51.6 (36.0 to 87.5) PFMT: 48.1 (22.8 to 80.6) 6 months follow-up Pessary: 42.8 (21.0 to 81.3); p=0.87 PFMT: 41.0 (19.8 to 80.7) 12 months follow-up	Limitations Random sequence: Low risk of bias Allocation concealment: Low risk of bias Blinding: High risk of bias (assessor blinded only) Incomplete outcome data: High risk of bias (>10% dropout) Selective reporting: Low risk of bias Other bias: Unclear risk of

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
controlled trial with 12 months follow-up Aim of the study To compare pelvic floor symptoms, quality of life, and complications in women with symptomatic POP with or without vaginal pessaries in addition to pelvic floor exercises for 12 months. Study dates December 2011 to November 2014 Source of funding None stated	Post menopausal - n (%) PFMT: 105 (76.6) Pessary: 112 (80.6) History of hysterectomy - n (%) PFMT: 6 (4.4) Pessary: 3 (2.2) Stage of prolapse - n (%) Stage I PFMT: 14 (10) Controls: 11 (8) Stage II PFMT: 92 (67) Pessary: 96 (69) Stage III PFMT: 31 (23) Pessary: 32 (23) Type of POP (most severe compartment) - n (%) Anterior PFMT: 91 (66.4) Pessary: 90 (64.7) Posterior PFMT: 8 (5.8) Pessary: 4 (2.9) Apical PFMT: 38 (27.7)		management or surgery was discussed. Randomisation Concealed randomisation with 1-to-1 ratio stratified in POP stage I or II and POP stage III by computer-generated random number series in serially numbered sealed envelopes. Statistical analyses PFDI and PFIQ scores compared between baseline and 12 months using multiple linear regression model. A square root transformation was used to obtain a normal distribution of the scores. Missing values were imputed by a multiple imputation model, generated for each subscale score by multiple linear regression in which the squared subscale score was the dependent variable and age, BMI, parity, and compliance of pelvic floor exercises were independent variables. Mean score difference between groups analysed	Pessary: 39.4 (16.9 to 74.7); p=0.57 PFMT: 37.5 (16.7 to 67.5) CRADI - median (IQR) - baseline Pessary: 44.5 (17.9 to 84.3) PFMT: 41.1 (12.1 to 82.9) 6 months follow-up Pessary: 42.3 (12.1 to 86.9); p=0.92 PFMT: 40.6 (15.5 to 83.0) 12 months follow-up Pessary: 32.1 (15.8 to 75.5); p=0.80 PFMT: 32.1 (14.9 to 68.0) POPIQ - median (IQR) - baseline Pessary: 25.8 (0 to 77.2) PFMT: 16.6 (0 to 51.6) 6 month follow-up Pessary: 5.6 (0 to 42.4); p=0.22 PFMT: 8.3 (0 to 76.5) 12 month follow-up Pessary: 0.3 (0 to 22.2); p= 0.02 PFMT: 8.9 (0 to 64.9); p=0.02 UIQ - median (IQR) - baseline Pessary: 16.7 (0 to 63.9)	bias (PFMT adherence unclear) Other information The authors acknowledged the following limitations: • Only ring pessaries were used. • Adherence rates were low. • At 12 months, a total of 61 women crossed over to receive different treatment. • The study did not measure anatomical outcome or sexual symptoms.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Pessary: 45 (32.4) PFDI score - median (IQR) POPDI PFMT: 60.1 (25 to 101.2) Pessary: 73.8 (39.2 to 118.5) UDI PFMT: 48.1 (22.8 to 80.6) Pessary: 51.6 (36.0 to 87.5) CRADI PFMT: 41.1 (12.1 to 82.9) Pessary: 44.5 (17.9 to 84.3) PFIQ score - median (IQR) POPIQ PFMT: 16.6 (0 to 51.6) Pessary: 25.8 (0 to 77.2) UIQ PFMT: 18.1 (0 to 53.0) Pessary: 16.7 (0 to 63.9) CRAIQ PFMT: 0 (0 to 12.1) Pessary: 0 (0 to 11.1)		by paired t test. Linear logistic regression analysis used to assess effect of different factors on subjective improvements. Power calculation 120 women in each group required for 80% power. Intention-to-treat Primary outcome analyses on an ITT basis.	PFMT: 18.1 (0 to 53.0) 6 months follow-up Pessary: 15.3 (1.6 to 48.6); p=0.33 PFMT: 11.1 (0 to 56.9) 12 months follow-up Pessary: 13.3 (0 to 40.3); p=0.71 PFMT: 9.7 (0 to 54.8); p=0.71 CRAIQ - median (IQR) - baseline Pessary: 0 (0 to 11.1) PFMT: 0 (0 to 12.1) 6 months follow-up Pessary: 0 (0 to 5.6); p=0.90 PFMT: 0 (0 to 8.5) 12 months follow-up Pessary: 0 (0 to 5.6); p=0.77 PFMT: 0 (0 to 5.6); p=0.77 Adverse events - n/N (%) Failed to retain pessary Pessary: 56/132 (42.4) PFMT: Not applicable Abnormal vaginal bleeding Pessary: 9/132 (6.8) PFMT: 4/128 (3.1); p=0.17 Significant vaginal discharge Pessary: 6/132 (4.5) PFMT: 2/128 (1.6); p=0.16	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Inclusion criteria • Women with dominant symptoms of prolapse stage I to III POP using POP-Q system • No previous treatment received Exclusion criteria • Women with active complications arising from the prolapse • Impaired mobility • Cognitive impairment • Language barrier			De novo urinary symptoms - stress urinary incontinence Pessary: 24/50 (48.0) PFMT: 13/58 (22.4); p=0.01 Urge urinary incontinence Pessary: 17/73 (23.3) PFMT: 19/84 (22.6); p=0.85 Voiding difficulty Pessary: 10/92 (10.9) PFMT: 8/97 (8.2); p=0.54 Improvement of pre-existing symptoms - stress urinary incontinence Pessary: 19/82 (23.2) PFMT: 15/70 (21.4); p=0.80 Urge urinary incontinence Pessary: 17/59 (28.8) PFMT: 18/44 (40.9); p=0.20 Voiding difficulty Pessary: 25/40 (62.5) PFMT: 11/31 (35.5); p=0.02	
Full citation Hagen, S., Stark, D., Glazener, C., Dickson, S., Barry, S., Elders, A., Frawley, H., Galea, M. P., Logan, J., McDonald, A., McPherson, G., Moore, K. H.,	Sample size N = 447 Supervised PFMT + Lifestyle advice: n=225 Lifestyle advice alone: n=222 Characteristics	Interventions Supervised PFMT: 5 1-to-1 appointments for PFMT over 16 weeks with health physiotherapist. Included correct exercise technique (using PERFECT Scheme); individualised home	Details Postal questionnaires used to collect data at baseline, and 6 months and 12 months follow-up. Randomisation 1:1 randomisation with remote-computer-	Results POP-SS - mean ± SD 6 months follow-up Supervised PFMT (n=188): 3.16 (4.78) Lifestyle advice (n=189): 9.17 (5.81) 12 months follow-up	Limitations Random sequence: Low risk of bias Allocation concealment: Unclear risk of bias

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Norrie, J., Walker, A., Wilson, D., Individualised pelvic floor muscle training in women with pelvic organ prolapse (POPPY): A multicentre randomized controlled trial, The Lancet, 383, 796-806, 2014 Ref Id 653171 Country/ies where the study was carried out UK Study type Parallel-group, multicentre, randomised trial Aim of the study To assess whether one-to-one PFMT reduces the symptoms of prolapse and the need for further prolapse treatment in women with stage I to III prolapse, and whether it is cost-effective compared with a prolapse	Age - mean ± SD (years) Supervised PFMT: 56.20 (11.60) Lifestyle advice: 57.50 (11.39) BMI - mean ± SD (kg/m²) Supervised PFMT (n=214): 27.15 (4.99) Lifestyle advive (n=210): 27.42 (4.57) Parity - median (IQR) Supervised PFMT (n=223): 2 (2 to 3) Lifestyle advice (n=217): 2 (2 to 3) Stage of Prolapse - n (%) Stage I Supervised PFMT: 23 (10) Lifestyle advice: 18 (8) Stage II (above hymen) Supervised PFMT: 48 (21) Lifestyle advice: 47 (21) Stage II (at or below hymen)	exercise programme (10 times 10 second maximum holds and up to 50 fast contractions 3 times per day). Taught 'knack' exercise and encouraged to do daily. Use of electromyography biofeedback, pressure biofeedback, and electrical stimulation not permitted. Plus, prolapse lifestyle advice leaflet (weight loss, constipation, avoidance of heavy lifting, coughing, and high-impact exercise - received at first appointment. Lifestyle advice: Identical lifestyle advice leaflet, but received through the post.	determined randomisation application, using minimisation to balance group sizes for key prognostic factors at baseline (centre, stage of prolapse, and motivation for prolapse surgery (women considering surgery vs those not considering surgery)). Statistical analyses Linear mixed-effects model fitted to change from baseline in POP-SS at 6 months and 12 months, with a random intercept for patient within centre, and a random slope for time within patient, and adjusted for baseline POP-SS score and minimisation variables. Multiple imputation used to assess the assumption of data missing at random and corresponding effect of missing responses on the primary outcome. For POP-Q stage, pooled odds ratios from ordinal model calculated with a 95% CI and p value. Other secondary outcomes	Supervised PFMT (n=145): 5.74 (4.89) Lifestyle advice (n=139): 7.04 (5.43) Reduction in POP-SS from baseline - mean ± SD 6 months follow-up Supervised PFMT: 3.16 (4.78) Lifestyle advice: 0.12 (3.86) Adjusted difference in mean change from baseline: 2.84 (2.05 to 3.63); p<0.0001 12 months follow-up Supervised PFMT: 3.77 (5.62) Lifestyle advice: 2.09 (5.39) Adjusted difference in mean change from baseline: 1.52 (0.46 to 2.59); p=0.0053 Self-reported prolapse symptoms - n/N (%) Better - 6 months follow-up Supervised PFMT: 98/187 (52) Lifestyle advice: 32/189 (17); p<0.0001 12 months follow-up Supervised PFMT: 83/145 (57) Lifestyle advice: 63/141 (45); p=0.0125	Blinding: High risk of bias (assessor blinded only) Incomplete outcome data: High risk of bias (>10% dropout) Selective reporting: Low risk of bias Other bias: Unclear risk of bias (PFMT adherence unclear; potential for controls to perform exercises). Other information Women in the control group increased uptake of supplementary treatments (mainly pelvic floor muscle training) after 6 months. The authors acknowledged the following limitations:

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
lifestyle advice leaflet. Study dates June 2007 to April 2010 Source of funding Chief Scientist Office of the Scottish Government Health and Social Care Directorates, New Zealand lottery Board, and National Health and Medical Research Council (Australia).	Supervised PFMT: 116 (52) Lifestyle advice: 127 (57) Stage III Supervised PFMT: 38 (17) Controls: 29 (13) Stage IV Supervised PFMT: 0 Controls: 1 (<1) Type of prolapse - n (%) Anterior Supervised PFMT: 23 (10) Controls: 25/220 (11) Posterior Supervised PFMT: 13 (6) Controls: 11/220 (5) Anterior and posterior Supervised PFMT: 54 (24) Controls: 54/220 (24) Anterior and upper Supervised PFMT: 27 (12) Controls: 22/220 (10) Posterior and upper Supervised PFMT: 6 (3) Controls: 8/220 (4)		compared between groups with the Mann-Whitney U test for continuous and ordinal variables and the X^2 or Fisher's exact test for categorical variables. Planned subgroup analyses explored effect of prolapse stage and type, age, and motivation for surgery on the primary outcome. Power calculation Based on 80% power, 253 women per group required to detect a difference of 2.5 points in the primary outcome measure, assuming a common SD of 8 points. Intention-to-treat Used to compare the primary outcome at 12 months. by fitting a linear mixed-effects model to change from baseline in POP-SS at 6 months and 12 months, with a random intercept for patient within centre, and a random slope for time within patient, and adjusted for baseline POP-SS score and minimisation variables.	The same - 6 months follow-up Supervised PFMT: 77/187 (41) Lifestyle advice: 114/189 (60) 12 months follow-up Supervised PFMT: 49/145 (34) Lifestyle advice: 52/141 (37) Worse - 6 months follow-up Supervised PFMT: 12/187 (6) Lifestyle advice: 43/189 (23) 12 months follow-up Supervised PFMT: 13/145 (9) Lifestyle advice: 26/141 (18) Change in POP-Q Stage at 6 months - n/N (%) +2 stages Supervised PFMT: 4/168 (2) Lifestyle advice: 9/171 (5) +1 stage Supervised PFMT: 26/168 (16) Lifestyle advice: 29/171 (17) No change Supervised PFMT: 93/168 (55) Lifestyle advice: 100/171 (58) -1 stage	• Low rate of questionnaire response at 12 months. • Attrition at 6 months in POP-Q responses. • Crossover of women in control group to intervention group after 6 months. • Short-term follow-up of 12 months.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Anterior and posterior and upper Supervised PFMT: 102 (45) Controls: 100/220 (56) Duration of prolapse symptoms - median (IQR) (months) Supervised PFMT (n=196): 12 (6 to 24) Controls (n=201) 12 (6 to 24) Baseline POP-SS - mean ± SD Supervised PFMT (n=224): 10.04 (6.0) Controls (n=222): 9.51 (5.64) Inclusion criteria • Women of any age with stage I to III prolapse of any type (anterior, posterior, apical, or a combination), as confirmed by their gynaecologist on vaginal			Supervised PFMT: 34/168 (20) Lifestyle advice: 8/171 (5) -2 stages Supervised PFMT: 11/168 (7) Lifestyle advice: 8/171 (5) Further treatment received by 12 months - n/N (%) Any further treatment received Supervised PFMT: 35/145 (24) Lifestyle advice: 71/143 (50); p<0.0001 Surgery Supervised PFMT: 16/145 (11) Lifestyle advice: 14/143 (10); p=0.84 Pessary Supervised PFMT: 8/145 (5) Lifestyle advice: 16/143 (11); p=0.13 Physiotherapy referral Supervised PFMT: 2/145 (1) Lifestyle advice: 38/143 (27); p<0.0001 Oestrogen drugs, or other Supervised PFMT: 14/145 (10) Lifestyle advice: 15/143 (11); p=0.85	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	examination with POP-Q • Prolapse as the main complaint Women who needed treatment for vaginal atrophy were eligible after completing a course of local oestrogens. Exclusion criteria • Previous treatment for prolapse, including surgery. • Pregnant women or less than 6 months postnatal. • Unable to comply with the intervention (ie. if they were not able to attend the clinic for appointments with the physiotherapist). 			Self-reported effect of prolapse symptoms - median (IQR) Interference of prolapse symptoms with - 6 months follow-up: Everyday life Supervised PFMT (n=188): 1 (0 to 3) Lifestyle advice (n=189): 3 (1 to 6); p=0.001 Physical activity Supervised PFMT (n=187): 2 (0 to 5) Lifestyle advice (n=189): 3 (0 to 6); p=0.010 Social activity Supervised PFMT (n=187): 0 (0 to 3) Lifestyle advice: (n=189): 1 (0 to 4); p=0.012 Personal hygiene Supervised PFMT (n=188): 0 (0 to 2) Lifestyle advice (n=189): 1 (0 to 5); p=0.003 12 months follow-up Everyday life Supervised PFMT (n=145): 1 (0 to 3) Lifestyle advice (n=138): 1 (0 to 4); p=0.095 Physical activity	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Supervised PFMT (n=128): 1 (0 to 3) Lifestyle advice (n=124): 1 (0 to 4); p=0.251 Social activity Supervised PFMT (n=128): 0 (0 to 1) Lifestyle advice (n=123): 0 (0 to 2); p=0.173 Personal hygiene Supervised PFMT (n=128): 0 (0 to 2) Lifestyle advice (n=124): 1 (0 to 3); p=0.079 Interference of prolapse symptoms with sex life - n/N (%) 6 months follow-up Not at all Supervised PFMT: 75/146 (51) Lifestyle advice: 53/145 (37); p=0.033 A little/somewhat Supervised PFMT: 54/146 (37) Lifestyle advice: 76/145 (53) A lot Supervised PFMT: 17/146 (12) Lifestyle advice: 16/145 (11) 12 months follow-up Not at all	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Supervised PFMT: 52/95 (55) Lifestyle advice: 47/95 (50); p=0.510 A little/somewhat Supervised PFMT: 36/95 (38) Lifestyle advice: 39/95 (41) A lot Supervised PFMT: 7/95 (7) Lifestyle advice: 9/95 (9) Bladder symptoms 6 months follow-up Urine leakage - n/N (%) Supervised PFMT: 103/188 (55) Lifestyle advice: 129/189 (68); p=0.01 12 months follow-up Supervised PFMT: 72/132 (54) Lifestyle advice: 77/128 (60); p=0.430 ICIQ-UI SF score - median (IQR) 6 month follow-up Supervised PFMT (n=183): 3 (0 to 5) Lifestyle advice (n=181): 4 (0 to 7); p<0.0001 12 months follow-up	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Supervised PFMT (n=126): 3 (0 to 5) Lifestyle advice (n=126): 3 (0 to 6); p=0.118 Bowel symptoms - n/N (%) 6 month follow-up Faecal urgency Supervised PFMT: 96/188 (51) Lifestyle advice: 114.189 (60); p=0.041 Faecal incontinence Supervised PFMT: 42/188 (22) Lifestyle advice: 47/189 (40); p=0.479 12 months follow-up Faecal urgency Supervised PFMT: 63/130 (49) Lifestyle advice: 71/126 (56); p=0.120 Faecal incontinence Supervised PFMT: 23/130 (18) Lifestyle advice: 34/127 (27); p=0.072 Adverse events Supervised PFMT: 8: Vaginal symptoms: 6 Back pain: 1	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Unexpected serious adverse event (skiing injury) 1 Lifestyle advice: 0	
Full citation Wiegersma, M., Panman, C. M. C. R., Kollen, B. J., Berger, M. Y., Leeuwen, Y. L. V., Dekker, J. H., Effect of pelvic floor muscle training compared with watchful waiting in older women with symptomatic mild pelvic organ prolapse: Randomised controlled trial in primary care, BMJ (Online), 349 (no pagination), 2014 Ref Id 653258 Country/ies where the study was carried out The Netherlands Study type Randomised controlled trial Aim of the study	Sample size N = 287 PFMT: n=145 No conservative treatment: n=142 Characteristics Age - mean ± SD (years) PFMT: 64.5 (6.8) No conservative treatment: 64.0 (6.5) BMI - mean ± SD (kg/m²) PFMT: 27.0 (4.7) No conservative treatment: 26.6 (4.8) Parity - mean ± SD (n, %) PFMT: 2.4 (1.2) No conservative treatment: 2.4 (1.1) Post menopausal - n (%) PFMT: 142 (98) No conservative treatment: 140 (99)	Interventions PFMT: Individual 1-to-1 PFMT with physiotherapist combined with home exercise (including knack technique). Homer exercises encouraged for 3 to 5 times a week, twice or three times each day. No conservative treatment: No treatment and no recommendations.	Details Women received a postal questionnaire asking about vaginal bulging, pelvic heaviness, urinary incontinence, and vaginal splinting to assist micturition or defecation. Women who responded positively to one or more screening questions were invited to complete another questionnaire and visit for a baseline assessment. Randomisation 1:1 ratio. Block randomisation by means of an external computer system with an interactive voice response system (accessible by telephone) was used. The research physician enrolling the patients was blinded to the block size and allocation sequence. Statistical analyses For PFIQ-7, square root transformation used to	Results Change in questionnaire scores - mean ± SD PFDI-20 Baseline PFMT (n=140): 65.2 (39.9) No conservative treatment (n=138): 59.0 (32.2) 3-month follow-up PFMT (n=117): 46.9 (37.4) No conservative treatment (n=127): 51.3 (29.7) Difference (95% CI, in mean change from baseline (imputed): 19.1 (-15.4 to -2.8); p=0.005 POPDI-6 - mean ± SD Baseline PFMT (n=145): 15.5 (13.4) No conservative treatment (n=141): 13.6 (12.4) 3-month follow-up PFMT (n=118): 10.5 (12.3) No conservative treatment (n=129): 11.4 (11.3)	Limitations Random sequence: Low risk of bias Allocation concealment: Low r isk of bias Blinding: High risk of bias (assessor blinded only) Incomplete outcome data: High risk of bias (>10% dropout) Selective reporting: Low risk of bias Other bias: High risk of bias (PFMT adherence unclear; potential for controls to perform exercises). Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
To compare the effects of PFMT and watchful waiting on pelvic floor symptoms in a primary care population of women aged 55 years or over with symptomatic mild prolapse. Study dates October 2009 to October 2012 Source of funding The Netherlands Organisation for Health Research and Development (ZonMw).	Surgical history - n (%) Hysterectomy PFMT: 30 (21) No conservative treatment: 24 (17) Pelvic floor surgery PFMT: 13 (9) No conservative treatment: 6 (4) Previous POP treatment (surgical or conservative management >1 year previously) - n (%) PFMT: 25 (17) No conservative treatment: 18 (13) POP stage - n (%) Stage I PFMT: 70 (48) No conservative treatment: 85 (60) Stage II PFMT: 75 (52) No conservative treatment: 57 (40) Type of POP - n (%) Anterior PFMT: 77 (53)		obtain normal distribution of the residuals. Logistic regression analysis used to assess POP-Q stage. Bonferroni correction applied to correct reported p values for multiple testing. Missing values were imputed for primary and secondary outcomes by multiple imputation. Power calculation For 80% power, 92 women in each treatment arm were required to detect a difference of 15 points with a SD of 36 points. Intention-to-treat ITT and per protocol analyses conducted.	Difference (95% CI) in mean change from baseline (imputed): -2.0 (-4.5 to 0.5); p=0.110 CRADI-8 Baseline PFMT (n=144): 17.2 (15.3) No conservative treatment (n=140): 16.2 (14.4) 3-month follow-up PFMT (n=118): 13.7 (15.3) No conservative treatment (n=129): 26.3 (15.5) Difference (95% CI) in mean change from baseline (imputed): -1.8 (-4.3 to 0.7); p=0.165 UDI-6 Baseline PFMT (n=141): 32.4 (19.7) No conservative treatment (n=140): 29.4 (15.8) 3-month follow-up PFMT (n=118): 22.8 (17.2) No conservative treatment (n=129): 26.3 (15.5) Difference (95% CI) in mean change from baseline	Myofeedback was used in 23 (16%) participants, and electric stimulation was used in 11 (8%) women in PFMT group. The authors acknowledged the following limitations: • Many women had mild symptoms at baseline, there was little room for improvement and may underestimate the effect of PFMT. • PFMT protocol was not standardised, and not possible to register amount of home exercises performed.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	No conservative treatment: 75 (53) Posterior PFMT: 6 (4) No conservative treatment: 6 (4) Apical PFMT: 1 (1) No conservative treatment: 1 (1) Anterior and posterior PFMT: 30 (21) No conservative treatment: 31 (22) Anterior and apical PFMT: 22 (15) No conservative treatment: 19 (13) Posterior and apical PFMT: 2 (1) No conservative treatment: 4 (3) Anterior and posterior and apical PFMT: 6 (4) No conservative treatment: 6 (4) PFDI-20 score - mean ± SD PFMT: 65.2 (39.9) No conservative treatment: 59.0 (32.2)			(imputed): -5.0 (-8.6 to -1.4); p=0.007 PFIQ-7 Baseline PFMT (n=139): 22.1 (39.9) No conservative treatment (n=131): 12.1 (17.9) 3-month follow-up PFMT (n=110): 18.0 (36.1) No conservative treatment (n=120): 11.7 (23.7) Difference (95% CI) in mean change from baseline (imputed): 0.03 (-0.5 to 1.1); p=0.478 PSIQ-12 Baseline PFMT (n=64): 35.5 (5.3) No conservative treatment (n=70): 36.4 (5.4) 3-month follow-up PFMT (n=43): 35.5 (6.4) No conservative treatment (n=58): 37.1 (4.6) Difference (95% CI) in change from baseline (imputed): -0.1 (-2.3 to 2.1); p=0.925 PCS-12 Baseline	• Short term follow-up.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	POPDI-6 score - mean ± SD PFMT: 15.5 (13.4) No conservative treatment: 13.6 (12.4) CRADI-8 score - mean ± SD PFMT: 17.2 (15.3) No conservative treatment: 16.2 (14.4) UDI-6 score - mean ± SD PFMT: 32.4 (19.7) No conservative treatment: 29.4 (15.8) Inclusion criteria Women aged at least 55 years with mild prolapse (defined as leading edge of prolapse staying above the hymen (POP-Q stage I and mild stage II)) and not meeting exclusion criteria. Exclusion criteria • Current prolapse treatment or			PFMT (n=122): 45.1 (10.5) No conservative treatment (n=130): 46.8 (9.7) 3-month follow-up PFMT (n=111): 46.5 (10.3) No conservative treatment (n=121): 46.6 (10.4) Difference (95% CI) in mean change from baseline (imputed): 0.6 (-1.8 to 3.0); p=0.606 MCS-12 Baseline PFMT (n=122): 52.7 (8.5) No conservative treatment (n=130): 52.8 (8.5) 3-month follow-up PFMT (n=111): 53.4 (7.1) No conservative treatment (n=121): 53.7 (8.3) Difference (95% CI) in mean change from baseline (imputed): -0.9 (-2.7 to 0.8); p=0.307 Self-reported change in symptoms from baseline (imputed data) - n (%) Better PFMT (n=145): 82 (57) No conservative treatment (n=142): 18 (13); p<0.001	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	treatment in previous year. • Pelvic organ malignancy. • Current treatment for another gynaecological disorder. • Severe/terminal illness. • Impaired mobility. • Cognitive impairment. • Insufficient command of the Dutch language.			Same PFMT: 58 (40) No conservative treatment: 115 (81); p<0.001 Worse PFMT: 16 (11) No conservative treatment: 17 (12); p=1.000 Improvement of 1 or more POP-Q stages (imputed) - n (%) Anterior PFMT: 39/145 (27) No conservative treatment: 24/142 (17); p=0.222 Posterior PFMT: 13/145 (9) No conservative treatment: 14/142 (10); p=1.000 Apical PFMT: 23/145 (16) No conservative treatment: 22/142 (15); p=1.000 Adverse events No participants reported any adverse effects of pelvic floor muscle training.	

Appendix E – Forest plots

Forest plots for review question: What lifestyle interventions are effective for managing pelvic organ prolapse (POP)?

No studies were identified which were applicable to this review question.

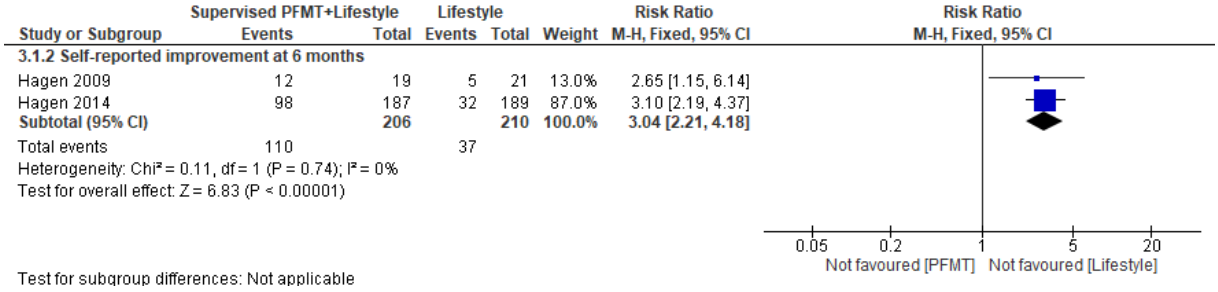
Forest plots for review question 8.2: What is the effectiveness of topical oestrogen for managing pelvic organ prolapse (POP) with vaginal atrophy?

No studies were identified which were applicable to this review question.

Forest plots for the review question: What are the most effective conservative management options (for example, pelvic floor exercises and pessaries) for pelvic organ prolapse (POP)?

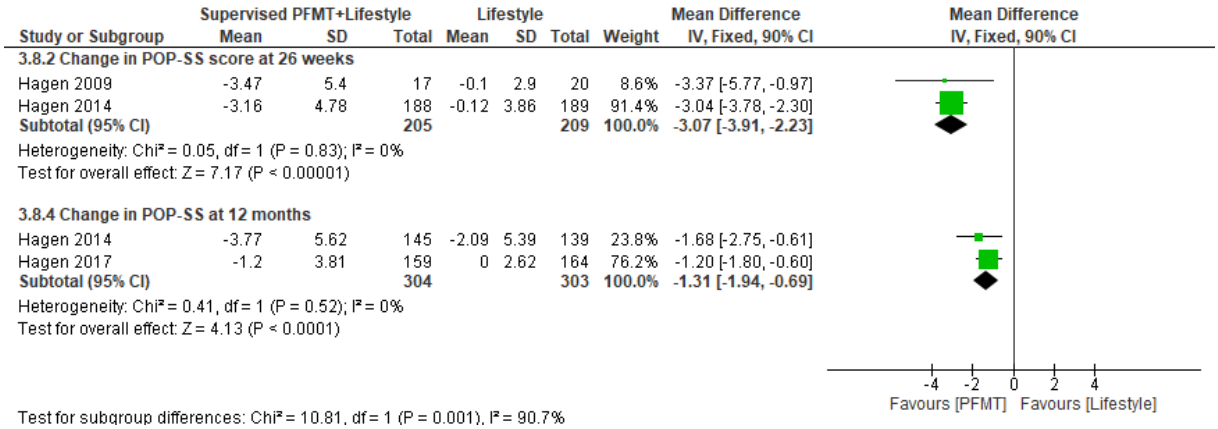
Comparison 1c: Supervised PFMT + Lifestyle advice vs Lifestyle advice alone

Figure 4: Self-reported improvement in prolapse symptoms



Comparison 1c: Supervised PFMT + Lifestyle advice vs Lifestyle advice alone

Figure 5: Change in POP-SS scores



Appendix F – GRADE tables

GRADE tables for review question: What lifestyle interventions are effective for managing pelvic organ prolapse (POP)?

No studies were identified which were applicable to this review question.

GRADE tables for review question: What is the effectiveness of topical oestrogen for managing pelvic organ prolapse (POP) with vaginal atrophy?

No studies were identified which were applicable to this review question.

GRADE tables for the review questions: What are the most effective conservative management options (for example, pelvic floor exercises and pessaries) for pelvic organ prolapse (POP)?

Table 9: Clinical evidence profile Pelvic floor muscle exercises versus no conservative treatment

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PFMT	No conservative treatment	Relative (95% CI)	Absolute		
Self-reported symptom improvement - Symptoms better (follow-up 3 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	82/145 (56.6%)	18/142 (12.7%)	RR 4.46 (2.83 to 7.03)	439 more per 1000 (from 232 more to 764 more)	⨁⊖⊖⊖ VERY LOW	CRITICAL
Change in symptom scores - Change in PFDI-20 scores (follow-up 3 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	117	127	-	MD 10.6 lower (17.07 to 4.13 lower)	⨁⨁⊖⊖ LOW	CRITICAL
Change in symptom scores - Change in POPDI-6 scores (follow-up 3 months; Better indicated by lower values)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PFMT	No conservative treatment	Relative (95% CI)	Absolute		
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	118	129	-	MD 2.8 lower (5.09 to 0.51 lower)	⨁⨁⊖⊖ LOW	CRITICAL
Change in symptom scores - Change in UDI-6 scores (follow-up 3 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no seriousimprecisions[4]	none	118	129	-	MD 6.5 lower (9.67 to 3.33 lower)	⨁⨁⊖⊖ LOW	CRITICAL
Change in symptom scores - Change in CRADI-8 scores (follow-up 3 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	118	128	-	MD 0.9 lower (3.52 lower to 1.72 higher)	⨁⨁⊖⊖ LOW	CRITICAL
Change in QoL scores - Change in PFIQ-7 scores (follow-up 3 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	110	120	-	MD 3.7 lower (9.43 lower to 2.03 higher)	⨁⨁⊖⊖ VERY LOW	CRITICAL
Change in sexual function scores - Change in PISQ-12 scores (follow-up 3 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	43	58	-	MD 0.7 lower (2.32 lower to 0.92 higher)	⨁⨁⊖⊖ LOW	IMPORTANT

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PFMT	No conservative treatment	Relative (95% CI)	Absolute		
Change in symptom scores - Change in PFDI-20 scores (follow-up 12 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	111	128	-	MD 15.9 lower (22.47 to 9.33 lower)	⨁⨁⊖⊖ LOW	CRITICAL
Change in symptom scores - Change in POPDI-6 scores (follow-up 12 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision[6]	none	115	131	-	MD 4.1 lower (6.39 to 1.81 lower)	⨁⨁⊖⊖ LOW	CRITICAL
Change in symptom scores - Change in UDI-6 scores (follow-up 12 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	114	129	-	MD 7.7 lower (10.9 to 4.5 lower)	⨁⨁⊖⊖ LOW	CRITICAL
Change in symptom scores - Change in CRADI-8 scores (follow-up 12 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	112	129	-	MD 3.7 lower (6.36 to 1.04 lower)	⨁⊖⊖⊖ VERY LOW	CRITICAL
Change in QoL scores - Change in PFIQ-7 scores (follow-up 12 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision[5]	none	111	123	-	MD 9.5 lower (15.2 to 3.8 lower)	⨁⨁⊖⊖ LOW	CRITICAL
Change in sexual function scores - Change in PISQ-12 scores (follow-up 12 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	110	123	-	MD 0.2 lower	⨁⨁⊖⊖	IMPORTANT

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PFMT	No conservative treatment	Relative (95% CI)	Absolute		
										(1.17 lower to 0.77 higher)	LOW	
Change in symptom scores - Change in PFDI-20 scores (follow-up 24 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	122	129	-	MD 13.6 lower (19.96 to 7.24 lower)	⨁⨁⊖⊖ LOW	CRITICAL
Change in symptom scores- Change in POPDI-6 scores (follow-up 24 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	127	134	-	MD 4.1 lower (6.32 to 1.88 lower)	⨁⨁⊖⊖ LOW	CRITICAL
Change in symptom scores - Change in UDI-6 scores (follow-up 24 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	127	132	-	MD 6.6 lower (9.68 to 3.52 lower)	⨁⨁⊖⊖ LOW	CRITICAL
Change in symptom scores - Change in CRADI-8 scores (follow-up 24 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	124	130	-	MD 2.8 lower (5.39 to 0.21 lower)	⨁⊖⊖⊖ VERY LOW	CRITICAL
Change in QoL scores - Change in PFIQ-7 scores (follow-up 24 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	122	128	-	MD 6.9 lower (12.37 to	⨁⨁⊖⊖	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**PFMT**	**No conservative treatment**	**Relative (95% CI)**	**Absolute**		
										1.43 lower)	LOW	
Change in sexual function scores - Change in PISQ-12 scores (follow-up 24 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	44	52	-	MD 0 higher (1.52 lower to 1.52 higher)	⨁⨁⊖⊖ LOW	IMPORTANT
Improvement of 1 or more POP-Q stages - Anterior (follow-up 3 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[4]	none	39/145 (26.9%)	24/142 (16.9%)	RR 1.59 (1.01 to 2.5)	100 more per 1000 (from 2 more to 254 more)	⨁⊖⊖⊖ VERY LOW	IMPORTANT
Improvement of 1 or more POP-Q stages - Posterior (follow-up 3 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	13/145 (8.9%)	14/142 (9.9%)	RR 0.91 (0.44 to 1.87)	10 fewer per 1000 (from 55 fewer to 84 more)	⨁⊖⊖⊖ VERY LOW	IMPORTANT
Improvement of 1 or more POP-Q stages - Apical (follow-up 3 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	23/145 (15.9%)	22/142 (15.5%)	RR 1.02 (0.6 to 1.75)	3 more per 1000 (from 62 fewer to 116 more)	⨁⊖⊖⊖ VERY LOW	IMPORTANT

[1] Random sequence generation: Low risk of bias; Allocation concealment (Low risk of bias); Blinding: High risk of bias (investigator blinded only); Incomplete outcome data: (>10% dropout); Other bias: High risk of bias (unclear adherence to PFMT; potential for controls to perform exercise).
[2] Evidence downgraded by 2 due to risk of very serious imprecision, 95% confidence intervals crosses both default MID for dichotomous outcomes, (0.8 and 1.25)
[3] Evidence downgraded by 1 due to risk of serious imprecision, 95% confidence intervals crosses one default MID for continuous outcomes, MID used was 5 as reported in Jelovsek et al. 2014.

[4] Evidence downgraded by 1 due to risk of serious imprecision, 95% confidence intervals crosses one default MID for dichotomous outcomes, (0.8 or 1.25)
NB MIDS used as follows: PFDI-20, 45; POPDI-6, 16; UDI-6, 11; CRADI-8, 5; PFIQ-7, 36 and PISQ-12, 6.

[3]

Table 10: Clinical evidence profile for comparison Supervised PFMT versus lifestyle advice

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Supervised PFMT**	**Lifestyle**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
Improvement in prolapse symptoms - Reduced frequency (follow-up 6 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	32/43 (74.4%)	8/26 (30.8%)	RR 2.42 (1.32 to 4.42)	437 more per 1000 (from 98 more to 1000 more)	⨁⊖⊖⊖ VERY LOW	IMPORTANT
Improvement in prolapse symptoms - Reduced bother (follow-up 6 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	29/43 (67.4%)	11/26 (42.3%)	RR 1.59 (0.97 to 2.61)	250 more per 1000 (from 13 fewer to 681 more)	⨁⊖⊖⊖ VERY LOW	IMPORTANT
Self-reported Improvement in sexual function (follow-up 6 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	19/49 (38.8%)	2/41 (4.9%)	RR 7.95 (1.97 to 32.13)	339 more per 1000 (from 47 more to 1000 more)	⨁⊖⊖⊖ VERY LOW	IMPORTANT

[1] Random sequence: Low risk of bias; Allocation concealment: Low risk of bias; Blinding: High risk of bias (assessor blinded only); Incomplete outcome data: High risk of bias (>10% dropout); Selective reporting: Low risk of bias; Other bias: Unclear risk of bias (PFMT adherence unclear; potential for controls to perform exercises).
[2] Evidence downgraded by 2 due to risk of very serious imprecision, 95% confidence intervals crosses both default MID for dichotomous outcomes, (0.8 and 1.25)
[3] Evidence downgraded by 1 due to risk of serious imprecision, 95% confidence intervals crosses one default MID for dichotomous outcomes, (0.8 or 1.25)

Table 11: Clinical evidence profile for comparison Supervised PFMT + lifestyle advice versus lifestyle advice alone

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Supervised PFMT + Lifestyle advice	Control	Relative (95% CI)	Absolute	Quality	Importance
Self-reported improvement in symptoms (follow-up 20 weeks)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	10/19 (52.6%)	1/21 (4.8%)	RR 11.01 (2.3 to 18.96)	477 more per 1000 (from 62 more to 855 more)	⨁⊖⊖⊖ VERY LOW	CRITICAL
Self-reported improvement in symptoms (follow-up 6 months)												
2	randomised trials	very serious[1,3]	no serious inconsistency	no serious indirectness	very serious[2]	none	110/206 (53.4%)	37/210 (17.6%)	RR 3.04 (2.21 to 4.18)	358 more per 1000 (from 211 more to 557 more)	⨁⊖⊖⊖ VERY LOW	CRITICAL
Self-reported improvement in symptoms (follow-up 12 months)												
1	randomised trials	very serious[3]	no serious inconsistency	no serious indirectness	serious[4]	none	83/145 (57.2%)	63/141 (44.7%)	RR 1.28 (1.02 to 1.53)	125 more per 1000 (from 9 more to 237 more)	⨁⊖⊖⊖ VERY LOW	CRITICAL
Change in symptom scores - PFDI-20 (follow-up 3 months; Better indicated by lower values)												
1	randomised trials	very serious[5]	no serious inconsistency	serious[6]	no serious imprecision	none	56	53	-	MD 3.2 lower (17.33 lower to 10.93 higher)	⨁⊖⊖⊖ VERY LOW	CRITICAL
Change in symptom scores - POPDI-6 (follow-up 3 months; Better indicated by lower values)												
1	randomised trials	very serious[5]	no serious inconsistency	serious[6]	no serious imprecision	none	56	53	-	MD 5.6 lower (11.48 lower to	⨁⊖⊖⊖	CRITICAL

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Supervised PFMT + Lifestyle advice	Control	Relative (95% CI)	Absolute	Quality	Importance
										0.28 higher)	VERY LOW	
Change in symptom scores - UDI-6 (follow-up 3 months; Better indicated by lower values)												
1	randomised trials	very serious[5]	no serious inconsistency	serious[6]	no serious imprecision	none	56	53	-	MD 1 higher (5.08 lower to 7.08 higher)	⨁⊖⊖⊖ VERY LOW	CRITICAL
Change in symptom scores- CRADI-8 (follow-up 3 months; Better indicated by lower values)												
1	randomised trials	very serious[5]	no serious inconsistency	serious[6]	serious[7]	none	56	53	-	MD 1.1 higher (4.2 lower to 6.4 higher)	⨁⊖⊖⊖ VERY LOW	CRITICAL
Change in symptom scores - PFDI-20 (follow-up 6 months; Better indicated by lower values)												
1	randomised trials	very serious[5]	no serious inconsistency	serious[6]	no serious imprecision	none	40	45	-	MD 3.6 higher (12.6 lower to 19.8 higher)	⨁⊖⊖⊖ VERY LOW	CRITICAL
Change in symptom scores - POPDI-6 (follow-up 6 months; Better indicated by lower values)												
1	randomised trials	very serious[5]	no serious inconsistency	serious[6]	no serious imprecision	none	40	45	-	MD 6.7 lower (13.43 lower to 0.03 higher)	⨁⊖⊖⊖ VERY LOW	CRITICAL
Change in symptom scores - UDI-6 (follow-up 6 months; Better indicated by lower values)												
1	randomised trials	very serious[5]	no serious inconsistency	serious[6]	serious[8]	none	40	45	-	MD 5.7 higher (1.21 lower	⨁⊖⊖⊖	CRITICAL

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Supervised PFMT + Lifestyle advice	Control	Relative (95% CI)	Absolute	Quality	Importance
										to 12.61 higher)	VERY LOW	
Change in symptom scores CRADI-8 (follow-up 6 months; Better indicated by lower values)												
1	randomised trials	very serious[5]	no serious inconsistency	serious[6]	serious[7]	none	40	45	-	MD 2.3 higher (3.75 lower to 8.35 higher)	⨁⊖⊖⊖ VERY LOW	CRITICAL
Change in POP-SS score - Change in POP-SS score (follow-up 20 weeks; Better indicated by lower values)												
1	randomised trials	very serious[2]	no serious inconsistency	no serious indirectness	serious[9]	none	17	20	-	MD 2.34 lower (4.97 lower to 0.29 higher)	⨁⊖⊖⊖ VERY LOW	CRITICAL
Change in POP-SS score - Change in POP-SS score (follow-up 26 weeks; Better indicated by lower values)												
2	randomised trials	very serious[2]	no serious inconsistency	no serious indirectness	very serious[10]	none	205	209	-	MD 3.07 lower (3.91 to 2.23 lower)	⨁⊖⊖⊖ VERY LOW	CRITICAL
Change in POP-SS score - Change in POP-SS (follow-up 12 months; Better indicated by lower values)												
2	randomised trials	very serious[1,2]	no serious inconsistency	no serious indirectness	serious[9]	none	304	303	-	MD 1.31 lower (1.94 to 0.69 lower)	⨁⊖⊖⊖ VERY LOW	CRITICAL
Change in POP-SS score - Change in POP-SS (follow-up 24 months; Better indicated by lower values)												
1	randomised trials	very serious[2]	no serious inconsistency	no serious indirectness	serious[9]	none	161	180	-	MD 1.5 lower (2.12 to 0.88 lower)	⨁⊖⊖⊖ VERY LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Supervised PFMT + Lifestyle advice	Control	Relative (95% CI)	Absolute		
Change in quality of life scores- PFIQ-7 (follow-up 3 months; Better indicated by lower values)												
1	randomised trials	very serious[5]	no serious inconsistency	serious[6]	no serious imprecision	none	56	53	-	MD 6.5 higher (5.72 lower to 18.72 higher)	⨁⊖⊖⊖ VERY LOW	CRITICAL
Change in quality of life scores - POPIQ-7 (follow-up 3 months; Better indicated by lower values)												
1	randomised trials	very serious[5]	no serious inconsistency	serious[6]	no serious imprecision	none	56	53	-	MD 1.1 higher (4.03 lower to 6.23 higher)	⨁⊖⊖⊖ VERY LOW	CRITICAL
Change in quality of life scores - UIQ-7 (follow-up 3 months; Better indicated by lower values)												
1	randomised trials	very serious[5]	no serious inconsistency	serious[6]	no serious imprecision	none	56	53	-	MD 3.4 higher (1.78 lower to 8.58 higher)	⨁⊖⊖⊖ VERY LOW	CRITICAL
Change in quality of life scores - CRAIQ-7 (follow-up 3 months; Better indicated by lower values)												
1	randomised trials	very serious[5]	no serious inconsistency	serious[6]	no serious imprecision	none	56	53	-	MD 2.65 higher (1.96 lower to 7.26 higher)	⨁⊖⊖⊖ VERY LOW	CRITICAL
Change in quality of life scores - PFIQ-7 (follow-up 6 months; Better indicated by lower values)												
1	randomised trials	very serious[5]	no serious inconsistency	serious[6]	no serious imprecision	none	40	45	-	MD 9.7 higher (4.18 lower to 23.58 higher)	⨁⊖⊖⊖ VERY LOW	CRITICAL
Change in quality of life scores - UIQ-7 (follow-up 6 months; Better indicated by lower values)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Supervised PFMT + Lifestyle advice	Control	Relative (95% CI)	Absolute		
1	randomised trials	very serious[5]	no serious inconsistency	serious[6]	no serious imprecision	none	40	45	-	MD 0.6 lower (6.41 lower to 5.21 higher)	⨁⊖⊖⊖ VERY LOW	CRITICAL
Change in quality of life scores - POPIQ-7 (follow-up 6 months; Better indicated by lower values)												
1	randomised trials	very serious[5]	no serious inconsistency	serious[6]	no serious imprecision	none	40	45	-	MD 7.1 higher (1.25 to 12.95 higher)	⨁⊖⊖⊖ VERY LOW	CRITICAL
Change in quality of life scores - CRAIQ-7 (follow-up 6 months; Better indicated by lower values)												
1	randomised trials	very serious[5]	no serious inconsistency	serious[6]	serious[11]	none	40	45	-	MD 3.45 higher (1.81 lower to 8.71 higher)	⨁⊖⊖⊖ VERY LOW	CRITICAL
Change in PISQ-12 sexual function score (follow-up 24 months; Better indicated by lower values)												
1	randomised trials	very serious[12]	no serious inconsistency	no serious indirectness	no serious imprecision	none	128	134	-	MD 0.30 higher (0.84 lower to 1.44 higher)	⨁⨁⊖⊖ LOW	IMPORTANT
Change in POP-Q stage - Improvement by 2 stages (follow-up 20 weeks)												
1	randomised trials	serious[5]	no serious inconsistency	serious[6]	NC	none	0/11 (0%)	0/9 (0%)	NC	NC	⨁⨁⊖⊖ LOW	IMPORTANT
Change in POP-Q stage - Improvement by 1 stage (follow-up 20 weeks)												
1	randomised trials	serious[5]	no serious inconsistency	serious[6]	very serious[2]	none	1/11 (9.1%)	3/9 (33.3%)	0.20 (0.2 to 2.39)	267 fewer per 1000	⨁⊖⊖⊖	IMPORTANT

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Supervised PFMT + Lifestyle advice	Control	Relative (95% CI)	Absolute	Quality	Importance
										(from 267 fewer to 463 more)	VERY LOW	
Change in POP-Q stage - Improvement by 2 stages (follow-up 6 months)												
	randomised trials	serious[5]	no serious inconsistency	serious[6]	serious[4]	none	4/168 (2.4%)	9/171 (5.3%)	RR 0.44 (0.16 to 1.20)	29 fewer per 1000 (from 44 fewer to 11 more)	⨁⊖⊖⊖ VERY LOW	IMPORTANT
Change in POP-Q stage - Improvement by 1 stage (follow-up 6 months; assessed with: POP-Q)												
1	randomised trials	serious[5]	no serious inconsistency	serious[6]	serious[4]	none	26/168 (15.5%)	29/171 (17%)	RR 0.90 (0.50 to 1.60)	17 fewer per 1000 (from 85 fewer to 102 more)	⨁⊖⊖⊖ VERY LOW	IMPORTANT
Adverse events through study period - pain in tail bone, fall, shortness of breath and chest pain (follow-up 24 months)												
1	randomised trials	very serious[12]	no serious inconsistency	no serious indirectness	very serious[2]	none	3/206 (1.5%)	0/206 (0%)	RR 7.0 (0.36 to 134.67)	-	⨁⊖⊖⊖ VERY LOW	IMPORTANT

[1] Random sequence: Low risk of bias; Allocation concealment: Unclear risk of bias (not mentioned in text); Blinding: High risk of bias (the study was not blinded); Incomplete outcome data: Low risk of bias; Selective reporting: Low risk of bias; Other bias: Unclear risk of bias (PFMT adherence unclear; potential for controls to perform exercises).
[2] Evidence downgraded by 2 due to risk of very serious imprecision, 95% confidence intervals crosses both default MID for dichotomous outcomes, (0.8 and 1.25)
[3]Random sequence: Low risk of bias (computer-generated); Allocation concealment: Low risk of bias; Blinding: High risk of bias (participants and physiotherapists not blinded); Incomplete outcome data: Unclear risk of bias (reasons for discontinuing over 2 years not stated); Selective reporting: Low risk of bias; Other bias: Unclear risk of bias (PFMT adherence unclear; potential for controls to perform exercises).
[4] Evidence downgraded by 1 due to risk of serious imprecision, 95% confidence intervals crosses one default MID for dichotomous outcomes, (0.8 or 1.25)
[5] Random sequence: Low risk of bias (computer-generated random numbers with stratification for age groups ≥60 years; Allocation concealment: Low risk of bias (randomised closed envelopes); Blinding: High risk of bias (single primary investigator blinded); Incomplete outcome data: Low risk of bias (reasons for discontinuing stated and do not appear to be related to treatment); Selective reporting: Low risk of bias; Other bias: Unclear risk of bias (authors acknowledge potential for selection bias - only 11% of women contacted from hospital referral lists accepted recruitment; PFMT adherence unclear; potential for controls to perform exercises)..
[6] Potential for selection bias - only 11% of women contacted from hospital referral lists accepted recruitment.

[7] Evidence downgraded by 1 due to risk of serious imprecision, 95% confidence intervals crosses one default MID for continuous outcomes, MID used was 5 as reported in Jelovsek et al. 2014.
[8] Evidence downgraded by 1 due to risk of serious imprecision, 95% confidence intervals crosses one default MID for continuous outcomes, MID used was 11 as reported in Barber et al. 2009.
[9] Evidence downgraded by 1 due to risk of serious imprecision, 95% confidence intervals crosses one default MID for continuous outcomes, MID used was 1.5 as reported in Hagen et al. 2010.
[10] Evidence downgraded by 2 due to risk of very serious imprecision, 95% confidence intervals cross both default MID for continuous outcomes, MID used was 1.5 as reported in Hagen et al 2010
[11] Evidence downgraded by 1 due to risk of serious imprecision, 95% confidence intervals crosses one default MID for continuous outcomes, MID used was 8 as reported in Jelovsek et al. 2014.
[12] Random sequence: Low risk of bias (computer-generated); Allocation concealment: Low risk of bias; Blinding: High risk of bias (participants and physiotherapists not blinded); Incomplete outcome data: Unclear risk of bias (reasons for discontinuing over 2 years not stated) Selective reporting: Low risk of bias; Other bias: Unclear risk of bias (PFMT adherence unclear; potential for controls to perform exercises).
NB MIDS used as follows: PFDI-20, 45; POPDI-6, 16; UDI-6, 11; CRADI-8, 5; PFIQ-7, 36; POPIQ-7, 29; UIQ-7, 16; CAIQ-7, 8; POP-SS, 1.5 and PISQ-12, 6.

Table 12: Clinical evidence profile for comparison PFMT + Self Instruction Manual (SIM) vs SIM alone

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**PFMT + SIM**	**Control**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
Change in POP-SS score (follow-up 24 weeks; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	N=70 MD -2.99 SD NR	N=70 MD -1.25 SD NR	P=0.002		⨁⨁⊖⊖ LOW	CRITICAL
Change in QoL scores - PFIQ-7 score (follow-up 24 weeks)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	- N=70 Mean 8.3 SD NR	- N=70 Mean 11.01 SD NR	- p<0.001		⨁⨁⊖⊖ LOW	CRITICAL

[1] Random sequence: Low risk of bias; Allocation concealment: Low risk of bias; Blinding: High risk of bias (not blinded); Incomplete outcome data: High risk of bias (>10% dropout); Selective reporting: Low risk of bias; Other bias: Unclear risk of bias (unclear adherence to exercise).
[2] The evidence was downgraded by 1 because there were no 95% CI, therefore uncertain of the imprecision

Table 13: Clinical evidence profile for comparison Supervised PFMT + Lifestyle advice vs Unsupervised PFMT + Lifestyle advice

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Supervised PFMT + Lifestyle advice	Unsupervised PFMT + Lifestyle advice	Relative (95% CI)	Absolute	Quality	Importance
Change in POP-Q stage - Improvement by 2 stages - anterior (follow-up 14 weeks)												
1	randomised trials	serious[1]	no serious inconsistency	serious[2]	NC	none	0/21 (0%)	0/16 (0%)	NC	NC	⨁⨁⊖⊖ LOW	IMPORTANT
Change in POP-Q stage - Improvement by 2 stages - posterior (follow-up 14 weeks)												
1	randomised trials	serious[1]	no serious inconsistency	serious[2]	very serious[3]	none	1/21 (4.8%)	0/16 (0%)	RR 2.32 (0.1 to 53.42)	-	⨁⊖⊖⊖ VERY LOW	IMPORTANT
Change in POP-Q stage - Improvement by 1 stage - anterior (follow-up 14 weeks)												
1	randomised trials	serious[1]	no serious inconsistency	serious[2]	NC	none	0/21 (0%)	0/16 (0%)	NC	NC	⨁⨁⊖⊖ LOW	IMPORTANT
Change in POP-Q stage - Improvement by 1 stage - posterior (follow-up 14 weeks)												
1	randomised trials	serious[1]	no serious inconsistency	serious[2]	NC	none	0/21 (0%)	0/16 (0%)	NC	NC	⨁⨁⊖⊖ LOW	IMPORTANT

[1] Random sequence: Low risk of bias (computer-generated); Allocation concealment: Unclear risk of bias; Blinding: High risk of bias (single blinded); Incomplete outcome data: Low risk of bias; Selective reporting: Low risk of bias; Other bias: Unclear risk of bias (potential for selection bias as patients with apical prolapse were excluded from the study; PFMT adherence unclear).

[2] Potential for selection bias as patients with apical prolapse were excluded from the study.

[3] Evidence downgraded by 2 due to risk of very serious imprecision, 95% confidence intervals crosses both default MID for dichotomous outcomes, (0.8 and 1.25)

Table 14: Clinical evidence profile for comparison Pessary + PFMT vs PFMT alone

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PFMT + vaginal pessary	PFMT alone	Relative (95% CI)	Absolute		
Symptom scores at 6 months - POPDI												
1	- randomised trials	Very serious[1]	No serious inconsistency	no serious indirectness	serious[2]	none	Median 40.7 IQR 11.3 to 100)	Median 54.8 IQR 22.6 to 103.6	p=0.02		⊕⊖⊖⊖ VERY LOW	CRITICAL
Symptom scores at 6 months – UDI												
1	- randomised trials	Very serious[1]	No serious inconsistency	no serious indirectness	serious[2]	none	Median 42.8 IQR 21.0 to 81.3	Median 41.0 IQR 19.8 to 80.7	p=0.87		⊕⊖⊖⊖ VERY LOW	CRITICAL
Symptom scores at 6 months - CRADI												
1	- randomised trials	Very serious[1]	No serious inconsistency	no serious indirectness	serious[2]	none	Median 42.3 IQR 12.1 to 86.9	Median 40.6 IQR 15.5 to 83.0	p=0.92		⊕⊖⊖⊖ VERY LOW	CRITICAL
Symptom scores at 6 months – POPIQ												
1	- randomised trials	Very serious[1]	No serious inconsistency	no serious indirectness	serious[2]	none	Median 5.6 IQR 0 to 42.4	Median 8.3 IQR 0 to 76.5	p=0.22		⊕⊖⊖⊖ VERY LOW	CRITICAL
Symptom scores at 6 months - UIQ												
1	- randomised trials	Very serious[1]	No serious inconsistency	no serious indirectness	serious[2]	none	Median 15.3 IQR 1.6 to 48.6	Median 11.1 IQR 0 to 56.9	p=0.33		⊕⊖⊖⊖ VERY LOW	CRITICAL
Symptom scores at 6 months – CRAIQ												

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**PFMT + vaginal pessary**	**PFMT alone**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
1	- randomised trials	Very serious[1]	No serious inconsistency	no serious indirectness	serious[2]	None	Median 0 IQR 0 to 5.6	Median 0 IQR 0 to 8.5	p=0.90		⨁⊖⊖⊖ VERY LOW	CRITICAL
Symptom scores at 12 months – POPDI												
1	- randomised trials	Very serious[1]	No serious inconsistency	no serious indirectness	serious[2]	none	Median 32.1 IQR 12.5 to 78.6	Median 49.4 IQR 21.4 to 95.2	p=0.04		⨁⊖⊖⊖ VERY LOW	CRITICAL
Symptom scores at 12 months – UDI												
1	- randomised trials	Very serious[1]	No serious inconsistency	no serious indirectness	serious[2]	none	Median 39.4 IQR 16.9 to 74.7	Median 37.5 IQR 16.7 to 67.5	p=0.57		⨁⊖⊖⊖ VERY LOW	CRITICAL
Symptom scores at 12 months - CRADI												
1	- randomised trials	Very serious[1]	No serious inconsistency	no serious indirectness	serious[2]	none	Median 32.1 IQR 15.8 to 75.5	Median 32.1 IQR 14.9 to 68.0	p=0.80		⨁⊖⊖⊖ VERY LOW	CRITICAL
Symptom scores at 12 months – POPIQ												
1	- randomised trials	Very serious[1]	No serious inconsistency	no serious indirectness	serious[2]	none	Median 0.3 IQR 0 to 22.2	Median: 8.9 IQR 0 to 64.9	p= 0.02		⨁⊖⊖⊖ VERY LOW	CRITICAL
Symptom scores at 12 months - UIQ												
1	- randomised trials	Very serious[1]	No serious inconsistency	no serious indirectness	serious[2]	none	Median 13.3 IQR 0 to 40.3	Median 9.7 IQR 0 to 54.8	p=0.71		⨁⊖⊖⊖ VERY LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**PFMT + vaginal pessary**	**PFMT alone**	**Relative (95% CI)**	**Absolute**		
Symptom scores at 12 months – CRAIQ												
1	- randomised trials	Very serious[1]	No serious inconsistency	no serious indirectness	serious[2]	None	Median 0 IQR 0 to 5.6	Median 0 IQR 0 to 5.6	p=0.77		⨁⊖⊖⊖ VERY LOW	CRITICAL
Adverse events - Abnormal vaginal bleeding (follow-up 12 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	9/132 (6.8%)	4/128 (3.1%)	RR 2.18 (0.69 to 6.91)	37 more per 1000 (from 10 fewer to 185 more)	⨁⊖⊖⊖ VERY LOW	IMPORTANT
Adverse events - Significant vaginal discharge (follow-up 12 months)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	6/132 (4.5%)	2/128 (1.6%)	RR 2.91 (0.6 to 14.15)	30 more per 1000 (from 6 fewer to 205 more)	⨁⊖⊖⊖ VERY LOW	IMPORTANT

[1] Random sequence: Low risk of bias; Allocation concealment: Low risk of bias Blinding: High risk of bias (assessor blinded only); Incomplete outcome data: High risk of bias (>10% dropout); Selective reporting: Low risk of bias; Other bias: Unclear risk of bias (PFMT adherence unclear).
[2] The evidence was downgraded by 1 because there were no 95% CI, therefore uncertain of the imprecision
[3]. Evidence downgraded by 2 due to risk of very serious imprecision, 95% confidence intervals crosses both default MID for dichotomous outcomes, (0.8 and 1.25)

Table 15: Clinical evidence profile for comparison Pessary vs PFMT + Feedback/electrical stimulation/lifestyle advice

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	PFMT + Feedback/ electrical stimulation/lifestyle advice	Relative (95% CI)	Absolute	Quality	Importance
Change in symptom scores - Change in PFDI-20 (follow-up 3 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	69	43	-	MD 0.5 higher (8.79 lower to 9.79 higher)	⊕⊕⊖⊖ LOW	CRITICAL
Change in symptom scores - Change in POPDI-6 (follow-up 3 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	70	45	-	MD 2.9 higher (0.62 lower to 6.42 higher)	⊕⊕⊖⊖ LOW	CRITICAL
Change in symptom scores - Change in UDI-6 (follow-up 3 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	70	44	-	MD 3.6 lower (8.21 lower to 1.01 higher)	⊕⊕⊖⊖ LOW	CRITICAL
Change in symptom scores - Change in CRADI-8 (follow-up 3 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	70	43	-	MD 2 higher (1.83 lower to 5.83 higher)	⊕⊖⊖⊖ VERY LOW	CRITICAL
Change in symptom scores - Change in PFDI-20 (follow-up 12 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	66	45	-	MD 4.4 higher (4.86 lower	⊕⊕⊖⊖	CRITICAL

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	PFMT + Feedback/ electrical stimulation/lifestyle advice	Relative (95% CI)	Absolute	Quality	Importance
										to 13.66 higher)	LOW	
Change in symptom scores - Change in POPDI-6 (follow-up 12 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	69	48	-	MD 4.1 higher (0.64 to 7.56 higher)	⨁⨁⊖⊖ LOW	CRITICAL
Change in symptom scores - Change in UDI-6 (follow-up 12 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	68	47	-	MD 0.5 lower (5.05 lower to 4.05 higher)	⨁⨁⊖⊖ LOW	CRITICAL
Change in symptom scores - Change in CRADI-8 (follow-up 12 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	66	48	-	MD 1.1 higher (2.67 lower to 4.87 higher)	⨁⨁⊖⊖ LOW	CRITICAL
Change in symptom scores - Change in PFDI-20 (follow-up 24 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	67	71	-	MD 6.9 higher (1.31 lower to 15.11 higher)	⨁⨁⊖⊖⊖ LOW	CRITICAL
Change in symptom scores Change in POPDI-6 (follow-up 24 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	68	73	-	MD 4.7 higher	⨁⨁⊖⊖	CRITICAL

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	PFMT + Feedback/ electrical stimulation/lifestyle advice	Relative (95% CI)	Absolute	Quality	Importance
										(1.61 to 7.79 higher)	LOW	
Change in symptom scores - Change in UDI-6 (follow-up 24 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	68	72	-	MD 1 lower (5.04 lower to 3.04 higher)	⨁⨁⨀⨀ LOW	CRITICAL
Change in symptom scores - Change in CRADI-8 (follow-up 24 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	69	72	-	MD 2.1 higher (1.27 lower to 5.47 higher)	⨁⨁⨀⨀ LOW	CRITICAL
Change in QoL scores - Change in PFIQ-7 (follow-up 3 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	65	41	-	MD 1.3 higher (6.25 lower to 8.85 higher)	⨁⨁⨀⨀ LOW	CRITICAL
Change in QoL scores - Change in PFIQ-7 (follow-up 12 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	66	50	-	MD 4.2 lower (11.28 lower to 2.88 higher)	⨁⨁⨀⨀ LOW	CRITICAL
Change in QoL scores - Change in PFIQ-7 (follow-up 24 months; Better indicated by lower values)												

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	PFMT + Feedback/ electrical stimulation/lifestyle advice	Relative (95% CI)	Absolute	Quality	Importance
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	60	70	-	MD 2.1 higher (4.48 lower to 8.68 higher)	⨁⨁⊖⊖ LOW	CRITICAL
Change in sexual function - PISQ-12 (follow-up 3 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	19	25	-	MD 2.70 higher (0.87 to 4.53 higher)	⨁⨁⊖⊖ LOW	IMPORTANT
Change in sexual function - PISQ-12 (follow-up 12 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	24	24	-	MD 2.60 higher (0.88 to 4.32 higher)	⨁⨁⊖⊖ LOW	IMPORTANT
Change in sexual function - PISQ-12 (follow-up 24 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	70	60	-	MD 1.30 higher (0.25 to 2.35 higher)	⨁⨁⊖⊖ LOW	IMPORTANT
Adverse events through study period - increased vaginal discharge, increase of urinary incontinence, and irritation or erosions of the vaginal walls on physical examination. (follow-up 24 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	21/35 (60%)	0/35 (0%)	RR 0.02 (0 to 0.37)	-	⨁⊖⊖⊖ VERY LOW	IMPORTANT

[1] Random sequence: Low risk of bias; Allocation concealment: Low risk of bias; Blinding: High risk of bias (not blinded); Incomplete outcome data: High risk of bias (>10% dropout); Selective reporting: Low risk of bias; Other bias: Unclear risk of bias (PFMT adherence unclear).
[2]Evidence downgraded by 1 due to risk of serious imprecision, 95% confidence intervals crosses one default MID for continuous outcomes, MID used was 5 as reported in Jelovsek et al. 2014.
[3] Evidence downgraded by 1 due to risk of serious imprecision, 95% confidence intervals crosses one default MID for dichotomous outcomes, (0.8 or 1.25)
NB MIDS used as follows: PFDI-20, 45; POPDI-6, 16; UDI-6, 11; CRADI-8, 5; PFIQ-7, 36 and PSIQ-12, 6.

Appendix G – Economic evidence study selection

Economic evidence study selection for review question: What lifestyle interventions are effective for managing pelvic organ prolapse (POP)?

One global search was conducted for this review question. See supplementary material D for further information.

Economic evidence study selection for review question: What is the effectiveness of topical oestrogen for managing pelvic organ prolapse (POP) with vaginal atrophy?

One global search was conducted for this review question. See supplementary material D for further information.

Economic evidence study selection for review question: What are the most effective conservative management options (for example, pelvic floor exercises and pessaries) for pelvic organ prolapse (POP)?

One global search was conducted for this review question. See supplementary material D for further information.

Appendix H – Economic evidence tables

Economic evidence tables for review question: What lifestyle interventions are effective for managing pelvic organ prolapse (POP)?

No economic evidence was identified which was applicable to this review question.

Economic evidence tables for review question: What is the effectiveness of topical oestrogen for managing pelvic organ prolapse (POP) with vaginal atrophy?

No economic studies were identified which were applicable to this review question.

Economic evidence tables for review question: What are the most effective conservative management options (for example, pelvic floor exercises and pessaries) for pelvic organ prolapse (POP)?

Table 16: Economic evidence tables

Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
Hagen, S., Glazener, C., McClurg, D., Macarthur, C., Elders, A., Herbison, P., Wilson, D., Toozs-Hobson, P., Hemming, C., Hay-Smith, J., Collins, M., Pelvic floor muscle training for secondary prevention of pelvic organ	Interventions: Supervised Pelvic Floor Muscle Training (PFMT) plus lifestyle advice and vs. lifestyle advice only PFMT included five one-to-one appointments over 16 weeks with a women's health physiotherapist.	Adult women with POP-Q stage 1-3 pelvic organ prolapse (anterior, posterior, apical, or a combination) RCT (Hagen 2017) Source of clinical effectiveness data: RCT (N=412 baseline; N=323 at 12 months; N=341 at 24 months)	Costs: physiotherapy appointments, the initial appointment letter, the prolapse lifestyle advice leaflet, six Pilates-based classes, physiotherapy review appointment, GP visits. The incremental cost of supervised PFMT plus lifestyle advice per woman: • Year 1: £519 • Year 2: £329 Primary outcome measure: Quality-adjusted life years, QALYs (weights derived using SF-12 data converted to SF-6D)	The ICER of PFMT plus lifestyle advice (vs. lifestyle advice only) was £21,996 per QALY at year 1 and £28,267 per QALY at year 2	Perspective: UK NHS Currency: UK£ Cost year: likely 2011/12 Time horizon: 12 and 24 months Discounting: none Applicability: directly applicable Quality: minor limitations

Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
prolapse (PREVPROL): a multicentre randomised controlled trial, The Lancet, 389, 393-402, 2017 UK Cost-utility analysis Conflict of interest: none. Funding: Chief Scientist Office of the Scottish Government Health and Social Care Directorates, New Zealand Lottery Board, and National Health and Medical Research Council (Australia)	Women were also offered Pilates classes and an exercise DVD for home use); plus review appointments at years 1 and 2 and lifestyle advice. Lifestyle advice leaflet gave advice about weight loss, constipation, avoidance of heavy lifting, coughing, and high-impact exercise. Women received this leaflet by post.	Source of resource use data: RCT (N= as above) Source of unit costs: national sources	The incremental QALYs of supervised PFMT plus lifestyle advice at: • Year 1: 0.02 • Year 2: 0.01		
Hagen, S., Stark, D., Glazener, C.,	Interventions:	Adult women with POP-Q stage 1-3 pelvic organ	Costs: physiotherapy appointments, costs associated with the clinic space, consultations with family doctor or a	The ICER of supervised PFMT plus lifestyle advice (vs.	Perspective: UK NHS Currency: UK£ Cost year: likely 2010

Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
Dickson, S., Barry, S., Elders, A., Frawley, H., Galea, M. P., Logan, J., McDonald, A., McPherson, G., Individualised pelvic floor muscle training in women with pelvic organ prolapse (POPPY): a multicentre randomised controlled trial, The Lancet, 383, 796-806, 2014 UK Cost-effectiveness analysis Conflict of interest: none. Funding: Chief Scientist Office of the Scottish Government Health and	Supervised pelvic floor muscle training (PFMT) plus lifestyle advice vs. lifestyle advice only PFMT included five one-to-one appointments over 16 weeks with a women's health physiotherapist. Lifestyle advice leaflet gave advice about weight loss, constipation, avoidance of heavy lifting, coughing, and high-impact exercise. Women received this leaflet by post	prolapse (anterior, posterior, or acombination) RCT (Hagen 2014) Source of clinical effectiveness data: RCT (N=477 baseline; N=295 at 12 months) Source of resource use data: RCT (N=295) Source of unit costs: national sources	practice nurse, and any further prolapse treatment including surgery, pessary, physiotherapy, oestrogen or HRT Mean cost per woman: • Supervised PFMT plus lifestyle advice: £438.47 (95% CI: £380.59; £503.83). • Lifestyle advice: £306.86 (95% CI: £250.74; £368.29) • The difference: £131.61 (95% CI: £43.83; £212.19) Primary outcome measure: change in POP-SS scores Mean POP-SS scores at 12 months (reduction from baseline): • Supervised PFMT plus lifestyle advice: 2.09 (SD: 5.39) • Lifestyle advice: 3.77 (SD: 5.62) Adjusted difference for baseline score, POP-Q stage, centre, and whether or not woman was motivated to have surgery: 1.52 (95% CI: 0.46; 2.59), p = 0.0053 (in favour of supervised PFMT plus lifestyle advice)	lifestyle advice only) was £86.59 per additional point improvement on the POP-SS scale	Time horizon: 12 months Discounting: NA Applicability: partially applicable Quality: minor limitations

Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
Social Care Directorates, New Zealand Lottery Board, and National Health and Medical Research Council (Australia).					
Panman, C. M., Wiegersma, M., Kollen, B. J., Berger, M. Y., Lisman-van Leeuwen, Y., Vermeulen, K. M., Dekker, J. H., Effectiveness and cost-effectiveness of pessary treatment compared with pelvic floor muscle training in older women with pelvic organ prolapse: 2-year follow-up of a randomized controlled trial in primary care, Menopause, 23,	Interventions: Pelvic floor muscle training (PFMT) (face to face and at home, 3-5 times a week, 2-3 times each day) vs. pessary treatment (first choice was an open ring pessary, followed by a ring pessary with support; if ring pessary could not be fitted a Shaatz or Gellhorn pessary was tried)	Adult women with advanced stage 2 or 3 pelvic organ prolapse RCT (Panman 2016) Source of clinical effectiveness data: RCT (N=162) Source of resource use data: RCT Source of unit costs: unclear	Costs: pessaries and pessary-related visits, physical therapy, consultations with GPs and medical specialists, absorbent pads, medication, operative procedures. Mean cost per participant: • Pessary: $309 • PFMT: $437 • The difference: $128 (95% CI: $27; $236) Primary outcome measures: change of pelvic floor symptoms (PFDI-20 score [range 0 to 300 – higher score is higher distress), QALYs (EQ-5D-3L, UK general population norms) Mean PFDI-20 scores at 24 months (ITT analysis): • PFMT: 62.6 • Pessary: 50.5 • Adjusted difference for baseline score and baseline POP stage: -3.7 (95% CI:	The pessary is dominant using both outcome measures According to bootstrapping pessary is dominant in 71% and 95% of the replications when using PFDI-20 and QALYs as outcome measures, respectively	Perspective: health care payer Currency: USD Cost year: 2014 Time horizon: 2 years Discounting: No Applicability: partially applicable Quality: minor limitations Bootstrapping was undertaken to capture uncertainty in costs and outcomes

Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
1307-1318, 2016 Netherlands Cost-effectiveness and cos-utility analysis Conflict of interest: none. Funding: the Netherlands Organisation for Health research and Development.			-12.8; 5.3), p = 0.42 (in favour of the pessary) Pessary resulted in the mean QALY gain of 0.041 when compared with PFMT.		
Panman, C. M., Wiegersma, M., Kollen, B. J., Berger, M. Y., Leeuwen, L. V., Vermeulen, K. M., Dekker, J. H., Two-year effects and cost-effectiveness of pelvic floor muscle training in mild pelvic organ prolapse: a randomised controlled trial	Interventions: PFMT (face to face contact and practising at home 3-5 times a week for 2-3 times each day) vs. watchful waiting (women received information on pelvic anatomy and pelvic floor muscle function by illustrated leaflets; they were also	Older women (≥55 years) with a symptomatic mild pelvic organ prolapse RCT (Panman 2016) Source of clinical effectiveness data: RCT (N=287) Source of resource use data: RCT	Costs: physical therapy, consultations with GPs and medical specialists, absorbent pads, other prolapse-related treatments (pessaries, pelvic floor muscle training and prolapse surgery) Mean cost per participant: • PFMT: €330 • Watchful waiting: €91 • The difference: €239 (95% CI; €161; €319) Primary outcome measures: change of pelvic floor symptoms (PFDI-20 score range 0 to 300 – higher score is higher	The ICER of PFMT (vs. watchful waiting): €43 per additional point improvement on PFDI-20; and €31,983/QALY gained According to bootstrapping PFMT results in better outcomes and higher costs in 98% and 55% of the replications when using PFDI-20 and QALYs as an	Perspective: health care payer Currency: Euro Cost year: 2013 Time horizon: 2 years Discounting: None Applicability: partially applicable Quality: minor limitations Bootstrapping was undertaken to capture uncertainty in costs and outcomes

Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
in primary care. BJOG: An International Journal of Obstetrics & Gynaecology, 124, 511-520, 2017 Netherlands Cost-effectiveness and cost-utility analysis Conflict of interest: none. Funding: the Netherlands Organisation for Health research and Development.	informed about the degree of their prolapse and the function of their pelvic floor muscles).	Source of unit costs: unclear	distress), QALY (EQ-5D-3L, UK general population norms) Mean PFDI-20 scores at 24 months (ITT analysis): • PFMT: reduction of 19 points (from 65.2 to 46.2). • Watchful waiting: reduction of 5.4. points (from 59 to 53.6) • The adjusted difference (for baseline PFDI-20 score and prolapse stage): 12.2 point reduction (95% CI; 7.2; 17.2) (in favour of PFMT) PFMT was associated with a QALY gain of 0.006 when compared with watchful waiting.	outcome measure, respectively	

Appendix I – Economic evidence profiles

Economic profiles for review question: What lifestyle interventions are effective for managing pelvic organ prolapse (POP)?

No studies were identified which were applicable to this review question.

Economic evidence profiles for review question: What is the effectiveness of topical oestrogen for managing pelvic organ prolapse (POP) with vaginal atrophy?

No economic studies were identified which were applicable to this review question.

Economic evidence profiles for review question: What are the most effective conservative management options (for example, pelvic floor exercises and pessaries) for pelvic organ prolapse (POP)?

Table 17: Economic evidence profiles for supervised pelvic floor muscle training (PFMT) plus lifestyle advice versus lifestyle advice only

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental outcome	ICER	Uncertainty
Hagen 2017 UK	Minor limitations[1]	Directly applicable[2]	Cost-utility analysis Time horizon: 12 and 24 months Primary measure of outcome: QALYs	£519 – year 1 £329 – year 2	0.02 – year 1 0.01 – year 2	£21,996 per QALY – year 1 £28,267 per QALY - year 2	None
Hagen 2014 UK	Minor limitations[3]	Partially applicable[4]	Cost effectiveness analysis Time horizon: 12 months	£131.61	1.52	£86.59 per additional point improvement on the POP-SS scale	The 95% CI around the cost difference £43.83 to £212.19 The 95% CI around the outcome difference 0.46 to 2.59, p = 0.0053

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental outcome	ICER	Uncertainty
			Primary measure of outcome: change in POP-SS scores				

1. No statistical analysis on costs or QALYs reported
2. UK study, QALYs (SF-6D, UK population norms)
3. Short time horizon
4. UK study, however, no QALYs

Table 18: Economic evidence profile for PFMT versus pessary treatment

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental outcome	ICER	Uncertainty
Panman 2016 Netherlands	Minor limitations[1]	Partially applicable[2]	Cost effectiveness and cost-utility analysis Time horizon: 2 years Primary measure of outcome: change in PFDI-20 scores and QALYs	$128	-3.7 – PFDI-20 -0.041 - QALY	Pessary dominant using both outcomes	The 95% CI around the difference in PFDI-20 score: -12.8 to 5.3, p = 0.42 The 95% CI around the cost difference: $27 to $236 According to bootstrapping pessary was dominant in 71% and 95% of the replications when using PFDI-20 and QALYs as outcome measures, respectively

1. Unclear source of unit cost data
2. Non-UK study

Table 19: Economic evidence profile for PFMT versus watchful waiting

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental outcome	ICER	Uncertainty
Panman 2017 Netherlands	Minor limitations[1]	Partially applicable[2]	Cost effectiveness and cost-utility analysis Time horizon: 2 years Primary measure of outcome: change in PFDI-20 scores and QALYs	€239	-12.2 – PFDI-20 0.006 - QALY	€43 per additional point improvement on PFDI-20; and €31,983/QALY gained	The 95% CI around the difference in PFDI-20 score: -7.2 to 17.2 The 95% CI around the cost difference: €161 to €319 According to bootstrapping PFMT resulted in better outcomes and higher costs in 98% and 55% of the replications when using PFDI-20 and QALYs as an outcome measure, respectively

1. Unclear source of unit cost data
2. Non-UK study

Appendix J – Economic analysis

Economic analysis for review question: What lifestyle interventions are effective for managing pelvic organ prolapse (POP)?

No economic analysis was conducted for this review question.

Economic analysis for review question: What is the effectiveness of topical oestrogen for managing pelvic organ prolapse (POP) with vaginal atrophy?

No economic analysis was conducted for this review question.

Economic analysis for review question: What are the most effective conservative management options (for example, pelvic floor exercises and pessaries) for pelvic organ prolapse (POP)?

No economic analysis was conducted for this review question.

Appendix K – Excluded studies

Excluded studies for review question: What lifestyle interventions are effective for managing pelvic organ prolapse (POP)?

Clinical studies

Table 20: Excluded clinical studies with reasons for exclusion

Excluded studies – Lifestyle interventions for POP	
Study	**Reason for Exclusion**
Gozukara, Y. M., Akalan, G., Tok, E. C., Aytan, H., Ertunc, D., The improvement in pelvic floor symptoms with weight loss in obese women does not correlate with the changes in pelvic anatomy, International Urogynecology Journal, 25, 1219-25, 2014	Results not presented separately for women with POP.
Groutz, A., Leshem, A., Gordon, D., Shimonov, M., Effects of bariatric surgery on female lower urinary tract symptoms and sexual function, Neurourology and urodynamics, 36, S145-S146, 2017	Conference abstract only
Hagen, S., Glazener, C., McClurg, D., Macarthur, C., Elders, A., Herbison, P., Wilson, D., Toozs-Hobson, P., Hemming, C., Hay-Smith, J., Collins, M., Dickson, S., Logan, J. Pelvic floor muscle training for secondary prevention of pelvic organ prolapse (PREVPROL): a multicentre randomised controlled trial. The Lancet, 393-402, 2017	Intervention not relevant to protocol.
Hagen, S., Stark, D., Glazener, C., Dickson, S., Barry, S., Elders, A., Frawley, H., Galea, M. P., Logan, J., McDonald, A., McPherson, G., Moore, K. H., Norrie, J., Walker, A., Wilson, D. Individualised pelvic floor muscle training in women with pelvic organ prolapse (POPPY): A multicentre randomized controlled trial. The Lancet, 796-806, 2014	Intervention not relevant to protocol.
Hagen, S., Stark, D., Glazener, C., Sinclair, L., Ramsay, I. A randomized controlled trial of pelvic floor muscle training for stages I and II pelvic organ prolapse. International Urogynecology Journal, 45-51, 2009	Intervention not relevant to protocol.
Leshem, A., Shimonov, M., Amir, H., Gordon, D., Groutz, A., Effects of Bariatric Surgery on Female Pelvic Floor Disorders, Urology, 105, 42-47, 2017	Comparative data not relevant to protocol.
Myers, D. L., Sung, V. W., Richter, H. E., Creasman, J., Subak, L. L., Prolapse symptoms in overweight and obese women before and after weight loss, Female Pelvic Medicine & Reconstructive Surgery, 18, 55-9, 2012	Population not relevant to protocol - majority received previous hysterectomy/surgery.

Excluded studies – Lifestyle interventions for POP	
Shariati, A., Maceda, J. S., Hale, D. S., High-fiber diet for treatment of constipation in women with pelvic floor disorders, Obstetrics and gynecology, 111, 908-913, 2008	Outcomes not relevant to protocol.

Economic studies

No economic evidence was identified for this review. See supplementary material D for further information.

Excluded studies table with reasons for exclusion for review question: What is the effectiveness of topical oestrogen for managing pelvic organ prolapse (POP) with vaginal atrophy?

Clinical studies

Table 21: Excluded clinical studies with reasons for exclusion

Excluded studies – RQ 8.2 Oestrogen for POP and vaginal atrophy	
Study	**Reason for Exclusion**
Anonymous,, Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society, Menopause, 20, 888-902; quiz 903-4, 2013	Position statement - paper does not refer to pelvic organ prolapse
Beckley, I., Harris, N., Pelvic organ prolapse: A urology perspective, Journal of Clinical Urology, 6, 68-76, 2013	Narrative literature review
Bidmead, J., Cardozo, L. D., Pelvic floor changes in the older woman, British Journal of Urology, 82, 18-25, 1998	Narrative literature review
Bruyniks, N., Biglia, N., Palacios, S., Mueck, A. O., Systematic indirect comparison of ospemifene versus local estrogens for vulvar and vaginal atrophy, Climacteric, 20, 195-204, 2017	Population do not meet inclusion criteria - women do not have pelvic organ prolapse
Cardozo,L., Bachmann,G., McClish,D., Fonda,D., Birgerson,L., Meta-analysis of estrogen therapy in the management of urogenital atrophy in postmenopausal women: second report of the Hormones and Urogenital Therapy Committee, Obstetrics and Gynecology, 92, 722-727, 1998	Population do not meet inclusion criteria - women do not have pelvic organ prolapse
Chism,L.A., Overcoming resistance and barriers to the use of local estrogen therapy for the treatment of vaginal atrophy, International Journal of Women's Health, 4, 551-557, 2012	Narrative literature review
Crandall, C., Vaginal estrogen preparations: A review of safety and efficacy for vaginal atrophy, Journal of Women's Health, 11, 857-877, 2002	Narrative literature review on efficacy and adverse effects of commonly prescribed vaginal oestrogens
Felding,C., Mikkelsen,A.L., Clausen,H.V., Loft,A., Larsen,L.G., Preoperative treatment with oestradiol in women scheduled for vaginal operation for genital prolapse. A randomised, double-blind trial, Maturitas, 15, 241-249, 1992	No relevant outcomes reported

Excluded studies – RQ 8.2 Oestrogen for POP and vaginal atrophy	
Griebling, T. L., Vaginal pessaries for treatment of pelvic organ prolapse in elderly women, Current Opinion in Urology, 26, 201-6, 2016	Narrative literature review
Ismail, Sharif I, Bain, Christine, Hagen, Suzanne, Oestrogens for treatment or prevention of pelvic organ prolapse in postmenopausal women, Cochrane Database of Systematic Reviews, 2010	Systematic review - references checked for inclusion
Karp,D.R., Jean-Michel,M., Johnston,Y., Suciu,G., Aguilar,V.C., Davila,G.W., A randomized clinical trial of the impact of local estrogen on postoperative tissue quality after vaginal reconstructive surgery, Female Pelvic Medicine and Reconstructive Surgery, 18, 211-215, 2012	Population does not meet the inclusion criteria - all women had pelvic reconstructive surgery
Kingsberg,S.A., Krychman,M.L., Resistance and barriers to local estrogen therapy in women with atrophic vaginitis, Journal of Sexual Medicine, 10, 1567-1574, 2013	Narrative literature review
Krychman,M.L., Vaginal estrogens for the treatment of dyspareunia, Journal of Sexual Medicine, 8, 666-674, 2011	Narrative literature review
Lethaby, Anne, Ayeleke, Reuben Olugbenga, Roberts, Helen, Local oestrogen for vaginal atrophy in postmenopausal women, Cochrane Database of Systematic Reviews, 2016	Systematic review - references checked for inclusion
Lindahl,S.H., Reviewing the options for local estrogen treatment of vaginal atrophy, International Journal of Women's Health, 6, 307-312, 2014	Narrative literature review
Mazzarello, S., Hutton, B., Ibrahim, M. F., Jacobs, C., Shorr, R., Smith, S., Ng, T., Clemons, M., Management of urogenital atrophy in breast cancer patients: a systematic review of available evidence from randomized trials, Breast Cancer Research & TreatmentBreast Cancer Res Treat, 152, 1-8, 2015	Systematic review - references checked for inclusion. Population considered in the review do not meet the inclusion criteria
Mikkelsen, A. L., Felding, C., Clausen, H. V., Clinical effects of preoperative oestradiol treatment before vaginal repair operation - A double-blind, randomized trial, Gynecologic and obstetric investigation, 40, 125-128, 1995	No relevant outcomes reported
Naunton, M., Al Hadithy, A. F. Y., Brouwers, J. R. B. J., Archer, D. F., Estradiol gel: Review of the pharmacology, pharmacokinetics, efficacy, and safety in menopausal women, Menopause, 13, 517-527, 2006	Narrative literature review
Onwude, J. L., Genital prolapse in women, Clinical Evidence, 2012	Systematic review - references checked for inclusion
Palacios,S., Managing urogenital atrophy, Maturitas, 63, 315-318, 2009	Narrative literature review
Rees, M., Perez-Lopez, F. R., Ceasu, I., Depypere, H., Erel, T., Lambrinoudaki, I., Schenck-Gustafsson, K., Simoncini, T., Van Der Schouw, Y. T., Tremollieres, F., EMAS clinical guide: Low-dose vaginal estrogens for postmenopausal vaginal atrophy, Maturitas, 73, 171-174, 2012	Narrative literature review on topical estrogen for vaginal atrophy

Excluded studies – RQ 8.2 Oestrogen for POP and vaginal atrophy	
Robinson,D., Cardozo,L.D., The role of estrogens in female lower urinary tract dysfunction, Urology, 62, 45-51, 2003	Narrative literature review
Roehl,B., Buchanan,E.M., Urinary incontinence evaluation and the utility of pessaries in older women, Care Management Journals, 7, 213-217, 2006	Narrative literature review
Sun, Z., Zhu, L., Xu, T., Shi, X., Lang, J., Effects of preoperative vaginal estrogen therapy for the incidence of mesh complication after pelvic organ prolapse surgery in postmenopausal women: is it helpful or a myth? A 1-year randomized controlled trial, Menopause, 23, 740-8, 2016	Population do not meet inclusion criteria - women do not have vaginal atrophy
Tontivuthikul, P., Sanmee, U., Wongtra-Ngan, S., Pongnarisorn, C., Effect of local estrogen cream on vaginal health after pessary use for prolapsed pelvic organ: A randomized controlled trial, Journal of the Medical Association of Thailand, 99, 757-763, 2016	Unable to obtain full text
Vaccaro, C. M., Mutema, G. K., Fellner, A. N., Crisp, C. C., Estanol, M. V., Kleeman, S. D., Pauls, R. N., Histologic and cytologic effects of vaginal estrogen in women with pelvic organ prolapse: a randomized controlled trial, Female Pelvic Medicine & Reconstructive Surgery, 19, 34-9, 2013	No relevant outcomes reported
Weber, M. A., Kleijn, M. H., Langendam, M., Limpens, J., Heineman, M. J., Roovers, J. P., Local Oestrogen for Pelvic Floor Disorders: A Systematic Review, PLoS ONE [Electronic Resource], 10, e0136265, 2015	Systematic review - references checked for inclusion

Economic studies

No economic evidence was identified for this review. See supplementary material D for further information.

Excluded studies with reasons for exclusions for the review question: What are the most effective conservative management options (for example, pelvic floor exercises and pessaries) for pelvic organ prolapse (POP)?

Clinical studies

Table 22: Excluded clinical studies with reasons for exclusion

Study	Reason for exclusion
Can pelvic floor muscle training prevent and treat pelvic organ prolapse?, Journal of the Association of Chartered Physiotherapists in Women's Health, 12-12, 2011	Conference abstract

Study	Reason for exclusion
Gynecology. Vaginal pessaries, ACOG Clinical Review, 11, 9-10, 2006	Unable to obtain full text
Use of pessary for pelvic organ prolapse, ACOG Clinical Review, 9, 6-6, 2004	Commentary paper
Abdool, Z., Thakar, R., Sultan, A. H., Oliver, R. S., Prospective evaluation of outcome of vaginal pessaries versus surgery in women with symptomatic pelvic organ prolapse, International Urogynecology Journal, 22, 273-278, 2011	Study design does not meet the inclusion criteria - prospective cohort. Intervention not relevant -surgery study
Abdool, Z., Thakar, R., Sultan, A., Oliver, R., Prospective evaluation of outcome of vaginal pessaries versus surgery in women with symptomatic pelvic organ prolapse, International Journal of Gynecology and Obstetrics, 107, S94, 2009	Study design does not meet the inclusion criteria - prospective cohort. Intervention not relevant -surgery study
Abrams, P., Andersson, K. E., Birder, L., Brubaker, L., Cardozo, L., Chapple, C., Cottenden, A., Davila, W., De Ridder, D., Dmochowski, R., Drake, M., DuBeau, C., Fry, C., Hanno, P., Hay Smith, J., Herschorn, S., Hosker, G., Kelleher, C., Koelbl, H., Khoury, S., Madoff, R., Milsom, I., Moore, K., Newman, D., Nitti, V., Norton, C., Nygaard, I., Payne, C., Smith, A., Staskin, D., Tekgul, S., Thuroff, J., Tubaro, A., Vodusek, D., Wein, A., Wyndaele, J. J., Fourth international consultation on incontinence recommendations of the international scientific committee: Evaluation and treatment of urinary incontinence, pelvic organ prolapse, and fecal incontinence, Neurourology and Urodynamics, 29, 213-240, 2010	Consultation document
Ahmed, F., Sotelo, T., Management of pelvic organ prolapse, Canadian Journal of UrologyCan J Urol, 18, 6050-3, 2011	Narrative literature review
Alves, F. K., Riccetto, C., Adami, D. B. V., Marques, J., Pereira, L. C., Palma, P., Botelho, S., A pelvic floor muscle training program in postmenopausal women: A randomized controlled trial, Maturitas, 81, 300-305, 2015	Population do not meet inclusion criteria
Andersen, S., Bor, P., Limited evidence of the effect of prophylactic pelvic floor muscle training on genital prolapse, Acta obstetricia et gynecologica Scandinavica, 91, 61, 2012	Conference abstract
Bazi, T., Takahashi, S., Ismail, S., Bo, K., Ruiz-Zapata, A. M., Duckett, J., Kammerer-Doak, D., Prevention of pelvic floor disorders: international urogynecological association research and development committee opinion, International Urogynecology Journal, 12, 12, 2016	Narrative literature review
Beaumont, T., Goode, K., Evaluation of the Gynaecology Physiotherapy Assessment Service Pilot Program--an advanced scope physiotherapy model of care for women referred with incontinence and/or pelvic organ prolapse symptoms...25th National Conference on Incontinence in association with the Urogynaecological Society of Australasia 9-12 November 2016 Adelaide Convention Centre, Adelaide, South Australia, Australian & New Zealand Continence Journal, 22, 109-111, 2016	Study design does not meet inclusion criteria - no comparator group

Study	Reason for exclusion
Bernardes, B. T., Resende, A. P. M., Stupp, L., Oliveira, E., Castro, R. A., di Bella, Z. I. K. J., Girao, M. J. B. C., Sartori, M. G. F., Efficacy of pelvic floor muscle training and hypopressive exercises for treating pelvic organ prolapse in women: Randomized controlled trial, Sao Paulo Medical Journal, 130, 5-9, 2012	Outcomes not relevant to the protocol
Betschart, C., Cervigni, M., Contreras Ortiz, O., Doumouchtsis, S. K., Koyama, M., Medina, C., Haddad, J. M., la Torre, F., Zanni, G., Management of apical compartment prolapse (uterine and vault prolapse): A FIGO Working Group report, Neurourology & UrodynamicsNeurourol Urodyn, 36, 507-513, 2017	Narrative literature review
Bo, K., Pelvic floor muscle training in treatment of female stress urinary incontinence, pelvic organ prolapse and sexual dysfunction, World Journal of Urology, 30, 437-43, 2012	Narrative literature review
Bo, K., Can pelvic floor muscle training prevent and treat pelvic organ prolapse?, Acta Obstetricia et Gynecologica Scandinavica, 85, 263-8, 2006	Narrative literature review
Bo, K., Hilde, G., Staer-Jensen, J., Siafarikas, F., Tennfjord, M. K., Engh, M. E., Postpartum pelvic floor muscle training and pelvic organ prolapse - A randomized trial of primiparous women, American journal of obstetrics and gynecology, 212, 38e1-38e7, 2015	Conference abstract
Bo, K., Hilde, G., Tennfjord, M. K., Jensen, J. S., Siafarikas, F., Engh, M. E., Randomized controlled trial of pelvic floor muscle training to prevent and treat pelvic organ prolapse in postpartum primiparous women, Neurourology and Urodynamics, 32 (6), 806-807, 2013	Data not presented in a format to extract
Braaekken, I. H., Majida, M., Ellstrom Engh, M., Bo, K., Can pelvic floor muscle training improve sexual function in women with pelvic organ prolapse? a randomized controlled trial, Physiotherapy (United Kingdom), 101, eS168-eS169, 2015	Conference abstract
Braekken, I. H., Majida, M., Engh, M. E., Bo, K., Morphological changes after pelvic floor muscle training measured by 3-dimensional ultrasonography: a randomized controlled trial.[Erratum appears in Obstet Gynecol. 2010 May;115(5):1092 Note: Hoff Braekken, Ingeborg [corrected to Braekken, Ingeborg Hoff]], Obstetrics & Gynecology, 115, 317-24, 2010	Outcomes not relevant to the protocol
Braekken,I.H., Majida,M., Engh,E.M., Bo,K., Pelvic floor muscle training in treatment of pelvic organ prolapse - A single blind randomised controlled trial, Neurourology and Urodynamics, 28, 663-664, 2009	Conference abstract
Colaco, M., Badlani, G., Pelvic organ prolapsed in women: Is training beneficial?, National medical journal of India, 27, 86-87, 2014	Commentary paper
Coolen, A. L., Troost, S., Mol, B. W., Roovers, J. P., Bongers, M. Y., Primary treatment of vaginal prolapse, pessary use versus prolapse surgery, International Urogynecology Journal and Pelvic Floor Dysfunction, 1), S61-S62, 2016	Study design does not meet the inclusion criteria - prospective cohort. Intervention not relevant -surgery study

Study	Reason for exclusion
Coolen, A. W. M., Troost, S., Mol, B. W. J., Roovers, Jpwr, Bongers, M. Y., Primary treatment of pelvic organ prolapse: pessary use versus prolapse surgery, International urogynecology journal, 09, 09, 2017	Study design does not meet the inclusion criteria - prospective cohort. Intervention not relevant -surgery study
Coolen, Alwm, Primary treatment of vaginal prolapse: Pessary use versus prolapse surgery - ROK, Http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=2856, 2011	Trail registration
Doaee, M., Moradi-Lakeh, M., Nourmohammadi, A., Razavi-Ratk, S. K., Nojomi, M., Management of pelvic organ prolapse and quality of life: A systematic review and meta-analysis, International Urogynecology Journal and Pelvic Floor Dysfunction, 25, 153-163, 2014	Systematic review - references checked for inclusion
Due, U., Brostrom, S., Lose, G., Lifestyle advices with or without pelvic floor muscle training for women with symptomatic stage II-III pelvic organ prolapse, a singleblinded randomized controlled trial, Neurourology and Urodynamics, 34, S445-S446, 2015	Conference abstract
Fitz, F. F., Resende, A. P. M., Stupp, L., Sartori, M. G. F., Girao, M. J. B. C., Castro, R. A., Biofeedback for the treatment of female pelvic floor muscle dysfunction: A systematic review and meta-analysis, International urogynecology journal and pelvic floor dysfunction, 23, 1495-1516, 2012	Systematic review - population not relevant to the protocol
Frawley, H, The effect of a physiotherapy-supervised pelvic floor muscle training (PFMT) program on pelvic organ prolapse severity and pelvic floor muscle strength, Http://www.anzctr.org.au/ACTRN12608000113358.aspx, 2008	Conference abstract - full text included (Hagen 2007)
Frawley, H, Sherburn, M, Hagen, S, Galea, M, Pelvic organ prolapse physiotherapy (POPPY), Australian and new zealand continence journal, 14, 50-51, 2008	Protocol paper
Frawley, H. C., Hagen, S., Sherburn, M., Neumann, P., Herbison, P., Hay-Smith, J., Galea, M. P., Changes in prolapse following pelvic floor muscle training: A randomised controlled trial, Neurourology and Urodynamics, 31 (6), 938-939, 2012	Conference abstract
Ghroubi, S, Kharrat, O, Chaari, M, Ben, Ayed B, Guermazi, M, Elleuch, Mh, Effect of conservative treatment in the management of low-degree urogenital prolapse, Annales de readaptation et de medecine physique, 51, 96-102, 2008	Unable to obtain full text
Giraudo, D., Beccaria, N., Lamberti, G., Pelvic floor muscle training, negative pressure abdominal exercise and pelvic organ prolapse symptoms: A randomized clinical trial, Neurourology and Urodynamics, 30 (6), 1009-1011, 2011	Conference abstract
Giraudo, D., Lamberti, G., Pelvic floor muscles tranining and negative perssure abdominal exercise: A conservative treatment for pelvic organ prolapse, Neurourology and Urodynamics, 30, 18-19, 2011	Conference abstract

Study	Reason for exclusion
Gozukara, Y. M., Akalan, G., Tok, E. C., Aytan, H., Ertunc, D., The improvement in pelvic floor symptoms with weight loss in obese women does not correlate with the changes in pelvic anatomy, International Urogynecology Journal, 25, 1219-25, 2014	Outcome data not presented separately for women with prolapse
Groutz, A., Leshem, A., Gordon, D., Shimonov, M., Effects of bariatric surgery on female lower urinary tract symptoms and sexual function, Neurourology and urodynamics, 36, S145-S146, 2017	Conference abstract
Hagen, S, Stark, D, Glazener, C, Sinclair, L, Norrie, J, Wilson, D, A multi-centre randomised controlled trial of a pelvic floor muscle training intervention for women with pelvic organ prolapse (Trials Registry numbers: iSRCTN35911035 ; NCT00476892), ISRCTN register (available at: http://www.controlled-trials.com/isrctn35911035) [accessed 22 march 2010], 2007	Trial registration - publication of study included (Hagen 2007)
Hagen, S, Stark, D, Ramsay, I, Glazener, C, A feasibility study for an RCT of a pelvic floor muscle training intervention for pelvic organ prolapse (Trials Registry numbers: iSRCTN44995705; NCT00158626), ISRCTN register (available at: http://www.controlled-trials.com/isrctn44995705/isrctn44995705) [accessed 22 march 2010], 2010	Trial registration of excluded study (Hagen 2006)
Hagen, S., Glazener, C., Sinclair, L., Stark, D., Bugge, C., Psychometric properties of the pelvic organ prolapse symptom score, BJOG: An International Journal of Obstetrics & Gynaecology, 116, 25-31, 2009	Narrative literature review
Hagen, S., Stark, D., Glazener, C. M., Elde Rs, A., Long-term follow-up of a multicentre randomised controlled trial of a pelvic floor muscle training inte rvention for women with pelvic organ prolapse, International Urogynecology Journal and Pelvic Floor Dysfunction, 1), S25-S26, 2015	Conference abstract
Hagen, S., Stark, D., Glazener, C., Sinclair, L., Wilson, D., Norrie, J., Dickson, S., McPherson, G., Logan, J., Frawley, H., Moore, K., Walker, A., A multicentre randomised controlled trial of a pelvic floor muscle training intervention for women with pelvic organ prolapse, Neurourology and Urodynamics, 30 (6), 983-984, 2011	Conference abstract
Hagen,Suzanne, Stark,Diane, Conservative prevention and management of pelvic organ prolapse in women, Cochrane Database of Systematic Reviews, -, 2011	Systematic review - references checked for inclusion
Harnsomboon, T., Manonai, J., Sarit-Apirak, S., Wattanayingcharoenchai, R., Chittacharoen, A., Sututvoravut, S., Effect of colpexin sphere on pelvic floor muscle strength in women with pelvic organ prolapse: a randomized controlled trial (a preliminary report), Archives of Gynecology & Obstetrics, 283, 575-9, 2011	Outcomes not relevant to the protocol
Kashyap, R, Comparative impact of two packages of pelvic floor muscle training on clinical course of stage 1-3 pelvic organ prolapse. "A hospital based randomised controlled trial", Http://www.ctri.nic.in/Clinicaltrials/pmaindet2.php?trialid=1989, 2011	Trial registration - publication to study included (Kashyap 2013)
Kinjo, M., Yoshimura, Y., Sekiguchi, Y., Nutahara, K., Comparison of effectiveness between tension-free vaginal mesh surgery and vaginal pessary in patients with symptomatic pelvic organ prolapse, International Urogynecology Journal and Pelvic Floor Dysfunction, 24, S126-S127, 2013	Study design does not meet the inclusion criteria - prospective cohort. Intervention not relevant -surgery study

Study	Reason for exclusion
Kovoor,E., Hooper,P., Assessment and management of pelvic organ prolapse, Obstetrics, Gynaecology and Reproductive Medicine, 18, 241-246, 2008	Narrative literature review
Lamers, B. H. C., Broekman, B. M. W., Milani, A. L., Pessary treatment for pelvic organ prolapse and health-related quality of life: A review, International Urogynecology Journal, 22, 637-644, 2011	Narrative literature review
Lee, Hsj, Randomised controlled trial of vaginal ring pessary versus conservative management in women with pelvic organ prolapse, Http://www.chictr.org/en/proj/show.aspx?proj=2263, 2011	Unable to obtain full text
Leshem, A., Shimonov, M., Amir, H., Gordon, D., Groutz, A., Effects of Bariatric Surgery on Female Pelvic Floor Disorders, Urology, 105, 42-47, 2017	Population do not meet inclusion criteria - women undergoing bariatric surgery
Lone, F., Thakar, R., Sultan, A., A one year prospective comparison of vaginal pessaries and surgery in the treatment of pelvic organ prolapse using the validated iciq-vs questionnaire, International Urogynecology Journal and Pelvic Floor Dysfunction, 1), S123-S124, 2012	Conference abstract
Lone, F., Thakar, R., Sultan, A. H., One-year prospective comparison of vaginal pessaries and surgery for pelvic organ prolapse using the validated ICIQ-VS and ICIQ-UI (SF) questionnaires, International Urogynecology Journal, 26, 1305-12, 2015	Study design does not meet the inclusion criteria - prospective cohort. Intervention not relevant -surgery study
Manonai, J., Harnsomboon, T., Sarit-apirak, S., Wattanayingcharoenchai, R., Chittacharoen, A., Suthutvoravut, S., Effect of Colpexin Sphere on pelvic floor muscle strength and quality of life in women with pelvic organ prolapse stage I/II: a randomized controlled trial, International Urogynecology Journal, 23, 307-12, 2012	Outcomes not relevant to the protocol
Manonai, J., Harnsomboon, T., Sarit-Apirak, S., Wattanayingcharoenchai, R., Chittacharoen, A., Sututvoravut, S., Effect of colpexin sphere on pelvic floor muscle strength in women with pelvic organ prolapse: A randomized controlled trial, International urogynecology journal and pelvic floor dysfunction, 22, S947-S948, 2011	Conference abstract
Maxwell, M, Implementation of an evidence based pelvic floor muscle training intervention for women with pelvic organ prolapse (PROlapse and PFMT: implementing Evidence Locally - PROPEL) [protocol], NHS NIHR Website (available at Http://www.nets.nihr.ac.uk/projects/hsdr/140402), 2016	Protocol paper
Myers, D. L., Sung, V. W., Richter, H. E., Creasman, J., Subak, L. L., Prolapse symptoms in overweight and obese women before and after weight loss, Female Pelvic Medicine & Reconstructive Surgery, 18, 55-9, 2012	Population do not meet inclusion criteria - majority of women had received previous surgery
Nct,, Can Pelvic Floor Muscle Training Reduce my Prolapse? A Randomised Controlled Trial Comparing the Effect of Pelvic Floor Muscle Training and Lifestyle Advice on Pelvic Organ Prolapse, Http://clinicaltrials.gov/show/NCT01612637, 2012	Trial registration

Study	Reason for exclusion
Nct,, Bo, K, Effect of Pelvic Floor Muscle Training (PFMT) in Prevention and Treatment of Female Pelvic Organ Prolapse (POP), Http://clinicaltrials.gov/show/NCT00271297, 2005	Trial registration
Nct,, Hagen, S, A Feasibility Study for an RCT of a Pelvic Floor Muscle Training Intervention for Pelvic Organ Prolapse, Http://clinicaltrials.gov/show/NCT00158626, 2003	Trial registration
Nct,, Hagen, S, A Multi-centre Randomised Controlled Trial of a Pelvic Floor Muscle Training Intervention for Women With Pelvic Organ Prolapse, Http://clinicaltrials.gov/show/NCT00476892, 2007	Trial registration
Nct,, Resende, Apm, Impact of Pelvic Floor Muscle Training and Hypopressive Exercises in Women With Pelvic Organ Prolapse: Randomized Controlled Trial, Http://clinicaltrials.gov/show/NCT01196598, 2008	Trial registration
O. Zengin N, Yildirim, N. U., Duran, B., A comparison between stabilization exercises and pelvic floor muscle training in women with pelvic organ prolapse, Turk Jinekoloji ve Obstetrik Dernegi Dergisi, 12, 11-17, 2015	Study design not relevant to the protocol
Onwude, J. L., Genital prolapse in women, Clinical Evidence, 2012	Systematic review - references checked inclusion
Panman, C. M., Wiegersma, M., Kollen, B. J., Berger, M. Y., Lisman-Van Leeuwen, Y., Dekker, J. H., Effects of pelvic floor muscle training and pessary treatment in women >=55 years with an advanced pelvic organ prolapse, International urogynecology journal and pelvic floor dysfunction, 1), S79-S80, 2014	Conference abstract
Penson, D. F., Re: Can pelvic floor muscle training reverse pelvic organ prolapse and reduce prolapse symptoms? An assessor-blinded, randomized, controlled trial, Journal of Urology, 185, 1383, 2011	Commentary paper
Piya-Anant, M., Therasakvichya, S., Leelaphatanadit, C., Techatrisak, K., Integrated health research program for the Thai elderly: Prevalence of genital prolapse and effectiveness of pelvic floor exercise to prevent worsening of genital prolapse in elderly women, Journal of the Medical Association of Thailand, 86, 509-515, 2003	Outcome data not relevant to the protocol
Resende, A. M., Stupp, L., Bernardes, B. T., Torelli, L., Oliveira, E., Castro, R. A., Girao, M. J., Sartori, M. G., Pelvic organ prolapse symptoms: Can exercises program improve it?, International urogynecology journal and pelvic floor dysfunction, 24, S64, 2013	Conference abstract
Resende, A. P., Stupp, L., Bernardes, B. T., Oliveira, E., Castro, R. A., Girao, M. J., Sartori, M. G., Can hypopressive exercises provide additional benefits to pelvic floor muscle training in women with pelvic organ prolapse?, Neurourology & Urodynamics, 31, 121-5, 2012	Outcomes not relevant to the protocol
Resende,A.P.M., Stupp,L., Bernardes,B.T., Oliveira,E., Castro,R.A., Girao,M.J., Sartori,M.G., Pelvic floor muscle training alone or in combination with hypopressive exercises: Randomized controlled trial, Neurourology and Urodynamics, 29, 973-975, 2010	Conference abstract

Study	Reason for exclusion
Robert, M., Schulz, J. A., Harvey, M. A., Lovatsis, D., Walter, J. E., Chou, Q., Easton, W. A., Epp, A., Farrell, S. A., Geoffrion, R., Girouard, L., Gupta, C. K., Larochelle, A., Maslow, K. D., Neustaeder, G., Pascali, D., Pierce, M., Ross, S., Schachter, J., Senikas, V., Wilkie, D. H. L., Technical Update on Pessary Use, Journal of Obstetrics and Gynaecology Canada, 35, 664-674, 2013	Narrative literature review
Shariati, A., Maceda, J. S., Hale, D. S., High-fiber diet for treatment of constipation in women with pelvic floor disorders, Obstetrics and gynecology, 111, 908-913, 2008	Outcomes not relevant to the protocol
Shobeiri, S. A., Santiago, A. C., Individualised pelvic floor muscle training is an effective conservative treatment in women with pelvic organ prolapse, Evidence-based medicine, 19, 213, 2014	Commentary paper
Stupp, L., Resende, A. P. M., Bernardes, B. T., Oliveira, E., Castro, R. A., Girao, M. J., Sartori, M. G. F., Pelvic floor muscle training for treatment of pelvic organ prolapse: Randomized controlled trial, International urogynecology journal and pelvic floor dysfunction, 21, S236-S237, 2010	Conference abstract
Sultana, C. J., Non-surgical and Surgical Management of Pelvic Organ Prolapse in the Older Woman, Current Geriatrics Reports, 6, 81-89, 2017	Narrative literature review
Sung, V. W., Wohlrab, K. J., Madsen, A., Raker, C., Patient-reported goal attainment and comprehensive functioning outcomes after surgery compared with pessary for pelvic organ prolapse, American Journal of Obstetrics & GynecologyAm J Obstet Gynecol, 215, 659.e1-659.e7, 2016	Study design does not meet the inclusion criteria - prospective cohort. Intervention not relevant -surgery study
Tam, Ms, Randomised controlled trial on time interval of replacement of vaginal ring pessary for pelvic organ prolapse: a pilot study on the effects of complications and patient's satisfaction, Http://www.chictr.org.cn/showproj.aspx? Proj=14558, 2016	Comparator not relevant to the protocol - compares time intervals for vaginal ring pessary
Trowbridge, E. R., Fenner, D. E., Conservative management of pelvic organ prolapse, Clinical Obstetrics and Gynecology, 48, 668-681, 2005	Narrative literature review
Vakili, B., Chesson, R. R., Behavioral therapy for urinary incontinence and nonsurgical management of pelvic organ prolapse, Journal of Pelvic Medicine and Surgery, 11, 105-127, 2005	Narrative literature review
Van Geelen, J. M., Dwyer, P. L., Where to for pelvic organ prolapse treatment after the FDA pronouncements?: A systematic review of the recent literature, International Urogynecology Journal and Pelvic Floor Dysfunction, 24, 707-718, 2013	Systematic review - references checked for inclusion
Waarsenburg, Mk, Vaart, Ch, Pessary or prolapse surgery for symptomatic pelvic organ prolapse - PEOPLE, Http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=4883, 2014	Trial registration
Wiegersma, M, Dekker, Jh, Pelvic Organ Prolapse in general practice: effects of Pelvic muscle training and peSsary treatment - POPPS, Http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=2047, 2009	Trial registration

Study	Reason for exclusion
Wiegersma, M., Panman, C. M. C. R., Kollen, B. J., Vermeulen, K. M., Schram, A. J., Messelink, E. J., Berger, M. Y., Lisman-Van Leeuwen, Y., Dekker, J. H., Pelvic floor muscle training versus watchful waiting or pessary treatment for pelvic organ prolapse (POPPS): Design and participant baseline characteristics of two parallel pragmatic randomized controlled trials in primary care, Maturitas, 77, 168-173, 2014	Protocol paper
Wiegersma, M., Panman, C. M., Kollen, B. J., Berger, M. Y., Lisman-Van Leeuwen, Y., Dekker, J. H., Effect of pelvic floor muscle training compared with watchful waiting in older women with symptomatic mild pelvic organ prolapse: randomised controlled trial in primary care, BMJ, 349, g7378, 2014	Conference abstract
Wiegersma, M., Panman, C. M., Kollen, B. J., Berger, M. Y., Lisman-Van Leeuwen, Y., Dekker, J. H., Effect of pelvic floor muscle training in women with mild pelvic organ prolapse, International urogynecology journal and pelvic floor dysfunction, 1), S26-S27, 2014	Conference abstract
Zhang, X., Chen, Y., Ding, J., Huang, J., Hua, K., Superior to the traditional treatment, individual biofeedback combined with electrostimulation fits type II pelvic floor muscle injury best and contributes to sexual satisfaction, Journal of minimally invasive gynecology, 23 (7 Supplement 1), S11, 2016	Conference abstract

Economic studies

No economic evidence was identified for this review. See supplementary material D for further information.

Appendix L – Research recommendations

Research recommendation for review question: What lifestyle interventions are effective for managing pelvic organ prolapse (POP)?

No research recommendation was made for this review question.

Research recommendation for review question: What is the effectiveness of topical oestrogen for managing pelvic organ prolapse (POP) with vaginal atrophy?

No research recommendation was made for this review question.

Research recommendation for the review question: What are the most effective conservative management options (for example, pelvic floor exercises and pessaries) for pelvic organ prolapse (POP)?

No research recommendation was made for this review question.

Appendix M – Economic evidence methodology checklists

Economic methodology checklists for review question: What lifestyle interventions are effective for managing pelvic organ prolapse (POP)?

There is no additional information for this review question.

Economic methodology checklists for review question: What is the effectiveness of topical oestrogen for managing pelvic organ prolapse POP) with vaginal atrophy?

There is no additional information for this review question.

Economic methodology checklists for review question: What are the most effective conservative management options (for example, pelvic floor exercises and pessaries) for pelvic organ prolapse (POP)?

Table 23: Economic evidence methodology checklist for Hagen 2017

Study identification Hagen, S., Glazener, C., McClurg, D., Macarthur, C., Elders, A., Herbison, P., Wilson, D., Toozs-Hobson, P., Hemming, C., Hay-Smith, J., Collins, M., Dickson, S., Logan, J. Pelvic floor muscle training for secondary prevention of pelvic organ prolapse (PREVPROL): a multicentre randomised controlled trial, The Lancet, 389, 393-402, 2017		
Guidance topic: conservative management options for pelvic organ prolapse		**Review question no: 8.3**
Checklist completed by: Eric Slade		
Section 1: Applicability (relevance to specific review questions and the NICE reference case as described in section 7.5)	**Yes/partly/no /unclear/NA**	**Comments**
1.1 Is the study population appropriate for the review question?	Yes	Adult women with POP
1.2 Are the interventions appropriate for the review question?	Yes	Supervised PFMT plus lifestyle advice vs. lifestyle advice only
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Yes	UK study
1.4 Are the perspectives clearly stated and are they appropriate for the review question?	Yes	NHS
1.5 Are all direct effects on individuals included, and are all other effects included where they are material?	Yes	QALYs
1.6 Are all future costs and outcomes discounted appropriately?	No	Time horizon: 2 years
1.7 Is QALY used as an outcome, and was it derived using NICE's preferred methods? If not, describe rationale and outcomes used in line with analytical perspectives taken (item 1.4 above).	Partly	QALYs (SF-12 converted to SF-6D utility index; UK general population norms)
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?	NA	
1.9 Overall judgement: Directly applicable		
Other comments:		

Section 2: Study limitations (the level of methodological quality)	Yes/partly/no /unclear/NA	Comments
2.1 Does the model structure adequately reflect the nature of the topic under evaluation?	NA	Economic analysis alongside RCT
2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	Yes	Time horizon: 2 years
2.3 Are all important and relevant outcomes included?	Yes	QALYs
2.4 Are the estimates of baseline outcomes from the best available source?	Partly	From RCT
2.5 Are the estimates of relative intervention effects from the best available source?	Partly	From a single RCT
2.6 Are all important and relevant costs included?	Yes	
2.7 Are the estimates of resource use from the best available source?	Partly	From RCT
2.8 Are the unit costs of resources from the best available source?	Yes	National sources
2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?	Yes	
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Yes	Statistical analyses
2.11 Is there any potential conflict of interest?	No	None reported. Funded by the Chief Scientist Office of the Scottish Government Health and Social Care Directorates, New Zealand Lottery Board, and National Health and Medical Research Council (Australia).
2.12 Overall assessment: Minor methodological limitations		
Other comments:		

Table 24: Economic evidence methodology checklist for Hagen 2014

Study identification Hagen, S., Stark, D., Glazener, C., Dickson, S., Barry, S., Elders, A., Frawley, H., Galea, M. P., Logan, J., McDonald, A., McPherson, G., Moore, K. H., Norrie, J., Walker, A., Wilson, D. Individualised pelvic floor muscle training in women with pelvic organ prolapse (POPPY): A multicentre randomized controlled trial, The Lancet, 383, 796-806, 2014		
Guidance topic: conservative management options for pelvic organ prolapse		**Review question no: 8.3**
Checklist completed by: Eric Slade		
Section 1: Applicability (relevance to specific review questions and the NICE reference case as described in section 7.5)	**Yes/partly/no /unclear/NA**	**Comments**
1.1 Is the study population appropriate for the review question?	Yes	Adult women with POP
1.2 Are the interventions appropriate for the review question?	Yes	Supervised PFMT plus lifestyle advice vs. lifestyle advice only

1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Yes	UK study
1.4 Are the perspectives clearly stated and are they appropriate for the review question?	Yes	NHS
1.5 Are all direct effects on individuals included, and are all other effects included where they are material?	Partially	POP-SS (pelvic organ prolapse symptomology only)
1.6 Are all future costs and outcomes discounted appropriately?	No	Time horizon: 2 years
1.7 Is QALY used as an outcome, and was it derived using NICE's preferred methods? If not, describe rationale and outcomes used in line with analytical perspectives taken (item 1.4 above).	No	
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?	NA	
1.9 Overall judgement: Partially applicable		
Other comments:		
Section 2: Study limitations (the level of methodological quality)	**Yes/partly/no /unclear/NA**	**Comments**
2.1 Does the model structure adequately reflect the nature of the topic under evaluation?	NA	Economic analysis alongside RCT
2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	Yes	Time horizon: 2 years
2.3 Are all important and relevant outcomes included?	Partly	POP-SS
2.4 Are the estimates of baseline outcomes from the best available source?	Partly	From RCT
2.5 Are the estimates of relative intervention effects from the best available source?	Partly	From a single RCT
2.6 Are all important and relevant costs included?	Yes	
2.7 Are the estimates of resource use from the best available source?	Partly	From RCT
2.8 Are the unit costs of resources from the best available source?	Yes	National sources
2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?	Yes	
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Yes	Statistical analyses
2.11 Is there any potential conflict of interest?	No	None reported. Funded by Wellbeing of Women charity, the New Zealand Continence Association, and the Dean's Bequest Fund of Dunedin School of Medicine.
2.12 Overall assessment: Minor methodological limitations		
Other comments:		

Table 25: Economic evidence checklist for Panman 2016

Study identification Panman, C. M. C. R., Wiegersma, M., Kollen, B. J., Berger, M. Y., Lisman-Van Leeuwen, Y., Vermeulen, K. M., Dekker, J. H., Effectiveness and cost-effectiveness of pessary treatment compared with pelvic floor muscle training in older women with pelvic organ prolapse: 2-year follow-up of a randomized controlled trial in primary care, Menopause, 23, 1307-1318, 2016		
Guidance topic: conservative management options for pelvic organ prolapse		**Review question no: 8.3**
Checklist completed by: Eric Slade		
Section 1: Applicability (relevance to specific review questions and the NICE reference case as described in section 7.5)	**Yes/partly/no /unclear/NA**	**Comments**
1.1 Is the study population appropriate for the review question?	Yes	Adult women with POP
1.2 Are the interventions appropriate for the review question?	Yes	Pessary vs. PFMT
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Partly	Dutch study
1.4 Are the perspectives clearly stated and are they appropriate for the review question?	Yes	Health care payer
1.5 Are all direct effects on individuals included, and are all other effects included where they are material?	Yes	PFDI-20; QALYs
1.6 Are all future costs and outcomes discounted appropriately?	No	Time horizon: 2 years
1.7 Is QALY used as an outcome, and was it derived using NICE's preferred methods? If not, describe rationale and outcomes used in line with analytical perspectives taken (item 1.4 above).	Yes	QALYs (EQ-5D-3L, UK general population norms)
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?	NA	
1.9 Overall judgement: Partially applicable		
Other comments:		
Section 2: Study limitations (the level of methodological quality)	**Yes/partly/no /unclear/NA**	**Comments**
2.1 Does the model structure adequately reflect the nature of the topic under evaluation?	NA	Economic analysis alongside RCT
2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	Yes	Time horizon: 2 years
2.3 Are all important and relevant outcomes included?	Yes	PFDI-20; QALYs
2.4 Are the estimates of baseline outcomes from the best available source?	Partly	From RCT
2.5 Are the estimates of relative intervention effects from the best available source?	Partly	From a single RCT
2.6 Are all important and relevant costs included?	Yes	
2.7 Are the estimates of resource use from the best available source?	Partly	From RCT
2.8 Are the unit costs of resources from the best available source?	Unclear	
2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?	Yes	
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Yes	Statistical analyses; bootstrapping

2.11 Is there any potential conflict of interest?	No	None reported. Funded by the Netherlands Organisation for Health Research and Development.
2.12 Overall assessment: Minor methodological limitations		
Other comments:		

Table 26: Economic evidence methodology checklist for Panman 2017

Study identification Panman, C. M. C. R., Wiegersma, M., Kollen, B. J., Berger, M. Y., Lisman-Van Leeuwen, Y., Vermeulen, K. M., Dekker, J. H. Two-year effects and cost-effectiveness of pelvic floor muscle training in mild pelvic organ prolapse: a randomised controlled trial in primary care, BJOG, An International Journal of Obstetrics and Gynaecology, 124,511-520, 2017		
Guidance topic: conservative management options for pelvic organ prolapse		**Review question no: 8.3**
Checklist completed by: Eric Slade		
Section 1: Applicability (relevance to specific review questions and the NICE reference case as described in section 7.5)	**Yes/partly/no /unclear/NA**	**Comments**
1.1 Is the study population appropriate for the review question?	Yes	Adult women with POP
1.2 Are the interventions appropriate for the review question?	Yes	PFMT vs. wait list
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Partly	Dutch study
1.4 Are the perspectives clearly stated and are they appropriate for the review question?	Yes	Health care payer
1.5 Are all direct effects on individuals included, and are all other effects included where they are material?	Yes	PFDI-20; QALYs
1.6 Are all future costs and outcomes discounted appropriately?	No	Time horizon: 2 years
1.7 Is QALY used as an outcome, and was it derived using NICE's preferred methods? If not, describe rationale and outcomes used in line with analytical perspectives taken (item 1.4 above).	Yes	QALYs (EQ-5D-3L, UK general population norms)
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?	NA	
1.9 Overall judgement: Partially applicable		
Other comments:		
Section 2: Study limitations (the level of methodological quality)	**Yes/partly/no /unclear/NA**	**Comments**
2.1 Does the model structure adequately reflect the nature of the topic under evaluation?	NA	Economic analysis alongside RCT
2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	Yes	Time horizon: 2 years
2.3 Are all important and relevant outcomes included?	Yes	PFDI-20; QALYs
2.4 Are the estimates of baseline outcomes from the best available source?	Partly	From RCT
2.5 Are the estimates of relative intervention effects from the best available source?	Partly	From a single RCT

2.6 Are all important and relevant costs included?	Yes	
2.7 Are the estimates of resource use from the best available source?	Partly	From RCT
2.8 Are the unit costs of resources from the best available source?	Unclear	
2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?	Yes	
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Yes	Statistical analyses; bootstrapping
2.11 Is there any potential conflict of interest?	No	None reported. Funded by the Netherlands Organisation for Health Research and Development
2.12 Overall assessment: Minor methodological limitations		
Other comments:		