National Institute for Health and Care Excellence

Final

Pelvic floor dysfunction: prevention and non-surgical management

[N] Physical devices for the management of pelvic floor dysfunction

NICE guideline NG210

Evidence review underpinning recommendations 1.6.21 to 1.6.27 as well as a research recommendation in the NICE guideline

December 2021

Final

These evidence reviews were developed by the National Guideline Alliance which is a part of the Royal College of Obstetricians and Gynaecologists

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ISBN: 978-1-4731-4364-7

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Physical devices for the management of pelvic floor dysfunction

Review question

What is the effectiveness of physical devices (including support garments, pessaries and dilators) for improving symptoms of pelvic floor dysfunction?

Introduction

A variety of physical devices are used to manage the symptoms associated with pelvic floor dysfunction. Physical devices are currently used for urinary incontinence, pelvic organ prolapse, faecal incontinence and emptying disorders of the bowel. However, evidence that these devices can significantly improve these symptoms has not been synthesised. Therefore, the aim of this review was to determine what types of physical devices, if any, should be recommended to women with pelvic floor dysfunction.

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 the protocol (PICO table)

Population	Women and young women (aged 12 years and older) with symptoms associated with pelvic floor dysfunction
Intervention	The following interventions will be considered: • anal plug / bung / insert device • bladder neck support device • dilators / vaginal trainers • FEMI cushion • intermittent catheter • Procon incontinence device • Queen's square bladder stimulator • rectal irrigation • rectal realignment vaginal split (for example, FEMEZE) • support garments (for example, V brace) • trans-anal irrigation • insert • urethral/urine seals • vaginal pessaries • combined interventions (for example, those with a mixture of those listed above or with other treatments for example weight loss interventions)

Comparison	• any of the above
	• no treatment
	• pelvic floor exercises, including:
	  ○ pelvic floor muscle contraction exercises
	  ○ pelvic floor muscle strengthening exercises
	  ○ pelvic floor muscle training
	  ○ pelvic floor muscle retraining
	  ○ Knack

	○ pelvic floor muscle relaxation exercises / relaxation retraining ○ biofeedback training (for example, transperineal ultrasound, EMG biofeedback, pressure perinometry, digital biofeedback) ○ weighted vaginal cones, ○ electrical stimulation (for example, transcutaneous stimulation, percutaneous stimulation, intravaginal stimulation) ○ neuromuscular stimulation ○ magnetic stimulation
Outcome	**Critical** • subjective measure of change in the following symptoms: ○ urinary incontinence, ○ emptying disorders of the bladder, ○ faecal incontinence, ○ emptying disorders of the bowel, ○ pelvic organ prolapse, ○ sexual dysfunction ○ chronic pelvic pain syndromes • infection (such as recurrent urinary tract infection) • adverse events • total number (for example, device-associated trauma, migration of urethral device) • those leading to withdrawal/discontinuation **Important** • satisfaction with intervention • continuation and/or adherence of intervention • anxiety and depression (only validated scales will be included) • health related quality of life (only validated scales will be included)

EMG: Electromyography

For further 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. Methods specific to this review question are described in the review protocol in appendix A and the methods document (Supplement 1: methods).

Declarations of interest were recorded according to NICE's conflicts of interest policy.

Clinical evidence

Included studies

Fourteen randomised controlled trials (RCTs) were included for this review (Cheung 2016, Cornu 2012, Glavind 1997, Kenton 2012, Lovatsis 2017, Lucena 2019, Nygaard 1995, Okayama 2019, Panman 2016, Richter 2010, Robinson 2003, Tam, 2019, Thyssen 2001, Zarski 2017)

Six studies included interventions using a pessary (Cheung 2016, Kenton 2012, Panman 2016, Richter 2010, Nygaard 1995), 5 studies included interventions using an intravaginal device (Cornu 2012, Lucena 2019, Lovatsis 2017, Thyssen 2001, Glavind 1997), 1 study addressed support garments (Okayama 2019), 1 study included interventions using an intraurethral device (Robinson 2003) and 1 study included interventions using vaginal dilators (Zarski 2017).

The included studies are summarised in Table 2 to Table 6.

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

Excluded studies

Studies not included in this review are listed, and reasons for their exclusion are provided in appendix K.

Summary of studies included in the evidence review

Summaries of the studies that were included in this review are presented in Table 2 to Table 6.

Table 2: Summary of included studies: pessary based interventions.

Study	Population	Intervention	Comparison	Outcomes
Cheung 2016 Hong Kong RCT	N=276 Women with symptomatic POP Mean Age=62.6	Pelvic floor muscle training added to ring pessary n=139	Pelvic floor muscle training n=137	• Symptoms: PFDI subscales (POPDI, UDI, CRADI), number with improved SUI/UUI/VD • Quality of life: PFIQ subscales (POP-IQ, UDI, CRAIQ) • Adverse events: discomfort (VAS), abnormal vaginal bleeding, significant vaginal discharge, new (SUI,UUI,VD)
Kenton 2012 (secondary analysis of Richer 2010) USA RCT	N=446 Women with symptoms of SUI Mean Age= 49	Pessary n=149	Behavioural Therapy (Pelvic floor muscle training) n=146 Combination n=150	• Symptoms: UDI, UDI-stress, UDI – obstructive, UDI-irritative, POPDI. CRADI, QUID, QUID-stress, QUID-urge • Quality of life: POPIQ, CRAIQ, UQI
Nygaard 1995 Cross-over RCT USA	N=18 Women with SUI Mean age= 50.5	Hodge pessary with support n=18	Tampax super tampon n=18 No treatment n=18	• Symptoms: Pad weight
Panman 2016 The Netherlands RCT	N=162 women with symptomatic POP Mean Age=65	Pessary n=82	Pelvic floor muscle training n=80	• Symptoms: PDFI subscales (POPDI. UDI, CRADI, QUID, PISQ-12) • Quality of life: PFIQ, PCS- 12, MCS-12

Study	Population	Intervention	Comparison	Outcomes
Richter 2010 USA RCT	n=446 Women with SUI Mean Age=49.8	Pessary n=149	Behavioural treatment (Pelvic floor muscle training) n=146 Pessary + Behavioural treatment (Pelvic floor muscle training) n=150	• Symptoms: PGI-I, >75% reduction weekly incontinence episodes, PDFI • Patient satisfaction-PSQ
Tam 2019 Hong Kong RCT	n=60 Women with POP Mean Age=69.4	Ring Pessary 3 months n=30	Ring Pessary 6 months n=30	• Symptoms: POPQ • Patient Satisfaction (VAS)

PGI-I: Patient Global Impression of Improvement; UIQ: Urinary Impact Questionnaire; POPIQ: Prolapse Impact Questionnaire 7; CRAIQ: Colorectal and Anal Impact Questionnaire; QUID: Questionnaire for female Urinary Incontinence Diagnosis; CRADI-8:Colorectal Anal Distress Inventory-8; MCS-12: Mental Component Health Summary (SF-12); PCS-12:Physical Component Health Summary (SF-12); PFDI-20: Pelvic Floor Distress Inventory-20; PFIQ-7:Pelvic Floor Impact Questionnaire-7; PFMT: pelvic floor muscle training; PISQ-12:Pelvic Organ Prolapse/Incontinence Sexuality Questionnaire-12; POPDI-6:Pelvic Organ Prolapse Distress Inventory-6; UDI-6:Urinary/Urogenital Distress Inventory-6; RCT: randomised controlled trial; VAS: Visual Analogue Scale; PFDI: Pelvic floor distress inventory; POP: Pelvic organ prolapse; UUI: Urge urinary incontinence; SUI: Stress urinary incontinence; VD: Voiding dysfunction; UI: Urinary incontinence; POPQ: Pelvic Organ Prolapse Quantifications System

Table 3: Summary of included studies: Intravaginal device-based interventions

Study	Population	Intervention	Comparison	Outcomes
Cornu 2012 France RCT	N=68 Women with UI Mean Age=60.6	75NC007 (locates beneath the urethra (cylindrical and proximal part) and bladder (ring shaped and distal part)- constitutes a support for the urethra and bladder neck. n=29	No treatment n=27	• Symptoms: incontinence episode frequency (IEF), USP, pad test • Patient satisfaction (VAS) • *CONTILIFE® questionnaire*
Glavind 1997 Denmark Cross-over RCT	N=6 Women with SUI completing 30 minutes of aerobic exercise No mean age reported Age Range=44-68	With vaginal sponge n=6	Without vaginal sponge n=6	• Symptoms: Pad weight (grams lost)

Study	Population	Intervention	Comparison	Outcomes
Lovatsis 2017 Canada RCT	N =36 Women with urodynamically proven SUI Mean Age=51	Uresta device n=18	Vaginal silastic ring. n=18	• Symptoms: 50% reduction in pad weight
Medina 2019 UK RCT	N=80 Women with symptoms of urge, stress or mixed incontinence No mean age reported Median age reported= 45	Inco-stress intravaginal device + Pelvic floor muscle training n=51	Pelvic floor muscle training n=29	• Symptoms: ICIQ-FLUTS • Quality of life: IQOL
Thyssen 2002 Denmark, Australia, UK Cross over RCT	N=94 Women with predominant symptom of SUI and no major uterovaginal prolapse Mean Age= 50.4	Conveen Continence Disposable Intravaginal Device(CCG) → Contrelle continence Tampon (CCT) n=94	Contrelle continence Tampon(CCT) → Conveen Continence Disposable Intravaginal Device(CCG) n=94	• Symptoms: Self-reported • Improvement in stress urinary incontinence: • Subjective continence, urinary leakage

ICIQ-FLUTS: International Consultation on Incontinence Questionnaire Female Lower Urinary Tract Symptoms Modules; ICIQ-SF: International Consultation on Incontinence Questionnaire Short form; IQOL: Incontinence Quality of Life questionnaire; RCT: randomised controlled trial; UI: Urinary Incontinence; IEF: Incontinence episode frequency; USP: Urinary Symptom Profile;

Table 4: Summary of included studies: support garments

Study	Population	Intervention	Comparison	Outcomes
Okayama 2019 Japan RCT	N=150 Women with SUI Median age =44	Shaper underwear (lifts bladder neck) n=50	Pelvic floor muscle training n=50 No treatment n=50	• Symptoms: UI episodes per week • Improvement in UI, Cure of UI • Quality of life ICIQ-SF score

ICIQ-SF: International Consultation on Incontinence Questionnaire Short form; RCT: randomised controlled trial; SUI: stress urinary incontinence; UI; Urinary incontinence

Table 5: Summary of included studies: Intraurethral device-based interventions

Study	Population	Intervention	Comparison	Outcomes
Robinson 2003 Canada RCT	N= 24 Women with stress or mixed urinary incontinence	NEAT Expandable Tip Continence Device n=13	Reliance urethral insert n=11	• Symptoms: Pad weight (50% or greater reduction in urine loss), Leakage scores (leakage

Study	Population	Intervention	Comparison	Outcomes
	Mean Age= 51.2			assessment questionnaire) • Adverse events: UTI

RCT: randomised controlled trial; UTI: urinary tract infection

Table 6: Summary of included studies: Vaginal dilator device-based interventions

Study	Population	Intervention	Comparison	Outcomes
Zarski 2017 Germany RCT	N=77 Women with vaginismus Mean Age= 27.3	internet-based intervention 10 sessions and included modules for psychoeducation (sessions 1 and 2), relaxation exercises (session 3), cognitive restructuring (session 4), body exposure (session 5), sensate focus exercises (session 6), gradual exposure using insertion exercises with fingers and dilators (sessions 7 and 8), and preparation exercises for intercourse with the partner (sessions 9 and 10) n=40	Waitlist control group (Participants assigned to the WCG did not have access to the intervention during the first 6 months after randomization but were allowed to use it after 6 months.) n=37	• Symptoms: PEQ, FSQ, FSFI, DCI questionnaires

DCI: Dyadic Coping Inventory; FSFI: Female Sexual Function Index; FSQ: Fear of Sexuality Questionnaire; IG . intervention group; PEQ: Primary Endpoint Questionnaire; RCT: randomised controlled trial

See the full evidence tables in appendix D and the forest plots in appendix E.

Quality assessment of studies included in the evidence review

See the GRADE evidence profiles in appendix F.

Economic evidence

Included studies

A single economic search was undertaken for all topics included in the scope of this guideline. One economic study was identified which was relevant to this question (Panman 2016).

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

Excluded studies

Economic studies not included in this review are listed, and reasons for their exclusion are provided in appendix K.

Summary of studies included in the economic evidence review

See the economic evidence table in appendix H and the economic evidence profile in appendix I.

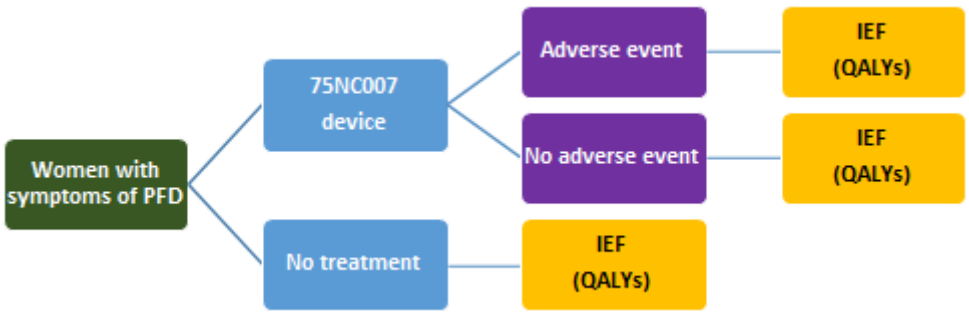
A Dutch study (Panman 2016) compared pessary treatment in older women with pelvic organ prolapse with PFMT alongside a randomised controlled trial. Cost included pessary and pessary related visits, consultations with health care professionals and consummables such as medication and pads. The analysis was based on a 2014 price year. Quality Adjusted Life Years (QALYs) were derived from the EQ-5D questionnaire using a UK tariff. Over a 2-year follow-up the PFMT group had $128 (95% confidence interval: $27 to $236) higher costs per person. Both groups experience QALY losses but the loss was less in the pessary group implying that the pessary dominated PFMT. Probabilistic analysis was undertaken with 5,000 bootstrap replications and 95% of these reported cost and QALY combinations showing pessary dominance over PFMT.

Economic model

An original economic analysis was undertaken for this guideline to consider the cost-effectiveness of the 75NC007 intravaginal device compared to no treatment for women with pelvic floor dysfunction. The model is summarised below with full details in appendix J.

The model took the form of a cost-utility analysis and was for an NHS setting adopting an NHS and Personal Social Services (PSS) perspective. Incontinence episode frequency (IEF) was used as a proxy for all symptoms of pelvic floor dysfunction, reflecting the outcome in the randomised controlled trial (Cornu 2012) used to inform model estimates of treatment effectiveness. The time horizon for the model was 14 days, reflecting the duration of treatment in the trial.The decision analytic framework for the model is illustrated in Figure 1. The model evaluated the cost-effectiveness of the intravaginal device at different levels of symptom severity, with a mean of 3.3 incontinence episode per day used in the base case analysis. Costs in the model were assigned to both treatment and adverse events. QALYs were derived from IEF and from adverse events, which were assumed to be urinary tract infections.

Figure 1: The model decison framework



PFD = pelvic floor dysfunction; IEF = incontinence episode frequency; QALYs = Quality Adjusted Life Years

A number of sensitivity analyses were used in addition to the base case analysis and probabilistic sensitivity analysis was used to assess the impact of parameter uncertainty on the model's conclusions. In addition to Tornado analysis, one-way and two-way sensitivity analysis, a number of threshold analyses were undertaken to estimate the mean number of

urinary incontinence episodes per day at which treatment would become cost-effective and the treatment cost threshold for cost-effectiveness with mean IEF set at its baseline value.

The model's results suggested that the intravaginal device was likely to be cost-effective where the mean incontinence episodes per day was greater then 5. They also indicated that below a mean of 3 incontinence episodes per day, treatment was unlikely to be cost-effective. Between a mean of 3 and 5 incontinence episodes per day the cost-effectiveness is somewhat borderline.

The model has a number of important limitations and these need to be taken into account when interpreting the results. First, it is based on a one fairly small study of one intravaginal device. Whilst it is likely that other devices would have similar clinical effectiveness that it not known with certainty. Also, the cost-effectiveness of similar alternative devices would depend on the cost of those devices even where similar effectivenss was known. Also, although the economic analysis was based on a randomised study it was graded in this review as being low quality evidence with a high risk of bias.

Brief summary of evidence

Intravaginal devices

- Very low to low quality evidence indicated that, compared to no treatment, no clinically important reduction was found in the incontinence episode frequency or pad test weight with intravaginal devices. However, a clinically important reduction was found in the urinary symptoms profile questionnaire - SUI, OAB and dysuria subscales.
- Very low to low quality evidence indicated that compared to a placebo (vaginal sialistic ring- placed high in posterior fornix to ensure no effect on urethral forces), there was a clinically important reduction in pad weight.

Support garments

- Very low quality evidence indicated no important difference between a support garment and PFMT in terms of UI symptoms.
- Very low to low quality evidence indicated a benefit with a support garment compared to no treatment in some, but not all, measures of UI symptoms.

Intraurethral device:

- Very low quality evidence indicated no clinically important difference in urine leakage or pad weight between two intraurethral devices.

Pessary:

- Very low quality evidence showed a clinically important reduction in POPDI and POPIQ scores from baseline at 6 and 12-month follow-up with pessary use in comparison to pelvic floor muscle training (PFMT). However, very low to low quality evidence indicated there was no difference in other symptom/health related quality of life scores such as PGI-I, PFDI, UDI, PFIQ, CRADI, QUID.
- Very low to low quality evidence showed no difference in UI episodes in comparison to PFMT alone or with combined therapy (pessary and PFMT).
- Very low quality evidence showed PFMT only was associated with an improvement in bothersome symptoms of stress incontinence at 3 months in comparison to pessary use, however this was not sustained over time (12 months)
- Very low quality evidence showed no difference in complications such as vaginal bleeding and discharge found with pessary in comparison to PFMT alone. However, there was a greater number of women reporting new SUI was in the pessary group compared to PFMT alone.

- Low quality evidence indicated no difference in the change in the POPQ score from baseline when a pessary is used for 3 months in comparison to 6 months.

Vaginal dilators:

- Very low quality evidence showed no difference between vaginal dilators (when used in combination with psychological therapies) and no treatment in terms of intercourse penetration. However, there was an improvement in non-intercourse penetration at 6 months and an improvement in overall sexual functioning by 10 weeks.

The committee's discussion of the evidence

Interpreting the evidence

The outcomes that matter most

The committee agreed that subjective measurement of symptoms were critical outcomes, as they define the effectiveness of the intervention. Other critical outcomes for this review included infection and adverse events, these were critical due to the nature of the intervention, devices are generally inserted into the body and as such risk infection or adverse events to a higher degree than other conservative interventions for pelvic floor dysfunction. Important outcomes were satisfaction, health related quality of life, adherence, anxiety and depression. These outcomes were included as they relate to the woman's experience of these intervention, some of which can be difficult to tolerate. Additionally, pelvic floor dysfunction has a considerable physiological impact and therefore these outcomes are important.

The quality of the evidence

The quality of evidence was assessed using GRADE and ranged from very low to moderate. Generally, outcomes were downgraded due to risk of bias in the study design, due to the nature of the interventions, studies could not be blinded; however, there were also concerns with potential deviations from the intended protocols, and missing data. Outcomes were also downgraded for imprecision, meaning the confidence in the true effect size is uncertain.

No evidence was identified which was specifically focused on pelvic floor dysfunction; the included evidence investigated urinary incontinence, pelvic organ prolapse, and sexual dysfunction but studies did not explicitly state that the reason for these symptoms were caused by pelvic floor dysfunction. No evidence was identified on physical devices for emptying disorders of the bowel or faecal incontinence. There was also a lack of evidence on adverse events such as urinary tract infection or haematuria that might be associated with physical devices.

Benefits and harms

The committee recognised that although the quality of the evidence was low overall, the data presented was in keeping with their clinical expertise and experience.

Intravaginal continence devices

Very low to low quality evidence suggested that intravaginal continence devices improved subjective symptoms (such as the urinary symptoms profile questionnaire) but not objective improvement in urinary incontinence symptoms (such as incontinence episode frequency or pad test weight). The committee agreed that subjective measures are important as they indicate the woman's perception of success, and this can have benefits on quality of life. In the committee's experience, intravaginal continence devices can be used in certain situations to prevent urinary leakage, for example during physical exercise or sexual intercourse, however they may be associated with side effects such as local irritation. The committee

therefore decided to recommend that women could have a trial period of intravaginal devices. However, because the evidence was not strong, they recommended this only if other non-surgical options had been tried but had been unsuccessfully. The committee discussed that this recommendation differed from recommendation 1.4.23 in the NICE guideline on urinary incontinence and pelvic organ prolapse which recommends against the use of intravaginal devices. However, the committee noted that recommendation 1.4.23 had not been updated since 2006 and that the majority of the identified evidence considered by them had been published since. Even though the findings from the evidence were not entirely certain, they decided that these devices should not be ruled out if other non-surgical options were unsuccessful. This would provide another option which may prevent the need for more invasive treatment.

Pessaries for symptomatic pelvic organ prolapse

Very low to low quality evidence showed that pessaries improved symptoms of pelvic organ prolapse; however, the included studies were heterogeneous, and not all urinary and bowel symptom measures showed effectiveness of pessary use. The committee agreed that pessaries are a suitable management option for symptomatic pelvic organ prolapse with few adverse effects, but the evidence was not strong enough to have this routinely offered to every woman. However, the committee were aware that from their clinical experience that new onset stress urinary incontinence was a known complication following pessary insertion and the committee decided that if this would happen it is important to give the woman a choice to either treat the new stress incontinence or have the pessary removed. Complications were only evaluated in one study with a short follow up period of 3 months and because of this limited evidence the committee specified particular benefits and harms to discuss with women, based on the evidence that was available and their clinical experience. The committee noted that this will help women to make an informed decision on whether a pessary is right for them.

Continence pessaries

The committee were presented with three different comparisons on the effectiveness of continence pessaries in the management of urinary incontinence. The evidence favoured the use of pelvic floor muscle training in combination with continence pessaries in order to improve symptoms of urinary incontinence; but the evidence was unclear and not sustained in the long-term (12 months). Therefore, the committee decided not to make a recommendation for their use.

Support garments

The committee acknowledged that supportive underwear as a management option may be useful in certain populations, for example women with cognitive impairment, where adherence to other management strategies may be difficult. However, the committee decided not to make recommendations on supportive underwear because the evidence was based only on one study and because there was no direct evidence in women with cognitive impairment.

Intraurethral devices

The only evidence identified for intraurethral devices compared two different types and did not report adverse events. The committee based on experience were conscious of the potentially more prevalent adverse events associated with the use of intraurethral devices including, urinary tract infection, haematuria and device migration requiring removal by cystoscopy surgical removal. The committee decided that there was insufficient evidence to make a recommendation against their use. They therefore agreed not to make a recommendation for or against the use of intraurethral devices.

Vaginal Dilators

The evidence presented suggested that the use of vaginal dilators in combination with psychological therapy improved non-penetrative sex and overall sexual function. Although no improvement in penetrative sex was shown, the committee agreed that in their experience, sexual dysfunction is multifactorial in aetiology and certain symptoms may take longer to improve.

There was a lack of evidence on the effectiveness of physical devices on other symptoms of pelvic floor dysfunction including faecal incontinence, emptying disorders of the bowel and chronic pelvic pain syndromes. Many of the excluded studies using devices such as anal plugs, transanal irrigation systems and vaginal splints contained mixed populations and did not separate men and women in their analysis.

Review and information

In the UK some women with a pessary are reviewed by a health care professional for pessary change. However, other women chose to self-manage, which can reduce the number of outpatient clinic visits. This allows women to remove, clean and re-insert their pessary themselves, when they wish by following provided insructions. The committee agreed it was important that women are informed about how to seek advice if they have problems with any intravaginal device (including pessary). A review may be necessary for women who are at risk of complications for example because of physical or cognitive impairment, if given to these women, regular reviews to assess ongoing self-management should be in place. The committee recognised that there was a recommendation addressing this point in another NICE guideline and cross referred to it (see ‘other consideration’ section below).

Research recommendation

The committee discussed that the range of symptoms covered in this review was not very wide and that faecal incontinence is a common symptom which is particularly distressing for women. They noted that there are devices that could be used for these symptoms but the existing evidence for such devices consists of studies in mixed populations which do not separate men and women in their analyses and could therefore not be included. They therefore made a research recommendation to investigate this in women with pelvic floor dysfunction (see appendix L).

Cost effectiveness and resource use

Evidence from a Dutch economic evaluation conducted alongside a randomised controlled trial (Panman 2016) compared pessary treatment with PFMT in women with pelvic organ prolapse. Their analysis suggested that pessary treatment dominated PFMT with lower costs of $128 (95% confidence interval: $27 to $236) and 0.041 more Quality Adjusted Life Years (QALYs).

An original economic analysis undertaken for this guideline compared the cost-effectiveness of the 75NC007 intravaginal device compared to no treatment for women with pelvic floor dysfunction. The analysis suggested that the cost-effectiveness of treatment depended on symptom severity as estimated by incontinence episode frequency but that treatment was not likely to be cost-effective at a cost-effectiveness threshold of £20,000 per QALY for women with a mean of less than 3 incontinence episodes per day. On the other hand, treatment was likely to be cost-effective for women with a mean of more than 5 incontinence episodes per day. However, the committee did not want to make a recommendation for the use of intravaginal devices based on frequency as in their experience there can be a wide variation in the distress caused by incontinence episodes at the individual level. The committee noted that this analysis was based on one small study of one device and that the cost of the device itself was an important determinant of cost-effectiveness. The committee

was also aware that the clinical effectiveness evidence derived from the study was assessed as being of low quality with a high risk of bias. However, the committee was also aware that the economic analysis does not account for any longer term impact that the 75NC007 may have in averting or delaying surgery which may cause the cost-effectiveness to be under-estimated.

The committee did not consider that the cost-effectiveness or clinical evidence was sufficiently robust to support the routine use of this device. However, the committee also took into account the Independent Medicines and Medical Devices Safety Review (Cumberlege Report (2020), which promotes conservative management to in order to avert surgery and decided that the use of devices could be considered as a treatment option where appropriate and where other non-surgical oprions had been unsuccessfully tried..

Intravaginal devices have a relatively low cost and are currently used by some units in the UK. Therefore, the committee did not anticipate that their recommendation would have a significant unit cost.

Other Considerations

The committee cross referred to the NICE guideline on urinary incontinence and pelvic organ prolapse which includes guidance on pessaries for women with pelvic organ prolapse, issues to discuss with the woman when considering a pessary and regular review of pessaries for women who are at risk of complications (for example because of physical or cognitive impairment)..

Recommendations supported by this evidence review

This evidence review supports recommendations 1.6.21 to 1.6.27 as well as a research recommendation on anal plug devices and rectal irrigation in the NICE guideline.

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Appendices

Appendix A – Review protocol

Review protocol for review question: What is the effectiveness of physical devices (including support garments, pessaries and dilators) for improving symptoms of pelvic floor dysfunction?

Table 7: Review protocol

ID	Field	Content
0.	PROSPERO registration number	CRD42019162207
1.	Review title	Physical devices
2.	Review question	What is the effectiveness of physical devices (including support garments, pessaries and dilators) for improving symptoms of pelvic floor dysfunction?
3.	Objective	The objective of this review is to determine whether physical devices can effectively improve symptoms associate with pelvic floor dysfunction (including urinary incontinence, pelvic organ prolapse, emptying disorders of the bladder, faecal incontinence, emptying disorders of the bowel, sexual dysfunction and chronic pelvic floor dysfunction
4.	Searches	The following databases will be searched: • Cochrane Database of Systematic Reviews (CDSR) • Cochrane Central Register of Controlled Trials (CENTRAL) • MEDLINE & Medline in Process • Embase • CINAHL or Emcare • PsycINFO Searches will be restricted by: • Date limit: 1980 onwards (see section 10 for justification) • English language • Human studies Other searches: Inclusion lists of potentially relevant systematic reviews

ID	Field	Content
		The full search strategies for MEDLINE database will be published in the final review. For each search, the principal database search strategy is quality assured by a second information scientist using an adaptation of the PRESS 2015 Guideline Evidence-Based Checklist.
5.	Condition or domain being studied	The following symptoms will be addressed as long as they are associated with pelvic floor dysfunction: urinary incontinence, emptying disorders of the bladder, faecal incontinence, emptying disorders of the bowel, pelvic organ prolapse, sexual dysfunction and chronic pelvic pain syndromes.
6.	Population	Inclusion • Women and young women (aged 12 years and older) with symptoms associated with pelvic floor dysfunction Exclusion • Studies which include women with urinary incontinence, emptying disorders of the bladder, faecal incontinence, emptying disorders of the bowel, pelvic organ prolapse, sexual dysfunction and chronic pelvic pain syndromes which are not due to pelvic floor dysfunction will be excluded. For example, women who have urinary incontinence due to a neurological condition or pelvic cancer will be excluded. During the screening stage, the reported inclusion/exclusion criteria of studies will be examined carefully. We do not anticipate studies on urinary incontinence, emptying disorders of the bladder or pelvic organ prolapse will explicitly state "associated with pelvic floor dysfunction" therefore this will be a pragmatic decision based on the description of the condition provided by the study authors. Some of these symptoms (for example urinary incontinence) are most often due to a failure in the pelvic floor and therefore unless the exclusion criteria states a different cause, these studies are likely to be included. However, for studies on faecal incontinence, emptying disorders of the bowel, sexual dysfunction and pelvic pain the causes are more numerous. As such for these symptoms unless the study specifically states "associated with pelvic floor dysfunction" they will be excluded. If any ambiguity exists, at least two reviewers will make the final decision if to include or exclude the study. • Men • Babies and children
7.	Intervention	The following interventions will be considered: • anal plug / bung / insert devices • bladder neck support device • dilators / vaginal trainers • FEMI cushion • intermittent catheter • Procon incontinence device • Queen's square bladder stimulator

ID	Field	Content
		• rectal irrigation • rectal realignment vaginal split (e.g FEMEZE) • support garments (e.g V brace) • trans-anal irrigation • insert • uethral/urine seals • vaginal pessaries Combined interventions (such as those with a mixture of those listed above or with other treatments for example weight loss interventions)
8.	Comparator	• any of the above • no treatment • pelvic floor exercises including: ○ pelvic floor muscle contraction exercises ○ pelvic floor muscle strengthening exercises ○ pelvic floor muscle training ○ pelvic floor muscle retraining ○ knack ○ pelvic floor muscle relaxation exercises / relaxation retraining ○ biofeedback training (such as transperineal ultrasound, emg biofeedback, pressure perinometry, digital biofeedback) ○ weighted vaginal cones, ○ electrical stimulation (such as transcutenaeous stimulation, percutenaeous stimulation, intravaginal stimulation) ○ neuromuscular stimulation ○ magnetic stimulation
9.	Types of study to be included	Systematic reviews of RCTs RCTs If there is no RCT evidence then other studies designs will be considered, namely Non-randomised controlled studies Prospective cohort studies The decision to include non RCT study designs will be determined for each of the listed symptoms associated with pelvic floor dysfunction. For example if we identify an RCT on urinary incontinence but not for pelvic organ prolapse, then we

ID	Field	Content
		will continue our search for observational studies on pelvic organ prolapse but we will not search for further study designs for or urinary incontinence. The decision to include non RCT study designs was made to ensure all relevant symptoms associated with pelvic floor dysfunctions are given equal consideration. Additionally, interventions may influence the various symptoms differently, and it is important this is considered. Within each symptom category (such as faecal incontinence), the committee has agreed a subset of symptoms that are specifically associated with pelvic floor dysfunction, as such each symptom only includes those sub-symptoms which occur as a result of pelvic floor dysfunction (rather than anybody with faecal incontinence). The committee agreed these subsets of symptoms by examining the population search strategy. Therefore, if lower level of evidence is identified it will only be relevant to symptoms that specifically result from pelvic floor dysfunction, rather than the entire population for which there could potentially have been a higher level of evidence. Potentially important confounders which should be considered include BMI, age, ethnicity, dietary factors and weight loss. Appropriate adjustment for these confounders within the included studies will be considered during the GRADE process. Note: For further details, see the algorithm in appendix H, Developing NICE guidelines: the manual..
10.	Other exclusion criteria	• Studies with a mixed population (specifically women with symptoms such as urinary incontinence which are associated with pelvic floor dysfunction and women with symptoms that are not associated with pelvic floor dysfunction) will be excluded, unless subgroup analysis for those women with symptoms associated with pelvic floor dysfunction has been reported. • Conference abstracts will be excluded because these do not typically provide sufficient information to fully assess risk of bias. • Only articles published after 1980 will be included. This was agreed by the committee as this is the date that the condition “pelvic floor dysfunction” was recognised to include agreed terminology on symptoms. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2815805/
11.	Context	Studies which explicitly demonstrate a change in outcomes for symptoms associated with pelvic floor dysfunction will be prioritised for decision making in regards to recommendations, and these recommendations will apply to those receiving care in any healthcare settings (such as community, primary, secondary care). However, the context of recommendations is likely broader than just the health care setting itself. Women who are not currently accessing services may benefit from the recommendations in order to make lifestyle changes which could improve symptoms they are experiencing. Specific recommendations for groups listed in the Equality Considerations section of the scope may be also be made as appropriate.
12.	Primary outcomes (critical outcomes)	• subjective change in the following symptoms: ○ urinary incontinence

ID	Field	Content
		○ emptying disorders of the bladder ○ faecal incontinence ○ emptying disorders of the bowel ○ pelvic organ prolapse ○ sexual dysfunction ○ chronic pelvic pain syndromes • infection (e.g recurrent urinary tract infection) • adverse events ○ total number (e.g device-associated trauma, migration or urethral device) ○ those leading to withdrawal/discontinuation For primary outcomes listed, only validated tools will be included (for example: ICIQ-UI, ICIQ-VS, BFLUTS, KHQ, UDI, ISI, ePAQ, POPSS, PISQ, POPQ, FISI, FIQL, GIQLI, PAC-QM, PAC –SYM, PDI, BPI)
	Secondary outcomes (important outcomes)	• Satisfaction with intervention • Continuation and/or adherence to intervention • Anxiety and depression (validated tools only) • Health related quality of life (only validated scales will be included Outcomes are in line with those described in the core outcome set
14.	Data extraction (selection and coding)	All references identified by the searches and from other sources will be uploaded into STAR and de-duplicated. Titles and abstracts of the retrieved citations will be screened to identify studies that potentially meet the inclusion criteria outlined in the review protocol. Duplicate screening will not be undertaken for this question. Full versions of the selected studies will be obtained for assessment. Studies that fail to meet the inclusion criteria once the full version has been checked will be excluded at this stage. Each study excluded after checking the full version will be listed, along with the reason for its exclusion. A standardised form will be used to extract data from studies. One reviewer will extract relevant data into a standardised form, and this will be quality assessed by a senior reviewer. Information to be extracted from studies includes: study type, study dates, location of study, funding, inclusion and exclusion criteria, participant characteristics, and details of the intervention and comparator.

ID	Field	Content
15.	Risk of bias (quality) assessment	Quality assessment of individual studies will be performed using the following checklists • ROBIS tool for systematic reviews • Cochrane RoB tool v.2 for RCTs and quasi-RCTs • Cochrane ROBINS-I tool for non-randomised (clinical) controlled trials and cohort studies The quality assessment will be performed by one reviewer and this will be quality assessed by a senior reviewer.
16.	Strategy for data synthesis	Depending on the availability of the evidence, the findings will be summarised narratively or quantitatively. <u>Data Synthesis</u> Where possible, pair wise meta-analyses will be conducted using Cochrane Review Manager software. A fixed effect meta-analysis will be conducted and data will be presented as risk ratios for dichotomous outcomes. Peto odds ratio will be used for outcomes with zero events Mean differences or standardised mean differences will be calculated for continuous outcomes. Where possible the interventions will be grouped according to mode of action, this can only be determined once the included studies have been identified. <u>Heterogeneity</u> Heterogeneity in the effect estimates of the individual studies will be assessed using the I^2 statistic. I^2 values of greater than 50% and 80% will be considered as significant and very significant heterogeneity, respectively. In the presence of heterogeneity sub-group analysis will be conducted • According to risk of bias of individual studies • According to socioeconomic status of population included • By ethnicity of included populations Exact subgroup analysis may vary depending on differences identified within included studies. If heterogeneity cannot be explained through subgroup analysis then a random effects model will be used for meta-analysis. If heterogeneity remains above 80% reviewers will consider if meta-analysis is appropriate given the characteristics of included. <u>Minimal important differences (MIDs):</u> For outcomes where validated tools are included (for example ICIQ), then the published MIDs will be used. Where no published MID is available, default MIDs will be used:

ID	Field	Content	
		For risk ratios: 0.8 and 1.25. For continuous outcomes: For one study: the MID is calculated as +/-0.5 times the baseline SD of the control arm. For two studies: the MID is calculated as +/-0.5 times the mean of the SDs of the control arms at baseline. If baseline SD is not available, then SD at follow up will be used. For three or more studies (meta-analysed): the MID is calculated by ranking the studies in order of SD in the control arms. The MID is calculated as +/- 0.5 times median SD. For studies that have been pooled using SMD (meta-analysed): +0.5 and -0.5 in the SMD scale are used as MID boundaries. Validity: The confidence in the findings across all available evidence will be 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/	
17.	Analysis of sub-groups	Stratification All data will initially be pooled for overall analysis; however, if data is available, separate analysis will also be conducted on: • Women who are pregnant • Women before and after gynaecological surgery • Women aged 65 or older • Women with physical disabilities • Women with cognitive impairment • According to those who do not identify themselves as women, but who have female pelvic organs *Recommendations will apply to all those with pelvic floor dysfunction unless there is evidence of a difference in these stratified groups*	
18.	Type and method of review	☒	Intervention
		☐	Diagnostic
		☐	Prognostic
		☐	Qualitative
		☐	Epidemiologic
		☐	Service Delivery

ID	Field	Content		
		☐	Other (please specify)	
19.	Language	English		
20.	Country	England		
21.	Anticipated or actual start date	TBC		
22.	Anticipated completion date	August 2021		
23.	Stage of review at time of this submission	Review stage	Started	Completed
		Preliminary searches	x	x
		Piloting of the study selection process	x	x
		Formal screening of search results against eligibility criteria	x	x
		Data extraction	x	x
		Risk of bias (quality) assessment	x	x
		Data analysis	x	x
24.	Named contact	**5a. Named contact** National Guideline Alliance **5b Named contact e-mail** PreventionofPOP@nice.org.uk **5e Organisational affiliation of the review** National Institute for Health and Care Excellence (NICE) and the National Guideline Alliance		
25.	Review team members	NGA technical team		

ID	Field	Content	
26.	Funding sources/sponsor	This systematic review is being completed by the National Guideline Alliance, which is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists. NICE funds the National Guideline Alliance to develop guidelines for those working in the NHS, public health, and social care in England.	
27.	Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.	
28.	Collaborators	Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual. Members of the guideline committee are available on the NICE website: https://www.nice.org.uk/guidance/indevelopment/gid-ng10123/	
29.	Other registration details		
30.	Reference/URL for published protocol	[Give the citation and link for the published protocol, if there is one.]	
31.	Dissemination plans	NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as: notifying registered stakeholders of publication publicising the guideline through NICE's newsletter and alerts issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE.	
32.	Keywords		
33.	Details of existing review of same topic by same authors	Not applicable	
34.	Current review status	☒	Ongoing
		☐	Completed but not published
		☐	Completed and published
		☐	Completed, published and being updated

ID	Field	Content	
		☐	Discontinued
35. .	Additional information		
36.	Details of final publication	www.nice.org.uk	

BFLUTS: Bristol Female Lower Urinary Tract Symptoms Questionnaire; BPI: Brief pain inventory; CDSR: Cochrane Database of Systematic Reviews; CENTRAL: Cochrane Central Register of Controlled Trials; DARE: Database of Abstracts of Reviews of Effects; ePAQ: Electronic personal health questionnaire; FIQL: Faecal incontinence quality of life scale; FISI: Faecal incontinence severity index; GIQLI: Gastrointestinal quality of life index; GRADE: Grading of Recommendations Assessment, Development and Evaluation; HTA: Health Technology Assessment; ICIQ-UI: International Consultation on Incontinence Questionnaire- Urinary incontinence; ICIQ-VA: International Consultation on Incontinence questionnaire – vaginal symptoms; ISI: Incontinence symptom index; KHQ: Kings health questionnaire; MID: minimally important difference; NGA: National Guideline Alliance; NHS: National health service; NICE: National Institute for Health and Care Excellence; PAC-QL: patient assessment of constipation - quality of life; PAC-SYM: Patient assessment of constipation symptoms; PDI: Pain disability index; PISQ: Pelvic organ prolapse/urinary incontinence sexual questionnaire; POPQ: Pelvic organ prolapse quantification system; POP-SS: Pelvic organ prolapse symptom score; RCT: randomised controlled trial; RoB: risk of bias; SD: standard deviation: UDI: Urinary distress index

Appendix B – Literature search strategies

Literature search strategies for review question: What is the effectiveness of physical devices (including support garments, pessaries and dilators) for improving symptoms of pelvic floor dysfunction?

Clinical Search

Database(s): Medline & Embase (Multifile)
Last searched on **Embase Classic+Embase** 1947 to 2021 February 01, **Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily** 1946 to February 01, 2021
Date of last search: 2nd February 2021

Multifile database codes: emczd = Embase Classic+Embase; ppez= MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily

#	Searches
1	Pelvic Floor/ use ppez
2	Pelvic Floor Disorders/ use ppez
3	pelvis floor/ use emczd
4	pelvic floor disorder/ use emczd
5	(pelvi$ adj (floor$ or diaphragm$) adj3 (dysfunction$ or disorder$ or fail$ or impair$ or incompeten$ or insufficien$ or dyssynerg$ or symptom$ or laxity or change$ or care$ or health$ or wellbeing$ or well-being$ or prevent$ or rehabilitat$ or weak$ or hypertonic$ or overactiv$ or over activ$ or over-activ$)).tw.
6	(pelvi$ adj (dysfunction$ or disorder$ or fail$ or impair$ or incompeten$ or insufficien$ or dyssynerg$ or symptom$ or laxity or care$ or health$ or wellbeing$ or well-being$ or prevent$ or rehabilitat$ or weak$ or hypertonic$ or overactiv$ or over activ$ or over-activ$)).tw.
7	or/1-6
8	exp *Urinary Incontinence/ use ppez
9	*Urinary Bladder, Overactive/ use ppez
10	exp *urine incontinence/ use emczd
11	*overactive bladder/ use emczd
12	*bladder instability/ use emczd
13	((stress$ or mix$ or urg$ or urin$) adj5 incontinen$).ti.
14	(bladder$ adj5 (overactiv$ or over activ$ or over-activ$ or instabilit$ or hyper-reflex$ or hyperreflex$ or hyper reflex$ or incontinen$)).ti.
15	(detrusor$ adj5 (overactiv$ or over activ$ or over-activ$ or instabilit$ or hyper-reflex$ or hyperreflex$ or hyper reflex$)).ti.
16	((urgency adj2 frequency) or (frequency adj2 urgency)).ti.
17	((urin$ or bladder$) adj2 (urg$ or frequen$)).ti.
18	(SUI or OAB).ti.
19	or/8-18
20	exp *Pelvic Organ Prolapse/ use ppez
21	exp *pelvic organ prolapse/ use emczd
22	*Rectocele/ use ppez
23	*rectocele/ use emczd
24	(pelvic$ adj3 organ$ adj3 prolaps$).ti.
25	(urinary adj3 bladder adj3 prolaps$).ti.
26	((vagin$ or urogenital$ or genit$ or uter$ or viscer$ or anterior$ or posterior$ or apical or pelvi$ or vault$ or urethr$ or bladder$ or cervi$ or rectal or rectum) adj3 prolaps$).ti.
27	(splanchnoptos$ or visceroptos$).ti.
28	(hernia$ adj3 (pelvi$ or vagin$ or urogenital$ or uter$ or bladder$ or urethr$ or viscer$)).ti.
29	(urethroc?ele$ or enteroc?ele$ or sigmoidoc?ele$ or proctoc?ele$ or rectoc?ele$ or cystoc?ele$ or rectoenteroc?ele$ or cystourethroc?ele$).ti.
30	or/20-29
31	*Fecal Incontinence/ use ppez
32	*feces incontinence/ use emczd
33	((faecal or fecal or faeces or feces or fecally or faecally or anal or anally or stool or stools or bowel or double or defecat$ or defaecat$) adj5 (incontinence or incontinent or urge$ or leak or leaking or leakage or soiling or seeping or seepage or impacted or impaction)).ti.
34	or/31-33
35	Urinary Retention/ use ppez
36	urine retention/ use emczd
37	(urin$ adj3 (retention$ or retain$)).tw.
38	(voiding adj (disorder$ or dysfunction$ or problem$)).tw.
39	(empty$ adj disorder$ adj3 (bowel$ or bladder$ or vesical$ or stool$)).tw.

#	Searches
40	((urogeni$ or anorec$ or ano-rec$ or ano rec$) adj3 dysfunction$).tw.
41	defecation disorder/ use emczd
42	Fecal Impaction/ use ppez
43	Feces Impaction/ use emczd
44	((difficult$ or delay$ or irregular$ or infrequen$ or pain$) adj3 (defecat$ or defaecat$ or stool$ or faeces or feces or bowel movement$)).tw.
45	(obstruct$ adj3 (defecat$ or defaecat$)).tw.
46	((defecat$ or defaecat$ or evacuat$) adj3 (disorder$ or dysfunction$)).tw.
47	outlet$ dysfunction$ constipa$.tw.
48	(dys?ynerg$ adj (defecat$ or defaecat$)).tw.
49	(pelvi$ adj3 dyskines$).tw.
50	pelvi$ outlet$ obstruct$.tw.
51	anismus$.tw.
52	puborectal$ contract$.tw.
53	((rectal or rectum) adj3 urge$).tw.
54	or/35-53
55	female sexual dysfunction/ use emczd
56	(female adj sex$ adj (dysfunct$ or satisf$ or problem$ or symptom$ or arous$ or activit$ or disorder$)).tw.
57	(obstruct$ adj3 intercourse).tw.
58	(vagin$ adj3 laxity$).tw.
59	(vagin$ adj wind).tw.
60	Vaginismus/ use ppez
61	vaginism/ use emczd
62	vaginismus$.tw.
63	(vagin$ adj penetrat$ adj disorder$).tw.
64	or/55-63
65	7 or 19 or 30 or 34 or 54 or 64
66	*Conservative treatment/ use ppez
67	*conservative treatment/ use emczd
68	*clothing/ use ppez
69	protective clothing/ use emczd
70	protective equipment/ use emczd
71	(support adj (pant$ or garment$ or underwear)).mp.
72	(v-brace$ or vbrace$ or fembrace$ or pro-portare$).mp.
73	Pessaries/ use ppez
74	vagina pessary/ use emczd
75	pessar$.mp.
76	femicushion$.mp.
77	*Dilation/ use ppez
78	vaginal dilator/ use emczd
79	dilator$.mp.
80	(vagin$ adj5 trainer$).mp.
81	(vaginal adj (tampon$ or sponge$)).mp.
82	(Amielle$ or Femmax$ or Femmeze$).mp.
83	Absorbent Pads/ use ppez
84	absorbent pad/ use emczd
85	Tampons, Surgical/ use ppez
86	surgical tampon/ use emczd
87	((anal or vagin$ or urethra$ or intraurethra$ or intra-urethra$ or intravagin$ or intra-vagin$) adj2 (plug$ or insert or device$)).mp.
88	((mechanical or physical) adj (insert or device$)).mp.
89	Disposable Equipment/ use ppez
90	disposable equipment/ use emczd
91	((urethr$ or urin$) adj3 seal$).mp.
92	((dispos$ or adhesiv$) adj patch$).mp.
93	(control adj device$).mp.
94	FemAssist.mp.
95	bladder stimulator/ use emczd
96	bladder stimulation/ use emczd
97	(bladder$ adj stimulat$).mp.
98	Therapeutic Irrigation/ use ppez
99	lavage/ use emczd
100	"transanal irrigation"/ use emczd
101	((rectal$ or rectum$ or trans-anal$ or transanal$) adj3 irrigat$).mp.
102	exp incontinence aid/ use emczd
103	((procon$ or incontinen$ or continen$ or anti-incontinen$ or antiincontinen$ or anti-SUI) adj2 device$).mp.
104	(IncoStress$ or Fenix$).mp.
105	(occlusive adj device$).mp.
106	(bladder$ adj3 neck$ adj3 support$ adj3 (device$ or prosthes$)).mp.
107	((rectal$ or rectum$) adj3 (realign$ or re-align$ or re align$)).mp.

#	Searches
108	(vagin$ adj3 splint$).mp.
109	or/66-108
110	65 and 109
111	limit 110 to english language
112	limit 111 to yr="1980 -Current"
113	Intermittent Urethral Catheterization/ use ppez
114	*intermittent catheterization/ use emczd
115	(intermittent adj3 (self-catheter$ or selfcatheter$ or self-cather$ or selfcather$)).tw.
116	(ISC adj5 (catheter$ or self-catheter$ or selfcatheter$ or cather$ or self-cather$ or selfcather$)).tw.
117	(self-catheter$ or selfcatheter$ or self-cather$ or selfcather$).ti.
118	or/113-117
119	(7 or 54) and 118
120	limit 119 to english language
121	limit 120 to yr="1980 -Current"
122	112 or 121

Database(s): Cochrane Library
Last searched on **Cochrane Database of Systematic Reviews**, Issue 2 of 12, February 2021, **Cochrane Central Register of Controlled Trials**, Issue 2 of 12, February 2021
Date of last search: 2nd February 2021

#	Searches
#1	MeSH descriptor: [Pelvic Floor] this term only
#2	MeSH descriptor: [Pelvic Floor Disorders] this term only
#3	((pelvi* NEXT (floor* or diaphragm*) NEAR/3 (dysfunction* or disorder* or fail* or impair* or incompeten* or insufficien* or dyssynerg* or symptom* or laxity or change* or care* or health* or wellbeing* or well-being* or prevent* or rehabilitat* or weak* or hypertonic* or overactiv* or over activ* or over-activ*)):ti,ab,kw
#4	((pelvi* NEXT (dysfunction* or disorder* or fail* or impair* or incompeten* or insufficien* or dyssynerg* or symptom* or laxity or care* or health* or wellbeing* or well-being* or prevent* or rehabilitat* or weak* or hypertonic* or overactiv* or over activ* or over-activ*)):ti,ab,kw
#5	MeSH descriptor: [Urinary Incontinence] explode all trees
#6	MeSH descriptor: [Urinary Bladder, Overactive] this term only
#7	(((stress* or mix* or urg* or urin*) NEAR/5 incontinen*)):ti,ab,kw
#8	(((bladder* NEAR/5 (overactiv* or over activ* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or hyper reflex* or incontinen*)))):ti,ab,kw
#9	(((detrusor* NEAR/5 (overactiv* or over activ* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or hyper reflex*)))):ti,ab,kw
#10	(((((urgency NEAR/2 frequency) or (frequency NEAR/2 urgency))))):ti,ab,kw
#11	((((urin* or bladder*) NEAR/2 (urg* or frequen*)))):ti,ab,kw
#12	(((SUI or OAB))):ti,ab,kw
#13	MeSH descriptor: [Pelvic Organ Prolapse] explode all trees
#14	MeSH descriptor: [Rectocele] this term only
#15	(((pelvic* NEAR/3 organ* NEAR/3 prolaps*))):ti,ab,kw
#16	(((urinary NEAR/3 bladder NEAR/3 prolaps*))):ti,ab,kw
#17	((((vagin* or urogenital* or genit* or uter* or viscer* or anterior* or posterior* or apical or pelvi* or vault* or urethr* or bladder* or cervi* or rectal or rectum) NEAR/3 prolaps*))):ti,ab,kw
#18	(((splanchnoptos* or visceroptos*))):ti,ab,kw
#19	(((hernia* NEAR/3 (pelvi* or vagin* or urogenital* or uter* or bladder* or urethr* or viscer*)))):ti,ab,kw
#20	(((urethroc?ele* or enteroc?ele* or sigmoidoc?ele* or proctoc?ele* or rectoc?ele* or cystoc?ele* or rectoenteroc?ele* or cystourethroc?ele*))):ti,ab,kw
#21	MeSH descriptor: [Fecal Incontinence] this term only
#22	((((faecal or fecal or faeces or feces or fecally or faecally or anal or anally or stool or stools or bowel or double or defecat* or defaecat*) NEAR/5 (incontinence or incontinent or urge* or leak or leaking or leakage or soiling or seeping or seepage or impacted or impaction)))):ti,ab,kw
#23	MeSH descriptor: [Urinary Retention] this term only
#24	(((urin* NEAR/3 (retention* or retain*)))):ti,ab,kw
#25	(((voiding NEXT (disorder* or dysfunction* or problem*)))):ti,ab,kw
#26	(((empty* NEXT disorder* NEAR/3 (bowel* or bladder* or vesical* or stool*)))):ti,ab,kw
#27	((((urogeni* or anorec* or ano-rec* or ano rec*) NEAR/3 dysfunction*))):ti,ab,kw
#28	MeSH descriptor: [Fecal Impaction] this term only
#29	((((difficult* or delay* or irregular* or infrequen* or pain*) NEAR/3 (defecat* or defaecat* or stool* or faecal or fecal or faeces or feces or fecally or faecally or bowel movement*)))):ti,ab,kw
#30	(((obstruct* NEAR/3 (defecat* or defaecat*)))):ti,ab,kw
#31	((((defecat* or defaecat* or evacuat*) NEAR/3 (disorder* or dysfunction*)))):ti,ab,kw
#32	((outlet* dysfunction* constipa*)):ti,ab,kw
#33	(((dys?ynerg* NEXT (defecat* or defaecat*)))):ti,ab,kw
#34	(((pelvi* NEAR/3 dyskines*))):ti,ab,kw
#35	((pelvi* outlet* obstruct*)):ti,ab,kw
#36	((anismus*)):ti,ab,kw
#37	((puborectal* contract*)):ti,ab,kw
#38	((((rectal or rectum) NEAR/3 urge*))):ti,ab,kw

#	Searches
#39	(((female NEXT sex* NEXT (dysfunct* or satisf* or problem* or symptom* or arous* or activit* or disorder*))):ti,ab,kw
#40	(((obstruct* NEAR/3 intercourse))):ti,ab,kw
#41	(((vagin* NEAR/3 laxity*))):ti,ab,kw
#42	(((vagin* NEXT wind))):ti,ab,kw
#43	MeSH descriptor: [Vaginismus] this term only
#44	((vaginismus*)):ti,ab,kw
#45	(((vagin* NEXT penetrat* NEXT disorder*))):ti,ab,kw
#46	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #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 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45
#47	MeSH descriptor: [Conservative Treatment] this term only
#48	MeSH descriptor: [Clothing] this term only
#49	#46 AND #48
#50	((support NEXT (pant* or garment* or underwear))):ti,ab,kw
#51	((v-brace* or vbrace* or fembrace* or pro-portare*)):ti,ab,kw
#52	MeSH descriptor: [Pessaries] this term only
#53	((pessar* or femicushion*)):ti,ab,kw
#54	MeSH descriptor: [Dilatation] this term only
#55	(dilator*):ti,ab,kw
#56	((vagin* NEAR/5 trainer*)):ti,ab,kw
#57	((vaginal NEXT (tampon* or sponge*))):ti,ab,kw
#58	((Amielle* or Femmax* or Femmeze*)):ti,ab,kw
#59	MeSH descriptor: [Absorbent Pads] this term only
#60	MeSH descriptor: [Tampons, Surgical] this term only
#61	(((anal or vagin* or urethra* or intraurethra* or intra-urethra* or intravagin* or intra-vagin*) NEAR/2 (plug* or insert or device*))):ti,ab,kw
#62	(((mechanical or physical) NEXT (insert or device*))):ti,ab,kw
#63	MeSH descriptor: [Disposable Equipment] this term only
#64	(((urethr* or urin*) NEAR/3 seal*)):ti,ab,kw
#65	(((dispos* or adhesiv*) NEXT patch*)):ti,ab,kw
#66	((control NEXT device*)):ti,ab,kw
#67	(FemAssist*):ti,ab,kw
#68	((bladder* NEXT stimulat*)):ti,ab,kw
#69	MeSH descriptor: [Therapeutic Irrigation] this term only
#70	(((rectal* or rectum* or trans-anal* or transanal*) NEAR/3 irrigat*)):ti,ab,kw
#71	(((procon* or incontinen* or continen* or anti-incontinen* or antiincontinen* or anti-SUI) NEAR/2 device*)):ti,ab,kw
#72	((IncoStress* or Fenix*)):ti,ab,kw
#73	((occlusive NEXT device*)):ti,ab,kw
#74	((bladder* NEAR/3 neck* NEAR/3 support* NEAR/3 (device* or prosthes*))):ti,ab,kw
#75	(((rectal* or rectum*) NEAR/3 (realign* or re-align* or re align*))):ti,ab,kw
#76	((vagin* NEAR/3 splint*)):ti,ab,kw
#77	#47 OR #48 OR #49 OR #50 OR #51 OR #52 OR #53 OR #54 OR #55 OR #56 OR #57 OR #58 OR #59 OR #60 OR #61 OR #62 OR #63 OR #64 OR #65 OR #66 OR #67 OR #68 OR #69 OR #70 OR #71 OR #72 OR #73 OR #74 OR #75 OR #76
#78	#46 AND #77
#79	MeSH descriptor: [Intermittent Urethral Catheterization] this term only
#80	((intermittent NEAR/3 (self-catheter* or selfcatheter* or self-cather* or selfcather*))):ti,ab,kw
#81	((ISC NEAR/5 (catheter* or self-catheter* or selfcatheter* or cather* or self-cather* or selfcather*))):ti,ab,kw
#82	((self-catheter* or selfcatheter* or self-cather* or selfcather*)):ti
#83	#79 OR #80 OR #81 OR #82
#84	#1 OR #2 OR #3 OR #4 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
#85	#83 AND #84
#86	#78 OR #85

Database(s): CRD: Database of Abstracts of Reviews of Effects (DARE), HTA Database
Date of last search: 2nd February 2021

#	Searches
1	MeSH DESCRIPTOR Pelvic Floor IN DARE,HTA
2	MeSH DESCRIPTOR Pelvic Floor Disorders IN DARE,HTA
3	((pelvi* NEXT (floor* or diaphragm*) NEAR3 (dysfunction* or disorder* or fail* or impair* or incompeten* or insufficien* or dyssynerg* or symptom* or laxity or change* or care* or health* or wellbeing* or well-being* or prevent* or rehabilitat* or weak* or hypertonic* or overactiv* or over activ* or over-activ*))) IN DARE, HTA
4	((pelvi* NEXT (dysfunction* or disorder* or fail* or impair* or incompeten* or insufficien* or dyssynerg* or symptom* or laxity or care* or health* or wellbeing* or well-being* or prevent* or rehabilitat* or weak* or hypertonic* or overactiv* or over activ* or over-activ*))) IN DARE, HTA
5	MeSH DESCRIPTOR Urinary Incontinence EXPLODE ALL TREES IN DARE,HTA
6	MeSH DESCRIPTOR Urinary Bladder, Overactive IN DARE,HTA

#	Searches
7	(((stress* or mix* or urg* or urin*) NEAR5 incontinen*)) IN DARE, HTA
8	((bladder* NEAR5 (overactiv* or over activ* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or hyper reflex* or incontinen*))) IN DARE, HTA
9	((detrusor* NEAR5 (overactiv* or over activ* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or hyper reflex*))) IN DARE, HTA
10	(((urgency NEAR2 frequency) or (frequency NEAR2 urgency))) IN DARE, HTA
11	(((urin* or bladder*) NEAR2 (urg* or frequen*))) IN DARE, HTA
12	((SUI or OAB)) IN DARE, HTA
13	MeSH DESCRIPTOR Pelvic Organ Prolapse EXPLODE ALL TREES IN DARE,HTA
14	MeSH DESCRIPTOR Rectocele IN DARE,HTA
15	((pelvic* NEAR3 organ* NEAR3 prolaps*)) IN DARE, HTA
16	((urinary NEAR3 bladder NEAR3 prolaps*)) IN DARE, HTA
17	(((vagin* or urogenital* or genit* or uter* or viscer* or anterior* or posterior* or apical or pelvi* or vault* or urethr* or bladder* or cervi* or rectal or rectum) NEAR3 prolaps*)) IN DARE, HTA
18	((splanchnoptos* or visceroptos*)) IN DARE, HTA
19	((hernia* NEAR3 (pelvi* or vagin* or urogenital* or uter* or bladder* or urethr* or viscer*))) IN DARE, HTA
20	((urethroc?ele* or enteroc?ele* or sigmoidoc?ele* or proctoc?ele* or rectoc?ele* or cystoc?ele* or rectoenteroc?ele* or cystourethroc?ele*)) IN DARE, HTA
21	MeSH DESCRIPTOR Fecal Incontinence IN DARE,HTA
22	(((faecal or fecal or faeces or feces or fecally or faecally or anal or anally or stool or stools or bowel or double or defecat* or defaecat*) NEAR5 (incontinence or incontinent or urge* or leak or leaking or leakage or soiling or seeping or seepage or impacted or impaction))) IN DARE, HTA
23	MeSH DESCRIPTOR Urinary Retention IN DARE,HTA
24	((urin* NEAR3 (retention* or retain*))) IN DARE, HTA
25	((voiding NEXT (disorder* or dysfunction* or problem*))) IN DARE, HTA
26	((empty* NEXT disorder* NEAR3 (bowel* or bladder* or vesical* or stool*))) IN DARE, HTA
27	(((urogeni* or anorec* or ano-rec* or ano rec*) NEAR3 dysfunction*)) IN DARE, HTA
28	MeSH DESCRIPTOR Fecal Impaction IN DARE,HTA
29	(((difficult* or delay* or irregular* or infrequen* or pain*) NEAR3 (defecat* or defaecat* or stool* or faecal or fecal or faeces or feces or fecally or faecally or bowel movement*))) IN DARE, HTA
30	((obstruct* NEAR3 (defecat* or defaecat*))) IN DARE, HTA
31	(((defecat* or defaecat* or evacuat*) NEAR3 (disorder* or dysfunction*))) IN DARE, HTA
32	(((outlet* NEXT dysfunction* NEXT constipa*))) IN DARE, HTA
33	((dys?ynerg* NEXT (defecat* or defaecat*))) IN DARE, HTA
34	((pelvi* NEAR3 dyskines*)) IN DARE, HTA
35	((pelvi* NEXT outlet* NEXT obstruct*)) IN DARE, HTA
36	((anismus*)) IN DARE, HTA
37	((puborectal* NEXT contract*)) IN DARE, HTA
38	(((rectal or rectum) NEAR3 urge*)) IN DARE, HTA
39	((female NEXT sex* NEXT (dysfunct* or satisf* or problem* or symptom* or arous* or activit* or disorder*))) IN DARE, HTA
40	((obstruct* NEAR3 intercourse)) IN DARE, HTA
41	((vagin* NEAR3 laxity*)) IN DARE, HTA
42	((vagin* NEXT wind)) IN DARE, HTA
43	MeSH DESCRIPTOR Vaginismus IN DARE,HTA
44	((vaginismus*)) IN DARE, HTA
45	((vagin* NEXT penetrat* NEXT disorder*)) IN DARE, HTA
46	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #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 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45
47	MeSH DESCRIPTOR Conservative treatment IN DARE,HTA
48	MeSH DESCRIPTOR clothing IN DARE,HTA
49	((support NEAR1 (pant* or garment* or underwear)))
50	(v-brace* or vbrace* or fembrace* or pro-portare*)
51	MeSH DESCRIPTOR Pessaries IN DARE,HTA
52	(pessar*) IN DARE, HTA
53	(femicushion*) IN DARE, HTA
54	MeSH DESCRIPTOR Dilatation IN DARE,HTA
55	(dilator*) IN DARE, HTA
56	(vagin* NEAR5 trainer*) IN DARE, HTA
57	(vaginal NEAR1 (tampon* or sponge*)) IN DARE, HTA
58	(Amielle* or Femmax* or Femmeze*) IN DARE, HTA
59	MeSH DESCRIPTOR Absorbent Pads IN DARE,HTA
60	MeSH DESCRIPTOR Tampons, Surgical IN DARE,HTA
61	(((anal or vagin* or urethra* or intraurethra* or intra-urethra* or intravagin* or intra-vagin*) NEAR2 (plug* or insert or device*))) IN DARE, HTA
62	(((mechanical or physical) NEAR1 (insert or device*))) IN DARE, HTA
63	MeSH DESCRIPTOR Disposable Equipment IN DARE,HTA
64	(((urethr* or urin*) NEAR3 seal*)) IN DARE, HTA
65	(((dispos* or adhesiv*) NEAR1 patch*)) IN DARE, HTA

#	Searches
66	("control device*") IN DARE, HTA
67	(FemAssist*) IN DARE, HTA
68	("bladder* stimulat*") IN DARE, HTA
69	MeSH DESCRIPTOR Therapeutic Irrigation IN DARE,HTA
70	(((rectal* or rectum* or trans-anal* or transanal*) NEAR3 irrigat*)) IN DARE, HTA
71	(((procon* or incontinen* or continen* or anti-incontinen* or antiincontinen* or anti-SUI) NEAR2 device*)) IN DARE, HTA
72	(IncoStress* or Fenix*) IN DARE, HTA
73	("occlusive device*") IN DARE, HTA
74	((bladder* NEAR3 neck* NEAR3 support* NEAR3 (device* or prosthes*))) IN DARE, HTA
75	(((rectal* or rectum*) NEAR3 (realign* or re-align* or re align*))) IN DARE, HTA
76	((vagin* NEAR3 splint*)) IN DARE, HTA
77	#47 OR #48 OR #49 OR #50 OR #51 OR #52 OR #53 OR #54 OR #55 OR #56 OR #57 OR #58 OR #59 OR #60 OR #61 OR #62 OR #63 OR #64 OR #65 OR #66 OR #67 OR #68 OR #69 OR #70 OR #71 OR #72 OR #73 OR #74 OR #75 OR #76
78	#46 AND #77
79	MeSH DESCRIPTOR Intermittent Urethral Catheterization IN DARE,HTA
80	((intermittent NEAR3 (self-catheter* or selfcatheter* or self-cather* or selfcather*))) IN DARE, HTA
81	((ISC NEAR5 (catheter* or self-catheter* or selfcatheter* or cather* or self-cather* or selfcather*))) IN DARE, HTA
82	((self-catheter* or selfcatheter* or self-cather* or selfcather*)):TI IN DARE, HTA
83	#79 OR #80 OR #81 OR #82
84	#46 AND #83
85	#78 OR #84

Database(s): Emcare & PsycINFO (Multifile)
Last searched on **Emcare** 1995 to present, **APA PsycINFO** 1806 to January Week 4 2021
Date of last search: 2nd February 2021

#	Searches
1	pelvis floor/
2	pelvic floor disorder/
3	(pelvi$ adj (floor$ or diaphragm$) adj3 (dysfunction$ or disorder$ or fail$ or impair$ or incompeten$ or insufficien$ or dyssynerg$ or symptom$ or laxity or change$ or care$ or health$ or wellbeing$ or well-being$ or prevent$ or rehabilitat$ or weak$ or hypertonic$ or overactiv$ or over activ$ or over-activ$)).tw.
4	(pelvi$ adj (dysfunction$ or disorder$ or fail$ or impair$ or incompeten$ or insufficien$ or dyssynerg$ or symptom$ or laxity or care$ or health$ or wellbeing$ or well-being$ or prevent$ or rehabilitat$ or weak$ or hypertonic$ or overactiv$ or over activ$ or over-activ$)).tw.
5	or/1-4
6	exp *Urinary Incontinence/
7	*overactive bladder/
8	*bladder instability/
9	((stress$ or mix$ or urg$ or urin$) adj5 incontinen$).ti.
10	(bladder$ adj5 (overactiv$ or over activ$ or over-activ$ or instabilit$ or hyper-reflex$ or hyperreflex$ or hyper reflex$ or incontinen$)).ti.
11	(detrusor$ adj5 (overactiv$ or over activ$ or over-activ$ or instabilit$ or hyper-reflex$ or hyperreflex$ or hyper reflex$)).ti.
12	((urgency adj2 frequency) or (frequency adj2 urgency)).ti.
13	((urin$ or bladder$) adj2 (urg$ or frequen$)).ti.
14	(SUI or OAB).ti.
15	or/6-14
16	exp *pelvic organ prolapse/
17	*rectocele/
18	(pelvic$ adj3 organ$ adj3 prolaps$).ti.
19	(urinary adj3 bladder adj3 prolaps$).ti.
20	((vagin$ or urogenital$ or genit$ or uter$ or viscer$ or anterior$ or posterior$ or apical or pelvi$ or vault$ or urethr$ or bladder$ or cervi$ or rectal or rectum) adj3 prolaps$).ti.
21	(splanchnoptos$ or visceroptos$).ti.
22	(hernia$ adj3 (pelvi$ or vagin$ or urogenital$ or uter$ or bladder$ or urethr$ or viscer$)).ti.
23	(urethroc?ele$ or enteroc?ele$ or sigmoidoc?ele$ or proctoc?ele$ or rectoc?ele$ or cystoc?ele$ or rectoenteroc?ele$ or cystourethroc?ele$).ti.
24	or/16-23
25	exp *Fecal Incontinence/
26	((faecal or fecal or faeces or feces or fecally or faecally or anal or anally or stool or stools or bowel or double or defecat$ or defaecat$) adj5 (incontinence or incontinent or urge$ or leak or leaking or leakage or soiling or seeping or seepage or impacted or impaction)).ti.
27	25 or 26
28	urine retention/
29	(urin$ adj3 (retention$ or retain$)).tw.
30	(voiding adj (disorder$ or dysfunction$ or problem$)).tw.
31	(empty$ adj disorder$ adj3 (bowel$ or bladder$ or vesical$ or stool$)).tw.
32	((urogeni$ or anorec$ or ano-rec$ or ano rec$) adj3 dysfunction$).tw.

#	Searches
33	defecation disorder/
34	feces impaction/
35	((difficult$ or delay$ or irregular$ or infrequen$ or pain$) adj3 (defecat$ or defaecat$ or stool$ or faeces or feces or bowel movement$)).tw.
36	(obstruct$ adj3 (defecat$ or defaecat$)).tw.
37	((defecat$ or defaecat$ or evacuat$) adj3 (disorder$ or dysfunction$)).tw.
38	outlet$ dysfunction$ constipa$.tw.
39	(dys?ynerg$ adj (defecat$ or defaecat$)).tw.
40	(pelvi$ adj3 dyskines$).tw.
41	pelvi$ outlet$ obstruct$.tw.
42	anismus$.tw.
43	puborectal$ contract$.tw.
44	((rectal or rectum) adj3 urge$).tw.
45	or/28-44
46	female sexual dysfunction/
47	(female adj sex$ adj (dysfunct$ or satisf$ or problem$ or symptom$ or arous$ or activit$ or disorder$)).tw.
48	(obstruct$ adj3 intercourse).tw.
49	(vagin$ adj3 laxity$).tw.
50	(vagin$ adj wind).tw.
51	Vaginismus/
52	vaginismus$.tw.
53	(vagin$ adj penetrat$ adj disorder$).tw.
54	or/46-53
55	5 or 15 or 24 or 27 or 45 or 54
56	*conservative treatment/
57	*clothing/
58	protective clothing/
59	protective equipment/
60	(support adj (pant$ or garment$ or underwear)).mp.
61	(v-brace$ or vbrace$ or fembrace$ or pro-portare$).mp.
62	pessaries/
63	pessar$.mp.
64	femicushion$.mp.
65	*dilation/
66	vaginal dilator/
67	dilator$.mp.
68	(vagin$ adj5 trainer$).mp.
69	(vaginal adj (tampon$ or sponge$)).mp.
70	(Amielle$ or Femmax$ or Femmeze$).mp.
71	absorbent pad/
72	surgical tampon/
73	((anal or vagin$ or urethra$ or intraurethra$ or intra-urethra$ or intravagin$ or intra-vagin$) adj2 (plug$ or insert or device$)).mp.
74	((mechanical or physical) adj (insert or device$)).mp.
75	disposable equipment.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, tc, id, tm, mh]
76	((urethr$ or urin$) adj3 seal$).mp.
77	((dispos$ or adhesiv$) adj patch$).mp.
78	(control adj device$).mp.
79	FemAssist.mp.
80	bladder stimulator/
81	bladder stimulation/
82	(bladder$ adj stimulat$).mp.
83	lavage/
84	transanal irrigation/
85	((rectal$ or rectum$ or trans-anal$ or transanal$) adj3 irrigat$).mp.
86	exp incontinence aid/
87	((procon$ or incontinen$ or continen$ or anti-incontinen$ or antiincontinen$ or anti-SUI) adj2 device$).mp.
88	(IncoStress$ or Fenix$).mp.
89	(occlusive adj device$).mp.
90	(bladder$ adj3 neck$ adj3 support$ adj3 (device$ or prosthes$)).mp.
91	((rectal$ or rectum$) adj3 (realign$ or re-align$ or re align$)).mp.
92	(vagin$ adj3 splint$).mp.
93	or/56-92
94	55 and 93
95	*intermittent urethral catheterization/
96	*intermittent catheterization/
97	(intermittent adj3 (self-catheter$ or selfcatheter$ or self-cather$ or selfcather$)).tw.
98	(ISC adj5 (catheter$ or self-catheter$ or selfcatheter$ or cather$ or self-cather$ or selfcather$)).tw.
99	(self-catheter$ or selfcatheter$ or self-cather$ or selfcather$).ti.
100	or/95-99

#	Searches
101	(5 or 45) and 100
102	94 or 101
103	limit 102 to english language
104	limit 103 to yr="1980 -Current" [General Exclusions filter applied]

Economic Search

One global search was conducted for economic evidence across the guideline.

Database(s): CRD: NHS Economic Evaluation Database (NHS EED), HTA Database
Date of last search: 3rd February 2021

#	Searches
1	MeSH DESCRIPTOR Pelvic Floor IN NHSEED,HTA
2	MeSH DESCRIPTOR Pelvic Floor Disorders IN NHSEED,HTA
3	MeSH DESCRIPTOR Urinary Bladder, Overactive IN NHSEED,HTA
4	(((pelvi* NEXT (floor* or diaphragm*) NEAR3 (dysfunction* or disorder* or fail* or impair* or incompeten* or insufficien* or dyssynerg* or symptom* or laxity or change* or care* or health* or wellbeing* or well-being* or prevent* or rehabilitat* or weak* or hypertonic* or overactiv* or over activ* or over-activ*)))) IN NHSEED, HTA
5	MeSH DESCRIPTOR Urinary Incontinence EXPLODE ALL TREES IN NHSEED,HTA
6	MeSH DESCRIPTOR Urinary Bladder, Overactive IN NHSEED,HTA
7	((((stress* or mix* or urg* or urin*) NEAR5 incontinen*))) IN NHSEED, HTA
8	(((bladder* NEAR5 (overactiv* or over activ* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or hyper reflex* or incontinen*)))) IN NHSEED, HTA
9	(((detrusor* NEAR5 (overactiv* or over activ* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or hyper reflex*)))) IN NHSEED, HTA
10	(((((urgency NEAR2 frequency) or (frequency NEAR2 urgency)))) IN NHSEED, HTA
11	((((urin* or bladder*) NEAR2 (urg* or frequen*)))) IN NHSEED, HTA
12	(((SUI or OAB))) IN NHSEED, HTA
13	MeSH DESCRIPTOR Pelvic Organ Prolapse EXPLODE ALL TREES IN NHSEED,HTA
14	MeSH DESCRIPTOR Rectocele IN NHSEED,HTA
15	(((pelvic* NEAR3 organ* NEAR3 prolaps*))) IN NHSEED, HTA
16	(((urinary NEAR3 bladder NEAR3 prolaps*))) IN NHSEED, HTA
17	((((vagin* or urogenital* or genit* or uter* or viscer* or anterior* or posterior* or apical or pelvi* or vault* or urethr* or bladder* or cervi* or rectal or rectum) NEAR3 prolaps*))) IN NHSEED, HTA
18	(((splanchnoptos* or visceroptos*))) IN NHSEED, HTA
19	(((hernia* NEAR3 (pelvi* or vagin* or urogenital* or uter* or bladder* or urethr* or viscer*)))) IN NHSEED, HTA
20	(((urethroc?ele* or enteroc?ele* or sigmoidoc?ele* or proctoc?ele* or rectoc?ele* or cystoc?ele* or rectoenteroc?ele* or cystourethroc?ele*))) IN NHSEED, HTA
21	MeSH DESCRIPTOR Fecal Incontinence IN NHSEED,HTA
22	((((faecal or fecal or faeces or feces or fecally or faecally or anal or anally or stool or stools or bowel or double or defecat* or defaecat*) NEAR5 (incontinence or incontinent or urge* or leak or leaking or leakage or soiling or seeping or seepage or impacted or impaction)))) IN NHSEED, HTA
23	MeSH DESCRIPTOR Urinary Retention IN NHSEED,HTA
24	(((urin* NEAR3 (retention* or retain*)))) IN NHSEED, HTA
25	(((voiding NEXT (disorder* or dysfunction* or problem*)))) IN NHSEED, HTA
26	(((empty* NEXT disorder* NEAR3 (bowel* or bladder* or vesical* or stool*)))) IN NHSEED, HTA
27	((((urogeni* or anorec* or ano-rec* or ano rec*) NEAR3 dysfunction*))) IN NHSEED, HTA
28	MeSH DESCRIPTOR Fecal Impaction IN NHSEED,HTA
29	((((difficult* or delay* or irregular* or infrequen* or pain*) NEAR3 (defecat* or defaecat* or stool* or faecal or fecal or faeces or feces or fecally or faecally or bowel movement*)))) IN NHSEED, HTA
30	(((obstruct* NEAR3 (defecat* or defaecat*)))) IN NHSEED, HTA
31	((((defecat* or defaecat* or evacuat*) NEAR3 (disorder* or dysfunction*)))) IN NHSEED, HTA
32	((((outlet* NEXT dysfunction* NEXT constipa*)))) IN NHSEED, HTA
33	(((dys?ynerg* NEXT (defecat* or defaecat*)))) IN NHSEED, HTA
34	(((pelvi* NEAR3 dyskines*))) IN NHSEED, HTA
35	(((pelvi* NEXT outlet* NEXT obstruct*))) IN NHSEED, HTA
36	(((anismus*))) IN NHSEED, HTA
37	(((puborectal* NEXT contract*))) IN NHSEED, HTA
38	((((rectal or rectum) NEAR3 urge*))) IN NHSEED, HTA
39	(((female NEXT sex* NEXT (dysfunct* or satisf* or problem* or symptom* or arous* or activit* or disorder*)))) IN NHSEED, HTA
40	(((obstruct* NEAR3 intercourse))) IN NHSEED, HTA
41	(((vagin* NEAR3 laxity*))) IN NHSEED, HTA
42	(((vagin* NEXT wind))) IN NHSEED, HTA
43	MeSH DESCRIPTOR Vaginismus IN NHSEED,HTA
44	(((vaginismus*))) IN NHSEED, HTA
45	(((vagin* NEXT penetrat* NEXT disorder*))) IN NHSEED, HTA
46	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #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

#	Searches
	#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) IN NHSEED, HTA

Database(s): Medline & Embase (Multifile)
Embase Classic+Embase 1947 to 2021 February 01, **Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily** 1946 to February 01, 2021
Date of last search: 3rd February 2021

Multifile database codes: emczd = Embase Classic+Embase; ppez= MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily

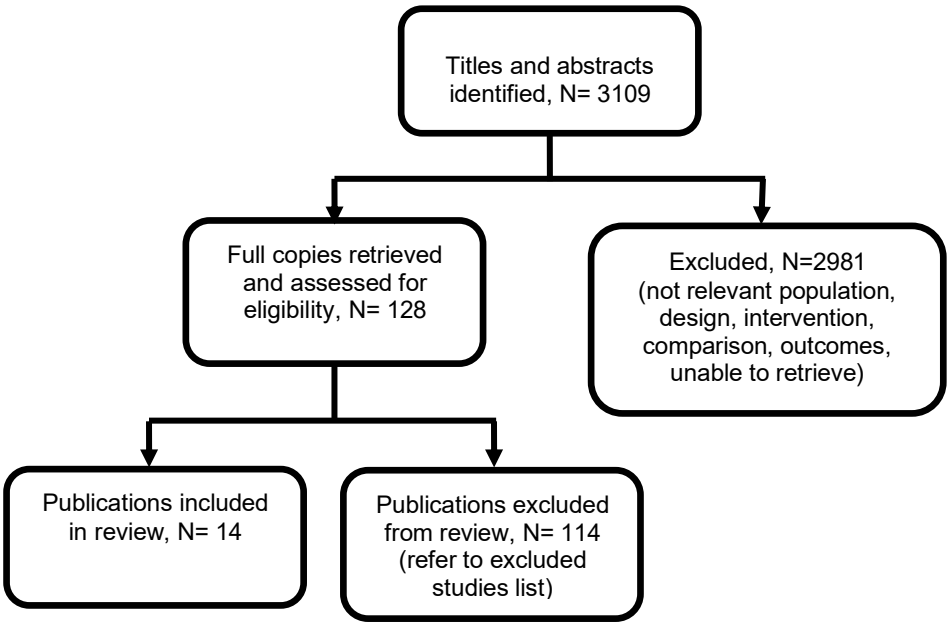
#	Searches
1	Pelvic Floor/ use ppez
2	Pelvic Floor Disorders/ use ppez
3	pelvis floor/ use emczd
4	pelvic floor disorder/ use emczd
5	(pelvi$ adj (floor$ or diaphragm$) adj3 (dysfunction$ or disorder$ or fail$ or impair$ or incompeten$ or insufficien$ or dyssynerg$ or symptom$ or laxity or change$ or care$ or health$ or wellbeing$ or well-being$ or prevent$ or rehabilitat$ or weak$ or hypertonic$ or overactiv$ or over activ$ or over-activ$)).tw.
6	(pelvi$ adj (dysfunction$ or disorder$ or fail$ or impair$ or incompeten$ or insufficien$ or dyssynerg$ or symptom$ or laxity or care$ or health$ or wellbeing$ or well-being$ or prevent$ or rehabilitat$ or weak$ or hypertonic$ or overactiv$ or over activ$ or over-activ$)).tw.
7	or/1-6
8	exp *Urinary Incontinence/ use ppez
9	*Urinary Bladder, Overactive/ use ppez
10	exp *urine incontinence/ use emczd
11	*overactive bladder/ use emczd
12	*bladder instability/ use emczd
13	((stress$ or mix$ or urg$ or urin$) adj5 incontinen$).ti.
14	(bladder$ adj5 (overactiv$ or over activ$ or over-activ$ or instabilit$ or hyper-reflex$ or hyperreflex$ or hyper reflex$ or incontinen$)).ti.
15	(detrusor$ adj5 (overactiv$ or over activ$ or over-activ$ or instabilit$ or hyper-reflex$ or hyperreflex$ or hyper reflex$)).ti.
16	((urgency adj2 frequency) or (frequency adj2 urgency)).ti.
17	((urin$ or bladder$) adj2 (urg$ or frequen$)).ti.
18	(SUI or OAB).ti.
19	or/8-18
20	exp *Pelvic Organ Prolapse/ use ppez
21	exp *pelvic organ prolapse/ use emczd
22	*Rectocele/ use ppez
23	*rectocele/ use emczd
24	(pelvic$ adj3 organ$ adj3 prolaps$).ti.
25	(urinary adj3 bladder adj3 prolaps$).ti.
26	((vagin$ or urogenital$ or genit$ or uter$ or viscer$ or anterior$ or posterior$ or apical or pelvi$ or vault$ or urethr$ or bladder$ or cervi$ or rectal or rectum) adj3 prolaps$).ti.
27	(splanchnoptos$ or visceroptos$).ti.
28	(hernia$ adj3 (pelvi$ or vagin$ or urogenital$ or uter$ or bladder$ or urethr$ or viscer$)).ti.
29	(urethroc?ele$ or enteroc?ele$ or sigmoidoc?ele$ or proctoc?ele$ or rectoc?ele$ or cystoc?ele$ or rectoenteroc?ele$ or cystourethroc?ele$).ti.
30	or/20-29
31	*Fecal Incontinence/ use ppez
32	*feces incontinence/ use emczd
33	((faecal or fecal or faeces or feces or fecally or faecally or anal or anally or stool or stools or bowel or double or defecat$ or defaecat$) adj5 (incontinence or incontinent or urge$ or leak or leaking or leakage or soiling or seeping or seepage or impacted or impaction)).ti.
34	or/31-33
35	Urinary Retention/ use ppez
36	urine retention/ use emczd
37	(urin$ adj3 (retention$ or retain$)).tw.
38	(voiding adj (disorder$ or dysfunction$ or problem$)).tw.
39	(empty$ adj disorder$ adj3 (bowel$ or bladder$ or vesical$ or stool$)).tw.
40	((urogeni$ or anorec$ or ano-rec$ or ano rec$) adj3 dysfunction$).tw.
41	defecation disorder/ use emczd
42	Fecal Impaction/ use ppez
43	Feces Impaction/ use emczd
44	((difficult$ or delay$ or irregular$ or infrequen$ or pain$) adj3 (defecat$ or defaecat$ or stool$ or faeces or feces or bowel movement$)).tw.
45	(obstruct$ adj3 (defecat$ or defaecat$)).tw.
46	((defecat$ or defaecat$ or evacuat$) adj3 (disorder$ or dysfunction$)).tw.
47	outlet$ dysfunction$ constipa$.tw.

#	Searches
48	(dys?ynerg$ adj (defecat$ or defaecat$)).tw.
49	(pelvi$ adj3 dyskines$).tw.
50	pelvi$ outlet$ obstruct$.tw.
51	anismus$.tw.
52	puborectal$ contract$.tw.
53	((rectal or rectum) adj3 urge$).tw.
54	or/35-53
55	female sexual dysfunction/ use emczd
56	(female adj sex$ adj (dysfunct$ or satisf$ or problem$ or symptom$ or arous$ or activit$ or disorder$)).tw.
57	(obstruct$ adj3 intercourse).tw.
58	(vagin$ adj3 laxity$).tw.
59	(vagin$ adj wind).tw.
60	Vaginismus/ use ppez
61	vaginism/ use emczd
62	vaginismus$.tw.
63	(vagin$ adj penetrat$ adj disorder$).tw.
64	or/55-63
65	7 or 19 or 30 or 34 or 54 or 64
66	Economics/ use ppez
67	Value of life/ use ppez
68	exp "Costs and Cost Analysis"/ use ppez
69	exp Economics, Hospital/ use ppez
70	exp Economics, Medical/ use ppez
71	Economics, Nursing/ use ppez
72	Economics, Pharmaceutical/ use ppez
73	exp "Fees and Charges"/ use ppez
74	exp Budgets/ use ppez
75	health economics/ use emczd
76	exp economic evaluation/ use emczd
77	exp health care cost/ use emczd
78	exp fee/ use emczd
79	budget/ use emczd
80	funding/ use emczd
81	budget*.ti,ab.
82	cost*.ti.
83	(economic* or pharmaco?economic*).ti.
84	(price* or pricing*).ti,ab.
85	(cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.
86	(financ* or fee or fees).ti,ab.
87	(value adj2 (money or monetary)).ti,ab.
88	or/66-87
89	65 and 88
90	limit 89 to english language

Appendix C – Clinical evidence study selection

Study selection for: What is the effectiveness of physical devices (including support garments, pessaries and dilators) for improving symptoms of pelvic floor dysfunction?

Figure 2: Study selection flow chart



Appendix D – Evidence tables

Evidence tables for review question: What is the effectiveness of physical devices (including support garments, pessaries and dilators) for improving symptoms of pelvic floor dysfunction?

Table 8: Evidence tables

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Cheung, R. Y. K., Lee, J. H. S., Lee, L. L., Chung, T. K. H., Chan, S. S. C., Vaginal pessary in women with symptomatic pelvic organ prolapse, Obstetrics and gynecology, 128, 73-80, 2016 **Ref Id** 1174414 **Country/ies where the study was carried out** Hong Kong **Study type** Two-armed, single-blind, randomised controlled trial	**Sample size** N=276 Intervention n=139 Control n=137 **Characteristics** Women with symptomatic pelvic organ prolapse Mean Age=62.6 **Inclusion criteria** Dominant symptoms of prolapse, stage I tolII POP (POP-Q), no previous treatment received **Exclusion criteria** Active complications arising from the prolapse, impaired	**Interventions** A. Ring Pessary + pelvic floor muscle training B. Pelvic floor muscle training	**Details** All eligible women completed the Pelvic Floor Distress Inventory and the Pelvic Floor Impact Questionnaire before the first consultation. A visual analog scale (VAS) score was asked to describe the bothersome of their prolapse symptoms and their preferred treatment before the consultation. A standardized pelvic floor exercise training course was offered to all women by registered nurse specialists who	**Results** PFDI and PFIQ subscales (median/IQR) POPDI 6 months A.40.7(11.3-100) B.54.8(22.6-103.6) 12 months A.32.1(12.5-78.6) B.49.4(21.4-95.2) UDI 6 months A. 42.8 (21.0–81.3) B. 41.0 (19.8–80.7) 12 months A.39.4 (16.9–74.7) B. 37.5 (16.7–67.5) CRADI 6 months A.42.3 (12.1–86.9) B. 40.6 (15.5–83.0) 12 months A.32.1 (15.8–75.5) B.32.1 (14.9–68.0) POPIQ 6 months A.5.6 (0–42.4) B. 8.3 (0–76.5) 12 months A 0.3 (0–22.2) B 8.9(0-64.9) UIQ	**Limitations** Limitations were assessed using the revised Cochrane risk of bias tool for randomised trials (RPB2). **Domain 1 - randomisation: Low risk** 1.1: Yes 1.2: Probably Yes 1.3: No **Domain 2a - Deviations from intended interventions (effect of assignment to intervention): High risk** 2.1: Yes 2.2: Yes 2.3: Probably No 2.6: No Information 2.7: No Information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
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**	mobility, cognitive impairment, or language barrier		were trained as continence advisors. At the 6-month follow-up, both groups repeated the Pelvic Floor Distress Inventory, Pelvic Floor Impact Questionnaire, and VAS before the consultation	6 months A.15.3 (1.6–48.6) .33 B. 11.1 (0–56.9) 12 months A.13.3 (0–40.3) B. 9.7 (0–54.8) CRAIQ 6months A.0 (0–5.6) B 0(0-8.5) 12 months A. 0 (0–5.6) B.0(0-5.6) Adverse Events: Abnormal vaginal bleeding A 9/132 B 4/128 Significant vaginal discharge A 6/132B 2/128 SUI A 24/50 B 13/58 UUI A 17/73 B 19/84 VD A 10/92 B 8/97 Improvement in SUI A 19/82 B 15/70 Improvement in UUI A 17/59 B 18/44 Improvement in VDA 25/40 B 11/31	**Domain 2b - Deviations from intended interventions (effect of adhering to intervention): High risk** 2.1: Yes 2.2: Probably Yes 2.3: Not Applicable 2.4: Probably No 2.5: Probably Yes 2.6: No Information **Domain 3 - Missing outcome data: Low risk** 3.1: Probably Yes **Domain 4 - Measurement of the outcome:** 4.1: Probably No 4.2: Probably No 4.3: Yes 4.4: No **Domain 5 - Selection of the reported result: Low risk** 5.1: Probably Yes 5.2: No 5.3: No

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Domain 6 - Overall judgement: High risk of bias
Full citation Cornu, J. N., Mouly, S., Amarenco, G., Jacquetin, B., Ciofu, C., Haab, F., N. C. Study Group, 75NC007 device for noninvasive stress urinary incontinence management in women: a randomized controlled trial, International urogynecology journal, 23, 1727-34, 2012 **Ref Id** 1174432 **Country/ies where the study was carried out** France **Study type** Multicenter randomized controlledtrial	**Sample size** N=68 Intervention n=29 Control n=27 **Characteristics** Women with urinary incontinence Mean Age=60.6 **Inclusion criteria** Age 18 or more SUI assessed by clinical examination (stress test) with more than 8 incontinence episodes on 2-week bladder diary (at least 4/week) Mixed urinary incontinence with predominant SUI component Postmenopausal or under contraception **Exclusion criteria** Vaginal delivery in the past 2 months	**Interventions** A.75NC007(locates beneath the urethra (cylindrical and proximal part) and bladder (ring shaped and distal part) B. No Treatment	**Details** 14-day washout period completed initially where episodes of urine leakage were recorded in a bladder diary and a 24-h pad test was performed. After a washout period (P1), patients were enrolled and randomly assigned to either the treatment or the control arm for 14 days (P2). Efficacy was assessed in the two parallel groups at the end of P2. Then all patients were treated with the device for another 14-day period (P3). Tolerance and acceptability of the device were estimated at the end of P3.	**Results** **Intent to Treat (mean[SD])** Incontinence Episode Frequency variation (%) A -31.7 (65.1) B -7.6(24.5) Variation of SUI subscore of USP (%) A -2.4 (2.5) B -0.2(2.3) Variation of OAB subscore of USP (%) A -1.46 (2.38) B +0.21 (1.82) Variation of dysuria subscore of USP (%) A -0.2 (0.8) B +0.3 (0.8) Pad test relative variation A +8.4 (116) B +41.3 (166) Patient satisfaction (VAS 0-100) A 59.9 (39.4) B 5 (18) **Per-Protocol** Incontinence Episode Frequency variation (%) A -68.8 (22) B -8.25(25.4) Variation of SUI subscore of USP (%) A -3 (2.3) B -0.21(2.3) Variation of OAB subscore of USP (%) A -1.5 (2.4) B –0.2 (1.8) Variation of dysuria subscore of USP (%) A -0.29 (0.81) B -0.12 (0.78) Pad test relative variation A -12.8 (128) B +41.3(166) Patient satisfaction (VAS 0-100) A 78 (27) B 5(18)	**Limitations** Limitations were assessed using the revised Cochrane risk of bias tool for randomised trials (RPB2). **Domain 1 - randomisation: High risk** 1.1: Yes 1.2: No Information 1.3: Yes **Domain 2a - Deviations from intended interventions (effect of assignment to intervention): Some concerns** 2.1: Yes 2.2: Yes 2.3: No 2.6: Yes **Domain 2b - Deviations from intended interventions**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study Evaluate the efficacy of a new intravaginal device for the management stress urinary incontinence **Study dates** December 2011 to November 2014 **Source of funding** B.BRAUN Medical SAS	Bladder or vaginal active disease Acute or recurrent urinary infection (negative dipstick urine analysis) POP ≥stage II Surgical intervention for SUI in the past 6 months Drug treatment for urinary incontinence in the last month Currently having supervised pelvic floor muscle training		The patients were asked to maintain their usual physical activity during the study, and the device had to be worn at least 6 h a day, with a maximum of 24 h, then changed on a daily basis	CONTILIFE quality of life questionnaire total score: A -12.7 (22.6) B -2.4 (11.3)	**(effect of adhering to intervention): High risk** 2.1: Yes 2.2: Yes 2.3: Not Applicable 2.4: Probably No 2.5: Probably Yes 2.6: No Information **Domain 3 - Missing outcome data: Low risk** 3.1: No 3.2: No 3.3: Probably No **Domain 4 - Measurement of the outcome: Low risk** 4.1: No 4.2: Probably No 4.3: No Information 4.4: No **Domain 5 - Selection of the reported result: Low risk** 5.1: Probably Yes 5.2: Probably No 5.3: Probably No

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Domain 6 - Overall judgement: High risk of bias
Full citation Glavind, K., Use of a vaginal sponge during aerobic exercises in patients with stress urinary incontinence, International Urogynecology Journal, 8, 351-3, 1997 **Ref Id** 1147277 **Country/ies where the study was carried out** Denmark **Study type** Randomised controlled crossover trial **Aim of the study** Evaluate the efficacy of a new intravaginal device for the management stress urinary incontinence	**Sample size** N=6 Intervention n=6 Control n=6 **Characteristics** Women with stress urinary incontinence (completing 30 mins of aerobic exercise) **Inclusion criteria** Positive 1 hour pad test (>2g) Bladder volume of three-quarters of the cystometric capacity. **Exclusion criteria** Previous incontinence surgery	**Interventions** A. With vaginal sponge B. Without vaginal sponge	**Details** Half an hour before the aerobic exercise patients emptied their bladders and drank 4 dl of water. The vaginal sponge was soaked in water and then inserted. On 2 consecutive days the patients performed half an hour of aerobic exercises with and without the vaginal sponge. The exercises were performed as a group activity. The patients were randomised on day 1 with sealed envelopes to plus/minus or minus/plus the vaginal sponge. The aerobic exercises were performed identically on days 1 and 2. A	**Results** Pad weight (grams lost) from each patient A. 5,5,18,7,4,2 B. 0,0,0,1,1,0	**Limitations** Limitations were assessed using the revised Cochrane risk of bias tool for randomised trials (RPB2). **Domain 1 - randomisation: Low risk** 1.1: No Information 1.2: Yes 1.3: No **Domain 2a - Deviations from intended interventions (effect of assignment to intervention): Some concerns** 2.1: Yes 2.2: Probably Yes 2.3: No Information 2.6: No Information 2.7: No **Domain 2b - Deviations from intended interventions (effect of adhering**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates Not reported **Source of funding** Not reported			pad was worn and weighed before and after the exercises. A questionnaire was filled out after the exercises each day.		**to intervention): Low risk** 2.1: Yes 2.2: Probably Yes 2.3: Not Applicable 2.4: Not Applicable 2.6: Not Applicable **Domain 3 - Missing outcome data: Low risk** 3.1: Yes **Domain 4 - Measurement of the outcome: Low risk** 4.1: No 4.2: No 4.3: Probably Yes 4.4: Probably No 4.5: Probably No **Domain 5 - Selection of the reported result: Some concerns** 5.1: No Information 5.2: No 5.3: No **Domain 6 - Overall judgement: Some concerns**
Full citation	**Sample size** N = 446	**Interventions** A. Pessary (n =149).	**Details**	**Results**	**Other information:**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Kenton, K., Barber, M., Wang, L., Hsu, Y., Rahn, D., Whitcomb, E., Amundsen, C., Bradley, C. S., Zyczynski, H., Richter, H. E., Pelvic Floor Disorders, Network, Pelvic floor symptoms improve similarly after pessary and behavioral treatment for stress incontinence, Female Pelvic Medicine & Reconstructive Surgery, 18, 118-21, 2012 **Ref Id** 541486 **Country/ies where the study was carried out** USA **Study type** Secondary analysis of a multicentre, 3-arm randomised controlled trial, parallel design	**Characteristics** Women with symptoms of stress urinary incontinence Mean Age= 49 **Inclusion criteria** **Exclusion criteria**	B. Behavioural therapy [pelvic floor muscle training] (n=146) C. Pessary and Behavioural therapy (n=150)	Secondary analysis of a multicenter, randomised trial (ATLAS) that assigned 446 women with symptoms of SUI to continence pessary, behavioral therapy (pelvic floor muscle training and continence strategies), or combination therapy	Change in Symptom Frequency, Bother, and Impact 3 Months After Starting Pessary or Behavioural Therapy or Combined Therapy UDI A -33.9 (38.5) B -30.7 (33.4) C -35.2 (42) UDI stress A -19.9 (23.6) B -18.2 (20.5) C -19.0 (23.6) UDI obstructive A -5.4 (12.3) B -5.1 (10.2) C -7.0 (12.9) UDI irritative A -8.6 (13.4) B -7.3 (12.2) C -9.9 (15.7) POPDI A -13.5 (30.1) B -14.7 (34.1) C -18.9 (32.0) CRADI A -16.4 (39.2) B -15.4 (41.0) C -19.1 (41.5) UIQ A -31.4 (50.0) B -32.1 (38.4) C -36.0 (45) POPIQ A -7.2 (42.5) B -5.25 (28.99) C -9.6 (37.8) CRAIQ A -12.9 (37.8) B -10.7 (28.7) C -16.1 (40.4) QUID stress A -4.2 (6.2) B -4.0 (3.6) C -4.4 (3.4) QUID urge A -2.0 (5.4) B -2.3 (2.8) C -2.5 (2.7) Change in Symptom Frequency, Bother, and Impact 1 Year After Starting Pessary or Behavioural Therapy (mean[sd]) UDI A -34.0(50.2); B -37.7(46.1) UDI stress A -24.4(25.7) ;B -21.3(20.6) UDI Obstructive A -4.7(14.4) ;B -5.9(9.4) UDI irritative A -7.9(14.7);B -8.9(13)	secondary analysis of Richer 2010

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study Determine whether use of pessary or behavioral therapy for treatment of SUI results in overall improvements in bother and HRQOL from global urinary, prolapse, and colorectal symptoms. Secondary analysis of Richter 2010 **Study dates** Not reported **Source of funding** Not reported				POPDI A -16(42.1) ;B -15.6(32.2) CRADI A-18.9(41.2) ; B-15.6(37.7) UQI A -34.0(50.2) ; B -37.6(46.1) POPIQ A -5.2(42.1) ; B -5.9(22.3) CRAIQ A -7.40(38.6) ;B -8.4(37.0) QUID stress A-3.5(5.4) ;B -4.0(3.7) QUID urge A-1.3(4.7) ; B-2.3(2.9)	
Full citation Lovatsis, D., Best, C., Diamond, P., Short-term Uresta efficacy (SURE) study: a randomized controlled trial of the Uresta continence device, International urogynecology	**Sample size** N=36 Intervention n=18 Control n=18 **Characteristics** Women with urodynamically proven SUI that subjectively described as having SUI	**Interventions** A. Uresta device B. Vaginal silastic ring.	**Details** Before placing any device, a baseline pad test was performed. The bladder was filled in a retrograde fashion with 300 mL of sterile saline, with each	**Results** 50% reduction in pad weight (N/Total) A 12/18 ; B 4/18	**Limitations** Limitations were assessed using the revised Cochrane risk of bias tool for randomised trials (RPB2). **Domain 1 - randomisation: High risk** 1.1: Yes

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
journal, 28, 147-150, 2017 **Ref Id** 1174582 **Country/ies where the study was carried out** Canada **Study type** Multicentre, 3-arm randomised controlled trial, parallel design **Aim of the study** Determine whether the Uresta device provides the necessary urethral support to stop urine leakage from SUI **Study dates** February 2011 and March 2013. **Source of funding** Not reported	that had a moderate to severe impact on lifestyle, such that they would consider surgical treatment Mean Age=51 **Inclusion criteria** Urodynamic diagnosis of stress urinary incontinence **Exclusion criteria** Urodynamic diagnosis of mixed incontinence Bladder capacity less than 300mls Post-void residual over 100mls Pelvic organ prolapse greater than POP-Q stage 2 Haematuria Undiagnosed vaginal bleeding Current pregnancy Previous incontinence or prolapse surgery Failed use of an incontinence pessary Physically unable to perform the activities included in the pad test		participant then completing five repetitions of the following physical activities: coughing, step climbing, heel bounce, standing from a sitting position, and walking 50 yards. A drape was used to conceal from the patient whether the Uresta device or silastic ring had been placed in the vagina. The identical pad test protocol was conducted, and the difference in pad weight before and after device placement was calculated.		1.2: Probably No 1.3: No **Domain 2a - Deviations from intended interventions (effect of assignment to intervention):Low risk** 2.1: No 2.2: Yes 2.3: No Information 2.6: Yes **Domain 2b - Deviations from intended interventions (effect of adhering to intervention):Low risk** 2.1: Yes 2.2: Yes 2.3: Not Applicable 2.4: No 2.5: Not Applicable **Domain 3 - Missing outcome data: Low risk** 3.1: Yes 3.2: Yes 3.3: Not Applicable

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Domain 4 - Measurement of the outcome: Low risk 4.1: No 4.2: Probably No 4.3: Yes 4.4: No 4.5: Probably No **Domain 5 - Selection of the reported result: Low risk** 5.1: Yes 5.2: No 5.3: Probably No **Domain 6 - Overall judgement: High risk of bias**
Full citation Medina Lucena, H., Williams, K., Tincello, D. G., Lipp, A., Shaw, C., Evaluation of the IncoStress device for urinary incontinence: a feasibility study and pilot randomised controlled trial, International Urogynecology Journal, 30, 1365-1369, 2019	**Sample size** N=80 Intervention n=51 Control n=29 **Characteristics** Women with symptoms of urge, stress or mixed incontinence median age= 45 **Inclusion criteria**	**Interventions** A. Inco-stress intravaginal device + Pelvic floor muscle training B. Pelvic floor muscle training alone	**Details** The treatment period was for 6 months and assessments were carried out at baseline (prior to randomisation), 3 and 6 months post-randomization.	**Results** IQOL at 3 or 6 months: median (IQR) A 68.2 (5-98) B 53.0(0-94) ICIQFLUTS at 3 or 6 months A 12.5 (3-26) B 14 (6-38)	**Limitations** Limitations were assessed using the revised Cochrane risk of bias tool for randomised trials (RPB2). **Domain 1 - randomisation: Some concerns** 1.1: Yes 1.2: Yes 1.3: Probably Yes

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Ref Id 1149776 **Country/ies where the study was carried out** UK **Study type** Multicentre randomised feasibility RCT **Aim of the study** Examine the use of the IncoStress, assess recruitment and retention as well as acceptability of the device to patients, and use of potential outcome measures. **Study dates** Not reported **Source of funding** University of South Wales	Women over the age of 18 Women with symptoms of urge, stress or mixed incontinence attending the Continence Service or the Women's Health Physiotherapy Service **Exclusion criteria** Current medical history of microscopic/macroscopic haematuria Recurrent or persistent urinary tract infection (UTI) (two or more UTI's treated in the preceding 6 months) Identified pelvic mass Moderate or severe prolapse (stages 3 and 4) Palpable bladder Bladder or urethral pain Possible neurological problem Possible urogenital fistula Previous radiotherapy or surgery for pelvic cancer Symptoms of voiding difficulty Pregnancy or intention to get pregnant during the study period				**Domain 2a - Deviations from intended interventions (effect of assignment to intervention):** 2.1: Yes 2.2: Yes 2.3: No Information 2.6: No 2.7: No Information **Domain 2b - Deviations from intended interventions (effect of adhering to intervention): High risk** 2.1: Yes 2.2: Yes 2.3: Not Applicable 2.4: No Information 2.5: No Information 2.6: No Information **Domain 3 - Missing outcome data: High risk** 3.1: No 3.2: No 3.3: No Information 3.4: Probably Yes **Domain 4 - Measurement of**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Inability to use the device due to either physical or mental impairment, including severe atrophic vaginitis or complete lack of pelvic tone (grade 0 on the modified Oxford Scale) Vaginal or urinary infection (these women will be eligible once the infection has been treated) Known allergy or sensitivity to silicone				**the outcome: High risk** 4.1: No 4.2: Probably No 4.3: No Information 4.4: No **Domain 5 - Selection of the reported result: Some concerns** 5.1: No Information 5.2: No Information 5.3: No Information **Domain 6 - Overall judgement: High risk of bias**
Full citation Nygaard, I., Prevention of exercise incontinence with mechanical devices, Journal of Reproductive MedicineJ Reprod Med, 40, 89-94, 1995 **Ref Id** 1147393 **Country/ies where the study was carried out**	**Sample size** N =18 **Characteristics** Women with exercise induced stress incontinence mean age=50.5 **Inclusion criteria** History of incontinence during exercise, physical ability to participate in a 40-	**Interventions** Hodge pessary with support n=18 Tampax super tampon n=18 No mechanical device n=18	**Details** One hour before each session, participants voided and then drank 240ml of a non caffeinated beverage. The allocated vaginal device was placed by the investigator 1-20ml minutes before beginning the exercise session. Women were blind to which device was	**Results** Urine loss g: mean (SD) women incontinent during exercise n=14 A 36.4 (67.1) B 31.0 (46.2) C 45.3 (45.7)	**Limitations** Limitations were assessed using the revised Cochrane risk of bias tool for randomised trials (RPB2). **Domain 1 – randomisation: Low risk** 1.1: Yes 1.2: Yes 1.3: No **Domain 2a - Deviations from intended**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
USA **Study type** Randomised crossover trial **Aim of the study** Continence during exercise **Study dates** Not reported **Source of funding** Not reported	minute aerobic exercise session, demonstrable immediate urine loss after coughing **Exclusion criteria** Prolapse of the uterus or vagina through the introitus, failure to demonstrate visible incontinence, a stenotic vagina precluding pessary placement, pelvic mass, unwillingness to participate in group exercise with other incontinent women.		inserted. If the women were allocated to wearing no mechanical device, a ring diaphragm was inserted into the vagina and immediately removed.		**interventions (effect of assignment to intervention): Some concerns** 2.1: No 2.2: No 2.6: No Information 2.7: No **Domain 2b - Deviations from intended interventions (effect of adhering to intervention): Low risk** 2.1: No 2.2: No 2.3: No 2.4: No 2.5: No **Domain 3 - Missing outcome data: Low risk** 3.1: Yes **Domain 4 - Measurement of the outcome: Low risk** 4.1: No 4.2: No 4.3: No

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Domain 5 - Selection of the reported result: Some concerns 5.1: No Information 5.2: Probably No 5.3: Probably No **Domain 6 - Overall judgement: Some concerns**
Full citation Okayama H, Ninomiya S, Naito K, Endo Y, Morikawa S. Effects of wearing supportive underwear versus pelvic floor muscle training or no treatment in women with symptoms of stress urinary incontinence: an assessor-blinded randomized control trial. International Urogynecology Journal. 2019;30(7): 1093–1099 **Ref Id** 1174546	**Sample size** N=150 Intervention n=50 Pelvic floor muscle training n=50 Control n=50 **Characteristics** Women with stress urinary incontinence Median age =44 **Inclusion criteria** Presence of SUI symptoms at least once per week **Exclusion criteria** Current pregnancy, delivery within 3 months, previous and/or	**Interventions** A Shaper underwear B Pelvic floor muscle training C No Treatment	**Details** Participants in the shaper group were instructed to wear the shaper from waking up to bedtime during the 12-week intervention period and not to wear other supportive underwear and/or tights when wearing the shaper. Two shapers were sent to each participant in the shaper group. The participants in the PELVIC FLOOR MUSCLE TRAINING group were instructed to	**Results** UI episodes/week: median (IQR) 6th week A.1.0 (0.0-4.0) B 1.0(0.0-3.5) C 2.0(1.0-5.0) 12th week A 0.5(0.0-2.3) B 0.0(0.0-2.0) C 1.5(1.0-3.0) Improvement: A 22/30 B 23/31 C 7/28 Cure: A 15/30 B 17/31 C 5/28 ICIQ-SF score 6th week A 5.0(1.0-8.0) B 6.0(1.0-9.0) C 6.0(4.0-9.0) 12th week A 5.5(4.0-8.3) B 5.0(1.0-7.0) C 6.0(4.3-10.0)	**Limitations** Limitations were assessed using the revised Cochrane risk of bias tool for randomised trials (RPB2). **Domain 1 - randomisation: High risk** 1.1: Yes 1.2: Probably No 1.3: No **Domain 2a - Deviations from intended interventions (effect of assignment to intervention): Some concerns** 2.1: Yes 2.2: Yes 2.3: Probably No

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Country/ies where the study was carried out Japan **Study type** Assessor-blinded 3-arm randomized control trial **Aim of the study** To determine the effects of wearing shaper underwear compared with pelvic floor muscle training at home using a CD with music, or no treatment **Study dates** February to May 2012 **Source of funding** Research grants from the Research Institute of Science and Technology for Society	current treatments for UI, and waist size out of the specified range (waist measurement approximately 58–82 cm) for wearing the shaper.		perform the PELVIC FLOOR MUSCLE TRAINING according to a training CD with music, 3min exercise before going out at home twice per day during the 12-week intervention period. No intervention was administered to the no treatment group during the 12-week intervention period.		2.6: Yes **Domain 2b - Deviations from intended interventions (effect of adhering to intervention): Low risk** 2.1: Yes 2.2: Yes 2.3: Not Applicable 2.4: No 2.5: Not Applicable **Domain 3 - Missing outcome data: Low risk** 3.1: No 3.2: No 3.3: Probably No 3.4: Probably No **Domain 4 - Measurement of the outcome: Some concerns** 4.1: No 4.2: Probably No 4.3: Yes 4.4: Yes 4.5: Probably No **Domain 5 - Selection of the**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					reported result: Some concerns 5.1: No 5.2: No 5.3: No **Domain 6 - Overall judgement: High risk of bias**
Full citation 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, 8, 8, 2016 **Ref Id** 541602	**Sample size** N = 162 Intervention n=82 Control n=80 **Characteristics** Women with symptomatic pelvic organ prolapse Mean age=65.3 **Inclusion criteria** Women (55 y) with symptomatic pelvic organ prolapse-POP 2, 3 **Exclusion criteria** Prolapse treatment in the previous year Women currently undergoing treatment for another urogynecological disorder	**Interventions** A Pelvic floor muscle training B pessary	**Details** Pessaries were fitted by a trained research physician. 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. If a pessary was not fitted successfully after three attempts, pessary fitting was regarded as unsuccessful (pessary fitting reviewed every 2 weeks) pelvic floor muscle training - referred to a	**Results** PDFI mean(SD) 3 month: A 55.8(37.4); B 50.1(30.6) 12 month: A 60.2(40.9; B 50.6(35.9) 24 month: A 62.6(43.8); B 50.5(34.7) POPDI 3 month: A 16.9(13); B 13.2(12.5) 12 month: A 15.6(13.6); B 12.8(12.8) 24 month: A 17.1(15.9); B 12.9(13.1) CRADI 3 month: A 16.(16.4); B 12.4(10.5) 12 month: A 17.7(15.5); B 14.2(12.3) 24 month: A 18.1(16.0); B 13.6(13.4) UDI 3 month: A 23.3(16.6); B 23.7(16.3) 12 month: A 25.0(18.5); B 22.3(17.9) 24 month: A 26.6(20.6); B 24.4(16.0)	**Limitations** Limitations were assessed using the revised Cochrane risk of bias tool for randomised trials (RPB2). **Domain 1 - randomisation: Low risk** 1.1: Yes 1.2: Yes 1.3: No **Domain 2a - Deviations from intended interventions (effect of assignment to intervention): Low risk** 2.1: Yes 2.2: Yes 2.3: Probably No 2.6: Yes

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Country/ies where the study was carried out Netherlands **Study type** Multicentre randomised control trial **Aim of the study** To compare the effectiveness, defined as improvement of pelvic floor symptoms, and the 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 pelvic organ prolapse at or beyond the hymen **Study dates** **October** 14, 2009 and December 15, 2012	Pelvic organ malignancy, Impaired mobility, severe or terminal illness or cognitive impairment Insufficient Dutch language comprehension		pelvic physiotherapist and their treatment started with an explanation of the function of the pelvic floor women initially this. They received feedback during digital palpation or, if necessary, by applying myofeedback or electrical stimulation. As soon as they were able to control their pelvic floor they started the training by doing exercises during face-to-face contact and at home (3-5 times a wk, 2 or 3 times each d).	PFIQ 3 month: A 15.3(20.1); B 13.1(26.1) 12 month: A 15.8(26.); B 19.1(36.9) 24 month: A 19.0(28.5); B 16.0(28.7) PISQ 3 month: A 37.7(4.7); B 37.7(4.5) 12 month: A 37.6(4.2); B 35.3(5.9) 24 month: A 36.7(4.5); B 35.7(50.1) PCS 3 month: A 46.4(10.0); B 46.7(9.5) 12 month: A 46.0(10.4); B 47.2(8.8) 24 month: A 44.9(10.4); B 47.2(8.6) MCS 3 month: A 52.3(8.7); B 52.1(10.4) 12 month: A 53.5(8.3) ;B 51.6(10.3) 24 month: A 53.9(7.9); B 52.2 (9.4)	**Domain 2b - Deviations from intended interventions (effect of adhering to intervention): High risk** 2.1: Yes 2.2: Yes 2.3: No 2.4: Probably Yes 2.5: Probably Yes 2.6: No **Domain 3 - Missing outcome data: High risk** 3.1: Probably No 3.2: No 3.3: Probably Yes 3.4: Yes **Domain 4 - Measurement of the outcome: Low risk** 4.1: No 4.2: Probably No 4.3: No **Domain 5 - Selection of the reported result: Low risk** 5.1: Probably Yes 5.2: No 5.3: No

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding The Netherlands Organisation for Health Research and Development					**Domain 6 - Overall judgement: High risk of bias**
Full citation Richter, H. E., Burgio, K. L., Brubaker, L., Nygaard, I. E., Ye, W., Weidner, A., Bradley, C. S., Handa, V. L., Borello-France, D., Goode, P. S., Zyczynski, H., Lukacz, E. S., Schaffer, J., Barber, M., Meikle, S., Spino, C., Pelvic Floor Disorders, Network, Continence pessary compared with behavioral therapy or combined therapy for stress incontinence: a randomized controlled trial, Obstetrics & GynecologyObstet Gynecol, 115, 609-17, 2010 **Ref Id** 1174708	**Sample size** N=446 **Characteristics** Women with symptoms of stress only or stress-predominant mixed-incontinence symptoms were enrolled. Mean age=49.8 **Inclusion criteria** At least 18 years old with symptoms of stress only or stress-predominant mixed-incontinence symptoms. **Exclusion criteria**	**Interventions** A. Continence pessary alone group (n = 149). B. Behavioural therapy (pelvic floor muscle training + continence strategies) (n = 146). C. Continence pessary + behavioural therapy (combined) (n = 150)	**Details**	**Results** 1. PGI-I, success defined as the proportion of participants with a response of 'much better' or 'very much better': N/ Total 3 months: A: 59/149; B: 72/146; C: 80/150 12 months: A: 47/149; B: 48/146; C: 49/150 2. Condition-specific quality of life using UDI - Success defined as the proportionof participants with absence of bothersome stress incontinence symptoms (indicated by an answer of 'no' to all 6 items on the sub-scale or a response of 'yes' but with a bother of 'not at all' or 'somewhat' 3 months: A: 49/149; B:71/146; C 66/150 12 months: A: 52/149; B: 59/146; C: 49/150 3. 75% or more reduction in frequency of incontinence episodes 3 months: A: 69/149; B: 68/146; C: 80/150 12 months: A: 51/149; B: 54/146; C: 52/150 4. Patient satisfaction with treatment: this was assessed	**Limitations** Limitations were assessed using the revised Cochrane risk of bias tool for randomised trials (RPB2). **Domain 1 - randomisation: Low risk** 1.1: No Information 1.2: Yes 1.3: No **Domain 2a - Deviations from intended interventions (effect of assignment to intervention): Low risk** 2.1: Yes 2.2: Yes 2.3: Probably No 2.6: Yes **Domain 2b - Deviations from**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Country/ies where the study was carried out USA **Study type** Multicentre, 3-arm randomised controlled trial, parallel design **Aim of the study** To evaluate the effectiveness of a continence pessary compared with established behavioral therapy in women with stress incontinence. **Study dates** May 2005 and October 2007 **Source of funding** Not reported				using the validated Patient Satisfaction Questionnaire 3 months: 94/149; B: 110/146; C: 118/150 12 months: A: 75/149; B: 79/146; C: 81/150	**intended interventions (effect of adhering to intervention): High risk** 2.1: Yes 2.2: Yes 2.3: No Information 2.4: Probably No 2.5: Probably Yes 2.6: No Information **Domain 3 - Missing outcome data: Low risk** 3.1: Probably Yes **Domain 4 - Measurement of the outcome: Low risk** 4.1: Probably No 4.2: Probably No 4.3: No **Domain 5 - Selection of the reported result: Low risk** 5.1: Probably Yes 5.2: No 5.3: No **Domain 6 - Overall judgement: High risk of bias**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Robinson,H., Schulz,J., Flood,C., Hansen,L., A randomized controlled trial of the NEAT expandable tip continence device, International Urogynecology Journal and Pelvic Floor Dysfunction, 14, 199-203, 2003 **Ref Id** 254798 **Country/ies where the study was carried out** Canada **Study type** Randomised Control Trial **Aim of the study** First, the safety and efficacy of the NEAT device was to be assessed as an alternative conservative treatment option for stress or mixed	**Sample size** n=24 **Characteristics** Women with stress or mixed urinary incontinence Mean age 51.2 **Inclusion criteria** 1. Female age 30–75 years 2. Sound mental condition and manual dexterity 3. Experience >2 stress incontinence episodes per week 4. >2 g urine loss on baseline pad weight study 5. Willing to return for follow-up6 Willing to use minimum 3 devices per week **Exclusion criteria** Not reported	**Interventions** A. Reliance urethral insert n=11 B. NEAT Expandable TipContinence Device n=13	**Details** The efficacy of the devices was assessed by pad weight studies performed at 0 and 4 months. These involved measuring the difference in urine loss with and without the device inserted. For the study, the first pad weight was determined without a device in place. Between 250 and 350 ml of sterile saline was instilled into the bladder before the test was started. The pad was then weighed to the nearest one-tenth of a gram. The subject then performed a sequence of activities (stair climbing, vigorous coughing, running on the spot, washing her hands under water, jumping on the spot with her	**Results** Successful pad weight reduction (Success was defined as a 50% or greater reduction in urine loss): N/total A 5/8 B 6/8	**Limitations** Limitations were assessed using the revised Cochrane risk of bias tool for randomised trials (RPB2). **Domain 1 - randomisation: Some concerns** 1.1: Yes 1.2: No Information 1.3: No **Domain 2a - Deviations from intended interventions (effect of assignment to intervention): High risk** 2.1: No 2.2: No Information 2.3: No Information 2.6: No 2.7: No Information **Domain 2b - Deviations from intended interventions (effect of adhering to intervention): High risk** 2.1: No

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
urinary incontinence. Second, the comparability in safety and efficacy of the NEAT device and the Reliance Insert was to be demonstrated. Finally, the ease of use of each device was to be evaluated. **Study dates** May 1996 to January 1998 **Source of funding** Sponsored by Uromed Corporation the company producing both devices.			feet together, and jumping on the spot with her feet apart). The pad was then removed and weighed a second time. The total increase in the pad's weight was the recorded as the loss of urine in grams (subjects who exhibited <2 g urine loss were excluded). The subject then voided any remaining fluid and the same amount of sterile saline was again instilled into the bladder. The appropriate size of device was then inserted, the pad weight study repeated and the urine loss again recorded. By measuring the difference in urine loss, the study subjects served as their own controls		2.2: No Information 2.3: No Information 2.4: Probably No 2.5: No 2.6: No Information **Domain 3 - Missing outcome data: High risk** 3.1: No 3.2: Probably No 3.3: No Information 3.4: No Information **Domain 4 - Measurement of the outcome: Low risk** 4.1: No 4.2: No 4.3: No Information 4.4: No 4.5: No **Domain 5 - Selection of the reported result: Some concenrs** 5.1: No Information 5.2: No Information 5.3: No Information **Domain 6 - Overall judgement: High risk of bias**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Tam, M. S., Lee, V. Y. T., Yu, E. L. M., Wan, R. S. F., Tang, J. S. M., He, J. M. Y., Lui, L. K. Y., Chiu, K. P., Cheung, R. Y. K., Lee, K. W., The effect of time interval of vaginal ring pessary replacement for pelvic organ prolapse on complications and patient satisfaction: A randomised controlled trial, Maturitas, 128, 29-35, 2019 **Ref Id** 1174751 **Country/ies where the study was carried out** Hong Kong **Study type** Double-blinded, parallel, randomised controlled trial **Aim of the study**	**Sample size** N=60 **Characteristics** Women with stage I to IV POP Mean Age=69.4 **Inclusion criteria** Included women on PVC vaginal ring pessary for POP, women with stage I to IV POP, aged 18 years or above and women who opted for the use of vaginal pessaries as long-term treatment or while waiting for surgery. **Exclusion criteria** Complications which required discontinuation of use at the time of recruitment, women who could not attend follow-up during study period, who would not use the ring pessary for more than 6 months, who were unwilling to continue ring pessary	**Interventions** Ring Pessary 3 months n=30 Ring Pessary 6 months n=30	**Details** All eligible women were assessed by pelvic examination at first visit. The old ring pessary was removed from the vagina. A new PVC vaginal ring pessary of the same size would be inserted. All women were arranged to attend the second visit at 3 months and the final visit at 6 months. At the second visit, all women were interviewed about any symptoms or complications. Vaginal pessary would be removed, and speculum exam was performed by the investigator. In women in the 3- monthly group, the old ring pessary was discarded and changed to a new one with same	**Results** POPQ change: 6 months Aa -0.07(0.94) Ba -0.4(1.2) C 0.2(1.3) GH 0(0.42) PB 0(0.19) TVL 0.2(0.6) Ap -0.07(0.45) Bp -0.1(0.7) D 0.2(0.5) 3 months Aa 0.3(1.2) Ba 0.07(1.46) C 0(2.2) GH -0.03(0.88) PB 0(0.4) TVL 0.03(0.73) Ap -0.07(0.37) Bp -0.2(0.5) D 0.3(1.1) Change in satisfaction (Satisfaction VAS) (mean/SD) 3 months -0.4(1.3) 6 months -0.2(1.8)	**Limitations** Limitations were assessed using the revised Cochrane risk of bias tool for randomised trials (RPB2). **Domain 1 - randomisation: Low risk** 1.1: Yes 1.2: Yes 1.3: No **Domain 2a - Deviations from intended interventions (effect of assignment to intervention): Some concerns** 2.1: No 2.2: No 2.3: No 2.6: No Information 2.7: No **Domain 2b - Deviations from intended interventions (effect of adhering to intervention): Low risk** 2.1: No

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Comparing the effect of two replacement pessary intervals: 3-monthly and 6-monthly; on the complication rates and patient satisfaction **Study dates** June 2016 to November 2017 **Source of funding** Not reported	treatment, or who did not understand written Chinese or English		size. For women in the 6-monthly group, their vaginal pessary would be removed. After speculum examination, the same pessary was replaced back after cleaning of debris if necessary. Routine douching of vagina would not be performed. K–Y jelly was used as lubricants. All women were blinded to the changing of a new or old ring pessary at the second visit. A face mask was used to cover their eyes at the second visit. The investigators were blinded to the replacement interval during the first and final assessment.		2.2: No 2.4: No 2.5: No **Domain 3 - Missing outcome data: Low risk** 3.1: Yes **Domain 4 - Measurement of the outcome: Low risk** 4.1: No 4.2: Probably No 4.3: No **Domain 5 - Selection of the reported result: Low risk** 5.1: Probably Yes 5.2: Probably No 5.3: Probably No **Domain 6 - Overall judgement: Some concerns**
Full citation	**Sample size** n=94	**Interventions** A Conveen ContinenceDisposable	**Details** Block randomization	**Results** A=CCG B=CCT	**Limitations** Limitations were assessed using the revised Cochrane

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Thyssen, H., Bidmead, J., Lose, G., Moller Bek, K., Dwyer, P., Cardozo, L., A new intravaginal device for stress incontinence in women, BJU International, 88, 889-92, 2001 **Ref Id** 610652 **Country/ies where the study was carried out** Denmark, Australia, UK **Study type** Randomized, prospective, multicentre crossover study **Aim of the study** To compare the efficacy, acceptability and ease of use of the Contrelle continence tampon and Conveen Continence Guard	**Characteristics** Women with predominant symptom of SUI and no major uterovaginal prolapse Mean Age= 50.4 **Inclusion criteria** Women with predominant symptom of SUI **Exclusion criteria** no major uterovaginal prolapse	Intravaginal Device/Guard(CCG)-->Contrelle continence tampon(CCT) B Contrelle continence Tampon(CCT)-->Conveen Continence Disposable Intravaginal Device/Guard(CCG)	was used to allocate the women to use one of the two devices first. Women assessed which size of the device suited them best and were then instructed to insert the devices daily for 5 weeks. The number of pads used was registered and a questionnaire about the subjective effect and adverse events when using the device completed. The patients then crossed into the other arm of the study and repeated the process with the other device.	Number of pads used(mean) A 1.4 B 1.2 Subjective improvement in incontinence (n/%) Continent A 22(36%) B 30(48%) Improvement A 22(36%) B 10(16%) No change A 15(24%) B 10(16%) Pad test (mean/95% CI) A 20.2(12.8) B 10.8(5.4)	risk of bias tool for randomised trials (RPB2). **Domain 1 - randomisation: Low risk** 1.1: Yes 1.2: Probably Yes 1.3: Probably Yes **Domain 2a - Deviations from intended interventions (effect of assignment to intervention): High risk** 2.1: Yes 2.2: Probably Yes 2.3: No Information 2.6: No 2.7: No Information **Domain 2b - Deviations from intended interventions (effect of adhering to intervention): High risk** 2.1: Yes 2.2: Probably Yes 2.3: Not Applicable 2.4: No Information 2.5: No Information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates Not reported **Source of funding** Not reported					2.6: No Information **Domain 3 - Missing outcome data: High risk** 3.1: No 3.2: No 3.3: No Information 3.4: No Information **Domain 4 - Measurement of the outcome: Low risk** 4.1: No 4.2: Probably No 4.3: Probably Yes 4.4: Probably No 4.5: Probably No **Domain 5 - Selection of the reported result: Some concerns** 5.1: No Information 5.2: Probably No 5.3: Probably No **Domain 6 - Overall judgement: High risk of bias**
Full citation Zarski, A. C., Berking, M.,	**Sample size** N=77	**Interventions** A. Intervention group n=40 internet-based intervention 10 sessions	**Details** Intervention group:	**Results** PEQ Non intercourse penetration 10 weeks: A 1.11(0.75); B 0.74(0.64)	**Limitations** Limitations were assessed using the revised Cochrane risk of bias tool for

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Fackiner, C., Rosenau, C., Ebert, D. D., Internet-Based Guided Self-Help for Vaginal Penetration Difficulties: Results of a Randomized Controlled Pilot Trial, Journal of sexual medicine, 14, 238-254, 2017 **Ref Id** 1174804 **Country/ies where the study was carried out** Germany **Study type** Two arm randomized controlled trial **Aim of the study** To compare the acceptability and effectiveness of a newly developed internet-based guided self-help intervention for vaginismus (ie, Vaginismus-Free)	**Characteristics** Women with vaginismus Mean Age= 27.3 **Inclusion criteria** Women who were not able to have sexual intercourse in at least the past 6 months because of vaginismus > 18 years old, were in a heterosexual relationship for at least 3 months, had internet access, had sufficient reading and writing skills in German, and were willing to give their informed consent **Exclusion criteria** Individuals with current or previous post-traumatic stress disorder, current or previous psychosis or dissociative symptoms, current substance abuse or dependency, current moderate or severe depression, or bipolar disorder orcurrent treatment for vaginismus	and included modules for psycho-education(sessions 1 and 2), relaxation exercises (session 3), cognitive restructuring (session 4), body exposure (session 5), sensate focus exercises (session 6), gradual exposure using insertion exercises with fingers and dilators (sessions 7 and 8), and preparation exercises for intercourse with the partner (sessions 9 and 10) B. Waitlist control group n=37	During the training, the partner participated in the sensate focus exercises and the gradual exposure exercises in which the partner inserted, guided by the woman, at least one finger or a dilator. For the intercourse exercises, the partner (i) touched the vagina with the erect penis without insertion, (ii) inserted the erect penis without moving, and (iii) moved the erect penis inside the vagina. In addition, participants received five diary modules between sessions 2 and 7, in which they were asked to reflect on their feelings and thoughts regarding the training and their progress. Each	6 months: A 1.47(0.89); B 0.75(0.62) Non-intercourse self-insertion 10 weeks: A 1.65 (1.04); B 0.99(0.90) 6 months: A 1.83(1.10); B 0.53(0.64) Non-intercourse insertion by the partner 10 weeks: A 0.57(0.78); B 0.48(0.64) 6 months: A 1.11(0.89); B 0.53(0.64) FSQ Fear of coitus 10 weeks: A 13.78(3.80); B 14,90(4.56) 6 months: A 13.55(4.56); B 14.31(4.74) Fear of non-coital sexual activity 10 weeks: A 5.39(2.21); B 5.77(2.79) 6 months: A 5.41(1.97); B 5.62(3.06) FSFI Overall sexual functioning 10 weeks: A 21.86(6.59); B 18.62(6.64) 6 months: A 23.10(5.93); B 19.74(6.06) Desire 10 weeks: A 3.37(1.08); B 3.21(0.90) 6 months A 3.11(1.07); B 3.17(073) Arousal 10 weeks: A 4.18(1.45); B 3.58(1.75)	randomised trials (RPB2). **Domain 1 - randomisation: Low risk** 1.1: Yes 1.2: Yes 1.3: No **Domain 2a - Deviations from intended interventions (effect of assignment to intervention): Some concerns** 2.1: Yes 2.2: Yes 2.3: No Information 2.6: Yes **Domain 2b - Deviations from intended interventions (effect of adhering to intervention): High risk of bias** 2.1: Yes 2.2: Yes 2.3: Not Applicable 2.4: Not Applicable 2.5: No Information 2.6: No Information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
compared with a waitlist control condition (WCG) in a superiority RCT. **Study dates** 2012-2014 **Source of funding** None			session could be completed in approximately 30 to 45 minutes. The participants were advised to complete at least one session, but no more than two sessions, per week. The training was intended to last for 5 to 10 weeks. Waitlist control group: Participants assigned to the WCG did not have access to the intervention during the first 6 months after randomisation but were allowed to use it after 6 months.	6 months: A 4.46(1.31); B 3.84(1.39) Lubrication 10 weeks: A 4.53(1.54); B 3.55(1.75) 6 months: A 4.80(1.45); B 3.76(1.40) Orgasm 10 weeks: A 3.81(1.82); B 3.46(2.13) 6 months: A 4.57(1.28); B 3.64(1.96) Satisfaction 10 weeks: A 4.18(1.28); B 3.39(1.37) 6 months: A 4.08(1.45); B 3.77(1.39) Pain 10 weeks: A 1.79(1.89); B 1.42(1.88) 6 months: A 2.08(1.81); B 1.57(1.83) DCI Supportive dyadic coping 10 weeks: A 18.69(3.82); B 18.39(4.09) 6 months: A 18.71(4.51); B 18.90(3.83) Negative dyadic coping 10 weeks: A 6.58(2.38); B 7.29(3.24) 6 months: A 5.95(2.54); B 6.69(2.93) Delegated dyadic coping 10 weeks: A 9.94(2.64); B 10.87(2.93) 6 months: A 10.10(3.03); B 11.48(2.50) Joint dyadic coping	**Domain 3 - Missing outcome data: Low risk** 3.1: Probably No 3.2: Probably Yes **Domain 4 - Measurement of the outcome: Low risk** 4.1: No 4.2: No 4.3: Yes 4.4: Probably No **Domain 5 - Selection of the reported result: Some concern** 5.1: No Information 5.2: Probably No 5.3: Probably No **Domain 6 - Overall judgement: Some concerns**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				10 weeks: A 12.00(3.46); B 12.03(3.21) 6 months: A 11.38(3.84); B 12.48(3.10) Evaluation of dyadic coping 10 weeks: A 7.33(1.79); B 7.58(2.08) 6 months: A 7.24(2.19); B 7.83(2.32) Intercourse penetration mean(sd) 10 weeks: A 0.47(0.84); B 0.42(0.62) 6 months: A 1.08(1.21); B 0.66(0.90)	

PGI-I:Patient Global Impression of Improvement; UIQ: Urinary Impact Questionnaire; POPIQ: Prolapse Impact Questionnaire 7; CRAIQ: Colorectal and Anal Impact Questionnaire; QUID: Questionnaire for female Urinary Incontinence Diagnosis; CRADI-8:Colorectal Anal Distress Inventory-8; MCS-12: Mental Component Health Summary (SF-12); PCS-12:Physical Component Health Summary (SF-12); PFDI-20: Pelvic Floor Distress Inventory-20; PFIQ-7:Pelvic Floor Impact Questionnaire-7; PFMT:pelvic floor muscle training; PISQ-12:Pelvic Organ Prolapse/Incontinence Sexuality Questionnaire-12; POPDI-6:Pelvic Organ Prolapse Distress Inventory-6; UDI-6:Urinary/Urogenital Distress Inventory-6; VAS: Visual Analogue Scale; PFDI: Pelvic floor distress inventory; POP: Pelvic organ prolapse; UUI: Urge urinary incontinence; SUI: Stress urinary incontinence; VD: Voiding dysfunction; UI: Urinary incontinence; POPQ: Pelvic Organ Prolapse Quantifications System; ICIQ-FLUTS; International Consultation on Incontinence Questionnaire Female Lower Urinary Tract Symptoms Modules; ICIQ-SF: International Consultation on Incontinence Questionnaire Short form; IQOL: Incontinence Quality of Life questionnaire; UI: Urinary Incontinence; IEF: Incontinence episode frequency; USP: Urinary Symptom Profile; UTI; Urinary tract infection DCI: Dyadic Coping Inventory; FSFI: Female Sexual Function Index; FSQ: Fear of Sexuality Questionnaire; IG . intervention group; PEQ: Primary Endpoint Questionnaire

Appendix E – Forest plots

Forest plots for review question: What is the effectiveness of physical devices (including support garments, pessaries and dilators) for improving symptoms of pelvic floor dysfunction?

This section includes forest plots only for outcomes that are meta-analysed. Outcomes from single studies are not presented here; the quality assessment for such outcomes is provided in the GRADE profiles in appendix F.

Figure 3: Variation in UDI Score at 3, 12 and 24 months for women using a pessary in comparison to pelvic floor muscle training alone

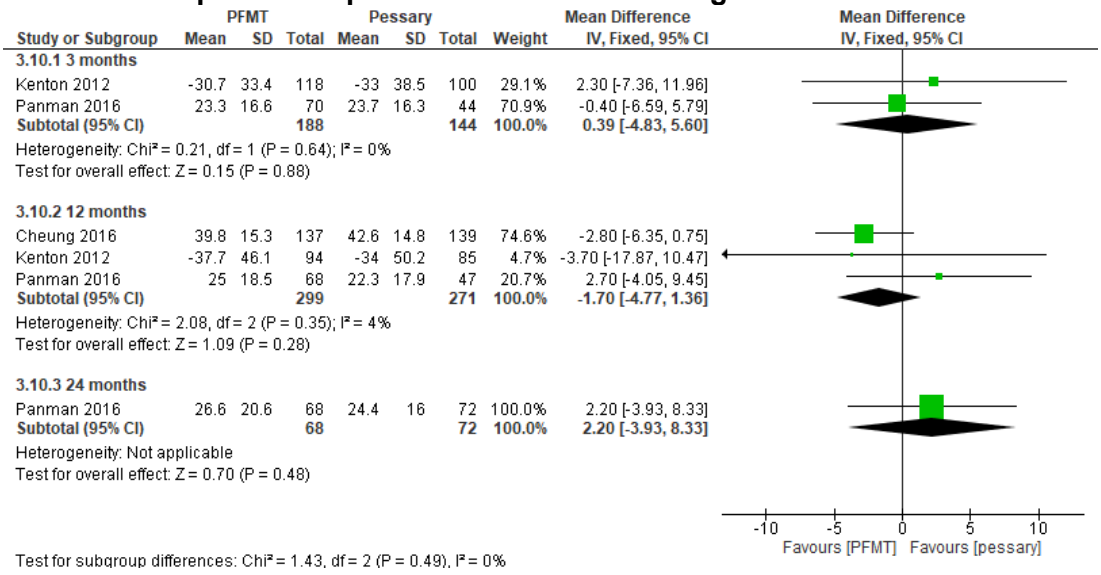


Figure 4: CRADI Score at 3, 12 and 24 months for women using a pessary in comparison to pelvic floor muscle training alone

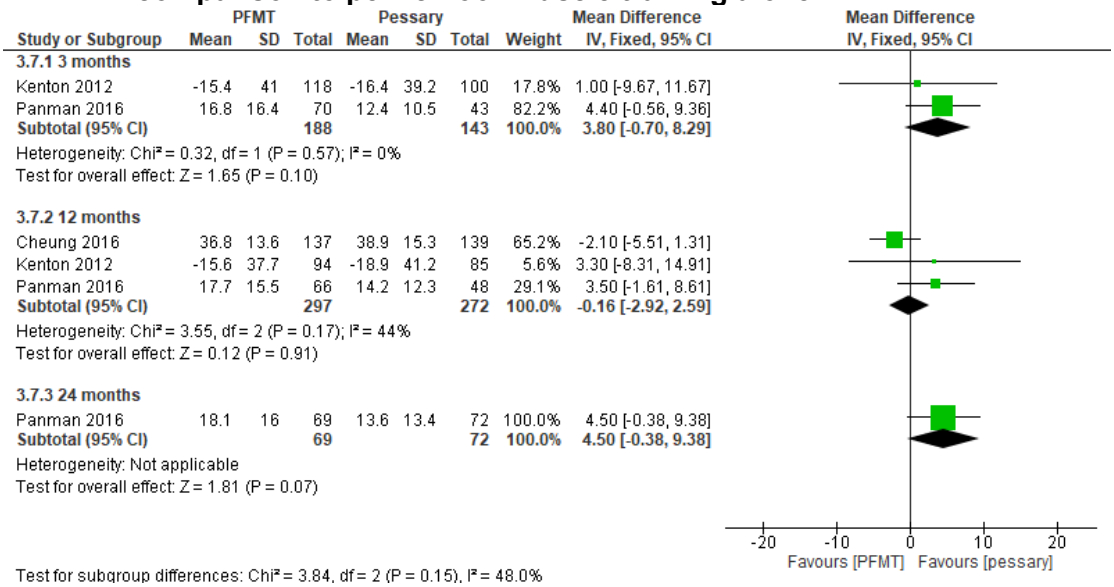
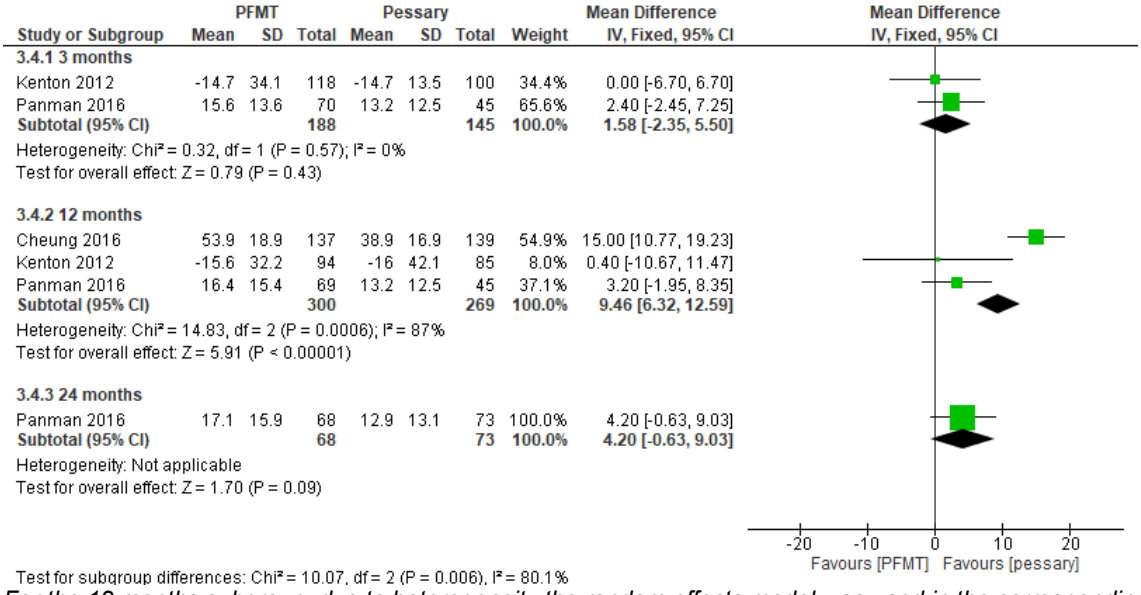
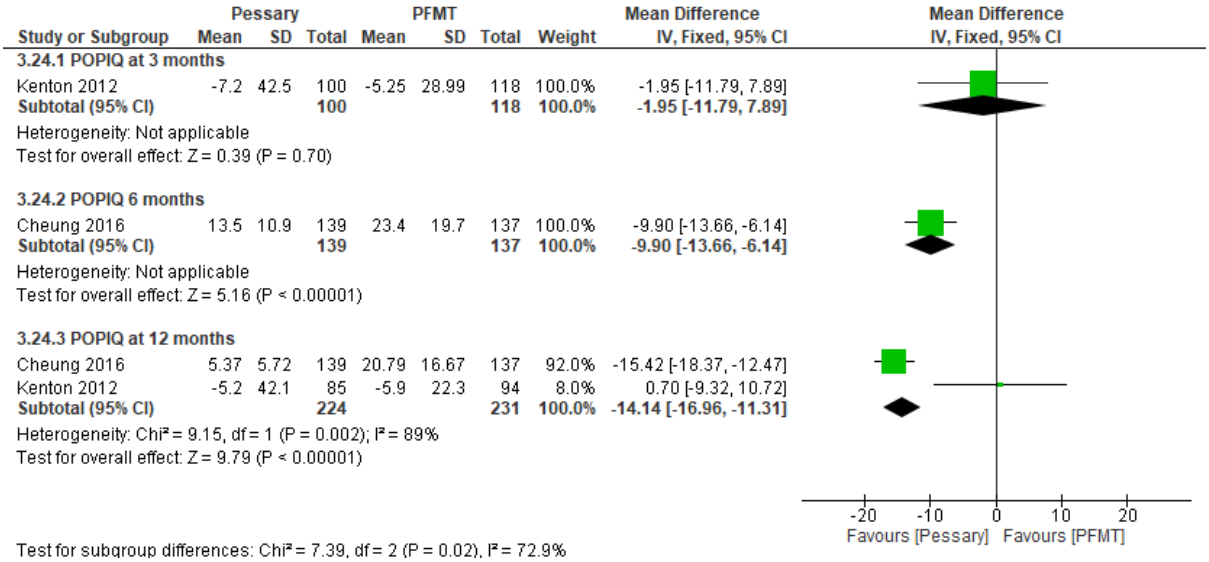


Figure 5: POPDI Score at 3, 12 and 24 months for women using a pessary in comparison to pelvic floor muscle training alone



For the 12 months subgroup, due to heterogeneity the random effects model was used in the corresponding GRADE table: MD 6.89 95% CI [-2.70 to 16.48]

Figure 6: POPIQ score at 3, 6 and 12 months for women using a pessary in comparison to pelvic floor muscle training alone.



Appendix F – GRADE tables

GRADE tables for review question: What is the effectiveness of physical devices (including support garments, pessaries and dilators) for improving symptoms of pelvic floor dysfunction?

Table 9: Clinical evidence profile for intravaginal device vs pelvic floor muscle training/no treatment

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intravaginal Device	No treatment/PFMT	Relative (95% CI)	Absolute		
Variation of SUI subscore of USP (follow-up mean 12 days; Better indicated by lower values)												
1 Cornu 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	29	26	-	MD 2.2 lower (3.47 to 0.93 lower)	VERY LOW	CRITICAL
Variation of OAB subscore of USP (follow-up mean 12 days; Better indicated by lower values)												
1 Cornu 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	29	26	-	MD 1.67 lower (2.78 to 0.56 lower)	VERY LOW	CRITICAL
Variation of dysuria subscore of USP (follow-up mean 12 days; Better indicated by lower values)												
1 Cornu 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[4]	none	29	26	-	MD 0.5 lower (0.92 to 0.08 lower)	VERY LOW	CRITICAL
Pad Test Difference (follow-up mean 12 days; 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	Intravaginal Device	No treatment/PFMT	Relative (95% CI)	Absolute		
1 Cornu 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[5]	none	29	26	-	MD 32.9 lower (109.41 lower to 43.61 higher)	VERY LOW	CRITICAL
Patient Satisfaction (follow-up mean 12 days; Better indicated by higher values)												
1 Cornu 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	29	26	-	MD 54.9 higher (38.98 to 70.82 higher)	LOW	IMPORTANT
Relative variation of IEF (follow-up mean 12 days; Better indicated by lower values)												
1 Cornu 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[6]	none	29	26	-	MD 24.1 lower (49.6 lower to 1.4 higher)	VERY LOW	CRITICAL
CONTILIFE quality of life variation (follow-up mean 12 days; Better indicated by lower values)												
1 Cornu 2012	randomised trials	serious[7]	no serious inconsistency	no serious indirectness	serious[10]	none	17	24	-	MD 10.3 lower (21.96 lower to 1.36 higher)	LOW	IMPORTANT
IQOL at 6 months (follow-up mean 6 months; Better indicated by higher values)												
1 Lucena 2019	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[8]	none	51	29	-	MD 9.8 higher (1.81 lower to 21.41 higher)	VERY LOW	IMPORTANT

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intravaginal Device	No treatment/PFMT	Relative (95% CI)	Absolute		
ICIQ-FLUTS at 6 months (follow-up mean 6 months; Better indicated by lower values)												
1 Lucena 2019	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[9]	none	51	29	-	MD 4.37 lower (7.98 to 0.76 lower)	VERY LOW	IMPORTANT

CI: confidence interval; MD: mean difference; OAB: overactive bladder; PFMT: pelvic floor muscle training; SUI: stress urinary incontinence
1 Very serious risk of bias in the evidence contributing to the outcomes as per RoB 2
2 95% CI crosses 1 MID (0.5 x SD of control; 2.3)
3 95% CI crosses 1 MID (0.5 x SD of control; 1.82)
4 95% CI crosses 1 MID (0.5 x SD of control; 0.8)
5 95% CI crosses 1 MID (0.5 x SD of control; 41.3)
6 95% CI crosses 1 MID (0.5 x SD of control; 24.5)
7 Serious risk of bias in the evidence contributing to the outcomes as per RoB 2
8 95% CI crosses 1 published MID (2.5)
9 95% CI crosses 2 MIDs (0.5 x SD of control; 8.91)
10 95% CI crosses 1 MID

Table 10: Clinical evidence profile for intravaginal device vs pessary/no treatment

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intravaginal Device	Pessary/No treatment	Relative (95% CI)	Absolute		
50% reduction in pad weight (follow-up mean 1 days)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intravaginal Device	Pessary/No treatment	Relative (95% CI)	Absolute		
1 Lovatsis 2017	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	12/18 (66.7%)	4/18 (22.2%)	RR 3 (1.19 to 7.56)	444 more per 1000 (from 42 more to 1000 more)	VERY LOW	CRITICAL
Urine loss (pad weight in g) during exercise (follow-up mean 1 days; Better indicated by lower values)												
1 Nygaard 1995	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	very serious[4]	none	14	14	-	MD 5.4 higher (37.27 lower to 48.07 higher)	VERY LOW	CRITICAL
Urine loss (pad weight in g) during exercise (follow-up mean 1 days; Better indicated by lower values)												
1 Nygaard 1995	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	serious[5]	none	14	14	-	MD 14.3 lower (48.34 lower to 19.74 higher)	LOW	CRITICAL
Urine loss (pad weight in g) during exercise (follow-up mean 1 days; Better indicated by lower values)												
1 Nygaard 1995	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	serious[5]	none	14	14	-	MD 8.9 lower (51.43 lower to 33.63 higher)	LOW	CRITICAL

CI: confidence interval; MD: mean difference; RR: relative risk
1 Very serious risk of bias in the evidence contributing to the outcomes as per RoB 2
2 95% CI crosses 1 MID (0.8, 1.25)
3 Serious risk of bias in the evidence contributing to the outcomes as per RoB 2
4 95% CI crosses 2 MIDs (0.5 x SD of control; 46.2)
5 95% CI crosses 1 MID (0.5 x SD of control; 45.7)

Table 11: Clinical evidence profile for support garment vs pelvic floor muscle training

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Support garment	PFMT	Relative (95% CI)	Absolute		
UI episodes/week - 6 weeks (follow-up 6 weeks; Better indicated by lower values)												
1 Okayama 2019	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	30	31	-	Median no difference Median (IQR): Support garment.1.0 (0.0-4.0), PFMT 1.0(0.0-3.5)	VERY LOW	CRITICAL
UI episodes/week - 12 weeks (follow-up 12 weeks; Better indicated by lower values)												
1 Okayama 2019	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	30	31	-	Median 0.5 higher Median (IQR): Support garment 0.5(0.0-2.3), PFMT 0.0(0.0-2.0)	VERY LOW	CRITICAL
ICIQ-SF score - 6 weeks (follow-up 6 weeks; Better indicated by lower values)												
1 Okayama 2019	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	30	31	-	Median 1 higher Median (IQR): Support garment 5.0(1.0-8.0), PFMT 6.0(1.0-9.0)	VERY LOW	CRITICAL
ICIQ-SF score - 12 weeks (follow-up 12 weeks; Better indicated by lower values)												
1 Okayama 2019	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	30	31	-	Median 0.5 higher Median (IQR): Support garment 5.5(4.0-8.3), PFMT 5.0(1.0-7.0)	VERY LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Support garment**	**PFMT**	**Relative (95% CI)**	**Absolute**		
UI Improvement/Cure at 12 weeks - Improvement or Cure (follow-up 12 weeks)												
1 Okayama 2019	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	22/30 (73.3%)	23/31 (74.2%)	RR 0.99 (0.73 to 1.33)	7 fewer per 1000 (from 200 fewer to 245 more)	VERY LOW	CRITICAL
UI Improvement/Cure at 12 weeks - Cure only (follow-up 12 weeks)												
1 Okayama 2019	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	15/30 (50%)	17/31 (54.8%)	RR 0.91 (0.56 to 1.47)	49 fewer per 1000 (from 241 fewer to 258 more)	VERY LOW	CRITICAL

CI: confidence interval; MD: mean difference; PFMT: pelvic floor muscle training; UI: urinary incontinence
1 Very serious risk of bias in the evidence contributing to the outcomes as per RoB 2
2 Downgraded by one as imprecision cannot be assessed
3 95% CI crosses 2 MIDs (0.8, 1.25)

Table 12: Clinical evidence profile for support garment vs no treatment

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Support garment**	**No treatment**	**Relative (95% CI)**	**Absolute**		
UI episodes/week - 6 weeks (follow-up 6 weeks; 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	Support garment	No treatment	Relative (95% CI)	Absolute		
1 Okayama 2019	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	30	28	-	Median 1 lower Median (IQR): Support garment.1.0 (0.0-4.0), No treatment 2.0(1.0-5.0)	VERY LOW	CRITICAL
UI episodes/week - 12 weeks (follow-up 12 weeks; Better indicated by lower values)												
1 Okayama 2019	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	30	28	-	Median 1 lower Median (IQR): Support garment 0.5(0.0-2.3), No treatment 1.5(1.0-3.0)	VERY LOW	CRITICAL
ICIQ-SF score - 6 weeks (follow-up 6 weeks; Better indicated by lower values)												
1 Okayama 2019	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	30	31	-	Median 1 lower Median (IQR): Support garment 5.0(1.0-8.0), No treatment 6.0(4.0-9.0)	VERY LOW	CRITICAL
ICIQ-SF score - 12 weeks (follow-up 12 weeks; Better indicated by lower values)												
1 Okayama 2019	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	30	28	-	Median 0.5 lower Median (IQR): Support garment 5.5(4.0-8.3), No treatment 6.0(4.3-10.0)	VERY LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Support garment	No treatment	Relative (95% CI)	Absolute		
UI Improvement/Cure at 12 weeks - Improvement or cure (follow-up 12 weeks)												
1 Okayama 2019	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	22/30 (73.3%)	7/28 (25%)	RR 2.93 (1.49 to 5.77)	483 more per 1000 (from 123 more to 1000 more)	LOW	CRITICAL
UI Improvement/Cure at 12 weeks - Cure only (follow-up 12 weeks)												
1 Okayama 2019	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	15/30 (50%)	5/28 (17.9%)	RR 2.8 (1.17 to 6.69)	321 more per 1000 (from 30 more to 1000 more)	VERY LOW	CRITICAL

CI: confidence interval; MD: mean difference; PFMT: pelvic floor muscle training; UI: urinary incontinence
1 Very serious risk of bias in the evidence contributing to the outcomes as per RoB 2
2 Downgraded by one as imprecision cannot be assessed
3 95% CI crosses 1 MID (0.8, 1.25)

Table 13: Clinical evidence profile for pessary vs pelvic floor muscle training

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	PFMT	Relative (95% CI)	Absolute		
PDFI score - 3 months (follow-up mean 24 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	Pessary	PFMT	Relative (95% CI)	Absolute		
1 Panman 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	69	43	-	MD 5.7 higher (7.01 lower to 18.41 higher)	VERY LOW	CRITICAL
PDFI score - 12 months (follow-up mean 24 months; Better indicated by lower values)												
1 Panman 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	66	45	-	MD 9.6 higher (4.8 lower to 24 higher)	VERY LOW	CRITICAL
PDFI score - 24 months (follow-up mean 24 months; Better indicated by lower values)												
1 Panman 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	67	71	-	MD 12.1 higher (1.13 lower to 25.33 higher)	VERY LOW	CRITICAL
No bothersome symptoms on UDIS subscale of PFDI - 3 months (follow-up mean 12 months)												
1 Richter 2010	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[6]	none	66/150 (44%)	71/149 (47.7%)	RR 0.92 (0.72 to 1.18)	38 fewer per 1000 (from 133 fewer to 86 more)	VERY LOW	CRITICAL
No bothersome symptoms onUDIS subscale of PFDI - 12 months (follow-up mean 12 months)												
1 Richter 2010	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[6]	none	49/150 (32.7%)	59/149 (39.6%)	RR 0.82 (0.61 to 1.12)	71 fewer per 1000 (from 154 fewer to 48 more)	VERY LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	PFMT	Relative (95% CI)	Absolute		
No bothersome symptoms on UDIS subscale of PFDI - 3 months (follow-up mean 12 months)												
1 Richter 2010	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[6]	none	71/149 (47.7%)	49/146 (33.6%)	RR 1.42 (1.07 to 1.89)	141 more per 1000 (from 23 more to 299 more)	VERY LOW	
No bothersome symptoms on UDIS subscale of PFDI - 12 months (follow-up mean 12 months)												
1 Richter 2010	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[6]	none	59/149 (39.6%)	52/146 (35.6%)	RR 1.11 (0.83 to 1.49)	39 more per 1000 (from 61 fewer to 175 more)	VERY LOW	CRITICAL
POPDI Score/Score Change from Baseline - 3 months (follow-up mean 18 months; Better indicated by lower values)												
2 Kenton 2012/ Panman 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	188	145	-	MD 1.58 higher (2.35 lower to 5.5 higher)	LOW	CRITICAL
POPDI Score/Score Change from Baseline - 12 months (follow-up mean 16 months; Better indicated by lower values)												
3 Cheung 2016/ Kenton 2012/ Panman 2016	randomised trials	very serious[1]	very serious[3]	no serious indirectness	serious[4]	none	300	269	-	MD 6.89 higher (2.70 lower to 16.48 higher)	VERY LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	PFMT	Relative (95% CI)	Absolute		
POPDI Score - 24 months (follow-up mean 24 months; Better indicated by lower values)												
1 Panman 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[5]	none	68	73	-	MD 4.2 higher (0.63 lower to 9.03 higher)	VERY LOW	CRITICAL
"Much better" or "very much better" on PGI-I - 3 months (follow-up mean 12 months)												
1 Richter 2010	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[6]	none	72/149 (48.3%)	59/146 (40.4%)	RR 1.2 (0.92 to 1.55)	81 more per 1000 (from 32 fewer to 222 more)	VERY LOW	CRITICAL
"Much better" or "very much better" on PGI-I - 12 months (follow-up mean 12 months)												
1 Richter 2010	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[7]	none	48/149 (32.2%)	47/146 (32.2%)	RR 1 (0.72 to 1.39)	0 fewer per 1000 (from 90 fewer to 126 more)	VERY LOW	CRITICAL
"Much better" or "very much better" on PGI-I - 3 months (follow-up mean 12 months)												
1 Richter 2010	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[6]	none	80/150 (53.3%)	59/146 (40.4%)	RR 1.32 (1.03 to 1.69)	129 more per 1000 (from 12 more to 279 more)	VERY LOW	CRITICAL
"Much better" or "very much better" on PGI-I - 12 months (follow-up mean 12 months)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	PFMT	Relative (95% CI)	Absolute		
1 Richter 2010	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[7]	none	49/150 (32.7%)	47/146 (32.2%)	RR 1.01 (0.73 to 1.41)	3 more per 1000 (from 87 fewer to 132 more)	VERY LOW	CRITICAL
CRADI score/score change from baseline - 3 months (follow-up mean 18 months; Better indicated by lower values)												
2 Kenton 2012/ Panman 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	188	143	-	MD 3.8 higher (0.7 lower to 8.29 higher)	LOW	CRITICAL
CRADI score/score change from baseline - 12 months (follow-up mean 16 months; Better indicated by lower values)												
3 Cheung 2016/ Kenton 2012/ Panman 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	297	272	-	MD 0.16 lower (2.92 lower to 2.59 higher)	LOW	CRITICAL
CRADI score - 24 months (follow-up mean 24 months; Better indicated by lower values)												
1 Panman 2016	randomised trials	very serious[3]	no serious inconsistency	no serious indirectness	serious[11]	none	69	72	-	MD 4.5 higher (0.38 lower to 9.38 higher)	VERY LOW	CRITICAL
No bothersome symptoms on UDIS subscale of PFDI - 3 months (follow-up mean 12 months)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	PFMT	Relative (95% CI)	Absolute		
1 Richter 2010	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[6]	none	66/150 (44%)	49/146 (33.6%)	RR 1.31 (0.98 to 1.75)	104 more per 1000 (from 7 fewer to 252 more)	VERY LOW	CRITICAL
No bothersome symptoms on UDIS subscale of PFDI - 12 months (follow-up mean 12 months)												
1 Richter 2010	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[7]	none	49/150 (32.7%)	52/146 (35.6%)	RR 0.92 (0.67 to 1.26)	28 fewer per 1000 (from 118 fewer to 93 more)	VERY LOW	CRITICAL
>75% reduction in weekly urinary incontinence episodes - 3 months (follow-up mean 12 months)												
1 Richter 2010	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[6]	none	80/150 (53.3%)	68/149 (45.6%)	RR 1.17 (0.93 to 1.47)	78 more per 1000 (from 32 fewer to 214 more)	VERY LOW	CRITICAL
>75% reduction in weekly urinary incontinence episodes - 12 months (follow-up mean 12 months)												
1 Richter 2010	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[7]	none	52/150 (34.7%)	54/149 (36.2%)	RR 0.96 (0.7 to 1.3)	14 fewer per 1000 (from 109 fewer to 109 more)	VERY LOW	CRITICAL
UDI score/score change from baseline - 3 months (follow-up mean 18 months; Better indicated by lower values)												
2	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	188	144	-	MD 0.39 higher (4.83 lower to 5.6 higher)	LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	PFMT	Relative (95% CI)	Absolute		
Kenton 2012/ Panman 2016												
UDI score/score change from baseline - 12 months (follow-up mean 16 months; Better indicated by lower values)												
3 Cheung 2016/ Kenton 2012/ Panman 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	299	271	-	MD 1.7 lower (4.77 lower to 1.36 higher)	LOW	CRITICAL
UDI score variation - 24 months (follow-up mean 24 months; Better indicated by lower values)												
1 Panman 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	68	72	-	MD 2.2 higher (3.93 lower to 8.33 higher)	LOW	CRITICAL
>75% reduction in weekly urinary incontinence episodes - 3 months (follow-up mean 12 months)												
1 Richter 2010	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[6]	none	68/149 (45.6%)	69/146 (47.3%)	RR 0.97 (0.76 to 1.23)	14 fewer per 1000 (from 113 fewer to 109 more)	VERY LOW	CRITICAL
>75% reduction in weekly urinary incontinence episodes - 12 months (follow-up mean 12 months)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	PFMT	Relative (95% CI)	Absolute		
1 Richter 2010	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[7]	none	54/149 (36.2%)	51/146 (34.9%)	RR 1.04 (0.76 to 1.41)	14 more per 1000 (from 84 fewer to 143 more)	VERY LOW	CRITICAL
>75% reduction in weekly urinary incontinence episodes - 3 months (follow-up mean 12 months)												
1 Richter 2010	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[6]	none	80/150 (53.3%)	69/146 (47.3%)	RR 1.13 (0.9 to 1.42)	61 more per 1000 (from 47 fewer to 198 more)	VERY LOW	CRITICAL
>75% reduction in weekly urinary incontinence episodes - 12 months (follow-up mean 12 months)												
1 Richter 2010	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[7]	none	52/150 (34.7%)	51/146 (34.9%)	RR 0.99 (0.73 to 1.36)	3 fewer per 1000 (from 94 fewer to 126 more)	VERY LOW	CRITICAL
PFIQ score - 3 months (follow-up mean 24 months; Better indicated by lower values)												
1 Panman 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	65	41	-	MD 2.2 higher (7.16 lower to 11.56 higher)	LOW	IMPORTANT
PFIQ score - 12 months (follow-up mean 24 months; Better indicated by lower values)												
1 Panman 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	66	50	-	MD 3.3 lower (15.3 lower to 8.7 higher)	LOW	IMPORTANT

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	PFMT	Relative (95% CI)	Absolute		
PFIQ score - 24 months (follow-up mean 24 months; Better indicated by lower values)												
1 Panman 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	66	67	-	MD 3 higher (6.72 lower to 12.72 higher)	LOW	IMPORTANT
Patient Satisfaction - 3 months (follow-up mean 12 months)												
1 Richter 2010	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	118/150 (78.7%)	110/149 (73.8%)	RR 1.07 (0.94 to 1.21)	52 more per 1000 (from 44 fewer to 155 more)	LOW	IMPORTANT
Patient Satisfaction - 12 months (follow-up mean 12 months)												
1 Richter 2010	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[6]	none	81/150 (54%)	79/149 (53%)	RR 1.02 (0.82 to 1.26)	11 more per 1000 (from 95 fewer to 138 more)	VERY LOW	IMPORTANT
Patient Satisfaction - 3 months												
1 Richter 2010	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[6]	none	110/149 (73.8%)	94/146 (64.4%)	RR 1.15 (0.98 to 1.34)	97 more per 1000 (from 13 fewer to 219 more)	VERY LOW	IMPORTANT
Patient Satisfaction - 12 months (follow-up mean 12 months)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	PFMT	Relative (95% CI)	Absolute		
1 Richter 2010	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[6]	none	79/149 (53%)	75/146 (51.4%)	RR 1.03 (0.83 to 1.28)	15 more per 1000 (from 87 fewer to 144 more)	VERY LOW	IMPORTANT
PISQ score - 3 months (follow-up mean 24 months; Better indicated by higher values)												
1 Panman 2016	randomised trials	very serious[3]	no serious inconsistency	no serious indirectness	no serious imprecision	none	25	19	-	MD 0 higher (2.74 lower to 2.74 higher)	LOW	IMPORTANT
PISQ score - 12 months (follow-up mean 24 months; Better indicated by higher values)												
1 Panman 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	24	24	-	MD 2.3 higher (0.6 lower to 5.2 higher)	LOW	CRITICAL
PISQ score - 24 months (follow-up mean 24 months; Better indicated by higher values)												
1 Panman 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	24	34	-	MD 1 higher (1.49 lower to 3.49 higher)	LOW	CRITICAL
Patient Satisfaction – 3 months (follow-up mean 12 months)												
1 Richter 2010	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[6]	none	118/150 (78.7%)	94/146 (64.4%)	RR 1.22 (1.06 to 1.41)	142 more per 1000 (from 39 more to 264 more)	VERY LOW	IMPORTANT

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	PFMT	Relative (95% CI)	Absolute		
Patient Satisfaction - 12 months (follow-up mean 12 months)												
1 Richter 2010	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[6]	none	87/150 (58%)	75/146 (51.4%)	RR 1.05 (0.85 to 1.3)	26 more per 1000 (from 77 fewer to 154 more)	VERY LOW	IMPORTANT
UDI score change - UDI at 3 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	100	118	-	MD 2.3 lower (11.96 lower to 7.36 higher)	LOW	CRITICAL
UDI score change - UDI stress at 3 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	100	118	-	MD 1.7 lower (7.62 lower to 4.22 higher)	LOW	CRITICAL
UDI score change - UDI Obstructive at 3 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	100	118	-	MD 0.3 lower (3.33 lower to 2.73 higher)	LOW	CRITICAL
UDI score change - UDI Irritative at 3 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	100	118	-	MD 1.3 lower (4.73 lower to 2.13 higher)	LOW	

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	PFMT	Relative (95% CI)	Absolute		
UDI score change - UDI at 12 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[12]	none	85	94	-	MD 3.7 higher (10.47 lower to 17.87 higher)	VERY LOW	CRITICAL
UDI score change - UDI Stress at 12 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[13]	none	85	94	-	MD 3.1 lower (9.97 lower to 3.77 higher)	VERY LOW	CRITICAL
UDI score change - UDI Obstructive at 12 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	85	94	-	MD 1.2 higher (4.58 lower to 6.98 higher)	LOW	CRITICAL
UDI score change - UDI irritative at 12 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	85	94	-	MD 1 higher (3.08 lower to 5.08 higher)	LOW	CRITICAL
PSC score - 3 months (follow-up mean 24 months; Better indicated by higher values)												
1 Panman 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	64	44	-	MD 0.3 lower (4.03 lower to 3.43 higher)	LOW	IMPORTANT

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	PFMT	Relative (95% CI)	Absolute		
PSC score - 12 months (follow-up mean 24 months; Better indicated by higher values)												
1 Panman 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	65	43	-	MD 1.2 lower (4.85 lower to 2.45 higher)	LOW	IMPORTANT
PSC score - 24 months (follow-up mean 24 months; Better indicated by lower values)												
1 Panman 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	60	70	-	MD 2.3 lower (5.61 lower to 1.01 higher)	LOW	IMPORTANT
POPDI change - POPDI at 3 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	100	118	-	MD 1.2 higher (7.32 lower to 9.72 higher)	LOW	CRITICAL
POPDI change - POPDI at 12 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	85	94	-	MD 0.4 lower (11.47 lower to 10.67 higher)	LOW	CRITICAL
CRADI score change - CRADI at 3 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	100	118	-	MD 1 lower (11.67 lower to 9.67 higher)	LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	PFMT	Relative (95% CI)	Absolute		
CRADI score change - CRADI at 12 months (Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	85	94	-	MD 3.3 lower (14.91 lower to 8.31 higher)	LOW	CRITICAL
MSC score - 3 months (follow-up mean 24 months; Better indicated by lower values)												
1 Panman 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	64	44	-	MD 0.2 higher (3.54 lower to 3.94 higher)	LOW	IMPORTANT
MSC score - 12 months (follow-up mean 24 months; Better indicated by lower values)												
1 Panman 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[8]	none	64	43	-	MD 0.8 higher (2.94 lower to 4.54 higher)	VERY LOW	IMPORTANT
MSC score - 24 months (follow-up mean 24 months; Better indicated by lower values)												
1 Panman 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	65	70	-	MD 1 higher (1.99 lower to 3.99 higher)	LOW	IMPORTANT
UIQ score change at 3 months - UIQ at 3 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	100	118	-	MD 0.7 higher (11.3 lower to 12.7 higher)	LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	PFMT	Relative (95% CI)	Absolute		
UIQ score change at 3 months - UIQ at 12 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	85	94	-	MD 3.7 higher (10.47 lower to 17.87 higher)	LOW	CRITICAL
POPIQ score change - POPIQ at 3 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	100	118	-	MD 1.95 lower (11.79 lower to 7.89 higher)	LOW	CRITICAL
POPIQ at 6 months (follow-up mean 12 months; Better indicated by lower values)												
1 Cheung 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	139	137	-	MD 9.9 lower (13.66 to 6.14 lower)	LOW	CRITICAL
POPIQ score/ score change - POPIQ at 12 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012 Cheung 2016	randomised trials	very serious[1]	very serious[3]	no serious indirectness	no serious imprecision	none	224	231	-	MD 14.14 lower (16.96 to 11.31 lower)	⊕OOO VERY LOW	CRITICAL
"Much better" or "very much better"on PGI-I - 3 months (follow-up mean 12 months)												
1 Richter 2010	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[6]	none	80/150 (53.3%)	72/149 (48.3%)	RR 1.1 (0.88 to 1.38)	48 more per 1000 (from 58 fewer to 184 more)	VERY LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	PFMT	Relative (95% CI)	Absolute		
"Much better" or "very much better"on PGI-I - 12 months (follow-up mean 12 months)												
1 Richter 2010	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[7]	none	49/150 (32.7%)	48/149 (32.2%)	RR 1.01 (0.73 to 1.41)	3 more per 1000 (from 87 fewer to 132 more)	VERY LOW	CRITICAL
CRAIQ score change - CRAIQ at 3 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	100	118	-	MD 2.2 lower (11.24 lower to 6.84 higher)	LOW	CRITICAL
CRAIQ score change - CRAIQ at 12 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	85	94	-	MD 1 higher (10.1 lower to 12.1 higher)	LOW	CRITICAL
QUID score change - QUID stress at 3 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	100	118	-	MD 0.2 lower (1.58 lower to 1.18 higher)	LOW	CRITICAL
QUID score change - QUID Urge at 3 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	100	118	-	MD 0.3 higher (0.87 lower to 1.47 higher)	LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	PFMT	Relative (95% CI)	Absolute		
QUID score change - QUID stress at 12 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[9]	none	85	94	-	MD 0.5 higher (0.87 lower to 1.87 higher)	VERY LOW	CRITICAL
QUID score change - QUID urge at 12 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[10]	none	85	94	-	MD 1 higher (0.16 lower to 2.16 higher)	VERY LOW	CRITICAL
UDI score change at 3 months - UDI (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	118	119	-	MD 4.5 higher (5.16 lower to 14.16 higher)	LOW	CRITICAL
UDI score change at 3 months - UDI Stress (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	118	119	-	MD 0.8 higher (4.83 lower to 6.43 higher)	LOW	CRITICAL
UDI score change at 3 months - UDI obstructive (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	118	119	-	MD 1.9 higher (1.06 lower to 4.86 higher)	LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	PFMT	Relative (95% CI)	Absolute		
UDI score change at 3 months - UDI irritative (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	118	119	-	MD 2.6 higher (0.98 lower to 6.18 higher)	LOW	CRITICAL
POPDI score change at 3 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	118	119	-	MD 4.2 higher (4.22 lower to 12.62 higher)	LOW	CRITICAL
CRADI score change at 3 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	118	119	-	MD 3.7 higher (6.8 lower to 14.2 higher)	LOW	CRITICAL
UIQ score change at 3 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	118	119	-	MD 3.9 higher (6.75 lower to 14.55 higher)	LOW	CRITICAL
POPIQ score change at 3 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	118	119	-	MD 4.35 higher (4.22 lower to 12.92 higher)	LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	PFMT	Relative (95% CI)	Absolute		
CRAIQ score change at 3 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	118	119	-	MD 5.4 higher (3.52 lower to 14.32 higher)	LOW	CRITICAL
QUID score change at 3 months - QUID stress (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	118	119	-	MD 0.4 higher (0.49 lower to 1.29 higher)	LOW	CRITICAL
QUID score change at 3 months - QUID urge (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	118	119	-	MD 0.2 higher (0.5 lower to 0.9 higher)	LOW	CRITICAL
UDI score change at 3 months - UDI stress (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	100	119	-	MD 0.9 lower (7.17 lower to 5.37 higher)	LOW	CRITICAL
UDI score change at 3 months - UDI Obstructive (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	100	119	-	MD 1.6 higher (1.74 lower to 4.94 higher)	LOW	CRITICAL
UDI score change at 3 months - UDI irritative (follow-up mean 12 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	Pessary	PFMT	Relative (95% CI)	Absolute		
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	100	119	-	MD 1.3 higher (2.55 lower to 5.15 higher)	LOW	CRITICAL
UDI score change at 3 months - UDI (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	100	119	-	MD 1.3 higher (9.37 lower to 11.97 higher)	LOW	CRITICAL
POPDI score change at 3 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	100	119	-	MD 5.4 higher (2.84 lower to 13.64 higher)	LOW	CRITICAL
CRADI score change at 3 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	100	119	-	MD 2.7 higher (8.01 lower to 13.41 higher)	LOW	CRITICAL
UIQ score change at 3 months (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	100	119	-	MD 4.6 higher (8.1 lower to 17.3 higher)	LOW	CRITICAL
POPIQ score change at 3 months (follow-up mean 12 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	Pessary	PFMT	Relative (95% CI)	Absolute		
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	100	119	-	MD 2.4 higher (8.35 lower to 13.15 higher)	LOW	CRITICAL
QUID score change at 3 months - QUID stress (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	100	119	-	MD 0.2 higher (1.16 lower to 1.56 higher)	LOW	CRITICAL
QUID score change at 3 months - QUID urge (follow-up mean 12 months; Better indicated by lower values)												
1 Kenton 2012	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[10]	none	100	119	-	MD 0.5 higher (0.66 lower to 1.66 higher)	VERY LOW	CRITICAL
POPDI at 6 months (follow-up mean 6 months; Better indicated by lower values)												
1 Cheung 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[14]	none	139	137	-	Median 14.1 fewer. Median (IQR): Intervention 40.7 (11.3-100) Control 54.8 (22.6-103.6)	VERY LOW	CRITICAL
UDI at 6 months (follow-up mean 6 months; Better indicated by lower values)												
1 Cheung 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[14]	none	139	137	-	Median 1.8 more. Median (IQR): Intervention 42.8 (21.0-81.3) Control 41.0 (19.8-80.7)	VERY LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	PFMT	Relative (95% CI)	Absolute		
CRADI at 6 months (follow-up mean 6 months; Better indicated by lower values)												
1 Cheung 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[14]	none	139	137	-	Median 1.7 more. Median (IQR): Intervention 42.3 (12.1-86.9) Control 40.6 (15.5-83.0)	VERY LOW	CRITICAL
UIQ at 6 6 months (follow-up mean 6 months; Better indicated by lower values)												
1 Cheung 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[14]	none	139	137	-	Median 4.2 more. Median (IQR): Intervention 15.3 (1.6-48.6) Control 11.1 (0-56.9)	VERY LOW	CRITICAL
UIQ at 12 months (follow-up mean 12 months; Better indicated by lower values)												
1 Cheung 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[14]	none	139	137	-	Median 3.6 more. Median (IQR): Intervention 13.3 (0-40.3) Control 9.7 (0-54.8)	VERY LOW	CRITICAL
CRAIQ 6 months (follow-up mean 6 months; Better indicated by lower values)												
1 Cheung 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[14]	none	139	137	-	Median 0 more. Median (IQR): Intervention 0 (0-5.6)	VERY LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	PFMT	Relative (95% CI)	Absolute		
										Control 0 (0-8.5)		
CRAIQ 12 months (follow-up mean 12 months; Better indicated by lower values)												
1 Cheung 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[14]	none	139	137	-	Median 0 more. Median (IQR): Intervention 0 (0-5.6) Control 0 (0-5.6)	VERYLOW	CRITICAL
Complications - Abnormal vaginal bleeding (follow-up mean 12 months)												
1 Cheung 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[7]	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	CRITICAL
Complications - Significant vaginal discharge (follow-up mean 12 months)												
1 Cheung 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[7]	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	CRITICAL
Complications - New SUI (follow-up mean 12 months)												
1 Cheung 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[6]	none	24/50 (48%)	13/58 (22.4%)	RR 2.14 (1.22 to 3.75)	256 more per 1000 (from 49 more to 616 more)	VERY LOW	CRITICAL
Complications - New Urge UI (follow-up mean 12 months)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	PFMT	Relative (95% CI)	Absolute		
1 Cheung 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[7]	none	17/73 (23.3%)	19/84 (22.6%)	RR 1.03 (0.58 to 1.83)	7 more per 1000 (from 95 fewer to 188 more)	VERY LOW	CRITICAL
Complications - Voiding difficulty (follow-up mean 12 months)												
1 Cheung 2016	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[7]	none	10/92 (10.9%)	8/97 (8.2%)	RR 1.32 (0.54 to 3.19)	26 more per 1000 (from 38 fewer to 181 more)	VERY LOW	CRITICAL

CI: confidence interval; PGI-I: Patient Global Impression of Improvement; UIQ: Urinary Impact Questionnaire; POPIQ: Prolapse Impact Questionnaire 7; CRAIQ: Colorectal and Anal Impact Questionnaire; QUID: Questionnaire for female Urinary Incontinence Diagnosis; CRADI-8:Colorectal Anal Distress Inventory-8; MCS-12: Mental Component Health Summary (SF-12); PCS-12:Physical Component Health Summary (SF-12); PFDI-20: Pelvic Floor Distress Inventory-20; PFIQ-7:Pelvic Floor Impact Questionnaire-7; PFMT: pelvic floor muscle training; PISQ-12:Pelvic Organ Prolapse/Incontinence Sexuality Questionnaire-12; POPDI-6:Pelvic Organ Prolapse Distress Inventory-6; UDI-6:Urinary/Urogenital Distress Inventory-6;
1 Very serious risk of bias in the evidence contributing to the outcomes as per RoB 2
2 95% CI crosses 1 MID (0.5 x SD of control; 17.9)
3 Very serious heterogeneity unexplained by subgroup analysis, random effects model used
4 95% CI crosses 1 MID (0.5 x SD of control; 11.08)
5 95% CI crosses 1 MID (0.5 x SD of control; 6.5)
6 95% CI crosses 1 MID (0.8, 1.25)
7 95% CI crosses 2 MIDs (0.8, 1.25)
8 95% CI crosses 1 MID (0.5 x SD of control; 4.45)
9 95% CI crosses 1 MID (0.5 x SD of control; 1.6)
10 95% CI crosses 1 MID (0.5 x SD of control; 1.65)
11 95% CI crosses 1 MID(0.5 x SD of control; 7.5)
12 95% CI crosses 1 MID(0.5 x SD of control; 17.85)
13 95% CI crosses 1 MID(0.5 x SD of control; 8.85)

14 Imprecision could not be assessedTable 14: Clinical evidence profile for pessary vs pessary:

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	Pessary	Relative (95% CI)	Absolute		
Change in patient satisfaction (follow-up mean 6 months; Better indicated by higher values)												
1 Tam 2019	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	29	30	-	MD 0.2 lower (1 lower to 0.6 higher)	LOW	IMPORTANT
POPQ change from baseline - Aa (follow-up mean 6 months; Better indicated by lower values)												
1 Tam 2019	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	29	30	-	MD 0.37 higher (0.18 lower to 0.92 higher)	LOW	CRITICAL
POPQ change from baseline - Ba (follow-up mean 6 months; Better indicated by lower values)												
1 Tam 2019	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	29	30	-	MD 0.47 higher (0.21 lower to 1.15 higher)	LOW	CRITICAL
POPQ change from baseline - C (follow-up mean 6 months; Better indicated by lower values)												
1 Tam 2019	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	29	30	-	MD 0.2 lower (1.13 lower to 0.73 higher)	VERY LOW	CRITICAL
POPQ change from baseline - GH (follow-up mean 6 months; Better indicated by lower values)												
1 Tam 2019	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	29	30	-	MD 0.03 lower (0.38 lower to 0.32 higher)	VERY LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	Pessary	Relative (95% CI)	Absolute		
POPQ change from baseline - PB (follow-up mean 6 months; Better indicated by lower values)												
1 Tam 2019	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	29	30	-	MD 0 higher (0.16 lower to 0.16 higher)	VERY LOW	CRITICAL
POPQ change from baseline - TVL (follow-up mean 6 months; Better indicated by lower values)												
1 Tam 2019	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	29	30	-	MD 0.17 lower (0.56 lower to 0.22 higher)	LOW	CRITICAL
POPQ change from baseline - Bp (follow-up mean 6 months; Better indicated by lower values)												
1 Tam 2019	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	29	30	-	not reported	LOW	CRITICAL
POPQ change from baseline - D (follow-up mean 6 months; Better indicated by lower values)												
1 Tam 2019	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	29	30	-	MD 0.1 higher (0.34 lower to 0.54 higher)	VERY LOW	CRITICAL
POPQ change from baseline - Ap (follow-up mean 6 months; Better indicated by lower values)												
1 Tam 2019	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	29	30	-	MD 0 higher (0.21 lower to 0.21 higher)	MODERATE	CRITICAL

CI: confidence interval; MD: mean difference; POPQ: Prolapse Impact Questionnaire
1 Serious risk of bias in the evidence contributing to the outcomes as per RoB 2

2 95% CI crosses 1 MID (0.5 x SD of control)
3 95% CI crosses 2 MIDs (0.5 x SD of control)

Table 15: Clinical evidence profile for intravaginal device vs intravaginal device:

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intravaginal Device	Intravaginal Device	Relative (95% CI)	Absolute		
Pad weight (follow-up mean 2 days; Better indicated by lower values)												
1 Glavind 1997	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	6	6	-	MD 6.53 lower (11.04 to 2.02 lower)	LOW	CRITICAL
Subjective Continence - Cure (follow-up mean 5 weeks)												
1 Thyssen 2001	randomised trials	very serious[3]	no serious inconsistency	no serious indirectness	serious[4]	none	30/62 (48.4%)	22/62 (35.5%)	RR 1.36 (0.89 to 2.08)	128 more per 1000 (from 39 fewer to 383 more)	VERY LOW	CRITICAL
Subjective Continence - Improvement (follow-up mean 5 weeks)												
1 Thyssen 2001	randomised trials	very serious[3]	no serious inconsistency	no serious indirectness	very serious[5]	none	22/62 (35.5%)	25/62 (40.3%)	RR 0.88 (0.56 to 1.38)	48 fewer per 1000 (from 177 fewer to 153 more)	VERY LOW	CRITICAL
Subjective Continence - No Change (follow-up mean 5 weeks)												
1 Thyssen 2001	randomised trials	very serious[3]	no serious inconsistency	no serious indirectness	very serious[5]	none	15/62 (24.2%)	10/62 (16.1%)	RR 1.5 (0.73 to 3.08)	81 more per 1000 (from 44 fewer to 335 more)	VERY LOW	CRITICAL

CI: confidence interval; RR: relative risk

1 Serious risk of bias in the evidence contributing to the outcomes as per RoB 2
2 95% CI crosses 1 MID (0.5 x SD of control; 5.61)
3 Very serious risk of bias in the evidence contributing to the outcomes as per RoB 2
4 95% CI crosses 1 MID (0.8, 1.25)
5 95% CI crosses 2 MIDs (0.8, 1.25)

Table 16: Clinical evidence profile for intraurethral device vs intraurethral device:

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Intraurethral Devices**	**Intraurethral Device**	**Relative (95% CI)**	**Absolute**		
Successful pad weight reduction (follow-up mean 4 months)												
1 Robinson 2003	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	5/8 (62.5%)	6/8 (75%)	RR 0.83 (0.43 to 1.63)	128 fewer per 1000 (from 428 fewer to 472 more)	VERY LOW	CRITICAL

CI: confidence interval; RR: relative risk
1 Very serious risk of bias in the evidence contributing to the outcomes as per RoB 2
2 95% CI crosses 2 MIDs (0.8, 1.25)

Table 17: Clinical evidence profile for vaginal dilator vs no treatment:

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Vaginal dilator**	**No treatment**	**Relative (95% CI)**	**Absolute**		
Intercourse penetration - 10 weeks (follow-up mean 6 months; Better indicated by higher values)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Vaginal dilator	No treatment	Relative (95% CI)	Absolute		
1 Zarski 2017	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	36	31	-	MD 0.05 higher (0.3 lower to 0.4 higher)	VERY LOW	CRITICAL
Intercourse penetration - 6 months (follow-up mean 6 months; Better indicated by higher values)												
1 Zarski 2017	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	22	29	-	MD 0.42 higher (0.18 lower to 1.02 higher)	VERY LOW	CRITICAL
Non-intercourse penetration (PEQ) - Non-intercourse penetration 10 weeks (follow-up mean 6 months; Better indicated by higher values)												
1 Zarski 2017	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	36	31	-	MD 0.37 higher (0.04 to 0.7 higher)	VERY LOW	CRITICAL
Non-intercourse penetration (PEQ) - Non-intercourse self-insertion 10 weeks (follow-up mean 6 months; Better indicated by higher values)												
1 Zarski 2017	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	36	31	-	MD 0.66 higher (0.2 to 1.12 higher)	VERY LOW	CRITICAL
Non-intercourse penetration (PEQ) - Non-intercourse insertion by the partner 10 weeks (follow-up median 6 months; Better indicated by higher values)												
1 Zarski 2017	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	36	31	-	MD 0.09 higher (0.25 lower to 0.43 higher)	VERY LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Vaginal dilator	No treatment	Relative (95% CI)	Absolute		
Non-intercourse penetration (PEQ) - Non-intercourse penetration at 6 months (follow-up mean 6 months; Better indicated by higher values)												
1 Zarski 2017	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	22	29	-	MD 0.72 higher (0.28 to 1.16 higher)	VERY LOW	CRITICAL
Non-intercourse penetration (PEQ) - Non-intercourse self-insertion 6 months (follow-up mean 6 months; Better indicated by higher values)												
1 Zarski 2017	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	22	29	-	MD 0.85 higher (0.29 to 1.41 higher)	VERY LOW	CRITICAL
Non-intercourse penetration (PEQ) - Non-intercourse insertion by the partner at 6 months (follow-up mean 6 months; Better indicated by higher values)												
1 Zarski 2017	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	22	29	-	MD 0.58 higher (0.14 to 1.02 higher)	VERY LOW	CRITICAL
Fear of sexuality (FSQ) - Fear of coitus at 10 weeks (follow-up mean 6 months; Better indicated by lower values)												
1 Zarski 2017	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	36	31	-	MD 1.12 lower (3.11 lower to 0.87 higher)	VERY LOW	IMPORTANT
Fear of sexuality (FSQ) - Fear of non-coital sexual activity 10 weeks (follow-up mean 6 months; Better indicated by lower values)												

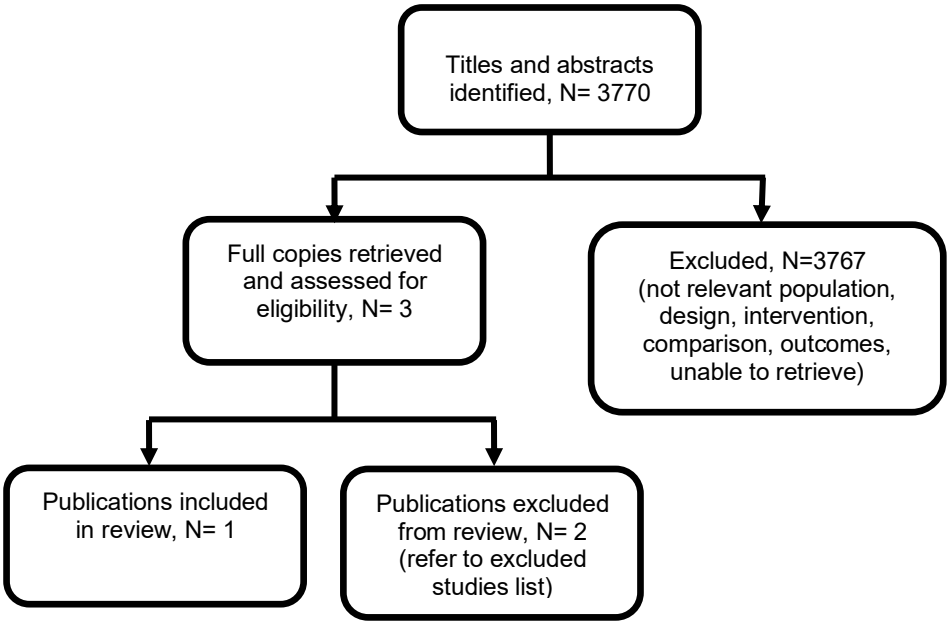
Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Vaginal dilator	No treatment	Relative (95% CI)	Absolute		
1 Zarski 2017	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	36	31	-	MD 0.38 lower (1.6 lower to 0.84 higher)	VERY LOW	IMPORTANT
Fear of sexuality (FSQ) - Fear of coitus at 6 months (follow-up mean 6 months; Better indicated by lower values)												
1 Zarski 2017	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	22	29	-	MD 0.76 lower (3.33 lower to 1.81 higher)	VERY LOW	IMPORTANT
Fear of sexuality (FSQ) - Fear of non-coital sexual activity at 6 months (follow-up mean 6 months; Better indicated by lower values)												
1 Zarski 2017	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	22	29	-	MD 0.21 lower (1.59 lower to 1.17 higher)	VERY LOW	IMPORTANT
Female sexual function (FSFI) - Overall sexual functioning at 10 weeks (follow-up mean 6 months; Better indicated by higher values)												
1 Zarski 2017	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	36	31	-	MD 3.24 higher (0.27 to 6.21 higher)	VERY LOW	CRITICAL
Female sexual function (FSFI) - Overall sexual function at 6 months (follow-up mean 6 months; Better indicated by higher values)												
1 Zarski 2017	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	22	29	-	MD 3.36 higher (0.04 to 6.68 higher)	VERY LOW	CRITICAL

CI: confidence interval; MD: mean difference
1 Very serious risk of bias in the evidence contributing to the outcomes as per RoB 2
2 95% CI crosses 1 MID (0.5 x SD of control)

Appendix G – Economic evidence study selection

Economic evidence study selection for review question: What is the effectiveness of physical devices (including support garments, pessaries and dilators) for improving symptoms of pelvic floor dysfunction?

Figure 7: Study selection flow chart



Appendix H – Economic evidence tables

Economic evidence tables for review question: What is the effectiveness of physical devices (including support garments, pessaries and dilators) for improving symptoms of pelvic floor dysfunction?

Table 18: Economic evidence table

Study country and type	Intervention and comparator	Study population, design and data sources	Costs and outcomes (descriptions and values)	Results	Comments
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 [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 2016;8:8. The Netherlands	*Intervention:* Pessary treatment Pelvic Floor Muscle Training (3-5 times a week, 2-3 times a day)	Women aged 55+ Alongside a Randomised Controlled Trial Source of baseline data: Randomised Controlled Trial (N=162) Source of effectiveness data: Randomised Controlled Trial (N=162) Source of cost data: Randomised Controlled Trial (N=162) Source of unit cost data: National, UK tariffs	Costs (type): pessaries and pessary-related visits, physical therapy, consultations with GPs, medical specialists, absorbent pads, medication Mean cost per participant: Pessary treatment: $309 (over 2 years) Pelvic Floor Muscle Training: $437 (over 2 years) Primary measure of outcome: QALYs Mean outcome per participant: Pessary treatment: -0.024 (over 2 years) Pelvic Floor Muscle Training: -0.065 (over 2 years)	Pessary dominated Pelvic Floor Muscle Training Sensitivity analysis: 5,000 bootstrap replications, 95% located in the south west quadrant	Currency: USD Cost year: likely 2012 Time horizon: 2 years Discounting: NR Applicability: partially applicable Limitations: minor limitations

Study country and type	Intervention and comparator	Study population, design and data sources	Costs and outcomes (descriptions and values)	Results	Comments
Cost-effectiveness analysis Conflict of interest: None reported Source of funding: The Netherlands Organisation for Health Research and Development					

N: number; NR: not reported

Appendix I – Economic evidence profiles

Economic evidence profiles for review question: What is the effectiveness of physical devices (including support garments, pessaries and dilators) for improving symptoms of pelvic floor dysfunction?

Table 19: Economic evidence profile

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
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 [Effectiveness and cost-effectiveness of pessary treatment compared with	Minor limitations	Partially applicable [1]	Type of economic analysis: cost-effectiveness analysis Time horizon: 2 years Primary measure of outcome: QALYs	Additional cost for Pelvic Floor Muscle Training (vs. Pessary): $128	Additional QALYs for Pelvic Floor Muscle Training (vs. Pessary): -0.041	Pessary dominates Pelvic Floor Muscle Training	Deterministic sensitivity analyses: none undertaken PSA: 95% located in the south west quadrant Bootstrapping 5,000 iterations

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
pelvic floor muscle training in older women with pelvic organ prolapse: 2-year follow-up of a randomized controlled trial in primary care]. Menopause 2016;8:8. The Netherlands							
National Guideline Alliance Cost-utility analysis of 75NC007 intravaginal device	Potentially serious limitations [2]	Directly applicable	**Type of economic analysis**: Cost-utility analysis **Time horizon:** 14 days **Primary measure of outcome:** Incremental net monetary benefit	£20.73	0.007	£30.437 per QALY iNMB [3] = -£7.11	**For base case analysis:** 19.1% probability of being cost-effective at a cost-effectiveness threshold of £20,000 per QALY 50.4% probability of being cost-effective at a cost-effectiveness threshold of £30,000 per QALY

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
							Threshold analysis: Treatment likely to be cost-effective when mean of 5 or more incontinence episodes per day

1. *Netherlands setting for a population of women aged over 55 years*
2. *Estimate of clinical effectiveness is derived from a single small study rated as very low quality with a high risk of bias*
3. *iNMB calculated using a cost-effectiveness threshold of £20,000 per QALY*

Appendix J – Economic analysis

Economic analysis for review question: What is the effectiveness of physical devices (including support garments, pessaries and dilators) for improving symptoms of pelvic floor dysfunction?

Cost-utility analysis of the 75NC007 intravaginal device compared to no treatment for women with pelvic floor dysfunction

Introduction

For most of the interventions considered in the review, the committee did not consider there was sufficient clinical evidence to make a recommendation for their use in the NHS (continence pessaries, support garments, intraurethral devices and vaginal dilators). However, there was some evidence indicating a benefit from intravaginal devices and therefore an economic analysis was deemed important in order to assess cost-effectiveness.

A total of 5 studies using an intravaginal device were included in the systematic review undertaken for this question (Cornu 2012, Lucena 2019, Lovatsis 2017, Thyssen 2001, Glavind 1997). However, it was not possible to synthesise the data from these studies. Furthermore, many of the included studies had very small sample sizes and did not report outcomes that would readily allow an economic evaluation using NICE's preferred outcome of Quality Adjusted Life Years (QALYs). Therefore, the decision was made to base an analysis on the single study (Cornu 2012) which appraised the 75NC007 intravaginal device, as this was thought to provide the best available evidence for the purposes of economic evaluation. Table 20 summarises the reasons why other included studies were not utilised for an economic analysis.

Table 20: Included studies not considered for economic analysis

Study	Reason not included in the economic analysis
Glavind 1997	Very small sample size (n=6) and outcome of pad weight not easily amenable to economic analysis as outlined in NICE reference case
Thyssen 2001	Outcome of number of pads used and subjective improvement in continence not easily amenable to economic analysis as outlined in the NICE reference case
Lovatsis 2017	Small sample size (n=36) and outcome of pad weight not easily amenable to economic analysis as outlined in NICE reference case
Lucena 2019	Outcome of IQOL and ICIQFLUTS not easily amenable to economic analysis as outlined in the NICE reference case

(a) IQOL: Urinary Incontinence Quality of Life Scale; ICIQFLUTS: International Consultation on Incontinence Questionnaire-Female Lower Urinary Tract Symptoms

Methods

Setting and population

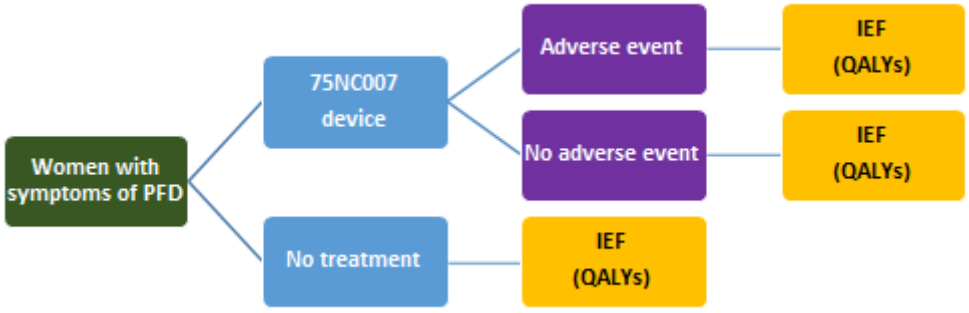
The model was for NHS settings and a population of women with pelvic floor dysfunction. The time horizon for the analysis was 14 days which reflected treatment duration in Cornu (2012), the randomised study which informed estimates of treatment effectiveness in this analysis.

Model structure

A decision analytic model was developed in Microsoft Excel® to assess the cost-utility of the 75NC007 intravaginal device when compared to no treatment. A schematic of the model is

shown in Figure 8. Costs are assigned to treatment and adverse events and QALYs are calculated according to incontinence episode frequency and treatment related adverse events.

Figure 8: The model decision tree



PFD = pelvic floor dysfunction; IEF = incontinence episode frequency; QALYs = Quality Adjusted Life Years

Clinical outcomes

The primary endpoint in Cornu (2012) was incontinence episode frequency (IEF) and that was also used in this analysis because data exists which enable QALYs to be estimated from IEF using EQ-5D, as per the preferred method in the NICE reference case (https://www.nice.org.uk/process/pmg9/chapter/the-reference-case#measuring-and-valuing-health-effects). As secondary endpoints the Cornu (2012) study also assessed variation of Urinary Symptom Profile (USP) score, 24-hour pad test and CONTILIFE questionnaire scores. However, these measures are closely related with incontinence episode frequency and could not be usefully incorporated in the analysis to derive a single generic measure of effect.

Cornu (2012) also recorded 2 treatment related adverse events. These were

i. 1 case of urinary tract infection (UTI)
ii. 1 case of metrorrhagia

Metrorrhagia is a dated term and is considered as an aspect of abnormal uterine bleeding (AUB). As we were unable to identify health state utilities associated with acute AUB, the model assumes that all costs and health state utilities associated with adverse treatment effects are those associated with a short term UTI.

Baseline

The model is constructed so that cost-effectiveness of the intravaginal device can be assessed by symptom severity, as assessed by mean number of incontinence frequency episodes per day at baseline. Whilst in practice, the number of daily incontinence episodes for each woman will vary, the model assumes a constant daily IEF that corresponds to the mean number of incontinence episodes per day. This assumption is consistent with measures of health state utility which are based on the mean IEF. A relative treatment effect derived from the Cornu (2012) can then be applied to this baseline IEF to estimate the absolute reduction in episodes over the 14-day treatment course.

In the base case analysis, the baseline mean number of incontinence episodes per 14-day period was based on Cornu (2012). The weighted average of episodes in the intervention and control group was calculated based on leakage diaries completed in the 14-day washout period prior to commencement of treatment as shown in Table 21 below. It was deemed reasonable to pool the intervention and control group as the difference was not statically

significant (p=0.18). The overall baseline mean number of incontinence episodes per 14-day period equates to a mean of 3.3 incontinence episodes per day.

Table 21: Baseline incontinence episode frequency

Trial arm	n	Mean number of incontinence episodes per 14-days [a] (Standard deviation)
Control (no treatment)	26	57.4 (64.8)
Intervention (intravaginal device)	29	35.4 (35.4)
Overall baseline	**55**	**45.8 (51.4)**

(a) Measured in the washout period prior to the commencement of treatment

To model a situation where symptom severity is not known, the population baseline IEF is similarly estimated from Cornu (2012) but can then be sampled as part of a probabilistic sensitivity analysis using a normal distribution.

Treatment effectiveness and adverse event rate

The relative treatment effect was derived from the mean difference in the change in IEF between the intervention and control arms in the Cornu (2012) study using the intention-to-treat analysis, see Table 9 and Table 22.

Table 22: Treatment effectiveness estimate

Outcome	Mean Difference in IEF from baseline	Standard error	Distribution
Incontinence episode frequency	-24.1%	12.8%	Normal

Similarly, the rate of treatment related adverse events was estimated from the number of adverse events reported in Cornu (2012) and summarised in Table 23 below.

Table 23: Treatment related adverse events

Outcome	Event rate	Alpha	Beta	Distribution
Urinary tract infection	6.9%	2	27	Beta

Health state utilities and QALYs

Health state utilities were derived from the estimated impact of treatment on incontinence episode frequency. 4 studies were identified from the literature which presented a relationship between EQ-5D and incontinence episode frequency, and all were included in this model either for the base case evaluation or as part of a sensitivity analysis. The health state utility data is summarised in Table 24 below. For the base case analysis, the NICE (2012) relationship was chosen but data from other studies was used in sensitivity analysis to assess uncertainty in the base case point estimates. The NICE (2012) relationship was chosen simply because it had been used in a published NICE single technology appraisal but no greater weighter should be attached to results using the NICE (2012) relationship than those derived using the other studies.

Health state utilities parameters for incontinence episode frequency were not sampled in the probabilistic sensitivity analysis as the point estimates were based on large samples resulting in small standard errors.

Table 24: Relationship between incontinence episode frequency and health state utilities derived from EQ-5D

	Study health state utility			
Incontinence episodes	**NICE 2012 [a]**	**Yamanishi 2018 [b]**	**Dezroziers 2013 [c]**	**Korbis 2015 [d]**
0 per day	0.850	0.813	0.856	0.848
0.5 per day [e]	0.820	0.793	0.837	N/A
1.0 per day	N/A	N/A	N/A	0.784
1.5 per day [f]	0.800	0.783	0.817	N/A
2.5 per day [g]	0,780	0.763	0.802	0.777
3.5 per day [h]	0.760	0.753	0.788	N/A
4.5 per day [i]	N/A	N/A	N/A	0.742

(a) https://www.nice.org.uk/guidance/ta290/documents/overactive-bladder-mirabegron-astellas-pharma2
(b) https://onlinelibrary.wiley.com/doi/epdf/10.1111/iju.13764
(c) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3842710/ - based on figure for adjusted health state utility estimates rather than the table which has the same values as NICE. Yamanshi (2018) provided health state utilities for incontinence episode frequency and micturition episode combinations. It was possible to calculate a weighted average for each given incontinence episode frequency level as the study reported the distribution across each category
(d) https://hqlo.biomedcentral.com/articles/10.1186/s12955-015-0274-9
(e) 0-1 episodes per day
(f) 1-2 episodes
(g) 2-3 episodes per day
(h) >3 episodes per day
(i) >4 episodes per day

It was necessary to model IEF of greater frequency than that indicated by the maximum value in Table 24. This was to allow the model to assess higher baseline IEF for the purposes of sensitivity analysis and because higher values could be obtained as a result of sampling from the treatment effect in the probabilistic analysis. One option, which appears to have been how the data was reported in the studies, was to categorise all incontinence episodes above a certain level at the same health state utility. However, it was likely that this represented the average level of health state utility across the range and given the lower prevalence of greater severity it is likely that the average would be skewed towards those with incontinence episode that just fell within the lower bound of the range. Therefore, we chose to extrapolate to greater incontinence episodes by fitting an equation to the existing data points in order to provide a mathematical relationship between number of episodes and health state utility. The model was constructed so that a trend line could be fitted according to one of the 3 following functional forms:

i. Linear
ii. Exponential
iii. 3rd order polynomial

In undertaking these extrapolations, a “logical floor” to health state utilities was applied such that the value could never fall below zero. This was only relevant when using the 3rd order polynomial functional form to extrapolate and then only for NICE (2012) and Korbis (2015) studies.

The mathematical relationship for these 3 functional forms using the NICE data on IEF and health state utility is shown in Figure 9, Figure 10 and Figure 11 respectively. For the base case analysis, the exponential relationship was chosen as it seemed to provide a marginally better fit to the data than a linear approximation and because, in assuming a levelling off in fall of health state utility with increasing IEF, it is consistent with the approach in the studies which assume a plateau above a certain threshold of episodes per day.

Figure 9: The relationship between mean incontinence episodes per day and health state utility for NICE (2012) data assuming an exponential functional form

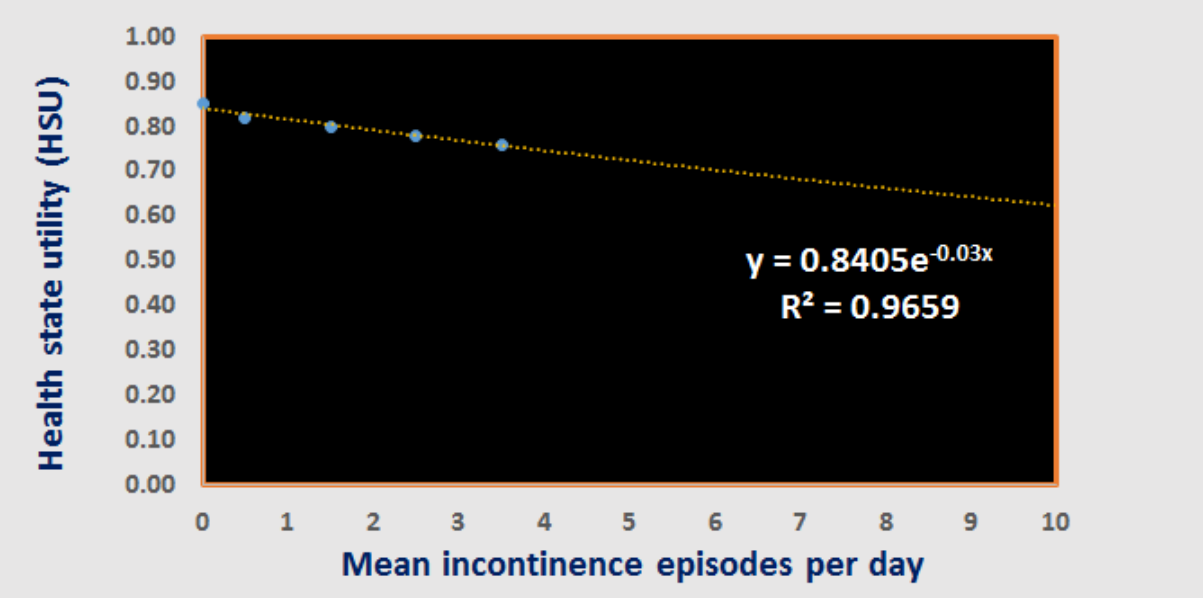


Figure 10: The relationship between mean incontinence episodes per day and health state utility for NICE (2012) data assuming a linear functional form

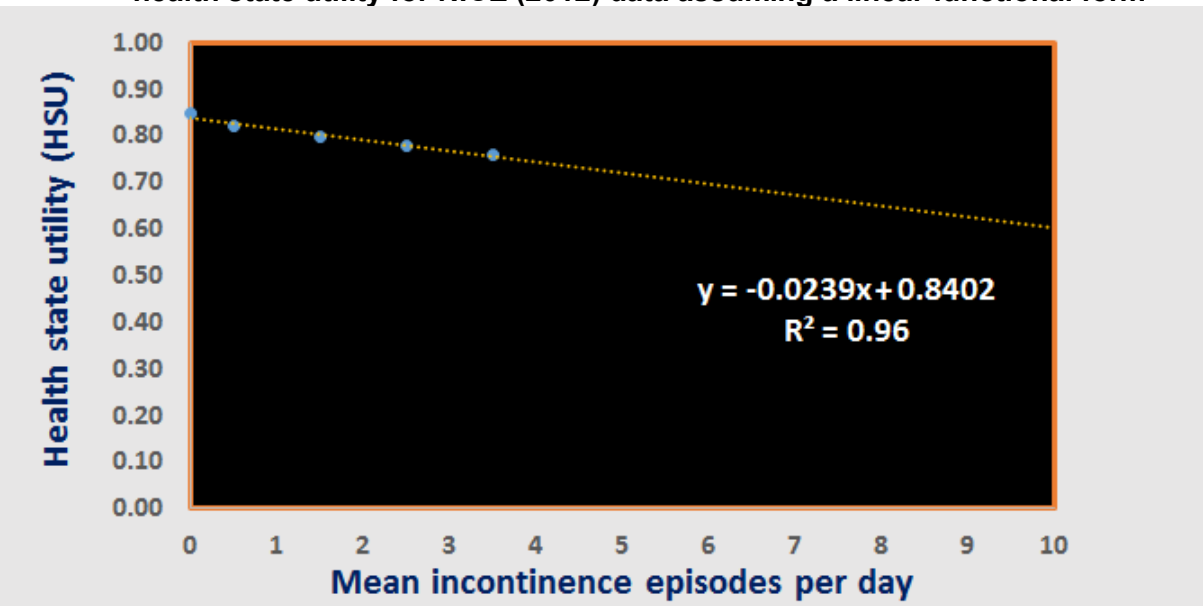
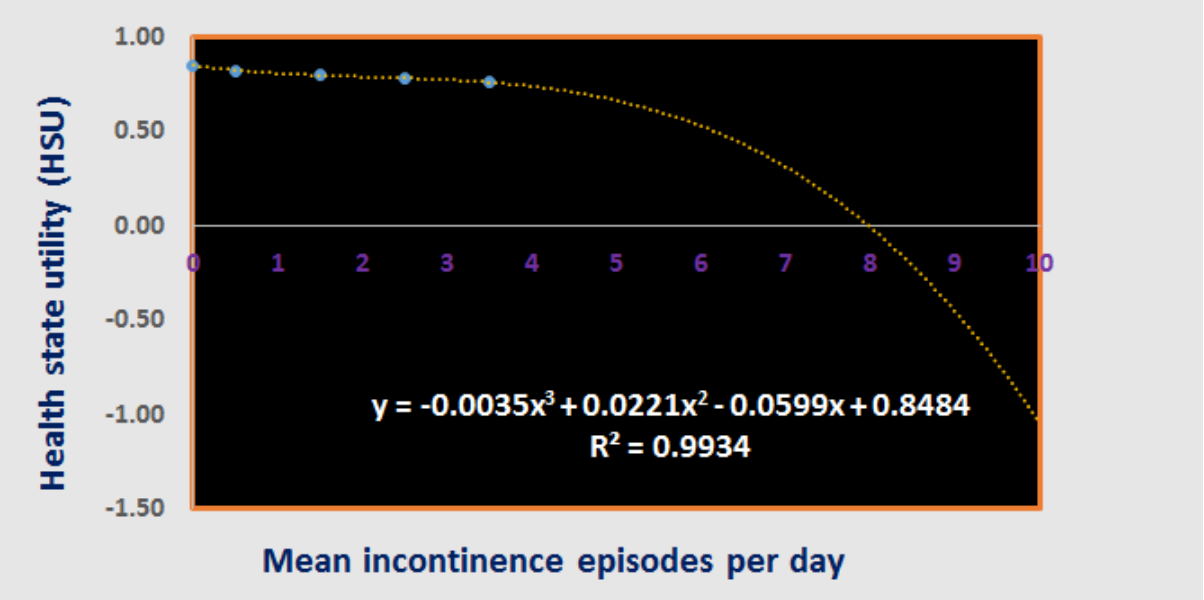


Figure 11: The relationship between mean incontinence episodes per day and health state utility for NICE (2012) data assuming a 3rd order polynomial functional form



Note: a health state utility of zero is applied in the model where the extrapolated value is negative

It was assumed that the treatment effect was achieved instantly with insertion of the intravaginal device and that the treatment effect would be maintained for the 14-day time horizon of the model. QALYs were calculated for the intervention and no treatment by multiplying the health state utility by 14/365.

The model also incorporated QALY losses arising from treatment related adverse events. The published literature was used to estimate the health state utility loss associated with a short-term urinary tract infection (UTI). It was assumed that with treatment the UTI would last for 3 days and therefore the QALY loss from treatment related adverse events was calculated as the health state utility loss multiplied by 3/365. This is summarised in Table 25.

Table 25: Health state utility loss from treatment related adverse events

Adverse event	Health state utility loss	Duration (Days)	Source
Urinary tract infection	0.019	3	Sonnenberg (2004)

Values for health state utility were treated deterministically in the probabilistic sensitivity analysis in the absence of any sampling data to quantify dispersion and uncertainty. Therefore, deterministic sensitivity analysis was used to assess the extent to which model conclusions were robust with respect to health state utility parameters. The duration of urinary tract infection was also not sampled in probabilistic sensitivity analysis for the same reason and the impact of different assumptions was assessed through one-way sensitivity analysis.

Treatment duration is a structural feature of the model and is based on Cornu (2012). There was no data on which to base extrapolation to a longer timeframe but it would be reasonable to assume that costs and QALYs would broadly increase in a linear fashion with time.

Costs and resource use

In accordance with NICE methodology a NHS and Personal Social Services (PSS) perspective was adopted for this analysis (https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/developing-

NICE-guidelines-the-manual.pdf). Costs were based on a 2020 price year with the exception of the costs of a GP visit which are based on Unit Costs of Health and Social Care (https://kar.kent.ac.uk/79286/), the most recently available.

As per the manufacturer's instructions (https://www.bbraun.com/en/patients/urinary-incontinence/diveen/frequently_asked_questions.html, accessed 12/11/2020) each device can be used twice and the total treatment cost is based on 14 days of treatment as per the model time horizon using 7 devices. It is assumed that a urinary tract infection would require 1 GP consultation, 1 diagnostic test with a urine test trip and a 3-day course, twice daily, of nitrofurantoin 100mg modified-release capsules as per NICE's antimicrobial guidance for managing common infections. Trimethoprim is a cheaper alternative first line treatment but it is only deemed suitable if there is a low risk of resistance.

Table 26 gives the unit costs for the resource use included in this analysis, which relate to treatment and treatment related adverse events.

Table 26: Unit costs

Resource item	Cost	Source
Treatment cost	£17.74	NHS Drugs Tariff (accessed 12/11/2020) [a]
GP visit	£39.23	Unit Costs of Health and Social Care 2019 [b]
Urine test strip	£0.07	ValueMed [c]
Antibiotics	£4.07	NHS Drugs Tariff (accessed 12/11/2020)

(a) £38.00 for a pack of 15 devices and applicator (http://www.drugtariff.nhsbsa.nhs.uk/#/00789028-DC/DC00788459/INSERT%20FOR%20FEMALE%20STRESS%20INCONTINENCE)
(b) Based on a consultation of 9.22 minute, including qualification and direct care staff costs (https://kar.kent.ac.uk/79286/),
(c) Based on 100 pack of 100 strips at £610

The short time horizon of the model means that it was not necessary to discount costs.

Sensitivity analysis

A wide range of sensitivity analyses were undertaken to explore and quantify the extent to which conclusions about the cost-effectiveness of the 75NC007 intravaginal device were robust with respect to uncertainty in the model inputs.

i. Tornado analysis

A Tornado analysis is a form of one-way sensitivity analysis where inputs for model variables are varied one at a time between an upper and lower level, holding all other model inputs constant in order to demonstrate the sensitivity of the results to changes in selected variables. These analyses are then incorporated into a single Tornado diagram which gives a visual indication as to the relative importance of uncertainty to the cost-effectiveness results in these selected variables.

The variable covered in the Tornado analysis, their upper and lower values and rationale for the range are given in Table 27.

Table 27: Variables and parameter values used in Tornado analysis

Variable	Lower value	Upper Value
Treatment cost [a]	£14	£21
Adverse event cost [b]	£35	£52

Variable	Lower value	Upper Value
Adverse event rate [c]	0.009	0.183
Mean difference in IEF from baseline [d]	-49.6%	1.4%
HSU from adverse event [e]	0.019	0.196
Duration of adverse event [f]	3 days	14 days

(a) The lower and upper values are based on ± 20% of the model default
(b) The lower and upper values are based on ± 20% of the model default
(c) The lower and upper values are derived from the values which bound 95% of the probability distribution (0.025 to 0.975)
(d) The lower and upper values are taken from the 95% confidence intervals for treatment effect in the Cornu (2012) study
(e) The lower value is based on the model default and the upper value is based on Ellis (2000) which reported a much higher health state utility loss from a urinary tract infection
(f) The lower value is based on the model default which reflect antibiotic treatment duration and the upper value is based on the model time horizon

ii. Threshold analysis

As noted earlier the base case analysis uses a particular frequency of incontinence episodes. In order to assess how cost-effectiveness changes with symptom severity a number of one-way sensitivity analyses were undertaken varying the mean number of urinary incontinence episodes per day. Collectively these analyses can illustrate the threshold value for the mean number of urinary incontinence episodes per day at which treatment would be judged cost-effective. Threshold analysis was also used to determine at what treatment cost the 75NC007 would be cost-effective.

iii. Structural sensitivity analysis

To assess uncertainty associated with the relationship between incontinence episode frequency and health state utility, estimates were also used from different studies and using different functional forms to extrapolate the impact of higher rates of incontinence episode frequency on health related quality of life.

iv. Two-way sensitivity analysis

Similar to one-way sensitivity analysis this involves changing the input parameters for 2 variables whilst holding all other model inputs constant. It can highlight the relationship between the 2 variables in determining cost-effectiveness and the extent of any trade-offs between them.

v. Probabilistic sensitivity analysis

To assess parameter simultaneously uncertainty across all model inputs having well quantified uncertainty, probabilistic sensitivity analysis was undertaken. This involved 10,000 Monte Carlo simulations of the model with model inputs sampled from a specified probability distribution, reflecting sampling uncertainty for each iteration.

Results

The base case deterministic results are presented in Table 28 and Figure 12 below. They are based on a woman with pelvic floor dysfunction and with a mean of 3.3 incontinence episodes per day and using NICE (2012) data with an exponential functional form to estimate the relationship between urinary incontinence episodes and health state utility. The incremental cost-effectiveness ratio of £30,437 and negative incremental net monetary benefit indicates that the 75NC007 intravaginal device would not be considered cost-effective at a cost-effectiveness threshold of £20,000 per QALY.

Table 28: Base case analysis results using NICE (2012) data with an exponential function to estimate the relationship between urinary incontinence episodes and health state utility

Treatment	Cost	QALY	Inc Cost	Inc QALY	ICER	iNMB [a]
No treatment	£0	0.0292	-	-	-	-
75NC007	£20.73	0.0299	£20.73	0.0007	£30,437	-£7.11

(a) Based on a cost-effectiveness threshold of £20,000 per QALY
ICER = Incremental cost-effectiveness ratio; Inc = Incremental; iNMB = Incremental net monetary benefit; QALY = Quality adjusted life-years

Figure 12: Graph to illustrate base case incremental costs and QALYs of 75NC007 intravaginal device relative to no treatment

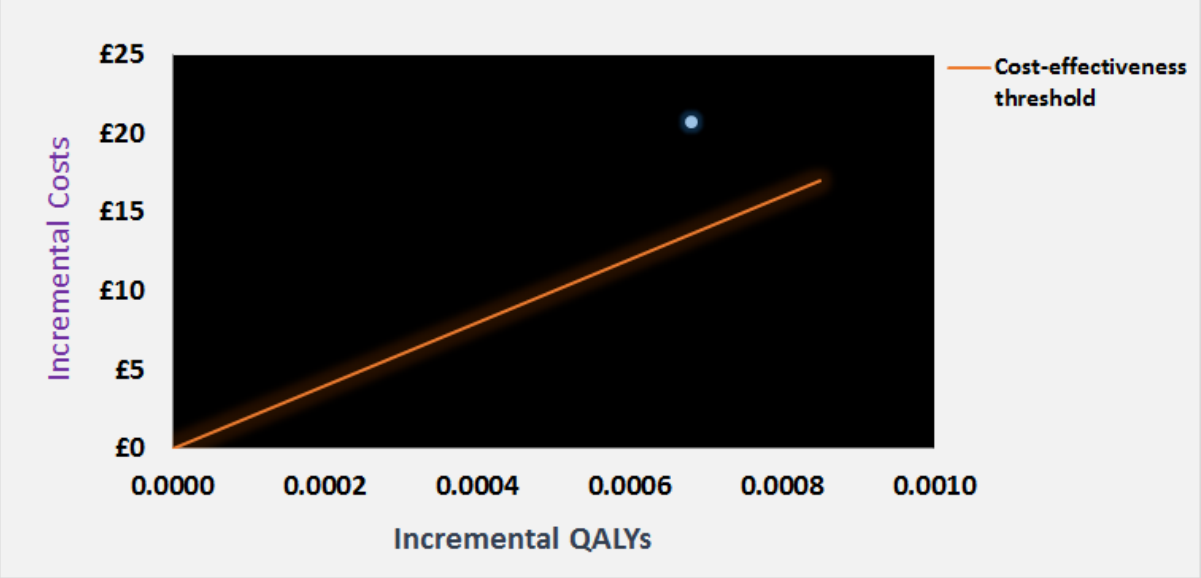


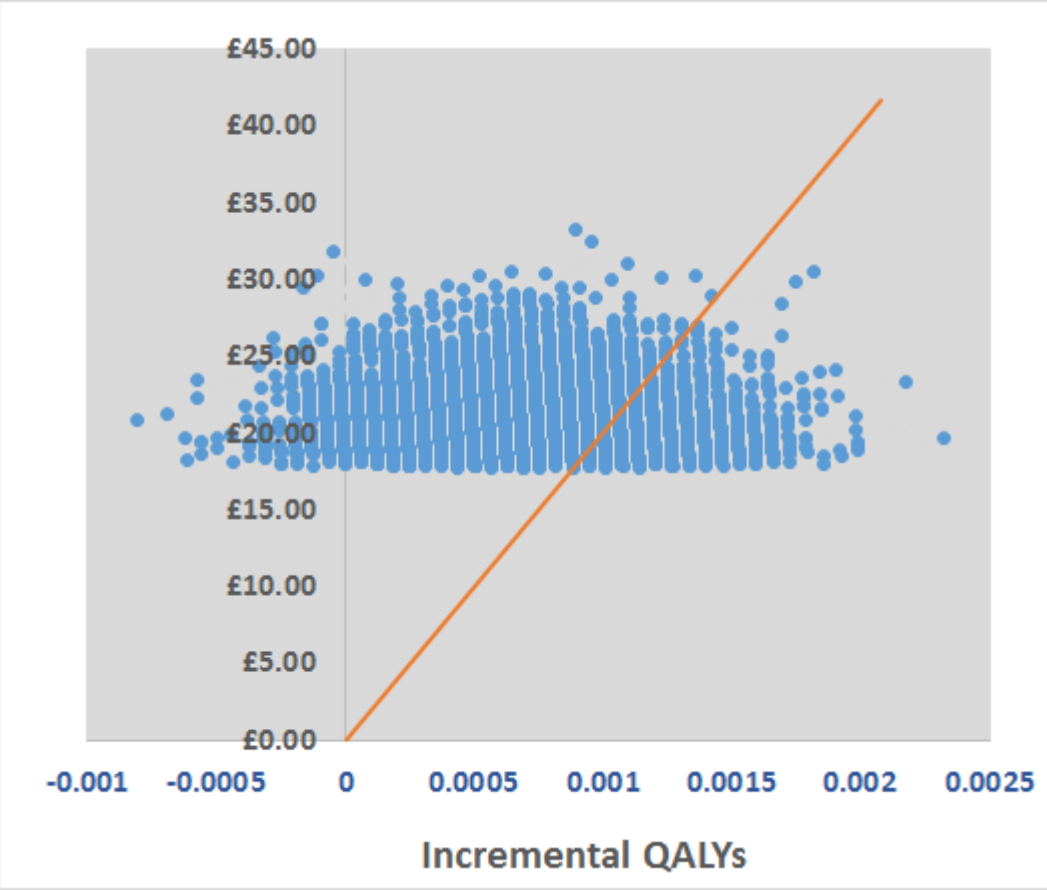
Table 29 shows the results of the probabilistic sensitivity analysis for the base case inputs, using NICE (2012) data and an exponential functional form to estimate the relationship between urinary incontinence episodes and health state utility. The results of each 10,000 simulations are plotted on the cost-effectiveness plane in Figure 13. The negative mean incremental net monetary benefit of -£6.67 suggests that the 75NC007 intravaginal device is not cost-effective at a cost-effectiveness threshold of £20,000 per QALY. Data from the simulations suggested that there was only a relatively small probability of 19% that the intravaginal device was cost-effective when parameter uncertainty was taken into account.

Table 29: Results of probabilistic sensitivity analysis comparing the 75NC007 intravaginal device with for the base case analysis

Intervention	Mean Inc Costs (95% Cr Int)	Mean Inc QALYs (95% Cr Int)	Mean iNMB [a] (95% Cr Int)	Prob CE
75NC007	£20.73 (£18.13 to £25.66)	0.0007 (-0.00002 to 0.00143)	-£6.67 (-£21.94 to £8.38)	19.1%

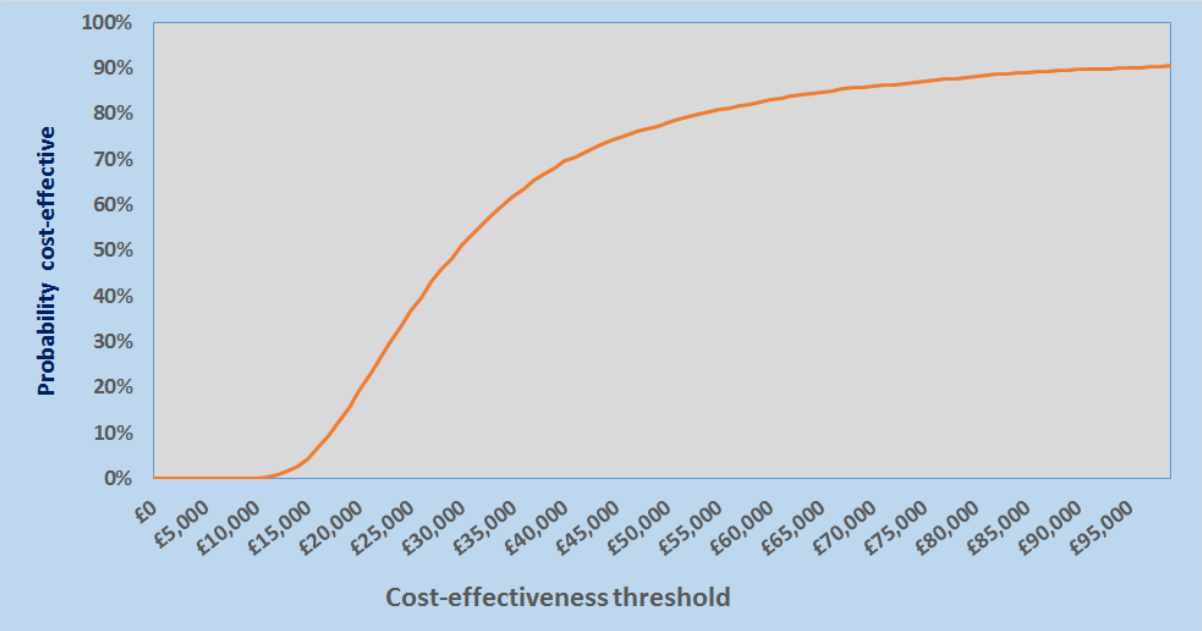
(a) Based on a cost-effectiveness threshold of £20,000 per QALY
Cr Int = Credible interval; Inc = Incremental; iNMB = Incremental net monetary benefit; Prob = Probability; QALYs = Quality adjusted life-years

Figure 13: Cost-effectiveness plane showing incremental costs and incremental QALYs of 75NC007 intravaginal device relative to no treatment in the Monte Carlo simulations for the base case analysis



The impact of varying the cost-effectiveness threshold is shown in the cost-effectiveness acceptability curve (CEAC) in Figure 14. This shows that at a £30,000 cost-effectiveness threshold there was a 50.4% probability that the 75NC007 intravaginal device was cost-effective.

Figure 14: CEAC for base case analysis showing probability that 75NC007 intravaginal device is cost-effective at different cost-effectiveness thresholds



Structural sensitivity analysis

Table 30 shows the ICERs with deterministic analysis for the 75NC007 intravaginal device relative to no treatment using alternative data sources and functional forms to estimate the relationship between urinary incontinence episodes and health state utility. Only when using the NICE (2012) data and a linear functional form to estimate the relationship between incontinence episodes and health state utility is the 75NC007 intravaginal device borderline cost-effective when using a £30,000 per QALY cost-effectiveness threshold.

Table 30: Incremental net monetary benefits of a deterministic analysis varying the source of estimate and functional form to estimate the relationship between urinary incontinence episodes and health state utility

	Linear	Exponential	3rd order polynomial
NICE (2012)	£29,215	£30,437	£32,777
Yamanishi (2018)	£43,035	£44,279	£54,224
Dezroziers (2013)	£37,706	£38,903	£48,670
Korbis (2015)	£34,040	£35,066	Dominated

Table 31 and Table 32 show the probabilistic implications of alternative structural assumptions with respect to the relationship between urinary incontinence episodes and health state utility as cost-effectiveness thresholds of £20,000 per QALY and £30,000 per QALY respectively.

Table 31: Incremental net monetary benefits (probability cost-effective) of a probabilistic sensitivity analysis varying the source of estimate and functional form to estimate the relationship between urinary incontinence

episodes and health state utility using a cost-effectiveness threshold of £20,000 per QALY

	Linear	Exponential	3rd order polynomial
NICE (2012)	-£6.30 (21.0%)	-£6.67 (19.2%)	-£8.41 (5.8%)
Yamanishi (2018)	-£10.86 (2.8%)	-£11.10 (2.5%)	-£12.94 (0.3%)
Dezroziers (2013)	-£9.45 (7.1%)	-£9.72 (6.0%)	-£12.07 (0.7%)
Korbis (2015)	-£8.29 (11.5%)	-£8.51 (10.7%)	-£22.76 (0.0%)

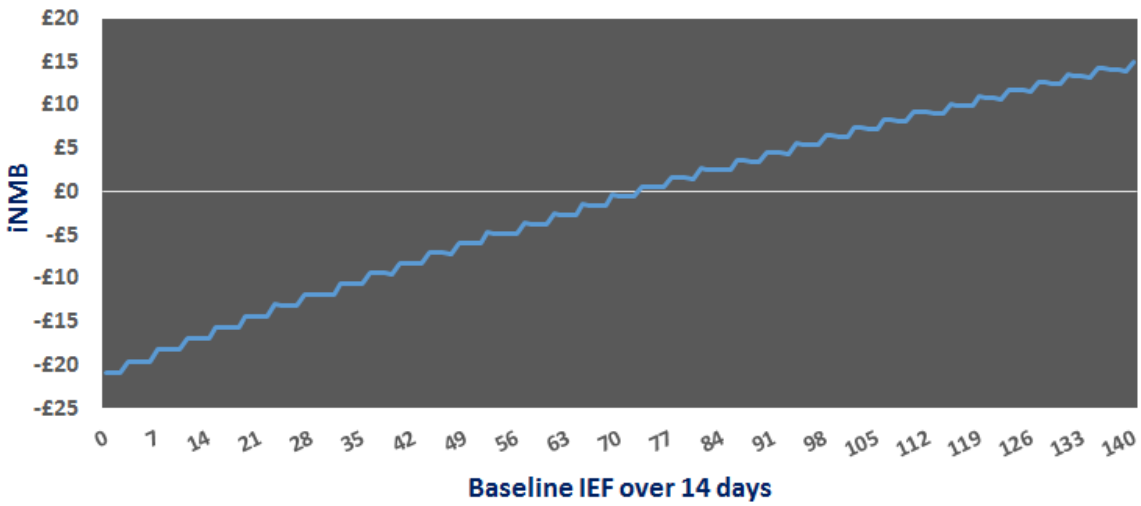
Table 32: Incremental net monetary benefits (probability cost-effective) of a probabilistic sensitivity analysis varying the source of estimate and functional form to estimate the relationship between urinary incontinence episodes and health state utility using a cost-effectiveness threshold of £30,000 per QALY

	Linear	Exponential	3rd order polynomial
NICE (2012)	£0.91 (53.3%)	£0.42 (51.4%)	-£2.37 (42.0%)
Yamanishi (2018)	-£5.95 (23.9%)	-£6.17 (22.1%)	-£9.14 (7.6%)
Dezroziers (2013)	-£3.92 (33.3%)	-£4.41 (30.9%)	-£7.86 (12.1%)
Korbis (2015)	-£1.98 (42.4%)	-£2.82 (39.1%)	-£23.76 (0.0%)

Threshold analysis

Figure 15 illustrates the impact of baseline mean incontinence episodes per day on the cost-effectiveness of the 75NC007 intravaginal device. This suggests that the intravaginal device is cost-effective for a woman with a baseline of above 72 incontinence episodes per 14-day period (a mean of 5.2 incontinence episodes per day) when using NICE (2012) data and an exponential functional form to estimate the relationship between urinary incontinence episodes and health state utility.

Figure 15: Relationship between baseline urinary incontinence episode frequency and iNMB using NICE (2012) data and an exponential functional form to estimate the relationship between urinary incontinence episodes and health state utility



The probabilistic analysis for a woman with a baseline of 5 incontinence episodes per day using NICE (2012) data and an exponential functional form to estimate the relationship

between urinary incontinence episodes and health state utility is shown in Table 33 below and illustrated in the cost-effectiveness plane in Figure 16 and the CEAC in Figure 17. This shows that the intervention is borderline cost-effective at a cost-effectiveness threshold of £20,000 per QALY and has a fairly high probability (71.6%) of being cost-effective at a cost-effectiveness threshold of £30,000 per QALY.

Table 33: Results of probabilistic sensitivity analysis comparing the 75NC007 intravaginal device with no treatment for a woman with a baseline of 5 incontinence episodes per day and using NICE (2012) data and an exponential functional form to estimate the relationship between incontinence episode frequency and health state utility

Intervention	Mean Inc Costs (95% Cr Int)	Mean Inc QALYs (95% Cr Int)	Mean iNMB [a] (95% Cr Int)	Prob CE
75NC007	£20.74 (£18.12 to £25.53)	0.0010 (-0.00001 to 0.00208)	-£0.38 (-£22 to £21.84)	48.5%

(a) Based on a cost-effectiveness threshold of £20,000 per QALY
Cr Int = Credible interval; Inc = Incremental; iNMB = Incremental net monetary benefit; Prob = Probability; QALYs = Quality adjusted life-years

Figure 16: Cost-effectiveness plane showing incremental costs and incremental QALYs of 75NC007 intravaginal device relative to no treatment for a woman with a mean of 5 urinary incontinence episodes per day and using NICE (2012) data and an exponential functional form to estimate the relationship between urinary incontinence episodes and health state utility

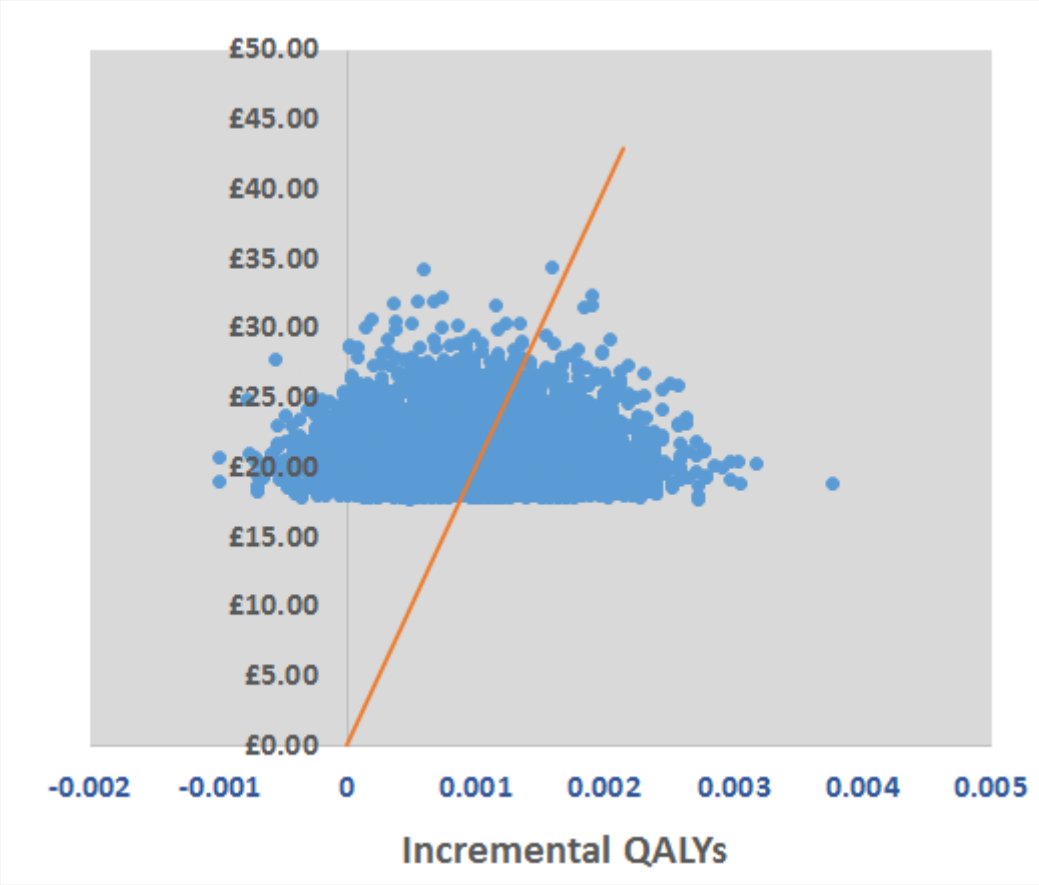


Figure 17: CEAC for a woman with a mean of 5 urinary incontinence episodes showing the probability that 75NC007 intravaginal device is cost-effective at different cost-effective thresholds using NICE (2012) data and an exponential functional form to estimate the relationship between urinary incontinence episodes and health state utility

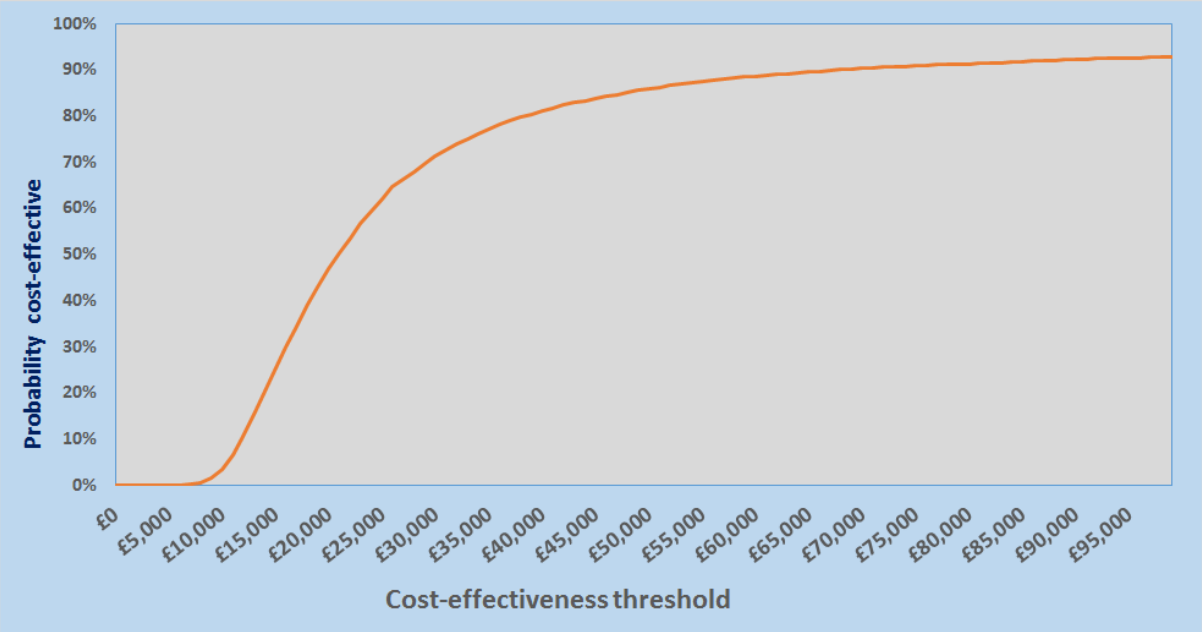


Figure 18 and Figure 19 illustrate the cost-effectiveness threshold for baseline urinary incontinence episodes for the 75NC007 intravaginal device when compared to no intervention, for a linear and 3rd order polynomial functional form when using NICE (2012) data to estimate the relationship between urinary incontinence episodes and health state utility. For a linear functional form, it shows that the 75NC007 is cost-effective for a mean baseline of above 4.6 urinary incontinence episodes per day (64 episodes per 14-day period). For a 3rd order polynomial the threshold is above 3.8 urinary incontinence episodes per day (52 episodes per 14-day period). The incremental net monetary benefit peaks at 112 episodes per 14-day period. The reason for this is because health state utility is constrained to a "floor" of zero beyond this. Therefore, utility gains are only realised for the the number of episodes below 112 per 14-day period and as the absolute baseline is increased above 112 per 14-day period there is a reduction in the number of episodes giving a gain in health state utility. At the extreme there would be no gain in health state utility from a reduction in IEF if the post-treatment level was greater than 112 episodes per 14-day period.

Figure 18: Relationship between baseline urinary incontinence episode frequency and iNMB when using NICE (2012) data and a linear functional form to estimate the relationship between urinary incontinence episodes and health state utility

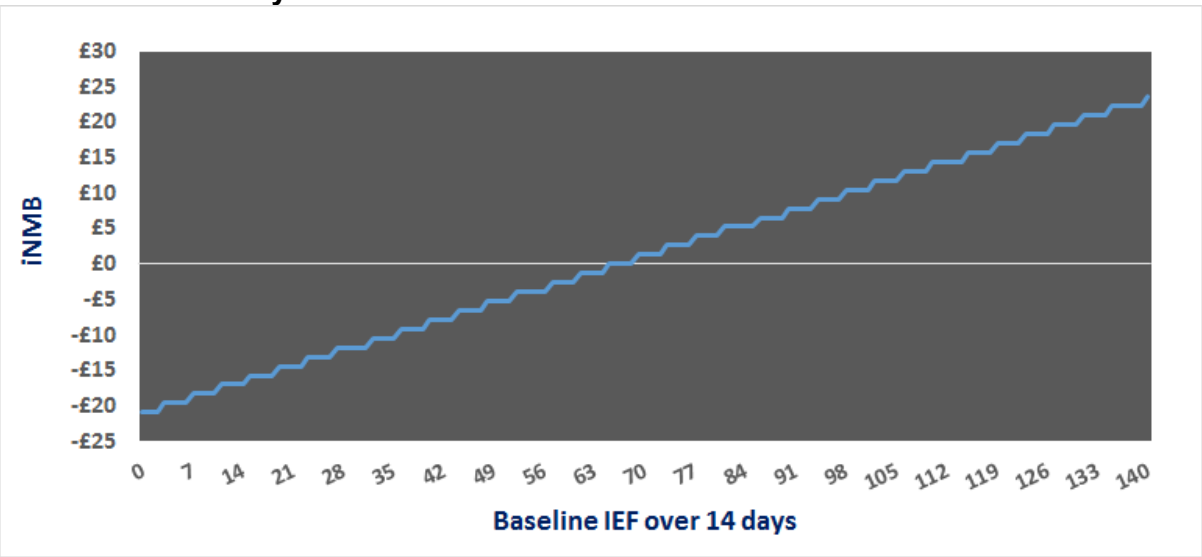


Figure 19: Relationship between baseline urinary incontinence episode frequency and iNMB when using NICE (2012) data and a 3rd order polynomial functional form to estimate the relationship between urinary incontinence episodes and health state utility

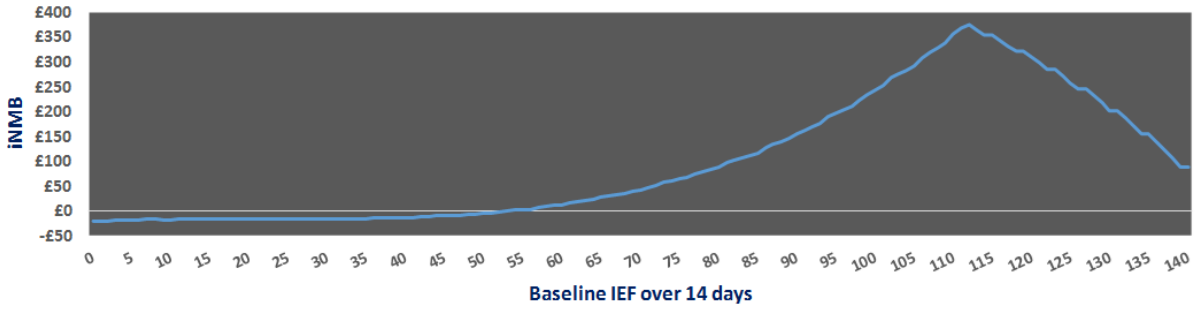


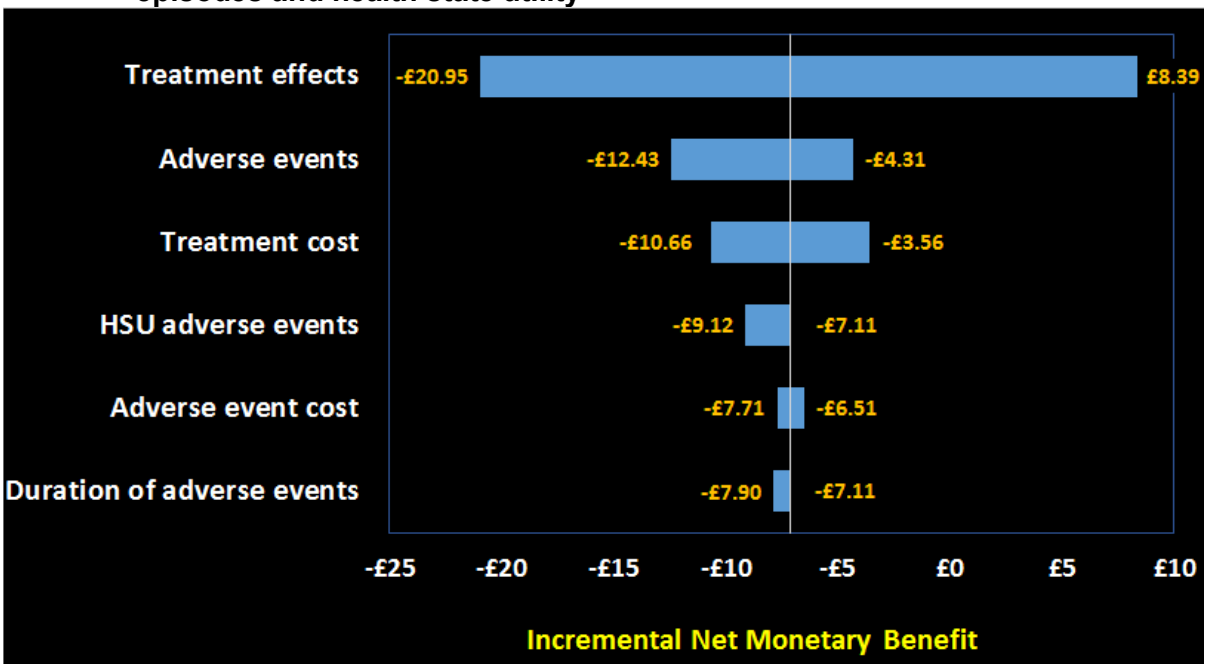
Figure 20 shows the relationship between treatment cost and the iNMB holding all other model inputs constant at their base case value and using NICE (2012) data and an exponential form to estimate the relationship between urinary incontinence episodes and health state utility. It indicates that the 75NC007 intravaginal device would be cost-effective relative to no intervention, at a cost-effectiveness threshold of £20,000 per QALY, if the treatment cost fell below £11.

Figure 20: Relationship between treatment cost and iNMB when using NICE (2012) data and an exponential functional form to estimate the relationship between urinary incontinence episodes and health state utility

Tornado analysis

Figure 21 shows the results of the Tornado analysis for the pre-specified variables and for the base case analysis using NICE (2012) data and an exponential functional form to estimate the relationship between urinary incontinence episodes and health state utility. The Tornado analysis suggests that treatment effectiveness is an important driver of the cost-effectiveness result and that the conclusions are likely to be robust with respect to parameter uncertainty for variables relating to adverse events. The Tornado analysis does not indicate that the results are particularly sensitive to treatment costs within the range specified but the value for this variable is known with certainty.

Figure 21: Tornado diagram when using NICE (2012) data and an exponential functional form to estimate the relationship between urinary incontinence episodes and health state utility



HSU = Health state utility

Two-way sensitivity analysis

For the 2-way sensitivity analyses the input parameters for the 2 variables were varied between the same ranges specified for the Tornado analysis (see Table 27). The results are presented for a number of 2-way sensitivity analyses in Figure 22, Figure 23, Figure 24, Figure 25 and Figure 26 below. All analyses were based on NICE (2012) data and using an exponential functional form to estimate the relationship between urinary incontinence episodes and health state utility. The analyses shown are limited to those 2-way sensitivity analyses involving treatment effectiveness as one of the variables varied as other comparators did not exhibit any trade-off between cost-effectiveness across the specified range for parameter values.

Figure 22: Two-way sensitivity analysis showing relationship between treatment effectiveness and treatment cost on cost-effectiveness using NICE (2012) data and an exponential functional form to estimate the relationship between urinary incontinence episodes and health state utility

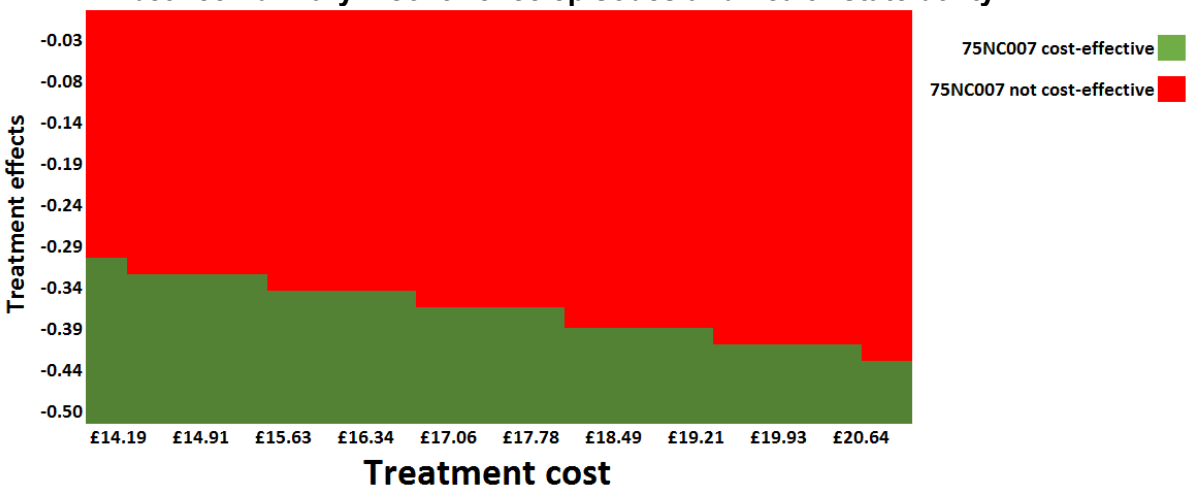


Figure 22 shows the extent that a greater treatment effect (through a larger percentage reduction in urinary incontinence episode frequency) is needed to offset greater treatment costs.

Figure 23: Two-way sensitivity analysis showing the relationship between treatment effectiveness and the cost of treatment related adverse events on cost-effectiveness using NICE (2012) data and an exponential functional form to estimate the relationship between urinary incontinence episodes and health state utility

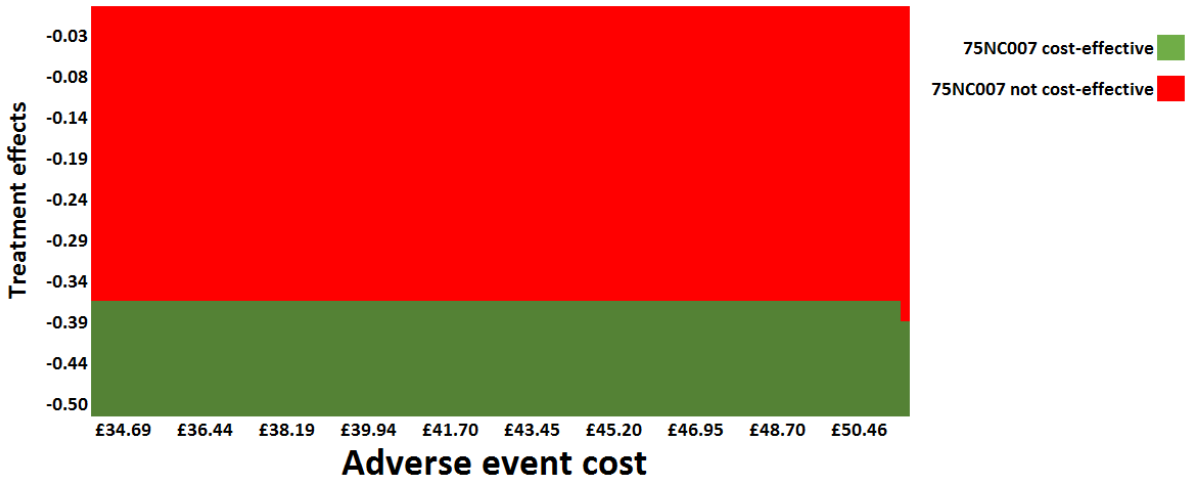


Figure 23 indicates that there is only a very gradual trade-off between the cost of treatment related adverse events and treatment effectiveness. This reinforces the results of the Tornado diagram that the cost of treatment related adverse events has only a very small impact on the model's results.

Figure 24: Two-way sensitivity analysis showing the relationship between treatment effectiveness and treatment related adverse events on cost-effectiveness using NICE (2012) data and exponential functional form to estimate the relationship between urinary incontinence episodes and health state utility

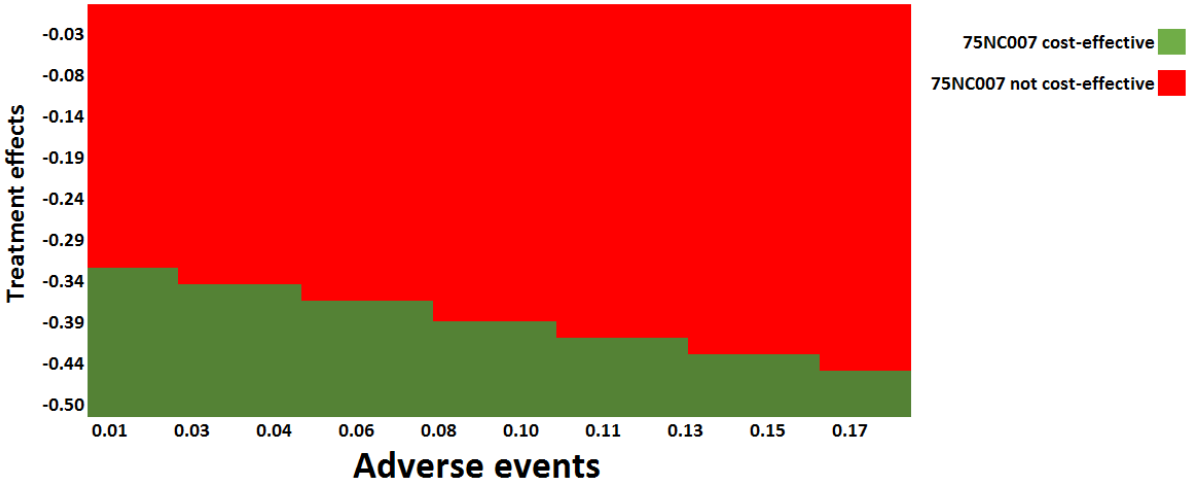
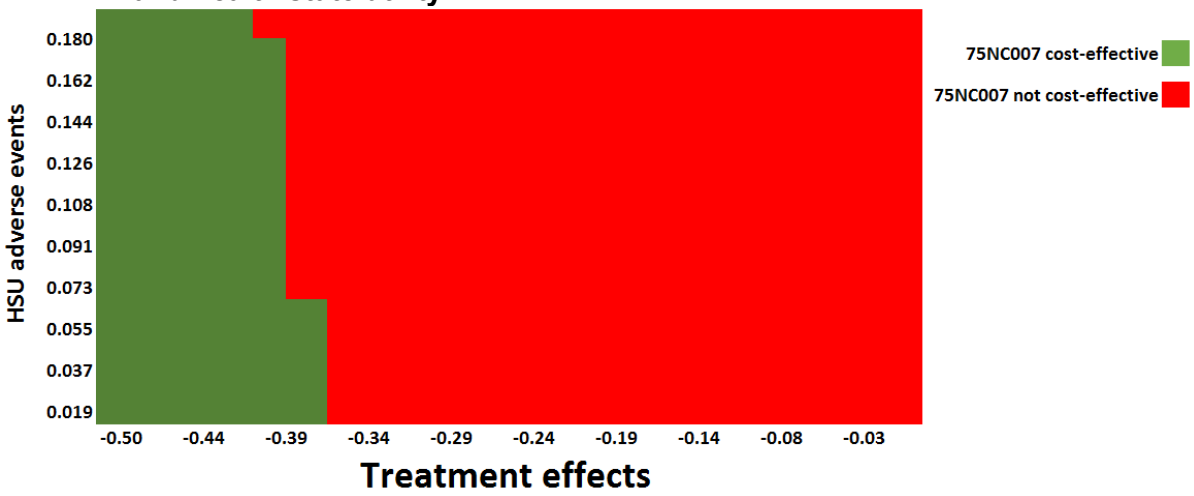


Figure 24 shows the extent of the trade-off between higher levels of treatment related adverse events and higher levels of treatment effectiveness required for cost-effectiveness.

Figure 25: Two-way sensitivity analysis showing the relationship between treatment effectiveness and the health state utility from adverse events on cost-effectiveness using NICE (2012) data and an exponential functional form to estimate the relationship between urinary incontinence episodes and health state utility



HSU = Health state utility

Figure 25 shows the extent to which greater treatment effectiveness is required to offset worse quality of life, or health state utility, associated with treatment related adverse events.

Figure 26: Two-way sensitivity analysis showing relationship between treatment effectiveness and the duration of treatment related adverse events on cost-effectiveness using NICE (2012) data and an exponential functional form to estimate the relationship between urinary incontinence episodes and health state utility

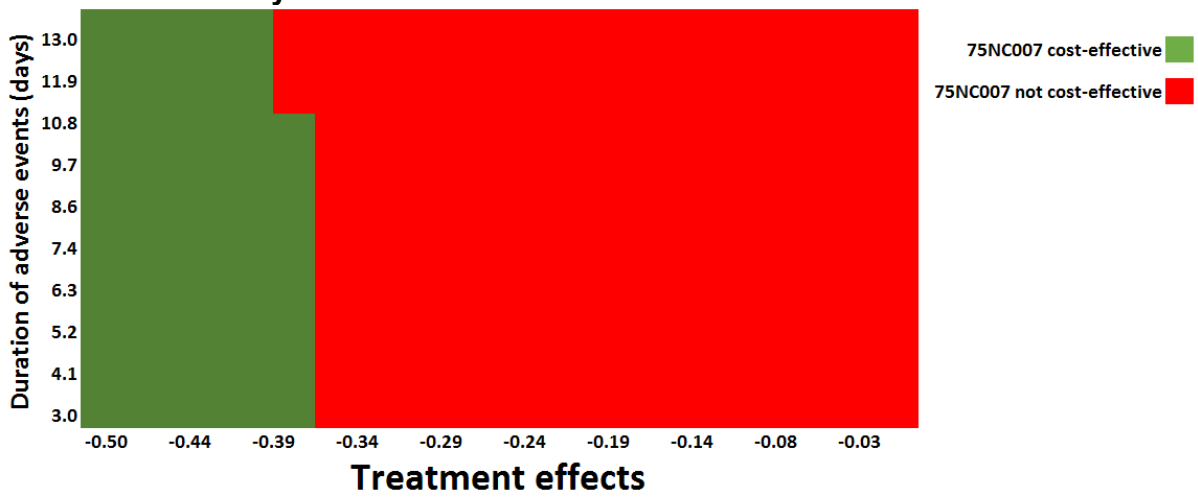


Figure 26 shows that there is only a very small trade-off between longer duration of treatment related adverse events and treatment effectiveness, at least for the relatively low level of health state utility loss associated with a urinary tract infection in the base case analysis.

Discussion

There are a number of major limitations that need to be considered in the interpretation of this analysis. This economic evaluation was undertaken to provide evidence about the cost-effectiveness of intravaginal devices but is based on just one fairly small study of one device. Whilst it may be reasonable to assume that other intravaginal devices would have similar clinical effectiveness, that it not known with certainty and any assumption about cost-effectiveness would also have to take into account any differences in the costs of the device.

Although the clinical evidence underpinning the economic model was based on a randomised study it was considered very low quality evidence with a high risk of bias.

The base case analysis considers a woman with a baseline of 45 urinary incontinence episode per 14-day period (or a mean of 3.3 urinary episodes per day). The results presented in Figure 15, Figure 16, Figure 17, Figure 18, Figure 19 and Table 33 clearly show that the baseline incontinence episode frequency is an important driver of the model's cost-effectiveness conclusions with cost-effectiveness increasing with greater symptom severity. However, all the results suggested that for a woman with a mean of 3.3 urinary incontinence episodes per day, that the 75NC007 intravaginal device was unlikely to be cost-effective when using a cost-effectiveness threshold of £20,000 per QALY. Even when using the most favourable assumptions about the relationship between urinary incontinence episodes and health state utility, the 75NC007 was only borderline cost-effective when using a higher cost-effectiveness threshold of £30,000 per QALY. Of course, for baseline of less than 3 urinary incontinence episodes per day, the model suggests that the 75NC007 intravaginal device was unlikely to be cost-effective even at this higher threshold. Conversely, the threshold analyses did indicate that for a woman with a mean of 5 or more urinary incontinence episodes per day at baseline, then the 75NC007 was reasonably likely to be cost-effective especially when using a £30,000 per QALY cost-effectiveness threshold.

Whilst the device cost is a known in the model and not a source of uncertainty when interpreting results, Figure 20 does indicate that the cost-effectiveness of the 75NC007 device is quite sensitive to large reductions in price, so that if the device was to fall in price over time then different cost-effectiveness conclusions could be reached.

The Tornado analysis in Figure 21 demonstrated that clinical effectiveness is a very important determinant of cost-effectiveness. It also shows that if the true treatment effect were to be nearer the upper limit of the 95% confidence interval then the cost-effectiveness conclusion would be likely to be very different. Of course, the likelihood of the true mean taking such values is reflected in the probabilistic sensitivity analysis. The Tornado analysis generally suggests that the model conclusions are much less affected by other model inputs although it should be noted that the model becomes markedly more sensitive to values relating to adverse events if a higher health state utility decrement from a urinary tract infection is assumed. So, adopting a relatively low health state utility decrement from a urinary tract infection in the base case analysis represents something of a "best-case" scenario for the 75NC007 intravaginal device.

However, it is also important to note the short time horizon of the model which is consistent with the guideline's recommendation that the device can be considered for a trial period. The model does not take into account a more comprehensive patient pathway where clinically efficacious 75NC007 could eliminate or delay progression to surgical management with its associated costs and risk of complications. In this respect the model may underestimate the cost-effectiveness of the 75NC007 intravaginal device.

Conclusion

This economic analysis provides good evidence that the 75NC007 device is cost-effective for women with a mean of 5 or more urinary incontinence episodes per day. For women with less than 3 urinary incontinence episodes per day then this evaluation does not provide

evidence that the 75NC007 intravaginal device would be cost-effective. For women with between 3 and 5 urinary incontinence episodes per day then the cost-effectiveness evidence is somewhat equivocal.

However, the committee's recommendations also should be seen in the context of the Independent Medicines and Medical Devices Safety Review (Cumberlege Report (2020) which aims to promote conservative management as an alternative to surgery, which has been associated with significant complications. The model does not take into account any "downstream" impact that 75NC007 may have in averting or delaying surgery which may mean that the cost-effectiveness is under-estimated.

Appendix K – Excluded studies

Excluded studies for review question: What is the effectiveness of physical devices (including support garments, pessaries and dilators) for improving symptoms of pelvic floor dysfunction?

Clinical studies

Table 34: Excluded studies and reasons for their exclusion (RCTs)

Study	Reason for Exclusion
Ayeleke, R. O., Hay-Smith, E. J. C., Omar, M. I., Pelvic floor muscle training added to another active treatment versus the same active treatment alone for urinary incontinence in women, Cochrane Database of Systematic Reviews, 2015	Systematic review. References checked One relevant study included (Richter 2010)
Baesler, K., Aigmuller, T., Albrich, S., Anthuber, C., Finas, D., Fink, T., Funfgeld, C., Gabriel, B., Henscher, U., Hetzer, F. H., Hubner, M., Junginger, B., Jundt, K., Kropshofer, S., Kuhn, A., Loge, L., Nauman, G., Peschers, U., Pfiffer, T., Schwandner, O., Strauss, A., Tunn, R., Viereck, V., Diagnosis and Therapy of Female Pelvic Organ Prolapse. Guideline of the DGGG, SGGG and OEGGG (S2e-Level, AWMF Registry Number 015/006, April 2016), Geburtshilfe und Frauenheilkunde, 76, 1287-1301, 2016	Systematic Review. Contains non-RCT including non-comparative observational studies and conference abstracts
Bastani, P., Danandeh Osgui, N., Improvement of concomitant symptoms of pelvic organ prolapsed with applied pessary, Clinical and Experimental Obstetrics and Gynecology, 46, 42-44, 2019	No clear evidence of randomisation
Bo, K., Urinary incontinence, pelvic floor dysfunction, exercise and sport, Sports MedicineSports Med, 34, 451-64, 2004	Systematic review. No relevant comparisons. Contains non-RCTs including cross sectional and retrospective studies in its analysis.
Bond, C., Youngson, G., MacPherson, I., Garrett, A., Bain, N., Donald, S., Macfarlane, T. V., Anal plugs for the management of fecal incontinence in children and adults: A randomized control trial, Journal of Clinical Gastroenterology, 41, 45-53, 2007	Mixed population. Includes all patients (children and adults-males and females) with faecal incontinence
Boos, K., Anders, K., Hextall, A., Toozs-Hobson, P., Cardozo, L., Randomised trial of reliance versus femassist devices in the management of genuine stress incontinence, Neurourology and urodynamics, 17, 455, 1998	Research thesis and abstract, not published data. Full text unavailable.
Bugge, C., Adams, E. J., Gopinath, D., Reid, F., Pessaries (mechanical devices) for pelvic organ prolapse in women, Cochrane Database of Systematic Reviews, 2, CD004010, 2013	Systematic review. Only one trial included, unable to combine outcome measures into a meta-analysis to provide a pooled effect estimate for each outcome. References checked, one relevant study included(Cundiff 2007).
Buono, K., Dave-Heliker, B., Mechanical inserts for the treatment of faecal incontinence: A	Mixed population. Includes all patients (children and adults-males and females) with faecal incontinence.

Study	Reason for Exclusion
systematic review, Arab Journal of Urology PrintArab J, 17, 69-76, 2019	
Christensen, P., Krogh, K., Transanal irrigation for disordered defecation: A systematic review, Scandinavian Journal of Gastroenterology, 45, 517-527, 2010	Systematic review. Mixed population. Includes all patients (children and adults-males and females) with faecal incontinence. Also includes patients with emptying disorders of the bowel not due to pelvic floor dysfunction(neurogenic)
Cundiff, G. W., Amundsen, C. L., Bent, A. E., Coates, K. W., Schaffer, J. I., Strohbehn, K., Handa, V. L., The PESSRI study: symptom relief outcomes of a randomized crossover trial of the ring and Gellhorn pessaries, American Journal of Obstetrics & Gynecology, 196, 405.e1-8, 2007	Study data not presented in a format we can extract.
de Boer, T. A., Salvatore, S., Cardozo, L., Chapple, C., Kelleher, C., van Kerrebroeck, P., Kirby, M. G., Koelbl, H., Espuna-Pons, M., Milsom, I., Tubaro, A., Wagg, A., Vierhout, M. E., Pelvic organ prolapse and overactive bladder, Neurourology & Urodynamics, 29, 30-9, 2010	Systematic review. References reviewed, which contain non-RCTs.
Deutekom, M., Dobben, A. C., Plugs for containing faecal incontinence, Cochrane Database of Systematic Reviews, 2015	Mixed population. Includes all patients (children and adults-males and females) with faecal incontinence.
Gupta, A., Cox, C., Dunivan, G. C., Gaskins, J. T., Rogers, R. G., Iglesia, C. B., Meriwether, K. V., Desire for continued pessary use among women of different ethnic and racial backgrounds for pelvic floor disorders, Female pelvic medicine & reconstructive surgery, 24, S101-, 2018	Secondary analysis of RCT. Only intervention group(pessary) analysed.
Lamers, B. H., Broekman, B. M., Milani, A. L., Pessary treatment for pelvic organ prolapse and health-related quality of life: a review, International Urogynecology Journal, 22, 637-44, 2011	Narrative review
Lee, H. S. J., 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	Full text unavailable from British Library
Leek, H., Stephenson, Z., Reus, A., Karantanis, E., Moore, K. H., Clean intermittent self-catheterisation: A randomised controlled crossover trial of single-use versus multiple re-use of non-coated catheters; is cystitis rate altered?, Neurourology and Urodynamics, 32, 759-760, 2013	conference abstract
Lipp, A., Shaw, C., Glavind, K., Mechanical devices for urinary incontinence in women, Cochrane Database of Systematic Reviews, CD001756, 2014	Systematic review. References checked. Eight relevant studies included.
Lukacz, E. S., Segall, M. M., Wexner, S. D., Evaluation of an Anal Insert Device for the Conservative Management of Fecal	Mixed population. Includes all patients (children and adults-males and females) with faecal incontinence.

Study	Reason for Exclusion
Incontinence, Diseases of the colon and rectum, 58, 892-898, 2015	
Meriwether, K. V., Komesu, Y. M., Craig, E., Qualls, C., Davis, H., Rogers, R. G., Sexual Function and Pessary Management among Women Using a Pessary for Pelvic Floor Disorders [Erratum Journal of Sexual Medicine. Vol.13(3), 2016, pp. 464], Journal of sexual medicine, 12, 2339-49, 2015	Secondary analysis of RCT. Only intervention group(pessary) analysed.
Montalti, C. S., Santos, N. F., Kasawara, K. T., Marques, A. A., Ferreira, N. O., Physical therapy to the treatment of female sexual dysfunction: A systematic review, Journal of Women's Health, 22 (3), 16, 2013	Conference abstract
Nager, C. W., Richter, H. E., Nygaard, I., Paraiso, M. F., Wu, J. M., Kenton, K., Atnip, S. D., Spino, C., Pelvic Floor Disorders, Network, Incontinence pessaries: size, POPQ measures, and successful fitting, International Urogynecology Journal, 20, 1023-8, 2009	Secondary analysis of RCT. Only intervention group(pessary) analysed.
Nielsen, K. K., Walter, S., Maegaard, E., Kromann-Andersen, B., The urethral plug II: an alternative treatment in women with genuine urinary stress incontinence, British journal of urology, 72, 428-32, 1993	Study data not presented in a format we can extract.
Norton, C., Kamm, M. A., Anal plug for faecal incontinence, Colorectal disease, 3, 323-327, 2001	Mixed population. Includes males and females with faecal incontinence.
Nygaard, I. E., Zinsmeister, A. R., Treatment of exercise incontinence with a vaginal pessary: A preliminary study, International Urogynecology Journal, 4, 133-137, 1993	Cross sectional study
Scarabelot, K., Pereira, F., Ghizzo, L., Willing, J., Virtuoso, J., Use of pessary in the treatment of pelvic floor dysfunctions: A systematic review, Physiotherapy Quarterly, 26, 1-8, 2018	Systematic review. No relevant comparisons. Evaluation of quality of studies, not results.
Schnyder, U., Schnyder-Luthi, C., Ballinari, P., Blaser, A., Therapy for vaginismus: in vivo versus in vitro desensitization, Canadian Journal of Psychiatry - Revue Canadienne de PsychiatrieCan J Psychiatry, 43, 941-4, 1998	Intervention does not meet the inclusion criteria. Comparison in behavioural/psychological techniques, not dilators.
Seav, S. M., Dominick, S. A., Stepanyuk, B., Gorman, J. R., Chingos, D. T., Ehren, J. L., Krychman, M. L., Su, H. I., Management of sexual dysfunction in breast cancer survivors: a systematic review, Womens Midlife HealthWomen's midlife health, 1, 9, 2015	Systematic review. No relevant comparisons.
Shamliyan,T.A., Kane,R.L., Wyman,J., Wilt,T.J., Systematic review: Randomized, controlled trials of nonsurgical treatments for urinary incontinence in women, Annals of Internal Medicine, 148, 459-473, 2008	Systematic review. References checked three relevant studies included (Robinson 2003, Nygaard 1995, Thyssen 2001)
Simillis, C., Lal, N., Pellino, G., Baird, D., Nikolaou, S., Kontovounisios, C., Smith, J. J., Tekkis, P. P., A systematic review and network meta-analysis comparing treatments for faecal	Mixed population. Includes males and females with faecal incontinence

Study	Reason for Exclusion
incontinence, International Journal of Surgery, 66, 37-47, 2019	
Tod, A. M., Stringer, E., Levery, C., Dean, J., Brown, J., Rectal irrigation in the management of functional bowel disorders: a review, British Journal of Nursing, 16, 858-64, 2007	Systematic review. Mixed population. Includes males and females.
Vitton, V., Soudan, D., Siproudhis, L., Abramowitz, L., Bouvier, M., Faucheron, J. L., Leroi, A. M., Meurette, G., Pigot, F., Damon, H., Treatments of faecal incontinence: Recommendations from the French national society of coloproctology, Colorectal disease, 16, 159-166, 2014	Systematic review including non-RCTs. References reviewed, no relevant comparisons. Patients with anal incontinence and constipation secondary to neurological disease included- not pelvic floor dysfunction
Ziv, E., Erlich, T., Keller, N., Vaginal prevalence of staphylococcus aureus with pop pessaries-is there a reason for concern?, Female pelvic medicine & reconstructive surgery, 25, S142-S143, 2019	Conference Abstract
Ziv, E., Erlich, T., Keller, N., Vaginal microflora and signs and symptoms of vaginal infection using a new disposable vaginal device for pop, Neurourology and urodynamics, 38, S423-S424, 2019	Conference Abstract
Study	Reason for Exclusion
Ayeleke, R. O., Hay-Smith, E. J. C., Omar, M. I., Pelvic floor muscle training added to another active treatment versus the same active treatment alone for urinary incontinence in women, Cochrane Database of Systematic Reviews, 2015	Systematic review. References checked One relevant study included (Richter 2010)
Baesler, K., Aigmuller, T., Albrich, S., Anthuber, C., Finas, D., Fink, T., Funfgeld, C., Gabriel, B., Henscher, U., Hetzer, F. H., Hubner, M., Junginger, B., Jundt, K., Kropshofer, S., Kuhn, A., Loge, L., Nauman, G., Peschers, U., Pfiffer, T., Schwandner, O., Strauss, A., Tunn, R., Viereck, V., Diagnosis and Therapy of Female Pelvic Organ Prolapse. Guideline of the DGGG, SGGG and OEGGG (S2e-Level, AWMF Registry Number 015/006, April 2016), Geburtshilfe und Frauenheilkunde, 76, 1287-1301, 2016	Systematic Review. Contains non-RCT including non-comparative observational studies and conference abstracts
Bastani, P., Danandeh Osgui, N., Improvement of concomitant symptoms of pelvic organ prolapsed with applied pessary, Clinical and Experimental Obstetrics and Gynecology, 46, 42-44, 2019	No clear evidence of randomisation
Bo, K., Urinary incontinence, pelvic floor dysfunction, exercise and sport, Sports MedicineSports Med, 34, 451-64, 2004	Systematic review. No relevant comparisons. Contains non-RCTs including cross sectional and retrospective studies in its analysis.
Bond, C., Youngson, G., MacPherson, I., Garrett, A., Bain, N., Donald, S., Macfarlane, T. V., Anal plugs for the management of fecal incontinence in children and adults: A randomized control trial, Journal of Clinical Gastroenterology, 41, 45-53, 2007	Mixed population. Includes all patients (children and adults-males and females) with faecal incontinence

Study	Reason for Exclusion
Boos, K., Anders, K., Hextall, A., Toozs-Hobson, P., Cardozo, L., Randomised trial of reliance versus femassist devices in the management of genuine stress incontinence, Neurourology and urodynamics, 17, 455, 1998	Research thesis and abstract, not published data. Full text unavailable.
Bugge, C., Adams, E. J., Gopinath, D., Reid, F., Pessaries (mechanical devices) for pelvic organ prolapse in women, Cochrane Database of Systematic Reviews, 2, CD004010, 2013	Systematic review. Only one trial included, unable to combine outcome measures into a meta-analysis to provide a pooled effect estimate for each outcome. References checked, one relevant study included(Cundiff 2007).
Buono, K., Dave-Heliker, B., Mechanical inserts for the treatment of faecal incontinence: A systematic review, Arab Journal of Urology PrintArab J, 17, 69-76, 2019	Mixed population. Includes all patients (children and adults-males and females) with faecal incontinence.
Christensen, P., Krogh, K., Transanal irrigation for disordered defecation: A systematic review, Scandinavian Journal of Gastroenterology, 45, 517-527, 2010	Systematic review. Mixed population. Includes all patients (children and adults-males and females) with faecal incontinence. Also includes patients with emptying disorders of the bowel not due to pelvic floor dysfunction(neurogenic)
Cundiff, G. W., Amundsen, C. L., Bent, A. E., Coates, K. W., Schaffer, J. I., Strohbehn, K., Handa, V. L., The PESSRI study: symptom relief outcomes of a randomized crossover trial of the ring and Gellhorn pessaries, American Journal of Obstetrics & Gynecology, 196, 405.e1-8, 2007	Study data not presented in a format we can extract.
de Boer, T. A., Salvatore, S., Cardozo, L., Chapple, C., Kelleher, C., van Kerrebroeck, P., Kirby, M. G., Koelbl, H., Espuna-Pons, M., Milsom, I., Tubaro, A., Wagg, A., Vierhout, M. E., Pelvic organ prolapse and overactive bladder, Neurourology & Urodynamics, 29, 30-9, 2010	Systematic review. References reviewed, which contain non-RCTs.
Deutekom, M., Dobben, A. C., Plugs for containing faecal incontinence, Cochrane Database of Systematic Reviews, 2015	Mixed population. Includes all patients (children and adults-males and females) with faecal incontinence.
Gupta, A., Cox, C., Dunivan, G. C., Gaskins, J. T., Rogers, R. G., Iglesia, C. B., Meriwether, K. V., Desire for continued pessary use among women of different ethnic and racial backgrounds for pelvic floor disorders, Female pelvic medicine & reconstructive surgery, 24, S101-, 2018	Secondary analysis of RCT. Only intervention group(pessary) analysed.
Lamers, B. H., Broekman, B. M., Milani, A. L., Pessary treatment for pelvic organ prolapse and health-related quality of life: a review, International Urogynecology Journal, 22, 637-44, 2011	Narrative review
Lee, H. S. J., 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	Full text unavailable from British Library
Leek, H., Stephenson, Z., Reus, A., Karantanis, E., Moore, K. H., Clean intermittent self-	conference abstract

Study	Reason for Exclusion
catheterisation: A randomised controlled crossover trial of single-use versus multiple re-use of non-coated catheters; is cystitis rate altered?, Neurourology and Urodynamics, 32, 759-760, 2013	
Lipp, A., Shaw, C., Glavind, K., Mechanical devices for urinary incontinence in women, Cochrane Database of Systematic Reviews, CD001756, 2014	Systematic review. References checked. Eight relevant studies included.
Lukacz, E. S., Segall, M. M., Wexner, S. D., Evaluation of an Anal Insert Device for the Conservative Management of Fecal Incontinence, Diseases of the colon and rectum, 58, 892-898, 2015	Mixed population. Includes all patients (children and adults-males and females) with faecal incontinence.
Meriwether, K. V., Komesu, Y. M., Craig, E., Qualls, C., Davis, H., Rogers, R. G., Sexual Function and Pessary Management among Women Using a Pessary for Pelvic Floor Disorders [Erratum Journal of Sexual Medicine. Vol.13(3), 2016, pp. 464], Journal of sexual medicine, 12, 2339-49, 2015	Secondary analysis of RCT. Only intervention group(pessary) analysed.
Montalti, C. S., Santos, N. F., Kasawara, K. T., Marques, A. A., Ferreira, N. O., Physical therapy to the treatment of female sexual dysfunction: A systematic review, Journal of Women's Health, 22 (3), 16, 2013	Conference abstract
Nager, C. W., Richter, H. E., Nygaard, I., Paraiso, M. F., Wu, J. M., Kenton, K., Atnip, S. D., Spino, C., Pelvic Floor Disorders, Network, Incontinence pessaries: size, POPQ measures, and successful fitting, International Urogynecology Journal, 20, 1023-8, 2009	Secondary analysis of RCT. Only intervention group(pessary) analysed.
Nielsen, K. K., Walter, S., Maegaard, E., Kromann-Andersen, B., The urethral plug II: an alternative treatment in women with genuine urinary stress incontinence, British journal of urology, 72, 428-32, 1993	Study data not presented in a format we can extract.
Norton, C., Kamm, M. A., Anal plug for faecal incontinence, Colorectal disease, 3, 323-327, 2001	Mixed population. Includes males and females with faecal incontinence.
Nygaard, I. E., Zinsmeister, A. R., Treatment of exercise incontinence with a vaginal pessary: A preliminary study, International Urogynecology Journal, 4, 133-137, 1993	Cross sectional study
Scarabelot, K., Pereira, F., Ghizzo, L., Willing, J., Virtuoso, J., Use of pessary in the treatment of pelvic floor dysfunctions: A systematic review, Physiotherapy Quarterly, 26, 1-8, 2018	Systematic review. No relevant comparisons. Evaluation of quality of studies, not results.
Schnyder, U., Schnyder-Luthi, C., Ballinari, P., Blaser, A., Therapy for vaginismus: in vivo versus in vitro desensitization, Canadian Journal of Psychiatry - Revue Canadienne de PsychiatrieCan J Psychiatry, 43, 941-4, 1998	Intervention does not meet the inclusion criteria. Comparison in behavioural/psychological techniques, not dilators.
Seav, S. M., Dominick, S. A., Stepanyuk, B., Gorman, J. R., Chingos, D. T., Ehren, J. L., Krychman, M. L., Su, H. I., Management of sexual dysfunction in breast cancer survivors: a	Systematic review. No relevant comparisons.

Study	Reason for Exclusion
systematic review, Womens Midlife HealthWomen's midlife health, 1, 9, 2015	
Shamliyan,T.A., Kane,R.L., Wyman,J., Wilt,T.J., Systematic review: Randomized, controlled trials of nonsurgical treatments for urinary incontinence in women, Annals of Internal Medicine, 148, 459-473, 2008	Systematic review. References checked three relevant studies included (Robinson 2003, Nygaard 1995, Thyssen 2001)
Simillis, C., Lal, N., Pellino, G., Baird, D., Nikolaou, S., Kontovounisios, C., Smith, J. J., Tekkis, P. P., A systematic review and network meta-analysis comparing treatments for faecal incontinence, International Journal of Surgery, 66, 37-47, 2019	Mixed population. Includes males and females with faecal incontinence
Tod, A. M., Stringer, E., Levery, C., Dean, J., Brown, J., Rectal irrigation in the management of functional bowel disorders: a review, British Journal of Nursing, 16, 858-64, 2007	Systematic review. Mixed population. Includes males and females.
Vitton, V., Soudan, D., Siproudhis, L., Abramowitz, L., Bouvier, M., Faucheron, J. L., Leroi, A. M., Meurette, G., Pigot, F., Damon, H., Treatments of faecal incontinence: Recommendations from the French national society of coloproctology, Colorectal disease, 16, 159-166, 2014	Systematic review including non-RCTs. References reviewed, no relevant comparisons. Patients with anal incontinence and constipation secondary to neurological disease included- not pelvic floor dysfunction
Ziv, E., Erlich, T., Keller, N., Vaginal prevalence of staphylococcus aureus with pop pessaries-is there a reason for concern?, Female pelvic medicine & reconstructive surgery, 25, S142-S143, 2019	Conference Abstract
Ziv, E., Erlich, T., Keller, N., Vaginal microflora and signs and symptoms of vaginal infection using a new disposable vaginal device for pop, Neurourology and urodynamics, 38, S423-S424, 2019	Conference Abstract

Table 35: Excluded studies and reasons for their exclusion (non-RCTs)

Study	Reason for Exclusion
Abdool, Z., Should we use pessaries for pelvic organ prolapse?, Obstetrics and Gynaecology Forum, 19, 57-59, 2009	Narrative review
Abdool, Z., Swart, P., Symptomatic pelvic organ prolapse: Experience at a tertiary urogynaecology clinic, South African Journal of Obstetrics and Gynaecology, 22, 18-20, 2016	Study outcomes not relevant, study reports demographic data of women only. Comparison group does not meet the inclusion criteria, surgical comparison
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	Comparative group does not meet the inclusion criteria, surgical comparison
Altman, D., Mikkola, T. S., Bek, K. M., Rahkola-Soisalo, P., Gunnarsson, J., Engh, M. E., Falconer, C., For the Nordic, T. V. M. group, Pelvic organ prolapse repair using the UpholdTM Vaginal Support System: a 1-year	Intervention does not meet the criteria, Uphold Vaginal Support system is a surgical mesh kit

Study	Reason for Exclusion
multicenter study, International Urogynecology Journal and Pelvic Floor Dysfunction, 27, 1337-1345, 2016	
Anand, M., Carbone, M., Heisler, C., Koehler, T., Davis, A., Bladder management following vaginal surgery for pelvic organ prolapse, American Journal of Obstetrics and Gynecology, 1), S506-S507, 2016	Conference abstract
Anders, K., Devices for continence and prolapse, BJOG: An International Journal of Obstetrics and Gynaecology, 111, 61-66, 2004	Narrative review
Awamlh, B. A. H. A., Wang, L., Stone, B., Bedretdinova, D., Forde, J., Li, P., Chugtai, B., Lee, R., Trends and failure rates in the medical treatment of pelvic organ prolapse for medicare patients, Journal of Urology, 1), e109-e110, 2016	Conference abstract
Bastawros, D., Rabon, H., Noor, N., Florian Rodriguez, M. E., Hobson, D., Tarr, M. E., Patient regretand satisfaction following uterosacral ligament suspension and sacral colpopexy: A prospective multicenter analysis from the fellows' pelvic research network, Female Pelvic Medicine and Reconstructive Surgery, 24 (5 Supplement 1), S97, 2018	Conference abstract
Bauer, C., Arnold-Long, M., Kent, D. J., Colostomy irrigation to maintain continence: An old method revived, Nursing, 46, 59-62, 2016	Narrative review
Bernstein, M. A., Purdy, C. H., Becker, A., Magar, R., Three-year cost-effectiveness model for non-animal stabilized hyaluronic acid and dextranomer copolymer compared with sacral nerve stimulation after conservative therapy for the management of fecal incontinence, Clinical Therapeutics, 36, 890-905, 2014	Cost effectiveness model study
Bo, K., Majida, M., Engh, M. E., Does a ring pessary in situ influence the pelvic floor muscle function of women with pelvic organ prolapse when tested in supine?, International urogynecology journal, 23, 573-577, 2012	Study design does not meet the inclusion criteria, cross over study. Outcomes not relevant - only resting pressure and muscle strength
Bradley,C.S., Rahn,D.D., Nygaard,I.E., Barber,M.D., Nager,C.W., Kenton,K.S., Siddiqui,N.Y., Abel,R.B., Spino,C., Richter,H.E., The questionnaire for urinary incontinence diagnosis (QUID): validity and responsiveness to change in women undergoing non-surgical therapies for treatment of stress predominant urinary incontinence, Neurourology and Urodynamics, 29, 727-734, 2010	Study design does not meet the criteria, non-comparative
Bulsei, J., Lehur, P., Durand-Zaleski, I., A comparison of magnetic anal sphincter and sacral neuromodulation for fecal incontinence: The MOS-STIC study costeffectiveness results, Colorectal Disease, 20 (Supplement 4), 6, 2018	Conference abstract
Cantarella, F., Magni, E., Conservative management of septic complication after internal Delorme procedure for occult rectal prolapse	Study design does not meet the inclusion criteria: case report

Study	Reason for Exclusion
and rectocele in obstructed defecation syndrome, Techniques in Coloproctology., 2018	
Carcio, H., The vaginal pessary: an effective yet underused tool for incontinence and prolapse, Advance for nurse practitioners, 12, 47-48, 50, 52-54 passim, 2004	Full text unavailable from the British Library
Cazemier, M., Felt-Bersma, R. J., Mulder, C. J., Anal plugs and retrograde colonic irrigation are helpful in fecal incontinence or constipation, World Journal of Gastroenterology, 13, 3101-5, 2007	Study design does not meet the inclusion criteria: non-comparative study
Coggins, J., Thomson, H. R., Cartwright, R., Self-reported changes in pelvic floor training frequency and incontinence symptoms with the intravaginal elvie device, Neurourology and Urodynamics, 36 (Supplement 3), S162-S164, 2017	Conference abstract
Dietz, H. P., Kamisan Atan, I., Langer, S., Shek, K. L., Guzman Rojas, R., Daly, J. O., Caudwell-Hall, J., Authors' reply re: Does the Epi-No birth trainer prevent vaginal birth-related pelvic floor trauma? A multicenter prospective randomised controlled trial, BJOG: An International Journal of Obstetrics & GynaecologyBjog, 123, 2225, 2016	Letter to the editor, original study checked for relevance; excluded as population and intervention do not meet the inclusion criteria
Dunn, M., Brandt, D., Nygaard, I., Treatment of exercise incontinence with a urethral insert: A pilot study in women, Physician and Sportsmedicine, 30, 45-48, 2002	Study design does not meet the inclusion criteria, non-comparative study
Fomenko, O., Titov, A., Belousova, S., Aleshin, D., Kozlov, V., Moscow, M., Alekseev, R., Mudrov, A., Nekrasov, M., Comparison of different schemes of conservative treatment of anal incontinence, Colorectal Disease, 20 (Supplement 4), 33, 2018	Conference abstract
Grzybowska, M. E., Wydra, D., 24/7 usage of continence pads and quality of life impairment in women with urinary incontinence, International Journal of Clinical Practice, 73 (8) (no pagination), 2019	Comparator group does not meet the inclusion criteria, study compares different levels of pad use not different devices
Holmes, P., Cones for continence, Nursing times, 86, 20-1, 1990	Full text unavailable from the British Library
Imamura, M., Jenkinson, D., Vale, L., Wallace, S., Buckley, B., Pickard, R., Conservative treatment options for women with stress urinary incontinence: Clinical update, British Journal of General Practice, 63, 218-220, 2013	Narrative review
Junemann, K. P., The management of female urinary stress incontinence: II. The use of devices, BJU International, 87, 449-55, 2001	Narrative review
Lacima, G., Pera, M., Amador, A., Escaramis, G., Pique, J. M., Long-term results of biofeedback treatment for faecal incontinence: A comparative study with untreated controls, Colorectal Disease, 12, 742-749, 2010	Intervention and comparison do not meet the inclusion criteria: Biofeedback versus control

Study	Reason for Exclusion
Lehur, P. A., Wyart, V., Riche, V. P., SaFaRI: sacral nerve stimulation versus the Fenix magnetic sphincter augmentation for adult faecal incontinence: a randomised investigation, International journal of colorectal disease, 31, 1505, 2016	Letter to the editor, study referenced checked for inclusion - only the protocol is published to date
Leong, A. F., Yunos, A. B., Stoma management in a tropical country: colostomy irrigation versus natural evacuation, Ostomy/wound management, 45, 52-56, 1999	Study design does not meet the inclusion criteria, cross over study. Participants included men, and no separate analysis was conducted
Lo, T., Ko, P., Tseng, L., Wang, A. C., Liang, C., Lin, Y., Pessary for pelvic organ prolapse: Quality of life, compliance and failure at one year follow up, International Urogynecology Journal and Pelvic Floor Dysfunction, 22, S954-S955, 2011	Conference abstract
Mouritsen, L., Effect of vaginal devices on bladder neck mobility in stress incontinent women, Acta Obstetricia et Gynecologica Scandinavica, 80, 428-431, 2001	Study design does not meet the inclusion criteria: non-comparative study
Norton, C., Kamm, M. A., Anal plug for faecal incontinence, Colorectal disease, 3, 323-327, 2001	Study design does not meet the inclusion criteria: non-comparative study
Oh, S. J., Ja, H. K., Seung, H. L., Hwang, G. J., Son, H., Effect of a 'centralized intensive education system' for clean intermittent self-catheterization in patients with voiding dysfunction who start catheterization for the first time, International Journal of Urology, 13, 905-909, 2006	Intervention does not meet the inclusion criteria, study on education. Study also included male participants
Overby, Z., Persons, R. K., Carrillo, M. J., Martin, S. N., What is the best nonsurgical therapy for pelvic organ prolapse?, Journal of Family PracticeJ, 63, 471, 2014	Narrative review
Pacik, P. T., Geletta, S., Vaginismus Treatment: Clinical Trials Follow Up 241 Patients, Sexual Medicine, 5, e114-e123, 2017	Study design does not meet the inclusion criteria: non-comparative cohort study
Rao, S. S. C., Diagnosis and management of fecal incontinence, American Journal of Gastroenterology, 99, 1585-1604, 2004	Narrative review
Rodenberg, T. A., Pessaries and prolapse, The Journal of the Florida Medical Association, 68, 895-897, 1981	Narrative review
Simpson, A. N., Garbens, A., Dossa, F., Coyte, P. C., Baxter, N. N., McDermott, C. D., A Cost-Utility Analysis of Nonsurgical Treatments for Stress Urinary Incontinence in Women, Obstetrical and Gynecological Survey, 74, 341-342, 2019	Intervention does not meet the inclusion criteria, cost-model analysis study
Stafford, T., Intermittent self-catheterisation today, British journal of community nursing, 22, 214-217, 2017	Narrative review
Steele, S. R., Varma, M. G., Prichard, D., Bharucha, A. E., Vogler, S. A., Erdogan, A., Rao, S. S. C., Lowry, A. C., Lange, E. O., Hall, G. M., Bleier, J. I. S., Senagore, A. J., Maykel,	Narrative review and data on surgical approaches

Study	Reason for Exclusion
J., Chan, S. Y., Paquette, I. M., Audett, M. C., Bastawrous, A., Umamaheswaran, P., Fleshman, J. W., Caton, G., O'Brien, B. S., Nelson, J. M., Steiner, A., Garely, A., Noor, N., Desrosiers, L., Kelley, R., Jacobson, N. S., The evolution of evaluation and management of urinary or fecal incontinence and pelvic organ prolapse, Current Problems in Surgery, 52, 92-136, 2015	
Suhail, M. A., Memon, S. U. R., Shaikh, U., The comparative role of optical urethrotomy with and without clean intermittent self catheterization (CISC) in urethral stricture, Medical Forum Monthly, 22, 13-17, 2011	Full text unavailable from the British Library
Swan, E., The VitalaTM Continence Control Device, British Journal of Nursing, 19, S4, 2010	Narrative summary of the product
Sze, E. H., Hobbs, G., A retrospective comparison of ring pessary and multicomponent behavioral therapy in managing overactive bladder, International Urogynecology Journal, 25, 1583-8, 2014	Comparative retrospective study. Does not meet the inclusion criteria.
Trsinar,B., Kraij,B., Maximal electrical stimulation in children with unstable bladder and nocturnal enuresis and/or daytime incontinence: a controlled study, Neurourology and Urodynamics, 15, 133-142, 1996	Population does not meet the inclusion criteria; the study included girls with a mean age of 9 years
Urzua, M., Alvarez, J., Rondini, C., Monroy, M., Pessary use in pelvic organ prolapse in women, International Urogynecology Journal, 28 (1 Supplement 1), S214, 2017	Conference abstract
Van Der Hagen, S. J., Van Der Meer, W., Soeters, P. B., Baeten, C. G., Van Gemert, W. G., A prospective non-randomized two-centre study of patients with passive faecal incontinence after birth trauma and patients with soiling after anal surgery, treated by elastomer implants versus rectal irrigation, International journal of colorectal disease, 27, 1191-1198, 2012	Intervention does not meet the inclusion criteria. Comparison is invasive procedure- elastomer implant injection.
Vierhout, M. E., Lose, G., Preventive vaginal and intra-urethral devices in the treatment of female urinary stress incontinence, Current Opinion in Obstetrics & GynecologyCurr Opin Obstet Gynecol, 9, 325-8, 1997	Non-systematic review
Wong, M., Meurette, G., Stangherlin, P., Lehur, P., The magnetic anal sphincter versus the artificial bowel sphincter-a comparison of 2 treatments for fecal incontinence, Diseases of the Colon and Rectum, 54 (5), e34-e35, 2011	Intervention and comparison do not meet the inclusion criteria; invasive procedures.
Woodward, S., Treating chronic constipation and faecal incontinence using transanal irrigation, British Journal of Nursing, 26, 1220-1222, 2017	Narrative review

Economic studies

Table 36: Excluded economic studies

Study	Reason for Exclusion
Fader, M., Cottenden, A., Getliffe, K., Gage, H., Clarke-O'Neill, S., Jamieson, K., et al.,, Absorbent products for urinary/faecal incontinence: a comparative evaluation of key product designs, Health Technology Assessment, 12, 1-208, 2008	Study is quite dated and analysis is not restricted to NHS costs. Effectiveness and health related quality of life was not assessed using EQ-5D
Yamasato, K., Kaneshiro, B., Oyama, I. A., A simulation comparing the cost-effectiveness of adult incontinence products, Journal of Wound, Ostomy, & Continence Nursing, 41, 467-72, 2014	Costing undertaken from patient perspective

Appendix L – Research recommendations

Research recommendations for review question: What is the effectiveness of physical devices (including support garments, pessaries and dilators) for improving symptoms of pelvic floor dysfunction?

Research question

How effective are anal plug devices and rectal irrigation, for bowel symptoms in women with pelvic floor dysfunction?

Why this is important

Bowel symptoms such as faecal incontinence are commonly associated with pelvic floor dysfunction. Physical devices are regularly used in clinical practice to manage faecal incontinence but there is little evidence about their effectiveness in women with pelvic floor dysfunction and some people find physical devices difficult to tolerate. The existing evidence for such devices consists of studies in mixed populations which do not separate men and women in their analyses.

Table 37: Research recommendation rationale

Research question	
Why is this needed	
Importance to 'patients' or the population	Managing bowel symptoms, such as faecal incontinence, effectively has a huge impact on a person's quality of life and independence.
Relevance to NICE guidance	The NICE guideline on Faecal incontinence in adults: management has recommendations on physical devices for faecal incontinence in the general adult population.
Relevance to the NHS	NHS policy puts an emphasis on prevention and keeping people well for longer. Incontinence is reported as a significant reason for care home admissions Prevention is a key part of any strategy to minimise harm and reduce health care costs.
National priorities	See NHS England Excellence in Continence Care (2018).
Current evidence base	Evidence is lacking in women with PFD.
Equality	Potential equality issues related to age, physical and learning disabilities in the practical use of these physical devices.
Feasibility	RCTs have been carried out investigating physical devices for faecal incontinence in other populations, so a trial should be feasible. These devices are already in used current clinical practice.
Other comments	None

PFD: pelvic floor dysfunction; RCT: randomised controlled trial

Table 38: Research recommendation modified PICO table

Criterion	Explanation
Population	Women (aged 12 or older) with pelvic floor dysfunction and bowel symptoms (faecal incontinence)
Intervention	• anal plug devices • rectal irrigation
Comparator	• Standard care
Outcomes	• bowel symptoms (including faecal incontinence)

Criterion	Explanation
	• quality of life • side-effects • satisfaction & tolerability
Study design	RCT
Timeframe	12 months
Additional information	None

RCT: randomised controlled trial