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TABLE OF CONTENTS

[Intervention Protocol]

Conservative interventions for managing urinary incontinence after prostate surgery

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ABSTRACT

Objectives

This is a protocol for a Cochrane Review (intervention). The objectives are as follows:

To assess the effects of conservative interventions for managing urinary incontinence after prostate surgery; and to summarise the principal findings of relevant economic evaluations.

BACKGROUND

For a glossary of terms used, see Appendix 1.

Description of the condition

Urinary incontinence (UI) in men, especially older men, may be multifactorial and can be broadly attributed to non-neurologic and neurologic causes (Hester 2017). The International Continence Society (ICS) defines urinary incontinence as the "complaint of an involuntary loss of urine" (D'Ancona 2019). It can be further categorised as urgency urinary incontinence (UUI; the loss of urine associated with a sudden strong desire to urinate), stress urinary incontinence (SUI; involuntary loss of urine on effort or physical exertion (e.g. when sneezing, coughing or laughing)), or mixed urinary incontinence (MUI; where a person has both UUI and SUI).

The prostate is a walnut-sized gland which helps to make semen. It is located below the urinary bladder and wraps around the urethra (the channel allowing urine from the urinary bladder to leave the body). Enlargement of the prostate may be associated with difficulties in urination, such as a weak or intermittent urinary stream, a more frequent or urgent urination, nocturia (waking up in the night to go to the toilet) and a prolonged dribbling at the end of urination, among others. Such symptoms are termed lower urinary tract symptoms (LUTS). Benign (non-cancerous) prostate enlargement may block the urinary bladder outlet, preventing urine flow (known as benign prostatic obstruction (BPO)). BPO is relatively common in older men and, when symptoms are minimally bothersome, it can often be managed with lifestyle changes. Men with moderate to severe LUTS are usually managed with medications if conservative treatment has failed or is not appropriate (NICE 2015). Surgery for treating LUTS secondary to BPO (LUTS/BPO) aims to remove the excess prostate tissue blocking the urethra and preventing urine flow. It may be offered to men whose symptoms have not resolved after alternative options have been explored or men who present with complications of BPO. Surgical options include transurethral resection of the prostate (TURP), where the central obstructing part of the prostate is removed using electricity through a loop of thin wire. On the other hand, surgery offered to men with prostate cancer - radical prostatectomy (RP) - aims to remove the entire prostate gland harbouring the cancer.

Men with LUTS, as well as those with prostate cancer, may develop urinary incontinence as a consequence of surgery (Sandhu 2019). Gravas 2020 reported the prevalence of urinary incontinence after TURP as 2.2%. Birder 2017 indicated that 2% to 60% of men report urinary incontinence after radical prostatectomy. Although urinary incontinence often improves in the early postoperative period, Nelson 2020 reported that 3.6% of men who have undergone radical prostatectomy will eventually have a surgical procedure for urinary incontinence. Several factors have been reported that may affect the risk of developing urinary incontinence following radical prostatectomy, including advanced age, obesity, a history of TURP, a higher tumour stage or grade, higher prostate-specific antigen levels, a larger prostate volume or preoperative detrusor overactivity (Goldman 2017; Kim 2016; Pastore 2017). The experience of the surgeon may also have a significant impact, with lower urinary incontinence rates at centres performing large numbers of radical prostatectomies (Chen 2019; Fossati 2017).

The type of surgery applied for treating LUTS/BPO may influence the risk of urinary incontinence, which is attributed to direct external sphincter injury during surgery, often reflecting the surgeon's level of experience (Rassweiler 2006; Shigemura 2016). However, comparative data from randomised controlled trials (RCTs) evaluating the risk of urinary incontinence after the various types of surgery for treating LUTS/BPO are scarce (Cornu 2015). Urinary incontinence following radical prostatectomy is caused by external sphincter dysfunction, bladder dysfunction or both. External sphincter dysfunction is the primary abnormality in most cases with severe urinary incontinence, regardless of the presence of abnormal bladder function (Holm 2015). External sphincter dysfunction can be caused during the surgery by inadvertent injury to the external sphincter or damage to the pudendal nerve that innervates (supplies nerves to) this mechanism, or be due to the loss of pliability associated with post-operative fibrosis (formation of scar tissue) (Arcila-Ruiz 2018; Goldman 2017). External sphincter dysfunction is the most common cause of refractory SUI (which does not resolve on its own) following radical prostatectomy (Arcila-Ruiz 2018).

Urinary incontinence has a significant economic cost. The economic burden of urinary incontinence following radical prostatectomy is comparable to that of the instigating surgery (Lent 2015). The estimated economic burden of managing urinary incontinence in men in the USA was USD 18.8 billion (USD 18,800 million, USD 1998/1999), with a trend showing a rapid increase for men above the age of 65 years (Stothers 2005). Urinary incontinence was associated with an annual per-person expenditure of USD 7702 (USD 1998/1999), which was more than double those without the condition (Stothers 2005). Urinary incontinence also has a significant impact on the personal well-being of both men and women, with an increased prevalence of mental health problems (Cheng 2020).

Description of the intervention

Where possible, urinary incontinence following prostate surgery is managed conservatively. Lifestyle management options include moderating caffeine intake, physical exercise, modifying diet or fluid intake, weight loss and smoking cessation (Imamura 2015).

Pelvic floor muscle training (PFMT), described by the joint terminology document of the International Urogynecology Association (IUGA)/International Continence Society (ICS), as exercises to improve pelvic floor muscle strength, endurance, power, relaxation or a combination of these parameters (Bo 2017), may also be suggested. PFMT may be combined with biofeedback, which utilises an external sensor to give an indication of the muscle activity, which in turn helps the individual to improve their techniques (Bo 2017). Biofeedback includes verbal feedback, electromyographic feedback from anal or perineal electrodes or feedback from manometry or ultrasonography (Berghmans 2020; Nunes 2019). In its simplest form, biofeedback could be verbal communication by an assessor who confirms the contraction (or relaxation) of the pelvic floor by physical examination.

In some cases, electrical stimulation (ES) is offered to men with urinary incontinence following prostate surgery. Electrical stimulation can be applied through three routes:

- intracavitary (intrarectal) or perineal surface electrical stimulation: used to directly stimulate the urethral sphincter and pelvic floor muscles;
- percutaneous stimulation: applied to the posterior tibial nerve with a fine needle, which is inserted just above the medial aspect of the ankle (P-PTNS); or
- transcutaneous surface stimulation: applied to the posterior tibial nerve for treating UUI (T-PTNS).

A less invasive treatment is magnetic stimulation therapy, which is the application of a magnetic flux to stimulate the pelvic floor, urethral sphincter and perineal muscles. It can be applied through clothing without the need for surface electrodes or intracavitary probes.

How the intervention might work

There is uncertainty about the benefit of conservative treatments for men with urinary incontinence after prostate surgery. Much of the evidence base for the effect of individual lifestyle interventions for the treatment of urinary incontinence is limited or inconsistent (Burkhard 2020). The effects on urinary incontinence of reducing caffeine and fluid intake, regular exercise and reducing weight have mostly been studied in women (Danforth 2006; Hannestad 2003; Harding 2021; Hunskaar 2008; Subak 2009). However, it is possible that these effects could be broadened to men.

PFMT improves bladder outlet resistance, which is confirmed by both subjective and objective tests, with a reduction in the volume, symptoms and bother of urinary incontinence following prostate surgery. PFMT has been shown to improve UUI both by inhibiting the bladder during storage as well as by urethral obstruction (Dumoulin 2017).

Electrical stimulation can be used to treat the sphincteric weakness associated with SUI or for the treatment of UUI with or without detrusor overactivity. Magnetic stimulation has been used to resolve detrusor overactivity for UUI, as well as for SUI by passive stimulation of the pelvic floor (Lim 2015).

Why it is important to do this review

The value of the various approaches to conservative management of urinary incontinence after prostate surgery remains uncertain, and the evidence is conflicting. This review aims to summarise the best available evidence in an attempt to provide definite answers on the value of the conservative management options available for urinary incontinence following any type of surgery. In addition, understanding the cost implications of conservative treatment within a brief economic commentary will help to place the treatments within an economic context.

OBJECTIVES

To assess the effects of conservative interventions for managing urinary incontinence after prostate surgery; and to summarise the principal findings of relevant economic evaluations.

METHODS

Criteria for considering studies for this review

Types of studies

We will include RCTs and quasi-RCTs (studies that are not necessarily random, e.g. allocated by day of the week) assessing conservative interventions for managing urinary incontinence following prostate surgery.

We will exclude cross-over RCTs and cluster-RCTs because neither study designs is appropriate for addressing the review question. For a cross-over study, this is because it is inappropriate to assess long-term performance. In addition, an effective treatment provided in the first period of a cross-over study cannot clearly be separated from the second period. Cluster randomised designs are adopted to avoid contamination between randomised groups, an issue that would be less important for this study question.

Types of participants

We will include studies of adult men (aged 18 or over) with urinary incontinence following prostate surgery for treating prostate cancer or LUTS/BPO. We will include studies where men have undergone either radical prostatectomy (open, laparoscopic or robot-assisted) or any one of the established techniques of prostate surgery for treating LUTS/BPO: monopolar transurethral resection of the prostate (M-TURP); bipolar transurethral resection of the prostate (B-TURP); thulium laser vaporesection of the prostate (ThuVAPR); transurethral incision of the prostate (TUIP); open prostatectomy (OP); bipolar transurethral enucleation of the prostate (B-TUEP); holmium laser enucleation of the prostate (HoLEP); thulium laser enucleation of the prostate (ThuLEP); diode laser enucleation of the prostate (DiLEP); bipolar transurethral vaporisation of the prostate (B-TUVP); 532 nm ('Greenlight') laser vaporisation of the prostate; and prostatic urethral lift (PUL)) (Gravas 2021).

We will only include studies of men with urinary incontinence after prostate surgery has been performed. We will not include studies of men who had urinary incontinence prior to prostate surgery, or studies in which there is a mixed population of men (i.e. those who did and did not have urinary incontinence prior to surgery), unless data for those who subsequently developed urinary incontinence are presented separately.

Types of interventions

We will include any studies where at least one arm includes a conservative intervention for treating urinary incontinence after prostate surgery. We will exclude trials comparing conservative management options with medical or surgical treatments.

Due to the major difference in the aetiology of urinary incontinence following radical prostatectomy and prostatic surgery for LUTS/BPO, we will explore the effects of conservative interventions on these procedures through subgroup analysis (see Subgroup analysis and investigation of heterogeneity).

We will include these comparisons:

- PFMT versus no treatment or sham treatment;
- PFMT versus verbal or written instructions;
- PFMT plus biofeedback versus no treatment or sham treatment;

- electrical or magnetic stimulation versus no treatment or sham treatment;
- lifestyle interventions versus no treatment or sham treatment;
- combinations of conservative treatments versus no treatment or sham treatment; and
- one conservative treatment versus another conservative treatment.

In this review, 'sham treatment' means any treatment that could not influence the pelvic floor muscles, such as placing an electrical stimulation probe in the anus but not turning it on. We have split comparisons with PFMT as no treatment or sham treatment is 'passive', whereas receiving verbal or written instructions can be considered 'active' in that they may encourage people to undertake PFMT, which could further affect results. Biofeedback is often given as an adjunct to PFMT to improve its effectiveness.

We will consider 'PFMT plus biofeedback versus no treatment or sham treatment', 'electrical or magnetic stimulation versus no treatment or sham treatment' and 'combinations of conservative treatments versus no treatment or sham treatment' for the 'Summary of findings' tables as these comparisons help to answer whether conservative treatments may be beneficial in managing urinary incontinence after prostate surgery.

Types of outcome measures

We will assess the following outcome measures.

Primary outcomes

- Subjective cure or improvement (patient-reported as defined by the trialists)
- Condition-specific quality of life assessed using validated questionnaires (e.g. International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form (ICIQ-UI-SF) or ICIQ-SF)

Secondary outcomes

- Objective cure or improvement of urinary incontinence (e.g. pad test per 24 hours, frequency per 24 hours or other standardised test)
- Participant adherence to the intervention (as reported by the trialists)
- General quality of life (e.g. Short Form 36 (Ware 1993))
- Number of participants experiencing local adverse events (e.g. skin reactions, bruising, hypersensitivity to gel)
- Number of participants experiencing muscle-related adverse events (e.g. soreness, discomfort, cramps, pain)
- Number of participants experiencing organ dysfunction (e.g. bowel dysfunction or painful defecation, for example after a intracavitary rectal probe, or erectile dysfunction)

Timing of outcome assessment

We will assess outcomes in the short term (> 3 to 6 months) and long term (> 6 to 12 months).

Main outcomes for 'Summary of findings' tables

We will include the following outcome measures in the 'Summary of findings' tables.

- Subjective cure or improvement (patient-reported as defined by the trialists)
- Condition-specific quality of life assessed using validated questionnaires (e.g. International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form (ICIQ-UI-SF) or ICIQ-SF)
- Objective cure or improvement of urinary incontinence (e.g. pad test per 24 hours, frequency per 24 hours or other standardised test)
- Participant adherence to the intervention (as reported by the trialists)
- General quality of life (e.g. Short Form 36 (Ware 1993))
- Number of participants experiencing local adverse events (e.g. skin reactions, bruising, hypersensitivity to gel)
- Number of participants experiencing muscle-related adverse events (e.g. soreness, discomfort, cramps, pain)

We will measure outcomes for the 'Summary of findings' tables in the long term (> 6 to 12 months).

Search methods for identification of studies

We will not impose any language or other limitations on any of the searches described below.

Electronic searches

Search for clinical effectiveness studies

We will identify relevant trials from the Cochrane Incontinence Specialised Register. For more details of the search methods used to build the Specialised Register, please see the Group's webpages where details of the Register's development (from inception) and the most recent searches performed to populate the Register can be found. To summarise, the Register contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, MEDLINE In-Process, MEDLINE Epub Ahead of Print, ClinicalTrials.gov, and WHO ICTRP, and handsearching of journals and conference proceedings. Many of the trials in the Cochrane Incontinence Specialised Register are also contained in CENTRAL. The terms that we will use to search the Cochrane Incontinence Specialised Register are given in Appendix 2.

Search for economic evaluations

We will perform additional searches for the brief economic commentary (BEC). We will search:

- The NHS Economic Evaluation Database (NHS EED) on the Centre for Reviews and Dissemination (CRD) website (covering from the earliest record in NHS EED, dating from 1968, up to and including 31 December 2014 when their coverage ended).

As NHS EED is no longer actively updated, we will perform additional searches of these databases to identify eligible studies added to them from 1 January 2015 onwards:

- MEDLINE on OvidSP (covering 1 January 1946 to the most recent available version); and
- Embase (on OvidSP) (covering 1 January 1974 to the most recent available version).

Details of the searches that will be performed can be found in Appendix 3.

Searching other resources

We will search the reference lists of included studies and any relevant systematic reviews to identify other potentially eligible trials.

Data collection and analysis

We will conduct data collection and analysis in accordance with methods specified in the *Cochrane Handbook for Systematic Reviews of Interventions* (hereafter referred to as the *Cochrane Handbook,* Higgins 2019).

Selection of studies

Two review authors (EJ and SS) will independently screen the titles and abstracts identified by the search. We will obtain the full-texts of any potentially relevant reports and assess these against our eligibility criteria. The two review authors will compare results and will resolve any disagreements through discussion or arbitration by a third review author (MIO or CM) if necessary.

Data extraction and management

Two review authors (EJ and SS) will independently extract information from included studies using a prepiloted data extraction form. The two review authors will discuss their individual extractions and come to a consensus. We will resolve any disagreements through discussion or arbitration by a third review author (MIO or CM) if necessary.

Assessment of risk of bias in included studies

We will use Cochrane's 'risk of bias' tool to assess the risk of bias in included studies (Chapter 8 of the *Cochrane Handbook*; Higgins 2011). Two review authors (EJ and SS) will independently assess each eligible study against each of the six domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessors, incomplete outcome data, selective reporting and other potential sources of bias. We will rate each domain as either 'high', 'unclear' or 'low' risk of bias for each study. We will resolve any disagreements through discussion or arbitration by a third review author (MIO).

Measures of treatment effect

For dichotomous outcomes, we will measure treatment effect using risk ratios (RR) with their corresponding 95% confidence intervals (CIs). For continuous outcome data, we will use mean difference (MD) with corresponding 95% CI. Where continuous outcomes are reported using different scales, we will use standardised mean difference (SMD) and 95% CI if the scales are reported using similar means (e.g. higher score equals more positive result).

Unit of analysis issues

Where included studies have more than two treatment arms, we will analyse each pair of arms in separate comparisons where appropriate. In order to avoid double-counting study participants in multi-arm studies that have three treatment arms that can be included in the same meta-analysis, we will divide in half the number of participants and events for the arm that will be included twice.

Dealing with missing data

Where possible, we will analyse data on an intention-to-treat (ITT) basis. If ITT data are not available, we will contact the study authors of trials where data are missing or incomplete for further information. If we are unable to obtain this information from the study authors, we will use per protocol data in meta-analyses but indicate where this is the case.

Assessment of heterogeneity

We will assess the level of heterogeneity within meta-analyses by calculating the Chi^2 and I^2 statistics using RevMan 5 software (Review Manager 2020). We will use the thresholds indicated by the *Cochrane Handbook* (Higgins 2019):

- 0% to 40%: might not be important;
- 30% to 60%: may represent moderate heterogeneity;
- 50% to 90%: may represent substantial heterogeneity;
- 75% to 100%: considerable heterogeneity.

Assessment of reporting biases

If more than 10 studies are included in a meta-analysis, we will generate a funnel plot in RevMan 5 to determine whether small-study bias is present (Review Manager 2020).

Data synthesis

We will use RevMan 5 to perform meta-analyses, where possible (Review Manager 2020). We will use a fixed-effect model unless there is substantial or considerable heterogeneity as defined by the *Cochrane Handbook* (Higgins 2019). In this case, we will use a random-effects model. If meta-analyses are not possible, we will narratively report the results of included studies.

Subgroup analysis and investigation of heterogeneity

We plan to perform these subgroup analyses:

- type of urinary incontinence (SUI, UUI, MUI); and
- type of surgical procedure (prostate surgery for treating prostate cancer and prostate surgery for treating LUTS/BPO).

Sensitivity analysis

We will perform sensitivity analyses for studies within meta-analyses that are deemed to be at a high risk of bias. We will judge any study assessed to be at 'high' risk for at least one domain to be at an overall high risk of bias.

Incorporating economics evidence

Following the search outlined in the Search methods for identification of studies, we will develop a BEC to summarise the availability and principal findings of full economic evaluations that assess conservative interventions for managing urinary incontinence after prostate surgery (Aluko 2020). This BEC will encompass full economic evaluations (i.e. cost-effectiveness analyses, cost-utility analyses and cost-benefit analyses) conducted as part of a single empirical study, such as a RCT, a model based on a single such study or a model based on several such studies.

Summary of findings and assessment of the certainty of the evidence

We will prepare 'Summary of findings' tables using the GRADEpro software for the main comparisons prestated in the Types of interventions if there is sufficient evidence (GRADEpro GDT).

We will use the GRADE approach to assess the certainty of evidence related to the primary and secondary outcomes as listed in the Types of outcome measures (Schünemann 2020). We will use the five GRADE considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the certainty of the body of evidence for the prespecified outcomes. We will justify all decisions to downgrade the certainty of studies using footnotes.

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APPENDICES

Appendix 1. Glossary of terms

532 nm ('Greenlight') laser vaporisation of the prostate	An operation performed through the urethra (the channel allowing urine from the urinary bladder to leave the body) for men who have problems passing urine because of a benign (non-cancerous) enlargement of the prostate gland that surrounds the urethra. It utilises a specific type of laser absorbed by blood cells (Greenlight) to enlarge the urinary channel by melting away (vaporising) excess prostate tissue that is blocking the urethra and preventing urine flow.
Benign prostatic obstruction (BPO)	Blocking of the bladder outlet for urine flow due to non-cancerous enlargement of the prostate gland.
Bipolar transurethral enucleation of the prostate (B-TUEP)	An operation performed through the urethra for men who have problems passing urine because of non-cancerous enlargement of the prostate gland. It utilises electrical energy delivered through an electrical circuit completed at the operation site (bipolar circuitry) to enlarge the urinary channel. It does this by removing as a whole (enucleating) the central part of the prostate tissue that is blocking the urethra (the adenoma, or benign tumour) to the urinary bladder. Another instrument (a morcellator) is then used to cut the adenoma into small pieces in the urinary bladder. The small pieces are then easily removed from the urinary bladder.
Bipolar transurethral vaporisation of the prostate (B-TUVP)	An operation performed through the urethra for men who have problems passing urine because of non-cancerous enlargement of the prostate gland. It utilises electrical energy delivered through an electrical circuit completed at the operation site (bipolar circuitry) to enlarge the urinary chan-

(Continued)

	nel by melting away (vaporising) excess prostate tissue that is blocking the urethra and preventing urine flow.
Bipolar TURP (B-TURP)	An operation performed through the urethra for men who have problems passing urine because of non-cancerous enlargement of the prostate gland. It utilises electrical energy delivered through an electrical circuit completed at the operation site (bipolar circuitry) to enlarge the urinary channel by cutting into small pieces (resecting) excess prostate tissue that is blocking the urethra and preventing urine flow. The small pieces are then easily removed from the urinary bladder.
Biofeedback	A form of feedback using an external sensor that can be combined with pelvic floor muscle training as a way of enhancing the therapy.
Detrusor	A muscle found in the wall of the urinary bladder.
Detrusor overactivity (DO)	Involuntary sudden spasms of the muscle that surrounds the urinary bladder (detrusor) resulting in a sudden urge to urinate that may be followed by an involuntary loss of urine.
Diode laser enucleation of the prostate (DiLEP)	An operation performed through the urethra for men who have problems passing urine because of non-cancerous enlargement of the prostate gland. It utilises a specific type of laser absorbed by water (diode laser) to enlarge the urinary channel by removing as a whole (enucleating) the central part of the prostate tissue that is blocking the urethra (adenoma) to the urinary bladder. Another instrument (a morcellator) is then used to cut the adenoma into small pieces in the urinary bladder that are easily removed.
Electrical therapy	The use of electrical potential or electrical currents to encourage therapeutic responses.
Holmium laser enucleation of the prostate (HoLEP)	An operation performed through the urethra for men who have problems passing urine because of non-cancerous enlargement of the prostate gland. It utilises a specific type of laser absorbed by water (holmium laser) to enlarge the urinary channel by removing as a whole (enucleating) the central part of the prostate tissue that is blocking the urethra (adenoma) to the urinary bladder. Another instrument (a morcellator) is then used to cut the adenoma into small pieces in the urinary bladder that are easily removed.
Intracavitary electrical stimulation	Delivery of electrical stimuli through the anus.
Magnetic stimulation:	The use of a magnetic field to encourage therapeutic responses.
Micturition	Micturition, or urination, is the act of passing urine from the body
Mixed urinary incontinence (MUI)	Incontinence that occurs when a person has symptoms of both stress urinary incontinence and urgency urinary incontinence.
Monopolar transurethral resection of the prostate (M-TURP)	An operation performed through the urethra for men who have problems passing urine because of non-cancerous enlargement of the prostate gland. It utilises electrical energy delivered through an electrical circuit that travels through the body to reach a skin pad (monopolar circuitry) to enlarge the urinary channel by cutting into small pieces (resecting) excess prostate tissue that is blocking the urethra and preventing urine flow. The small pieces are then easily removed from the urinary bladder.
Open prostatectomy (OP)	An operation performed through an incision (cutting) of the body for men who have problems passing urine because of non-cancerous enlargement of the prostate gland. The index finger of the surgeon is used to enlarge the urinary channel by removing as a whole (enucleate) the central part of the prostate tissue (the adenoma, or benign tumour) that is blocking the urethra.
Pelvic floor muscle training (PFMT)	Training and exercises that include a correct contraction of the pelvic floor muscles into daily activities (e.g. lifting, getting out of bed).

(Continued)

Prostate enucleation methods	Methods that remove as a whole (enucleate) the central part of the prostate tissue that is blocking the urethra (adenoma).
Prostatic urethral lift (PUL)	An operation performed through the urethra for men who have problems passing urine because of non-cancerous enlargement of the prostate gland. It utilises small permanent suture-based implants to enlarge the urinary channel by pushing aside (encroaching) the excess prostate tissue that is blocking the urethra and preventing urine flow.
Radical prostatectomy (RP) surgery	An operation for men with prostate cancer that aims to remove the entire prostate gland.
Refractory SUI	Stress urinary incontinence that does not resolve or improve on its own.
Stress urinary incontinence (SUI)	Incontinence that is caused by physical exertion (e.g. sneezing or coughing).
Thulium laser vaporesection of the prostate treatment (ThuVAPR)	An operation performed through the urethra for men who have problems passing urine because of non-cancerous enlargement of the prostate gland. It utilises a specific type of laser absorbed by water (thulium laser) to enlarge the urinary channel by simultaneously cutting into small pieces (resecting) and melting away (vaporising) excess prostate tissue that is blocking the urethra and preventing urine flow. The small pieces are then easily removed from the urinary bladder.
Thulium laser enucleation of the prostate (ThuLEP)	An operation performed through the urethra for men who have problems passing urine because of non-cancerous enlargement of the prostate gland. It utilises a specific type of laser absorbed by water (thulium laser) to enlarge the urinary channel by removing as a whole (enucleating) the central part of the prostate tissue that is blocking the urethra (adenoma) to the urinary bladder. Another instrument (a morcellator) is then used to cut the adenoma into small pieces in the urinary bladder that are easily removed.
Transcutaneous electrical stimulation	Delivery of electrical stimuli through the skin using patches.
Transient urinary incontinence (UI)	Urinary incontinence that resolves or improves on its own.
Transurethral incision of the prostate (TUIP)	An operation performed through the urethra for men who have problems passing urine because of non-cancerous enlargement of the prostate gland. It utilises electrical energy to open the bladder outlet by cutting (incising) it without prostatic tissue removal.
Urgency urinary incontinence (UUI)	Incontinence where a sudden urge to urinate is followed by an involuntary loss of urine.
Urodynamics	Procedures that look at how well the bladder, sphincters and urethra are storing and releasing urine. Most urodynamic tests focus on the bladder's ability to hold urine and empty steadily and completely. Urodynamic tests can also show whether the bladder is having involuntary contractions that cause urine leakage.

Appendix 2. Search for clinical effectiveness studies

We will search the Cochrane Incontinence Specialised Register using the following terms:

topic.urine.incon.postprost*
AND
(design.cct* OR design.rct*)

All searches will be of the keywords field of EndNote 2018.

Appendix 3. Search for economic evaluations for the brief economic commentary (BEC)

We will perform electronic searches designed to identify published reports of relevant economic evaluations to inform the BEC (see 'Incorporating economic evidence' in the Methods). We will search:

- The NHS Economic Evaluation Database (NHS EED) on the UK Centre for Reviews and Dissemination (CRD) website (covering from the earliest record in NHS EED, dating from 1968, up to and including 31 December 2014 when their coverage ended).

As NHS EED is no longer actively updated we will perform additional searches of the following databases to identify eligible studies added to these databases from 1 January 2015 onwards:

- MEDLINE on OvidSP (covering 1 January 1946 to the most recent available version); and
- Embase (on OvidSP) (covering 1 January 1974 to the most recent available version).

The economic evaluation search filters which will be applied to our MEDLINE and Embase search strategies will be those formerly used by the CRD to identify published reports of full economic evaluations for indexing on NHS EED. These economic evaluation search filters remain freely available on the CRD Database website (CRD 2015). The other search lines in the MEDLINE and Embase search strategies will be adapted from the electronic search strategies run for our Cochrane Incontinence Specialised Register along with additional terms for this population developed specifically for this review. Similarly, our NHS EED search strategy will be adapted from search strategies run for our Specialised Register and based on textword and MeSH terms (capturing relevant P-I-C concepts) used to identify eligible studies of intervention effects. We will follow the current economic methods guidance (Aluko 2020).

CONTRIBUTIONS OF AUTHORS

EJ: conceived the methods, contributed to the development of the PICO, commented on the Background
CM: contributed to the development of the PICO, commented on the Background
MIO: helped conceive the methods, contributed to the development of the PICO, commented on the Background
SS: contributed to the development of the PICO, developed and helped revise the Background

EJ is the guarantor of this review.

DECLARATIONS OF INTEREST

In accordance with Cochrane's Commercial Sponsorship Policy, the following declarations are relevant from 36 months before the title was registered.

EJ: Training Fellow and Assistant Managing Editor for Cochrane Incontinence. She will take no part in the editorial process for this protocol or the subsequent review.
CM: Panel Member of the European Association of Urology (EAU) Working Group for the EAU Guidelines on Management of Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS), including Benign Prostatic Obstruction (BPO)
MIO: I work for the European Association of Urology, Guidelines Office, as the Vice-Chair of the Methods Committee, Guidelines Office Methodology Supervisor and a member of the non-neurogenic female LUTS panel.
SS: None known

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NOTES

To aid clarity, the previous Cochrane Review on this topic has been split into prevention and management (this review) of this condition (Anderson 2015).