# National Institute for Health and Care Excellence

Final

# Pelvic floor dysfunction: prevention and non-surgical management

[F] Pelvic floor muscle training for the prevention of pelvic floor dysfunction.

NICE guideline number NG210

Evidence review underpinning recommendations 1.3.9 to 1.3.16 and 6 research recommendations (of which 3 were prioritised as key recommendations 2, 3 and 6) in the NICE guideline

Evidence reviews

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**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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# Pelvic floor muscle training for the prevention of pelvic floor dysfunction

## **Review question**

What is the effectiveness of pelvic floor muscle training for preventing pelvic floor dysfunction?

#### Introduction

Primary prevention aims to prevent disease or injury before it ever occurs. Identifying strategies such as pelvic floor muscle training that can be undertaken to prevent pelvic floor dysfunction is important to reduce the incidence long term. Determining the absence of symptoms can be difficult when undertaking these studies, for example all women who have had a vaginal delivery would potentially have Stage 1 pelvic organ prolapse (POP) which often does not bother them or they may not even know they have it and would not seek help. The aim of this review is to assess whether pelvic floor muscle training will help prevent pelvic floor dysfunction in women (regardless of whether they are in an obstetric or non-obstetric setting).

#### 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)

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Population	Women and young women (aged 12 years and older) without symptoms of pelvic floor dysfunction
Intervention	<ul> <li>Pelvic floor muscle exercises / Kegel exercise, to include:         <ul> <li>Pelvic floor muscle contraction exercises</li> <li>Pelvic floor muscle strengthening exercises</li> <li>Pelvic floor muscle training</li> <li>Pelvic floor muscle retraining</li> <li>Knack</li> </ul> </li> <li>Pelvic floor relaxation exercises/relaxation training</li> </ul>
Comparison	<ul> <li>No treatment</li> <li>Other preventive measures (for example leaflets, weight loss advice)</li> <li>Alternative method of PFMT delivery (app vs face to face, group vs individual)</li> <li>Combination therapies (PFMT alone or in combination)</li> </ul>
Outcome	Critical
	Development of the following symptoms, associated with pelvic floor dysfunction:     urinary incontinence     emptying disorders of the bladder     faecal incontinence     emptying disorders of the bowel     pelvic organ prolapse     sexual dysfunction     chronic pelvic pain syndromes
	For the above outcomes, only validated tools will be included
	Important
	Adherence to PFMT

PFMT: pelvic floor muscle training

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 <u>Developing NICE guidelines: the manual</u>. Methods specific to this review question are described in the review protocol in appendix A and the methods document (supplementary document 1).

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

#### Clinical evidence

#### Included studies

Fifteen studies from 18 citations were included for this review, 14 randomised controlled trials (RCTs) from 17 citations (Agur 2008 & Reilly 2002, Berzuk 2015, Chiarelli 2002 & 2004, Citak 2010, Golmakani 2015, Kahyaoglu 2016, Lin 2020, Pelaez 2014, Pourkhiz 2017, Qi 2019, Sacomori 2019, Sampselle 2005 & Diokno 2004, Sangsawang 2016, Yang 2017) and 1 quasi-randomised controlled trial (Kocaoz 2013).

The included studies are summarised in Table 2.

Of the 15 studies, 13 recruited women in an obstetric setting, of which 6 studies recruited women in the antenatal period (Agur 2008 & Reilly 2002, Kahyaoglu 2016, Kocaoz 2013, Pelaez 2014, Pourkhiz 2017 and Sangsawang 2016) and 7 studies recruited women in the postnatal period (Chiarelli 2002 & 2004, Citak 2010, Golmakani 2015, Lin 2020, Qi 2019, Sacomori 2019 and Yang 2017). One study recruited women through an office environment (Berzuk 2015) and 1 through the community (Sampselle 2005 & Diokno 2004).

One study investigated pelvic floor muscle training (PFMT) for preventing symptoms of pelvic floor disorder (Berzuk 2015); 5 studies for stress urinary incontinence (Agur 2008 & Reilly 2002, Kocaoz 2013, Lin, 2020, Qi 2019 and Sangsawang 2016); 6 studies for urinary incontinence (Chiarelli 2002 & 2004, Kahyaoglu 2016, Pelaez 2014, Sacomori 2019, Sampselle 2005 & Diokno 2004 and Yang 2017); 1 study for pelvic organ prolapse (Yang 2017); and 3 studies for sexual dysfunction (Citak 2010, Golmakani 2015 and Pourkhiz 2017).

Seven studies reported adherence to the PFMT intervention (Agur 2008 & Reilly 2002, Chiarelli 2002 & 2004, Pelaez 2014, Pourkhiz 2017, Sacomori 2019, Sampselle 2005 & Diokno 2004 and Sangsawang 2016).

No studies were identified for PFMT at prevention of faecal incontinence, emptying disorders of the bowel, emptying disorders of the bladder or chronic pelvic pain syndrome.

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.

Table 2: Summary of included studies.

Table 2: Summary of included studies.					
				Outcomes	
Study	Population	Intervention <sup>1</sup>	Comparison	and follow-up	
Agur 2008 (8 year follow-up from Reilley 2002) RCT UK	N=268, primigravidae women  N=164 included for analysis  Age (years), median (range): Intervention 27 (17-42); Control 29 (16-47)  Women recruited in an obstetric setting (at 20 weeks gestation)	Intervention Women received supervised PFMT from a physiotherapist from 20 weeks to birth  8 year follow-up from Reilly n=79	Control Usual postpartum care n=85	<ul> <li>SUI at 8 years</li> <li>Adherence to PFMT at 8 years</li> </ul>	
Berzuk 2015 RCT Canada	N=161, women working in an office  N=145 included for analysis  Age 18-29 years (n): 12 30-39 years (n): 32 40-49 years (n): 48 50-59 years (n): 47 60-69 years (n): 4  Women were recruited from an office environment	Intervention A 60-min educational presentation on pelvic floor health and PFM exercises, including verbal instructions for a PFM home strengthening program. Re- education occurred 2 months later. n=54  Intervention B 60-min presentation only n=55	Control No educational presentation n=52	<ul> <li>PFD symptoms at 2 months</li> <li>PFD QoL at 2 months</li> <li>Note: adherence to education intervention was not reported</li> </ul>	
Chiarelli 2002 RCT Australia	N=720, postnatal women  N=676 included for analysis  Age 15-19 years, n (%): 42 20-24 years, n (%): 131 25-29 years, n (%): 253 30-34 years, n (%): 210 35-39 years, n (%): 75 40-44 years, n (%): 9  Women were recruited on the postnatal ward (within 48h of birth)	Intervention Women saw a physiotherapist for PFMT during hospital stay and again at 8 weeks. Intervention included discussion, booklet actively competing the exercises, compliance aids. n=370	Control Usual postpartum care n=350	<ul> <li>UI at 3 months postpartum</li> <li>Severe UI symptoms at 3 months postpartum</li> <li>Adherence to PFMT at 3 months</li> </ul>	

				Outcomes
Study	Population	Intervention <sup>1</sup>	Comparison	and follow-up
Chiarelli 2004 (12 month follow up from Chiarelli 2002) RCT Australia	N=720, postnatal women  N=569 included for analysis  Women were recruited on the postnatal ward (within 48h of birth)	Intervention Women saw a physiotherapist for PFMT during hospital stay and again at 8 weeks. Intervention included discussion, booklet actively competing the exercises, compliance aids.  12 month follow up from Chiarelli 2002 n=294	Control Usual postpartum care n=275	<ul> <li>UI at 12 months postpartum</li> <li>Adherence to PFMT at 12 months</li> </ul>
Citak 2010 RCT	N=118, primiparous women who delivered vaginally	Intervention Women were instructed in PFM	Control Usual postpartum	<ul><li>FSFI at 4 months</li><li>FSFI at 7</li></ul>
Turkey	N=75 included for analysis  Age (years), mean (SD): Intervention 23.0 (3.2); Control 22.2 (3.1)  Women were recruited in an obstetric setting (within the first week post birth)	training by a special nurse, given a booklet and a programme of exercises to follow along with being educated on PFM and how to contract correctly.  n=58	care n=60	months  Note: Adherence to PFMT was checked through follow up phone calls, but was not reported
Diokno 2004 (originating from the same RCT as described in Sampselle 2005) RCT	N=480, post- menopausal women without UI  N=395 included for analysis  Age (years), mean (SD): Intervention 65.4 (6.7); Control 66.2 (6.4)  Post-menopausal women recruited from the community	Intervention Women attended a 2 hour education session on PFMT, including instructions and practice in locating and exercising the PFMs, prescription for PFMT and strategies on how to include PFMT in everyday life n=238	Control No education n=242	• UI at 12 months
Golmakani 2015 RCT	N=104, nulliparous women 8 weeks after vaginal delivery	Intervention Supervised PFM and Kegel exercises, following a PFM	Control Usual postpartum care	<ul> <li>Bailes sexual self-efficacy questionnaire after 4 weeks of training</li> </ul>
Iran	N=79 included for analysis  Age (years), mean (SD): Intervention 25.19	exercise plan n=52	n=52	<ul> <li>Bailes sexual self-efficacy questionnaire after 8 weeks of training</li> </ul>

				Outcomes
Study	Population	Intervention <sup>1</sup>	Comparison	and follow-up
	(3.78); Control 26.57 (3.92)  Women were recruited in an obstetric setting (at 8 weeks postpartum)			
Kahyaoglu 2016 RCT Turkey	N=64, pregnant women  N=60 included for analysis  Age (years), mean (SD): Intervention 30.0 (6.5); Control 27.2 (6.3)  Women recruited in an obstetric setting (in the 3 <sup>rd</sup> trimester of pregnancy)	Intervention Women were taught how to perform Kegel exercises and given an exercise plan to follow n=32	Control Usual postpartum care n=32	<ul> <li>UDI-6 at 36-38 weeks gestation</li> <li>IIQ-7 at 36-38 weeks gestation</li> <li>OAB-q total score at 36-38 weeks gestation</li> <li>UDI-6 at 6-8 weeks postpartum</li> <li>IIQ-7 at 6-8 weeks postpartum</li> <li>OAB-q total score at 6-8 weeks postpartum</li> </ul>
Kocaoz 2013  Quasi-RCT  Turkey	N=136, pregnant women without UI  N=102 included for analysis  Age (years), mean (SD): Intervention 26.33 (4.8); Control 25.70 (4.4)  Women recruited in an obstetric setting (at 14 to 20 weeks gestation)	Intervention Women were given training and information about their PFMs and an exercise programme to follow n=68	Control Usual postpartum care n=68	<ul> <li>SUI (via pad test) at 28 weeks gestation</li> <li>SUI (via pad test) at 32 weeks gestation</li> <li>SUI (via pad test) at 12 weeks postpartum</li> </ul>
Lin 2020 RCT China	N=97, puerperae and primiparae women with singleton pregnancies  N=97 included for analysis  Age (years), mean (SD): Intervention 28.01 (2.23); Control 27.99 (2.41)  Women recruited in an obstetric setting	Intervention A PFMT programme including Kegel exercises for 6-8 weeks, biofeedback and electrical stimulation for 6 months, and vaginal cone training. n=49	Control Usual postpartum rehabilitation nursing n=48	<ul> <li>SUI incidence at 6 months</li> <li>ICIQ-SF score at 6 months</li> <li>I-QOL score at 6 months</li> </ul>

				01
Study	Population	Intervention <sup>1</sup>	Comparison	Outcomes and follow-up
Otady	(postpartum, puerperae women)	intervention	Companison	una fonow-up
Pelaez 2014  RCT  Spain	N=169, primiparous pregnant women with singleton pregnancy  N=152 included for analysis  Age (years), mean (SD): Intervention 29.9 (3.3); Control 29.1 (4.5)  Women recruited in an obstetric setting (at 10-14 weeks gestation)	Intervention A 22 week structured PFM exercise programme, 3 times a week for 60 mins including other exercises along with 10 mins of PFMT n=73	Control Usual antenatal care n=96	<ul> <li>ICIQ-Score at 36-40 weeks gestation</li> <li>Adherence to PFMT</li> </ul>
Pourkhiz 2017 RCT Iran	N=84, pregnant women with singleton pregnancies  N=82 included for analysis  Age (years), mean (SD): Intervention 26.0 (4.1); Control 25.3 (4.7)  Women recruited in an obstetric setting (at 17 to 20 weeks gestation)	Intervention Women were given a PFM exercise programme to follow n=42	Control Usual postpartum care n=42	<ul> <li>FSFI at 28-30 weeks gestation</li> <li>SQOL-F at 28-30 weeks gestation</li> <li>FSFI at 3 months postpartum</li> <li>SQOL-F at 3 months postpartum</li> <li>Adherence to PFMT</li> </ul>
Qi 2019 RCT China	N=240, women with singleton pregnancies with vaginal delivery  N=240 included for analysis  Age (years), mean (SD): Intervention 29.6 (4.3); Control 30.3 (4.8)  Women recruited in an obstetric setting (within 1 week of birth)	Intervention Women were given educational materials at discharge and a 6 week exercise programme to follow from weeks 2 to 8 postpartum n=120	Control Usual postpartum care, which included information about PFMT n=120	SUI at 8     weeks     postpartum
Reilly 2002 RCT UK	N=268, primigravidae women  N=230 included for analysis  Age (years), median (range): Intervention 27	Intervention Women received supervised PFMT from a physiotherapist from 20 weeks to birth n=139	Control Usual postpartum care n=129	<ul> <li>SUI at 3         months         postpartum</li> <li>Pad test at 3         months         postpartum</li> <li>Adherence to         PFMT from 20         weeks to birth</li> </ul>

				Outcomes
Study	Population	Intervention <sup>1</sup>	Comparison	and follow-up
	(17-42); Control 29 (16-47)  Women recruited in an obstetric setting (at 20 weeks gestation)			
Sacomori 2019 RCT Brazil	N=202, women immediately postpartum  N= 132 included for analysis  All women were over 18 years  Women recruited in an obstetric setting (soon after birth, on the ward)	Intervention Women attended an education session explain PFM function and how to do the exercises along with being given an exercise plan to follow n=98	Control Usual postpartum care n=104	<ul> <li>ICIQ at 3         months         postpartum</li> <li>Adherence to         PFMT over 3         months</li> </ul>
Sampselle 2005 (same RCT as Diokno 2004 with different outcomes) RCT USA	N=480, postmenopausal women without UI  N=359 included for analysis  Age (years), mean (SD): Intervention 65.4 (6.7); Control 66.2 (6.4)  Postmenopausal women recruited from the community	Intervention Women attended a 2 hour education session on PFMT, including instructions and practice in locating and exercising the PFMs, prescription for PFMT and strategies on how to include PFMT in everyday life n=238	Control No education n=242	<ul> <li>Voiding frequency (reported in a way that data could not be extracted)</li> <li>Adherence to PFMT at 3 months</li> <li>Adherence to PFMT at 6 months</li> <li>Adherence to PFMT at 9 months</li> <li>Adherence to PFMT at 12 months</li> </ul>
Sangsawang 2016 RCT Thailand	N=70, pregnant women with singleton pregnancies  N=63 included for analysis  Age (years), mean (SD): Intervention 27.6 (5.09); Control 28.2 (5.01)  Women recruited in an obstetric setting (at 20-30 weeks gestation)	Intervention Women completed a 6 week PFMT program n=35	Control Usual postpartum care n=35	<ul> <li>SUI at 38 weeks gestation</li> <li>Adherence to PFMT</li> </ul>
Yang 2017 RCT	N=240, primiparas with singleton pregnancy	Intervention Women were given a PFMT programme to complete from day 2	Control Usual postpartum care	<ul><li>POP-Q at 3 months</li><li>UI at 3 months</li></ul>

Study	Population	Intervention <sup>1</sup>	Comparison	Outcomes and follow-up
China	N=126 included for analysis  Age (years), mean (SD): Intervention 28.64 (2.16); Control 29.0 (1.97)  Women recruited in an obstetric setting (on the delivery ward)	after birth up to 3 months postpartum which included Kegel exercises and pelvic movements n=80  A third group received a combination treatment but this was not relevant to the protocol.	n=80	<ul><li>Pad test at 3 months</li></ul>

<sup>&</sup>lt;sup>1</sup> n in this column refers to the number randomised (for numbers analysed see the evidence tables in appendix D FSFI: female sexual function index; ICIQ: International Consultation on Incontinence Questionnaire; ICIQ-SF: International Consultation on Incontinence Questionnaire — short form; IIQ-7: incontinence impact questionnaire; I-QoL: Incontinence quality of life questionnaire; OAB-q: overactive bladder questionnaire; PFD: Pelvic floor dysfunction; PFM: Pelvic floor muscle; PFMT: pelvic floor muscle training; POP-Q: pelvic organ prolapse questionnaire; QoL: quality of life; RCT: randomised controlled trial; SD: standard deviation; SQOL-F: Sexual quality of life-female; SUI: stress urinary incontinence; UDI-6: Urinary Distress Inventory, short form; UI: urinary incontinence

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 evidence profiles in appendix F.

#### **Economic evidence**

#### Included studies

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

#### **Economic model**

An original economic analysis was undertaken for this guideline to address the cost-effectiveness of PFMT as a preventative strategy for pelvic floor dysfunction compared to no preventative PFMT in a population of pregnant women. The model is summarised below with full details in appendix J.

The model took the form of a cost-utility analysis and was undertaken from an NHS and Personal Social Services (PSS) perspective. Urinary incontinence (UI) was used as a proxy for all symptoms of pelvic floor dysfunction, reflecting the primary outcome of the clinical studies (Reilly 2002, Agur 2008) that were used to estimate the effectiveness of preventative PFMT over time. A decision analytic Markov approach was utilised to capture transition to symptomatic pelvic floor dysfunction over a lifetime horizon. A schematic of the model structure is shown in Figure 1.

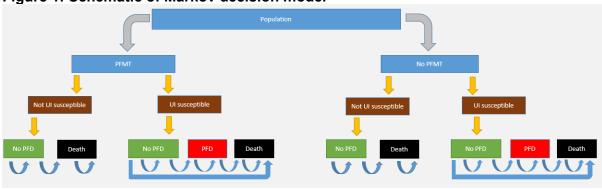


Figure 1: Schematic of Markov decision model

A natural history model was developed in order to estimate the proportion of women who would develop urinary incontinence over time in the absence of preventative PFMT. This was estimated from Reilly (2002), Agur (2008) and the UR-CHOICE prediction model. These sources gave the UI risk at 3 months, 8 years, 12 years and 20 years postpartum respectively.

To estimate the temporal effectiveness of preventative PFMT, Reilly (2002) and Agur (2008) were used to provide data on relative treatment effect at 2 distinct points in time. These 2 data points were then used to estimate a relationship between the relative treatment effect and the number of months since the woman gave birth.

Health state utilities were determined according to the presence or absence of UI with Quality Adjusted Life Years (QALYs) calculated from the health states, depending on the time spent in the various health states. Costs in the model were assigned to treatment and the management of UI symptoms.

Probabilistic sensitivity analysis was used to assess the impact of parameter uncertainty on the model's conclusions. Threshold analysis was undertaken to estimate at what level of population risk it would become cost-effective to initiate preventative PFMT. Further one-way sensitivity analyses were also undertaken to explore the impact of structural assumptions, varying the cost of preventative PFMT, management costs of UI and the discount rate for costs and QALYs on the model's conclusions.

For the base case analysis, with a population UI risk of 50%, the results suggested that preventative PFMT was a cost-effective strategy with an incremental cost-effectiveness ratio of £11,188 per QALY. Probabilistic sensitivity analysis suggested that there was 62.5% probability that preventative PFMT was cost-effective in this population when compared to no preventative PFMT. The threshold analysis suggested that cost-effective preventative PFMT would result when the population risk of UI was approximately 30% or greater.

There are a number of caveats to take into account when interpreting the results of the analysis. Estimates of the treatment effect were based on a single study and any limitations in that study will be embedded within this economic analysis. To derive the natural history model, the estimates of UI prevalence at different time points were derived from different sources and populations, although prediction model variables were chosen to try and reflect the population in the clinical trial as closely as possible. The natural history model also assumes that in the women who will go on to develop UI in the absence of preventative PFMT will have the same risk of UI at different points in time irrespective of the underlying population risk. The model focuses on UI, just 1 symptom of PFD, but if preventative PFMT can avert or delay other symptoms, then the cost-effectiveness in this analysis may be underestimated.

In summary this model provided evidence showing that preventative PFMT can be cost-effective dependent on the overall population risk of UI.

#### Brief summary of the evidence

#### Community: Postmenopausal women over 55yrs

#### **Urinary incontinence**

• Low quality evidence indicated that PFMT in women recruited through the community had a clinically important benefit in increasing the number of women without UI at 12 months.

#### Community: Mixed age group

#### **Pelvic floor dysfunction**

 Very low quality evidence in women recruited from an office indicated that PFMT education and re-education did not help to prevent symptoms of PFD developing 2 months later.

#### Obstetric setting (antenatally or postnatally)

#### **Urinary incontinence**

- Low to moderate quality evidence showed that PFMT in women recruited on the postnatal ward has a clinically important benefit in preventing symptoms of UI developing at 3 month, but not at 12 months postpartum.
- Very low to moderate quality evidence showed that PFMT in women recruited on the postnatal ward prevented symptoms of severe UI developing at 3 months postpartum.
- Very low to moderate quality evidence not show a clinically important benefit with PFMT when measured using UDI-6, IIQ-7 and OAB-Q at 36-38 weeks gestation and at 6-8 weeks postpartum.
- Low to moderate quality evidence showed a clinically important benefit for PFMT in lowering the ICIQ scores at 36-40 weeks gestation but this was not maintained at 3 months postpartum

#### **Stress Urinary incontinence**

- Very low to moderate quality evidence in women recruited antenatally showed that PFMT had a clinically important benefit in preventing symptoms of stress UI developing at 38 weeks gestation, 2 months postpartum and 3 months postpartum.
- Very low quality evidence showed there was no clinically important benefit with PFMT for preventing symptoms of SUI at 6 months follow up in women recruited postnatally or at 8 years postpartum (in women recruited antenatally.
- Moderate quality evidence in women recruited antenatally indicated PFMT had a clinically important benefit in preventing women having positive pad tests at 28 weeks gestation and 32 weeks gestation.
- Very low quality evidence showed that PFMT had a possibly clinically important benefit in preventing women having positive pad tests at 3 months postpartum in women recruited antenatally and women recruited 1 week postnatally.
- Moderate quality evidence in women recruited antenatally showed PFMT had a clinically important benefit for scores getting lower on the ICIQ-SF and higher scores on the I-QOL at 6 months follow up.

#### Pelvic organ prolapse

 Low quality evidence in women recruited on the postnatal ward showed PFMT had a clinically important benefit at increasing the number of women with POP Grade 0 (indicating no POP present) and reducing the number of women with Grade 1 or 2 POP.

#### **Sexual dysfunction**

- Low to moderate quality evidence in women recruited antenatally showed PFMT had a clinically important benefit at improving scores on the FSFI at 28-30 weeks gestation and 3 and 7 months postpartum.
- Low to moderate quality evidence in women recruited 8 weeks postpartum showed PFMT had a clinically important benefit in improving scores on the Bailes sexual self-efficacy total at 4 months postpartum but not at 3 months.
- Moderate quality evidence in women recruited antenatally showed PFMT had a clinically important benefit in increasing scores on the SQOL-F at 3 months postpartum.

#### **Adherence**

Eight studies reported adherence to the PFM training interventions. Adherence rates are presented in Table 3.

Table 3: Adherence to pelvic floor muscle training

Study	<b>Participants</b>	Recruited	Adherence	Follow up
Postmenop	ausal women d	over 55 years recr	uited in the community	
Sampselle 2005	Intervention: n=164	In the community	Low: 1 time per week: 18% Medium: 2-3 times per week: 17% High: at least once a day: 65%	3 months
			Low: 1 time per week: 25% Medium: 2-3 times per week: 24% High: at least once a day: 51%	6 months
			Low: 1 time per week: 37% Medium: 2-3 times per week: 18% High: at least once a day: 45%	9 months
			Low: 1 time per week: 32% Medium: 2-3 times per week: 32% High: at least once a day: 36%	12 months
Women rec	ruited from an	obstetric setting	(antenatally or postnatally)	
Agur 2008 & Reilly 2002	Intervention: n=120	Antenatally, around 20 weeks gestation	Adherence was recorded in a diary by the participants: No diaries: 43.3% <28 days of exercise: 10.8% 28+ days of exercises: 45.8%	20 weeks gestation to delivery
	Intervention at 8 year follow-up: n=79		Still performed PFMT: 68.4%  Of those who were still performing PFMT, those who	8 years

Study	Participants	Recruited	Adherence	Follow up
	·		were doing their PFMT exercises twice or more per week: 38%	
Chiarelli 2002 & 2004 (also see appendix	Intervention: n=348 Control n=328	Postnatally, within 48hours of giving birth	PFM exercises 3 times per week or more: Intervention: 83.9% Control: 57.6%	3 months
F)	Intervention at 12 months follow-up: n=294 Control n=275		PFM exercises 3 times per week or more: Intervention: 39.8% Control: 32.4%  PFM exercises performed: None at all: Intervention 5.4% vs Control 29.8% Weekly or less: Intervention 54.8% vs Control 37.8% Several times per week: Intervention 25.9% vs Control 21.1% Daily or more: Intervention 13.9% vs Control 11.3%	12 months
Pelaez 2014	Intervention: n=63	Antenatally, around 10-14 weeks gestation	Participants attended at least 80% of 70–78 exercise sessions.	22 weeks of training
Pourkhiz 2017	Intervention: n=42	Antenatally, around 17-20 weeks gestation	Participants performed at least 70% of the exercises.	3 months
Sacomori 2019	Intervention: n=67	Postnatally, on the delivery ward	Doing PFME: 68.7%  Doing PFME: 31.3  Frequency of PFME: 1-2 times a week: 32.3% 3-7 times a week: 49.3%	2months 3 months Unclear time point
Sangsawa 2016	Intervention: n=33	Antenatally, around 20 weeks gestation	Participants did not fail the intervention, by performing their PFME for <28 days	6 weeks

PFMT: pelvic floor muscle training; PFM: pelvic floor muscle; PFME: pelvic floor muscle exercise

#### The committee's discussion of the evidence

#### Interpreting the evidence

#### The outcomes that matter most

As pelvic floor dysfunction is a complex, multi-factorial process the committee agreed that the risk of developing the individual associated symptoms (urinary incontinence, emptying disorder of the bladder, emptying disorder of the bowel, faecal incontinence, sexual

dysfunction, pelvic organ prolapse, pelvic pain) were the most appropriate critical outcomes for this review; as any prevention tool should aim to avoid symptoms developing. Adherence to the intervention was also considered important as it can determine the success of an intervention.

#### The quality of the evidence

The quality of the evidence for this review was assessed using GRADE and ranged from very low to moderate. In general, the evidence was downgraded for 2 reasons (i) concerns with the risk of bias, predominantly selection of the reported results and (ii) the precision of the data, with either 1 or both of the confidence intervals crossing the line of no effect or passing default or published MIDs; as such confidence in the effect sizes is low.

There was no evidence about the use of PFMT for preventing emptying disorders of the bowel, emptying disorders of the bladder, faecal incontinence or chronic pelvic pain.

#### Benefits and harms

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

#### All women

The evidence presented suggested that pelvic floor muscle training (PFMT) can prevent the development of symptoms of pelvic floor dysfunction. Overall, the evidence mainly addressed women during or after pregnancy. However, one study also showed that pelvic floor muscle training significantly reduced the number of post-menopausal women developing urinary incontinence. The committee acknowledged this and, also taking into account their clinical expertise, made a consensus recommendation that all women should be encouraged to do pelvic floor muscle exercises. The committee noted that most studies looked at pregnant women (antenatal and postnatal) where there would be specific healthcare professionals who would provide information on pelvic floor dysfunction (such as midwifes or health visitors). However, the committee acknowledged that all healthcare professionals can and should provide encouragement to all women in all settings.

There was limited evidence on long-term effectiveness, as only 2 studies had a longer follow-up period (12 months in 1 study and 8 years in the other). However, all the studies showed that adherence decreased over time. In the committee's experience, continuing with the training is key for continued prevention of symptoms, and they agreed that low long-term adherence is likely to explain the limited evidence for long-term effectiveness. Recognising these problems with adherence, the committee agreed that women should be encouraged to continue pelvic floor muscle training throughout their life.

#### **Pregnant women**

Since there are particular obstetric risk factors associated with pelvic floor dysfunction (see evidence report B on risk factors), the committee noted that in their experience pelvic floor muscle training is particularly beneficial for pregnant women. The evidence supported this, because pelvic floor muscle training was shown to be effective in preventing pelvic floor symptoms when started during or after pregnancy. The committee recognised that the evidence presented did not specifically address the effectiveness of pelvic floor muscle exercises in women with additional obstetric risk factors. They decided that a supervised programme of pelvic floor muscle training should be considered for pregnant women with a first degree relative with pelvic floor dysfunction (PFD) because they are at higher risk of developing PFD (see evidence review B and box 1 in the guideline). The committee noted that this had been rated as high quality evidence and that this was also consistent with their experience. They also recognised that pregnant women who develop risk factors during labour arising from assisted vaginal birth (forceps or vacuum), a vaginal birth when the baby

is lying face up (occipito-posterior) or an anal sphincter injury would also benefit from such a programme. They acknowledged that these were shown to be strong risk factors in evidence report B. The committee also discussed when in the antenatal period PFMT information should be provided. Since most of the included studies started their PFMT intervention in the second trimester and these were effective at preventing PFD, week 20 (the central point of the second trimester) was recommended as an appropriate time to educate women on starting PFMT. The committee discussed that in their experience the most effective time to provide information about pelvic floor muscle training and its effect on symptoms is the antenatal period. The committee discussed that in their experience, contraction and relaxation of the correct muscles of the pelvic floor is more likely to be achieved in the antenatal period, due to the effect advanced pregnancy and child-birth may have on the pelvic floor. There was some uncertainty about the conclusion generated from the economic analysis that was conducted for this review which was based on evidence from only 1 study. Due to these and taking into account the resource impact associated with this the committee decided not recommend this to be routinely offered to all of these women. The committee still recommended the training as an option, because it is likely to be cost effective for some women in these groups.

The committee also recognised that pregnant women with any other additional risk factors, may also benefit from such a programme. The committee discussed that there was more certainty around risk when there is a first degree relative (since this was identified in high quality evidence as a risk factor in evidence review B but also supported by the economic evidence – see below) and risk factors developing during labour (since this was supported by the evidence in evidence report B and was also consistent with the committee's experience) than other risk factors such as being older than 30 years of age or having children previously where it is less clear how much of a risk increase would be associated with each. They therefore decided not to recommend PFMT programmes to all pregnant women with any other additional risk factors (as per box 1 in the guideline).

The evidence suggested that introduction of pelvic floor muscle training in the immediate postnatal period prevented the development of pelvic organ prolapse and urinary incontinence. However, the committee were aware that from their clinical experience, the postnatal period can often be a difficult time for new mothers to adhere to the intervention. Therefore, they agreed that pelvic floor muscle training should be encouraged before discharge from maternity services and during routine postnatal care.

#### Supervising pelvic floor muscle training

In all the studies, pelvic floor muscle training was supervised by health care professionals with relevant expertise. The committee agreed that this is important for ensuring that women are able to contract and relax their pelvic floor correctly. In their experience, it is also important to tailor the training for each woman, to ensure that the exercises are manageable and do not cause discomfort, such as back or stomach pain. The committee noted, based on the evidence related to adherence, that motivating women to complete the training programme is also an important aspect of supervising pelvic floor muscle training because it takes a while for the muscles to become strong enough to improve symptoms.

#### Research recommendations

There was a lack of evidence on the effectiveness of pelvic floor muscle training on other symptoms of pelvic floor dysfunction including faecal incontinence, emptying disorders of the bowel and chronic pelvic pain syndromes. However, in the committee's experience faecal incontinence and emptying disorders of the bowel are symptoms that are often experienced following childbirth and managed with pelvic floor muscle training. Therefore, it was agreed that more research was needed to support this and a research recommendation was made.

The committee made research recommendations to investigate several gaps in the evidence:

- Most effective ways to provide training: the studies did not give much detail on how training should be conducted.
- Younger women: there was no evidence on training for young women (between 12 and 17 years).
- Older women: there was only one study supporting training for women over 60.
- Women who are at particular risk of pelvic floor dysfunction: there was little evidence specific to women with particular risk factors (such as those identified in box 1 in the guideline).
- Faecal incontinence and emptying disorders of the bowel: there was no evidence on whether pelvic floor muscle training improves these symptoms (which can be particularly distressing).
- The <u>Independent Medicine and Medical Devices Safety Review</u> recommended 'that the NHS adopts the French model for universal postnatal pelvic floor rehabilitation', to help prevent pelvic floor dysfunction. The committee did not think the evidence (in particular the cost-effectiveness evidence) was strong enough to support this, but rather recommended this for pregnant women with risk factor and also made a research recommendation to investigate further.

#### Cost effectiveness and resource use

Original economic analysis undertaken for this guideline, for a population of women in their first pregnancy, suggested that preventative supervised pelvic floor muscle training, undertaken at monthly intervals (with instructions to do the exercise twice daily), from week 20 of pregnancy would be cost-effective providing the underlying population risk of urinary incontinence was greater than 30%.

The committee noted that the economic analysis was only based on a single trial (but 2 studies reflecting different follow-up duration) as it was not possible to synthesise the evidence from other included studies. However, the committee noted that preventative pelvic floor muscle training was, in the short term, quite effective across these studies.

The committee also noted that the economic analysis focused only on the symptom of urinary incontinence, reflecting the outcome reported in the randomised controlled trial used to estimate the clinical effectiveness of preventative pelvic floor muscle training. However, if preventative pelvic floor muscle training can avert or delay other symptoms of pelvic floor dysfunction, then the cost-effectiveness may have been underestimated in the economic model.

Therefore, given the economic evidence the committee made a recommendation to consider supervised pelvic floor muscle training to pregnant women from week 20 of pregnancy, reflecting the model population in the economic analysis. However, they additionally stipulated that this recommendation should apply to women who have a first-degree relative with pelvic floor dysfunction. This reflected the model finding that the cost-effectiveness of preventative pelvic floor muscle training depended on the underlying population risk of urinary incontinence. The model utilised the UR-CHOICE online risk calculator and prediction model (Jelovsek 2018), which was developed to predict the risk of pelvic floor disorders (focusing on urinary incontinence) based on known antenatal and mode of birth variables. The UR-CHOICE prediction model suggested that family history of pelvic organ prolapse and urinary incontinence were important predictors for increased risk of pelvic floor dysfunction and this tallied with the committee's own expertise and experience. Whilst the model gives a guide to the urinary incontinence risk threshold at which preventative PFMT becomes costeffective there is uncertainty as to a precise cut-off. Table 27 illustrates that there are women who would have a relatively low risk of urinary incontinence in the absence of either a family history of pelvic organ prolapse or urinary incontinence. Therefore, the committee considered the evidence for the cost-effectiveness of preventative PFMT was stronger for women with a first-degree relative of pelvic floor dysfunction.

The committee also recommended that supervised pelvic floor muscle training should be considered to women in the postnatal period if they developed pelvic floor dysfunction risk factors during labour. Whilst this was not the population directly addressed by the model, the committee were strongly of the view that this group would be at a particularly high risk of developing pelvic floor dysfunction. Whilst the included studies did not readily facilitate the development of an original economic model in a postnatal population, there was nevertheless evidence suggesting that pelvic floor muscle training could prevent the development of pelvic organ prolapse and urinary incontinence when undertaken in the immediate postnatal period. Therefore, the committee believed that preventative pelvic muscle floor training was likely to be cost-effective in those who developed certain risk factors for pelvic floor dysfunction during labour.

The committee recognised that preventative pelvic floor muscle training was rarely provided by the NHS and that their recommendations could have a significant resource impact and be difficult to implement with current staffing. However, they considered that this was supported by both cost-effectiveness evidence and published national NHS priorities. The committee expected there to be some savings from reduced costs of management of pelvic floor dysfunction, which could offset the cost of preventative pelvic floor muscle training to some extent.

#### Other factors the committee took into account

The committee noted that this topic is relevant to some key national priorities for the NHS. The NHS long term plan published in 2019 sets out that 'We will improve access to postnatal physiotherapy to support women who need it to recover from birth' with the aim to prevent birth related symptoms of pelvic floor dysfunction. The severe adverse effects of mesh surgery for pelvic organ prolapse led to an Independent Medicine and Medical Devices Safety Review (Cumberledge review) in 2020. One of their recommendations was 'that the NHS adopts the French model for universal post-natal pelvic floor rehabilitation'. The committee concluded that currently there are still uncertainties around the details related to the effectiveness of universal physiotherapy in the prevention of pelvic floor dysfunction and concluded that further research in the postnatal period needs to be conducted to establish this. They therefore made several research recommendations to ensure that these key priorities can have a sufficient evidence base.

The committee made reference to the <u>NICE guideline on behaviour change</u> as it contains useful recommendations for interventions such as PFMT requiring long term adherence.

#### Recommendations supported by this evidence review

This evidence review supports recommendations 1.3.9 to 1.3.16 and 6 research recommendations relating to:

- how to best conduct the training,
- pelvic floor muscle training for younger women (aged between 12 and 17 years),
- pelvic floor muscle training for older women,
- pelvic floor muscle training for women who are at particular risk of pelvic floor dysfunction,
- · pelvic floor muscle training to prevent bowel symptoms
- universal postnatal pelvic floor muscle training.

Of those research recommendations the committee prioritised 3 as key recommendations training for younger women (key research recommendation 2), training for risk groups (key research recommendation 3) and training for older women (key recommendation 6) in the NICE guideline.

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# **Appendices**

## Appendix A – Review protocol

Review protocol for review question: What is the effectiveness of pelvic floor muscle training for preventing pelvic floor dysfunction?

Table 4: Review protocol

ID	Field	Content			
0.	PROSPERO registration number	CRD42020170143			
1.	Review title	Pelvic floor muscle training for the prevention of pelvic floor dysfunction.			
2.	Review question	What is the effectiveness of pelvic floor muscle training for preventing pelvic floor dysfunction?			
3.	Objective	It is assumed that pelvic floor muscle training can prevent women developing pelvic floor dysfunction; however, to date the evidence has not been systematically synthesized.  Therefore, the objective of this review is to determine whether pelvic floor muscle training can prevent women going on to develop symptoms (including urinary incontinence, pelvic organ prolapse, emptying disorders of the bladder, faecal incontinence, emptying disorders of the bowel, sexual dysfunction and chronic pelvic pain syndromes) associated with 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  Searches will be restricted by:  Date: 1980 onwards (see section 10 for justification)  Human studies  English language studies only  Other searches:  Inclusion lists of potentially relevant systematic review			

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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	<ul> <li>Inclusion</li> <li>Women and young women (aged 12 years and older) without symptoms of pelvic floor dysfunction</li> <li>Exclusion</li> <li>Women and young women (aged 12 years and older) with symptoms associated 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 pain syndromes).</li> <li>Prevention studies where over 20% of the population have a symptom of pelvic floor dysfunction at baseline.</li> <li>Men</li> <li>Babies and children (younger than 12 years)</li> </ul>
7.	Intervention/Exposure/Test	Included interventions will include:  • Pelvic floor muscle exercises / Kegel exercise, to include:  • Pelvic floor muscle contraction exercises  • Pelvic floor muscle strengthening exercises  • Pelvic floor muscle training  • Pelvic floor muscle retraining  • Knack  • Pelvic floor relaxation exercises/relaxation training
8.	Comparator/Reference standard/Confounding factors	<ul> <li>No treatment</li> <li>Other preventive measures (for example leaflets, weight loss advice)</li> <li>Alternative method of PFMT delivery (app vs face to face, group vs individual)</li> </ul>

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ID	Field	Content
		Combination therapies (PFMT alone or in combination)
9.	Types of study to be included	<ul> <li>Systematic reviews of RCTs</li> <li>Systematic reviews of cohort studies</li> <li>RCTs</li> <li>Non-randomised trials</li> <li>Prospective cohort studies</li> <li>If available comparative cohort studies, and non-randomised studies will be prioritised over non-comparative cohort studies</li> <li>Note: For further details, see the algorithm in appendix H, <u>Developing NICE guidelines: the manual.</u></li> </ul>
10.	Other exclusion criteria	<ul> <li>Conference abstracts will be excluded because these do not typically provide sufficient information to fully assess risk of bias.</li> <li>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. <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2815805/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2815805/</a></li> <li>Interventions not considered relevant for prevention will be excluded, these include: 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, Transcutaneous sacral nerve stimulation, Transcutaneous posterior tibial nerve stimulation, Percutaneous sacral nerve stimulation, Percutaneous sacral nerve stimulation (also known as sacral neuromodulation)</li> </ul>
11.	Context	Comparative studies which explicitly demonstrate an association between pelvic floor muscle training and the development of symptoms associated with pelvic floor dysfunction will be prioritised for decision making in regards to recommendations.  Recommendations will apply to all women (over the age of 12 years) in the community, and women within the health care setting (for example community, primary, secondary care).  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)	<ul> <li>Development of the following symptoms, associated with pelvic floor dysfunction:</li> <li>urinary incontinence</li> <li>emptying disorders of the bladder</li> </ul>

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ID	Field	Content
		<ul> <li>faecal incontinence</li> <li>emptying disorders of the bowel</li> <li>pelvic organ prolapse</li> <li>sexual dysfunction</li> <li>chronic pelvic pain syndromes</li> </ul> For the above outcomes, only validated tools will be included (for example: ICIQ-UI, ICIQ-VS, BFLUTS, UDI, ISI, POPSS, PISQ, POPQ, FISI, FIQL, GIQLI, PAC-QM, PAC -SYM, PDI, BPI)
13.	Secondary outcomes (important outcomes)	Adherence to PFMT     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 deduplicated.  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. Draft included and excluded study lists will be circulated to the committee for their comments, resolution of any disputes will be by discussion between the senior reviewer, topic advisor and chair.  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 pelvic muscle floor training.
15.	Risk of bias (quality) assessment	Quality assessment of individual studies will be performed using the following checklists  ROBIS tool for systematic reviews ROBINS for non-randomised trials

ID	Field	Content
		Cochrane RoB tool v.2 for RCTs
		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>
		Hazard ratios (HR) and their corresponding 95% confidence intervals will be extracted from the included studies. Where possible those HR which have adjusted for potentially relevant confounders (i.e. age, BMI and ethnicity, parity) will be used.
		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.
		<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
		<ul> <li>According to socioeconomic status of population included</li> <li>By ethnicity of included populations</li> </ul>
		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.
		Minimal important differences (MIDs)

ID	Field	Content
		Published MIDs will be used where available, alternatively the committee will be asked for appropriate pre-specified MIDs. In the absence of these, default MIDs will be used for risk ratios and continuous outcomes as follows:  • 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  If data is available, separate analysis will be conducted on:  • Women who are pregnant or women after pregnancy  • Women before and after gynaecological surgery  • Women aged 65 or older  • Women with physical disabilities  • Women with cognitive impairment  • Women who are in perimenopause (pre- and post-)  • Younger women (that is 12-18 year olds)  • According to those who do not identify themselves as women, but who have female pelvic organs

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ID	Field	Content					
		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	χ Intervention					
		□ Diagnostic					
		□ Prognostic					
		□ Qualitative					
			Epidemio	logic			
			□ Service Delivery				
			Other (ple	ease specify)			
19.	Language	English					
20.	Country	England					
21.	Anticipated or actual start date	April 2020					
22.	Anticipated completion date	August 2021					
23.	Stage of review at time of this	Review stage		Started	Completed		
	submission	Preliminary searches					
		Piloting of the st selection proces					
		Formal screening of search results against eligibility criteria					
		Data extraction					
		Risk of bias (quality) assessment					
		Data analysis					
24.	Named contact	<b>5a. Named</b> National G		lliance			
		rvational O		ilia loc			

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ID	Field	Content
		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
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 <a href="Developing NICE guidelines: the manual">Developing NICE guidelines: the manual</a> . Members of the guideline committee are available on the NICE website: <a href="https://www.nice.org.uk/guidance/indevelopment/gid-ng10123/">https://www.nice.org.uk/guidance/indevelopment/gid-ng10123/</a>
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	<ul> <li>NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as:</li> <li>notifying registered stakeholders of publication</li> <li>publicising the guideline through NICE's newsletter and alerts</li> </ul>

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ID	Field	Content			
		<ul> <li>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.</li> </ul>			
32.	Keywords	Pelvic floo	Pelvic floor muscle training, prevention of pelvic floor dysfunction		
33.	Details of existing review of same topic by same authors	Not applicable			
34.	Current review status	Χ	Ongoing		
			Completed but not published		
			Completed and published		
			Completed, published and being updated		
			Discontinued		
35	Additional information	None			
36.	Details of final publication	www.nice.c	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; EMG: Electromyography; 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-VS: 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; PFMT: pelvic floor muscle training; 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; ROBIS: Risk Of Bias In Systematic reviews; ROBINS: Risk Of Bias In Non-randomised Studies; SD: standard deviation: UDI: Urinary distress index

## Appendix B – Literature search strategies

Literature search strategies for review question: What is the effectiveness of pelvic floor muscle training for preventing pelvic floor dysfunction?

#### **Clinical Search**

Database(s): Medline & Embase (Multifile) – OVID interface 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: 2 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

	i-i rocess & Other Non-Indexed Chations and Daily
#	Searches
1	Pelvic Floor/ or Pelvic Floor Disorders/ or exp *Urinary Incontinence/ or *Urinary Bladder, Overactive/ or exp *Pelvic Organ Prolapse/ or *Rectocele/ or *Fecal Incontinence/ or Urinary Retention/ or Fecal Impaction/ or Vaginismus/
2	1 use ppez
3	pelvis floor/ or pelvic floor disorder/ or exp *urine incontinence/ or *overactive bladder/ or *bladder instability/ or exp *pelvic organ prolapse/ or *rectocele/ or *feces incontinence/ or urine retention/ or defecation disorder/ or Feces Impaction/ or female sexual dysfunction/ or vaginism/
4	3 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	((stress\$ or mix\$ or urg\$ or urin\$) adj5 incontinen\$).ti.
8	(bladder\$ adj5 (overactiv\$ or over activ\$ or over-activ\$ or instabilit\$ or hyper-reflex\$ or hyperreflex\$ or hyper reflex\$ or incontinen\$)).ti.
9	(detrusor\$ adj5 (overactiv\$ or over activ\$ or over-activ\$ or instabilit\$ or hyper-reflex\$ or hyperreflex\$ or hyper reflex\$)).ti.
10	((urgency adj2 frequency) or (frequency adj2 urgency)).ti.
11	((urin\$ or bladder\$) adj2 (urg\$ or frequen\$)).ti.
12	(SUI or OAB).ti.
13	(pelvic\$ adj3 organ\$ adj3 prolaps\$).ti.
14	(urinary adj3 bladder adj3 prolaps\$).ti.
15	((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.
16	(splanchnoptos\$ or visceroptos\$).ti.
17	(hernia\$ adj3 (pelvi\$ or vagin\$ or urogenital\$ or uter\$ or bladder\$ or urethr\$ or viscer\$)).ti.
18	(urethroc?ele\$ or enteroc?ele\$ or sigmoidoc?ele\$ or proctoc?ele\$ or rectoc?ele\$ or cystoc?ele\$ or rectoenteroc?ele\$ or cystourethroc?ele\$).ti.
19	((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.
20	(urin\$ adj3 (retention\$ or retain\$)).tw.
21	(voiding adj (disorder\$ or dysfunction\$ or problem\$)).tw.
22	(empty\$ adj disorder\$ adj3 (bowel\$ or bladder\$ or vesical\$ or stool\$)).tw.
23	((urogeni\$ or anorec\$ or ano-rec\$ or ano rec\$) adj3 dysfunction\$).tw.
24	((difficult\$ or delay\$ or irregular\$ or infrequen\$ or pain\$) adj3 (defecat\$ or defaecat\$ or stool\$ or faeces or bowel movement\$)).tw.
25	(obstruct\$ adj3 (defecat\$ or defaecat\$)).tw.
26	((defecat\$ or defaecat\$ or evacuat\$) adj3 (disorder\$ or dysfunction\$)).tw.
27	outlet\$ dysfunction\$ constipa\$.tw.
28	(dys?ynerg\$ adj (defecat\$ or defaecat\$)).tw.
29	(pelvi\$ adj3 dyskines\$).tw.
30	pelvi\$ outlet\$ obstruct\$.tw.
31	anismus\$.tw.
32	puborectal\$ contract\$.tw.
33	((rectal or rectum) adj3 urge\$).tw.
34	(female adj sex\$ adj (dysfunct\$ or satisf\$ or problem\$ or symptom\$ or arous\$ or activit\$ or disorder\$)).tw.
35	(obstruct\$ adj3 intercourse).tw.
26	(vagin\$ adj3 laxity\$).tw.
36	(vagini adjo laxity y).tw.

#	Searches
38	vaginismus\$.tw.
39	(vagin\$ adj penetrat\$ adj disorder\$).tw.
40	or/2,4-39
41	exp Exercise Therapy/ or Physical Therapy Modalities/ or Electric Stimulation/ or *Electric Stimulation Therapy/ or Transcutaneous Electric Nerve Stimulation/ or *Magnetics/ or Magnetic Field Therapy/ or Biofeedback, Psychology/ or Resistance Training/
42	41 use ppez
43	*physiotherapy/ or pelvic floor muscle training/ or kinesiotherapy/ or *muscle exercise/ or vaginal cone/ or vaginal cone/ or weighted vaginal cone/ or electrostimulation/ or electrotherapy/ or transcutaneous nerve stimulation/ or magnetic stimulation/ or magnetic stimulation/ or magnetotherapy/ or extracorporeal magnetic innervation therapy/ or feedback system/ or biofeedback/ or perineometry/ or resistance training/
44 45	43 use emczd (((pelvi\$ adj (floor\$ or muscl\$)) or PFM\$) adj3 (training or exercise\$ or re-training or retraining or rehabilitat\$ or strengthen\$)).tw.
46	(pelvi\$ adj floor\$ adj muscl\$ adj (physiotherap\$ or therap\$ or treatment)).tw.
47	(pelvi\$ adj floor\$ adj (physiotherap\$ or physical therap\$)).tw.
48	(PFMT or PFME or PFPT).tw.
49 50	(kegel\$ or kegal\$ or knack\$).tw. (physiotherap\$ or physical therap\$).ti.
51	physiotherapy-led.tw.
52	(vagin\$ adj3 (cone or cones)).tw.
53	(vagin\$ adj (ball or balls)).tw.
54	(weight adj (cone or cones)).tw.
55	(pelvi\$ adj floor\$ adj2 (cone or cones)).tw.
56	((cone or cones) adj5 (continen\$ or incontinen\$)).ti.
57	(electr\$ adj3 stimulat\$).tw. (electrostimulat\$ or electro-stimulat\$).tw.
58 59	((transcutaneous\$ or percutaneous\$ or neuromusc\$ or posterior\$ or anterior\$ or tibia\$ or perine\$ or intravagin\$ or intra-vagin\$) adj4 stimulat\$).tw.
60 61	((magnet\$ or electro-magnet\$ or electromagnet\$) adj (stimulation\$ or therap\$ or treatment\$)).tw. ((magnet\$ or electro-magnet\$ or electromagnet\$) adj (nerve\$ or energ\$ or pelvi\$ floor or pelvi\$ muscl\$) adj (stimulation\$ or therap\$ or treatment\$)).tw.
62	((magnet\$ or electro-magnet\$ or electromagnet\$) adj innervation\$).tw.
63	(interferential\$ adj3 (current or currents or therap\$ or treatment\$)),tw.
64	hifem\$.tw.
65	(biofeedback\$ or bio-feedback\$).mp.
66	((digital\$ or manual\$) adj3 (feedback\$ or palpat\$ or assess\$ or contract\$)).tw.
67 68	(pressure\$ adj3 perin?ometr\$).tw. ((strength\$ or resistan\$) adj3 (training or exercise\$ or physiotherap\$)).tw.
69	((strengths of resistans) adjs (training of exercises of physiotheraps)).tw.
70	(myofascia\$ adj3 (release\$ or therap\$ or technique\$)).tw.
71	or/42,44-70
72	40 and 71
73	limit 72 to english language
74	limit 73 to yr="1980 -Current"
75 76	(controlled clinical trial or pragmatic clinical trial or randomized controlled trial).pt. or drug therapy.fs. or (groups or placebo or randomi#ed or randomly or trial).ab.  crossover procedure/ or double blind procedure/ or randomized controlled trial/ or single blind procedure/ or (assign*
70	or allocat* or crossover* or cross over* or ((doubl* or singl*) adj blind*) or factorial* or placebo* or random* or volunteer*).ti,ab.
77	meta-analysis/
78	meta-analysis as topic/
79 80	systematic review/ meta-analysis/
81	(meta-analy* or metanaly* or metaanaly*).ti,ab.
82	((systematic or evidence) adj2 (review* or overview*)).ti.ab.
83	((systematic* or evidence*) adj2 (review* or overview*)).ti,ab.
84	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
85	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
86	(search* adj4 literature).ab.
87	(medline or pubmed or cochrane or embase or psychlit or psychinfo or psychinfo or cinahl or science citation index or bids or cancerlit).ab.
88 89	cochrane.jw. ((pool* or combined) adj2 (data or trials or studies or results)).ab.
90	75 use ppez
91	76 use emczd
92	90 or 91
93	(or/77-78,81,83-88) use ppez
94	(or/79-82,84-89) use emczd
95	93 or 94
96	92 or 95

#	Searches
97	74 and 96 [General Exclusions filter applied]

# Database(s): Cochrane Library – Wiley interface

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: 2 February 2021

ate of	last search: 2 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
#8	(((bladder* NEAR/5 (overactiv* or over activ* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or hyperreflex* or incontinen*)))):ti
#9	(((detrusor* NEAR/5 (overactiv* or over activ* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or hyperreflex*)))):ti
#10	((((urgency NEAR/2 frequency) or (frequency NEAR/2 urgency)))):ti
#11	((((urin* or bladder*) NEAR/2 (urg* or frequen*)))):ti
#12	(((SUI or OAB))):ti
#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
#16	(((urinary NEAR/3 bladder NEAR/3 prolaps*))):ti
#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
#18	(((splanchnoptos* or visceroptos*))):ti
#19	(((hernia* NEAR/3 (pelvi* or vagin* or urogenital* or uter* or bladder* or urethr* or viscer*)))):ti
#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
#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 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
#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 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
#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 MeSH descriptor: [Vaginismus] this term only
#43 #44	, , ,
	(((vaginismus*)):ti,ab,kw
#45 #46	(((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: [Exercise Therapy] explode all trees

#	Searches
#49	((((pelvi* NEXT (floor* or muscl*)) or PFM*) NEAR/3 (training or exercise* or re-training or retraining or rehabilitat* or strengthen*))):ti,ab,kw
#50	((pelvi* NEXT floor* NEXT muscl* NEXT (physiotherap* or therap* or treatment))):ti,ab,kw
#51	((pelvi* NEXT floor* NEXT (physiotherap* or physical therap*))):ti,ab,kw
#52	((PFMT or PFME or PFPT)):ti,ab,kw
#53	((kegel* or Kegel* or knack*)):ti,ab,kw
#54	((physiotherap* or "physical therap*")):ti
#55	(physiotherapy-led):ti,ab,kw
#56	((vagin* NEAR/3 (cone or cones))):ti,ab,kw
#57	((vagin* NEXT (ball or balls))):ti,ab,kw
#58	((weight NEXT (cone or cones))):ti,ab,kw
#59	(pelvi* NEXT floor* NEAR/2 (cone or cones)):ti,ab,kw
#60	(((cone or cones) NEAR/5 (continen* or incontinen*))):ti
#61	MeSH descriptor: [Electric Stimulation] this term only
#62	MeSH descriptor: [Electric Stimulation Therapy] this term only
#63	MeSH descriptor: [Transcutaneous Electric Nerve Stimulation] this term only
#64	((electr* NEAR/3 stimulat*)):ti,ab,kw
#65	((electrostimulat* or electro-stimulat*)):ti,ab,kw
#66	(((transcutaneous* or percutaneous* or neuromusc* or posterior* or anterior* or tibia* or perine* or intravagin* or intra-vagin*) NEAR/4 stimulat*)):ti,ab,kw
#67	MeSH descriptor: [Magnetics] this term only
#68	MeSH descriptor: [Magnetic Field Therapy] this term only
#69	(((magnet* or electro-magnet* or electromagnet*) NEXT (stimulation* or therap* or treatment*))):ti,ab,kw
#70	(((magnet* or electro-magnet* or electromagnet*) NEXT (nerve* or energ* or pelvi* floor or pelvi* muscl*) NEXT (stimulation* or therap* or treatment*))):ti,ab,kw
#71	(((magnet* or electro-magnet* or electromagnet*) NEXT innervation*)):ti,ab,kw
#72	((interferential* NEAR/3 (current or currents or therap* or treatment*))):ti,ab,kw
#73	(hifem*):ti,ab,kw
#74	MeSH descriptor: [Biofeedback, Psychology] this term only
#75	((biofeedback* or bio-feedback*)):ti,ab,kw
#76	(((digital* or manual*) NEAR/3 (feedback* or palpat* or assess* or contract*))):ti,ab,kw
#77	((pressure* NEAR/3 perin?ometr*)):ti,ab,kw
#78	MeSH descriptor: [Resistance Training] this term only
#79	(((strength* or resistan*) NEAR/3 (training or exercise* or physiotherap*))):ti,ab,kw
#80	((manual NEAR/3 therap*)):ti,ab,kw
#81	(myofascia* NEAR/3 (release* or therap* or technique*)):ti,ab,kw
#82	#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 OR #77 OR #78 OR #79 OR #80 OR #81
#83	#46 AND #82

# Database(s): Database of Abstracts of Reviews of Effects (DARE); HTA Database – CRD interface

Date of last search: 2<sup>nd</sup> February 2021

<ul> <li>MeSH DESCRIPTOR Pelvic Floor IN DARE,HTA</li> <li>MeSH DESCRIPTOR Pelvic Floor Disorders IN DARE,HTA</li> <li>((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*))) IN DARE, HTA</li> <li>((pelvi* NEXT (dysfunction* or disorder* or fail* or impair* or incompeten* or insufficien* or dysynerg* or symptom* or laxity or care* or health* or wellbeing* or well-being* or prevent* or rehabilitat* or weak* or hypertonic* or over-activ*)) IN DARE, HTA</li> <li>MeSH DESCRIPTOR Urinary Incontinence EXPLODE ALL TREES IN DARE,HTA</li> <li>MeSH DESCRIPTOR Urinary Bladder, Overactive IN DARE,HTA</li> <li>(((stress* or mix* or urg* or urin*) NEARS incontinen*)) IN DARE, HTA</li> <li>(((bladder* NEAR5 (overactiv* or over activ* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or hyper reflex* or incontinen*))) IN DARE, HTA</li> <li>(((detrusor* NEAR5 (overactiv* or over activ* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or hyper reflex*)) IN DARE, HTA</li> <li>((((urigency NEAR2 frequency) or (frequency NEAR2 urgency))) IN DARE, HTA</li> <li>(((sul or OAB)) IN DARE, HTA</li> <li>MeSH DESCRIPTOR Pelvic Organ Prolapse EXPLODE ALL TREES IN DARE,HTA</li> <li>MeSH DESCRIPTOR Rectoccele IN DARE,HTA</li> <li>((pelvic* NEAR3 organ* NEAR3 prolaps*)) IN DARE, HTA</li> <li>(((urinary NEAR3 bladder NEAR3 prolaps*)) IN DARE, HTA</li> <li>(((urinary NEAR3 bladder NEAR3 prolaps*)) IN DARE, HTA</li> <li>(((urinary or rectal or rectum) NEAR3 prolaps*)) IN DARE, HTA</li> <li>(((splanchnoptos* or visceroptos*)) IN DARE, HTA</li> </ul>	Date of	riast search: 2 <sup>nd</sup> February 2021
MeSH DESCRIPTOR Pelvic Floor Disorders IN DARE, HTA  ((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  ((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  MeSH DESCRIPTOR Urinary lincontinence EXPLODE ALL TREES IN DARE, HTA  (((stress* or mix* or urg* or urin*) NEAR5 incontinen*)) IN DARE, HTA  (((bladder* NEAR5 (overactiv* or over-activ* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or hyper reflex* or incontinen*))) IN DARE, HTA  (((detrusor* NEAR5 (overactiv* or over activ* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or hyper reflex*))) IN DARE, HTA  (((urina* or bladder*) NEAR2 (urg* or frequency NEAR2 urgency))) IN DARE, HTA  (((urina* or bladder*) NEAR2 (urg* or frequen*))) IN DARE, HTA  ((SUI or OAB)) IN DARE, HTA  MeSH DESCRIPTOR Pelvic Organ Prolapse EXPLODE ALL TREES IN DARE, HTA  ((pelvic* NEAR3 organ* NEAR3 prolaps*)) IN DARE, HTA  ((pelvic* NEAR3 organ* NEAR3 prolaps*)) IN DARE, HTA  (((urinary NEAR3 bladder NEAR3 prolaps*)) IN DARE, HTA	#	Searches
((pelvi* NEXT (floor* or diaphragm*) NEAR3 (dysfunction* or disorder* or fail* or impair* or incompeten* or insufficient* 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*))) IN DARE, HTA  ((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  MeSH DESCRIPTOR Urinary Incontinence EXPLODE ALL TREES IN DARE, HTA  (((stress* or mix* or urg* or urin*) NEAR5 incontinen*))) IN DARE, HTA  (((stress* or mix* or urg* or urin*) NEAR5 incontinen*))) IN DARE, HTA  (((bladder* NEAR5 (overactiv* or over activ* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or hyper reflex* or incontinen*))) IN DARE, HTA  (((detrusor* NEAR5 (overactiv* or over activ* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or hyper reflex*))) IN DARE, HTA  (((urina* or bladder*) NEAR2 (urg* or frequency NEAR2 urgency)))) IN DARE, HTA  (((urina* or bladder*) NEAR2 (urg* or frequen*))) IN DARE, HTA  (((sUl or OAB)) IN DARE, HTA  MeSH DESCRIPTOR Pelvic Organ Prolapse EXPLODE ALL TREES IN DARE, HTA  ((pelvic* NEAR3 organ* NEAR3 prolaps*)) IN DARE, HTA  (((pelvic* NEAR3 organ* NEAR3 prolaps*)) IN DARE, HTA  (((urinary NEAR3 bladder NEAR3 prolaps*)) IN DARE, HTA	1	MeSH DESCRIPTOR Pelvic Floor IN DARE, HTA
insufficien* or dyssynerg* or symptom* or laxity or change* or care* or health* or wellbeing* or prevent* or rehabilitat* or weak* or hypertonic* or overactiv* or over activ* or over-activ*))) IN DARE, HTA  4	2	MeSH DESCRIPTOR Pelvic Floor Disorders IN DARE, HTA
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  Mesh descriptor Urinary Incontinence explode all trees in dare, Hta  (((stress* or mix* or urg* or urin*) Nears incontinen*))) IN dare, Hta  (((bladder* Nears (overactiv* or over activ* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or hyper reflex* or incontinen*))) IN dare, Hta  (((detrusor* Nears (overactiv* or over activ* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or hyper reflex*))) IN dare, Hta  ((((urgency Nears (urg* or frequency Nears (urg* or frequency))))) IN dare, Hta  ((((urin* or bladder*) Nears (urg* or frequen*)))) IN dare, Hta  Mesh descriptor Revice organ Prolapse explode all trees in dare, Hta  Mesh descriptor Rectocele in dare, Hta  (((pelvic* Nears organ* Nears prolaps*))) IN dare, Hta  (((urinary Nears bladder Nears prolaps*))) IN dare, Hta  (((urinary Nears bladder Nears prolaps*))) IN dare, Hta  ((((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) Nears prolaps*)) IN dare, Hta	3	insufficien* or dyssynerg* or symptom* or laxity or change* or care* or health* or wellbeing* or well-being* or
Mesh Descriptor Urinary Bladder, Overactive IN Dare, HTA  (((stress* or mix* or urg* or urin*) NEAR5 incontinen*)) IN Dare, HTA  (((bladder* NEAR5 (overactiv* or over activ* or over-activ* or instabilit* or hyper-reflex* or hyper reflex* or incontinen*))) IN Dare, HTA  (((detrusor* NEAR5 (overactiv* or over activ* or over-activ* or instabilit* or hyper-reflex* or hyper reflex*))) IN Dare, HTA  (((urgency NEAR2 frequency) or (frequency NEAR2 urgency))) IN Dare, HTA  (((urin* or bladder*) NEAR2 (urg* or frequen*))) IN Dare, HTA  (((sUl or OAB)) IN Dare, HTA  Mesh Descriptor Pelvic Organ Prolapse Explode All Trees IN Dare, HTA  Mesh Descriptor Rectocele IN Dare, HTA  (((pelvic* NEAR3 organ* NEAR3 prolaps*)) IN Dare, HTA  (((urinary NEAR3 bladder NEAR3 prolaps*)) IN Dare, HTA  ((((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	4	or laxity or care* or health* or wellbeing* or well-being* or prevent* or rehabilitat* or weak* or hypertonic* or
<ul> <li>(((stress* or mix* or urg* or urin*) NEAR5 incontinen*)) IN DARE, HTA</li> <li>(((bladder* NEAR5 (overactiv* or over activ* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or hyper reflex* or incontinen*))) IN DARE, HTA</li> <li>(((detrusor* NEAR5 (overactiv* or over activ* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or hyper reflex*))) IN DARE, HTA</li> <li>((((urgency NEAR2 frequency) or (frequency NEAR2 urgency))) IN DARE, HTA</li> <li>(((((urin* or bladder*) NEAR2 (urg* or frequen*))) IN DARE, HTA</li> <li>(((SUI or OAB)) IN DARE, HTA</li> <li>MeSH DESCRIPTOR Pelvic Organ Prolapse EXPLODE ALL TREES IN DARE, HTA</li> <li>(((pelvic* NEAR3 organ* NEAR3 prolaps*)) IN DARE, HTA</li> <li>((((urinary NEAR3 bladder NEAR3 prolaps*)) IN DARE, HTA</li> <li>((((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</li> </ul>	5	MeSH DESCRIPTOR Urinary Incontinence EXPLODE ALL TREES IN DARE, HTA
((bladder* NEAR5 (overactiv* or over activ* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or hyper reflex* or incontinen*))) IN DARE, HTA  ((detrusor* NEAR5 (overactiv* or over activ* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or hyper reflex*))) IN DARE, HTA  (((urgency NEAR2 frequency) or (frequency NEAR2 urgency))) IN DARE, HTA  (((urin* or bladder*) NEAR2 (urg* or frequen*))) IN DARE, HTA  (((sUl or OAB)) IN DARE, HTA  Mesh descriptor Pelvic Organ Prolapse EXPLODE ALL TREES IN DARE, HTA  Mesh descriptor Rectocele IN DARE, HTA  (((pelvic* NEAR3 organ* NEAR3 prolaps*))) IN DARE, HTA  (((urinary NEAR3 bladder NEAR3 prolaps*))) IN DARE, HTA  ((((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	6	MeSH DESCRIPTOR Urinary Bladder, Overactive IN DARE, HTA
reflex* or incontinen*))) IN DARE, HTA  ((detrusor* NEAR5 (overactiv* or over activ* or over-activ* or instabilit* or hyper-reflex* or hyper reflex*))) IN DARE, HTA  (((urgency NEAR2 frequency) or (frequency NEAR2 urgency))) IN DARE, HTA  (((urin* or bladder*) NEAR2 (urg* or frequen*))) IN DARE, HTA  (((SUI or OAB)) IN DARE, HTA  Mesh descriptor Pelvic Organ Prolapse EXPLODE ALL TREES IN DARE, HTA  Mesh descriptor Rectocele IN DARE, HTA  (((pelvic* NEAR3 organ* NEAR3 prolaps*)) IN DARE, HTA  (((urinary NEAR3 bladder NEAR3 prolaps*)) IN DARE, HTA  (((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	7	(((stress* or mix* or urg* or urin*) NEAR5 incontinen*)) IN DARE, HTA
reflex*))) IN DARE, HTA  (((urgency NEAR2 frequency) or (frequency NEAR2 urgency))) IN DARE, HTA  (((urin* or bladder*) NEAR2 (urg* or frequen*))) IN DARE, HTA  (((sUl or OAB)) IN DARE, HTA  Mesh descriptor Pelvic Organ Prolapse EXPLODE ALL TREES IN DARE, HTA  Mesh descriptor Rectocele IN DARE, HTA  (((pelvic* NEAR3 organ* NEAR3 prolaps*)) IN DARE, HTA  (((urinary NEAR3 bladder NEAR3 prolaps*)) IN DARE, HTA  ((((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	8	
<ul> <li>(((urin* or bladder*) NEAR2 (urg* or frequen*))) IN DARE, HTA</li> <li>(((SUI or OAB)) IN DARE, HTA</li> <li>MeSH DESCRIPTOR Pelvic Organ Prolapse EXPLODE ALL TREES IN DARE, HTA</li> <li>MeSH DESCRIPTOR Rectocele IN DARE, HTA</li> <li>(((pelvic* NEAR3 organ* NEAR3 prolaps*)) IN DARE, HTA</li> <li>(((urinary NEAR3 bladder NEAR3 prolaps*)) IN DARE, HTA</li> <li>((((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</li> </ul>	9	,,
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	10	(((urgency NEAR2 frequency) or (frequency NEAR2 urgency))) IN DARE, HTA
<ul> <li>MeSH DESCRIPTOR Pelvic Organ Prolapse EXPLODE ALL TREES IN DARE,HTA</li> <li>MeSH DESCRIPTOR Rectocele IN DARE,HTA</li> <li>((pelvic* NEAR3 organ* NEAR3 prolaps*)) IN DARE, HTA</li> <li>((urinary NEAR3 bladder NEAR3 prolaps*)) IN DARE, HTA</li> <li>(((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</li> </ul>	11	(((urin* or bladder*) NEAR2 (urg* or frequen*))) IN DARE, HTA
<ul> <li>MeSH DESCRIPTOR Rectocele IN DARE, HTA</li> <li>((pelvic* NEAR3 organ* NEAR3 prolaps*)) IN DARE, HTA</li> <li>((urinary NEAR3 bladder NEAR3 prolaps*)) IN DARE, HTA</li> <li>(((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</li> </ul>	12	((SUI or OAB)) IN DARE, HTA
<ul> <li>((pelvic* NEAR3 organ* NEAR3 prolaps*)) IN DARE, HTA</li> <li>((urinary NEAR3 bladder NEAR3 prolaps*)) IN DARE, HTA</li> <li>(((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</li> </ul>	13	MeSH DESCRIPTOR Pelvic Organ Prolapse EXPLODE ALL TREES IN DARE, HTA
<ul> <li>((urinary NEAR3 bladder NEAR3 prolaps*)) IN DARE, HTA</li> <li>(((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</li> </ul>	14	MeSH DESCRIPTOR Rectocele 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	15	11 // /
bladder* or cervi* or rectal or rectum) NEAR3 prolaps*)) IN DARE, HTA	16	
18 ((splanchnoptos* or visceroptos*)) IN DARE, HTA	17	
	18	((splanchnoptos* or visceroptos*)) IN DARE, HTA

.,	
#	Searches  (/bornio* NICAD2 (no.);;* or yearin* or urganital* or uter* or bladder* or urgther* or viscou*\\\) IN DADE LITA
19 20	((hernia* NEAR3 (pelvi* or vagin* or urogenital* or uter* or bladder* or urethr* or viscer*))) IN DARE, HTA ((urethroc?ele* or enteroc?ele* or sigmoidoc?ele* or proctoc?ele* or rectoc?ele* or cystoc?ele* or rectoenteroc?ele*
20	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 26	((voiding NEXT (disorder* or dysfunction* or problem*))) IN DARE, HTA ((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 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 37	((anismus*)) IN DARE, HTA ((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 Exercise Therapy EXPLODE ALL TREES IN DARE, HTA
48	MeSH DESCRIPTOR Physical Therapy Modalities IN DARE, HTA
49	((((pelvi* NEXT (floor* or muscl*)) or PFM*) NEAR3 (training or exercise* or re-training or retraining or rehabilitat* or strengthen*))) IN DARE, HTA
50	((pelvi* NEXT floor* NEXT muscl* NEXT (physiotherap* or therap* or treatment))) IN DARE, HTA
51	((pelvi* NEXT floor* NEXT (physiotherap* or physical therap*))) IN DARE, HTA
52	(((PFMT or PFME or PFPT))) IN DARE, HTA
53	(((kegel* or Kegel* or knack*))) IN DARE, HTA
54 55	(((physiotherap* or "physical therap*"))):TI IN DARE, HTA
55 56	((physiotherapy-led)):TI IN DARE, HTA (((vagin* NEAR3 (cone or cones)))):TI IN DARE, HTA
57	(((vagin* NEXT (ball or balls)))):TI IN DARE, HTA
58	(((weight NEXT (cone or cones)))):TI IN DARE, HTA
59	((pelvi* NEXT floor* NEAR2 (cone or cones))):TI IN DARE, HTA
60	((((cone or cones) NEAR5 (continen* or incontinen*)))):TI IN DARE, HTA
61	MeSH DESCRIPTOR Electric Stimulation IN DARE,HTA
62	MeSH DESCRIPTOR Electric Stimulation therapy IN DARE,HTA
63	MeSH DESCRIPTOR Transcutaneous Electric Nerve Stimulation IN DARE, HTA
64	(((electr* NEAR3 stimulat*))):TI IN DARE, HTA
65	(((electrostimulat* or electro-stimulat*))):TI IN DARE, HTA
66	((((transcutaneous* or percutaneous* or neuromusc* or posterior* or anterior* or tibia* or perine* or intravagin* or intra-vagin*) NEAR4 stimulat*))):TI IN DARE, HTA
67	MeSH DESCRIPTOR Transcutaneous Electric Nerve Stimulation IN DARE, HTA
68	MeSH DESCRIPTOR Magnetic Field Therapy IN DARE,HTA
69	MeSH DESCRIPTOR Magnetics IN DARE,HTA
70	(((((magnet* or electro-magnet* or electromagnet*) NEXT (stimulation* or therap* or treatment*)))):TI IN DARE, HTA
71	((((magnet* or electro-magnet* or electromagnet*) NEXT (nerve* or energ* or pelvi* floor or pelvi* muscl*) NEXT (stimulation* or therap* or treatment*)))):TI IN DARE, HTA
72	((((magnet* or electro-magnet* or electromagnet*) NEXT innervation*))):TI IN DARE, HTA
73	(((interferential* NEAR3 (current or currents or therap* or treatment*)))):TI IN DARE, HTA
74	((hifem*)):TI IN DARE, HTA
75	MeSH DESCRIPTOR Biofeedback, Psychology IN DARE, HTA
76	(((biofeedback* or bio-feedback*))):TI IN DARE, HTA
77 78	((((digital* or manual*) NEAR3 (feedback* or palpat* or assess* or contract*)))):TI IN DARE, HTA
10	(((pressure* NEAR3 perin?ometr*))):TI IN DARE, HTA

#	Searches
79	MeSH DESCRIPTOR Resistance Training IN DARE, HTA
80	((((strength* or resistan*) NEAR3 (training or exercise* or physiotherap*)))):TI IN DARE, HTA
81	(((manual NEAR3 therap*))):TI IN DARE, HTA
82	((myofascia* NEAR3 (release* or therap* or technique*))):TI IN DARE, HTA
83	#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 OR #77 OR #78 OR #79 OR #80 OR #81 OR #82
84	#46 AND #83

### **Economic Search**

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

## Database(s): NHS Economic Evaluation Database (NHS EED); HTA Database – CRD interface

Date of last search: 3 February 2021

	or last search: 3 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*)))) 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 cystoc?ele* or cystoc?ele* or cystoc?ele* or rectoenteroc?ele*
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 faeces 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

42

Fecal Impaction/ use ppez Feces Impaction/ use emczd

# Searches

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

#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) – OVID interface 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: 3 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

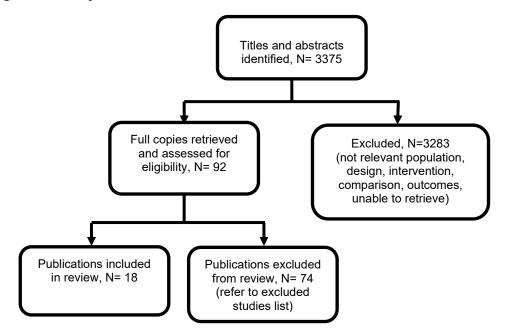
rint,	In-Process & Other Non-Indexed Citations and Daily
#	Searches
1	Pelvic Floor/ use ppez
2	Pelvic Floor Disorders/ use ppez
3	pelvis floor/ use emczd
4	pelvic floor disorder/ use emczd
5	(pelvi\$ adj (floor\$ or diaphragm\$) adj3 (dysfunction\$ or disorder\$ or fail\$ or impair\$ or incompeten\$ 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
40	

#### # **Searches** ((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. ((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 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. (vagin\$ adj wind).tw. 60 Vaginismus/ use ppez 61 vaginism/ use emczd 62 vaginismus\$.tw. 63 (vagin\$ adj penetrat\$ adj disorder\$).tw. or/55-63 65 7 or 19 or 30 or 34 or 54 or 64 Economics/ use ppez 67 Value of life/ use ppez 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 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. (cost\* adj2 (effective\* or utilit\* or benefit\* or minimi\* or unit\* or estimat\* or variable\*)).ab. 85 (financ\* or fee or fees).ti,ab. 87 (value adj2 (money or monetary)).ti,ab. 88 or/66-87 89 65 and 88 limit 89 to english language 90

### Appendix C - Clinical evidence study selection

Study selection for: What is the effectiveness of pelvic floor muscle training for preventing pelvic floor dysfunction?

Figure 2: Study selection flow chart



## Appendix D –Evidence tables

Evidence tables for review question: What is the effectiveness of pelvic floor muscle training for preventing pelvic floor dysfunction?

Table 5: Evidence tables

Study details	Participants	Interventions	Methods	Outcomes	Comments
Full citation  Agur,W.I., Steggles,P., Waterfield,M., Freeman,R.M., The long- term effectiveness of antenatal pelvic floor muscle training: eight-year follow up of a randomised controlled trial, BJOG: An International Journal of Obstetrics and Gynaecology, 115, 985- 990, 2008  Ref Id	Sample size See Reilly 2002 Starting sample size N=268 randomised. At 8 years, response from: Intervention: n=79 Control: n=85  Characteristics See Reilly 2002  Inclusion criteria	Interventions See Reilly 2002	Details Women were invited to take part in an 8-year follow-up though letter and then follow-up telephone call. The prevalence of Stress UI at 8 years was assessed using the symptoms questionnaire used in Reilly 2002 (See Reilly 2002).	Results Stress UI, n (%): Intervention 28 (35.5); Control 33 (38.8)  Adherence to PFMT as measured by frequency of PFMT (%): Still performed PFMT: 68.4% Of those who were still performing PFMT, those who were doing their PFMT exercises twice or more per week: 38%	Limitations See Reilly 2002
Country/ies where the study was carried out UK Study type RCT	Exclusion criteria See Reilly 2002				
Aim of the study 8-year follow-up to Reilly 2002					

Study details	Participants	Interventions	Methods	Outcomes	Comments
Study dates See Reilly 2002  Source of funding See Reilly 2002					
Full citation  Berzuk, K., Shay, B., Effect of increasing awareness of pelvic floor muscle function on pelvic floor dysfunction: a randomized controlled trial, International Urogynecology Journal, 26, 837-44, 2015  Ref Id  1147266  Country/ies where the study was carried out  Canada  Study type RCT  Aim of the study  1. To evaluate the pelvic floor knowledge in women working in an office	Sample size n=161 randomised n=54 allocated to group A, n=48 analysed n=55 allocated to group B, n=48 analysed n=52 allocated to group C, n=49 analysed  Characteristics Group A: Education and re-education; Group B: Single education only: Group C: Control  Age 18-29 years (n): Group A: 5; Group B: 4; Group C: 5 30-39 years (n): Group A: 11; Group B: 11; Group C: 10 40-49 years (n): Group A: 15; Group B: 15; Group C: 18 50-59 years (n): Group A: 16; Group B: 17; Group C: 14 60-69 years (n): Group A: 1; Group B: 17; Group C: 2 Pregnancies (number)	Interventions Group A: 60-min educational presentation on pelvic floor health and pelvic floor muscle function. Education included verbal instruction in a pelvic floor muscle home strengthening program. Approximately after 2 months from the education intervention, participants were invited to attend a second 60-min presentation. Group B: 60-min educational presentation on pelvic floor health and pelvic floor muscle function. Education included verbal instruction in a pelvic floor muscle home strengthening program Group C: Control - no intervention	Details Online survey was used to measure pelvic floor knowledge and presence of pelvic floor dysfunction symptoms and quality of life relating to PFD using the PFDI-20 and PFIQ-7. The first survey was completed at baseline. The second survey was 24hrs after the education intervention (completed by groups A and B). The third survey was completed after the second education intervention (completed by group A), approximately 2 months after the first survey.	Results Group A: Education and re-education; Group B: Single education only: Group C: Control  PFD symptoms (PFDI-20): Baseline - all scores near 17% for all groups 2 month follow-up - Group A: 6%; Group B: 8%; Group C: no change Data converted into n's by NGA team: Group A: 3; Group B: 4; Group C: 8  PFD quality of life (PFIQ-7): Baseline - all scores near 8% for all groups 2 month follow-up - Group A: 4%; Group B: 4%; Group B: 4%; Group C: no change Data converted into n's by NGA team: Group A: 2; Group B: 2; Group C: 4	Limitations Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB2).  Domain 1 - randomisation: Low risk 1.1 Random sequence generation: Yes - computer-based system 1.2 Allocation concealment: Probably yes - no information given, but as computer based, likely to be concealed 1.3 Baseline differences: No - no significant differences reported  Domain 2 - Deviations from intended interventions (effect of assignment to interventions): Low risk 2.1 Participants aware of allocation: Yes - no information given, but likely women knew if they were receiving intervention or control 2.2 Carers and people delivering the intervention

Study details	Participants	Interventions	Methods	Outcomes	Comments
environment before and after Pelvic Floor Health and Pelvic Floor Muscle exercise education sessions 2. To objectively measure the presence of PFD symptoms within a female population and whether raising pelvic floor knowledge would impact PFD symptoms and PFD-related quality of life.	O (n): Group A: 13; Group B: 14; Group C: 12 1 (n): Group A: 7; Group B: 10; Group C: 5 2 (n): Group A: 12; Group B: 11; Group C: 17 3 (n): Group A: 11; Group B: 6; Group C: 9 4 (n): Group A: 4; Group B: 1; Group C: 2 5 or more (n): Group A: 1; Group B: 6; Group C: 4  Vaginal deliveries (number)				aware of allocation: Yes - education session delivery staff 2.3 Deviations from intended intervention: Probably no, participants did not complete intended intervention if they could not attend presentation times, or failed to respond to survey 2.6 Appropriate analysis to estimate effect of assignment: Yes - analysis excluded participants with missing outcomes  Domain 3 - Risk of bias due to missing outcome data: Low risk 3.1 Missing outcome data: Yes, data available for over 85% of the population
Source of funding Manitoba Hydro and the Women's Health Research Foundation of Canada	5 or more (n): Group A: 0; Group B: 1; Group C: 1  Caesarean deliveries (number) 0 (n): Group A: 41; Group B: 40; Group C: 45 1 (n): Group A: 5; Group B: 5; Group C: 2 2 (n): Group A: 2; Group B: 3; Group A: 0; Group B: 0; Group A: 0; Group B: 0; Group C: 1  Menstrual status (number)				Domain 4 - Measurement of the outcome: Low risk 4.1 Method for measuring outcome inappropriate: No - online survey, self- reporting 4.2 Could measurement of outcome differed between groups: No - online survey - self reporting 4.3 Outcome assessors aware of the intervention: NA - self reported

Study details	Participants	Interventions	Methods	Outcomes	Comments
	Regular periods (n): Group A: 23; Group B: 23; Group C: 28 Irregular periods (n): Group A: 6; Group B: 5; Group C: 4 Pregnant (n): Group A: 0; Group B: 1; Group C: 0 Perimenopausal (n): Group A: 6; Group B: 9; Group C: 4 Menopausal (n): Group A: 13; Group B: 10; Group C: 13  Inclusion criteria  Women from a large local corporation  Able to independently complete the online survey  Exclusion criteria  Failed to respond to email contact attempts				Domain 5 - Selection of the reported result: Some concerns 5.1 Data produced according to pre-specified plan: No information 5.2. Are results assessed likely to be selected on basis of results from multiple eligible outcome measurements: Probably no, data collected at 3 time points and reported as such 5.3 Are results assessed likely to be selected on basis of results from multiple eligible analysis of the data: Probably no  Domain 6 - Overall judgment of bias: Some concerns
Full citation  Chiarelli, P., Cockburn, J., Promoting urinary continence in women after delivery: randomised controlled trial, BMJ (Clinical research ed.), 324, 1241, 2002  Ref Id 480975	Sample size n=720 n=370 allocated to intervention; n=348 completed 3 month follow up n=350 allocated to usual care; n=328 completed 3 month follow up	Interventions Intervention: women were seen by a physiotherapist once during their stay in hospital (approx 20 mins) and again for a single visit at 8 weeks postpartum (approx 30 mins). The physiotherapist covered viewing the perineum, practising PFM contractions, 'the knack' and transverse	Details Women were interviewed by telephone 3 months after recruitment to the study and were sent a bladder diary before the interview to complete. Urinary Incontinence was measured using the following questions: "In the past month have you:	Results Prevalence of urinary incontinence at 3 months postpartum: Intervention: 108/348 (31%) Control: 125/328 (38.4%) (NB Chiarelli 2004 reports 126/328) Severe symptoms: Intervention: 35/348 (10.1%)	Limitations Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB2). Domain 1 - randomisation: Low risk 1.1 Random sequence generation: Yes - computer- generated randomisation list

Study details	Participants	Interventions	Methods	Outcomes	Comments
Country/ies where the study was carried out  Australia  Study type RCT  Aim of the study To test the effectiveness of a physiotherapist delivered intervention designed to prevent urinary incontinence among women 3 months after giving birth.  Study dates August 1998 to February 2000  Source of funding Medical Benefits Fund, Physiotherapy Foundation, and University of Newcastle Research Management Committee.	Age: 15-19 years, n (%): Intervention 15 (4); Control 27 (8) 20-24 years, n (%): Intervention 69 (19); Control 62 (18) 25-29 years, n (%): Intervention 128 (35); Control 125 (36) 30-34 years, n (%): Intervention 118 (32); Control 92 (26) 35-39 years, n (%): Intervention 34 (9); Control 41 (12) 40-44 years, n (%): Intervention 6 (2); Control 3 (1)  No of pregnancies: One, n (%): Intervention 198 (54); Control 187 (53) Two, n (%): Intervention 98 (27); Control 95 (27) Three, n (%): Intervention 60 (16); Control 44 (13) Four or more, n (%): Intervention 14 (4); Control 24 (7)  Inclusion criteria  • Women from a postpartum ward of 3 hospitals in NSW, Australia  • Women who had had a forceps or ventouse deliveries or their baby had had a birth weight of 400g or more	abdominus co- contractions, and discussion of the accompanying booklet which covered UI, PFD, PFM exercises, bladder habits etc. Control: received usual postpartum care, which did not include a visit from a physiotherapist but did include a brochure on PFM exercises.	I leaked even small amounts of urine when you were coughing, sneezing, laughing, or lifting;  I gone to the toilet urgently for fear you would leak; x leaked even small amounts if you had to wait to use the toilet;  I leaked even small amounts on your way to the toilet; or  I leaked even small amounts if you hadn't gone to the toilet immediately you first felt the need."  If the answer was 'often' or 'always' the woman was classified as incontinent.  Severity of incontinence was also assessed by asking about the frequency and amount of urine loss on the basis of a validated scale.	Control: 55/328 (16.8%)  Adherence – PFMT exercises 3 times per week or more: Intervention: 292/348 (83.9%) [80% to 87.8%] Control: 189/328 (57.6%) [52.3 to 62.9%]	1.2 Allocation concealment: Yes - sealed opaque envelopes 1.3 Baseline differences: No - no significant differences reported  Domain 2 - Deviations from intended interventions (effect of assignment to interventions): Low risk 2.1 Participants aware of allocation: No - women was told at the structured interview point which study group she was allocated to 2.2 Carers and people delivering the intervention aware of allocation: No - physiotherapist blinded to woman's allocation until structured interview point. 2.6 Appropriate analysis to estimate effect of assignment: Yes - analysis excluded participants with missing outcomes  Domain 3 - Risk of bias due to missing outcome data: Low risk 3.1 Missing outcome data Yes, data available for over 94% of the population  Domain 4 - Measurement of the outcome: Low risk

Study details	Participants	Interventions	Methods	Outcomes	Comments
	Exclusion criteria None reported				4.1 Method for measuring outcome inappropriate: No - survey interview 4.2 Could measurement of outcome differed between groups: Probably no - structured survey interview 4.3 Outcome assessors aware of the intervention: No - blinded to allocation  Domain 5 - Selection of the reported result: Some concerns 5.1 Data produced according to pre-specified plan: No information 5.2. Are results assessed likely to be selected on basis of results from multiple eligible outcome measurements: Probably no, data collected at 2 time points and reported as such 5.3 Are results assessed likely to be selected on basis of results from multiple eligible analysis of the data: Probably no
					judgment of bias: Some concerns
Full citation  Chiarelli, P., Murphy, B., Cockburn, J., Promoting urinary continence in	Sample size See Chiarelli 2002 for initial participant inclusion At 12 months: Intervention: n=294	Interventions See Chiarelli 2002	<b>Details</b> 12 month follow-up by telephone interview.	Results Urinary incontinence: Intervention: 101/294 (34.4) Control: 100/275 (36.4)	Limitations See Chiarelli 2002

Study details	Participants	Interventions	Methods	Outcomes	Comments
postpartum women: 12- month follow-up data from a randomised controlled trial, International Urogynecology Journal, 15, 99-105; discussion 105, 2004	Control N=275  Characteristics See Chiarelli 2002			Adherence – PFM exercises 3 times per week or more: Intervention: 117/294 (39.8%) Control: 89/275 (32.4%)	
<b>Ref Id</b> 825440	Inclusion criteria See Chiarelli 2002			PFM exercises performed: None at all: Intervention 16/294 (5.4%) vs Control 82/275 (29.8)	
Country/ies where the study was carried out  Australia	Exclusion criteria See Chiarelli 2002			Weekly or less: Intervention 161/294 (54.8%) vs Control 104/275 (37.8)	
Study type RCT				Several times per week: Intervention 76/294 (25.9%) vs Control 58/275 (21.1%)	
Aim of the study To compare pelvic floor exercise frequency and continence status for women in the intervention and 'usual care' control groups at 12 months postpartum – 12 month follow up to Chiarelli 2002				Daily or more: Intervention 41/294 (13.9%) vs Control 31/275 (11.3)	
Study dates See Chiarelli 2002					
Source of funding See Chiarelli 2002					
Full citation	Sample size N=118 randomised	Interventions Every woman in the exercise group was given	<b>Details</b> Female sexual function index (FSFI) was	Results Female Sexual Function Index (FSFI):	<b>Limitations</b> Limitations were assessed using the revised

Study details	Participants	Interventions	Methods	Outcomes	Comments
Citak, Nevin, Cam, Cetin, Arslan, Hediye, Karateke, Ates, Tug, Niyazi, Ayaz, Reyhan, Celik, C. E. M., Postpartum sexual function of women and the effects of early pelvic floor muscle exercises, Acta Obstetricia et Gynecologica Scandinavica, 89, 817- 822, 2010  Ref Id 1232726  Country/ies where the study was carried out Turkey  Study type RCT  Aim of the study To evaluate the effects of early pelvic floor muscle training after vaginal delivery on sexual function  Study dates June and September 2006  Source of funding	n=58 allocated to intervention, n=37 analysed n=60 allocated to control, n=38 analysed  Characteristics Age (years), mean (SD): Intervention 23.0 (3.2); Control 22.2 (3.1)  Duration of marriage (months), mean (SD): Intervention 19.7 (13.9); Control 14.7 (6.6)  Inclusion criteria  primiparous women who delivered vaginally in Zeynep Kamil Hospital  Exclusion criteria  PFM training before or during the pregnancy pregnancies complicated by gynaecological (adnexal mass, fibroids, etc.) or systemic diseases, difficulties in communication (illiteracy and language problems)	a booklet describing the exercises and containing a surveillance chart, which was completed by the patient herself after each exercise. Women were educated about the anatomy and function of the PFM and how to correctly contract their muscles and instructed to carry out contraction and relaxation periods for 3 seconds, followed by faster contraction and relaxation periods of 2 seconds 10 times a day in the first 15 days. Thereafter, the duration of contraction and relaxation was changed to 5 seconds, but the duration of the following periods, although faster, was the same. All patients in the study group continued to increase the durations to 10 seconds and the number of workouts to 15 sessions/day up to the end of the study.	measured at 4th and 7th month postpartum.  Women in the intervention group were called regarding both their adherence to the exercise programs and any other problems, twice in the first month and once in the following second and third months.	Total Score at 4 months: Intervention 24.09 (5.37); Control 24.94 (4.12) Total Score at 7 months: Intervention 28.92 (4.50); Control 26.58 (4.58)	Cochrane risk-of-bias tool for randomised trials (RoB2).  Domain 1 - randomisation: Low risk 1.1 Random sequence generation: Yes -statistical software program 1.2 Allocation concealment: Probably yes - no information given but as computer based, likely to be concealed 1.3 Baseline differences: No - no significant differences reported  Domain 2 - Deviations from intended interventions (effect of assignment to interventions): Low risk 2.1 Participants aware of allocation: Yes - no information given, but likely women knew if they were receiving intervention or control 2.2 Carers and people delivering the intervention aware of allocation: Yes - no information given, but delivery staff likely knew 2.3 Deviations from intended intervention: No information given 2.6 Appropriate analysis to estimate effect of assignment: Yes - analysis excluded participants with missing outcomes

FINAL Pelvic floor muscle training for the prevention of pelvic floor dysfunction

Study details	Participants	Interventions	Methods	Outcomes	Comments
					Domain 3 - Risk of bias due to missing outcome data: Low risk 3.1 Missing outcome data: No, data available for over 63% of the population 3.2 Results not biased by missing outcomes: No, analysis does not correct for missing data 3.3 Missingness in the outcome depend on its true value: No, loss to follow-up even between groups and reasons documented that are unrelated to the outcomes  Domain 4 - Measurement of the outcome: Low risk 4.1 Method for measuring outcome inappropriate: No - self-reporting 4.2 Could measurement of outcome differed between groups: No - self-reporting 4.3 Outcome assessors aware of the intervention: No - blinded to the women's group allocations
					Domain 5 - Selection of the reported result: Some concerns 5.1 Data produced according to pre-specified plan: No information 5.2. Are results assessed likely to be selected on basis of results from

Study details	Participants	Interventions	Methods	Outcomes	Comments
					multiple eligible outcome measurements: Probably no, data collected at 3 time points and reported as such 5.3 Are results assessed likely to be selected on basis of results from multiple eligible analysis of the data: Probably no  Domain 6 - Overall judgment of bias: Some concerns
Full citation  Diokno, A. C., Sampselle, C. M., Herzog, A. R., Raghunathan, T. E., Hines, S., Messer, K., Karl, C., Leite, M. C., Prevention of urinary incontinence by behavioral modification program: a randomized, controlled trial among older women in the community, Journal of Urology, 171, 1165-71, 2004	Sample size See Sampselle 2005  Characteristics See Sampselle 2005  Inclusion criteria See Sampselle 2005  Exclusion criteria See Sampselle 2005	Interventions See Sampselle 2005	Details See Sampselle 2005	Results Women who reported zero days of UI at baseline, % of women still continent (zero or 1 to 5 days of UI) at 12 months: 37% for treatment group; 28% for control group Women who reported zero or 1 to 5 days of UI episodes at baseline, % of women still continent (zero or 1 to 5 days of UI) at 12 months: 56% for treatment group; 41% for control group	Limitations See Sampselle 2005
<b>Ref Id</b> 1176620				Mean voiding frequencies: Over a 24hr period: PFMT 6.1 voids per day; Control	
Country/ies where the study was carried out USA				7.5 voids per day Voids during awake period: PFMT 5.4 voids per day; Control 6.6 voids	
Study type RCT				per day	

Study details	Participants	Interventions	Methods	Outcomes	Comments
Aim of the study To determine whether a behavioral modification program (BMP) taught to groups of continent older women would decrease the incidence of urinary incontinence, increase pelvic muscle strength and improve voiding control (originating from the same RCT as described in Sampselle (2005), but with additional outcomes)  Study dates Not reported  Source of funding Not reported				Voids during sleep period: PFMT 0.7 voids per day; Control 0.9 voids per day Mean voiding interval: PFMT 3.69 hrs; Control 3.09 hrs	
Full citation  Golmakani, N., Zare, Z., Khadem, N., Shareh, H., Shakeri, M. T., The effect of pelvic floor muscle exercises program on sexual self-efficacy in primiparous women after delivery, Iran J Nurs Midwifery Res, 20, 347-53, 2015	Sample size N=104 randomised n=52 allocated to intervention, n=40 analysed n=52 allocated to control, n=39 analysed  Characteristics	Interventions Women were given face- to-face training about the anatomy and function of the PFM and how to do Kegel exercises. Women were also given a pamphlet and audio CD about how to do the exercises. Women were asked to complete their PFM exercises - 1 block would be to contract their	Details Women were recruited 8 weeks after childbirth. Outcomes were examined at 12 and 16 weeks after delivery (i.e. week 4 and week 8 after the start of the study). The Bailes sexual self-efficacy questionnaire was used - higher scores indicated higher sexual self- efficacy.	Results The Bailes sexual self- efficacy questionnaire was used - higher scores indicated higher sexual self-efficacy: At week 4: Intervention 51.68 (11.14); Control 50.82 (12.61) At week 8: Intervention 62.78 (12.16); Control 52.28 (13.18)	Limitations Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB2). Domain 1 - randomisation: Some concerns 1.1 Random sequence generation: No information

Study details	Participants	Interventions	Methods	Outcomes	Comments
Ref Id  1232727  Country/ies where the study was carried out  Iran  Study type RCT  Aim of the study To define the effects of an 8-week pelvic floor muscle exercise program on sexual self-efficacy in primiparous women after childbirth	Age (years), mean (SD): Intervention 25.19 (3.78); Control 26.57 (3.92)  BMI (kg/m2), mean (SD): Intervention 24.17 (2.90); Control 24.64 (3.14)  Marriage duration (years), mean (SD): Intervention 3.55 (1.78); Control 4.21 (2.13)  Inclusion criteria  • being nulliparous  • Iranians living in Mashhad  • having the ability to read and write	PFM for 5-10 seconds and relaxing for 5-10 seconds repeating 15-20 times, each block should be interspersed with 2 mins rest before being repeated a total of 4 times, twice a day. Women were to complete checklist of completing their PFM exercises, checklists were collected every 4 weeks and telephone check-ins were every 2 weeks.	Methods	Outcomes	1.2 Allocation concealment: No information 1.3 Baseline differences: No - no significant differences reported  Domain 2 - Deviations from intended interventions (effect of assignment to interventions): Some concerns 2.1 Participants aware or allocation: No information 2.2 Carers and people delivering the interventio aware of allocation: No information 2.3 Deviations from intended intervention: No information 2.6 Appropriate analysis
Study dates 2013	<ul><li>living with husband</li><li>beginning the sexual activity after delivery</li><li>having passed 8 weeks</li></ul>				to estimate effect of assignment: Probably ye not ITT analysis, but appropriate for the data
Source of funding Research Deputy of Mashhad University of Medical Sciences	of vaginal delivery  having a healthy baby  no postpartum complications  lack of special medical disease  lack of psychological				Domain 3 - Risk of bias due to missing outcome data: Low risk 3.1 Missing outcome dat Yes, data available for over 75% of the population
	disorder in couples     non-addictive couples     not using alcohol or drugs affecting sexual function				Domain 4 - Measurement of the outcome: Low risk 4.1 Method for measurin outcome inappropriate: No - self-reporting

Study details	Participants	Interventions	Methods	Outcomes	Comments
	<ul> <li>no uterine prolapse or cystocele or rectocele grade 3 and 4</li> <li>not having undergone stressful event during a month ago</li> <li>Exclusion criteria</li> <li>being pregnant during the study</li> <li>doing regular exercises during the study</li> <li>not regularly performing Kegel exercise program based on the method proposed in the study.</li> </ul>				4.2 Could measurement of outcome differed between groups: No - self reporting 4.3 Outcome assessors aware of the intervention: No information 4.4 Assessment of outcome be influenced by knowledge of intervention: No  Domain 5 - Selection of the reported result: Some concerns 5.1 Data produced according to pre-specified plan: No information 5.2. Are results assessed likely to be selected on basis of results from multiple eligible outcome measurements: Probably no, data collected at 3 time points and reported as such 5.3 Are results assessed likely to be selected on basis of results from multiple eligible analysis of the data: Probably no
Full citation  Kahyaoglu Sut, H.,  Balkanli Kaplan, P., Effect of pelvic floor muscle	Sample size N=64 randomised n=32 allocated to training group; n=30 analysed	Interventions Intervention group: Participants were instructed by a researcher on how to perform Kegel	Details The following questionnaires were collected: UDI-6, IIQ-7, OAB-q and voiding	Results Baseline - week 28 of gestation UDI-6: Intervention 45.8 (11.5); Control 40.6 (10.6)	Limitations Limitations were assessed using the revised Cochrane risk-of-bias tool

Study details	Participants	Interventions	Methods	Outcomes	Comments
exercise on pelvic floor muscle activity and voiding functions during pregnancy and the postpartum period, Neurourology & UrodynamicsNeurourol Urodyn, 35, 417-22, 2016  Ref Id 1197020  Country/ies where the study was carried out  Turkey  Study type RCT  Aim of the study To investigate the effects of pelvic floor muscle	n=32 allocated to control group; n=30 analysed  Characteristics Age (years), mean (SD): Intervention 30.0 (6.5); Control 27.2 (6.3)  BMI (kg/m2), mean (SD): Intervention 29.9 (5.7); Control 27.7 (5.0)  Gravidity, mean (SD): Intervention 2.8 (1.5); Control 2.3 (1.7)  Parity, mean (SD): Intervention 1.2 (1.1); Control 0.8 (1.1)  Number of vaginal deliveries, mean (SD): Intervention 0.9 (1.2);	exercises, according to the following information:  1. The bladder must be emptied prior to exercise; 2. Exercises can be done in a supine or sitting position by bending the legs at the knee; 3. Pelvic floor muscles should be contracted by pulling inward as with urine or gas output and held for 10sec; 4. Following 10 sec of contraction, the muscles should be completely relaxed; and 5. This contraction	diaries. Questionnaires and voiding diaries were completed at week 28, week 36-38 of pregnancy and postpartum week 6-8.	IIQ-7: Intervention 3.0 (6.9); Control 0.9 (2.9) OAB-q - coping: Intervention 85.0 (21.0); Control 95.0 (9.7) OAB-q - concern: Intervention 85.1 (19.4); Control 95.1 (9.6) OAB-q - sleep: Intervention 74.1 (25.0); Control 87.8 (15.3) OAB-q - social: Intervention 95.0 (11.4); Control 99.7 (1.0) OAB-q - total score: Intervention 84.9 (18.3); Control 94.5 (8.5)  Week 36-38 of gestation UDI-6: Intervention 46.9 (8.7); Control 44.1 (8.7) IIQ-7: Intervention 4.7 (10.0); Control 1.2 (3.2) OAB-q - coping: Intervention 85.8 (15.6);	for randomised trials (RoB2).  Domain 1 - randomisation: Low risk 1.1 Random sequence generation: Yes - block design, computer- generated numbers table 1.2 Allocation concealment: Yes - randomly blinded 1.3 Baseline differences: No - no significant differences reported  Domain 2 - Deviations from intended interventions (effect of assignment to interventions): Low risk 2.1 Participants aware of allocation: Probably yes - cannot blind taught sessions and phone calls 2.2 Carers and people
exercise during pregnancy and the postpartum period on pelvic floor muscle activity and voiding functions.  Study dates September 2011 to August 2012	Control 0.4 (0.8)  Number of caesarean deliveries, mean (SD): Intervention 0.3 (0.5); Control 0.4 (0.7)  Delivery type Vaginal, n (%): Intervention 20 (66.7); Control 12 (40.0) Caesarean, n (%): Intervention 10 (33.3); Control 18 (60.0)	should be performed a total of 10 times. These sets of 10 contractions should be performed 3 times per day (for example morning, afternoon, and evening).		Control 89.1 (18.5) OAB-q - concern: Intervention 84.3 (16.3); Control 89.4 (18.5) OAB-q - sleep: Intervention 76.4 (18.6); Control 84.5 (14.9) OAB-q - social: Intervention 96.6 (6.2); Control 97.6 (6.3) OAB-q - total score: Intervention 85.7 (13.5); Control 90.0 (13.6)	delivering the intervention aware of allocation: Probably yes - researcher would have likely known the purpose of the intervention 2.3 Deviations from intended intervention: Probably no, no mention of deviation 2.6 Appropriate analysis to estimate effect of assignment: Yes -
Source of funding Trakya University Research Foundation (TUBAP 2011-58)	Inclusion criteria	Women were called every 2 weeks to be reminded about their exercises.		Week 6-8 postpartum UDI-6: Intervention 34.1 (6.6); Control 34.0 (8.2)	analysis excluded participants with missing outcomes

Study details	Participants	Interventions	Methods	Outcomes	Comments
	pregnant women who were in their third trimester (28th week) over the age of 18 attending the Gynaecology and Obstetrics Department of the University Faculty of Medicine  Exclusion criteria pregnant women who: had twin or high-risk pregnancies, urinary tract infections, prolapses, neuropathy, collagen tissue disease, neurological illnesses, diabetes mellitus, chronic pulmonary disease, a history of pelvic surgery, had a high risk of early delivery	Control group: No instructions given		IIQ-7: Intervention 1.7 (6.4); Control 0.3 (1.7) OAB-q - coping: Intervention 97.4 (10.3); Control 98.2 (5.8) OAB-q - concern: Intervention 97.3 (8.9); Control 97.4 (7.7) OAB-q - sleep: Intervention 94.5 (12.0); Control 94.9 (11.2) OAB-q - social: Intervention 99.3 (3.6); Control 99.8 (0.7) OAB-q - total score: Intervention 97.2 (8.7); Control 97.6 (6.3)	Domain 3 - Risk of bias due to missing outcome data: Low risk 3.1 Missing outcome data: Yes, data available for over 93% of the population  Domain 4 - Measurement of the outcome: Low risk 4.1 Method for measuring outcome inappropriate: No - self-reporting questionnaires 4.2 Could measurement of outcome differed between groups: No - self-reporting questionnaires 4.3 Outcome assessors aware of the intervention: No information 4.4 Could assessment have been influenced by intervention knowledge: No  Domain 5 - Selection of the reported result: Some concerns 5.1 Data produced according to pre-specified plan: No information 5.2. Are results assessed likely to be selected on basis of results from multiple eligible outcome measurements: Probably no, data collected at 3 time points and reported as such

Study details	Participants	Interventions	Methods	Outcomes	Comments
					5.3 Are results assessed likely to be selected on basis of results from multiple eligible analysis of the data: Probably no  Domain 6 - Overall judgment of bias: Some concerns
Full citation  Kocaoz, S., Eroglu, K., Sivaslioglu, A. A., Role of pelvic floor muscle exercises in the prevention of stress urinary incontinence during pregnancy and the postpartum period, Gynecologic & Obstetric InvestigationGynecol Obstet Invest, 75, 34-40, 2013  Ref Id  1196619  Country/ies where the study was carried out  Turkey  Study type Quasi-randomised controlled study  Aim of the study To evaluate the role of pelvic floor muscle	Sample size N= 136 quasi-randomised n=68 allocated to intervention; n=52 analysed n=68 allocated to control; n=50 analysed  Characteristics Age (years), mean (SD): Intervention 26.33 (4.8); Control 25.70 (4.4)  BMI before pregnancy: <20, n (%): Intervention 12 (23.1); Control 5 (10.0) 20-24.9, n (%): Intervention 29 (55.8); Control 25 (50.0) 25-29.9, n (%): Intervention 9 (17.3); Control 14 (28.0) 30-39, n (%): Intervention 2 (3.8); Control 6 (12.0)  Inclusion criteria	Interventions Intervention: Women were given training and information about the reproductive and urinary organs, functions of the PFM and how PFM exercises can strengthen PFMs, how pregnancy and vaginal delivery impact incontinence, issues with UI and benefits and application of PFM exercises. Women built up to 3 exercise sessions per day, - each session containing 3 sets of 10 contractions and relaxations of PFMs for 10 s for endurance and to build strength contraction/relaxation for 2 s. Women were asked to perform these exercises during pregnancy and in the postpartum period Control: women were not instructed to do PFM exercises, but after the 12th week home visit, women were given a	Details At baseline women completed the 1hr pad test, trained to use urinary diaries. The presence of SUI was based on a negative 1-hour pad test (<2g in weight).	Results Presence of SUI based on 1-hour pad test: Gestational week 28, n(%): Intervention 3 (5.8); Control 15 (30.0)  Gestational week 32, n(%): Intervention 9 (17.3); Control 24 (48.0)  12th week postpartum, n(%): Intervention 1 (1.9); Control 9 (18.0)	Limitations Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB2). Domain 1 - randomisation: Some concerns 1.1 Random sequence generation: No - quasirandom, odd days women were assigned to intervention and even days women were assigned to control 1.2 Allocation concealment: Yes - women were not informed which group they were in 1.3 Baseline differences: Probably no - significant differences not assessed, participants baseline looks evenly distributed  Domain 2 - Deviations from intended interventions (effect of assignment to interventions): Low risk

Study details	Participants	Interventions	Methods	Outcomes	Comments
exercises in preventing the development of SUI in the pregnancy and postpartum periods in women without UI	<ul> <li>able to attend pregnancy outpatient visits regularly</li> <li>in the 14th–20th gestational week during the first attendance</li> <li>between 20 and 35</li> </ul>	brochure and relevant information.			2.1 Participants aware of allocation: No -women were not informed which group they were in 2.2 Carers and people delivering the intervention aware of allocation: Yes
Study dates May 2006 to February 2007	<ul> <li>between 20 and 35 years of age</li> <li>completed at least elementary school</li> <li>having no UI complaints or urinary tract infection</li> </ul>				- not blinded 2.3 Deviations from intended intervention: Probably yes, some women discontinued intervention (8/86, 12%)
Source of funding Not reported	<ul> <li>(UTI)</li> <li>a BMI below 40</li> <li>no chronic disease (such as asthma) or genitourinary pathology (such as pelvic organ prolapse) requiring treatment.</li> </ul>				2.4 Deviations likely to affect outcome? No, women excluded from analysis 2.6 Appropriate analysis to estimate effect of assignment: Yes - analysis excluded participants with missing outcomes
	Exclusion criteria None reported				Domain 3 - Risk of bias due to missing outcome data: Low risk 3.1 Missing outcome data: Probably no, data available for 74% of the population in control arm and 76% in intervention arm 3.2 Results not biased by missing outcomes: Yes, missing outcome data well matched between groups
					Domain 4 - Measurement of the outcome: Low risk

FINAL Pelvic floor muscle training for the prevention of pelvic floor dysfunction

Study details	<b>Participants</b>	Interventions	Methods	Outcomes	Comments
					4.1 Method for measuring outcome inappropriate: No - pad test 4.2 Could measurement of outcome differed between groups: No - pad test 4.3 Outcome assessors aware of the intervention: Yes - investigators were not blinded 4.4 Could assessment be influenced by knowledge of intervention: No - weight of pad test is not subjective  Domain 5 - Selection of the reported result: Some concerns 5.1 Data produced according to pre-specified plan: No information 5.2. Are results assessed likely to be selected on basis of results from multiple eligible outcome measurements: Probably no, data collected at 3 time points and reported as such 5.3 Are results assessed likely to be selected on basis of results from multiple eligible analysis of the data: Probably no
					Domain 6 - Overall judgment of bias: Some concerns

Study details	Participants	Interventions	Methods	Outcomes	Comments
Full citation  Lin, R., Chen, X., Jin, T., Li, W., Zhu, L., The feasibility of nursing intervention in postpartum pelvic floor muscle rehabilitation among puerperae and its influence on sui incidence and comprehensive muscle strength, International Journal of Clinical and Experimental Medicine, 13, 4571-4579, 2020  Ref Id  1290383  Country/ies where the study was carried out China  Study type RCT  Aim of the study To study the feasibility of postpartum pelvic floor muscle (PFM) rehabilitation in puerperae and analyse the influence of intervention on the incidence of postpartum stress urinary incontinence (SUI) and comprehensive muscle strength	Sample size n=97 n=49 randomised to intervention n=48 randomised to control  Characteristics Age (mean, SD): Intervention 28.01 (2.23); Control 27.99 (2.41)  BMI (mean, SD): Intervention 21.34 (3.21); control 21.22 (3.51)  Inclusion criteria (1) puerperae aged 20-35 years old (2) primiparae with singleton pregnancies; (3) puerperae who could finish the investigation with a clear consciousness and self- care ability (4) the study participants or their family members signed an Informed Consent Form  Exclusion criteria (1) puerperae with mental diseases (2) those with a history of PFD	Interventions PFMT: The SG received one-on-one nursing intervention in postpartum PFM rehabilitation and health education, with the contents mainly including the steps, methods, principles, and cautions of PFM rehabilitation training. At the same time, the nursing intervention in PFM rehabilitation was implemented, with the specific measures shown below.  (1) Kegel training. Women were kept in a horizontal position with their legs bent and separated. Then they contracted the anus for about 6-8 s while breathing in and relaxed the anus while breathing out. This exercise was repeated for 30 min each time, 3 times a day. The treatment course was 6-8 weeks. Attention was paid to avoiding the participation of the leg and gluteal muscles. After mastering the basics of the exercise, the women could do the exercises in a sitting or standing position, gradually prolonging the contracting and exercise times. During the exercise, intermittent urination training was added,	Details SUI incidence was assessed at 1, 3 and 6 months after the intervention. ICIQ-SF and IQoL were assessed before the intervention and at 6 months after the intervention.	Results SUI incidence (number, %) 1 month  Intervention group: 12 (24.49%) Control group: 21 (42.75%)  3 months  Intervention group: 4 (8.16%) Control group: 11 (22.92%)  6 months  Intervention group: 1 (2.04%) Control group: 6 (12.50%)  ICIQ-SF (mean, SD) Baseline  Intervention group: 12.67 (2.01) Control group: 12.71 (1.87)	Limitations Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB2).  Domain 1 - randomisation: Low risk 1.1 Random sequence generation: No information, method of randomisation is not reported 1.2 Allocation concealment: No information, allocation concealment is not reported 1.3 Baseline differences: No - no significant differences reported  Domain 2 - Deviations from intended interventions (effect of assignment to interventions): Low risk 2.1 Participants aware of allocation: Yes - could not be blinded 2.2 Carers and people delivering the intervention aware of allocation: Yes - could not be blinded 2.3 Deviations from intended intervention: Not reported 2.6 Appropriate analysis to estimate effect of assignment: Yes - all participants were included

Study details	Participants	Interventions	Methods	Outcomes	Comments
Source of funding Startup Fund for Scientific Research, Fujian Medical University	(3) those malignant tumors (4) those with urinary tract infections (5) those with a history of pelvic surgery (6) those with impaired cognition (7) those with vesical fistula or other diseases that could affect the results.	namely stopping or slowing down the urine stream while urinating.  (2) Biological feedback and electrical stimulation of PFM. The electrodes of PFM rehabilitation instrument were put into the vagina for high-frequency electrical stimulation under high current intensity (not exceeding 100 mA). The stimulation lasted for 2 s each time and the interval time was 4 s. This therapy was performed for 30 min each time, twice a week. The treatment course was 6 months.  (3) Vaginal cone training. Cones were inserted into the vagina to the depth of a finger after it was covered with lubricating fluid. Women were advised to tighten their muscles and then stand up for the exercise after feeling the rising of the cone inside the vagina. This exercise lasted for 20 min each time, once a day. After women tolerated a heavier cone, the exercise could be combined with cough and jump, etc.  Control: The CG only received routine postpartum rehabilitation		<ul> <li>Intervention group: 3.87 (0.32)</li> <li>Control group: 6.91 (0.29)</li> <li>I-QoL (mean, SD) Baseline</li> <li>Intervention group: 35.38 (3.23)</li> <li>Control group: 35.61 (3.43)</li> <li>6 months</li> <li>Intervention group: 70.28 (3.44)</li> <li>Control group: 61.28 (3.29)</li> </ul>	Domain 3 - Risk of bias due to missing outcome data: Low risk 3.1 Missing outcome data: Yes, data available for all participants  Domain 4 - Measurement of the outcome: Some concerns 4.1 Method for measuring outcome inappropriate: No - validated questionnaires 4.2 Could measurement of outcome differed between groups: No - self-reporting 4.3 Outcome assessors aware of the intervention: Yes - self-reported 4.4 Could assessment have been influenced by knowledge of intervention: Yes, due to self reporting 4.5 Likely that assessment was influenced by knowledge of intervention: Probably no, control group still received an intervention (usual care)  Domain 5 - Selection of the reported result: Some concerns 5.1 Data produced according to pre-specified plan: No information 5.2. Are results assessed likely to be selected on basis of results from

Study details	Participants	Interventions	Methods	Outcomes	Comments
		nursing. The medical workers explained the significance and necessity of postpartum pelvic floor rehabilitation to the women and provided them with health education materials, excluding one-to-one guidance on rehabilitation training. Meanwhile, the women were advised to return to the clinic at 1, 3, and 6 months after childbirth and to receive telephone follow-up.			multiple eligible outcome measurements: Probably no, data collected at 3 time points and reported as such 5.3 Are results assessed likely to be selected on basis of results from multiple eligible analysis of the data: Probably no  Domain 6 - Overall judgment of bias: Some concerns
Full citation  Pelaez, M., Gonzalez-Cerron, S., Montejo, R., Barakat, R., Pelvic floor muscle training included in a pregnancy exercise program is effective in primary prevention of urinary incontinence: a randomized controlled trial, Neurourology & UrodynamicsNeurourol Urodyn, 33, 67-71, 2014  Ref Id  1197038  Country/ies where the study was carried out  Spain  Study type  RCT	Sample size N=169 randomised n=73 allocated to intervention; n=63 analysed n=96 allocated to usual care; n=89 analysed  Characteristics Age (years), mean (SD): Intervention 29.9 (3.3); Control 29.1 (4.5)  Pre-pregnancy BMI (kg/m2), mean (SD): Intervention 23.6 (4.3); Control 22.7 (3.8)  Pre-pregnancy physical activity levels: Inactive, n (%): Intervention 33 (53.2); Control 56 (62.9)	Interventions Intervention: A structured exercise program lasting 22 weeks (from 14–36 weeks of gestation). Sessions were 3 times per week and 55–60 min in duration conducted at the hospital. Session consisted of 8 min of warm-up; 30 min of low impact aerobics (performing different choreographies) including 10 min of general strength training (for example core muscles, pectoralis, gluteus, quadriceps, calves, biceps); 10 min of PFMT and 7 min of cool down, which included stretching, relaxation or massage. Women received information of anatomy and function of	Details Outcomes included reported frequency, amount, and impact on daily life of UI, measured using the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF). Women completed the forms at the end of intervention (between 36 and 40 weeks of gestation).	Results ICIQ-Score, mean (SD): Intervention 0.24 (1.2); Control 2.66 (4.1)  Adherence to PFMT - Participants included in the analysis attended at least 80% of 70–78 exercise sessions during at least 22 weeks.	Limitations Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB2).  Domain 1 - randomisation: Low risk 1.1 Random sequence generation: Yes - statistical randomisation computer program 1.2 Allocation concealment: Probably yes - no information given, but as computer based, likely to be concealed 1.3 Baseline differences: No - no significant differences reported  Domain 2 - Deviations from intended interventions (effect of

Study details	Participants	Interventions	Methods	Outcomes	Comments
Aim of the study To investigate the effect of pelvic floor muscle training (PFMT) taught in a general exercise class during pregnancy on the prevention of urinary incontinence (UI) in nulliparous continent pregnant women.  Study dates October 2009 to October 2011  Source of funding None reported	Active, n (%): Intervention 29 (46.8); Control 33 (37.1)  Inclusion criteria  • healthy and primiparous pregnant with singleton foetus  • in gestational week 10–14  • not suffering from UI  • able to communicate in Spanish  • able to give informed written consent.  Exclusion criteria  • planning not to give birth in Fuenlabrada University Hospital  • any contraindication according to the American College of Obstetricians and Gynaecologists Guidelines	the PFM and why the muscles may prevent and treat the UI. At first, women learned to perceive their pelvic floor, and then learned how to do adequate contractions. The PFMT followed a progression, starting with 1 set of 8 contractions and increasing the number of total contractions to 100, divided in different sets of slow (6 sec) and fast contractions (5 contractions as fast as possible). To increase motivation and abilities, different exercises, positions and sometimes music to follow the beat. Women were encouraged to perform 100 contractions distributed in different sets every day. Control group: received usual care (which included follow up by midwifes including information about PFMT) and were not asked not to train their pelvic floor muscles.			assignment to interventions): Low risk 2.1 Participants aware of allocation: Yes - women knew if they were receiving intervention or control 2.2 Carers and people delivering the intervention aware of allocation: Yes - exercise delivery staff knew 2.3 Deviations from intended intervention: Probably no, reported high adherence 2.6 Appropriate analysis to estimate effect of assignment: Yes - analysis excluded participants with missing outcomes  Domain 3 - Risk of bias due to missing outcome data: Low risk 3.1 Missing outcome data: Yes, data available for over 85% of the population  Domain 4 - Measurement of the outcome: Low risk 4.1 Method for measuring outcome inappropriate: No - self-reporting questionnaire 4.2 Could measurement of outcome differed between groups: No - self- reporting questionnaire

Study details	Participants	Interventions	Methods	Outcomes	Comments
					4.3 Outcome assessors aware of the intervention: NA - self reported  Domain 5 - Selection of the reported result: Some concerns 5.1 Data produced according to pre-specified plan: No information 5.2. Are results assessed likely to be selected on basis of results from multiple eligible outcome measurements: Probably no, data collected at 2 time points and reported as such 5.3 Are results assessed likely to be selected on basis of results from multiple eligible analysis of the data: Probably no
Full citation  Pourkhiz, Z., Mohammad-Alizadeh-Charandabi, S., Mirghafourvand, M., Haj-Ebrahimi, S., Ghaderi, F., Effect of Pelvic Floor Muscle Training on Female Sexual Function During Pregnancy and Postpartum: A Randomized Controlled Trial, Iran Red Crescent Med J, 19, e63218, 2017	Sample size N=84 randomised n= 42 allocated to intervention; n=41 analysed n=42 allocated to control; n=41 analysed  Characteristics Age (years), mean (SD): Intervention 26.0 (4.1); Control 25.3 (4.7)	Interventions Intervention: Women were instructed to perform PFM exercises at least twice a day, at any time and any position based on individual comfort. The exercises include 8 - 12 sets of contractions at each time and each contraction set comprised 1 strong contraction with a maximum possible power holding for 6 - 8 seconds	Details Sexual function and sexual quality of life were assessed at baseline, the 28th - 30th weeks' gestation, and also at the 3rd month (80 - 90 days). The female sexual function index (FSFI) was used to assess the sexual function. Sexual quality of life-female (SQOL-F) was used to assess the sexual quality of life.	Results  FSFI: Overall sexual function, 28-30 weeks gestation: Intervention 29.3 (4.2); Control 21.1 (4.2) 3 months postpartum: Intervention 28.7 (1.8); Control 16.0 (2.1)  SQOL-F: Sexual quality of life,	Limitations Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB2). Domain 1 - randomisation: Low risk 1.1 Random sequence generation: Yes - block randomisation, computer generated

Study details	Participants	Interventions	Methods	Outcomes	Comments
Ref Id 1232729 Country/ies where the study was carried out Iran Study type RCT	BMI (kg/m2), mean (SD): Intervention 25.0 (3.3); Control 24.1 (4.5)  Inclusion criteria  • singleton pregnant women at 17 - 20 weeks gestation  • aged 18 - 35 years	followed by 3 or 4 contractions in a shorter period, with a 10-second complete relaxation after each contraction.  Exercises were performed from recruitment until 36 - 37 weeks gestation and then resumed after giving birth as soon as possible. A midwife gave theoretical and practical individual education, as well as a pamphlet explaining the		28-30 weeks gestation: Intervention 52.8 (13.6); Control 34.3 (9.0) 3 months postpartum: Intervention 62.3 (11.4); Control 30.5 (6.1)  Adherence to PFMT: Women in the intervention group performed at least 70% of the exercises.	1.2 Allocation concealment: Yes - sealed opaque envelopes 1.3 Baseline differences: No - no significant differences reported  Domain 2 - Deviations from intended interventions (effect of assignment to interventions): Low risk 2.1 Participants aware of allocation: Yes - could not
Aim of the study To examine the effect of PFM training on sexual function (primary outcome), sexual quality of life, and PFM strength (secondary outcomes) in pregnant and postpartum women  Study dates Enrolment May to	<ul> <li>Exclusion criteria</li> <li>having less than 6 years of education</li> <li>no permanent marriage or not living with husband</li> <li>prior history of 2 or more abortions</li> <li>any pregnancy-related complications limiting sexual function (for example placenta</li> </ul>	exercises to each participant. The session took 20 - 30 minutes and included a brief explanation of the anatomy of pelvic floor muscles and how to do the exercises at different positions, also examining pelvic floor muscle contractions by hand during exercise to ensure accuracy of the exercises. 3 follow-up group			be blinded 2.2 Carers and people delivering the intervention aware of allocation: Yes - could not be blinded 2.3 Deviations from intended intervention: Not reported 2.6 Appropriate analysis to estimate effect of assignment: Yes - analysis excluded participants with missing outcomes
November 2014 and follow-up until July 2015  Source of funding Tabriz University of Medical Sciences	previa, cervical cerclage)  addiction to drugs or alcohol  experience of severe emotional stress within the past 3 months  medical conditions associated with sexual dysfunction (for example cardiovascular or respiratory diseases, epilepsy, depression, mania, limb amputation	meetings held at 22 - 24, 28 - 30, and 34 - 36 weeks gestation, each meeting lasting about 30-minutes to check on the exercises and PFM function. Telephone follow-ups were done weekly in the first month and every other week afterwards to emphasize the exercises in addition to a diary recording the exercises.			Domain 3 - Risk of bias due to missing outcome data: Low risk 3.1 Missing outcome data: Yes, data available for over 98% of the population  Domain 4 - Measurement of the outcome: Low risk 4.1 Method for measuring outcome inappropriate: No - self-reporting

Study details	Participants	Interventions	Methods	Outcomes	Comments
	or paralysis, vaginusmus)  • taking medications likely to in- fluence sexual function (including blood pressure drugs, thiazide diuretics, antidepressants, antihistamines, barbiturates, narcotics, diazepines, and amphetamines, cocaine)  • hereditary diseases affecting connective tissue (such as Marfan syndrome, muscular dystrophy) or known abnormalities in reproductive system; 10, having 12 or more urinary incontinence episodes per day  • addiction, or mental or physical problems, of the husband having an effect on a couple's sexual function.	Control: routine care, including health education related to any stage of pregnancy by their own healthcare provider.			4.2 Could measurement of outcome differed between groups: No - self-reporting 4.3 Outcome assessors aware of the intervention: No - blinded to treatment allocation  Domain 5 - Selection of the reported result: Some concerns 5.1 Data produced according to pre-specified plan: No information 5.2. Are results assessed likely to be selected on basis of results from multiple eligible outcome measurements: Probably no, data collected at 3 time points and reported as such 5.3 Are results assessed likely to be selected on basis of results from multiple eligible analysis of the data: Probably no
Full citation  Qi, X., Shan, J., Peng, L., Zhang, C., Xu, F., The effect of a comprehensive care and rehabilitation program on enhancing pelvic floor muscle functions and preventing	Sample size N=240 randomised n=120 to intervention group; and n=120 included in ITT analysis n=120 to control group; and n=120 included in ITT analysis	Interventions Intervention: women received postpartum educational materials at discharged from the hospital. The comprehensive care and rehabilitation program was performed in the 2nd	Details Woman were asked if: 'have you leaked even small amounts of urine when you were coughing, sneezing, laughing, or lifting in the past weeks' an answer of yes would indicate SUI. SUI was	Results Incidence of SUI: Intervention group: 18/120 (15%); Control group: 38/120 (31.7%) N.B. n/N calculated by NGA team	Limitations Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB2). Domain 1 - randomisation: Low risk

Study details	Participants	Interventions	Methods	Outcomes	Comments
postpartum stress urinary incontinence, Medicine, 98, e16907, 2019  Ref Id  1151455  Country/ies where the study was carried out  China  Study type RCT  Aim of the study To investigate the incidence and the risk factors of postpartum SUI, and to explore the effect of a comprehensive care and rehabilitation program preventing postpartum SUI and strengthening pelvic floor muscle functions.  Study dates January 2015 to December 2016 (stage 1)	Characteristics Age (years), mean (SD): Intervention 29.6 (4.3); Control 30.3 (4.8)  BMI (kg/m2), mean (SD): Intervention 23.1 (2.7); Control 23.4 (2.7)  Primiparous, n (%): Intervention 42 (35); Control 54 (45) Multiparous, n (%): Intervention 78 (65); Control 66 (55)  Previous deliveries 0, n (%): Intervention 78 (65); Control 67 (55.8) 1, n (%): Intervention 40 (33.3); Control 52 (43.3) 2, n (%): Intervention 2 (1.7); Control 1 (0.9)  Inclusion criteria  • singleton term vaginal delivery  • bladder pressure was normal  • no neurologic bladder dysfunction	week after delivery, which was conducted weekly for a total of 6 weeks and consisted of 4 parts:  1. Intensive healthy education: the women were given the postpartum educational materials and were asked to visit the nurse weekly for receiving the educational sessions in the hospital lasting 30 minutes. Sessions covered knowledge of SUI, the function and structure of the pelvic floor, the effect of childbirth on the pelvic floor, perineal care, good bladder habits, and instructions about avoiding constipation.  2. Detailed guidance of PFMT: women were given detailed demonstration of PFMT procedures for 30 minutes, and they were asked to exercise 3 times per day at home. The exercise started with	Methods assessed at week 8 postpartum	Outcomes	1.1 Random sequence generation: Yes - block randomisation computer-based system 1.2 Allocation concealment: Probably yes - no information given, but as computer based, likely to be concealed 1.3 Baseline differences: No - no significant differences reported  Domain 2 - Deviations from intended interventions (effect of assignment to interventions): Low risk 2.1 Participants aware of allocation: Yes - no information given, but likely women knew if they were receiving intervention or control 2.2 Carers and people delivering the intervention aware of allocation: Yes - education session delivery staff 2.3 Deviations from intended intervention: Probably no, no information on deviation given 2.6 Appropriate analysis to estimate effect of
Source of funding None reported		a near maximal pelvic floor muscle contractions held for 6 to 8 seconds and			assignment: Yes - ITT analysis
None reported	Exclusion criteria	ended with 3 or 4 fast contractions; the exercises were repeated in lying,			Domain 3 - Risk of bias due to missing outcome data: Low risk

Study details	Participants	Interventions	Methods	Outcomes	Comments
	<ul> <li>age younger than 18 years old</li> <li>history of SUI</li> <li>prenatal urinary incontinence</li> <li>urinary tract infection or kidney disease</li> <li>tumours in the genital area.</li> </ul>	sitting, kneeling, and standing positions with legs apart to emphasize the pelvic floor muscles and to help relax the other muscles; and a set of exercises consisted of 12 times maximal pelvic floor muscle contractions.  3. Psychologic counselling: for women with psychologic problems (for example postpartum depression), nurse would communicate with the them sincerely after each session and attempt to listen, understand, comfort, sympathy, support, and help them manage the negative emotion.  4. Regular supervision: women were given a poster and sticky red dots to place in relevant places at home (to serve as reminders to do the PFMT) and a manual for recording times of PFMT. At each weekly visit, except for giving the educational sessions to the puerperae, the nurse performed a vaginal palpation to			3.1 Missing outcome data: Yes, data available for over 93% of the population  Domain 4 - Measurement of the outcome: Low risk  4.1 Method for measuring outcome inappropriate: No - self-reporting answer to question  4.2 Could measurement of outcome differed between groups: No - self-reporting answer to question  4.3 Outcome assessors aware of the intervention: NA - self reported  Domain 5 - Selection of the reported result: Some concerns  5.1 Data produced according to pre-specified plan: No information  5.2. Are results assessed likely to be selected on basis of results from multiple eligible outcome measurements: Probably no, data collected at 2 time points and reported as such  5.3 Are results assessed likely to be selected on basis of results from multiple eligible analysis of the data: Probably no

Study details	Participants	Interventions	Methods	Outcomes	Comments
		puerperae for correcting the exercise of contraction of the pelvic floor muscles, inquired puerperae how often they practiced the PFMT, reviewed the records of PFMT, and encouraged them to keep exercising.  Control: women were given usual guidance before discharge from hospital which included healthy education and instructions of PFMT. If women were interested in PFMT, nurses provided more in-depth guidance.			Domain 6 - Overall judgment of bias: Some concerns
Full citation  Reilly,E.T., Freeman,R.M., Waterfield,M.R., Waterfield,A.E., Steggles,P., Pedlar,F., Prevention of postpartum stress incontinence in primigravidae with increased bladder neck mobility: a randomised controlled trial of antenatal pelvic floor exercises, BJOG: An International Journal of Obstetrics and Gynaecology, 109, 68-76, 2002  Ref Id	Sample size N=268 recruited n=139 assigned to pelvic floor exercises; data available on n=120 n=129 assigned to no intervention; data available on n=110  Characteristics Intervention n=120; Control n=110  Age (years), median (range): Intervention 27 (17-42); Control 29 (16- 47)	Interventions Both intervention and control would likely receive verbal advice on pelvic floor exercises from the midwives in antenatal classes as part of routine antenatal care. Intervention: supervised pelvic floor exercises, attended by a physiotherapist at monthly intervals from 20 weeks until delivery on a 1 to 1 basis.  Exercises comprised of 3 repetitions of 8 contractions each held for 6 seconds with 2 minutes rest between repetitions.	At 3 months postpartum, women were assed for stress incontinence - classified as mild (once a week), moderate (twice or more per week) or severe (daily).  Women were questioned about stress incontinence either by letter or telephone.  Women also completed a 1 hour International Continence Society pad test, performed at home with instructions and sealed bags to return as soon as possible for weighing.	Results: Postpartum stress incontinence, at 3 months n (%): Intervention 23 (19.2); Control 36 (32.7) Positive pad test at 3 months, n (%): Intervention 7 (9.5); Control 8 (10.8)  Adherence to PFMT: from intervention group (n=120) from 20 weeks to delivery No diaries n=52 <28 days of exercise: n=13 28+ days of exercises: n=55	Limitations Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB2). Domain 1 - randomisation: Low risk 1.1 Random sequence generation: Yes - pseudorandom numbers generated by computer 1.2 Allocation concealment: Yes - allocation schedule held by study co-ordinator 1.3 Baseline differences: Probably no - significant differences not reported,

Study details	Participants	Interventions	Methods	Outcomes	Comments
Study details  125709  Country/ies where the study was carried out  UK  Study type RCT  Aim of the study To test whether supervised pelvic floor exercises antenatally will reduce the incidence of postpartum stress incontinence in at-risk primigravidae with bladder neck mobility, ultrasonically proven.  Study dates Recruitment: 1998 to 1999 (From Agur 2008)  Source of funding Wellbeing and local NHS trust	Participants  Bladder neck mobility >10mm, n%: Intervention 25 (20.8); Control 29 (26.4)  Mode of delivery, n (%): Normal vaginal delivery: Intervention 78 (66.1); Control 72 (65.5) Ventous: Intervention 13 (11.0); Control 22 (20.0) Forceps: Intervention 8 (6.8); Control 2 (1.8) Caesarean section: Intervention 19 (16.1); Control 14 (12.7)  BMI, mean (SD): Intervention 24.9 (4.2); Control 24.1 (4.3)  Inclusion criteria Primigravidae attending the antenatal clinic of a NHS trust hospital Bladder neck mobility >5mm  Exclusion criteria Pre-pregnancy urinary incontinence Neurological disorder	Interventions  To be repeated twice daily.  Patients were instructed to contract their pelvic floor muscle every time they coughed or sneezed. At 34 weeks, the number of contractions increased to 12.	Methods	Outcomes	Domain 2 - Deviations from intended interventions (effect of assignment to interventions): Some concerns 2.1 Participants aware of allocation: Yes 2.2 Carers and people delivering the intervention aware of allocation: No - blinded to allocation 2.3 Deviations from intended intervention: NI, unclear if reasons for non-adherence were related to the intervention 2.4 Would deviations affect outcomes: Probably yes 2.5 Are deviations balanced between groups: Yes 2.6 Appropriate analysis to estimate effect of assignment: Yes  Domain 3 - Risk of bias due to missing outcome data: High risk 3.1 Missing outcome data: No, 38% vs. 33% missing data for 1 outcome 3.2 Results not biased by

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Study details	Participants	Interventions	Methods	Outcomes	Comments
					No, no data presented demonstrating different assumptions for the reasons for dropping out 3.3 Could missingness in outcome depend on true value: No information on whether the missing data could be related to the participants health status for some of the drop outs 3.4. Likely that missingness in outcome depended on true value: Yes
					Domain 4 - Measurement of the outcome: Low risk 4.1 Method for measuring outcome inappropriate: No - self reported and pad test 4.2 Could measurement of outcome differed between groups: No - self reported and pad test 4.3 Outcome assessors aware of the intervention: No - blinded
					Domain 5 - Selection of the reported result: Some concerns 5.1 Data produced according to pre-specified plan: No information 5.2. Are results assessed likely to be selected on basis of results from multiple eligible outcome measurements: Probably no

Study details	Participants	Interventions	Methods	Outcomes	Comments
					5.3 Are results assessed likely to be selected on basis of results from multiple eligible analysis of the data: Probably no  Domain 6 - Overall judgment of bias: High risk
Full citation  Sacomori, C., Zomkowski, K., dos Passos Porto, I., Cardoso, F. L., Sperandio, F. F., Adherence and effectiveness of a single instruction of pelvic floor exercises: a randomized clinical trial, International Urogynecology Journal., 2019  Ref Id  1147320  Country/ies where the study was carried out  Brazil  Study type RCT  Aim of the study  1. To evaluate the effectiveness of a single PFM exercise session	Sample size N=202 randomised n=98 allocated to intervention; n=67 analysed n=104 allocated to control; n=65 analysed  Characteristics Mode of delivery: Caesarean, n (%): Intervention 27 (40.3); Control 28 (43.1) Normal, n (%): Intervention 40 (59.7); Control 37 (56.9)  Number of births: Primiparous, n (%): Intervention 33 (49.3); Control 27 (41.5) Multiparous, n (%): Intervention 34 (50.7); Control 38 (58.5)  Inclusion criteria • women >18 years of age	Interventions Intervention: Aimed to reinforce knowledge of PFMT and stimulate the practice of home-based PFMT exercises. The intervention was 2-staged.  1. An educational approach, involving a full explanation and a brochure containing information about the pelvic floor structure, physiological changes, common problems during pregnancy, PFD (UI, pelvic organ prolapses, anal incontinence, loose vagina sensation, dyspareunia), and how to localise the pelvic floor and	Details A telephone interview was conducted on the 3rd month postpartum using a structed questionnaire. Quality of life with UI was assessed using the ICIQ-SF.	Results ICIQ-SF at 3 months postpartum, median (IQR): Intervention 0 (±1.06); Control 0 (±1.06)  Adherence to PFMT (of intervention group) Frequency of PFMT, n (%): 1-2 times a week: 22 (32.3) 3-7 times a week: 33 (49.3)  Duration of PFMT, n (%) 3 months postpartum: 21 (31.3) 2 months postpartum: 46 (68.7)	Limitations Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB2). Domain 1 - randomisation: High risk 1.1 Random sequence generation: No information - randomisation was cluster (i.e. 2 women at a time, based on the women sharing a room on the maternity ward) 1.2 Allocation concealment: No information 1.3 Baseline differences: Probably yes - differences between maternal smoking  Domain 2 - Deviations from intended interventions (effect of assignment to interventions): Low risk 2.1 Participants aware of allocation: Yes -

Study details	Participants	Interventions	Methods	Outcomes	Comments
immediately post-partum to prevent urinary incontinence at 3-month follow- up; 2. To verify adherence rates to home-based PFM exercises among multiparous and primiparous women.  Study dates September 2011 to December 2011  Source of funding None reported	able to understand Portuguese     immediately postpartum after having given birth to a live child.  Exclusion criteria     had previous UI due to neurological disorders     had a history of cancer in the genitourinary tract     had a previous diagnosis of a neurological disease     were blind     were illiterate     had drug addiction problems     mentioned not having a telephone/mobile phone number.	how to perform the exercises twice a day, repeating 10 times each: maximal voluntary contractions maintained for up to 10 s, 1-s fast contractions, and the knack.  2. To provide a comprehensive PFME with a 3-step protocol: (1) perform 10 repetitions of each contraction for up to 10 s (endurance and strength training) using the pedagogic analogy of an "elevator exercise", where the contraction starts lightly (first floor) and intensifies until the maximum contraction and strength are reached (last floor). (2) Perform 5 fast and strong contractions using the paedagogic analogy of a baby's sucking			participants were not blinded to their allocation 2.2 Carers and people delivering the intervention aware of allocation: Yes - assessors were not blinded to the allocations 2.3 Deviations from intended intervention: Probably no, not reported, but unlikely 2.6 Appropriate analysis to estimate effect of assignment: Yes - ITT analysis and also analysis that excluded participants with missing outcomes  Domain 3 - Risk of bias due to missing outcome data: Low risk 3.1 Missing outcome data: No, data available for over 62% of the population 3.2 Results not biased by missing outcomes: Yes, ITT analysis and also analysis of those with data, missing data evenly split between 2 groups  Domain 4 - Measurement of the outcome: Low risk 4.1 Method for measuring outcome inappropriate: No - self-reporting 4.2 Could measurement of outcome differed between groups: No - self reporting

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Study details	Participants	Interventions	Methods	Outcomes	Comments
		rhythm during breastfeeding (strength training). (3) Perform 'the knack', a contraction before and during a sneeze or a cough. The participants were encouraged to exercise twice daily at home (without professional supervision) while breastfeeding to establish a routine.  Control: Did not receive any kind of intervention regarding PFME but were interviewed personally at the Maternity hospital immediately postpartum with questions about UI before and during pregnancy (T0 and T1) and by telephone/mobile phone in the 3rd month postpartum (T2) when the ICIQ-SF and sociodemographic information was assessed.			4.3 Outcome assessors aware of the intervention: NA - self reported  Domain 5 - Selection of the reported result: Some concerns 5.1 Data produced according to pre-specified plan: No information 5.2. Are results assessed likely to be selected on basis of results from multiple eligible outcome measurements: Probably no, data collected at 2 time points and reported as such 5.3 Are results assessed likely to be selected on basis of results from multiple eligible analysis of the data: Probably no  Domain 6 - Overall judgment of bias: High risk of bias
Full citation	Sample size N=480 randomised	Interventions Intervention: a 2-h group education session and	<b>Details</b> Participants were recruited through a	Results Voiding frequencies on 3 parameters (24 h, while	Limitations Limitations were assessed using the revised

Study details	Participants	Interventions	Methods	Outcomes	Comments
Sampselle, C. M., Messer, K. L., Seng, J. S., Raghunathan, T. E., Hines, S. H., Diokno, A. C., Learning outcomes of a group behavioral modification program to prevent urinary incontinence, International Urogynecology Journal, 16, 441-446, 2005  Ref Id  1176510  Country/ies where the study was carried out  USA  Study type RCT  Aim of the study To describe Behavioural Modification Program participants' acquisition of Bladder Training and PFMT knowledge and motor skill immediately following group instruction and to document adherence over 1 year.  Study dates Not reported	n=238 assigned to intervention; n=164 analysed n=242 assigned to control; n=195 analysed  Characteristics Age (years), mean (SD): Intervention 65.4 (6.7); Control 66.2 (6.4)  Race - white: Intervention 81%; Control 84%  One or more births: Intervention 88%; Control 90%  Inclusion criteria Female 55 years through 80 years of age Postmenopausal defined as no menstrual cycle for the past 12 months except those who are on hormone replacement therapy Continent of urine: no UI ever except during pregnancy and immediate postpartum period, or urine loss of no more than 1–5 days during the last 12 months, and no previous or present UI treatment with pharmacologic agents,	additional individualised instructions in bladder training and PFMT. Education covered anatomy and physiology of the lower urinary tract and pelvis, daily fluid intake requirement, voiding frequency and bladder capacity, types and causes of UI, and life impact of UI. It also covered concepts of selfcare, identification of personal voiding interval, instruction in Bladder Training, instruction and practice in locating and exercising pelvic floor muscles, prescription for PFMT, and strategies to incorporate Bladder Training and PFMT into daily life. Control: no education	phased mass mailings into targeted community zip codes or through referral from the Human Subject Core of the Older Americans Independence Center at the University of Michigan.  At 1 year follow-up, women completed a 3-day voiding diary and clinical evaluations.	asleep, while awake) showed significant reductions in the treatment group (p<0.0001) – reported in a way that data could not be extracted.  3 months adherence to PFMT (%): Low: 1 time per week: 18 Medium: 2-3 times per week: 17 High: at least once a day: 65 6 months adherence to PFMT (%): Low: 1 time per week: 25 Medium: 2-3 times per week: 24 High: at least once a day: 51 9 months adherence to PFMT (%): Low: 1 time per week: 37 Medium: 2-3 times per week: 18 High: at least once a day: 45 12 months adherence to PFMT (%): Low: 1 time per week: 32 Medium: 2-3 times per week: 32 High: at least once a day: 36	Cochrane risk-of-bias tool for randomised trials (RoB2).  Domain 1 - randomisation: Some concerns  1.1 Random sequence generation: No information 1.2 Allocation concealment: No information 1.3 Baseline differences: No - no significant differences reported  Domain 2 - Deviations from intended interventions (effect of assignment to interventions): Low risk 2.1 Participants aware of allocation: Probably no, assessors did not ask questions about PFMT as this might have increased awareness in the control group about the studies purpose 2.2 Carers and people delivering the intervention aware of allocation: Probably yes, no information given, but likely knew 2.3 Deviations from intended intervention: Probably no, assessors did not ask questions about PFMT as this might have increased awareness in the control

Study details	Participants	Interventions	Methods	Outcomes	Comments
Source of funding National Institutes of Health-National Institute of Aging MERIT Award R37 AGO8511 and Nursing R01 NR0718.	behavioural techniques, or surgical therapy  No neurologic disease  No difficulties with activities of daily living  Self-report UI questionnaire showing no UI or UI episodes of 5 days or less in the last 12 months  Mini-mental status score of 24 or higher  Negative paper towel cough stress test with bladder volume at least 150 ml  No grade 4 uterine prolapse (prolapsing beyond the vaginal introitus) on pelvic examination  No introital stenosis precluding digital examination  Ability to voluntarily contract pelvic muscles  Exclusion criteria None reported				group about the studies purpose 2.6 Appropriate analysis to estimate effect of assignment: Yes - analysis excluded participants with missing outcomes  Domain 3 - Risk of bias due to missing outcome data: Low risk 3.1 Missing outcome data: Yes, data available for over 86% of the population at follow up  Domain 4 - Measurement of the outcome: Low risk 4.1 Method for measuring outcome inappropriate: No - self-reporting 4.2 Could measurement of outcome differed between groups: No - self reporting 4.3 Outcome assessors aware of the intervention: NA - self reported  Domain 5 - Selection of the reported result: Some concerns 5.1 Data produced according to pre-specified plan: No information 5.2. Are results assessed likely to be selected on basis of results from multiple eligible outcome measurements: Probably no, data collected at 4

Study details	Participants	Interventions	Methods	Outcomes	Comments
					time points and reported as such 5.3 Are results assessed likely to be selected on basis of results from multiple eligible analysis of the data: Probably no  Domain 6 - Overall judgment of bias: Some concerns
Full citation  Sangsawang, B., Sangsawang, N., Is a 6- week supervised pelvic floor muscle exercise program effective in preventing stress urinary incontinence in late pregnancy in primigravid women?: a randomized controlled trial, European Journal of Obstetrics, Gynecology, & Reproductive Biology, 197, 103-10, 2016  Ref Id 663833  Country/ies where the study was carried out Thailand  Study type RCT	Sample size N=70 Randomised n=35 allocated to intervention, n=33 analysed n=35 allocated to control, n=30 analysed  Characteristics Age (years), mean (SD): Intervention 27.6 (5.09); Control 28.2 (5.01)  BMI before pregnancy (kg/m2), mean (SD): Intervention 21.7 (1.89); Control 22 (1.92)  Inclusion criteria • pregnant women who were age 18 years and older • gestational ages of 20— 30 weeks • singleton foetus	Interventions Intervention group: followed a 6-week supervised PFME program where all women were trained by 1 midwife in small groups of 4–5 participants for 45 min per session once every 2 weeks for a period of 6 weeks (at the 1st, 3rd and 5th week of the program). Women who participated in the PFME instruction session were instructed about the: (1) risk factors of SUI, (2) how pregnancy can cause SUI, (3) the functions of the PFM, (4) how the PFME can prevent SUI, (5) the benefits of PFME and (6) performance of PFME. Women had to ascertained they could recruit the correct muscles, by using "stop test" - to stop or slow urinary flow over a toilet for a one or 2 s, then relax	Details SUI was measured by self-reported of SUI in late (38th weeks) of pregnancy. SUI symptoms (involuntary leakage of urine on sneezing, coughing, effort or physical exertion) 1 or more times per week at 38th weeks of pregnancy were categorized as incontinent. Severity of SUI in pregnant women who reported SUI symptoms was also assessed by the frequency, amount of urine leakage and score of perceived severity of SUI at 38th weeks of pregnancy.	Results Women with SUI at 38 weeks, n (%): Intervention 9 (27.3); Control 16 (53.3)  Adherence to PFMT: No women in the intervention failed by performing their PFME for <28 days	Limitations Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB2).  Domain 1 - randomisation: Low risk 1.1 Random sequence generation: Yes - computer-generated system 1.2 Allocation concealment: Yes - opaque envelopes used 1.3 Baseline differences: No - no significant differences reported  Domain 2 - Deviations from intended interventions (effect of assignment to interventions): Low risk 2.1 Participants aware of allocation: Yes - participants not blinded 2.2 Carers and people delivering the intervention aware of allocation: Yes

Study details	Participants	Interventions	Methods	Outcomes	Comments
Aim of the study To investigate the effect of a 6-week supervised pelvic floor muscle exercise (PFME) program to prevent stress urinary incontinence (SUI) at 38 weeks' gestation.  Study dates July 2012 and October 2012 and follow-up until March 2013  Source of funding Faculty of Nursing, Srinakharinwirot University.	<ul> <li>pre-pregnancy body mass index (BMI) of &lt;30 kg/m2.</li> <li>Exclusion criteria</li> <li>pregnant women with SUI symptoms during pregnancy,</li> <li>pregnancy complications such as preterm labour</li> <li>pregnancy induced hypertension (PIH)</li> <li>gestational diabetes mellitus (GDM)</li> <li>antenatal haemorrhage, etc.</li> <li>pain during pelvic floor muscle contraction</li> <li>diseases that could interfere with the participant</li> </ul>	and finish emptying without straining. Women were then trained to repeat 20 sets of PFME exercises twice a day for a total of 40 sets per day, at least 5 days per week for an overall period of 6 weeks, and to practice PFME in various positions including lying down, sitting, and standing, regardless how strong contraction of the PFM. One set of PFME consists of 1 slow contraction (hold for 10 seconds) followed by 1 fast contraction (brief contraction and relaxing). Handbooks were also provide to the women.  Control group: received regular prenatal care according to the hospital guideline.			- health providers not blinded 2.3 Deviations from intended intervention: No information 2.6 Appropriate analysis to estimate effect of assignment: Yes - analysis excluded participants with missing outcomes  Domain 3 - Risk of bias due to missing outcome data: Low risk 3.1 Missing outcome data: Yes, data available for over 86% of the population  Domain 4 - Measurement of the outcome: Low risk 4.1 Method for measuring outcome inappropriate: No - self reporting 4.2 Could measurement of outcome differed between groups: No - self reporting 4.3 Outcome assessors aware of the intervention: Yes - assessors not blinded 4.4 Outcome assessment influenced by intervention knowledge: No - self reported  Domain 5 - Selection of the reported result: Some concerns

Study details	Participants	Interventions	Methods	Outcomes	Comments
					5.1 Data produced according to pre-specified plan: No information 5.2. Are results assessed likely to be selected on basis of results from multiple eligible outcome measurements: Probably no, data collected at 2 time points and reported as such 5.3 Are results assessed likely to be selected on basis of results from multiple eligible analysis of the data: Probably no
Full citation  Yang, S., Sang, W., Feng, J., Zhao, H., Li, X., Li, P., Fan, H., Tang, Z., Gao, L., The effect of rehabilitation exercises combined with direct vagina low voltage low frequency electric stimulation on pelvic nerve electrophysiology and tissue function in primiparous women: A randomised controlled trial, Journal of clinical nursing, 02, 02, 2017  Ref Id  650704	Sample size N=240 randomised n=80 allocated to training group, n=63 analysed n=80 allocated to combination group, n=66 analysed (data not reported as not relevant to this research question) n=80 allocated to control group, n=60 analysed  Characteristics Age (years), mean (SD): Intervention 28.64 (2.16); Control 29.0 (1.97)	Interventions  PFMT group  • Kegel exercises: Patients were to lay down and kept both legs unbent, placed both hands at their sides and relaxed. Patients were instructed to shrink their hypogastria, perineum and anal muscles for 5-s while inhaling to create the feeling of lifting the pelvic floor muscles, then to relax the hypogastria while exhaling for 5-s. Each	Details Women were followed until 3 months postpartum. Pelvic organ prolapse was assessed according to the POP-Q scoring system. International Continence Society standards were used to score incontinence severity. The pad test was also conducted where the bladder was filled with 300ml of saline, and then the women jumped 20 time and coughed 3 times.	Results POP-Q grade at 3 months: Grade 0, n (%): Intervention 42 (66.7); Control 28 (46.7) Grade I, n (%): Intervention 18 (28.6); Control 27 (45.0) Grade II, n (%): Intervention 3 (4.8); Control 5 (8.3) Grade III, n (%): Intervention 0 (0); Control 0 (0) Grade IV, n (%): Intervention 0 (0); Control 0 (0)	Limitations Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB2). Domain 1 - randomisation: Low risk 1.1 Random sequence generation: Yes - random number table 1.2 Allocation concealment: Probably yes - no information given, but likely to be concealed 1.3 Baseline differences: No - no significant differences reported
000704		training lasted 20 min with the exercises		Score of urinary incontinence	Domain 2 - Deviations from intended

Study details	Participants	Interventions	Methods	Outcomes	Comments
Country/ies where the study was carried out China Study type RCT  Aim of the study To evaluate the effect of rehabilitation exercises combined with Direct Vagina Low Voltage Low Frequency Electric Stimulation (DES) on pelvic nerve electrophysiology and tissue function after delivery  Study dates January 2011 to May 2014  Source of funding No funding reported	BMI (kg/m2), mean (SD): Intervention 26.22 (1.90); Control 25.65 (1.47)  Spontaneous vaginal delivery, n (%): Intervention 21 (31.8); Control 18 (30) Assisted delivery, n (%): Intervention 45 (68.2); Control 42 (70)  Inclusion criteria  • primiparas with a single surviving baby  • between 20 and 35 years old  • have an episiotomy or second degree episiotomy tear during spontaneous vaginal delivery (bulbocavernosus, superficial transverse perineal muscle, deep transverse perineal muscle, levator)  • or have an episiotomy as a result of instrument midwifery (vacuum extraction or forceps).  Exclusion criteria  • participants with heart diseases, diabetes, high blood pressure, SUI or POP	performed 6 times per minute.  Pelvic movements: patients were to lay down and put their bucking knees together. Their thighs and shanks were driven by both knees to swing from left to right 5 times.  unbend their legs, bent the right knee and then used the right hand to hold the right knee and left hand to hold the right knee to the chest.  Loosen the right hand's pressure slowly and used the right hand holding the right knee to move in a gently swaying motion from left to right.  Patients were to alternate between the right and left legs to perform this method 10 times for each leg Patients were instructed to do the exercises above 2-3 times a day and were told to continue the training from the second day after delivery to 3 months postpartum  Control group	Methods	Score 0, n (%): Intervention 22 (34.9); Control 4 (6.7) Score 1, n (%): Intervention 30 (47.6); Control 4 (6.7) Score 2, n (%): Intervention 10 (15.9); Control 25 (41.7) Score 3, n (%): Intervention 1 (1.6); Control 25 (41.7) Score 4, n (%): Intervention 0 (0); Control 2 (3.3) Score 5, n (%): Intervention 0 (0); Control 0 (0)  Pad test Positive, n (%): Intervention 12 (19); Control 15 (25.0)	interventions (effect of assignment to interventions): Some concerns  2.1 Participants aware of allocation: Yes - no information given, but likely women knew if they were receiving intervention or control  2.2 Carers and people delivering the intervention aware of allocation: Probably yes - specialised training staff delivered the intervention  2.3 Deviations from intended intervention: No information  2.6 Appropriate analysis to estimate effect of assignment: Yes - analysis excluded participants with missing outcomes  Domain 3 - Risk of bias due to missing outcome data: Low risk  3.1 Missing outcome data: Yes, data available for over 75% of the population  Domain 4 - Measurement of the outcome: Low risk  4.1 Method for measuring outcome inappropriate: Predominately self-reporting  4.2 Could measurement of outcome differed

Study details	Participants	Interventions	Methods	Outcomes	Comments
	<ul> <li>participants with rubra, serosa or lochia alba</li> <li>participants with a heart pacemaker</li> <li>participants who had a laparotomy</li> <li>patients with cancer</li> <li>participants with a nervous system disease</li> </ul>	A third group received a combination treatment but this was not relevant to the protocol.			between groups: Predominately self-reporting 4.3 Outcome assessors aware of the intervention No - data collection staff did not know group allocations  Domain 5 - Selection of the reported result: Some concerns 5.1 Data produced according to pre-specific plan: No information 5.2. Are results assesse likely to be selected on basis of results from multiple eligible outcome measurements: Probabl no, data collected at 2 time points and reported as such 5.3 Are results assessed likely to be selected on basis of results from multiple eligible analysis of the data: Probably no
					Domain 6 - Overall judgment of bias: Some concerns

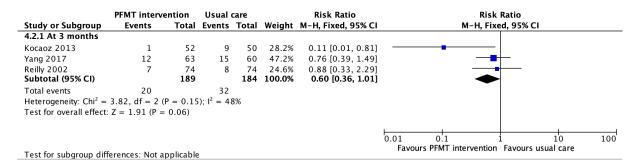
BMI: body mass index; FSFI: female sexual function index; ICIQ: International Consultation on Incontinence Questionnaire; IIQ-7: Incontinence impact questionnaire; I-QOL: Incontinence quality of life questionnaire; ITT: Intention to treat; NGA: National Guideline Alliance; OAB-q: overactive bladder questionnaire; PFD: pelvic floor disability index-20; PFIQ: pelvic floor impact questionnaire; PFM: pelvic floor muscle; PFME: pelvic floor muscle exercises; PFMT: pelvic floor muscle training; POP: pelvic organ prolapse; POP-Q: pelvic organ prolapse questionnaire; QoL: quality of life; RCT: randomised controlled trial; RoB: Risk of bias; SUI: stress urinary incontinence; SQOL-F: Sexual quality of life-female; SD: standard deviation; SF: short form; SUI: stress urinary incontinence; UDI-6: Urinary Distress Inventory, short form; UI: urinary incontinence

### **Appendix E – Forest plots**

# Forest plots for review question: What is the effectiveness of pelvic floor muscle training for preventing 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 Positive pad test at 3 months



### Appendix F – GRADE tables

GRADE tables for review question: What is the effectiveness of pelvic floor muscle training for preventing pelvic floor dysfunction?

Table 6: Clinical evidence profile for comparison pelvic floor muscle training to no treatment for symptoms of urinary incontinence

(Setting: Community - postmenopausal women over 55 years)

	Quality assessment					<u> </u>	No of	f patients		Effect	Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PFMT	No treatment for UI			Í	
Without U	Without UI – at 12 months (Better indicated by higher values)											
Diokno 2004	randomised trials		no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	92/164 (56.1%)	80/195 (41.0%)	RR 1.37 (1.10 to 1.70)	152 more per 1000 (from 41 more to 287 more)	LOW	CRITICAL

CI: confidence interval; ICIQ: International Consultation on Incontinence Questionnaire; IIQ-7: incontinence impact questionnaire; MD: Mean difference; OAB-Q: Overactive bladder questionnaire; PFMT: Pelvic floor muscle training; RR: Relative risk; UI: urinary incontinence; UDI-6: Urinary Distress Inventory, short form

Table 7: Clinical evidence profile for comparison pelvic floor muscle education and re-education to no treatment for symptoms of pelvic floor dysfunction (Setting: Community – mixed age group)

**Effect Quality assessment** No of patients Quality Importance No of Risk of Other PFM education No treatment Relative Design Inconsistency Indirectness Imprecision **Absolute** studies considerations and re-education for PFD (95% CI) PFD symptoms (PFDI-20) - After 2 months (Better indicated by lower values) Berzuk randomised serious1 no serious 3/48 8/49 RR 0.38 101 fewer per 1000 **VERY CRITICAL** no serious none very 2015 trials inconsistency indirectness serious<sup>2</sup> (6.3%)(16.3%)(0.11 to 1.36) (from 145 fewer to 59 LOW more)

<sup>&</sup>lt;sup>1</sup> Serious risk of bias in the evidence contributing to the outcomes as per RoB 2

<sup>&</sup>lt;sup>2</sup> 95% CI crosses 1 MID (0.8 or 1.25)

PFD QoL	FD QoL symptoms (PFIQ-7) - After 2 months (Better indicated by lower values)											
Berzuk 2015	randomised trials	serious <sup>1</sup>		no serious indirectness	very serious <sup>2</sup>	none	2/48 (4.2%)	4/49 (8.2%)	RR 0.51 (0.1 to 2.66)	40 fewer per 1000 (from 73 fewer to 136 more)	VERY LOW	CRITICAL

CI: confidence interval; PFD: Pelvic floor dysfunction; PFDI: Pelvic Floor Distress Inventory; PFIQ: Pelvic Floor Impact Questionnaire; PFM: Pelvic floor muscle; QoL: Quality of Life; RR: Relative risk

Table 8: Clinical evidence profile for comparison pelvic floor muscle education to no treatment for symptoms of pelvic floor dysfunction (Setting: Community – mixed age group)

	aysiund	cion (S	etting: Comm	iuility – iilike	tu aye yi	Jup <i>)</i>						
			Quality asse	essment			No of	patients		Effect	Quality	Importance
No of studies	dies Design bias Inconsistency Indirectness Imprecision cons						PFM education	No treatment for PFD	Relative (95% CI)	Absolute		
PFD symp	otoms (PFDI-2	0) - After 2	2 months (Better in	ndicated by lowe	r values)							
Berzuk 2015	randomised trials		no serious inconsistency		very serious²	none	4/48 (8.3%)	8/49 (16.3%)	RR 0.51 (0.16 to 1.58)	80 fewer per 1000 (from 137 fewer to 95 more)	VERY LOW	CRITICAL
PFD QoL symptoms (PFIQ-7) - After 2 months (Better indicated by lower values)												
Berzuk 2015	randomised trials		no serious inconsistency	no serious indirectness	very serious²	none	2/48 (4.2%)	4/49 (8.2%)	RR 0.51 (0.1 to 2.66)	40 fewer per 1000 (from 73 fewer to 136 more)	VERY LOW	CRITICAL

CI: confidence interval; PFD: Pelvic floor dysfunction; PFDI: Pelvic Floor Distress Inventory; PFIQ: Pelvic Floor Impact Questionnaire; PFM: Pelvic floor muscle; QoL: Quality of Life; RR: Relative risk

<sup>&</sup>lt;sup>1</sup> Serious risk of bias in the evidence contributing to the outcomes as per RoB 2

<sup>&</sup>lt;sup>2</sup> 95% CI crosses 2 MIDs (0.8 and 1.25)

<sup>&</sup>lt;sup>1</sup> Serious risk of bias in the evidence contributing to the outcomes as per RoB 2

<sup>&</sup>lt;sup>2</sup> 95% CI crosses 2 MIDs (0.8 and 1.25)

Table 9: Clinical evidence profile for comparison pelvic floor muscle training to no treatment for symptoms of urinary incontinence (Obstetric setting: antenatally or postnatally)

	(Obstetri	c settir	ng: antenatali	y or postna	tally)							
			Quality ass	essment			No o	f patients		Effect	Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PFMT	No treatment for UI	Relative (95% CI)	Absolute	quanty	importanioc
Urinary ince	ontinence - At	3 months	s postpartum (Bet	ter indicated by	lower values)							
Chiarelli 2002	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	108/348 (31%)	126/328 (38.4%)	RR 0.81 (0.66 to 0.99)	73 fewer per 1000 (from 4 fewer to 131 fewer)	LOW	CRITICAL
Urinary inco	ontinence - At	12 month	ns postpartum (Be	etter indicated b	y lower values)							
Chiarelli 2004	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	101/294 (34.4%)	100/275 (36.4%)	RR 0.94 (0.76 to 1.18)	22 fewer per 1000 (from 87 fewer to 65 more)	LOW	CRITICAL
UI Score at	3 months - So	core 0 (Be	tter indicated by I	nigher values)								
Yang 2017	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	22/63 (34.9%)	4/60 (6.7%)	RR 5.24 (1.92 to 14.31)	283 more per 1000 (from 61 more to 887 more)	MODERATE	CRITICAL
UI Score at	3 months - So	core 1 (Be	tter indicated by I	nigher values)								
Yang 2017	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	30/63 (47.6%)	4/60 (6.7%)	RR 7.14 (2.68 to 19.06)	409 more per 1000 (from 112 more to 1000 more)	MODERATE	CRITICAL
UI Score at	3 months - So	core 2 (Be	tter indicated by I	ower values)								
Yang 2017	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	10/63 (15.9%)	25/60 (41.7%)	RR 0.38 (0.2 to 0.72)	258 fewer per 1000 (from 117 fewer to 333 fewer)	MODERATE	CRITICAL
UI Score at	3 months - So	core 3 (Be	tter indicated by I	ower values)								
Yang 2017	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	1/63 (1.6%)	25/60 (41.7%)	RR 0.04 (0.01 to 0.27)	400 fewer per 1000 (from 304 fewer to 413 fewer)	MODERATE	CRITICAL

			Quality ass	essment			No o	of patients		Effect	Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PFMT	No treatment for UI	Relative (95% CI)	Absolute	quality	
UI Score at	3 months - So	core 4 (Be	etter indicated by	lower values)								
Yang 2017	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>3</sup>	none	0/63 (0%)	2/60 (3.3%)	Peto OR 0.13 (0.01 to 2.05)	29 fewer per 1000 (from 33 fewer to 32 more)	VERY LOW	CRITICAL
Severe UI -	At 3 months (	Better inc	dicated by lower v	values)								
Chiarelli 2002	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	35/348 (10.1%)	55/328 (16.8%)	RR 0.6 (0.4 to 0.89)	67 fewer per 1000 (from 18 fewer to 101 fewer)	MODERATE	CRITICAL
UDI-6 - At 3	6-38 weeks g	estation (I	Better indicated b	y lower values)								
Kahyaoglu 2016	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>3</sup>	none	30	30	-	MD 2.8 lower (1.60 lower to 7.20 higher)	VERY LOW	CRITICAL
IIQ-7 - At 36	6-38 weeks ge	station (B	etter indicated by	/ lower values)								
Kahyaoglu 2016	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>3</sup>	none	30	30	-	MD 3.50 higher (0.26 lower to 7.26 higher)	VERY LOW	CRITICAL
OAB-q - At	36-38 weeks	gestation	(Better indicated	by lower values)	1							
Kahyaoglu 2016	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>3</sup>	none	30	30	-	MD 4.30 lower (11.16 lower to 2.56 higher)	VERY LOW	CRITICAL
UDI-6 - At 6	i-8 weeks pos	tpartum (E	Better indicated b	y lower values)			•					
Kahyaoglu 2016	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>3</sup>	none	30	30	-	MD 0.1 higher (3.67 lower to 3.87 higher)	VERY LOW	CRITICAL
IIQ-7 - At 6-	8 weeks post	partum (B	etter indicated by	lower values)								
Kahyaoglu 2016	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	30	30	-	MD 1.4 higher (0.97 lower to 3.77 higher)	LOW	CRITICAL
OAB-q - At	6-8 weeks po	stpartum	(Better indicated	by lower values)								

			Quality ass	essment			No d	of patients		Effect	- Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PFMT	No treatment for UI	Relative (95% CI)	Absolute	Quanty	importance
	randomised trials			no serious indirectness	very serious <sup>3</sup>	none	30	30	-	MD 0.4 lower (4.24 lower to 3.44 higher)	VERY LOW	CRITICAL
ICIQ - At 36	-40 weeks of	gestation	(Better indicated	by lower values)								
Pelaez 2014	randomised trials				no serious imprecision	none	63	89	-	MD 2.42 lower (3.32 to 1.52 lower)	MODERATE	CRITICAL
ICIQ - At 3 n	nonths postp	artum (Be	etter indicated by I	lower values)								
	randomised trials	very serious <sup>4</sup>		no serious indirectness	serious <sup>5</sup>	none	104	98	-	Median 0 higher. Median was 0 [IQR±1.06]] for both groups	VERY LOW	CRITICAL

CI: confidence interval; ICIQ: International Consultation on Incontinence Questionnaire; IIQ-7: incontinence impact questionnaire; MD: Mean difference; OAB-Q: Overactive bladder questionnaire; PFMT: Pelvic floor muscle training; RR: Relative risk; UI: urinary incontinence; UDI-6: Urinary Distress Inventory, short form

Table 10: Clinical evidence profile for comparison pelvic floor muscle training to no treatment for symptoms of stress urinary incontinence (Obstetric setting: antenatally or postnatally)

			Quality	<i>r</i> assessment				No of patients	Ef	ffect	Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PFMT	No treatment for Stress UI	Relative (95% CI)	Absolute		
Stress urina	ry incontin	ence - At	: 38 weeks ges	tation (Better indi	cated by lower va	lues)						

<sup>1</sup> Serious risk of bias in the evidence contributing to the outcomes as per RoB 2

<sup>2 95%</sup> CI crosses 1 MID (0.8 or 1.25)

<sup>3 95%</sup> CI crosses 2 MIDs (0.8 and 1.25)

<sup>4</sup> Very serious risk of bias in the evidence contributing to the outcomes as per RoB 2

<sup>5</sup> Subjective assessment of imprecision

			Quality	/ assessment				No of patients	Ef	ffect	Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PFMT	No treatment for Stress UI	Relative (95% CI)	Absolute		
Sangsawang 2016	grandomised trials			no serious indirectness	serious <sup>2</sup>	none	9/33 (27.3%)	16/30 (53.3%)	RR 0.51 (0.27 to 0.98)	261 fewer per 1000 (from 11 fewer to 389 fewer)	LOW	CRITICAL
Stress urina	ary incontine	ence - At	t 8 weeks post <sub>l</sub>	partum (Better in	dicated by lower va	alues)						
Qi 2019	randomised trials			no serious indirectness	no serious imprecision	none	18/120 (15%)	38/120 (31.7%)	RR 0.47 (0.29 to 0.78)	168 fewer per 1000 (from 70 fewer to 225 fewer)	MODERATE	CRITICAL
Stress urina	ary incontine	ence - At	t 3 months pos	tpartum (Better i	ndicated by lower	values)						
Reilly 2002	randomised trials		no serious inconsistency	no serious indirectness	serious²	none	23/120 (19.2%)	36/110 (32.7%)	RR 0.59 (0.37 to 0.92)	134 fewer per 1000 (from 26 fewer to 206 fewer)	VERY LOW	CRITICAL
Stress urina	ary incontine	ence - At	t 6 months follo	ow up (Better ind	icated by lower val	ues)						
Lin 2020	randomised trials			no serious indirectness	very serious <sup>4</sup>	none	1/49 (2%)	6/48 (12.5%)	RR 0.16 (0.02 to 1.31)	105 fewer per 1000 (from 123 fewer to 39 more)	VERY LOW	CRITICAL
Stress urina	ary incontine	ence - At	t 8 year follow-	up (Better indicat	ted by lower values	s)						
Agur 2008	randomised trials			no serious indirectness	very serious <sup>4</sup>	none	28/79 (35.4%)	33/85 (38.8%)	RR 0.91 (0.61 to 1.36)	35 fewer per 1000 (from 151 fewer to 140 more)	VERY LOW	CRITICAL
Positive page	d test - At 28	weeks	gestation (Bett	er indicated by lo	wer values)							
Kocaoz 2013	randomised trials			no serious indirectness	no serious imprecision	none	3/52 (5.8%)	15/50 (30.0%)	RR 0.19 (0.06 to 0.62)	243 fewer per 1000 (from 114	MODERATE	CRITICAL

			Quality	/ assessment				No of patients	Ef	fect	Quality	Importanc
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PFMT	No treatment for Stress UI	Relative (95% CI)	Absolute		
										fewer to 282 fewer)		
Positive pa	d test - At 32	weeks	gestation (Bett	er indicated by lo	wer values)						r	
Kocaoz 2013	randomised trials			no serious indirectness	no serious imprecision	none	9/52 (17.3%)		RR 0.36 (0.19 to 0.70)	307 fewer per 1000 (from 144 fewer to 389 fewer)	MODERATE	CRITICAL
Positive pa	d test - At 3 i	months	(Better indicate	ed by lower value	s)							
<b>3</b> <sup>5</sup>	randomised trials			no serious indirectness	serious <sup>2</sup>	none	20/189 (10.6%)	32/184 (17.4%)	RR 0.6 (0.36 to 1.01)	70 fewer per 1000 (from 111 fewer to 2 more)	VERY LOW	CRITICAL
ICIQ-SF – a	t 6 months fo	ollow up	(Better indicat	ted by lower value	es)							
_in 2020	randomised trials			no serious indirectness	no serious imprecision	none	49	48	-	MD 3.04 lower (3.16 lower to 2.92 higher)	MODERATE	CRITICAL
I-QOL – at 6	6 months foll	ow up (	Better indicated	d by higher value	s)							
_in 2020	randomised trials			no serious indirectness	no serious imprecision	none	49	9 48	-	MD 9 higher (7.66 to 10.34 higher)	MODERATE	CRITICAL

CI: confidence interval; ICIQ: International Consultation on Incontinence Questionnaire; I-QOL: Incontinence quality of life questionnaire; MD: Mean difference; PFMT: pelvic floor muscle training; RR: Relative risk; UI: urinary incontinence

<sup>&</sup>lt;sup>1</sup> Serious risk of bias in the evidence contributing to the outcomes as per RoB 2

<sup>&</sup>lt;sup>2</sup> 95% CI crosses 1 MID (0.8 or 1.25) <sup>3</sup> Very serious risk of bias in the evidence contributing to the outcomes as per RoB 2 <sup>4</sup> 95% CI crosses 2 MIDs (0.8 and 1.25)

<sup>&</sup>lt;sup>5</sup> See forest plot

Table 11: Clinical evidence profile for comparison pelvic floor muscle training to no treatment for symptoms of pelvic organ prolapse (Obstetric setting: antenatally or nostnatally)

	(Obsteti	ic settii	ng: antenatan	y or postriate	iii <b>y</b> )							
			Quality asse	essment			No	of patients		Effect	Quality	Importan
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PFMT	No treatment for POP	Relative (95% CI)	Absolute		
POP Grad	e at 3 months	- Grade 0	(Better indicated b	y higher values)								
Yang 2017	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	42/63 (66.7%)	28/60 (46.7%)	RR 1.43 (1.04 to 1.97)	201 more per 1000 (from 19 more to 453 more)	LOW	CRITICA
POP Grad	e at 3 months	- Grade I	or II (Better indicate	ed by lower value	s)							
Yang 2017	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	18/63 (28.6%)	27/60 (45%)	RR 0.63 (0.41 to 0.95)	167 fewer per 1000 (from 266 to 23 fewer)	LOW	CRITICA

CI: confidence interval; PFMT: pelvic floor muscle training; POP: pelvic organ prolapse; RR: Relative risk <sup>1</sup> Serious risk of bias in the evidence contributing to the outcomes as per RoB 2

Table 12 Clinical evidence profile for comparison pelvic floor muscle training to no treatment for symptoms of sexual dysfunction (Obstetric setting: antenatally or postnatally)

	`		Quality asse		37			No of patients		Effect	Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PFMT		Relative (95% CI)	Absolute	Quanty	Importance
FSFI total sc	ore - At 28-30	) weeks ge	estation (Better in	dicated by lower	values)							

<sup>&</sup>lt;sup>2</sup> 95% CI crosses 1 MID (0.8 or 1.25)

			Quality ass	essment				No of patients		Effect	- Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PFMT	No treatment for Sexual Dysfunction	Relative (95% CI)	Absolute	Quanty	mportance
Pourkhiz 2017	randomised trials		no serious inconsistency	no serious indirectness	no serious imprecision	none	41	41	-	MD 27.2 higher (25.38 to 29.02 higher)	MODERATE	CRITICAL
FSFI total so	core - At 3 mo	nths post	partum (Better inc	dicated by lower	values)							
Pourkhiz 2017	randomised trials		no serious inconsistency	no serious indirectness	no serious imprecision	none	41	41	-	MD 12.7 higher (11.85 to 13.55 higher)	MODERATE	CRITICAL
FSFI total so	core - At 4 mo	nths post	partum (Better inc	dicated by lower	values)							
Citak 2010	randomised trials		no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	37	38	-	MD 0.85 lower (3.02 lower to 1.32 higher)	LOW	CRITICAL
FSFI total so	core - At 7 mo	nths post	partum (Better inc	dicated by lower	values)							
Citak 2010	randomised trials		no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	37	38	-	MD 2.34 higher (0.29 to 4.39 higher)	LOW	CRITICAL
Bailes sexua	al self-efficac	y total sco	ore - At 12 weeks p	oostpartum (Bett	er indicated by	lower values)						
Golmakani 2015	randomised trials		no serious inconsistency	no serious indirectness	no serious imprecision	none	40	39	-	MD 0.86 higher (4.39 lower to 6.11 higher)	MODERATE	CRITICAL
Bailes sexua	al self-efficac	y total sco	ore - At 16 weeks p	oostpartum (Bett	er indicated by	lower values)						
Golmakani 2015	randomised trials		no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	40	39	-	MD 10.5 higher (4.9 to 16.1 higher)	LOW	CRITICAL
SQOL-F - At	3 months po	stpartum	(Better indicated I	oy lower values)								
Pourkhiz 2017	randomised trials		no serious inconsistency	no serious indirectness	no serious imprecision	none	41	41	-	MD 18.5 higher (13.51 to 23.49 higher)	MODERATE	CRITICAL
SQOL-F - At	3 months po	stpartum	(Better indicated I	oy lower values)								

			Quality ass	essment				No of patients		Effect	Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PFMT		Relative (95% CI)	Absolute	quanty	mportunico
Pourkhiz 2017	randomised trials				no serious imprecision	none	41	41	-	MD 31.8 higher (27.84 to 35.76 higher)	MODERATE	CRITICAL

CI: confidence interval; FSFI: female sexual function index; MD: Mean difference; PFMT: pelvic floor muscle training; SQOL-F: Sexual quality of life-female <sup>1</sup> Serious risk of bias in the evidence contributing to the outcomes as per RoB 2

Table 13: Clinical evidence profile for adherence to pelvic floor muscle training (Obstetric setting; antenatally or postnatally)

Tubic 1	o. Omnea	CVIGCI	ice prome io	adilciciec	to pervie in	or mascic ti	anning	(Obsteti)	c setting.	antenatany or po	Striatury	
			Quality as	sessment			No o	of patients		Effect	Quality	Importance
No of studies	Design	Dias			Imprecision	Other considerations	PFMT	No treatment for UI	Relative (95% CI)	Absolute		
PFMT exe	rcises 3 time	s per weel	k or more - After 1	2 months (Bette	r indicated by h	igher values)						
Chiarelli 2002	randomised trials	serious <sup>1</sup>			no serious imprecision	none	292/348 (83.9%)		RR 3.83 (2.68 to 5.50)	1000 more per 1000 (from 968 more to 1000 more)	-	IMPORTANT
PFMT exe	T exercises 3 times per week or more - After 12 months (Better indicated by higher values)											
Chiarelli 2004	randomised trials	serious <sup>1</sup>			no serious imprecision	none	117/294 (39.8%)		RR 1.38 (0.98 to 1.95)	123 more per 1000 (from 6 fewer to 307 more)	MODERATE	IMPORTANT

CI: confidence interval; PFMT: pelvic floor muscle training;

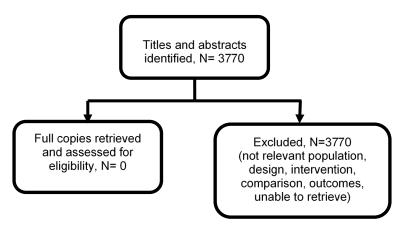
<sup>&</sup>lt;sup>2</sup> 95% CI crosses 1 MID (published - 2.1) <sup>3</sup> 95% CI crosses 1 MID (0.5 x baseline control SD, MID=6.15)

<sup>&</sup>lt;sup>1</sup> Serious risk of bias in the evidence contributing to the outcomes as per RoB 2

## Appendix G – Economic evidence study selection

Economic evidence study selection for review question: What is the effectiveness of pelvic floor muscle training for preventing pelvic floor dysfunction?

Figure 4: Study selection flowchart



## **Appendix H – Economic evidence tables**

Economic evidence tables for review question: What is the effectiveness of pelvic floor muscle training for preventing pelvic floor dysfunction?

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

# **Appendix I – Economic evidence profiles**

Economic evidence profiles for review question: What is the effectiveness of pelvic floor muscle training for preventing pelvic floor dysfunction?

**Table 14: Economic evidence profile** 

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
National Guideline Alliance Cost-utility analysis of preventative PFMT UK	Minor limitations <sup>1</sup>	Directly applicable	Type of economic analysis: Costutility analysis  Time horizon: Lifetime  Primary measure of outcome: Incremental net monetary benefit	£282	0.025	£11,188  iNMB <sup>2</sup> = £222	For base case analysis: 62.5% probability of being costeffective at a costeffectiveness threshold of £20,000 per QALY and a population urinary incontinence risk of 50%  Threshold analysis: Treatment likely to be costeffective when population urinary incontinence risk is greater than 30%

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty

- Urinary incontinence is used as a proxy for pelvic floor dysfunction but there are other symptoms of pelvic floor dysfunction not captured in the analysis
   iNMB calculated using a cost-effectiveness threshold of £20,000 per QALY

### Appendix J - Economic analysis

Economic evidence analysis for review question: What is the effectiveness of pelvic floor muscle training for preventing pelvic floor dysfunction?

Cost-utility analysis of supervised pelvic floor muscle training provided antenatally to prevent pelvic floor dysfunction

#### Introduction

The NHS Long Term Plan (NHS Long Term Plan v1.2 August 2019) stated that "physiotherapy is by far the most cost-effective intervention for preventing and treating mild to moderate incontinence and prolapse". In addition the Cumberlege Report (First Do No Harm (immdsreview.org.uk)), which considered the harms of medicines and medical devices (relevant to this guideline topic due to the inclusion of mesh surgery for pelvic organ prolapse in the review) reported by women, noted that 'prevention is better than cure' and in that context suggested that; "pelvic floor education should be encouraged where appropriate, in schools and certainly in antenatal classes. In addition, we recommend that the NHS adopts the French model for universal post-natal pelvic floor rehabilitation."

As preventative pelvic floor muscle training (PFMT) could potentially avert or delay pelvic floor dysfunction, with implications for the requirement for subsequent conservative and surgical intervention and the costs associated with treatments, this was considered an important clinical topic for this guideline. It was prioritised for economic analysis as recommendations could potentially lead to a change in current NHS practice.

A total of 15 studies were included in this review but it was not possible to synthesise the individual studies to provide an aggregated measure of treatment effect. Most of the studies had follow-up of less than 12 months or less and therefore it was decided to use the Reilly (2002) and Agur (2008) study pair as the basis for this economic analysis. These 2 papers were based on the same intervention but reported outcomes at a follow-up at 3 months' post-partum and 8 years respectively. In addition to the longer follow-up provided, the studies were also considered suitable for economic analysis because the intervention was undertaken in a UK population and reported stress urinary incontinence as a main outcome, from which an impact on health related quality of life can be estimated. The intervention consisted of supervised PFMT in the antenatal period starting at a gestational age of 20 weeks and continuing at monthly intervals until birth and this is the intervention that is assessed in this economic evaluation. It is compared to no preventative PFMT. Although there were other populations of interest there was a lack of suitable clinical data and studies on which to populate an economic model.

#### Methods

#### Setting and population

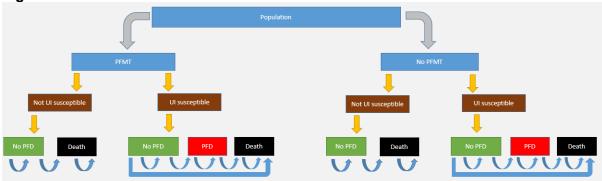
The model was for an NHS settings and, reflecting Reilly (2002) and Agur (2008), was in a population of 28-year old women (the median age in Reilly (2002)) in their first pregnancy and at a gestational age of 20 weeks at the commencement of supervised PFMT. In addition, the women had bladder neck mobility of more than 5mm on linear movement following standardised Valsalva. A lifetime horizon was taken for the base case analysis but shorter horizons of 8, 12 and 20 years were assessed in sensitivity analysis.

Reflecting the outcomes in Reilly (2002) and Agur (2008) stress urinary incontinence was used as a proxy for pelvic floor dysfunction.

#### Model structure

A decision analytic Markov model was developed in Microsoft Excel® to assess the costutility of supervised PFMT to prevent pelvic floor dysfunction during their first pregnancy when compared to no preventative PFMT. A schematic of the model is shown in Figure 5 which illustrates the 2 decision alternatives under comparison.

Figure 5: Schematic of Markov decision model



The Markov model comprises of 3 possible mutually exclusive health states:

- i. No pelvic floor dysfunction (No PFD)
- ii. Pelvic floor dysfunction (PFD)
- iii. Death

The passage of time is considered in discrete periods known as 'cycles', which are set to 1 month in this analysis. At the end of each cycle, as illustrated in Figure 5, a woman can remain in the same health state or transition from PFD to No PFD or to death from either PFD or No PFD. A simplifying assumption is made that there is no transition from PFD to No PFD recognising that, in practice, progression and remission occur across the natural history.

Transition probabilities determine movements to alternative health states. The transition to death is independent of pelvic floor status and probabilities are derived from ONS life tables (https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/lifeexpectancies/datasets/nationallifetablesenglandandwalesreferencetables). However, ONS life tables do not go beyond 100 years of age and to predict annual mortality above 100 years of age an exponential curve was fitted to the mortality trend between 90 years and 100 years of age and this relationship was then used to extrapolate the annual mortality rate for women aged over 100 years. This functional relationship between age and mortality is shown in Figure 6.

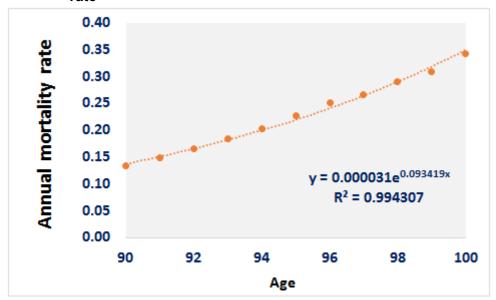


Figure 6: Graph to show relationship between increasing age and the annual mortality rate

The transition probabilities from No PFD to PFD are determined from a natural history model alongside the relative treatment effect from preventative PFMT where relevant.

In the model the population is divided into those who are susceptible to PFD and those who are not susceptible. It is assumed that the susceptible group will go on to develop PFD in the absence of preventative PFMT and therefore, this group could potentially benefit from preventative treatment. It is assumed that those who are not susceptible to PFD will not develop PFD regardless of whether they receive preventative PFMT and therefore there is no treatment benefit in this group. For women who are not susceptible there is no transition to PFD. The proportion in the susceptible group is given by the population risk, a variable which can be varied in the model.

In the base case analysis, it is assumed that the population lifetime risk of PFD (as measured by urinary incontinence) is 50% which approximates the lifetime risk estimated for the population in the Reilly (2002) and Agur (2008), see Figure 8.

#### Natural history model

In order to model the natural history of urinary incontinence in the model population, the rate or risk of urinary incontinence at different points in time was estimated. It was then possible to fit a mathematical relationship to these points to give a rate of urinary incontinence as a function of time, measured in months, since the woman gave birth. The risk of urinary continence at 3 months' post-partum and at 8 years was taken from the control arm of Reilly (2002) and Agur (2008) respectively.

In order to estimate urinary incontinence risk at later time points we used formulas for the outcome of urinary incontinence in the pelvic floor disorders UR-CHOICE online risk calculator and prediction model (Jelovsek 2018), which was developed to predict the risk of pelvic floor disorders (focusing on urinary incontinence) based on known antenatal and mode of birth variables. This particular prediction model was chosen based on the committees advice based on their knowledge of the available literature.

We used both 12-year and 20-year models to give 2 additional time point estimates for urinary incontinence but some important limitations and caveats of this approach are discussed later. The logistic regression equations to predict risk are listed below:

#### i. 12-year model

```
Log-odds of risk (LO <sub>risk</sub>) =
-0.10286298 - (0.094854567 x parity) + (0.024763229 x age) +
(0.0086028615 x pre-pregnancy weight) - (0.010742873 x height) +
(1.7818611 x pre-pregnancy UI) + (1.4080395 x UI during pregnancy) +
(0.63365899 x family history of pelvic organ prolapse) +
(0.40814509 x vaginal birth)
```

Pre-pregnancy UI = 1 (yes) 0 (no)

UI during pregnancy = 1 (yes) 0 (no)

Family history of pelvic organ prolapse = 1 (yes) 0 (no)

Vaginal birth = 1 (vaginal birth) 0 (caesarean birth)

Risk = 
$$1 \div (1 + \exp(LO_{risk}))$$

#### ii. 20-year model

```
Log-odds of risk (LO _{risk}) =
-0.3263724 + (0.02606663 \text{ x age}) +
(0.018820574 \text{ x pre-pregnancy weight}) - (0.018268529 \text{ x height}) +
(1.5764999 \text{ x family history of UI}) + (0.53946364 \text{ x vaginal birth})
```

Family history of UI = 1 (yes) 0 (no)

Vaginal birth = 1 (vaginal birth) 0 (caesarean birth)

Risk = 
$$1 \div (1 + \exp(LO_{risk}))$$

The inputs for the UR-CHOICE prediction are given in Table 15 and were chosen to match the model population as closely as possible.

Table 15: Population risk factors for predicting urinary incontince from UR-CHOICE prediction model

prediction in	prediction model							
Risk factor	Value	Source	Comment					
Parity	0	Reilly (2002)	Study population was primigravidae					
Age (years)	28	Reilly (2002)	Median age in study					
Pre-pregnancy weight (kg)	64.2	Reilly (2002), calculated	Mean BMI in study 24.5 <sup>a</sup>					
Height (cm)	161.9	Health and Social Care Information Centre (2017) http://healthsurvey.hscic.gov.uk/media/63757/ HSE2016-Adult-trends.pdf	Average female height in England					
Pre-pregnancy UI	0	Reflects intervention and model population	As model is preventative the population has no existing pelvic floor dysfunction					
UI during pregnancy	0	Reflects intervention and model population	As model is preventative the population has no existing pelvic floor dysfunction					
Vaginal birth proportion	0.86	Reilly (2002)	Used to derive a weighted average from UR-CHOICE prediction					
Proportion with family history of POP	0.10	NICE (2019) https://www.nice.org.u k/guidance/ng123/cha pter/Context	Used to derive a weighted average from UR-CHOICE prediction					
Proportion with family history of UI	0.45	Milsom (2019)	Used to derive a weighted average from UR-CHOICE prediction					

(a) Weight = BMI x height<sup>2</sup>;  $24.5 \times 1.619^2$ 

The UR-CHOICE predictions for the model population were obtained for the values given in Table 15 and for the various permutations of mode of birth and family history of POP and UI. These are tabulated in Table 16 below.

Table 16: UR-CHOICE predictions for model pop

UR-CHOICE prediction model	Mode of birth	Family History POP	Family History UI	Weighting	UI Risk
12-year	Vaginal	No	N/A	0.774	0.448
12-year	Caesarean	No	N/A	0.126	0.350
12-year	Vaginal	Yes	N/A	0.086	0.605
12-year	Caesarean	Yes	N/A	0.014	0.504
20-year	Vaginal	N/A	No	0.473	0.285
20-year	Caesarean	N/A	No	0.077	0.189
20-year	Vaginal	N/A	Yes	0.387	0.659

UR-CHOICE prediction model	Mode of birth	Family History POP	Family History UI	Weighting	UI Risk
20-year	Caesarean	N/A	Yes	0.063	0.529

In addition, there is the option for the user to set a lifetime prevalence. This is used as a 5<sup>th</sup> time point in estimating a best fit line rather than the final prevalence at the end of life. The default of this parameter is set to 70% with uncertainty assessed through one-way sensitivity analysis. The risk at the 5 data points is depicted in Table 17.

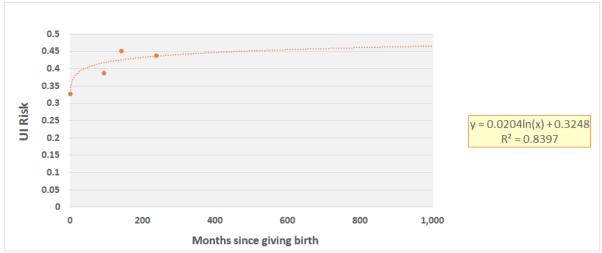
Table 17: Data used to estimate the risk of UI as a function of time (months)

Time in months	UI risk	Source				
3 months post-partum	0.327	Reilly (2002)				
96 months	0.388	Agur (2008)				
144 months	0.455	UR-CHOICE 12-year				
240 months	0.441	UR-CHOICE 20-year				
1,000 months	0.700	User defined <sup>a</sup>				

<sup>(</sup>a) The use of this UI risk is optional and a mathematical relationship can be fitted either with or without this value

The model is configured to allow either a linear or logarithmic relationship to be fitted to these data points and 4 alternatives functions are illustrated in Figure 7, Figure 8, Figure 9 and Figure 10, reflecting the mathematical form and whether the relationship includes the user defined lifetime risk at 1,000 months. In the base case analysis, a logarithmic relationship is assumed utilising the 4 data points derived from Reilly (2002), Agur (2008) and the UR-CHOICE prediction model. The best fit lines were fitted deterministically as it was not possible to quantify the uncertainty around data points estimated from the prediction model.

Figure 7: Estimated relationship between UI risk and time using 4 data points and a logarithmic functional form



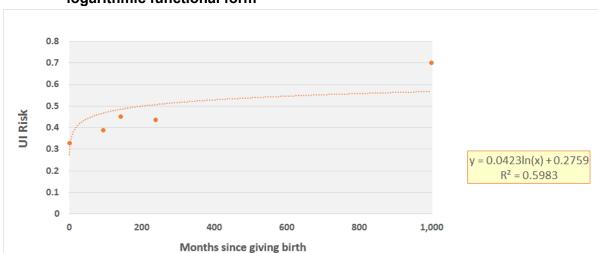
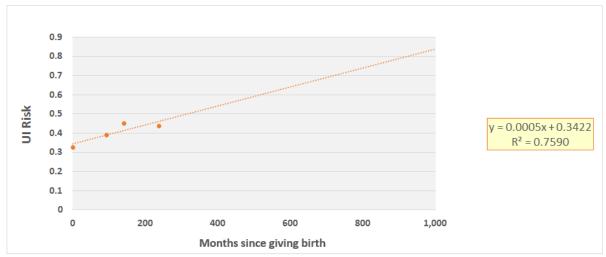


Figure 8: Estimated relationship between UI risk and time using 5 data points and a logarithmic functional form

Figure 9: Estimated relationship between UI risk and time using 4 data points and a linear functional form



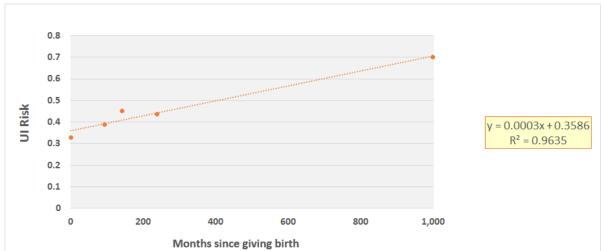


Figure 10: Estimated relationship between UI risk and time using 5 data points and a linear functional form

However, the first data point is at 3-months post-partum and therefore there is additionally the period from birth to 3-months post-partum to consider. The model allows 3 different relationships for this period, which are shown in Figure 11:

- i. Use the same relationship between UI risk and time as for the period beyond 3-months post-partum
- ii. Assume a linear increase in UI risk from zero at birth to the estimated risk at 3-months post-partum
- iii. Assume that the UI risk is constant before 3-months post-partum at the same level of risk estimated for 3-months post-partum



Months since giving birth

Figure 11: Graph to show alternative functional forms for natural history of UI in susceptible women from birth to 3-months post-partum

The relationships derived thus far model the risk of UI across the entire model population. However, the model assumes that the population comprises 2 distinct groups. It assumes that some women are susceptible to UI and could potentially benefit from treatment which could avert or delay the onset of UI. Conversely, it assumes that there are non-susceptible women who will not develop UI and therefore have no capacity to benefit from treatment. The risk of UI across the entire population is a weighted average of the risk in these 2 groups but, of course, this risk is zero in the non-susceptible group. It is therefore straightforward to scale up this population risk to give the risk of UI in the susceptible group over time. Figure 12 illustrates this mapping from population to susceptible risk, where the lifetime risk of UI in the absence of treatment is 100%. So the population risk will be determined by the relative

proportions of susceptible and non-susceptible women, which will be determined by the risk characteristics in that particular population but the model assumes that susceptible women have the same natural history regardless of the underlying risk characteristics in the population.

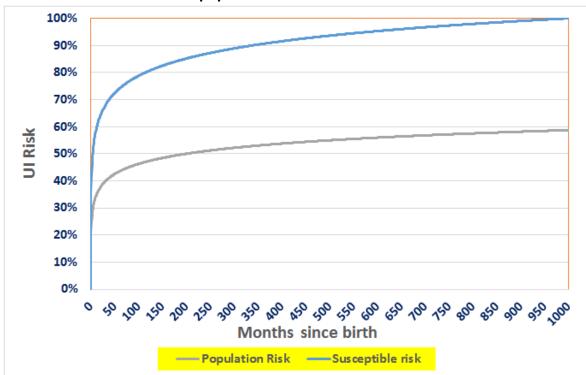


Figure 12: Graph to show how natural history in susceptible women was derived from the estimated population risk over time

#### **Effectiveness**

The baseline in the model is given by the natural history model and effectiveness data from Reilly (2002) and Agur (2008) is used to estimate the impact of preventative PFMT on the natural history of UI. The measures of relative treatment effect used in this analysis are shown in Table 18.

Table 18: Relative treatment effectiveness estimates derived from clinical review.

Time since birth	Relative risk	Low 95% CI	High 95% CI	Distribution	Source
3 months	0.59	0.37	0.92	Log-normal	Reilly (2002)
96 months	0.91	0.61	1.36	Log-normal	Agur (2008)

This clinical evidence gives data on the relative treatment effect at 2 points in time. A temporal relationship was then fitted to these 2 points in order to estimate the relative risk as a function of time (in months) since birth. The model allowed either a logarithmic or linear relationship to be fitted as illustrated in Figure 13 and Figure 14 below. The logarithmic functional form was used in the base case analysis with the linear relationship evaluated as part of a sensitivity analysis. In probabilistic sensitivity analysis the relative risks for the 2 time points are sampled independently. Whilst treatment effectiveness will be declining over time in most samples, independent sampling of relative risks does mean that occasionally the relative risk sample at the second time point will be lower than at the first.

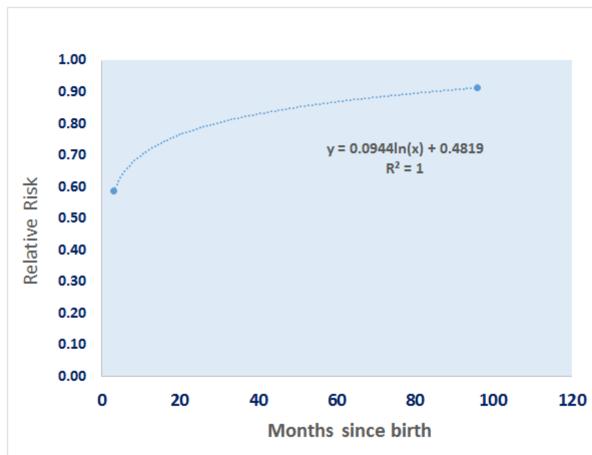


Figure 13: Relative risk as a function of time estimated from study point estimates and assuming a logarithmic relationship

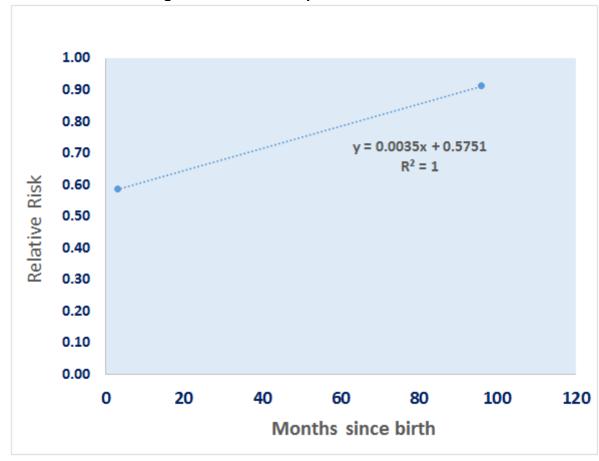


Figure 14: Relative risk as a function of time estimated from study point estimates and assuming a linear relationship

A number of logical constraints are placed on relative risk values when the relationship is extrapolated over a longer time period. The first constraint is for when the estimated relative risk for the 2 time points is increasing but lower than 1 for both values, as is the case in Figure 13 and Figure 14 above. Whilst it is quite plausible that treatment effect declines over time (increasing relative risk) extrapolating the functional relationship over a longer time period would often lead to a relative risk of greater than 1, implying harms from treatment which is less plausible especially without direct evidence of harm from the 2 study points. Therefore, in these scenarios the relative risk is capped at a maximum of 1, a situation of neither benefit or harm. Figure 15 illustrates the impact this constraint has when modelling the impact of preventative PFMT on the natural history of UI on susceptible women.

A second constraint is that the proportion of susceptible women with UI can never exceed 100%. Thus, if the relative risk is increasing and has a value of greater than 1 at one or more of the 2 time points, then the proportion is capped at 100%. In this scenario it may take less time for all susceptible women to have UI, as shown by the example in Figure 16.

The final constraint is that when relative risk is falling the proportion of women with UI can never fall as that would violate the model assumption that there is no transition from PFD to No PFD. This constraint is depicted in Figure 17.

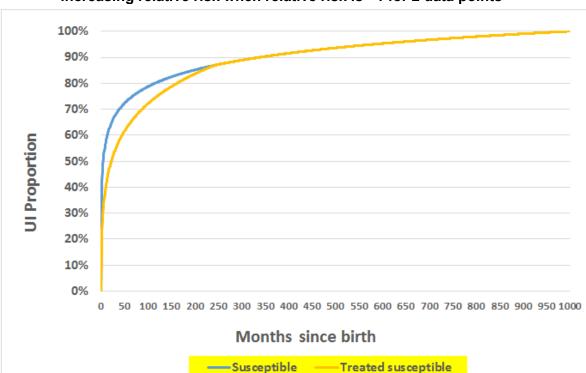
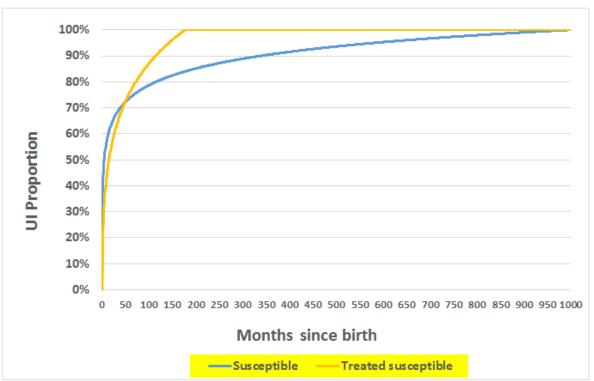


Figure 15: Graph to show impact of preventative PFMT on natural history of UI with increasing relative risk when relative risk is <1 for 2 data points

Figure 16: Graph to show impact of preventative PFMT on natural history of UI with increasing relative risk when relative risk >1 for second data point



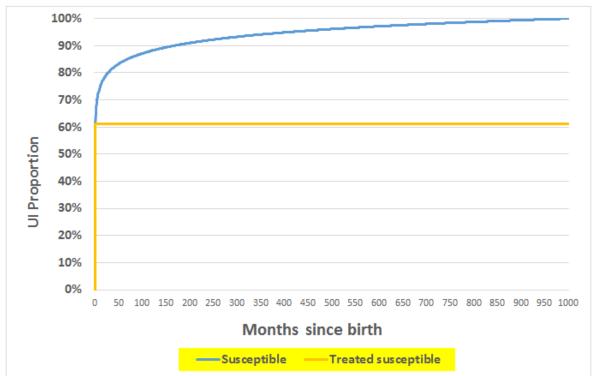


Figure 17: Graph to show impact of preventative PFMT on natural history of UI with declining relative risk

#### Health state utilities and QALYs

Women are estimated to live with a health state utility derived for women from UK EQ-5D population norms for their age (Kind 1999). This data is summarised in Table 19. For probabilistic sensitivity analysis the method of moments was used to fit beta distributions to utility values (Briggs 2011).

Table 19: Health state utility for women based on UK EQ-5D population norms

Age band (years)	Health state utility	Sample	Standard deviation	Standard error
<25	0.94	176	0.12	0.009
25-34	0.93	423	0.12	0.006
35-44	0.91	305	0.16	0.009
45-54	0.85	267	0.23	0.014
55-64	0.81	288	0.26	0.015
65-74	0.78	260	0.25	0.016
≥75	0.71	206	0.28	0.020

To capture improvements to health related quality of life from delaying or averting the onset of urinary incontinence in susceptible women it was necessary to assign a health state utility decrement to urinary incontinence. A NICE single technology appraisal (<a href="https://www.nice.org.uk/guidance/ta290/documents/overactive-bladder-mirabegron-astellas-pharma2">https://www.nice.org.uk/guidance/ta290/documents/overactive-bladder-mirabegron-astellas-pharma2</a>) used data from the SCORPIO study to estimate health state utility according to incontinence episode frequency. This data is summarised in Table 20.

Table 20: Health state utility as measured by incontinence episode frequency

Incontinence episode frequency	Health state utility	Sample	Weight
0 per day	0.813	741	-
>0 to ≤1 per day <sup>a</sup>	0.793	359	0.307
>1 to ≤2 per day <sup>a</sup>	0.783	279	0.239
>2 to ≤3 per day <sup>a</sup>	0.763	175	0.150
>3 per day <sup>a</sup>	0.753	352	0.301

<sup>(</sup>a) Used to calculate a weighted mean health state utility from urinary incontinence

The weighted mean health state utility in those with urinary incontinence (>0 incontinence episodes per day) was calculated as:

$$(0.793 \times 0.307) + (0.783 \times 0.239) + (0.763 \times 0.150) + (0.753 \times 0.301) = 0.774$$

The health state utility (HSU) decrement from urinary incontinence was calculated as the difference in HSU without incontinence and the weighted mean HSU with urinary incontinence:

 $HSU_{UI}$  decrement = 0.813 - 0.774 = 0.039

A Dirichlet distribution was used in the probabilistic sensitivity analysis to sample the weighted mean health state utility in women with urinary incontinence. The count for each severity level of incontinence episode frequency is based on the sample recorded in Table 20 and sampled using the cumulative gamma function. The sampled weight for each severity level was then calculated as its sample count ÷ sum of the sample counts for all severity levels.

In line with NICE guideline methods, an annual discount rate of 3.5% was applied to health state utilities.

#### 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 and it was assumed that each woman would receive 5 supervised PFMT sessions on the basis that sessions started in the 20<sup>th</sup> week of pregnancy and continued at monthly intervals till birth. A monthly cost for management of symptoms was applied to women who developed urinary incontinence and an annual discount rate of 3.5%, in line with NICE methods, was applied to these costs. This estimate of the cost of management was a fairly crude estimate but reflected easily accessible data that was in the public domain. The estimates were also of a similar order to an analysis (https://www.ics.org/Abstracts/Publish/43/000156.pdf) that estimated the costs of different types of urinary incontinence to the NHS when updated to 2020 prices. No discounting was applied to the preventative PFMT intervention as these costs were all incurred within the first year.

**Table 21: Unit costs** 

Resource item	Cost	Source
PFMT session	£64	Unit Costs of Health and Social Care 2020 <sup>a</sup>
Monthly cost of urinary incontinence	£4.06	https://www.sfh-tr.nhs.uk/media/8270/bladder-problems-and- urinary-incontinence-policy.pdf b

<sup>(</sup>a) Cost of a one-to-one physiotherapy session

<sup>(</sup>b) This report cites that the estimated cost to the NHS of urinary incontinence is £233 million per year at 2017 and that 4 million women over the age of 40 are regularly incontinent. It was assumed that women account for 80% of urinary continence costs in the NHS (https://www.birmingham.ac.uk/Documents/college-

<u>mds/haps/projects/HCNA/02HCNA3D3.pdf</u>). The cost was updated to 2020 prices using the NHS cost inflation index (NHSCII) and a monthly cost derived =  $(£233 \times 1.046 \times 0.8 \div 4) \div 12$ 

All costs were treated deterministically in the analysis with the impact of uncertainty explored through one-way sensitivity analysis.

# Sensitivity analysis

Probabilistic sensitivity analysis was undertaken to assess parameter uncertainty simultaneously across a number of model inputs. This involved 10,000 Monte Carlo simulations of the model, with model inputs sampled from a specified probability distribution for each iteration.

Sensitivity analysis was also undertaken to assess the importance of a number of structural assumptions on the model's conclusions. Sensitivity analysis was also undertaken on the following variables, where the source of uncertainty is other than that due to sampling

- i. Population risk
- ii. Cost of preventative PFMT
- iii. Monthly costs to the NHS of urinary incontinence
- iv. Discount rate for costs and QALYs

#### Results

# Base case analysis

The base case analysis was based on a population risk of urinary incontinence of 50%. A logarithmic functional form, estimated from 2 trial data points and predictions from UR-CHOICE, was used to estimate the natural history of UI in a susceptible population in the absence of any preventative PFMT provided in the antenatal period. The analysis was based on a lifetime horizon and it was assumed that UI rate in the first 3 months after birth could be estimated from the logarithmic equation used to estimate UI as a function of time.

#### i. Deterministic results

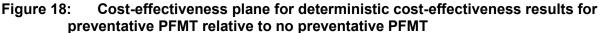
The deterministic results are shown in Table 22, Figure 18 and Figure 19. These results suggest that an intervention to provide antenatal preventative PFMT to prevent pelvic floor dysfunction is cost-effective for a population with a 50% risk at a cost-effectiveness threshold of £20,000 per QALY. Table 22 shows that the intervention is cost increasing, with a small reduction in the costs of UI management not offsetting the costs of the PFMT sessions. However as Table 22 and Figure 18 show, the ICER of £11,432 falls below the cost-effectiveness threshold indicating that the QALY gain represents good value for NHS resources. Figure 19, which shows the impact of the transitions between health states over time, indicates that the benefits of preventative PFMT are a consequence of delayed UI onset rather than averted UI.

Table 22: Table of deterministic cost-effectiveness results for preventative PFMT relative to no preventative PFMT

Totality to no provontative i i in i								
Item	No preventative PFMT	Preventative PFMT						
Treatment cost	03	£320						
UI management costs	£539	£507						
Total costs	£539	£827						
Total QALYs	20.952	20.977						
Incremental costs	n/a	£288						
Incremental QALYs	n/a	0.025						

Item	No preventative PFMT	Preventative PFMT
ICER	n/a	£11,432
iNMB	n/a	£216
Cost-effective	No	Yes

ICER = Incremental cost-effectiveness ratio; iNMB = incremental Net Monetary Benefit; QALYs = Quality Adjusted Life Years



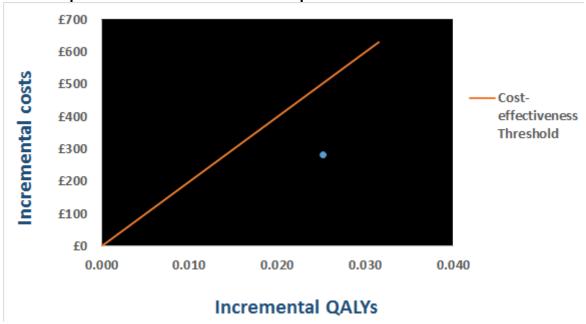
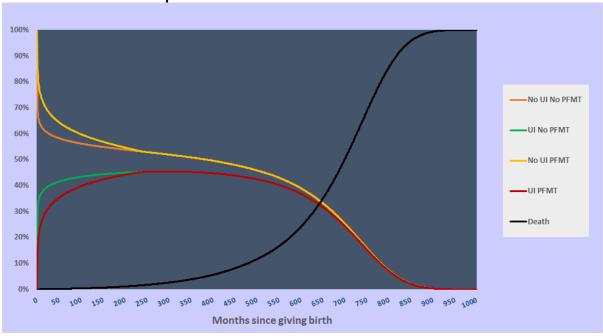


Figure 19: Graph to show the transition to health states over time for preventative PFMT and no preventative PFMT



# ii. Probabilistic sensitivity analysis

Table 23 and Figure 20 show the probabilistic results based on 10,000 model simulations for the base case model and quantify some of the uncertainty with respect to the cost-effectiveness conclusions. The mean iNMB of £481 indicates that the preventative PFMT is cost-effective as the value is positive, although there is uncertainty with respect to this conclusion as the 95% credible interval includes negative values. However, preventative PFMT was cost-effective in 63.0% of the simulations. The simulations depicted in Figure 20 show a very strong negative correlation between incremental costs and incremental QALYs which is because of the very close link between QALY gains from averted or delayed UI and "downstream" savings from averted or delayed UI.

Table 23: Table of probabilistic cost-effectiveness results for preventative PFMT relative to no preventative PFMT

Outcome	Value (95% Crl)
Mean incremental cost of preventative PFMT	£273 (£114 to £365)
Mean incremental QALYs of PFMT	0.0377 (-0.0363 to 0.1644)
Mean iNMB	£481 (-£1,091 to £3,174)
Probability cost-effective	63.0%



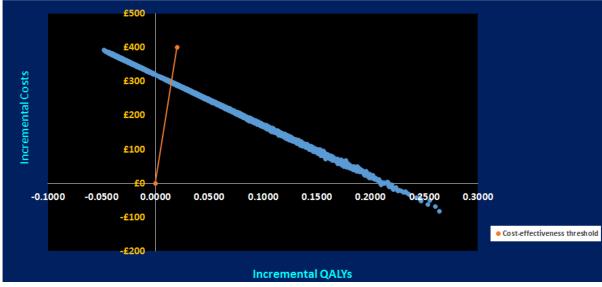


Figure 21 shows the cost-effectiveness acceptability curve, which charts the probability that preventative PFMT is cost-effective relative to no PFMT for the base case analysis at different cost-effectiveness thresholds. This indicates that preventative PFMT is likely to be cost-effective relative to no preventative PFMT providing the cost-effectiveness threshold is greater that £11,000 per QALY. It also shows that the probability of preventative PFMT being cost-effective only increases slowly for increasing cost-effectiveness thresholds above £25,000 per QALY. This follows from the non-negligible number of simulations that fall in the north east quadrant of the cost-effectiveness plane (see Figure 20) where no preventative

PFMT dominates (cheaper and more QALYs) preventative PFMT. These simulations would never be considered cost-effective irrespective of the cost-effectiveness threshold.

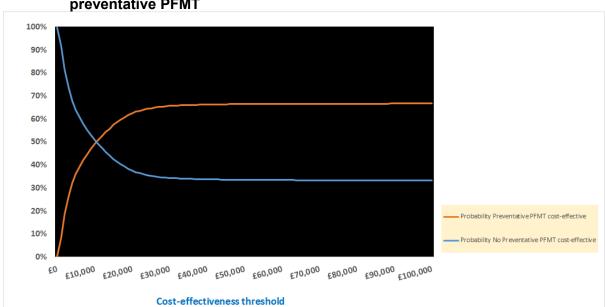


Figure 21: CEAC for the base case analysis for preventative PFMT compared to no preventative PFMT

## Sensitivity analysis

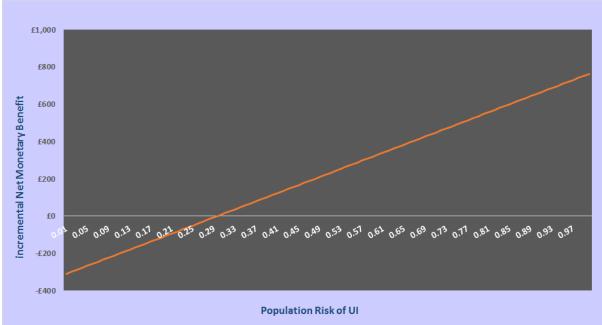
# Varying population risk

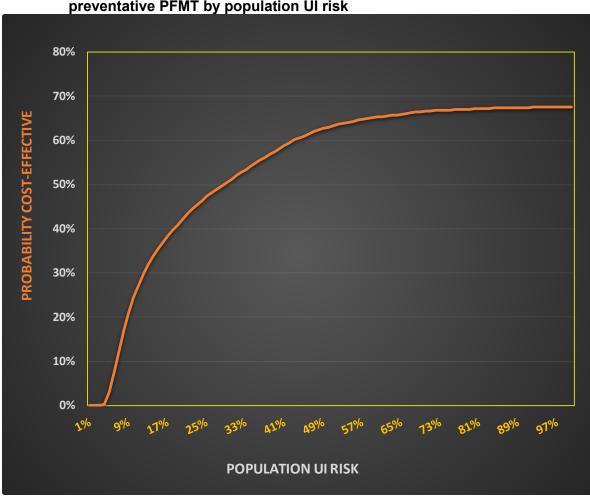
The population risk is a very important parameter in the model as it reflects the capacity to benefit from preventative PFMT and the absolute benefit of treatment is likely to rise with increasing risk. Therefore, a sensitivity analysis was undertaken varying the population risk of PFD (as measured by UI risk) whilst maintaining other model inputs and structural assumptions as per the base case analysis. Figure 22 shows the deterministic relationship between the antenatal population risk of UI and the iNMB and shows, as expected, improved cost-effectiveness with increasing risk. It also shows that the threshold at which antenatal preventative PFMT becomes cost-effective is at a risk level of 30% and above.

Figure 23 shows the results of Monte Carlo simulations and indicate the probability that antenatal preventative PFMT is cost-effective according to the level of population risk. It shows that the likelihood of preventative PFMT being cost-effective increases with risk and that there is a greater than 50% probability of antenatal preventative PFMT being cost-effective when the risk of UI is 29% and above. Figure 24 further quantifies the uncertainty by illustrating the 95% credible intervals for the iNMB based on 10,000 model simulations. It shows that the width of the credible interval increases as population risk of UI increases. Not shown on the chart but at a UI risk of less than 7% the mean iNMB is negative and the upper bound of the 95% credible intervals is also negative, which corroborates Figure 23 in demonstrating that antenatal preventative PFMT is very unlikely to be cost-effective if the risk of UI is very low. For UI risk of greater than 7% or greater the 95% credible intervals include positive (upper bound) and negative (lower bound) values for iNMB indicating that there is some uncertainty with respect to the cost-effectiveness of antenatal preventative PFMT even at high levels of risk. However, it should be noted that the credible intervals

become more heavily weighted to positive values at higher levels of risk, reflecting their higher probability of cost-effectiveness.

Figure 22: Graph to illustrate the deterministic relationship between risk of UI and incremental net monetary benefit of antenatal preventative PFMT





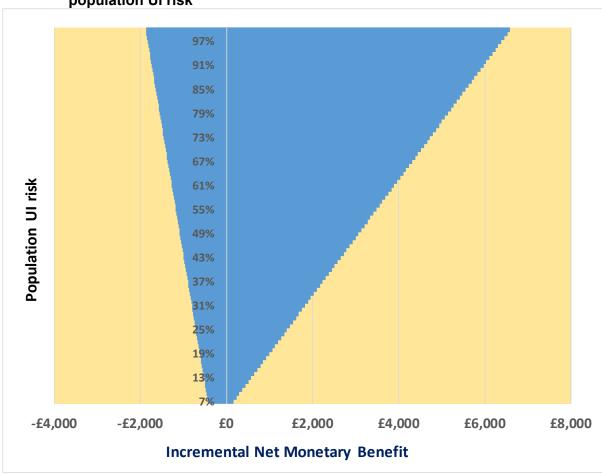


Figure 24: 95% credible intervals for mean iNMB of antenatal preventative PFMT by population UI risk

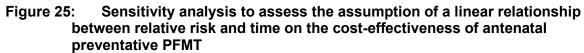
Blue shaded bar represents the 95% credible intervals

## ii. Varying structural assumptions

The structural assumptions on the model were varied in one-way sensitivity analyses to assess the extent to which model conclusions were sensitive to these assumptions. All other model inputs and structural assumptions were held constant as per their base case value.

Figure 25 shows the impact of assuming a linear relationship for the change in relative risk over time instead of a logarithmic one. It shows that the iNMB is slightly higher at each level of population UI risk and consequently the threshold risk at which antenatal preventative PFMT becomes cost-effective is slightly lower.

Figure 26 illustrates the impact of alternative time horizon's on the model's inclusions. It indicates that a longer time horizon increases the cost-effectiveness up to a certain number of years but the results for a 20-year timeframe are identical to a lifetime horizon in this case as the decline in relative risk means that no further benefits accrue beyond 20 years as UI is delayed rather than averted (see Figure 19).



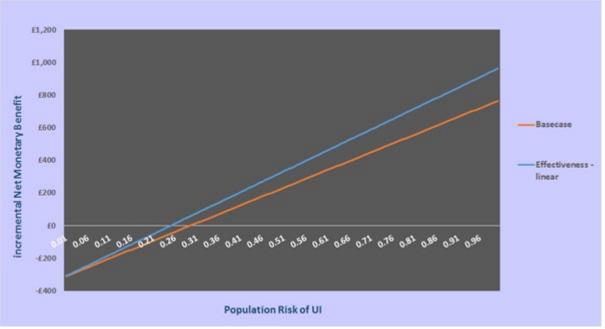


Figure 26: Sensitivity analysis to assess the impact of the model time horizon on the cost-effectiveness of antenatal PFMT

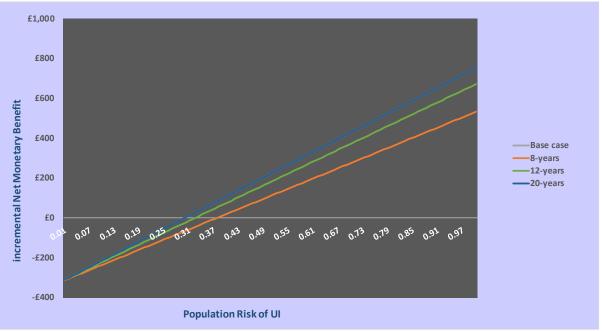


Figure 27 considers different assumptions about the UI rate in the period from birth to 3 months post-partum as outlined in Figure 11. This shows that the impact of these assumptions has a negligible impact on the iNMB for this analysis.

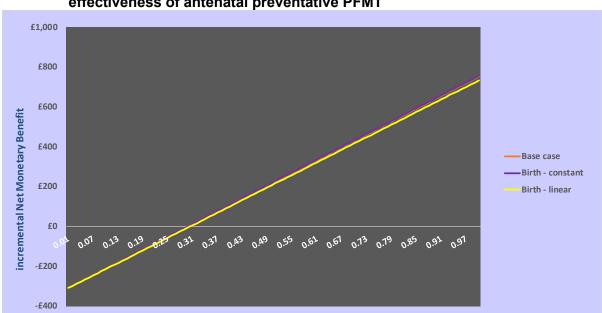


Figure 27: Sensitivity analysis to assess the impact of different assumptions about the natural history of UI from birth to 3 months post-partum on the cost-effectiveness of antenatal preventative PFMT

In Figure 28 the effect of fitting different functional forms to the observed and predicted UI risks in order to estimate the natural history of UI in a susceptible population is assessed.

**Population Risk of UI** 

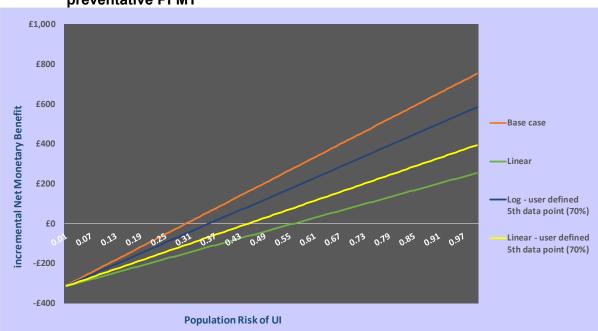


Figure 28: Sensitivity analysis to assess the impact of fitting different functional forms to the UI risk over time on the cost-effectiveness of antenatal preventative PFMT

This sensitivity analysis suggests that this assumption does have an impact on costeffectiveness conclusions and the assumption made in the base case analysis produces a more favourable assessment of cost-effectiveness. Using the least favourable assumption to model natural history raises the UI risk threshold at which antenatal PFMT becomes cost-effective to 56%.

Table 24 summarises the cost-effectiveness results arising from these sensitivity analyses on the model's structural assumptions

Table 24: Summary table of results for one-way sensitivity analyses on the model's structural assumptions

	Determi	nistic	Probabilistic			
Assumption	ICER	iNMB	Mean iNMB (95% Crl)	Probability cost-effective		
Base case	£11,432	£216	£481 (-£1,091 to £3,174)	63.0%		
Linear relative risk	£9,479	£314	£380 (-£823 to £2,810)	66.1%		
8-year time horizon	£14,722	£106	£68 (-£567 to £634)	60.7%		
12-year time horizon	£12,476	£175	£145 (-£697 to £1,040)	62.1%		
20-year time horizon	£11,432	£216	£259 (-£880 to £1,676)	62.7%		
Constant UI: 0-3 months	£11,397	£218	£461 (-£1,107 to £3,140)	62.5%		
Linear UI: 0-3 months	£11,676	£206	£468 (-£1,103 to £3,158)	62.2%		
Linear: Natural history	£22,445	-£33	-£157 (-£2,553 to £1,783)	49.5%		
Log: Natural history (5 data points)	£13,814	£131	£287 (-£1,526 to £2,959)	58.5%		
Linear: Natural history (5 data points)	£17,787	£37	-£100 (-£2,618 to £2,186)	53.8%		

# iii. Varying model inputs

A number of model input values were varied as indicated in Table 25. Most of these values were varied at one at a time but the discount rate for costs and QALYs were both lowered simultaneously to the value suggested in the NICE guidelines manual (https://www.nice.org.uk/process/pmg20/chapter/incorporating-economic-evaluation).

Table 25: Variables where input values were varied as part of a sensitivity analysis

•	-	
Variable	Lower bound	Upper bound
Number of PFMT sessions	4 a	5 (base case)
Cost of PFMT session	£64 (Base case)	£100 b
Cost to NHS of UI management per month	£4.06 (base case)	£8.12
UI HSU decrement	0.01	0.07
Discount rate	1.5%	3.5% (base case)

<sup>(</sup>a) This has the impact of lowering the cost of the antenatal preventative PFMT intervention: 4 x £64 = £256

<sup>(</sup>b) This has the impact of increasing the cost of the antenatal preventative PFMT intervention:  $5 \times £100 = £500$ 

Figure 29 illustrates the impact of different model inputs for cost and resource use variables. Self-evidently, higher intervention cost leads to reduced cost-effectiveness and lower intervention costs (from a reduction in sessions to deliver the intervention) increases it. Doubling the costs to the NHS of UI management also leads to improved cost-effectiveness especially at higher levels of population UI risk. However, even when the cost of antenatal preventative PFMT rises to £500, it remains cost-effective providing the population risk of UI is 47% or above.

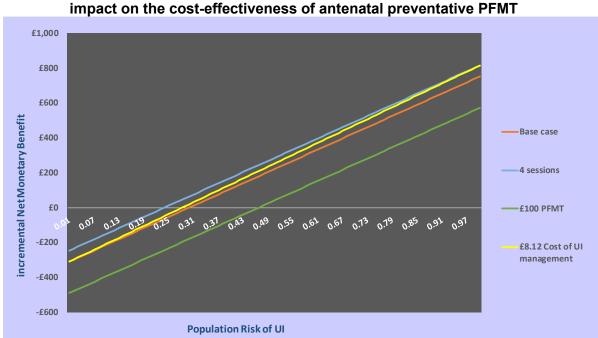
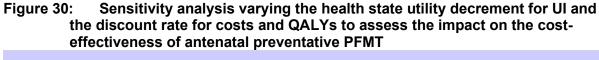


Figure 29: Sensitivity analysis varying resource use and cost inputs to assess the impact on the cost-effectiveness of antenatal preventative PFMT

The consequences of different assumptions about the health state utility decrement from UI and a lower discount rate are charted in Figure 30. The lower discount rate has only a relatively small impact in improving the cost-effectiveness of antenatal preventative PFMT and the risk threshold at which the intervention becomes cost-effective is barely changed. The sensitivity analysis does indicate that the health state utility decrement from UI is an important driver of the model's conclusions. However, it should be noted that parameter uncertainty for this model input is addressed by sampling in the probabilistic analyses. Table 26 summarises the results of the sensitivity analyses changing model parameters on the model's cost-effectiveness results



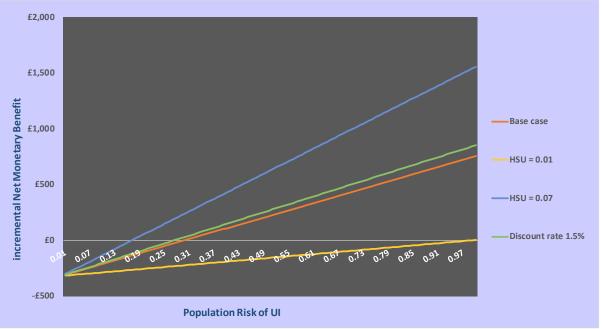


Table 26: Summary table of results for sensitivity analyses on the model variable input values

Tuidoo							
	Deterministic		Probabilistic				
			Mean iNMB	Probability			
Assumption	ICER	iNMB	(95% Crl)	cost-effective			
Base case	£11,432	£216	£481 (-£1,091 to £3,174)	63.0%			
£100 PFMT cost/session	£18,567	£36	£316 (-£1,279 to £2,996)	53.7%			
4 PFMT sessions	£8,895	£280	£538 (-£1,027 to £3,196)	64.8%			
£8.12 cost UI management	£10,179	£248	£523 (-£1,140 to £3,367)	63.6%			
HSU UI decrement 0.01	£44,567	-£159	-	-			
HSU UI decrement 0.07	£6,367	£618	-	-			
1.5% discount rate	£10,367	£265	£802 (-£1,404 to £5,128)	63.5%			

#### **Discussion**

As indicated by the NHS 5-year plan and the Cumberledge report there is desire from policy makers to prevent symptoms arising from pelvic floor disorders. As far as we are aware, the analysis provides the first economic evaluation of preventative PFMT, especially in an NHS context.

It should be remembered that this is an economic evaluation in a very specific antenatal population and of a specific intervention, supervised PFMT sessions given at monthly intervals (with instructions to do the exercise twice daily) in pregnancy from the 20<sup>th</sup> week of pregnancy to birth. Therefore, the cost-effectiveness of preventative PFMT in other populations and setting cannot be assumed.

The results from the base case analysis and the various sensitivity analyses generally show that in an antenatal population with a 50% risk of UI that the preventative PFMT is cost-effective with incremental cost effectiveness ratios (ICERs) below £20,000 per QALY, positive net monetary benefits and with higher than 50% probabilities of being cost effective relative to no PFMT. The only real exception to this finding was when the natural history of UI was modelled with a linear relationship based on the 2 observed data points in Reilly (2002) and Agur (2008) in addition to the UR-CHOICE predictions at 12 years and 20 years. Even then the intervention could be considered borderline cost-effective with an ICER of £22,445 and a 50% probability of being cost-effective.

The model does provide evidence that the threshold level of UI risk at which preventative PFMT may become cost-effective may be considerably below 50%. For example, when the threshold analysis was undertaken on the base case inputs the threshold of UI risk at which PFMT became cost-effective was 30%. However, there would obviously be less confidence in the cost-effectiveness of preventative PFMT at lower levels of risk.

Even at very high levels of population risk there is some uncertainty with respect to the cost-effectiveness of antenatal preventative PFMT. In a hypothetical population which had a 100% risk of UI the probability of preventative PFMT being cost-effective would still fall just short of 70% (see Figure 23). This reflects the uncertainty in the clinical evidence with regard to temporal relative treatment effects. The evidence from Reilly (2002) and Agur (2008) suggests that the treatment effectiveness wanes over time and that is why in the deterministic analysis PFMT only serves to delay onset of UI rather than preventing it entirely, although prevention is likely in some of the Monte Carlo simulations. The 95% credible intervals for iNMB which are shown in Figure 24 also indicate some level of uncertainty as the lower bound encompasses negative values.

It is important to interpret the results of this analysis in the context of its limitations. The relative treatment effects are derived from a single study and any limitations of that study will automatically feed into this economic analysis.

The natural history model was developed so as to represent the natural history of UI for the population included in the Reilly (2002) and Agur (Studies) and that is why those studies were used to inform estimates of the proportion with UI at 3 months' post-partum and 8 years. In predicting UI rates at 12 years and 20 years the UR-CHOICE prediction model was used with inputs that reflected the Reilly (2002) and Agur (2008) study population as closely as possible. However, the UR-CHOICE prediction models were not developed in that population (although the 12-year prediction model was based on a UK dataset). Furthermore, the 12-year prediction model and 20-year prediction model were developed in different populations and not all the predictors are the same in both models. These differences explain the slight anomaly where the predicted UI rate is lower in the 20-year model than the 12-year model (see Figure 7, Figure 8, Figure 9 and Figure 10). Nevertheless, the 2 observed UI rates in the control arms of Reilly (2002) and Agur (2008) do seem to exhibit a logarithmic pattern, especially when assuming no UI prior to birth and therefore the conclusions of this model are unlikely to depend crucially on estimating risk at 12 years and 20 years with a very high level of precision. The ability of the user to add a 5<sup>th</sup> data point also allows for some sensitivity analysis around the natural history.

The model assumes that the natural history model derived from Reilly (2002) and Agur (2008) is the same for women in the susceptible group regardless of the overall UI risk in that population. This is a simplifying assumption which allows different hypothetical population risks to be assessed, from 1% through to 100% in this analysis. Of course, the model

population of women in their first pregnancy and without UI will be important determinants of the risk in a preventative PFMT intervention for this group. The natural history model makes a simplifying assumption that UI is a permanent state although in practice it may sometimes go into remission or have a lower impact on health related quality of life. However, the committee considered that this was a reasonable assumption to make and given that most of the benefit is derived in the early months after treatment it is unlikely to be an important limitation in the model.

The model uses UI as a proxy for pelvic floor dysfunction more generally but it might be expected that preventative PFMT would have benefits on a broader range of symptoms related to pelvic floor disorders. If that is the case the model may underestimate both the QALY gain from antenatal preventative PFMT and also the "downstream" savings. Thus in this respect the model could be seen as providing a lower bound estimate of cost-effectiveness.

Finally, whilst the model allows some management of symptoms in order to capture "downstream" costs it does not consider treatments which have the ability to fundamentally improve health related quality of life. These are considered to represent a different economic decision problem for policy makers and it would have been necessary to take a whole disease pathway approach to incorporate this.

# Examples of groups from UR choice who meet risk criteria for cost-effective preventative PFMT

The information in Table 27 gives some examples of the UI risk predicted by the UR-CHOICE prediction model.

Parity	Age	Weight (kg)	Height (cm)	FH POP	FH UI	Mode of Birth	12-year Ul risk	20-year UI Risk
0	28	69	168	No	No	Caesarean	35.0%	18.8%
0	28	69	168	No	No	Vaginal	44.7%	28.4%
0	28	69	168	Yes	No	Vaginal	60.4%	28.4%
0	28	69	168	Yes	Yes	Vaginal	60.4%	65.7%
0	28	69	168	Yes	Yes	Caesarean	50.3%	52.8%
0	28	100	168	No	No	Caesarean	41.2%	29.3%
0	28	100	168	No	No	Vaginal	51.4%	41.6%
0	28	100	168	Yes	Yes	Vaginal	66.5%	77.5%
0	28	100	168	Yes	Yes	Caesarean	56.9%	66.7%
0	28	100	140	Yes	Yes	Caesarean	64.1%	77.0%
0	28	100	140	Yes	Yes	Vaginal	72.9%	85.2%
0	40	100	140	Yes	Yes	Vaginal	78.3%	88.3%
0	40	100	140	Yes	Yes	Caesarean	70.6%	81.4%
0	18	69	168	No	No	Caesarean	29.6%	15.6%
0	18	50	168	No	No	Caesarean	26.4%	11.5%
0	18	50	180	Yes	Yes	Vaginal	47.0%	46.2%

FH = Family History, POP = Pelvic Organ Prolapse; UI = Urinary Incontinence

#### Conclusions

This economic analysis suggests that antenatal preventative PFMT can be cost-effective dependent on the overall population risk of UI. If this risk is 50% or above, then the model

suggests there is a fairly high probability that antenatal preventative PFMT would be cost-effective. As the model only considers one symptom of pelvic floor dysfunction, urinary incontinence, it may under-estimate the cost-effectiveness if antenatal PFMT has a positive impact on other symptoms.

# Acknowledgements

With the kind permission of the developers and authors, this analysis makes use of the UR Choice Pelvic Floor Disorders Risk Calculator (<a href="https://riskcalc.org/UR\_CHOICE/">https://riskcalc.org/UR\_CHOICE/</a>) and we would like to thank them for their support for our work.

Jelovsek JE, Chagin K, Gyhagen M, et al. Predicting risk of pelvic floor disorders 12 and 20 years after delivery. Am J Obstet Gynecol 2018;218:222.e1-19.

# Appendix K – Excluded studies

Excluded studies for review question: What is the effectiveness of pelvic floor muscle training for preventing pelvic floor dysfunction?

# **Clinical studies**

Table 28: Excluded studies and reasons for their exclusion

Table 28: Excluded studies and reasons for their exclusion	December evaluation
Study	Reason for exclusion
Alves, F. K., Riccetto, C., Adami, D. B., Marques, J., Pereira, L. C., Palma, P., Botelho, S., A pelvic floor muscle training program in postmenopausal women: A randomized controlled trial, Maturitas, 81, 300-5, 2015	Whole population has PFD
Anonymous,, Pelvic floor muscle training for prevention and treatment of urinary and faecal incontinence in antenatal and postnatal women, Obstetrics and gynecology, 113, 733-735, 2009	Short report
Artymuk, N. V., Khapacheva, S. Y., Device-assisted pelvic floor muscle postpartum exercise programme for the management of pelvic floor dysfunction after delivery, Journal of Maternal-Fetal & Neonatal MedicineJ Matern Fetal Neonatal Med, 1-5, 2020	Over 20% of the population have PFD
Berghmans, L. C., Hendriks, H. J., Bo, K., Hay-Smith, E. J., de Bie, R. A., van Waalwijk van Doorn, E. S., Conservative treatment of stress urinary incontinence in women: a systematic review of randomized clinical trials, British journal of urology, 82, 181-191, 1998	Systematic review - included studies checked for relevance for this review
Bo, K., Haakstad, L. A., Is pelvic floor muscle training effective when taught in a general fitness class in pregnancy? A randomised controlled trial, Physiotherapy, 97, 190-5, 2011	Over 20% of the population have PFD
Bo, K., Hilde, G., Staer-Jensen, J., Siafarikas, F., Tennfjord, M. K., Engh, M. E., Postpartum pelvic floor muscle training and pelvic organ prolapsea randomized trial of primiparous women, American Journal of Obstetrics & Gynecology, 212, 38.e1-7, 2015	Over 20% of the population have PFD
Boyle, R., Hay-Smith, E. J., Cody, J. D., Morkved, S., Pelvic floor muscle training for prevention and treatment of urinary and fecal incontinence in antenatal and postnatal women: a short version Cochrane review, Neurourology & UrodynamicsNeurourol Urodyn, 33, 269-76, 2014	Systematic review - included studies checked for relevance for this review
Burch, Jane Tort Sera, In pregnant women, does antenatal pelvic floor muscle training help to prevent urinary incontinence?, Cochrane Clinical Answers, 2018	Short report
Chiarelli, P., Murphy, B., Cockburn, J., Acceptability of a urinary continence promotion programme to women in postpartum, BJOG: An International Journal of Obstetrics & Gynaecology, 110, 188-96, 2003	No relevant outcomes
Culligan, P. J., Blackwell, L., Murphy, M., Ziegler, C., Heit, M. H., A randomized, double-blinded, sham-controlled trial of postpartum extracorporeal magnetic innervation to restore pelvic muscle strength in primiparous patients, American Journal of Obstetrics & GynecologyAm J Obstet Gynecol, 192, 1578-82, 2005	No relevant outcomes
Culligan, P. J., Scherer, J., Dyer, K., Priestley, J. L., Guingon-White, G., Delvecchio, D., Vangeli, M., A randomized clinical trial comparing pelvic floor muscle training to a Pilates exercise program for improving pelvic muscle strength, International urogynecology journal, 21, 401-408, 2010	Population has PFD
Dannecker, C., C. Baur, E. Ruckhaberle, U. Peschers, K. Jundt, A. Reich, M. Bauerle, and K. T. M. Schneider. The effect of the pelvic floor training device Epi-No (R) on the maternal pelvic floor function six	Language

Study	Reason for exclusion
months after childbirth-Follow-up study of a randomised controlled trial. Geburtshilfe und frauenheilkunde 1192-1198. 2004	
Davenport, M. H., Nagpal, T. S., Mottola, M. F., Skow, R. J., Riske, L., Poitras, V. J., Jaramillo Garcia, A., Gray, C. E., Barrowman, N., Meah, V. L., Sobierajski, F., James, M., Nuspl, M., Weeks, A., Marchand, A. A., Slater, L. G., Adamo, K. B., Davies, G. A., Barakat, R., Ruchat, S. M., Prenatal exercise (including but not limited to pelvic floor muscle training) and urinary incontinence during and following pregnancy: a systematic review and meta-analysis [Erratum 2019; 53(2): e1], British Journal of Sports MedicineBJSM online, 52, 1397-1404, 2018	Systematic review - included studies checked for relevance for this review
de Andrade, R. L., Bo, K., Antonio, F. I., Driusso, P., Mateus-Vasconcelos, E. C. L., Ramos, S., Julio, M. P., Ferreira, C. H. J., An education program about pelvic floor muscles improved women's knowledge but not pelvic floor muscle function, urinary incontinence or sexual function: a randomised trial, Journal of physiotherapy, 64, 91-96, 2018	Over 20% of the population have PFD
de Oliveira, C., Lopes, M. A., Carla Longo e Pereira, L., Zugaib, M., Effects of pelvic floor muscle training during pregnancy, Clinics (Sao Paulo, Brazil), 62, 439-46, 2007	No relevant outcomes
Dias, N. T., Ferreira, L. R., Fernandes, M. G., Resende, A. P. M., Pereira-Baldon, V. S., A Pilates exercise program with pelvic floor muscle contraction: Is it effective for pregnant women? A randomized controlled trial, Neurourology & UrodynamicsNeurourol Urodyn, 37, 379-384, 2018	No relevant outcomes
Dierick, F., Galtsova, E., Lauer, C., Buisseret, F., Bouche, A. F., Martin, L., Clinical and MRI changes of puborectalis and iliococcygeus after a short period of intensive pelvic floor muscles training with or without instrumentation: A prospective randomized controlled trial, European Journal of Applied PhysiologyEur J Appl Physiol, 118, 1661-1671, 2018	Comparator not relevant
Dornowski, M., Sawicki, P., Wilczynska, D., Vereshchaka, I., Piernicka, M., Bludnicka, M., Worska, A., Szumilewicz, A., Six-Week Pelvic Floor Muscle Activity (sEMG) Training in Pregnant Women as Prevention of Stress Urinary Incontinence, Medical Science MonitorMed Sci Monit, 24, 5653-5659, 2018	No relevant outcomes
Dufour, S., Fedorkow, D., Kun, J., Deng, S. X., Fang, Q., Exploring the impact of a mobile health solution for postpartum pelvic floor muscle training: Pilot randomized controlled feasibility study, Journal of Medical Internet Research, 21 (7) (no pagination), 2019	Intervention not relevant
Ferreira, S., Ferreira, M., Carvalhais, A., Santos, P. C., Rocha, P., Brochado, G., Reeducation of pelvic floor muscles in volleyball athletes, 60, 428-433, 2014	All population have PFD
Fritel, X., De Tayrac, R., Bader, G., Savary, D., Gueye, A., Deffieux, X., Fernandez, H., Richet, C., Guilhot, J., Fauconnier, A., Preventing Urinary Incontinence with Supervised Prenatal Pelvic Floor Exercises: A Randomized Controlled Trial, Obstetrics and Gynecology, 126, 370-377, 2015	Over 20% of the population have PFD
Fritel, X., Fauconnier, A., de Tayrac, R., Amblard, J., Cotte, L., Fernandez, H., Prevent postnatal urinary incontinence by prenatal pelvic floor exercise? Rationale and protocol of the multicenter randomized study PreNatal Pelvic floor Prevention (3PN), Journal de gynecologie, obstetrique ET biologie de la reproduction, 37, 441-448, 2008	Language
Glazener, C. M., MacArthur, C., Hagen, S., Elders, A., Lancashire, R., Herbison, G. P., Wilson, P. D., ProLong Study, Group, Twelve-year follow-up of conservative management of postnatal urinary and faecal incontinence and prolapse outcomes: randomised controlled trial,	All population have PFD

Study	Reason for exclusion
BJOG: An International Journal of Obstetrics & Gynaecology, 121, 112-20, 2014	
Gorbea Chávez, V. del Pilar Velázquez Sánchez, M., Kunhardt Rasch, J. R., Effect of pelvic floor exercise during pregnancy and puerperium on prevention of urinary stress incontinence, Ginecologia y obstetricia de mexico, 72, 628-636, 2004	Language
Haddow, G., Watts, R., Robertson, J., Effectiveness of a pelvic floor muscle exercise program on urinary incontinence following childbirth, JBI Library of Systematic Reviews, 3, 153-214, 2014	Systematic review - included studies checked for relevance for this review
Haddow,G., Watts,R., Robertson,J., Effectiveness of a pelvic floor muscle exercise program on urinary incontinence following childbirth, International Journal of Evidence-Based Healthcare, 3, 103-146, 2005	Systematic review - included studies checked for relevance for this review
Hadizadeh-Talasaz, Z., Sadeghi, R., Khadivzadeh, T., Effect of pelvic floor muscle training on postpartum sexual function and quality of life: A systematic review and meta-analysis of clinical trials, Taiwanese Journal of Obstetrics and Gynecology, 58, 737-747, 2019	Systematic review - included studies checked for relevance for this review
Hagen, S., Glazener, C., McClurg, D., Macarthur, C., Elders, A., Herbison, P., Wilson, D., Toozs-Hobson, P., Hemming, C., Hay-Smith, J., Collins, M., Dickson, S., Logan, J., Pelvic floor muscle training for secondary prevention of pelvic organ prolapse (PREVPROL): a multicentre randomised controlled trial, LancetLancet, 389, 393-402, 2017	All population have PFD
Hagen, S., Stark, D., Conservative prevention and management of pelvic organ prolapse in women, Cochrane Database of Systematic Reviews, CD003882, 2011	Systematic review - included studies checked for relevance for this review
Harvey, M. A., Pelvic floor exercises during and after pregnancy: a systematic review of their role in preventing pelvic floor dysfunction, Journal of Obstetrics & Gynaecology Canada: JOGC, 25, 487-98, 2003	Systematic review - included studies checked for relevance for this review
Hay-Smith, J., Morkved, S., Herbison, G. P., Physical therapies for prevention of urinary and faecal incontinence in adults, Cochrane Database of Systematic Reviews, 2007	Review
Hilde, G., Staer-Jensen, J., Siafarikas, F., Ellstrom Engh, M., Bo, K., Postpartum pelvic floor muscle training and urinary incontinence: a randomized controlled trial [Erratum: 2014; 124(3): 639], Obstetrics & GynecologyObstet Gynecol, 122, 1231-8, 2013	Over 20% of the population have PFD
Hyakutake, M. T., Han, V., Baerg, L., Koenig, N. A., Cundiff, G. W., Lee, T., Geoffrion, R., Pregnancy-Associated Pelvic Floor Health Knowledge and Reduction of Symptoms: the PREPARED Randomized Controlled Trial, Journal of Obstetrics and Gynaecology Canada, 40, 418-425, 2018	No relevant outcomes
Johannessen, H. H., Morkved, S., Salvesen, K. A., Stafne, S. N., Risk of anal incontinence three months postpartum, Female Pelvic Medicine and Reconstructive Surgery, 25 (5 Supplement 1), S57-S58, 2019	Conference abstract
Kim, B. I., Hwang-Bo, G., Kim, H. R., Comparison of abdominal muscle thickness with vaginal pressure changes in healthy women, Journal of Physical Therapy ScienceJ Phys Ther Sci, 26, 427-30, 2014	No relevant outcomes
Ko,P.C., Liang,C.C., Chang,S.D., Lee,J.T., Chao,A.S., Cheng,P.J., A randomized controlled trial of antenatal pelvic floor exercises to prevent and treat urinary incontinence, International Urogynecology Journal, 22, 17-22, 2011	Over 20% of the population have PFD
Kolberg Tennfjord, M., Hilde, G., Stær-Jensen, J., Siafarikas, F., Engh, M. Ellström, Bø, K., Effect of postpartum pelvic floor muscle training on	Over 20% of the population have PFD

Chudu	Passan for evaluaion
Study vaginal symptoms and sexual dysfunction. Secondary analysis of a	Reason for exclusion
randomised trial, BJOG: An International Journal of Obstetrics & Gynaecology, 123, 634-642, 2016	
Lee,I.S., Choi,E.S., Pelvic floor muscle exercise by biofeedback and electrical stimulation to reinforce the pelvic floor muscle after normal delivery, Daehan Ganho Haghoeji, 36, 1374-1380, 2006	Not relevant intervention
Lemos, A., de Souza, A. I., Ferreira, A. L., Figueiroa, J. N., Cabral-Filho, J. E., Do perineal exercises during pregnancy prevent the development of urinary incontinence? A systematic review, International journal of urology, 15, 875-80, 2008	Systematic review - included studies checked for relevance for this review
Marques, J., Botelho, S., Pereira, L. C., Lanza, A. H., Amorim, C. F., Palma, P., Riccetto, C., Pelvic floor muscle training program increases muscular contractility during first pregnancy and postpartum: Electromyographic study, Neurourology and Urodynamics, 32, 998-1003, 2013	Not relevant intervention
Martinho, N. M., Silva, V. R., Marques, J., Carvalho, L. C., Iunes, D. H., Botelho, S., The effects of training by virtual reality or gym ball on pelvic floor muscle strength in postmenopausal women: a randomized controlled trial, Brazilian journal of physical therapy, 20, 248-257, 2016	No relevant outcomes
Mason, L., Roe, B., Wong, H., Davies, J., Bamber, J., The role of antenatal pelvic floor muscle exercises in prevention of postpartum stress incontinence: a randomised controlled trial, Journal of clinical nursing, 19, 2777-86, 2010	Over 20% of the population have PFD
Mateus-Vasconcelos, E. C. L., Brito, L. G. O., Driusso, P., Silva, T. D., Antonio, F. I., Ferreira, C. H. J., Effects of three interventions in facilitating voluntary pelvic floor muscle contraction in women: a randomized controlled trial, Brazilian journal of physical therapy, 22, 391-399, 2018	All population have PFD
Miquelutti, M. A., Cecatti, J. G., Makuch, M. Y., Evaluation of a birth preparation program on lumbopelvic pain, urinary incontinence, anxiety and exercise: a randomized controlled trial, BMC Pregnancy & Childbirth, 13, 154, 2013	Over 20% of the population have PFD
Morkved, S., Bo, K., Effect of pelvic floor muscle training during pregnancy and after childbirth on prevention and treatment of urinary incontinence: a systematic review, Database of Abstracts of Reviews of Effects, 299-310, 2014	Systematic review - included studies checked for relevance for this review
Morkved, S., Bo, K., The effect of postpartum pelvic floor muscle exercise in the prevention and treatment of urinary incontinence, International Urogynecology Journal, 8, 217-222, 1997	Over 20% of the population have PFD
Morkved, S., Bo, K., The effect of post-natal exercises to strengthen the pelvic floor muscles, Acta Obstetricia et Gynecologica Scandinavica, 75, 382-5, 1996	No relevant outcomes
Morkved, S., Bo, K., Effect of postpartum pelvic floor muscle training in prevention and treatment of urinary incontinence: a one-year follow up, BJOG: an international journal of obstetrics and gynaecology, 107, 1022-8, 2000	Over 20% of the population have PFD
Morkved, S., Bo, K., Schei, B., Salvesen, K. A., Pelvic floor muscle training during pregnancy to prevent urinary incontinence: A single-blind randomized controlled trial, Obstetrics and gynecology, 101, 313-319, 2003	Over 20% of the population have PFD
Oblasser, C., Christie, J., McCourt, C., Vaginal cones or balls to improve pelvic floor muscle performance and urinary continence in women post partum: A quantitative systematic review, Midwifery, 31, 1017-25, 2015	Systematic review - includes checked for relevance
Oblasser, C., McCourt, C., Hanzal, E., Christie, J., Vibrating vaginal balls to improve pelvic floor muscle performance in women after	Protocol

Study	Reason for exclusion
childbirth: a protocol for a randomised controlled feasibility trial, Journal of Advanced Nursing, 72, 900-914, 2016	
Park, S. H., Kang, C. B., Jang, S. Y., Kim, B. Y., Effect of kegel exercise to prevent urinary and fecal incontinence in antenatal and postnatal women: Systematic review, Journal of Korean Academy of Nursing, 43, 420-430, 2013	Language
Pereira-Baldon, V. S., Avila, M. A., Dalarmi, C. B., de Oliveira, A. B., Driusso, P., Effects of different regimens for pelvic floor muscle training in young continent women: Randomized controlled clinical trial, Journal of Electromyography & KinesiologyJ Electromyogr Kinesiol, 44, 31-35, 2019	No relevant outcomes
Reilly, E. T., Freeman, R. M., Waterfield, M. R., Waterfield, A. E., Steggles, P., Pedlar, F., Prevention of postpartum stress incontinence in primigravidae with increased bladder neck mobility: a randomised controlled trial of antenatal pelvic floor exercises, BJOG, 121 Suppl 7, 58-66, 2014	Duplication of the 2002 paper
Saboia, D. M., Bezerra, K. C., Vasconcelos Neto, J. A., Bezerra, Lrps Oria M. O. B., Vasconcelos, C. T. M., The effectiveness of post-partum interventions to prevent urinary incontinence: a systematic review, Revista Brasileira de EnfermagemRev Bras Enferm, 71, 1460-1468, 2018	Systematic review - included studies checked for relevance for this review
Sackley, C. M., Rodriguez, N. A., van den Berg, M., Badger, F., Wright, C., Besemer, J., van Reeuwijk, K. T., van Wely, L., A phase II exploratory cluster randomized controlled trial of a group mobility training and staff education intervention to promote urinary continence in UK care homes, Clinical rehabilitation, 22, 714-21, 2008	Over 20% of the population have PFD
Sampselle, C. M., Miller, J. M., Mims, B. L., Delancey, J. O., Ashton-Miller, J. A., Antonakos, C. L., Effect of pelvic muscle exercise on transient incontinence during pregnancy and after birth, Obstetrics and Gynecology, 91, 406-412, 1998	Outcome data not useable – raw data not reported
Sampselle, C. M., Behavioral interventions in young and middle-age women: simple interventions to combat a complex problem, The American journal of nursing, Suppl, 9-19, 2003	Review
Schreiner, L., Crivelatti, I., de Oliveira, J. M., Nygaard, C. C., dos Santos, T. G., Systematic review of pelvic floor interventions during pregnancy, International Journal of Gynecology and Obstetrics, 143, 10-18, 2018	Systematic review - included studies checked for relevance for this review
Soave, I., Scarani, S., Mallozzi, M., Nobili, F., Marci, R., Caserta, D., Pelvic floor muscle training for prevention and treatment of urinary incontinence during pregnancy and after childbirth and its effect on urinary system and supportive structures assessed by objective measurement techniques, Archives of Gynecology & ObstetricsArch Gynecol Obstet, 299, 609-623, 2019	Systematic review - included studies checked for relevance for this review
Sobhgol, S. S., Priddis, H., Smith, C. A., Dahlen, H. G., Evaluation of the effect of an antenatal pelvic floor muscle exercise programme on female sexual function during pregnancy and the first 3 months following birth: Study protocol for a pragmatic randomised controlled trial, Trials, 20 (1) (no pagination), 2019	Protocol - unable to find published study
Stafne, S. N., Salvesen, K. A., Romundstad, P. R., Torjusen, I. H., Morkved, S., Does regular exercise including pelvic floor muscle training prevent urinary and anal incontinence during pregnancy? A randomised controlled trial, BJOG: An International Journal of Obstetrics & Gynaecology, 119, 1270-80, 2012	Over 20% of the population have PFD
Sun, Z., Zhu, L., Lang, J., Zhang, Y., Liu, G., Chen, X., Feng, S., Zhang, J., Yao, Y., Zhang, J., al, et, Postpartum pelvic floor rehabilitation on prevention of female pelvic floor dysfunction: a	Language

Study	Reason for exclusion
multicenter prospective randomized controlled study, Zhonghua fu chan ke za zhi, 50, 420â427, 2015	
Szumilewicz, A., Dornowski, M., Piernicka, M., Worska, A., Kuchta, A., Kortas, J., Błudnicka, M., Radzimiński, Ł. and Jastrzębski, Z., High-low impact exercise program including pelvic floor muscle exercises improves pelvic floor muscle function in healthy pregnant women–a randomized control trial. Frontiers in physiology, 9, 1867. 2019	Duplicate
Szumilewicz, A., Dornowski, M., Piernicka, M., Worska, A., Kuchta, A., Kortas, J., Bludnicka, M., Radziminski, L., Jastrzebski, Z., High-Low Impact Exercise Program Including Pelvic Floor Muscle Exercises Improves Pelvic Floor Muscle Function in Healthy Pregnant Women - A Randomized Control Trial, Frontiers in Physiology, 9, 1867, 2018	Intervention more about exercise than PFM training
Szumilewicz, A., Hopkins, W. G., Dornowski, M., Piernicka, M., Exercise Professionals Improve Their Poor Skills in Contracting Pelvic-Floor Muscles: A Randomized Controlled Trial, Research Quarterly for Exercise & SportRes Q Exerc Sport, 90, 641-650, 2019	No relevant outcomes
Szumilewicz, A., Kuchta, A., Kranich, M., Dornowski, M., Jastrzebski, Z., Prenatal high-low impact exercise program supported by pelvic floor muscle education and training decreases the life impact of postnatal urinary incontinence: A quasiexperimental trial, Medicine, 99, e18874, 2020	Over 20% of the population have PFD
Tannenbaum, C., Agnew, R., Benedetti, A., Thomas, D., Van Den Heuvel, E., Effectiveness of continence promotion for older women via community organisations: A cluster randomised trial, BMJ open, 3 (12) (no pagination), 2013	All population have PFD
Thorp Jr, J. M., Stephenson, H., Jones, L. H., Cooper, G., Pelvic floor (Kegel) exercises - A pilot study in nulliparous women, International Urogynecology Journal, 5, 86-89, 1994	No relevant outcomes
Torelli, L., de Jarmy Di Bella, Z. I., Rodrigues, C. A., Stupp, L., Girao, M. J., Sartori, M. G., Effectiveness of adding voluntary pelvic floor muscle contraction to a Pilates exercise program: an assessor-masked randomized controlled trial, International Urogynecology Journal, 27, 1743-1752, 2016	No relevant outcomes
Van Kampen, M., Devoogdt, N., De Groef, A., Gielen, A., Geraerts, I., The efficacy of physiotherapy for the prevention and treatment of prenatal symptoms: a systematic review, International Urogynecology JournalInt Urogynecol J Pelvic Floor Dysfunct, 26, 1575-86, 2015	Systematic review - relevant includes checked for relevance
Villot, A., Deffieux, X., Billecocq, S., Auclair, L., Amarenco, G., Thubert, T., Influence of cognitive rehabilitation on pelvic floor muscle contraction: A randomized controlled trial, Neurourology & UrodynamicsNeurourol Urodyn, 36, 1636-1644, 2017	No relevant outcomes
Woodley, S. J., Boyle, R., Cody, J. D., Morkved, S., Hay-Smith, E. J. C., Pelvic floor muscle training for prevention and treatment of urinary and faecal incontinence in antenatal and postnatal women, Cochrane Database of Systematic Reviews, 2017	Systematic review - included studies checked for relevance for this review
Zhang, N., He, Y., Wang, J., Zhang, Y., Ding, J., Hua, K. Q., Effects of a new community-based reproductive health intervention on knowledge of and attitudes and behaviors toward stress urinary incontinence among young women in Shanghai: a cluster-randomized controlled trial, International Urogynecology Journal, 27, 545-553, 2016	No relevant outcomes

PFD: pelvic floor dysfunction; PFM: pelvic floor muscle

# **Economic studies**

No economic evidence was identified for this review.

# Appendix L - Research recommendations

Research recommendations for review question: What is the effectiveness of pelvic floor muscle training for preventing pelvic floor dysfunction?

#### Research recommendation 1:

# Research question

Is pelvic floor muscle training in children and young women effective in preventing pelvic floor dysfunction?

# Why this is important

Prevention is always better than cure, and it is important to know if teaching pelvic floor muscle training to children and young women will prevent the development of pelvic floor dysfunction in later life, thus reducing the possible long term implications of decreased quality of life and increased costs to the NHS. The <a href="NHS long term plan">NHS long term plan</a> published in 2019 sets out that 'We will improve access to postnatal physiotherapy to support women who need it to recover from birth' with the aim to prevent birth related symptoms of pelvic floor dysfunction. However, this is only related to childbirth and it is unclear whether a more general preventative strategy starting earlier in life would be a more effective approach to prevent symptoms of pelvic floor dysfunction later.

Table 29: Research recommendation rationale

Research question	Is pelvic floor muscle training in children and young women effective in preventing pelvic floor dysfunction?
Why is this needed	
Importance to 'patients' or the population	Pelvic floor muscle exercises are often suggested to women who have pelvic floor dysfunction with evidence of effectiveness. However, there is no evidence that teaching pelvic floor muscle training (PFMT) to children or young women will prevent symptoms arising later in life. It would however seem a reasonable hypothesis that if young girls are taught these exercises then the muscles will be stronger and more resilient. Without knowing if it does prevent symptom development in later life then advising uptake may not be the right thing to do. On the other hand, if it does reduce the development of pelvic floor dysfunction then it could be part of a national health campaign.
Relevance to NICE guidance	The relative absence of evidence regarding this topic currently restricts NICE guidance from making recommendations regarding the teaching of these exercises to young women. The outcome of this research would allow such recommendations to be developed and become part of the NICE guidance.
Relevance to the NHS	Pelvic floor muscle training is an intervention with relatively low cost and may reduce the need for interventions with higher cost impacts on the NHS, such as further assessment and treatment and surgical intervention
National priorities	One of the key national priorities in the NHS long term plan (2019) is the use of physiotherapy to prevent symptoms of pelvic floor dysfunction associated with childbirth.  Pelvic floor muscle training to prevent pelvic floor dysfunction is also a key recommendation, following the Independent Medicine and Medical Devices Safety Review (Cumberledge review) into mesh surgery in 2020.

Research question	Is pelvic floor muscle training in children and young women effective in preventing pelvic floor dysfunction?
Current evidence base	There is currently no evidence regarding when pelvic floor muscle training should be taught, at what time during someone's life span they should be undertaken, and who should teach them at the specified time to help prevent symptoms associated with pelvic floor dysfunction. There is also a lack of long term studies looking at adherence to pelvic floor muscle training regimes.
Equality	This may be more difficult for young women with disabilities who would find such training difficult. Considerations should be given to how groups with physical disabilities could strengthen these muscle groups and what types of training may be suitable for them depending on their individual abilities and preferences. Following instructions could be difficult for young women with learning or cognitive disabilities and efforts should be made to produce instruction material that is accessible to these groups.
Feasibility	This will present challenges as it will not be a simple single- change intervention, such as starting a medication. However there have been a number of studies looking at pelvic floor muscle training, but not many looking at pelvic floor muscle training in the prevention of symptoms pelvic floor dysfunction, when the optimum time is to start pelvic floor muscle training and who should be providing the training.
Other comments	The relative absence of evidence regarding this topic currently restricts NICE guidance from making recommendations regarding the most effective way of providing pelvic floor muscle training in the prevention of symptoms of pelvic floor dysfunction. The outcome of this research would allow such recommendations to be developed and become part of NICE guidance.

Table 30: Research recommendation modified PICO table

Table 50. Research recommendation modified 1 100 table	
Criterion	Explanation
Population	Young women over the age of 12 years
Intervention	Pelvic floor muscle training
Comparator	No pelvic floor muscle training
Outcomes	Pelvic floor dysfunction in later life  Quality of life
Study design	Longitudinal RCT
Timeframe	20 years
Additional information	Difficult as this would need to be a longitudinal study and women may come across the exercises at various other times in their lives.

RCT: randomised controlled trial

#### Research recommendation 2:

# Research question

Is pelvic floor muscle training in peri-, post-menopausal and elderly women effective in preventing pelvic floor dysfunction?

# Why this is important

Risk of pelvic floor dysfunction increases in older women around the time of menopause The NHS long term plan published in 2019 sets out that 'We will improve access to postnatal physiotherapy to support women who need it to recover from birth' with the aim to prevent birth related symptoms of pelvic floor dysfunction. However, this is only related to childbirth and it is unclear whether a preventative strategy starting later in life for women who do not have symptoms can effectively prevent symptoms of pelvic floor dysfunction later. It is important to develop strategies to prevent pelvic floor dysfunction and thus reducing the possible long term implications of decreased quality of life and increased costs to the NHS.

Table 31: Research recommendation rationale

Research question	Is pelvic floor muscle training in peri-, post-menopausal and elderly women effective in preventing pelvic floor dysfunction?
Why is this needed	
Importance to 'patients' or the population	Pelvic floor dysfunction increases with age and it is important to develop strategies to prevent it happening. PFMT may be such a strategy and if it works then quality of life in older age will be improved and NHS costs reduced.
Relevance to NICE guidance	The lack of evidence regarding this topic currently restricts NICE guidance from making recommendations regarding the teaching of these exercises to older women to prevent PFD. The outcome of this research would allow such recommendations to be developed and become part of NICE guidance.
Relevance to the NHS	Pelvic floor muscle training is an intervention with relatively low cost and may reduce the need for interventions with higher cost impacts on the NHS such as further assessment and treatment, provision of containment products and surgical intervention
National priorities	One of the key national priorities in the NHS long term plan (2019) is the use of physiotherapy to prevent symptoms of pelvic floor dysfunction associated with childbirth.  Pelvic floor muscle training to prevent pelvic floor dysfunction is also a key recommendation, following the Independent Medicine and Medical Devices Safety Review (Cumberledge review) into mesh surgery in 2020.
Current evidence base	There is currently no evidence regarding when pelvic floor muscle training should be taught, at what time during someone's life span they should be undertaken, and who should teach them at the specified time to help prevent symptoms associated with pelvic floor dysfunction. There is also a lack of long term studies looking at adherence to pelvic floor muscle training regimes.
Equality	This may be more difficult for young women with disabilities who would find such training difficult. Considerations should be given to how groups with physical disabilities could strengthen these muscle groups and what types of training may be suitable for them depending on their individual abilities and preferences. Following instructions could be difficult for young women with

Research question	Is pelvic floor muscle training in peri-, post-menopausal and elderly women effective in preventing pelvic floor dysfunction?
	learning or cognitive disabilities and efforts should be made to produce instruction material that is accessible to these groups.
Feasibility	This will present challenges as it will not be a simple single- change intervention, such as starting a medication. However, there have been a number of studies looking at pelvic floor muscle training, but only one looking at pelvic floor muscle training in the prevention of symptoms pelvic floor dysfunction in women who are in peri-menopause or post menopause.
Other comments	The relative absence of evidence regarding this topic currently restricts NICE guidance from making recommendations regarding providing PFMT to elderly women. The outcome of this research would allow such recommendations to be developed and become part of NICE guidance.

PFD: pelvic floor dysfunction

Table 32: Research recommendation modified PICO table

Criterion	Explanation
Population	Women who are peri- or post the menopause and over the age of 60 who do not have symptoms of pelvic floor dysfunction
Intervention	Pelvic floor muscle training
Comparator	No pelvic floor muscle training
Outcomes	<ul><li>Symptoms of pelvic floor dysfunction</li><li>Quality of life</li></ul>
Study design	Longitudinal RCT
Timeframe	5-10 years
Additional information	This may be difficult as some women may already know about pelvic floor muscle training, and others will receive information within the trial. However, it is an important question with consequences for this population such as maintaining general exercise tolerance and sociability if symptoms of pelvic floor dysfunction are reduced.

RCT: Randomised controlled trial

#### Research recommendation 3:

# Research question

What is the most effective way (what type, at what time, by whom) of providing pelvic floor muscle training to prevent symptoms associated with pelvic floor dysfunction and improve adherence?

# Why this is important

Pelvic floor exercises are an important part of the management of the prevention of symptoms of pelvic floor dysfunction; undertaking pelvic floor muscle training has been shown to significantly impact on an individual's health and improve symptoms of pelvic floor dysfunction. However, there are a number of issues related to pelvic floor muscle training in the prevention of pelvic floor dysfunction that are uncertain. The <a href="NHS">NHS</a> long term plan published in 2019 sets out that 'We will improve access to postnatal physiotherapy to support women who need it to recover from birth' with the aim to prevent birth related symptoms of pelvic floor dysfunction. However, currently there is little evidence of the details of pelvic floor muscle training (what specific type of training, when to start using it and who would best give instructions) that are effective in preventing the whole range of symptoms associated with pelvic floor dysfunction. For this reason, research on these specific details is required to allow recommendations for advice about the use of pelvic floor muscle training in the prevention of pelvic floor dysfunction to be developed.

Table 33: Research recommendation rationale

Research question	What is the most effective way (what type, at what time, by whom) of providing pelvic floor muscle training to prevent symptoms associated with pelvic floor dysfunction and improve adherence?
Why is this needed	
Importance to 'patients' or the population	Pelvic floor exercises are often suggested to women with pelvic floor dysfunction. However, there is very limited evidence to guide the most effective way of providing pelvic floor muscle training (PFMT) to prevent symptoms associated with pelvic floor dysfunction. Without this information, people may undertake pelvic floor muscle training no useful purpose for the management of pelvic floor dysfunction.
Relevance to NICE guidance	The relative absence of evidence regarding this topic currently restricts NICE guidance from making recommendations regarding the most effective way of providing pelvic floor muscle training in the prevention of symptoms of pelvic floor dysfunction. The outcome of this research would allow such recommendations to be developed and become part of NICE guidance.
Relevance to the NHS	Pelvic floor muscle training is an intervention with relatively low cost and may reduce the need for interventions with higher cost impacts on the NHS such as further assessment and treatment and surgical intervention
National priorities	One of the key national priorities in the NHS long term plan (2019) is the use of physiotherapy to prevent symptoms of pelvic floor dysfunction associated with childbirth.  Pelvic floor muscle training to prevent pelvic floor dysfunction is also a key recommendation, following the Independent Medicine and Medical Devices Safety Review (Cumberledge review) into mesh surgery in 2020.
Current evidence base	There is currently little evidence regarding what type of pelvic floor muscle training should be undertaken, how this should be

Research question	What is the most effective way (what type, at what time, by whom) of providing pelvic floor muscle training to prevent symptoms associated with pelvic floor dysfunction and improve adherence?
	delivered and who should teach them at the specified time to help prevent symptoms associated with pelvic floor dysfunction. There is also a lack of long term studies looking at adherence to pelvic floor muscle training regimes.
Equality	This may be more difficult for young women with disabilities who would find such training difficult. Considerations should be given to how groups with physical disabilities could strengthen these muscle groups and what types of training may be suitable for them depending on their individual abilities and preferences. Following instructions could be difficult for young women with learning or cognitive disabilities and efforts should be made to produce instruction material that is accessible to these groups.
Feasibility	This will present challenges as it will not be a simple single-change intervention, such as starting a medication. However there have been a number of studies looking at pelvic floor muscle training, but not many looking at pelvic floor muscle training in the prevention of symptoms pelvic floor dysfunction, when the optimum time is to start pelvic floor muscle training and who should be providing the training.
Other comments	Not applicable

PFMT: pelvic floor muscle training

Table 34: Research recommendation modified PICO table

Criterion	Explanation
Population	Women over 12 years of age with no pre-existing pelvic floor dysfunction capable of understanding and responding to pelvic floor muscle training
	Including younger participants
	<ul> <li>The included population must be strongly encouraged to adhere to the intervention</li> </ul>
	<ul> <li>Identifying any psychological predictors of who can engage with the intervention</li> </ul>
Intervention	Different Pelvic floor muscle training regimens given by different professionals in different ways (providing leaflets, group education and physical instruction), for example Advice on how to do pelvic floor muscle exercises PFMT provided by a qualified professional such as physiotherapists, nurse specialists, midwives, school nurses, practice nurses.
Comparator	Usual care
Outcomes	<ul> <li>Change in pelvic floor strength.</li> <li>Validated assessments of pelvic floor dysfunction symptoms (such as urinary incontinence, pelvic organ prolapse, sexual dysfunction, faecal incontinence).</li> <li>Adherence to training schedule</li> <li>Long term and short term adherence data- presence and</li> </ul>
	severity of symptoms over time.
Study design	Multi-arm controlled RCT  Or  Prospective case controlled separt, with matched participants
	Prospective case-controlled cohort, with matched participants

Criterion	Explanation
Timeframe	Intermediate points would allow determination of the likely length of intervention before an improvement is achieved. It may also offset some of the dropout in the long-term.
Additional information	It would be useful to compare the results of this study with previous studies looking at adherence and PFMT interventions. This would show synergies between the existing advice and any new advice to help answer the question in the guideline.

PFMT: pelvic floor muscle training; RCT – randomised controlled trial

#### Research recommendation 4:

# Research question

Is prescribed universal postnatal physiotherapy for pelvic floor muscle training (as is provided in the French healthcare system) effective in preventing symptoms of pelvic floor dysfunction?

#### Why this is important

One in 3 women suffer with incontinence, and 1 in 5 pelvic organ prolapse. Pregnancy and birth are key risk factors for injury and weakness to the pelvic floor. In addition, if you have symptoms of pelvic floor dysfunction in pregnancy then one is more likely in later life to suffer with symptoms of pelvic floor dysfunction, reducing a person's quality of life. This may also lead to a significant impact on costs to the healthcare system, if medication, surgery, medical devices, or pads are needed to be provided. If there is an opportunity to provide preventive care for women post birth, which reduces the impact of the incidence of pelvic floor dysfunction this would have significant benefits to the healthcare system, and improve the quality of life of women.

The NHS long term plan published in 2019 sets out that 'We will improve access to postnatal physiotherapy to support women who need it to recover from birth' with the aim to prevent birth related symptoms of pelvic floor dysfunction. The severe adverse effects of mesh surgery for pelvic organ prolapse led to an Independent Medicine and Medical Devices Safety Review (Cumberledge review) in 2020. One of their recommendations was 'that the NHS adopts the French model for universal post-natal pelvic floor rehabilitation'. The committee concluded that currently there are still uncertainties and further research in the postnatal period needs to establish the details of what types of pelvic floor muscle training should be provided and how to prevent these symptoms occurring later on in life.

Table 35: Research recommendation rationale

Research question	Is prescribed universal postnatal physiotherapy for pelvic floor muscle training (as is provided in the French healthcare system) effective in preventing symptoms of pelvic floor dysfunction?
Why is this needed	
Importance to 'patients' or the population	There is a lack of evidence demonstrating that preventive treatment is effective in reducing the incidence of pelvic floor dysfunction. In the UK the estimated prevalence of urinary incontinence in women is 1 in 3. However, in France, the incidence in 1 in 4. In France all women are provided with a treatment programme of supervised pelvic floor training postnatally provided by physiotherapists. However, there is a lack of evidence to what specific treatment is needed, and how much treatment, and where this is the causative reason for the reduction in pelvic floor dysfunction in this population. Without this information care may be provided which is not beneficial on reducing the overall population incidence of pelvic floor dysfunction in the UK.
Relevance to NICE guidance	The limited evidence regarding this topic currently restricts NICE guidance from making supervised pelvic floor exercise training mandatory for all women in the postnatal period. The outcome of this research would support such recommendations to be delivered in the future.
Relevance to the NHS	Providing all women with supervised pelvic floor exercise training of approx. 10 appointments, as per the French model of care, would be a significant increase in cost to the NHS. However, if effective

Research question	Is prescribed universal postnatal physiotherapy for pelvic floor muscle training (as is provided in the French healthcare system) effective in preventing symptoms of pelvic floor dysfunction?
	this may have a larger cost saving by reducing the need for other interventions, such as pads, medication and surgery.
National priorities	One of the key national priorities in the <a href="NHS long term plan">NHS long term plan</a> (2019) is the use of physiotherapy to prevent symptoms of pelvic floor dysfunction associated with childbirth.  Pelvic floor muscle training to prevent pelvic floor dysfunction is also a key recommendation, following the <a href="Independent Medicine">Independent Medicine</a> and <a href="Medical Devices Safety Review">Medicine</a> and <a href="Medical Devices Safety Review">Medicine</a> (Cumberledge review) into mesh surgery in 2020.
Current evidence base	There is current evidence showing that supervised pelvic floor exercises can prevent pelvic floor dysfunction. In particular, urinary incontinence, pelvic organ prolapse and sexual dysfunction. However, the amount of care that is needed to be provided in the postnatal period is not clear, or what particular interventions are most effective.
Equality	This may be more difficult for young women with disabilities who would find such training difficult. Considerations should be given to how groups with physical disabilities could strengthen these muscle groups and what types of training may be suitable for them depending on their individual abilities and preferences. Following instructions could be difficult for young women with learning or cognitive disabilities and efforts should be made to produce instruction material that is accessible to these groups.
Feasibility	It would be simple to provide women with 10 supervised pelvic floor exercise training sessions by a physiotherapist post birth. The challenges would be in collecting high quality data. It would not be possible to blind women to the intervention, and costly to review the data over a long period of time, with further challenges in ensuring women are not lost to follow up.
Other comments	Not applicable

Table 36: Research recommendation modified PICO table

able 30. Research recommendation modified 1100 table	
Criterion	Explanation
Population	Postnatal women including all modes of delivery.
Intervention	The model used in France: All new mothers receive a full abdominal check- up 6 weeks after giving birth followed by a postnatal rehab programme. As part of this standard check a 12-week postnatal rehabilitation programme is provided where women are given exercises and advice on how to correct their posture and strengthen their abdominal and pelvic area. During the recovery process, some women are also given vaginal electrical stimulation and bio feedback via vaginal probes such as Kegel 8 to rehabilitate the pelvic floor area and strengthen it after the trauma of pregnancy and giving birth.
Comparator	<ul> <li>Usual care, i.e. provide training as part of management rather than prevention</li> <li>Written instructions</li> <li>Group education in pelvic floor muscle training</li> </ul>
Outcomes	Symptoms of pelvic floor dysfunction
Study design	Multi arm RCT
Timeframe	Long term intervention with intermediate points every 10 years.
Additional information	Not applicable

RCT – randomised controlled trial

#### Research recommendation 5:

# Research question

What is the effectiveness of pelvic floor muscle training in the prevention of bowel symptoms associated with pelvic floor dysfunction?

## Why this is important

Pelvic floor muscle training is an important part of management of pelvic floor dysfunction; it has been shown that introduction of such training can be used to prevent urinary incontinence in women. The <a href="NHS long term plan">NHS long term plan</a> published in 2019 focuses on introducing pelvic floor physiotherapy to prevent any symptoms associated with pelvic floor dysfunction in the post-natal period. However, the role of pelvic floor muscle training in prevention of bowel symptoms associated with pelvic floor dysfunction, such as faecal/ flatal incontinence and urgency, is not known (no studies were identified in the systematic review). Such symptoms are very distressing and have an adverse effect on the women's confidence and her social life. The hypothesis is that strengthening muscles in the pelvic floor will not only support the bladder but also the bowel and therefore could be an effective way of preventing these symptoms and the burden associated with them. For these reasons, research on the topic is required, to allow recommendations for advice about pelvic floor muscle training in the prevention of bowel symptoms of pelvic floor dysfunction.

Table 37: Research recommendation rationale

Research question	What is the effectiveness of pelvic floor muscle training in the prevention of bowel symptoms associated with pelvic floor dysfunction?
Why is this needed	
Importance to 'patients' or the population	PFMT is often recommended as prevention for PFD due to its potential benefits in prevention of urinary incontinence. However, it unclear as to whether PFMT serves as an effective intervention in the prevention of bowel symptoms associated with PFD. Without this information people may adopt PFMT without full understanding of its value in preventing bowel symptoms.
Relevance to NICE guidance	Absence of information restricts the guideline from making recommendations regarding PFMT in the prevention of bowel symptoms related to PFD. The outcome of this research would allow recommendations to be developed as part of the guideline.
Relevance to the NHS	PFMT is a relatively low cost intervention. If successful in preventing bowel symptoms associated with PFD it may reduce the need for higher cost treatments. In addition, prevention may reduce the number of patients presenting with bowel symptoms and therefore reduce demand on services.
National priorities	One of the key national priorities in the NHS long term plan (2019) is the use of physiotherapy to prevent symptoms of pelvic floor dysfunction associated with childbirth.  Pelvic floor muscle training to prevent pelvic floor dysfunction is also a key recommendation, following the Independent Medicine and Medical Devices Safety Review (Cumberledge review) into mesh surgery in 2020.

Research question	What is the effectiveness of pelvic floor muscle training in the prevention of bowel symptoms associated with pelvic floor dysfunction?
Current evidence base	There is some evidence to suggest that PFMT may be effective in preventing urinary incontinence but very limited evidence regarding prevention of bowel symptoms.
Equality	This may be more difficult for young women with disabilities who would find such training difficult. Considerations should be given to how groups with physical disabilities could strengthen these muscle groups and what types of training may be suitable for them depending on their individual abilities and preferences. Following instructions could be difficult for young women with learning or cognitive disabilities and efforts should be made to produce instruction material that is accessible to these groups.
Feasibility	This study may present challenges as outcomes depend on participants complying with a PFMT programme. Similar long term studies have also highlighted potential difficulties with retention of participants. However, there have been numerous studies looking at PFMT and symptoms of PFD.
Other comments	None.

PFD - pelvic floor dysfunction; PFMT - pelvic floor muscle training

Table 38: Research recommendation modified PICO table

Criterion	Explanation
Population	<ul> <li>Women aged over age 12 without pre-existing bowel symptoms, capable of understanding and responding to PFMT programme.</li> <li>Including younger participants</li> <li>Included population must be able to adhere to the intervention</li> <li>Identifying any psychological predictors of who can engage with the intervention</li> </ul>
Intervention	<ul> <li>Initial teaching of PFMT including frequency and correct technique by a competent professional.</li> <li>A long term self-led PFMT programme i.e. after teaching participants would be expected to continue the initial teaching sessions.</li> </ul>
Comparator	Usual care.
Outcomes	Presence and severity of bowel symptoms over time (as measured by a validated tool).
Study design	Longitudinal RCT
Timeframe	5-10 years; would need to be long term to determine presence of symptoms.
Additional information	None

PFMT – pelvic floor muscle training; RCT: Randomised controlled trial

#### Research recommendation 6:

## Research question

What is the effectiveness of pelvic floor muscle training in the prevention of pelvic floor dysfunction during pregnancy in women who are in higher risk groups (some of those identified in evidence reviews related to obstetric and non-obstetric risk factors for pelvic floor dysfunction)?

# Why this is important

Pelvic floor muscle training is routinely recommended as part of standard antenatal care. Evidence suggests that pelvic floor muscle training could be helpful for pregnant women in preventing later symptoms of pelvic floor dysfunction such as stress incontinence. Currently there is little evidence to suggest whether pelvic floor muscle training has equal benefit for women already at higher risk of pelvic floor dysfunction. Women identified at higher risk of pelvic floor dysfunction include the following:

- BMI >30
- age over 30 years old
- multiparous (has given birth before)
- family history of urinary incontinence, overactive bladder or faecal incontinence

As these women are already at higher risk is would be important to determine whether pelvic floor muscle training is a useful intervention for them in preventing pelvic floor dysfunction. For these reasons, research on this topic is required, to allow recommendations about pelvic floor muscle training for women at higher risk to be developed.

Table 39: Research recommendation rationale

Research question	What is the effectiveness of pelvic floor muscle training in the prevention of pelvic floor dysfunction during pregnancy in women who are in higher risk groups (those identified in evidence reviews related to obstetric and non-obstetric risk factors for pelvic floor dysfunction)?
Why is this needed	
Importance to 'patients' or the population	PFMT is often recommended to pregnant women as part of standard antenatal care. However, there is limited evidence around its effectiveness in prevention of symptoms for women already at higher risk of PFD. Without this information women at higher risk of PFD may adopt PFMT without a complete understanding of its benefit in preventing PFD.
Relevance to NICE guidance	The absence of information around using PFMT as prevention for pregnant women at higher risk of PFD, restricts the guidelines from making recommendations for this group. Carrying out this research would allow recommendations to be developed as part of the guideline.
Relevance to the NHS	PFMT is a relatively low cost intervention. If successful in preventing PFD in women at higher risk it may reduce the need for higher cost treatments. In addition, prevention may reduce the number of patients presenting with bowel symptoms and therefore reduce demand on services.
National priorities	One of the key national priorities in the NHS long term plan (2019) is the use of physiotherapy to prevent symptoms of pelvic floor dysfunction associated with childbirth.  Pelvic floor muscle training to prevent pelvic floor dysfunction is also a key recommendation, following the Independent

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	Medicine and Medical Devices Safety Review (Cumberledge review) into mesh surgery in 2020.
Current evidence base	There is currently evidence to suggest that PFMT during pregnancy may prevent urinary stress incontinence and improve sexual function. However, there is an absence of evidence regarding the effect of PFMT during pregnancy in preventing PFD in higher risk groups.
Equality	This may be more difficult for young women with disabilities who would find such training difficult. Considerations should be given to how groups with physical disabilities could strengthen these muscle groups and what types of training may be suitable for them depending on their individual abilities and preferences. Following instructions could be difficult for young women with learning or cognitive disabilities and efforts should be made to produce instruction material that is accessible to these groups.
Feasibility	This study may present challenges as outcomes depend on participants complying with a PFMT programme. Similar studies have also highlighted potential difficulties with retention of participants. However, there have been numerous studies looking at PFMT in pregnancy and symptoms of PFD.
Other comments	None

PFD – pelvic floor dysfunction; PFMT – pelvic floor muscle training

Table 40: Research recommendation modified PICO table

Criterion	Explanation
Population	Women (aged 12 years old or over) without symptoms of pelvic floor dysfunction who have one or more of the following risk factors:  • BMI >30  • Age over 30 years old
	<ul> <li>Multiparous (has given birth before)</li> <li>Family history of urinary incontinence, overactive bladder or faecal incontinence</li> </ul>
	<ul> <li>Must be capable of understanding and responding to PFMT programme.</li> </ul>
	<ul> <li>Including younger participants</li> <li>Included population must be able to adhere to the intervention</li> <li>Identifying any psychological predictors of who can engage with the intervention</li> </ul>
Intervention	<ul> <li>Initial teaching on PFMT including frequency and correct technique by a competent professional during the first trimester</li> <li>A self-led PFMT programme throughout the rest of i.e. after teaching, participants would be expected to continue the intervention.</li> </ul>
Comparator	Usual care/ no intervention.
Outcomes	Presence and severity of symptoms of PFD throughout the rest of pregnancy and in the postnatal period.
Study design	Longitudinal Randomised controlled trial (RCT).
Timeframe	2-5 years following birth.
Additional information	None

PFD – pelvic floor dysfunction; PFMT – pelvic floor muscle training; RCT: Randomised controlled trial