

Pelvic floor dysfunction: prevention and non- surgical management

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

NICE guideline number tbc

Evidence review underpinning recommendations 1.3.8 to 1.3.15 and 6 research recommendations (of which 3 were prioritised as key recommendations 2, 3 and 6) in the NICE guideline

Evidence reviews

June 2021

Draft for consultation

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

Disclaimer

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or service users. The recommendations in this guideline are not mandatory and the guideline does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

Local commissioners and/or providers have a responsibility to enable the guideline to be applied when individual health professionals and their patients or service users wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with compliance with those duties.

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the [Welsh Government](#), [Scottish Government](#), and [Northern Ireland Executive](#). All NICE guidance is subject to regular review and may be updated or withdrawn.

Copyright

© NICE 2021. All rights reserved. Subject to [Notice of rights](#).

ISBN:

Contents

Contents	4
Pelvic floor muscle training for the prevention of pelvic floor dysfunction	6
Review question	6
Introduction	6
Summary of the protocol	6
Methods and process	7
Clinical evidence	7
Summary of studies included in the evidence review.....	7
Quality assessment of studies included in the evidence review	13
Economic evidence	13
Economic model.....	13
Brief summary of the evidence	15
The committee’s discussion of the evidence.....	17
Recommendations supported by this evidence review	21
References	22
Appendices	25
Appendix A – Review protocol.....	25
Review protocol for review question: What is the effectiveness of pelvic floor muscle training for preventing pelvic floor dysfunction?.....	25
Appendix B – Literature search strategies	34
Literature search strategies for review question: What is the effectiveness of pelvic floor muscle training for preventing pelvic floor dysfunction?.....	34
Appendix C – Clinical evidence study selection	42
Study selection for: What is the effectiveness of pelvic floor muscle training for preventing pelvic floor dysfunction?	42
Appendix D –Evidence tables.....	43
Evidence tables for review question: What is the effectiveness of pelvic floor muscle training for preventing pelvic floor dysfunction?.....	43
Appendix E – Forest plots.....	83
Forest plots for review question: What is the effectiveness of pelvic floor muscle training for preventing pelvic floor dysfunction?.....	83
Appendix F – GRADE tables	84
GRADE tables for review question: What is the effectiveness of pelvic floor muscle training for preventing pelvic floor dysfunction?.....	84
Appendix G – Economic evidence study selection.....	94
Economic evidence study selection for review question: What is the effectiveness of pelvic floor muscle training for preventing pelvic floor dysfunction?.....	94
Appendix H – Economic evidence tables.....	95
Economic evidence tables for review question: What is the effectiveness of pelvic floor muscle training for preventing pelvic floor dysfunction?.....	95

Appendix I – Economic evidence profiles	96
Economic evidence profiles for review question: What is the effectiveness of pelvic floor muscle training for preventing pelvic floor dysfunction?	96
Appendix J – Economic analysis	98
Economic evidence analysis for review question: What is the effectiveness of pelvic floor muscle training for preventing pelvic floor dysfunction?	98
Cost-utility analysis of supervised pelvic floor muscle training provided antenatally to prevent pelvic floor dysfunction	98
Appendix K – Excluded studies	127
Excluded studies for review question: What is the effectiveness of pelvic floor muscle training for preventing pelvic floor dysfunction?	127
Appendix L – Research recommendations	133
Research recommendations for review question: What is the effectiveness of pelvic floor muscle training for preventing pelvic floor dysfunction?	133

1 Pelvic floor muscle training for the 2 prevention of pelvic floor dysfunction

3 Review question

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

6 Introduction

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

16 Summary of the protocol

17 See Table 1 for a summary of the Population, Intervention, Comparison and Outcome
18 (PICO) characteristics of this review.

19 **Table 1: Summary of the protocol (PICO table)**

Population	Women and young women (aged 12 years and older) without symptoms of pelvic floor dysfunction
Intervention	<ul style="list-style-type: none">• Pelvic floor muscle exercises / Kegel exercise, to include:<ul style="list-style-type: none">○ 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
Comparison	<ul style="list-style-type: none">• No treatment• Other preventive measures (for example leaflets, weight loss advice)• Alternative method of PFMT delivery (app vs face to face, group vs individual)• Combination therapies (PFMT alone or in combination)
Outcome	<p>Critical</p> <ul style="list-style-type: none">• Development of the following symptoms, associated with pelvic floor dysfunction:<ul style="list-style-type: none">○ urinary incontinence○ emptying disorders of the bladder○ faecal incontinence○ emptying disorders of the bowel○ pelvic organ prolapse○ sexual dysfunction○ chronic pelvic pain syndromes <p>For the above outcomes, only validated tools will be included</p> <p>Important</p> <ul style="list-style-type: none">• Adherence to PFMT

20 *PFMT: pelvic floor muscle training*

1 For further details see the review protocol in appendix A.

2 **Methods and process**

3 This evidence review was developed using the methods and process described in
4 [Developing NICE guidelines: the manual](#). Methods specific to this review question are
5 described in the review protocol in appendix A and the methods document (supplementary
6 document 1).

7 Declarations of interest were recorded according to [NICE's conflicts of interest policy](#).

8 **Clinical evidence**

9 **Included studies**

10 Fifteen studies from 18 citations were included for this review, 14 randomised controlled trials
11 (RCTs) from 17 citations (Agur 2008 & Reilly 2002, Berzuk 2015, Chiarelli 2002 & 2004,
12 Citak 2010, Golmakani 2015, Kahyaoglu 2016, Lin 2020, Pelaez 2014, Pourkhiz 2017, Qi
13 2019, Sacomori 2019, Sampselles 2005 & Diokno 2004, Sangsawang 2016, Yang 2017) and
14 1 quasi-randomised controlled trial (Kocaoz 2013).

15 The included studies are summarised in Table 2.

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

22 One study investigated pelvic floor muscle training (PFMT) for preventing symptoms of pelvic
23 floor disorder (Berzuk 2015); 5 studies for stress urinary incontinence (Agur 2008 & Reilly
24 2002, Kocaoz 2013, Lin, 2020, Qi 2019 and Sangsawang 2016); 6 studies for urinary
25 incontinence (Chiarelli 2002 & 2004, Kahyaoglu 2016, Pelaez 2014, Sacomori 2019,
26 Sampselles 2005 & Diokno 2004 and Yang 2017); 1 study for pelvic organ prolapse (Yang
27 2017); and 3 studies for sexual dysfunction (Citak 2010, Golmakani 2015 and Pourkhiz
28 2017).

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

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

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

35 **Excluded studies**

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

38 **Summary of studies included in the evidence review**

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

1 **Table 2: Summary of included studies.**

Study	Population	Intervention ¹	Comparison	Outcomes 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)	<u>Intervention</u> Women received supervised PFMT from a physiotherapist from 20 weeks to birth 8 year follow-up from Reilly n=79	<u>Control</u> Usual postpartum care n=85	<ul style="list-style-type: none"> • SUI at 8 years • Adherence to PFMT at 8 years
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	<u>Intervention A</u> 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 <u>Intervention B</u> 60-min presentation only n=55	<u>Control</u> No educational presentation n=52	<ul style="list-style-type: none"> • PFD symptoms at 2 months • PFD QoL at 2 months • Note: adherence to education intervention was not reported
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)	<u>Intervention</u> 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	<u>Control</u> Usual postpartum care n=350	<ul style="list-style-type: none"> • UI at 3 months postpartum • Severe UI symptoms at 3 months postpartum • Adherence to PFMT at 3 months

Study	Population	Intervention ¹	Comparison	Outcomes 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)	<u>Intervention</u> 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	<u>Control</u> Usual postpartum care n=275	<ul style="list-style-type: none"> • UI at 12 months postpartum • Adherence to PFMT at 12 months
Citak 2010 RCT Turkey	N=118, primiparous women who delivered vaginally 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)	<u>Intervention</u> Women were instructed in PFM 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	<u>Control</u> Usual postpartum care n=60	<ul style="list-style-type: none"> • FSFI at 4 months • FSFI at 7 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 USA	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	<u>Intervention</u> Women attended a 2 hour education session on PFMT, including instructions and practice in locating and exercising the PFM, prescription for PFMT and strategies on how to include PFMT in everyday life n=238	<u>Control</u> No education n=242	<ul style="list-style-type: none"> • UI at 12 months
Golmakani 2015 RCT Iran	N=104, nulliparous women 8 weeks after vaginal delivery N=79 included for analysis Age (years), mean (SD): Intervention 25.19	<u>Intervention</u> Supervised PFM and Kegel exercises, following a PFM exercise plan n=52	<u>Control</u> Usual postpartum care n=52	<ul style="list-style-type: none"> • Bailes sexual self-efficacy questionnaire after 4 weeks of training • Bailes sexual self-efficacy questionnaire after 8 weeks of training

Study	Population	Intervention ¹	Comparison	Outcomes 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 rd trimester of pregnancy)	<u>Intervention</u> Women were taught how to perform Kegel exercises and given an exercise plan to follow n=32	<u>Control</u> Usual postpartum care n=32	<ul style="list-style-type: none"> • UDI-6 at 36-38 weeks gestation • IIQ-7 at 36-38 weeks gestation • OAB-q total score at 36-38 weeks gestation • UDI-6 at 6-8 weeks postpartum • IIQ-7 at 6-8 weeks postpartum • OAB-q total score at 6-8 weeks postpartum
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)	<u>Intervention</u> Women were given training and information about their PFMs and an exercise programme to follow n=68	<u>Control</u> Usual postpartum care n=68	<ul style="list-style-type: none"> • SUI (via pad test) at 28 weeks gestation • SUI (via pad test) at 32 weeks gestation • SUI (via pad test) at 12 weeks postpartum
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	<u>Intervention</u> A PFMT programme including Kegel exercises for 6-8 weeks, biofeedback and electrical stimulation for 6 months, and vaginal cone training. n=49	<u>Control</u> Usual postpartum rehabilitation nursing n=48	<ul style="list-style-type: none"> • SUI incidence at 6 months • ICIQ-SF score at 6 months • I-QOL score at 6 months

Study	Population	Intervention ¹	Comparison	Outcomes and follow-up
	(postpartum, puerperae women)			
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)	<u>Intervention</u> 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	<u>Control</u> Usual antenatal care n=96	<ul style="list-style-type: none"> • ICIQ-Score at 36-40 weeks gestation • Adherence to PFMT
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)	<u>Intervention</u> Women were given a PFM exercise programme to follow n=42	<u>Control</u> Usual postpartum care n=42	<ul style="list-style-type: none"> • FSFI at 28-30 weeks gestation • SQOL-F at 28-30 weeks gestation • FSFI at 3 months postpartum • SQOL-F at 3 months postpartum • Adherence to PFMT
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)	<u>Intervention</u> Women were given educational materials at discharge and a 6 week exercise programme to follow from weeks 2 to 8 postpartum n=120	<u>Control</u> Usual postpartum care, which included information about PFMT n=120	<ul style="list-style-type: none"> • SUI at 8 weeks postpartum
Reilly 2002 RCT UK	N=268, primigravidae women N=230 included for analysis Age (years), median (range): Intervention 27	<u>Intervention</u> Women received supervised PFMT from a physiotherapist from 20 weeks to birth n=139	<u>Control</u> Usual postpartum care n=129	<ul style="list-style-type: none"> • SUI at 3 months postpartum • Pad test at 3 months postpartum • Adherence to PFMT from 20 weeks to birth

Study	Population	Intervention ¹	Comparison	Outcomes 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)	<u>Intervention</u> 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	<u>Control</u> Usual postpartum care n=104	<ul style="list-style-type: none"> • ICIQ at 3 months postpartum • Adherence to PFMT over 3 months
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	<u>Intervention</u> 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	<u>Control</u> No education n=242	<ul style="list-style-type: none"> • Voiding frequency (reported in a way that data could not be extracted) • Adherence to PFMT at 3 months • Adherence to PFMT at 6 months • Adherence to PFMT at 9 months • Adherence to PFMT at 12 months
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)	<u>Intervention</u> Women completed a 6 week PFMT program n=35	<u>Control</u> Usual postpartum care n=35	<ul style="list-style-type: none"> • SUI at 38 weeks gestation • Adherence to PFMT
Yang 2017 RCT	N=240, primiparas with singleton pregnancy	<u>Intervention</u> Women were given a PFMT programme to complete from day 2	<u>Control</u> Usual postpartum care	<ul style="list-style-type: none"> • POP-Q at 3 months • UI at 3 months

Study	Population	Intervention ¹	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 style="list-style-type: none"> • Pad test at 3 months •

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

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

10 Quality assessment of studies included in the evidence review

11 See the evidence profiles in appendix F.

12 Economic evidence

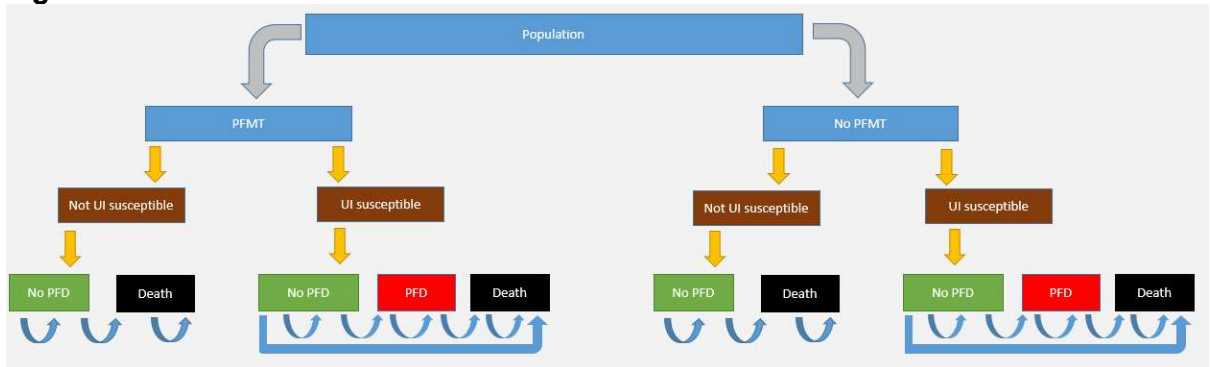
13 Included studies

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

16 Economic model

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

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

Figure 1: Schematic of Markov decision model

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

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

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

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

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

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

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

1 **Brief summary of the evidence**

2 ***Community: Postmenopausal women over 55yrs***

3 **Urinary incontinence**

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

6 ***Community: Mixed age group***

7 **Pelvic floor dysfunction**

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

11 ***Obstetric setting (antenatally or postnatally)***

12 **Urinary incontinence**

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

24 **Stress Urinary incontinence**

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

40 **Pelvic organ prolapse**

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

1 Sexual dysfunction

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

10 Adherence

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

13 **Table 3: Adherence to pelvic floor muscle training**

Study	Participants	Recruited	Adherence	Follow up
Postmenopausal women over 55 years recruited in the community				
Sampselle 2005	Intervention: n=164	In the community	Low: 1 time per week: 18%	3 months
			Medium: 2-3 times per week: 17%	
			High: at least once a day: 65%	6 months
			Low: 1 time per week: 25%	
Medium: 2-3 times per week: 24%	9 months			
High: at least once a day: 51%				
Low: 1 time per week: 37%	12 months			
Medium: 2-3 times per week: 18%				
High: at least once a day: 45%				
Low: 1 time per week: 32%				
Medium: 2-3 times per week: 32%				
High: at least once a day: 36%				
Women recruited 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%	20 weeks gestation to delivery
			<28 days of exercise: 10.8%	
	Intervention at 8 year follow-up: n=79		28+ days of exercises: 45.8%	
			Still performed PFMT: 68.4%	8 years
			Of those who were still performing PFMT, those who	

Study	Participants	Recruited	Adherence	Follow up
			were doing their PFMT exercises twice or more per week: 38%	
Chiarelli 2002 & 2004 (also see appendix F)	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
	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% <u>PFM exercises performed:</u> 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%	2months
			Doing PFME: 31.3	3 months
			Frequency of PFME: 1-2 times a week: 32.3% 3-7 times a week: 49.3%	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

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

2 The committee's discussion of the evidence

3 Interpreting the evidence

4 The outcomes that matter most

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

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

5 ***The quality of the evidence***

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

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

13 ***Benefits and harms***

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

16 **All women**

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

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

35 **Pregnant women**

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

1 is lying face up (occipito-posterior) or an anal sphincter injury would also benefit from such a
2 programme. They acknowledged that these were shown to be strong risk factors in evidence
3 report B. The committee also discussed when in the antenatal period PFMT information
4 should be provided. Since most of the included studies started their PFMT intervention in the
5 second trimester and these were effective at preventing PFD, week 20 (the central point of
6 the second trimester) was recommended as an appropriate time to educate women on
7 starting PFMT. The committee discussed that in their experience the most effective time to
8 provide information about pelvic floor muscle training and its effect on symptoms is the
9 antenatal period. The committee discussed that in their experience, contraction of the correct
10 muscles of the pelvic floor is more likely to be achieved in the antenatal period, due to the
11 effect advanced pregnancy and child-birth may have on the pelvic floor.

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

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

28 **Supervising pelvic floor muscle training**

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

37 **Research recommendations**

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

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

- 45 • Most effective ways to provide training: the studies did not give much detail on how
46 training should be conducted.
- 47 • Younger women: there was no evidence on training for young women (between 12 and 17
48 years).
- 49 • Older women: there was only one study supporting training for women over 60.

- 1 • Women who are at particular risk of pelvic floor dysfunction: there was little evidence
2 specific to women with particular risk factors (such as those identified in box 1 in the
3 guideline).
- 4 • Faecal incontinence and emptying disorders of the bowel: there was no evidence on
5 whether pelvic floor muscle training improves these symptoms (which can be particularly
6 distressing).
- 7 • The [Independent Medicine and Medical Devices Safety Review](#) recommended 'that the
8 NHS adopts the French model for universal postnatal pelvic floor rehabilitation', to help
9 prevent pelvic floor dysfunction. The committee did not think the evidence (in particular
10 the cost-effectiveness evidence) was strong enough to support this, but rather
11 recommended this for pregnant women with risk factor and also made a research
12 recommendation to investigate further.

13 **Cost effectiveness and resource use**

14 Original economic analysis undertaken for this guideline, for a population of women in their
15 first pregnancy, suggested that preventative supervised pelvic floor muscle training,
16 undertaken at monthly intervals (with instructions to do the exercise twice daily), from week
17 20 of pregnancy would be cost-effective providing the underlying population risk of urinary
18 incontinence was greater than 30%.

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

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

29 Therefore, given the strength of the economic evidence the committee made a
30 recommendation to offer supervised pelvic floor muscle training to pregnant women from
31 week 20 of pregnancy, reflecting the model population in the economic analysis. However,
32 they additionally stipulated that this recommendation should apply to women who have a
33 first-degree relative with pelvic floor dysfunction. This reflected the model finding that the
34 cost-effectiveness of preventative pelvic floor muscle training depended on the underlying
35 population risk of urinary incontinence. The model utilised the UR-CHOICE online risk
36 calculator and prediction model (Jelovsek 2018), which was developed to predict the risk of
37 pelvic floor disorders (focusing on urinary incontinence) based on known antenatal and mode
38 of birth variables. The UR-CHOICE prediction model suggested that family history of pelvic
39 organ prolapse and urinary incontinence were important predictors for increased risk of
40 pelvic floor dysfunction and this tallied with the committee's own expertise and experience.
41 Whilst the model gives a guide to the urinary incontinence risk threshold at which
42 preventative PFMT becomes cost-effective there is uncertainty as to a precise cut-off. Table
43 27 illustrates that there are women who would have a relatively low risk of urinary
44 incontinence in the absence of either a family history of pelvic organ prolapse or urinary
45 incontinence. Therefore, the committee considered the evidence for the cost-effectiveness of
46 preventative PFMT was stronger for women with a first-degree relative of pelvic floor
47 dysfunction.

48 The committee also recommended that supervised pelvic floor muscle training should be
49 offered to women in the postnatal period if they developed pelvic floor dysfunction risk factors
50 during labour. Whilst this was not the population directly addressed by the model, the
51 committee were strongly of the view that this group would be at a particularly high risk of

1 developing pelvic floor dysfunction. Whilst the included studies did not readily facilitate the
2 development of an original economic model in a postnatal population, there was
3 nevertheless evidence suggesting that pelvic floor muscle training could prevent the
4 development of pelvic organ prolapse and urinary incontinence when undertaken in the
5 immediate postnatal period. Therefore, the committee believed that preventative pelvic
6 muscle floor training was like to be cost-effective in those who developed certain risk factors
7 for pelvic floor dysfunction during labour.

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

14 **Other factors the committee took into account**

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

27 The committee made reference to the [NICE guideline on behaviour change](#) as it contains
28 useful recommendations for interventions such as PFMT requiring long term adherence.

29 **Recommendations supported by this evidence review**

30 This evidence review supports recommendations 1.3.8 to 1.3.15 and 6 research
31 recommendations relating to:

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

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

42

1 References

2 **Agur 2008**

3 Agur,W.I., Steggles,P., Waterfield,M., Freeman,R.M., The long-term effectiveness of
4 antenatal pelvic floor muscle training: eight-year follow up of a randomised controlled trial,
5 BJOG: An International Journal of Obstetrics and Gynaecology, 115, 985-990, 2008

6 **Berzuk 2015**

7 Berzuk, K., Shay, B., Effect of increasing awareness of pelvic floor muscle function on pelvic
8 floor dysfunction: a randomized controlled trial, International Urogynecology Journal, 26, 837-
9 44, 2015

10 **Chiarelli 2002**

11 Chiarelli, P., Cockburn, J., Promoting urinary continence in women after delivery: randomised
12 controlled trial, BMJ (Clinical research ed.), 324, 1241, 2002

13 **Chiarelli 2004**

14 Chiarelli, P., Murphy, B., Cockburn, J., Promoting urinary continence in postpartum women:
15 12-month follow-up data from a randomised controlled trial, International Urogynecology
16 Journal, 15, 99-105; discussion 105, 2004

17 **Citak 2010**

18 Citak, Nevin, Cam, Cetin, Arslan, Hediye, Karateke, Ates, Tug, Niyazi, Ayaz, Reyhan, Celik,
19 C. E. M., Postpartum sexual function of women and the effects of early pelvic floor muscle
20 exercises, Acta Obstetrica et Gynecologica Scandinavica, 89, 817-822, 2010

21 **Claxton 1999**

22 Claxton, K., The irrelevance of inference: a decision making approach to the stochastic
23 evaluation of health care technologies. Journal of Health Economics, 18, 341-64, 1999

24 **Diokno 2004**

25 Diokno, A. C., Sampsel, C. M., Herzog, A. R., Raghunathan, T. E., Hines, S., Messer, K.,
26 Karl, C., Leite, M. C., Prevention of urinary incontinence by behavioral modification program:
27 a randomized, controlled trial among older women in the community, Journal of Urology, 171,
28 1165-71, 2004

29 **Golmakani 2015**

30 Golmakani, N., Zare, Z., Khadem, N., Shareh, H., Shakeri, M. T., The effect of pelvic floor
31 muscle exercises program on sexual self-efficacy in primiparous women after delivery, Iran J
32 Nurs Midwifery Res, 20, 347-53, 2015

33 **Jelovsek 2018**

34 Jelovsek, J.E, Chagin, K., Gyhagen, M., Hagen, S., Wilson, D., Kattan, M.W., Elders, A.,
35 Barber, M.D., Areskoug, B., MacArthur, C., Milsom, I. Predicting pelvic floor disorders 12 and
36 20 years after delivery. American Journal of Obstetrics and Gynaecology, 218,222, 2018
37 Kahyaoglu Sut, H., Balkanli Kaplan, P., Effect of pelvic floor muscle exercise on pelvic floor
38 muscle activity and voiding functions during pregnancy and the postpartum period,
39 Neurourology & Urodynamics, 35, 417-22, 2016

40 **Kahyaoglu 2016**

- 1 Kahyaoglu Sut, H., Balkanli Kaplan, P., Effect of pelvic floor muscle exercise on pelvic floor
2 muscle activity and voiding functions during pregnancy and the postpartum period,
3 *Neurourology & Urodynamics*, 35, 417-22, 2016
- 4 **Kocaoz 2013**
- 5 Kocaoz, S., Eroglu, K., Sivaslioglu, A. A., Role of pelvic floor muscle exercises in the
6 prevention of stress urinary incontinence during pregnancy and the postpartum period,
7 *Gynecologic & Obstetric Investigation*, 75, 34-40, 2013
- 8 **Lin 2020**
- 9 Lin, R., Chen, X., Jin, T., Li, W., Zhu, L., The feasibility of nursing intervention in postpartum
10 pelvic floor muscle rehabilitation among puerperae and its influence on sui incidence and
11 comprehensive muscle strength, *International Journal of Clinical and Experimental Medicine*,
12 13, 4571-4579, 2020
- 13 **Milsom 2019**
- 14 Milsom, I., Gyhagen, M. The prevalence of urinary incontinence. *Climacteric*, 22,217-22,
15 2018
- 16 **Pelaez 2014**
- 17 Pelaez, M., Gonzalez-Cerron, S., Montejo, R., Barakat, R., Pelvic floor muscle training
18 included in a pregnancy exercise program is effective in primary prevention of urinary
19 incontinence: a randomized controlled trial, *Neurourology & Urodynamics*, 33, 67-71, 2014
- 20 **Pourkhiz 2017**
- 21 Pourkhiz, Z., Mohammad-Alizadeh-Charandabi, S., Mirghafourvand, M., Haj-Ebrahimi, S.,
22 Ghaderi, F., Effect of Pelvic Floor Muscle Training on Female Sexual Function During
23 Pregnancy and Postpartum: A Randomized Controlled Trial, *Iran Red Crescent Med J*, 19,
24 e63218, 2017
- 25 **Qi 2019**
- 26 Qi, X., Shan, J., Peng, L., Zhang, C., Xu, F., The effect of a comprehensive care and
27 rehabilitation program on enhancing pelvic floor muscle functions and preventing postpartum
28 stress urinary incontinence, *Medicine*, 98, e16907, 2019
- 29 **Reilly 2002**
- 30 Reilly,E.T., Freeman,R.M., Waterfield,M.R., Waterfield,A.E., Steggle,P., Pedlar,F.,
31 Prevention of postpartum stress incontinence in primigravidae with increased bladder neck
32 mobility: a randomised controlled trial of antenatal pelvic floor exercises, *BJOG: An
33 International Journal of Obstetrics and Gynaecology*, 109, 68-76, 2002
- 34 **Sacomori 2019**
- 35 Sacomori, C., Zomkowski, K., dos Passos Porto, I., Cardoso, F. L., Sperandio, F. F.,
36 Adherence and effectiveness of a single instruction of pelvic floor exercises: a randomized
37 clinical trial, *International Urogynecology Journal.*, 2019
- 38 **Sampselle 2005**
- 39 Sampselle, C. M., Messer, K. L., Seng, J. S., Raghunathan, T. E., Hines, S. H., Diokno, A.
40 C., Learning outcomes of a group behavioral modification program to prevent urinary
41 incontinence, *International Urogynecology Journal*, 16, 441-446, 2005
- 42 **Sangsawang 2016**

- 1 Sangsawang, B., Sangsawang, N., Is a 6-week supervised pelvic floor muscle exercise
- 2 program effective in preventing stress urinary incontinence in late pregnancy in primigravid
- 3 women?: a randomized controlled trial, *European Journal of Obstetrics, Gynecology, &*
- 4 *Reproductive Biology*, 197, 103-10, 2016
- 5 **Yang 2017**
- 6 Yang, S., Sang, W., Feng, J., Zhao, H., Li, X., Li, P., Fan, H., Tang, Z., Gao, L., The effect of
- 7 rehabilitation exercises combined with direct vagina low voltage low frequency electric
- 8 stimulation on pelvic nerve electrophysiology and tissue function in primiparous women: A
- 9 randomised controlled trial, *Journal of clinical nursing*, 02, 02, 2017

1 Appendices

2 Appendix A – Review protocol

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

5 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: <ul style="list-style-type: none"> • Cochrane Database of Systematic Reviews (CDSR) • Cochrane Central Register of Controlled Trials (CENTRAL) • MEDLINE & Medline in Process • Embase Searches will be restricted by: <ul style="list-style-type: none"> • Date: 1980 onwards (see section 10 for justification) • Human studies • English language studies only Other searches: <ul style="list-style-type: none"> • Inclusion lists of potentially relevant systematic review

ID	Field	Content
		<p>The full search strategies for MEDLINE database will be published in the final review.</p> <p>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.</p>
5.	Condition or domain being studied	<p>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.</p>
6.	Population	<p>Inclusion</p> <ul style="list-style-type: none"> • Women and young women (aged 12 years and older) without symptoms of pelvic floor dysfunction <p>Exclusion</p> <ul style="list-style-type: none"> • 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). • Prevention studies where over 20% of the population have a symptom of pelvic floor dysfunction at baseline. • Men • Babies and children (younger than 12 years)
7.	Intervention/Exposure/Test	<p>Included interventions will include:</p> <ul style="list-style-type: none"> • Pelvic floor muscle exercises / Kegel exercise, to include: <ul style="list-style-type: none"> ○ 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 style="list-style-type: none"> • No treatment • Other preventive measures (for example leaflets, weight loss advice) • Alternative method of PFMT delivery (app vs face to face, group vs individual)

ID	Field	Content
9.	Types of study to be included	<ul style="list-style-type: none"> • Combination therapies (PFMT alone or in combination) • Systematic reviews of RCTs • Systematic reviews of cohort studies • RCTs • Non-randomised trials • Prospective cohort studies <p>If available comparative cohort studies, and non-randomised studies will be prioritised over non-comparative cohort studies</p> <p>Note: For further details, see the algorithm in appendix H, Developing NICE guidelines: the manual.</p>
10.	Other exclusion criteria	<ul style="list-style-type: none"> • Conference abstracts will be excluded because these do not typically provide sufficient information to fully assess risk of bias. • Only articles published after 1980 will be included. This was agreed by the committee as this is the date that the condition “pelvic floor dysfunction” was recognised to include agreed terminology on symptoms. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2815805/ <p>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 posterior tibial nerve stimulation, Percutaneous sacral nerve stimulation (also known as sacral neuromodulation)</p>
11.	Context	<p>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.</p> <p>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).</p> <p>Specific recommendations for groups listed in the Equality Considerations section of the scope may be also be made as appropriate.</p>
12.	Primary outcomes (critical outcomes)	<ul style="list-style-type: none"> • Development of the following symptoms, associated with pelvic floor dysfunction: <ul style="list-style-type: none"> ○ urinary incontinence ○ emptying disorders of the bladder

ID	Field	Content
		<ul style="list-style-type: none"> ○ faecal incontinence ○ emptying disorders of the bowel ○ pelvic organ prolapse ○ sexual dysfunction ○ chronic pelvic pain syndromes <p><i>For the above outcomes, only validated tools will be included (for example: ICIQ-UI, ICIQ-VS, BFLUTS, UDI, ISI, POPSS, PISQ, POPQ, FISl, FIQL, GIQLI, PAC-QM, PAC –SYM, PDI, BPI)</i></p>
13.	Secondary outcomes (important outcomes)	<ul style="list-style-type: none"> ● Adherence to PFMT <p><i>Outcomes are in line with those described in the core outcome set</i></p>
14.	Data extraction (selection and coding)	<p>All references identified by the searches and from other sources will be uploaded into STAR and de-duplicated.</p> <p>Titles and abstracts of the retrieved citations will be screened to identify studies that potentially meet the inclusion criteria outlined in the review protocol.</p> <p>Duplicate screening will not be undertaken for this question.</p> <p>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.</p> <p>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.</p>
15.	Risk of bias (quality) assessment	<p>Quality assessment of individual studies will be performed using the following checklists</p> <ul style="list-style-type: none"> ● ROBIS tool for systematic reviews ● ROBINS for non-randomised trials

ID	Field	Content
		<ul style="list-style-type: none"> • Cochrane RoB tool v.2 for RCTs <p>The quality assessment will be performed by one reviewer and this will be quality assessed by a senior reviewer.</p>
16.	Strategy for data synthesis	<p>Depending on the availability of the evidence, the findings will be summarised narratively or quantitatively.</p> <p><u>Data Synthesis</u></p> <p>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.</p> <p>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.</p> <p><u>Heterogeneity</u></p> <p>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</p> <ul style="list-style-type: none"> • According to risk of bias of individual studies • According to socioeconomic status of population included • By ethnicity of included populations <p>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.</p> <p><u>Minimal important differences (MIDs)</u></p>

ID	Field	Content
		<p>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:</p> <ul style="list-style-type: none"> • For risk ratios: 0.8 and 1.25. • For continuous outcomes: <ul style="list-style-type: none"> ○ 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. <p><u>Validity</u></p> <p>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/</p>
17.	Analysis of sub-groups	<p>Stratification</p> <p>If data is available, separate analysis will be conducted on:</p> <ul style="list-style-type: none"> • 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

ID	Field	Content		
		<i>Recommendations will apply to all those with pelvic floor dysfunction unless there is evidence of a difference in these stratified groups</i>		
18.	Type and method of review	<input checked="" type="checkbox"/>	Intervention	
		<input type="checkbox"/>	Diagnostic	
		<input type="checkbox"/>	Prognostic	
		<input type="checkbox"/>	Qualitative	
		<input type="checkbox"/>	Epidemiologic	
		<input type="checkbox"/>	Service Delivery	
		<input type="checkbox"/>	Other (please 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 submission	Review stage	Started	Completed
		Preliminary searches	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
		Piloting of the study selection process	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
		Formal screening of search results against eligibility criteria	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
		Data extraction	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
		Risk of bias (quality) assessment	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
		Data analysis	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
24.	Named contact	5a. Named contact National Guideline Alliance		

ID	Field	Content
		<p>5b Named contact e-mail</p> <p>PreventionofPOP@nice.org.uk</p> <p>5e Organisational affiliation of the review</p> <p>National Institute for Health and Care Excellence (NICE) and the National Guideline Alliance</p>
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 Developing NICE guidelines: the manual . Members of the guideline committee are available on the NICE website: https://www.nice.org.uk/guidance/indevelopment/gid-ng10123/
29.	Other registration details	
30.	Reference/URL for published protocol	[Give the citation and link for the published protocol, if there is one.]
31.	Dissemination plans	<p>NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as:</p> <ul style="list-style-type: none"> • notifying registered stakeholders of publication • publicising the guideline through NICE's newsletter and alerts

ID	Field	Content	
		<ul style="list-style-type: none"> issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE. 	
32.	Keywords	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	<input checked="" type="checkbox"/>	Ongoing
		<input type="checkbox"/>	Completed but not published
		<input type="checkbox"/>	Completed and published
		<input type="checkbox"/>	Completed, published and being updated
		<input type="checkbox"/>	Discontinued
35..	Additional information	None	
36.	Details of final publication	www.nice.org.uk	

1 BFLUTS: Bristol Female Lower Urinary Tract Symptoms Questionnaire; BPI: Brief pain inventory; CDSR: Cochrane Database of Systematic Reviews; CENTRAL: Cochrane
2 Central Register of Controlled Trials; EMG: Electromyography; ePAQ: Electronic personal health questionnaire; FIQL: Faecal incontinence quality of life scale; FISI: Faecal
3 incontinence severity index; GIQLI: Gastrointestinal quality of life index; GRADE: Grading of Recommendations Assessment, Development and Evaluation; HTA: Health
4 Technology Assessment; ICIQ-UI: International Consultation on Incontinence Questionnaire- Urinary incontinence; ICIQ-VS: International Consultation on Incontinence
5 questionnaire – vaginal symptoms; ISI: Incontinence symptom index; KHQ: Kings health questionnaire; MID: minimally important difference; NGA: National Guideline Alliance;
6 NHS: National health service; NICE: National Institute for Health and Care Excellence; PAC-QL: patient assessment of constipation - quality of life; PAC-SYM: Patient
7 assessment of constipation symptoms; PDI: Pain disability index; PFMT: pelvic floor muscle training; PISQ: Pelvic organ prolapse/urinary incontinence sexual questionnaire;
8 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
9 In Systematic reviews; ROBINS: Risk Of Bias In Non-randomised Studies; SD: standard deviation; UDI: Urinary distress index

1 Appendix B – Literature search strategies

2 Literature search strategies for review question: What is the effectiveness of 3 pelvic floor muscle training for preventing pelvic floor dysfunction? 4

5 Clinical Search 6

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

8 Embase Classic+Embase 1947 to 2021 February 01; Ovid MEDLINE(R) and Epub Ahead
9 of Print, In-Process & Other Non-Indexed Citations and Daily 1946 to February 01, 2021

10 Date of last search: 2 February 2021

11
12 Multifile database codes: emczd = Embase Classic+Embase; ppez= MEDLINE(R) and Epub Ahead of
13 Print, In-Process & Other Non-Indexed Citations 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	(pelvis\$ 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	(pelvis\$ 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 pelvis\$ or vault\$ or urethr\$ or bladder\$ or cervi\$ or rectal or rectum) adj3 prolaps\$).ti.
16	(splachnoptos\$ or visceroptos\$).ti.
17	(hernia\$ adj3 (pelvis\$ 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 feces 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	(pelvis\$ adj3 dyskines\$).tw.
30	pelvis\$ 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.
36	(vagin\$ adj3 laxity\$).tw.

#	Searches
37	(vagin\$ adj wind).tw.
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 vagina cone/ or weighted vaginal cone/ or electrostimulation/ or electrotherapy/ or transcutaneous nerve stimulation/ or magnetic stimulation/ or magnetotherapy/ or extracorporeal magnetic innervation therapy/ or feedback system/ or biofeedback/ or perineometry/ or resistance training/
44	43 use emczd
45	((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	(kegel\$ or kegal\$ or knack\$).tw.
50	(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.
58	(electrostimulat\$ or electro-stimulat\$).tw.
59	((transcutaneous\$ or percutaneous\$ or neuromusc\$ or posterior\$ or anterior\$ or tibia\$ or perine\$ or intravagin\$ or intra-vagin\$) adj4 stimulat\$).tw.
60	((magnet\$ or electro-magnet\$ or electromagnet\$) adj (stimulation\$ or therap\$ or treatment\$)).tw.
61	((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	(pressure\$ adj3 perin?ometr\$).tw.
68	((strength\$ or resistan\$) adj3 (training or exercise\$ or physiotherap\$)).tw.
69	(manual adj3 therap\$).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	(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.
76	crossover procedure/ or double blind procedure/ or randomized controlled trial/ or single blind procedure/ or (assign* 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	systematic review/
80	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 psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
88	cochrane.jw.
89	((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

#	Searches
94	(or/79-82,84-89) use emczd
95	93 or 94
96	92 or 95
97	74 and 96 [General Exclusions filter applied]

1
2
3
4
5

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

#	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 hyper reflex* or incontinen*)):ti
#9	((detrusor* NEAR/5 (overactiv* or over activ* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or hyper reflex*)):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	((splachnoptos* or visceroptos*)):ti
#19	((hernia* NEAR/3 (pelvi* or vagin* or urogenital* or uter* or bladder* or urethr* or viscer*)):ti
#20	((urethro?ele* or enteroc?ele* or sigmoidoc?ele* or proctoc?ele* or rectoc?ele* or cystoc?ele* or rectoenteroc?ele* or cystourethro?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 double or defecat* or defaecat*) NEAR/5 (incontinence or incontinent or urge* or leak or leaking or leakage or soiling or seeping or seepage or impacted or impaction)):ti
#23	MeSH descriptor: [Urinary Retention] this term only
#24	((urin* NEAR/3 (retention* or retain*)):ti,ab,kw
#25	((voiding NEXT (disorder* or dysfunction* or problem*)):ti,ab,kw
#26	((empty* NEXT disorder* NEAR/3 (bowel* or bladder* or vesical* or stool*)):ti,ab,kw
#27	((urogeni* or anorec* or ano-rec* or ano rec*) NEAR/3 dysfunction*)):ti,ab,kw
#28	MeSH descriptor: [Fecal Impaction] this term only
#29	((difficult* or delay* or irregular* or infrequen* or pain*) NEAR/3 (defecat* or defaecat* or stool* or faecal* or fecal or faeces or feces or fecally or faecally or bowel movement*)):ti,ab,kw
#30	((obstruct* NEAR/3 (defecat* or defaecat*)):ti,ab,kw
#31	((defecat* or defaecat* or evacuat*) NEAR/3 (disorder* or dysfunction*)):ti,ab,kw
#32	((outlet* dysfunction* constipa*)):ti,ab,kw
#33	((dys?ynerg* NEXT (defecat* or defaecat*)):ti,ab,kw
#34	((pelvi* NEAR/3 dyskines*)):ti,ab,kw
#35	((pelvi* outlet* obstruct*)):ti,ab,kw
#36	((anismus*)):ti,ab,kw
#37	((puborectal* contract*)):ti,ab,kw
#38	((rectal or rectum) NEAR/3 urge*)):ti,ab,kw
#39	((female NEXT sex* NEXT (dysfunc* or satisf* or problem* or symptom* or arous* or activit* or disorder*)):ti,ab,kw
#40	((obstruct* NEAR/3 intercourse)):ti,ab,kw
#41	((vagin* NEAR/3 laxity*)):ti,ab,kw
#42	((vagin* NEXT wind)):ti,ab,kw
#43	MeSH descriptor: [Vaginismus] this term only
#44	((vaginismus*)):ti,ab,kw
#45	((vagin* NEXT penetrat* NEXT disorder*)):ti,ab,kw
#46	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29

#	Searches
	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
#48	MeSH descriptor: [Physical Therapy Modalities] this term only
#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

- 1
- 2
- 3
- 4

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

Date of last search: 2nd February 2021

#	Searches
1	MeSH DESCRIPTOR Pelvic Floor IN DARE,HTA
2	MeSH DESCRIPTOR Pelvic Floor Disorders IN DARE,HTA
3	((pelvi* NEXT (floor* or diaphragm*) NEAR3 (dysfunction* or disorder* or fail* or impair* or incompeten* or insufficien* or dyssynerg* or symptom* or laxity or change* or care* or health* or wellbeing* or well-being* or prevent* or rehabilitat* or weak* or hypertonic* or overactiv* or over-activ*))) IN DARE, HTA
4	((pelvi* NEXT (dysfunction* or disorder* or fail* or impair* or incompeten* or insufficient* or dyssynerg* or symptom* or laxity or care* or health* or wellbeing* or well-being* or prevent* or rehabilitat* or weak* or hypertonic* or overactiv* or over-activ* or over-activ*))) IN DARE, HTA
5	MeSH DESCRIPTOR Urinary Incontinence EXPLODE ALL TREES IN DARE,HTA
6	MeSH DESCRIPTOR Urinary Bladder, Overactive IN DARE,HTA
7	((stress* or mix* or urg* or urin*) NEAR5 incontinen*) IN DARE, HTA
8	((bladder* NEAR5 (overactiv* or over-activ* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or hyper reflex* or incontinen*))) IN DARE, HTA
9	((detrusor* NEAR5 (overactiv* or over-activ* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or hyper reflex*))) IN DARE, HTA
10	((urgency NEAR2 frequency) or (frequency NEAR2 urgency))) IN DARE, HTA
11	((urin* or bladder*) NEAR2 (urg* or frequen*))) IN DARE, HTA
12	((SUI or OAB)) IN DARE, HTA
13	MeSH DESCRIPTOR Pelvic Organ Prolapse EXPLODE ALL TREES IN DARE,HTA

#	Searches
14	MeSH DESCRIPTOR Rectocele IN DARE,HTA
15	((pelvic* NEAR3 organ* NEAR3 prolaps*)) IN DARE, HTA
16	((urinary NEAR3 bladder NEAR3 prolaps*)) IN DARE, HTA
17	((vagin* or urogenital* or genit* or uter* or viscer* or anterior* or posterior* or apical or pelvi* or vault* or urethr* or bladder* or cervi* or rectal or rectum) NEAR3 prolaps*)) IN DARE, HTA
18	((splanchnoptos* or visceroptos*)) IN DARE, HTA
19	((hernia* NEAR3 (pelvi* or vagin* or urogenital* or uter* or bladder* or urethr* or viscer*))) IN DARE, HTA
20	((urethroc?ele* or enteroc?ele* or sigmoidoc?ele* or proctoc?ele* or rectoc?ele* or cystoc?ele* or rectoenteroc?ele* or cystourethroc?ele*)) IN DARE, HTA
21	MeSH DESCRIPTOR Fecal Incontinence IN DARE,HTA
22	((faecal or fecal or faeces or feces or fecally or faecally or anal or anally or stool or stools or bowel or double or defecat* or defaecat*) NEAR5 (incontinence or incontinent or urge* or leak or leaking or leakage or soiling or seeping or seepage or impacted or impaction))) IN DARE, HTA
23	MeSH DESCRIPTOR Urinary Retention IN DARE,HTA
24	((urin* NEAR3 (retention* or retain*))) IN DARE, HTA
25	((voiding NEXT (disorder* or dysfunction* or problem*))) IN DARE, HTA
26	((empty* NEXT disorder* NEAR3 (bowel* or bladder* or vesical* or stool*))) IN DARE, HTA
27	((urogeni* or anorec* or ano-rec* or ano rec*) NEAR3 dysfunction*) IN DARE, HTA
28	MeSH DESCRIPTOR Fecal Impaction IN DARE,HTA
29	((difficult* or delay* or irregular* or infrequen* or pain*) NEAR3 (defecat* or defaecat* or stool* or faecal or fecal or faeces or feces or fecally or faecally or bowel movement*)) IN DARE, HTA
30	((obstruct* NEAR3 (defecat* or defaecat*))) IN DARE, HTA
31	((defecat* or defaecat* or evacuat*) NEAR3 (disorder* or dysfunction*)) IN DARE, HTA
32	((outlet* NEXT dysfunction* NEXT constipa*)) IN DARE, HTA
33	((dys?ynerg* NEXT (defecat* or defaecat*))) IN DARE, HTA
34	((pelvi* NEAR3 dyskines*)) IN DARE, HTA
35	((pelvi* NEXT outlet* NEXT obstruct*) IN DARE, HTA
36	((anismus*)) IN DARE, HTA
37	((puborectal* NEXT contract*)) IN DARE, HTA
38	((rectal or rectum) NEAR3 urge*) IN DARE, HTA
39	((female NEXT sex* NEXT (dysfunct* or satisf* or problem* or symptom* or arouse* 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	((physiotherap* or "physical therap*")):TI IN DARE, HTA
55	((physiotherapy-led)):TI IN DARE, HTA
56	((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

#	Searches
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	(((digital* or manual*) NEAR3 (feedback* or palpat* or assess* or contract*)))):TI IN DARE, HTA
78	(((pressure* NEAR3 perin?omet*)):TI IN DARE, HTA
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

1

2

Economic Search

3

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

4

5

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

6

Date of last search: 3 February 2021

7

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

#	Searches
34	(((pelvi* NEAR3 dyskines*))) IN NHSEED, HTA
35	(((pelvi* NEXT outlet* NEXT obstruct*))) IN NHSEED, HTA
36	(((anismus*))) IN NHSEED, HTA
37	(((puborectal* NEXT contract*))) IN NHSEED, HTA
38	(((rectal or rectum) NEAR3 urge*))) IN NHSEED, HTA
39	(((female NEXT sex* NEXT (dysfunct* or satisf* or problem* or symptom* or arous* or activit* or disorder*))) IN NHSEED, HTA
40	(((obstruct* NEAR3 intercourse))) IN NHSEED, HTA
41	(((vagin* NEAR3 laxity*))) IN NHSEED, HTA
42	(((vagin* NEXT wind))) IN NHSEED, HTA
43	MeSH DESCRIPTOR Vaginismus IN NHSEED,HTA
44	(((vaginismus*))) IN NHSEED, HTA
45	(((vagin* NEXT penetrat* NEXT disorder*))) IN NHSEED, HTA
46	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #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

1
2
3
4
5
6
7
8

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

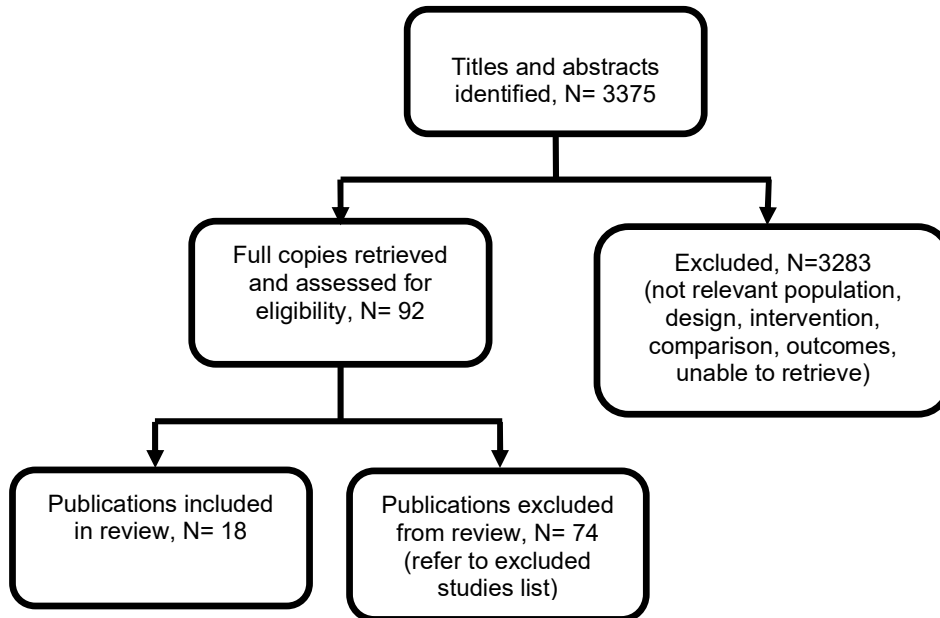
#	Searches
1	Pelvic Floor/ use ppez
2	Pelvic Floor Disorders/ use ppez
3	pelvis floor/ use emczd
4	pelvic floor disorder/ use emczd
5	(pelvi\$ adj (floor\$ or diaphragm\$) adj3 (dysfunction\$ or disorder\$ or fail\$ or impair\$ or incompeten\$ or insufficien\$ or dyssynerg\$ or symptom\$ or laxity or 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

#	Searches
33	((faecal or fecal or faeces or feces or fecally or faecally or anal or anally or stool or stools or bowel or double or defecat\$ or defaecat\$) adj5 (incontinence or incontinent or urge\$ or leak or leaking or leakage or soiling or seeping or seepage or impacted or impaction)).ti.
34	or/31-33
35	Urinary Retention/ use ppez
36	urine retention/ use emczd
37	(urin\$ adj3 (retention\$ or retain\$)).tw.
38	(voiding adj (disorder\$ or dysfunction\$ or problem\$)).tw.
39	(empty\$ adj disorder\$ adj3 (bowel\$ or bladder\$ or vesical\$ or stool\$)).tw.
40	((urogeni\$ or anorec\$ or ano-rec\$ or ano rec\$) adj3 dysfunction\$).tw.
41	defecation disorder/ use emczd
42	Fecal Impaction/ use ppez
43	Feces Impaction/ use emczd
44	((difficult\$ or delay\$ or irregular\$ or infrequen\$ or pain\$) adj3 (defecat\$ or defaecat\$ or stool\$ or faeces or feces or bowel movement\$)).tw.
45	(obstruct\$ adj3 (defecat\$ or defaecat\$)).tw.
46	((defecat\$ or defaecat\$ or evacuat\$) adj3 (disorder\$ or dysfunction\$)).tw.
47	outlet\$ dysfunction\$ constipa\$.tw.
48	(dys?ynerg\$ adj (defecat\$ or defaecat\$)).tw.
49	(pelvi\$ adj3 dyskines\$).tw.
50	pelvi\$ outlet\$ obstruct\$.tw.
51	anismus\$.tw.
52	puborectal\$ contract\$.tw.
53	((rectal or rectum) adj3 urge\$).tw.
54	or/35-53
55	female sexual dysfunction/ use emczd
56	(female adj sex\$ adj (dysfunct\$ or satisf\$ or problem\$ or symptom\$ or arous\$ or activit\$ or disorder\$)).tw.
57	(obstruct\$ adj3 intercourse).tw.
58	(vagin\$ adj3 laxity\$).tw.
59	(vagin\$ adj wind).tw.
60	Vaginismus/ use ppez
61	vaginism/ use emczd
62	vaginismus\$.tw.
63	(vagin\$ adj penetrat\$ adj disorder\$).tw.
64	or/55-63
65	7 or 19 or 30 or 34 or 54 or 64
66	Economics/ use ppez
67	Value of life/ use ppez
68	exp "Costs and Cost Analysis"/ use ppez
69	exp Economics, Hospital/ use ppez
70	exp Economics, Medical/ use ppez
71	Economics, Nursing/ use ppez
72	Economics, Pharmaceutical/ use ppez
73	exp "Fees and Charges"/ use ppez
74	exp Budgets/ use ppez
75	health economics/ use emczd
76	exp economic evaluation/ use emczd
77	exp health care cost/ use emczd
78	exp fee/ use emczd
79	budget/ use emczd
80	funding/ use emczd
81	budget*.ti,ab.
82	cost*.ti.
83	(economic* or pharmaco?economic*).ti.
84	(price* or pricing*).ti,ab.
85	(cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.
86	(financ* or fee or fees).ti,ab.
87	(value adj2 (money or monetary)).ti,ab.
88	or/66-87
89	65 and 88
90	limit 89 to english language

1 Appendix C – Clinical evidence study selection

2 Study selection for: What is the effectiveness of pelvic floor muscle training for 3 preventing pelvic floor dysfunction?

4 Figure 2: Study selection flow chart



5

1 Appendix D –Evidence tables

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

4 Table 5: Evidence tables

Study details	Participants	Interventions	Methods	Outcomes	Comments
<p>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</p> <p>Ref Id 109918</p> <p>Country/ies where the study was carried out UK</p> <p>Study type RCT</p> <p>Aim of the study 8-year follow-up to Reilly 2002</p>	<p>Sample size See Reilly 2002 Starting sample size N=268 randomised. At 8 years, response from: Intervention: n=79 Control: n=85</p> <p>Characteristics See Reilly 2002</p> <p>Inclusion criteria</p> <p>Exclusion criteria See Reilly 2002</p>	<p>Interventions See Reilly 2002</p>	<p>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).</p>	<p>Results Stress UI, n (%): Intervention 28 (35.5); Control 33 (38.8)</p> <p>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%</p>	<p>Limitations See Reilly 2002</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
<p>Study dates See Reilly 2002</p> <p>Source of funding See Reilly 2002</p>					
<p>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</p> <p>Ref id 1147266</p> <p>Country/ies where the study was carried out Canada</p> <p>Study type RCT</p> <p>Aim of the study 1. To evaluate the pelvic floor knowledge in women working in an office</p>	<p>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</p> <p>Characteristics Group A: Education and re-education; Group B: Single education only; Group C: Control</p> <p>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: 1; Group C: 2</p> <p>Pregnancies (number)</p>	<p>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</p>	<p>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.</p>	<p>Results Group A: Education and re-education; Group B: Single education only; Group C: Control</p> <p>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</p> <p>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 C: no change Data converted into n's by NGA team: Group A: 2; Group B: 2; Group C: 4</p>	<p>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</p> <p>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</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
<p>environment before and after Pelvic Floor Health and Pelvic Floor Muscle exercise education sessions</p> <p>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.</p> <p>Study dates Not reported</p> <p>Source of funding Manitoba Hydro and the Women's Health Research Foundation of Canada</p>	<p>0 (n): Group A: 13; Group B: 14; Group C: 12</p> <p>1 (n): Group A: 7; Group B: 10; Group C: 5</p> <p>2 (n): Group A: 12; Group B: 11; Group C: 17</p> <p>3 (n): Group A: 11; Group B: 6; Group C: 9</p> <p>4 (n): Group A: 4; Group B: 1; Group C: 2</p> <p>5 or more (n): Group A: 1; Group B: 6; Group C: 4</p> <p>Vaginal deliveries (number)</p> <p>0 (n): Group A: 21; Group B: 20; Group C: 18</p> <p>1 (n): Group A: 5; Group B: 13; Group C: 8</p> <p>2 (n): Group A: 14; Group B: 8; Group C: 17</p> <p>3 (n): Group A: 7; Group B: 5; Group C: 5</p> <p>4 (n): Group A: 1; Group B: 1; Group C: 0</p> <p>5 or more (n): Group A: 0; Group B: 1; Group C: 1</p> <p>Caesarean deliveries (number)</p> <p>0 (n): Group A: 41; Group B: 40; Group C: 45</p> <p>1 (n): Group A: 5; Group B: 5; Group C: 2</p> <p>2 (n): Group A: 2; Group B: 3; Group C: 1</p> <p>3 (n): Group A: 0; Group B: 0; Group C: 1</p> <p>Menstrual status (number)</p>				<p>aware of allocation: Yes - education session delivery staff</p> <p>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</p> <p>2.6 Appropriate analysis to estimate effect of assignment: Yes - analysis excluded participants with missing outcomes</p> <p>Domain 3 - Risk of bias due to missing outcome data: Low risk</p> <p>3.1 Missing outcome data: Yes, data available for over 85% of the population</p> <p>Domain 4 - Measurement of the outcome: Low risk</p> <p>4.1 Method for measuring outcome inappropriate: No - online survey, self-reporting</p> <p>4.2 Could measurement of outcome differed between groups: No - online survey - self reporting</p> <p>4.3 Outcome assessors aware of the intervention: NA - self reported</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
	<p>Regular periods (n): Group A: 23; Group B: 23; Group C: 28</p> <p>Irregular periods (n): Group A: 6; Group B: 5; Group C: 4</p> <p>Pregnant (n): Group A: 0; Group B: 1; Group C: 0</p> <p>Perimenopausal (n): Group A: 6; Group B: 9; Group C: 4</p> <p>Menopausal (n): Group A: 13; Group B: 10; Group C: 13</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> • Women from a large local corporation • Able to independently complete the online survey <p>Exclusion criteria</p> <ul style="list-style-type: none"> • Failed to respond to e-mail contact attempts 				<p>Domain 5 - Selection of the reported result: Some concerns</p> <p>5.1 Data produced according to pre-specified plan: No information</p> <p>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</p> <p>5.3 Are results assessed likely to be selected on basis of results from multiple eligible analysis of the data: Probably no</p> <p>Domain 6 - Overall judgment of bias: Some concerns</p>
<p>Full citation</p> <p>Chiarelli, P., Cockburn, J., Promoting urinary continence in women after delivery: randomised controlled trial, BMJ (Clinical research ed.), 324, 1241, 2002</p> <p>Ref Id</p> <p>480975</p>	<p>Sample size</p> <p>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</p> <p>Characteristics</p>	<p>Interventions</p> <p>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</p>	<p>Details</p> <p>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:</p>	<p>Results</p> <p>Prevalence of urinary incontinence at 3 months postpartum: Intervention: 108/348 (31%) Control: 125/328 (38.4%) (NB Chiarelli 2004 reports 126/328)</p> <p>Severe symptoms: Intervention: 35/348 (10.1%)</p>	<p>Limitations</p> <p>Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB2).</p> <p>Domain 1 - randomisation: Low risk</p> <p>1.1 Random sequence generation: Yes - computer-generated randomisation list</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
<p>Country/ies where the study was carried out</p> <p>Australia</p> <p>Study type</p> <p>RCT</p> <p>Aim of the study</p> <p>To test the effectiveness of a physiotherapist delivered intervention designed to prevent urinary incontinence among women 3 months after giving birth.</p> <p>Study dates</p> <p>August 1998 to February 2000</p> <p>Source of funding</p> <p>Medical Benefits Fund, Physiotherapy Foundation, and University of Newcastle Research Management Committee.</p>	<p>Age:</p> <p>15-19 years, n (%): Intervention 15 (4); Control 27 (8)</p> <p>20-24 years, n (%): Intervention 69 (19); Control 62 (18)</p> <p>25-29 years, n (%): Intervention 128 (35); Control 125 (36)</p> <p>30-34 years, n (%): Intervention 118 (32); Control 92 (26)</p> <p>35-39 years, n (%): Intervention 34 (9); Control 41 (12)</p> <p>40-44 years, n (%): Intervention 6 (2); Control 3 (1)</p> <p>No of pregnancies:</p> <p>One, n (%): Intervention 198 (54); Control 187 (53)</p> <p>Two, n (%): Intervention 98 (27); Control 95 (27)</p> <p>Three, n (%): Intervention 60 (16); Control 44 (13)</p> <p>Four or more, n (%): Intervention 14 (4); Control 24 (7)</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> • 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 	<p>abdominus co-contractions, and discussion of the accompanying booklet which covered UI, PFD, PFM exercises, bladder habits etc.</p> <p>Control: received usual postpartum care, which did not include a visit from a physiotherapist but did include a brochure on PFM exercises.</p>	<ul style="list-style-type: none"> • leaked even small amounts of urine when you were coughing, sneezing, laughing, or lifting; • gone to the toilet urgently for fear you would leak; x leaked even small amounts if you had to wait to use the toilet; • leaked even small amounts on your way to the toilet; or • leaked even small amounts if you hadn't gone to the toilet immediately you first felt the need." <p>If the answer was 'often' or 'always' the woman was classified as incontinent.</p> <p>Severity of incontinence was also assessed by asking about the frequency and amount of urine loss on the basis of a validated scale.</p>	<p>Control: 55/328 (16.8%)</p> <p>Adherence – PFMT exercises 3 times per week or more:</p> <p>Intervention: 292/348 (83.9%) [80% to 87.8%]</p> <p>Control: 189/328 (57.6%) [52.3 to 62.9%]</p>	<p>1.2 Allocation concealment: Yes - sealed opaque envelopes</p> <p>1.3 Baseline differences: No - no significant differences reported</p> <p>Domain 2 - Deviations from intended interventions (effect of assignment to interventions): Low risk</p> <p>2.1 Participants aware of allocation: No - women was told at the structured interview point which study group she was allocated to</p> <p>2.2 Carers and people delivering the intervention aware of allocation: No - physiotherapist blinded to woman's allocation until structured interview point.</p> <p>2.6 Appropriate analysis to estimate effect of assignment: Yes - analysis excluded participants with missing outcomes</p> <p>Domain 3 - Risk of bias due to missing outcome data: Low risk</p> <p>3.1 Missing outcome data: Yes, data available for over 94% of the population</p> <p>Domain 4 - Measurement of the outcome: Low risk</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
	<p>Exclusion criteria None reported</p>				<p>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</p> <p>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</p> <p>Domain 6 - Overall judgment of bias: Some concerns</p>
<p>Full citation Chiarelli, P., Murphy, B., Cockburn, J., Promoting urinary continence in</p>	<p>Sample size See Chiarelli 2002 for initial participant inclusion At 12 months: Intervention: n=294</p>	<p>Interventions See Chiarelli 2002</p>	<p>Details 12 month follow-up by telephone interview.</p>	<p>Results Urinary incontinence: Intervention: 101/294 (34.4) Control: 100/275 (36.4)</p>	<p>Limitations See Chiarelli 2002</p>

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

Study details	Participants	Interventions	Methods	Outcomes	Comments
<p>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 Obstetrica et Gynecologica Scandinavica, 89, 817-822, 2010</p> <p>Ref id 1232726</p> <p>Country/ies where the study was carried out Turkey</p> <p>Study type RCT</p> <p>Aim of the study To evaluate the effects of early pelvic floor muscle training after vaginal delivery on sexual function</p> <p>Study dates June and September 2006</p> <p>Source of funding None reported</p>	<p>n=58 allocated to intervention, n=37 analysed n=60 allocated to control, n=38 analysed</p> <p>Characteristics Age (years), mean (SD): Intervention 23.0 (3.2); Control 22.2 (3.1)</p> <p>Duration of marriage (months), mean (SD): Intervention 19.7 (13.9); Control 14.7 (6.6)</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> • primiparous women who delivered vaginally in Zeynep Kamil Hospital <p>Exclusion criteria</p> <ul style="list-style-type: none"> • 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) 	<p>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.</p>	<p>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.</p>	<p>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)</p>	<p>Cochrane risk-of-bias tool for randomised trials (RoB2).</p> <p>Domain 1 - randomisation: Low risk</p> <p>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</p> <p>Domain 2 - Deviations from intended interventions (effect of assignment to interventions): Low risk</p> <p>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</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
					<p>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</p> <p>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</p> <p>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</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
					<p>multiple eligible outcome measurements: Probably no, data collected at 3 time points and reported as such</p> <p>5.3 Are results assessed likely to be selected on basis of results from multiple eligible analysis of the data: Probably no</p> <p>Domain 6 - Overall judgment of bias: Some concerns</p>
<p>Full citation</p> <p>Diokno, A. C., Sampsel, 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, <i>Journal of Urology</i>, 171, 1165-71, 2004</p> <p>Ref Id</p> <p>1176620</p> <p>Country/ies where the study was carried out</p> <p>USA</p> <p>Study type</p> <p>RCT</p>	<p>Sample size</p> <p>See Sampsel 2005</p> <p>Characteristics</p> <p>See Sampsel 2005</p> <p>Inclusion criteria</p> <p>See Sampsel 2005</p> <p>Exclusion criteria</p> <p>See Sampsel 2005</p>	<p>Interventions</p> <p>See Sampsel 2005</p>	<p>Details</p> <p>See Sampsel 2005</p>	<p>Results</p> <p>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</p> <p>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</p> <p><u>Mean voiding frequencies:</u></p> <p>Over a 24hr period: PFMT 6.1 voids per day; Control 7.5 voids per day</p> <p>Voids during awake period: PFMT 5.4 voids per day; Control 6.6 voids per day</p>	<p>Limitations</p> <p>See Sampsel 2005</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
<p>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 Sampsele (2005), but with additional outcomes)</p> <p>Study dates Not reported</p> <p>Source of funding Not reported</p>				<p>Voids during sleep period: PFMT 0.7 voids per day; Control 0.9 voids per day</p> <p>Mean voiding interval: PFMT 3.69 hrs; Control 3.09 hrs</p>	
<p>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</p>	<p>Sample size N=104 randomised n=52 allocated to intervention, n=40 analysed n=52 allocated to control, n=39 analysed</p> <p>Characteristics</p>	<p>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</p>	<p>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.</p>	<p>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)</p>	<p>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</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
<p>Ref Id 1232727</p> <p>Country/ies where the study was carried out Iran</p> <p>Study type RCT</p> <p>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</p> <p>Study dates 2013</p> <p>Source of funding Research Deputy of Mashhad University of Medical Sciences</p>	<p>Age (years), mean (SD): Intervention 25.19 (3.78); Control 26.57 (3.92)</p> <p>BMI (kg/m²), mean (SD): Intervention 24.17 (2.90); Control 24.64 (3.14)</p> <p>Marriage duration (years), mean (SD): Intervention 3.55 (1.78); Control 4.21 (2.13)</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> • being nulliparous • Iranians living in Mashhad • having the ability to read and write • living with husband • beginning the sexual activity after delivery • having passed 8 weeks of vaginal delivery • having a healthy baby • no postpartum complications • lack of special medical disease • lack of psychological disorder in couples • non-addictive couples • not using alcohol or drugs affecting sexual function 	<p>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.</p> <p>Women were to complete checklist of completing their PFM exercises, checklists were collected every 4 weeks and telephone check-ins were every 2 weeks.</p>			<p>1.2 Allocation concealment: No information</p> <p>1.3 Baseline differences: No - no significant differences reported</p> <p>Domain 2 - Deviations from intended interventions (effect of assignment to interventions): Some concerns</p> <p>2.1 Participants aware of allocation: No information</p> <p>2.2 Carers and people delivering the intervention aware of allocation: No information</p> <p>2.3 Deviations from intended intervention: No information</p> <p>2.6 Appropriate analysis to estimate effect of assignment: Probably yes - not ITT analysis, but appropriate for the data</p> <p>Domain 3 - Risk of bias due to missing outcome data: Low risk</p> <p>3.1 Missing outcome data: Yes, data available for over 75% of the population</p> <p>Domain 4 - Measurement of the outcome: Low risk</p> <p>4.1 Method for measuring outcome inappropriate: No - self-reporting</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
	<ul style="list-style-type: none"> no uterine prolapse or cystocele or rectocele grade 3 and 4 not having undergone stressful event during a month ago <p>Exclusion criteria</p> <ul style="list-style-type: none"> being pregnant during the study doing regular exercises during the study not regularly performing Kegel exercise program based on the method proposed in the study. 				<p>4.2 Could measurement of outcome differed between groups: No - self reporting</p> <p>4.3 Outcome assessors aware of the intervention: No information</p> <p>4.4 Assessment of outcome be influenced by knowledge of intervention: No</p> <p>Domain 5 - Selection of the reported result: Some concerns</p> <p>5.1 Data produced according to pre-specified plan: No information</p> <p>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</p> <p>5.3 Are results assessed likely to be selected on basis of results from multiple eligible analysis of the data: Probably no</p> <p>Domain 6 - Overall judgment of bias: Some concerns</p>
<p>Full citation</p> <p>Kahyaoglu Sut, H., Balkanli Kaplan, P., Effect of pelvic floor muscle</p>	<p>Sample size</p> <p>N=64 randomised n=32 allocated to training group; n=30 analysed</p>	<p>Interventions</p> <p>Intervention group: Participants were instructed by a researcher on how to perform Kegel</p>	<p>Details</p> <p>The following questionnaires were collected: UDI-6, IIQ-7, OAB-q and voiding</p>	<p>Results</p> <p>Baseline - week 28 of gestation</p> <p>UDI-6: Intervention 45.8 (11.5); Control 40.6 (10.6)</p>	<p>Limitations</p> <p>Limitations were assessed using the revised Cochrane risk-of-bias tool</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
<p>exercise on pelvic floor muscle activity and voiding functions during pregnancy and the postpartum period, Neurourology & UrodynamicsNeurourol Urodyn, 35, 417-22, 2016</p> <p>Ref Id 1197020</p> <p>Country/ies where the study was carried out Turkey</p> <p>Study type RCT</p> <p>Aim of the study To investigate the effects of pelvic floor muscle exercise during pregnancy and the postpartum period on pelvic floor muscle activity and voiding functions.</p> <p>Study dates September 2011 to August 2012</p> <p>Source of funding Trakya University Research Foundation (TUBAP 2011-58)</p>	<p>n=32 allocated to control group; n=30 analysed</p> <p>Characteristics Age (years), mean (SD): Intervention 30.0 (6.5); Control 27.2 (6.3)</p> <p>BMI (kg/m²), mean (SD): Intervention 29.9 (5.7); Control 27.7 (5.0)</p> <p>Gravidity, mean (SD): Intervention 2.8 (1.5); Control 2.3 (1.7)</p> <p>Parity, mean (SD): Intervention 1.2 (1.1); Control 0.8 (1.1)</p> <p>Number of vaginal deliveries, mean (SD): Intervention 0.9 (1.2); Control 0.4 (0.8)</p> <p>Number of caesarean deliveries, mean (SD): Intervention 0.3 (0.5); Control 0.4 (0.7)</p> <p>Delivery type Vaginal, n (%): Intervention 20 (66.7); Control 12 (40.0) Caesarean, n (%): Intervention 10 (33.3); Control 18 (60.0)</p> <p>Inclusion criteria</p>	<p>exercises, according to the following information:</p> <ol style="list-style-type: none"> 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 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). <p>Women were called every 2 weeks to be reminded about their exercises.</p>	<p>diaries. Questionnaires and voiding diaries were completed at week 28, week 36-38 of pregnancy and postpartum week 6-8.</p>	<p>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)</p> <p>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); 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)</p> <p>Week 6-8 postpartum UDI-6: Intervention 34.1 (6.6); Control 34.0 (8.2)</p>	<p>for randomised trials (RoB2).</p> <p>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</p> <p>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 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 - analysis excluded participants with missing outcomes</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
	<ul style="list-style-type: none"> 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 <p>Exclusion criteria pregnant women who:</p> <ul style="list-style-type: none"> 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		<p>IIQ-7: Intervention 1.7 (6.4); Control 0.3 (1.7)</p> <p>OAB-q - coping: Intervention 97.4 (10.3); Control 98.2 (5.8)</p> <p>OAB-q - concern: Intervention 97.3 (8.9); Control 97.4 (7.7)</p> <p>OAB-q - sleep: Intervention 94.5 (12.0); Control 94.9 (11.2)</p> <p>OAB-q - social: Intervention 99.3 (3.6); Control 99.8 (0.7)</p> <p>OAB-q - total score: Intervention 97.2 (8.7); Control 97.6 (6.3)</p>	<p>Domain 3 - Risk of bias due to missing outcome data: Low risk</p> <p>3.1 Missing outcome data: Yes, data available for over 93% of the population</p> <p>Domain 4 - Measurement of the outcome: Low risk</p> <p>4.1 Method for measuring outcome inappropriate: No - self-reporting questionnaires</p> <p>4.2 Could measurement of outcome differed between groups: No - self-reporting questionnaires</p> <p>4.3 Outcome assessors aware of the intervention: No information</p> <p>4.4 Could assessment have been influenced by intervention knowledge: No</p> <p>Domain 5 - Selection of the reported result: Some concerns</p> <p>5.1 Data produced according to pre-specified plan: No information</p> <p>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</p>

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
<p>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 Investigation Gynecol Obstet Invest, 75, 34-40, 2013</p> <p>Ref Id 1196619</p> <p>Country/ies where the study was carried out Turkey</p> <p>Study type Quasi-randomised controlled study</p> <p>Aim of the study To evaluate the role of pelvic floor muscle</p>	<p>Sample size N= 136 quasi-randomised n=68 allocated to intervention; n=52 analysed n=68 allocated to control; n=50 analysed</p> <p>Characteristics Age (years), mean (SD): Intervention 26.33 (4.8); Control 25.70 (4.4)</p> <p>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)</p> <p>Inclusion criteria</p>	<p>Interventions Intervention: Women were given training and information about the reproductive and urinary organs, functions of the PFM and how PFM exercises can strengthen PFM, 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 PFM 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</p>	<p>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).</p>	<p>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)</p>	<p>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 - quasi-random, 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</p>

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

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

Study details	Participants	Interventions	Methods	Outcomes	Comments
<p>Full citation</p> <p>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</p> <p>Ref Id</p> <p>1290383</p> <p>Country/ies where the study was carried out</p> <p>China</p> <p>Study type</p> <p>RCT</p> <p>Aim of the study</p> <p>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</p>	<p>Sample size</p> <p>n=97 n=49 randomised to intervention n=48 randomised to control</p> <p>Characteristics</p> <p>Age (mean, SD): Intervention 28.01 (2.23); Control 27.99 (2.41)</p> <p>BMI (mean, SD): Intervention 21.34 (3.21); control 21.22 (3.51)</p> <p>Inclusion criteria</p> <p>(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</p> <p>Exclusion criteria</p> <p>(1) puerperae with mental diseases (2) those with a history of PFD</p>	<p>Interventions</p> <p>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.</p> <p>(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,</p>	<p>Details</p> <p>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.</p>	<p>Results</p> <p>SUI incidence (number, %)</p> <p>1 month</p> <ul style="list-style-type: none"> Intervention group: 12 (24.49%) Control group: 21 (42.75%) <p>3 months</p> <ul style="list-style-type: none"> Intervention group: 4 (8.16%) Control group: 11 (22.92%) <p>6 months</p> <ul style="list-style-type: none"> Intervention group: 1 (2.04%) Control group: 6 (12.50%) <p>ICIQ-SF (mean, SD)</p> <p>Baseline</p> <ul style="list-style-type: none"> Intervention group: 12.67 (2.01) Control group: 12.71 (1.87) <p>6 months</p>	<p>Limitations</p> <p>Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB2).</p> <p>Domain 1 - randomisation: Low risk</p> <p>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</p> <p>Domain 2 - Deviations from intended interventions (effect of assignment to interventions): Low risk</p> <p>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</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
<p>Study dates Not reported</p> <p>Source of funding Startup Fund for Scientific Research, Fujian Medical University</p>	<p>(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.</p>	<p>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.</p> <p>Control: The CG only received routine postpartum rehabilitation</p>		<ul style="list-style-type: none"> Intervention group: 3.87 (0.32) Control group: 6.91 (0.29) <p>I-QoL (mean, SD) Baseline</p> <ul style="list-style-type: none"> Intervention group: 35.38 (3.23) Control group: 35.61 (3.43) <p>6 months</p> <ul style="list-style-type: none"> Intervention group: 70.28 (3.44) Control group: 61.28 (3.29) 	<p>Domain 3 - Risk of bias due to missing outcome data: Low risk 3.1 Missing outcome data: Yes, data available for all participants</p> <p>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)</p> <p>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</p>

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
<p>Full citation</p> <p>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, <i>Neurourology & Urodynamics</i> 33, 67-71, 2014</p> <p>Ref Id</p> <p>1197038</p> <p>Country/ies where the study was carried out</p> <p>Spain</p> <p>Study type</p> <p>RCT</p>	<p>Sample size</p> <p>N=169 randomised n=73 allocated to intervention; n=63 analysed n=96 allocated to usual care; n=89 analysed</p> <p>Characteristics</p> <p>Age (years), mean (SD): Intervention 29.9 (3.3); Control 29.1 (4.5)</p> <p>Pre-pregnancy BMI (kg/m²), mean (SD): Intervention 23.6 (4.3); Control 22.7 (3.8)</p> <p>Pre-pregnancy physical activity levels: Inactive, n (%): Intervention 33 (53.2); Control 56 (62.9)</p>	<p>Interventions</p> <p>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</p>	<p>Details</p> <p>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).</p>	<p>Results</p> <p>ICIQ-Score, mean (SD): Intervention 0.24 (1.2); Control 2.66 (4.1)</p> <p>Adherence to PFMT - Participants included in the analysis attended at least 80% of 70–78 exercise sessions during at least 22 weeks.</p>	<p>Limitations</p> <p>Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB2).</p> <p>Domain 1 - randomisation: Low risk</p> <p>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</p> <p>Domain 2 - Deviations from intended interventions (effect of</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
<p>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.</p> <p>Study dates October 2009 to October 2011</p> <p>Source of funding None reported</p>	<p>Active, n (%): Intervention 29 (46.8); Control 33 (37.1)</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> • 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. <p>Exclusion criteria</p> <ul style="list-style-type: none"> • planning not to give birth in Fuenlabrada University Hospital • any contraindication according to the American College of Obstetricians and Gynaecologists Guidelines 	<p>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 midwives including information about PFMT) and were not asked not to train their pelvic floor muscles.</p>			<p>assignment to interventions): Low risk</p> <p>2.1 Participants aware of allocation: Yes - women knew if they were receiving intervention or control</p> <p>2.2 Carers and people delivering the intervention aware of allocation: Yes - exercise delivery staff knew</p> <p>2.3 Deviations from intended intervention: Probably no, reported high adherence</p> <p>2.6 Appropriate analysis to estimate effect of assignment: Yes - analysis excluded participants with missing outcomes</p> <p>Domain 3 - Risk of bias due to missing outcome data: Low risk</p> <p>3.1 Missing outcome data: Yes, data available for over 85% of the population</p> <p>Domain 4 - Measurement of the outcome: Low risk</p> <p>4.1 Method for measuring outcome inappropriate: No - self-reporting questionnaire</p> <p>4.2 Could measurement of outcome differed between groups: No - self-reporting questionnaire</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
					<p>4.3 Outcome assessors aware of the intervention: NA - self reported</p> <p>Domain 5 - Selection of the reported result: Some concerns</p> <p>5.1 Data produced according to pre-specified plan: No information</p> <p>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</p> <p>5.3 Are results assessed likely to be selected on basis of results from multiple eligible analysis of the data: Probably no</p> <p>Domain 6 - Overall judgment of bias: Some concerns</p>
<p>Full citation</p> <p>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</p>	<p>Sample size</p> <p>N=84 randomised n= 42 allocated to intervention; n=41 analysed n=42 allocated to control; n=41 analysed</p> <p>Characteristics</p> <p>Age (years), mean (SD): Intervention 26.0 (4.1); Control 25.3 (4.7)</p>	<p>Interventions</p> <p>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</p>	<p>Details</p> <p>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.</p>	<p>Results</p> <p>FSFI: Overall sexual function, <u>28-30 weeks gestation:</u> Intervention 29.3 (4.2); Control 21.1 (4.2) <u>3 months postpartum:</u> Intervention 28.7 (1.8); Control 16.0 (2.1)</p> <p>SQOL-F: Sexual quality of life,</p>	<p>Limitations</p> <p>Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB2).</p> <p>Domain 1 - randomisation: Low risk</p> <p>1.1 Random sequence generation: Yes - block randomisation, computer generated</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
<p>Ref Id 1232729</p> <p>Country/ies where the study was carried out Iran</p> <p>Study type RCT</p> <p>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</p> <p>Study dates Enrolment May to November 2014 and follow-up until July 2015</p> <p>Source of funding Tabriz University of Medical Sciences</p>	<p>BMI (kg/m²), mean (SD): Intervention 25.0 (3.3); Control 24.1 (4.5)</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> • singleton pregnant women at 17 - 20 weeks gestation • aged 18 - 35 years <p>Exclusion criteria</p> <ul style="list-style-type: none"> • having less than 6 years of education • no permanent marriage or not living with husband • prior history of 2 or more abortions • any pregnancy-related complications limiting sexual function (for example placenta 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) 	<p>followed by 3 or 4 contractions in a shorter period, with a 10-second complete relaxation after each contraction.</p> <p>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 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 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.</p>		<p><u>28-30 weeks gestation:</u> Intervention 52.8 (13.6); Control 34.3 (9.0)</p> <p><u>3 months postpartum:</u> Intervention 62.3 (11.4); Control 30.5 (6.1)</p> <p>Adherence to PFMT: Women in the intervention group performed at least 70% of the exercises.</p>	<p>1.2 Allocation concealment: Yes - sealed opaque envelopes</p> <p>1.3 Baseline differences: No - no significant differences reported</p> <p>Domain 2 - Deviations from intended interventions (effect of assignment to interventions): Low risk</p> <p>2.1 Participants aware of allocation: Yes - could not be blinded</p> <p>2.2 Carers and people delivering the intervention aware of allocation: Yes - could not be blinded</p> <p>2.3 Deviations from intended intervention: Not reported</p> <p>2.6 Appropriate analysis to estimate effect of assignment: Yes - analysis excluded participants with missing outcomes</p> <p>Domain 3 - Risk of bias due to missing outcome data: Low risk</p> <p>3.1 Missing outcome data: Yes, data available for over 98% of the population</p> <p>Domain 4 - Measurement of the outcome: Low risk</p> <p>4.1 Method for measuring outcome inappropriate: No - self-reporting</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
	<p>or paralysis, vaginismus)</p> <ul style="list-style-type: none"> taking medications likely to influence sexual function (including blood pressure drugs, thiazide diuretics, anti-depressants, anti-histamines, barbiturates, narcotics, diazepam, 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.			<p>4.2 Could measurement of outcome differed between groups: No - self-reporting</p> <p>4.3 Outcome assessors aware of the intervention: No - blinded to treatment allocation</p> <p>Domain 5 - Selection of the reported result: Some concerns</p> <p>5.1 Data produced according to pre-specified plan: No information</p> <p>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</p> <p>5.3 Are results assessed likely to be selected on basis of results from multiple eligible analysis of the data: Probably no</p> <p>Domain 6 - Overall judgment of bias: Some concerns</p>
<p>Full citation</p> <p>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</p>	<p>Sample size</p> <p>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</p>	<p>Interventions</p> <p>Intervention: women received postpartum educational materials at discharged from the hospital. The comprehensive care and rehabilitation program was performed in the 2nd</p>	<p>Details</p> <p>Women 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</p>	<p>Results</p> <p>Incidence of SUI: Intervention group: 18/120 (15%); Control group: 38/120 (31.7%) N.B. n/N calculated by NGA team</p>	<p>Limitations</p> <p>Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB2).</p> <p>Domain 1 - randomisation: Low risk</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
<p>postpartum stress urinary incontinence, Medicine, 98, e16907, 2019</p> <p>Ref Id</p> <p>1151455</p> <p>Country/ies where the study was carried out</p> <p>China</p> <p>Study type</p> <p>RCT</p> <p>Aim of the study</p> <p>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.</p> <p>Study dates</p> <p>January 2015 to December 2016 (stage 1)</p> <p>Source of funding</p> <p>None reported</p>	<p>Characteristics</p> <p>Age (years), mean (SD): Intervention 29.6 (4.3); Control 30.3 (4.8)</p> <p>BMI (kg/m²), mean (SD): Intervention 23.1 (2.7); Control 23.4 (2.7)</p> <p>Primiparous, n (%): Intervention 42 (35); Control 54 (45)</p> <p>Multiparous, n (%): Intervention 78 (65); Control 66 (55)</p> <p>Previous deliveries 0, n (%): Intervention 78 (65); Control 67 (55.8)</p> <p>1, n (%): Intervention 40 (33.3); Control 52 (43.3)</p> <p>2, n (%): Intervention 2 (1.7); Control 1 (0.9)</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> • singleton term vaginal delivery • bladder pressure was normal • no neurologic bladder dysfunction • able to perform a correct PFM contraction <p>Exclusion criteria</p>	<p>week after delivery, which was conducted weekly for a total of 6 weeks and consisted of 4 parts:</p> <ol style="list-style-type: none"> 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 a near maximal pelvic floor muscle contractions held for 6 to 8 seconds and ended with 3 or 4 fast contractions; the exercises were repeated in lying, 	<p>assessed at week 8 postpartum</p>		<p>1.1 Random sequence generation: Yes - block randomisation computer-based system</p> <p>1.2 Allocation concealment: Probably yes - no information given, but as computer based, likely to be concealed</p> <p>1.3 Baseline differences: No - no significant differences reported</p> <p>Domain 2 - Deviations from intended interventions (effect of assignment to interventions): Low risk</p> <p>2.1 Participants aware of allocation: Yes - no information given, but likely women knew if they were receiving intervention or control</p> <p>2.2 Carers and people delivering the intervention aware of allocation: Yes - education session delivery staff</p> <p>2.3 Deviations from intended intervention: Probably no, no information on deviation given</p> <p>2.6 Appropriate analysis to estimate effect of assignment: Yes - ITT analysis</p> <p>Domain 3 - Risk of bias due to missing outcome data: Low risk</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
	<ul style="list-style-type: none"> • age younger than 18 years old • history of SUI • prenatal urinary incontinence • urinary tract infection or kidney disease • tumours in the genital area. 	<p>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.</p> <p>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.</p> <p>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</p>			<p>3.1 Missing outcome data: Yes, data available for over 93% of the population</p> <p>Domain 4 - Measurement of the outcome: Low risk</p> <p>4.1 Method for measuring outcome inappropriate: No - self-reporting answer to question</p> <p>4.2 Could measurement of outcome differed between groups: No - self-reporting answer to question</p> <p>4.3 Outcome assessors aware of the intervention: NA - self reported</p> <p>Domain 5 - Selection of the reported result: Some concerns</p> <p>5.1 Data produced according to pre-specified plan: No information</p> <p>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</p> <p>5.3 Are results assessed likely to be selected on basis of results from multiple eligible analysis of the data: Probably no</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
		<p>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.</p> <p>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.</p>			Domain 6 - Overall judgment of bias: Some concerns
<p>Full citation</p> <p>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</p> <p>Ref Id</p>	<p>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</p> <p>Characteristics Intervention n=120; Control n=110</p> <p>Age (years), median (range): Intervention 27 (17-42); Control 29 (16-47)</p>	<p>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.</p>	<p>Details At 3 months postpartum, women were assessed 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.</p>	<p>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)</p> <p>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</p>	<p>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 - pseudo-random 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,</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
<p>125709</p> <p>Country/ies where the study was carried out</p> <p>UK</p> <p>Study type</p> <p>RCT</p> <p>Aim of the study</p> <p>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.</p> <p>Study dates</p> <p>Recruitment: 1998 to 1999 (From Agur 2008)</p> <p>Source of funding</p> <p>Wellbeing and local NHS trust</p>	<p>Bladder neck mobility >10mm, n%: Intervention 25 (20.8); Control 29 (26.4)</p> <p>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)</p> <p>BMI, mean (SD): Intervention 24.9 (4.2); Control 24.1 (4.3)</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> • Primigravidae attending the antenatal clinic of a NHS trust hospital • Bladder neck mobility >5mm <p>Exclusion criteria</p> <ul style="list-style-type: none"> • Pre-pregnancy urinary incontinence • Neurological disorder 	<p>To be repeated twice daily.</p> <p>Patients were instructed to contract their pelvic floor muscle every time they coughed or sneezed.</p> <p>At 34 weeks, the number of contractions increased to 12.</p>			<p>but data looks similar between groups</p> <p>Domain 2 - Deviations from intended interventions (effect of assignment to interventions): Some concerns</p> <p>2.1 Participants aware of allocation: Yes</p> <p>2.2 Carers and people delivering the intervention aware of allocation: No - blinded to allocation</p> <p>2.3 Deviations from intended intervention: NI, unclear if reasons for non-adherence were related to the intervention</p> <p>2.4 Would deviations affect outcomes: Probably yes</p> <p>2.5 Are deviations balanced between groups: Yes</p> <p>2.6 Appropriate analysis to estimate effect of assignment: Yes</p> <p>Domain 3 - Risk of bias due to missing outcome data: High risk</p> <p>3.1 Missing outcome data: No, 38% vs. 33% missing data for 1 outcome</p> <p>3.2 Results not biased by missing outcome data:</p>

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

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
<p>Full citation</p> <p>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</p> <p>Ref Id</p> <p>1147320</p> <p>Country/ies where the study was carried out</p> <p>Brazil</p> <p>Study type</p> <p>RCT</p> <p>Aim of the study</p> <p>1. To evaluate the effectiveness of a single PFM exercise session</p>	<p>Sample size</p> <p>N=202 randomised n=98 allocated to intervention; n=67 analysed n=104 allocated to control; n=65 analysed</p> <p>Characteristics</p> <p>Mode of delivery: Caesarean, n (%): Intervention 27 (40.3); Control 28 (43.1) Normal, n (%): Intervention 40 (59.7); Control 37 (56.9)</p> <p>Number of births: Primiparous, n (%): Intervention 33 (49.3); Control 27 (41.5) Multiparous, n (%): Intervention 34 (50.7); Control 38 (58.5)</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> women >18 years of age 	<p>Interventions</p> <p>Intervention: Aimed to reinforce knowledge of PFMT and stimulate the practice of home-based PFMT exercises. The intervention was 2-staged.</p> <p>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</p>	<p>Details</p> <p>A telephone interview was conducted on the 3rd month postpartum using a structured questionnaire. Quality of life with UI was assessed using the ICIQ-SF.</p>	<p>Results</p> <p>ICIQ-SF at 3 months postpartum, median (IQR): Intervention 0 (\pm1.06); Control 0 (\pm1.06)</p> <p>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)</p> <p>Duration of PFMT, n (%) 3 months postpartum: 21 (31.3) 2 months postpartum: 46 (68.7)</p>	<p>Limitations</p> <p>Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB2).</p> <p>Domain 1 - randomisation: High risk</p> <p>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</p> <p>Domain 2 - Deviations from intended interventions (effect of assignment to interventions): Low risk</p> <p>2.1 Participants aware of allocation: Yes -</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
<p>immediately post-partum to prevent urinary incontinence at 3-month follow-up;</p> <p>2. To verify adherence rates to home-based PFM exercises among multiparous and primiparous women.</p> <p>Study dates September 2011 to December 2011</p> <p>Source of funding None reported</p>	<ul style="list-style-type: none"> able to understand Portuguese immediately postpartum after having given birth to a live child. <p>Exclusion criteria</p> <ul style="list-style-type: none"> 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. 	<p>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.</p> <p>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</p>			<p>participants were not blinded to their allocation</p> <p>2.2 Carers and people delivering the intervention aware of allocation: Yes - assessors were not blinded to the allocations</p> <p>2.3 Deviations from intended intervention: Probably no, not reported, but unlikely</p> <p>2.6 Appropriate analysis to estimate effect of assignment: Yes - ITT analysis and also analysis that excluded participants with missing outcomes</p> <p>Domain 3 - Risk of bias due to missing outcome data: Low risk</p> <p>3.1 Missing outcome data: No, data available for over 62% of the population</p> <p>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</p> <p>Domain 4 - Measurement of the outcome: Low risk</p> <p>4.1 Method for measuring outcome inappropriate: No - self-reporting</p> <p>4.2 Could measurement of outcome differed between groups: No - self reporting</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
		<p>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.</p> <p>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.</p>			<p>4.3 Outcome assessors aware of the intervention: NA - self reported</p> <p>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</p> <p>Domain 6 - Overall judgment of bias: High risk of bias</p>
Full citation	Sample size N=480 randomised	Interventions Intervention: a 2-h group education session and	Details 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
<p>Sampsel, 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, <i>International Urogynecology Journal</i>, 16, 441-446, 2005</p> <p>Ref id 1176510</p> <p>Country/ies where the study was carried out USA</p> <p>Study type RCT</p> <p>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.</p> <p>Study dates Not reported</p>	<p>n=238 assigned to intervention; n=164 analysed n=242 assigned to control; n=195 analysed</p> <p>Characteristics Age (years), mean (SD): Intervention 65.4 (6.7); Control 66.2 (6.4)</p> <p>Race - white: Intervention 81%; Control 84%</p> <p>One or more births: Intervention 88%; Control 90%</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> 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, 	<p>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 self-care, 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.</p> <p>Control: no education</p>	<p>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.</p> <p>At 1 year follow-up, women completed a 3-day voiding diary and clinical evaluations.</p>	<p>asleep, while awake) showed significant reductions in the treatment group (p<0.0001) – reported in a way that data could not be extracted.</p> <p>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</p> <p>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</p> <p>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</p> <p>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</p>	<p>Cochrane risk-of-bias tool for randomised trials (RoB2).</p> <p>Domain 1 - randomisation: Some concerns</p> <p>1.1 Random sequence generation: No information 1.2 Allocation concealment: No information 1.3 Baseline differences: No - no significant differences reported</p> <p>Domain 2 - Deviations from intended interventions (effect of assignment to interventions): Low risk</p> <p>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</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
<p>Source of funding National Institutes of Health-National Institute of Aging MERIT Award R37 AG08511 and Nursing R01 NR0718.</p>	<p>behavioural techniques, or surgical therapy</p> <ul style="list-style-type: none"> • 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 <p>Exclusion criteria None reported</p>				<p>group about the studies purpose</p> <p>2.6 Appropriate analysis to estimate effect of assignment: Yes - analysis excluded participants with missing outcomes</p> <p>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</p> <p>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</p> <p>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</p>

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
<p>Full citation</p> <p>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, <i>European Journal of Obstetrics, Gynecology, & Reproductive Biology</i>, 197, 103-10, 2016</p> <p>Ref Id</p> <p>663833</p> <p>Country/ies where the study was carried out</p> <p>Thailand</p> <p>Study type</p> <p>RCT</p>	<p>Sample size</p> <p>N=70 Randomised n=35 allocated to intervention, n=33 analysed n=35 allocated to control, n=30 analysed</p> <p>Characteristics</p> <p>Age (years), mean (SD): Intervention 27.6 (5.09); Control 28.2 (5.01)</p> <p>BMI before pregnancy (kg/m²), mean (SD): Intervention 21.7 (1.89); Control 22 (1.92)</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> pregnant women who were age 18 years and older gestational ages of 20–30 weeks singleton foetus 	<p>Interventions</p> <p>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 ascertain 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</p>	<p>Details</p> <p>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.</p>	<p>Results</p> <p>Women with SUI at 38 weeks, n (%): Intervention 9 (27.3); Control 16 (53.3)</p> <p>Adherence to PFMT: No women in the intervention failed by performing their PFME for <28 days</p>	<p>Limitations</p> <p>Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB2).</p> <p>Domain 1 - randomisation: Low risk</p> <p>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</p> <p>Domain 2 - Deviations from intended interventions (effect of assignment to interventions): Low risk</p> <p>2.1 Participants aware of allocation: Yes - participants not blinded 2.2 Carers and people delivering the intervention aware of allocation: Yes</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
<p>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.</p> <p>Study dates July 2012 and October 2012 and follow-up until March 2013</p> <p>Source of funding Faculty of Nursing, Srinakharinwirot University.</p>	<ul style="list-style-type: none"> pre-pregnancy body mass index (BMI) of <30 kg/m². <p>Exclusion criteria</p> <ul style="list-style-type: none"> pregnant women with SUI symptoms during pregnancy, pregnancy complications such as preterm labour pregnancy induced hypertension (PIH) gestational diabetes mellitus (GDM) antenatal haemorrhage, etc. pain during pelvic floor muscle contraction diseases that could interfere with the participant 	<p>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.</p> <p>Control group: received regular prenatal care according to the hospital guideline.</p>			<p>- health providers not blinded</p> <p>2.3 Deviations from intended intervention: No information</p> <p>2.6 Appropriate analysis to estimate effect of assignment: Yes - analysis excluded participants with missing outcomes</p> <p>Domain 3 - Risk of bias due to missing outcome data: Low risk</p> <p>3.1 Missing outcome data: Yes, data available for over 86% of the population</p> <p>Domain 4 - Measurement of the outcome: Low risk</p> <p>4.1 Method for measuring outcome inappropriate: No - self reporting</p> <p>4.2 Could measurement of outcome differed between groups: No - self reporting</p> <p>4.3 Outcome assessors aware of the intervention: Yes - assessors not blinded</p> <p>4.4 Outcome assessment influenced by intervention knowledge: No - self reported</p> <p>Domain 5 - Selection of the reported result: Some concerns</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
					<p>5.1 Data produced according to pre-specified plan: No information</p> <p>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</p> <p>5.3 Are results assessed likely to be selected on basis of results from multiple eligible analysis of the data: Probably no</p> <p>Domain 6 - Overall judgment of bias: Some concerns</p>
<p>Full citation</p> <p>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</p> <p>Ref Id</p> <p>650704</p>	<p>Sample size</p> <p>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</p> <p>Characteristics</p> <p>Age (years), mean (SD): Intervention 28.64 (2.16); Control 29.0 (1.97)</p>	<p>Interventions</p> <p>PFMT group</p> <ul style="list-style-type: none"> • 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 hypogastrica, perineum and anal muscles for 5-s while inhaling to create the feeling of lifting the pelvic floor muscles, then to relax the hypogastrica while exhaling for 5-s. Each training lasted 20 min with the exercises 	<p>Details</p> <p>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.</p>	<p>Results</p> <p>POP-Q grade at 3 months:</p> <p>Grade 0, n (%): Intervention 42 (66.7); Control 28 (46.7)</p> <p>Grade I, n (%): Intervention 18 (28.6); Control 27 (45.0)</p> <p>Grade II, n (%): Intervention 3 (4.8); Control 5 (8.3)</p> <p>Grade III, n (%): Intervention 0 (0); Control 0 (0)</p> <p>Grade IV, n (%): Intervention 0 (0); Control 0 (0)</p> <p>Score of urinary incontinence</p>	<p>Limitations</p> <p>Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB2).</p> <p>Domain 1 - randomisation: Low risk</p> <p>1.1 Random sequence generation: Yes - random number table</p> <p>1.2 Allocation concealment: Probably yes - no information given, but likely to be concealed</p> <p>1.3 Baseline differences: No - no significant differences reported</p> <p>Domain 2 - Deviations from intended</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
<p>Country/ies where the study was carried out</p> <p>China</p> <p>Study type RCT</p> <p>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</p> <p>Study dates January 2011 to May 2014</p> <p>Source of funding No funding reported</p>	<p>BMI (kg/m²), mean (SD): Intervention 26.22 (1.90); Control 25.65 (1.47)</p> <p>Spontaneous vaginal delivery, n (%): Intervention 21 (31.8); Control 18 (30) Assisted delivery, n (%): Intervention 45 (68.2); Control 42 (70)</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> • 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). <p>Exclusion criteria</p> <ul style="list-style-type: none"> • participants with heart diseases, diabetes, high blood pressure, SUI or POP 	<p>performed 6 times per minute.</p> <ul style="list-style-type: none"> • Pelvic movements: patients were to <ul style="list-style-type: none"> ○ 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 ankle while pulling 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 <p>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</p> <p>Control group</p>		<p>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)</p> <p>Pad test Positive, n (%): Intervention 12 (19); Control 15 (25.0)</p>	<p>interventions (effect of assignment to interventions): Some concerns</p> <p>2.1 Participants aware of allocation: Yes - no information given, but likely women knew if they were receiving intervention or control</p> <p>2.2 Carers and people delivering the intervention aware of allocation: Probably yes - specialised training staff delivered the intervention</p> <p>2.3 Deviations from intended intervention: No information</p> <p>2.6 Appropriate analysis to estimate effect of assignment: Yes - analysis excluded participants with missing outcomes</p> <p>Domain 3 - Risk of bias due to missing outcome data: Low risk</p> <p>3.1 Missing outcome data: Yes, data available for over 75% of the population</p> <p>Domain 4 - Measurement of the outcome: Low risk</p> <p>4.1 Method for measuring outcome inappropriate: Predominately self-reporting</p> <p>4.2 Could measurement of outcome differed</p>

Study details	Participants	Interventions	Methods	Outcomes	Comments
	<ul style="list-style-type: none"> • participants with rubra, serosa or lochia alba • participants with a heart pacemaker • participants who had a laparotomy • patients with cancer • participants with a nervous system disease 	<p>Usual postpartum care</p> <p>A third group received a combination treatment but this was not relevant to the protocol.</p>			<p>between groups: Predominately self-reporting</p> <p>4.3 Outcome assessors aware of the intervention: No - data collection staff did not know group allocations</p> <p>Domain 5 - Selection of the reported result: Some concerns</p> <p>5.1 Data produced according to pre-specified plan: No information</p> <p>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</p> <p>5.3 Are results assessed likely to be selected on basis of results from multiple eligible analysis of the data: Probably no</p> <p>Domain 6 - Overall judgment of bias: Some concerns</p>

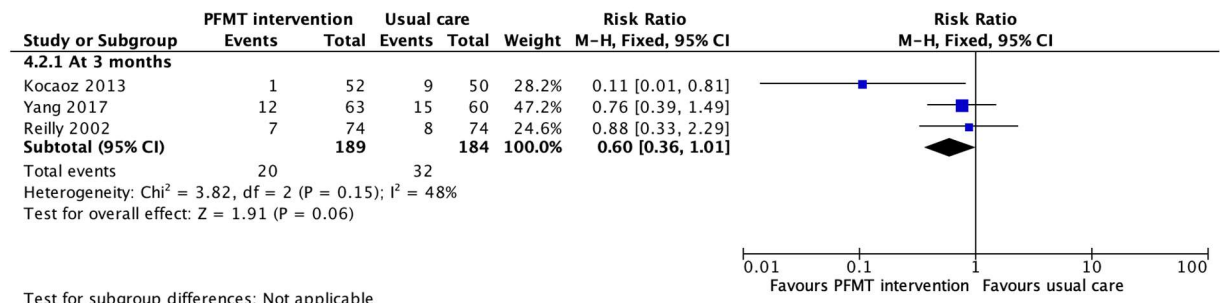
1 BMI: body mass index; FSFI: female sexual function index; ICIQ: International Consultation on Incontinence Questionnaire; IIQ-7: Incontinence impact questionnaire; I-QOL:
2 Incontinence quality of life questionnaire; ITT: Intention to treat; NGA: National Guideline Alliance; OAB-q: overactive bladder questionnaire; PFD: pelvic floor dysfunction;
3 PFDI-20: pelvic floor disability index-20; PFIQ: pelvic floor impact questionnaire; PFM: pelvic floor muscle; PFME: pelvic floor muscle exercises; PFMT: pelvic floor muscle
4 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
5 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:
6 urinary incontinence
7

8 Appendix E – Forest plots

9 Forest plots for review question: What is the effectiveness of pelvic floor muscle training for preventing pelvic floor dysfunction?

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

14 Figure 3 Positive pad test at 3 months



1 Appendix F – GRADE tables

2 GRADE tables for review question: What is the effectiveness of pelvic floor muscle training for preventing pelvic floor 3 dysfunction?

4 **Table 6: Clinical evidence profile for comparison pelvic floor muscle training to no treatment for symptoms of urinary incontinence**
5 **(Setting: Community - postmenopausal women over 55 years)**

Quality assessment							No 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		
Without UI – at 12 months (Better indicated by higher values)												
Diokno 2004	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	serious ²	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

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

8 ¹ Serious risk of bias in the evidence contributing to the outcomes as per RoB 2

9 ² 95% CI crosses 1 MID (0.8 or 1.25)

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

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PFM education and re-education	No treatment for PFD	Relative (95% CI)	Absolute		
PFD symptoms (PFDI-20) - After 2 months (Better indicated by lower values)												
Berzuk 2015	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	very serious ²	none	3/48 (6.3%)	8/49 (16.3%)	RR 0.38 (0.11 to 1.36)	101 fewer per 1000 (from 145 fewer to 59 more)	VERY LOW	CRITICAL

PFD QoL symptoms (PFIQ-7) - After 2 months (Better indicated by lower values)												
Berzuk 2015	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	very serious ²	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

¹ Serious risk of bias in the evidence contributing to the outcomes as per RoB 2

² 95% CI crosses 2 MIDs (0.8 and 1.25)

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)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PFM education	No treatment for PFD	Relative (95% CI)	Absolute		
PFD symptoms (PFDI-20) - After 2 months (Better indicated by lower values)												
Berzuk 2015	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	very serious ²	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	serious ¹	no serious inconsistency	no serious indirectness	very serious ²	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

¹ Serious risk of bias in the evidence contributing to the outcomes as per RoB 2

² 95% CI crosses 2 MIDs (0.8 and 1.25)

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

Quality assessment							No 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		
Urinary incontinence - At 3 months postpartum (Better indicated by lower values)												
Chiarelli 2002	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	serious ²	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 incontinence - At 12 months postpartum (Better indicated by lower values)												
Chiarelli 2004	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	serious ²	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 - Score 0 (Better indicated by higher values)												
Yang 2017	randomised trials	serious ¹	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 - Score 1 (Better indicated by higher values)												
Yang 2017	randomised trials	serious ¹	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 - Score 2 (Better indicated by lower values)												
Yang 2017	randomised trials	serious ¹	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 - Score 3 (Better indicated by lower values)												
Yang 2017	randomised trials	serious ¹	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 assessment							No 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		
UI Score at 3 months - Score 4 (Better indicated by lower values)												
Yang 2017	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	very serious ³	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 indicated by lower values)												
Chiarelli 2002	randomised trials	serious ¹	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 36-38 weeks gestation (Better indicated by lower values)												
Kahyaoglu 2016	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	very serious ³	none	30	30	-	MD 2.8 lower (1.60 lower to 7.20 higher)	VERY LOW	CRITICAL
IIQ-7 - At 36-38 weeks gestation (Better indicated by lower values)												
Kahyaoglu 2016	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	very serious ³	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)												
Kahyaoglu 2016	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	very serious ³	none	30	30	-	MD 4.30 lower (11.16 lower to 2.56 higher)	VERY LOW	CRITICAL
UDI-6 - At 6-8 weeks postpartum (Better indicated by lower values)												
Kahyaoglu 2016	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	very serious ³	none	30	30	-	MD 0.1 higher (3.67 lower to 3.87 higher)	VERY LOW	CRITICAL
IIQ-7 - At 6-8 weeks postpartum (Better indicated by lower values)												
Kahyaoglu 2016	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	serious ²	none	30	30	-	MD 1.4 higher (0.97 lower to 3.77 higher)	LOW	CRITICAL
OAB-q - At 6-8 weeks postpartum (Better indicated by lower values)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PFMT	No treatment for UI	Relative (95% CI)	Absolute		
Kahyaoglu 2016	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	very serious ³	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	serious ¹	no serious inconsistency	no serious indirectness	no serious imprecision	none	63	89	-	MD 2.42 lower (3.32 to 1.52 lower)	MODERATE	CRITICAL
ICIQ - At 3 months postpartum (Better indicated by lower values)												
Sacomori 2019	randomised trials	very serious ⁴	no serious inconsistency	no serious indirectness	serious ⁵	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

1 Serious risk of bias in the evidence contributing to the outcomes as per RoB 2

2 95% CI crosses 1 MID (0.8 or 1.25)

3 95% CI crosses 2 MIDs (0.8 and 1.25)

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

5 Subjective assessment of imprecision

1
2
3
4
5
6
7

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

Quality assessment							No of patients		Effect		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 urinary incontinence - At 38 weeks gestation (Better indicated by lower values)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PFMT	No treatment for Stress UI	Relative (95% CI)	Absolute		
Sangsawang 2016	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	serious ²	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 urinary incontinence - At 8 weeks postpartum (Better indicated by lower values)												
Qi 2019	randomised trials	serious ¹	no serious inconsistency	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 urinary incontinence - At 3 months postpartum (Better indicated by lower values)												
Reilly 2002	randomised trials	very serious ³	no serious inconsistency	no serious indirectness	serious ²	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 urinary incontinence - At 6 months follow up (Better indicated by lower values)												
Lin 2020	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	very serious ⁴	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 urinary incontinence - At 8 year follow-up (Better indicated by lower values)												
Agur 2008	randomised trials	very serious ³	no serious inconsistency	no serious indirectness	very serious ⁴	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 pad test - At 28 weeks gestation (Better indicated by lower values)												
Kocaoz 2013	randomised trials	serious ¹	no serious inconsistency	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		Effect		Quality	Importance
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 pad test - At 32 weeks gestation (Better indicated by lower values)												
Kocaoz 2013	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	no serious imprecision	none	9/52 (17.3%)	24/50 (48.0%)	RR 0.36 (0.19 to 0.70)	307 fewer per 1000 (from 144 fewer to 389 fewer)	MODERATE	CRITICAL
Positive pad test - At 3 months (Better indicated by lower values)												
3 ⁵	randomised trials	very serious ³	no serious inconsistency	no serious indirectness	serious ²	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 – at 6 months follow up (Better indicated by lower values)												
Lin 2020	randomised trials	serious ¹	no serious inconsistency	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 months follow up (Better indicated by higher values)												
Lin 2020	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	no serious imprecision	none	49	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

¹ Serious risk of bias in the evidence contributing to the outcomes as per RoB 2

² 95% CI crosses 1 MID (0.8 or 1.25)

³ Very serious risk of bias in the evidence contributing to the outcomes as per RoB 2

⁴ 95% CI crosses 2 MIDs (0.8 and 1.25)

⁵ See forest plot

1
2
3
4
5
6
7
8
9
10

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

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PFMT	No treatment for POP	Relative (95% CI)	Absolute		
POP Grade at 3 months - Grade 0 (Better indicated by higher values)												
Yang 2017	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	serious ²	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	CRITICAL
POP Grade at 3 months - Grade I or II (Better indicated by lower values)												
Yang 2017	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	serious ²	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	CRITICAL

3 *CI: confidence interval; PFMT: pelvic floor muscle training; POP: pelvic organ prolapse; RR: Relative risk*

4 ¹ *Serious risk of bias in the evidence contributing to the outcomes as per RoB 2*

5 ² *95% CI crosses 1 MID (0.8 or 1.25)*

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

Quality assessment							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		
FSFI total score - At 28-30 weeks gestation (Better indicated by lower values)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PFMT	No treatment for Sexual Dysfunction	Relative (95% CI)	Absolute		
Pourkhiz 2017	randomised trials	serious ¹	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 score - At 3 months postpartum (Better indicated by lower values)												
Pourkhiz 2017	randomised trials	serious ¹	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 score - At 4 months postpartum (Better indicated by lower values)												
Citak 2010	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	serious ²	none	37	38	-	MD 0.85 lower (3.02 lower to 1.32 higher)	LOW	CRITICAL
FSFI total score - At 7 months postpartum (Better indicated by lower values)												
Citak 2010	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	serious ²	none	37	38	-	MD 2.34 higher (0.29 to 4.39 higher)	LOW	CRITICAL
Bailes sexual self-efficacy total score - At 12 weeks postpartum (Better indicated by lower values)												
Golmakani 2015	randomised trials	serious ¹	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 sexual self-efficacy total score - At 16 weeks postpartum (Better indicated by lower values)												
Golmakani 2015	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	serious ³	none	40	39	-	MD 10.5 higher (4.9 to 16.1 higher)	LOW	CRITICAL
SQOL-F - At 3 months postpartum (Better indicated by lower values)												
Pourkhiz 2017	randomised trials	serious ¹	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 postpartum (Better indicated by lower values)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PFMT	No treatment for Sexual Dysfunction	Relative (95% CI)	Absolute		
Pourkhiz 2017	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	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

¹ Serious risk of bias in the evidence contributing to the outcomes as per RoB 2

² 95% CI crosses 1 MID (published - 2.1)

³ 95% CI crosses 1 MID (0.5 x baseline control SD, MID=6.15)

1
2
3
4
5

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

Quality assessment							No 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		
PFMT exercises 3 times per week or more - After 12 months (Better indicated by higher values)												
Chiarelli 2002	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	no serious imprecision	none	292/348 (83.9%)	189/328 (57.6%)	RR 3.83 (2.68 to 5.50)	1000 more per 1000 (from 968 more to 1000 more)	MODERATE	IMPORTANT
PFMT exercises 3 times per week or more - After 12 months (Better indicated by higher values)												
Chiarelli 2004	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	no serious imprecision	none	117/294 (39.8%)	89/275 (32.4%)	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;

¹ Serious risk of bias in the evidence contributing to the outcomes as per RoB 2

7
8
9
10

1 **Appendix G – Economic evidence study selection**

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

4

5

1 **Appendix H – Economic evidence tables**

2 **Economic evidence tables for review question: What is the effectiveness of pelvic floor muscle training for preventing pelvic** 3 **floor dysfunction?**

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

5

1 Appendix I – Economic evidence profiles

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

4 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 ¹	Directly applicable	Type of economic analysis: Cost-utility analysis Time horizon: Lifetime Primary measure of outcome: Incremental net monetary benefit	£282	0.025	£11,188 iNMB ² = £222	For base case analysis: 62.5% probability of being cost-effective at a cost-effectiveness threshold of £20,000 per QALY and a population urinary incontinence risk of 50% Threshold analysis: Treatment likely to be cost-effective when population urinary incontinence risk is greater than 30%

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
<ol style="list-style-type: none"> <li data-bbox="309 300 1957 328">1. <i>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</i> <li data-bbox="309 328 1155 357">2. <i>iNMB calculated using a cost-effectiveness threshold of £20,000 per QALY</i> 							

1
 2
 3
 4
 5
 6
 7
 8
 9
 10

1 Appendix J – Economic analysis

2 Economic evidence analysis for review question: What is the effectiveness of 3 pelvic floor muscle training for preventing pelvic floor dysfunction?

4 Cost-utility analysis of supervised pelvic floor muscle training provided 5 antenatally to prevent pelvic floor dysfunction

6 Introduction

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

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

21 A total of 15 studies were included in this review but it was not possible to synthesise the
22 individual studies to provide an aggregated measure of treatment effect. Most of the studies
23 had follow-up of less than 12 months or less and therefore it was decided to use the Reilly
24 (2002) and Agur (2008) study pair as the basis for this economic analysis. These 2 papers
25 were based on the same intervention but reported outcomes at a follow-up at 3 months’ post-
26 partum and 8 years respectively. In addition to the longer follow-up provided, the studies
27 were also considered suitable for economic analysis because the intervention was
28 undertaken in a UK population and reported stress urinary incontinence as a main outcome,
29 from which an impact on health related quality of life can be estimated. The intervention
30 consisted of supervised PFMT in the antenatal period starting at a gestational age of 20
31 weeks and continuing at monthly intervals until birth and this is the intervention that is
32 assessed in this economic evaluation. It is compared to no preventative PFMT. Although
33 there were other populations of interest there was a lack of suitable clinical data and studies
34 on which to populate an economic model.

35 Methods

36 *Setting and population*

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

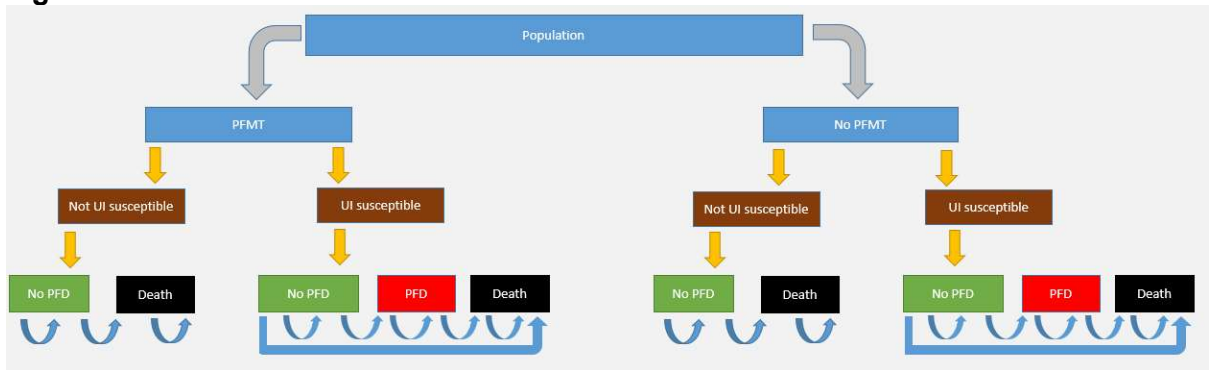
43 Reflecting the outcomes in Reilly (2002) and Agur (2008) stress urinary incontinence was
44 used as a proxy for pelvic floor dysfunction.

1

2 **Model structure**

3 A decision analytic Markov model was developed in Microsoft Excel® to assess the cost-
4 utility of supervised PFMT to prevent pelvic floor dysfunction during their first pregnancy
5 when compared to no preventative PFMT. A schematic of the model is shown in Figure 4
6 which illustrates the 2 decision alternatives under comparison.

Figure 4: Schematic of Markov decision model



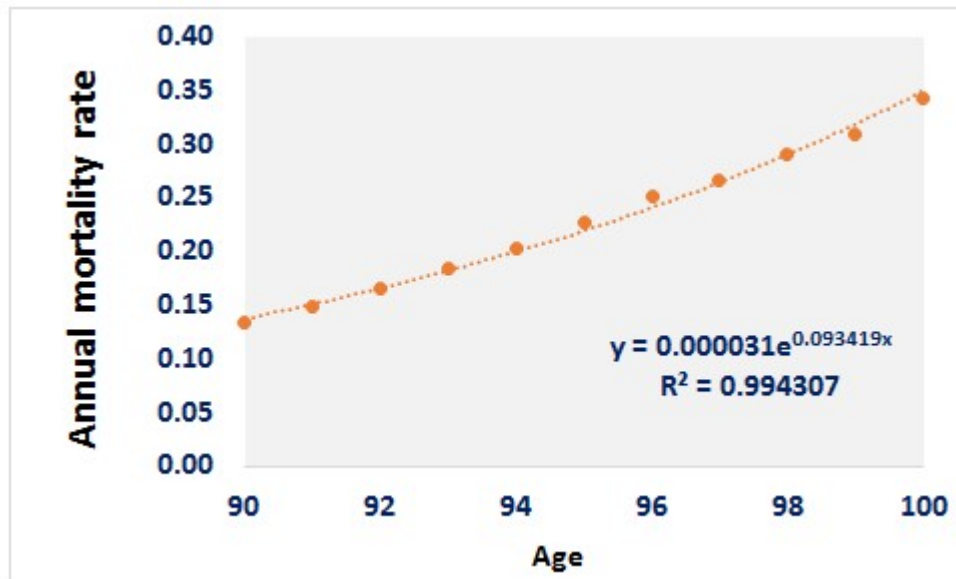
7 The Markov model comprises of 3 possible mutually exclusive health states:

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

11 The passage of time is considered in discrete periods known as 'cycles', which are set to 1
12 month in this analysis. At the end of each cycle, as illustrated in Figure 4, a woman can
13 remain in the same health state or transition from PFD to No PFD or to death from either
14 PFD or No PFD. A simplifying assumption is made that there is no transition from PFD to No
15 PFD recognising that, in practice, progression and remission occur across the natural history.

16 Transition probabilities determine movements to alternative health states. The transition to
17 death is independent of pelvic floor status and probabilities are derived from ONS life tables
18 (<https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/lifeexpectancies/datasets/nationallifetablesenglandandwalesreferencetables>). However, ONS life
19 tables do not go beyond 100 years of age and to predict annual mortality above 100 years of
20 age an exponential curve was fitted to the mortality trend between 90 years and 100 years of
21 age and this relationship was then used to extrapolate the annual mortality rate for women
22 aged over 100 years. This functional relationship between age and mortality is shown in
23 Figure 5.
24

Figure 5: Graph to show relationship between increasing age and the annual mortality rate



1

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

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

12 In the base case analysis, it is assumed that the population lifetime risk of PFD (as measured
13 by urinary incontinence) is 50% which approximates the lifetime risk estimated for the
14 population in the Reilly (2002) and Agur (2008), see Figure 7.

15 **Natural history model**

16 In order to model the natural history of urinary incontinence in the model population, the rate
17 or risk of urinary incontinence at different points in time was estimated. It was then possible
18 to fit a mathematical relationship to these points to give a rate of urinary incontinence as a
19 function of time, measured in months, since the woman gave birth. The risk of urinary
20 continence at 3 months' post-partum and at 8 years was taken from the control arm of Reilly
21 (2002) and Agur (2008) respectively.

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

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

4

5 **i. 12-year model**

6 Log-odds of risk (LO_{risk}) =

$$\begin{aligned} 7 & -0.10286298 - (0.094854567 \times \text{parity}) + (0.024763229 \times \text{age}) + \\ 8 & (0.0086028615 \times \text{pre-pregnancy weight}) - (0.010742873 \times \text{height}) + \\ 9 & (1.7818611 \times \text{pre-pregnancy UI}) + (1.4080395 \times \text{UI during pregnancy}) + \\ 10 & (0.63365899 \times \text{family history of pelvic organ prolapse}) + \\ 11 & (0.40814509 \times \text{vaginal birth}) \end{aligned}$$

12

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

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

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

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

17

18 $\text{Risk} = 1 \div (1 + \exp (LO_{risk}))$

19

20 **ii. 20-year model**

21 Log-odds of risk (LO_{risk}) =

$$\begin{aligned} 22 & -0.3263724 + (0.026066663 \times \text{age}) + \\ 23 & (0.018820574 \times \text{pre-pregnancy weight}) - (0.018268529 \times \text{height}) + \\ 24 & (1.5764999 \times \text{family history of UI}) + (0.53946364 \times \text{vaginal birth}) \end{aligned}$$

25

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

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

28

29 $\text{Risk} = 1 \div (1 + \exp (LO_{risk}))$

30

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

1 **Table 15: Population risk factors for predicting urinary incontinence from UR-CHOICE**
 2 **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 ^a
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.uk/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

3 (a) $Weight = BMI \times height^2$; 24.5×1.619^2

4

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

8 **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

1

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

6 **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 ^a

7

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

8 The model is configured to allow either a linear or logarithmic relationship to be fitted to these
 9 data points and 4 alternatives functions are illustrated in Figure 6, Figure 7, Figure 8 and
 10 Figure 9, reflecting the mathematical form and whether the relationship includes the user
 11 defined lifetime risk at 1,000 months. In the base case analysis, a logarithmic relationship is
 12 assumed utilising the 4 data points derived from Reilly (2002), Agur (2008) and the UR-
 13 CHOICE prediction model. The best fit lines were fitted deterministically as it was not
 14 possible to quantify the uncertainty around data points estimated from the prediction model.

Figure 6: Estimated relationship between UI risk and time using 4 data points and a logarithmic functional form

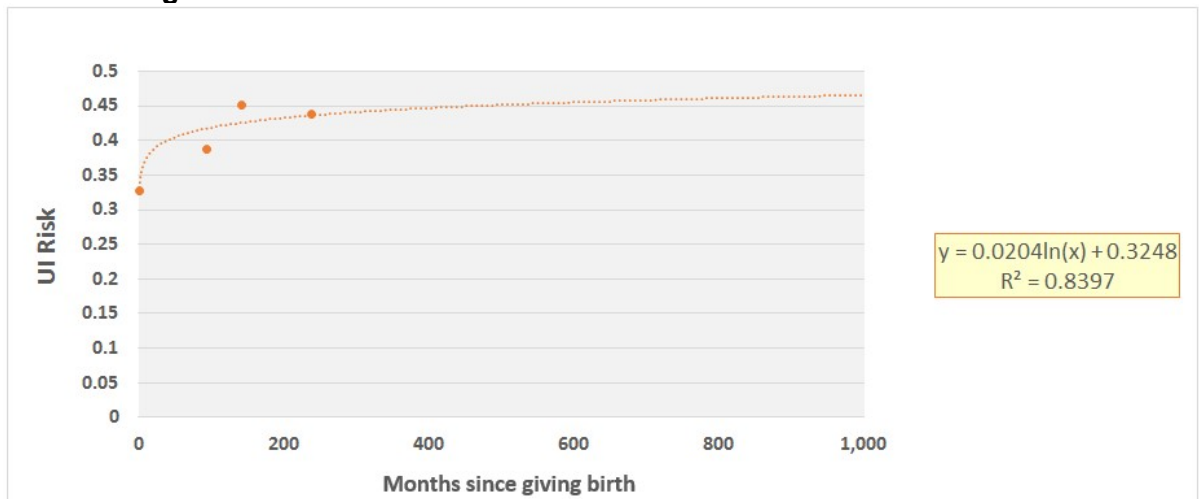
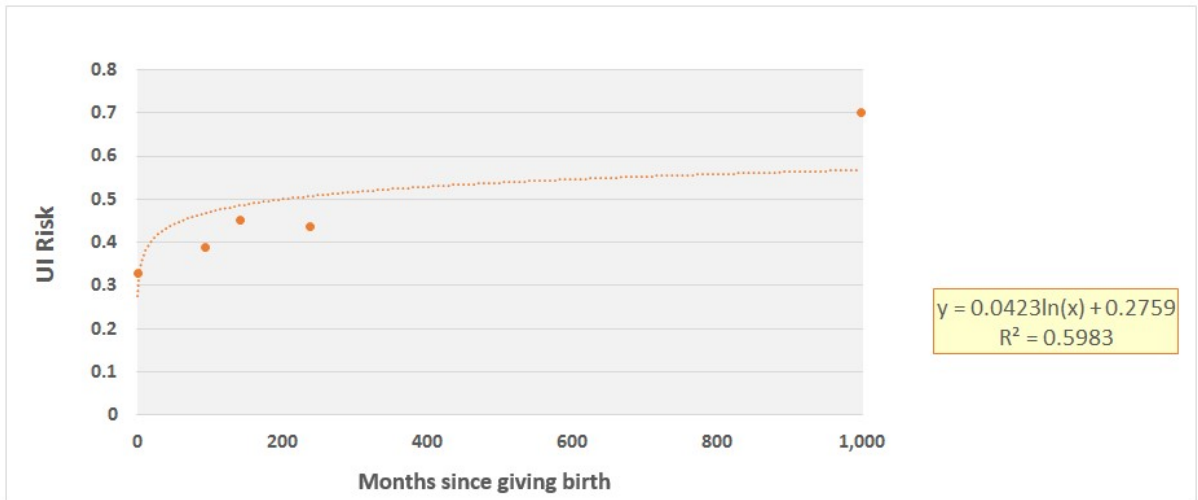


Figure 7: Estimated relationship between UI risk and time using 5 data points and a logarithmic functional form



1

Figure 8: Estimated relationship between UI risk and time using 4 data points and a linear functional form

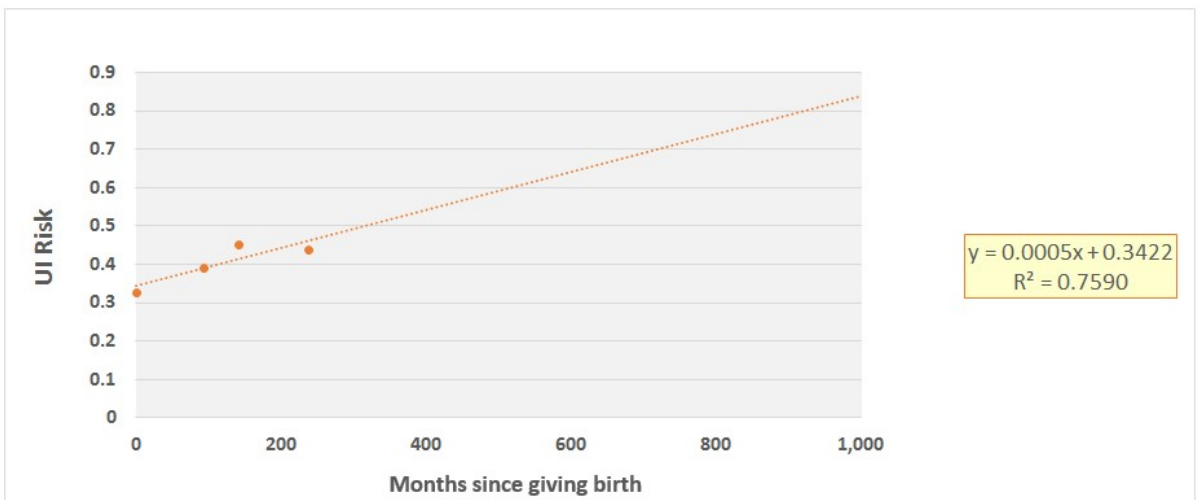
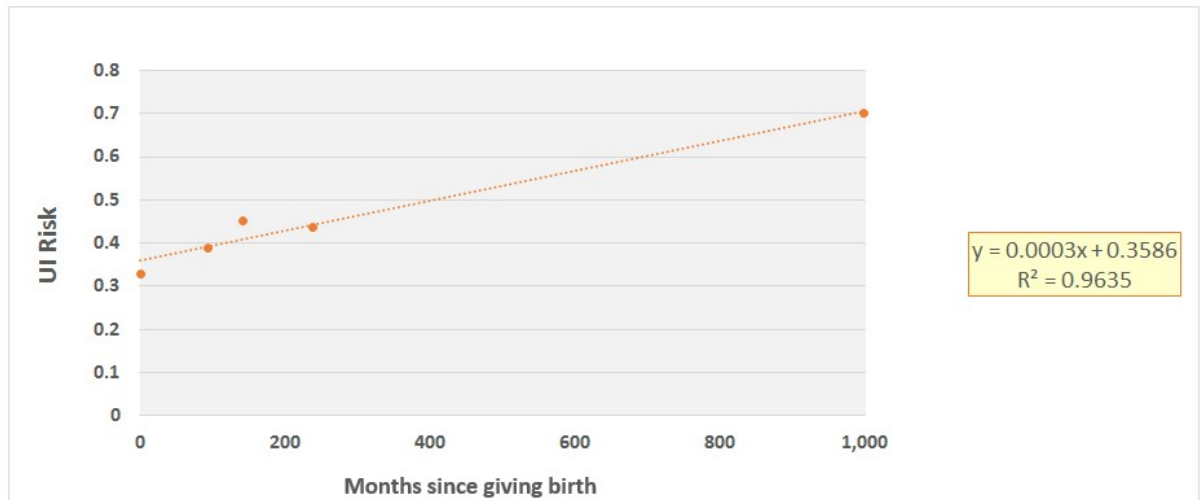
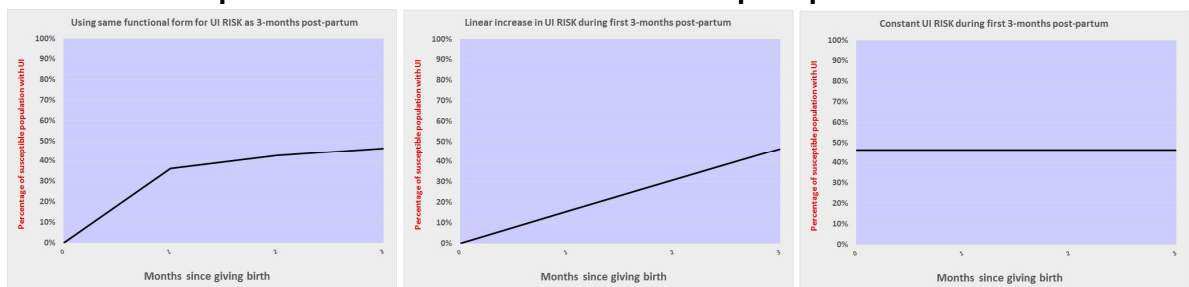


Figure 9: Estimated relationship between UI risk and time using 5 data points and a linear functional form



- 1 However, the first data point is at 3-months post-partum and therefore there is additionally
- 2 the period from birth to 3-months post-partum to consider. The model allows 3 different
- 3 relationships for this period, which are shown in Figure 10:
- 4 i. Use the same relationship between UI risk and time as for the period beyond 3-
- 5 months post-partum
- 6 ii. Assume a linear increase in UI risk from zero at birth to the estimated risk at 3-
- 7 months post-partum
- 8 iii. Assume that the UI risk is constant before 3-months post-partum at the same level
- 9 of risk estimated for 3-months post-partum

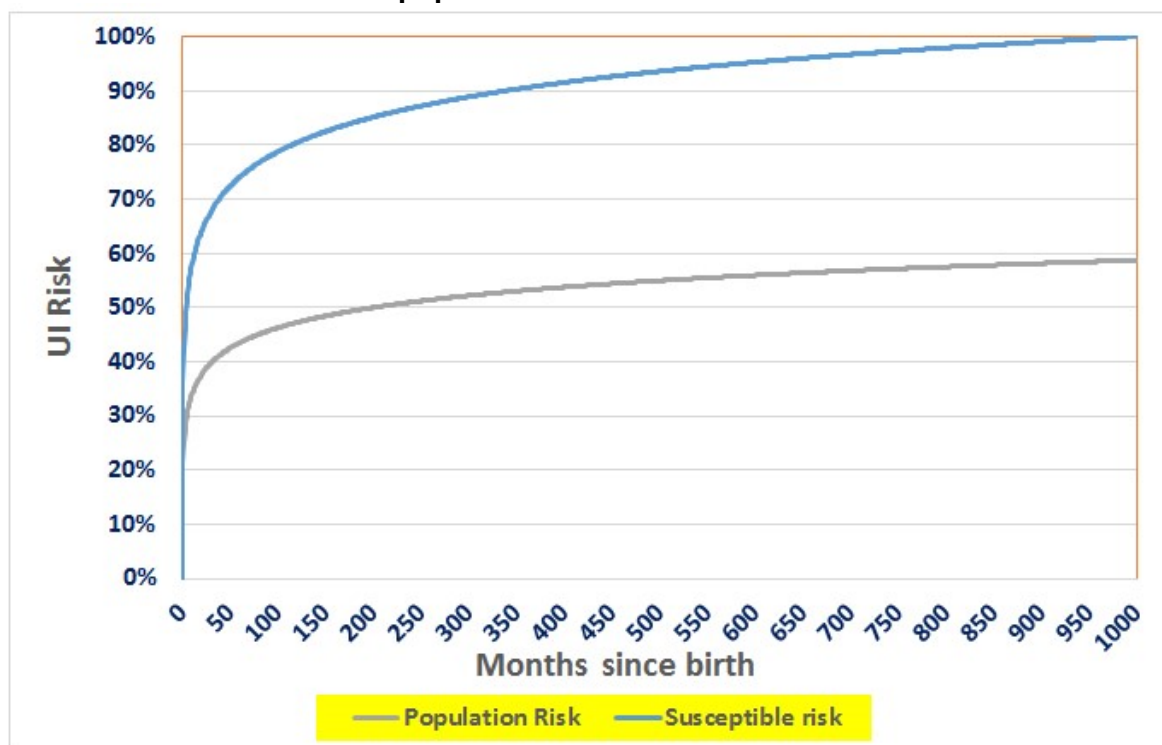
Figure 10: Graph to show alternative functional forms for natural history of UI in susceptible women from birth to 3-months post-partum



- 10 The relationships derived thus far model the risk of UI across the entire model population.
- 11 However, the model assumes that the population comprises 2 distinct groups. It assumes
- 12 that some women are susceptible to UI and could potentially benefit from treatment which
- 13 could avert or delay the onset of UI. Conversely, it assumes that there are non-susceptible
- 14 women who will not develop UI and therefore have no capacity to benefit from treatment. The
- 15 risk of UI across the entire population is a weighted average of the risk in these 2 groups but,
- 16 of course, this risk is zero in the non-susceptible group. It is therefore straightforward to scale
- 17 up this population risk to give the risk of UI in the susceptible group over time. Figure 11
- 18 illustrates this mapping from population to susceptible risk, where the lifetime risk of UI in the
- 19 absence of treatment is 100%. So the population risk will be determined by the relative

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

Figure 11: Graph to show how natural history in susceptible women was derived from the estimated population risk over time



5 Effectiveness

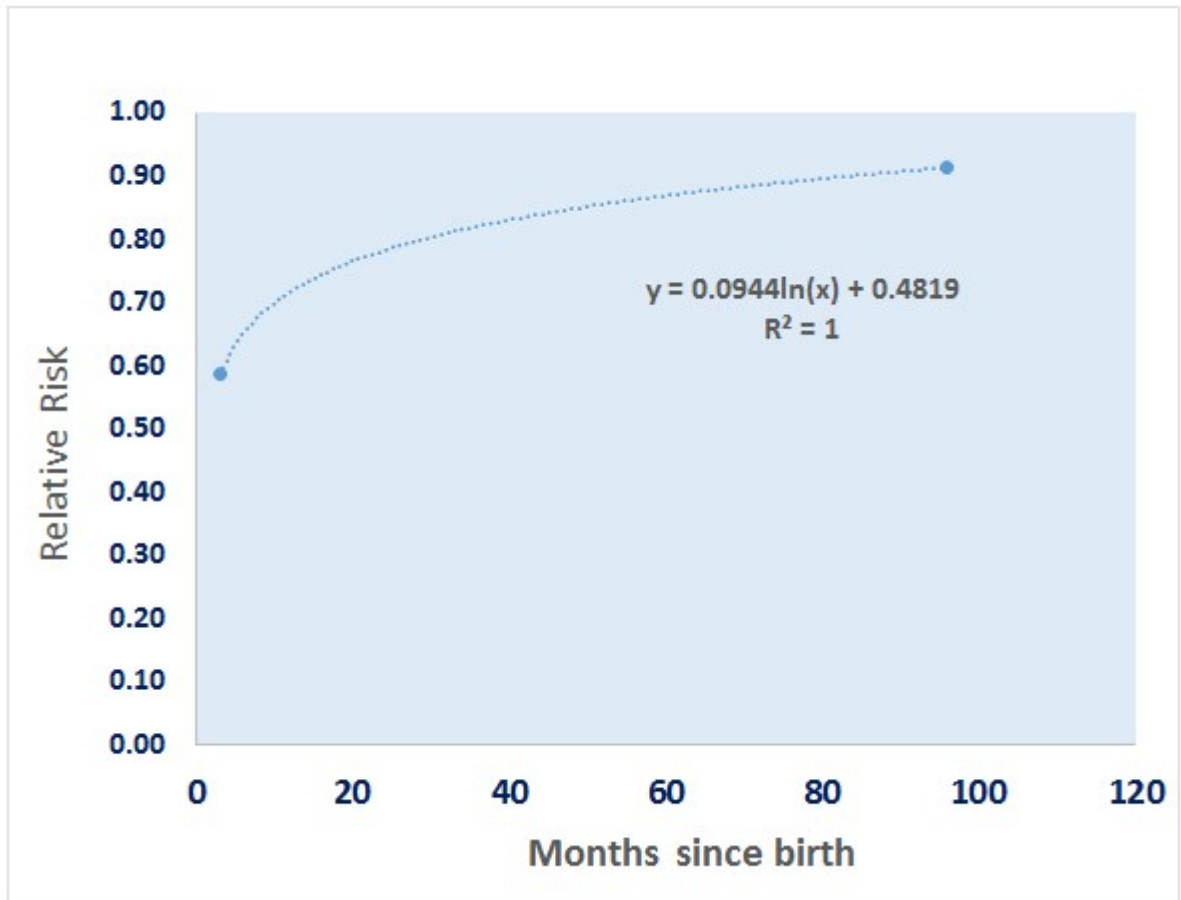
- 6 The baseline in the model is given by the natural history model and effectiveness data from
 7 Reilly (2002) and Agur (2008) is used to estimate the impact of preventative PFMT on the
 8 natural history of UI. The measures of relative treatment effect used in this analysis are
 9 shown in Table 18.

10 **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)

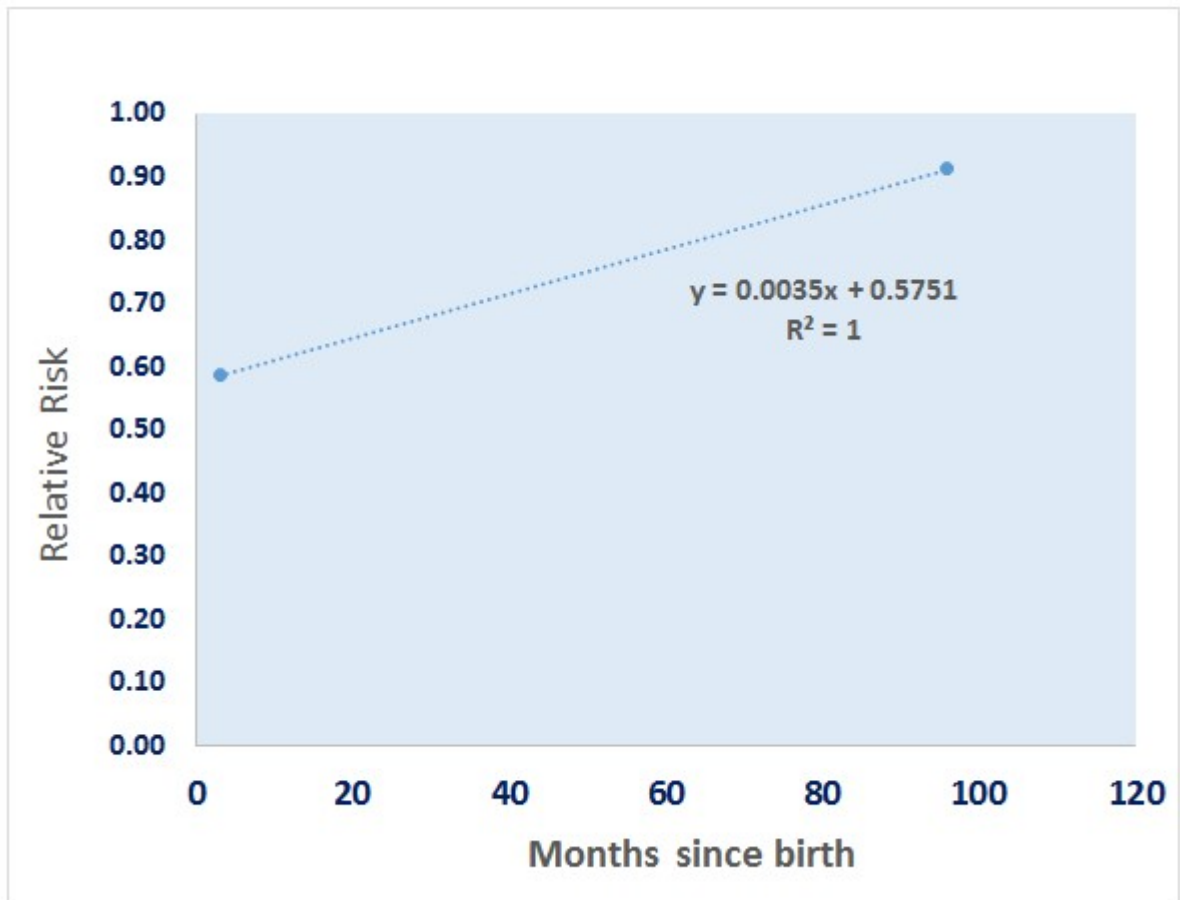
- 11 This clinical evidence gives data on the relative treatment effect at 2 points in time. A
 12 temporal relationship was then fitted to these 2 points in order to estimate the relative risk as
 13 a function of time (in months) since birth. The model allowed either a logarithmic or linear
 14 relationship to be fitted as illustrated in Figure 12 and Figure 13 below. The logarithmic
 15 functional form was used in the base case analysis with the linear relationship evaluated as
 16 part of a sensitivity analysis. In probabilistic sensitivity analysis the relative risks for the 2
 17 time points are sampled independently. Whilst treatment effectiveness will be declining over
 18 time in most samples, independent sampling of relative risks does mean that occasionally
 19 the relative risk sample at the second time point will be lower than at the first.

Figure 12: Relative risk as a function of time estimated from study point estimates and assuming a logarithmic relationship



1

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



- 1 A number of logical constraints are placed on relative risk values when the relationship is
 2 extrapolated over a longer time period. The first constraint is for when the estimated relative
 3 risk for the 2 time points is increasing but lower than 1 for both values, as is the case in
 4 Figure 12 and Figure 13 above. Whilst it is quite plausible that treatment effect declines over
 5 time (increasing relative risk) extrapolating the functional relationship over a longer time
 6 period would often lead to a relative risk of greater than 1, implying harms from treatment
 7 which is less plausible especially without direct evidence of harm from the 2 study points.
 8 Therefore, in these scenarios the relative risk is capped at a maximum of 1, a situation of
 9 neither benefit or harm. Figure 14 illustrates the impact this constraint has when modelling
 10 the impact of preventative PFMT on the natural history of UI on susceptible women.
- 11 A second constraint is that the proportion of susceptible women with UI can never exceed
 12 100%. Thus, if the relative risk is increasing and has a value of greater than 1 at one or more
 13 of the 2 time points, then the proportion is capped at 100%. In this scenario it may take less
 14 time for all susceptible women to have UI, as shown by the example in Figure 15.
- 15 The final constraint is that when relative risk is falling the proportion of women with UI can
 16 never fall as that would violate the model assumption that there is no transition from PFD to
 17 No PFD. This constraint is depicted in Figure 16.

Figure 14: 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

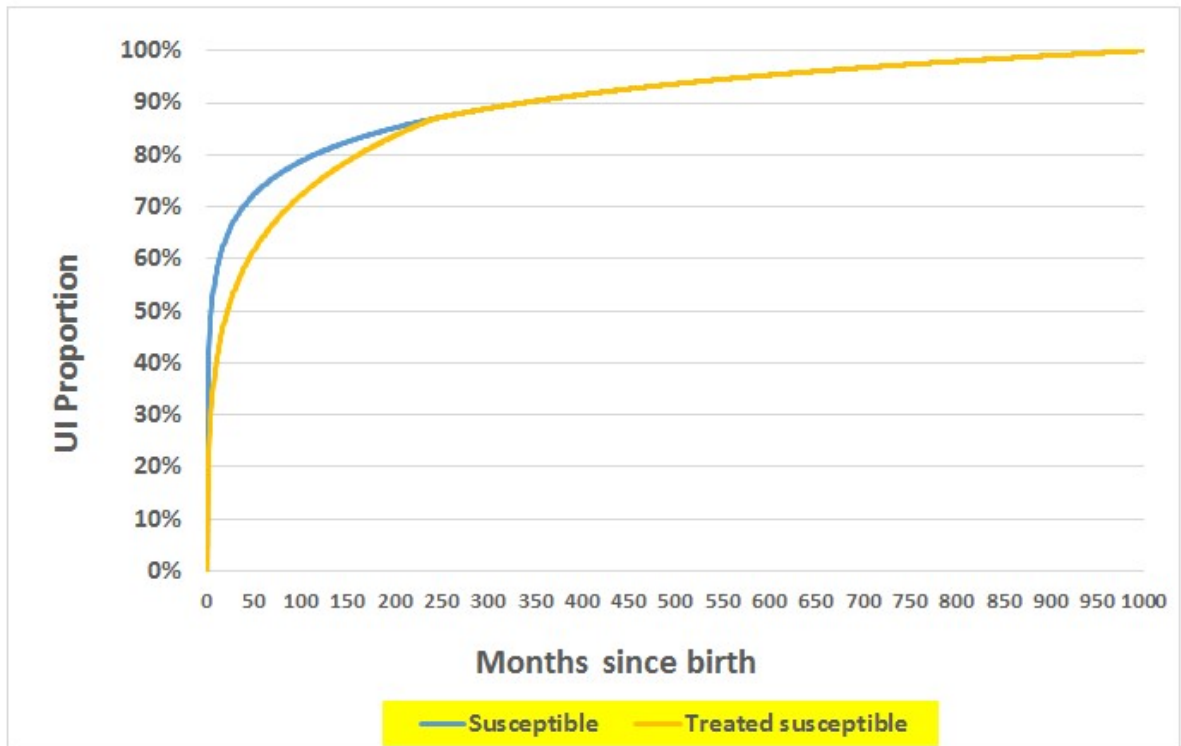


Figure 15: Graph to show impact of preventative PFMT on natural history of UI with increasing relative risk when relative risk >1 for second data point

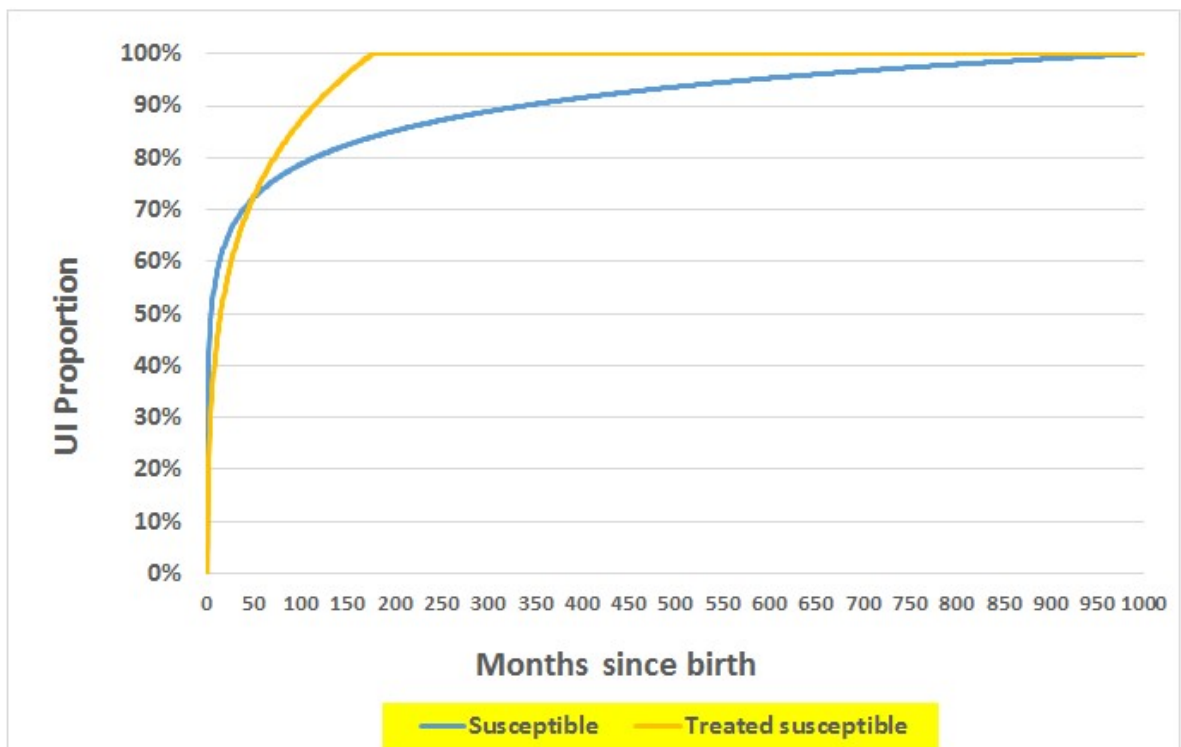
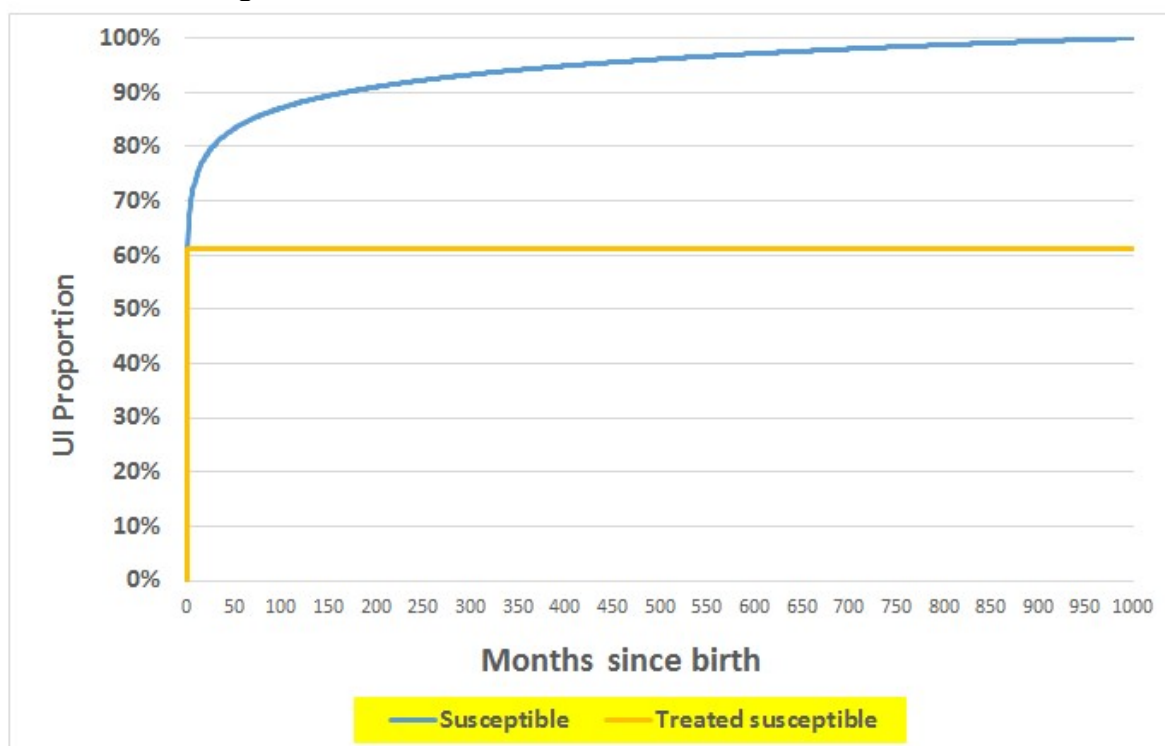


Figure 16: Graph to show impact of preventative PFMT on natural history of UI with declining relative risk



1 Health state utilities and QALYs

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

6 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

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

1 **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 ^a	0.793	359	0.307
>1 to ≤2 per day ^a	0.783	279	0.239
>2 to ≤3 per day ^a	0.763	175	0.150
>3 per day ^a	0.753	352	0.301

2 (a) Used to calculate a weighted mean health state utility from urinary incontinence

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

5
$$(0.793 \times 0.307) + (0.783 \times 0.239) + (0.763 \times 0.150) + (0.753 \times 0.301) = 0.774$$

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

9
$$\text{HSU}_{\text{UI}} \text{ decrement} = 0.813 - 0.774 = 0.039$$

10 A Dirichlet distribution was used in the probabilistic sensitivity analysis to sample the
11 weighted mean health state utility in women with urinary incontinence. The count for each
12 severity level of incontinence episode frequency is based on the sample recorded in Table
13 20 and sampled using the cumulative gamma function. The sampled weight for each severity
14 level was then calculated as its sample count ÷ sum of the sample counts for all severity
15 levels.16 In line with NICE guideline methods, an annual discount rate of 3.5% was applied to health
17 state utilities.18 **Costs and resource use**19 In accordance with NICE methodology a NHS and Personal Social Services (PSS)
20 perspective was adopted for this analysis
21 ([https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/developing-](https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/developing-NICE-guidelines-the-manual.pdf)
22 [NICE-guidelines-the-manual.pdf](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
23 assumed that each woman would receive 5 supervised PFMT sessions on the basis that
24 sessions started in the 20th week of pregnancy and continued at monthly intervals till birth. A
25 monthly cost for management of symptoms was applied to women who developed urinary
26 incontinence and an annual discount rate of 3.5%, in line with NICE methods, was applied to
27 these costs. This estimate of the cost of management was a fairly crude estimate but
28 reflected easily accessible data that was in the public domain. The estimates were also of a
29 similar order to an analysis (<https://www.ics.org/Abstracts/Publish/43/000156.pdf>) that
30 estimated the costs of different types of urinary incontinence to the NHS when updated to
31 2020 prices. No discounting was applied to the preventative PFMT intervention as these
32 costs were all incurred within the first year.33 **Table 21: Unit costs**

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

34 (a) Cost of a one-to-one physiotherapy session

35 (b) This report cites that the estimated cost to the NHS of urinary incontinence is £233 million per year at 2017
36 and that 4 million women over the age of 40 are regularly incontinent. It was assumed that women account for
37 80% of urinary continence costs in the NHS (<https://www.birmingham.ac.uk/Documents/college->

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

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

5 **Sensitivity analysis**

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

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

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

17 **Results**

18 **Base case analysis**

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

- 25
- 26 i. Deterministic results
- 27

28 The deterministic results are shown in Table 22, Figure 17 and Figure 18. These results
29 suggest that an intervention to provide antenatal preventative PFMT to prevent pelvic floor
30 dysfunction is cost-effective for a population with a 50% risk at a cost-effectiveness threshold
31 of £20,000 per QALY. Table 22 shows that the intervention is cost increasing, with a small
32 reduction in the costs of UI management not offsetting the costs of the PFMT sessions.
33 However as Table 22 and Figure 17 show, the ICER of £11,432 falls below the cost-
34 effectiveness threshold indicating that the QALY gain represents good value for NHS
35 resources. Figure 18, which shows the impact of the transitions between health states over
36 time, indicates that the benefits of preventative PFMT are a consequence of delayed UI
37 onset rather than averted UI.

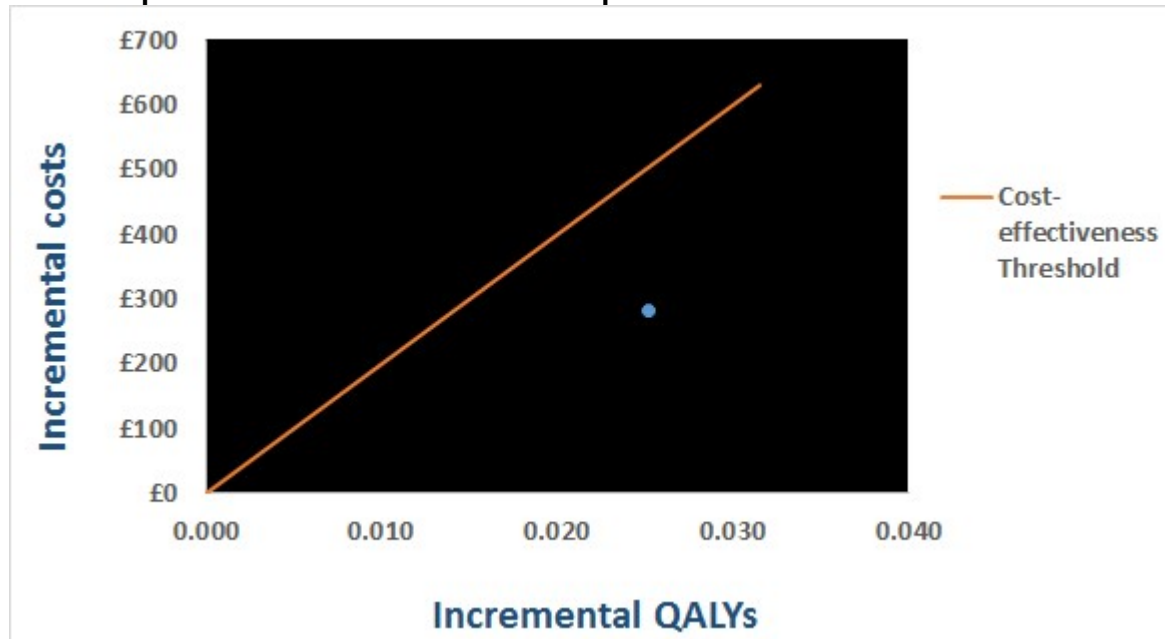
38 **Table 22: Table of deterministic cost-effectiveness results for preventative PFMT**
39 **relative to no preventative PFMT**

Item	No preventative PFMT	Preventative PFMT
Treatment cost	£0	£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

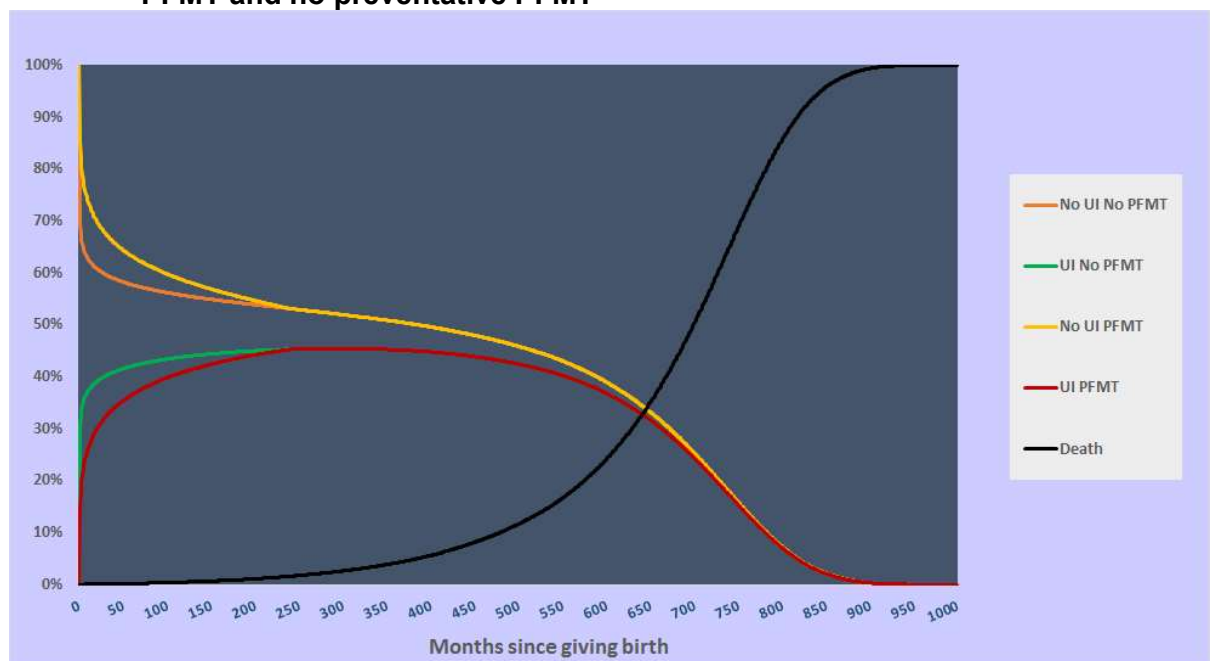
1 ICER = Incremental cost-effectiveness ratio; iNMB = incremental Net Monetary Benefit; QALYs = Quality Adjusted
 2 Life Years
 3

Figure 17: Cost-effectiveness plane for deterministic cost-effectiveness results for preventative PFMT relative to no preventative PFMT



4

Figure 18: Graph to show the transition to health states over time for preventative PFMT and no preventative PFMT



1

2 ii. Probabilistic sensitivity analysis

3

4 Table 23 and Figure 19 show the probabilistic results based on 10,000 model simulations for
 5 the base case model and quantify some of the uncertainty with respect to the cost-
 6 effectiveness conclusions. The mean iNMB of £481 indicates that the preventative PFMT is
 7 cost-effective as the value is positive, although there is uncertainty with respect to this
 8 conclusion as the 95% credible interval includes negative values. However, preventative
 9 PFMT was cost-effective in 63.0% of the simulations. The simulations depicted in Figure 19
 10 show a very strong negative correlation between incremental costs and incremental QALYs
 11 which is because of the very close link between QALY gains from averted or delayed UI and
 12 “downstream” savings from averted or delayed UI.

13

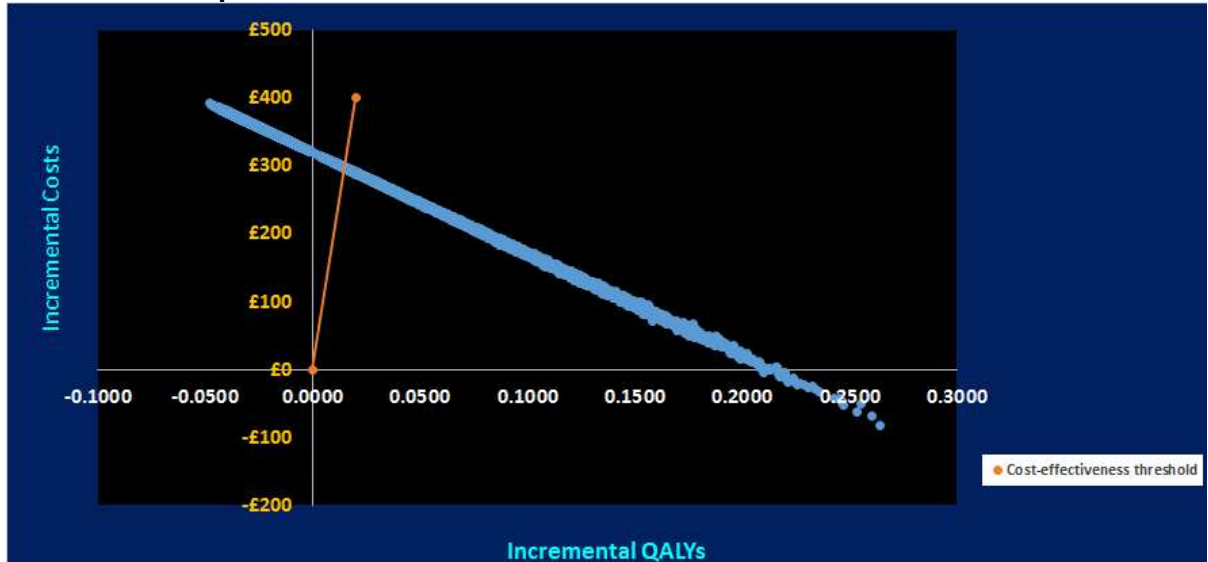
Table 23: Table of probabilistic cost-effectiveness results for preventative PFMT relative to no preventative PFMT

14

Outcome	Value (95% CrI)
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%

15

Figure 19: Cost-effectiveness plane for simulations of preventative PFMT relative to no preventative PFMT

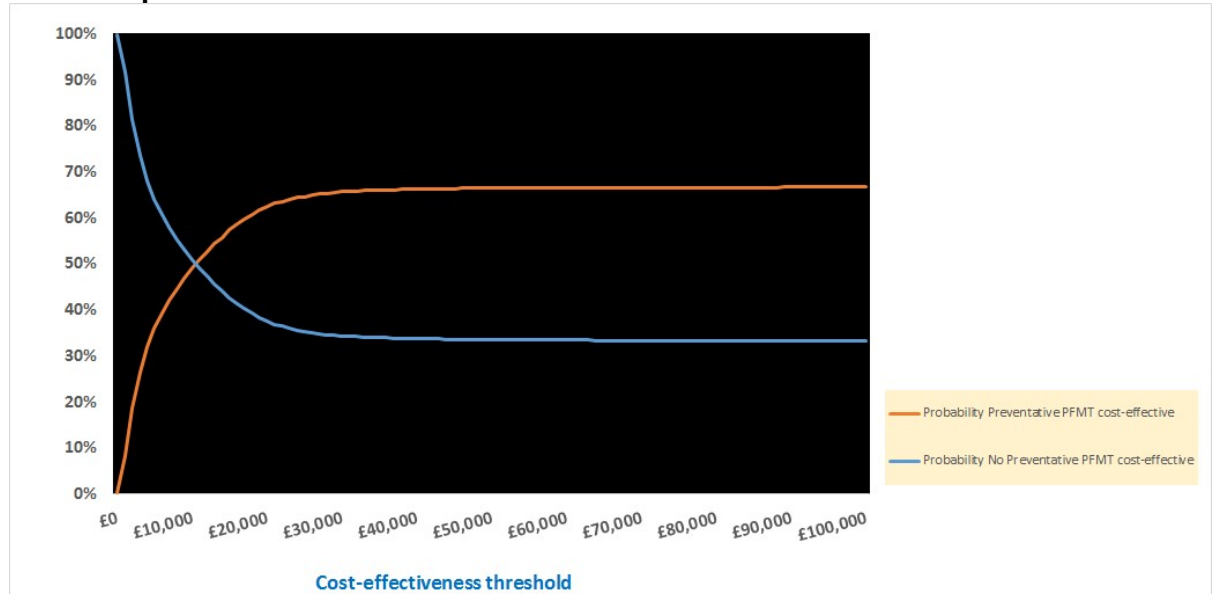


16

17 Figure 20 shows the cost-effectiveness acceptability curve, which charts the probability that
 18 preventative PFMT is cost-effective relative to no PFMT for the base case analysis at
 19 different cost-effectiveness thresholds. This indicates that preventative PFMT is likely to be
 20 cost-effective relative to no preventative PFMT providing the cost-effectiveness threshold is
 21 greater than £11,000 per QALY. It also shows that the probability of preventative PFMT being
 22 cost-effective only increases slowly for increasing cost-effectiveness thresholds above
 23 £25,000 per QALY. This follows from the non-negligible number of simulations that fall in the
 24 north east quadrant of the cost-effectiveness plane (see Figure 19) where no preventative

- 1 PFMT dominates (cheaper and more QALYs) preventative PFMT. These simulations would
 2 never be considered cost-effective irrespective of the cost-effectiveness threshold.
 3

Figure 20: CEAC for the base case analysis for preventative PFMT compared to no preventative PFMT



4 Sensitivity analysis

5

6 i. Varying population risk

7

8 The population risk is a very important parameter in the model as it reflects the capacity to
 9 benefit from preventative PFMT and the absolute benefit of treatment is likely to rise with
 10 increasing risk. Therefore, a sensitivity analysis was undertaken varying the population risk
 11 of PFD (as measured by UI risk) whilst maintaining other model inputs and structural
 12 assumptions as per the base case analysis. Figure 21 shows the deterministic relationship
 13 between the antenatal population risk of UI and the iNMB and shows, as expected, improved
 14 cost-effectiveness with increasing risk. It also shows that the threshold at which antenatal
 15 preventative PFMT becomes cost-effective is at a risk level of 30% and above.

16

17 Figure 22 shows the results of Monte Carlo simulations and indicate the probability that
 18 antenatal preventative PFMT is cost-effective according to the level of population risk. It
 19 shows that the likelihood of preventative PFMT being cost-effective increases with risk and
 20 that there is a greater than 50% probability of antenatal preventative PFMT being cost-
 21 effective when the risk of UI is 29% and above. Figure 23 further quantifies the uncertainty by
 22 illustrating the 95% credible intervals for the iNMB based on 10,000 model simulations. It
 23 shows that the width of the credible interval increases as population risk of UI increases. Not
 24 shown on the chart but at a UI risk of less than 7% the mean iNMB is negative and the upper
 25 bound of the 95% credible intervals is also negative, which corroborates Figure 22 in
 26 demonstrating that antenatal preventative PFMT is very unlikely to be cost-effective if the
 27 risk of UI is very low. For UI risk of greater than 7% or greater the 95% credible intervals
 28 include positive (upper bound) and negative (lower bound) values for iNMB indicating that
 29 there is some uncertainty with respect to the cost-effectiveness of antenatal preventative
 30 PFMT even at high levels of risk. However, it should be noted that the credible intervals

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

Figure 21: Graph to illustrate the deterministic relationship between risk of UI and incremental net monetary benefit of antenatal preventative PFMT

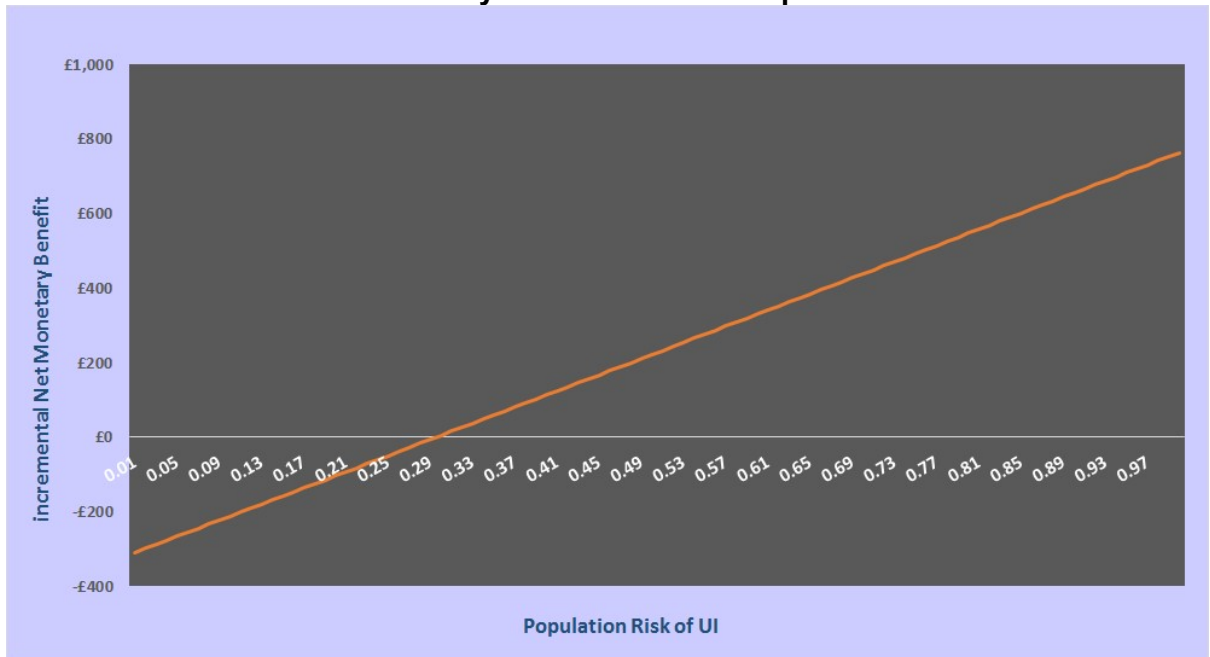
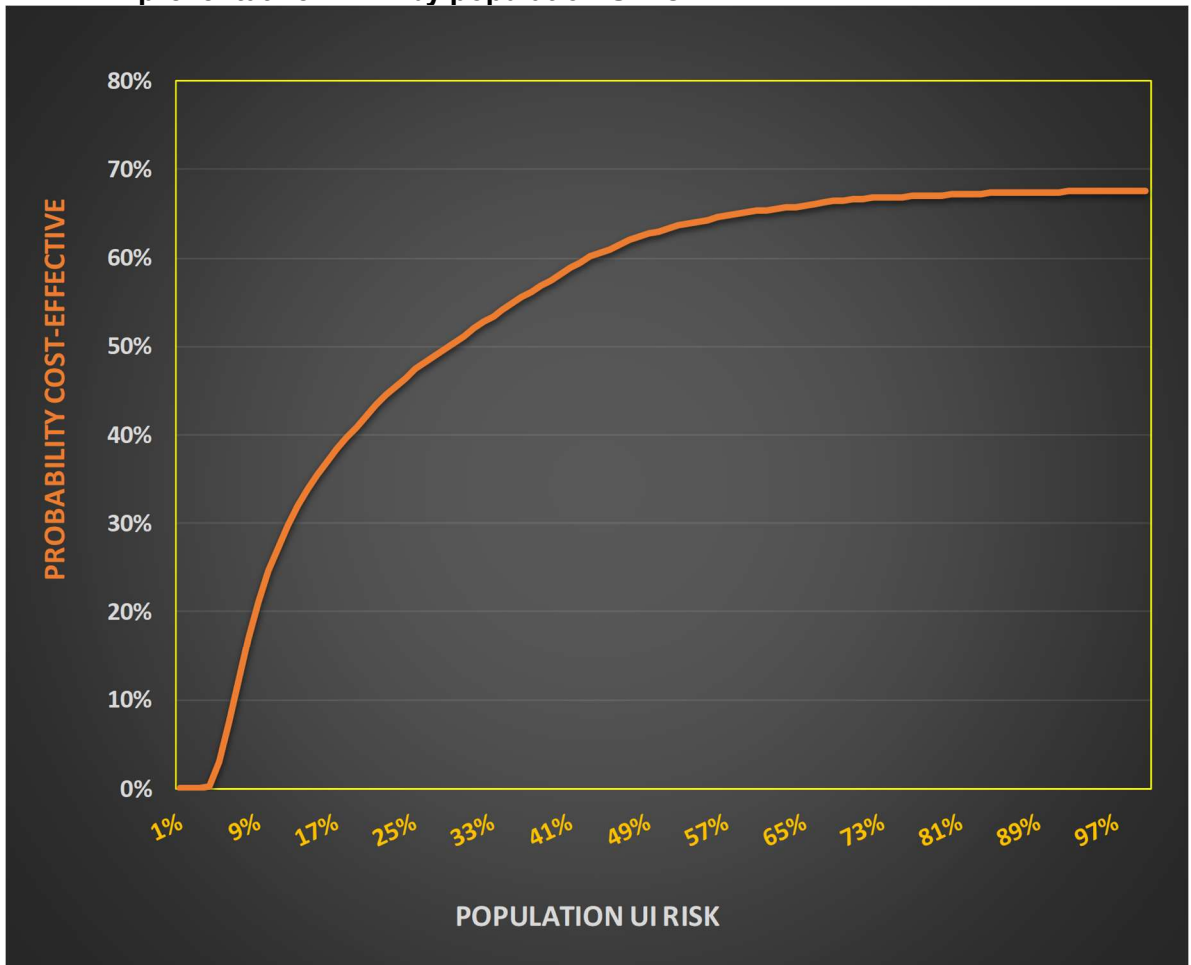
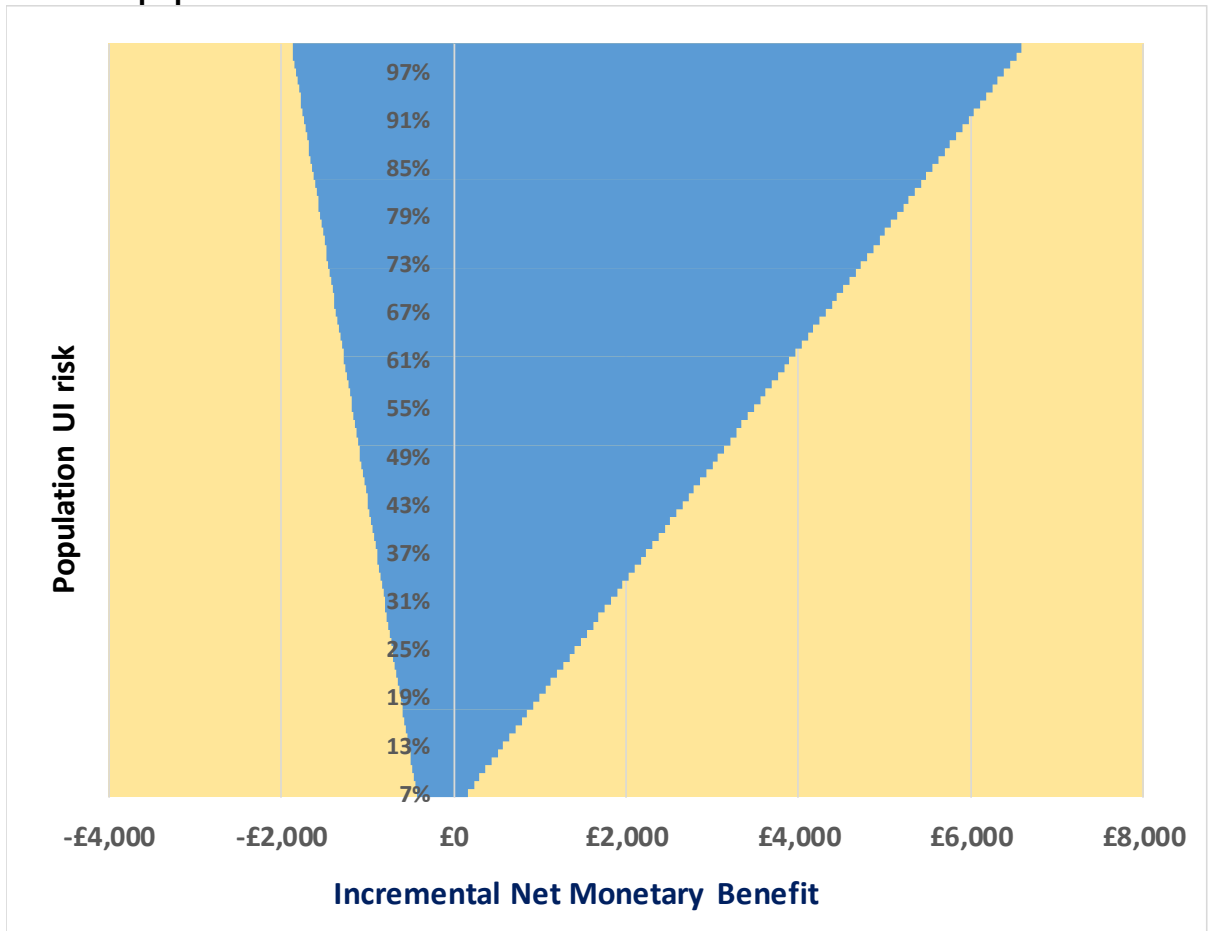


Figure 22: Probability antenatal preventative PFMT cost-effective relative to preventative PFMT by population UI risk



1

Figure 23: 95% credible intervals for mean iNMB of antenatal preventative PFMT by population UI risk



Blue shaded bar represents the 95% credible intervals

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17

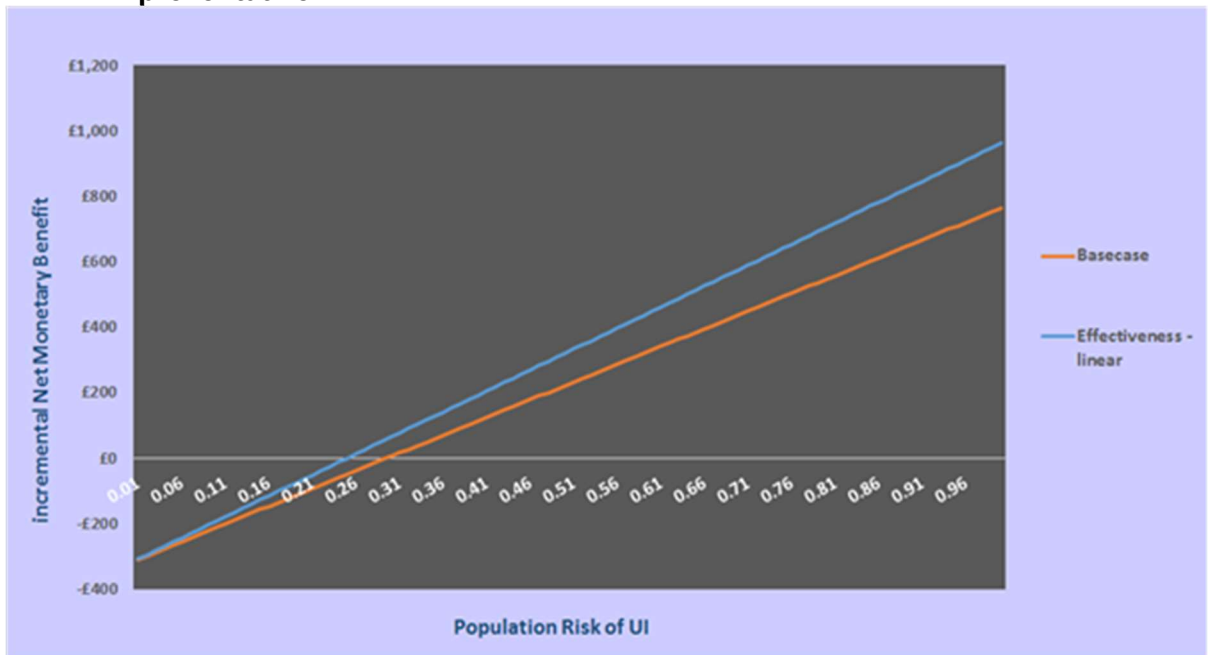
ii. Varying structural assumptions

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 24 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.

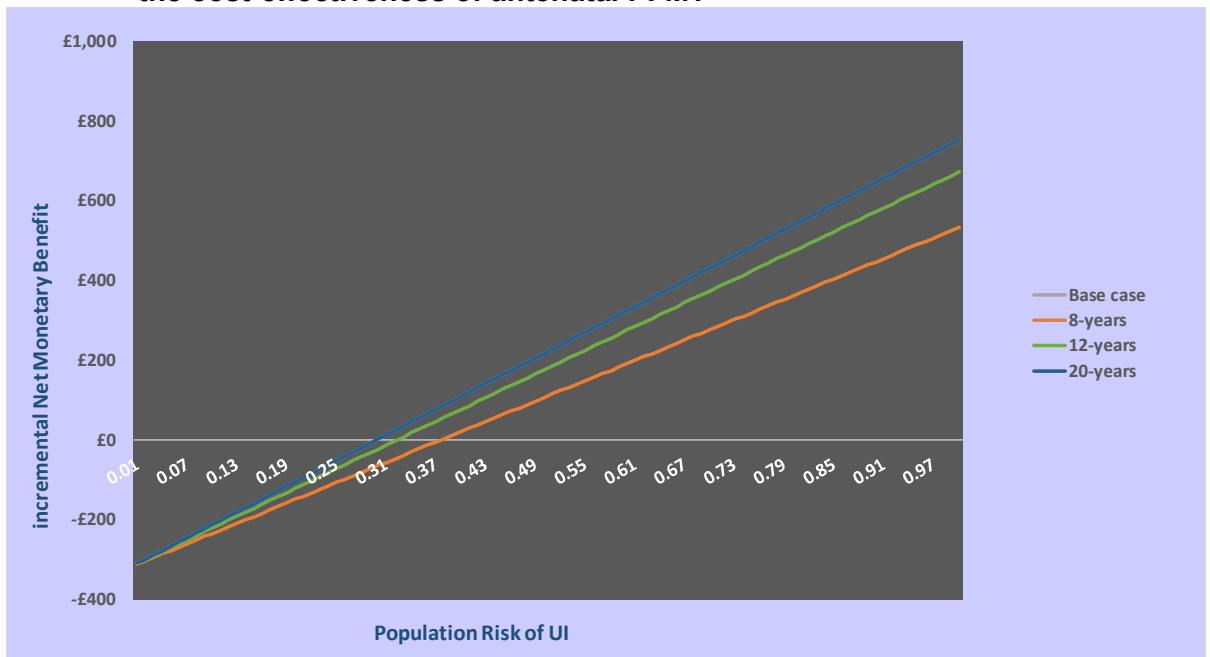
Figure 25 illustrates the impact of alternative time horizon's on the model's inclusions. It indicates that a longer time horizon increases the cost-effectiveness up to a certain number of years but the results for a 20-year timeframe are identical to a lifetime horizon in this case as the decline in relative risk means that no further benefits accrue beyond 20 years as UI is delayed rather than averted (see Figure 18).

Figure 24: Sensitivity analysis to assess the assumption of a linear relationship between relative risk and time on the cost-effectiveness of antenatal preventative PFMT



1
2

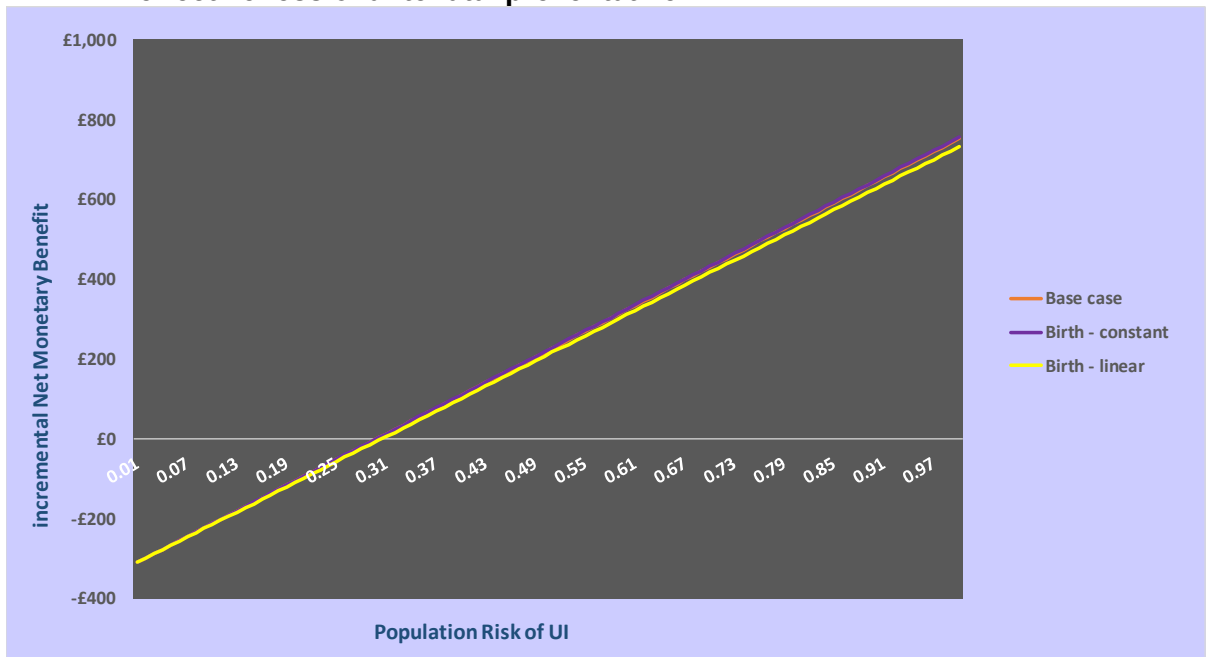
Figure 25: Sensitivity analysis to assess the impact of the model time horizon on the cost-effectiveness of antenatal PFMT



3
4
5
6

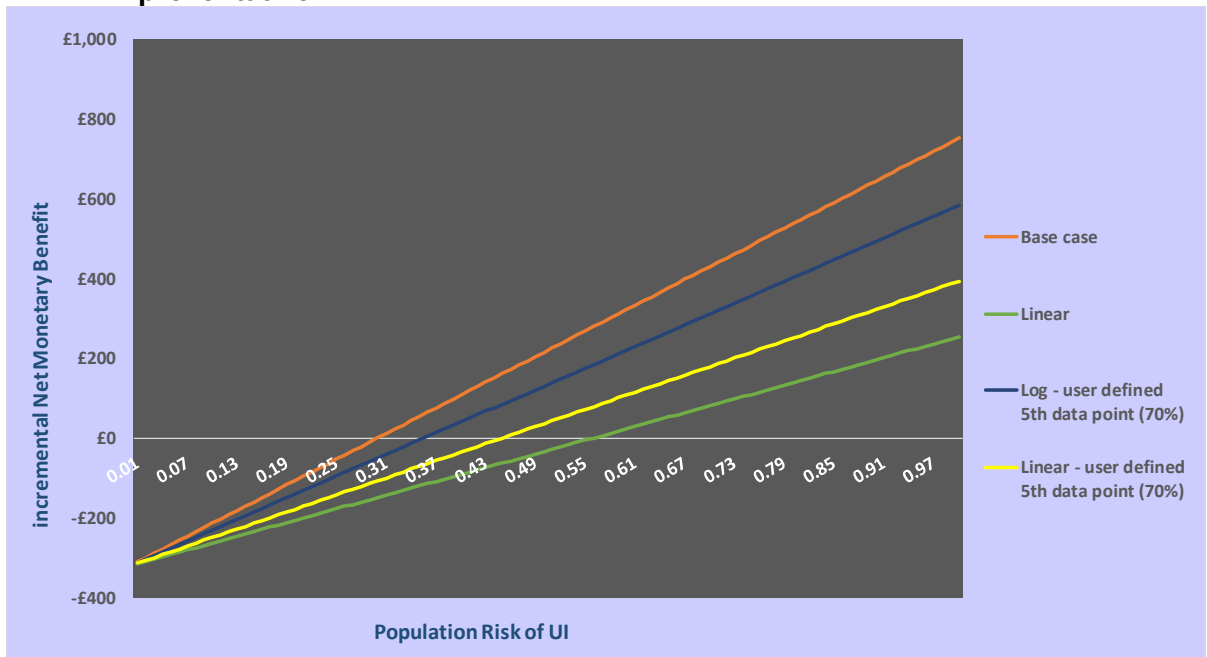
Figure 26 considers different assumptions about the UI rate in the period from birth to 3 months post-partum as outlined in Figure 10. This shows that the impact of these assumptions has a negligible impact on the iNMB for this analysis.

Figure 26: 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



- 1 In Figure 27 the effect of fitting different functional forms to the observed and predicted UI
- 2 risks in order to estimate the natural history of UI in a susceptible population is assessed.

Figure 27: 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



- 3 This sensitivity analysis suggests that this assumption does have an impact on cost-
- 4 effectiveness conclusions and the assumption made in the base case analysis produces a
- 5 more favourable assessment of cost-effectiveness. Using the least favourable assumption to

1 model natural history raises the UI risk threshold at which antenatal PFMT becomes cost-
2 effective to 56%.

3

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

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

Assumption	Deterministic		Probabilistic	
	ICER	iNMB	Mean iNMB (95% CrI)	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%

8

9 iii. Varying model inputs

10

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

15

16 **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)

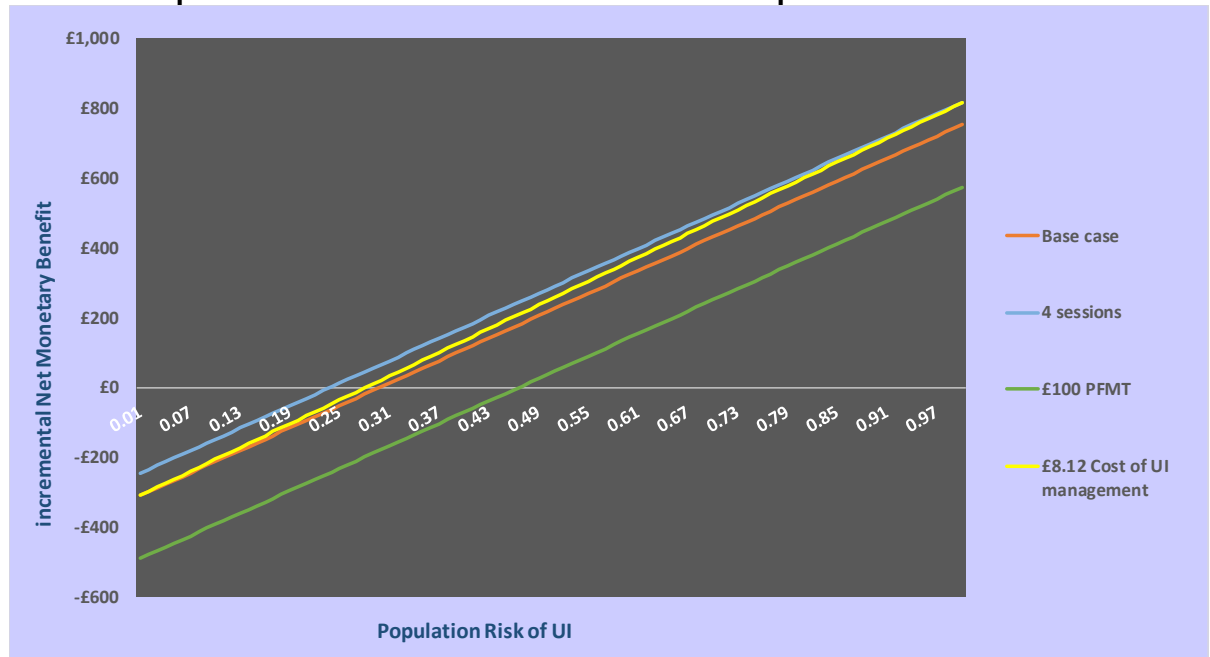
17 (a) This has the impact of lowering the cost of the antenatal preventative PFMT intervention: $4 \times £64 = £256$

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

19

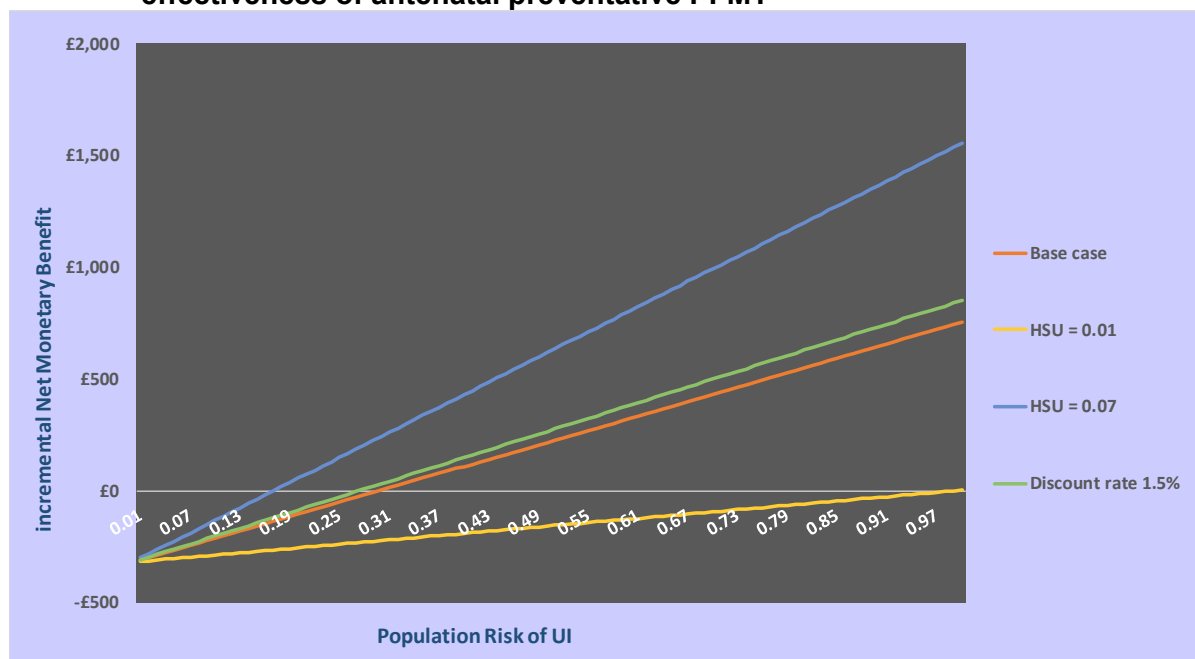
- 1 Figure 28 illustrates the impact of different model inputs for cost and resource use variables.
- 2 Self-evidently, higher intervention cost leads to reduced cost-effectiveness and lower
- 3 intervention costs (from a reduction in sessions to deliver the intervention) increases it.
- 4 Doubling the costs to the NHS of UI management also leads to improved cost-effectiveness
- 5 especially at higher levels of population UI risk. However, even when the cost of antenatal
- 6 preventative PFMT rises to £500, it remains cost-effective providing the population risk of UI
- 7 is 47% or above.

Figure 28: Sensitivity analysis varying resource use and cost inputs to assess the impact on the cost-effectiveness of antenatal preventative PFMT



- 8
- 9 The consequences of different assumptions about the health state utility decrement from UI
- 10 and a lower discount rate are charted in Figure 29. The lower discount rate has only a
- 11 relatively small impact in improving the cost-effectiveness of antenatal preventative PFMT
- 12 and the risk threshold at which the intervention becomes cost-effective is barely changed.
- 13 The sensitivity analysis does indicate that the health state utility decrement from UI is an
- 14 important driver of the model's conclusions. However, it should be noted that parameter
- 15 uncertainty for this model input is addressed by sampling in the probabilistic analyses. Table
- 16 26 summarises the results of the sensitivity analyses changing model parameters on the
- 17 model's cost-effectiveness results

Figure 29: Sensitivity analysis varying the health state utility decrement for UI and the discount rate for costs and QALYs to assess the impact on the cost-effectiveness of antenatal preventative PFMT



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

Assumption	Deterministic		Probabilistic	
	ICER	iNMB	Mean iNMB (95% CrI)	Probability 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%

3

4 Discussion

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

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

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

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

20 Even at very high levels of population risk there is some uncertainty with respect to the cost-
21 effectiveness of antenatal preventative PFMT. In a hypothetical population which had a
22 100% risk of UI the probability of preventative PFMT being cost-effective would still fall just
23 short of 70% (see Figure 22). This reflects the uncertainty in the clinical evidence with regard
24 to temporal relative treatment effects. The evidence from Reilly (2002) and Agur (2008)
25 suggests that the treatment effectiveness wanes over time and that is why in the
26 deterministic analysis PFMT only serves to delay onset of UI rather than preventing it
27 entirely, although prevention is likely in some of the Monte Carlo simulations. The 95%
28 credible intervals for iNMB which are shown in Figure 23 also indicate some level of
29 uncertainty as the lower bound encompasses negative values.

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

33 The natural history model was developed so as to represent the natural history of UI for the
34 population included in the Reilly (2002) and Agur (Studies) and that is why those studies
35 were used to inform estimates of the proportion with UI at 3 months' post-partum and 8
36 years. In predicting UI rates at 12 years and 20 years the UR-CHOICE prediction model was
37 used with inputs that reflected the Reilly (2002) and Agur (2008) study population as closely
38 as possible. However, the UR-CHOICE prediction models were not developed in that
39 population (although the 12-year prediction model was based on a UK dataset). Furthermore,
40 the 12-year prediction model and 20-year prediction model were developed in different
41 populations and not all the predictors are the same in both models. These differences explain
42 the slight anomaly where the predicted UI rate is lower in the 20-year model than the 12-year
43 model (see Figure 6, Figure 7, Figure 8 and Figure 9). Nevertheless, the 2 observed UI rates
44 in the control arms of Reilly (2002) and Agur (2008) do seem to exhibit a logarithmic pattern,
45 especially when assuming no UI prior to birth and therefore the conclusions of this model are
46 unlikely to depend crucially on estimating risk at 12 years and 20 years with a very high level
47 of precision. The ability of the user to add a 5th data point also allows for some sensitivity
48 analysis around the natural history.

49 The model assumes that the natural history model derived from Reilly (2002) and Agur
50 (2008) is the same for women in the susceptible group regardless of the overall UI risk in that
51 population. This is a simplifying assumption which allows different hypothetical population
52 risks to be assessed, from 1% through to 100% in this analysis. Of course, the model

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

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

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

19 **Examples of groups from UR choice who meet risk criteria for cost-effective preventative** 20 **PFMT**

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

23 **Table 27: Risk predicted from UR-CHOICE**

Parity	Age	Weight (kg)	Height (cm)	FH POP	FH UI	Mode of Birth	12-year UI 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%

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

25

26 Conclusions

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

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

5 **Acknowledgements**

6 With the kind permission of the developers and authors, this analysis makes use of the UR
7 Choice Pelvic Floor Disorders Risk Calculator (https://riskcalc.org/UR_CHOICE/) and we
8 would like to thank them for their support for our work.

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

11

12

1 Appendix K – Excluded studies

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

4 Clinical studies

5 Table 28: Excluded studies and reasons for their exclusion

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, <i>Maturitas</i> , 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, <i>Obstetrics and gynecology</i> , 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, <i>Journal of Maternal-Fetal & Neonatal MedicineJ Matern Fetal Neonatal Med</i> , 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, <i>British journal of urology</i> , 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, <i>Physiotherapy</i> , 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 prolapse--a randomized trial of primiparous women, <i>American Journal of Obstetrics & Gynecology</i> , 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, <i>Neurourology & UrodynamicsNeurourol Urodyn</i> , 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?, <i>Cochrane Clinical Answers</i> , 2018	Short report
Chiarelli, P., Murphy, B., Cockburn, J., Acceptability of a urinary continence promotion programme to women in postpartum, <i>BJOG: An International Journal of Obstetrics & Gynaecology</i> , 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, <i>American Journal of Obstetrics & GynecologyAm J Obstet Gynecol</i> , 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, <i>International urogynecology journal</i> , 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. <i>Geburtshilfe und frauenheilkunde</i> 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], <i>British Journal of Sports Medicine</i> BJSM 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, <i>Journal of physiotherapy</i> , 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, <i>Clinics (Sao Paulo, Brazil)</i> , 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, <i>Neurourology & Urodynamics</i> NeuroUrol 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, <i>European Journal of Applied Physiology</i> Eur 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, <i>Medical Science Monitor</i> Med 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, <i>Journal of Medical Internet Research</i> , 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, <i>Obstetrics and Gynecology</i> , 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), <i>Journal de gynecologie, obstetrique ET biologie de la reproduction</i> , 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 Ch̃vez, V., Vel̃quez S̃nchez Mdel, P., 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., Staer-Jensen, J., Siafarikas, F., Engh, M., Ellström, Bø, K., Effect of postpartum pelvic floor muscle training on	Over 20% of the population have PFD

Study	Reason for exclusion
vaginal symptoms and sexual dysfunction. Secondary analysis of a 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., Lunes, 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 Obstetrica 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, <i>Journal of Advanced Nursing</i> , 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, <i>Journal of Korean Academy of Nursing</i> , 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, <i>Journal of Electromyography & KinesiologyJ Electromyogr Kinesiol</i> , 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, <i>BJOG</i> , 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, <i>Revista Brasileira de EnfermagemRev Bras Enferm</i> , 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, <i>Clinical rehabilitation</i> , 22, 714-21, 2008	Over 20% of the population have PFD
Sampsel, 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, <i>Obstetrics and Gynecology</i> , 91, 406-412, 1998	Outcome data not useable – raw data not reported
Sampsel, C. M., Behavioral interventions in young and middle-age women: simple interventions to combat a complex problem, <i>The American journal of nursing</i> , 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, <i>International Journal of Gynecology and Obstetrics</i> , 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, <i>Archives of Gynecology & ObstetricsArch Gynecol Obstet</i> , 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, <i>Trials</i> , 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, <i>BJOG: An International Journal of Obstetrics & Gynaecology</i> , 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, 420-427, 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. <i>Frontiers in physiology</i> , 9, 1867. 2019	Duplicate
Szumilewicz, A., Dornowski, M., Piernicka, M., Worska, A., Kuchta, A., Kortas, J., Błudnicka, M., Radzimiński, 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, <i>Frontiers in Physiology</i> , 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, <i>Research Quarterly for Exercise & Sport</i> , 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, <i>Medicine</i> , 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, <i>BMJ open</i> , 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, <i>International Urogynecology Journal</i> , 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, <i>International Urogynecology Journal</i> , 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, <i>International Urogynecology Journal</i> <i>Int Urogynecol J Pelvic Floor Dysfunct</i> , 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, <i>Neurourology & Urodynamics</i> <i>Neurourol Urodyn</i> , 36, 1636-1644, 2017	No relevant outcomes
Woodley, S. J., Boyle, R., Cody, J. D., Mikkelsen, S., Hay-Smith, E. J. C., Pelvic floor muscle training for prevention and treatment of urinary and faecal incontinence in antenatal and postnatal women, <i>Cochrane Database of Systematic Reviews</i> , 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, <i>International Urogynecology Journal</i> , 27, 545-553, 2016	No relevant outcomes

1 PFD: pelvic floor dysfunction; PFM: pelvic floor muscle

2 Economic studies

3 No economic evidence was identified for this review.

4

1 Appendix L – Research recommendations

2 Research recommendations for review question: What is the effectiveness of 3 pelvic floor muscle training for preventing pelvic floor dysfunction?

4 Research recommendation 1:

5 Research question

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

8 Why this is important

9 Prevention is always better than cure, and it is important to know if teaching pelvic floor
 10 muscle training to children and young women will prevent the development of pelvic floor
 11 dysfunction in later life, thus reducing the possible long term implications of decreased
 12 quality of life and increased costs to the NHS. The [NHS long term plan](#) published in 2019
 13 sets out that ‘*We will improve access to postnatal physiotherapy to support women who need*
 14 *it to recover from birth*’ with the aim to prevent birth related symptoms of pelvic floor
 15 dysfunction. However, this is only related to childbirth and it is unclear whether a more
 16 general preventative strategy starting earlier in life would be a more effective approach to
 17 prevent symptoms of pelvic floor dysfunction later.

18 **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.

1 **Table 30: Research recommendation modified PICO 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.

2 *RCT: randomised controlled trial*

3

4

1 **Research recommendation 2:**

2 **Research question**

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

5 **Why this is important**

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

14 **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.

1 *PF: pelvic floor dysfunction*

2 **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 style="list-style-type: none"> • Symptoms of pelvic floor dysfunction • Quality of life
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.

3 *RCT: Randomised controlled trial*

4

5

1 Research recommendation 3:

2 Research question

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

6 Why this is important

7 Pelvic floor exercises are an important part of the management of the prevention of
 8 symptoms of pelvic floor dysfunction; undertaking pelvic floor muscle training has been
 9 shown to significantly impact on an individual’s health and improve symptoms of pelvic floor
 10 dysfunction. However, there are a number of issues related to pelvic floor muscle training in
 11 the prevention of pelvic floor dysfunction that are uncertain. The [NHS long term plan](#)
 12 published in 2019 sets out that ‘*We will improve access to postnatal physiotherapy to support*
 13 *women who need it to recover from birth*’ with the aim to prevent birth related symptoms of
 14 pelvic floor dysfunction. However, currently there is little evidence of the details of pelvic floor
 15 muscle training (what specific type of training, when to start using it and who would best give
 16 instructions) that are effective in preventing the whole range of symptoms associated with
 17 pelvic floor dysfunction. For this reason, research on these specific details is required to
 18 allow recommendations for advice about the use of pelvic floor muscle training in the
 19 prevention of pelvic floor dysfunction to be developed.

20 **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	<ul style="list-style-type: none"> • Not applicable

1 *PFMT: pelvic floor muscle training*

2 **Table 34: Research recommendation modified PICO table**

Criterion	Explanation
Population	<p>Women over 12 years of age with no pre-existing pelvic floor dysfunction capable of understanding and responding to pelvic floor muscle training</p> <ul style="list-style-type: none"> • Including younger participants • The included population must be strongly encouraged to adhere to the intervention • Identifying any psychological predictors of who can engage with the intervention
Intervention	<p>Different Pelvic floor muscle training regimens given by different professionals in different ways (providing leaflets, group education and physical instruction), for example</p> <p>Advice on how to do pelvic floor muscle exercises</p> <p>PFMT provided by a qualified professional such as physiotherapists, nurse specialists, midwives, school nurses, practice nurses.</p>
Comparator	<ul style="list-style-type: none"> • Usual care
Outcomes	<ul style="list-style-type: none"> • Change in pelvic floor strength. • Validated assessments of pelvic floor dysfunction symptoms (such as urinary incontinence, pelvic organ prolapse, sexual dysfunction, faecal incontinence). • Adherence to training schedule • Long term and short term adherence data- presence and severity of symptoms over time.
Study design	<p>Multi-arm controlled RCT</p> <p>Or</p> <p>Prospective case-controlled cohort, with matched participants</p>

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.

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

2

1 Research recommendation 4:

2 Research question

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

6 Why this is important

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

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

25 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 is 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 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 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

1 **Table 36: Research recommendation modified PICO 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 style="list-style-type: none"> • Usual care, i.e. provide training as part of management rather than prevention • Written instructions • Group education in pelvic floor muscle training
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

2 *RCT – randomised controlled trial*

1

2 **Research recommendation 5:**

3 **Research question**

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

6 **Why this is important**

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

20 **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.

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

2 **Table 38: Research recommendation modified PICO table**

Criterion	Explanation
Population	Women aged over age 12 without pre-existing bowel symptoms, capable of understanding and responding to PFMT programme. <ul style="list-style-type: none"> • Including younger participants • Included population must be able to adhere to the intervention • Identifying any psychological predictors of who can engage with the intervention
Intervention	<ul style="list-style-type: none"> • Initial teaching of PFMT including frequency and correct technique by a competent professional. • A long term self-led PFMT programme i.e. after teaching participants would be expected to continue the initial teaching sessions.
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

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

4

1 Research recommendation 6:

2 Research question

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

7 Why this is important

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

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

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

22 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

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)?
	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

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

2 **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: <ul style="list-style-type: none"> • BMI >30 • Age over 30 years old • Multiparous (has given birth before) • Family history of urinary incontinence, overactive bladder or faecal incontinence • Must be capable of understanding and responding to PFMT programme. • Including younger participants • Included population must be able to adhere to the intervention • Identifying any psychological predictors of who can engage with the intervention
Intervention	<ul style="list-style-type: none"> • Initial teaching on PFMT including frequency and correct technique by a competent professional during the first trimester • A self-led PFMT programme throughout the rest of i.e. after teaching, participants would be expected to continue the intervention.
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

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