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| **CRITICALLY APPRAISED TOPIC** |

**FOCUSED CLINICAL QUESTION**

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| Are short-term conservative management techniques (pelvic floor muscle training) during pregnancy or within 1 year following childbirth effective at reducing urinary incontinence for women more than 1 year following childbirth? |

**AUTHOR**

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**CLINICAL SCENARIO**

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| Over a third of women immediately post-partum will experience mild-moderate urinary incontinence (UI).1 Many women will experience UI frequently for several years post-partum and rarely receive treatment (while available) or talk to their medical professionals about UI. Many physical therapists are unaware that there is treatment within their scope of practice that can help to alleviate symptoms.UI has been linked to a decrease in physical activity due to fear of experiencing episodes of UI, leading to a slower recover and loss of healthy habits. In older adults, UI has frequently been linked to a loss of independence and decreased quality of life2 and thus has a significant social and economic cost. Conservative management techniques such as pelvic floor muscle training (PFMT) have been shown to reduce episodes and severity of episodes of UI in older women in both the short and long term.3 The short-term efficacy of pelvic floor muscle training has been established in many populations, but the short- and long–term efficacy of ante- and postnatal interventions is relevant to how intervention programs are structured and how potential recurrent episodes of UI are approached by clinicians.An estimated 50% of women will lose some supportive function of the pelvic floor muscles (PFM) as a result of pregnancy and childbirth and 20-26% of women will experience major injury to the PFM following vaginal delivery.17 UI has been linked to a decrease in physical activity for all populations. Given that physical activity is recommended for pregnant and postpartum women, UI is important and necessary to address and treat early for the sake of improved pregnancy-related outcomes. |

**SUMMARY OF SEARCH**

[Best evidence appraised and key findings]

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| * 3 electronic databases searched, 18 articles and reviews identified.
	+ Randomized controlled trials, controlled trials, and systematic reviews identified
* Evidence from the highest quality three studies:
	+ Pelvic floor muscle training (PFMT) programs can help to prevent and treat urinary incontinence in pregnant and postnatal women when performed during or following pregnancy.
	+ More intensive programs (near maximal contractions, longer program duration) with more clinician supervision, in addition to home exercise programs (HEP), provide more preventative and treatment benefit than shorter, less intensive, more independent programs.
	+ Additional therapies, including biofeedback, transverse abdominus training, and pelvic floor weights do not appear to provide additional benefit in the form of decreased UI symptoms.
	+ There is significant heterogeneity of research protocols and study populations; long-term outcomes have been insufficiently assessed to judge the value of limited duration (up to 12 week) PFMT programs after 6 months. However, like all muscles, PFM will suffer from disuse atrophy, which may lead to decreased benefit after 6 months without maintenance HEP.
* Quality: inherent limitations lower the overall quality of research in this area, since subject and interventionist blinding to therapy is not possible. Overall methodology quality is moderate to good (6-8/10 on PEDro scale, 9-11/11 on AMSTAR).
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**CLINICAL BOTTOM LINE**

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| Short-term (6-12 week) intensive PFMT programs performed during the antenatal or postnatal periods provide protection against and treatment for UI in the short- and medium-term (up to six months postnatally). The longer term efficacy of PFMT has not been satisfactorily established by the literature.  |

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| ***This critically appraised topic has been individually prepared as part of a course requirement and has been peer-reviewed by one other independent course instructor*** |

*The above information should fit onto the first page of your CAT*

**SEARCH STRATEGY**

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| **Terms used to guide the search strategy** |
| **P**atient/Client Group | **I**ntervention (or Assessment) | **C**omparison | **O**utcome(s) |
| Women | Pelvic floor muscle training | (not applicable) | Urinary continence |
| Pregnant women | Bladder training |  | Urinary incontinence  |
| Urinary incontinence | (Pelvic floor) AND (physical therapy OR physiotherapy) |  |  |
| Stress urinary incontinence | Post-natal care |  |  |
| SUI | Prenatal care |  |  |
| Gravida | Women\* health physical therapy |  |  |
| female |  |  |  |
| Pregnan\* |  |  |  |
| Primipar\* |  |  |  |

**Final search strategy:**

*Show your final search strategy from one of the databases you searched. In the table below, show how many results you got from your search from each database you searched.*

Final strategy for PubMed:

(((Pregnant women OR gravida OR pregnan\* OR female OR primipar\* OR postnatal OR post-natal OR post natal OR prenatal OR pre-natal OR pre natal OR postpartum OR post-partum OR post partum)) AND (Stress urinary incontinence OR urinary incontinence OR SUI OR UI OR urinary incontinence, stress[MeSH Terms])) AND (bladder training OR ((pelvic floor) AND (muscle training OR physical therapy OR physiotherapy)) OR post-natal care OR prenatal care) Filters: Case Reports; Clinical Trial; Systematic Reviews; Randomized Controlled Trial; Practice Guideline; Multicenter Study; Meta-Analysis; Comparative Study; published in the last 10 years; Humans; English; Female; Adult: 19+ years; Adult: 19-44 years

-Further refinement to be shown in table below.

Final strategy for PEDro:

pregnant AND women AND urinary incontinence

Final strategy for Cochrane:

pregnant AND women AND urinary incontinence

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| **Databases and Sites Searched** | **Number of results** | **Limits applied, revised number of results (if applicable)** |
| PubMedPEDroCochrane  | 875 originally16 results3 results | -English only (750)-Limited search by article type (case report, clinical trials, comparative study, meta-analysis, multicentre study, practice guidelines, RCT, systematic reviews) (378)-Added terms post-natal, postnatal, prenatal, pre-natal, pre natal, postpartum (all separated by AND); filtered by last 10 years (237)- Manually excluded non-experimental studies, studies identifying risk factors exclusively, studies not involving pregnant or recently post-partum women, studies not involving PFMT, studies exclusively involving electrotherapy (13)-English only (14)-Manually excluded trials not involving UI as outcome (11)-Manual excluded repeated results from PubMed, results which did not lead to working links (5)**-**Manually excluded trials not involving PFMT (1) |

## INCLUSION and EXCLUSION CRITERIA

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| **Inclusion Criteria** |
| * Experimental studies, randomized controlled trials (RCTs), systematic reviews, and meta-analyses
* Studies examining the use of pelvic floor muscle therapy (PFMT) on pregnant and post-partum women
* Studies involving the prevention or treatment of urinary incontinence (UI)
* Studies involving urinary continence as primary outcome
 |
| **Exclusion Criteria** |
| * Studies not involving PFMT as primary intervention
* Studies not involving antenatal or postnatal women
* Non-experimental studies, risk factor identifying studies
* Studies not involving urinary continence as primary outcome/UI as primary impairment/condition
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**RESULTS OF SEARCH**

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| A total of  | 18 | *(insert number)* relevant studies were located and categorised as shown in the following table (based on Levels of Evidence, Centre for Evidence Based Medicine, 2011) and (insert name of) quality assessment rating scale |

**Summary of articles retrieved that met inclusion and exclusion criteria**

*Note that this table is arranged differently from the example CAT on Sakai. For each article that meets your inclusion and exclusion criteria, score for methodological quality on an appropriate scale, categorize the level of evidence, and note the study design (e.g., RCT, systematic review, case study). Add more rows as necessary.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Author (Year)** | **Study quality score** | **Level of Evidence** | **Study design** |
| Hilde G, Stær-Jensen J, Siafarikas F, Ellström Engh M, Bø K. (2013) | 9/11 | 1b | RCT |
| Glazener CM, MacArthur C, Hagen S, Elders A, Lancashire R, Herbison GP, Wilson PD; ProLong Study Group. (2014) | 8/11 | 1b | RCT |
| Miquelutti MA, Cecatti JG, Makuch MY. (2013) | 9/11 | 1b | RCT |
| Ahlund S, Nordgren B, Wilander EL, Wiklund I, Fridén C. (2013) | 8/11 | 1b | RCT |
| Dumoulin C, Martin C, Elliott V, Bourbonnais D, Morin M, Lemieux MC, Gauthier R. (2013) | 8/11 | 1b | RCT |
| Pelaez M, Gonzalez-Cerron S, Montejo R, Barakat R. (2014) | 7/11 | 2b | RCT |
| Marques J, Botelho S, Pereira LC, Lanza AH, Amorim CF, Palma P, Riccetto C. (2013) | 8/11 | 2b | Controlled trial |
| Kocaöz S, Eroğlu K, Sivaslıoğlu AA. (2013) | 7/11 | 2b | RCT |
| Sangsawang B, Serisathien Y. (2012) | 9/11 | 1b | RCT |
| Ko PC, Liang CC, Chang SD, Lee JT, Chao AS, Cheng PJ. (2011) | 8/11 | 1b | RCT |
| Dumoulin C, Bourbonnais D, Morin M, Gravel D, Lemieux MC. (2010) | 8/11 | 1b | RCT |
| Dinc A1, Kizilkaya Beji N, Yalcin O. (2009) | 6/11 | 2b | RCT |
| Woldringh C1, van den Wijngaart M, Albers-Heitner P, Lycklama à Nijeholt AA, Lagro-Janssen T. | 8/11 | 1b | RCT |
| Boyle R, Hay-Smith EJC, Cody JD, Morkved S. (2012) | 11/11 | 1a | Systematic Review, Cochrane Review  |
| Morkved S, Bo K. (2014) | 9/11 | 1a | Systematic Review |
| Neumann PB, Grimmer KA, Deenadayalan Y. (2006) | 7/11 | 1a | Systematic Review |
| Stafne SN, Salvesen KA, Romundstad PR, Torjusen IH, Morkved S. (2012) | 7/11 | 2b | RCT |
| Mason L, Roe B, Wong H, Davies J, Bamber J. (2010) | 7/11 | 2b | RCT |

**BEST EVIDENCE**

The following 3 studies were identified as the ‘best’ evidence and selected for critical appraisal. Reasons for selecting these studies were:

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| * Boyle R, Hay-Smith EJC, Cody JD, Morkved S. (2012) This is a high quality systematic review from the Cochrane database. This includes many high quality RCTs discussed in detail, including variation in populations, treatment protocols, outcome measures, as well as primary and secondary prevention. Bias within studies is addressed in a concise and consistent manner. Clinical application is well summarized.
* Morkved S, Bo K. (2014). A high quality systematic review, which includes discussion of PFMT to prevent and treat UI in pregnant and post-partum women. It includes a detailed description of variation within populations and experimental protocols between studies, as well as an excellent description of the dose-response relationship shown by the included studies.
* Dumoulin C, Martin C, Elliott V, Bourbonnais D, Morin M, Lemieux MC, Gauthier R. (2013). This RCT should be included despite the presence of an additional moderate to high quality systematic review because it is the only study to include follow up longer than 1 year and is not included in the other systematic reviews. It is still a high quality RCT (8/11). It is also one of the only studies which stratified group subjects based on severity of baseline UI (based on a pad test) and number of prior pregnancies.

One study (Miquelutti et al.) received a high PEDro score, but is not clinically useful, as it does not sufficiently describe the intervention procedure, duration, instruction, or frequency. Several other high quality RCTs were not included as “best” evidence as moderate to high quality systematic reviews will contain higher quality evidence for critical appraisal. The remaining systematic review was excluded as it is of lower quality than the other two. |

**SUMMARY OF BEST EVIDENCE**

**(1) Description and appraisal of Randomized Controlled Trial of Physiotherapy for Postpartum Stress Incontinence: 7-year Follow-up by Dumoulin et al. (2013).**

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| **Aim/Objective of the Study:** |
| The aim of this study was to assess the long-term effect of an 8-week intensive program with pelvic floor muscle therapy (PFMT) in combination with or without deep (transverse) abdominal muscle training (TrA) for the relief or improvement of postpartum stress urinary incontinence (SUI). |
| **Study Design**[e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]Note: For systematic review, use headings ‘search strategy’, ‘selection criteria’, ‘methods’ etc. For qualitative studies, identify data collection/analyses methods. |
| * Randomized controlled trial, with outcomes assessed pre and post intervention, and at 7 year follow up.
* Randomized via balanced block randomization schedule, to create stratified randomization.
	+ Participants stratified into three groups (described under Participants section), based on parity (primipara and multipara) and severity of UI, based on pad test results (5-10 g or >10g of leakage)
* Control group was randomized into one of the two intervention groups following end of phase one (after initial 8-week intervention).
* Allocation was blinded and conducted by a research investigator not involved in the intervention or outcome assessment.
* Evaluators and treatment clinicians were blinded to group allocation.
* After 7 years, subjects were invited to participate in follow-up. A urology nurse, blinded to allocation, asked the subjects to complete 20-minute pad test and the three written outcome measures (described below under Outcome Measures section).
 |
| **Setting**[e.g., locations such as hospital, community; rural; metropolitan; country] |
| Women were recruited from a hospital in an urban area (Montreal, Quebec, Sainte-Justine Hospital). Article does not state if interventions were conducted at a clinic within the hospital or elsewhere.  |
| **Participants**[N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article. |
| * Recruitment: postpartum women (at least 3 months after most recent delivery) recruited from Sainte-Justine Hospital’s obstetrics clinic during their annual gynaecological visit.
* N=64 subjects
	+ N=62 Completed first phase of RCT (control group n=20, PFMT group n=21, PFMT+TrA group n=23)
		- 2 lost prior to 8-week data collection due to appendectomy (n=1) and time constraints (n=1)
	+ N=57 After control group re-randomization, subjects receiving PFMT with (n=29) or without TrA (n=28)
		- 5 control group subjects lost prior to re-randomization, reasons unreported
	+ N= 35 After 7 year follow up, subjects completing pad test and questionnaires (n=26) or questionnaires alone (n=19).
		- 22 subjects were lost before data collection of 7-year follow up. 10 subjects had changed phone numbers and were unable to be contacted. 11 did not want to participate due to other reasons (one had moved, several felt they were too busy with work or family).
* All female
* Mean age = 36 years (range 33-39)
* Mean parity = 2 (range 1.5-3)
* Diagnosis: SUI symptoms, as defined by the International Continence Society: one UI episode at least once a week, 3 or more months after their most recent delivery (p. 15).
* Stratified into three groups based on parity (primipara or multipara) and severity of incontinence based on pad test (5-10 g or more than 10 g loss during test).
* Groups did not vary significantly at baseline, after intervention, or at 7-year follow-up in regards to age (p=0.802), parity (p=0.995), duration of SUI symptoms (p=0.545), or BMI (p=0.469). Groups did not vary significantly at baseline for outcome measures, including pad test (p=0.875), VAS (p=0.768), UDI (p=0.483), IIQ (p=0.174), PFM maximum strength (p=0.952), or PFM rate of force generation (p=0.636). Outcome measures to be discussed below.
 |
| **Intervention Investigated**[Provide details of methods, who provided treatment, when and where, how many hours of treatment provided] |
| *Control* (For first phase only) |
| * 8 weekly sessions of relaxation back and extremities massage performed by a physical therapist (PT), session duration unspecified.
* Later (15/19 “control” subjects), randomized into one of two experimental groups, described below.
 |
| *Experimental* (two groups) |
| * PFMT+TrA group: 8 weeks of PFMT with TrA
* PFMT group: 8 weeks of PFMT alone
* Both groups received in person physical therapy (PT) once a week for 8 weeks, and a home exercise program (HEP).
	+ PFMT training for both groups consisted of 15 minutes of electrical stimulation, followed by 25 minutes of PFMT with a pelvic floor physical therapist.
	+ PFMT+TrA group additionally received 10 minutes of deep abdominal (transverse abdominus) muscle exercises.
	+ PT session (both groups) included:
		- 15 minutes of electrical stimulation of PFM (biphasic rectangular form, frequency 50Hz, pulse width 250μs, duty cycle: 6 seconds on and 18 seconds off for the first 4 weeks and 8 seconds on and 24 seconds off for the last 4 weeks, maximal tolerated current intensity) (Dumoulin 2010, p.1060).
		- 25 minutes of PFMT with biofeedback, consisting of strengthening and motor relearning.
		- (TrA group only) 30 minutes of deep abdominal training
	+ HEP consisted of PFMT with or without TrA (depending on group allocation) to be performed once daily, 5 times a week, at home. Program details not specified.
 |
| **Outcome Measures** (Primary and Secondary)[Give details of each measure, maximum possible score and range for each measure, administered by whom, where] |
| Outcomes: * Primary:
	+ Modified 20-minute pad test
		- A urine-loss quantification method; measures the weight gain in an absorbent sanitary pad during a 20 minute time period under standardized conditions.
		- Modified to include 10 jumping jacks instead of standard jumping exercises.
		- Weight gain/leakage of <2g considered continent.
		- Best score is 0 g. No floor.
		- Range: 0g and up (no maximum possible score formally recorded, though physiologically limited)
		- Administered by urology nurse-assessor unaware of treatment allocation.
		- Administrated location is unspecified.
* Secondary:
	+ Visual Analog Scale (VAS) for how subject perceived the burden of incontinence
		- 0-10 point scale, with 0 being the least burden perceived, 10 being maximum possible perceived burden.
		- Administering practitioner and location not specified.
	+ Urogenital Distress Inventory (UDI)
		- A 19 item paper questionnaire regarding lower urinary tract symptoms. Covers 3 domains: symptoms related to SUI, detrusor overactivity, and bladder outlet obstruction.
		- Items scored 0-3 points (0= not at all; 1, slightly; 2, moderately; 3, greatly)
		- Score range 0-57; high scores indicate worse conditions.
		- Administered location not specified. Subject completed independently.
	+ Incontinence Impact Questionnaire (IIQ)
		- A 26 item paper questionnaire assessing the psychological impact of UI, including daily living, social interactions, sex life, quality of life, and self-perception.
		- Items scored 0-3 points (0= not at all; 1, slightly; 2, moderately; 3, greatly)
		- Score range 0-78; high scores indicate worse conditions.
		- Administered location not specified. Subject completed independently.
	+ Measurements of PFM function
		- Assessing PFM strength and speed of contraction measured by PFM dynamometer
		- Range 0- up, in Newtons for strength and N/s for force development.
		- No known maximum possible score for strength or speed.
		- Administering practitioner and location not specified.
		- Not administered at 7-year follow-up.
 |
| **Main Findings**[Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided – if you need to calculate these data yourself, put calculations here and add interpretation later, under ‘critical appraisal’ on next page] |
| * Previously published study reported short-term outcomes (after 8 week intervention)
	+ Immediately post-intervention:
		- 70% (31/43) women in experimental groups (14/20 in PFMT, 17/23 in PFMT+TrA) were continent, compared to 0% (0/19) of control group subjects.

**Table 1**. Changes in Outcome Measure Score Between Baseline and After Treatment

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | PFMT group (n=20)median (★) | PFMT + TrA group (n= 23)median (★) | Control group (n=19)median (★) | P |
| Pad test (g) | 8.00 (4.00–25.25) | 19.00 (6.00–25.00) | 0.00 (-3.00 to 9.75) | 0.000 |
| VAS (out of 10) | 2.50 (0.75–5.0) | 3.00 (2.00–4.00) | 0.00 (-0.05 to 0.02 | 0.000 |
| UDI (out of 57) | 7.00 (3.00–8.00) | 4.00 (1.00–10.00 | 0.00 (-2.25 to 6.50 | 0.027 |
| IIQ (out of 90) | 13.00 (6.00–25.00) | 10.00 (2.00–16.00) | 0.50 (-6.50 to 5.00) | 0.000 |
| PFM strength (N) | 0.49(-0.58-2.54) | 0.69(0.24–2.34) | -0.48(-1.68-1.00) | 0.109 |
| Max rate of force development (N/s) | 0.31 (-1.11 to 1.93) | 0.82 (-1.05 to 2.92 | -0.46 (-2.05 to 0.76) | 0.219 |

★25th and 75th percentiles* + VAS, UDI, and IIQ scores improved significantly (p<0.002) in treatment groups, but no significant changes were observed with control group.
* After second phase (including re-randomized control group participants)
	+ 76% of PFMT only subjects with no SUI symptoms, 0 g on pad test
	+ 77% of PFMT+TrA with no SUI symptoms, 0 g on pad test
* At 7-year follow-up
	+ 35/57 participants who completed the initial study (61.4%) agreed to follow-up
	+ 26 (45.6% of participants who finished treatment) took the modified 20-minute pad test and paper questionnaires (12 from PFMT and 14 from PFMT+TrA); 9 (15.8%) completed paper questionnaires only.
	+ 22 subjects lost to follow up (discussed under Participants section). No differences in baseline clinical characteristics, including age, parity, BMI, or symptom severity, were found between those who agreed to follow up and those who did not, or between experimental groups.
	+ 53% (14/26) of subjects were still continent at 7 year follow up.
	+ 63.2% (12/19) of women who were continent immediately after initial intervention were still continent at 7-year follow-up.
	+ Pad test (severity), VAS (incontinence burden), and IIQ (quality of life) scores were all lower than baseline measures (see table 2 for p-values).
	+ UDI (incontinence symptoms) were lower than at baseline, but did not reach significance (p=0.10).
	+ Non-response rate around 40%. No identifiable differences at baseline between responders and non-responders in terms of age (p=0.59), parity (p=0.76), or BMI (p=0.18).

**Table 2**. Outcome Measure Scores of PFMT and PFMT+TrA groups at Baseline

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | PFMT group (n=18)median (★) | PFMT + TrA group (n= 17) median (★) | Mann– Whitney’s U-value | P |
| Pad test (g) | 13.00 (7.00–34.00) | 10.00 (6.00–48.00 | 146.00 | 0.82 |
| VAS (out of 10) | 8.00 (6.75–8.00) | 7.00 (4.50–8.00) | 112.00 | 0.16 |
| UDI (out of 57) | 12.00 (10.00–13.25) | 10.00 (6.5–13.50) | 112.50 | 0.18 |
| IIQ (out of 90) | 26.00 (16.75–41.00) | 14.00 (3.00–28.00) | 87.00 | 0.03 |

★25th and 75th percentilesPFMT strength and rate of force development data was not taken at 7-year follow-up.**Table 3**. Outcome Measure Scores of PFMT and PFMT+TrA groups at 7-year Follow-up

|  |  |  |  |
| --- | --- | --- | --- |
| PFMT group (n=18)median (★) | PFMT + TrA group (n= 17) median (★) | Mann– Whitney’s U-value  | P |
| 2.50 (0.25–17.25)\* | 2.00 (1.00–6.00)\*\* | 79.5  | 0.82 |
| 5.50 (3.75–7.00) | 3.00 (1.00–7.00) | 108.00  | 0.13 |
| 9.00 (6.75–15.50) | 7.00 (2.00–12.5) | 105.00 | 0.10 |
| 10 (7–15) | 6 (2–10) | 91.50  | 0.05 |

★25th and 75th percentiles\*n=12\*\*n=14PFMT strength and rate of force development data was not taken at 7-year follow-up.Non-parametric Friedman rank (Fr) was used for multiple comparisons between conditions.**Table 4.** Comparison of the Treatment Groups (scores combined) Between Baseline, Post-Treatment, and 7-year Follow-up

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Baseline median | Post-treatment median | 7-year Follow-up median | Friedman Rank Test | Post hoc comparison |
| Pad test (n=26) | 10 (7-32) | 1 (0-3) | 2 (1–9) | 32.49\* | E-PT\*\*, E-F\*\*, PT-F\*\* |
| UDI (n=35) | 11 (8-13) | 5 (2-9) | 7 (6–14) | 17.96\* | E-PT\*\*, E-F, PT-F |
| IIQ (n=35) | 24 (11-35) | 8 (1-13) | 11 (3–24) | 30.24\* | E-PT\*\*, E-F\*\*, PT-F\*\* |
| VAS (n=35) | 7(6-8) | 3 (1-6) | 11 (3–24) | 23.40\* | E-PT\*\*, E-F\*\*, PT-F |

PFMT strength and rate of force development data was not taken at 7-year follow-up.★25th and 75th percentiles in parenthesesFriedman rank test post hoc comparisons E=Entry; PT=post-treatment; F=7-year follow-up.\*p≤0.05\*\*p≤0.01The authors calculated the effect size of Mann-Witney’s U-test to be r=0.11 (small to medium). |
| **Original Authors’ Conclusions**[Paraphrase as required. If providing a direct quote, add page number] |
| The main aim of this study was to determine if PFMT with or without TrA can provide long-term benefits to continence in postpartum women, and to this end, this follow-up study provides evidence that while PFMT does provide long-term benefits, TrA provides no additional short or long term benefits to continence outcomes. There are no significant differences at 7-year follow-up between PFMT alone and PFMT+TrA in any outcome measures. Though treatment improved long-term continence outcomes, the benefits are less apparent at 7-year follow-up than immediately post-treatment. However, roughly 67% of women who were continent following treatment remained continent at 7-year follow-up. At 7-year follow-up, subjects receiving PFMT experienced decreased SUI symptoms and severity, decreased UI burden, and improved SUI-related quality of life outcomes. |
| **Critical Appraisal** |
| **Validity**[Methodology, rigour, selection, sources of bias, quality score on methodology quality rating scale (indicate the quality assessment tool used and the maximum possible score on that scale, e.g., 7/10 on PEDro scale), appropriateness of analytical approach (e.g., adjustments for confounding variables, management of missing data).]Comment on missing information in original paper. |
| Though greater efforts should have been taken to maintain contact with subjects to reduce the number of individuals lost to follow-up, the overall compliance and relatively low drop-out rate makes this in some ways a more powerful study than many that have come before that have had much higher drop-out and non-compliance rates. However, the losses that occurred between post-treatment and follow-up reduce the number of subjects below the necessary sample size to maintain 80% power, and thus unfortunately this study risks being underpowered. The original study was conducted assuming 29 subjects were necessary per group for 80% power at the 0.05 significance level to detect statistical significance. After the re-randomization of the “control” group, only the PFMT+TrA group had the necessary 29 subjects, while the PFMT only group had only 28 subjects. After losses to follow-up, the PFMT+TrA group had only 17 subjects while the PFMT group had only 18. Thus, the risk of this study being underpowered and a type II error cannot be ruled out. This is likely the largest issue this study has and calls the results, at least from the follow-up period, into question. Other issues with this study exist as well. Though rating an 8/11 on the PEDro scale, they lack some important statistical information, and did not publish the information necessary with which to calculate it. They lack confidence intervals, but also do not report on standard deviation, making it difficult to calculate other important information.This study does not specifically mention how women were chosen for the study, though the recruitment was conducted at a hospital clinic during annual visits. A simple possibility of selection bias occurs here—how are the women who chose to enter this study different from those who decided not to? Equally, how are women at this hospital different from those at other nearby hospitals? This article specifically discusses the results from the follow-up 7 years after the initial intervention. Though the authors mention the reasons that some women were lost to follow-up, it is unclear if the women lost to follow-up are somehow different from other subjects, though not in the specific ways mentioned (age, parity, BMI, and UI severity). Though UI severity is not different, it is unknown if other factors, such as quality of life changes, perceived burden, social isolation, tobacco use, family support, or other factors were different with the women lost to follow-up or those who participated in it.The authors use the Mann–Whitney’s U-value to show that baseline characteristics of age, parity, and BMI of responders (those who became continent during the study) and non-responders did not have statistical significant differences. However, they do not perform similar statistical analyses for baseline outcome measure ratings, social support, educational level, smoking status, or other potentially influential aspects that could contribute to the subject’s response to treatment. Overall, there are many baseline characteristics, such as those previously mentioned, that are relevant to SUI outcomes that are not reported on. The absence of covariate analysis other than further pregnancy and continued PFM practice post-intervention is a significant limitation of this study. The authors also do not mention if subjects missed treatment sessions in the clinic, and if they did, how that was handled (that is, were they rescheduled or not). Given that the PT-led therapeutic exercise is an important portion of this intervention, knowledge of compliance is highly relevant and its absence further questions the validity of results.As a further methodology concern, the authors state that they saw no need to continue the control group for the sake of the 7-year follow-up, since data does exist for what happens when no treatment is received. The researchers state ethically it did not make sense to continue withholding treatment, as these data already exist and the benefits of treatment, at least in the short term, became apparent with the initial treatment groups. However, without this data, it is hard to compare long-term outcomes. That is, it is difficult to know if some formerly non-responder subjects experienced some recovery of continence slowly over the 7 years, or to what extend and rate spontaneous recovery of continence occurs in healthy adult women. Detailed information regarding recovery of continence following pregnancy is sparse, and studies on this subject often are of low quality.This article uses a per protocol follow-up design instead of intention to treat analysis. Since 22 individuals were lost to follow-up prior to the 7-year follow-up data collection, including these individuals in statistical analysis would substantial cloud data interpretation.Unfortunately, minimally clinically important difference (MCID) and minimal detectable change (MDC) values to not exist for any of the outcome measures used in this study, making understanding of the clinical relevance somewhat difficult. While many women passed under the 2 g maximum for urinary continence on the modified pad test, this outcome measure does not have an established MCID. Thus, if a subject experienced a decrease in leakage, it is unknown if that change is real or measurement error. This is a limitation of the outcome measures chosen by the authors. The use of the control group and PT-performed extremity massage in the first phase helps to control for the response of subjects to special attention from a licensed clinician.Mean, standard deviation, and confidence intervals are not reported in this study, as the data was not normally distributed. Instead, median and IQR were reported.  |
| **Interpretation of Results**[Favourable or unfavourable, specific outcomes of interest, size of treatment effect, statistical and clinical significance, minimal clinically important difference. You may calculate effect size or confidence intervals yourself from the data provided in the article.] Describe in your own words what the results mean. |
| The first article published from this study (2004) examines the effect of PFMT with or without TrA on SUI in postpartum women and defines continence as a loss of less than 2 g during the modified Pad Test. To this end, both immediately post-intervention and at 7-year follow-up, this protocol provides significant relief of SUI in postpartum women. Not only does this PFMT protocol decrease the frequency and severity of SUI, it also improves the subject’s sense of burden from SUI, and improves overall symptoms and quality of life related to UI. However, the effect of PFMT does lessen over time, particularly for burden and overall symptoms. Nonetheless, the number of subjects who continue to be continent from immediately post-intervention until 7-year follow-up makes this a clinically important study. Though the benefits received are less noticeable than immediately following treatment, the fact that improvement is noticeable at all is impressive, given that only 54% (19/35) of subjects continued the HEP independently following treatment, though how long and how often they continued the HEP is unreported. Regarding changes from baseline to post-treatment, and baseline to 7-year follow-up, both PFMT and PFMT+TrA had significant differences in pad test, VAS, UDI, and IIQ scores, though PFM strength and rate of force development (for baseline to post-treatment) were not statistically significantly different. While PFMT may be a useful modality in reducing SUI, TrA does not provide appear to provide additional benefit, as there were no significant statistical differences at any time point between PFMT and PFMT+TrA groups.As previously stated, this study appears underpowered due to small follow-up sample size. Given that the same result (no difference between PFMT with or without TrA in improving continence outcomes) was found immediately post-intervention, these results appear reasonable, though future, larger studies would need to be conducted to ensure the reliability of these data.Pad test results for experimental groups demonstrate significant differences between entry, post-treatment, and 7-year follow up (all time points) (p≤0.01). All outcome measures show statistical significant at the p≤0.01 level between baseline and post-treatment. Only the pad test and IIQ show significance at the p≤0.01 level between post-treatment and follow-up, and only the UDI does not show significance at the p≤0.01 level between baseline and follow-up. |

**(2) Description and appraisal of Pelvic floor muscle training for prevention and treatment of urinary and faecal incontinence in antenatal and postnatal women (Boyle R, Hay-Smith EJC, Cody JD, Mørkved S, 2012)**

|  |
| --- |
| **Aim/Objective of the Systematic Review:** |
| The aim of this Cochrane systematic review is to compare PFMT with usual antenatal and postnatal care on the prevention and treatment of urinary and faecal incontinence in antenatal and postpartum women.  |
| **Study Design**[e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]Note: For systematic review, use headings ‘search strategy’, ‘selection criteria’, ‘methods’ etc. For qualitative studies, identify data collection/analyses methods. |
| * Systematic review and meta-analysis of randomized controlled trials and quasi-randomized trials
* Search strategy
	+ Trials were identified via the Cochrane Incontinence Group Specialised Register, the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, CINAHL, and the hand searching of journals and conference proceedings.
	+ MeSH terms: Exercise Therapy [\*methods]; Fecal Incontinence [prevention & control; \*therapy]; Pelvic Floor; Postnatal Care; Pregnancy Complications [prevention & control; \*therapy]; Prenatal Care; Randomized Controlled Trials as Topic; Urinary Incontinence [prevention & control; \*therapy]
	+ MeSH check words: female; humans; pregnancy
* Selection criteria
	+ Articles included were randomized controlled trials or quasi-randomized trials, conducted on pregnant or post-partum women with urinary, fecal, or mixed incontinence (UI, FI, MI)
	+ Articles must include PFMT and an alternative therapy control (no PFMT or usual antenatal/postnatal care).
	+ No articles published after February 2012.
	+ No restriction on language of publication
	+ No restriction on publication status (full publication, grey literature, etc.)
* Methods
	+ Potentially eligible studies were reviewed for inclusion by two review authors.
	+ Disagreements were resolved via discussion. In cases where resolution was not achieved, a third reviewer was given final decision-making power.
	+ Data was extracted by the two review authors and cross checked. Data processing followed the method described in the Cochrane Handbook for Systematic Reviews of Interventions.
	+ In cases of missing data, further clarification was sought from study authors.
	+ 785 titles were assessed for review; 73 full text articles were obtained; 22 studies were found to be eligible for inclusion.
	+ Study populations were considered in three groups:
		- Continent at baseline (prevention trials)
		- Incontinent at baseline (treatment trials)
		- Mixed continent and incontinent at baseline (mixed prevention and treatment trials)
	+ Study interventions were divided into two categories
		- PFMT beginning in antenatal period
		- PFMT beginning in postnatal period
 |
| **Setting**[e.g., locations such as hospital, community; rural; metropolitan; country] |
| Systematic review conducted through the Cochrane Collaboration, by the Cochrane Incontinence Group.Trial settings include: * Multicenter hospital based
* Multicenter outpatient based
* Outpatient physical therapy clinic; primary care setting
* University-conducted primary care, single center
* Hospital obstetric clinic, single center
* Single center, not otherwise specified
* Recruitment from obstetric clinic; intervention location not specified
* Not specified
* Home based home exercise program (HEP)

Geographic locations* Brazil
* Canada
* China
* Italy
* Mexico
* The Netherlands
* New Zealand
* Norway
* Switzerland
* UK
* USA
 |
| **Participants**[N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article. |
| * 22 trials included (more information on trials included under Intervention Investigated: Experimental subheading)
* Subjects
	+ All women
	+ Pooled sample characteristics
		- Pooled sample size: 8485 women (4231 PFMT, 4254 control) from 22 studies
		- Antenatal PFMT subjects were nulliparous or primigravid
		- Postnatal PFMT subjects were primigravid or multigravida
		- Age of subjects ranged from 20-42 between trials
		- Median age was not similar between trials (range of median age of participants: 28-36)
		- BMI reported in 11/22 trials; non-homogenous between trials; mean BMI range: 21-“overweight or obese”
		- Delivery type data reported in 5/7 trials with antenatal PFMT
		- Delivery data not reported in postnatal PFMT trials.
	+ Sample size range: 25-1800 participants
* Trial characteristics
	+ Databases searched
		- Cochrane Incontinence Group Specialised Register, CENTRAL, MEDLINE, CINAHL
	+ Inclusion criteria
		- Experimental studies conducted on pregnant or post-partum women with urinary, fecal, or mixed incontinence (UI, FI, MI)
		- Articles that include PFMT and an alternative therapy (no PFMT or usual antenatal/postnatal care).
		- Randomized controlled trials and quasi-randomized trials only
	+ Exclusion criteria
		- 8 excluded because they did not collect any UI or FI outcome data.
		- 5 excluded because while they included PFMT as an intervention, but PFMT was not included as primary comparison intervention.
		- 1 excluded due to internal inconsistencies and data discrepancies
		- 1 excluded due to inability to locate trial
 |
| **Intervention Investigated**[Provide details of methods, who provided treatment, when and where, how many hours of treatment provided] |
| *Control* |
| Control group protocol varied significantly between studies. Details on control group treatment and number of trials follow. Some studies may be represented in multiple categories below.* 2/22: received verbal or written instruction in correct voluntary PFM contraction
* 1/22: received written instruction on PFMT that was part of usual care
* 7/22: usual care that may have included PFMT
* 1/22: did not discourage independent PFMT
* 2/22: asked control group not to perform PFMT
* 11/22: lacked sufficient detail to classify control protocol
 |
| *Experimental* |
| All included trials compared PFMT with usual care or no PFMT for antenatal or postnatal women. Experimental group protocol varied significantly between studies.* 4/22 primary or secondary\*\* prevention trials (no participants had incontinence at baseline)
	+ PFMT begun antenatally
* 6/22 treatment trials (all participants had incontinence at baseline)
	+ 3 studies started PFMT antenatally
	+ 3 studies started PFMT postnatally
* 12/22 studies were mixed prevention and treatment (some participants had incontinence at baseline)
	+ 7 studies started PFMT antenatally
	+ 5 studies started PFMT postnatally
* 6/22 trials used conference abstracts, without sufficient details for categorization
* 11/22 included sufficient details for categorization of training regimens
* PFMT training regimens
	+ 7/22: Strength and effort training PFMT (short, maximal PFM contractions, small number of repetitions)
	+ 2/22: Strength training without details on effort/intensity (strength of contractions) or frequency (number of repetitions)
	+ 2/22: Strength and endurance training (fast and slow contractions, large number of sets with few repetitions, large number of daily contractions), without details on effort/intensity.
	+ 11/22: did not include sufficient information on experimental protocol for classification
	+ Additional characteristics:
		- 2/22: included “the Knack” training (voluntary PFM contraction prior to rises in intra-abdominal pressure, or “squeeze before you sneeze” training).
	+ Range of duration of intervention: 7-20 weeks
	+ Follow up: 34-36 weeks antenatally. Post-natal follow-up range: 9-52 weeks

\*\*Primary prevention aims to remove the causes of a disease or condition. The authors define secondary prevention as prevention programs or interventions which aim to detect asymptomatic dysfunction and treat it early to stop progression. However, included prevention trials did not screen for asymptomatic dysfunction with participants who were continent at baseline. As discussed in Dumolin et al.,8 a valid and reliable screen for asymptomatic dysfunction may not exist. Thus, primary and secondary prevention were considered together in this systematic review. |
| **Outcome Measures** (Primary and Secondary)[Give details of each measure, maximum possible score and range for each measure, administered by whom, where] |
| No specific outcome measures used in the trial were mentioned in this review.* Primary outcome
	+ Self-reported UI, FI, or MI
* Secondary outcomes
	+ Quantification of symptoms
		- Number of UI or FI episodes
		- Frequency of UI or FI episodes
		- Symptom severity
	+ Clinician measures
		- Measures of pelvic floor muscle function
			* Electromyography, vaginal or anal squeeze pressure
	+ Quality of life measures
		- Severity of incontinence
		- Impact of incontinence on quality of life
		- Psychological measures
		- General health status
	+ Socioeconomic outcomes
		- Costs of intervention(s)
		- Resource implications in differences between outcomes
		- Formal economic analysis, including cost effectiveness and cost utility
	+ Adverse outcomes
		- Discomfort or pain associated with PFMT
	+ Other outcomes
		- Treatment protocol adherence
		- Delivery outcomes (for antenatal treatment only), including type of delivery and perineal trauma
		- Sexual function
		- Pelvic organ prolapse
		- Outcomes that were not specified prior to data collection that were judged important when performing the review
 |
| **Main Findings**[Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided – if you need to calculate these data yourself, put calculations here and add interpretation later, under ‘critical appraisal’ on next page] |
| Findings are divided up by prevention, treatment, and mixed trial types.Table 1 reports on the reported risk ratios (RR) with 95% confidence intervals, for incontinence at various points in time (late pregnancy, early/mid/late postnatal, and medium/long term outcomes), with PFMT initiated in antenatal or postnatal periods. Data for some time periods is insufficient for RR calculation, and is marked. **Table 1.** Risk ratios of pelvic floor muscle treatment initiation on different time periods during pregnancy and the postpartum period, stratified by study category.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Prevention trials | Treatment Trials | Mixed Trials |
|  |
|  | AntenatalTreatment | Postnatal Treatment | AntenatalTreatment | Postnatal Treatment | AntenatalTreatment | Postnatal Treatment |
| Late pregnancy  | RR 0.44 (0.14, 1.33)  | N/A | RR 0.81 (0.56, 1.18) | N/A | RR 0.74 (0.58, 0.94) | N/A |
| Early postnatal | RR 0.50 (0.31, 0.80) ★ | \*★ | RR 0.88 (0.70, 1.11)★ | \*★ | RR 0.77 (0.59, 1.01)★ | \*★ |
| Mid postnatal | RR 0.71 (0.54, 0.95) ★ | \*★ | RR 0.00 (0.00, 0.00)★ | \*★ | RR 0.79 (0.60, 1.03) | RR 1.00 (0.79, 1.26) |
| Late postnatal | RR 0.0 (0.0, 0.0) ★ | \*★ | RR 0.50 (0.14, 1.93) | RR 0.60 (0.35, 1.03) | RR 0.96 (0.70, 1.32)★ | RR 0.94 (0.75, 1.16)★ |
| Medium term | \*★ | \*★ | \*★ | RR 0.96 (0.88, 1.05)★ | \*★ | \*★ |
| Long Term | RR 1.07 (0.77, 1.48) ★ | \*★ | \*★ | RR 1.03 (0.94, 1.12)★ | \*★ | \*★ |

Risk ratios presented as estimate (95% CI)\* Insufficient trial information to estimateEarly postnatal period: 0-3 months, mid-postnatal period: 3-6 months, late postnatal period: 6-12 months, medium term: 1-5 years, long term: >5 years Mantel-Haenszel test, random effects model★ Mantel-Haesnzel test, fixed effects modelHeterogeneity of study participants and study design makes statistical analysis difficult. Table 2 provides information regarding statistically significant heterogeneity.**Table 2**. Heterogeneity across study participants, stratified by study category.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Prevention trials | Treatment Trials | Mixed Trials |
|  |
|  | AntenatalTreatment | Postnatal Treatment | AntenatalTreatment | Postnatal Treatment | AntenatalTreatment | Postnatal Treatment |
| Late pregnancy  | P=0.003 | N/A | P=0.09 | N/A | P=0.00022 | N/A |
| Early postnatal | P=0.14 | \* | P=0.09 | \* | P=0.76 | \* |
| Mid postnatal | P=0.71 | \* | \* | \* | P=0.06 | P=0.03 |
| Late postnatal | \* | \* | P=0.00007 | P=0.005 | P=0.72 | 0.79 |
| Medium term | \* | \* | \* | P=0.41 | \* | \* |
| Long Term | P=0.25 | \* | \* | P=0.55 | \* | \* |

\* Insufficient trial information to estimateEarly postnatal period: 0-3 months, mid-postnatal period: 3-6 months, late postnatal period: 6-12 months, medium term: 1-5 years, long term: >5 yearsα<0.05Many of the included studies have significant sources of bias. These sources have been categorized in Table 3.**Table 3**. Percentage estimates of studies possessing specific sources of bias in systematic review.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Low Risk | Uncertain Risk | High Risk |
| Selection bias: random sequence generation | 55% | 45% | 0% |
| Selection bias: allocation concealment | 30% | 70% | 0% |
| Performance bias: blinding of participants and personnel | 0% | 0% | 100% |
| Detection bias: blinding of outcome assessors | 30% | 60% | 10% |
| Attrition bias: incomplete outcome data | 55% | 30% | 15% |

 |
| **Original Authors’ Conclusions**[Paraphrase as required. If providing a direct quote, add page number] |
| PFMT can be safely used to reduce prevalence of UI during and up to 1 year following pregnancy. The author’s conclusions vary slightly on when PFMT is initiated and based on outcome time period, though in general, the author’s conclude that PFMT is an effective and safe means of preventing and treating incontinence. PFMT initiated early in pregnancy is effective at reducing the incidence and severity of incontinence during late pregnancy and up to six months after delivery. The authors conclude there is insufficient information at current to conclude if PFMT is effective at preventing incontinence in the long term (more than one year). Regarding prevention, antenatal PFMT is effective at preventing incontinence up to six months postnatally, compared to usual care. However, these continent pregnant women may require more “intensive” PFMT programs, with higher dose and intensity, to prevent incontinence, compared to treatment programs for women already with incontinence.Regarding mixed prevention and treatment, antenatal PFMT is effective at reducing prevalence of UI in late pregnancy, though this benefit does not appear to continue long into the postnatal period. The authors conclude there is insufficient information to assess a mixed treatment/prevention approach in the postnatal period.For pregnant primiparous women, PFMT is effective at preventing the development of UI up to six months following delivery. This systematic review of the available evidence provides support that PFMT is an appropriate method for the prevention and treatment of persistent postpartum UI. It may be more beneficial to create a more targeted intervention or prevention approach, as the exercise duration and intensity needs of these populations may vary.  |
| **Critical Appraisal** |
| **Validity**[Methodology, rigour, selection, sources of bias, quality score on methodology quality rating scale (indicate the quality assessment tool used and the maximum possible score on that scale, e.g., 7/10 on PEDro scale), appropriateness of analytical approach (e.g., adjustments for confounding variables, management of missing data).]Comment on missing information in original paper. |
| This Cochrane review uses a high quality design with low bias, increasing the validity and strength of their conclusions. Overall, sources of bias in the included studies are varied, though in this review are minimal. The authors chose only study designs at the top of the evidence hierarchy (RCTs and quasi-randomized controlled trials). The authors provided both their search terms and a detailed list of inclusion and exclusion criteria. They also included the list of excluded trials and reasons for exclusion. Reasons for exclusion are provided under Participants section. This systematic review received an AMSTAR rating of 11/11.Though some of the included studies have either unknown or moderate risk of bias, the authors attempted to take this into account when drawing conclusions from study data. The authors attempted a sensitivity analysis with respect to study quality, to account for the varying quality of studies on the meta-analysis. However, the authors found an insufficient number of trials with useable data and excessive heterogeneity between trials to make this sensitivity analysis useful.The authors grade the included studies based on risk of bias on five items:1. Selection bias: random sequence generation. Were the groups randomly assigned?
2. Selection bias: allocation concealment. Were the group allocations concealed?
3. Performance bias: blinding of participants and personnel. Were study participants and interventionists blinded to group allocation?
4. Detection bias: blinding of outcome assessment. Were outcome assessors blinded to group allocation?
5. Attention bias: incomplete outcome data. Did the studies report dropout and withdrawal, and perform analysis by intention to treat?

This information is included as pooled data (percent of studies with high, unclear, or low risk of bias in each of the five areas), as well as individual rating for each study on each of the five areas. Pooled data can be seen in Table 3. The largest sources of potential bias in the studies are performance bias—lack of blinding of participants and personnel, with 100% of studies being at high risk of bias, and detection bias—with 70% of studies being at unknown or high risk of bias for lack of blinding of assessors.The authors did not exclude studies on the basis of language or publication status, and included grey literature and conference abstracts, which reduces the risk of publication bias. The authors used individual patient data when available from the study authors. However, since this data was only available from a small number of trials, significant analysis using this data is not feasible.The authors used a fixed effects model for most time periods, implying that the authors believed differences in results of the individuals studies were due to chance variation. However, given the significant heterogeneity between studies, a random effects model, which assumes differences are meaningful (but cannot be explained) was used on some data points.The following is a list of other potential sources bias in included studies:* Brevity of reporting was a concern in 6/22 trials (conference abstracts), 1/22 without sample size.
* 1/22 were small trials (under 25) and 6/22 were of moderate size (25-50). 12/22 had more than 50 per group. 5/22 were greater than 300 per group, and 2/22 had 500 per group. The smallest trials risk being underpowered, while the largest may risk being overpowered, resulting in the potential for type II and type I errors, respectively.
* 13/22 reported on a priori power calculation. Without a priori power calculation, it is unclear how the remaining studies determined the necessary sample size for sufficient power.
* Random allocation is described only in 13/22 studies. 3/22 stated random allocation but did not include method, so it is impossible to judge method quality. 6/22 did not include sufficient information on allocation.
* Random allocation concealment was only reported in 7/22 trials. 2/22 included insufficient information to assess concealment. 13/22 did not report any concealment.
* Blinding: no studies could blind participants or interventionists to treatment; this increases risk of performance bias across all studies. No studies mention blinding participants to study hypotheses.
* Blinding of outcome assessment: 7/22 studies blinded outcome assessment of primary outcome measure, or use an anonymised method of collecting patient-report symptom data. 2/22 did not include any assessor blinding. 13/22 did not include sufficient information to judge assessor blinding.
* Reporting of dropout and withdrawal: 4/22 did not report losses to follow up or intention to treat analysis. 11/22 carried out intention to treat analysis based on group assignment. 14/22 reported similar drop out rates between groups.
* Generally, the largest sources of known bias within the included studies are the lack of blinding of participants and treatment personnel, blinding of outcome assessors, and incomplete outcome data. Incomplete data makes assessment of bias difficult in some areas, including random group allotment and group concealment.
* There is also risk of contamination bias in many of these studies, since control groups received some level of advice regarding PFMT, though some control groups received no information on PFMT at all.

As previously noted, there is significant heterogeneity in the included studies of reported information, including BMI, age, parity, delivery method, control and treatment protocol (duration, intensity, repetitions, frequency), outcome assessment timing, treatment initiation, and overall study design. This heterogeneity of study participants and study design makes comparison across trials difficult and may limit the clinical applicability of the review’s conclusions. Heterogeneity data can be seen in Table 2. Heterogeneity is statistically significant for prevention trials examining antenatal treatment on late pregnancy outcomes, treatment trials examining antenatal and postnatal treatment on late postnatal period outcomes, and in mixed treatment trials for antenatal treatment in late pregnancy as well as postnatal treatment in the mid postnatal period. For all of these time periods, heterogeneity is statistically significant and is not the result of chance. Variation in outcome data also complicates meta-analysis. There is a lack of consistency between the studies on the definition of UI and continence (any/no episodes, loss of more than 5g/any loss/no loss of urine on a pad test, etc.), which makes comparison across trials difficult. Some studies report on incontinence as a binary statistic (absence/presence), some report on quantitative decreases (a decrease in urine lost during a pad test, or a decrease in number of episodes). A subject in a dichotomous trial might experience a large decrease in severity and number of incidents, but still be considered incontinent, and would not be reported as having improved. This variation makes conclusions across trials difficult. |
| **Interpretation of Results**[Favourable or unfavourable, specific outcomes of interest, size of treatment effect, statistical and clinical significance, minimal clinically important difference. You may calculate effect size or confidence intervals yourself from the data provided in the article.] Describe in your own words what the results mean. |
| The pooled data show the statistically significant protective and treatment effect of PFMT on continence outcomes in pregnant and postpartum women. Continent pregnant women who receive intensive antenatal PFMT will be less likely to report incontinence during late pregnancy (RR 0.44, 95% CI 0.14, 1.33)\*, the early postnatal period (RR 0.50, 95% CI 0.31, 0.80), and the mid postnatal period (RR 0.71, 95% CI 0.54, 0.95), compared to women who receive usual care. Overall, antenatal PFMT for prevention leads to around a 30% decrease in likelihood of UI development up to six months post-delivery. However, after six months, antenatal PFMT appears to no longer provide preventative benefits, with no effect during the late postnatal period (RR 1.20, 95% CI 0.65, 2.21) and or on long-term outcomes (RR 1.07, 95% CI 0.77, 1.48). However, given that only 1/22 trial include late postnatal period outcomes and 2/22 trials included in this review included long-term outcomes, more research is necessary to determine the effect of preventative antenatal PFMT on outcomes longer than 6 months. Currently, there is not significant evidence to support or deny the efficacy of preventative postnatal treatment on incontinence.\*These results should be interpreted with caution, as their confidence intervals are imprecise and cross the midline. One of the reasons for the lack of precision may be that the only one of the 5 preventative antenatal PFMT studies that did not find statistical significance had a small sample size and high drop out rate, increasing the risk of being underpowered. Preventative antenatal PFMT clearly requires more research to determine efficacy. For treatment of incontinence, antenatal PFMT has a noticeable though decreased effect in late pregnancy (RR 0.81, 95% CI 0.56, 1.18) and during the early postnatal period (RR 0.88, 95% CI 0.70, 1.11). However, caution should again be used when interpreting these data as the confidences intervals are imprecise and cross the midline of no effect. During the mid postnatal period, PFMT appears to have no effect, though this may be as a result of data from underpowered studies with small sample sizes. During the late postnatal period, the strength of antenatal PFMT to reduce UI is more pronounced (RR 0.50, 95% CI 0.14, 1.93), though there is considerable variation between included studies, leading to a relatively wide confidence interval that again crosses the midline of no effect. Postnatal treatment of UI in treatment trials are similarly varied and include confidence intervals that cross the midline during the late postnatal period (RR 0.60, 95% CI 0.35, 1.03), during the medium term (RR 0.96, 95% CI 0.88, 1.05) and in the long term (RR 1.03, 95% CI 0.94, 1.12). Though these results should be interpreted with caution due to imprecise confidence intervals, it appears that women with UI at 3 months post-delivery who receive PFMT are around 40% less likely to report UI symptoms at 12 months, compared to women who receive usual care (RR 0.60, 95% CI 0.35 to 1.03). Additionally, the pooled data from 5/22 trials provides evidence that antenatal and postnatal treatment up to one year after delivery provides statistically significant improvement in symptoms (RR 0.58, 95% CI 0.39, 0.87). More research is clearly necessary to understand the variation between trials. Mixed prevention and treatment trials appear to have slightly reduced ability to prevent and treat UI compared to prevention only and treatment only trials. Antenatal treatment appears slightly more effective in mixed trials compared to postnatal treatment, though data is sparse, particularly for longer-term outcomes (after 6 months). Antenatal PFMT mixed prevention and treatment for late pregnancy continence provides the best outcomes (RR 0.74, 95% CI 0.58, 0.94), followed by the early post-natal period (RR 0.77, 95% CI 0.59, 1.01) and the mid postnatal period (RR 0.79, 95% CI 0.60, 1.03). Antenatal treatment does not appear to have a large effect on outcomes during the late postnatal period (RR 0.96, 95% CI 0.70, 1.32), or does postnatal treatment during the mid postnatal period (RR 1.00, 95% CI 0.79, 1.26) or late postnatal period (RR 0.94, 95% CI 0.75, 1.16). However, the number of trials in the mixed prevention/treatment category is relatively low, and they had lower methodological quality than the prevention or treatment only trials. Thus, it is unclear if PFMT is effective when given to a mixed (continent and incontinent) population of postpartum women. PFMT initiated antenatally or postnatally is effective in reducing incontinence during late pregnancy and up to 6 months following delivery. Medium and long-term results are to be interpreted with caution, as only 3/22 trials reported long-term results after the first year, and several of them have low power from small sample sizes. Several trials did not find statistically significant differences at long term follow up between PMFT and control groups. However, continued adherence was low, 50% in one study for occasional PFMT, and 6% for daily in the intervention group. These result are further complicated by the fact that many women went on to have further pregnancies. |

 **(3) Description and appraisal of Effect of pelvic floor muscle training during pregnancy and after childbirth on prevention and treatment of urinary incontinence: A systematic review by (Mørkved S, Bø K, 2012)**

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| **Aim/Objective of the Systematic Review:** |
| The objective of this systematic review was to examine the effect of PFMT during and after pregnancy in the prevention and treatment of UI. They aim to answer the questions: does the evidence support advising pregnant and postpartum women to perform PFMT to prevent or treat UI? What is the optimal dosage for antenatal and postnatal PFMT for prevention and treatment of UI? Finally, what is the long-term effect of PFMT performed during antenatal and postnatal periods? |
| **Study Design**[e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]Note: For systematic review, use headings ‘search strategy’, ‘selection criteria’, ‘methods’ etc. For qualitative studies, identify data collection/analyses methods. |
| * Systematic review of randomized controlled trials (RCTs) and quasi-experimental studies
* Search strategy
	+ Keywords: pregnancy, pelvic floor muscle, exercise, training, incontinence, after delivery, postpartum, childbirth, effect, prevention
* Selection criteria
	+ Article types: RCTs and quasi-experimental trials
	+ Publication requirements: full publications or meeting abstracts
	+ Published in English or Scandinavian languages
	+ Participants: primiparous or multiparous, pregnant or post-partum
	+ Interventions: PFMT with or without biofeedback, vaginal cones, or electrical stimulation
* Methods
	+ Two reviewers independently reviewed, grouped, and qualitatively synthesized trials.
	+ The two authors conducted scoring for methodological quality of studies using the PEDro rating scale independently. Disagreements were solved via consensus.
	+ 117 references after deduplication.
	+ 22 articles included for review
 |
| **Setting**[e.g., locations such as hospital, community; rural; metropolitan; country] |
| * Location
	+ Single center
	+ Multiple outpatient physical therapy clinics
	+ Multiple hospitals
	+ Multicenter
	+ Survey based follow-up
	+ Home based HEP
* Country
	+ Australia
	+ Brazil
	+ Canada
	+ Korea
	+ Mexico
	+ The Netherlands
	+ New Zealand
	+ Norway
	+ Switzerland
	+ Taiwan
	+ Thailand
	+ Turkey
	+ UK
	+ USA
 |
| **Participants**[N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article. |
| * 22 trials included (more information on trials included under Intervention Investigated: Experimental subheading). Trials split into 3 categories
	+ Antenatal PFMT to prevent UI in continent and incontinent women
		- 10 RCTs and 2 long-term follow-up studies
		- Women recruited at between 11-24 weeks gestation
		- 3/22 primary prevention trials, included continent women only
			* 1 of 3/22 only included continent women with increased bladder neck mobility (increased risk of UI development)
		- 7/22: participants selected independent of risk factors or UI status
		- PEDro score range 7-8/10. Abstracts included in this category not scored with PEDro scale.
	+ Antenatal PFMT to treat UI in incontinent women
		- 2/22 RCTs, 1/22 quasiexperimental trials
		- PEDro score range 5-7/10.
	+ Postnatal PFMT to prevent UI in continent and incontinent women
		- 7/22 studies, 2 RCTs, 1 quasirandomized study, 1 matched controlled study
		- 5/22 studies with short-term results, 2/22 with long-term results.
		- PEDro score range 4-8/10.
	+ Postnatal PFMT to treat UI in incontinent women
		- 4/22 RCTs, 2/22 with follow-up.
		- PEDro score range 4-8/10.
* Subjects
	+ All women, pooled sample size=8187 from 22 studies
	+ Sample size range: 20-1800
* Trial characteristics
	+ Databases searched: PubMed, CENTRAL, EMBASE, PEDro. Manual searching in meeting abstract books by the World Confederation of Physical Therapy (1993-2011), the International Continence Society, and the International Urogynecology Association (1990-2011).
	+ Inclusion criteria:
		- RCTs, quasi-experimental studies, or meeting abstracts
		- Published in English or Scandinavian languages
		- Subjects must be primiparous, mulitiparous, or postpartum women
		- Studies must include PFMT as primary intervention. Studies may include additional interventions including biofeedback, vaginal cones, and/or electrical stimulation, in addition to PFMT.
	+ Exclusion criteria:
		- Studies of nulligravid women
		- Studies not involving PFMT as primary intervention
		- Studies not involving urinary incontinence as primary outcome
 |
| **Intervention Investigated**[Provide details of methods, who provided treatment, when and where, how many hours of treatment provided] |
| *Control* |
| Groups are divided into categories defined by the review authors.Description of control group interventions almost all included the term “standard care,” which is not defined by the review authors. Control protocols are divided into the four treatment group categories.* Antenatal PFMT to prevent UI in continent and incontinent women
	+ Control groups not discouraged from PFMT independently. Received standard care, including verbal and/or written advice about PFMT.
* Antenatal PFMT to treat UI in incontinent women
	+ Control groups received standard care, including verbal and/or written instruction on PFMT.
* Postnatal PFMT to prevent UI in continent and incontinent women
	+ Control groups received standard care, allowing self-managed PFMT without supervision.
	+ 1/22 study gave individual verbal instructions on PFMT.
* Postnatal PFMT to treat UI in incontinent women
	+ 1/22 included intervention (massage) to control group.
	+ 2/22 received standard care with self-managed PFMT.
 |
| *Experimental* |
| Experimental protocols are divided into the four treatment group categories defined by study authors.* Antenatal PFMT to prevent UI in continent and incontinent women
	+ Significant variation in training protocol (duration of program, follow-up period, training intensity and frequency)
	+ All but one included home exercise program (HEP)
	+ Duration not specified
	+ Intensity: near maximal contractions
	+ Frequency: low repetitions (up to 30 contractions/day)
	+ Follow-up: 12 weeks-1 year
	+ Adherence reported in studies, but classification of adherence varies between studies. Adherence rates not reported in review.
* Antenatal PFMT to treat UI in incontinent women
	+ Significant variation in training protocol (duration of program, follow-up period, training intensity and frequency) and follow-up.
	+ Duration range: 7 weeks-12 weeks
	+ Intensity: near maximal contraction
	+ Frequency: low repetitions (up to 30 contractions/day)
	+ Follow-up range: 10-20 weeks (antenatal)
	+ Note: 1/22 study had high drop out rate (50%) and moderate adherence (77%) which may limit power.
* Postnatal PFMT to prevent UI in continent and incontinent women
	+ Significant variation in training protocol (duration of program, follow-up period, training intensity and frequency) and follow-up.
	+ Initiation of program ranges from hospital stay (from childbirth) to 8 weeks postnatal.
	+ Duration range: 4-8 weeks
	+ Follow-up range: 3-10 months
	+ 1/22 programs included biofeedback and electrical stimulation with PFMT
	+ 4/22: adherence reported in studies but classification of adherence varies between studies. Adherence not reported in review.
* Postnatal PFMT to treat UI in incontinent women
	+ Significant variation in training protocol (duration of program, follow-up period, training intensity and frequency) and follow-up.
	+ Duration range: 8 week-12 year
	+ Intensity: near maximal
	+ Frequency: low repetitions
	+ Follow-up range: 12 month-7 years
	+ 1/22: included biofeedback and electrical stimulation
	+ 2/22 Adherence information reported, but via unknown method.
 |
| **Outcome Measures** (Primary and Secondary)[Give details of each measure, maximum possible score and range for each measure, administered by whom, where] |
| Specific outcome measures used in trials not mention in review.* Reduction in UI symptoms and episodes
* Reduction in prevalence of women in study populations with UI symptoms
* Adverse outcomes
 |
| **Main Findings**[Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided – if you need to calculate these data yourself, put calculations here and add interpretation later, under ‘critical appraisal’ on next page] |
| Findings will be divided into author-defined categories.* Antenatal PFMT to prevent UI in continent and incontinent women
	+ Clinically and statistically significant effects in all trials for reduction in symptoms, episodes, and/or prevalence.
	+ Preventative power of PFMT shown during this time period
	+ No adverse effects reported by any studies
	+ No significant difference between intervention and control groups at 8-year follow-up.
	+ Benefits appear to last at least until 3- and 6-month follow-up.
* Antenatal PFMT to treat UI in incontinent women
	+ Contradictory findings between studies.
		- 1/22 study found no difference between groups at any time point (during pregnancy, 6 month postpartum, or 12 months postpartum).
		- 2/22 studies found significant differences in UI incidence between intervention and control groups in late pregnancy, and 6-8 weeks postpartum.
* Postnatal PFMT to prevent UI in continent and incontinent women
	+ 3/22: clinically and statistically significant effects of PFMT on continence; significant reduction in symptoms and frequency of UI post-intervention.
	+ 2/22: no statistically significant difference between PFMT and control groups at any time period or follow-up.
	+ 1/22 found long term reduction in UI symptoms 1 year post-intervention
	+ 1/22 found short-term but no long-term benefits (1 year and 6 year follow up), but that continued adherence to PFMT HEP at 12 months was predictive of increased continence.
* Postnatal PFMT to treat UI in incontinent women
	+ All 4/22 reported clinically and statistically significant short-term benefits (reduction in symptoms and/or frequency) of PFMT.
	+ 1/22 found no difference between experimental and control groups at 6-year follow-up
	+ 1/22 found 50% of experimental group women who were continent at the end of program were still continent at 7-year follow-up.
 |
| **Original Authors’ Conclusions**[Paraphrase as required. If providing a direct quote, add page number] |
| The authors conclude that studies with high adherence and appropriate PFMT dosage can effectively prevent and treat incontinence symptoms during pregnancy and following delivery. Programs with low dosage are ineffective at providing relief of UI symptoms. However, optimal dosage has not been determined by the included studies. Until optimal dosage is established, higher dosage and more intensive programs (near maximal contractions, supervision lasting at least 8-weeks) with more supervision by a physical therapist or other clinician may provide more relief of symptoms.Given the high prevalence of incontinence in pregnant and postpartum women, and the efficacy of supervised, higher intensity PFMT training, the authors conclude that exercise guidelines for all pregnant and postpartum women should be updated to include PFMT. |
| **Critical Appraisal** |
| **Validity**[Methodology, rigour, selection, sources of bias, quality score on methodology quality rating scale (indicate the quality assessment tool used and the maximum possible score on that scale, e.g., 7/10 on PEDro scale), appropriateness of analytical approach (e.g., adjustments for confounding variables, management of missing data).]Comment on missing information in original paper. |
| This systematic review shows the significant heterogeneity between studies in terms of populations, exercise protocols, outcome measures, and definitions of continence and incontinence. However, the methodology of this systematic review is generally high, receiving an AMSTAR score of 9/11.The investigators included search methods, and a priori inclusion and exclusion criteria. They included meeting abstracts as well as published studies, though did not include other “grey literature” which may be a source of bias. Only studies written in English and Scandinavian language were published, though the influence this has on the rigor of the systematic review is unclear.11 Though language criteria were set, publications from a variety of countries were included, which may help to decrease this bias, as well as increase the generalizability of the authors’ conclusions.In general, this review used higher levels of evidence (randomized controlled trials, quasi-randomized trials), though they also included one quasi-experimental trial. Included trials are generally of higher methodological quality, with 13 of the 18 applicable studies receiving a PEDro score of at least a 7 or 8/10. Given the nature of the intervention, it is not possible to blind participants or interventionists to the treatment, though participants can be blinded to study hypotheses and interventions blinded to group allocation. Though some included studies have dose or adherence concerns, the research methodology of included trials is moderate to strong.Several included trials had high losses to follow-up and poor adherence, which may be a source of bias if it creates systematic imbalances in group characteristics. No method of intention to treat or per-protocol analysis is mentioned in this systematic review.While many of the included studies have small sample sizes and thus risk being underpowered, several trials have over a thousand participants and use very weak interventions (few visits with interventionist, and very short duration of program). These very large studies can dilute the effect of smaller, higher quality studies should their participant data be pooled for meta-analysis. The dose-response relationship in exercise training in general is quite strong. The specificity of exercise, frequency, intensity, duration, and program adherence all play a large role in determining effect size. The 6/22 trials with little or no effect have problematic training protocols. 2/22 use low training dosages that may be inadequate for neuromuscular re-education or muscle hypertrophy. 3/22 gave participants home programs but did not give sufficient time in the clinic for interventionist education and instruction. 5/22 of these low effect studies had high dropout rates and low adherence. If participants do not follow the training protocol, and appropriate statistical analyses such as intention to treat are not performed, it is not possible to evaluate the effect of PFMT. Equally, insignificant results from suboptimal training protocols do not provide valuable evidence for clinicians in decision-making. |
| **Interpretation of Results**[Favourable or unfavourable, specific outcomes of interest, size of treatment effect, statistical and clinical significance, minimal clinically important difference. You may calculate effect size or confidence intervals yourself from the data provided in the article.] Describe in your own words what the results mean. |
| This systematic review provides evidence that antenatal and postnatal PFMT is protective against the development of UI during or following pregnancy, and is effective at reducing the incidence and severity of UI during and following pregnancy, as well as up to 6 months postpartum. Studies examining long-term outcomes of PFMT are generally of lower quality and have significant concerns such as loss to follow-up, making conclusions about PFMT after 6 months difficult.Antenatal prevention PFMT provides preventative benefits to pregnant and postpartum women up to 6 months after delivery. There is currently no evidence that antenatal PFMT provides long-term benefit (longer than 6 months).There are fewer studies on antenatal treatment of PFMT, and their conclusions do not agree. There is some evidence that PFMT does not provide a reduction in symptoms at any time point. However, this study may be underpowered. Two studies found significant reductions in UI incidence during and up to 8 weeks postpartum.Studies examining postnatal PFMT in the prevention and treatment of UI generally found clinically and statistically significant preventative and treatment effects of PFMT, resulting in reduction in frequency, incidence, and severity of UI in their participants. There is contradiction between studies if long-term benefits exist from postnatal PFMT, though short-term benefits were found in all studies. One study found that continued patient adherence to the PFMT HEP was predictive of increased continence at 1 year follow-up. One study found that 50% of experimental group participants who were continent at the end of the program were still continent at 7-year follow-up, though did not mention continence rates of the control group, making comparisons difficult.Generally speaking, antenatal and postnatal PFMT can be used to prevent and treat UI in pregnant or postpartum women, up to 6 months postpartum. There is considerable disagreement regarding long-term efficacy of PFMT, though this may be due to adherence to independent continuation of HEP by participants after program cessation, subsequent pregnancies, or differences in study design. The lack of long-term results may be as a result of the natural decrease in strength that comes with disuse. Given that few participants continued the independent PFMT HEP for long-term follow up, the lack of long-term results is unsurprising. Previous studies on muscle atrophy have identified a 5-10% loss of muscle strength per week following training cessation, though that percentage may increase with age.26 It is likely unreasonable to expect maintenance of strength, and the benefits thereof, in the absence of continued strength training. |

**IMPLICATIONS FOR PRACTICE and FUTURE RESEARCH**

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| These studies and systematic reviews provide evidence that antenatal and postnatal intensive PFMT programs for UI can provide protection and relief from UI symptoms during and up to 6 months following pregnancy. The quality and paucity of research regarding outcomes longer than 6 months limits the clinical applicability of PFMT for long-term outcomes. Dosage, intensity, education, and adherence are all vital to achieving desired outcomes.Additional therapies, including TrA, electrical stimulation, and biofeedback do not appear to provide additional benefit specifically for treatment or prevention of UI. Neither PFMT nor the above mentioned additional therapies are associated with any adverse outcomes. Patients seeking treatment for decreased abdominal strength as well as UI can safely receive both PFMT and TrA. No studies included in this critically appraised topic found adverse outcomes such as birth complications associated with those receiving PFMT. Clinicians can safely recommend PFMT to their patients complaining of UI symptoms during pregnancy.Interestingly, the data from the 2004 Dumoulin et al.9 study, comparing baseline to post-intervention data, implies that PFM strength and speed of contraction is not directly related to continence, as though continence improved significantly in both treatment groups, PFM strength and maximum rate of force development did not change significantly. This has significant implications for clinical practice, as it implies simply increasing strength and speed of contraction are not enough to improve continence outcomes. Motor learning, appropriately timed contraction, good practice (such as “squeeze before you sneeze”) and other factors are more likely to bring about improvements in continence. Though surely a minimum amount of strength is necessary for continence, this implies that clinicians seeking to improve outcomes should focus less on improving the strength of contractions, except to get PFM to a (currently unestablished) minimal level. Goals should focus on functional outcomes and control, such as the ability to contract and relax PFM in a timely and appropriate manner, and less on the ability to generate a specific amount of force.The pelvic floor consists of muscles that, like any muscle group, will atrophy without use. Given that UI increases with age (and appears to be part of typical aging), the fact that observable benefits decrease over time is not surprising. However, having a control group to compare with would be useful, to see if their incontinence rates and severity scores changed over time as well. Additionally, it is no surprise that women who do not continue their PFMT HEP experience a decrease in benefits over time, as the PFM is susceptible to disuse atrophy, similar to all muscle groups. Patients with recurrent UI symptoms may continue to receive benefits from PFMT, though a low level maintenance HEP may be more cost-effective. More research is needed to find a low level maintenance HEP that continues to provide continence benefits to postpartum women. Additionally, women may receive benefit from adding PFMT to regular total body strengthening activity programs, though more research will be needed to confirm this hypothesis.Currently, PFMT is in practice in outpatient orthopaedic physical therapy clinics throughout the country and indeed, many parts of the world. It requires no further equipment than other pelvic floor physical therapy equipment, though clinicians will benefit from additional continuing education or residencies. Unfortunately, the number needed to treat (NNT) has not been established, though given the lack of equipment, relatively little additional training needed, and established efficacy, PFMT is a very cost-effective means of treating UI, especially given the expensive alternatives of surgery and pharmacotherapies, both of which are unavailable to pregnant women.Several outcome measures for urinary incontinence and pelvic floor dysfunction exist, and while several have been validated, few of them have MCID or MDC values established, limiting their use in goal setting and in the clinic.The dose-response relationship is not made sufficiently clear in these studies. The general recommendations for strength training are 3 sets of 8-12 repetitions of maximal or close to maximal contractions, performed 3-4 times per week.18 Many studies which use close to maximal contraction have shown clinically and statistically significant improvements in continence scores. Equally, the studies that involved less frequent visits with the physical therapist (less than twice a month) were less effective at improving continence. Many of the studies included in these two systematic reviews attempt to be more cost-effective by involving less frequent physical therapy contact. However, pelvic floor dysfunction is not dissimilar from any other musculoskeletal concern, which may warrant 1-3 weekly visits for a short time period. A more intensive program with an appropriate level of contact with the physical therapist appears to provide greater reductions in incontinence symptoms and severity than a program which requires participants to be independent sooner. Future research would benefit from standardized means of assessing adherence, as self-report may overestimate actual adherence. Additionally, a standardized definition of continence may help further analysis of future research.Currently, usual postpartum “usual care” involves PFMT, though instruction may be written or verbal, without palpation. Future studies should compare three groups: “usual care” including verbal or written instruction of PFMT, PT-instructed PFMT, and no exercise. This may help to distinguish more rigorously between the efficacy of including PFMT in usual care without and without supervision by a physical therapist.Pregnancy and birth are two of the largest risk factors for development of incontinence in women. Given this, women who have children should be considered at risk for the development of incontinence. At this time, sufficient evidence exists to promote the use of PFMT in pregnant and postpartum women to reduce the prevalence, severity, and burden of UI. However, more research is needed to determine how to promote the continued continence of women more than one year following childbirth. Given that few trials report rigorously on PFMT protocols, it is difficult to replicate experimental trials in the clinic. The lack of description of exercise protocol, strength of contraction, duration, and other details significantly limits the applicability of this study. More research is necessary to determine best practice protocols. |

*Notes on Implications Section*

* *This section synthesizes your comments from the appraisal of your articles, and may mention other related research that you have read or that supports your interpretation and discussion*
* *Comment on whether the intervention is used in practice in your region/country, cost of that treatment, need for education of local therapists/students about this intervention and/or outcome measures used in the CAT*
* *Students may wish/need to discuss implications with clinicians or peers for suggestions -- use the discussion board!*
* *This section should be ¾-1 page*
* *Be sure to address both implications for clinical practice and future research (separately)*

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[List all references cited in the CAT]

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