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Comparison between the significant of antenatal pelvic floor exercises and non-intervention in preventing urinary incontinence: A systematic Literature Review

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Abstract
Background:
Epidemiology evidence reported that women who had a baby are at increased risk of developing urinary incontinence, particularly those who have had vaginal deliveries (27). Conservative intervention such as pelvic floor muscle training (PFMT) are superior in preventing and treating urinary incontinence (15).
Purpose:
To systematically review the literature and present the best available evidence for the efficacy and effectiveness of antenatal pelvic floor muscle training in preventing and treating the urinary incontinence rather than non-intervention.
Data source:
PubMed, Cochrane library, BMJ Group, BioMed Central, Wiley online library.
Study selection:
9 randomized, control trials (RCTs) published in English from 2001-2014.
Data extraction:
Incontinence due to other causes other than childbirth.
Data synthesis:
The study focus on pelvic floor exercise versus non-intervention for the antenatal women, incontinence must be as a result of childbirth, and randomized control study.
Limitation of the study:
The reviewed study are limited to 9 randomized control trial.
Conclusion:
There is significant evidence that pelvic floor muscle training (PFMT) are superior in preventing and treating urinary incontinence as compared to non-intervention.
Keywords: *Antenatal pelvic floor exercise, non –intervention, urinary incontinence, pelvic floor exercise training.*

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I. Introduction

Urinary incontinence as defined by the International Continence Society is the complain of any involuntary leakage of urine.(10). According to Boyle (3), up to a third of women have urinary incontinence while about a 10th of them have stool incontinence after delivery. Urinary incontinence is a major clinical problem with profound effects on the quality of life and day-to-day activities of the affected women. It's physically debilitating and socially incapacitating, with loss of self-confidence, helplessness, depression and anxiety all related to its occurrence. Affected women suffer social stigma and are withdrawn socially. As a result their productivity is significantly reduced and may lose interest in life.

Chiarelli P.(4) indicates that the prevalence of urinary incontinence among women increases during young adult life: a study with over 40000 women estimated a prevalence of 12.8% in women aged 18-22 years, 36.1% in women aged 40-49, and 35% in women aged 70-74 years.

The severity of urinary incontinence varies in severity ranging from mild, moderate to severe forms. These levels of incontinence require different approaches in management in terms of duration and intensity. Epidemiological studies have shown an association between more severe forms of urinary incontinence and assisted vaginal deliveries or birth of high birth weight neonates which suggest the potential for an intervention promoting continence that is targeted at women who have just given birth (1).

According to the National Association for Continence (NAFC), pelvic floor exercises (PFEs) or pelvic floor muscle training (PFMT), also called Kegel exercises, are essential parts of behavioral treatment techniques that help increase bladder control and decrease bladder leakage. Though the technique requires conscious effort, consistent discipline, and a lifetime commitment, PFEs have been shown to improve mild to moderate urge and stress incontinence. When performed regularly and correctly, they strengthen bladder support, and build control and endurance to help improve, regain and maintain bladder and bowel control.

As such, health workers usually recommend pelvic floor exercise both during pregnancy and after childbirth. This aims at both preventing and treating faecal and urinary incontinence. Physiotherapists train expectant women who are expected to undertake the exercise several times a day in order to strengthen her pelvic floor muscles. This review will summarize the recent published data on the use of pelvic floor muscle training in preventing and treating urinary incontinence in pre-post-natal women.

II. Methodology

Data Source:

The studies identified from PubMed, Cochrane library, BMJ Group, Biomed Central, Wiley online library, and manual search of reference lists from systematic reviews and the proceedings of the International Continence Society (available at www.annals.org).

Study selection:

One investigator independently decided on study eligibility according to recommendations from the Scotish intercollegiate Guideline developer handbook for systematic reviews of interventions to include original publications of randomized controlled trials (RCTs) that were published in English form from 2001- May 2014. Full texts of the RCTs that examined the effects of pelvic floor muscle training on urinary incontinence in pre-post-natal.

The study excluded secondary data analysis, case reports, case series, and RCTs that did not report patient outcomes.

Assessment of Methodological quality:

The quality of study was analyzed by using the following criteria: participant selection, length and loss of follow-up, use of intention- to –treat principle, masking of the treatment status, randomization sheme, adequacy of randomization and allocation concealment, and justification of sample size.Several strategies were used to reduce bias, including a comprehensive literature search for published evidence in several database, a search of reference lists of systematic reviews and proceeding of the International Continence Society. The quality of the selected studies was assessed using a standard grading system, as Scottish Intercollegiate guideline network (SIGN, 2012). Evidence table can be found at Appendix 1 &2

Since the methodological quality was dependent on the trial reports contained in the selected studies, this assessment might have been influenced by the quality of the corresponding reports. Part of the literature used for this study was published only as abstracts. As a result, there was insufficient methodological detail, which made the assessment of methodological quality somewhat inaccurate.

In some cases, it was disappointing that some studies did not sufficiently describe the randomization process. Thus, it was difficult to ascertain whether there was sufficient concealment. Regardless, it was encouraging that more than two-thirds of the selected studies used blinded outcomes inspectors, given the trouble of blinding treatment providers and participants to PFMT.

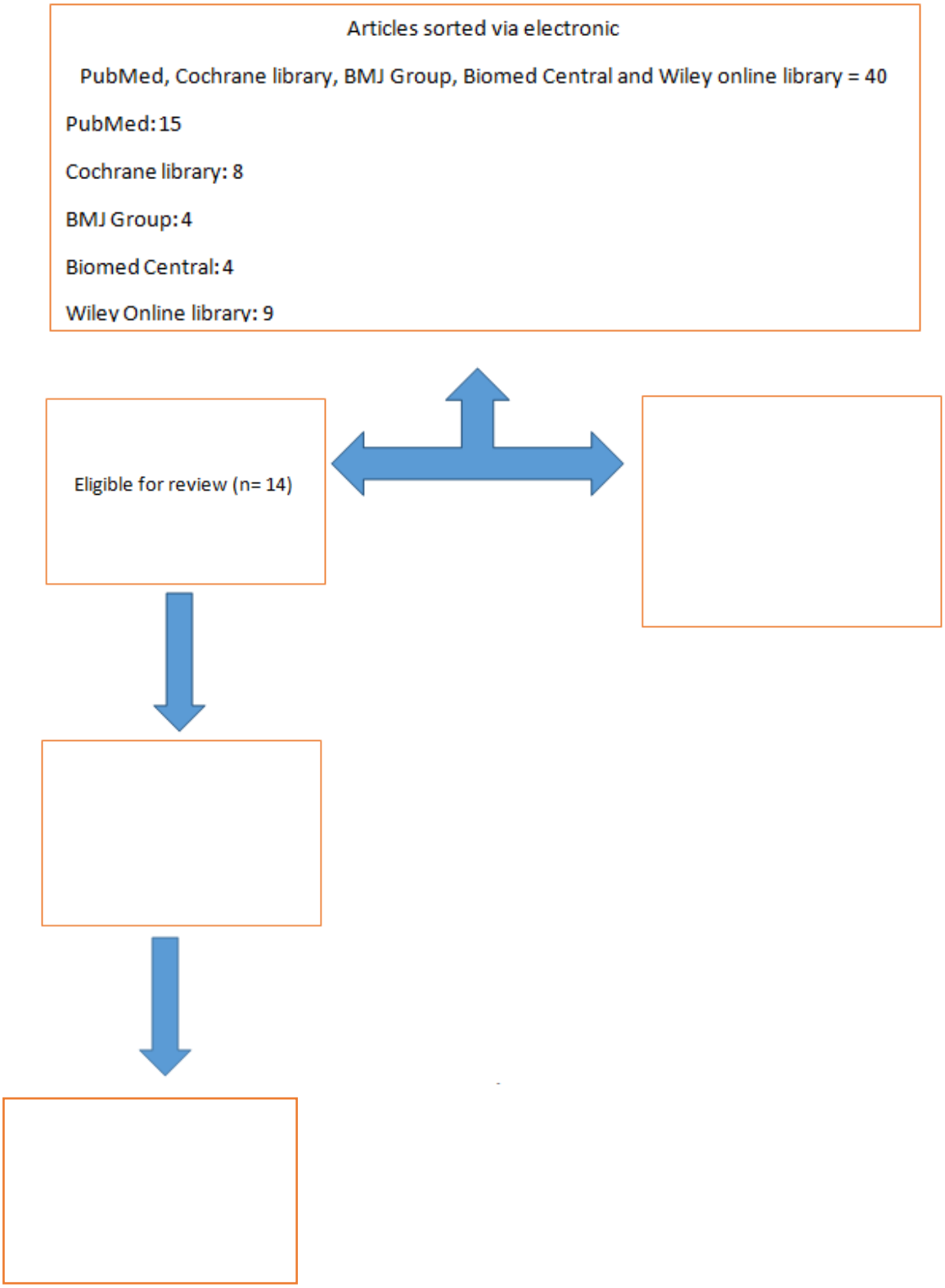
Methodological quality was also affected by the age of the selected studies. The more recent studies, for instance, considering the trial reports, tended to be less likely to be biased as compared to the older ones. Of all the selected studies, those that were found to be more likely to be biased recorded the largest treatment effect as compared to the studies which were found to be less likely to be biased. This affected the methodological quality since it represents a possible overestimation of treatment effect. It is also important to note that this trend was particularly observed in the selected studies with insufficient concealment of random allocation.

Also, the methodological quality would be higher if the testers who carried out the outcomes of incontinence study would have carefully chosen a primary outcome measure that was relevant to women, selected secondary methods to include a range of domains, and chose standardized tools with recognized responsiveness, reliability, and validity.

Data Synthesis:

Forty articles were selected from electronic bibliographies and screened for retrieval (n=40). Thirty sex articles were excluded for not meeting the selection criteria (n=36) such as ineligible target population or case report or secondary data analysis, or no full texts available. The resultant was fourteen randomized control trials full articles (n=14). Five articles were exempted for not meeting the inclusion criteria (n=5) such as incontinence due to other cause other than childbirth. The nine most appropriate articles were left (n=9) Figure 1

Figure1: Results of search



Summaries of the studies included in the review are provided in **Table 1**. Studies are presented the information about the level of evidence, population, interventions investigated, outcome measures and information of determine the generalizability of the study findings.

Table 1: Best Evidence

Evidence table (Mackway K, et al. nd.)

Bibliographic citation	Study type & Evi. Lev	Population	Intervention/ comparison	Follow-up time	Outcome measures	Effect size
Aqur WI, Steggles P, Waterfield M, Freeman RM (2008): The long-term effectiveness of antenatal pelvic floor muscle training; 8-year follow up of a randomized controlled trial. Published in British journal of Obstetrics and gynaecology 2008 July	RCTs ++	Participant in RCT of antenatal PFMT 8years previously. 170 out of the 230 women responded	68.4% reported continuing with PFMT exercise as taught. Versus 31.6% stopped PFMT	8 years	Directly asking about the presence of stress urinary incontinence (SUI) and quality of life	The significant improvement in postnatal SUI originally shown in the PFMT compared with controls (19.2% versus 32.7%, P=0.02) at 3 months was not evident 8 years later (35.4 % versus 38.8%, P=0.7).
General Comments: The study design is good but there is no proof that the women actually continued with PFMT as trained. The study findings can be generalized to the pregnant population. The study gives verified figures with confidence intervals and significant P-Values.						
Boyle R, Hay-Smith EJ, Cody JD, Morkved S. (2012)Pelvic floor muscle training for prevention and treatment of urinary and fecal incontinence in antenatal and postnatal women.	RCTs +	8485 women (4231 on PFMT, 4254 control)	Pelvic floor muscle training(PFMT), versus Non-intervention (usual antenatal or postnatal care)	12 months	Presence, reduction or absence of urinary incontinence	Pregnant women without UI on PFMT were less likely to report UI up to six months after delivery (30% less, risk ratio (RR)0.71, 95% CI 0.58 to 0.95, combined results of 5 studies) than non-intervention . Postnatal women with UI 3 months after delivery on PFMT, 40% were less likely to report UI 12 months after delivery (RR0.60 , 95%CI, 0.35 to 1.03. combined results of 3 trials) as compared to non-intervention.
General Comments: The study is good designed. There is improved function with intervention on postnatal women. There is treatment integrity and inter observer agreement. Results in scientific terms with P-Value and confidence intervals well evaluated. It can be generalized on the pregnant population.						
Glazener CM , Herbison GP, McArthur C, Grant AM, Wilson PD, (2005) RCT of conservative management of postnatal urinary and	RCTs +	747 women with urinary incontinence, 516 (69%) followed up for 6years	Active conservative treatment (PFMT) at 5, 7 and 9 months after delivery versus Standard postnatal care	6 years	Presence, reduction or absence of Urinary and faecal incontinence, performance of PFMT	At 1 year, UI improvement, 60% versus 69% controls, faecal incontinence 4% versus 11% control. At 6 years 76% versus 79%, (95% CI for

fecal incontinence: six year follow up						difference in means- 10.2% to 4.1%) for UI. (12%vs 13%, -6.4% to 5.1%) for faecal incontinence irrespective of subsequent obstetric event.
General Comments: Study Design is good. But there is no proof that the women actually will continue with PFMT. Results in scientific terms with P-Value and confidence intervals well evaluated. Can be generalized to the pregnant population.						

Glazener CM, Herbison GP, Wilson PD, MacArthur C, Lang GD, Gee H, Grant AM (2001). Conservative management of persistent postnatal urinary and faecal incontinence	RCT +	747 women with urinary incontinence 3 months postnatal. 371 randomly allocated to intervention, 376 to control.	Reinforcement of pelvic floor muscle training by exercise at 5, 7 and 9 months after delivery supplemented with bladder training where appropriate at 7 and 9 months. Versus Standard postnatal care for the control	9 months	Primary; persistence and severity of urinary incontinence 12 month postnatal. Secondary; change in co-existing fecal incontinence, Use of pads per day, rating of UI severity with visual analogue scale wellbeing, anxiety, depression and performance of pelvic floor exercise.	Women on PFMT had significantly less UI (59.9%) versus 69%, a difference of 9.1% (95% CI 1% to 17.3%, P=0.037) for any incontinence. Severe incontinence, 19.7% versus 31.8%, a difference of 12.1% (4.7% to 19.6%,P=0.002). fecal Incontinence was also less common, 4.4% versus 10.5% Difference of 6.1% (6.1% To 10.8%, P=0.012. At 12 months women in intervention group were more likely to be performing PFMT (79%) versus (48%) P < 0.001
General Comments: the study design is good; there is treatment integrity, results in scientific terms with P-Value and confidence intervals well evaluated. Can be generalized for the pre-pot-natal population as the sample is representative and intervention inexpensive.						

Hay-Smith J, Morkved S, Fairbrother KA, Herbison GP (2008),Pelvic floor muscle training for prevention and treatment of urinary and fecal incontinence in antenatal and postnatal women. Cochrane database	RCTs ++	6181 women pregnant and postnatal women (3040 PFMT, 3114 Controls)	PFMT versus No PFMT, usual antenatal care	12 months	Primary self-reported Urinary and fecal incontinence Secondary QOL Questionnaires, Symptoms of severity.	Women without UI at baseline, PFMT reduced UI in late pregnancy > 34 weeks by 56% (RR 0.44, 95% CI 0.3 to 0.65) and 30% less up to 6months postpartum and mid-postpartum (RR 0.71,95% CI 0.52 to 0.97) Postnatal

System review 2008 October						women with UI 3months post-delivery, on PFMT reported 20% UI 12 months after Delivery (RR 0.79, 95% CI 0.70 to 0.90)
General Comments: The study invalid as the result of improvements were made by subjective observation, the results are applicable since the study is randomized, and subject are women with incontinence after delivery. It can be generalized to pre-post-natal women population.						

Ko PC, Liang CC, Chang SD, Lee JT, Chao AS, Cheng PJ (2011): A randomized controlled trial of antenatal pelvic floor exercises to prevent and treat urinary incontinence	RCTs ++	300 pregnant women	200 women were randomly assigned PFMT The remaining 100 were non-intervention group (usual antenatal care	Up to 6 months postpartum	Measured by Urogenital Distress Inventory-6 (UDI-6), Incontinence Impact Questionaire-7(IIQ-7), and self-reporting.	During late pregnancy and postpartum period, PFMT Exercise group had significantly lower total UDI-6 and IIQ-7 scores. Self-report rate of urinary incontinence was also less than in control.
General Comments: The study is strongly designed, but no indication of treatment integrity. Results collected by standard scientific tool so no bias, but no numerical values. The result could be generalized for pre-pot-natal population. It consistent with PFMT reduces UI.						
Morkved S, Bo K, Schei B, Salvesen KA (2003) Pelvic floor muscle training during pregnancy to prevent urinary incontinence: a single-blind randomized controlled trial. Obstetric gynecol. 2003 Feb. 101 (2): 313-9	RCTs +	301 healthy nulliparous women(148 intevention,153 control)	12 week intensive PFMT during pregnancy Versus Customary information	Up to 3 months postnatal	Primary-self reported UI Secondary-pelvic floor muscle strength	32% of training group reported UI compared to 48% control at 36 weeks gestation (P=0.007), and 20% versus 32% 3months after delivery (P=0.018). Strength of Pelvic floor muscle was significantly higher in training group at 36 weeks (p=0.008) and 3 months after delivery (P=0.048)
General Comments: good quality with internal validity, there is treatment integrity, results in scientific terms with P-Value and confidence intervals well evaluated. Applicable to the pre-post –natal population.						

Reilly ET, Freeman RM, Waterfield MR, Waterfield AE, Steggles P, Pedlar F(2002): Prevention of postpartum stress incontinence in primigravidae with increased bladder neck mobility	RCTs ++	268 primigravidaat 20weeks gestation. Median age 28years (16 to 47years)	139 on supervised pelvic floor exercises monthly from 20wks to birth Versus Non-intervention (usual antenatal care)	20 weeks gestation to 3 months postpartum	Subjective reporting of stress incontinence 3 months postpartum. Pelvic floor strength, using perineometry, and bladder neck mobility measured by perinea ultrasound.	19.2% of women in the supervised pelvic floor exercise had postpartum stress incontinence , compared with 32.7% in the non-intervention (control) group.(RR 0.59 {0.37 - 0.92})
General Comments: the study is good quality, there is treatment integrity and the sample is randomized. There is no bias in the outcome measure it is standardized. The group on PFMT significantly improved as compared to untreated group. The result can be generalized to pre-post-natal population.						

Stafne SN, Salvesen KA, Romundstad PR, Tojusen IH, Morkved S. (2012): Does regular exercise including pelvic floor muscle training prevent urinary incontinence during pregnancy?	RCTs +	855 pregnant women between 20 and 36 weeks	Intervention was a 12-week exercise program including PMFT. One weekly Versus Controls received normal antenatal care	From 20 weeks' gestation to 36 weeks' gestation	Self-reported urinary and fecal incontinence after intervention period (at 32-36 weeks gestation).	11% of the women in the intervention reported any weekly urinary incontinence compared to 19% of the non-intervention group (P =0.004). 3% of women in the intervention reported fecal incontinence versus 5% in non-intervention.
General Comments: the study is high quality with interval validity, but the study is in doubt as it does not show the outcomes that were as a result of PFMT. There is treatment integrity and the study methods is valid with P-Value indicated. The result can be generalized to the pre-pot-natal population.						

Nine RCTs (n=9) were included. All studies reported adequacy of randomization, discussed participant selection, length and loss of follow up, use of intention-to-treat principle, and masking of the treatment status for both subjects and investigators. Seven RCTs reported adequate allocation concealment. There are marked heterogeneity in the type and intensity of interventions in both groups. All the studies used validated measurement tools.

One RCT (n=170) reported significant improvement in postnatal urinary incontinence, who participated in the PFMT compared with control group (19.2% versus 32.7% P=0.02), but no statistically significant effect at 3 months and they found significant difference between the groups at 8 years 35.8% versus 38.8% (P=0.7).

Second RCT (n=8485) reported a statistically significant reduction in sever incontinence in the intervention group at 12 months after delivery (response rate, RR 0.60, 95% confidence interval, CI: 0.35 to 1.03). The third RCT (n=747) found a statistically significant improvement in urinary incontinence in the intervention group 60%versus 69% control group at one year follow –up, and fecal incontinence 4% versus 11% control group. With significant ongoing difference over 6 years follow-up 76%versus 79% (95% CI: 10.2% to 4.1% for urinary incontinence, 12% versus 13%- 6.4% to 5.1%for fecal incontinence).

The fourth RCT reported statistically significant reduction in urinary incontinence by 59.9%in the intervention group versus 69% control group (95% CI: 1%to 1.7% P=0.037). Fecal incontinence in the intervention group improved by 19.7% versus 31.8% control group (4.7% to 19.6% P=0.002). The fifth RCT (n=6181), which reported a statistically significant reduction in incontinence in the intervention group at 34 weeks of pregnancy (RR0.44, 95%, CI: 0.52 to 0.97), and 20% less up to 12 months postnatal (RR 0.79, 95% CI: 0.70 to 0.90).

The sixth RCT (n=300) reported a decrease in UDI-6 and IIQ-7 scores in intervention group versus the control group. The seventh RCT (n=301) reported 32% of training group had urinary incontinence compared to 48% control group at 36 weeks of pregnancy (P=0.007) and 20% versus 32% at 3 months after delivery (P=0.018).

The eighth RCT (n=268) reported 19.2% of women in the supervised pelvic floor exercise had post-natal stress incontinence compared to 32.7% in the non-intervention group (RR0.59 "0.37-0.92"). The ninth RCT (n=855) reported that 11% of the women in the intervention group had urinary incontinence versus 19% of control group (P=0.004), and 3% had fecal incontinence in the intervention group versus to 5% in the control group.

III. Discussion

This systematic review reports the evidence of PFMT intervention in the treatment and prevention of urinary incontinence in pre-post-natal women from full text studies published in English during the last 13 years. The quality of most of the RCTs was good; participants were not excluded from the analysis of outcomes, and randomized was adequate. However, allocation concealment was not addressed in two studies. Variations in outcome measures rather than RCT quality, resulted in heterogeneity between studies.

Despite extensive efforts to standardize outcome assessment for urinary incontinence (1). The included RCTs measured a variety of outcomes, including adherence to PFMT, self-reported symptoms, signs, and improvement; severity of urinary/ fecal incontinence as assessed by pad number/day and condition- specific quality of life. The measurement of outcomes was inconsistent across the studies. Another factor which may influence outcome is the degree to which subjects actually comply with the treatment program prescribed and adhered to the PFMT. Subject compliance or adherence was infrequently and generally poorly reported with no standardized, validated or reliable approach to its assessment.

The following is a summary of the discussion regarding the overall completeness and applicability of evidence in the selected studies.

Outcomes measures and reporting:

Some of the studies did not provide data in ways that could apply to meta-analysis or did not provide data for any of the pre-indicated outcomes of interests. Some challenges include reporting a measure of central tendency and leaving out a measure of dispersion, and inaccurate values for P without additional supporting information (Dumoulin and Hay-Smith, 2010). In the end, there was an overall lack of consistency in the most of the outcomes measures applied and reported in the selected studies. In other words, there were no particular outcomes that were shared among the trials, while at the same time, similar outcomes were measured and recorded in various ways (Ismail, 2009). Also, there was no validity and reliability testing conducted for some of the continence outcomes. As a result, it was difficult to carry out adequate comparisons between studies.

Most of the selected studies reported adverse effects of other approaches and only a few gave such a report for PFMT. In fact, the only adverse effect associated with PFMT was discomfort with training, which can be reversed by simply stopping the training programme (National Associated for Continence, 2016). Even though randomized trials are not the most suitable means of addressing safety, none of the selected studies suggest that PFMT is likely to be harmful.

Implications for practice:

The findings of the selected studies suggest that PFMT brings about better outcomes as compared to non-treatment and other inactive treatment for treating urinary incontinence. In the cases where PFMT was used, the women were more likely to experience improvement or get cured entirely (Dumoulin and Hay-Smith, 2010; Reilly et al., 2002). These women also reported fewer leakage episodes per day, better quality of life, and have less urine leakage on short pad tests as compared to non-treatment.

Most of the selected studies imply that treatment, especially in self-reported cases, has a greater impact for women with urinary incontinence taking part in a closely monitored PFMT programme for no less than three months (Dumoulin and Hay-Smith, 2010). Additionally, age does not matter can, therefore, not reduce the effect of treatment in urinary incontinent women. In trials, the outcomes for older women were similar to those of younger women.

The selected studies imply suggest that the treatment effect is magnified if the PFMT programme is focused on valid psychological principles. For a successful programme, the right contraction has to be

confirmed and recorded before the training, and the participants are monitored and supported to continue with the programme (Aqur et al., 2008; Haylen et al., 2010). There is an overall widespread endorsement among the selected studies that PFMT should be integrated into the first line conservative management programmes for women with urinary incontinence.

However, most of the selected studies lack follow up past the completion of the treatment programme. Therefore, it would be difficult to establish the long-term results from the application of PFMT (Dumoulin and Hay-Smith, 2010; Sahakian, 2012). Regardless, some of the studies hold that long-term outcomes of PFMT are significantly greater when the participants are supervised for no less than three months. If the participant continues with the programme for an extended period, the treatment effect is likely to be enhanced accordingly or at least remain constant.

IV. Conclusion

Overall, there is evidence for the widespread recommendation for use of pelvic floor muscle training in preventing and treating urinary incontinence for pre-post-natal women as compared to non-intervention. The limited nature of follow-up beyond the end of treatment in the majority of the published studies means that the long-term effects may be greater in women participating in supervised PFMT for at least three months. Continued adherence to training may be associated with maintained or increased treatment effect, but this hypothesis needs further testing. There is a need for at least one large, well conducted, and explicitly reported randomized trial, comparing PFMT with a control to investigate the longer-term clinical effectiveness of PFMT.

In conclusion, pelvic floor exercises are beneficial and have no significant adverse effects. Substantially and durable improvements in continence can be achieved, when the patient is appropriately selected and the exercises are adequately performed.

Table 2: Comparative Summary Of Best Evidence

Considered judgment table	
Key question: Are antenatal pelvic floor exercises significantly better than non-intervention in preventing urinary incontinence?	
1.Quality of evidence: Nine studies have surveyed the significance of pelvic floor muscle training exercises in preventing and treating urinary incontinence both in late pregnancy and after delivery. All the studies were of good quality methodologically and have reduction in urinary incontinence or regaining of continence as the primary end point.	
2. Applicability: The evidence is fully applicable as it shows PFMT reduces existing urinary incontinence as well as significantly reducing its occurrence in pregnancy	
3. External validity: It is reasonable to generalize the results of all the 9 studies in the target population and the general population as the integrity of the studies is safeguarded and a sizeable randomized sample of the population with similar characteristics used.	
4 Consistency: There is a high degree of consistency in the available evidence. There is no study that demonstrated conflicting results.	
5**. Quantity of evidence:** All the studies included had evidence that was statistically significant and with significant impact in reduction of urinary incontinence**.**	
6. Clinical impact: Pelvic floor muscle training if implemented both correctly and consistently will have a great impact in urinary incontinence reduction during late pregnancy and early postpartum period as compared to normal antenatal and postnatal care. It also significantly reduces existing urinary incontinence in postnatal women. There are no indicated risks of the intervention in the evidence available.	
7. Other factors: There were no other factors taken into consideration when assessing evidence base.	
8.Evidence statement: In an expectant lady without urinary incontinence, starting them on pelvic floor muscle training exercise with good supervision at between gestation weeks 20 and 34 ,will significantly reduce episodes of urinary incontinence in late pregnancy and early postpartum. In a postpartum woman with urinary incontinence, pelvic floor muscle exercise will significantly reduce incontinence by 6 to 12 months. In the long run, there is no significant difference between control and PFMT.	**Evidence level** **1++** **1+**

9.Reccommendation: Prenatal women should actively participate in PFMT to reduce late pregnancy and postnatal urinary and fecal incontinence. Post-natal women with stress incontinence should enroll for PFMT early enough (within 3 months) to enhance the prognosis of incontinence reduction.	**A** **B**

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APPENDICES

APPENDIX 1; SIGN 50 levels of evidence (2012)

KEY TO EVIDENCE STATEMENTS AND GRADES OF RECOMMENDATIONS

Levels of evidence

1++ High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias

1+ Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias

1- Meta-analyses, systematic reviews, or RCTs with a high risk of bias

2++ High quality systematic reviews of case control or cohort or studies
High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+ Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2- Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3 Non-analytic studies, e.g. case reports, case series
4 Expert opinion

Grades of recommendations

[A] At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results
[B] A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or
Extrapolated evidence from studies rated as 1++ or 1+
[C] A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++
[D] Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+ 25

Appendix 2: SIGN 50 COMPLETED RCT CHECKLIST (VARIOUS APPRAISED STUDIES; TABLE 2.1 TO 2.9)

Table 2.1

Completed Appraisal Checklist		
Study Identification: Aqur WI, Steggles P, Waterfield M, Freeman RM (2008): The long-term effectiveness of antenatal pelvic floor muscle training; 8-year follow up of a randomized controlled trial. Published in British journal of Obstetrics and gynaecology 2008 July		
Guideline Topic: Pelvic floor muscle exercise versus non-intervention in prevention of urinary incontinence		
Checklist completed by: NAJWA ALFARRA		
Section 1: Internal validity		
In a well conducted RCT study		In this study this criterion is:
1.1	The study addresses an appropriate and clearly focused question	**Well covered**
1.2	The assignment of subjects to treatment groups is randomized	**Well covered**
1.3	An adequate concealment method is used	**Adequately covered**
1.4	Subjects and investigators are kept 'blind' about treatment allocation	**Well covered**
1.5	The treatment and control groups are similar at the start of the trial	**Well covered**
1.6	The only difference between groups is the treatment under investigation	**Well covered**
1.7	All relevant outcomes are measured in a standard, valid and reliable way.	**Well covered**
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	**Not stated**
1.9	All the subjects analyzed in the groups to which they were randomly allocated(often referred to as intention to treat analysis)	**Well covered**
1.10	Where the study is carried out at more than one site, results are comparable for all sites	**Not applicable**
Section 2:Overall assessment of the study		
2.1	How well was the study done to minimize bias? Code ++,+,or -	**++**

2.2	If coded as +, or – what is the likely direction in which bias might affect the study results	
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, is you certain that the overall effect is due to the study intervention?	**yes**
2.4	Are the results of the study directly applicable to the patient group targeted by this guideline?	**Yes- studies long term effect of PFMT and its impact and shows better response than in control**
Section 3: Description of the study		
3.1	How many patients are included in the study (No. in each arm at the beginning)	**170women, 116 in PFMT and 54 control**
3.2	What are the main characteristics of the patient population?	**Women who had participated in an antenatal PFMT RCT 8years before**
3.3	What intervention (treatment, procedure) is being investigated in the study?	**PFMT**
3.4	What comparison are made in the study	**Pelvic floor muscle exercise v Non-intervention (Usual pre and postnatal care)**
3.5	How long are patients followed up in the study?	**8 Years**
3.6	What outcome measure(s) are used in the study?	**Stress urinary incontinence (SUI) and quality of life**
3.7	What size of the effect is identified in the study?	**The significant improvement in postnatal SUI originally shown in the PFMT compared with controls (19.2% versus 32.7%, P=0.02) at 3 months was not evident 8 years later (35.4 versus 38.8%, P=0.7).**
3.8	How was this study funded/	**Not stated**
3.9	Does this study help to answer the key question?	**Yes, PFMT group gives better outcome than non-intervention both in short and long terms.**

Table 2.2

Completed Appraisal Checklist		
Study Identification: Boyle R, Hay-Smith EJ, Cody JD, Morkved S. (2012) Pelvic floor muscle training for prevention and treatment of urinary and fecal incontinence in antenatal and postnatal women.Cochrane Database Systematic Rev. 2012 Oct 17; 10:CD007471. doi: 10.1002/14651858.CD007471.pub2. Review		
Guideline topic: Pelvic floor muscle exercise versus non-intervention in prevention of urinary incontinence		
Checklist completed by: NAJWA ALFARRA		
Section 1: Internal validity		
In a well conducted RCT study		In this study this criterion is:
1.1	The study addresses an appropriate and clearly focused question	**Well covered**
1.2	The assignment of subjects to treatment groups is randomized	**Well covered**
1.3	An adequate concealment method is used	**Adequately addressed**
1.4	Subjects and investigators are kept 'blind' about treatment allocation	**Well covered**
1.5	The treatment and control groups are similar at the start of the trial	**Well covered**
1.6	The only difference between groups is the treatment under investigation	**Well covered**
1.7	All relevant outcomes are measured in a standard, valid and reliable way.	**Well covered**
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	**None**
1.9	All the subjects analyzed in the groups to which they were randomly	**Well covered**

	allocated(often referred to as intention to treat analysis)	
1.10	Where the study is carried out at more than one site, results are comparable for all sites	**Not applicable**
Section 2:Overall assessment of the study		
2.1	How well was the study done to minimize bias? Code ++,+,or -	**+**
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results	**Overestimate the effect**
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, is you certain that the overall effect is due to the study intervention?	**Yes**
2.4	Are the results of the study directly applicable to the patient group targeted by this guideline?	**Yes –studies women with urinary incontinence postnatal**
Section 3: Description of the study		
3.1	How many patients are included in the study (No. in each arm at the beginning)	**4231 for intervention(PFMT) and 4254 control**
3.2	What are the main characteristics of the patient population?	**Pregnant women and those with urinary incontinence 3months post-delivery.**
3.3	What intervention (treatment, procedure) is being investigated in the study?	**Pelvic floor muscle training exercises**
3.4	What comparison are made in the study	**Pelvic floor muscle exercise v Non-intervention (Usual pre and postnatal care)**
3.5	How long are patients followed up in the study?	**Up to 12 month after delivery**
3.6	What outcome measure(s) are used in the study?	**Reduction in urinary incontinence**
3.7	What size of the effect is identified in the study?	**Significant reduction in urinary incontinence in PFMT group delivery (30% less, risk ratio (RR) 0.71, 95% CI 0.58 to 0.95)**
3.8	How was this study funded/	**Not stated**
3.9	Does this study help to answer the key question?	**Yes, there is significant improvement in urinary continence hence the patient would benefit in her intended pregnancy if she employed PFMT than without**

Table 2.3

Completed Appraisal Checklist		
Study Identification: Glazener CM, Herbison GP, McArthur C, Grant AM, Wilson PD (2005) RCT of conservative management of postnatal urinary and faecal incontinence: six year follow up. BMJ.2005 February 12:330 (7487): 337.		
Guideline Topic: Pelvic floor muscle exercise versus non-intervention in prevention of urinary incontinence		
Checklist completed by: NAJWA ALFARRA		
Section 1: Internal validity		
In a well conducted RCT study		In this study this criterion is:
1.1	The study addresses an appropriate and clearly focused question	**Well covered**
1.2	The assignment of subjects to treatment groups is randomized	**Well covered**
1.3	An adequate concealment method is used	**Adequately addressed**
1.4	Subjects and investigators are kept 'blind' about treatment allocation	**Adequately addressed**
1.5	The treatment and control groups are similar at the start of the trial	**Well covered**
1.6	The only difference between groups is the treatment under investigation	**Well covered**
1.7	All relevant outcomes are measured in a standard, valid and reliable way.	**Well covered**
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	**31%**
1.9	All the subjects analyzed in the groups to which they were randomly allocated(often referred to as intention to treat analysis)	**Adequately covered**
1.10	Where the study is carried out at more than one site, results are comparable for all sites	**Not applicable**

Section 2:Overall assessment of the study		
2.1	How well was the study done to minimize bias? Code ++,+,or -	++
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results	
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, is you certain that the overall effect is due to the study intervention?	**Yes**
2.4	Are the results of the study directly applicable to the patient group targeted by this guideline?	**YES –shows improvement even after one year**
Section 3: Description of the study		
3.1	How many patients are included in the study (No. in each arm at the beginning)	**516**
3.2	What are the main characteristics of the patient population?	Women with urinary incontinence after child birth
3.3	What intervention (treatment, procedure) is being investigated in the study?	PFMT
3.4	What comparison are made in the study	**Pelvic floor muscle exercise(PFMT)e v Non- intervention (Usual pre and postnatal care)**
3.5	How long are patients followed up in the study?	**6 YEARS**
3.6	What outcome measure(s) are used in the study?	**Urinary and faecal incontinence**
3.7	What size of the effect is identified in the study?	**At 1yr, 60% PFMT Group,69% control urinary incontinence(UI).4% PFMT and 11% control in faecal continence.6yrs, 76% and 79% UI (95% CI,difference in means- 10.2% to 4.1%))**
3.8	How was this study funded/	**Not stated**
3.9	Does this study help to answer the key question?	**Yes-up to I year there is significant improvement in continence for PFMT group. In six years the improvement shrinks and the difference in effect between the intervention group and the control is minimal.**

Table 2.4

Completed Appraisal Checklist		
Study Identification: Glazener CM, Herbison GP, Wilson PD, MacArthur C, Lang GD, Gee H, Grant AM (2001). Conservative management of persistent postnatal urinary and faecal incontinence. BMJ 2001 Sep. 15,323.		
Guideline topic: Pelvic floor muscle exercise versus non-intervention in prevention of urinary incontinence		
Checklist completed by: NAJWA ALFARRA		
Section 1: Internal validity		
In a well conducted RCT study		In this study this criterion is:
1.1	The study addresses an appropriate and clearly focused question	**Well covered**
1.2	The assignment of subjects to treatment groups is randomized	**Well covered**
1.3	An adequate concealment method is used	**Poorly addressed**
1.4	Subjects and investigators are kept 'blind' about treatment allocation	**No**
1.5	The treatment and control groups are similar at the start of the trial	**Well covered**
1.6	The only difference between groups is the treatment under investigation	**Well covered**
1.7	All relevant outcomes are measured in a standard, valid and reliable way.	**Well covered**
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	**none**
1.9	All the subjects analyzed in the groups to which they were randomly allocated(often referred to as intention to treat analysis)	**Well covered**
1.10	Where the study is carried out at more than one site, results are comparable for all sites	**Three centres (Dunedin, New Zealand, Birmingham Aberdeen. Compared the overall trial result.**
Section 2:Overall assessment of the study		
2.1	How well was the study done to minimize bias? Code ++,+,or -	**+**
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results	**Reporting incontinence is subjective and we cannot accurately quantify the reduction, so this will lead to study bias**
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, is you certain that the overall effect is due to the study intervention?	**YES**
2.4	Are the results of the study directly applicable to the patient group targeted by this guideline?	**Yes –compares PFMT and non-intervention and the intervention group has significantly better results**
Section 3: Description of the study		
3.1	How many patients are included in the study (No. in each arm at the beginning)	**747 women,371 on PFMT and 376 on control**

3.2	What are the main characteristics of the patient population?	**3months postnatal women with urinary incontinence**
3.3	What intervention (treatment, procedure) is being investigated in the study?	**PFMT**
3.4	What comparison are made in the study	**Pelvic floor muscle exercise(PFMT) v Non-intervention (Usual pre and postnatal care)**
3.5	How long are patients followed up in the study?	**9 MONTHS**
3.6	What outcome measure(s) are used in the study?	**Primary; persistence and severity of urinary incontinence Secondary: change in co-existing faecal incontinence, use of pads per day, rating of severity of UI with visual analogue scale, well-being, depression, anxiety, performance of pelvic floor exercise.**
3.7	What size of the effect is identified in the study?	**UI (59.9%) versus 69%, a difference of 9.1% (95% CI 1% to 17.3%, P=0.037) for any incontinence. Severe incontinence, 19.7% versus 31.8%, a difference of 12.1% (4.7% to 19.6%, P=0.002). exercise (79%) versus (48%), P<0.001**
3.8	How was this study funded/	**Not stated**
3.9	Does this study help to answer the key question?	**Yes- PFMT has a better prognosis for postpartum urinary and faecal incontinence than non-intervention**

Table 2. 5

Completed Appraisal Checklist		
Study Identification: Hay-Smith J, Morkved S, Fairbrother KA, Herbison GP (2008). Pelvic floor muscle training for prevention and treatment of urinary and faecal incontinence in antenatal and postnatal women. Published in British Journal of Obstetrics and gynaecology 2008 July.		
Guideline topic: Pelvic floor muscle training for urinary/faecal incontinence in women		
Checklist completed by: NAJWA ALFARRA		
Section 1: Internal validity		
In a well conducted RCT study		In this study this criterion is:
1.1	The study addresses an appropriate and clearly focused question	**Well covered**
1.2	The assignment of subjects to treatment groups is randomized	**Well covered.**
1.3	An adequate concealment method is used	**Poorly addressed**
1.4	Subjects and investigators are kept 'blind' about treatment allocation	**No**
1.5	The treatment and control groups are similar at the start of the trial	**Well covered**
1.6	The only difference between groups is the treatment under investigation	**Well covered**
1.7	All relevant outcomes are measured in a standard, valid and reliable way.	**Well covered**
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	**27 women**
1.9	All the subjects analyzed in the groups to which they were randomly allocated(often referred to as intention to treat analysis)	**Well covered**
1.10	Where the study is carried out at more than one site, results are comparable for all sites	**Not applicable**
Section 2:Overall assessment of the study		
2.1	How well was the study done to minimize bias? Code ++,+,or -	**+ +**
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results	
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, is you certain that the overall effect is due to the study intervention?	**Yes**
2.4	Are the results of the study directly applicable to the patient group targeted by this guideline?	**Yes**
Section 3: Description of the study		
3.1	How many patients are included in the study (No. in each	**3040 for supervised PFMT and 3114 control**

	arm at the beginning)	
3.2	What are the main characteristics of the patient population?	**Pregnant and postnatal women**
3.3	What intervention (treatment, procedure) is being investigated in the study?	**Pelvic floor muscle exercise (PFMT)**
3.4	What comparison are made in the study	**Pelvic floor muscle exercise v Non- intervention (Usual pre and postnatal care)**
3.5	How long are patients followed up in the study?	**12 months**
3.6	What outcome measure(s) are used in the study?	**Reduction in urinary / faecal incontinence.**
3.7	What size of the effect is identified in the study?	**56% less urinary incontinence in late pregnancy, (RR 0.44, 95 CI 0.3 T0 0.65) and 30% less up to 6 months postpartum (RR 0.71, 95%CI 0.52 to 0.97). Postnatal women with UI 3 month's post- delivery, on PFMT reported 20% UI 12 months after delivery (RR 0.79, 95% CI 0.70 to 0.90).**
3.8	How was this study funded/	**Not stated**
3.9	Does this study help to answer the key question?	**Yes, women on PFMT show better response than the control group**

Table 2.6

Completed Appraisal Checklist		
Study Identification: Ko PC, Liang CC, Chang SD, Lee JT, Chao AS, Cheng PJ (2011): A randomized controlled trial of antenatal pelvic floor exercises to prevent and treat urinary incontinence. International Urogyaecological Journal 2011 January.		
Guideline Topic: Pelvic floor muscle exercise versus non-intervention in prevention of urinary incontinence		
Checklist completed by: NAJWA ALFARRA		
Section 1: Internal validity		
In a well conducted RCT study		In this study this criterion is:
1.1	The study addresses an appropriate and clearly focused question	**Well covered**
1.2	The assignment of subjects to treatment groups is randomized	**Well covered**
1.3	An adequate concealment method is used	**Adequately addressed**
1.4	Subjects and investigators are kept 'blind' about treatment allocation	**Well covered**
1.5	The treatment and control groups are similar at the start of the trial	**Well covered**
1.6	The only difference between groups is the treatment under investigation	**Well covered**
1.7	All relevant outcomes are measured in a standard, valid and reliable way.	**Well covered**
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	**None**
1.9	All the subjects analyzed in the groups to which they were randomly allocated(often referred to as intention to treat analysis)	**Well covered**
1.10	Where the study is carried out at more than one site, results are comparable for all sites	**Not applicable**
Section 2:Overall assessment of the study		
2.1	How well was the study done to minimize bias? Code ++,+,or -	**++**
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results	
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, is you certain that the overall effect is due to the study intervention?	**YES-**
2.4	Are the results of the study directly applicable to the patient group targeted by this guideline?	**YES -**
Section 3: Description of the study		
3.1	How many patients are included in the study (No. in each arm at the beginning)	**300 pregnant women;200 on PFMT and 100 on usual antenatal care(control)**
3.2	What are the main characteristics of the patient population?	**Pregnant women on antenatal clinic**
3.3	What intervention (treatment, procedure) is being investigated in the study?	**Supervised PFMT**
3.4	What comparison are made in the study	**Pelvic floor muscle exercise v Non- intervention (Usual pre and postnatal care)**
3.5	How long are patients followed up in the study?	**Up to 6months postpartum**
3.6	What outcome measure(s) are used in the study?	**Urogenital distress and urinary incontinence**
3.7	What size of the effect is identified in the study?	**Significantly lower UDI-6 and IIQ-7 SCORES for PFMT group compared to control. Also less episodes of self-reported incontinence**
3.8	How was this study funded/	**Not stated**

3.9	Does this study help to answer the key question?	**Evidence derived shows that women on PFMT have better urinary incontinence prognosis compared to non-intervention group**

Table 2.7

Completed Appraisal Checklist		
Study Identification: Morkved S, Bo K, Schei B, Salvesen KA (2003). Pelvic floor training during pregnancy to prevent urinary incontinence: a single-blind randomized controlled trial. Obstetric Gynecol. 2003 Feb: 101 (2): 313-9.		
Guideline topic: Pelvic floor muscle exercise versus non-intervention in prevention of urinary incontinence		
Checklist completed by: NAJWA ALFARRA		
Section 1: Internal validity		
In a well conducted RCT study		In this study this criterion is:
1.1	The study addresses an appropriate and clearly focused question	**Well covered**
1.2	The assignment of subjects to treatment groups is randomized	**Well covered.**
1.3	An adequate concealment method is used	**Well covered**
1.4	Subjects and investigators are kept 'blind' about treatment allocation	**Well covered**
1.5	The treatment and control groups are similar at the start of the trial	**Well covered**
1.6	The only difference between groups is the treatment under investigation	**Well covered**
1.7	All relevant outcomes are measured in a standard, valid and reliable way.	**Well covered**
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	**None**
1.9	All the subjects analyzed in the groups to which they were randomly allocated(often referred to as intention to treat analysis)	**Well covered**
1.10	Where the study is carried out at more than one site, results are comparable for all sites	**Not applicable**
Section 2:Overall assessment of the study		
2.1	How well was the study done to minimize bias? Code ++,+,or -	**+**
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results	**Overestimate effects**
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, is you certain that the overall effect is due to the study intervention?	**Yes**
2.4	Are the results of the study directly applicable to the patient group targeted by this guideline?	**Yes**
Section 3: Description of the study		
3.1	How many patients are included in the study (No. in each arm at the beginning)	**301 pregnant women, 148 on PFMT and 153 on control.**
3.2	What are the main characteristics of the patient population?	**healthy nulliparous women**
3.3	What intervention (treatment, procedure) is being investigated in the study?	**Pelvic floor muscle exercise (PFMT)**
3.4	What comparison are made in the study	**Pelvic floor muscle exercise during pregnancy v customary information.**
3.5	How long are patients followed up in the study?	**24 weeks gestation to 3 months after delivery (8months)**
3.6	What outcome measure(s) are used in the study?	**Reduction in urinary incontinence , and pelvic floor strength**
3.7	What size of the effect is identified in the study?	**32% episodes of urinary incontinence in the PFMT compared with 48% in non-intervention group, and 20% versus 32% 3 months after delivery.**
3.8	How was this study funded/	**Norwegian Fund, public health association.**
3.9	Does this study help to answer the key question?	**Yes, women on PFMT show better response than the control group**

Table 2.8

Completed Appraisal Checklist	
Study Identification: Reilly ET, Freeman RM, Waterfield MR, Waterfield AE, Steggles P, PedlarF. (2002): Prevention of postpartum stress incontinence in primigravidae with increased bladder neck mobility.BJOG. 2002 Jan;109(1):68-76	
Guideline Topic: Pelvic floor muscle exercise versus non-intervention in prevention of urinary incontinence	
Checklist completed by: NAJWA ALFARRA	
Section 1: Internal validity	
In a well conducted RCT study	In this study this criterion is:

1.1	The study addresses an appropriate and clearly focused question	**Well covered**
1.2	The assignment of subjects to treatment groups is randomized	**Well covered.**
1.3	An adequate concealment method is used	**Not addressed**
1.4	Subjects and investigators are kept 'blind' about treatment allocation	**Well covered**
1.5	The treatment and control groups are similar at the start of the trial	**Well covered**
1.6	The only difference between groups is the treatment under investigation	**Well covered**
1.7	All relevant outcomes are measured in a standard, valid and reliable way.	**Well covered**
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	**Not addressed**
1.9	All the subjects analyzed in the groups to which they were randomly allocated(often referred to as intention to treat analysis)	**Adequately addressed**
1.10	Where the study is carried out at more than one site, results are comparable for all sites	**Not applicable**
Section 2:Overall assessment of the study		
2.1	How well was the study done to minimize bias? Code ++,+,or -	**+**
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results	**Overestimate effects**
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, is you certain that the overall effect is due to the study intervention?	**Yes**
2.4	Are the results of the study directly applicable to the patient group targeted by this guideline?	**Yes**
Section 3: Description of the study		
3.1	How many patients are included in the study (No. in each arm at the beginning)	**139 for supervised PFMT and 129 control**
3.2	What are the main characteristics of the patient population?	**Primigravidae at 20 weeks' gestation, median age 28years (16 -47 years**)
3.3	What intervention (treatment, procedure) is being investigated in the study?	**Pelvic floor muscle exercise (PFMT)**
3.4	What comparison are made in the study	**Pelvic floor muscle exercise v Non-intervention (Usual pre and postnatal care)**
3.5	How long are patients followed up in the study?	**20 weeks gestation to 3 months after delivery (8months)**
3.6	What outcome measure(s) are used in the study?	**Reduction in urinary incontinence ,pelvic floor strength and urinary bladder mobility**
3.7	What size of the effect is identified in the study?	**19.2% episodes of urinary incontinence in the PFMT compared with 32.7% in non-intervention group(RR =0.59, 0.37 -0.92)**
3.8	How was this study funded/	**Not stated**
3.9	Does this study help to answer the key question?	**Yes, women on PFMT show better response than the control group**

Table 2.9

Completed Appraisal Checklist		
Study Identification: SStafne SN, Salvesen KA, Romundstad PR, Tojusen IH, Morkved S. (2012). Does regular exercise including pelvic floor muscle training prevent urinary incontinence during pregnancy? A randomized controlled trial: BJOG.2012 Sep; 119(10).		
Guideline Topic: Pelvic floor muscle exercise versus non-intervention in prevention of urinary incontinence		
Checklist completed by: NAJWA ALFARRA		
Section 1: Internal validity		
In a well conducted RCT study		In this study this criterion is:
1.1	The study addresses an appropriate and clearly focused question	**Well covered**
1.2	The assignment of subjects to treatment groups is randomized	**Well covered.**
1.3	An adequate concealment method is used	**Not addressed**
1.4	Subjects and investigators are kept 'blind' about treatment allocation	**Not addressed**
1.5	The treatment and control groups are similar at the start of the trial	**Well covered**
1.6	The only difference between groups is the treatment under investigation	**Well covered**
1.7	All relevant outcomes are measured in a standard, valid and reliable way.	**Well covered**
1.8	What percentage of the individuals or clusters	**Not addressed**

	recruited into each treatment arm of the study dropped out before the study was completed?	
1.9	All the subjects analyzed in the groups to which they were randomly allocated(often referred to as intention to treat analysis)	**Well covered**
1.10	Where the study is carried out at more than one site, results are comparable for all sites	**Yes, Trondheim University Hospital (St. Olavs Hospital) and Stavanger University Hospital, in Norway**
Section 2:Overall assessment of the study		
2.1	How well was the study done to minimize bias? Code ++,+,or -	**+**
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results	**Self-reporting UI is subjective which will lead to high study bias.**
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, is you certain that the overall effect is due to the study intervention?	**Yes**
2.4	Are the results of the study directly applicable to the patient group targeted by this guideline?	**Yes**
Section 3: Description of the study		
3.1	How many patients are included in the study (No. in each arm at the beginning)	**855 pregnant women, 553 received PFMT, 302 control.**
3.2	What are the main characteristics of the patient population?	**Pregnant women between 20 and 36 weeks.**
3.3	What intervention (treatment, procedure) is being investigated in the study?	**Pelvic floor muscle exercise (PFMT)**
3.4	What comparison are made in the study	**Pelvic floor muscle exercise v Non- intervention (received normal prenatal care)**
3.5	How long are patients followed up in the study?	**From 20 weeks gestation to 36 weeks gestation.**
3.6	What outcome measure(s) are used in the study?	**Self-reported urinary and anal incontinence after the intervention period (at 32-36 weeks gestation).**
3.7	What size of the effect is identified in the study?	**11% of women in the intervention reported any weekly urinary incontinence compared to 19% of the non-intervention group (P= 0.004). 3% of women in the intervention reported faecal incontinence versus 5% in non-intervention.**
3.8	How was this study funded/	**Not stated**
3.9	Does this study help to answer the key question?	**Yes, women on PFMT show better response than the control group**

Dr. Najwa Alfarra Comparison between the significant of antenatal pelvic floor exercises and non-intervention in preventing urinary incontinence: A systematic Literature Review." IOSR Journal of Nursing and Health Science (IOSR-JNHS) , vol. 6, no.6 , 2017, pp. 38-56.