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	**The significant improvement in postnatal SUI originally shown in the PFMT compared with**

	study?	**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	**Well covered**

	clearly focused question	
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	**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	**Yes –studies women with urinary incontinence postnatal**

	guideline?	
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	**Adequately covered**

	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	
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: Hatice Kahyaoglu, Petek Balkanli Kaplan, (2015). Effect of pelvic floor muscle exercise on pelvic floor muscle activity and voiding functions during pregnancy and postpartum period.		
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 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	**Not applicable**

	all sites	
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)	**60 women, 30 in PFMT and 30 control**
3.2	What are the main characteristics of the patient population?	**Women who had participated in an antenatal PFMT RCT , 28 weeks, 36-38 weeks of pregnancy and 6-8 post partum**
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?	**6-8 postpartum**
3.6	What outcome measure(s) are used in the study?	**Urinary Distress Inventory (UDI-6), Incontinence Impact Questionnaires (IIQ-7), The Overactive Bladder Questionnaires (OBQ-q). Uroflowmetry and three day voiding diaries. Using perineometry device to measure muscle**

		power of the pelvic .
3.7	What size of the effect is identified in the study?	**Pelvic floor muscle strength improved in the training group compared to the control group (P < 0.001).** **UDI-6 and OAB-q scores were improved during postpartum weeks 6-8 (P < 0.05).**
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 2.6

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 arm at the beginning)	**3040 for supervised PFMT and 3114 control**
3.2	What are the main characteristics of the patient	**Pregnant and postnatal women**

	population?	
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 2.7

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	**300 pregnant women;200 on PFMT and**

	arm at the beginning)	**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 2.8

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	**Yes**

	patient group targeted by this guideline?	
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 2.9

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 2.10

Completed Appraisal Checklist
Study Identification: S Stafne 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 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)	**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**