National Institute for Health and Care Excellence

FINAL

Antenatal care

[U] Management of pelvic girdle pain in pregnancy

NICE guideline NG201

Evidence reviews underpinning recommendation 1.4.15

August 2021

Final

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

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Management of pelvic girdle pain in pregnancy

Review question

What interventions are effective in treating mild to moderate pelvic girdle pain during pregnancy?

Introduction

It is estimated that 1 in 5 women experience pain in the pelvic girdle region during pregnancy. Pelvic girdle pain can make daily activities during pregnancy difficult for women and may have an effect on pain intensity felt during labour or birth. The question aims to identify which treatment options are the most effective for pelvic girdle pain during pregnancy.

Summary of the protocol

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

Table 1: Summary of the protocol (PICO table)

Population	Pregnant women with mild to moderate pelvic girdle pain
Intervention	• Acupuncture/Acupressure exercises • Analgesics - only opiates and paracetamol will be considered • Ice packs and heat packs • Manual therapy • Pelvic girdle support • Physiotherapy-delivered advice • Pillow • Reflexology
Comparison	• No treatment • Any other intervention listed above
Outcomes	**Critical outcomes** • Pain intensity (pain levels) during pregnancy (pain intensity during labour or birth will not be considered) • Pelvic-related functional disability/functional status during pregnancy (such as ability to perform daily activities) **Important outcomes** • Adverse effects during pregnancy • Days off work/sick leave (during pregnancy or prior to maternity leave) • Days in hospital admitted to antenatal ward for treatment of pelvic girdle pain (exclude admission for labour or early labour) • Women's experience and satisfaction • Admission at birth to the neonatal unit

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

Methods and process

This evidence review was developed using the methods and process described in Developing NICE guidelines: the manual 2014. Methods specific to this review question are described in the review protocol in appendix A.

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

Clinical evidence

Included studies

Eleven articles reporting 10 randomised controlled trials (RCTs) in pregnant women with pelvic girdle pain were included in this review (Elden 2005, Elden 2008a, Elden 2013, Gausel 2017, Kordi 2013, Melkersson 2017, Mirmolaei 2018, Nicolian 2019, Nilsson-Wikmar 2005 and Wedenberg 2000, with Elden 2008b reporting additional outcomes from the same study as Elden 2005).

The included studies are summarised in Table 2.

Four RCTs examined the effectiveness of acupuncture: 1 study compared an 8-week course of traditional body acupuncture and standard treatment to sham acupuncture and standard treatment (Elden 2008a); 1 study with 3-arms was reported in two articles and compared a 6-week course of body acupuncture and standard treatment, and physiotherapy-delivered in-home stabilising exercise and standard treatment, to standard treatment only (Elden 2005, Elden 2008b); 1 study compared a 4-week acupuncture course and standard treatment (Nicolian 2019); 1 study compared a 1-month course of traditional ear and body acupuncture to physiotherapy-delivered in-home exercise advice (Wedenberg 2000).

Three RCTs examined various forms of manual therapy: 1 study compared an 8-week course of craniosacral therapy and standard treatment to standard treatment only (Elden 2013); 1 study compared chiropractic treatment provided for the duration of the pregnancy to standard treatment (Gausel 2017); and 1 study compared a 6-week course of foot manipulation and physiotherapy-delivered in-home exercise advice to sham foot manipulation and physiotherapy-delivered in-home exercise advice (Melkersson 2017).

One 3-arm RCT compared a 6-week course of pelvic girdle support belt (a non-rigid lumbopelvic belt) and information to a combination of physiotherapy-delivered in-home exercise advice and information or information only (Kordi 2013).

Two RCTs assessed the effectiveness of physiotherapy-delivered exercise advice: 1 study with 3-arms compared physiotherapy-delivered in-home or in-clinic exercise advice, a pelvic girdle support belt (a non-elastic sacroiliac belt), and information provided from recruitment until gestation week 38 to a combination of pelvic girdle support belt and information (Nilsson-Wikmar 2005); 1 quasi-RCT compared a 12-week course of physiotherapy-delivered exercise advice to standard treatment (Mirmolaei 2018).

Five studies were conducted in Sweden (Elden 2005, Elden 2008a, Elden 2013, Melkersson 2017 and Nilsson-Wikmar 2005). One study conducted in France (Nicolian 2019), 2 studies conducted in Iran (Kordi 2013, Mirmolaei 2018) and 1 study in Norway (Gausel 2017).

One additional study (Scott 2018) was identified in final update searches for the review that met the protocol inclusion criteria but did not affect the evidence base or draft recommendations. The searches were initially updated in May 2020 but due to the atypical prolongation of guideline development to due COVID-19 pandemic, the searches were updated again in September 2020. New evidence identified in this final update search which

did not impact on the conclusions was not fully included in the report but is referenced in appendix M.

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

Excluded studies

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

Summary of studies included in the evidence review

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

Table 2: Summary of included studies

Study	Population	Intervention	Comparison	Outcomes
Elden 2008a RCT Sweden	N=115 Healthy pregnant women with pelvic pain and singleton fetuses at 12–29 completed gestational weeks 48% of the participants had severe pelvic girdle pain	• Acupuncture (body) + standard treatment (information + pelvic girdle support + physiotherapy-delivered in-home exercise advice) • Treatment length: 8 weeks	• Non-penetrating sham acupuncture + standard treatment (information + pelvic girdle support + physiotherapy-delivered in-home exercise advice)	• Pain intensity during pregnancy • Pelvic-related functional disability/functional status during pregnancy • Adverse effects during pregnancy • Days off work/sick leave
Elden 2005/2008b RCT Sweden	N=386 Healthy pregnant women with pelvic pain and singleton fetuses at 12–31 completed gestational weeks	• Acupuncture (body) + standard treatment (information + pelvic girdle support + physiotherapy-delivered in-home exercise advice) • Physiotherapy-delivered in-clinic exercise advice + standard treatment (general information + pelvic girdle support + physiotherapy-delivered in-home exercise advice) • Treatment length: 6 weeks	• Standard treatment (information + pelvic girdle support + physiotherapy-delivered in-home exercise advice)	• Pain intensity during pregnancy • Adverse effects during pregnancy • Women's experience and satisfaction of care • Admission at birth to the neonatal unit
Elden 2013 RCT Sweden	N=123 Healthy pregnant women with pelvic pain and singleton fetuses at 12–29 completed gestational weeks 47% of the participants had severe pelvic girdle pain	• Manual therapy (Craniosacral therapy) + standard treatment (information + pelvic girdle support + physiotherapy-delivered in-home exercise advice) • Treatment length: 8 weeks	• Standard treatment (information + pelvic girdle support + physiotherapy-delivered in-home exercise advice)	• Pain intensity during pregnancy • Pelvic-related functional disability/functional status during pregnancy • Days off work/sick leave

Study	Population	Intervention	Comparison	Outcomes
Gausel 2017 RCT Norway	N=56 Pregnant women with dominating one-sided pelvic girdle pain and singleton foetuses at 18 completed gestational weeks	• Manual therapy (Chiropractic treatment) • Treatment length: variable, as determined by the chiropractor, to birth	• Standard treatment (conventional primary healthcare)	• Pain intensity during pregnancy • Pelvic-related functional disability/functional status during pregnancy • Days off work/sick leave
Kordi 2013 RCT Iran	N=105 Healthy pregnant women with pelvic pain and singleton fetuses at 20–32 completed gestational weeks	• Pelvic girdle support (non-rigid belt) + information • Physiotherapy-delivered in-home exercise advice + information • Treatment length: 6 weeks	• Information	• Pain intensity during pregnancy • Pelvic-related functional disability/functional status during pregnancy
Melkersson 2017 RCT Sweden	N=97 Pregnant women at 12–31 completed gestational weeks with pelvic pain and joint dysfunction or decreased pain of foot movement	• Manual therapy (Foot manipulation) + physiotherapy-delivered in-home exercise advice • Treatment length: 6 weeks	• Sham manual therapy (Sham foot manipulation) + physiotherapy-delivered in-home exercise	• Pain intensity during pregnancy
Mirmolaei 2018 RCT Iran	N=180 Women between 18 to 35 years old, are pregnant in the gestational week between 17 and 22 and had singleton preg nancy 15% of the participants had back pain only	• Physiotherapy-delivered exercise advice • Treatment length: 12 weeks	• Standard treatment	• Pain intensity during pregnancy • Pelvic-related functional disability/functional status during pregnancy
Nicolian 2019 RCT France	N=199 Pregnant women aged 18 or over and between 16-34 weeks' gestation. Low back pain for at least two weeks with pain greater than 4 on a 10-point numerical rating scale. At least one positive provocation test.	• 5 acupuncture sessions performed by an acupuncturist midwife, in addition to standard care. • Acupuncture points were selected based on pain location and traditional Chinese medicine diagnosis of 'Qi kidney deficiency' versus 'blood stagnation'. • Treatment length: 4 weeks. Two sessions in week 1, then 3 weekly	• Standard care. Includes a pregnancy belt and lifestyle recommendations and exercises explained by the midwife in charge of the trail. • Painkillers, rest and sick leave were prescribed by the doctor or the midwife.	• Pain intensity during pregnancy • Pelvic-related functional disability/functional status during pregnancy • Adverse effects during pregnancy • Admission at birth to the neonatal unit.

Study	Population	Intervention	Comparison	Outcomes
		sessions. Additional sessions could be done at patient's request.		
Nilsson-Wikmar 2005 RCT Sweden	N=118 Pregnant women until gestation week 35 with back pain, who tested positive in at least 3 pelvic pain provocation tests including the symphysis while testing negative for pain in the lumbar spine area including radiating pain, were included.	• Physiotherapy-delivered in-home exercise advice + pelvic girdle support (non-elastic sacroiliac) belt + information • Physiotherapy-delivered in-clinic exercise advice + pelvic girdle support (non-elastic sacroiliac) belt + information • Treatment length: varied periods - twice a week until gestation week 39.	• Pelvic girdle support (non-elastic sacroiliac) belt + information	• Pain intensity during pregnancy • Pelvic-related functional disability/functional status during pregnancy
Wedenberg 2000 RCT Sweden	N=60 Pregnant women with a gestational age of no more than 32 weeks and who were suffering from back and pelvic pain 22% of the participants in the physiotherapy-delivered in-home exercise advice group had lower-back pain only	• Acupuncture (ear + body) • Treatment length: 4 weeks for acupuncture, and 6-8 weeks for physiotherapy-delivered advice	• Physiotherapy-delivered in-home exercise advice	• Adverse effects during pregnancy • Women's experience and satisfaction of care • Admission at birth to the neonatal unit

RCT: randomised controlled trial

See the full evidence tables in appendix D. No meta-analysis was conducted and there are thus no forest plots presented in appendix E.

Quality assessment of clinical outcomes included in the evidence review

See the evidence profiles in appendix F.

Economic evidence

Included studies

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

Excluded studies

A global search of the economic evidence was undertaken for all review questions in this guideline. See Supplement 2 for further information.

Summary of studies included in the economic evidence review

No economic evidence was identified for this review question, therefore, there are no economic evidence profiles

Economic model

An economic analysis was undertaken to estimate the cost-effectiveness of use of a lumbopelvic support belt versus usual cares set as information only or exercise advice. (See Appendix J – Economic analysis for the full report).

Overview of methods

The economic evaluation was conducted in the form of a cost-utility analysis (CUA), with outcomes expressed in terms of cost per quality adjusted life year (QALY) gained. The model setting was for the NHS. The studied population were pregnant women with mild to moderate pelvic girdle pain.

The interventions, population and the clinical inputs were informed entirely from 1 RCT (Kordi 2013) that was included in the accompanying clinical evidence review. This study assigned women to one of three groups; information only, a home based exercise programme and a non-rigid, lumbopelvic support belt (referred to as 'belt').

In accordance with NICE methodology, a NHS and Personal Social Services (PSS) perspective was adopted for this analysis. Costs were based on a 2017/18 price year, reflecting the most recently available NHS Reference Costs at the time of writing. Costs were not discounted as all relevant costs occurred within the relatively short time horizon of the model.

EQ-5D utilities were used in the model which were mapped from health-related quality of life scores reported in the Kordi study. Utility measurements at base, week 3 and week 6 were weighted against the time between each measurement to compute total QALYs. This method was followed for each intervention, with the intervention with the most QALYs being the most effective.

The belt was a clear intervention as this is not typically offered by the NHS. The clinical study, Kordi 2013, upon which this analysis is based also assessed information advice and exercise as treatment strategies. As there was ambiguity as to what constituted standard care in the UK context, the belt was compared to each of the interventions in separate pairwise analyses.

Main findings

Both deterministic and probabilistic sensitivity analysis (PSA) were conducted for when the belt is i) compared with information only and ii) exercise. A deterministic analysis computes the results from the reported point estimates of each input parameter. PSA calculates the results by accounting for uncertainty inherent in the model input values. This involved sampling model inputs from pre-specified probability distributions that reflected the uncertainty around the point estimates for the model values.

With both comparisons in the deterministic analysis, the belt was cost effective with an incremental cost effectiveness ratio between £1900 and £2930 per QALY gained – a large

distance from a threshold of £20000 per QALY. PSA demonstrated that the belt was 93% likely to be cost effective when compared to information only and 96% likely to be cost effective when compared to exercise.

Numerous one-way sensitivity analysis showed the model output was robust to low/high values, with the exception of the cost of a belt. This was because the one-way sensitivity analysis set an arbitrarily high unit cost of a belt at an extreme value to test robustness. There was some uncertainty as to which would be the correct costing of a belt, though all seemingly appropriate inputs were between £16-20. A threshold analysis indicated that the unit cost of a belt would have to increase from £17 to £164 for it not to be cost effective when compared with information only. When compared with exercise, the threshold analysis indicated that the belt would have to increase from £17 to £113 for the belt intervention to not be cost effective. The results of the base case analysis also held when subjected to various scenario analyses such as where treatment is hypothetically extended to 9 weeks.

There were some views among the committee that the cost of a physio might be included in the belt group only, but standard practice in the UK would see mild analgesics more commonly offered to women. However, even at this assumption, the incremental cost effectiveness ratios (ICERs) of the belt versus information only and the belt versus exercise were £9473 and £13816 respectively – still someway of a £20000 per QALY threshold.

Strengths/limitations

One key strength of this analysis is that it is the only known cost utility analysis in this topic area, applicable to the NICE decision making context.

The results show that the belt is likely to be a cost effective intervention when compared to standard care and be an efficient use of NHS resources. In both comparisons, the results of the deterministic and probabilistic analysis pointed towards the belt being cost effective. There was some uncertainty as to the correct unit cost of a lumbopelvic belt. However, a threshold analysis indicated that the belt would need to cost more than £100 per person for the belt intervention to not be cost effective. Given that all possible cost inputs fall some way under this figure, this key area of uncertainty is greatly minimised. The interpretation of the cost effectiveness of the belt was also robust to scenario analysis whereby those receiving the belt would also receive a single physio appointment.

The model has a number of limitations and, in particular, the health-related quality of life (HRQoL) inputs used to calculate QALYs are mapped into EQ-5D-5L data. Whilst mapping is a conventional method for deriving utilities, the 5 level version of the EQ-5D has not been validated by NICE. Nevertheless, in the absence of any other evidence, the estimates had face validity with the reported quality of life scores in the clinical evidence review and proved robust when subject to a probabilistic and deterministic sensitivity analysis. Furthermore, another limitation is that the model was informed by one RCT and did not include other interventions included in the clinical review. As this model estimates QALYs directly from Kordi 2013 however, it would be difficult to incorporate these other interventions within the same model.

Evidence statements

Clinical evidence statements

Comparison 1. Acupuncture + standard treatment versus standard treatment

Critical outcomes

Pain intensity during pregnancy

- Low quality evidence from 1 RCT (N=386) showed that there is a statistically significant difference favouring acupuncture plus standard treatment over standard treatment on pain intensity in the morning as assessed by a visual analogue scale one week after the treatment in pregnant women with pelvic girdle pain: difference between medians 13, p<0.0001.
- Low quality evidence from 1 RCT (N=386) showed that there is a statistically significant difference favouring acupuncture plus standard treatment over standard treatment on pain intensity in the evening as assessed by a visual analogue scale one week after the treatment in pregnant women with pelvic girdle pain: difference between medians 27, p<0.001.
- Low quality evidence from 1 RCT (N=199) showed that there is no clinically important difference between acupuncture plus standard treatment and standard treatment on pain intensity, assessed with the numerical rating scale: MD -0.9 (95% CI -1.56 to -0.24).

Pelvic-related functional disability/functional status during pregnancy

- Moderate quality evidence from 1 RCT (N=199) showed that there is no clinically important difference between acupuncture plus standard treatment and standard treatment on disability, assessed with Oswestry disability index: MD -3.5 (95% CI -7.27 to 0.27).

Important outcomes

Adverse effects during pregnancy

- Moderate quality evidence from 1 RCT (N=255) showed that there is a clinically important difference favouring standard treatment over acupuncture plus standard treatment on the number of women who experience adverse effects during pregnancy in women with pelvic girdle pain: RR 5.59 (95% CI 2.74 to 11.41).
- High quality evidence from 1 RCT (N=199) showed that there is a clinically important difference favouring standard treatment over acupuncture plus standard treatment on the number of women who experience acupuncture specific adverse effects during pregnancy: POR 11.68 (95% CI 5.49 to 24.85).
- Low quality evidence from 1 RCT (N=199) showed that there is no clinically important difference between acupuncture plus standard treatment and standard treatment on non-specific adverse effects during pregnancy: RR 1.04 (95% CI 0.86 to 1.59).

Days off work/sick leave

No evidence was identified to inform this outcome.

Days in hospital admitted to antenatal ward for treatment of pelvic girdle pain

No evidence was identified to inform this outcome.

Women's experience and satisfaction of care

- Very low quality evidence from 1 RCT (N=215) showed that there is no clinically important difference between acupuncture plus standard treatment and standard treatment on the number of pregnant women with pelvic girdle pain who reported no pain relief within one week of treatment: RR 0.62 (95% CI 0.11 to 3.62).
- Low quality evidence from 1 RCT (N=215) showed that there is no clinically important difference between acupuncture plus standard treatment and standard treatment on the number of pregnant women with pelvic girdle pain who reported that the treatments were harmful within one week of treatment: RR 0.78 (95% CI 0.58 to 1.05).

- Moderate quality evidence from 1 RCT (N=215) showed that there is a clinically important difference favouring acupuncture plus standard treatment over standard treatment on the number of pregnant women with pelvic girdle pain who reported that the treatment was not helpful within one week of treatment: RR 0.15 (95% CI 0.05 to 0.41).
- Moderate quality evidence from 1 RCT (N=215) showed that there is a clinically important difference favouring acupuncture plus standard treatment over acupuncture on the number of pregnant women with pelvic girdle pain who reported that the treatment was of good or very good help within one week of treatment: RR 3.92 (95% CI 2.63 to 5.86).

Admission at birth to the neonatal unit

- Very low quality evidence from 2 RCTs (N=452) showed that there is no clinically important difference between acupuncture plus standard treatment and standard treatment on the number of babies who are admitted to the neonatal unit: RR 0.81 (95% CI 0.36 to 1.82).

Comparison 2. Acupuncture + standard treatment versus non-penetrating sham acupuncture + standard treatment

Critical outcomes

Pain intensity during pregnancy

- Very low quality evidence from 1 RCT (N=115) showed that there is no statistically significant difference between acupuncture plus standard treatment and sham acupuncture plus standard treatment on pain intensity in the morning as assessed by a visual analogue scale during the last treatment week in pregnant women with pelvic girdle pain: difference between medians 1, p=0.29.
- Very low quality evidence from 1 RCT (N=115) showed that there is no statistically significant difference between acupuncture plus standard treatment and sham acupuncture plus standard treatment on pain intensity in the evening as assessed by a visual analogue scale during the last treatment week in pregnant women with pelvic girdle pain: difference between medians 5, p=0.48.
- Very low quality evidence from 1 RCT (N=115) showed that there is no statistically significant difference between acupuncture plus standard treatment and sham acupuncture plus standard treatment on the number of pregnant women with pelvic girdle pain who report discomfort during the last treatment week: difference between medians 5, p=0.15.

Pelvic-related functional disability/functional status during pregnancy

- Very low quality evidence from 1 RCT (N=115) showed that there is a statistically significant difference favouring acupuncture plus standard treatment over sham acupuncture plus standard treatment on pelvic-related functional disability/functional status during pregnancy as assessed by the disability rating index within 1 week after end of treatment in pregnant women with pelvic girdle pain: difference between medians 11, p<0.001.
- Very low quality evidence from 1 RCT (N=115) showed that there is no statistically significant difference between acupuncture plus standard treatment and sham acupuncture plus standard treatment on pelvic-related functional disability/functional status during pregnancy as assessed by the Oswestry disability index within 1 week after end of treatment in pregnant women with pelvic girdle pain: difference between medians 2, p=0.47.

Important outcomes

Adverse effects during pregnancy

- Low quality evidence from 1 RCT (N=115) showed that there is a clinically important difference favouring sham acupuncture plus standard treatment over acupuncture plus standard treatment on the number of women who experience a de qi sensation in pregnant women with pelvic girdle pain: RR 3.32 (95% CI 2.18 to 5.06).
- Very low quality evidence from 1 RCT (N=115) showed that there is no clinically important difference between acupuncture plus standard treatment and sham acupuncture plus standard treatment on the number of women who experience fainting in pregnant women with pelvic girdle pain: RR 1.23 (95% CI 0.35 to 4.34).
- Very low quality evidence from 1 RCT (N=115) showed that there is no clinically important difference between acupuncture plus standard treatment and sham acupuncture plus standard treatment on the number of women who experience haematoma in pregnant women with pelvic girdle pain: RR 0.98 (95% CI 0.56 to 1.73).
- Very low quality evidence from 1 RCT (N=115) showed that there is no clinically important difference between acupuncture plus standard treatment and sham acupuncture plus standard treatment on the number of women who experience needle pain in pregnant women with pelvic girdle pain: RR 0.91 (95% CI 0.45 to 1.82).
- Very low quality evidence from 1 RCT (N=115) showed that there is no clinically important difference between acupuncture plus standard treatment and sham acupuncture plus standard treatment on the number of women who experience sleepiness in pregnant women with pelvic girdle pain: RR 1.47 (95% CI 0.26 to 8.50).
- Very low quality evidence from 1 RCT (N=115) showed that there is no clinically important difference between acupuncture plus standard treatment and sham acupuncture plus standard treatment on the number of women who experience slight bleeding in pregnant women with pelvic girdle pain: RR 1.01 (95% CI 0.75 to 1.36).

Days off work/sick leave

No evidence was identified to inform this outcome.

Days in hospital admitted to antenatal ward for treatment of pelvic girdle pain

No evidence was identified to inform this outcome.

Women's experience and satisfaction of care

No evidence was identified to inform this outcome.

Admission at birth to the neonatal unit

No evidence was identified to inform this outcome.

Comparison 3. Acupuncture versus physiotherapy-delivered in-home exercise advice

Critical outcomes

Pain intensity during pregnancy

No evidence was identified to inform this outcome.

Pelvic-related functional disability/functional status during pregnancy

No evidence was identified to inform this outcome.

Important outcomes

Adverse effects during pregnancy

- Very low quality evidence from 1 RCT (N=46) showed that there is no clinically important difference between acupuncture and physiotherapy-delivery in-home exercise advice on the number of serious adverse effects during pregnancy in women with pelvic girdle pain: RD 0 (95% CI -0.09 to 0.09).
- Very low quality evidence from 1 RCT (N=46) showed that there is no clinically important difference between acupuncture and physiotherapy-delivered in-home exercise advice on the number of minor adverse effects during pregnancy in women with pelvic girdle pain: RR 0.26 (95% CI 0.06 to 1.19).

Days off work/sick leave

No evidence was identified to inform this outcome.

Days in hospital admitted to antenatal ward for treatment of pelvic girdle pain

No evidence was identified to inform this outcome.

Women's experience and satisfaction

- Very low quality evidence from 1 RCT (N=46) showed that there is no clinically important difference between acupuncture and physiotherapy-delivered in-home exercise advice on the number of pregnant women with pelvic girdle pain who reported that the treatments were good or excellent: RR 1.24 (95% CI 0.96 to 1.6).

Admission at birth to the neonatal unit

- Very low quality evidence from 1 RCT (N=60) showed that there is no clinically important difference between acupuncture and physiotherapy-delivered in-home exercise advice on the number of admissions at birth to the neonatal unit: RD 0 (95% CI -0.09 to 0.09).

Comparison 4. Acupuncture + standard treatment versus physiotherapy-delivered in-home exercise advice + standard treatment

Critical outcomes

Pain intensity during pregnancy

- Low quality evidence from 1 RCT (N=386) showed that there is no statistically significant difference between acupuncture and physiotherapy-delivered in-home exercise on morning pain intensity in the morning as assessed by a visual analogue scale one week after the treatment in pregnant women with pelvic girdle pain: difference between medians 3, p=not significant.
- Low quality evidence from 1 RCT (N=386) showed that there is a statistically significant difference favouring acupuncture over physiotherapy-delivered in-home exercise on evening pain intensity in the evening as assessed by a visual analogue scale one week after the treatment in pregnant women with pelvic girdle pain: difference between medians 14, p=0.01.

Pelvic-related functional disability/functional status during pregnancy

No evidence was identified to inform this outcome.

Important outcomes

Adverse effects during pregnancy

- Moderate quality evidence from 1 RCT (N=256) showed that there is a clinically important difference favouring physiotherapy-delivered in-home exercise over acupuncture on the number of women who experience adverse effects during pregnancy in women with pelvic girdle pain: RR 2.05 (95% CI 1.30 to 3.22).

Days off work/sick leave

No evidence was identified to inform this outcome.

Days in hospital admitted to antenatal ward for treatment of pelvic girdle pain

No evidence was identified to inform this outcome.

Women's experience and satisfaction of care

- Very low quality evidence from 1 RCT (N=219) showed that there is no clinically important difference between acupuncture and physiotherapy-delivered in-home exercise on the number of pregnant women with pelvic girdle pain who report pain relief within one week of treatment: RR 0.41 (95% CI 0.08 to 2.07).
- Moderate quality evidence from 1 RCT (N=219) showed that there is a clinically important difference favouring physiotherapy-delivered in-home exercise over acupuncture on the number of pregnant women with pelvic girdle pain who report that the treatments were harmful within one week of treatment: RR 2.01 (95% CI 1.29 to 3.12).
- Very low quality evidence from 1 RCT (N=219) showed that there is no clinically important difference between acupuncture and physiotherapy-delivered in-home exercise on the number of pregnant women with pelvic girdle pain who reported that the treatment was not helpful within one week of treatment I: RR 2.06 (95% CI 0.38 to 10.99).
- Very low quality evidence from 1 RCT (N=219) showed that there is no clinically important difference between acupuncture and physiotherapy-delivered in-home exercise on the number of pregnant women with pelvic girdle pain who the treatment was of good or very good help within one week of treatment: RR 1.05 (95% CI 0.9 to 1.22).

Admission at birth to the neonatal unit

- Very low quality evidence from 1 RCT (N=256) showed that there is no clinically important difference between acupuncture and physiotherapy-delivered in-home exercise on the number of babies admitted to the neonatal unit at birth: RR 0.70 (95% CI 0.26 to 1.91).

Comparison 5. Manual therapy (chiropractic treatment) versus standard treatment

Critical outcomes

Pain intensity during pregnancy

- Very low quality evidence from 1 RCT (N=56) showed that there is no clinically important difference between chiropractic therapy and standard treatment on pain intensity as assessed by a visual analogue scale between weeks 21 and 30 in pregnant women with pelvic girdle pain: MD -3.70 (95% CI -15.92 to 8.52).
- Very low quality evidence from 1 RCT (N=56) showed that there is no clinically important difference between chiropractic therapy and standard treatment on pain intensity as assessed by a visual analogue scale between weeks 33 and 40 in pregnant women with pelvic girdle pain: MD -3.90 (95% CI -21.81 to 14.01).

Pelvic-related functional disability/functional status during pregnancy

- Very low quality evidence from 1 RCT (N=56) showed that there is no clinically important difference between chiropractic therapy and standard treatment on pelvic-related functional disability/functional status during pregnancy as assessed by the disability rating index in pregnant women with pelvic girdle pain: MD 2.60 (95% CI -6.58 to 11.78).

Important outcomes

Adverse effects during pregnancy

No evidence was identified to inform this outcome.

Days off work/sick leave

- Very low quality evidence from 1 RCT (N=56) showed that there is no clinically important difference between chiropractic therapy and no treatment on number of sick leaves between week 19 and 30 in pregnant women with pelvic girdle pain: RR 0.88 (95% CI 0.37 to 2.09).
- Very low quality evidence from 1 RCT (N=56) showed that there is no clinically important difference between chiropractic therapy and no treatment on number of sick leaves between week 31 and 36 in pregnant women with pelvic girdle pain: RR 0.80 (95% CI 0.37 to 1.72).

Days in hospital admitted to antenatal ward for treatment of pelvic girdle pain

No evidence was identified to inform this outcome.

Women's experience and satisfaction

No evidence was identified to inform this outcome.

Admission at birth to the neonatal unit

No evidence was identified to inform this outcome.

Comparison 6. Manual therapy (craniosacral therapy) + standard treatment versus standard treatment

Critical outcomes

Pain intensity during pregnancy

- Very low quality evidence from 1 RCT (N=123) showed that there is a statistically significant difference favouring craniosacral therapy over standard treatment on pain intensity in the morning as assessed by a visual analogue scale during the treatment in pregnant women with pelvic girdle pain: difference between medians 8, p=0.02.
- Very low quality evidence from 1 RCT (N=123) showed that there is no statistically significant difference between craniosacral therapy and standard treatment on pain intensity in the evening as assessed by a visual analogue scale during the treatment in pregnant women with pelvic girdle pain: difference between medians 8, p=0.08.
- Very low quality evidence from 1 RCT (N=123) showed that there is no statistically significant difference between craniosacral therapy and standard treatment on pain discomfort within one week after end of treatment in pregnant women with pelvic girdle pain: difference between medians 0.5, p= 0.43.

Pelvic-related functional disability/functional status during pregnancy

- Very low quality evidence from 1 RCT (N=123) showed that there is no statistically significant difference between craniosacral therapy and standard treatment on pelvic-

related functional disability/functional status during pregnancy as assessed by the disability rating index within one week after end of treatment in pregnant women with pelvic girdle pain: difference between medians 3.5, p=0.30.

- Very low quality evidence from 1 RCT (N=123) showed that there is a statistically significant difference favouring craniosacral therapy over standard treatment on pelvic-related functional disability/functional status during pregnancy as assessed by the Oswestry disability index within one week after end of treatment in pregnant women with pelvic girdle pain: difference between medians 8, p=0.02.

Important outcomes

Adverse effects during pregnancy

No evidence was identified to inform this outcome.

Days off work/sick leave

- Very low quality evidence from 1 RCT (N=123) showed that there is no clinically important difference between craniosacral therapy and standard treatment on number of pregnant women with pelvic girdle pain who take sick leave: RR 1.43 (95% CI 0.70 to 2.93).

Days in hospital admitted to antenatal ward for treatment of pelvic girdle pain

No evidence was identified to inform this outcome.

Women's experience and satisfaction

No evidence was identified to inform this outcome.

Admission at birth to the neonatal unit

No evidence was identified to inform this outcome.

Comparison 7. Manual therapy (foot manipulation) + physiotherapy-delivered in-home exercise advice versus sham manual therapy (sham foot manipulation) + physiotherapy-delivered in-home exercises

Critical outcomes

Pain intensity during pregnancy

- Low quality evidence from 1 RCT (N=97) showed that there is no clinically important difference favouring foot manipulation over sham foot manipulation on morning pain intensity in the pelvic region as assessed by a visual analogue scale after 6 weeks of treatment in pregnant women with pelvic girdle pain: MD -9.00 (95% CI -19.78 to 1.78).
- Low quality evidence from 1 RCT (N=97) showed that there is a clinically important difference favouring foot manipulation over sham foot manipulation on evening pain intensity in the pelvic region as assessed by a visual analogue scale after 6 weeks of treatment in pregnant women with pelvic girdle pain: MD -18.00 (95% CI -29.97 to -6.03).
- Low quality evidence from 1 RCT (N=97) showed that there is no clinically important difference between foot manipulation and sham foot manipulation on pain intensity in the symphysis as assessed by a visual analogue scale after 6 weeks of treatment in pregnant women with pelvic girdle pain: MD -3.00 (95% CI -11.54 to 5.54).

Pelvic-related functional disability/functional status during pregnancy

No evidence was identified to inform this outcome.

Important outcomes
Adverse effects during pregnancy

No evidence was identified to inform this outcome.

Days off work/sick leave

No evidence was identified to inform this outcome.

Days in hospital admitted to antenatal ward for treatment of pelvic girdle pain

No evidence was identified to inform this outcome.

Women's experience and satisfaction

No evidence was identified to inform this outcome.

Admission at birth to the neonatal unit

No evidence was identified to inform this outcome.

Comparison 8. Pelvic girdle support belt + information versus information

Critical outcomes
Pain intensity during pregnancy

- Low quality evidence from 1 RCT (N=105) showed that there is a clinically important difference favouring non-rigid pelvic girdle support belt and information over information only on pain intensity after 6 weeks of treatment as assessed by a visual analogue scale in pregnant women with pelvic girdle pain: MD -34.20 (95% CI -41.62 to -26.78).

Pelvic-related functional disability/functional status during pregnancy

- Very low quality evidence from 1 RCT (N=105) showed that there is no clinically important difference between non-rigid pelvic girdle support belt and information and information only on Pelvic-related functional disability/functional status during pregnancy after 6 weeks of treatment as assessed by the Oswestry disability index in pregnant women with pelvic girdle pain: MD -5.60 (95% CI -9.86 to -1.34).

Important outcomes
Adverse effects during pregnancy

No evidence was identified to inform this outcome.

Days off work/sick leave

No evidence was identified to inform this outcome.

Days in hospital admitted to antenatal ward for treatment of pelvic girdle pain

No evidence was identified to inform this outcome.

Women's experience and satisfaction

No evidence was identified to inform this outcome.

Admission at birth to the neonatal unit

No evidence was identified to inform this outcome.

Comparison 9. Pelvic girdle support belt + information versus physiotherapy-delivered in-home exercise advice + information

Critical outcomes

Pain intensity during pregnancy

- Low quality evidence from 1 RCT (N=105) showed that there is a clinically important difference favouring non-rigid pelvic girdle support belt plus information over physiotherapy-delivered in-home exercise advice plus information on pain intensity after 6 weeks of treatment as assessed by a visual analogue scale in pregnant women with pelvic girdle pain: MD -20.10 (95% CI -28.29 to -11.91).

Pelvic-related functional disability

- Low quality evidence from 1 RCT (N=105) showed that there is no clinically important difference between non-rigid pelvic girdle support belt plus information and physiotherapy-delivered in-home exercise advice plus information on pelvic-related functional disability after 6 weeks of treatment as assessed by the Oswestry disability index in pregnant women with pelvic girdle pain in pregnant women with pelvic girdle pain: MD -1.40 (95% CI -5.13 to 2.33).

Important outcomes

Adverse effects during pregnancy

No evidence was identified to inform this outcome.

Days off work/sick leave

No evidence was identified to inform this outcome.

Days in hospital admitted to antenatal ward for treatment of pelvic girdle pain

No evidence was identified to inform this outcome.

Women's experience and satisfaction

No evidence was identified to inform this outcome.

Admission at birth to the neonatal unit

No evidence was identified to inform this outcome.

Comparison 10. Physiotherapy-delivered in-home exercise advice versus standard treatment

Critical outcomes

Pain intensity during pregnancy

- Very low quality evidence from 1 RCT (N=171) showed that there is a clinically important difference favouring physiotherapy-delivered in-home advice over standard treatment on pain intensity after 12 weeks of treatment as assessed by a visual analogue scale in pregnant women with pelvic girdle pain: MD -2.07 (95% CI -2.90 to -1.24).

Pelvic-related functional disability/functional status during pregnancy

- Very low quality evidence from 1 RCT (N=171) showed that there is a clinically important difference favouring physiotherapy-delivered in-home advice over standard treatment on pelvic-related functional disability/functional status during pregnancy after 12 weeks of treatment as assessed by the Oswestry disability rating index in pregnant women with pelvic girdle pain: MD -9.94 (95% CI -14.71 to -5.17).

Important outcomes

Adverse effects during pregnancy

No evidence was identified to inform this outcome.

Days off work/sick leave

No evidence was identified to inform this outcome.

Days in hospital admitted to antenatal ward for treatment of pelvic girdle pain

No evidence was identified to inform this outcome.

Women's experience and satisfaction

No evidence was identified to inform this outcome.

Admission at birth to the neonatal unit

No evidence was identified to inform this outcome.

Comparison 11. Physiotherapy-delivered in-home exercise advice + standard treatment versus standard treatment

Critical outcomes

Pain intensity during pregnancy

- Low quality evidence from 1 RCT (N=386) showed that there is a statistically significant difference favouring physiotherapy-delivered in-home exercise advice plus standard treatment over standard treatment only on pain intensity in the morning as assessed by a visual analogue scale one week after the treatment in pregnant women with pelvic girdle pain: difference between medians 9, p=0.03.
- Low quality evidence from 1 RCT (N=386) showed that there is a statistically significant difference favouring physiotherapy-delivered in-home exercise advice plus standard treatment over standard treatment only on pain intensity in the evening as assessed by a visual analogue scale one week after the treatment in pregnant women with pelvic girdle pain: difference between medians 13, p=0.02.

Pelvic-related functional disability/functional status during pregnancy

No evidence was identified to inform this outcome.

Important outcomes

Adverse effects during pregnancy

- Moderate quality evidence from 1 RCT (N=261) showed that there is a clinically important difference favouring standard treatment over physiotherapy-delivered in-home exercise advice plus standard treatment on the number of women who experience adverse effects during pregnancy in pregnant women with pelvic girdle pain: RR 2.73 (95% CI 1.26 to 5.91).

Days off work/sick leave

No evidence was identified to inform this outcome.

Days in hospital admitted to antenatal ward for treatment of pelvic girdle pain

No evidence was identified to inform this outcome.

Women's experience and satisfaction of care

- Very low quality evidence from 1 RCT (N=211) showed that there is no clinically important difference between physiotherapy-delivered in-home exercise advice plus standard treatment and standard treatment only on the number of pregnant women with pelvic girdle pain who reported no pain relief within one week of treatment: RR 1.5 (95% CI 0.37 to 6.12).
- Moderate quality evidence from 1 RCT (N=211) showed that there is a clinically important difference favouring physiotherapy-delivered in-home exercise advice plus standard treatment over standard treatment only on the number of pregnant women with pelvic girdle pain who reported that the treatments were harmful within one week of treatment: RR 0.39 (95% CI 0.26 to 0.59).
- Moderate quality evidence from 1 RCT (N=211) showed that there is a clinically important difference favouring physiotherapy-delivered in-home exercise advice plus standard treatment over standard treatment only on the number of pregnant women with pelvic girdle pain who reported that the treatment was not helpful within one week of treatment: RR 0.07 (95% CI 0.02 to 0.3).
- Moderate quality evidence from 1 RCT (N=211) showed that there is a clinically important difference favouring physiotherapy-delivered in-home exercise advice plus standard treatment over standard treatment only on the number of pregnant women with pelvic girdle pain who reported the treatment was of good or very good help within one week of treatment: RR 3.32 (95% CI 2.25 to 4.88).

Admission at birth to the neonatal unit

- Very low quality evidence from 1 RCT (N=259) showed that there is no clinically important difference between physiotherapy-delivered in-home exercise advice plus standard treatment and standard treatment only on the number of babies admitted at birth to the neonatal unit: RR 1.49 (95% CI 0.55 to 4.06).

Comparison 12. Physiotherapy-delivered in-home exercise advice + information versus information

Critical outcomes

Pain intensity during pregnancy

- Very low quality evidence from 1 RCT (N=105) showed that there is a clinically important difference favouring physiotherapy-delivered in-home exercise advice plus information over information only on pain intensity after 6 weeks of treatment as assessed by a visual analogue scale in pregnant women with pelvic girdle pain: MD -14.10 (95% CI -22.14 to -6.06).

Pelvic-related functional disability/functional status during pregnancy

- Very low quality evidence from 1 RCT (N=105) showed that there is no clinically important difference between physiotherapy-delivered in-home exercise advice plus information and information only on pelvic-related functional disability/functional status during pregnancy after 6 weeks of treatment as assessed by the Oswestry disability index in pregnant women with pelvic girdle pain: MD -4.20 (95% CI -8.55 to 0.15).

Important outcomes

Adverse effects during pregnancy

No evidence was identified to inform this outcome.

Days off work/sick leave

No evidence was identified to inform this outcome.

Days in hospital admitted to antenatal ward for treatment of pelvic girdle pain

No evidence was identified to inform this outcome.

Women's experience and satisfaction

No evidence was identified to inform this outcome.

Admission at birth to the neonatal unit

No evidence was identified to inform this outcome.

Comparison 13. Physiotherapy-delivered in-home exercise advice + information + pelvic girdle support belt versus information + pelvic girdle support belt

Critical outcomes

Pain intensity during pregnancy

- Low quality evidence from 1 RCT (N=118) reported that there was no group effect at gestation week 38 on pain intensity during pregnancy between physiotherapy-delivered in-home exercise advice or in-clinic exercise advice combined with information and pelvic girdle support belt and information and pelvic girdle support belt only, in pregnant women with pelvic girdle pain as assessed by a visual analogue scale: difference between medians 1, p=not reported.

Pelvic-related functional disability/functional status during pregnancy

- Low quality evidence from 1 RCT (N=118) reported that there was no group effect at gestation week 38 on pelvic-related functional disability/functional status during pregnancy between physiotherapy-delivered in-home or in-clinic exercise advice combined with information and pelvic girdle support belt, and information and pelvic girdle support belt

only in pregnant women with pelvic girdle pain as assessed by the disability rating index: difference between medians 1, p=not reported.

Important outcomes

Adverse effects during pregnancy

No evidence was identified to inform this outcome.

Days off work/sick leave

No evidence was identified to inform this outcome.

Days in hospital admitted to antenatal ward for treatment of pelvic girdle pain

No evidence was identified to inform this outcome.

Women's experience and satisfaction

No evidence was identified to inform this outcome.

Admission at birth to the neonatal unit

No evidence was identified to inform this outcome.

Comparison 14. Physiotherapy-delivered in-home exercise advice, + information + pelvic girdle support belt versus physiotherapy-delivered in-clinic exercise + information + pelvic girdle support belt

Critical outcomes

Pain intensity during pregnancy

- Low quality evidence from 1 RCT (N=118) reported that there was no group effect at gestation week 38 on pain intensity during pregnancy as assessed by a visual analogue scale between physiotherapy-delivered in-home or in-clinic exercise advice combined with information and pelvic girdle support belt and information and pelvic girdle support belt only in pregnant women with pelvic girdle pain: difference between medians 12, p=not reported.

Pelvic-related functional disability/functional status during pregnancy

- Low quality evidence from 1 RCT (N=118) reported that there was no group effect at gestation week 38 on pelvic-related functional disability/functional status during pregnancy as assessed by the disability rating index between physiotherapy-delivered in-home or in-clinic exercise advice combined with information and pelvic girdle support belt and information and pelvic girdle support belt only in pregnant women with pelvic girdle pain: difference between medians 7, p=not reported.

Important outcomes

Adverse effects during pregnancy

No evidence was identified to inform this outcome.

Days off work/sick leave

No evidence was identified to inform this outcome.

Days in hospital admitted to antenatal ward for treatment of pelvic girdle pain

No evidence was identified to inform this outcome.

Women's experience and satisfaction

No evidence was identified to inform this outcome.

Admission at birth to the neonatal unit

No evidence was identified to inform this outcome.

Comparison 15. Physiotherapy-delivered in-clinic exercise advice + information + pelvic girdle support belt versus information + pelvic girdle support

Critical outcomes

Pain intensity during pregnancy

- Low quality evidence from 1 RCT (N=118) reported that there was no group effect at gestation week 38 on pain intensity during pregnancy as assessed by a visual analogue scale between physiotherapy-delivered in-home or in-clinic exercise advice combined with pelvic girdle support belt, and information and pelvic girdle support belt only in pregnant women with pelvic girdle pain: difference between medians 13, p=not reported.

Pelvic-related functional disability/functional status during pregnancy

- Low quality evidence from 1 RCT (N=118) reported that there was no group effect at gestation week 38 on pelvic-related functional disability/functional status during pregnancy as assessed by the disability rating index between physiotherapy-delivered in-home or in-clinic exercise advice combined with information and pelvic girdle support belt, and information and pelvic girdle support belt only in pregnant women with pelvic girdle pain: difference between medians 6, p=not reported.

Important outcomes

Adverse effects during pregnancy

No evidence was identified to inform this outcome.

Days off work/sick leave

No evidence was identified to inform this outcome.

Days in hospital admitted to antenatal ward for treatment of pelvic girdle pain

No evidence was identified to inform this outcome.

Women's experience and satisfaction

No evidence was identified to inform this outcome.

Admission at birth to the neonatal unit

No evidence was identified to inform this outcome.

Economic evidence statements

Evidence from the guideline economic analysis suggested that use of a non-rigid lumbopelvic support belt may be a cost effective option when compared with either information only, or exercise. The economic analysis is directly applicable to the NICE decision-making context.

The committee's discussion of the evidence

Interpreting the evidence

The outcomes that matter most

The committee agreed that pain intensity during pregnancy and pelvic-related functional disability/functional status during pregnancy were critical as these demonstrate effectiveness of the interventions. The following were considered to be important outcomes: adverse effects during pregnancy, days off work/sick leave, days in hospital admitted to antenatal ward for treatment of pelvic girdle pain, women's experience and satisfaction of care, and admission of baby at birth to the neonatal unit.

The quality of the evidence

The quality of the evidence ranged from very low to high, with most of the evidence being of very low quality. This was predominately due to serious overall risk of bias in some outcomes; imprecision around the effect estimate in many outcomes; and indirectness in a few outcomes.

Reasons for serious risk of bias was due to concerns around randomisation as little information was provided around the process of randomisation and allocation concealment in a few outcomes. Other reasons for serious risk of bias included deviations from intended interventions due to not blinding participants in some outcomes, and high missing outcome data for a few outcomes. Some outcomes were also downgraded for risk of bias as they are subjective.

Some outcomes were downgraded for indirectness as there were some studies where a high percentage of the women had pain in regions other than the pelvic girdle.

There was no evidence identified for the use of analgesics or the use of ice or heat packs to treat pelvic girdle pain. No evidence was identified for the outcome days in hospital admitted to antenatal ward for pelvic girdle pain.

Benefits and harms

Referral to physiotherapy

Several studies compared physiotherapy-delivered exercise advice – that is, advice provided by a physiotherapist to perform specific exercises - with other interventions or combinations thereof. Although there was insufficient data to permit meta-analysis for any of the outcomes of interest and some evidence to suggest that there is an increased risk of experiencing adverse events (typically mild and related to the back pain itself) compared to standard treatment, the results suggest that engaging in physiotherapy-recommended exercise may ameliorate intensity of pelvic girdle pain and pelvic-related functional disability compared to standard treatment alone.

The committee discussed the evidence which they agreed was consistent overall with a benefit of physiotherapy-delivered exercise advice in women with pelvic girdle pain. However they noted the limited quality of the evidence and the fact that some outcomes, for example pelvic-related functional disability, were not universally improved by exercise advice and agreed that on this basis the recommendation should be weak ('consider').

Non-rigid pelvic girdle support belt

The committee also discussed the evidence which showed that a non-rigid lumbopelvic belt reduced pain intensity in women with pelvic girdle pain. One RCT of pregnant women with pelvic girdle pain compared non-rigid pelvic girdle support belt and information for 6 weeks, to physiotherapy-delivered in-home exercise advice and information, and information (concerning anatomy, body posture, and ergonomic advice about sitting, walking and lying down) only. This trial showed that there is a clinically important difference favouring a non-rigid pelvic girdle support belt and information over either physiotherapy-delivered in-home exercise advice and information or information only on the outcome of pain intensity during pregnancy. Although the same trial showed no clinically important difference between wearing a non-rigid pelvic girdle support belt and receiving either physiotherapy-delivered in-home exercise advice and information, or information only on the outcome of pelvic-related functional disability/functional status during pregnancy.

The committee used the evidence together with the economic model (see details in appendix J) to make a recommendation for referral to physiotherapy services for a non-rigid lumbopelvic belt. The committee discussed the economic evidence that supports a non-rigid lumbopelvic belt, but agreed not to make a strong recommendation. They highlighted some of the limitations of the study used to inform the economic analysis, such as a small sample size and the differences in the context of the study to the UK. They also discussed the implications of a strong recommendation on current practice. Current wait times for physiotherapy services on the NHS are long, and a strong recommendation may have a negative impact on wait times for all physiotherapy services. The committee discussed that not making a strong recommendation may mean women will purchase a non-rigid lumbopelvic belt without consulting physiotherapy services. They discussed whether there was potential for harm if women do not receive appropriate advice on how to wear a belt, however on balance the committee felt that risk was small.

The committee specified that referral for exercise advice or a belt should be to physiotherapy services rather than a physiotherapist, as neither of these interventions necessarily have to be delivered in person and can be, for example, via a telephone consultation.

Other interventions

Three RCTs on traditional body acupuncture or ear and body acupuncture, and 3 RCTs each examining a type of manual therapy, were identified. However, there was insufficient data to permit meta-analysis for any of the outcomes of interest for any comparison.

Acupuncture

The committee discussed the evidence on acupuncture that showed some improvements on pain intensity, and on women's experience and satisfaction. They agreed that the resources needed to implement a recommendation for acupuncture in the NHS are not currently adequate (for example, there may not be enough trained practitioners) and that it is therefore likely that such a recommendation would entail a substantial cost.. The committee felt that because the evidence was mixed regarding the benefits and harms of acupuncture, and the quality of the evidence was poor, they could not justify a recommendation that would have a substantial resource impact.

Manual therapy

The evidence on manual therapy for the treatment of pelvic girdle pain during pregnancy was sparse, with only 3 studies identified, and on disparate interventions. The committee discussed the importance of only 1 of these studies having investigated the effects of manual therapy alone, and not in combination with any other intervention. The evidence for this study showed that there were no important benefits on the outcomes of interest. Therefore, the committee agreed that there was insufficient evidence to show that manual therapy alone

had any important benefits on the outcomes of interest, and agreed not to make a recommendation. They discussed the 2 other studies which showed some benefit of manual therapy, however they highlighted that manual therapy was delivered in combination with physiotherapy delivered advice. The committee felt that although they were not able to make a judgement on the benefits and harms of manual therapy, they had considered the benefits of physiotherapy delivered advice from other available evidence and felt the recommendation they had agreed for this intervention was sufficient, and better supported with other evidence.

Cost effectiveness and resource use

The committee noted that no relevant published economic evaluations had been identified for this topic. They also deemed that the evidence presented in the clinical review was not of sufficient quality to allow for recommendations on acupuncture or manual therapy. These treatments are not routinely offered by the NHS, and the committee acknowledged there would be a significant resource impact were they to make such recommendations.

The committee also acknowledged the potential resource implications from recommending that women be offered a non-rigid lumbobelvic support. Given the relatively high proportion of women who experience mild to moderate pelvic girdle pain, the committee were mindful of that a recommendation could entail a significant national resource impact, despite the likelihood of the unit cost of a belt being relatively minimal in comparison to other interventions. An economic analysis developed for this guideline suggested that offering women use of a non-rigid lumbopelvic support belt was a cost effective option from an NHS perspective.

The recommendation to refer to physiotherapy services partly reflect current practice, though the committee acknowledged there is a significant degree of regional variation and take up in practice. Hence, an increase in resources may be required to provide services where they are not routinely available.

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Appendices

Appendix A – Review protocols

Review protocol for review question: What interventions are effective in treating mild to moderate pelvic girdle pain during pregnancy?

Table 3: Review protocol

Field (based on PRISMA-P)	Content
Review question	What interventions are effective in treating mild to moderate pelvic girdle pain during pregnancy? Note: the safety of pharmacological interventions to treat pelvic girdle pain during pregnancy will not be covered in this review. For information on the safety of any pharmacological interventions, please consult the BNF/MHRA.
Type of review question	Intervention
Objective of the review	The aim of this review is to evaluate the pregnancy outcomes of different treatment interventions for mild to moderate pelvic girdle pain during pregnancy and to establish whether there are harms to the women or baby associated with them. Women with severe pain may require specialist interventions initiated by physiotherapists.
Eligibility criteria – population	Pregnant women with mild to moderate pelvic girdle pain (also known as 'symphysis pubis dysfunction')
Eligibility criteria – intervention(s)	• Acupuncture/Acupressure exercises • Analgesics Note: Only opiates and paracetamol will be considered • Ice packs and heat packs • Manual therapy • Pelvic girdle support • Physiotherapy-delivered advice (such as exercise-related, use of support belts) • Pillow • Reflexology Note: Group or individual interventions will be analysed separately.

Field (based on PRISMA-P)	Content
Eligibility criteria – comparator(s)	• Any other intervention listed above • No treatment The following comparisons will be considered: 1. Any listed intervention vs sham treatment (such as sham acupuncture) or no treatment 2. Any listed intervention vs any other listed intervention
Outcomes and prioritisation	**Critical** • Pain intensity (pain levels) during pregnancy Note: pain intensity during labour or birth will not be considered. • Pelvic-related functional disability/functional status during pregnancy (such as ability to perform daily activities) **Important** • Adverse effects during pregnancy • Days off work/sick leave (during pregnancy or prior to maternity leave) • Days in hospital admitted to antenatal ward for treatment of pelvic girdle pain (exclude admission for labour or early labour) • Women's experience and satisfaction of care • Admission at birth to the neonatal unit
Eligibility criteria – study design	INCLUDE: • Systematic reviews • Randomised or quasi-randomised controlled trials (individual or cluster) If no evidence of these types is found for a listed class of intervention, the following types of non-randomised studies in order of priority will be considered: • Non-randomised controlled trials • Prospective cohort studies • Retrospective cohort studies Note: For further details, see the algorithm in appendix H, Developing NICE guidelines: the manual.
Other inclusion exclusion criteria	**Exclusion** POPULATION: • Multiple pregnancy • Pregnancy with known or pre-existing congenital anomalies STUDY DESIGN: • Case-control studies • Cross-over studies • Cross-sectional studies • Epidemiological reviews or reviews on associations

Field (based on PRISMA-P)	Content
	• Non-comparative studies PUBLICATION STATUS: • Conference abstract LANGUAGE: • Non-English **Inclusion** COUNTRY: • No restriction
Proposed sensitivity/sub-group analysis, or meta-regression	Subgroup analysis according to World Bank status (High-income countries; Low and middle-income countries) will be conducted (see https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups for classification of countries**)**. Note that the use of the World Bank definitions of low-, middle- and high-income countries in this guideline is consistent with its use in the Postnatal care up to 8 weeks after birth (update) NICE guideline CG37. In the presence of heterogeneity, the following subgroup analyses will be conducted: • Trimester of presentation • Group vs. individual therapy • Parity status (Nulliparous; primiparous; multiparous) These subgroup factors will be used as confounding factors to assess risk of bias of any included cohort studies using the relevant checklist. Other confounding factors that will be considered in the risk of bias evaluation when including cohort studies are: • BMI or body weight of woman • Multiple pregnancy Statistical heterogeneity will be assessed by visually examining the forest plots and by calculating the I^2 inconsistency statistic (with an I^2 value≥50% indicating serious heterogeneity, and ≥80% indicating very serious heterogeneity).
Selection process – duplicate screening/selection/analysis	Studies included in the 2008 NICE guideline on antenatal care for uncomplicated pregnancies (CG62) that satisfy the review protocol will be included in this review. Review questions selected as high priorities for health economic analysis (and those selected as medium priorities and where health economic analysis could influence recommendations) will be subject to dual weeding and study selection; any discrepancies above 10% of the dual weeded resources will be resolved through discussion between the first and second reviewers or by reference to a third person. All data extraction will quality assured by a senior reviewer. Draft excluded studies and evidence tables will be circulated to the Topic Group for their comments. Resolution of disputes will be by discussion between the senior reviewer, Topic Advisor and Chair.
Data management (software)	NGA STAR software will be used for generating bibliographies/citations, study sifting and data extraction. Pairwise meta-analyses, if possible, will be performed using Cochrane Review Manager (RevMan5). For details please see the methods chapter of the full guideline. 'GRADEpro' will be used to assess the quality of evidence for each outcome.

Field (based on PRISMA-P)	Content
Information sources – databases and dates	Sources to be searched: Medline, Medline In-Process, CCTR, CDSR, DARE, HTA, Embase Limits (date, study design): • Date limit: 2006 (date of last search for 2008 NICE guideline on antenatal care for uncomplicated pregnancies (CG62)) • Apply standard animal/non-English language exclusion • Limit to RCTs and systematic reviews in first instance but download all results.
Identify if an update	This antenatal care update will replace the 2008 NICE guideline on antenatal care for uncomplicated pregnancies (CG62), which will be taken down in due course. The following research recommendation in the 2008 NICE guideline on antenatal care for uncomplicated pregnancies (CG62) on symphysis pubis dysfunction was made: • More research on effective treatments for symphysis pubis dysfunction is needed.
Author contacts	Developer: National Guideline Alliance.
Highlight if amendment to previous protocol	For details please see section 4.5 of Developing NICE guidelines: the manual.
Search strategy – for one database	For details please see appendix B.
Data collection process – forms/duplicate	A standardised evidence table format will be used, and published as appendix G (clinical evidence tables) or D (economic evidence tables).
Data items – define all variables to be collected	For details please see evidence tables in appendix G (clinical evidence tables) or D (economic evidence tables).
Methods for assessing bias at outcome/study level	Quality assessment of individual studies will be performed using the following checklists: • ROBIS tool for systematic reviews • Cochrane RoB tool v.2 for RCTs ROBINS-I for non-randomised (clinical) controlled trials and cohort studies. For details please see section 6.2 of Developing NICE guidelines: the manual. The risk of bias across all available evidence will be evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group: http://www.gradeworkinggroup.org/
Criteria for quantitative synthesis (where suitable)	For details please see section 6.4 of Developing NICE guidelines: the manual.
Methods for analysis – combining studies and exploring (in)consistency	For details please see Supplement 1: methods.

Field (based on PRISMA-P)	Content
Meta-bias assessment – publication bias, selective reporting bias	For details please see the methods chapter of the full guideline and section 6.2 of Developing NICE guidelines: the manual. If sufficient relevant RCT evidence is available, publication bias will be explored using RevMan software to examine funnel plots. Trial registries will be examined to identify missing evidence: Clinical trials.gov, NIHR Clinical Trials Gateway.
Assessment of confidence in cumulative evidence	For details please see sections 6.4 and 9.1 of Developing NICE guidelines: the manual.
Rationale/context – Current management	For details please see the introduction to the evidence review in the full guideline.
Describe contributions of authors and guarantor	A multidisciplinary committee developed the guideline. The committee was convened by the National Guideline Alliance and chaired by Kate Harding in line with section 3 of Developing NICE guidelines: the manual. Staff from the National Guideline Alliance undertook systematic literature searches, appraised the evidence, conducted meta-analysis and cost-effectiveness analysis where appropriate, and drafted the guideline in collaboration with the committee. For details please see the methods chapter of the full guideline.
Sources of funding/support	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists.
Name of sponsor	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists.
Roles of sponsor	NICE funds the National Guideline Alliance to develop guidelines for those working in the NHS, public health, and social care in England.
PROSPERO registration number	This protocol is not registered with PROSPERO.

BNF: British National Formulary; CCTR: Cochrane Controlled Trials Register; CDSR: Cochrane Database of Systematic Reviews; DARE: Database of Abstracts of Reviews of Effects; GRADE: Grading of Recommendations Assessment, Development and Evaluation; HTA: Health Technology Assessment; MHRA: Medicines and Healthcare products Regulatory Agency; NGA: National Guideline Alliance; NICE: National Institute for Health and Care Excellence; NIHR: National Institute for Health Research; RCT(s): randomised controlled trial(s); RoB: risk of bias; ROBIS: Risk Of Bias In Systematic reviews tool; ROBINS-I: Risk Of Bias In Non-randomized studies – of Interventions tool.

Appendix B – Literature search strategies

Literature search strategies for review question: What interventions are effective in treating mild to moderate pelvic girdle pain during pregnancy?

Database(s): Medline & Embase (Multifile)
Last searched on **Embase Classic+Embase** 1947 to 2020 September 08, **Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily** 1946 to September 08, 2020
Date of last search: 9th September 2020
Multifile database codes: emczd = Embase Classic+Embase; ppez= MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily

#	Searches
1	Pregnancy/ use ppez
2	Pregnant Women/ use ppez
3	pregnancy/ use emczd
4	pregnant woman/ use emczd
5	pregnan$.tw,kw.
6	1 or 2 or 3 or 4 or 5
7	Pelvic Girdle Pain/ use ppez
8	Pelvic Pain/ use ppez
9	pelvic girdle pain/ use emczd
10	pelvic pain/ use emczd
11	pelvis pain syndrome/ use emczd
12	Back Pain/ use ppez
13	Low Back Pain/ use ppez
14	backache/ use emczd
15	low back pain/ use emczd
16	((pelvi$ or lumbopelvi$ or lumbo-pelvi$ or girdle$) adj3 pain$).tw.
17	(pubi$ adj3 (pain$ or dysfunction$)).tw.
18	((pelvi$ or lumbopelvi$ or lumbo-pelvi$ or girdle$) adj3 relax$).tw.
19	osteitis pubis.tw.
20	(back adj pain$).tw.
21	(backache$ or backpain$).tw.
22	((musculoskeletal$ or musculo-skeletal$) adj (pain$ or dysfunction$)).tw.
23	7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22
24	6 and 23
25	limit 24 to english language
26	limit 25 to yr="2006 -Current"
27	(controlled clinical trial or pragmatic clinical trial or randomized controlled trial).pt. or drug therapy.fs. or (groups or placebo or randomi#ed or randomly or trial).ab.
28	crossover procedure/ or double blind procedure/ or randomized controlled trial/ or single blind procedure/ or (assign* or allocat* or crossover* or cross over* or ((doubl* or singl*) adj blind*) or factorial* or placebo* or random* or volunteer*).ti,ab.
29	meta-analysis/
30	meta-analysis as topic/
31	systematic review/
32	meta-analysis/
33	(meta analy* or metanaly* or metaanaly*).ti,ab.
34	((systematic or evidence) adj2 (review* or overview*)).ti,ab.
35	((systematic* or evidence*) adj2 (review* or overview*)).ti,ab.
36	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
37	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
38	(search* adj4 literature).ab.
39	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
40	cochrane.jw.
41	((pool* or combined) adj2 (data or trials or studies or results)).ab.
42	letter/
43	editorial/
44	news/
45	exp historical article/
46	Anecdotes as Topic/
47	comment/
48	case report/
49	(letter or comment*).ti.

#	Searches
50	42 or 43 or 44 or 45 or 46 or 47 or 48 or 49
51	randomized controlled trial/ or random*.ti,ab.
52	50 not 51
53	animals/ not humans/
54	exp Animals, Laboratory/
55	exp Animal Experimentation/
56	exp Models, Animal/
57	exp Rodentia/
58	(rat or rats or mouse or mice).ti.
59	52 or 53 or 54 or 55 or 56 or 57 or 58
60	letter.pt. or letter/
61	note.pt.
62	editorial.pt.
63	case report/ or case study/
64	(letter or comment*).ti.
65	60 or 61 or 62 or 63 or 64
66	randomized controlled trial/ or random*.ti,ab.
67	65 not 66
68	animal/ not human/
69	nonhuman/
70	exp Animal Experiment/
71	exp Experimental Animal/
72	animal model/
73	exp Rodent/
74	(rat or rats or mouse or mice).ti.
75	67 or 68 or 69 or 70 or 71 or 72 or 73 or 74
76	59 use ppez
77	75 use emczd
78	76 or 77
79	27 use ppez
80	28 use emczd
81	79 or 80
82	(or/29-30,33,35-40) use ppez
83	(or/31-34,36-41) use emczd
84	82 or 83
85	26 and 78
86	26 not 85
87	81 or 84
88	86 and 87 [RCT/SR data]
89	86 not 88 [Non-RCT/SR data]

Database(s): Cochrane Library
Last searched on **Cochrane Database of Systematic Reviews**, Issue 9 of 12, September 2020, **Cochrane Central Register of Controlled Trials**, Issue 9 of 12, September 2020
Date of last search: 9th September 2020

#	Searches
#1	MeSH descriptor: [Pregnancy] this term only
#2	MeSH descriptor: [Pregnant Women] this term only
#3	(pregnan*):ti,ab,kw
#4	#1 OR #2 OR #3
#5	MeSH descriptor: [Pelvic Girdle Pain] this term only
#6	MeSH descriptor: [Pelvic Pain] this term only
#7	MeSH descriptor: [Back Pain] this term only
#8	MeSH descriptor: [Low Back Pain] this term only
#9	((pelvi* or lumbopelvi* or lumbo-pelvi* or girdle*) NEAR/3 pain*):ti,ab,kw
#10	(pubi* NEAR/3 (pain* or dysfunction*)):ti,ab,kw
#11	((pelvi* or lumbopelvi* or lumbo-pelvi* or girdle*) NEAR/3 relax*):ti,ab,kw
#12	osteitis pubis:ti,ab,kw
#13	(back NEXT pain*):ti,ab,kw
#14	(backache* or backpain*):ti,ab,kw
#15	((musculoskeletal* or musculo-skeletal*) NEXT (pain* or dysfunction*)):ti,ab,kw
#16	#5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15
#17	#4 AND #16 Publication Year from 2006 to current

Database(s): CRD: Database of Abstracts of Reviews of Effects (DARE), HTA Database
Date of last search: 9th September 2020

#	Searches
1	MeSH DESCRIPTOR Pregnancy EXPLODE ALL TREES IN DARE,HTA
2	MeSH DESCRIPTOR Pregnant Women EXPLODE ALL TREES IN DARE,HTA
3	(pregnan*) IN DARE, HTA
4	#1 OR #2 OR #3
5	MeSH DESCRIPTOR Pelvic Girdle Pain EXPLODE ALL TREES IN DARE,HTA
6	MeSH DESCRIPTOR Pelvic Pain EXPLODE ALL TREES IN DARE,HTA
7	MeSH DESCRIPTOR Back Pain EXPLODE ALL TREES IN DARE,HTA
8	MeSH DESCRIPTOR Low Back Pain EXPLODE ALL TREES IN DARE,HTA
9	(((pelvi* or lumbopelvi* or lumbo-pelvi* or girdle*) NEAR pain*)) IN DARE, HTA
10	((pubi* NEAR (pain* or dysfunction*))) IN DARE, HTA
11	(((pelvi* or lumbopelvi* or lumbo-pelvi* or girdle*) NEAR relax*)) IN DARE, HTA
12	(osteitis pubis) IN DARE, HTA
13	((back pain*)) IN DARE, HTA
14	((backache* or backpain*)) IN DARE, HTA
15	(((musculoskeletal* or musculo-skeletal*) NEAR (pain* or dysfunction*))) IN DARE, HTA
16	#5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15
17	#4 AND #16 Publication Year from 2006 to current

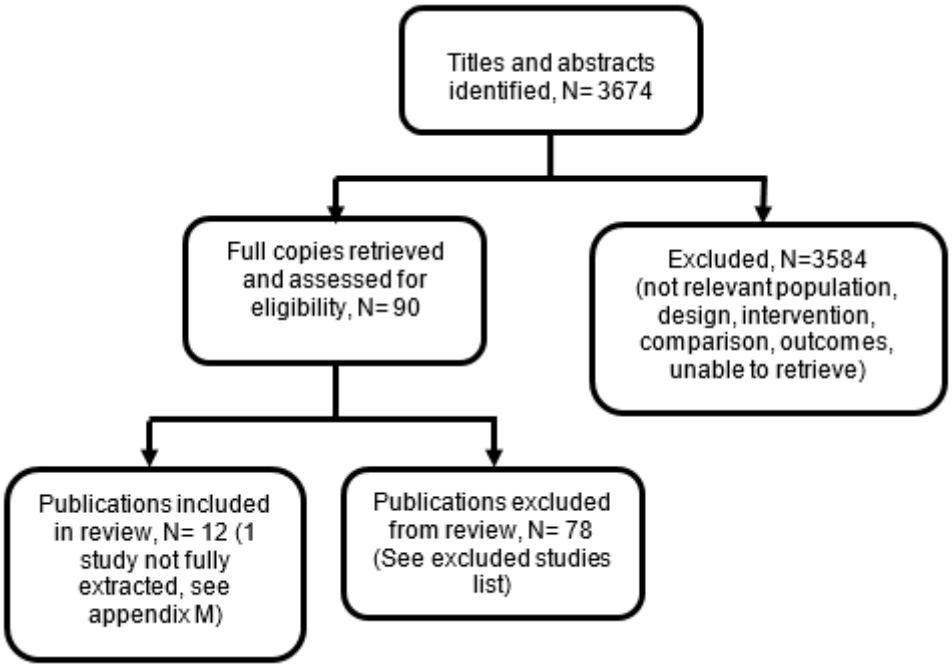
Database(s): Cinahl Plus
Date of last search: 9th September 2020

#	Searches
S17	S15 NOT S16 Limiters - Publication Year: 2006-2020; English Language;
S16	PT anecdote or PT audiovisual or PT bibliography or PT biography or PT book or PT book review or PT brief item or PT cartoon or PT commentary or PT computer program or PT editorial or PT games or PT glossary or PT historical material or PT interview or PT letter or PT listservs or PT masters thesis or PT obituary or PT pamphlet or PT pamphlet chapter or PT pictorial or PT poetry or PT proceedings or PT "questions and answers" or PT response or PT software or PT teaching materials or PT website
S15	S4 AND S14
S14	S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13
S13	TI ((musculoskeletal* or musculo-skeletal*) N1 (pain* or dysfunction*)) OR AB ((musculoskeletal* or musculo-skeletal*) N1 (pain* or dysfunction*))
S12	TI (backache* or backpain*) OR AB (backache* or backpain*)
S11	TI (back pain*) OR AB (back pain*)
S10	TI (osteitis pubis) OR AB (osteitis pubis)
S9	TI ((pelvi* or lumbopelvi* or lumbo-pelvi* or girdle*) N3 relax*) OR AB ((pelvi* or lumbopelvi* or lumbo-pelvi* or girdle*) N3 relax*)
S8	TI (pubi* N3 (pain* or dysfunction*)) OR AB (pubi* N3 (pain* or dysfunction*))
S7	TI ((pelvi* or lumbopelvi* or lumbo-pelvi* or girdle*) N3 pain*) OR AB ((pelvi* or lumbopelvi* or lumbo-pelvi* or girdle*) N3 pain*)
S6	(MH "Back Pain") OR (MH "Low Back Pain")
S5	(MH "Pelvic Pain")
S4	S1 OR S2 OR S3
S3	TI pregnan* OR AB pregnan*
S2	(MH "Expectant Mothers")
S1	(MH "Pregnancy")

Appendix C – Clinical evidence study selection

Clinical study selection for: What interventions are effective in treating mild to moderate pelvic girdle pain during pregnancy?

Figure 1: Study selection flow chart



Appendix D – Clinical evidence tables

Clinical evidence tables for review question: what interventions are effective in treating mild to moderate pelvic girdle pain during pregnancy?

Table 4: Clinical evidence tables

Study details	Participants	Interventions	Methods	Outcomes	Comments
Full citation Elden, H., Ladfors, L., Olsen, M. F., Ostgaard, H. C., Hagberg, H., Effects of acupuncture and stabilising exercises as adjunct to standard treatment in pregnant women with pelvic girdle pain: randomised single blind controlled trial, BMJ (Clinical research ed.), 330, 761, 2005 **Ref Id** 929048 **Country/ies where the study was carried out** Sweden **Study type** RCT	**Sample size** N=386 Acupuncture + Standard treatment (n=125) Physiotherapy-delivered in-home exercise advice + Standard treatment (n=130) Standard treatment (n=131) **Inclusion criteria** 1. Healthy women 2. between 12 to 31 weeks' gestation 3. fluent in Swedish 4. singleton fetus 5. had defined pregnancy-related PGP **Exclusion criteria** Other pain conditions, systemic disorders,	**Interventions** Standard treatment: general information about the condition and anatomy of the back and pelvis, adequate advice about activities of daily living, pelvic belt, home exercise programme designed to increase strength in the abdominal and gluteal muscles. Acupuncture: needles (Hegu AB, Landsbro, Sweden) were made of stainless steel (Ø 0.30) and inserted intramuscularly to a depth of 15-70 mm to evoke needle sensation (De Qi), described as tension, numbness, and often a radiating sensation from the point of insertion, reflecting activation of muscle-nerve afferents. The needles were left in situ for 30 minutes and manually stimulated every 10 minutes. Treatment was given twice a week over six weeks. Physiotherapy-delivered in-home exercise advice: The training programme started by emphasising activation and control of local deep lumbopelvic muscles. Training of more superficial muscles in dynamic exercises to improve mobility, strength, and endurance capacity was gradually included. Patients received treatments individually for a total	**Power analysis** For 90% power of detecting a significance at the two sided 5% level, 103 participants needed for each study group. To compensate for loss to follow up of 20%, 386 participants needed. **Statistical analysis** Intention to treat analysis. Significance level set at p<0.05. Medians, quartiles, means, and standard deviations were calculated when possible. Mann-Whitney U test used to compare changes between groups for continuous outcomes.	**Results** **Outcomes for the woman** **Pain intensity during pregnancy** Pain at morning (visual analogue scale (VAS))- median (IQR 25-75 centile) Acupuncture: 15 (7-29), n=107 Physiotherapy advice: 18 (9-37), n=106 Standard treatment: 27 (12-58), n=108 Standard vs acupuncture, p=ns; standard vs physiotherapy, p=0.0312; acupuncture vs physiotherapy, p<0.001. Pain at evening (VAS) - median (IQR 25-75 centile) Acupuncture: 31 (12-58, n=107 Physiotherapy advice: 45 (21-68), n=106 Standard treatment: 58 (40-74), n=108 Standard vs acupuncture, p<0.001; standard vs physiotherapy, p=0.0245; acupuncture vs physiotherapy, p=0.0130.	**Limitations** **Cochrane RoB tool, v.2** Randomisation process: Low risk (computer-generated random table was used. Allocation - pre-sealed opaque envelopes used, but no further information provided) Deviations from intended interventions: High risk (participants and providers were not blinded) Measurement of the outcome: Low risk (results coded and entered by personnel from independent institution; statistician blinded to group and treatment) Missing outcome data: Low risk (attrition and exclusions reported, similar reasons between the groups, and numbers add up) Selection of the reported result: Some concern (no protocol was found) Other bias: Low risk (groups similar at baseline)

Study details	Participants	Interventions	Methods	Outcomes	Comments
Aim of the study To compare the efficacy of standard treatment, standard treatment plus acupuncture, and standard treatment plus stabilising exercises for pelvic girdle pain during pregnancy. **Study dates** August 2000 - May 2002 **Source of funding** The Vardal Foundation, the Dagmar Foundation, the Trygg- Hansa Insurance Company, and Sahlgrenska University Foundation.	contraindications to treatment **Characteristics** Baseline characteristics were similar in both groups. Maternal age (years) - mean (SD): Standard group: 30.8 (4.8) Acupuncture group: 30.6 (4) Stabilising exercise group: 30.0 (4) Gestation weeks (+ days) at inclusion - mean Standard group: 24 (+3) Acupuncture group: 24 (+3) Stabilising exercise group: 24 (+3) First pregnancy - number (%) Standard group: 33 (25%) Acupuncture group: 34 (27%) Stabilising exercise group: 36 (27%) Smoker - number (%) Standard group: 12 (9%) Acupuncture group: 11 (9%) Stabilising exercise group: 13 (10%)	of six hours during six weeks. They were told to integrate the exercises in daily activities and to exercise in short sessions on several occasions during the day.			Overall: Some concern **Other information** Note: Elden 2008b reports additional data on adverse events of these treatments.

Study details	Participants	Interventions	Methods	Outcomes	Comments
	Previous low back pain number (%) Standard group: 90 (69%) Acupuncture group: 89 (71%) Stabilising exercise group: 84 (64%)				
Full citation Elden, H., Fagevik-Olsen, M., Ostgaard, H. C., Stener-Victorin, E., Hagberg, H., Acupuncture as an adjunct to standard treatment for pelvic girdle pain in pregnant women: Randomised double-blinded controlled trial comparing acupuncture with non-penetrating sham acupuncture, BJOG: An International Journal of Obstetrics and Gynaecology, 115, 1655-1668, 2008 **Ref Id** 911769	**Sample size** N=115 Acupuncture + Standard treatment (n = 58) Sham acupuncture + Standard treatment (n = 57) **Inclusion criteria** 1. healthy pregnant women 2. who are acupuncture-naive 3. with singleton fetuses at 12–29 completed gestational weeks 4. who experienced evening pain (according to the patient-kept diary) of more than 50-mm on a 100-mm visual analogue scale (VAS) during the baseline week 5. fluent in Swedish	**Interventions** Standard treatment: general information about condition and anatomy of back and pelvis, pelvic belt, advice and HEP designed to increase strength in the abdominal and gluteal muscles. Information supplemented by leaflet. Instructed to avoid other treatments during the intervention period. Acupuncture: Sterilised disposable needles were used and inserted intramuscularly to depth of 15-50mm. Needles were left in situ for 30 minutes and manually stimulated every 10 minutes. Sham acupuncture: used a validated sham acupuncture device (which looks like real acupuncture needles but the tip of needle is blunted). The shaft of the sham needle did not penetrate the skin, it collapsed into the handle and creates an illusion of insertion. Needles were left in situ for 30 minutes and manually stimulated every 10 minutes.	**Power analysis** 100 participants needed to detect an improvement of 15mm on the visual analogue scale, with 80% power and 5% significance level. **Statistical analysis** Intention to treat analysis. Significance level set at p<0.05. The median, CI, quartiles, means and SD were calculated when appropriate. The Mann–Whitney U test was used to compare differences between the groups for continuous outcomes.	**Results** Note: Number of participants in the intervention and control groups for all outcomes are n=58 and n=57 respectively, unless otherwise stated **Outcomes for the woman** **Pain intensity during pregnancy** Pain at morning during last treatment week (visual analogue scale (VAS))- median (95% CI) Intervention: 25 (18-31) Control: 24 (13-33); p=0.727 Pain at evening (VAS) during last treatment week- median (95% CI) Intervention: 36 (30-46) Control: 41 (31-52); p=0.483 Discomfort of PGP (VAS) - median (95% CI) Intervention: 36 (21–42) Control: 41 (26–53); p=0.146 Women fulfilling all Ostgaards criteria for PGP Intervention: 29/57 Control: 35/57; p=0.112 Severity of PGP assessed by an independent examiner	**Limitations** **Cochrane RoB tool, v.2** Randomisation process: Low risk (computer-generated random table was used. Allocation - pre-coded numbered identical opaque envelopes to assign participants to the groups) Deviations from intended interventions: Low risk (participants were blinded, not possible to blind personnel who delivered intervention) Measurement of the outcome: Low risk (blinded to treatment allocation, doctors handling decisions about sick-listing were also blinded) Missing outcome data: Low risk (attrition and exclusions were presented along with reasons, and numbers at each stage add up) Selection of the reported result: Low risk (study reported all

Study details	Participants	Interventions	Methods	Outcomes	Comments
Country/ies where the study was carried out Sweden **Study type** RCT **Aim of the study** To investigate whether acupuncture has a greater treatment effect than non-penetrating sham acupuncture in women with pelvic girdle pain (PGP) during pregnancy **Study dates** June 2006 - May 2007 **Source of funding** Grants from the Foundation of the Health and Medical care committee of the Region of Vastra Gotaland (Sweden), the Swedish Medical Research Council, and Swedish	6. diagnosis of PGP according to Ostgaards criteria **Exclusion criteria** 1. with other pain conditions 2. history of orthopaedic disease or surgery in the spine or pelvic girdle 3. systemic disorders 4. coagulation disturbances 5. increased risk of infection **Characteristics** Baseline characteristics were similar in both groups. Maternal age (years) - mean (SD): Intervention group: 31 (4) Control group: 30 (4) Nulliparous women - number (%): Intervention group: 21/58 (36) Control group: 28/57 (49) Body mass - mean (SD): Intervention group: 24 (5) Control group: 25 (4)			(active straight leg (ASLR) test) - mean (95% CI) Intervention: 2 (0–8), n=57 Control: 2.5 (0–9), n=57; p=0.705 **Pelvic-related functional disability** Disability rating index (DRI) - median (IQR 25-75 centile) Intervention: 44 (30-56) Control: 55 (44-73); p<0.001 Oswestry disability index (ODI) - median (95% CI) Intervention: 35 (30–42) Control: 37 (30–42); p=0.473 **Adverse effects during pregnancy** Fainting Intervention: 5/58 Control: 4/57; p=1.000 Slight bleeding Intervention: 35/58 Control: 34/57; p=1.000 Haematoma Intervention: 17/58 Control: 17/57; p=1.000 Needle pain Intervention: 12/58 Control: 13/57; p=0.824 Experience of de qi sensation Intervention: 54/58 Control: 16/57; p<0.001 Sleepiness Intervention: 3/58 Control: 2/57; p=1.000	outcomes as indicated in the protocol) Other bias: Low risk (no other concerns that may affect the results) Overall: Low risk **Other information** Note: 48% of the sample are women with severe pelvic pain.

Study details	Participants	Interventions	Methods	Outcomes	Comments
governmental grants to researchers in the public health service.	Gestational weeks + days - mean (SD): Intervention group: 22+3 (4+2) Control group: 23+4 (4+2) Previous PGP - number (%) Intervention group: 29/58 (50) Control group: 22/58 (39)				
Full citation Elden,H., Ostgaard,H.C., Fagevik-Olsen,M., Ladfors,L., Hagberg,H., Treatments of pelvic girdle pain in pregnant women: adverse effects of standard treatment, acupuncture and stabilising exercises on the pregnancy, mother, delivery and the fetus/neonate, BMC Complementary and Alternative Medicine, 8, 34-, 2008 **Ref Id** 123922	**Sample size** N=386 Acupuncture + Standard treatment (n=124) Physiotherapy-delivered in-home exercise advice + Standard treatment (n=130) Standard treatment (n=129) **Inclusion criteria** 1. Healthy pregnant women 2. between 12 to 31 weeks' gestation 3. fluent in Swedish, 4. singleton fetus, 5. had defined pregnancy-related PGP **Exclusion criteria**	**Interventions** Standard treatment: general information about the condition and anatomy of the back and pelvis, adequate advice about activities of daily living, pelvic belt, home exercise programme designed to increase strength in the abdominal and gluteal muscles. Acupuncture: needles (Hegu AB, Landsbro, Sweden) were made of stainless steel (Ø 0.30) and inserted intramuscularly to a depth of 15-70 mm to evoke needle sensation (De Qi), described as tension, numbness, and often a radiating sensation from the point of insertion, reflecting activation of muscle-nerve afferents. The needles were left in situ for 30 minutes and manually stimulated every 10 minutes. Treatment was given twice a week over six weeks. Physiotherapy-delivered in-home exercise advice: The training programme	**Power analysis** For 90% power of detecting a significance at the two sided 5% level, 103 participants needed for each study group. **Statistical analysis** Continuous data were tested for significance with Kruskal-Wallis test. Dichotomous data were tested for significance with Fischer's exact test.	**Results** **Outcomes for the woman** **Adverse effects during pregnancy** Number of women who experienced minor adverse events during treatment Acupuncture: 43/125 Physiotherapy advice: 22/131 Standard treatment: 8/130 **Women's experience and satisfaction** Overall satisfaction within one week of treatment Acupuncture: n=108, No help=4; Some help=21; Good help=37; Very good help=46 Physiotherapy advice:n=111, No help=2; Some help=28; Good help=38; Very good help=43 Standard treatment: n=100, No help=25; Some help=53; Good help=14; Very good help=8 No pain relief within one week of treatment Acupuncture: 2/108	**Limitations** **Cochrane RoB tool, v.2** Randomisation process: Low risk (computer-generated random table was used. Allocation - pre-sealed opaque envelopes to assign participants to the groups) Deviations from intended interventions: High risk (participants and providers were not blinded) Measurement of the outcome: Low risk (results coded and entered by personnel from independent institution; statistician blinded to group and treatment) Missing outcome data: Low risk (attrition and exclusions reported, similar reasons between the groups, and numbers add up, no differences between the women who withdrew during the trial and those who completed therapy)

Study details	Participants	Interventions	Methods	Outcomes	Comments
Country/ies where the study was carried out Sweden **Study type** RCT **Aim of the study** To assess adverse effects of acupuncture on the pregnancy, mother, delivery and the fetus/neonate in comparison with women that received stabilising exercises as adjunct to standard treatment or standard treatment alone. **Study dates** August 2000 - May 2002 **Source of funding** The Vardal Foundation, the Dagmar Foundation, the Trygg- Hansa Insurance	Women with other pain conditions, systemic disorders, or contraindications to treatment **Characteristics** Maternal age (years) - mean (SD) Intervention group: 30.5 (4.4) Control group: 30.4 (4.7) Primipara - number (%) Intervention group: 34/125 (27.4%) Control group: 33/130 (25.6%)	started by emphasising activation and control of local deep lumbopelvic muscles. Training of more superficial muscles in dynamic exercises to improve mobility, strength, and endurance capacity was gradually included. Patients received treatments individually for a total of six hours during six weeks. They were told to integrate the exercises in daily activities and to exercise in short sessions on several occasions during the day.		Physiotherapy advice: 5/111 Standard treatment: 3/100 Treatment harmful Acupuncture: 43/108 Physiotherapy advice: 22/111 Standard treatment: 51/100 **Outcomes for the baby** Admission at birth to the neonatal unit- number Acupuncture: 6/124 Physiotherapy advice: 9/130 Standard treatment: 6/129	Selection of the reported result: Some concern (no protocol was found) Other bias: Low risk (groups similar at baseline) Overall: Some concern

Study details	Participants	Interventions	Methods	Outcomes	Comments
Company, and Sahlgrenska University Foundation.					
Full citation Elden, H., Ostgaard, H. C., Glantz, A., Marciniak, P., Linner, A. C., Olsen, M. F., Effects of craniosacral therapy as adjunct to standard treatment for pelvic girdle pain in pregnant women: A multicenter, single blind, randomized controlled trial, Acta Obstetricia et Gynecologica Scandinavica, 92, 775-782, 2013 **Ref Id** 911772 **Country/ies where the study was carried out** Sweden **Study type** RCT **Aim of the study**	**Sample size** N=123 Manual therapy (Craniosacral therapy) + Standard treatment (n=63) Standard treatment (n=60) **Inclusion criteria** Healthy pregnant women 1. with singleton fetuses 2. at 12–29 completed gestational weeks 3. experiencing moderate evening pain, that is equal to or exceeding 40 mm on VAS 4. understand and read Swedish 5. diagnosed with PGP according to European guidelines. **Exclusion criteria** 1. women with other pain conditions 2. history of orthopaedic disease	**Interventions** Craniosacral therapy (CST) consisted of 'a manual release technique of the pelvis whilst supine' which lasted 45 minutes on each occasion and was delivered by 2 qualified CS therapists with 14 to 16 years experience each. Women received CST weekly for 2 weeks and then every second week for 6 weeks. Standard treatment consisted of general information about the condition and anatomy of the back and pelvis. Advice was given with respect to activities of daily living. The women received an elastic pelvic belt and a home training program including exercises to strengthen and stretch the trunk, hip and shoulder muscles. They could always call the physiotherapist if they had questions or needed additional advice or crutches.	**Power analysis** 50 women needed in each group to detect a change of 15 mm on the visual analogue scale between groups with 80% power and a 5% significance level. 123 women included to compensate for dropouts. **Statistical analysis** Intention to treat analysis. Significance level set at 5%. Medians, confidence intervals, quartiles, means and SDs were calculated when possible. Mann-Whitney U-test was used to calculate medians and confidence intervals. Mann–Whitney U-test was used to compare differences between groups for continuous outcomes. Chi-squared test or Fisher's exact test was used for categorical variables.	**Results** Note: N in the intervention and control group is n=63 and n=60 respectively for all outcomes, unless otherwise stated. **Outcomes for the woman** **Pain intensity during pregnancy** Pain in morning in last treatment week (visual analogue scale (VAS))- median (95% CI) Intervention: 27 (25-36) Control: 35 (34-46); p=0.017 Pain in evening in last treatment week (VAS) - median (95% CI) Intervention: 58 (48-60) Control: 66 (55-67); p=0.084 Discomfort of pain (VAS) in last treatment week - median (95% CI) Intervention: 51.5 (45-59) Control: 51 (42-70); p=0.432 **Pelvic-related functional disability** Disability rating index (DRI) within one week of treatment - median (95% CI) Intervention: 58.0 (50-66) Control: 61.5 (54-72); p=0.303 Oswestry disability index (ODI) within one week of treatment - median (95% CI)	**Limitations** **Cochrane RoB tool, v.2** Randomisation process: Low risk (computer-generated random table was used. Allocation - research assessor not involved in the study administered pre-coded, numbered identical opaque envelopes to assign participants to groups) Deviations from intended interventions: Some concern (blinding not possible for participants or providers, however the researchers did assess the credibility of treatment to reduce the effect of treatment preference for participants) Measurement of the outcome: Low risk (independent observer measured and entered VAS without knowledge of group assignment; Statistician blinded to group allocation and treatments) Missing outcome data: Low risk (attrition and exclusions reported, similar reasons between the groups, and numbers add up) Selection of the reported result: Low risk (study reported all outcomes as indicated in the protocol)

Study details	Participants	Interventions	Methods	Outcomes	Comments
To investigate the efficacy of craniosacral therapy as an adjunct to standard treatment compared with standard treatment alone for PGP during pregnancy. **Study dates** September 2009 - February 2011 **Source of funding** Grants from the Health & Medical Care Committee of the Regional Executive Board, Region Vastra Gotaland (Sweden)	or surgery of the spine or pelvic girdle 3. with systemic disorders. **Characteristics** Baseline characteristics (Table 1) were similar in the treatment groups except for higher discomfort in the intervention group (p = 0.046). Maternal age (year) - mean (SD): Intervention group: 30.6 (3.9) Control group: 31.3 (4.3) Nulliparous women - number (%): Intervention group: 19/63 (30.2) Control group: 18/58 (31) Body mass index before pregnancy - mean (SD): Intervention group: 23.4 (3.4) Control group: 23.7 (3.6) Gestational weeks - mean (SD): Intervention group: 21.0 (5.2) Control group: 22.3 (5.6)			Intervention: 40 (34-46) Control: 48 (40-56); p=0.016 **Days off work/sick leave during pregnancy and prior to maternity leave** Sick leave in last treatment week Intervention: 15/63 Control: 10/60 ; p=0.275	Other bias: Low risk (groups similar at baseline, women asked to conceal information about their treatment during assessment, interventions carried out by 2 experienced craniosacral therapists who met to ensure consistent approach throughout study) Overall: Low risk **Other information** Note: 48% of the sample are women with severe pelvic pain.

Study details	Participants	Interventions	Methods	Outcomes	Comments
	Previous PGP - number (%) Intervention group: 39/63 (61.9) Control group: 32/58 (55.2) Previous LBP - number (%) Intervention group: 38/63 (60.3) Control group: 37/58 (63.8) Discomfort of PGP, visual analog scale (VAS) Intervention group: 55 (51 to 59) Control group: 45 (38 to 54)				
Full citation Gausel, A. M., Kjaermann, I., Malmqvist, S., Andersen, K., Dalen, I., Larsen, J. P., Okland, I., Chiropractic management of dominating one-sided pelvic girdle pain in pregnant women; a randomized controlled trial, BMC Pregnancy and Childbirth, 17 (1) (no pagination), 2017 **Ref Id**	**Sample size** N=56 Chiropractic treatment (n=28) Standard treatment (n=28) **Inclusion criteria** Pregnant women 1. with low risk 2. singleton pregnancy 3. comprehension of the Norwegian language 4. at 18 weeks of pregnancy	**Interventions** The intervention consisted of manipulation, mobilization, soft tissue treatment, exercises, and advices chosen by the chiropractor to fit each participant individually. The frequency and number of visits were also determined by the chiropractor. The chiropractic treatment was conducted in two different private clinics, by five different chiropractors. The control group were asked to return to conventional primary health care without any restrictions or recommendations (no further details reported).	**Power analysis** Not reported **Statistical analysis** Intention to treat analysis. Proportion of women reporting new occurrence of sick leave were compared using Chi squared tests. For the secondary outcomes, treatment effects were estimated using linear regression analysis.	**Results** **Outcomes for the woman** **Pain intensity during pregnancy** Pain intensity, between week 21 and 30 (VAS)- mean (95% CI) Intervention: 42.7 (33.5-51.8); N= 25 Control: 46.4 (37.3-55.6); N= 21 Pain intensity, between week 33 and 40 (VAS)- mean (95% CI) Intervention: 40.3 (27.9-52.8); N= 24 Control: 44.2 (29.8-58.5); N= 21 **Pelvic-related functional disability during pregnancy**	**Limitations** **Cochrane RoB tool, v.2** Randomisation process: Some concern (a closed envelope containing complete ID-code, even ID-code assigned to the intervention, odd ID-code to the control group, no further information. Allocation - insufficient information). Deviations from intended interventions: High risk (participants and providers were not blinded) Measurement of the outcome: Low risk (assessor for clinical measures blinded); Unclear risk for VAS score

Study details	Participants	Interventions	Methods	Outcomes	Comments
911801 **Country/ies where the study was carried out** Norway **Study type** RCT **Aim of the study** To investigate the outcome of chiropractic management for a subgroup of pregnant women with dominating one-sided pelvic girdle pain (PGP). **Study dates** March 2010 − December 2010 **Source of funding** Grants from Stavanger University Hospital	5. diagnosed with dominating one-sided PGP **Exclusion criteria** Not reported **Characteristics** Age at inclusion (years) - mean (SD) Intervention group: 28.9 (4.5) Control group: 29.9 (4.8) Age ≥ 30 - number (%) Intervention group: 13/28 (46) Control group: 14/28 (50) Primiparous - number (%) Intervention group: 16/26 (62) Control group: 15/27 (56) Education length (years) - mean (SD) Intervention group: 14.7 (4.0) Control group: 14.8 (3.1) BMI before pregnancy - mean (SD) Intervention group: 23.4 (3.1)			Oswestry disability index (ODI) week 30 - mean (95% CI) Intervention: 29.7 (22.1-37.2); N= 25 Control: 27.1 (21.0-33.2); N= 21 **Days off work/sick leave during pregnancy prior to maternity leave** New sick leave due to PGP and/or LBP (week 19-30) - number Intervention: 7/28 Control: 8/28; p=0.75 New sick leave due to PGP and/or LBP (week 31-36) - number Intervention: 8/28 Control: 10/28; p=0.36	Missing outcome data: Low risk (very low drop-out rate, and similar reasons between the groups, and numbers add up) Selection of the reported result: High risk (study not reported all outcomes indicated in the protocol) Other bias: High risk (baseline imbalances between groups regarding exercise before pregnancy and having pelvic pain year before pregnancy) Overall: High risk **Other information**

Study details	Participants	Interventions	Methods	Outcomes	Comments
	Control group: 24.2 (4.0) Exercise before pregnancy - number (%) Intervention group: 5/26 (19) Control group: 12/27 (44) Exercise in early pregnancy (week 1 to18) - number (%) Intervention group: 2/27 (7) Control group: 5/27 (19) PP one year before pregnancy - number (%) Intervention group: 9/27 (33) Control group: 4/27 (15) PP and LBP in early pregnancy (week 1 to 18) - number (%) Intervention group: 22/26 (85) Control group: 22/27 (82) Sick leave in early pregnancy (week 1 to 18) - number (%) Intervention group: 6 of 28 (21) Control group: 3 of 28 (11)				
Full citation	**Sample size** N=105	**Interventions**	**Power analysis** Not specified	**Results** Note: number of participants in the belt, physiotherapy advice,	**Limitations** **Cochrane RoB tool, v.2**

Study details	Participants	Interventions	Methods	Outcomes	Comments
Kordi, R., Abolhasani, M., Rostami, M., Hantoushzadeh, S., Mansournia, M. A., Vasheghani-Farahani, F., Comparison between the effect of lumbopelvic belt and home based pelvic stabilizing exercise on pregnant women with pelvic girdle pain; A randomized controlled trial, Journal of Back and Musculoskeletal Rehabilitation, 26, 133-139, 2013 **Ref Id** 911881 **Country/ies where the study was carried out** Iran **Study type** RCT **Aim of the study** To compare the effect of lumbopelvic belt plus information,	Pelvic girdle support belt + Information (n=35) Physiotherapy-delivered in-home exercise advice + Information (n=35) Information (n=35) **Inclusion criteria** 1. Healthy pregnant women 2. with pain in lumbar region radiating between gluteal fold and posterior iliac crest 3. gestational age between 20 and 32 weeks 4. mono fetus pregnancy 5. age less than 40 years 6. having pelvic girdle pain **Exclusion criteria** 1. contraindications of exercise in pregnancy 2. previous history of back surgery 3. coexisting neurologic deficit 4. depression 5. inability in attending the follow-	General information about the anatomy, body posture, and ergonomic advices regarding sitting, walking and lying. Women were asked to use non-rigid lumbopelvic belt during the course of the study, and they were allowed to remove the belt only during the sleeping. Women were asked to follow a home-based exercise program. Exercises were designed to strengthen the pelvic girdle muscles. The subjects in the exercise group were asked to perform aerobic, stretching, and strengthening exercises.	**Statistical analysis** Level of significance set at p=0.05 or less. No further detail given.	and information group for all outcomes are 34, 31 and 31, respectively. **Outcomes for the woman** **Pain intensity during pregnancy** Pain at 3rd week (visual analogue scale (VAS))- mean (SD) Belt: 18.8 (15.76) Physiotherapy advice: 44.3 (14.87) Information: 44.2 (13.36) Pain at 6th week (VAS) - mean (SD) Belt: 11.0 (15.94) Physiotherapy advice: 31.1 (17.59) Information: 45.2 (14.57) **Pelvic-related functional disability during pregnancy** Oswestry disability index (ODI) at 3rd week- mean (SD) Belt: 23.9 (8.42) Physiotherapy advice: 24.8 (7.16) Information: 25.5 (9.26) Oswestry disability index at 6th week (ODI) - mean (SD) Belt: 20.1 (7.61) Physiotherapy advice: 21.5 (7.71) Information: 25.7 (9.67)	Randomisation process: Low risk (computer-generated block randomisation sequence was used. Allocation -no information provided about allocation concealment) Deviations from intended interventions: High risk (participants and providers were not blinded, it is difficult to blind them) Measurement of the outcome: Some concern (all measures were self-assessed by participants) Missing outcome data: Low risk (very low drop-out rate, and similar reasons between the groups, and numbers add up) Selection of the reported result: Low risk (study reported all outcomes as indicated in protocol) Other bias: Low risk (Use of pain provocation tests as well as self-report to diagnose PP increases validity of diagnosis. No significant differences in any of the primary or secondary outcomes at baseline) Overall: Some concern **Other information**

Study details	Participants	Interventions	Methods	Outcomes	Comments
home-based pelvic girdle stabilizing exercises plus information and information alone on pain intensity, functional status and quality of life of pregnant women with pelvic girdle pain. **Study dates** Not reported **Source of funding** Tehran University of Medical Sciences.	up sessions of the study 6. history of any dermatologic reaction due to using a belt 7. history of any following conditions in previous pregnancies: vaginal bleeding, preeclampsia, IUGR, placenta previa, preterm labor, incompetent cervix, cervix insufficiency or rupture of membrane 8. systemic diseases such as restrictive lung diseases, heart diseases, diabetes 9. use of any medicine or product containing corticosteroid in past 30 days 10. current use of analgesic medications other than acetaminophen **Characteristics** Maternal age (years) - mean (SD) Belt group: 28.26 (4.82) Exercise group:26.45 (5.37) Control group: 25.45 (5.59)				

Study details	Participants	Interventions	Methods	Outcomes	Comments
	Gestational age (week) - mean (SD) Belt group: 26.5 (3.7) Exercise group:24.7 (3.9) Control group: 25.3 (3.8) Gestational age at which present pain started (week) - mean (SD) Belt group: 16.2 (6.5) Exercise group:17.7 (5.3) Control group: 17.0 (6.2)				
Full citation Melkersson, C., Nasic, S., Starzmann, K., Bengtsson Bostrom, K., Effect of Foot Manipulation on Pregnancy-Related Pelvic Girdle Pain: A Feasibility Study, 16, 211-219, 2017 **Ref Id** 758582 **Country/ies where the study was carried out** Sweden **Study type** RCT	**Sample size** N=97 Manual therapy (Foot manipulation) + Physiotherapy-delivered in-home exercise advice (n=47) Sham manual therapy (sham foot manipulation) + Physiotherapy-delivered in-home exercise advice (n=50) **Inclusion criteria** 1. Swedish-speaking women 2. in weeks 12 to 31 of pregnancy 3. had PPGP as determined by	**Interventions** Foot manipulation: The subtalar joint was treated with gapping thrust with patient lying on the contra-lateral side. Mobilisation of the distal tibia-fibula was performed with the patient squatting and was repeated 10 times. Home training programs in order to maintain the mobility in the joints were given. Sham foot manipulation: it included downsizing (a massage technique) the section underneath the heel from the back forward with 4 grips and light palpation of the 5 metatarsal bones with the patient in the supine position on a psoas pillow. The comparative treatment was repeated 10 times. This group was also advised to perform home exercises in the mornings, repeating them 8 times: supine position, spreading and squeezing the toes; sitting position, lifting of heel and forefoot, with the feet	**Power analysis** 250 patients would be needed in each group to confirm the effect of foot manipulation compared with the comparator. **Statistical analysis** Intention to treat analysis. Level of significance was set at p=0.05 or less. The t test and the $\chi 2$ test were used to compare continuous outcomes Differences in VAS scores were calculated using a sign test with binomial approximation and with adjustment for differences in baseline pain on the VAS.	**Results** **Outcomes for the woman** **Pain intensity during pregnancy** Pain in pelvic region at morning after 1st session (visual analogue scale (VAS))- mean (SD) Intervention: 19 (16); N = 35 Control: 24 (23); N = 40; p=0.24 Pain in pelvic region at morning after 2nd session (VAS)- mean (SD) Intervention: 18 (14); N = 35 Control: 24 (19); N = 41; p=0.77 Pain in pelvic region at morning after 6th session (VAS)- mean (SD) Intervention: 20 (20); N = 31 Control: 29 (26); N = 39; p=0.64	**Limitations** **Cochrane RoB tool, v.2** Randomisation process: Some concern (sealed envelopes were used, but no further information provided. Allocation - sealed envelopes to assign participants to the groups, but no further information provided). Deviations from intended interventions: High risk (participants were blinded, one of the 2 physiotherapists was blinded, but not the other) Measurement of the outcome: Low risk (outcome assessment carried out by a blinded evaluator) Missing outcome data: Low risk (attrition and exclusions were presented along with reasons,

Study details	Participants	Interventions	Methods	Outcomes	Comments
Aim of the study To investigate if the research process to evaluate the effect of foot manipulation on pregnancy-related pelvic girdle pain (PPGP) is feasible. **Study dates** September 2009 - August 2011 **Source of funding** Grants from the Skaraborg Research and Development Council and the Skaraborg Primary Care Research and Development Council.	specific provocation tests 4. with joint dysfunction or decreased pain of foot movement **Exclusion criteria** 1. women with twin pregnancies 2. with lumbar pain 3. with rheumatic disease 4. with other serious diseases 5. non–Swedish-speaking women 6. had been treated with foot manipulation earlier 7. with only LBP **Characteristics** All baseline characteristics were similar in both groups Age (year) - mean (SD) Intervention group: 30 (6) Control group: 28 (6); p = 0.13 Parity - mean (SD) Intervention group: 2.0 (1.5) Control group: 1.8 (0.8); p = 0.36	remaining in plantar flexion; walking with small steps along a line with pelvis aligned over the feet, forward and backward; and tiptoeing in the erect position while maintaining normal lordosis.		Pain in pelvic region at evening after 1st session (VAS) - mean (SD) Intervention: 39 (23); N = 36 Control: 45 (29); N = 41; p=0.33 Pain in pelvic region at evening after 2nd session (VAS) - mean (SD) Intervention: 34 (17); N = 35 Control: 41 (25); N = 42; p=0.90 Pain in pelvic region at evening after 6th session (VAS) - mean (SD) Intervention: 29 (21); N = 29 Control: 47 (27); N = 33; p=0.28 Pain in symphysis after 1st session (VAS) - mean (SD) Intervention: 8 (17); N = 46 Control: 11 (20); N = 47; p=0.34 Pain in symphysis after 2nd session (VAS) - mean (SD) Intervention: 11 (19); N = 32 Control: 11 (20); N = 33; p=0.62 Pain in symphysis after 6th session (VAS) - mean (SD) Intervention: 9 (14); N = 28 Control: 12 (18); N = 27; p=0.92	and numbers at each stage add up) Selection of the reported result: Low risk (study reported all outcomes indicated in protocol) Overall: Some concern

Study details	Participants	Interventions	Methods	Outcomes	Comments
	Gestational age (week) - mean (SD) Intervention group: 24 (6) Control group: 23 (6); p = 0.52 Former girdle pain - number (%) Intervention group: 13/47 (37%) Control group: 22/50 (63%); p = 0.07 Foot trauma - number (%) Intervention group: 33/47 (44%) Control group: 30/50 (48%); p = 0.28				
Full citation Mirmolaei, S. T., Ansari, N. N., Mahmoudi, M., Ranjbar, F., Efficacy of a physical training program on pregnancy related lumbopelvic pain, International Journal of Women's Health and Reproduction Sciences, 6, 161-166, 2018 **Ref Id** 911929	**Sample size** N=171 Physiotherapy-delivered in-home exercise advice (n=88) Standard treatment (n=83) **Inclusion criteria** 1. women between 18 to 35 years old 2. in the gestational week between 17 and 22 3. had singleton pregnancy	**Interventions** The intervention consists of a 12-week exercise program developed by an expert physiotherapist and included a prenatal education class about simple anatomy, physiological changes in pregnancy, factors causing low back pain, proper posture in lying, sitting and standing, proper lifting techniques, and specific exercises. The exercises consisted of stretching and strengthening such as pelvic tilting, knee pull, Kegel exercise, wall squats, adductor stretch, pelvic elevation, pelvic rotation, arm and leg raise. Women were encouraged to perform each exercise 10 times a day for 12 weeks.	**Power analysis** Not specified **Statistical analysis** Intention to treat analysis. Significance level set at p<0.05. Clinical data was assessed by independent *t* tests or chi square as appropriate. The paired t test was used to analyse within-group changes.	**Results** Note: Number of participants in the intervention and control groups for all outcomes are 88 and 83 respectively. **Outcomes for the woman** **Pain intensity during pregnancy** Pain intensity after treatment (VAS) (0-10) - mean (SD) Intervention: 2.94 (2.39) Control: 5.01 (3.08); p<0.001 Pelvic-related functional disability after treatment (ODI) - mean (SD) Intervention: 16.2 (12.55) Control: 26.14 (18.53); p<0.001	**Limitations** **Cochrane RoB tool, v.2** Randomisation process: Some concern (it reported that subjects were randomly assigned into 2 groups but no further information reported. Allocation - no information provided regarding allocation concealment). Deviations from intended interventions: High risk (participants and personnel were not blinded, not possible to blind them) Measurement of the outcome: Some concern (no enough information reported regarding outcome assessment)

Study details	Participants	Interventions	Methods	Outcomes	Comments
Country/ies where the study was carried out Iran **Study type** RCT **Aim of the study** To investigate the efficacy of a physical training program on lumbopelvic pain and its physical disability during pregnancy **Study dates** 2010-2011 **Source of funding** Grant from Tehran University of Medical Sciences	**Exclusion criteria** 1. the absolute or relative contraindications for exercise in pregnancy 2. history of surgery, fracture or disease of spinal column and pelvis 3. with inflammatory disease or rheumatoid arthritis 4. history of recent abdominal surgery 5. threatened abortion 6. absence of patients in training classes 7. censoring performing physical training exercises less than 3 times a week **Characteristics** Age (years) - mean (SD) Intervention group: 26.46 (3.93) Control group: 25.56 (3.54) BMI - mean (SD) Intervention group: 23.97 (3.93) Control group: 23.63 (3.89) Gestational age - mean (SD)	The control group received routine prenatal care (no further details reported).			Missing outcome data: Low risk (attrition and exclusions were presented along with reasons, and numbers at each stage add up) Selection of the reported result: Some concern (no protocol was found) Overall: High risk **Other information** Note: 15% of the sample were women with back pain only.

Study details	Participants	Interventions	Methods	Outcomes	Comments
	Intervention group: 19.04 (2.07) Control group: 19.03 (2.10) <u>Low back pain - %</u> Intervention group: 44.6 Control group: 34.1 <u>Pelvic girdle back pain - %</u> Intervention group: 61.4 Control group: 75 <u>Employment - %</u> Intervention group: 12.5 Control group: 12				
Full citation Nicolian, S., Butel, T., Gambotti, L., Durand, M., Filipovic-Pierucci, A., Mallet, A., Kone, M., Durand-Zaleski, I., Dommergues, M., Cost-effectiveness of acupuncture versus standard care for pelvic and low back pain in pregnancy: A randomized controlled trial, PLoS ONE [Electronic Resource], 14, e0214195, 2019 **Ref Id**	**Sample size** N=199 Acupuncture group: n=96 Standard treatment: n=104 **Inclusion criteria** 1. Singleton pregnancy. 2. Age 18 or older. 3. Gestational age between 16 and 34 weeks. 4. Low back pain for at least two weeks with pain greater than 4 on a 10-point numerical rating scale (NRS).	**Interventions** Intervention: Acupuncture plus standard care 5 acupuncture sessions performed by an acupuncturist midwife. 2 sessions in the first week, then 3 weekly sessions. Additional sessions could be done at the patient's request. Acupuncture points were selected based on pain location and traditional Chinese medicine diagnosis of 'Qi kidney deficiency' versus 'blood stagnation'. Woman lay on her left side, and points were needled bilaterally. Needles were retained for 30 minutes per treatment.	**Power analysis:** Based on the ability to detect a clinically relevant difference of 25% in percentage of days with pain (NRS) between 4 groups, 150 patients in each group needed to give a power of 80% at 5% significance level. **Statistical analysis:** Intention to treat analysis. Significance level set at p<0.05. Categorical data were reported as frequencies. Continuous data were reported as mean +/- the standard deviation. Discrete variables were compared using the	**Results** Outcomes: Critical: **Pain intensity** Mean pain at baseline (95% CI): *Self-assessed with the numerical rating scale (NRS). Self reported pain daily, the worst pain in 24 hours is recorded.* Acupuncture: 7.4 (7.1 to 7.6) Control: 7.5 (7.2 to 7.7) Mean pain at week 5 after imputation (95% CI): *Self-assessed with NRS* Acupuncture: 5 (4.6 to 5.5) Control: 6 (5.5 to 6.5) Mean difference in pain between baseline and week after imputation *Self-assessed with NRS*	**Limitations** **Cochrane risk of bias tool V2:** Randomisation process: Low risk of bias. (Central web based generated allocation sequence. Allocation concealed as central method used. Baselines balanced). Deviations from intended interventions: Low risk of bias. (Participants aware of assignment, but deviations consistent with what could occur outside trial context. Appropriate analysis). Measurement of the outcome: Pain: High risk. (Appropriate method of measurement. Likely the assessment could have been influenced by knowledge of intervention).

Study details	Participants	Interventions	Methods	Outcomes	Comments
1242097 **Country/ies where the study was carried out** France **Study type** RCT **Aim of the study** Assess effectiveness of hospital acupuncture for pelvic girdle and low back pain. **Study dates** 2012-2014 **Source of funding** Not industry funded	5. At least one positive provocation test. **Exclusion criteria** 1. Obstetrical complications such as preeclampsia. 2. Small for gestational age fetus. 3. Pelvic or low back pain before pregnancy. 4. If they did not have social insurance coverage. **Characteristics** Mean age in years (SD): Intervention: 31 (5.2) Control: 30.7 (4.6) Mean gestational age at inclusion in weeks (SD): Intervention: 28 (4.7) Control: 27.4 (4.2) Mean pre gestational BMI (SD): Intervention: 23.7 (4.4) Control: 24.1 (5.3) Pain location number (%): Low back pain L3L5: 113/199 (56.8%)	Standard care. Control: Standard care Pregnancy belt. Lifestyle recommendations and exercises explained by the midwife in charge of the trail. Painkillers, rest and sick leave were prescribed by the doctor or the midwife.	Fisher exact test. Normally distributed continuous data compared using Student t-test, non-normally distributed data compared using Wilcoxon rank-sum test.	Acupuncture: -2.3 (-2.8 to 1.9) Control: -1.4 (-1.9 to -1.0) Difference: 0.9 (0.2 to 1.5) p=0.008 **Pelvic related functional disability/ functional status during pregnancy** Mean Oswestry disability index (ODI) at baseline (95% CI): Acupuncture: 36.0 (33.4 to 38.7) Control: 38.2 (35.6 to 41.0) ODI at week 5 after imputation (95% CI): Acupuncture: 30.0 (26.4 to 33.5) Control: 35.7 (32.4 to 38.9) Mean difference in ODI between baseline and week after imputation Acupuncture: 6.1 (3.5 to 8.7) Control: 2.7 (0.0 to 5.4) Difference: 3.5 (0.4 to 9.7) p=0.07 Percentage of weeks with ODI ≤20/100 after imputation (95% CI): *calculated between inclusion and delivery* Acupuncture: 30% (25 to 38) Control: 15% (11 to 21) Difference: 7% (-2 to 16) p<0.001 Important: **Adverse effects during pregnancy** Acupuncture specific side effects (Acupuncture group only) - number/n (%): Total: 32/96 (33%)	Other outcomes: Low risk of bias. (Appropriate measures of outcomes). Missing outcome data: Some concern. (Incomplete data for pain and disability assessment. Possible that the missingness could depend on the true value). Selection of the reported result: Low risk of bias. (All outcomes reported at pre-specified. Not like to have been selected). Overall: Some concern

Study details	Participants	Interventions	Methods	Outcomes	Comments
	Back pain higher than L3: 53/199 (26.6%) Sacro-ileal pain: 144/199 (72.4%) Anterior pelvic pain: 80/199 (40.2%) Sciatica: 79/199 (39.7%)			Bruising 24/96 (25%) Fatigue 9/96 (8%) Dizziness 1/96 (1%) Headache 1/96 (1%) Number of women with non-specific adverse events - number/n (%): Acupuncture: 29/96 (30%) Control: 30/103/ (29%) Hospitalisation because of nonspecific adverse event number/n (%): Acupuncture: 10/96 (10%) Control: 9/103 (9%) Total number of adverse events number/n (%): Acupuncture: 40/96 (42%) Control: 36/103 (35%) Events included cholestasis, gestational diabetes, hypertension/preeclampsia, unexplained transient fever, urinary infection, viral infection, other infection, threatened premature labour, premature delivery (34–36 weeks), intrauterine growth restriction, and thrombocytopenia.	

Study details	Participants	Interventions	Methods	Outcomes	Comments
				Admission to the neonatal unit: Admission to neonatal care unit number/n (%): Acupuncture: 3/96 (3%) Control: 4/103 (4%) Admission to neonatal intensive care unit number/n (%) Acupuncture: 1/96 (1%) Control: 3/103 (3%) Combined number/n (%): Acupuncture: 4/96 (4%) Control: 7/103 (7%)	
Full citation Nilsson-Wikmar, L., Holm, K., Oijerstedt, R., Harms-Ringdahl, K., Effect of three different physical therapy treatments on pain and activity in pregnant women with pelvic girdle pain: A randomized clinical trial with 3, 6, and 12 months	**Sample size** N=118 Physiotherapy-delivered in-home exercise advice + Information + Pelvic girdle support belt (n=41) Physiotherapy-delivered in-clinic exercise advice + Information + Pelvic girdle support belt (n=37)	**Interventions** Information Group: information was about the pelvic girdle pain including anatomy, body posture, and ergonomic advice and were provided with a non-elastic sacroiliac belt. Physiotherapy-delivered in-home exercise advice: The home exercise program consists of 3 exercises for stabilizing the muscles around the pelvic girdle. During the exercises, a ball	**Power analysis** Not specified. **Statistical analysis** Intention to treat analysis. Significance level set at $p<0.05$. Categorical variables were dichotomised, and the x^2 test was used to compare groups. The data were not normally distributed and measured on	**Results** **Outcomes for the woman** **Pain intensity during pregnancy** Pain intensity after treatment (VAS) - median (range) Information: 49 (0–98) Physiotherapy-delivered in-home exercise advice: 50 (18–99) Physiotherapy-delivered in-clinic exercise advice: 62 (0–100); p=0.82	**Limitations** **Cochrane RoB tool, v.2** Randomisation process: High risk (stratification factor was previous children) Allocation concealment: Some concern (no information provided regarding allocation concealment) Deviations from intended interventions: High risk (participants and physiotherapists were not blinded, it is difficult to blind them)

Study details	Participants	Interventions	Methods	Outcomes	Comments
follow-up postpartum, Spine, 30, 850-856, 2005 **Ref Id** 825565 **Country/ies where the study was carried out** Sweden **Study type** RCT **Aim of the study** To compare 3 different physical therapy treatments with respect to pain and activity in women with pelvic girdle pain during pregnancy and 3, 6, and 12 months postpartum. **Study dates** Not specified **Source of funding** the Vårdal Foundation	Information + Pelvic girdle support belt (n=40) **Inclusion criteria** 1. pregnant women until gestation week 35 2. with back pain 3. who attended 2 different antenatal clinics in a suburb of Stockholm, Sweden 4. who tested positive in at least 3 pelvic pain provocation tests including the symphysis **Exclusion criteria** Not specified **Characteristics** All baseline characteristics were similar in the 3 groups except for mean gestation week at inclusion. Age (year) - mean (SD) Information group: 28.4 (3.9) Physiotherapy-delivered in-home exercise	between the knees was used in sitting, in standing, and in 4-point kneeling position with movements of the arms or the legs. The program was ended with stretching of the hamstrings, hip flexors, and calf muscles. The instructions about the program were given within 1 week after inclusion, and the women were followed up once shortly after receiving the program. Women received information and sacroiliac belt as in the information group. Physiotherapy-delivered in-clinic exercise advice: it consists of 4 different strengthening and stabilization exercises with different pieces of equipment; the lateral pulls, standing leg-press, sit-down rowing, and curl-ups. For warm-up, biking on a stationary bike was used. The program was ended with stretching. The exercises were performed twice a week until gestation week 39. Women received information and sacroiliac belt as in the information group.	ordinal scales therefore nonparametric statistics were used. The Wilcoxon signed rank test or Friedman analysis of variance were used to assess changes in outcome within each group between inclusion and 38 weeks gestation, between 38 weeks gestation and 12 months postpartum and at follow ups.	p-value calculated for 3-way comparison **Pelvic-related functional disability during pregnancy** Pelvic-related functional disability after treatment (DRI) - median (range) Information group: 65 (13–92) Physiotherapy-delivered in-home exercise advice: 66 (21–91) Physiotherapy-delivered in-clinic exercise advice: 59 (14–91); p=0.58 p-value calculated for 3-way comparison	Measurement of the outcome: Low risk (outcome assessment carried out by a blinded physical therapist) Missing outcome data: Low risk (attrition and exclusions were presented along with reasons, and numbers at each stage add up) Selection of the reported result: Some concern (no protocol was found) Other bias: High risk (baseline imbalances between groups regarding gestation week at inclusion) Overall: High risk

Study details	Participants	Interventions	Methods	Outcomes	Comments
	advice group: 29.5 (3.3) Physiotherapy-delivered in-clinic exercise advice group: 29.7 (5.4) Weight before pregnancy (kg) - mean (SD): Information group: 60.4 (10.9) Physiotherapy-delivered in-home exercise advice group: 62.8 (9.7) Physiotherapy-delivered in-clinic exercise advice group: 63.4 (11.2) Weight at inclusion (kg) - mean (SD): Information group: 68.1 (11.7) Physiotherapy-delivered in-home exercise advice group: 69.2 (10.7) Physiotherapy-delivered in-clinic exercise advice group: 69.1 (11.4) Height (m) - mean (SD) Information group: 1.66 (0.06) Physiotherapy-delivered in-home exercise advice group: 1.67 (0.06)				

Study details	Participants	Interventions	Methods	Outcomes	Comments
	Physiotherapy-delivered in-clinic exercise advice group: 1.66 (0.06) Gestation week at inclusion (wk) - mean (SD) Information group: 25 (7) Physiotherapy-delivered in-home exercise advice group: 22 (7) Physiotherapy-delivered in-clinic exercise advice group: 21 (6)				
Full citation Wedenberg, K., Moen, B., Norling, A., A prospective randomized study comparing acupuncture with physiotherapy for low-back and pelvic pain in pregnancy, Acta obstetricia et gynecologica Scandinavica, 79, 331-5, 2000 **Ref Id** 929050 **Country/ies where the study was carried out**	**Sample size** N=60 Acupuncture (n=30) Physiotherapy (n=30) **Inclusion criteria** 1. pregnant women living in the eastern part of Östergötland 2. who were suffering from back and pelvic pain 3. with a gestational age of no more than 32 weeks **Exclusion criteria** Not specified	**Interventions** Acupuncture: it was given 3 times a week during the first two weeks, then twice a week, totalling 10 treatments within one month, each of 30 minutes. 2- 10 needles were used. it always started with ear-acupuncture, supplemented when needed by body-acupuncture. Needles were gently tapped or rotated about 15 minutes after insertion. Physiotherapy: it was given once or twice a week, totalling 10 treatments within 6–8 weeks, 50 minutes each. Individualised treatment based on assessment. information about the condition + advice on daily activities, ergonomics, correction of faulty posture and how to perform the physical exercises according to a home training program. Trochanter-belt for pelvic support, warmth, massage, soft-	**Power analysis** Not specified **Statistical analysis** Significance level set at $p<0.05$. Two-tailed Student's *t*-test was used to compare the differences of mean values between groups. Chi square test was used to compare differences of proportions between the groups.	**Results** **Outcomes for the woman** **Adverse effects during pregnancy** Serious adverse events during and after treatment: Acupuncture: 0/28 Physiotherapy: 0/18 Minor adverse events during and after treatment Acupuncture: 2/28 (subcutaneous hematomas) Physiotherapy: 5/18 (pre-term uterine contractions, pre-eclampsia, spells of absence) **Women's experience and satisfaction with care** Acupuncture: n=28, No help=0; Some help=1; Good or Excellent help=27	**Limitations** **Cochrane RoB tool, v.2** Randomisation process: Some concern (it reported that subjects were randomly assigned into 2 groups but no further information reported) Allocation concealment: Low risk (a closed envelope from a box) Deviations from intended interventions: High risk (participants and personnel were not blinded, not possible to blind them) Measurement of the outcome: Some concern (no enough information

Study details	Participants	Interventions	Methods	Outcomes	Comments
Sweden **Study type** RCT **Aim of the study** To describe the effects of acupuncture in the treatment of low-back and pelvic pain during pregnancy and compare it with physiotherapy **Study dates** August 1996 - February 1997 **Source of funding** Council of Research and Development (FoU rådet) of Vrinnevi Hospital	**Characteristics** Note: baseline characteristics were similar in both groups except for location of pain (back and/or pelvic pain) Maternal age (years) - mean (range) Acupuncture group: 28.4 (21–36) Physiotherapy group: 29.4 (22–36) Gestational age (years) - mean (range) Acupuncture group: 24.2 (20–32) Physiotherapy group: 24.2 (20–29) Primiparas - number (%) Acupuncture group: 8 (29%) Physiotherapy group: 6 (33%)	tissue mobilisation were offered if needed. All women were offered water gymnastics once or twice a week according to a defined program.		Physiotherapy: n=18, No help=0; Some help=4; Good or Excellent help=14 **Outcomes for the baby** Admission at birth to the neonatal unit- number Acupuncture: 0/28 Physiotherapy: 0/18	reported regarding outcome assessment) Missing outcome data: High risk (>20% dropout rate in control arm, imbalance in groups) Selection of the reported result: Some concern (no protocol was found) Other bias: High risk (other treatments offered to women who might benefit from them) Overall: High risk **Other information** In the acupuncture group, none (0%) was deemed to suffer from 'pure' low-back pain whereas in the physiotherapy group there were 4/18 (22%).

CI: Confidence interval; DRI: Disability rating index; IQR: Interquartile range; LBP: Low back pain; ODI: Oswestry disability index; PGP: Pelvic girdle pain; PP: pelvic pain; RCT: Randomised control trial; SD: Standard deviation; TAU: Treatment as usual; VAS: Visual analogue scale

Appendix E – Forest plots

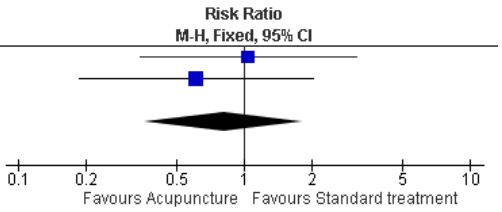
Forest plots for review question: What interventions are effective in treating mild to moderate pelvic girdle pain during pregnancy?

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

Figure 2: Acupuncture plus standard treatment care vs standard treatment – Outcome: admission to neonatal unit

Study or Subgroup	Acupuncture + Standard Events	Total	Standard treatment Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Elden 2005/2008b	6	124	6	129	46.5%	1.04 [0.34, 3.14]
Nicolian 2019	4	96	7	103	53.5%	0.61 [0.19, 2.03]
Total (95% CI)		**220**		**232**	**100.0%**	**0.81 [0.36, 1.82]**
Total events	10		13			

Heterogeneity: Chi² = 0.41, df = 1 (P = 0.52); I² = 0%
Test for overall effect: Z = 0.51 (P = 0.61)



Appendix F – GRADE tables

GRADE tables for review question: What interventions are effective in treating mild to moderate pelvic girdle pain during pregnancy?

Table 5: Clinical evidence profile for comparison of acupuncture and standard treatment versus standard treatment

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Acupuncture + Standard treatment	Standard treatment	Relative (95% CI)	Absolute		
Pain intensity during pregnancy - pain intensity in the morning (median) (follow-up 7 days; measured with: Visual analogue scale; range of scores: 0-100; Better indicated by lower values)												
1 (Elden 2005/2008b)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	107	108	-	acupuncture + standard median 15 (IQR 7 to 29), standard median 27 (IQR 12 to 58), p<0.001	⊕⊕OO LOW	CRITICAL
Pain intensity during pregnancy - pain intensity in the evening (median) (follow-up 7 days; measured with: Visual analogue scale; range of scores: 0-100; Better indicated by lower values)												
1 (Elden 2005/2008b)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	107	108	-	acupuncture + standard median 31 (IQR 12 to 58), standard median 58 (IQR 40 to 74), p<0.001	⊕⊕OO LOW	CRITICAL
Pain intensity during pregnancy (follow-up 5 weeks; measured with: Numerical rating scale; range of scores: 0-10; Better indicated by lower values)												
1 (Nicolian 2019)	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	serious[4]	none	96	103	-	MD 0.9 lower (1.56 to 0.24 lower)	⊕⊕OO LOW	CRITICAL
Pelvic related functional disability/functional status during pregnancy (follow-up 5 weeks; measured with: Oswestry disability index; range of scores: 0-100; Better indicated by lower values)												
1 (Nicolian 2019)	randomised trials	no serious	no serious inconsistency	no serious indirectness	serious[4]	none	96	103	-	MD 3.5 lower (7.27 lower to 0.27 higher)	⊕⊕⊕O MODERATE	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Acupuncture + Standard treatment	Standard treatment	Relative (95% CI)	Absolute		
		risk of bias										
Adverse effects during pregnancy - adverse events during treatment (assessed with: Self-reported)												
1 (Elden 2005/2008b)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	43/125 (34.4%)	8/130 (6.2%)	RR 5.59 (2.74 to 11.41)	282 more per 1000 (from 107 more to 641 more)	⊕⊕⊕O MODERATE	IMPORTANT
Adverse effects during pregnancy - acupuncture specific adverse events												
1 (Nicolian 2019)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	32/96 (33.3%)	0/103 (0%)	Peto OR 11.68 (5.49 to 24.85)	330 more per 1000 (from 240 more to 430 more)[5]	⊕⊕⊕⊕ HIGH	IMPORTANT
Adverse effects during pregnancy - non-specific adverse events												
1 (Nicolian 2019)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[6]	none	29/96 (30.2%)	30/103 (29.1%)	RR 1.04 (0.68 to 1.59)	12 more per 1000 (from 93 fewer to 172 more)	⊕⊕OO LOW	IMPORTANT
Women's experience and satisfaction with care - No pain relief from treatment (follow-up 7 days; assessed with: Self-administered questionnaire)												
1 (Elden 2005/2008b)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[6]	none	2/108 (1.9%)	3/100 (3%)	RR 0.62 (0.11 to 3.62)	11 fewer per 1000 (from 27 fewer to 79 more)	⊕OOO VERY LOW	IMPORTANT
Women's experience and satisfaction with care - Treatment harmful (follow-up 7 days; assessed with: Self-administered questionnaire)												
1 (Elden 2005/2008b)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[7]	none	43/108 (39.8%)	51/100 (51%)	RR 0.78 (0.58 to 1.05)	112 fewer per 1000 (from 214 fewer to 25 more)	⊕⊕OO LOW	IMPORTANT
Women's experience and satisfaction with care - Treatment no help (follow-up 7 days; assessed with: Self-administered questionnaire within 1 week of treatment)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Acupuncture + Standard treatment	Standard treatment	Relative (95% CI)	Absolute		
1 (Elden 2005/2008b)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	4/108 (3.7%)	25/100 (25%)	RR 0.15 (0.05 to 0.41)	213 fewer per 1000 (from 148 fewer to 237 fewer)	⊕⊕⊕O MODERATE	IMPORTANT
Women's experience and satisfaction with care - Treatment good or very good help (follow-up 7 days; assessed with: Self-administered questionnaire)												
1 (Elden 2005/2008b)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	83/108 (76.9%)	22/100 (22%)	RR 3.92 (2.63 to 5.86)	642 more per 1000 (from 359 more to 1000 more)	⊕⊕⊕O MODERATE	IMPORTANT
Admission at birth to the neonatal unit (assessed with: Medical Birth Register)												
2‡	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[6]	none	10/220 (4.5%)	13/232 (5.6%)	RR 0.81 (0.36 to 1.82)	11 fewer per 1000 (from 36 fewer to 46 more)	⊕OOO VERY LOW	IMPORTANT

CI: confidence interval; IQR: interquartile range; MD: mean difference; OR: odds ratio; RR: risk ratio

[1] Evidence downgraded by 1 level due to high risk of bias regarding deviations from intended interventions, and unclear risk of bias regarding allocation concealment and selection of the reported result.
[2] Evidence downgraded by 1 level due to serious imprecision surrounding small sample size.
[3] Evidence downgraded by 1 level due to high risk of bias regarding measurement of the outcome.
[4] Evidence downgraded by 1 level because 95% CI crosses one MID for continuous outcomes (0.5x SD control = 1.184 for pain intensity, 6.771 for pelvic disability).
[5] Absolute effect manually calculated as 0 events in control arm.
[6] Evidence downgraded by 2 levels because 95% CI crosses two default MIDs for dichotomous outcomes (0.8 and 1.25).
[7] Evidence downgraded by 1 level because 95% CI crosses one default MID for dichotomous outcomes (0.8 or 1.25).
‡ For references see corresponding Forest Plot

Table 6: Clinical evidence profile for comparison of acupuncture and standard treatment versus non-penetrating sham acupuncture and standard treatment

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Acupuncture + Standard treatment	Non-penetrating sham acupuncture + Standard treatment	Relative (95% CI)	Absolute		
Pain intensity during pregnancy - pain intensity in the morning (median) (follow-up 7 days; measured with: Visual analogue scale; range of scores: 0-100; Better indicated by lower values)												
1 (Elden 2008a)	randomised trials	no serious risk of bias	no serious inconsistency	very serious[1]	very serious[2]	none	58	57	-	acupuncture + standard median 25 (IQR 18 to 31), non-penetrating sham acupuncture + standard median 24 (IQR 13 to 33), p=0.29	⊕OOO VERY LOW	CRITICAL
Pain intensity during pregnancy - pain intensity in the evening (median) (follow-up 7 days; measured with: Visual analogue scale; range of scores: 0-100; Better indicated by lower values)												
1 (Elden 2008a)	randomised trials	no serious risk of bias	no serious inconsistency	very serious[1]	very serious[2]	none	58	57	-	acupuncture + standard median 36 (IQR 30 to 46), non-penetrating sham acupuncture + standard median 41 (IQR 31 to 52) p=0.48	⊕OOO VERY LOW	CRITICAL
Pain intensity during pregnancy - pelvic girdle pain discomfort (median) (follow-up 7 days; measured with: Visual analogue scale; range of scores: 0-100; Better indicated by lower values)												
1 (Elden 2008a)	randomised trials	no serious risk of bias	no serious inconsistency	very serious[1]	very serious[2]	none	58	57	-	acupuncture + standard median 36 (95% CI from 21 to 42), non-penetrating sham acupuncture + standard median 41 (95% CI from 26 to 53), p=0.15	⊕OOO VERY LOW	CRITICAL
Pelvic-related functional disability/functional status during pregnancy (median) (follow-up 7 days; measured with: Disability rating index questionnaire; range of scores: 0-100; Better indicated by lower values)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Acupuncture + Standard treatment	Non-penetrating sham acupuncture + Standard treatment	Relative (95% CI)	Absolute		
1 (Elden 2008a)	randomised trials	no serious risk of bias	no serious inconsistency	very serious[1]	very serious[2]	none	58	57	-	acupuncture + standard median 44 (IQR 30 to 56), non-penetrating sham acupuncture + standard median 55 (IQR 44 to 73), p=0.001	⊕OOO VERY LOW	CRITICAL
Pelvic-related functional disability/functional status during pregnancy (median) (follow-up 7 days; measured with: Oswestry disability index questionnaire; range of scores: 0-100; Better indicated by lower values)												
1 (Elden 2008a)	randomised trials	no serious risk of bias	no serious inconsistency	very serious[1]	very serious[2]	none	58	57	-	acupuncture + standard median 35 (95% CI from 30 to 42), non-penetrating sham acupuncture + standard median 37 (95% CI from 30 to 42), p=0.47	⊕OOO VERY LOW	CRITICAL
Adverse effects during pregnancy - Experience of de qi sensation (assessed with: Self-administered questionnaire)												
1 (Elden 2008a)	randomised trials	no serious risk of bias	no serious inconsistency	very serious[1]	no serious imprecision	none	54/58 (93.1%)	16/57 (28.1%)	RR 3.32 (2.18 to 5.06)	651 more per 1000 (from 331 more to 1000 more)	⊕⊕OO LOW	IMPORTANT
Adverse effects during pregnancy - Fainting (assessed with: Self-administered questionnaire)												
1 (Elden 2008a)	randomised trials	no serious risk of bias	no serious inconsistency	very serious[1]	very serious[3]	none	5/58 (8.6%)	4/57 (7%)	RR 1.23 (0.35 to 4.34)	16 more per 1000 (from 46 fewer to 234 more)	⊕OOO VERY LOW	IMPORTANT
Adverse effects during pregnancy - Haematoma (assessed with: Self-administered questionnaire)												
1 (Elden 2008a)	randomised trials	no serious risk of bias	no serious inconsistency	very serious[1]	very serious[3]	none	17/58 (29.3%)	17/57 (29.8%)	RR 0.98 (0.56 to 1.73)	6 fewer per 1000 (from 131 fewer to 218 more)	⊕OOO VERY LOW	IMPORTANT

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Acupuncture + Standard treatment	Non-penetrating sham acupuncture + Standard treatment	Relative (95% CI)	Absolute		
Adverse effects during pregnancy - Needle pain (assessed with: Self-administered questionnaire)												
1 (Elden 2008a)	randomised trials	no serious risk of bias	no serious inconsistency	very serious[1]	very serious[3]	none	12/58 (20.7%)	13/57 (22.8%)	RR 0.91 (0.45 to 1.82)	21 fewer per 1000 (from 125 fewer to 187 more)	⊕OOO VERY LOW	IMPORTANT
Adverse effects during pregnancy - Sleepiness (assessed with: Self-administered questionnaire)												
1 (Elden 2008a)	randomised trials	no serious risk of bias	no serious inconsistency	very serious[1]	very serious[3]	none	3/58 (5.2%)	2/57 (3.5%)	RR 1.47 (0.26 to 8.5)	16 more per 1000 (from 26 fewer to 263 more)	⊕OOO VERY LOW	IMPORTANT
Adverse effects during pregnancy - Slight bleeding (assessed with: Self-administered questionnaire)												
1 (Elden 2008a)	randomised trials	no serious risk of bias	no serious inconsistency	very serious[1]	very serious[3]	none	35/58 (60.3%)	34/57 (59.6%)	RR 1.01 (0.75 to 1.36)	6 more per 1000 (from 149 fewer to 215 more)	⊕OOO VERY LOW	IMPORTANT

CI: confidence interval; IQR: interquartile range; RR: risk ratio

[1] Evidence downgraded by 2 levels as 48% of the sample are women with severe pelvic pain.
[2] Evidence downgraded by 2 levels due to very serious imprecision surrounding small sample size..
[3] Evidence downgraded by 2 levels because 95% CI crosses two default MIDs for dichotomous outcomes (0.8 and 1.25).

Table 7: Clinical evidence profile for comparison of acupuncture versus physiotherapy-delivered in-home exercise advice

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Acupuncture + Standard treatment	Physiotherapy-delivered in-home exercise advice + Standard treatment	Relative (95% CI)	Absolute	Quality	Importance
Adverse effects during pregnancy - serious adverse events (assessed with: Self-reported)												
1 (Wedenberg 2000)	randomised trials	very serious[1]	no serious inconsistency	serious[2]	very serious[3]	none	0/28 (0%)	0/18 (0%)	RD 0 (-0.09 to 0.09)	0 fewer per 1000 (from 90 fewer to 90 more)	⊕OOO VERY LOW	IMPORTANT
Adverse effects during pregnancy - minor adverse events (assessed with: Self-reported)												
1 (Wedenberg 2000)	randomised trials	very serious[1]	no serious inconsistency	serious[2]	serious[4]	none	2/28 (7.1%)	5/18 (27.8%)	RR 0.26 (0.06 to 1.19)	206 fewer per 1000 (from 261 fewer to 53 more)	⊕OOO VERY LOW	IMPORTANT
Women's experience and satisfaction with care - Treatment excellent or good help (follow-up 1 weeks; assessed with: Self-report questionnaire)												
1 (Wedenberg 2000)	randomised trials	very serious[1]	no serious inconsistency	serious[2]	serious[4]	none	27/28 (96.4%)	14/18 (77.8%)	RR 1.24 (0.96 to 1.6)	187 more per 1000 (from 31 fewer to 467 more)	⊕OOO VERY LOW	IMPORTANT
Admission at birth to the neonatal unit (non-event)												
1 (Wedenberg 2000)	randomised trials	very serious[1]	no serious inconsistency	serious[2]	very serious[3]	none	0/28 (0%)	0/18 (0%)	RD 0 (-0.09 to 0.09)	0 fewer per 1000 (from 90 fewer to 90 more)	⊕OOO VERY LOW	IMPORTANT

CI: confidence interval; RD: risk difference; RR: risk ratio
[1] Evidence downgraded by 2 levels due to high risk regarding blinding of participants, missing outcome data (>20% dropout rate in control arm) and other bias (participants in the physiotherapy group received other treatments), and unclear risk of bias regarding randomisation process, measurement of the outcome, and selection of the reported result.
[2] Evidence downgraded by 1 level as 22% of the physiotherapy group had only back pain
[3] Evidence downgraded by 2 levels due to very serious imprecision surrounding small sample size.
[4] Evidence downgraded by 1 level because 95% CI crosses one default MID for dichotomous outcomes (0.8 or 1.25).

Table 8: Clinical evidence profile for comparison of acupuncture and standard treatment versus physiotherapy-delivered in-home exercise advice and standard treatment

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Acupuncture + Standard treatment	Physiotherapy-delivered in-home exercise advice + Standard treatment	Relative (95% CI)	Absolute		
Pain intensity during pregnancy - pain intensity in the morning (median) (follow-up 7 days; measured with: Visual analogue scale; range of scores: 0-100; Better indicated by lower values)												
1 (Elden 2005/2008b)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	107	108	-	acupuncture + standard median 15 (IQR 7 to 29), physiotherapy + standard median 18 (IQR 9 to 37), p=NS	⊕⊕OO LOW	CRITICAL
Pain intensity during pregnancy - pain intensity in the evening (median) (follow-up 7 days; measured with: Visual analogue scale; range of scores: 0-100; Better indicated by lower values)												
1 (Elden 2005/2008b)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	107	108	-	acupuncture + standard median 31 (IQR 12 to 58), physiotherapy + standard median 45 (IQR 21 to 68), p=0.01	⊕⊕OO LOW	CRITICAL
Adverse effects during pregnancy - adverse events (assessed with: Self-reported)												
1 (Elden 2005/2008b)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	43/125 (34.4%)	22/131 (16.8%)	RR 2.05 (1.3 to 3.22)	176 more per 1000 (from 50 more to 373 more)	⊕⊕⊕O MODERATE	IMPORTANT
Women's experience and satisfaction with care - No pain relief from treatment (follow-up 7 days)												
1 (Elden 2005/2008b)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	2/108 (1.9%)	5/111 (4.5%)	RR 0.41 (0.08 to 2.07)	27 fewer per 1000 (from 41 fewer to 48 more)	⊕OOO VERY LOW	IMPORTANT
Women's experience and satisfaction with care - Treatment harmful (follow-up 7 days)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Acupuncture + Standard treatment	Physiotherapy-delivered in-home exercise advice + Standard treatment	Relative (95% CI)	Absolute		
1 (Elden 2005/2008b)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	43/108 (39.8%)	22/111 (19.8%)	RR 2.01 (1.29 to 3.12)	200 more per 1000 (from 57 more to 420 more)	⊕⊕⊕O MODERATE	IMPORTANT
Women's experience and satisfaction with care - Treatment no help (follow-up 7 days)												
1 (Elden 2005/2008b)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	4/108 (3.7%)	2/111 (1.8%)	RR 2.06 (0.38 to 10.99)	19 more per 1000 (from 11 fewer to 180 more)	⊕OOO VERY LOW	IMPORTANT
Women's experience and satisfaction with care - Treatment good or very good help (follow-up 7 days)												
1 (Elden 2005/2008b)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	83/108 (76.9%)	81/111 (73%)	RR 1.05 (0.9 to 1.23)	36 more per 1000 (from 73 fewer to 168 more)	⊕⊕⊕O MODERATE	IMPORTANT
Admission at birth to the neonatal unit												
1 (Elden 2005/2008b)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	6/125 (4.8%)	9/131 (6.9%)	RR 0.7 (0.26 to 1.91)	21 fewer per 1000 (from 51 fewer to 63 more)	⊕OOO VERY LOW	IMPORTANT

CI: confidence interval; IQR: interquartile range; RR: risk ratio
[1] Evidence downgraded by 1 level due to high risk of bias regarding deviations from intended interventions, and unclear risk of bias regarding allocation concealment and Selection of the reported result.
[2] Evidence downgraded by 1 level due to serious imprecision surrounding small sample size.
[3] Evidence downgraded by 2 levels because 95% CI crosses two default MIDs for dichotomous outcomes (0.8 and 1.25).

Table 9: Clinical evidence profile for comparison of manual therapy (chiropractic treatment) versus standard treatment

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Manual therapy (Chiropractic treatment)	Standard treatment	Relative (95% CI)	Absolute		
Pain intensity during pregnancy - pain intensity between week 21 and 30 of pregnancy (follow-up 6 weeks; measured with: Visual analogue scale; range of scores: 0-100; Better indicated by lower values)												
1 (Gausel 2017)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	25	21	-	MD 3.7 lower (15.92 lower to 8.52 higher)	⊕OOO VERY LOW	CRITICAL
Pain intensity during pregnancy - pain intensity between week 33 and 40 of pregnancy (follow-up 6 weeks; measured with: Visual analogue scale; range of scores: 0-100; Better indicated by lower values)												
1 (Gausel 2017)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	24	21	-	MD 3.9 lower (21.81 lower to 14.01 higher)	⊕OOO VERY LOW	CRITICAL
Pelvic-related functional disability/functional status during pregnancy - pelvic-related functional disability at week 30 of pregnancy (follow-up 6 weeks; measured with: Oswestry disability index (ODI) questionnaire; range of scores: 0-100; Better indicated by lower values)												
1 (Gausel 2017)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	25	21	-	MD 2.6 higher (6.58 lower to 11.78 higher)	⊕OOO VERY LOW	CRITICAL
Days off work/sick leave during pregnancy or prior to maternity leave - New sick leave due to pelvic girdle pain and/or lower back pain (weeks 19-30)												
1 (Gausel 2017)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	7/21 (33.3%)	8/21 (38.1%)	RR 0.88 (0.39 to 1.98)	46 fewer per 1000 (from 232 fewer to 373 more)	⊕OOO VERY LOW	IMPORTANT
Days off work/sick leave during pregnancy or prior to maternity leave - New sick leave due to pelvic girdle pain and/or lower back pain (week 31-36)												
1 (Gausel 2017)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	8/28 (28.6%)	10/28 (35.7%)	RR 0.72 (0.36 to 1.45)	100 fewer per 1000 (from 229 fewer to 161 more)	⊕OOO VERY LOW	IMPORTANT

CI: confidence interval; MD: mean difference; RR: risk ratio
[1] Evidence downgraded by 2 levels due to high risk of bias regarding blinding of personnel, selection of the reported result, some baseline imbalances between groups, and unclear risk of bias regarding randomisation process and allocation concealment.

[2] Evidence downgraded by 2 levels because 95% CI cross 2 MIDs for continuous outcomes (0.5 x control group SD =8.25 for pain intensity, 5.57 for pelvic-related disability)
[3] Evidence downgraded by 2 levels because 95% CI crosses two default MIDs for dichotomous outcomes (0.8 and 1.25).

Table 10: Clinical evidence profile for comparison of manual therapy (craniosacral therapy) and standard treatment versus standard treatment

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Manual therapy (Craniosacral therapy) + Standard treatment	Standard treatment	Relative (95% CI)	Absolute		
Pain intensity during pregnancy - pain intensity in the morning (median) (follow-up 7 days; measured with: Visual analogue scale; range of scores: 0-100; Better indicated by lower values)												
1 (Elden 2008a)	randomised trials	no serious risk of bias	no serious inconsistency	very serious[1]	very serious[2]	none	63	60	-	manual therapy + standard median 27 (95% CI from 25 to 36), standard median 35 (95% CI from 34 to 46), p=0.02	⊕OOO VERY LOW	CRITICAL
Pain intensity during pregnancy - pain intensity in the evening (median) (follow-up 7 days; measured with: Visual analogue scale; range of scores: 0-100; Better indicated by lower values)												
1 (Elden 2008a)	randomised trials	no serious risk of bias	no serious inconsistency	very serious[1]	very serious[2]	none	63	60	-	manual therapy + standard median 58 (95% CI from 48 to 60), standard median 66 (95% CI from 55 to 67), p=0.08	⊕OOO VERY LOW	CRITICAL
Pain intensity during pregnancy - pelvic girdle pain discomfort (median) (follow-up 7 days; measured with: Visual analogue scale; range of scores: 0-100; Better indicated by lower values)												
1 (Elden 2008a)	randomised trials	no serious risk of bias	no serious inconsistency	very serious[1]	very serious[2]	none	63	60	-	manual therapy + standard median 51.5 (95% CI from 45 to 59), standard median 51 (95% CI from 42 to 70), p=0.43	⊕OOO VERY LOW	CRITICAL
Pelvic-related functional disability/functional status during pregnancy (median) (follow-up 7 days; measured with: Disability rating index questionnaire; range of scores: 0-100; Better indicated by lower values)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Manual therapy (Craniosacral therapy) + Standard treatment	Standard treatment	Relative (95% CI)	Absolute		
1 (Elden 2008a)	randomised trials	no serious risk of bias	no serious inconsistency	very serious[1]	very serious[2]	none	63	60	-	manual therapy + standard median 58 (95% CI from 50 to 66), standard median 61.5 (95% CI from 54 to 72) , p=0.30	⊕OOO VERY LOW	CRITICAL
Pelvic-related functional disability/functional status during pregnancy (median) (follow-up 7 days; measured with: Oswestry Disability Index questionnaire-revised version; range of scores: 0-100; Better indicated by lower values)												
1 (Elden 2008a)	randomised trials	no serious risk of bias	no serious inconsistency	very serious[1]	very serious[2]	none	63	60	-	manual therapy + standard median 40 (95% CI from 34 to 46), standard median 48 (95% CI from 40 to 56), p=0.02	⊕OOO VERY LOW	CRITICAL
Days off work/sick leave during pregnancy or prior to maternity leave - Sick leave (follow-up 7 days)												
1 (Elden 2013)	randomised trials	no serious risk of bias	no serious inconsistency	very serious[1]	very serious[3]	none	15/63 (23.8%)	10/60 (16.7%)	RR 1.43 (0.7 to 2.93)	72 more per 1000 (from 50 fewer to 322 more)	⊕OOO VERY LOW	IMPORTANT

CI: confidence interval; RR: risk ratio
[1] Evidence downgraded by 2 levels as 47% of the sample are women with severe pelvic pain.
[2] Evidence downgraded by 2 levels due to very serious imprecision surrounding small sample size.
[3] Evidence downgraded by 2 levels because 95% CI crosses two default MIDs for dichotomous outcomes (0.8 and 1.25).

Table 11: Clinical evidence profile for comparison of manual therapy (foot manipulation) and physiotherapy-delivered in-home exercise advice versus sham manual therapy (sham foot manipulation) and physiotherapy-delivered in-home exercise advice

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Manual therapy (Foot manipulation) + Physiotherapy-delivered in-home exercise advice	Sham manual therapy (sham foot manipulation) + Physiotherapy-delivered in-home exercise advice	Relative (95% CI)	Absolute		
Pain intensity during pregnancy - pain intensity in pelvic region at morning (measured with: Visual analogue scale after 6th weekly session; range of scores: 0-100; Better indicated by lower values)												
1 (Melkersson 2017)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	31	39	-	MD 9 lower (19.78 lower to 1.78 higher)	⊕⊕OO LOW	CRITICAL
Pain intensity during pregnancy - pain intensity in pelvic region at evening (measured with: Visual analogue scale after 6th weekly session; range of scores: 0-100; Better indicated by lower values)												
1 (Melkersson 2017)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	29	33	-	MD 18 lower (29.97 to 6.03 lower)	⊕⊕OO LOW	CRITICAL
Pain intensity during pregnancy - pain in symphysis (measured with: Visual analogue scale after 6th weekly session; range of scores: 0-100; Better indicated by lower values)												
1 (Melkersson 2017)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	28	27	-	MD 3 lower (11.54 lower to 5.54 higher)	⊕⊕OO LOW	CRITICAL

CI: confidence interval; MD: mean difference
[1] Evidence downgraded by 1 level due to high risk of bias regarding blinding of participants/personnel and unclear risk of bias regarding randomisation process and allocation concealment.
[2] Evidence downgraded by 1 levels because 95% CI cross 1 MID for continuous outcomes (0.5 x control group SD = 8 for pelvic pain in the morning at first follow up, 11.5 for pelvic pain in the evening at first follow up, 8.5 for symphysis pain before treatment)

Table 12: Clinical evidence profile for comparison of pelvic girdle support belt and information versus information

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pelvic girdle support belt + Information	Information	Relative (95% CI)	Absolute		
Pain intensity during pregnancy - pain intensity (measured with: Visual analogue scale: range of scores: 0-100; Better indicated by lower values)												
1 (Kordi 2013)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	34	31	-	MD 34.2 lower (41.62 to 26.78 lower)	⊕⊕OO LOW	CRITICAL
Pelvic-related functional disability/functional status during pregnancy - (measured with: Oswestry disability index questionnaire; range of scores: 0-100; Better indicated by lower values)												
1 (Kordi 2013)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	34	31	-	MD 5.6 lower (9.86 to 1.34 lower)	⊕OOO VERY LOW	CRITICAL

CI: confidence interval; MD: mean difference
[1] Evidence downgraded by 2 levels due to high risk of bias regarding blinding, unclear risk of bias regarding allocation concealment and measurement of the outcome.
[2] Evidence downgraded by 1 levels because 95% CI cross 1 MID for continuous outcomes (0.5 x control group SD = 5.85 for pelvic-related functional disability at baseline).

Table 13: Clinical evidence profile for comparison of pelvic girdle support belt and information versus physiotherapy-delivered in-home exercise advice and information

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pelvic girdle support belt + Information	Physiotherapy-delivered in-home exercise advice + Information	Relative (95% CI)	Absolute		
Pain intensity during pregnancy - pain intensity (measured with: Visual analogue scale; range of scores: 0-100; Better indicated by lower values)												
1 (Kordi 2013)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	34	31	-	MD 20.10 lower (28.29 to 11.91 lower)	⊕⊕OO LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pelvic girdle support belt + Information	Physiotherapy-delivered in-home exercise advice + Information	Relative (95% CI)	Absolute		
Pelvic-related functional disability/functional status during pregnancy - (measured with: Oswestry disability index questionnaire; range of scores: 0-100; Better indicated by lower values)												
1 (Kordi 2013)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	34	31	-	MD 1.4 lower (5.13 lower to 2.33 higher)	⊕⊕□OLOW	CRITICAL

CI: confidence interval; MD: mean difference
[1] Evidence downgraded by 2 levels due to high risk of bias regarding blinding, unclear risk of bias regarding allocation concealment and measurement of the outcome.

Table 14: Clinical evidence profile for comparison of physiotherapy-delivered in-home exercise advice versus standard treatment

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Physiotherapy-delivered in-home exercise advice	Standard treatment	Relative (95% CI)	Absolute		
Pain intensity during pregnancy - Pain intensity (measured with: Visual analogue scale after 12 weeks treatment; range of scores: 0-10; Better indicated by lower values)												
1 (Mirmolaei 2018)	randomised trials	serious[1]	no serious inconsistency	serious[2]	serious[3]	none	88	83	-	MD 2.07 lower (2.9 to 1.24 lower)	⊕OOO VERY LOW	CRITICAL
Pelvic-related functional disability/functional status during pregnancy - (measured with: Oswestry disability index questionnaire after 12 weeks treatment; range of scores: 0-100; Better indicated by lower values)												
1 (Mirmolaei 2018)	randomised trials	serious[1]	no serious inconsistency	serious[2]	serious[3]	none	88	83	-	MD 9.94 lower (14.71 to 5.17 lower)	⊕OOO VERY LOW	CRITICAL

CI: confidence interval; MD: mean difference

[1] Evidence downgraded by 1 level due to unclear risk of bias regarding randomisation process, allocation concealment, measurement of the outcome, and Selection of the reported result.
[2] Evidence downgraded by 1 level because 15% of the sample are women with back pain only
[4] Evidence downgraded by 1 levels because 95% CI cross 1 MID for continuous outcomes (0.5 x control group SD = 1.36 for pain intensity at baseline, 7.12 for pelvic-related disability at baseline).

Table 15: Clinical evidence profile for comparison of physiotherapy-delivered in-home exercise advice and standard treatment versus standard treatment

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Physiotherapy-delivered in-home exercise advice + Standard treatment	Standard treatment	Relative (95% CI)	Absolute		
Pain intensity during pregnancy - pain intensity in the morning (median) (follow-up 7 days; measured with: Visual analogue scale; range of scores: 0-100; Better indicated by lower values)												
1 (Elden 2005/2008b)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	106	108	-	physiotherapy + standard median 18 (IQR 9 to 37), standard median 27 (IQR 12 to 58), p=0.03	⊕⊕OO LOW	CRITICAL
Pain intensity during pregnancy - pain intensity in the evening (median) (follow-up 7 days; measured with: Visual analogue scale; range of scores: 0-100; Better indicated by lower values)												
1 (Elden 2005/2008b)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	106	108	-	physiotherapy + standard median 45 (IQR 21 to 68), standard median 58 (IQR 40 to 74) p=0.02	⊕⊕OO LOW	CRITICAL
Adverse effects during pregnancy - adverse events during treatment												
1 (Elden 2005/2008b)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	22/131 (16.8%)	8/130 (6.2%)	RR 2.73 (1.26 to 5.91)	106 more per 1000 (from 16 more to 302 more)	⊕⊕⊕O MODERATE	IMPORTANT
Women's experience and satisfaction with care - No pain relief from treatment (follow-up 7 days)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Physiotherapy-delivered in-home exercise advice + Standard treatment	Standard treatment	Relative (95% CI)	Absolute		
1 (Elden 2005/2008b)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	5/111 (4.5%)	3/100 (3%)	RR 1.5 (0.37 to 6.12)	15 more per 1000 (from 19 fewer to 154 more)	⊕OOO VERY LOW	IMPORTANT
Women's experience and satisfaction with care - Treatment harmful (follow-up 7 days)												
1 (Elden 2005/2008b)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	22/111 (19.8%)	51/100 (51%)	RR 0.39 (0.26 to 0.59)	311 fewer per 1000 (from 209 fewer to 377 fewer)	⊕⊕⊕O MODERATE	IMPORTANT
Women's experience and satisfaction with care - Treatment no help (follow-up 7 days)												
1 (Elden 2005/2008b)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	2/111 (1.8%)	25/100 (25%)	RR 0.07 (0.02 to 0.3)	233 fewer per 1000 (from 175 fewer to 245 fewer)	⊕⊕⊕O MODERATE	IMPORTANT
Women's experience and satisfaction with care - Treatment good or very good help (follow-up 7 days)												
1 (Elden 2005/2008b)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	81/111 (73%)	22/100 (22%)	RR 3.32 (2.25 to 4.88)	510 more per 1000 (from 275 more to 854 more)	⊕⊕⊕O MODERATE	IMPORTANT
Admission at birth to the neonatal unit												
1 (Elden 2005/2008b)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	9/130 (6.9%)	6/129 (4.7%)	RR 1.49 (0.55 to 4.06)	23 more per 1000 (from 21 fewer to 142 more)	⊕OOO VERY LOW	IMPORTANT

CI: confidence interval; IQR: interquartile range; RR: risk ratio
[1] Evidence downgraded by 1 level due to high risk of bias regarding deviations from intended interventions, and unclear risk of bias regarding allocation concealment and Selection of the reported result.
[2] Evidence downgraded by 1 level due to serious imprecision surrounding small sample size'.
[3] Evidence downgraded by 2 levels because 95% CI crosses two default MIDs for dichotomous outcomes (0.8 and 1.25).

Table 16: Clinical evidence profile for comparison of physiotherapy-delivered in-home exercise advice and information versus information

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Physiotherapy-delivered in-home exercise advice + Information	Information	Relative (95% CI)	Absolute		
Pain intensity during pregnancy - pain intensity (measured with: Visual analogue scale after 6 weeks treatment; range of scores: 0-100; Better indicated by lower values)												
1 (Kordi 2013)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	34	31	-	MD 14.1 lower (22.14 to 6.06 lower)	⊕OOO VERY LOW	CRITICAL
Pelvic-related functional disability/functional status during pregnancy - (measured with: Oswestry disability index questionnaire after 6 weeks treatment; range of scores: 0-100; Better indicated by lower values)												
1 (Kordi 2013)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	34	31	-	MD 4.2 lower (8.55 lower to 0.15 higher)	⊕OOO VERY LOW	CRITICAL

CI: confidence interval; MD: mean difference
[1] Evidence downgraded by 2 levels due to high risk of bias regarding blinding unclear risk of bias regarding allocation concealment and measurement of the outcome.
[2] Evidence downgraded by 1 levels because 95% CI cross 1 MID for continuous outcomes (0.5 x control group SD = 6.90 for pain intensity at baseline, 5.85 for pelvic-related disability at baseline).

Table 17: Clinical evidence profile for comparison of physiotherapy-delivered in-home exercise advice + information + pelvic girdle support belt versus information + pelvic girdle support belt

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Physiotherapy-delivered in-home exercise advice + Information + Pelvic girdle support belt	Information + Pelvic girdle support belt	Relative (95% CI)	Absolute		
Pain intensity during pregnancy - pain intensity (median) (measured with: Visual analogue scale at 38 weeks gestation; range of scores: 0-100; Better indicated by lower values)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Physiotherapy-delivered in-home exercise advice + Information + Pelvic girdle support belt	Information + Pelvic girdle support belt	Relative (95% CI)	Absolute		
1 (Nilsson-Wikmar 2005)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	41	40	-	physiotherapy in home + information + support belt median 50 (IQR 18 to 99), information + support belt median 49 (IQR 0 to 98), p=0.82[3]	⊕OOO VERY LOW	CRITICAL
Pelvic-related functional disability/functional status during pregnancy (median) (measured with: Disability rating index questionnaire at 38 weeks gestation; range of scores: 0-100; Better indicated by lower values)												
1 (Nilsson-Wikmar 2005)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	41	40	-	physiotherapy in home + information + support belt median 66 (IQR 21 to 91), information + support belt median 65 (IQR 13 to 92), p=0.58[3]	⊕OOO VERY LOW	CRITICAL

CI: confidence interval; IQR: interquartile range
[1] Evidence downgraded by 2 levels due to high risk of bias regarding blinding, randomisation process and imbalances between groups, and unclear risk of bias regarding allocation concealment and selection of the reported result.
[2] Evidence downgraded by 2 levels due to very serious imprecision surrounding small sample size.
[3] p value for group effect including 3 arms of trial, see clinical evidence table for more information.

Table 18: Clinical evidence profile for comparison of physiotherapy-delivered in-home exercise advice + information + pelvic girdle support belt versus physiotherapy-delivered in-clinic exercise advice + information + pelvic girdle support belt

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Physiotherapy-delivered in-home exercise advice + Information + Pelvic girdle support belt	Physiotherapy-delivered in-clinic exercise advice + Information + Pelvic girdle support belt	Relative (95% CI)	Absolute		
Pain intensity during pregnancy - pain intensity (median) (measured with: Visual analogue scale at 38 weeks gestation; range of scores: 0-100; Better indicated by lower values)												
1 (Nilsson-Wikmar 2005)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	41	37	-	physiotherapy in home + information + support belt median 50 (IQR 18 to 99), physiotherapy in clinic + information + support belt median 62 (IQR 0 to 100), p=0.82[3]	⊕OOO VERY LOW	CRITICAL
Pelvic-related functional disability/functional status during pregnancy (median) (measured with: Disability Rating Index questionnaire at 38 weeks gestation; range of scores: 0-100; Better indicated by lower values)												
1 (Nilsson-Wikmar 2005)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	41	37	-	physiotherapy in home + information + support belt median 66 (IQR 21 to 91), physiotherapy in clinic + information + support belt median 59 (IQR 14 to 91), p=0.58[3]	⊕OOO VERY LOW	CRITICAL

CI: confidence interval; IQR: interquartile range
[1] Evidence downgraded by 2 levels due to high risk of bias regarding blinding, randomisation process and imbalances between groups, and unclear risk of bias regarding allocation concealment and selection of the reported result.
[2] Evidence downgraded by 2 levels due to very serious imprecision surrounding small sample size.
[3] p value for group effect including 3 arms of trial, see clinical evidence table for more information.

Table 19: Clinical evidence profile for comparison of physiotherapy-delivered in-clinic exercise advice + information + pelvic girdle support belt versus information + pelvic girdle support belt

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Physiotherapy-delivered in-clinic exercise advice + Information + Pelvic girdle support belt	Information + Pelvic girdle support belt	Relative (95% CI)	Absolute		
Pain intensity during pregnancy - pain intensity (median) (measured with: Visual analogue scale at 38 weeks gestation; range of scores: 0-100; Better indicated by lower values)												
1 (Nilsson-Wikmar 2005)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	37	40	-	physiotherapy in clinic + information + support belt median 62 (IQR 0 to 100), information + support belt median 49 (IQR 0 to 98), p=0.82[3]	⊕OOO VERY LOW	CRITICAL
Pelvic-related functional disability/functional status during pregnancy (median) (measured with: Disability rating index questionnaire at 38 weeks gestation; range of scores: 0-100; Better indicated by lower values)												
1 (Nilsson-Wikmar 2005)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	37	40	-	physiotherapy in clinic + information + support belt median 59 (IQR 14 to 91), information + support belt median 65 (IQR 13 to 92), p=0.58[3]	⊕OOO VERY LOW	CRITICAL

CI: confidence interval; IQR: interquartile range
[1] Evidence downgraded by 2 levels due to high risk of bias blinding, regarding randomisation process and imbalances between groups, and unclear risk of bias regarding allocation concealment and selection of the reported result.
[2] Evidence downgraded by 2 levels due to very serious imprecision surrounding small sample size.
[3] p value for group effect including 3 arms of trial, see clinical evidence table for more information.

Appendix G – Economic evidence study selection

Economic evidence study selection for review question: What interventions are effective in treating mild to moderate pelvic girdle pain during pregnancy?

A single economic search was undertaken for all topics included in the scope of this guideline. No economic studies were identified which were applicable to this review question. See supplementary material 2 for details.

Appendix H – Economic evidence tables

Economic evidence tables for review question: What interventions are effective in treating mild to moderate pelvic girdle pain during pregnancy?

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

Appendix I – Economic evidence profiles

Economic evidence profiles for review question: What interventions are effective in treating mild to moderate pelvic girdle pain during pregnancy?

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

Appendix J – Economic analysis

Economic analysis for review question: What interventions are effective in treating mild to moderate pelvic girdle pain during pregnancy?

1.1 Introduction

A high proportion of women experience some form of pelvic girdle pain during pregnancy. Whilst current practice is variable, the committee advised it is most common to offer mild analgesics (such as paracetamol) to women who experience mild to moderate pelvic girdle pain during pregnancy. Evidence from the accompanying guideline systematic review pointed towards use of a lumbopelvic belt being an effective intervention as its use reduces pain intensity and improves quality of life when compared to alternate interventions.

No existing economic evidence on the cost effectiveness of interventions in treating pelvic girdle pain during pregnancy was found in the global health economic search. As a result of this decision uncertainty and the potential resource impact that may incur, the committee felt this topic area warranted bespoke economic analysis in order to inform their consideration of all available evidence.

This analysis compares the cost effectiveness of a non-rigid lumbopelvic support belt vs. (i) information only or (ii) exercise. Clinical effectiveness and quality of life in the model is informed by one study (Kordi 2013) that was included in the accompanying clinical evidence review. This analysis does not consider other interventions as the identified evidence was deemed insufficient to meaningfully include them in a cost effectiveness model.

1.1.1 Aim

To estimate the cost-effectiveness of use of a lumbopelvic support belt compared to usual care (set as either information only or exercise) for treating mild to moderate pelvic girdle pain in pregnant women.

1.2 Methods

1.2.1 Cost utility analysis (CUA)

This economic evaluation is conducted in the form of a cost-utility analysis (CUA), with outcomes expressed in terms of cost per quality-adjusted life year (QALY) gained. The cost effectiveness of an intervention is determined by examining the incremental cost (Ci – Cc) divided by the incremental effect (Ei – Ec), where Ci and Cc represent the cost of the intervention and comparator groups respectively, and Ei and Ec represent the outcomes of the intervention and comparator groups respectively. This analysis has assumed use of a lumbopelvic belt as the intervention as this is not routinely offered on the NHS and information or exercise only as the comparators. The main result is expressed as the incremental cost effectiveness ratio (ICER) and incremental net monetary benefit (iNMB). The analysis was conducted from the perspective of the NHS and Personal Social Services (PSS), as outlined in the NICE Reference Case.

1.2.2 Setting and population

The model setting was for the NHS and the population were pregnant women with mild to moderate pelvic girdle pain (also known as ‘symphysis pubis dysfunction’).

1.2.3 Interventions considered

This model considers three potential treatment strategies:

- A non-rigid lumbopelvic belt

Versus.

- Information Only or
- Exercise

The interventions assessed in the economic analysis were informed from 1 randomised controlled trial (RCT) (Kordi 2013) that was included in the accompanying guideline systematic review.

The information only (main control) group received general information about body posture and received ergonomic advice regarding sitting, walking and lying. Women in the exercise group, in addition to receiving information on body posture were assigned a home based exercise program with exercises that were designed to strengthen the pelvic girdle muscles. Specifically, the participants were asked to perform activities which included; 1) aerobic exercises: brisk walking with a medium intensity (defined as 64 to 76% of maximum heart rate) for 25 minutes per day and 3 days per week. 2) Stretching exercises: performing hamstring, inner thigh, side waist, quadriceps and back stretch for 3 times per week. 3) Strengthening exercises: a program including forward bending, back pressing, diagonal curling, upper body bending, leg lift crawling along with Kegel exercise and pelvic tilt was given to the patients. The patients were asked to repeat each exercise (duration of each occasion was asked to be 3 to 10 seconds) 3 to 5 times per each exercise session for both sides of the body while performing 2 exercise bouts per day and 3 days per week. The belt group, in addition to receiving information, received a non-rigid lumbopelvic support belt. Women were asked to use the belt during the course of the study and were advised to only remove the belt whilst sleeping. There was no evidence identified for other outcomes that could impact the results of the analysis such as; adverse effects during pregnancy, days in hospital admitted to antenatal ward for treatment of pelvic girdle pain and admission of baby at birth to the neonatal unit.

As the clinical study informing this analysis was from Iran, a number of assumptions were made in order to reflect the decision making context of the UK NHS. Currently, non-rigid lumbopelvic support belts are not routinely offered to women during pregnancy and so was set as the intervention in this analysis. Assigning the comparator was slightly more ambiguous. The committee believed that standard care varied greatly, though advised that an appropriate comparator typically involves offering a woman a mild analgesic. The committee also advised that current practice may involve some postural advice and therefore, the information only and exercise group were set as the comparators in this economic evaluation.

The Kordi study did not provide information on what form participants received each intervention which made it difficult to assess resource use. There were some views amongst the committee that the initial fitting of a lumbopelvic support belt would be provided by a physio. It was also assumed that information on body posture or exercise would also be provided by an initial physio session. Therefore, the main analysis assumes that the cost of a physio appointment is incurred by all three interventions.

However, many committee members also took the view that in current practice, none of the groups compared would receive physio support. Owing to this uncertainty on resource use, a separate analysis was conducted whereby only the belt group incurs the cost of physiotherapy.

It was anticipated prior to conducting this analysis that the results may be sensitive to many different assumptions on resource use. For this reason, the model was designed to allow for

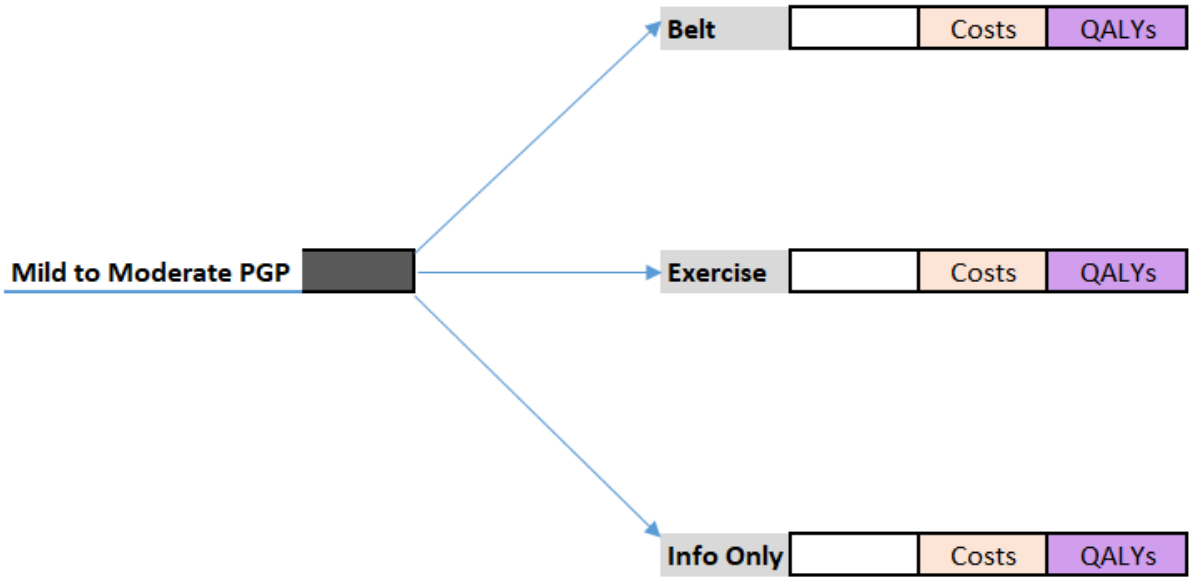
many dynamic sensitivity analyses on all input parameters to inform the committee's discussion of evidence during the committee meeting. The extent to which different scenario analyses impact the cost effectiveness interpretation will be will reflected in the discussion section.

1.2.4 Model structure

A simple decision tree was developed in Microsoft Excel® and Visual Basic (VBA). The model estimated the costs and quality of life gains associated with each treatment strategy. The time horizon of 6 weeks was determined by the availability of the length of the clinical trial and the lack of data on long term outcomes. An assumption is therefore implicitly made that there are no long term consequences of PGP on costs or quality of life. A schematic of the model is illustrated in Figure 3. A hypothetical cohort of patients is assigned to receiving either a lumbopelvic support belt or is assigned to a control treatment. The control group in this analysis is defined as either information only or exercise advice. All appropriate costs and QALYs for each treatment strategy are accrued according to the full length of the time horizon.

In keeping with the NICE Reference Case, all input parameters are assigned a probability distribution, from which Monte Carlo simulation is performed to express the results in the form of a probabilistic sensitivity analysis (PSA).

Figure 3: Model schematic of the cost effectiveness of interventions that relieve mild to moderate pelvic girdle pain (PGP) in pregnant women



1.2.5 Clinical outcomes and health-related quality of life

As recommended in the NICE reference case, the model estimates effectiveness in terms of QALYs. Typically, these are estimated by combining the life year estimates with utility values (or quality of life weights) associated with being in a particular health state. Utility values are on a scale of 0 (death) to 1 (perfect health). In this analysis, clinical effectiveness is expressed in the form of quality of life which is also used to inform the number of QALYs attributed to each intervention.

The time horizon of this analysis (as informed by the clinical review) is less than one year. Therefore, the QALY formula (which includes 'life years') is reorganised to calculate QALYs at each point of measurement for each treatment strategy:

[((Utility_Base + Utility_3rd week)/2)*(21/365.25)] + [((Utility_3rd week + Utility_6th week)/2)*(21/365.25)]

The NICE reference case preferred measure of HRQoL for use in cost utility analysis is the EuroQol five dimensions questionnaire (EQ-5D) (Brooks 1996) with preference 'weights' derived from the general population. No EQ-5D data was found for the relevant population of this analysis.

Kordi 2013 measured pain intensity and functional status using the visual analogue scale (VAS) and Oswestry Disability Index (ODI). However, neither of these measurements are *preference* based and thereby do not enable the computation of QALYs. The study does however measure HRQoL using the shorter version of the World Health Organisation's Quality of Life Questionnaire WHOQOL-BREF (WHO 1996) questionnaire which includes domains on physical health, psychosocial health, social relationships and environmental health. Measurements for all domains were taken from all treatments arms at baseline, 3 weeks and 6 weeks, as displayed in Table 20. It was anticipated that the responses to the WHOQOL-BREF could be converted into utilities (to enable the computation of QALYs) scores using a published algorithm.

Table 20: Mean WHOQOL-BREF scores at baseline, 3 weeks and 6 weeks as reported in Kordi 2013

Variables		Control	Exercise	Belt
Physical Health	Baseline	47.8 ± 15.82	51.1 ± 15.89	46.67 ± 16.47
	3rd Week	53.2 ± 15.39	55.0 ± 14.59	63.44 ± 14.25
	6th Week	52.7 ± 15.82	60.9 ± 13.95	68.68 ± 13.73
Psychosocial Health	Baseline	60.82 ± 12.27	53.5 ± 15.02	55.3 ± 13.77
	3rd Week	61.28 ± 12.03	55.5 ± 14.20	60.41 ± 12.78
	6th Week	61.55 ± 12.01	57.2 ± 13.34	61.51 ± 12.64
Social Relationships	Baseline	63.4 ± 10.47	62.1 ± 14.08	56.6 ± 16.34
	3rd Week	63.7 ± 10.44	63.2 ± 13.90	58.5 ± 14.93
	6th Week	63.7 ± 10.44	63.2 ± 13.90	58.8 ± 14.60
Environmental Health	Baseline	69.9 ± 11.45	63.8 ± 9.77	63.7 ± 13.95
	3rd Week	70.0 ± 11.40	64.4 ± 9.29	65.1 ± 14.23
	6th Week	70.2 ± 11.53	64.4 ± 9.29	65.4 ± 14.21

The only identified published study linking the WHOQOL survey to preference based data is Wee 2018 which links the WHOQOL-100 to the EQ-5D-5L. This study, based on a Singaporean population sample, links scores by linear regression from the physical domain of the WHOQOL-100 to EQ-5D utilities. The OLS mapping equation included in the study is:

$$[\text{EQ-5D utility} = 0.2621 - 46.87768 * \text{Physical}^{-2} + 0.1327 * \text{Physical}^{-0.5}]$$

As mentioned, Kordi 2013 used a shorter version of the WHOQOL-100 called the 'WHOQOL-BREF' (WHO 1996). Thus, the originally reported 'BREF' scores were converted to WHOQOL-100 scores (WHO, 1996) and these WHOQOL-100 values were then used as inputs in the regression equation provided by Wee 2018 to compute EQ-5D utility data. The converted EQ-5D utilities which were used as the model inputs are listed in Table 21. As this was converted EQ-5D data, it was felt that the triangular distribution using the low/high confidence intervals, as informed from the Kordi study, was more appropriate to use than assuming a beta distribution in the PSA. These values were also adjusted in the model so that all treatments had the same baseline utility, with the proportionate increases in utility kept the same. These converted values still had face validity with the original WHOQOL-100

scores, that is the 6th week HRQoL for information only was the lower than the 3rd week in both the WHOQOL-100 and the EQ-5D.

Table 21: EQ-5D utilities using Wee (2018) algorithm

Utility	Deterministic	Low CI	High CI	Probabilistic Distribution	Source
Information only - base	0.755	0.633	0.863	triangular	Clinical review (Kordi 2013) → EQ-5D (Wee 2018)
Information only – 3rd week	0.801	0.704	0.900	triangular	Clinical review (Kordi 2013) → EQ-5D (Wee 2018)
Information only – 6th week	0.755	0.704	0.900	triangular	Clinical review (Kordi 2013) → EQ-5D (Wee 2018)
Belt – base	0.755	0.633	0.863	triangular	Clinical review (Kordi 2013) → EQ-5D (Wee 2018)
Belt – 3rd week	0.868	0.787	0.917	triangular	Clinical review (Kordi 2013) → EQ-5D (Wee 2018)
Belt – 6th Week	0.904	0.833	0.949	triangular	Clinical review (Kordi 2013) → EQ-5D (Wee 2018)
Exercise - base	0.755	0.633	0.863	triangular	Clinical review (Kordi 2013) → EQ-5D (Wee 2018)
Exercise – 3rd week	0.801	0.633	0.863	triangular	Clinical review (Kordi 2013) → EQ-5D (Wee 2018)
Exercise – 6th week	0.842	0.691	0.880	triangular	Clinical review (Kordi 2013) → EQ-5D (Wee 2018)

1.2.6 Costs and resource Use

In accordance with NICE methodology, a NHS and Personal Social Services (PSS) perspective was adopted for this analysis. Costing was based on a 2017/2018 price year reflecting the most recently available NHS Reference Costs at the time of writing. Therefore, adjusting for inflation was deemed unnecessary. Costs were not discounted as all outcomes were assumed to occur within a year of treatment. The unit costs used in this economic analysis are listed in Table 22.

The accompanying clinical evidence review did not describe the setting in which the belt is offered. The committee believed, where a lumbopelvic belt is currently offered in the UK, it would be once a woman has already been referred to a physio and would be given advice on fitting. The committee were also of the view that a lumbopelvic belt might be offered at an antenatal care visit without referral to a physio. The default of this analysis assumes that all

treatment strategies are offered once a woman has been referred for an initial physio appointment. Given that the costs for a physio appointment are the highest cost input in the model, sensitivity analysis explored the impact of differing assumptions of this input.

There was considerable doubt around the correct costing of a lumbopelvic belt as there were no belts that included the word 'lumbopelvic' in the NHS supply catalogue, or of anything similar. In addition, the committee felt they did not possess the relevant knowledge to suggest a particular product. Thus, a decision was taken to use the 'Pelvic Support Belt' belt (all sizes) as a proxy cost variable (£17.42, all sizes). Similar belts in the catalogue cost in the range of £16-£20. A threshold analysis was conducted to assess the extent to which a belt would have to cost in order to not be cost effective.

Table 22: Model Unit Costs

Costs	Value	α	β	Probabilistic Distribution	Source
Pelvic Support Belt (all sizes)[a]	£17.42	11.11	1.57	gamma	NHS supply catalogue (2018) - 378555
Initial physio appointment	£61	11.11	5.49	gamma	NHS reference costs (2017-2018) - WF01B
Paracetamol, 500mg capsules[b]	£1.72	11.11	0.15	gamma	NHS Drug Tariff Part VIIIA (August 2019)
Information leaflet[c]	£1.00	11.11	0.09	gamma	Assumption [c]

(a) Proxy for most relevant cost for a lumbopelvic support belt.
(b) Cost per person based on a dosage of 4 times a day for two weeks.
(c) A conservatively high hypothetical cost of one leaflet.

1.2.7 Data analysis and presentation of results

A PSA was undertaken using Monte Carlo simulation in order to reflect uncertainty inherent in the model parameters by sampling from an assigned probability distribution to each model input. The mean costs and QALYs were calculated across all simulations and, as a summary measure of cost effectiveness, a mean iNMB was calculated based on a cost effectiveness threshold of £20,000 per QALY gained.

The results are also presented in deterministic form, where the results are computed from the original point estimates. In addition, a series of one-way sensitivity analyses were also undertaken, where a single parameter is varied according to a specified high/value, whilst holding all other inputs constant at their deterministic value. All relevant parameters were varied in order to ascertain the key drivers of the model. The degree to which varying one input impacts on the mean iNMB are stacked in rank order and have an appearance of a 'Tornado'. The values used in the analysis are displayed in Table 23.

Table 23: Tornado diagram inputs

Variable	Low Value	High Value	Rationale for value
Pelvic support belt †	1	180	Extreme low and high due to uncertainty of belt cost

Variable	Low Value	High Value	Rationale for value
Initial Physio appointment	50	100	Plausible range
Utility: Information only - base	0.633	0.863	Low/high confidence interval
Utility: Information only - 3rd week	0.704	0.900	Low/high confidence interval
Utility: Information only - 6th week	0.704	0.900	Low/high confidence interval
Utility: Belt - base	0.633	0.863	Low/high confidence interval
Utility: Belt - 3rd week	0.787	0.917	Low/high confidence interval
Utility: Belt - 6th week	0.833	0.949	Low/high confidence interval
Utility: Exercise - base	0.633	0.863	Low/high confidence interval
Utility: Exercise - 3rd week	0.633	0.863	Low/high confidence interval
Utility: Exercise - 6th week	0.691	0.880	Low/high confidence interval
Paracetamol (500mg)	£1.37	£2.06	High/Low 20% of deterministic value

(a) †Uncertainty if this is a lumbopelvic belt. High extreme value to assess impact on cost effectiveness

A threshold analysis was also conducted for the cost of a belt. In addition, scenario analysis on utility being extrapolated to 9 weeks was conducted. Kordi 2013 measured HRQoL at base and thrice weekly increments. Two assumptions tested were:

1. Utility would remain constant at 9 weeks from the value at 6 weeks, that is if utility of the belt at 6 weeks is 0.904, it would remain 0.904 at 9 weeks.
2. Utility in all interventions returns to baseline, that is if utility of the belt at base is 0.755, it would return to 0.755 at 9 weeks.

The base case analysis assumes that women receive either intervention once having been seen by a physio. However, the committee believed that this might not be an accurate reflection of current practice in some areas. It was believed that appropriate advice for fitting the belt might be important in its treatment effectiveness. Therefore, a scenario analysis was conducted where only the belt intervention receives a physio appointment.

1.4 Results

The results should be interpreted as follows. If the analysis conducted demonstrates that an intervention is less costly and more effective, it is classified as ‘dominating’ the comparator. A typical scenario is where an intervention is more effective but also costlier, in which case an ICER is considered as a measure of whether the extra cost of an intervention is an efficient use of resources for the NHS. The ICER is a composite ratio of the differences in costs, divided by the differences in QALYs.

1.4.1 Deterministic results

A deterministic analysis uses the reported point estimates to inform the model results, not taking into the account the inherent uncertainty of each parameter. Table 24 and Table 25 show the base case deterministic results for use of a belt versus information only and use of a belt versus exercise respectively. Pairwise comparisons are made with the belt set as the

intervention in each comparison due to some uncertainty as to which treatment strategy best reflected standard care.

Table 24: Deterministic (base-case) results: Comparison of incremental costs, quality adjusted life years and the resultant incremental cost effectiveness ratio of use of a lumbopelvic support belt versus information only

	Cost		QALYs		
Treatment Strategy	**Total**	**Incremental**	**Total**	**Incremental**	**ICER (n=10,000)**
Information only (standard care)	£63	-	0.090		-
Lumbopelvic support belt	£78	£16	0.098	0.08	£1,940

Table 25: Deterministic (base-case) results: Comparison of incremental costs, quality adjusted life years and the resultant incremental cost effectiveness ratio of use of a lumbopelvic support belt versus exercise

	Cost		QALYs		
Treatment Strategy	**Total**	**Incremental**	**Total**	**Incremental**	**ICER (n=10,000)**
Exercise (standard care)	£62	-	0.092		-
Lumbopelvic support belt	£78	£16	0.098	0.08	£2,930

When the belt is compared with information only, use of a belt is more effective and is costlier, resulting in an ICER of £1,940. Exercise elicits marginally more QALYs than information only, though when compared with the belt, elicits a similar ICER of £2,930.

1.4.2 Deterministic sensitivity analysis

The results of a series of one-way sensitivity analysis where the belt is compared with information only are displayed in Figure 4. This analysis displays the impact on cost effectiveness to a low/high change of the variables listed in Table 23, holding all other inputs as constant at their default values. The white translucent line in the middle represents the iNMB of the base-case analysis. The wider yellow bars indicate the variables that have the greater effect on the model output. The analysis was repeated (see Figure 5) for the comparison between the belt and exercise.

Figure 4: Tornado diagram displaying the effect of a high/low value of each parameter on the incremental net monetary benefit, set at £20,000 per QALY gained: belt versus information only

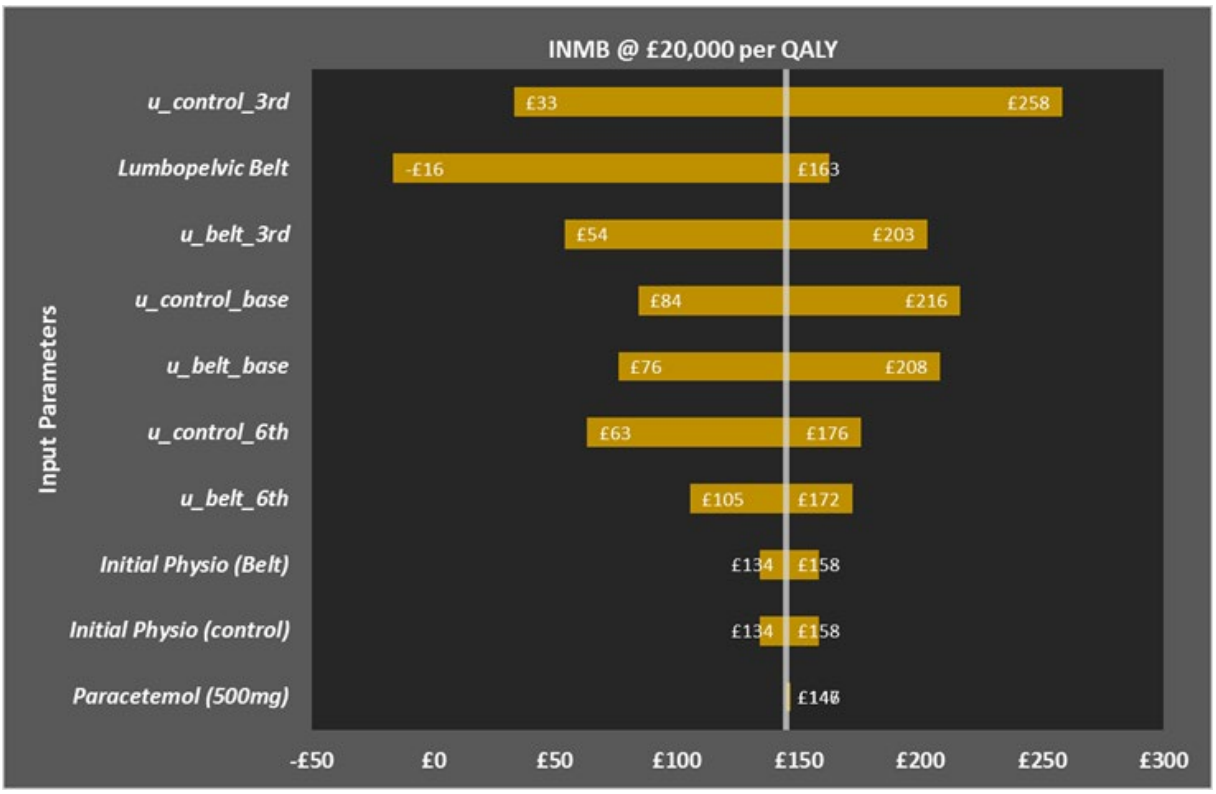
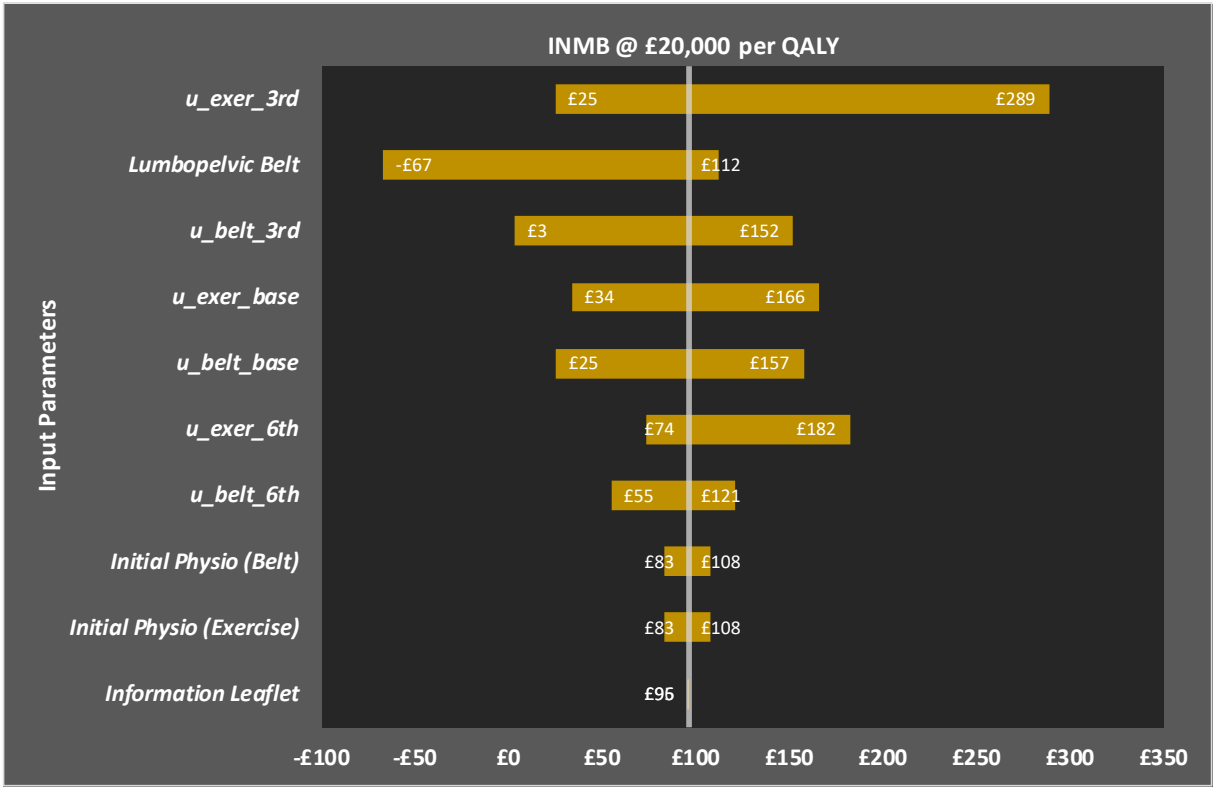


Figure 5: Tornado diagram displaying the effect of a high/low value of each parameter on the incremental net monetary benefit, set at £20,000 per QALY gained: belt versus exercise



In both Tornado diagrams, it can be seen that the cost of the belt at an arbitrarily high value of £180 is the only input which causes the iNMB to become negative. A threshold analysis indicates that the belt would need to cost £164 to not be cost effective. When the belt as an intervention is compared to exercise, the unit cost of the belt would need to be £113 to not be cost effective.

1.4.3 Scenario analysis

The following scenario analyses were conducted to assess areas of uncertainty:

1. Utility would remain constant at 9 weeks from the value at 6 weeks
2. Utility in all interventions returns to baseline
3. Only the belt intervention receives an initial physio appointment

Table 26: Utility would remain constant at 9 weeks from the value at 6 weeks: Lumbopelvic support belt versus information only (standard care)

	QALYs		
Treatment Strategy	**Total**	**Incremental**	**ICER (n=10,000)**
Information only (standard care)	0.133		-
Lumbopelvic support belt	0.150	0.017	£942

Table 27: Utility returns to base at 9 weeks: Lumbopelvic support belt versus information only (standard care)

	QALYs		
Treatment Strategy	**Total**	**Incremental**	**ICER (n=10,000)**
Information only (standard care)	0.133		-
Lumbopelvic support belt	0.145	0.012	£1,268

Table 28: Utility would remain constant at 9 weeks from the value at 6 weeks: Lumbopelvic support belt versus Exercise

	QALYs		
Treatment Strategy	**Total**	**Incremental**	**ICER (n=10,000)**
Information only (standard care)	0.141		-
Lumbopelvic support belt	0.150	0.009	£1,787

Table 29: Utility returns to base at 9 weeks: Lumbopelvic support belt versus Exercise

	QALYs		
Treatment Strategy	**Total**	**Incremental**	**ICER (n=10,000)**
Information only (standard care)	0.138		-
Lumbopelvic support belt	0.145	0.007	£2,220

Table 30: Cost of a physio only included in only the lumbopelvic belt intervention: Lumbopelvic belt versus information only

	Costs		
Treatment Strategy	**Total**	**Incremental**	**ICER (n=10,000)**
Information only (standard care)	£2		-
Lumbopelvic support belt	£78	£77	£9,473

Table 31: Cost of a physio only included in only the lumbopelvic belt intervention: Lumbopelvic belt versus exercise

	Costs		
Treatment Strategy	**Total**	**Incremental**	**ICER (n=10,000)**
Exercise	£1		-
Lumbopelvic support belt	£78	£77	£13,816

1.4.1 Probabilistic Sensitivity Analysis

The results of the PSA, based on 10,000 Monte Carlo simulations of the model are displayed in Table 32. The mean iNMB is based on a cost effectiveness threshold of £20,000 per QALY gained. A positive iNMB can be interpreted as the belt being cost effective, in contrast with the comparator.

Table 32: Mean incremental net monetary benefit and the probability of cost effectiveness

Pairwise comparison	**Mean iNMB**	**Probability lumbopelvic support belt intervention is IPS is cost effective (n=10,00)**
Lumbopelvic support belt versus information only	£113	93%
Lumbopelvic support belt versus exercise	£142	96%

Table 33 summarises the pairwise results for when the belt is compared to information only (standard care) and Table 34 displays the results of the belt versus exercise.

Table 33: Mean costs and quality adjusted life years: Lumbopelvic support belt versus information only

	Cost		QALYs		
Treatment Strategy	**Total**	**Incremental**	**Total**	**Incremental**	**ICER (n=10,000)**
Information Only	£63	-	0.090	-	-
Lumbopelvic support belt	£78	£16	0.097	0.008	£2,452

Table 34: Mean costs and quality adjusted life years: Lumbopelvic support belt versus information only

	Cost		QALYs		
Treatment Strategy	**Total**	**Incremental**	**Total**	**Incremental**	**ICER (n=10,000)**
Exercise	£62	-	0.089	-	-

	Cost		QALYs		
Treatment Strategy	**Total**	**Incremental**	**Total**	**Incremental**	**ICER (n=10,000)**
Lumbopelvic support belt	£78	£16	0.097	0.008	£2,036

Figure 6 displays the cost effectiveness plane of the individual simulations that generated the probabilistic result for the belt versus information only. The yellow plot represents the average of all simulations and the red line represents the cost effectiveness threshold at £20,000 per QALY. The results of the PSA are also displayed on a cost effectiveness acceptability curve (CEAC) in Figure 7, summarising the impact of uncertainty on the results of the model. The graph plots a range of cost-effectiveness thresholds on the horizontal axis against the probability that the intervention will be cost-effective at a particular threshold on the vertical axis.

Figure 6: Cost effectiveness plane: Lumbopelvic support belt versus information only

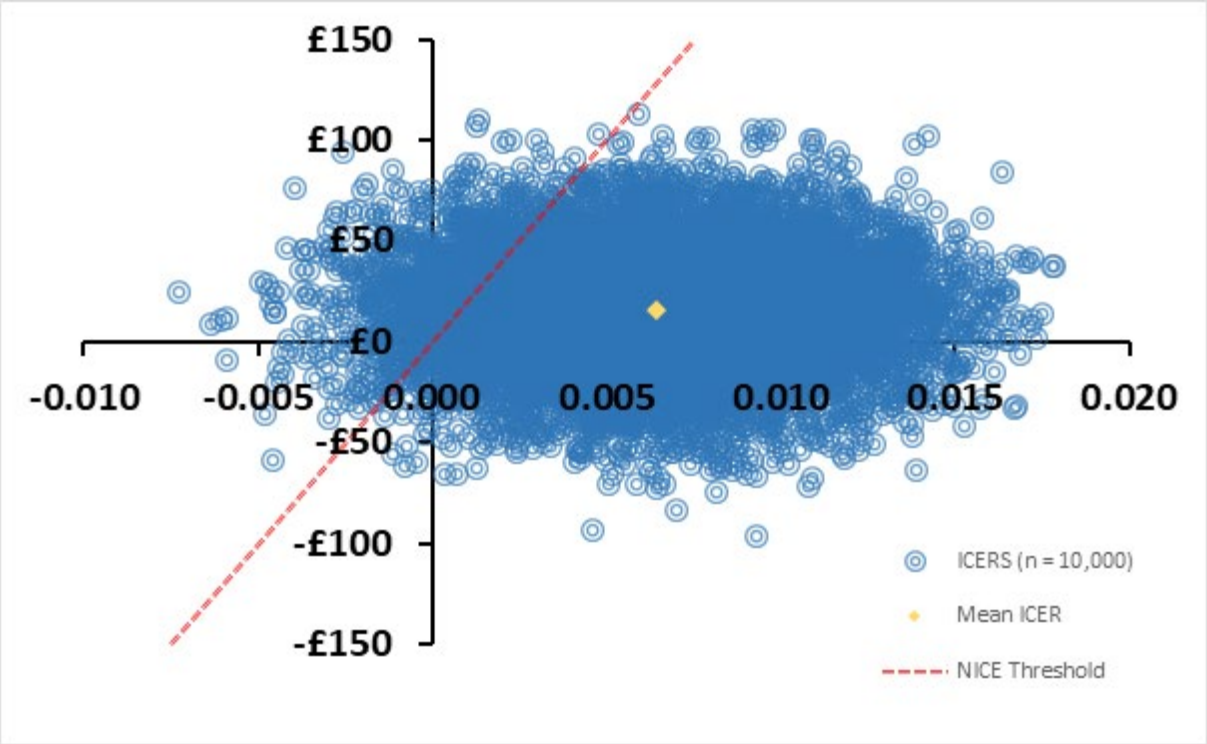
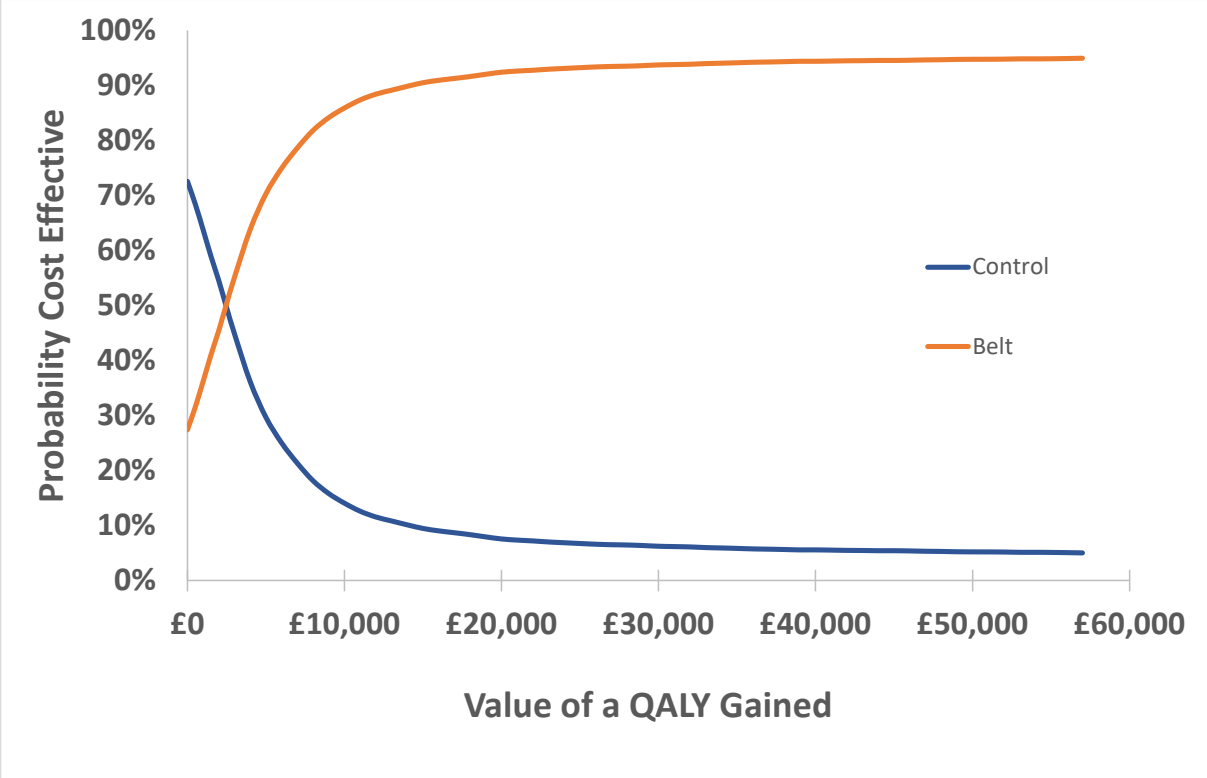


Figure 7: Cost effectiveness acceptability curve: Lumbopelvic support belt versus information only



The PSA was also run for the lumbopelvic support belt versus exercise. The cost effectiveness plane of the individual simulations is displayed in Figure 8 and the CEAC is displayed in Figure 9.

Figure 8: Cost effectiveness plane: Lumbopelvic support belt versus exercise

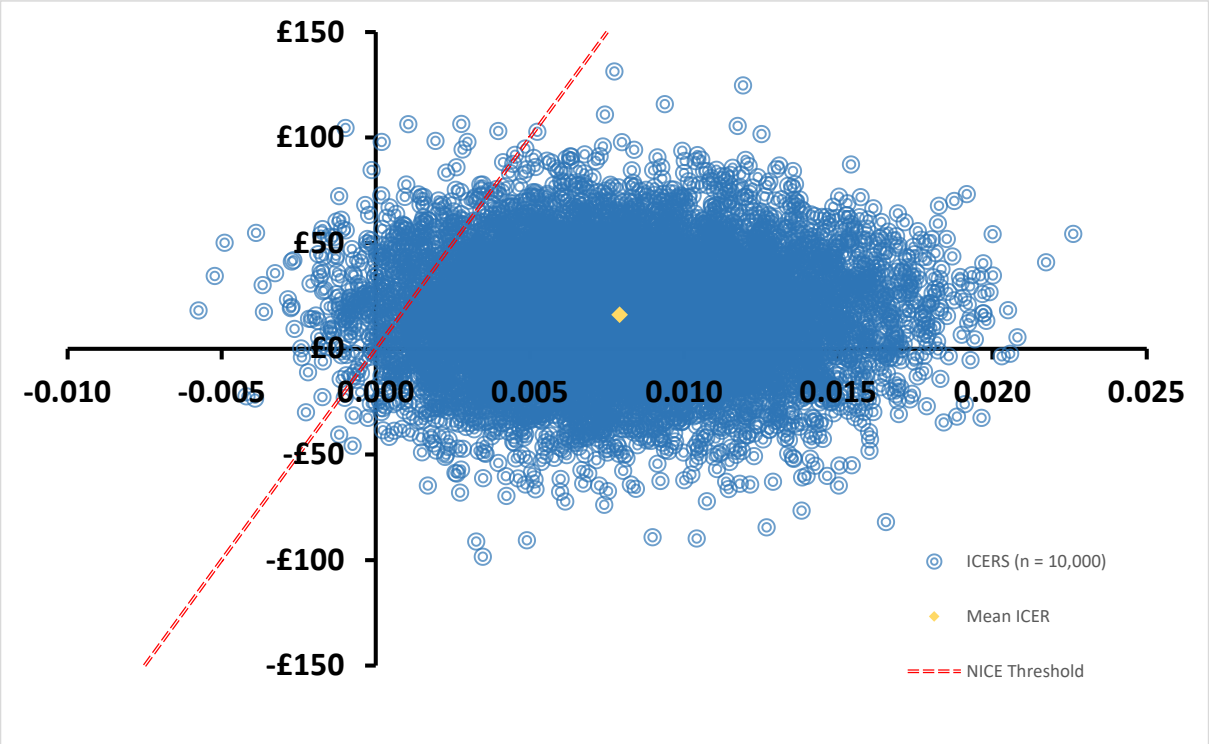
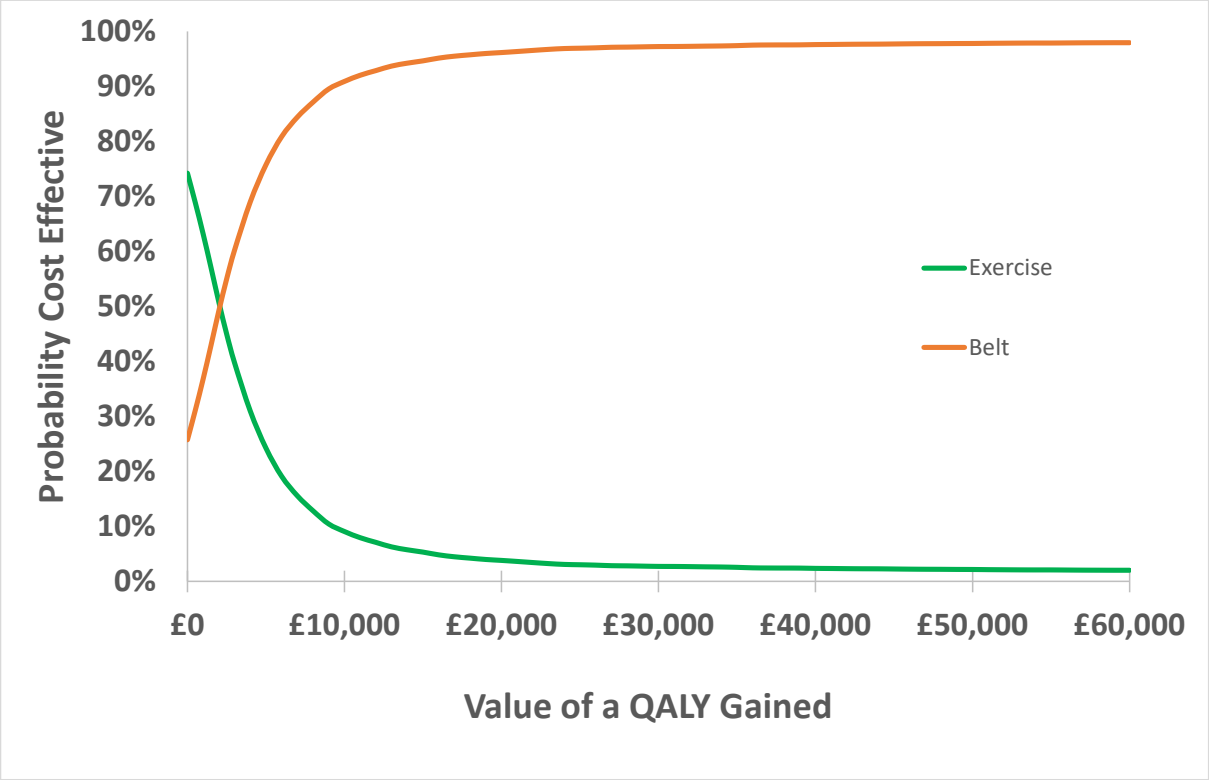


Figure 9: Cost effectiveness acceptability curve: Lumbopelvic support belt versus exercise



1.5 Discussion

This economic analysis provides evidence that use of a non-rigid, lumbopelvic support belt when compared to information only or exercise adviceis cost effective. Both the deterministic and probabilistic analysis demonstrate that use of a lumbopelvic belt is more costly and more effective than information only or exercise. At a threshold of £20,000 per QALY gained use of a belt is 93% cost effective when compared to the information only group and is 96% cost effective when compared to exercise.

The series of one-way sensitivity analysis illustrates, with the exception of the belt unit cost, that when all other variables are held constant, varying one input by a low/high value does not alter the cost effectiveness result in either pairwise comparison conducted. It is noted in the methods section that there was some uncertainty as to the 'true' cost of a belt. Therefore, an extreme high value was explored in the tornado analysis which showed it to be a key driver of the model. A threshold analysis showed that, holding all other inputs constant, the lumbopelvic belt could cost up to £163, before not being cost effective when compared with information only and £113 when compared with exercise. Given that all possible relevant unit costs for the belt were between £16 - 20, this suggests the findings are robust enough to allow for this uncertainty.

It is important to note the limitations on the input parameters informing this analysis when interpreting the results. One limitation is that this model was informed by 1 RCT (Kordi 2013) that was included in the clinical evidence review which was used to inform the computation of QALYs in this analysis. A conventional approach in economic evaluation either includes utilities specific to health states in a model or uses a 'mapping' algorithm to convert non-preference based HRQoL data into utilities. Given that outcomes reported included HRQoL, the most appropriate approach for this analysis was to undertake a 'mapping' approach, using HRQoL data in Kordi 2013 converted into EQ-5D data to compute QALYs for each intervention. Whilst mapping is an accepted method for deriving utilities (NICE guidelines manual 2018), values in this model are mapped only from the physical health domain of the WHOQOL-BREF survey in Kordi 2013. Moreover, this study used an algorithm based on adults from Singapore which may not be sufficiently similar to the population in the UK. Nevertheless, the computed EQ-5D utilities, as displayed in Table 21 appear to have face validity with the non-preference based HRQoL values in Kordi 2013.

Another limitation associated to the HRQoL data in the study is that Wee 2018 convert data from the WHOQOl-100 into EuroQoL 5 Dimensions *5 Levels* (EQ-5D-5L) utilities. As of the time of writing, NICE do not currently recommend using the 5L valuation set (NICE 2018). However, as this was the only relevant mapping study found, this economic analysis uses the EQ-5D-5L with the proviso that this is a severe limitation of the model.

As noted in the methods section, there was some uncertainty as to whether the cost of a physio appointment should be factored into the model. The clinical study upon which the model is based on did not state the context or resource use that each intervention would be given in the analysis. One view is that the cost of a physio should factored into the overall cost of the belt intervention as the fitting of the belt by a specialist may be a driver of clinical effectiveness. The committee also felt that there may be instances whereby the women are not referred to a physio at all when experiencing pelvic girdle pain and that current practice may be to offer mild analgesics. However, the belt was still cost effective (under £20,000 per QALY) when compared to either intervention under this assumption. Nevertheless, it remains an area of uncertainty as to whether physiotherapeutic advice is a driver if clinical effectiveness.

It is also pertinent to note that whilst this analysis does provide evidence that use of a lumbopelvic belt is cost effective when compared to information only or exercise, it does not provide evidence of use of a lumbopelvic belt in comparison to other interventions relevant to this topic area.

1.6 Conclusion

Notwithstanding the limitations outlined in the clinical review, this economic evaluation provides support for the committee's recommendation for clinicians to consider offering women who experience pelvic girdle pain a non-rigid lumbopelvic support belt. However, there are major limitations in the data underpinning the analysis, particularly with the inclusion of EQ-5D-5L data which need to be considered when using this analysis to inform recommendations.

1.7 References

NHS Drug Tariff Part VIII 2019

NHS Business Services Authority (2019). NHS Drug Tariff Part VIII. September 2019

NHS Reference Costs

NHS Improvement (2010). NHS reference costs 2017 to 2018

Wee 2018

Wee, H. L., Yeo, K. K., Chong, K. J., Khoo, E. Y. H., & Cheung, Y. B. (2018). Mean rank, Equipercentile, and regression mapping of World Health Organization quality of life brief (WHOQOL-BREF) to EuroQoL 5 dimensions 5 levels (EQ-5D-5L) utilities. Medical Decision Making, 38(3), 319-333.

WHO 1996

World Health Organization. (1996). WHOQOL-BREF: introduction, administration, scoring and generic version of the assessment: field trial version, December 1996 (No. WHOQOL-BREF). Geneva: World Health Organization.

Appendix K – Excluded studies

Excluded clinical and economic studies for review question: What interventions are effective in treating mild to moderate pelvic girdle pain during pregnancy?

Clinical studies

Table 35: Excluded studies

Study	Reason for exclusion
A Pilot Randomized Controlled Trial Evaluating Three Treatments for Pregnancy-Related Low Back Pain: Exercise, Spinal Manipulation, and Neuroemotional Technique, Journal of midwifery & women's health, 57, 537-537, 2012	Conference abstract. Published results have been considered separately, see reason for exclusion for Peterson 2014.
Abbasi, Osman Z., Zito, Patrick M., Osteopathic Manipulative Treatments for Common Pain Issues Encountered in Pregnancy, International Journal of Childbirth Education, 28, 76-78, 2013	Non-systematic review
Almousa, S., Lamprianidou, E., Kitsoulis, G., The effectiveness of stabilising exercises in pelvic girdle pain during pregnancy and after delivery: A systematic review, Physiotherapy research international : the journal for researchers and clinicians in physical therapy, 23, 2018	Systematic review. Included studies checked. No additional studies matching out protocol
Barfoot, C., Tudor, R., D'Almeida, I., Joice, D., Staples, S., Smith, R., Bateman, A., Mercer, C., Koulouglioti, C., A pilot randomised trial of 4 physiotherapy interventions for pregnancy related pelvic girdle pain, Physiotherapy (United Kingdom), 1), eS111, 2015	Conference abstract
Barkatsa, V., Wozniak, G., Syrmos, N., Iliadis, C., Roupa, Z., Intervetions for pelvic girdle pain in pregnant women, Bone, 1), S237, 2010	Conference abstract
Bergamo, T. R., Latorraca, C. O. C., Pachito, D. V., Martimbianco, A. L. C., Riera, R., Findings and methodological quality of systematic reviews focusing on acupuncture for pregnancy-related acute conditions, Acupuncture in Medicine, 36, 146-152, 2018	Systematic review. Included studies checked. No additional studies matching out protocol
Bertuit, J., Leyh, C., Feipel, V., Center of plantar pressure during gait in pregnancy-related pelvic girdle pain and the effect of pelvic belts, Acta of Bioengineering & Biomechanics, 20, 69-76, 2018	No outcomes of interest matching our protocol
Bhandiwad, A., Vaisravanath, S., Sujatha, M. S., Role of short term exercise intervention in pelvic girdle pain in pregnancy, Physiotherapy (United Kingdom), 1), eS147-eS148, 2015	Conference abstract
Buchberger, B., Krabbe, L., Evaluation of outpatient acupuncture for relief of pregnancy-related conditions, International Journal of Gynecology and Obstetrics, 141, 151-158, 2018	Systematic review. Included studies checked. No additional studies matching out protocol
Butel, T., Nicolian, S., Durand, M., Filipovic-Pierucci, A., Kone, M., Gambotti, L., Mallet, A., Durand-Zaleski, I., Dommergues, M., Cost-effectiveness of acupuncture versus standard care for pelvic and low back pain in pregnancy: An	Conference abstract

Study	Reason for exclusion
analysis of the game randomized trial, Value in Health, 19 (7), A588, 2016	
Cameron, L., Marsden, J., Watkins, K., Freeman, J., Management of antenatal pelvic-girdle pain study (MAPS): A single centred blinded randomised trial evaluating the effectiveness of two pelvic orthoses, Prosthetics and Orthotics International, 39, 447, 2015	Conference abstract
Ceprnja, D., Gupta, A., Does muscle energy technique have an immediate benefit for women with pregnancy-related pelvic girdle pain?, Physiotherapy Research International, 24, e1746, 2019	Crossover study design
Clarkson, C., Korean hand acupuncture for pregnancy-related pelvic girdle pain: a feasibility study, Journal of Pelvic, Obstetric & Gynaecological Physiotherapy, 36-41, 2017	Feasibility study - not looking at the outcomes specified in the protocol.
Close, C., Sinclair, M., Cullough, J. M., Liddle, D., Hughes, C., A pilot randomised controlled trial (RCT) investigating the effectiveness of reflexology for managing pregnancy low back and/or pelvic pain, Complementary therapies in clinical practice, 23, 117-124, 2016	Mixed sample <50% have pelvic pain (3% pelvic pain only; 44% pelvic and lower back pain; 53% lower back pain only)
Close, C., Sinclair, M., Liddle, S. D., Madden, E., McCullough, J. E., Hughes, C., A systematic review investigating the effectiveness of Complementary and Alternative Medicine (CAM) for the management of low back and/or pelvic pain (LBPP) in pregnancy, Journal of Advanced Nursing, 70, 1702-16, 2014	Systematic review. Included studies checked. No additional studies matching out protocol
Davenport, M. H., Marchand, A. A., Mottola, M. F., Poitras, V. J., Gray, C. E., Jaramillo Garcia, A., Barrowman, N., Sobierajski, F., James, M., Meah, V. L., Skow, R. J., Riske, L., Nuspl, M., Nagpal, T. S., Courbalay, A., Slater, L. G., Adamo, K. B., Davies, G. A., Barakat, R., Ruchat, S. M., Exercise for the prevention and treatment of low back, pelvic girdle and lumbopelvic pain during pregnancy: a systematic review and meta-analysis, British journal of sports medicine, 53, 90-98, 2019	Systematic review. Included studies checked. No additional studies matching our protocol.
Delshad, B., Zarean, E., Yeowell, G., Sadeghi-Demneh, E., The immediate effects of pelvic compression belt with a textured sacral pad on the sacroiliac function in pregnant women with lumbopelvic pain: A cross-over study, Musculoskeletal Science and Practice, (no pagination), 2020	Study design not a randomised controlled trial
Depledge, J., McNair, P. J., Keal-Smith, C., Williams, M., Management of symphysis pubis dysfunction during pregnancy using exercise and pelvic support belts, Physical therapy, 85, 1290-1300, 2005	No useful data reported
Ee, C. C., Manheimer, E., Pirotta, M. V., White, A. R., Acupuncture for pelvic and back pain in pregnancy: a systematic review, American Journal of Obstetrics and Gynecology, 198, 254-259, 2008	Systematic review. Included studies checked. No additional studies matching out protocol

Study	Reason for exclusion
Eggen,M.H., Stuge,B., Mowinckel,P., Jensen,K.S., Hagen,K.B., Can supervised group exercises including ergonomic advice reduce the prevalence and severity of low back pain and pelvic girdle pain in pregnancy? A randomized controlled trial, Physical Therapy, 92, 781-790, 2012	Study population does not meet protocol eligibility criteria - <50% women with pelvic girdle pain at baseline.
Ekdahl, L., Petersson, K., Acupuncture treatment of pregnant women with low back and pelvic pain--an intervention study, Scandinavian journal of caring sciences, 24, 175-182, 2010	No population of interest - Mixed sample including women with lower back pain, only 4 (10%) women with pelvic girdle pain.
Fisseha, B., Mishra, P. K., The effect of group training on pregnancy-induced lumbopelvic pain: systematic review and meta-analysis of randomized control trials, Journal of Exercise Rehabilitation, 12, 15-20, 2016	Systematic review - effective in improving lower back pain after pregnancy not during pregnancy.
Flack, N. A. M. S., Hay-Smith, E. J. C., Stringer, M. D., Gray, A. R., Woodley, S. J., Adherence, tolerance and effectiveness of two different pelvic support belts as a treatment for pregnancy-related symphyseal pain - A pilot randomized trial, BMC Pregnancy and Childbirth, 15 (1) (no pagination), 2015	No comparison of interest - Compares two different pelvic support belts
Fontana Carvalho, A. P., Dufresne, S. S., Rogerio de Oliveira, M., Couto Furlanetto, K., Dubois, M., Dallaire, M., Ngomo, S., da Silva, R. A., Effects of lumbar stabilization and muscular stretching on pain, disabilities, postural control and muscle activation in pregnant woman with low back pain, European journal of physical and rehabilitation medicine, 56, 297-306, 2020	Exclude on population. Low back pain only, not specific to pelvic girdle pain.
Franke, H., Franke, J. D., Belz, S., Fryer, G., Osteopathic manipulative treatment for low back and pelvic girdle pain during and after pregnancy: A systematic review and meta-analysis, Journal of Clinical Chiropractic Pediatrics, 17, 1468-1468, 2018	Journal Abstract
Franke, H., Franke, J. D., Belz, S., Fryer, G., Osteopathy in low back pain and pelvic girdle pain during and after pregnancy: Systematic review and meta-analysis, Osteopathische Medizin, 19, 11-19, 2018	Non-English study
George, J. W., Skaggs, C. D., Thompson, P. A., Nelson, D. M., Gavard, J. A., Gross, G. A., A randomized controlled trial comparing a multimodal intervention and standard obstetrics care for low back and pelvic pain in pregnancy, American Journal of Obstetrics and Gynecology, 208, 295.e1-295.e7, 2013	No population of interest - Mixed sample including women with lower back pain, percentage of women with pelvic pain not reported.
Guerreiro da Silva, J. B., Nakamura, M. U., Cordeiro, J. A., Kulay, L., Jr., Acupuncture for low back pain in pregnancy--a prospective, quasi-randomised, controlled study, Acupunct MedAcupuncture in medicine : journal of the British Medical Acupuncture Society, 22, 60-7, 2004	Mixed sample includes women with back pain or pelvic pain, percentage of women with pelvic pain is not reported.
Gutke, A., Betten, C., Degerskar, K., Pousette, S., Fagevik Olsen, M., Treatments for pregnancy-related lumbopelvic pain: A systematic review of	Systematic review - 1 additional study not identified in search (Guerreiro da Silva 2004) but not of interest.

Study	Reason for exclusion
physiotherapy modalities, Acta Obstetricia et Gynecologica Scandinavica, 94, 1156-1167, 2015	
Gutke, A., Sjodahl, J., Oberg, B., Specific muscle stabilizing as home exercises for persistent pelvic girdle pain after pregnancy: A randomized, controlled clinical trial, Physiotherapy (United Kingdom), 1), eS440-eS441, 2011	No outcome of interest - outcomes assessed after delivery
Haakstad, L. A., Bo, K., Effect of a regular exercise programme on pelvic girdle and low back pain in previously inactive pregnant women: A randomized controlled trial, Journal of Rehabilitation MedicineJ Rehabil Med, 47, 229-234, 2015	Study population does not meet protocol eligibility criteria - <50% women with pelvic girdle pain.
Hall, H., Cramer, H., Sundberg, T., Ward, L., Adams, J., Moore, C., Sibbritt, D., Lauche, R., The effectiveness of complementary manual therapies for pregnancy-related back and pelvic pain A systematic review with meta-analysis, Medicine (United States), 95 (38) (no pagination), 2016	Systematic review. Included studies checked. No additional studies matching out protocol
Haugland, K. S., Rasmussen, S., Daltveit, A. K., Group intervention for women with pelvic girdle pain in pregnancy. A randomized controlled trial, Acta Obstetricia et Gynecologica Scandinavica, 85, 1320-1326, 2006	No outcome of interest - examines outcomes after pregnancy not during pregnancy.
Jiang, Q., Wu, Z., Zhou, L., Dunlop, J., Chen, P., Effects of Yoga Intervention during Pregnancy: A Review for Current Status, American Journal of Perinatology, 32, 503-514, 2015	Systematic review. Included studies checked. No additional studies matching out protocol
Jorge, C., Santos-Rocha, R., Bento, T., Can group exercise programs improve health outcomes in pregnant women? A systematic review, Current Women's Health Reviews, 11, 75-87, 2015	Systematic review. Included studies checked. No additional studies matching out protocol
Kalus, S. M., Kornman, L. H., Quinlivan, J. A., Managing back pain in pregnancy using a support garment: A randomised trial, BJOG: An International Journal of Obstetrics and Gynaecology, 115, 68-75, 2008	No population of interest - Mixed sample including women with lower back pain, percentage of women with pelvic pain not reported.
Kinser, P. A., Pauli, J., Jallo, N., Shall, M., Karst, K., Hoekstra, M., Starkweather, A., Physical Activity and Yoga-Based Approaches for Pregnancy-Related Low Back and Pelvic Pain, Journal of obstetric, gynecologic, and neonatal nursing : JOGNN, 46, 334-346, 2017	Systematic review. Included studies checked. No additional studies matching out protocol
Koch, W., Acupuncture and its use in the management of low back and, pelvic girdle pain in pregnancy, Journal of the acupuncture association of chartered physiotherapists, 37â□□47, 2008	Literature review (not systematic)
Kuciel, N., Sutkowska, E., Cienska, A., Markowska, D., Wrzosek, Z., Myoelectrical activity of muscles stabilizing the sacroiliac joints before and after the use of elastic tapes in women suffering from Pregnancy-related Pelvic Girdle Pain, Ginekologia PolskaGinekol Pol, 91, 223-230, 2020	This is a non-randomised study. As there is randomised controlled trial data available this study is excluded.
Kvorning,N., Holmberg,C., Grennert,L., Aberg,A., Akeson,J., Acupuncture relieves pelvic and low-back pain in late pregnancy, Acta Obstetricia et Gynecologica Scandinavica, 83, 246-250, 2004	Mixed sample includes women with back pain and pelvic pain, percentage of women with pelvic pain was not reported.

Study	Reason for exclusion
Liddle, S. D., Pennick, V., A systematic review of interventions for preventing and treating low-back and/or pelvic pain during pregnancy, European Spine Journal, 1), S128, 2014	Conference abstract
Liddle, S. D., Pennick, V., Interventions for preventing and treating lowâ□□back and pelvic pain during pregnancy, Cochrane Database of Systematic Reviews, 2015	Systematic review - 3 studies not included in search (Elden 2005; Kvoring 2004; Wedenberg 2000). Elden 2005 and Wedenberg 2000 included in the review, whilst Kvoring 2004 does not match criteria set out in the protocol.
Lillios, S., Young, J., The effects of core and lower extremity strengthening on pregnancy-related low back and pelvic girdle pain: a systematic review, Journal of Women's Health Physical Therapy, 36, 116-124, 2012	Systematic review. Included studies checked. No additional studies matching our protocol.
Lund, I., Lundeberg, T., Lonnberg, L., Svensson, E., Decrease of pregnant women's pelvic pain after acupuncture: A randomized controlled single-blind study, Acta Obstetricia et Gynecologica Scandinavica, 85, 12-19, 2006	No comparison of interest - compares two type of acupuncture.
Martins, R. F., Pinto, E. Silva J. L., Treatment of pregnancy-related lumbar and pelvic girdle pain by the yoga method: A randomized controlled study, Journal of Alternative and Complementary Medicine, 20, 24-31, 2014	No intervention of interest - yoga
Melkersson, C., Nasic, S., Starzmann, K., Bengtsson Boström, K., Effect of Foot Manipulation on Pregnancy-Related Pelvic Girdle Pain: A Feasibility Study, Journal of Clinical Chiropractic Pediatrics, 17, 1470-1470, 2018	Journal abstract
Miquelutti, M. A., Cecatti, J. G., Makuch, M. Y., Evaluation of a birth preparation program on lumbopelvic pain, urinary incontinence, anxiety and exercise: a randomized controlled trial, BMC Pregnancy & Childbirth, 13, 154, 2013	No population of interest - includes all pregnant women with or without pelvic girdle pain
Monaghan, C., Haywood, A., Pelvic girdle pain - part 1: quantitative results from a mixed-methods service evaluation introducing a manual therapy treatment approach to usual care, Journal of Pelvic, Obstetric & Gynaecological Physiotherapy, 47-55, 2016	As there is randomised controlled trial data available, this study has been excluded.
Morkved, S., Salvesen, K. A., Schei, B., Lydersen, S., Bo, K., Does group training during pregnancy prevent lumbopelvic pain? A randomized clinical trial, Acta Obstetricia et Gynecologica Scandinavica, 86, 276-82, 2007	Study does not meet protocol eligibility criteria - Prevention of lumbopelvic pain - 43% had low back and/or pelvic girdle pain at baseline (unclear what proportion with pelvic pain).
Nct,, Effects of Specific Pelvic Stabilization Exercise With Transabdominal Ultrasonography-guided Biofeedback in Postpartum Women Suffering From Pregnancy-related Pelvic Girdle Pain, https://clinicaltrials.gov/show/NCT04377516, 2020	Clinical trial entry, full results not published however intervention does not meet the interventions specified in the protocol.
Nct,, Foot Manipulation for Pregnancy Related Pelvic Girdle Pain, Https://clinicaltrials.gov/show/nct01894009, 2013	Clinical trial record

Study	Reason for exclusion
Nct,, Laser Acupuncture and Acupressure for Low Back Pain, https://clinicaltrials.gov/show/NCT04423445, 2020	Clinical trial entry, full results not published however, population is not specific to pelvic girdle pain.
Nct,, Pelvic Girdle Pain in a Pregnant Population in Western Norway, Https://clinicaltrials.gov/show/nct01098136, 2010	Clinical trial record
Nct,, Ultrasound Guided Posterior Sacroiliac Ligament Corticosteroid Injection in Pregnancy-Related Pelvic Girdle Pain, Https://clinicaltrials.gov/show/nct02044991, 2014	Clinical trial record
Nct,, Trial for the Treatment of Pelvic and Back Pain in Pregnancy, Https://clinicaltrials.gov/show/nct00830934, 2009	Clinical trial record
Nct,, The Effects of a Water Based Exercise Programme and a Land Based Exercise Programme on Women Experiencing Pregnancy Related Pelvic Girdle Pain, Https://clinicaltrials.gov/show/nct03261687, 2017	Clinical trial record
Oduola, O., McDonagh, T., O'Leary, M., Pelvic Girdle Pain Survey in Pregnancy: A Maternity Hospital Experience, Irish Medical Journal, 111, 1-2, 2018	Study design not a randomised controlled trial.
Ostgaard, H. C., Zetherstrom, G., Roos-Hansson, E., Svanberg, B., Reduction of back and posterior pelvic pain in pregnancy, Spine, 19, 894-900, 1994	Study does not meet protocol eligibility criteria - unclear proportion of women with pelvic pain only; no useable outcome data.
Ozdemir, S., Bebis, H., Ortabag, T., Acikel, C., Evaluation of the efficacy of an exercise program for pregnant women with low back and pelvic pain: a prospective randomized controlled trial, Journal of advanced nursing, 71, 1926-1939, 2015	Study population does not meet protocol eligibility criteria - women with low back and pelvic pain.
Peng, Yueh-Chu, Chou, Fan-Hao, Different Exercise Intensities for Relieving Lumbopelvic Pain in Pregnant Women, Journal for Nurse Practitioners, 15, 249-249, 2019	Systematic review. Included studies checked. No additional studies matching our protocol.
Peters, R., van der Linde, M., Osteopathic treatment of women with back pain during pregnancy. A randomised controlled study, Osteopathische Medizin, 8, 26, 2007	Non-English study
Peterson, C. K., Muhlemann, D., Humphreys, B. K., Outcomes of pregnant patients with low back pain undergoing chiropractic treatment: A prospective cohort study with short term, medium term and 1 year follow-up, Chiropractic and Manual Therapies, 22 (1) (no pagination), 2014	As there is randomised controlled trial data available, this study has been excluded.
Quintero Rodriguez, C., Troynikov, O., The Effect of Maternity Support Garments on Alleviation of Pains and Discomforts during Pregnancy: A Systematic Review, Journal of PregnancyJ Pregnancy, 2019, 2163790, 2019	Systematic review. Included studies checked. No additional studies matching our protocol.
Ribnikar, N., Scepanovic, D., Verdenik, I., Zgur, L., Effect of pelvic belt and physiotherapy advice on pain in pregnant women with pelvic girdle pain, Physiotherapy (United Kingdom), 1), eS1306-eS1307, 2015	Conference abstract
Richards, E., Van Kessel, G., Virgara, R., Harris, P., Does antenatal physical therapy for pregnant	Systematic review. Included studies checked. No additional studies matching out protocol.

Study	Reason for exclusion
women with low back pain or pelvic pain improve functional outcomes? A systematic review, Acta Obstetricia et Gynecologica Scandinavica, 91, 1038-1045, 2012	
Rodrigues, P., Yamada, E., Simmer, C., Santos, K., Rangel, K., Prudente, L., Efficacy of therapeutic exercises and superficial heat in the posterior lumbar pelvic pain during pregnancy, Physiotherapy (United Kingdom), 97, eS1050-eS1051, 2011	No comparator of interest
Schiff Boissonnault, J., Klestinski, J. U., Pearcy,, The role of exercise in the management of pelvic girdle and low back pain in pregnancy: a systematic review of the literature, Journal of Women's Health Physical Therapy, 36, 69-77, 2012	Systematic review. Included studies checked. No additional studies matching our protocol.
Shafiee, M., Rostami, M., Comparison between the effect of lumbopelvic belt and home based pelvic stabilizing exercise on pregnant women with pelvic girdle pain; A randomized controlled trial, European Journal of Medical Research, 1), 35, 2011	Conference abstract
Shiri, R., Coggon, D., Falah-Hassani, K., Exercise for the prevention of low back and pelvic girdle pain in pregnancy: A meta-analysis of randomized controlled trials, European Journal of Pain (United Kingdom), 22, 19-27, 2018	Systematic review on prevention of pregnancy related pain - no additional relevant studies matching our protocol
Sklempe Kokic, I., Ivanisevic, M., Uremovic, M., Kokic, T., Pisot, R., Simunic, B., Effect of therapeutic exercises on pregnancy-related low back pain and pelvic girdle pain: Secondary analysis of a randomized controlled trial, Journal of Rehabilitation MedicineJ Rehabil Med, 49, 251-257, 2017	Study does not meet protocol eligibility criteria - Approximately 50% women had pre-pregnancy lumbopelvic pain; not clear how many had pelvic girdle pain - mix of women with low back and pelvic pain; outcome - occurrence of lumbopelvic pain.
Stafne, S. N., Salvesen, K. A., Romundstad, P. R., Stuge, B., Morkved, S., Does regular exercise during pregnancy influence lumbopelvic pain? A randomized controlled trial, Acta Obstetricia et Gynecologica Scandinavica, 91, 552-559, 2012	Study population does not meet protocol eligibility criteria - <50% women with lower back pain at baseline.
Upadhyay, K., Hoare, Z., Gholkar, N., A randomised controlled pilot analysis to assess a new flexible pelvic harness (harness gravidarum) for management of pelvic girdle pain in pregnancy, BJOG: An International Journal of Obstetrics and Gynaecology, 126 (Supplement 2), 167-168, 2019	Conference abstract
van Benten, E., Pool, J., Mens, J., Pool-Goudzwaard, A., Recommendations for physical therapists on the treatment of lumbopelvic pain during pregnancy: a systematic review, Journal of Orthopaedic & Sports Physical TherapyJ Orthop Sports Phys Ther, 44, 464-73, A1-15, 2014	Systematic review. Included studies checked. No additional studies matching out protocol
Vas, J., Cintado, M. C., Aranda-Regules, J. M., Aguilar, I., Rivas Ruiz, F., Effect of ear acupuncture on pregnancy-related pain in the lower back and posterior pelvic girdle: A multicenter randomized clinical trial, Acta Obstetricia et Gynecologica Scandinavica, 98, 1307-1317, 2019	Less than 50% of sample have pelvic pain

Study	Reason for exclusion
Vesentini, G., Prior, J., Ferreira, P. H., Hodges, P. W., Rudge, M., Ferreira, M. L., Pelvic floor muscle training for women with lumbopelvic pain: a systematic review and meta-analysis, European journal of pain, 31, 2020	Systematic review. Included studies checked. No additional studies matching out protocol
Wang, S. M., DeZinno, P., Lin, E. C., Lin, H., Yue, J. J., Berman, M. R., Braveman, F., Kain, Z. N., Auricular acupuncture as a treatment for pregnant women who have low back and posterior pelvic pain: a pilot study, American Journal of Obstetrics and Gynecology, 201, 271.e1-271.e9, 2009	Mixed sample <50% have pelvic pain (36% posterior pelvic pain only; 8% posterior pelvic pain lower back pain; 56% lower back pain only).
Wang, S. M., Lin, E., Braveman, F., Kain, Z., Auricular acupuncture as a treatment for posterior pelvic pain during pregnancy: a RCT, AnesthesiologyAnesthesiology, 107, Abstract no: A277, 2007	Conference abstract
Wuytack, F., O'Donovan, M., Outcomes and outcomes measurements used in intervention studies of pelvic girdle pain and lumbopelvic pain: A systematic review, Chiropractic and Manual Therapies, 27, 2019	Systematic review. Included studies checked. No additional studies matching our protocol.

Economic studies

A single economic search was undertaken for all topics included in the scope of this guideline. No economic studies were identified which were applicable to this review question. See supplementary material 2 for details.

Appendix L – Research recommendations

Research recommendations for review question: What interventions are effective in treating mild to moderate pelvic girdle pain during pregnancy

No research recommendations were made for this review question.

Appendix M – Additional studies in update searches

Table 36 : Summary of studies identified but not extracted

Study	Why the study was not fully extracted and included
Scott 2018	Study not comparing interventions being recommended by committee. The study found no important differences for any of the outcomes in the review protocol.