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.