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Community-based non-pharmacological interventions for improving pain, disability and quality of life in pregnant women with musculoskeletal conditions: protocol for a systematic review with meta-analyses

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ABSTRACT

Introduction Twenty five per cent of pregnant women with musculoskeletal pain have disabling symptoms that negatively influence quality of life. Studies have reported varying effects of non-pharmacological interventions including exercise, manipulation and pelvic belts for pregnant women with musculoskeletal problems. The overall effectiveness and acceptability of these interventions is uncertain due to lack of synthesised evidence. This protocol is for the first systematic review of community-based non-pharmacological interventions for improving pain, disability and quality of life in pregnant women with musculoskeletal conditions from studies published until August 2020.

Methods and analysis A detailed search of PubMed, CINAHL, CENTRAL, Global Index Medicus, African Index Medicus, African Journal Online, Western Pacific Region Index Medicus, Latin American and Caribbean Centre on Health Science Information, Index Medicus for South-East Asia Region, IRIS (WHO digital publications), British Library for Development Studies and Google Scholar. Additional studies will be located from the reference list of identified studies and relevant systematic reviews. The databases will be searched from inception to August 2020. Appraisal of study quality will be performed with the Mixed Methods Appraisal Tool. Data will be synthesised using a mixed-studies synthesis design—the convergent synthesis. The description of interventions in all study designs will be summarised narratively. Meta-analyses will be used to statistically summarise the effectiveness of interventions in randomised controlled trials and the factors that influence these. Other quantitative studies will be summarised narratively to answer the objectives. Thematic synthesis will be used to summarise results of qualitative studies. The outcomes of interest include pain, disability and quality of life. This paper is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols 2015 guidelines.

Ethics and dissemination Ethical clearance is not required. Findings will be presented at conferences and published in peer-reviewed journals.

Strengths and limitations of this study

► This review will involve synthesising quantitative and qualitative research evidence from different study designs using convergent synthesis to answer the review objectives.
► The description of interventions in all study designs will be summarised narratively.
► Meta-analysis (narrative synthesis where meta-analysis is precluded) will be used to determine the effectiveness of community-based non-pharmacological interventions in improving pain, disability and quality of life among pregnant women with musculoskeletal conditions and the factors influencing this, while thematic synthesis will be used to determine the acceptability of the interventions and the factors influencing this.
► This review will be limited to the findings in studies published in English.
► This protocol is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P) guidelines while the review will be conducted in line with PRISMA guidelines.

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INTRODUCTION
Rationale
There is an increasing global focus on maternal morbidity. This is because more women experience pregnancy-related complications than the number of women who die from these complications.[1] Nearly every woman experiences some degree of musculoskeletal pain during pregnancy. Twenty-five per cent of these women have disabling symptoms,[2] which can affect quality of life. Throughout pregnancy, the woman's

body slowly evolves and undergoes a lot of changes including psychological, physiological, biomechanical, hormonal and vascular transformations which can give rise to a variety of musculoskeletal problems.[3 4]

There are physiological processes through which several pregnancy-related musculoskeletal disorders arise. Carpal tunnel syndrome can arise from increased fluid retention due to the soft tissue swelling which occurs in about 80% of women during pregnancy especially during the last 8 weeks leading to compression and nerve entrapment.[5–7] Joint and ligamentous laxity occurs from increased oestrogen and progesterone serum levels[8] which when combined with weight gain can cause separation of the pelvic joint,[9] increased lumbar lordosis, stretching and separation of the anterior abdominal muscles.[10] As half of the gained weight in the abdominal area is anterior to the line of gravity,[11] this affects the centre of gravity leading to alteration of postural balance,[2] and increase in the risk of falling which occurs in about 28% of pregnant women.[12] The relaxation of abdominal muscles, compensatory lumbar lordosis and the shifting of the centre of gravity place a strain on the paraspinal muscles which can cause low back pain.[13] Higher adrenocortical activity, raised parathyroid hormone and increased stress from weight gain during pregnancy might be contributory to avascular necrosis of the femoral head.[14 15] Leg cramps which involve involuntary, painful contraction of the muscles can result from the build-up of lactic acid due to the increased workload of the muscles of the lower limbs.[16–19]

The high prevalence and adverse effects of these musculoskeletal complications of pregnancy underscore the importance of affordable and effective healthcare during pregnancy. The costs of antenatal care and delivery services in the health institutions, coupled with other challenges, can deter pregnant women from seeking much-needed care, endangering the lives of mothers and their babies. Over 5 million families across Africa, Asia, Latin America and the Caribbean spend over 40% of their household expenses on maternal health services every year. Nearly two-thirds of these households (approximately 3 million) were in Asia, while around 1.9 million were involved in Africa.[20] The significant economic burden suggests the importance of providing women with essential services that are affordable for their own health and that of their unborn child. This underscores the importance of investigating affordable and accessible interventions for pregnant women with musculoskeletal conditions which can be achieved using community-based interventions. Community-based interventions are multicomponent interventions that combine individual and environmental change strategies across multiple settings aiming to prevent diseases and to promote well-being among population groups in a defined local community outside of established hospitals such as secondary and tertiary health facilities.

Non-pharmacological interventions are interventions that do not involve the use of medications for treatment. They are often more affordable and accessible than pharmacological interventions.[21–23] Non-pharmacological interventions are very important in the management of musculoskeletal conditions as they provide reduction of pain, psychological distress, and disability with little or no risks/side effects.[24 25] These interventions may include but not limited to physical activity and patient education programmes, psychological interventions such as cognitive–behavioural therapy, acceptance and commitment therapy, relaxation techniques and mindfulness-based stress-reduction techniques.

Physical activity involves bodily movements produced by skeletal muscles that result in energy expenditure above basal rest levels.[26] Lack of physical activity is the fourth leading cause of mortality globally[27] and a cause of loss of muscular and cardiovascular fitness, weight gain, varicose veins, dyspnoea and lower back pain in pregnant women.[28] Pregnant women are advised to adopt and maintain healthy lifestyle of regular and consistent physical activity due to its numerous benefits[29 30] so long as there are no absolute or relative medical contraindications to exercise.[31] The beneficial effects of physical activity during pregnancy include maintenance of muscle tone, reduction in the risk of back pain, prevention of excess weight gain, and increased ability to effectively undergo labour and delivery.[32–34]

Patient education programmes teach patients about their condition and how efficient and effective self-management strategies can be employed.[24] During pregnancy, in line with the American College of Obstetricians and Gynecologists recommendations, patient education programmes focus on teaching pregnant women several safe practices such as how to practise correct posture while standing, walking and bending[35]; wearing of low-heeled shoes with good arch support; sitting in good chairs with back support and arm rest; sleeping on the side with pillows between the knees; squatting down, bending the knees and keeping the back straight while lifting things or getting help when lifting heavy objects.[17]

Psychological interventions, which can sometimes be part of self-management programmes, can improve psychological disorders as well as improve health behaviours such as physical activity during pregnancy. Pregnant women with musculoskeletal conditions are prone to psychological disorders due to limitation of mobility, functional ability, dexterity and ability to work, and disruption of sleep—all of which reduce the quality of life.[25 36] These psychological disorders including mood fluctuation, anxiety and depression can also result from hormonal changes during pregnancy.[37] Counselling reduces anxiety and depression during pregnancy,[38] which can result to a decrease in the consumption of anti-anxiety drugs and their side effects such as drowsiness, dizziness, preterm delivery and miscarriage.[39 40] Cognitive–behavioural therapy teaches patients pain-coping skills,[41] while acceptance and commitment therapy emphasises pain acceptance.[42] Relaxation therapy is a behavioural tool that may be effective for anxiety and mental stress.[43] Relaxation techniques (eg, muscle relaxation and breathing exercises) can reduce pain, stress, muscle tension, fatigue and blood pressure, and improve quality of life in pregnant women with low back pain.[44–47] Mindfulness-based therapy is another psychological intervention that may relieve psychological distress caused by musculoskeletal discomfort during pregnancy.[48 49]

There are several other non-pharmacological interventions that might be useful for pregnant women with musculoskeletal conditions such as transcutaneous electrical nerve stimulation, acupuncture, acupressure and manual therapy. There are systematic reviews of the effects of non-pharmacological interventions on anxiety and depression,[50–52] asthma,[53] migraine[54] and sleep quality[55] during pregnancy, but none exists for musculoskeletal disorders or pain, disability and quality of life during pregnancy. Individual clinical studies have investigated the effects of non-pharmacological interventions such as acupuncture, exercise, hydrotherapy, manipulation, pelvic belt and self-management programmes on pregnant women with musculoskeletal disorders with conflicting outcomes. The overall effectiveness and acceptability of these interventions remain uncertain due to lack of synthesised evidence. This will be addressed by this systematic review with meta-analyses, focusing on the interventions made accessible via community-based delivery.

This paper is reported according to the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) guidelines.[56]

Objectives
The overall objective of this study is to systematically review available evidence regarding community-based non-pharmacological interventions for pregnant women with musculoskeletal conditions. This study has the following specific objectives:

1. Summarise the available community-based non-pharmacological interventions for improving pain, disability and quality of life among pregnant women with musculoskeletal conditions.
2. Determine the effectiveness of community-based non-pharmacological interventions for improving pain, disability and quality of life among pregnant women with musculoskeletal conditions across countries and settings.
3. Determine the factors that influence the effectiveness of these interventions across countries and settings.
4. Determine the acceptability of these interventions for pregnant women with musculoskeletal conditions across countries and settings.
5. Determine the factors that influence the acceptability of these interventions across countries and settings.

METHODS
Protocol and registration
This systematic review protocol is registered with the International Prospective Register of Systematic Reviews .

Eligibility criteria
Inclusion criteria
1. Language: studies published in English.
2. Participants: pregnant women with musculoskeletal conditions in any country.
3. Interventions: all community-based non-pharmacological interventions. Interventions might involve contact with peers, health professional(s) or alternative practitioner(s). Interventions might be face-to-face, telephone-based or web-based.
4. Study or intervention setting: community settings outside of tertiary and secondary health facilities. This includes primary healthcare centres, outreach centres, schools, churches and other community settings such as small clinics.
5. Study design: all primary studies including randomised controlled trials (RCTs), non-RCTs, observational studies and qualitative studies.
6. Comparators/control: usual care, no intervention and placebo. Studies without control groups will also be included. In this case, participants will serve as their own control before treatment.
7. Timing: there is no restriction on timing of outcome assessment or delivery of interventions.
8. Outcomes: pain intensity, disability and quality of life.

Exclusion criteria
1. Papers that are duplicate publications of the same study. The most recent paper will be included incorporating the results of the entire study.
2. Systematic reviews, narrative reviews, articles, letters and any publications that do not have primary data.
3. Papers published only as abstracts (if three attempts made to obtain the full texts of studies from authors are not successful).

Information sources
The bibliographical databases that will be searched include PubMed, CINAHL, CENTRAL, Global Index Medicus, African Index Medicus, African Journal Online, Western Pacific Region Index Medicus, Latin American and Caribbean Centre on Health Science Information, Index Medicus for South-East Asia Region, IRIS (WHO digital publications), British Library for Development Studies and Google Scholar. Additional studies will be located from the reference list of identified studies and relevant systematic reviews. The databases will be searched from inception to August 2020. The search strategy will be informed by the Cochrane Handbook for Systematic Reviews of Interventions.[57]

The search strategy for this systematic review was developed and pilot tested in the different databases to establish sensitivity prior to searching (see online supplemental appendix for the search strategies for PubMed, CINAHL and CENTRAL (Register of Controlled Trials). Following the PRISMA guidelines, the search strategies involve Medical Subject Headings, free-text terms and word variants for pregnancy, musculoskeletal disorders (including but not limited to low back pain, hip pain, leg cramps, pelvic pain, diastasis of rectus abdominis, carpal tunnel syndrome, pubis symphysis dysfunction, arthralgia and arthritis) and non-pharmacological interventions including but not limited to physical activity interventions, patient education interventions, psychological interventions (cognitive–behavioural therapy, acceptance and commitment therapy, relaxation techniques and

mindful-based stress reduction), and others (transcutaneous electrical nerve stimulation, acupuncture, acupressure, manual therapy and so on).

Study records
Data management
Literature search results will be imported into Mendeley to check for duplication of studies and subsequent deduplication of records. The retrieved studies will be exported from Mendeley into Microsoft Excel to facilitate the critical evaluation, edition, management and selection of articles for inclusion into the review based on the eligibility criteria.

Selection process
Screening will be performed in two stages. GNE and OCO will independently conduct the initial screening based on the title and abstracts of the identified studies that meet the eligibility criteria. Disagreements at this stage will be resolved by discussion between the two reviewers and obtaining full texts of such studies. GNE will then read through the full texts of selected studies for further screening, using the eligibility criteria, and this will be cross-checked by OCO. Disagreement at this stage will be resolved by discussions with CNI-C. The reasons for excluding studies will be recorded. Details of the flow of study selection using the eligibility criteria will be presented in a flow chart.

Appraisal of study quality
Appraisal of the quality of included studies will be carried out after study selection is completed, during data extraction and synthesis using established quality criteria for the different primary study designs. The appraisal will be done by GNE and CNI-C independently using the Mixed Methods Appraisal Tool.[58] Any disagreements will be resolved via discussion of the two reviewers and if not resolved, the entire review team will be involved in order to reach a consensus.

Data collection process
GNE will extract the data from the studies and these will be reviewed by CNI-C. Any confusion will be addressed by discussion with the entire study team. Data from studies will be collected using a data extraction form which will be developed and piloted by CNI-C.

Data items
Data will be collected for variables including authors' names, the country where the study was conducted, the year of publication, the language of publication, participants' characteristics (age, ethnicity, occupation, education), study sample size, study design, intervention description, intervention setting, who delivered the intervention, intervention duration and follow-up period (where available), attrition rate, outcome(s) assessed, outcome measures, results and comments.

Outcomes and prioritisation
Most pregnant women with musculoskeletal disorders complain of pain, and one-quarter of them have disability, all of which reduce quality of life. The outcomes for this review include pain intensity, disability (functional and work-related disability) and quality of life. The focus for this review will include the magnitude of pain experienced; the degree of difficulty in the performance of activities of daily living and/or work-related activities, and/or the number of days absent from work; and the extent to which emotional, physical, material and social well-being are affected by pregnancy-related musculoskeletal disorders. All outcome tools used to measure these constructs in the eligible primary studies will be included and pooled, where possible.

Risk of bias in individual studies
The risk of bias will be done at both the study design level and at the outcome level. The risk of bias in clinical studies will be assessed using the Cochrane collaboration's risk of bias tool including sequence generation, allocation, concealment, blinding, completeness of outcome data, possibility of selective outcome reporting and other potential threats to validity.[59] The risk of bias in each clinical study will be rated as high risk or low risk; or unclear if there were insufficient details reported in the clinical study. The corresponding author of any clinical study lacking required details will be contacted up to three times by the corresponding author of this paper. The investigation of the risk of bias will be made independently by CNI-C and GNE by adopting the criteria for judging the risk of bias in table 8.5c in the Cochrane Handbook for Systematic Reviews of Interventions.[57] Disagreements will be resolved by discussion with the entire review team.

Data synthesis
Data will be synthesised using a mixed-studies synthesis design—the convergent synthesis.[58] The different study designs will be synthesised separately to answer the research objectives. The review findings will subsequently be combined to form a wider report of findings. The description of interventions in all study designs will be summarised narratively to answer objective 1, which is to summarise the available community-based non-pharmacological interventions for improving pain, disability and quality of life among pregnant women with musculoskeletal conditions. In order to answer objective 2, which is to determine the effectiveness of community-based non-pharmacological interventions in improving pain, disability and quality of life among pregnant women with musculoskeletal conditions across countries and settings, meta-analysis will be used to statistically summarise the findings in RCTs. In addition, non-RCTs, before-and-after, and observational studies will be summarised narratively to answer objective 2. The factors that influence the effectiveness of these interventions in improving pain, disability and quality of life among pregnant women with

musculoskeletal conditions across countries and settings will be identified from the meta-regression of RCTs, meta-analysis of observational studies, and narrative synthesis of non-RCTs and before-and-after studies where possible, to answer objective 3. Thematic synthesis will be used to summarise the findings of qualitative studies to answer objectives 4 and 5 which is to determine the acceptability of community-based non-pharmacological interventions and the factors influencing it among pregnant women with musculoskeletal conditions across countries and settings. Data will be collected from the different study designs of mixed-methods studies and combined with similar study designs in line with the above.

Three tables of characteristics will be designed. One table will be for RCTs, non-RCTs and before-and-after clinical studies, and will contain authors' citation, country of study, study designs, objectives, study quality, sample size, patient characteristics (gender, age range, socioeconomic status), outcomes measured, intervention description, control arm intervention, intervention provider, intervention setting (rural vs urban; facility), intervention duration, duration of follow-up, intervention outcomes and comments. A second table will be for observational studies and will contain authors' citation, country of study, study designs, objectives, study quality, sample size, patient characteristics (gender, age range, socioeconomic status), outcomes measured, intervention description, intervention provider, intervention setting (rural vs urban; facility), intervention duration, duration of follow-up, outcomes and comments. A third table will be for qualitative studies and will include authors' citation, country of study, study designs, objectives, study quality, sample size, patient characteristics (gender, age range, socioeconomic status), intervention description, intervention provider, intervention setting (rural vs urban; facility), intervention duration, duration of follow-up, summary of themes and comments. All adverse effects including worsening of outcomes or death will be documented in the comments section of all tables.

Statistical analyses for quantitative data
The primary outcomes for the meta-analyses will include changes in clinical outcomes including pain intensity, disability and quality of life. Results will be pooled for meta-analysis for studies that are homogenous in study design, outcomes and comparators using a random-effects model. Narrative synthesis will be used where there is significant heterogeneity of quantitative data.

For continuous data, the absolute change in means from the baseline with the 95% CIs in the intervention and control groups will be calculated. In situations where there are no baseline data, the relative percentage change between post-intervention values in the intervention and control groups will be ascertained. Other effect size metrics such as correlation coefficients and standardised regression (beta) coefficients will be also be pooled statistically where possible as for instance in observational studies. For dichotomous data, the risk difference will

be calculated from the absolute difference between the treatment and control groups. Risk ratio, rather than OR, with 95% CI will be used due to its higher sensitivity. For continuous outcomes, weighted mean differences and their 95% CIs will be estimated. In situations where different outcome measures were used to measure the same variable, standardised mean differences and their 95% CI will be calculated.

Clinical, methodological and statistical heterogeneity might be significant because of diverse musculoskeletal conditions, interventions, study designs, methods and outcomes. Heterogeneity will be assessed through the Cochrane's χ^2 test, based on a 10% level of significance cut-off as noted in a previous review[60] and will be reported. Meta-analysis will be done with Review Manager V.5.3 systematic review software.

Thematic synthesis for qualitative data
Qualitative data will be synthesised using thematic synthesis.[61] First, there will be a free line-by-line coding of the results of qualitative studies and translation of concepts from one study to the other. Second, there will be an organisation of the free codes into related constructs to form descriptive themes. Each descriptive theme will integrate several free codes while remaining close to the original accounts in the primary qualitative studies. Finally, analytical themes which directly address the objectives of this review will be developed by going beyond the results of the primary studies to develop higher order concepts from the reviewers' interpretations of the primary findings.

Meta-biases
The impact of publication bias will be assessed with funnel plots. Publication bias occurs when the findings of published studies are systematically different from those of unpublished studies. In funnel plots, there is an assumption that small studies are more likely to be susceptible to publication bias than large ones due to the greater likelihood of small negative clinical trials not getting published. Funnel plot will be determined by plotting the size of clinical trials against their reported effect sizes. We anticipate a non-systematic scattering of trials if there is no publication bias but a systematic asymmetry in the scatter of small studies (funnelling) with a greater number of small studies showing positive result than those showing a negative result.

Confidence in cumulative evidence
Table 1 highlights how the overall strength of evidence for this review will be reported using Grading of Recommendation, Assessment, Development and Evaluations (GRADE). GRADE is a framework that is used to present the summary of evidence and provide a systematic approach for making recommendations for evidence-based clinical practice.[62] GRADE is made up of four levels of evidence: very low, low, moderate and high based on several criteria such as certainty, inconsistency, impreciseness, indirectness and publication bias. High-quality evidence will be reported where further

Table 1	GRADE levels of evidence
Four levels of evidence	**Meaning**
Very low	The true effect is probably markedly different from the estimated effect
Low	The true effect might be markedly different from the estimated effect
Moderate	The authors believe that the true effect is probably close to the estimated effect
High	The authors have a lot of confidence that the true effect is similar to the estimated effect

GRADE, Grading of Recommendation, Assessment, Development and Evaluations.

research is unlikely to change the effect estimates determined in this systematic review. Moderate-quality evidence will be stated where further research is likely to have an important impact on the effect estimates or change the estimate. A low-quality evidence will be narrated where further research is very likely to have an important impact on the effect estimates and change the estimate or very low-quality evidence where the estimate of effects is very uncertain.

The web application, GRADEpro,[63] will be used to create, manage and develop the overall quality of evidence for the review findings.

Patient and public involvement

Patients and the public were not involved in the development or design of this systematic review protocol.

Potential amendments

We do not foresee any need to amend this protocol. Any unexpected amendments will not be due to the results of included studies in the final review, and will be approved and implemented by the first author.

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