

BMJ Open Women's well-being and functioning after evidence-based antenatal care: a protocol for a systematic review of intervention studies

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ABSTRACT

Introduction The 2016 WHO antenatal guidelines propose evidence-based recommendations to improve maternal outcomes. We aim to complement these recommendations by describing and estimating the effects of the interventions recommended by WHO on maternal well-being or functioning.

Methods and analysis We will conduct a systematic review of experimental and quasi-experimental studies evaluating women's well-being or functioning following the implementation of evidence-based antenatal interventions, published in peer-reviewed journals through a 15-year interval (2005–2020). The lead reviewer will screen all records identified at MEDLINE, EMBASE, CINAHL Plus, LILACS and SciELO. Two other reviewers will control screening strategy quality. Quality and risk of bias will be assessed using a specially designed instrument. Data synthesis will consider the instruments applied, how often they were used, conditions/interventions for positive or negative effects documented, statistical measures used to document effectiveness and how results were presented. A random-effects meta-analysis comparing frequently used instruments may be conducted.

Ethics and dissemination The study will be a systematic review with no human beings' involvement, therefore not requiring ethical approval. Findings will be disseminated through peer-reviewed publication and scientific events.

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INTRODUCTION

Antenatal care (ANC) is a key intervention to prevent women's morbidity and mortality. Maternal morbidity has been recently defined by the WHO Maternal Morbidity Working Group (MMWG) as 'any health condition attributed to and/or complicating pregnancy and childbirth that has a negative impact on the woman's well-being and/or functioning'.¹ Well-being refers to women's health-related quality of life (HRQoL), including their satisfaction with their health status.² Functioning relates to both physical and cognitive organic functions, as well as activities and participation in the family or in society, and it is the positive correlate of disability.^{3 4} Providing

Strengths and limitations of this study

- Our systematic review will address an information gap on the extent to which key antenatal care interventions may have positive or negative effects on women's well-being and functioning.
- This will be the first systematic review on effects of antenatal interventions on maternal well-being and functioning.
- Our results could be directly integrated in future antenatal guidelines or recommendations, and they could also lead research teams working on future guidelines to include their own analysis of the effectiveness of interventions using functioning and well-being as outcomes.
- One study limitation will be the study being solely based on interventions recommended in the 2016 WHO antenatal care guidelines, with only five interventions meeting our criteria of moderate/high certainty evidence of effectiveness.

well-established healthcare for women during pregnancy is known to be an effective measure to enhance obstetric outcomes. Therefore, evidence-based recommendations that might reduce maternal morbidity and mortality have been brought together in many global and country-specific guidelines on ANC.^{5–7}

In 2016, the WHO published its antenatal guidelines summarising and updating recommendations available to improve maternal and perinatal health. The document added an innovative human rights-based approach for management of pregnancy-related complications, prioritising a person-centred model that results in a positive pregnancy experience with ANC. The 2016 WHO antenatal guidelines are a detailed manual that presents a narrative description of several recommendations for specific health outcomes, and includes the level of evidence of the proposed interventions, classified as high, moderate and low certainty of evidence.⁸ Nonetheless, to date no guidelines have—so far as

we are aware—addressed how recommended interventions influence women's well-being and/or functioning (both of which are key elements of the broader maternal morbidity concept).

Many validated instruments exist that either measure well-being or functioning through several predetermined dimensions, concerned for example with physical and psychological health status and functions, abilities to perform daily activities, social participation, self-esteem and satisfaction with health.⁹ Frequently used instruments of HRQoL include 36-Item Short Form Survey and WHO-Quality of Life, while WHO-Disability Assessment Schedule is a commonly used functioning instrument.^{10–12} However, there is no consensus about which tool(s) most satisfactorily evaluate well-being and functioning during pregnancy and the postpartum period. Available instruments may include interviewer-administered, self-administered and proxy-administered questionnaires, using scores to identify women with important needs,^{13–16} as well as qualitative evaluations.^{10–12 17–20} Several maternal health or disease-specific questionnaires also exist for assessing HRQoL during pregnancy.^{21–23}

Maternal health has been under the scope of the Sustainable Development Goals (SDG) to be achieved until 2030, especially through the highlighted 'good health and well-being' (SDG 3) and 'gender equality' (SDG 5)²⁴ goals. Thus, together with reduction of morbidity and mortality, future antenatal measures/actions/recommendations should include promoting women's well-being and functioning, comprising a positive pregnancy experience and preventing violence. It is crucial to gather information available on which key healthcare interventions may have a positive effect on women's well-being and/or functioning, so that they might be tested in intervention studies among different populations and settings in the future. From a long-term perspective, such information could be integrated in forthcoming ANC guidelines or recommendations.

Our objectives will be to compare, appraise and summarise studies focusing on evidence-based interventions that are recommended in the WHO ANC guidelines and were applied during ANC, and that have/have not influenced maternal well-being or functioning. In the WHO ANC guidelines, evidence-based interventions consisted of treatment, procedures or more complex programmes that were evaluated using experimental and quasi-experimental studies as well as observational studies.

METHODS AND ANALYSIS

This will be a systematic review of experimental and quasi-experimental studies evaluating women's well-being and functioning associated with or as a result of the implementation of selected evidence-based antenatal interventions. We aim to analyse whether well-established interventions applied to pregnant women have affected their well-being and functioning.

The period covered will be studies published from 2005 until 2020. The initial search was already performed, and selection of studies is currently under quality analysis. There will be a language restriction to articles published in English, French, Portuguese and Spanish. The systematic review will follow the PRISMA-P statement (Preferred Reporting Items for Systematic Review and Meta-analysis Protocols)²⁵ and has been registered at the International Prospective Register of Systematic Reviews.

For the present review, exposure will be interventions recommended for ANC because they reduce the occurrence of direct or indirect obstetric conditions, and outcome will be women's well-being and/or functioning during pregnancy or after childbirth after receiving the recommended ANC interventions.

Eligibility criteria

There are no country/region inclusion or exclusion criteria. Included studies will have been conducted in primary care facilities, during home-based care or hospital-based care. The present review will include studies whose subjects are pregnant women at any gestational age, who have received one of the preselected interventions (outlined in the next paragraph), and who were evaluated from a well-being and functioning perspective (specifically designed tools/instruments or qualitative assessment) at any point in time during or after pregnancy. The inclusion of the postnatal period may provide data on longer term outcomes concerning well-being and functioning related to pregnancy.

The selection of interventions was based entirely on the 2016 WHO Antenatal Guideline.⁸ The WHO guidelines were intended to promote obstetric care within a broader framework, beyond prevention of death and morbidity, and to prioritise the applicability of interventions in low-income and middle-income countries. We selected the WHO guidelines on account of their wide international circulation, as well as their use as a model for health policies around the world. Health promotion and identification of risk factors are within the scope of these guidelines, whereas treatment of complications and concurrent diseases are not. In order to account for women's perspectives about the care provided to them, systematic reviews on women's expectations on ANC were carried out, and the final version of the document was intended to promote well-being as part of the 'positive pregnancy experience'.

The WHO guidelines list 49 recommendations grouped into 5 'types of interventions' and concerning 10 'maternal outcomes of interest' (figure 1), as well as fetal and neonatal outcomes. Among the 49 recommendations, 10 were included into the 2016 document from existing WHO guidelines approved by the review committee for the 2016 document. Evidence on the effectiveness of interventions was obtained from 47 systematic reviews. Additionally, findings from a scoping review on women's understanding of a positive ANC experience within high-resource, middle-resource and low-resource

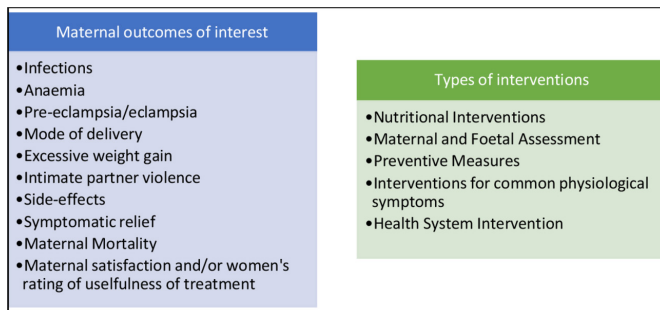


Figure 1 Maternal Outcomes of interest and types of interventions according to 2016 WHO Antenatal Guideline.

settings suggested the importance of effective clinical practices, relevant and timely information, and psychosocial and emotional support.²⁶ Consideration of women's perspectives was therefore applied together with quantitative evidence to evaluate the recommendations. The GRADE (Grading of Recommendations, Assessment, Development and Evaluations) approach was applied to appraise the quality of quantitative evidence.²⁷ The quality of evidence was rated as 'high', 'moderate', 'low' or 'very low', with randomised controlled trials (RCTs) providing 'high-quality' evidence, while non-randomised trials and observational studies provided 'low-quality or moderate-quality' evidence. Qualitative reviews were appraised using the GRADE-CERQual tool.²⁸

For the present systematic review, we reviewed the 49 recommendations findings with respect to their effects on 'maternal outcomes of interest' only, in order to ascertain the certainty of the evidence for the effectiveness of the intervention on women's health improvement. We did not include maternal well-being and functioning outcomes for selecting interventions at this point. We found five interventions that were presented as having either a high or a moderate level of certainty of evidence associated with one or more of the listed 'maternal outcomes of interest'. Those five interventions with high and moderate level of certainty of evidence will be further assessed in our systematic review to establish their effectiveness in improving maternal well-being or functioning.

The five interventions described as improving maternal outcomes that will therefore be included in our systematic review are listed below:

1. Daily iron and folic acid supplementation: reduces puerperal infections and anaemia (when daily and intermittent supplementation were compared, favouring daily).
2. Multiple micronutrient supplementation: reduces anaemia (similar effect to iron and folic acid supplementation).
3. Vitamin A supplementation: reduces anaemia (and night blindness at affected populations).
4. Diet and/or exercise: prevents hypertension and excessive weight gain (but not pre-eclampsia/eclampsia).
5. Midwife continuity of care: increases vaginal birth rates.

Data management

We will search MEDLINE, EMBASE, CINAHL Plus, LILACS and SciELO with customised search strategies for each electronic database according to their individual subject headings, syntax and searching structure. The search will combine free text and Medical Subject Headings terms for the proposed interventions and maternal outcomes. For the maternal outcomes, we will apply keywords and index terms for the concepts of HRQoL, well-being and functioning. The search strategy is shown in online supplemental appendix 1.

Initially, CBA (lead reviewer) will select manuscripts by scrutinising their titles and abstracts, excluding those that are not related to the proposed objectives. To maximise the identification of all relevant results and ensure quality control, VF and JGC will look at a proportion of manuscripts to check whether they were included or not, until perfect matching in selection has been obtained. Following this step, we will assess the full text of the remaining documents, discarding irrelevant records, unless they can provide additional interpretation data. CBA will extract the data from relevant studies using a screening form specifically designed for the present review (online supplemental appendix 2) and examining their reference lists to identify additional papers for inclusion. She will also scrutinise the reference lists of relevant literature reviews identified by our search strategy.

Prior to the final analysis, we will conduct a rerun of the searching strategy in order to check for more recent studies not initially included. Search results will be managed in EndNote and extracted data will be entered in an Excel spreadsheet.

We will list all instruments/questionnaires used for well-being and/or functioning measurement, and studies that applied the same instrument will be compared.

We will prepare a PRISMA flowchart to display results of the search, screening, review and extraction in a sequential manner, and a list of rejected articles along with the reasons for their exclusion.

Assessment of study quality/risk of bias

Two reviewers will appraise the data, and a third reviewer will be available for discussion if they are not in consensus. The planned analysis is a meta-analysis of published data in selected studies. The quality and risk of bias will be assessed using a tool specifically designed for this purpose, based on version 2 of Cochrane's tool for assessing bias in randomised trials,²⁹ and, if necessary, using statistical approach. For this, we included the bias domains and risk-of-bias questions in the study screening form (online supplemental appendix 2).

The dimensions analysed for bias include:

1. **Sampling:** What is the intended study population? (pregnant women with or without a condition; all pregnant women with a condition in the community; pregnant women attending health services; pregnant women with a condition attending health services; special categories of women).

- Detailed information written in full (extracted from manuscript) for the following:
 - Are the respondents representative of the intended study population?
 - Is there an adequate description of data collection location, including reasons for choice?
 - Is there an adequate description of inclusion and exclusion criteria? (sociodemographic characteristics of the study population such as age, gestational length, ethnicity, level of education, parity, previous health condition and so on).
 - Ethical issues (is there a consent form?).
- 2. **Completeness:** Are there enough women interviewed and followed up?
 - Detailed information written in full (extracted from manuscript) and then simple yes/no answers for the following:
 - Is the sample size calculation adequate?
 - What was the follow-up rate? Are particular subgroups of women more likely to be lost to follow-up? Are reasons for loss of follow-up explained? (explanations in full text).
- 3. **Study design:** Is the study design described properly?
 - Detailed information written in full (extracted from manuscript) and then simple yes/no answers for the following:
 - Is the methodology adequate for drawing cited results/conclusions?
 - If the study is an RCT, was randomisation properly conducted?
 - If the study is an RCT, are investigators ascertaining outcomes blind to intervention allocation?
 - What certainty is there that health-related functioning/well-being is a consequence of the evidence-based antenatal or postnatal intervention?
- 4. **Comparison:** Is there a comparison group of pregnant/postpartum women without evidence-based intervention?
 - Detailed information for each group written in full (extracted from manuscript) and then simple yes/no answers for the following:
 - If the study has a quasi-experimental design, are there concurrent comparison groups and/or 'before and after' evaluations?
 - What was the content of care in the control group?
- 5. **Validation:** If a standardised tool was used, was the validity of the tool known or established for the population of interest (pregnant or postpartum women; women of reproductive age; preferably in the same geographical location)? (yes/no).
Do applied well-being/functioning instruments have appropriate psychometric properties? (yes/no).
- 6. **Intervention:** Did the authors describe the content and implementation of the selected intervention in sufficient detail? (yes/no).

7. **Conceptualisation:** Did the authors provide a definition of health-related functioning/well-being? (yes/no).

Did the authors describe well-being and functioning instruments used? Are they correctly applied in the study? (yes/no).

Data synthesis

Among selected studies with any maternal outcome, our synthesis will consider the following:

- ▶ What were the instruments applied to evaluate well-being/functioning and how often were they used? What type of measures do they use?
- ▶ For which interventions have positive or negative effects been documented?
- ▶ What were the measures of effects used to quantify well-being or functioning?
- ▶ How were the results presented regarding impact on well-being/functioning?
- ▶ Can results from different studies be combined? (same instrument/methodology).

The findings of the systematic review will be displayed in tables with studies' characteristics (sample, design, results). A table with listed studies and instruments will be provided, detailing methods, participants and results, as well as the appraisal of the quality of selected studies and questionnaires. We will apply GRADE to summarise the level of evidence available from our systematic review findings.²⁷ Different HRQoL, well-being and functioning tools will be described according to their scoring systems, and then categorised in order to display their effects in an organised panel. We will calculate the proportion of studies with positive or negative effects for each selected intervention, and present the range of effects in a table format.

Finally, a narrative of the range of impact on well-being/functioning will be developed to summarise the findings. Fixed-effects or random-effects meta-analyses may be considered to analyse the results of the most frequently used well-being and functioning instruments, depending on the homogeneity of exposure/outcome characteristics.

Patient and public involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our study.

DISCUSSION

Recently, a standardised tool (WOICE) was developed by the WHO MMWG to identify maternal morbidity, recognising that there are many aspects of women's lives which may be affected by ill-health during pregnancy or delivery.^{1 2} Applications of the WOICE tool revealed that the prevalence of self-reported ill-health was higher than appraised by health professionals,³⁰ a conclusion found in other studies which compared self-reported

data with diagnoses.^{31 32} These findings suggest that pregnant women's own perceptions of their health allow for a more comprehensive identification of the health-related burden of pregnancy and complications than diagnoses alone.

We plan to identify and describe good quality studies evaluating the influence of well-established antenatal interventions/recommendations on maternal well-being and functioning. Furthermore, we plan to meta-analyse findings from studies that applied the same measurement instrument and provide a summarised narrative of findings from studies that could not be directly compared because of a lack of common instrument, but provided answers to our research question.

By the same token, our systematic review will provide much needed comprehensive insights on whether selected evidence-based interventions recommended for use during ANC have an impact on women's self-reported well-being and/or functioning during pregnancy or postnatally, as well as on diagnoses of clinical conditions. In addition, the review is likely to provide useful methodological insights on the instruments applied for this assessment, since it has been suggested that no currently available instrument is sufficiently comprehensive to capture the particularities of functioning and well-being during the pregnancy, childbirth and postpartum period, and that there is a need for the development of a new maternity-specific tool.^{4 33} We believe our systematic review is likely to highlight interventions for which further evidence-based investigation is required, since documenting well-being and functioning during pregnancy and childbirth is relatively new, particularly in low-income and middle-income settings.

Pregnancy, childbirth and the postpartum period constitute a unique period during which women need to cope with physiological modifications while taking care of their child and frequently their household and professional career. The broader approach towards women's health beyond reproductive aspects was already pointed as key measure to achieve sustainable development.³⁴ The strain of being pregnant, giving birth and facing the postpartum period may negatively impact women's well-being and functioning, even more if during these circumstances women also struggle with morbidity or hypothetical unwanted outcomes from antenatal interventions.^{15 35 36} Currently, we have no satisfactory means to properly identify and respond to these difficulties and empower women to thrive. Our proposed systematic review aligns with the objectives of the SDG in promoting well-being under a gender perspective.³⁷

We searched through several antenatal guidelines including, for example, The National Institute for Health and Care Excellence, the American College of Obstetrics and Gynaecology, the International Federation of Gynaecology and Obstetrics, the Society of Obstetricians and Gynaecologists of Canada, the Pregnancy Care Guidelines from Australian Department of Health, guidelines from the *Collège National des Gynécologues et Obstétriciens*

Français, guidelines for maternity care in South Africa and Brazilian guidelines for routine ANC. To the best of our knowledge, no available guidelines include an assessment of women's well-being or functioning as part of their evaluation of the evidence base for their recommended interventions.^{5 6 38–43} Future clinical guidelines should not only recommend clinical evidence-based measures based on the treatment of diseases, but also take into account the possible positive or negative impact of interventions on women's HRQoL or functioning.^{11 44} Appraising available evidence-based interventions recommended in the WHO ANC guidelines that have influenced maternal well-being or functioning might provide information to be integrated in forthcoming ANC guidelines or recommendations, under a women's well-being perspective.

ETHICS AND DISSEMINATION

The study will be a systematic review based on secondary data, therefore not requiring ethical approval. Patients were not directly involved in the study design, therefore dissemination of findings to participants is not applicable.

Any further amendments to this protocol will be documented and recorded in bibliographical databases.

The results will be disseminated using green or gold open access to ensure universal access for researchers, academics, caregivers and policymakers.

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