

INPLASY PROTOCOL

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None declared.

A critical appraisal and systematic review of clinical practice guidelines on hormone replacement therapy for menopause: assessment using the Appraisal of Guidelines for Research and Evaluation (AGREE II) Instrument

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Review question / Objective: To assess the quality of clinical practice guidelines (CPC) on hormone replacement therapy for menopause using the AGREE II instrument and to provide a summary of recommendations.

Information sources: Literature searches using MEDLINE, Embase, Scopus, Geneva Foundation for Medical Education and Research from inception to date will be searched. The search terms include guidelines / guidance / recommendation and hormone replacement therapy related keywords and MeSH terms. National and international organizations websites will be searched individually. Additional searches on the references of the primary included items may help identify any guidelines missed on the primary searches. In the case of more than one published guideline from the same national or international association, only the latest version of the guidelines will be included and evaluated. Any disagreements on inclusion criteria will be addressed through discussion and consensus meeting within the research team. Guidelines published in languages other than English will be considered on an individual basis. Guidelines must be publicly available on a website or in a peer-reviewed publication.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 December 2022 and was last updated on 22 December 2022 (registration number INPLASY2022120089).

INTRODUCTION

Review question / Objective: To assess the quality of clinical practice guidelines (CPC) on hormone replacement therapy for menopause using the AGREE II instrument

and to provide a summary of recommendations.

Condition being studied: This systematic review will focus on hormone replacement therapy for women in menopause.

METHODS

Participant or population: Women in menopause / menopausal transition.

Intervention: Hormone replacement therapy (HRT), also known as menopausal hormone therapy or postmenopausal hormone therapy, is a form of hormone therapy used to treat symptoms associated with menopause. Such symptoms can include hot flashes, vaginal atrophy, accelerated skin aging, vaginal dryness, decreased muscle mass, sexual dysfunction, and bone loss. Multiple treatment options are available and should be tailored based on individual requirements. Clinical practice guidelines have been developed to improve both the quality or process of care and patient outcomes. These guidelines will be evaluated using the AGREE II instrument.

Comparator: We will report an inventory of recommendations summarizing data published in different guidelines and provide comparisons on recommendations where appropriate.

Study designs to be included: We will include published clinical practice guidelines of national and international professional organizations or governmental bodies on hormone replacement therapy for menopause.

Eligibility criteria: Clinical practice guidelines on hormone replacement therapy for premenopausal women will be excluded.

Information sources: Literature searches using MEDLINE, Embase, Scopus, Geneva Foundation for Medical Education and Research from inception to date will be searched. The search terms include guidelines / guidance / recommendation and hormone replacement therapy related keywords and MeSH terms. National and international organizations websites will be searched individually. Additional searches on the references of the primary included items may help identify any guidelines missed on the primary searches. In the

case of more than one published guideline from the same national or international association, only the latest version of the guidelines will be included and evaluated. Any disagreements on inclusion criteria will be addressed through discussion and consensus meeting within the research team. Guidelines published in languages other than English will be considered on an individual basis. Guidelines must be publicly available on a website or in a peer-reviewed publication.

Main outcome(s): The main outcome will be the quality of the practice guidelines, based on the AGREE II tool.

The AGREE II comprises of 23 items grouped into 6 quality domains:

1. Scope and purpose
2. Stakeholder involvement
3. Rigour of development
4. Clarity of presentation
5. Applicability;
6. Editorial independence.

The AGREE II tool also includes one final overall assessment item that the appraisers apply to make overall judgements of the practice guideline.

Quality assessment / Risk of bias analysis: Four appraisers will independently score the included guidelines using the AGREE II reporting checklist. Any disagreements will be resolved by consensus within the research team.

The inter-rater reliability, which is the degree of agreement among independent observers who rate, code, or assess the same phenomenon, will be measured using intra-class correlation coefficient.

Strategy of data synthesis: Data will be extracted based on AGREE II checklist. An instruction manual which provides guidance on how to score and where to look in the guideline for relevant content in order to score each item for each domain will be used (more information available at: <http://www.agreetrust.org>). A minimum number of clinical practice guidelines will not be imposed.

Our research team within CHORUS has already completed and published reviews on guidelines in pelvic floor disorders and

aims to use the same strategy and methodology.

The clinical practice guidelines will be assigned quality scores (standardized domain score as a percentage) which are calculated for each of these six AGREE II domains. No additional software or tools are required to perform the AGREE II calculations.

Subgroup analysis: Not applicable.

Sensitivity analysis: Not applicable.

Country(ies) involved: Romania, England.

Keywords: Menopause; hormone replacement therapy; AGREE II; Clinical practice guidelines; Critical appraisal.

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