



Original Article

Clinical Practice Guideline on Acupuncture and Moxibustion: Adult Major Depressive Disorder (Mild-Moderate Degree): Determination of clinical questions[☆]



《针灸临床实践指南：成人轻中度抑郁症》：临床问题的确定

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ABSTRACT

Determining clinical questions is fundamental to the development of clinical practice guidelines (CPGs), which bridges the initial phases and the final recommendations. It is essential for evidence retrieval and the formulation of recommendations. The scientific rigor and precision in determination of clinical questions directly influence the future implementation and applicability of guidelines. In 2020, the World Federation of Acupuncture-Moxibustion Societies initiated the project of clinical practice guideline on acupuncture and moxibustion for adult major depressive disorder (mild-moderate degree) to address clinical and medical decision-making issues in acupuncture treatment for adult mild to moderate major depressive disorder. This CPG provides systematic recommendations based on clinical evidence, patient values, and other factors, aiding decision-makers, clinicians, and patients in selecting appropriate interventions. This paper discusses and analyzes the determination process of clinical questions, and the related issues during the development of this guideline, aiming to provide a reference for determining clinical questions and developing CPGs in the field of acupuncture and exploring more scientific tools and methods for determining clinical questions in future CPGs.

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1. Introduction

Evidence-based clinical practice guidelines (CPGs) are developed based on systematic reviews of evidence, considering the benefits, safety, and costs of different interventions to provide optimal recommendations [1]. In 2020, the World Federation of

Acupuncture-Moxibustion Societies (WFAS) [2] initiated a CPG on acupuncture and moxibustion for the treatment of depression (project number: WFASRP202001-SC03) to support clinical and policy decision-making for clinicians, patients, and policymakers in optimizing the treatment of major depressive disorder (MDD). It has been registered on the International Practice Guidelines

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Registry Platform (registration number: IPGRP-2019CN031, <http://www.guidelines-registry.org/>). The WFAS collaborated a multi-national and multidisciplinary guideline panel, leading to the development of the *Clinical Practice Guideline on Acupuncture and Moxibustion: Adult Major Depressive Disorder (Mild-Moderate Degree)*, hereinafter referred to as the *Acupuncture Guideline for MDD*.

At the initial phase of the guideline development process, the expert panels of the *Acupuncture Guideline for MDD* spent nearly one year extensively discussing the clinical questions. It has been realized that the determination of clinical questions is fundamental and crucial to develop high-quality acupuncture CPG. Clinical questions guide literature retrieval, evidence evaluation, and the formation of final recommendations. Therefore, it is the urgent need to launch methodological research on the determination of clinical questions for acupuncture guidelines. This paper takes *Acupuncture Guideline for MDD* as an example to explore the process of determining clinical questions, aiming to provide methodological references for the development of acupuncture CPGs.

2. Establish guideline groups

The panel of the *Acupuncture Guideline for MDD* included a guideline development group (GDG) and a guideline drafting group, which was appointed by the guideline development project team.

Establishing an effective GDG is a crucial step in developing a CPG. It requires an effective chair and a multidisciplinary membership to ensure smooth operation. The chair guides the GDG through the guideline development process, facilitates collaboration, and ensures equitable contributions from all members. GDG members are responsible for considering the evidence and reaching conclusions based on the above. Expert consensus are required to make decisions if the evidence is insufficient or lacking to formulate guideline recommendations. Therefore, the GDG members should be multidisciplinary, including healthcare providers, other professionals, and patients, to balance individual contributions with the need for broad experience and knowledge. The GDG members of this guideline included an expert panel and two patient representatives. The expert panel comprised twenty-one multidisciplinary experts: 1) guideline methodologists, 2) acupuncturists, 3) physicians, 4) psychologists, 5) psychiatrists, 6) obstetricians. These experts were from different countries, i.e. China, South Korea, the United States, Germany, Australia, and Norway.

The guideline drafting group had two experts who was specialized in systematic review and guideline development methodology, and in charge of the training for all the GDG members on the guideline development process, the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) methods [3], and the framework for formulating clinical questions. There were six master's and doctoral students in the drafting group, responsible for literature retrieval, data extraction, and evidence synthesis.

3. Clarify targeted population and setting

The *Acupuncture Guideline for MDD* targets at clinicians, patients, and policymakers worldwide who are interested in mild to moderate major depressive disorder in adults. It is applicable to hospitals with acupuncture specialties, primary hospitals or clinics engaged in acupuncture work, medical schools with acupuncture programs, and research institutions focused on acupuncture studies.

4. Methods for investigating clinical questions

4.1. Questionnaire survey

The online survey questionnaire developed by Questionnaire Star (www.wjx.cn) was used to explore areas of interest among experts. The questionnaire on themes and scope included items on clinical need, health policy demand, availability of supporting evidence, and existence of published guidelines. The questionnaire on clinical questions covered the core elements identified in preliminary discussions, such as different types of therapies, utilizing the PICO (population/intervention/comparison/outcome) framework. The drafting group proposed a list of potential clinical questions, which was then discussed and determined by GDG to identify key clinical questions for acupuncture treatment of adult MDD.

4.2. Delphi method

The drafting group employed the Delphi method [4], distributing anonymous questionnaires to GDG members via email for item selection. After identifying the items, GDG members rated their importance using a 5-point Likert scale (ranging from 1 “not important at all” to 5 “extremely important”) [5]. Following the first round of consultations, the initial item list was refined based on the feedback of GDG, and a second round of consultations was conducted. Through the communication and feedback adjustments, the experts' opinions were converged, and the final weights of each item were determined based on the comprehensive views of all experts.

4.3. Expert consensus meeting

Following the items evaluations obtained through the Delphi method, the drafting group organized several rounds of video meetings. Using the brainstorming method, GDG members shared their clinical experience-based opinions and engaged in discussions to ultimately reach a consensus on clinical questions. The drafting group incorporated literature review and expert opinions, identified the themes, scope, and raised clinical questions related to acupuncture treatment for MDD. The GDG members then selected and defined the outcome indicators for each clinical question, rating their importance using a 9-point scale (with 0-3 indicating “not important”, 4-6 “important”, and 7-9 “critical”) [6]. A flowchart illustrates the process for determining clinical questions in the acupuncture guideline of MDD in Fig. 1.

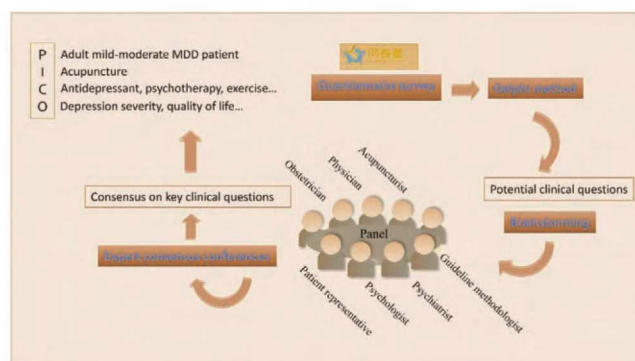


Fig. 1. Flowchart of determining clinical questions for acupuncture guideline for MDD.

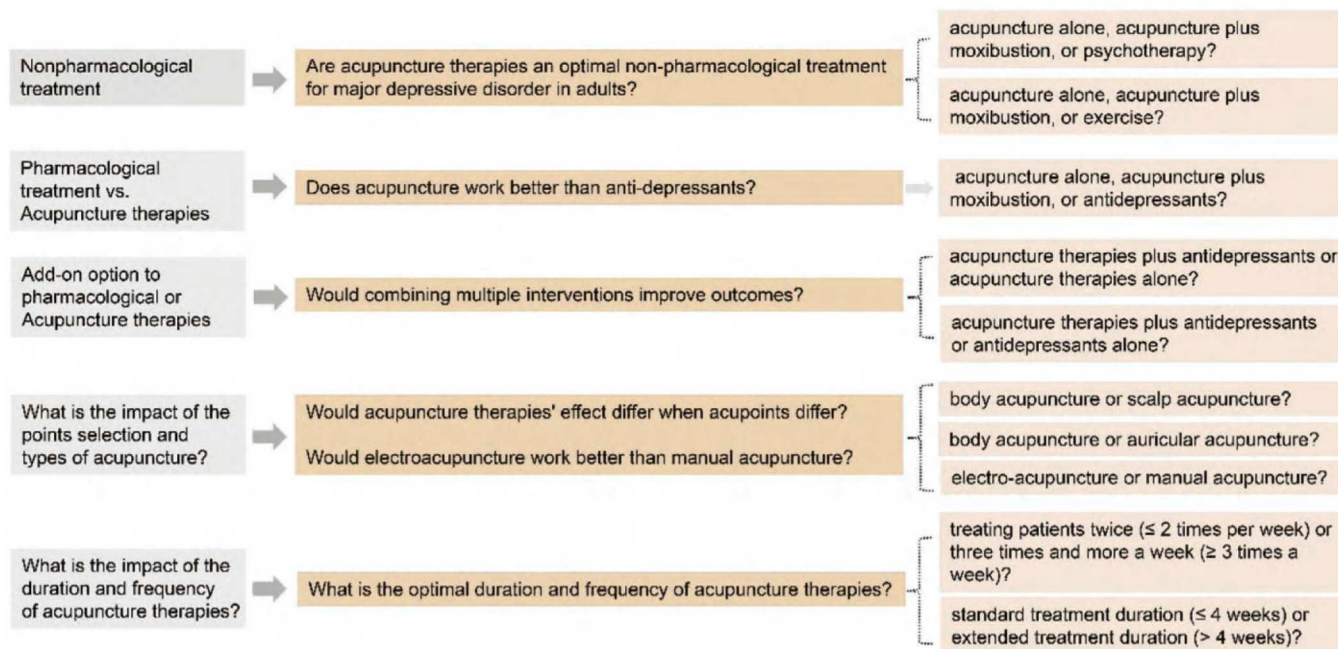


Fig. 2. The process of determining clinical question(s).

5. Determination of clinical question(s)

To identify clinical questions, the guideline panel began with a preliminary list of 16 potential questions based on clinical needs, literature review, and experts' opinion. Consequently, the five categories of clinical questions of greatest concern were summarized. 1) How does acupuncture therapy compare to the most commonly used non-pharmacological treatments for depression? 2) How does acupuncture compare to antidepressant medication? 3) Is the combination of acupuncture and antidepressant medication more effective than using either acupuncture or medication alone? 4) Does the choice of acupoints and stimulation methods affect the efficacy and safety of acupuncture treatment? and 5) What impact do the course and frequency of acupuncture therapy have on its efficacy and safety? Following these categories, through three rounds of Delphi surveys and two rounds of expert consensus meetings, the final set of ten key clinical questions was determined (Fig.2).

6. Generation of PICO question(s)

Following the determination of ten clinical questions, the panel of *Acupuncture Guideline for MDD* used the PICO framework to decompose these complex clinical questions into the four elements of PICO, thereby generating precise PICO questions.

6.1. Population(P)

To identify the population that would benefit optimally from acupuncture, the panel reached a consensus to limit the scope of the guidelines, focusing on adult patients with mild to moderate MDD.

The target population of the *Evidence-Based Guidelines of Clinical Practice with Acupuncture and Moxibustion: Depression(Revised) (ZJ/T E003-2014)* issued in 2014 included acupuncture recommendations for mild to severe depression, postpartum depression, post-stroke depression, and menopausal depression [7]. In updating this edition, the panel refined the scope to be more targeted to clinical practice. The international psychiatric experts on the panel had

a particular interest in postpartum depression due to the challenges posed by antidepressants affecting breastfeeding through breast milk [8]. These patients have a greater need for non-pharmacological interventions, such as acupuncture. However, due to the lack of high-quality clinical evidence on its effectiveness, postpartum depression was excluded from this guideline. Childhood and adolescent depression had distinct characteristics, therefore psychological therapy and antidepressants are taken as the preferred treatment [9,10]. Consequently, due to limited acceptance of acupuncture, the guideline excluded children and adolescents.

Although evidence suggested acupuncture can be effective for severe MDD [11], the experts generally agreed that acupuncture was more beneficial for mild to moderate cases. Psychiatrists believed severe MDD required specialist intervention and responded less effectively to non-pharmacological treatments. Therefore, severe MDD was excluded in the guideline.

MDD treatment was typically divided into three phases: acute, remission, and maintenance, with relapse possible at any stage [12]. Experts concluded that acupuncture targeted the symptoms consistently across all phases. Thus, the guideline did not specify a particular stage for acupuncture treatment.

6.2. Intervention(I)

Acupuncture Guideline for MDD identified acupuncture therapy as the intervention. Acupuncture can be broadly or narrowly defined. The World Health Organization (WHO) defines broad acupuncture to include traditional body acupuncture, moxibustion, electroacupuncture, and other related therapies [13]. Narrowly, acupuncture involves inserting needles along specific pathways or meridians, sometimes with heat, moxibustion, acupressure, or electrical stimulation. In this guideline, acupuncture follows the WHO's broad definition, including body acupuncture, moxibustion, electroacupuncture, and microsystem acupuncture (such as auricular and scalp acupuncture), but excluding acupressure and laser acupuncture. To determine the best acupuncture treatment for MDD, the expert panel compared different acupuncture methods, and optimal acupoint prescriptions, as well as treatment frequency and duration.

Table 1
PICO questions for clinical practice guideline on acupuncture and moxibustion: adult major depressive disorder (mild-moderate degree).

No.	PICO questions
1	For adults diagnosed with mild or moderate MDD, should we recommend acupuncture alone, acupuncture plus moxibustion, or psychotherapy?
2	For adults diagnosed with mild or moderate MDD, should we recommend acupuncture alone, acupuncture plus moxibustion, or exercise?
3	For adults diagnosed with mild or moderate MDD, should we recommend acupuncture alone, acupuncture plus moxibustion, or antidepressants?
4	For adults diagnosed with mild or moderate MDD, should we recommend acupuncture therapies plus antidepressants or acupuncture therapies alone?
5	For adults diagnosed with mild or moderate MDD, should we recommend acupuncture therapies plus antidepressants or antidepressants alone?
6	For adults diagnosed with mild or moderate MDD who will receive acupuncture therapies, should we recommend body acupuncture or scalp acupuncture?
7	For adults diagnosed with mild or moderate MDD who will receive acupuncture therapies, should we recommend body acupuncture or auricular acupuncture?
8	For adults diagnosed with mild or moderate MDD and who will receive acupuncture therapies, should we recommend electro-acupuncture or manual acupuncture?
9	For adults diagnosed with mild or moderate MDD and who will receive acupuncture therapies, should we recommend treating patients twice (≤ 2 times per week) or three times and more a week (≥ 3 times a week)?
10	For adults diagnosed with mild or moderate MDD and who will receive acupuncture therapies, should we recommend standard treatment duration (≤ 4 weeks) or extended treatment duration (> 4 weeks)?

6.3. Comparison(C)

MDD treatment includes both pharmacological and non-pharmacological methods. The guideline panel has included the following antidepressant medications for comparison, 1) selective serotonin reuptake inhibitors, 2) serotonin-norepinephrine reuptake inhibitors, 3) noradrenergic and specific serotonergic antidepressants, 4) serotonin antagonist and reuptake inhibitors, 5) selective 5-HT_{1A} receptor agonists, 6) tricyclic antidepressants, 7) monoamine oxidase inhibitors, and 8) tetracyclic antidepressants. Non-pharmacological therapies such as psychotherapy, physical exercise, and cognitive-behavioral therapy were also considered for comparison.

6.4. Outcome(O)

Based on literature reviews and expert discussions, this guideline had categorized outcomes into effectiveness indicators and safety indicators. The indicators of effectiveness included: 1) severity of depression, 2) remission rate of depression, 3) quality of life, 4) insomnia, 5) fatigue, and 6) changes in the use of medication or other support systems. The indicators of safety included: 1) total number of adverse events, 2) total number of serious adverse events, 3) total number of adverse reactions related to medication, and 4) changes in the use of medication or other interventions.

The panel rated the importance of these indicators using a 9-point scale. The following indicators were identified as critically important for all clinical questions: severity of depression, total number of serious adverse events, and remission rate of depression. Important outcomes included quality of life, insomnia, fatigue, total number of serious adverse events, changes in the use of medication or other interventions, and medication-related adverse events. For clinical questions 3 and 4, two additional outcomes were deemed critically important: total number of adverse reactions related to medication, and total number of adverse events. For clinical question 4, quality of life was also rated as a critically important.

7. Rationale for PICO questions

After determining ten key clinical questions, the panel generated the PICO questions for acupuncture guideline for MDD based on the PICO framework. The ten PICO questions for the guideline is shown in Table 1. The rationale for setting each PICO question is described as follows:

PICO 1: Acupuncture therapy is considered as one of the recommended interventions for MDD due to its minimal side

effects and high patient acceptance [14]. *Canadian Network for Mood and Anxiety Treatments Guidelines* recommend psychotherapy as a first-line treatment method [15]. Therefore, PICO 1 aimed to evaluate whether acupuncture therapies were the effective non-pharmacological treatment compared with psychotherapy for MDD.

PICO 2: Exercise is recommended as a first-line intervention for mild to moderate MDD [15]. Thus, PICO 2 aimed to evaluate whether acupuncture therapies were the effective non-pharmacological treatment compared with physical exercise for MDD.

PICO 3: There are many types of antidepressants recommended as first- and second-line interventions [16]. PICO 3 was developed to evaluate and compare the effectiveness and safety of acupuncture versus antidepressants for treating mild to moderate MDD.

PICO 4: Given the common use of medication alongside acupuncture in clinical settings [17], the question arises: Could the combination of various therapies improve outcomes? Therefore, PICO 4 was developed to evaluate whether combining acupuncture with antidepressants improves outcomes in comparison with acupuncture alone.

PICO 5: When patients do not respond to antidepressants, acupuncture combined could be a good choice. Thus, PICO 5 aimed to evaluate the effectiveness and safety of acupuncture combined with antidepressants versus antidepressants alone for treating mild to moderate MDD.

PICO 6/7/8: There are various methods of acupuncture treatment for MDD, such as manual acupuncture, electroacupuncture, auricular acupuncture, and scalp acupuncture [18,19]. Do different acupoints and stimulation methods affect the therapeutic effects? Is electroacupuncture more effective than manual acupuncture? Hence, PICO 6/7/8 aimed to evaluate which acupuncture method is more effective.

PICO 9/10: The frequency and duration of acupuncture treatment may be related to its therapeutic effects [20,21]. PICO 9/10 aimed to evaluate the optimal frequency and duration of acupuncture treatment for MDD.

8. Discussion

8.1. Importance of clinical questions in CPG development

Clinical questions are the foundation of the CPG framework and critical for developing evidence-based guidelines. These clinical questions represent the shared challenges faced by healthcare professionals and patients alike, aiming to clarify the objec-

tives and direction of the guideline [22]. In 2019, the WHO conducted an in-depth analysis on CPG development methods, emphasizing the importance of determining clinical questions [23]. The Chinese Medical Association's *Guidelines for Developing/Revising CPGs in China (2022 Edition)* also noted that the source, number, and composition of clinical questions in a guideline determine the length and content of recommendations and impact its dissemination and application: when clinical questions are highly relevant to frontline clinicians and clearly articulated, guideline implementation tends to be more effective [24]. Therefore, it is crucial to identify a reasonable range of clinical questions to meet clinical needs. This step clarifies the research focus and serves as the cornerstone for developing high-quality, practical guidelines

8.2. Comparison with other guidelines including acupuncture as an intervention for depression

MDD has consistently attracted attention in the realm of acupuncture therapy [25]. Over the past decade, authoritative institutions in the United States, Canada, and China have released guidelines for depression, among which, there are six recommendations with acupuncture treatment involved as an intervention. Guidelines issued by the American Psychological Association [26], the American College of Physicians [27], the Canadian Network for Mood and Anxiety Treatments [15], and the Chinese Major Depressive Disorder Working Group [28] focus on whether acupuncture can be used as a standalone therapy, an adjunct to antidepressants, or a supplementary non-pharmacological treatment. The 2014 *Evidence-based guidelines of clinical practice with acupuncture and moxibustion: Depression(revised)* issued by China Association of Acupuncture-Moxibustion offered valuable insights but was limited in the diversity of countries during its development, which affects its international impact [7].

8.3. Strengths of the acupuncture guideline for MDD

Acupuncture Guideline for MDD brings a global perspective by involving experts from North America, Europe, East Asia, and Australia, ensuring international applicability and representativeness. It involved experts from diverse countries, regions, hospital levels, and professional backgrounds, ensuring a multidisciplinary approach to enhance the guideline's quality. Patient opinions, as emphasized in the NICE guidelines, were also incorporated to select clinical questions that meet actual patient needs [29]. This approach ensures broad international applicability, representativeness, and relevance to clinical decision-making for clinicians, patients, and policymakers. Additionally, this guideline comprehensively compares acupuncture with other non-pharmacological therapies and antidepressants, discussing suitable types of acupuncture, treatment frequency and duration, and providing the most practical guidance to date for treating mild to moderate MDD with acupuncture.

Clear clinical question definitions, systematic evidence evaluation, multidisciplinary expert collaboration, patient representative inclusion, and strict conflict of interest management ensured the recommendations' credibility, scientific basis, and practicality. The guideline development integrated disease characteristics and academic discipline of acupuncture, focusing on clinical questions that highlights acupuncture's clinical advantages. Emphasizing practical clinical issues and based on clinical research evidence and multidisciplinary expert experience, this guideline provides a methodological reference for determining clinical questions of acupuncture and for enhancing the academic development of high-quality guidelines.

8.4. Limitations

The number of included clinical questions is not adequate, which is the primary limitation of this guideline, as only the most common and challenging issues in clinical practice were collected by the guideline panel.

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CRediT authorship contribution statement

Han TANG: Writing – original draft, Investigation, Data curation. **Qi FAN:** Data curation, Formal analysis. **Li-hua GUO:** Writing – review & editing. **Yu-qing ZHANG:** Methodology, Writing – review & editing. **Yi-xuan FENG:** Data curation. **Yu-qing XU:** Data curation. **Hong-jun KUANG:** Investigation. **Yun-hong YANG:** Investigation. **Yi GOU:** Investigation. **Hong ZHAO:** Conceptualization, Funding acquisition, Writing – review & editing.

Role of the funder/sponsor

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

State of human/animal rights

No need to declare in this paper.

Data sharing statement

Results and the full dataset will be available when the guideline is completed and published. For data requests, please contact the corresponding author, H. ZHAO.

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