



Developing clinical practice guidelines for Chinese herbal treatment of polycystic ovary syndrome: A mixed-methods modified Delphi study



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Delphi;
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Summary

Objectives: Preliminary evidence suggests Chinese herbal medicine (CHM) could be a viable treatment option for polycystic ovary syndrome (PCOS). Prior to conducting a clinical trial it is important to consider the characteristics of good clinical practice. This study aims to use professional consensus to establish good clinical practice guidelines for the CHM treatment of PCOS.

Design and setting: CHM practitioners participated in a mixed-methods modified Delphi study involving three rounds of structured group communication. Round 1 involved qualitative interviews with practitioners to generate statements regarding good clinical practice. In round 2, these statements were distributed online to the same practitioners to rate their agreement using a 7-point Likert scale, where group consensus was defined as a median rating of ≥ 5 . Statements reaching consensus were accepted for consideration onto the guideline whilst those not reaching consensus were re-distributed for consideration in round 3. Statements presented in the guidelines were graded from A (strong consensus) to D (no consensus) determined by median score and interquartile range.

Results: 11 CHM practitioners in the UK were recruited. After three Delphi rounds, 91 statement items in total had been considered, of which 89 (97.8%) reached consensus and 2 (2.2%) did not. The concluding set of guidelines consists of 85 items representing key features of CHM prescribing for PCOS.

Conclusions: These guidelines can be viewed as an initial framework that captures fundamental principles of good clinical practice for CHM.

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Introduction

Polycystic ovary syndrome (PCOS) affects 6–18% of women of reproductive age and is a heterogeneous condition characterised by endocrine and metabolic disturbances.^{1–3} Primary care management typically involves oral contraceptives and insulin-sensitising agents which have been associated with intolerable side-effects, poor adherence and increased metabolic risk.^{4–8} This highlights issues with current management and warrants exploration of other treatments that could be more acceptable.

Chinese herbal medicine (CHM) is used for symptoms of PCOS and there is emerging evidence from randomised controlled trials (RCTs) suggesting CHM could play an important role in the management of PCOS.⁹ However, many of these RCTs have been conducted in China and are methodologically poor thus limiting the generalisability of these findings.¹⁰ This necessitates further exploration of the effects of CHM with a fully-powered RCT in the UK. It is important however to ensure such a study is relevant to CHM practice in Western countries such as the UK, and that it takes into consideration characteristics of good clinical practice as determined by CHM practitioners. Accordingly, the aim of this study was to establish good clinical practice guidelines for the CHM treatment of PCOS.

Materials and methods

Design

We conducted a practitioner-consultation exercise using a modified Delphi method. The Delphi structures group communication to enable the views of informed individuals to be considered anonymously from each other and attempts to minimise the drawbacks of collective decision-making. It is particularly useful where diverse opinions exist and has other advantages as reducing the effect of prevailing opinions or dominant individuals, and enabling participants to alter previously expressed opinions without fear of losing face.¹¹ It is a formal consensus method recognised by the UK's National Institute for Health and Clinical Excellence (NICE) for developing guidelines.^{12–14} It has also been successfully employed in a number of CHM and acupuncture studies for generating consensus in clinical practice or protocol development.^{15–19}

Ethical approval was granted in June 2011 by the University of Southampton School of Medicine ethics committee (SOMSEC094.11).

Recruitment

We estimated 15 practitioners would be required to generate a sufficiently diverse range of views.^{16,18} Practitioners had to (1) have been in practice for a minimum of 4 years, (2) be a registered CHM practitioner in their respective country, (3) have self-reported expertise or interest in gynaecological conditions such as PCOS, (4) have access to the internet and to email, and (5) be fluent in English. To foster diversity in opinion, we purposively sampled for gender, country of CHM training, current country of practice and CHM practice

style to include traditional Chinese medicine and classical styles of practice.

We used expert and snowball sampling methods by providing CHM professional bodies in the UK, US, Australia and Canada with a project brief, inviting suggestions of approximately 10 suitable practitioners. When practitioners were contacted, we asked for further suggestions of practitioners. A number of practitioners known to the research team were approached directly. Practitioners were provided an invitation letter, participant information sheet and completed a consent form prior to the study.

Delphi rounds

The Delphi involves iterative rounds of structured group communication. Round 1 consists of an 'idea-generating' exercise which typically involves participants independently producing a list of ideas or statements. In this study however, the lead author conducted in-depth qualitative interviews with each participant. This is a modification of the Delphi method which has been successfully carried out in previous studies and which in our view would maximise participant involvement.^{18,20}

Interviews were conducted using a semi-structured interview guide which included open non-leading questions. Interviews were audio-recorded and transcribed verbatim by the lead author or an independent transcription service. All transcriptions were checked by the lead author. Additional field notes were taken and considered during analysis. Analysis was based on principles of thematic and framework analysis and conducted by coding in Microsoft Word 2010 using the 'Comments' function and charting in Microsoft Excel 2010. Framework analysis features a number of stages, involving familiarising self with the data, developing a thematic framework and charting and mapping to identify patterns within the data.²¹ This enabled a list of statements regarding clinical practice to be prepared for the next Delphi round.

In round 2, these statements were distributed back to the group using SurveyMonkey, a web-based questionnaire. Participants were asked to indicate their level of agreement with each statement using a 7-point Likert scale ('1 strongly disagree' to '7 strongly agree'), including a score of '4 neither agree nor disagree'. We provided a response option of 'not applicable' (NA) for each item and a free-text comments box. Where participants had chosen to respond 'NA' to a particular statement, they were removed as a denominator in response to that item only. Demographic and clinical background information was also collected within this questionnaire.

Statistical analysis was conducted using Microsoft Excel 2010. Group consensus was defined a priori as a median group rating of 5 or more as used in previous Delphi studies.¹⁸ Following the Delphi method, items achieving consensus were accepted. Items not achieving consensus were circulated back to the participants for reconsideration in round 3. These were presented with the participant's original rating, the group rating and an invitation to re-consider their rating which they could accept or decline. Where a new rating was offered, this was used to reanalyse the group rating. Free-text comments from round 2 were analysed qualitatively and

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