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Evaluating practitioner-blinding in Chinese herbal medicine research: Findings from a randomised feasibility study in the United Kingdom

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Purpose: Practitioner-blinding is often carried out in randomised controlled trials (RCTs) of Chinese herbal medicines (CHMs) yet evaluation of blinding is infrequently conducted. We aimed to evaluate the feasibility of practitioner-blinding within a UK study and identify reasons for practitioner guesses.

Methods: We conducted a practitioner and patient-blind feasibility study exploring CHM for polycystic ovary syndrome, randomising 40 women to standardised CHM or individualised CHM for 24 weeks. We evaluated practitioner-blinding at Week 4, 12 and End of Study (EoS). This questionnaire invited a treatment allocation guess (Standardised/Individualised) and certainty rating (Not at all sure, just guessed/Fairly sure/Entirely sure). This was used to calculate a Bang Blinding Index (BBI). The final item asked for reasons for their answer, analysed using content analysis.

Results: Completion rates of blinding-questionnaire was excellent (mean=86%). Practitioner-guessing and BBI at Week 4 was standardised random/individualised unblinded (standardised -0.11, 95%CI -0.35 to 0.14; individualised 0.47, 95%CI 0.2 to 0.71), at Week 12 standardised random/individualised unblinded (standardised -0.24, 95%CI -0.54 to 0.07; individualised 0.50, 95%CI 0.12 to 0.88); EoS standardised opposite/individualised unblinded (standardised -0.56, 95%CI -0.91 to -0.20; individualised 0.61, 95%CI 0.30 to 0.92). ‘Presence of effects’ was the highest ranking reason for treatment guess (52% of responses) and consistently led to a guess of ‘individualised treatment’/’not at all sure’, and ‘absence of effect’ consistently led to a guess of ‘standardised treatment’/’not at all sure’. This can be interpreted as ‘wishful thinking’ scenario whereby the practitioner consistently believed treatment response was due to individualised treatment, suggesting that blinding was likely secure.

Conclusion: We have demonstrated that practitioner-blinding is feasible and likely secure in this feasibility study. To our knowledge, this is the first time practitioner-blinding has been rigorously evaluated in a CHM study in the UK. Qualitative data has provided further insight into practitioner reasons for treatment guess which will be used to maximise practitioner-blinding in future studies.

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Acupuncture for stroke: an overview of systematic reviews

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Purpose: To overview the clinical research evidence, reflected by systematic reviews, of acupuncture related interventions for stroke and stroke related conditions.

Methods: This study was an overview of systematic reviews of acupuncture for stroke. We searched for all acupuncture systematic reviews on stroke in PubMed, the Cochrane Library, Chinese National Knowledge Infrastructure Databases, Chinese Biomedical Literature, Chongqing VIP Chinese Science and Technology Periodical Database and Wanfang Data from their inceptions to September 2014. Two authors extracted data independently. We performed descriptive data analysis using SPSS 17.0.

Results: 43 systematic reviews and meta-analyses were identified published between 2001 and 2014, included 4 (9.3%) published in English and 39 (90.7%) in Chinese. The number of trials included in reviews varied from 3 to 98 (16.0±1 4.8) and the number of participants was from 143 to 6144 per review (1428.8±1137.5). The objects of the studies included post-stroke depression (6/43, 14.0%), dysphagia after stroke (5/43, 11.6%), aphasia after stroke (4/43, 9.4%), hiccups after stroke (3/43, 7.0%), acute stroke (3/43, 7.0%) and so on. 7(16.3%) studies talked about acupuncture manipulations which included acupuncture method of inducing resuscitation (3/43, 7.0%), CT-aided enclosures needling (1/43, 2.3%), scalp acupuncture (1/43, 2.3%)and midnight-noon ebb-flow acupuncture (1/43, 2.3%). 12 (2.3%) study discussed about 17 kinds of acupuncture manipulations. Poor quality trials existed in every systematic review. Referring to the effectiveness, 23 (53.5%) reviews reported positive results, which meant effect of acupuncture better than non-acupuncture. 20 (46.5%) reviews reported both positive and negative results, which meant the overall evidence did not support the effectiveness of acupuncture for stroke. 41 (95.3%) reviews suggested further evidence needed.

Conclusion: Substantial numbers of systematic reviews of acupuncture for stroke have been published during the past decade, only half of reviews gave the positive assessment and the remaining half of them were uncertain about the effect of acupuncture for stroke while the high-quality trials are needed to test its effectiveness.

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