tions, the potential of network meta-analysis should be explored.

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P5.002

Incorporating Traditional Chinese Medicine Syndrome Differentiation in Randomized Trials: Methodological Issues (Cochrane CAM Field Invited Commentary)



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Purpose: In traditional Chinese medicine (TCM) practice, decision on prescription is based on a process called Bian Zheng Lun Zhi (syndrome differentiation guided treatment decision). The syndrome differentiation process may not be recognized in conventional standards of randomized controlled trial (RCT), limiting the model validity and generalizability of results.

Methods: This article discussed how syndrome differentiation, a classical TCM approach in diagnosis, can be incorporated into RCT design.

Results: Four methodological solutions were proposed: (i) Lesson learnt from the design of patient reported outcome questionnaire can inform how TCM diagnosis instrument could be developed. A proper TCM diagnostic tool with sound psychometric properties can reduce variation in the syndrome differentiation process. (ii) Treatment strategies for a specific TCM diagnosis could be highly diversified. Delphi technique can inform the design of optimal treatment program by facilitating consensus among experts. (iii) Subgroup analysis is often needed in RCT recruiting patient with several TCM diagnosis. It is highlighted that investigators should consider whether the design, analysis and context of the trial are robust enough to support a reliable claim of subgroup effect associated with a particular TCM diagnosis. (iv) Finally, we discussed alternative research and analysis approaches for handling misalignment of Western and TCM diagnoses, including the possibility of unifying TCM syndrome with Western phenotypes using latent class analysis.

Conclusion: Further methodological advances are needed in the better alignment of classical TCM theories and diagnostic instrument development, as well as in reducing bias during the expert consensus processes.

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P5.004

Chinese herbal medicine as adjuvant treatment to chemotherapy for multidrug-resistant tuberculosis (MDR-TB): a systematic review of randomised clinical trials



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Purpose: Chinese herbal medicine (CHM) has been increasingly used as an adjuvant treatment for multi-drug resistant tuberculosis (MDR-TB) in China. To inform clinical practice, we performed a systematic review on the beneficial effect and safety of CHM for MDR-TB.

Methods: We systematically searched the six electronic databases for randomised clinical trials (RCTs) of CHM plus chemotherapy for MDR-TB. RevMan 5.2 software was used for data analyses with effect estimates presented as risk ratio (RR) with 95% confidence interval (CI).

Results: 28 RCTs involving 3085 participants with MDR-TB were included. The methodological quality was generally poor in terms of risk of bias. Meta-analyses favoured CHM plus chemotherapy on sputum bacteriological conversion rate compared with chemotherapy alone after initiation of treatment (6th months: RR 1.29, 95% CI 1.14 to 1.46, n=11; 12th months: RR 1.38, 95% CI 1.19 to 1.59, n=5; 18th months: RR 1.19, 95% CI 1.11 to 1.28, n=7). Compared with chemotherapy alone, meta-analysis showed benefit from CHM plus chemotherapy on lung lesions absorption rate (12th months: RR 1.26, 95% CI 1.09 to 1.46, n=3; 18th months: RR 1.18, 95%CI 1.07 to 1.30, n=6) and pulmonary cavity closure rate by radiological examination (18th months: RR 1.24, 95%CI 1.01 to 1.51; n=4), relapse rate (RR 0.28, 95%CI 0.16 to 0.50, n=4), and abnormal liver function (RR 0.56, 95% CI 0.46 to 0.69, n=14).

Conclusion: CHM as an adjuvant to anti-TB chemotherapy may have beneficial effect for MDR-TB in terms of bacteriological and radiological outcomes, and is safe. However, due to poor methodology of the included trials, a confirmative conclusion needs to be supported through further robust clinical trial.

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