

The need to evaluate the clinical effectiveness of traditional Chinese medicine

JL Tang, TW Wong

Traditional Chinese medicine is gaining increasing attention and popularity in Hong Kong. There is no doubt that traditional Chinese medicine as a system of medicine works; however, this does not imply that every therapy is efficacious. Prevention of the initiation and continuation of ineffective intervention is extremely important for the efficiency of any health care system. The evaluation of the clinical effectiveness of traditional Chinese medicine is thus a top priority. Efforts should be made to register all randomised trials in traditional Chinese medicine and to regularly review and disseminate the evidence from organised research. These actions are essential for the promotion and practice of evidence-based decision making in traditional Chinese medicine.

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Traditional Chinese medicine (TCM) is gaining increasing attention and popularity in Hong Kong. The Government of the Hong Kong Special Administrative Region (SAR) has taken measures to promote, develop, and regulate the practice of TCM in the SAR.¹ Local universities are setting up educational programmes to train doctors in TCM. Approximately 50% to 60% of the population in Hong Kong have consulted TCM practitioners.² Our preliminary survey shows that Hong Kong residents spent about HK\$3 billion on TCM in 1996 (unpublished data). Traditional Chinese medicine is undoubtedly becoming a more important component of the SAR's health care services.

There has been an increasing general interest in traditional medicine. In Europe, traditional medicine has been used by 20% to 25% of the population; this figure is growing rapidly.³ Americans spent an equivalent of approximately HK\$100 billion on alternative therapies in 1990, which was comparable to the amount spent on visits to primary care physicians.⁴ The United States Government has set up an Office of Alternative

Medicine, and centres for alternative medicine have begun to appear in respected medical schools such as those at the universities of Harvard and Columbia.⁵

Traditional Chinese medicine has a history of several thousand years and is one of a few forms of 'alternative' (as opposed to conventional) medicine that are endorsed by the World Health Organization. There is, however, an urgent need to evaluate the clinical effectiveness of TCM. In acknowledgement of this need, the World Health Organization has established an Office for the Evaluation of Traditional Medicines and has developed guidelines for the evaluation of traditional medicines.⁶ The primary drive for the evaluation of TCM is concern about the efficiency of the health care system. The first step is to prevent the introduction of new but ineffective interventions to medical care and to stop those that are currently being used.⁷

There is no doubt that TCM works. It has developed its own coherent theories with regard to aetiology, diagnosis, and treatment of disease. It has also accrued a myriad of valuable clinical observations, some of which have provided the basis for some successful conventional medicines. Artemisinin (Qinghaosu), for example, is an extract that is prepared from the Qinghao plant (*Artemisia annua*) and has been used by TCM practitioners for 1500 years; it is now a very promising

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antimalarial drug.⁸ Ephedrine, a widely used medicine, was originally extracted from a plant that is used in TCM. In addition, a TCM cure for eczema has proved so successful in recent trials that a pharmaceutical company has patented its own version.^{9,10}

The fact that a system of medicine works as a whole, however, does not mean that its every intervention is efficacious. Many interventions that are widely used in conventional medicine have been shown by randomised controlled trials (RCTs) to be ineffective or even harmful.^{11,12} Evidently, convention is not the best indicator of the effectiveness of a medicine; popularity, enthusiasm, or anecdotes should also not be taken as evidence for clinical efficacy. It is thus reasonable to believe that many TCM interventions may not be clinically effective.

The most scientifically rigorous method for evaluating the clinical effectiveness is the RCT.¹³ This is particularly true for therapies that have a moderate (but worthwhile) effect.¹⁴ Many medical treatments have only moderate, rather than large, effects if major end-points (such as mortality) are concerned. Powerful interventions whose effect is clearly evident, such as penicillin and smallpox vaccine, are few and far between; most other interventions have only moderate effect. Conventional medicine has responded positively to this challenge—we now accept that virtually no new drug can enter clinical practice without a demonstration of its efficacy in clinical trials. Currently used interventions are also being subjected to RCTs. Should TCM be an exception?

To demonstrate what works and what does not in TCM has other important implications. Firstly, it will provide a scientific basis for the further advancement of TCM theories. Secondly, treatments of proven effectiveness will identify fruitful directions for basic research in disciplines such as physiology, biochemistry, and pharmacology. Thirdly, a clinically effective recipe may lead to the development of new drugs which may be refined for better formulation and research. Fourthly, diseases or syndromes that are only recognised and curable in TCM may open up new opportunities for research in conventional medicine. Fifthly, it will provide necessary information for the regulation of the practice of TCM. Finally, it will help to dispel misconceptions about TCM, increase its acceptance, and promote better and wider utilisation.

Much research has been done in TCM; most, however, is at the laboratory or biochemical level. Today, traditional therapies are still viewed by many as

quackery and stigmatised as mere superstition.¹⁵ The lack of understanding of the mechanisms underlying TCM is undoubtedly a major reason for the widespread misconception and reluctant acceptance of this form of medicine. There is thus a need to study how TCM works. Research also often helps in clinical practice and basic research to 'do the right things better'. However, research progress may be restricted by the available methodology and technology.

Clinical effectiveness is what matters most in any medical treatment. Understanding the mechanisms of action is secondary, and lack of this knowledge should not prevent the use of effective therapies. For example, many of the most powerful medical interventions in medical history (eg penicillin, digitalis, sulphonamides, smallpox vaccination) were accepted and widely used, long before their mechanisms of action were understood. Therapies that lack a demonstration of clinical effectiveness, such as blood-letting and radical mastectomy, have been discarded, regardless of whether we understood the mechanisms. In contrast, the mechanism underlying acupuncture has been well studied and documented; nevertheless, acupuncture does not seem to work for many diseases for which it claims to be effective.¹⁶ The misunderstanding and scepticism about TCM therapies will likely continue until their clinical effectiveness is demonstrated by RCTs. Demonstration of the clinical effectiveness of TCM is thus an immediate and urgent task for researchers of TCM.

Randomised controlled trials have already been conducted in TCM. There are, however, a few methodological issues that need to be resolved so that the quality of trials can be further improved. The first RCTs in TCM in China were conducted in the early 1980s; the number of trials has doubled every 2 to 3 years over the past 15 years. A preliminary systematic review of the evidence for the effectiveness of TCM has identified some 2800 RCTs that were published in medical journals in China. It is estimated that the total number of trials published in China alone is around 8000 (unpublished data).

Further work is needed to identify and to register all clinical trials ever published in the medical literature. The goal of the Cochrane Collaboration is to systematically review and summarise the evidence from clinical trials and to make the evidence available to practitioners and policy makers in an accessible and digestible manner.¹⁷ These efforts are essential for the promotion and practice of evidence-based decision making in TCM. It is a waste of human resources to

continue the use of clinically ineffective treatments. It is therefore ethically an obligation—and scientifically a challenge—for health workers to terminate the use of clinically ineffective TCM therapies and to promote the use of effective ones. This can only be achieved through the systematic evaluation, review, and dissemination of the evidence among decision makers.

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Editorial note

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