Response to Letter by Wu and Liu

To the Editor:

In their letter, Wu and Liu commented on our paper, “Complex Traditional Chinese Medicine for Poststroke Motor Dysfunction: A Systematic Review.” The main criticism is related to the quality of the studies included in the systematic review. However, a systematic review can be rigorously conducted even if it includes studies of very low quality.2 To point out the low quality of the studies retrieved can be considered one of the results of the review. In fact, the quality issue was underlined and discussed deeply from the authors in the review. Many flaws in the studies were identified. A large number of these trials actually claimed to be randomized, controlled trials, but most of the authors have apparently misunderstood the full concept of randomization. Allocation concealment was not reported in any of the trials included. Other important weaknesses were the very poor description of dropouts and of harm-related issues (none of the trials reported patient withdrawals and only one study described the occurrence of adverse events).

The primary studies available for this review were mostly inadequately designed trials characterized by definitional vagueness in outcomes measures. A variety of outcome measures were reported. None of the studies included in our review approached important end points like, for example, death, survival times, rate of dependency, reduction in length of stay in the hospital or long-term care institution, and so on. All of the trials were actually focused on ancillary or surrogate outcomes measured through subjective qualitative scores (ie, “notable,” “effective,” “ineffective,” and so on). In all of the trials, the duration of therapy and follow-up was indeed too short to allow to achieve conclusive results on more relevant outcomes.

The issues mentioned are not only related to trials on Traditional Chinese Medicine (TCM),3 but also to research conducted on Western medicine, and not only to articles published in China, but also in other countries.4 TCM has a unique theoretical system and comprises a variety of complex therapeutic approaches, which can in some cases add difficulties in the design and conduct of clinical trials. The application of modern evaluation theories and methods in TCM has recently started and many problems are still to be solved. Consolidated Standards of Reporting Trials (CONSORT) is of course a very powerful tool for the reporting of the results of clinical trials, but it should not be confused with guidelines for the conduction of a clinical trial. Randomized, controlled trials for the scientific evaluation of promising TCM treatments should be designed and conducted according to Good Clinical Practices, internationally accepted and adopted.

The evidence-based medicine approach is providing a great help in the scientific evaluation of TCM, and well-conducted systematic reviews and clinical trials are being published.5,6 Evidence-based medicine can help build a bridge between TCM and Western medicine, traditional theory and modern science. Open-mindedness, curiosity, and a willingness to collaborate are key attitudes necessary in this process.

TCM represents an enormous source of promising therapies to evaluate with scientific methods before considering integration with Western medicine. To evaluate the safety and efficacy of such a variety of traditional treatments requires the choice of areas of interest.7 We should prefer therapies that have been used for a long time and by a large number of patients, therapies for which there is enough preliminary data on efficacy and safety, therapies that address important public health problems taking into account the complexity of treatments and their transportability. It should be possible to standardize the treatment, diagnostic process, and indication for use, and last but not least, we should consider the possibility for integration with Western medicine.8

International collaboration should be encouraged, promoted, and financed from governments to improve research and establish a consensus on standardized relevant outcome measures and then design and conduct appropriate randomized, controlled trials that adopt those standards. Transparencies in the conduct of the studies and diffusion of results; therefore, ethical aspects are also important points to agree on.

None.

Junhua Zhang, MD
Tianjin University of Traditional Chinese Medicine
Tianjin, China

Francesca Menniti-Ippolito, MSc
National Institute of Health
Rome, Italy

Xiumei Gao, MD
Tianjin University of Traditional Chinese Medicine
Tianjin, China

Fabio Firenzuoli, MD
Empoli Local Health Unit 11
Empoli, Italy

Boli Zhang, MSc
Tianjin University of Traditional Chinese Medicine
Tianjin, China

Marco Massari, MSc
National Institute of Health
Rome, Italy

Hongcai Shang, MD
Tianjin University of Traditional Chinese Medicine
Tianjin, China

Yuhong Huang, PhD
Tianjin University of Traditional Chinese Medicine
Tianjin, China

Rita Ferrelli, MD
National Institute of Health
Rome, Italy

Limin Hu, MD
Tianjin University of Traditional Chinese Medicine
Tianjin, China


Key Words: clinical trials □ Traditional Chinese Medicine
Response to Letter by Wu and Liu
Junhua Zhang, Francesca Menniti-Ippolito, Xiumei Gao, Fabio Firenzuoli, Boli Zhang, Marco Massari, Hongcai Shang, Yuhong Huang, Rita Ferrelli, Limin Hu, Alice Fauci, Ranieri Guerra and Roberto Raschetti

Stroke. 2009;40:e643-e644; originally published online September 17, 2009; doi: 10.1161/STROKEAHA.109.563643

Stroke is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2009 American Heart Association, Inc. All rights reserved.
Print ISSN: 0039-2499. Online ISSN: 1524-4628

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://stroke.ahajournals.org/content/40/11/e643

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published in Stroke can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial Office. Once the online version of the published article for which permission is being requested is located, click Request Permissions in the middle column of the Web page under Services. Further information about this process is available in the Permissions and Rights Question and Answer document.

Reprints: Information about reprints can be found online at:
http://www.lww.com/reprints

Subscriptions: Information about subscribing to Stroke is online at:
http://stroke.ahajournals.org//subscriptions/