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PARADIGMS

Challenges Inherent to *T'ai Chi* Research: Part II—Defining the Intervention and Optimal Study Design

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ABSTRACT

Although a growing body of clinical research has begun to evaluate the efficacy and safety of *t'ai chi* as a therapeutic tool for a variety of health conditions, little attention has been devoted to evaluating "how" *t'ai chi* is scientifically studied, and the advantages or limitations of different methodological approaches. In a companion to this paper (Part I), we argued that *t'ai chi* is a complex, multicomponent intervention, which poses unique challenges regarding the distinction of specific versus nonspecific effects and limitations regarding the use of reductionistic research frameworks. In this second, companion paper, we discuss additional obstacles inherent in precisely defining the *t'ai chi* intervention in an experimental paradigm. These challenges include *t'ai chi*'s pluralism, the concept of *t'ai chi* dosage, and long- versus short-term evaluations of *t'ai chi*'s efficacy and safety. To address these challenges, and with a goal to provide complete and unbiased evidence, we propose a pluralistic methodological approach to clinical research that includes controlled randomized trials of fixed protocols, community-based pragmatic trials, cross-sectional studies of long-term practitioners, and studies that integrate qualitative methods.

INTRODUCTION

A growing body of research suggests that *t'ai chi* may be an effective preventative and rehabilitative intervention for many medical conditions.[1–7] However, the extent to which *t'ai chi* will become integrated into health care will depend upon the quality and breadth of evidence-based research. In a companion paper,[8] we suggested that *t'ai chi* is best viewed as a complex, multicomponent intervention integrating numerous physical, cognitive, and ritualistic components, and as such, that *t'ai chi*'s complexity poses research related challenges. In this paper, we examine some of the problems associated with defining a *t'ai chi* protocol in an experimental paradigm that result from *t'ai chi*'s pluralism/heterogeneity, the concept of *t'ai chi* dosage, and long- versus short-term evaluations of efficacy and safety. Given these challenges, in addition to those raised in our companion paper, we propose a pluralistic methodological approach that includes randomized controlled trials (RCTs) that evaluate pragmatic and fixed protocol interventions, alongside community-based observational studies, cross-sectional studies of long-term practitioners, and studies that integrate qualitative methods to capture the richness of participants' experiences and teachers' intentions in interventions. This pluralistic approach simultaneously recognizes the advantages of some forms of RCTs, but also acknowledges that a comprehensive and unbiased understanding of the efficacy and safety of *t'ai chi* requires other complementary forms of evidence.

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CHARACTERISTICS OF *T'AI CHI* THAT POSE CHALLENGES TO ITS SCIENTIFIC EVALUATION

Pluralism of t'ai chi

The scientific study of *t'ai chi*, and generalizations about its therapeutic effects and safety, are complicated by its pluralism. *T'ai chi* is an evolving art, and new styles have been developed based on the unique insights (and interpretations) of generations of practitioners. Currently, a number of styles (named after the originator or "lineage" holder) are widely recognized, including among others, the *Yang, Chen, Wu, Sun*, and *Hao* styles. Each of these styles is characterized by slightly different emphases in training content as well as core *t'ai chi* principles.[9] Additionally, within each style, there are many substyles, which further contribute to *t'ai chi*'s pluralism. For example, within the *Yang* style lineage, distinct forms have been developed that vary with respect to the numbers of choreographed movements and postures (e.g., 24-, 37-, 72-, 108-, and 150-movement forms), as well as overall emphasis (e.g., health maintenance, martial skills, meditation and self-realization, competitive performing arts). Many styles also include a rich variety of *t'ai chi* weapons training and 2-person interactive practices.

In addition to variation across *t'ai chi* styles, how *t'ai chi* is taught and transmitted adds further heterogeneity to *t'ai chi* students' experiences. For example, some schools that adopt more "traditional" methods or where language barriers exist may emphasize nonverbal instruction (mimicry, shadowing, physical posture adjustments), whereas others emphasize verbal instruction. There is also variability in the format of training programs, with some centered on group-based curricula where students progress as a cohort, while others are more individually based and students progress at their own rate. Additionally, there is great variability even within a school or lineage, depending on individual teachers. Most lineages do not have formalized teacher-certification programs, and there are no established criteria for labeling someone as a teacher or master. Although some recent programs have developed formal teacher training programs, there is no national or international organizing body analogous to the American Medical Association or National Certification Commission for Acupuncture and Oriental Medicine to evaluate program criteria or to administer competency examinations.

In summary, the pluralism of *t'ai chi* generated by different styles and teaching systems results in significant heterogeneity in the training that *t'ai chi* students experience in both research- and community-based settings. This heterogeneity poses significant limitations regarding the conclusions that can be drawn from individual studies, as well as the inferences that can be drawn from comparisons between studies. Some recommendations for better characterizing and accounting for *t'ai chi*'s pluralism are discussed below.

Dosage

Evaluation of the results of any clinical trial requires some knowledge of the dose of the therapy employed. *T'ai chi*'s complexity and pluralism poses challenges for developing a concept of dose that is equivalent to that commonly used in pharmacology (i.e., the quantity of an active agent taken in or absorbed at any one time). There are two aspects of dosage that should be considered in developing this concept for *t'ai chi*; a gross or obvious aspect, and a more subtle and functional one. At the gross level, dosage essentially involves practice time. Longer-term interventions, more frequent classes, and longer individual practice sessions correspond with higher doses. However, even at this gross level, one might expect that the dosage effects of 100 hours of *t'ai chi* for styles that vary in their relative emphasis of components (e.g., meditative breathing versus physically demanding movements) would be different. What is even more challenging is quantifying the more subtle distinction between what we will call here, "clock time" doing *t'ai chi* versus "effective practice time" doing *t'ai chi*. Using a pharmaceutical as an analogy, there is a distinction between the administered dose and the effective bioavailable dose across a population of patients, due to differences among patients in drug absorption rates and other pharmacokinetic processes. Similarly, there will be variations across *t'ai chi* practitioners in the benefits they experience after 100 hours of a given style of *t'ai chi*, due to different levels of training, practitioner commitment, and specific proficiencies. Some recommendations for better characterizing dosage in *t'ai chi* studies are presented below.

Although a growing number of studies have demonstrated that *t'ai chi* interventions as short as 10 to 12 weeks can have marked effects on balance,[10] cardiovascular health,[11] and immunity,[12] *t'ai chi* is more commonly viewed as a therapy that has rehabilitative and preventative benefits that take place over many years.[9,13,14] Moreover, like good wine, it is believed that the magnitude of the benefits of *t'ai chi* increases over time as practitioners' skills improve. Consequently, short-term prospective studies may regularly underestimate the potential benefits of *t'ai chi*.[1]

Long-term prospective controlled studies are not practical, and very few prospective controlled *t'ai chi* studies have been conducted for as long as 1 year.[15] Although numerous cross-sectional studies comparing physiologic characteristics of long-term practitioners to nonpractitioners have been conducted, conclusions from many of these studies are limited by biased choices of control groups and other methodological deficiencies.[5] As discussed below, to account for *t'ai chi*'s long-term benefits, evidence from prospective controlled studies must be complemented by well-designed

cross-sectional and observational studies of long-term practitioners.

CONSIDERATIONS FOR AN EVIDENCE-BASED EVALUATION OF *T'AI CHI*

The need for a pluralistic approach to generation of evidence

The richness and complexity of *t'ai chi*, the nonconventional nature of some of its therapeutic components, potential biases associated with randomization,[8] and the importance of long-term studies conducted in ecologically valid settings suggest that no one method will be able to provide the entirety of evidence needed to evaluate *t'ai chi*'s potential. The importance of a pluralistic research approach for the study of other individual or whole-system complementary and alternative medicine interventions has been previously noted.[16,17] As discussed in the companion paper to this one,[8] placebo-controlled efficacy trials are not feasible and may lack validity for the study of *t'ai chi*. Below, we discuss briefly some of the advantages and limitations of different research strategies for the clinical evaluation of *t'ai chi*, as well as some additional methodological guidelines.

Prospective controlled studies

Although we have argued that the placebo-controlled trial may not be valid for the clinical evaluation of *t'ai chi*, this does not mean that other types of RCTs cannot be used. One of the more commonly used approaches in randomized clinical trials of *t'ai chi* is to compare a well-described fixed *t'ai chi* protocol to a non- or limited-exercise control group intervention. For example, Wolf and colleagues[18–20] conducted a landmark randomized trial comparing the effects of a *t'ai chi* group (10 individually practiced movements) to an educational "control" group on balance in elderly subjects. Some advantages and disadvantages for this approach follow.

First, and as is the case in all clinical trials, randomization increases the likelihood that all study arms represent a random sample of the same population, and thus they are unlikely to differ from one another at baseline in any systematic way that may bias their response to interventions. However, as discussed in our companion paper,[8] the use of randomization in trials where participant belief in a therapy is integral to the therapy itself potentially introduces bias. In the case of Wolf's trial, it is conceivable that some participants enrolled in the trial had little interest in learning *t'ai chi* and would have preferred the educational intervention. Practicing *t'ai chi* in a nonengaged way (i.e., simply going through the movements without intention or positive expectation) may bias its evaluation. For these reasons, reports summarizing the results of randomized trials of *t'ai chi* should acknowledge the potential for bias related to lack of self-selected populations, and when possible, measures should be taken to assess expectancy- and belief-related characteristics across study arms. A number of tools for measuring expectancy and belief have been developed and used in the study of other complementary and alternative medicine (CAM) modalities.[8,21,22]

Second, the use of a "simplified' *t'ai chi* protocol in Wolf's study has many advantages: The protocol is easy to teach and learn in the short period of time afforded in most prospective clinical trials; the rationale for each protocol element can be described and articulated;[20] and the protocol can be more easily and reliably replicated for other populations, making comparisons between studies easier to interpret. In studies such as Wolf's where more traditional interventions are simplified or modified, it is important to articulate the rationale for such changes as was done,[20] and when possible, to include a representative panel of experts in the process of protocol development to assure the ecologic validity of the novel intervention.[23]

Finally, the use of an education intervention as a "control group" in Wolf's and other studies warrants comment. Education interventions are often used as exercise-controls because they do not provide opportunities for physical exercise, but do provide social interactions with medical providers and peers. However, as discussed above, comparison groups should not be mistaken as a "placebo" control for *t'ai chi* studies. Psychosocial interactions are an integral component of *t'ai chi*, not a nonspecific effect to be controlled for. Moreover, psychosocial factors in *t'ai chi* including interactions with teachers and classmates are likely to be more complex and have very different meanings and therapeutic impacts than psychosocial interactions between students and instructors in a didactic educational training. Consequently, although the use of a group education intervention offers a practical comparison group, exactly what such a group "controls" for is not always clear or easy to interpret.

Another type of randomized, controlled study design that may be particularly well suited to *t'ai chi* is the pragmatic trial. Pragmatic trials can vary considerably in design, but their key objective is to evaluate the overall effectiveness of interventions as they are practiced in a clinical or natural setting.[24] Pragmatic trials generally compare the treatment of interest with an already established, credible intervention, and thus help inform choices between treatments. MacPherson[25] summarizes a number of characteristics of pragmatic trials that make them well suited for CAM therapies such as *t'ai chi*. These include the following: explicit testing of the overall "package" of components in an intervention, including the therapeutic relationship between provider and patient; patients typically not blinded so their expectations are not modified; intervention can be conducted in a natural

setting; therapies not fixed and can be individualized to patients' needs; and high external validity. Limitations of pragmatic trials include the following: They cannot determine relative contributions of treatment components; because of increased heterogeneity across interventions, larger sample sizes are generally required; and there is reduced internal validity. Although a number of randomized pragmatic trials have been conducted to evaluate the clinical effectiveness and cost effectiveness of acupuncture,[26–28] surprisingly few *t'ai chi* trials have used pragmatic designs.

Preference trials provide one possible research design that overcomes the bias associated with modified patient expectancy/belief/satisfaction caused by randomization.[29,30] Adding the preference model into a pragmatic study design might increase the validity of controlled trials by allowing for self-selection. For example, in a preference trial comparing *t'ai chi* to standard care, participants with no treatment preference would be randomized as usual, but those with preferences would receive their preferred treatment, resulting in four groups. Differences between the *t'ai chi* and standard care group could then be evaluated in parallel for both randomized and nonrandomized patients. Although there is disagreement regarding the optimal statistical analyses for such designs, some approaches have been well-developed and used successfully.[31] Preference trials have the disadvantage that they often require large numbers of participants. Preference trials have not been used in *t'ai chi* research to date, however, they have been used to evaluate acupuncture.[32]

Outcome, observational and cross-sectional studies

A number of study designs have the potential to complement RCTs and provide important supplemental evidence. Outcome studies measure changes in health status before and after an intervention.[33] They entail the systematic monitoring of the outcomes resulting from normal clinical practice or, more generally, from a standardized form of practice. In the case of *t'ai chi*, outcome studies might entail collecting longitudinal data using easy-to-use health and quality-of-life assessment instruments (e.g., Measure Yourself Medical Outcomes Profile[34]) on students enrolled in a number of *t'ai chi* schools in a given geographic area. Such studies have the advantage of characterizing self-selected participants interested and invested in *t'ai chi*, are based in ecologically valid settings, are less expensive than controlled trials, and can be designed to assess long-term changes. Although this kind of nonexperimental approach cannot be used to test hypotheses regarding *t'ai chi*'s effectiveness, outcomes studies such as this could provide valuable information regarding the sociodemographic characteristics of populations enrolled in *t'ai chi* programs, the reasons they enroll, and some information related to changes in health status over time. These data could then be used to inform and design more definitive controlled trials. To date, surprisingly few systematic outcome studies of *t'ai chi* have been published.

Observational studies include cohort studies, case-control studies, and cross-sectional studies. In all of these designs, the researcher just observes people and classifies them with regard to disease outcome and exposure (in this case, *t'ai chi* practice). A cohort study, for example, might involve selecting seniors in a retirement center, classifying them with regard to *t'ai chi* practice, and following them up over time for health outcomes. Sometimes, two cohorts (one exposed to *t'ai chi* and a similar but unexposed group as a control) are compared with each other. Observational cohort studies in which systematically collected data on interventions are compared with parallel data from populations with different exposures have traditionally not been considered strong evidence for two reasons.[35] First, because patients are not randomly assigned to groups in observational studies, there is the risk of selection bias such that systematic differences in outcomes may not be due to the treatment itself. To address this issue, approaches have been proposed to analyze observational data using covariates to account for identifiable differences between groups. Second, early comparative studies concluded that observational studies consistently overestimated treatment effects in comparison to randomized trials. However, more recent meta-analyses suggest that large well-designed observational studies yield results comparable to RCTs.[36,37] As with outcome studies, observational studies can be less costly, have good external validity, and avoid the already discussed biases associated with randomization. Suggestions for minimizing bias in observational studies of CAM are discussed by Verhoef and colleagues.[38]

Cross-sectional studies are useful for characterizing and comparing attributes of populations with different histories or exposures at a single point in time. Advantages of cross-sectional studies include the following: comparisons can be made across groups with many long-standing differing characteristics; these studies are relatively inexpensive and do not require long periods of observation; randomization is not involved; and there are no losses to follow-up. As with other observational studies, cross-sectional studies are useful for generating hypotheses, but cannot be used to make causal inferences. As we have argued previously, prospective controlled trials will not always be feasible because at least some of the rehabilitative and preventive therapeutic effects of *t'ai chi* are thought to take place over long periods of time (i.e., many years). Cross-sectional studies will thus be needed to characterize the impact of long-term practice. A number of informative studies to date have compared physiologic and other health characteristics of long-term practitioners to age-matched sedentary controls,[39–41] novice *t'ai chi* practitioners,[42] practitioners of other sports,[43,44] and healthy younger populations.[45]

Qualitative research

The complexity of *t'ai chi* interventions makes it unlikely that even a battery of standardized outcomes will adequately capture the richness of practitioners' experiences. Qualitative research methods, which are often less structured than quantitative approaches, provide opportunities to explore in greater breadth and depth the impact of *t'ai chi*. Qualitative methods have been used to explore the meaning that patients ascribe to an intervention, the process and context by which healing occurs, outcomes that are relevant and meaningful to patients, and how interventions fit within everyday lives.[38] For example, open-ended questions administered to participants in the Wolf trial described above[38] as well as a few other studies[46] reveal important changes in psychologic well-being, general health, and exercise behavior not captured by quantitative instruments. Qualitative approaches including focus groups have also been employed to explore frail elders' perceptions of *t'ai chi*, and a group of *t'ai chi* experts' evaluation of a specific, novel study protocol.[24] Recent CAM studies that have combined qualitative and quantitative methods have demonstrated that this integrated research approach can be very informative.[47,49]

Characterization of protocols and intervention dose

One limitation of *t'ai chi* research to date, regardless of research design, is that protocols are poorly described. Details of interventions, including styles and forms practiced, ancillary warm-up and cool-down exercises, and characteristics of teachers are inadequately, if at all, described.[5] Future studies need to better characterize *t'ai chi* interventions. Guidelines similar to ones recently developed for reporting acupuncture protocols used in clinical trials[49] could easily be adapted for *t'ai chi* research.

As discussed above, an important characteristic of interventions that is difficult to quantify is dose. At a minimum, gross characteristics related to dose such as number, duration and frequency of classes, as well as participant compliance to regimens, should be reported. Characterization of subtle aspects related to dosage, such as "effective practice time" during which significant physiologic processes associated with therapeutic effects are activated, are much more challenging. One possibility lies in the recent development of miniature sensor technology capable of monitoring and logging various physiologic and mechanical parameters such as heart rate, respiration rate, body orientation, and even brainwaves. Use of such devices could be developed to provide tools for better tracking compliance, and for distinguishing between "clock time" and "effective practice time" doing *t'ai chi*.

CONCLUSIONS

T'ai chi shows great promise as an effective, safe, and practical rehabilitative and preventative intervention that can be widely integrated into current and future health care. Integration will be significantly catalyzed by sound research-based evidence. Because of a number of *t'ai chi*'s characteristics, including its pluralism, multicomponent complexity, and the intrinsic importance of practitioners' belief/expectation, teacher–student relationships, and the long-term nature of *t'ai chi* training, we believe no one method addresses all relevant aspects of evidence, and each approach has advantages and potential biases. We propose a pluralistic methodological approach to capture the richness of participants' experiences and teachers' intentions in interventions. Because of *t'ai chi*'s unique characteristics and the impossibility of constructing of a credible matching inert placebo control, the placebo-controlled trial as a method for the clinical evaluation of *t'ai chi* should not be considered as a valid option.

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