

TAI CHI STUDY Statistical Analysis Plan

R34AT009052

**Tai Chi for Chronic Low Back Pain in Older Adults: A Feasibility Randomized
Clinical Trial (Back Tai Chi)**

Karen J Sherman, PhD, Principal Investigator
Kaiser Permanente Washington Health Research Institute
Kaiser Permanente Washington
1730 Minor Avenue, Suite 1600
Seattle, Washington 98101
Telephone: (206) 287-2426
Fax: (206) 287-2871

Sponsored by:

OHRP IRB Registration Number: IRB00000668
OHRP IRB Registration Name: Kaiser Permanente Washington

February, 21st, 2017

Sample Size and Randomization

Because this is a feasibility study, the sample size is not designed to detect clinically important effects of the primary effectiveness outcomes, back-related dysfunction and pain intensity.¹ Rather, for this type of study, the sample size needs to be large enough to provide a high likelihood of surfacing any important problems that may exist in the study execution.¹ Our sample size of 64 was chosen based on practical considerations to provide ample opportunity to identify problems with the study procedures, intervention protocols (including adherence), outcome measures, and follow-up rates. Therefore, a trial of this size is insufficiently powered to detect clinically important effects in our outcomes. However, we believe that our proposed sample size is sufficient to determine whether the trial is feasible.

Data Analyses: Feasibility of a full-scale RCT

We will use descriptive analyses to examine many aspects of feasibility, including recruitment, randomization, Tai Chi adherence, adverse events and follow-up rates. To assess recruitment feasibility, we will collect information at every stage of our recruitment and randomization process. We will compute the rates of screening and enrollment per month. This will let us know how many invitation letters we would need to send to potentially eligible persons to meet recruitment goals in a large RCT. Because ICD codes do not distinguish between chronic and acute pain and do not always distinguish between pain in the lumbar spine (low back) from pain in mid-back or neck, most potentially-eligible persons will be found during screening interviews to not have cLBP. This information will help determine the number of recruitment sites that would be necessary to conduct an adequately-powered RCT. If our primary recruitment method proves inadequate for efficiently meeting our goals, we will evaluate the ability of alternative methods determined in the Administrative Year (e.g., advertising in the health plan's quarterly magazine) to accrue significant numbers of additional participants.

To assess RCT retention rates, we will compute the treatment specific retention rates, which are typically large in our trials. For Tai Chi treatment adherence, we will compute the number of classes attended and the amount of home practice per week. Benchmarks for Tai Chi adherence will be derived (in the Administrative Year) by a thorough literature review of adherence in RCTS evaluating exercise for cLBP, Tai Chi for chronic pain and Tai Chi in the elderly. Additional information, such as ratings of how well participants perform key aspects of the Tai Chi protocol, will be obtained.

To assess safety, we will compute the proportion of persons reporting adverse events as well as the type and seriousness of the event. In our prior studies, 15 to 29% of participants reported mild transient increases in pain when stretching or doing yoga. We think adverse events for Tai Chi may be similarly mild, but slightly less common because of the nature of the movement.

To assess follow-up rates, we will compute treatment specific and overall follow-up rates at each time point. While our prior trials have consistently had post-treatment

follow-up rates over 90% in the short term and close to that at one-year follow-ups, we will consider follow-up rates of 80% or better to indicate feasibility.

We will obtain qualitative feedback on all aspects of the study from 30 participants. Our prior experience suggests this number is sufficient to elicit a broad range of experience and to begin to see themes and experiences repeated across respondents (i.e., achieve “response saturation”)^{2,3} Dr. Rosenberg, an experienced qualitative researcher, will conduct these discussion groups, which will be audio recorded and transcribed. We will also invite suggestions for improvement in the study procedures and protocols. Because these debriefing interviews will inquire about specific experiences and suggestions for improving our procedures and protocols, our analyses will be largely descriptive and not require resource-intensive ethnographic analysis techniques.

References

1. Hoy D, March L, Brooks P, Blyth F, Woolf A, Bain C, Williams G, Smith E, Vos T, Barendregt J, Murray C, Burstein R, Buchbinder R. The global burden of low back pain: estimates from the Global Burden of Disease 2010 study. *Ann Rheum Dis*. 2014;73:968-74.
2. Arnstein P. Balancing analgesic efficacy with safety concerns in the older patient. *Pain Manag Nurs*. 2010;11:S11-22.
3. Martin BI, Deyo RA, Mirza SK, Turner JA, Comstock BA, Hollingworth W, Sullivan SD. Expenditures and health status among adults with back and neck problems. *JAMA*. 2008;299:656-64.