Reporting of Protocol Rationale and Content Validity in Randomized Clinical Trials of Tai Chi: A Systematic Evaluation

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BACKGROUND

• Mind-body exercise interventions such as Tai Chi are typically multimodal, complex, and pluralistic.
• It is thus critical for publications to provide context regarding the rationale and content validity of the specific protocol being evaluated with reference to the population, medical condition, or outcomes being targeted.

AIM: To assess the quality of reporting of protocol rationale and content validity for using a specific Tai Chi protocol in a randomized controlled trial.

METHOD

• This review was completed in accordance with PRISMA guidelines.
• Searched databases: PubMed/MEDLINE, EBSCO, and the Cochrane Library from inception to June 2015.
• Search strategy: Search terms were Tai Chi, Taiji, Tai Chi Chuan.
• Inclusion criteria: English-language RCTs w/ Tai Chi as an intervention. Exclusion criteria: Trials that evaluated multiple pragmatically-delivered community based protocols; Tai Chi used as a control group.
• Data extraction: Two independent reviewers.

RESULTS

Figure 2: Validity Scoring Criteria Flowchart for Tai Chi RCTs

Specific Tai Chi protocol mentioned

Yes (+1) Therapeutic principles/components mentioned

Yes (+1) Population/outcomes match mentioned

Yes (+1) References provided

Yes (+1) Formal validity testing

Yes (+1)

Figure 3. Characteristics of Tai Chi Protocols used in RCTs (n=171) and their Level of Validation

b. Validation

The 5-point grading system in Figure 1 reflects increasing degrees of validity for using a Tai Chi protocol in a trial. One point was given for each of the individual criterion met.

• Criterion #1 addresses whether a specific Tai Chi protocol was reported.
• Criterion #2 requires mention of therapeutic principles or components (e.g., body awareness, breathing, meditation, relaxation, imagery and visualization) of the specific Tai Chi protocol.
• Criterion #3 requires explicit mention of the relevancy or appropriateness of the specific Tai Chi protocol and/or its therapeutic principles to the targeted study population or study outcomes (e.g. use of shorter stances in Sung Style Tai Chi for Arthritis to minimize knee strain in patients with knee osteoarthritis).
• Criterion #4 requires references cited that discuss or support the therapeutic use of the specific Tai Chi protocol in prior studies or publications.
• Criterion #5 directly requires formal content validity testing of the specific Tai Chi protocol described (e.g. use of expert panels or systematic qualitative feedback from target stakeholders

Quality of Content Validity Reporting

• Validity scores for the 171 eligible trials ranged from 0-4 (max possible score of 5).
• Avg score was 2.52 (±S. D.1.24); median was 3.
• Twenty (12%) trials did not mention a specific Tai Chi protocol.
• Of the 151 trials that did mention a specific Tai Chi protocol, 47 (31%) studies received a total of 4 points for also mentioning Criteria 2, 3, and 4.
• Formal validity assessment (Criterion 5) was employed in only one trial (Figure 3).

CONCLUSIONS

• The relatively poor quality of protocol rationale and content validity reporting limits our ability to evaluate the evidence of Tai Chi as a therapeutic intervention.
• Standards for reporting Tai Chi protocol content should be developed and employed.
• Guidelines for evaluating and reporting intervention validity may improve aspects of the quality, interpretability, and return on investment in research.

Supported by NIH NCCIH K24AT009465 and K24AT009282