Assessing Methodological Quality of Acupuncture Clinical Trials of Korea

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Objectives: To evaluate the methodological quality of Korean Acupuncture Clinical trials

Methods: Two independent researchers reviewed 12 protocols of Acupuncture clinical trials which were conducted in Korea 2006. Also, Survey Principal Investigator of those was conducted. We compare the results of protocol review with investigator responses of actual practice. Quality assessment consisted of 5 items including random sequence generation, randomization method, allocation concealment, subject blinding, assessor blinding.

Results: Randomization was performed using the proper procedure to insure that treatment assignment is unbiased and concealed from subjects in all clinical trials. According to protocols, 6(50%) of 12 clinical trials used computer-generated random numbers, 6(50%) remaining trials didn’t describe the randomization method. Also all trials used appropriate randomization methods on the basis of the survey results: 8 trials used computer-generated random number, 2 used random table. Of 7 protocols in which allocation concealment was stated, 5(71%) reported appropriate method (Calling a central office or statisticians, Sealed opaque envelopes). However according to survey, 5(42%) of 12 trials used inappropriate allocation concealment (Keeping a master randomization list and referring to when subject entered the trial). In addition, the result of protocol review and survey response was not coincident in 5(42%) trials. Subject blinding was conducted in all except 1 clinical trials. Although 11(92%) of 12 trials