Title: The Effect of Oriental Medicine Music Therapy on Hwa-byung Patients: study protocol for a randomized controlled trial

Authors:

Jeong-Su Park (suyahpark@gmail.com)
Sunju Park (sjpark422@khu.ac.kr)
Chun-Hoo Cheon (pm.thehoo@khu.ac.kr)
Sun-Yong Chung (lovepwr@khu.ac.kr)
Jong-Woo Kim (aromagi@khu.ac.kr)
Yong-Cheol Shin (syc99@khu.ac.kr)
Seong-Gyu Ko (epiko@khu.ac.kr)

Version: 4 Date: 7 August 2012

Author's response to reviews: see over
August 3rd, 2012

Re: Manuscript #1001460512663772

Dear Editor,

Thank you very much for your 1st revisional decision on our manuscript—The Effect of Oriental Medicine Music Therapy on Hwa-byung Patient: study protocol for a randomized controlled trial for Trials Journal (#1001460512663772). We have taken your critiques under consideration and revised the manuscript accordingly.

The revised version of the manuscript is included along with this letter for publication in Trials Journal. The red letters in the revised draft mean changed methods, the blue letters are re-written sentences.

Thank you very much for giving us a chance to publish our work in your journal.

Yours sincerely,

Seong-Gyu Ko, M.D., Ph.D., M.P.H.

Professor
Center for Clinical Research and Genomics,
Kyung Hee University.
1, Hoegi-dong, Dongdaemun-gu,
Seoul, 130-701, Korea

(Email) epiko@khu.ac.kr
(Phone) 82-2-961-0329
(Fax) 82-2-966-1165
Major compulsory revisions

1) This is not a non-inferiority trial, something that would involve specification of a different that would count as non-inferior. Please revise accordingly.

When we discussed on the trial design we reviewed many journals and protocols and had a lot of debate to pick one between superior or non-inferior trial to be used this music therapy trial. And we decided to go with superior design and described all things by the superior design. There must have been some mistake describing this area during writing down the manuscript. We modified the phrase from non-inferior to superior trial by our first plan we made. The sample size is described and calculated based on the superior trial in the original manuscript.

2) The process of randomization must be described exactly, in particular, what procedures are put in place to prevent as individual guessing a patients allocation before registration? What is to prevent allocation being changed after a patient is registered on trial? Just stating that a firm is involved is insufficient.

We described more detail in the randomization. The randomization process will be carried out after the enrollment of 16 patients, so there will be no chance to be changed after a patient is registered on trial. Random number will be generated to allocate the patient by SPSS package. The odd number will be the MuTH group and the even number will be the control group. The allocation ratio is 1:1.

3) Please state the objectives in term of a four part scientific question in clear PICO format: Population, Intervention, Comparison, Outcome

We described the objectives in PICO format. The P is Hwa-byung patient, the I is the Oriental Medicine Music Therapy, the C is the control music therapy, the O is the STAI (State-Trait Anxiety Inventory).

4) Justify the use of multiple overlapping questionnaires, many of which measure similar psychologic domains. Alternatively, consider using fewer questionnaires.

We discussed for this issue. So we concluded to use fewer questionnaires, only the STAI (State-Trait Anxiety Inventory), the Hwa-byung scale, the CES-D (The Center for
Epidemiologic Studies Depression Scale), the H-VAS (Hwa-byung primary symptoms Visual Analogue Scale), the WHOQOL-BREF (World Health Organization Quality of Life Brief Version) and salivary cortisol level. The STAI measures the anxiety, the CES-D evaluates depression, the WHOQOL-BREF gauges the quality of life. The Hwa-byung scale and the H-VAS measure the change of hwa-byung symptoms. Salivary cortisol level stands for stress.

5) Do not use the term placebo for the control group.
   We changed the term placebo to the control group according to your advice.

6) Do not use statistical tests on baseline comparisons between groups. This is testing a null hypothesis that is known to be true (that any differences between groups are due to chance).
   We dismissed the statistical tests on baseline comparisons between groups.

7) Be specific in the statistics section: for example, several of the questionnaires have multiple domains. Will these be analyzed separately?
   We rewrote the statistics section. Only the total score will be analyzed.

8) Don’t use multiple tests to address the same question (e.g. ANCOVA and t-test).
   We corrected the statistics section not to use multiple tests to address the same question.