Author's response to reviews

Title: Music therapy to promote psychological and physiological relaxation in palliative care patients: Protocol of a randomized controlled trial

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Version: 3 Date: 2 December 2014

Author's response to reviews: see over
Dear editors and referees,

Thank you very much for your critical assessment of the manuscript entitled “Music therapy to promote psychological and physiological relaxation in palliative care patients: Protocol of a randomized controlled trial”. Your ideas and recommendations have been very helpful in order to further improve the quality of the manuscript. Please find a revised version in the BMC manuscript upload section.

We will reply to your comments point-by-point in the following sections:

- **Control group design and research questions:**
  The question of how to design an adequate control group for psychosocial interventions in palliative care is one of great importance for the implications that can be drawn from the results, and thus, for the research question in general. We believe that there is no “gold standard” in this case, as in RCTs *standard care alone* groups have been criticized for being unethical. Participants might be excluded from benefits of presumably effective treatments and wait-list control groups are hard to implement in palliative care research. Therefore, we decided to use an active control treatment so that study participation is not associated with disadvantages in the care services provided.
  We would object the view that the study design compares an “MBSR + music therapy” group to an “MBSR alone” group. The concept nowadays labeled as “mindfulness” is not one unique to Kabat-Zinn’s MBSR program, but has been used in various cultural traditions and health-care professions throughout the years – one of which is music therapy. However, it is true that shared factors in the two study arms need to be addressed in this manuscript (see discussion section).
  We revised the formulation of the study goals and address consequences of such a design in the discussion section, and refer to another manuscript on these methodological challenges, being published in the forthcoming issue of the Nordic Journal of Music Therapy.

- **Sample size calculations:**
  After Dr. Teut’s request for a more detailed information on the sample size calculation in this study, we consulted our department’s statistician. He provided us with some recent papers on power analysis in RCTs using ANCOVA models instead of the conventional repeated-measures ANOVA approach. Please find a revised sample size calculation based on Shan & Ma (2014) in the methods section.

- **Minor changes and language editions:**
  We asked a English native speaker to critically revise the manuscript with special regard to English language. Minor changes have been made addressing the discretionary revisions stated by Dr. O’Callaghan (wording in research findings section, Bradt & Dileo reference, EEG study, English translation of CD title, ICD abbreviation). We also made clear that we will not use a body tambura, but a monochord in the music therapy intervention, as requested by Dr. Teut.

Once again, thank you very much for your ideas.

Kind regards,
Marco Warth