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LETTER

Can Music Therapy Really Alleviate Chronic Pain? Reflections on the Design, Measurement, and Reporting of a Randomized Controlled Trial [Letter]

Fei-Yi Zhao[1–4,*], Qiang-Qiang Fu[5,*], Jie Qian[5,6]

[1]Department of Nursing, School of International Medical Technology, Shanghai Sanda University, Shanghai, 201209, People's Republic of China; [2]Sydney School of Health Sciences, Faculty of Medicine and Health, The University of Sydney, Camperdown, NSW, 2050, Australia; [3]School of Health and Biomedical Sciences, RMIT University, Bundoora, VIC, 3083, Australia; [4]Shanghai Municipal Hospital of Traditional Chinese Medicine, Shanghai University of Traditional Chinese Medicine, Shanghai, 200071, People's Republic of China; [5]Yangpu Hospital, School of Medicine, Tongji University, Shanghai, 200090, People's Republic of China; [6]Shanghai Mental Health Center, Shanghai Jiao Tong University School of Medicine, Shanghai, 200030, People's Republic of China

*These authors contributed equally to this work

Correspondence: Fei-Yi Zhao, Department of Nursing, School of International Medical Technology, Shanghai Sanda University, Shanghai, 201209, People's Republic of China, Tel +86 5021-0894, Fax +86 5021-0895, Email fyzhao@sandau.edu.cn; fei-yi.zhao@rmit.edu.au; Jie Qian, Department of Clinical Psychology, Yangpu Hospital, School of Medicine, Tongji University, Shanghai, 200090, People's Republic of China, Tel + 86 021-6569 0520, Fax + 86 021-6569 6249, Email bsb.qianjie@tongji.edu.cn

Dear editor

The U.S. FDA has advocated for the development of novel therapies for chronic pain with lower misuse potential.[1] In this context, we commend the recent RCT by Wang et al, which provides timely evidence regarding the effects of music therapy on pain, mood, and sleep outcomes in patients with chronic pain.[2] Nevertheless, several methodological and interpretative concerns warrant further discussion.

Imbalance in Assessment Scheduling and Analytical Approach

This study exhibits marked asymmetry in the scheduling of assessment time points. In the *Outcome Measures* section, the authors state that the experimental group was assessed using multiple instruments (SF-MPQ, PHQ-9, GAD-7, PSQI, and HRV) at three time points—baseline, immediately after the initial in-hospital music therapy session, and after 14 days of home-based self-administered intervention—whereas the control group was assessed only at baseline and post-intervention.[2] Such an imbalance may exaggerate or obscure intervention effects, thereby threatening internal validity.

Additionally, the statistical analysis relied on *t*-tests and the Mann–Whitney *U*-test, without incorporating analytical approaches suitable for longitudinal data, such as repeated measures ANOVA or mixed-effects models. Consequently, the analysis fails to adequately capture temporal effects or group × time interactions, and does not fully characterize the dynamic trajectories of outcomes across time. More concerning, although the *Results* section (Tables 2, 3, and 4) does not report data for the "immediately following the initial in-hospital music therapy session" time point, the footnotes of Table 4 include statistical comparisons involving this time point (eg, symbols such as # and &).[2] This discrepancy between study design and reporting raises concerns regarding selective outcome reporting and undermines transparency and reproducibility.

To strengthen internal validity, future investigations would benefit from implementing symmetric assessment schedules across groups and ensuring complete reporting of data from all prespecified time points, thereby enabling valid between- and within-group comparisons.

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Mismatch Between the Time Window of Assessment Tool and the Intervention Duration

Wang et al used the PSQI to assess sleep quality.[2] This instrument requires respondents to recall sleep conditions over the preceding one-month period,[3] whereas the intervention duration was limited to two weeks. As a result, the PSQI scores obtained following 14 days of home-based self-administered intervention reflect a composite of sleep conditions from both the pre-intervention period and the intervention phase, rather than representing changes attributable to the intervention itself. This temporal mismatch compromises construct validity and limits the sensitivity of the PSQI in detecting true intervention effects of music therapy. Pre-existing sleep disturbances may mask improvements, increasing the risk of false-negative findings.

Similarly, as noted above, participants in the experimental group were required to complete PHQ-9 and GAD-7 immediately after an initial in-hospital 10-minute music therapy session, but these instruments are not designed to detect ultra-short-term changes.

A more appropriate approach would be to select outcome measures whose assessment timeframes align with the intervention duration. For short-term interventions, instruments such as sleep diaries or the ISI, complemented by objective measures (eg, actigraphy/polysomnography-derived TST, SE, WASO), may provide more comprehensive and sensitive sleep assessments.

Lack of Consideration for Music Preference

The authors acknowledge that the analgesic efficacy is contingent upon the music type, with self-selected music generally superior. However, the present study utilized a standardized, soothing synthesized music track without accounting for individual preferences.[2] While such standardization controls confounders, it does so at the expense of individualized therapeutic benefits of music therapy. A lack of emotional engagement—or even aversion—to the assigned music may attenuate analgesic responses or elicit negative affective reactions.

Notably, the study did not detect significant between-group differences across several pain-related outcomes (eg, VAS, A-PRI, and S-PRI scores). These null findings may, at least in part, be attributable to the mismatch between standardized music and patient preferences, rather than to the ineffectiveness of music therapy per se. In other words, the current design cannot disentangle whether the lack of benefits stems from “music being ineffective” or “music being mismatched”, thereby limiting the interpretability of the conclusions.

To clarify this ambiguity, researchers employing standardized music interventions should concurrently assess participants’ preference, acceptance, and engagement with the assigned music, as well as any discomfort experienced. These variables may be incorporated as covariates in statistical models or examined through subgroup analyses to elucidate their influence on outcomes. Alternatively, a three-arm randomized controlled trial—comprising a self-selected music group, a standardized music group, and a no-music control group—would enable direct comparison of the advantages and disadvantages of different music therapy strategies.

Absence of Adherence Data Reporting

The study required participants to record the frequency and duration of daily music listening in a designated logbook. However, the *Results* section does not report any adherence-related data,[2] such as the proportion of participants who strictly completed all sessions, or the proportion missing any sessions during the intervention period. This omission precludes the assessment of whether the observed outcomes reflect true intervention effects and makes it difficult to exclude low adherence as a potential source of false-negative findings. For instance, insufficient adherence could obscure a genuine therapeutic effect in between-group comparison. Moreover, the absence of adherence data limits the ability to evaluate potential dose-response relationships, such as whether higher adherence is associated with greater improvements.

In future work, employing objective electronic monitoring methods (eg, mobile apps that automatically record playback frequency and duration) instead of self-reported logs is recommended. In addition, adherence metrics—including completion rates, mean adherence levels, adherence distributions, and correlation analyses between adherence and primary/secondary outcomes—should be systematically reported to enhance interpretability and methodological rigor.

Risk of Bias Due to Completer-Only Analysis

Of 86 participants, 79 completed the intervention and were analyzed; dropouts were excluded, with differing rates between groups (11.6% in the experimental group vs. 4.7% in the control group).[2] If attrition was related to intervention response—for instance, due to lack of pain improvement or aversion to the music—then a completer-only analysis may introduce selection bias and lead to systematic overestimation of treatment effects of music therapy.

It is advisable for future investigations to follow the CONSORT recommendations, using intention-to-treat analysis as the analytical strategy, complemented by sensitivity analyses based on per-protocol populations.[4] Missing data should be addressed using appropriate statistical methods, such as multiple imputation or maximum likelihood estimation, to ensure more reliable and unbiased effect estimates.

Absence of Safety and Adverse Events Reporting

Although music interventions are generally regarded as low risk, ethical and scientific standards require systematic reporting of adverse events. In Wang et al's study, the intervention—using noise-canceling headphones three times daily for 10 minutes over two weeks—may entail several risks. Prior evidence suggests that prolonged use of noise-canceling headphones can induce a sensation of constant ear pressure, leading to ear fatigue; high-volume use over extended periods may cause hearing loss. Additional risks include tinnitus aggravation or symptoms such as imbalance and dizziness due to altered sound pressure levels within the ear.[5] Nevertheless, the study did not report any safety outcomes, preventing assessment of the music therapy's risk-benefit profile and limiting its clinical and translational relevance.

Future studies should systematically collect and report adverse events, including those actively solicited by researchers (eg, headache, ear pain, dizziness, tinnitus) as well as any discomfort spontaneously reported by participants. Key safety parameters—such as incidence, severity, duration, and the assessed causal relationship with the music therapy—should be clearly documented. Use of standardized reporting frameworks, such as the CTCAE, is recommended to enhance consistency and transparency in safety reporting.

Conclusion

In summary, although music therapy shows promise for chronic pain management, establishing its true efficacy necessitates rigorous study designs, outcome measures that are sensitive and aligned with the intervention, and comprehensive reporting of adherence, safety, and individual preferences. Future research should combine personalized music interventions, appropriate control conditions, and robust analytical frameworks to elucidate the practical feasibility of integrating music therapy into comprehensive chronic pain management.

Abbreviations

ANCOVA, Analysis of Covariance; A-PRI, Affective Pain Rating Index; CTCAE, Common Terminology Criteria for Adverse Events; CONSORT, CONsolidated Standards Of Reporting Trials; FDA, Food and Drug Administration; GAD-7, Generalized Anxiety Disorder-7; HRV, Heart Rate Variability; ISI, Insomnia Severity Index; PHQ-9, Patient Health Questionnaire-9; PSQI, Pittsburgh Sleep Quality Index; RCT, Randomized Controlled Trial; SE, Sleep Efficiency; SF-MPQ, Short-Form McGill Pain Questionnaire; S-PRI, Sensory Pain Rating Index; TST, Total Sleep Time; VAS, Visual Analogue Scale; WASO, Wake After Sleep Onset.

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Data availability is not applicable as no new data was generated or analyzed in this communication.

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