Reviewer’s report

Title: Effectiveness of Music Therapy for Alleviating Pain During Haemodialysis Access Cannulation for Patients Undergoing Haemodialysis: A Multi-facility, Single-blind, Randomised Controlled Trial

Version: 0 Date: 12 Aug 2019

Reviewer: Matthew Roberts

Reviewer's report:

The authors have designed a novel study looking at the effects of music on pain when inserting needles for hemodialysis. They include an interesting mix of outcomes, including VAS pain score, salivary amylase and others.

The major difficulty with this protocol is recruiting participants with sufficient pain for the intervention to be beneficial. In their pilot study, the authors report a mean VAS pain score below the 30mm considered "moderate pain". The enrolment procedure (p8) makes no assessment of the level of pain and is a major weakness of the study. I don't believe using this enrolment questionnaire will be very different from approaching all patients to participate, regardless of pain experience. Is there a particular level of pain that the intervention is meant to alleviate, or is the study open to people with any level of pain (i.e. including VAS pain scores below 20mm or less)?

How much does the intervention rely on the timing of venepuncture being when the second movement commences? Nurses in dialysis units can be very busy and have competing priorities. I am not confident that they can be relied upon to needle a fistula at precisely the right time. This may be further delayed if the initial venepuncture is unsuccessful. Will the timing of venepuncture in relation to the start of the Sonata be recorded/reported?

The sample size is based on a 20% reduction in VAS pain score from 25.4 to 20.5mm in a pilot study. Is there any literature on what reduction in VAS pain score is clinically important?

The authors have worked hard to try to blind study personnel to the intervention, and this is appropriate. Are the any mechanisms in place to ensure/confirm that either the Mozart sonata or white noise was actually delivered? For example an equipment malfunction/headphones becoming unplugged would result in the intervention not being delivered, but the study personnel may not be aware.

The references are not formatted correctly and should include the title.

In the Discussion, the authors link the possibility of lowering the pre-dialysis BP by music therapy with improving prognosis. This is highly speculative, particularly given other studies of the pre-dialysis BP and outcome have had different results to the cited study.
Minor issues:
p5 line 70/71: "approximately 20% of patients experience excruciating pain" - this is somewhat emotive language. In the cited study (ref 4), 19.5% of people in the placebo arm reported VAS pain score above 54mm ("severe pain").
p10 - the "White noise" section is presumably about the control period. The phrase "During this period . . " suggests we are still talking about what has been happening in the previous paragraph. What is the relevance of the weather? (p12, bottom line)
p13 line 222/223 - if pain is only evaluated once per session, how is the highest pain score during a session to be used?

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