

Statement from Dr. Christian Gold, Principal Investigator of the TIME-A study published in JAMA, for the American Music Therapy Association

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First of all, I would like to thank the American Music Therapy Association for the opportunity to comment on our article in the JAMA issue of August 8, 2017 (pp. 525-535), and the coverage in the mass media, concerning the results of the Trial of Improvisational Music therapy's Effectiveness for children with Autism (TIME-A). This large, multinational randomized controlled trial (RCT) was "negative" in the sense that the primary outcome did not show an effect of music therapy compared to the control condition. However, it was a tremendous success for the study team and recognition of music therapy to be accepted in a top-tier medical journal.

I am grateful for all the congratulatory comments, as well as for the critical comments I received in the days and weeks following the publication. It is unusual for a music therapy study to receive so much attention from mainstream media. Therefore I understand that there have been some anxious and pessimistic reactions about a potential negative impact of that attention, alongside more optimistic views. I tend to be an optimist, and I will explain why.

1.) Is it unusual to have "negative" trials in medicine or in JAMA?

To get some wider context, it can be helpful to browse through the JAMA issue of August 8, or to listen to the audio commentary by the chief editor summarizing the issue. Directly after the TIME-A report, there were two other negative trial reports, both concerning surgery-related procedures – surgical aortic valve replacement and coronary artery bypass grafting, respectively. *Will surgeons stop working as a result of these negative trial findings?* Of course not. Surgeons will welcome these negative results as an opportunity to learn, perhaps to try other techniques, refine the techniques, or refocus them on those patients where they work best. (For those interested in the history of science, it is however interesting to note that surgeons have been long critical of RCTs. Not unlike music therapy, surgery can be seen as an art, with its success depending on the skills of the person conducting it.)

2.) Were there some positive results in the JAMA report?

It is important to know how to read reports of RCTs, especially in leading medical journals. Only the pre-specified primary outcome is allowed to enter the abstract, discussion, and key points. However, also reported in the JAMA article, just in less prominent places, were "*significant effects* [...] in several SRS subscales [where] music therapy was associated with greater improvements than standard care in *social motivation* [...] and *autistic mannerisms*"; "low-intensity music therapy, compared to standard care, was associated with greater improvements in *social awareness* [...]; high-intensity music therapy [...] with greater improvements in *autistic mannerisms*". There was also "a higher proportion of *improvement in ADOS social affect* [in] music therapy [...] (P = 0.047)", particularly in "participants who received *at least 15 music therapy sessions* [...] (P = 0.004)" (all cited from pp. 528-529).

4.) Did TIME-A have other positive results not published in JAMA?

Further positive effects were found in additional subgroup analyses, which we have presented at various conferences. However, they were not included in JAMA due to space limitations and the post-hoc nature of these analyses. I know from experience that less prominent journals, in music therapy or elsewhere, often allow or even encourage authors to emphasize such secondary findings. Such “cherry-picking” will however tend to overstate the actual effects, and therefore I believe that top-tier journals such as JAMA have very good reasons for abstaining from such practices. It is perfectly OK to explore the data for any such additional hints or hypotheses that can be generated – as we have done and will continue to do – but it has to be separated from the primary findings.

5.) How were the results interpreted in JAMA itself?

Although JAMA rightly insisted that the article be focused on the findings of the primary outcome, they also commissioned an editorial (pp. 523-524) and compiled a set of “quiz questions” for continuing medical education (p. 571). Both pieces were focused on explaining what improvisational music therapy is and what its potential benefits might be. The editorial also compared the TIME-A findings with those of our earlier Cochrane review, which showed more positive results, speculated about differences in study populations, and offered recommendations for future research on music therapy for autism.

My favorite questions from the CME quiz are these two:

“Which of the following therapies relies primarily on the spontaneous creation of music as a medium for social communication? (a) mindfulness therapy; (b) prolonged exposure therapy; (c) improvisational music therapy; (d) cognitive behavioral therapy.” The correct answer is of course c, but having this question there does establish the existence of improvisational music therapy for medical doctors.

“Although this trial of improvisational music therapy did not improve children’s social affect score, (a) it was well accepted by parents, children, and staff; (b) parents reported their children’s enjoyment and benefit from improvisational music therapy; (c) parents reported their own involvement in music therapy as positive; (d) all of the above.” The correct answer is “all of the above” (see p. 532 in our article), and the question shows that qualitative benefits reported very briefly were noted by JAMA editors.

Thus, my overall impression is that JAMA editors know that clinical research is seldom entirely black or white; instead, there are many reasons why one trial might show better results than another one, and that these are worth exploring.

6.) How were the results depicted in CNN and other mass media?

The CNN interview started with explaining what music therapy is, what it can do, and how it was experienced by a person with autism. It also included statements from influential people who were not involved in the study. One of them was Donna Murray, the vice president of clinical programs at Autism Speaks. She also explained what music therapy is and then made many positive statements that put the study into the right context: “many interventions for children with autism may be beneficial even if they show mixed results in clinical trials;” five months of therapy (although longer than previous music therapy trials) may not

be long enough; and finally, if you can engage a child with autism with "something appealing like music, at a minimum, that's a great start for some sort of social interaction." When did we last hear a prominent spokesperson of Autism Speaks say such positive things about music therapy?

Another person interviewed by CNN was music therapist Ken Aigen, who made important statements about the limitations of the study. For example, we agree that reducing autism severity may not be the most appropriate goal for music therapy "anymore," and have made a similar comment in the JAMA article (p. 533). However, what is known now was not known before the trial. Views on autism are constantly changing, and our project was part of that change.

It is true that there were also some really negative and superficial headlines, most notably in the British tabloid press. The worst I have seen was by the Daily Mail, with a heading that music therapy is a "waste of time and money."

However, these papers live on scandals. Oscar Wilde, who suffered a lot of negative media attention in his life, said that "the only thing that's worse than being talked about is – not being talked about." I think he was right. Many people have now heard of music therapy for autism who may not have heard about it otherwise. And many have explained music therapy and made positive statements about music therapy, including influential people who are unrelated to the study or the profession of music therapy.

7.) Where to from here for research on music therapy for autism?

In an insightful commentary, music therapist Alan Turry described the TIME-A report in JAMA as "the beginning of the path to validating that improvisation is in fact a bona fide treatment for children on the spectrum"

(<http://steinhardt.nyu.edu/music/nordoff/news/futureresearch>). He also compared the potential effects of our trial to a negative psychotherapy study in the 1950s, which is today often quoted as the event that marked the beginning of serious research on the outcomes of psychotherapy (see for example my chapter in Gelo et al., 2015, *Psychotherapy Research*, Springer).

Another valuable comment showing a possible path for music therapy research was made by Francis Collins, director of the National Institutes of Health (NIH). He was aware of the TIME-A results when he wrote that "the largest [music therapy] trials have yielded mostly inconclusive results, possibly because of the heterogeneity of affected individuals, interventions, and responses" (JAMA issue of June 2, 2017). He commented further that "music therapy likely requires interventions tailored to the individual," and that we need to explore these individual differences to advance music therapy research and practice.

TIME-A forces us to rethink music therapy and to develop it further. This process has already started, and some examples are quoted in our JAMA article (pp. 532-533). As I commented above, there are many negative trials in surgery, but surgeons have learned to interpret these trials and to use their results to improve their skills, combining individual artistic-like virtuosity and collective scientific wisdom. In this sense (but only in this sense!), I hope that music therapy can become a bit like surgery.