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Reporting Guidelines for Music-based Interventions

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Abstract

Music-based interventions are used to address a variety of problems experienced by individuals across the developmental lifespan (infants to elderly adults). In order to improve the transparency and specificity of reporting music-based interventions, a set of specific reporting guidelines is recommended. Recommendations pertain to reporting seven different components of music-based interventions including intervention theory, intervention content, intervention delivery schedule, interventionist, treatment fidelity, setting, and unit of delivery. Recommendations are intended to support CONSORT and TREND statements for transparent reporting of interventions while taking into account the variety, complexity, and uniqueness of music-based interventions.

Keywords

music therapy; music; reporting guidelines; evidence-based practice

INTRODUCTION

Music-based interventions in health care are generally considered low risk and palatable to patients of various ages from infants to elderly. While there is a strong intuitive appeal to most patients and healthcare providers regarding the use of music in healthcare environments, the evidence to support its integration into healthcare is equivocal. For example, a recent Cochrane review suggests that the influence of music on pain relief is highly variable, with tentative clinical importance (Cepeda, Carr, Lau, & Alvarez, 2006). Studies exploring the use of music to decrease anxiety are also inconclusive with results depending on intervention type (Pelletier, 2004). Integrative reviews conclude that divergent results are the result of methodological problems across studies (Evans, 2002; Pothoulaki, 2006). In particular, many studies lack sufficient description of music interventions to enable cross-study comparisons, generalization, and integration into practice.

Detailed intervention research reporting is essential to interpretation, replication, and eventual translation of music-based interventions into practice. The Consolidated Standards for Reporting Trials (CONSORT) and Transparent Reporting of Evaluations with Non-randomized Designs (TREND) statements, each with multiple item reporting checklists, were developed to help improve the quality of research reports (Altman, et al., 2001; Des

Jarlais, Lyles, & Crepaz, 2004; Schulz, Altman, & Moher, 2010). One specific item on CONSORT and TREND checklists is dedicated to intervention reporting, but limited in detail. Subsequent publications have explored complexities related to transparent reporting of behavioral and non-pharmacological interventions, especially in the area of intervention reporting (Altman, et al., 2001; Boutron, et al., 2008a, 2008b; Des Jarlais, et al., 2004; Dijkers, et al., 2002; Marks, 2009, 2010; Mayo-Wilson, 2007; Perera, Heneghan, & Yudkin, 2007; Schulz, et al., 2010).

Music-based interventions are especially difficult to fully and transparently describe because of the complexity of music stimuli and other factors such as choice of music, mode of delivery, or the combination of music with other intervention strategies. In a recent review, Robb and Carpenter (2009) identified 11 intervention components unique to music-based interventions. Despite the publication of elaborated CONSORT guidelines to describe intervention reporting complexities for non-pharmacologic treatment, herbal interventions, and behavioral medicine, there remain many issues specific to music-based intervention reporting that have not been addressed (Boutron, et al., 2008a, 2008b; Davidson, et al., 2003; Gagnier, et al., 2006). Given the variety and complexity of music-based interventions, we are recommending specific reporting guidelines to improve the transparency and specificity of reporting music-based intervention research. The proposed guidelines build on recommendations from CONSORT and TREND, with evidence-based arguments for the inclusion of specific information when reporting music-based interventions.

FORMULATION OF REPORTING GUIDELINES

The proposed recommendations focus on the area dedicated to interventions in the CONSORT and TREND guidelines (see Table 1). Our recommendations were formulated based on our systematic review of music-based intervention reporting (Robb & Carpenter, 2009) and on broader-based reviews of behavioral intervention reporting (Boutron, et al., 2008a, 2008b; Dzewaltowski, et al., 2004; Gagnier, et al., 2006; Lechago, Carr, Lechago, & Carr, 2008; Mayo-Wilson, 2007; Moher, Jones, & Lepage, 2001). We started by examining the 11 intervention components identified by Robb and Carpenter (2009) and generated an extensive list of reporting criteria.

Next we condensed the 11 components to seven using the criteria that reported information must be: 1) relevant across a wide range of music-based interventions; 2) essential for interpretation of outcomes; and 3) necessary for replication and translation. The following section presents our recommendations for music-based intervention reporting, along with an evidence-based rationale for inclusion of each reporting variable. Table 2 provides a concise overview of the seven criteria and is intended to be used as a checklist by investigators to verify that each criterion is addressed in published reports of music-based interventions.

RECOMMENDATIONS FOR MUSIC-BASED INTERVENTION REPORTING

Item 4A: Intervention Theory. Provide a rationale for the music selected; specify how qualities and delivery of the music are expected to impact targeted outcomes.

Our previous reviews indicate that many investigators do not provide rationale for use of music as an intervention. Although some authors provided a theoretical conceptualization of the problem, they did not describe the mechanistic or mediating variables explaining how the music was expected to or actually influenced specified outcomes. An atheoretical approach can become problematic when interpreting research results or performing cross-study comparisons. For example, music listening interventions are frequently used to decrease acute and/or chronic pain in cancer patients throughout the treatment trajectory (Cepeda, et al., 2006). Pain is a multi-dimensional phenomenon and different dimensions

may be more or less amenable to change with music-based interventions. Though music listening interventions seem to be somewhat beneficial in reducing pain (Cepeda, et al., 2006), results are mixed, perhaps due at least in part to differences in measurement of pain outcomes. A clear theoretical conceptualization with a proposed mechanism of action for music can help guide selection of outcome measures, which would in turn clarify any beneficial effects of music. Thus, we recommend that investigators provide a rationale for the music selected and specify how qualities and delivery of the music are expected to impact targeted outcomes.

Item 4B: Intervention Content. Provide precise details of the music intervention and, when applicable, descriptions of procedures for tailoring interventions to individual participants.

Item 4B.1: Who Selects the Music. Specify who selected the music: (1) pre-selected by investigator, (2) participant selected from limited set, (3) participant selected from own collection, or (4) tailored based on patient assessment.

Several meta-analytic and comparative studies have explored the potential influence of who selects music on intervention effectiveness; disparate findings support arguments for reporting this aspect of music-based interventions (Allen & Blascovich, 1994; Labbe, et al., 2007; Pelletier, 2004; Potteiger, Schroeder, & Goff, 2000; Silverman, 2003). Increased understanding about who selects music and the influence on health outcomes will provide clinically relevant information about delivery methods and related cost. However, meaningful cross-study comparisons and meta-analytic studies are difficult in the absence of clear reporting. A Medline search using the terms “self-selected music,” “patient-selected music,” and “participant-selected music” published between 2000 and 2009 resulted in 15 publications. Inspection of each article revealed more detailed information about how the term “participant/patient/self-selected music” was actually defined: 1) six studies (40%) used music from the participants own collection (i.e., they were asked to bring music from home or could request any piece of music) (Ebnesahidi, Mohseni, Ebnesahidi, & Mohseni, 2008; Hernandez-Ruiz & Hernandez-Ruiz, 2005; Labbe, et al., 2007; Sarkamo, et al., 2008; Simcock, et al., 2008; Wang, Kulkarni, Dolev, & Kain, 2002); 2) six studies (40%) asked participants to choose music they preferred from a limited set of investigator-selected music (Allen & Blascovich, 1994; Buffum, et al., 2006; Chlan, Tracy, Nelson, & Walker, 2001; Hayes, et al., 2003; Kang, et al., 2008; Smolen, et al., 2002); 3) two studies (13%) did not provide a clear enough description to determine how participant selected music was defined (Lee, et al., 2004; Potteiger, et al., 2000); and 4) one study (7%) tailored music based on patient assessment (Clark, et al., 2006). These data suggest the need for clearer terminology when reporting the use of participant-selected music and new terminology to capture the tailored selection of music.

Tailoring is defined by Kreuter and Skinner (2000) as “any combination of information or change strategies intended to reach one specific person, based on characteristics that are unique to that person, related to the outcome of interest, and have been derived from an individual assessment.” Although tailored interventions appear frequently in music therapy clinical practice, they have not been widely tested through controlled research – but have begun to appear in published literature (Enderlin & Richards, 2006; Okamoto, et al.; van der Geer, et al., 2009).

We recommend that investigators specify who selected the music for their study using the following 4 categories: 1) pre-selected by investigator, 2) participant selected from limited set (i.e., the participant is offered a choice of music from a list that was pre-selected by the investigative team), 3) participant selected from own collection (i.e., the participant brought music from home or was given the opportunity to request any piece of music), and 4)

tailored based on participant assessment (i.e., music is selected or created for each participant based on specified criteria).

Item 4B.2: Music. When using published music, provide reference for sheet music or sound recording.

When using improvised or original music, describe the music's overall structure (i.e., form, elements, instruments, etc).

Investigators must consider numerous qualities of music when designing and testing interventions including form, tempo, rhythm, melody, harmony, voicing, and tonality. For example, we know that changes in loudness, especially increases or sudden decreases in dynamics, will elicit attentive responses in the listener that are also associated with physiological arousal (Huron, 1992; Thaut, 2002, 2005). In contrast, sustained or limited changes in dynamics can lead to auditory habituation and diminished arousal – where the music becomes background (Huron, 1992; Thaut, 2002, 2005). In this example, eliciting or diminishing attention and arousal in the listener depends on the compositional features of the music; therefore, it is not enough to cite the title or genre of the composition. For instance, Pachelbel's Canon in D major has been used in studies seeking to elicit a relaxation response (Allen & Blascovich, 1994; Knight & Rickard, 2001). However, there are hundreds of recordings and arrangements that vary significantly in tempo and instrumentation – these include orchestral, string quartet, solo guitar, vocal, and heavy metal arrangements. Such variations likely contribute to disparate responses in listeners and final outcomes. Detailed reporting allows cross-study comparisons and better replication of findings. As such, we recommend that authors provide titles of music, including a reference for sheet music or sound recordings. In cases where original or improvised music is used, authors are encouraged to describe musical elements (e.g., tempo, rhythmic structure, form), especially those that are expected to impact targeted outcomes.

Item 4B.3: Music Delivery Method (Live or Recorded). When using live music, specify who delivered the music and the size of the performance group (e.g., interventionist only, interventionist and participant).

When using recorded music, specify placement of playback equipment and the use of headphones vs. speakers. Specify who determined/controlled volume (e.g., interventionist; participant). Specify decibel level of music delivered and/or use of volume controls to limit decibels.

A majority of authors report whether music delivered to study participants was live or recorded, but leave out more detailed information that is relevant to study interpretation and replication. Music perception studies indicate that factors such as musical training, gender, and the complexity of a musical arrangement (i.e., polyphonic vs. homophonic music) can have an impact on neurological processing of a sound stimulus; therefore, when using live music we recommend that authors specify who is delivering the music and the size of the performance group.

When using recorded music, investigators often overlook the importance of reporting details about how the music was delivered (i.e., headphones vs. speakers) and the volume of the music. The use of speakers or headphones can create a different listening experience that may positively impact intervention effects. For example, several studies have used headphones to block external, environmental sounds that can heighten anxiety or distract participants from the intervention (Fowler-Kerry & Lander, 1987; Hatem, Lira, & Mattos, 2006; Megel, Houser, & Gleaves, 1998; Noguchi, 2006; Robb, Nichols, Rutan, Bishop, & Parker, 1995). Other studies have delivered music using speakers to allow the participant to attend to both the music and other aspects of the environment. For example, Grasso and colleagues (2000) used music to structure chest physiotherapy exercises for children with

cystic fibrosis. The music was played from a speaker so that both the parent who delivered the exercises and the child could hear the music. Reporting these variables allows a more thorough examination of factors that may be responsible for intervention effects.

Second, the volume of the music, which is measured in decibels, is important to consider especially in terms of auditory health. Volume of auditory stimuli has been positively correlated with arousal levels experienced by the music listener (Huron, 1992). Reporting whether the investigator or the participant selects/controls the volume of music during the listening experience is an important factor to consider when evaluating and translating study outcomes. Volume limits on playback equipment allow the investigator to control for decibel level of presented stimuli and prevent unintended exposure to unhealthy sound levels. This is especially important when introducing additional sound stimuli in settings where noise levels may be particularly relevant for participant safety, as is the case with premature infants, individuals with dementia, or others (Dewing & Dewing, 2009; Graven, 2000; Philbin & Klaas, 2000; Ragneskog, Gerdner, Josefsson, & Kihlgren, 1998; Sloane, et al., 2002).

When using recorded music, in addition to reporting the type of playback equipment used (see Item 4B.4), we recommend that investigators also report the following information when applicable: 1) whether music was delivered using speakers or headphones, 2) placement of speakers, 3) who determined/controlled the volume of the music, and 4) the decibel (db) level of the music delivered and/or use of volume controls to limit db levels.

Item 4B.4: Intervention Materials. Specify music and/or non-music materials.

The vast majority of music-based intervention studies use materials other than the musical selections that are played or performed for study participants (Robb & Carpenter, 2009); therefore, any materials used for intervention delivery should be clearly identified and described. The term music material refers to musical instruments or items used to create musical sounds. Non-music materials refer to audio-playback equipment, headphones, or other non-musical items, such as illustrated books or tip sheets that were an integral part of the intervention. In the case of music instruments, the quality, timbre, and resonance of instruments vary greatly. For example, a six-string acoustic guitar with steel strings has a different timbre (sound quality) and is generally louder than a six-string classical guitar with nylon strings. Investigators cannot determine if these factors matter unless they get reported. Similarly, non-musical materials, such as audio playback equipment, visual or tactile aids, and/or printed material, can vary in quality, content, and composition. We recommend that authors list all materials by name and when possible include brand, model number, quantity, and descriptive information about all intervention materials. Reporting precise details allows for easier replication and evaluation about sensory stimuli introduced into the study environment.

Item 4B.5: Intervention Strategies. Describe music-based intervention strategies under investigation (examples: music listening, songwriting, improvisation, lyric analysis, rhythmic auditory stimulation, etc).

Although categorical descriptions of music-based interventions, such as music-assisted relaxation, songwriting, or music imagery, are frequently reported, the level of detail about categorical components varies greatly across studies. For example, categorical descriptions such as “music-based relaxation” or “music relaxation” strategies have been used to describe studies that combined music with progressive muscle relaxation, diaphragmatic breathing, imagery, or simply listening to music (Robb & Carpenter, 2009). This illustrates that simple categorical labels do not provide enough specificity to adequately describe an intervention, especially when the intervention uses multiple strategies or components. Terms may be defined differently by investigators, leading to different interventions with the same label.

Although such labels help investigators and clinicians categorize interventions, without additional information these categorical descriptions create a level of ambiguity that hinders or prohibits interpretation and replication of study findings. Incomplete information about the intervention often diminishes clinicians' ability to use study findings to inform practice and can lead to exclusion of studies in meta-analyses and literature reviews. We recommend that authors categorize and fully describe the content and procedural steps for each intervention component, such that the reader can fully interpret study findings.

Item 4C: Intervention Delivery Schedule. Report number of sessions, session duration, and session frequency including practice sessions.

Our review indicated consistent reporting about the number of sessions delivered; less consistent was reporting about session duration and frequency (i.e., how sessions were spaced over time). Information about duration and frequency of session administration is essential when evaluating studies, especially in terms of dosage. The number, duration, and frequency of sessions necessary to derive clinical benefit are questions of paramount importance to clinical practice. For example, a previous study with bone marrow transplant patients suggests that more music sessions are positively correlated to improvements in mood (Cassileth, Vickers, & Magill, 2003). Meta-analytic studies often seek to answer questions about treatment dose, but these questions are often left unanswered due to incomplete reporting. We recommend that authors report information about intervention delivery in all three areas: number, duration, and frequency of sessions.

Item 4D: Interventionist. Specify interventionist qualifications and credentials. Specify how many interventionists delivered study conditions.

Music-based interventions are delivered by a variety of professionals, with varied levels of training in music and/or the therapeutic application of music. It is important that authors report qualifications of individuals delivering an intervention, including professional credentials, because this information has implications for eventual translation of research to practice and future studies that may investigate the level of expertise required to effectively deliver an intervention. One meta-analytic study already suggests that interventionist qualifications may be related to music-based intervention outcomes (Standley, 2000). In addition, the use of multiple trained interventionists should be reported as this strengthens arguments for an intervention effect, rather than a person effect.

Item 4E: Fidelity Strategies for Treatment Delivery. Describe strategies used to ensure that treatment and/or control conditions were delivered as intended (e.g., interventionist training, manualized protocols, and intervention monitoring).

Interventionist training and intervention monitoring are two important aspects of treatment fidelity (Moncher, 1991; Resnick, et al., 2005; Santacroce, Maccarelli, & Grey, 2004). These procedures help to ensure that interventions are delivered consistently and accurately across study participants, yet treatment fidelity strategies are rarely reported in music-based intervention studies (Robb & Carpenter, 2009). The National Institutes of Health Behavior Change Consortium has published recommendations to encourage more consistent incorporation of treatment fidelity strategies into behavioral intervention research across five areas: 1) study design, 2) provider training, 3) treatment delivery, 4) treatment receipt, and 5) enactment of treatment skills. (Bellg, et al., 2004) We recommend that investigators describe fidelity strategies specific to two areas, provider training and treatment delivery, when reporting interventions. Common fidelity strategies for treatment delivery are fully described in several publications, but these generally include the use of standardized training for interventionists, manualized protocols, and methods to monitor intervention delivery (Radziewicz, et al., 2009; Resnick, et al., 2005; Robb, Burns, Docherty, & Haase, In Review). Fidelity strategies for intervention delivery are used to: 1) control for interventionist differences, 2) reduce differences within treatment, 3) ensure adherence to

treatment protocols, and 4) minimize contamination between study conditions. These strategies are important because they help ensure that study conditions were delivered as intended; the omission of strategies from intervention reporting impedes evaluation about how investigators addressed potential threats to intervention reliability and validity (Bellg, et al., 2004; Borrelli, et al., 2005).

Item 4F: Setting. Describe where the intervention was delivered; include location, privacy level, and ambient sound.

An apparent and defining quality of music-based interventions is the use of auditory stimuli to achieve desired changes in physiological and psychological function, yet few investigators report detailed information about the setting where music-based interventions are delivered (Robb & Carpenter, 2009). Understanding the sound environment, or setting, where music-based interventions are introduced is very important when interpreting and/or comparing study outcomes. Factors related to setting that may influence outcomes include the location where the intervention was delivered (e.g., a patient's room vs. post-operative recovery room), as well as the privacy level and amount of ambient sound in that location. For example, high levels of environmental noise or diminished speech privacy can increase distress and impede communication (Christensen, 2007; Joseph, 2007; Thomas & Martin, 2000). For example, differences in outcomes may occur with a music imagery intervention targeting pre-operative anxiety when it is delivered in a patient's private room, where there is little to no ambient sound, compared to the same intervention delivered in a pre-operative area with several beds separated only by curtains and moderate ambient sounds coming from televisions, family/staff conversations, and monitoring equipment. Disparate or even similar outcomes between these studies would raise interesting questions about the degree to which setting factors are relevant to study outcomes. Similarly, information about the setting would inform translation of the intervention to clinical practice.

Item 4G: Unit of Delivery. Specify whether interventions were delivered to individuals or groups of individuals, including the size of the group.

Interventions can be delivered to individuals or groups of people. Although a majority of intervention reports specify the unit of delivery, this information is not always explicitly stated and in some instances it has been overlooked. (Robb & Carpenter, 2009) Reasons for reporting unit of delivery include the possibility that social and cost-related benefits may occur when interventions are delivered to groups of people (Boyle, McCartney, Forbes, & O'Hare; Craigie, Nathan, Craigie, & Nathan, 2009; de Groot, et al., 2007; Dickson, et al., 2009; Osborn, et al., 2006; Valentine, 2001). Group interventions may have added value in terms of peer support, motivation through group accountability, and social interactions that may have effects above and beyond the intervention itself. Group interventions may also be less costly to implement if they prove to be efficacious. In order to determine the relevance of these and other factors, it is important that authors specify whether interventions were delivered to individuals or groups of individuals. When groups are the unit of delivery, authors should specify the number of individuals participating in each group.

CLOSING REMARKS

Clear, detailed intervention descriptions within research publications are essential to improve replication and translation of music-based interventions to clinical practice. Although previous reporting guidelines provide investigators with checklists for behavioral trials, music interventions have additional components that need to be reported to enhance transparency. We have identified and described major components of music-based interventions that we believe should be included in research reports. The main purpose of these guidelines and the corresponding checklist is to increase transparency. We do not suggest a particular order in which information should be reported; rather, our emphasis is

on the inclusion of information essential to understanding and interpreting study outcomes. Though we have attempted to be complete in the identification and description of music-based intervention content, it is impossible to capture all of the essential content investigators should report – ultimately this responsibility lies with the investigator and should be guided by the study's theoretical framework.

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Table 1

Consort and Trend Guidelines for Intervention Reporting

CONSORT Item	[Description of] The interventions for each group with sufficient details to allow replication, including how and when they were actually administered.
TREND Item	Details of the interventions intended for each study condition and how and when they were actually administered, specifically including: content, delivery method, unit of delivery, deliverer, setting, exposure quantity and duration, time span, and activities to increase compliance or adherence.

Table 2**Checklist for Reporting Music-based Interventions**

Music-based Intervention Reporting Criteria	Page:
<u>A: Intervention Theory</u>	
Provide a rationale for the music selected; specify how qualities and delivery of the music are expected to impact targeted outcomes.	
<u>B: Intervention Content</u>	
Provide precise details of the music intervention and, when applicable, descriptions of procedures for tailoring interventions to individual participants.	
<u>B.1: Person Selecting the Music</u>	
Specify who selected the music: (1) pre-selected by investigator, (2) participant selected from limited set, (3) participant selected from own collection, or (4) tailored based on patient assessment.	
<u>B.2: Music</u>	
When using published music, provide reference for sheet music or sound recording.	
When using improvised or original music, describe the music's overall structure (i.e., form, elements, instruments, etc).	
<u>B.3: Music Delivery Method (Live or Recorded)</u>	
When using live music, specify who delivered the music and the size of the performance group (e.g., interventionist only, interventionist and participant).	
When using recorded music, specify placement of playback equipment and the use of headphones vs. speakers. Specify who determined/controlled volume (e.g., interventionist; participant. Specify decibel level of music delivered and/or use of volume controls to limit decibels.	
<u>B.4: Intervention Materials</u>	
Specify music and/or non-music materials.	
<u>B.5: Intervention Strategies</u>	
Describe music-based intervention strategies under investigation (examples: music listening, songwriting, improvisation, lyric analysis, rhythmic auditory stimulation, etc).	
<u>C: Intervention Delivery Schedule</u>	
Report number of sessions, session duration, and session frequency including practice sessions.	
<u>D: Interventionist</u>	
Specify interventionist qualifications and credentials.	
Specify how many interventionists deliver study conditions.	
<u>E: Treatment Fidelity</u>	
Describe strategies used to ensure that treatment and/or control conditions were delivered as intended (e.g., interventionist training, manualized protocols, and intervention monitoring).	
<u>F: Setting</u>	
Describe where the intervention was delivered; include location, privacy level, and ambient sound.	
<u>G: Unit of Delivery</u>	
Specify whether interventions were delivered to individuals or groups of individuals, including the size of the group.	

Note: This checklist may be reprinted and used without permission as a tool to help ensure transparent reporting of music-based interventions. Robb, S. L., Carpenter, J. S., Burns, D. S. (2010). Reporting guidelines for music-based interventions. *Journal of Health Psychology*, 16(2), 342-352 DOI: 10.1177/1359105310374781.