Challenges related to conducting clinical studies in community healthcare settings

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Conducting clinical studies, especially ones that include a control group, in a community healthcare setting does not come without challenges. This reflection paper outlines some of the issues that we needed to consider while conducting a pilot study entitled *Creative Music Engagement to Improve Core Outcomes in Chronic Pain*. This study is part of the Arts Research on Chronic Stress (ARCS) NEA Research Lab, which is a project of the National Endowment for the Arts in cooperation with Drexel University. The study takes place at Drexel University's Stephen and Sandra Sheller 11th Street Family Health Services (11th Street). This health clinic is located in the 11th Street Corridor, a neighborhood of 20,000 low-income residents (90% African-American) in North Philadelphia, Pennsylvania. The purpose of the study is to examine the impact of a 12-week music therapy program followed by community music engagement on core outcomes in chronic pain management. A unique aspect of this study is the partnership with a community music organization, the Settlement Music School, to help patients transition from the group music therapy treatment program to engagement in community music groups (e.g., African drumming classes; choral programs; drum circles). This will enable us to begin to look at the feasibility and long-term health benefits of prolonged community-based music engagement in people with chronic pain.

Some of the challenges I want to outline here relate to the study design including selection of the control condition and duration of the intervention, recruitment for group interventions, study burden, and transition to community arts services.

An important consideration when designing a behavioral intervention study is the length of the treatment program. Our current study is based on a prior NIH-funded study (R03NR013551) that examined the impact of an 8-week music therapy treatment program on core outcomes in chronic pain management (Bradt, Norris, Shim, Gracely, & Gerrity, 2016). Focus groups with study participants at the end of that study resulted in the recommendation that the duration of the music therapy program be increased from 8 weeks to 12 weeks. In addition, the focus groups indicated that participants desired continued engagement in community music making. These two findings were the impetus for the current study.

Increasing the length of a treatment program in a clinical trial does not come without risks however. First, it can be difficult to get people to commit to a 12-week study, especially people with chronic health conditions such as chronic pain. Meeting recruitment targets is one of the greatest challenges in intervention trials even those that have significant funding. Second, the longer the treatment length, the greater the risk of attrition (i.e. participants dropping out of the study) which, in turn, can be detrimental to planned statistical analyses. Third, longer treatment programs are at greater risks for interruptions due to holidays, weather, etc. Finally, when seeking external funding for the clinical trials, reviewers of funding proposals may question the

duration of the intervention given that short-term interventions are more desirable and feasible in the current healthcare climate. At the same time, if a longer intervention duration leads to significantly greater improvements in targeted treatment outcomes, it is important that sufficiently long treatment programs be tested in clinical studies. All too often, behavioral intervention trials examine the impact of short-term interventions (even as short as 1 or 2 sessions) because of funding budget limits or out of fear that longer treatment durations will negatively affect the grant review and funding decision. Thus identifying a treatment length that appropriately balances the risks with potential treatment benefits is an important consideration when designing behavioral intervention studies.

A second challenge is the selection of a control condition. Typically, behavioral intervention studies progress from preliminary investigations without a control treatment arm to randomized controlled trials with an active control condition. In music therapy research, active control conditions are often low dose conditions (e.g. listening to prerecorded music) or comparative treatment conditions. In initial studies with a control condition, a no-treatment control or treatment-as-usual are often employed.

However, these may lead to high attrition as participants randomized to such control conditions may be disappointed to not receive the music therapy intervention and may therefore drop out of the study. Another option is to use comparative treatment or low dose treatment condition. For example, control group participants may be assigned to a verbal support group. However, when conducting studies in a small community clinic this may prove to be quite problematic; it is highly likely that participants assigned to different treatment arms may know each other, mention their experiences to others in the clinic's waiting room, or talk about the music therapy group while attending other treatments at the clinic. When control participants hear about the music therapy groups, they may feel resentful for not being able to join that group.

To address these issues, we opted to use a wait-list control group. Participants randomized to the waitlist control continue to receive regular treatment at 11th Street for the first 12 weeks. During this time, participants randomized to the music therapy treatment arm receive weekly music therapy sessions. Measurements are obtained from both treatment arms during this 12-week period. Once participants in the control study arm have completed the 12-week waiting period, they receive the 12-week music therapy treatment. Having participants wait for 12 weeks before they receive the intervention may still lead to some attrition but attrition in waitlist control group studies is typically less than in a no-treatment control or treatment-as-usual control scenario.

Another issue to consider is the "contamination" of the treatment groups in single-site studies, especially if the study site is a small community clinic. Contamination of treatment groups refers to the issue of participants in the control group learning about some treatment aspects or techniques of the intervention group and beginning to adopt those to improve their health. Even though participants are asked not to talk to other patients at the clinic about their experiences in the music therapy group, it is difficult to ensure that participants adhere to this request.

I would like to share one extreme example that happened in our prior study to illustrate this. Two patients independently signed up for the study and were randomized to a different treatment arm: the female patient was assigned to the music therapy treatment arm whereas the male patient was assigned to the wait-list control condition. It was only when the male patient exclaimed in the first music therapy group (after completion of the waitlist period) that his partner had taught him all about using music for his pain, that we discovered that these two patients were a couple. Unfortunately, because of this we were not able to use the male

patient's data in the study analysis. In the current study, we repeatedly remind participants not to talk about the music therapy group to other patients in the clinic.

A fourth challenge is the use of group interventions in controlled studies. When the study design is a randomized controlled trial, this can pose several issues. First, a sufficient number of participants need to be recruited before the intervention portion of the study can start given that half will be randomized to the treatment study arm and half to the waitlist control study arm. For example, for the current study, we aim to have approximately 8 people per group. Therefore, for each recruitment wave, we need to recruit 16 people before we can complete baseline measures and randomize people. Second, participants randomized to the treatment study arm need to be available at the same time during the week to attend the music therapy session. This can be facilitated by determining a treatment timeslot at the onset of recruitment. Only patients who can make themselves available for that timeslot for 12 weeks are consented and enrolled. This, of course, limits the recruitment pool of eligible participants. One could also opt to recruit without a predetermined timeslot and then hope to find a timeslot that will work for all group participants once they have been randomized. Our prior studies have shown, however, that this causes many logistical problems.

Even with predetermining a set timeslot for the treatment sessions, challenges remain when using a waitlist control group. For example, in our study, control participants need to wait 12 weeks before they can start the music therapy treatment. A lot can happen with people's schedules in 12 weeks and it is likely that the session timeslot that worked for participants at the time of recruitment no longer works after a 12-week waiting period. There is no easy solution for these scheduling issues. In our previous study, we solved this by splitting the waitlist control group participants in two smaller groups with different session times when needed.

A fifth important consideration is making sure that the study requirements place as little a burden as possible on the clinic's healthcare providers and staff. For our studies, we make sure that we bring in staff (either hired specifically for the study or student research assistants) to assist with study enrollment including recruitment, screening, and consenting. It is of crucial importance to the success of a study that a dedicated person is responsible for recruitment. Relying on passive recruitment methods such as posting study flyers on bulletin board, leaving study flyers in waiting rooms, and waiting for referrals is often not very successful. Instead, a dedicated recruitment person who can actively connect with healthcare providers at a regular basis (weekly or even daily) regarding eligible patients for the study is highly recommended. Such person can also review new patient lists (if approval for this has been obtained) to identify eligible patients and be available to immediately follow up with patients who express interest in the study. It is also important to have research assistants available to help with scheduling and placing reminder calls and completing the outcome assessments and data entry.

Finally, I want to address the challenge of helping participants transition into community arts organizations. For the current study, besides measuring the impact of the 12-week music therapy program, we are examining the feasibility of having participants transition from the 12-week music therapy treatment program at 11th Street to music classes that are offered in the Philadelphia community by the Settlement Music School. Participants will be offered one series of group music classes free of charge. Staff from the Settlement Music School will attend the previous to last music therapy session to introduce participants to available classes, help with enrollment and answer any questions participants may have.

In spite of the transition support we offered study participants, we anticipate several challenges. First, even though the Settlement Music School has branches at different locations, traveling to

a given branch may be difficult for some participants because of their chronic pain or because it may be tough for them to reach a given branch using public transportation. To address this, we have created a resource document that lists other community-based music making opportunities spread throughout their community such as local choirs, drum circles, and so on.

We also anticipate that some participants may be interested in taking individual music lessons instead of group classes. Unfortunately, our budget does not allow, at this time, for individual lessons. Moreover, many participants served at 11th Street may not have the means to purchase or rent a music instrument. At the end of the study, participants will be interviewed about their experiences of the 12-week program as well as successes and barriers related to their participation in community-based music programming. We hope that these interviews will help refine the treatment intervention as well as the transition into community arts programs. This information will be of crucial importance for optimization of the treatment program at 11th Street and our partnerships with community-based arts organizations.

References

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