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Relaxation Response with Acupuncture Trial in Patients with HIV: Feasibility and Participant Experiences

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Abstract

Objectives—The study of complementary and alternative medicine (CAM) using a randomized, controlled trial (RCT) design poses challenges, such as treatment standardization and blinding. We designed an RCT, which avoided these two common challenges, to evaluate the effect of adding the relaxation response (RR) to usual acupuncture treatment. In this paper, we report on the feasibility and patients' experience from the study participation.

Design, setting, and subjects—Our study was a two-arm, double-blind RCT conducted in an acupuncture clinic in Boston. Study subjects were patients with human immunodeficiency virus/immunodeficiency syndrome (HIV/AIDS), who reported having at least one of the highly prevalent HIV-related symptoms, and were receiving acupuncture treatment.

Intervention—The intervention group wore earphones to listen to tapes with instructions to elicit the RR and also soft music while receiving acupuncture treatment, while the control group only listened to soft music. The intervention group was also required to listen to the RR tapes at home daily.

Outcome measures—A study evaluation was completed upon termination of the 12-week study (36 intervention and 44 control patients).

Results—A majority of participants in both groups reported: no discomfort wearing earphones (82.9%, 81.8%); the study met their expectations (87.1%, 85.4%); and they would recommend the study to others (91.1%, 90.5%). Intervention participants reported better experiences with the tapes than the control group ($p = 0.056$) (72.4% versus 52.8% felt better with tapes; 3.5% versus 16.7% felt better without tapes; and 24.1% versus 30.6% felt no difference). Intervention participants were also more likely than the control group ($p = 0.02$) to report positive emotional/physical/spiritual changes (45.5% vs. 20.9%) and relaxed/peaceful/calm feelings (30.3% vs. 25.6%) from the study participation.

Conclusions—We demonstrated the feasibility of conducting a unique trial that examined the synergistic effects of two types of CAM practices. The intervention group reported more positive study-related experiences than the control group.

INTRODUCTION

Complementary and alternative medicine (CAM) use is widespread among people living with HIV infection.^{1,2} In light of the high prevalence of CAM use, the study of the effectiveness of these practices has become an important area of research and of great interest among researchers.³ The study of the effectiveness of CAM practices poses unique challenges for reasons such that the standardization of acupuncture treatment and the blinding of behavioral interventions can be difficult to achieve.⁴ Nevertheless, randomized, controlled trials are still considered the gold standard for evaluating the effectiveness of CAM practices.⁵

We designed a double-blind randomized trial to evaluate the effect of adding the relaxation response (RR) to usual acupuncture treatment. The rationale and scientific bases for combining these two CAM practices were described elsewhere.⁶ Since our interest is in evaluating the enhanced effects of the RR combined with acupuncture treatment, above and beyond the response to usual acupuncture treatment, the study did not interfere with individualized acupuncture protocols. The RR intervention was administered through listening to tapes using earphones while receiving acupuncture treatment. Our study design avoided the common challenges encountered by acupuncture and behavioral intervention researchers; namely, our study offered individualized acupuncture treatment as well as a behavioral intervention that was blinded to participants and to acupuncture staff. In this paper, we report on the feasibility of conducting a trial with such a design. We also describe the experiences reported by the study participants of the trial.

METHODS

Trial protocol

The protocol of this double-blind randomized trial was described in detail elsewhere.⁶ Briefly, the study subjects were patients with human immunodeficiency virus/autoimmunodeficiency syndrome (HIV/AIDS) who reported having at least one of the prevalent HIV-related symptoms and were receiving acupuncture treatment at the Pathways to Wellness/AIDS Care Project in Boston.

Enrolled patients were randomized into one of two study groups. Patients in the intervention group wore earphones to listen to tapes with instructions to elicit RR, followed by soft music that was similar to what is routinely played in the clinic while they received their weekly acupuncture treatment. As the usual acupuncture practice, the acupuncturist maintained communication with the participant while inserting needles, in order to ensure that placement was comfortable and well-tolerated. After ensuring that the participant was comfortably situated, a listening to the tapes would begin. The intervention group was also requested to listen to the RR tapes at home twice a day. Patients in the control group received acupuncture in the usual way while listening to tapes with soft music using earphones. The control group was not required to listen to tapes at home. The institutional review boards at the Boston University Medical (Boston, MA) campus and the Veterans Administration at Bedford and Boston approved this study.

Study intervention

Patients in the intervention group listened to tapes that contained instructions for the following RR techniques: (1) diaphragmatic breathing; (2) mental repetition of a word, sound, phrase, or prayer; (3) autogenics (self-hypnosis); (4) guided body scan/progressive muscle relaxation; (5) self-healing visualization; and (6) guided imagery. These six techniques are commonly used for eliciting the RR and have been used in our previous study on patients with chronic heart

failure.⁷ Patients in the control group listened only to tapes with soft music, such as sounds of nature or classical music, that was routinely played in the clinic during treatment.

Study outcomes

All study participants were asked to fill out an evaluation form at the completion of 12 weeks of study participation. The evaluation form included both multiple-choice and open-ended questions that were self-administered by patients. The items in the evaluation form included (1) experiences while listening to the tapes in the clinic; (2) changes in symptoms, emotions, response to stress, etc., since the beginning of the study participation; (3) willingness to recommend the study to others with similar health conditions; and (4) suggestions for improvement of the study. The intervention-group participants were also asked about their experiences with listening to the tapes at home with questions, including (1) factors that helped or hindered their home practice and (2) their preference of tapes.

Analysis methods

The responses to the open-ended questions in the evaluation form were coded independently by two authors (BHC and UB). The discrepancies in coding were then resolved through discussion. A Pearson chi-square test was used to compare categorical data. For ordinal categorical variables, Mantel-Haenszel chi-square tests were used to test the linear association between two variables.

RESULTS

One hundred and nineteen (119) patients enrolled in the study and were randomly assigned to either the intervention group ($N = 58$) or the control group ($N = 61$). A total of 80 patients (36 intervention and 44 controls) completed the 12-week study and filled out the evaluation form. For the control group, the main reason for drop-out was lost contact (76%), and 1 patient dropped out of the study because of a perception that the acupuncture was not effective. In the intervention group, 55% (12 of 22) of the dropout was due to lost contact, 3 moved away, 2 had no time to listen to the tapes, 2 could not make the acupuncture treatment schedule, and 2 lost interest in the study.

Dropout was not associated with the patient characteristics of age, gender, race, HIV status, and baseline CD4 count ($p > 0.05$). However, in comparison to those who completed the study, patients who left before completing the study were less likely to have college or higher education ($p < 0.0001$), and had lower income ($p = 0.05$) (Table 1). Despite these disproportionate dropout rates in terms of education and income levels, the two study groups were similar on these and other patient characteristics (Table 2).

Experience with acupuncture treatment

More than 80% of participants in both study groups reported that they did not experience any discomfort from wearing earphones while receiving acupuncture treatment. Among the respondents who reported discomfort, they mostly reported that the earphones did not fit well and fell out. Only 1 patient complained that it was uncomfortable to have the earphones on when there were needles in the ear. Since a majority (82%) of the participants had prior acupuncture experience, we were able to ask these patients to compare their experience of acupuncture treatment in the study, which required listening to tapes with earphones during the treatment, with prior acupuncture experience, which did not include listening to tapes with earphones. Intervention-group participants reported better experiences with the tape than the control group ($p = 0.056$) (72% vs. 53% felt better with tapes; 3% vs. 17% felt better without tapes; and 24% vs. 31% felt no difference).

Experience with home practice

Half of the 36 participants in the intervention group reported no difficulty listening to the tapes at home. Results of the multiple-choice questions indicated that the most cited difficulty (31%) was “falling asleep while listening to the tapes,” followed by “getting tired of the tapes” (25%), “forgetting to listen to tapes” (19%), “could not find the time” (17%), and “had difficulties following the spoken instructions” (14%). Three (3) patients indicated that they did not like the content of the tapes and 1 indicated that listening to the tapes was not helpful. When asked with an open-ended question, “What helped you to continue listening to the tapes at home?”, approximately half (15 of 32) of the respondents stated that the benefits they received from listening to the tapes kept them continuing to listen. The reported benefits included help with sleep and even a decreased need for sleep medications, mood changes, and feeling relaxed and peaceful. One (1) participant responded, “The tapes were working for me. I have never experienced such a state of no tension and felt true relaxation.” Another participant responded, “I allowed myself to listen to the tapes at night. Usually in preparation for sleep and found that I fell to sleep much more easily than without listening to the tape (soothing, not boring).” Interestingly, while some participants reported “falling asleep while listening to the tapes” as a difficulty, some used the tapes to help them falling asleep. Some respondents reported that they listened to the tapes because “it was a study requirement” (4 participants), “they were able to set up a place or time to listen” ($N = 3$), “they listened whenever they felt like to do so” ($N = 3$), “the tapes helped with their stress” ($N = 1$), and “listening to the tapes is a way of spending time for oneself” ($N = 1$). Five (5) participants reported that they were not able to listen to the tapes at home.

Participants showed variation in the tapes they liked and disliked. Many participants (13 of 33) listed having multiple favorite tapes from the selection of the six types of RR-elicitation techniques. Diaphragmatic breathing was the most liked tape (33% of participants), followed by imagery/visualization (27%) and progressive muscle relaxation (24%). Self-healing visualization and autogenic (self-hypnosis) were the least cited (<10% each) as being favorite tapes. Three (3) participants listed soft music as their favorite tape. Only 11 participants clearly listed the tapes they disliked the most. Among these 11 responses, progressive muscle relaxation was most frequently listed as a disliked tape (7 participants), although approximately the same number of participants reported that it was their favorite tape. Six (6) participants listed imagery/visualization as their disliked tapes. Six (6) participants indicated there was no tape that they disliked.

Changes attributed to study participation

There were significantly more participants in the intervention group than in the control group who reported having any changes from study participation (76% vs. 47%; $p = 0.01$). The reported changes were coded into the following categories: “good change emotionally,” “physical improvement,” “more spiritual,” and “feel peaceful/relaxed/calm.” The intervention group was more likely to report emotional, physical, and spiritual improvement (46% vs. 21%), as well as changes related to feeling peaceful, relaxed, and calm (30% vs. 26%), than the control group ($p = 0.02$). One (1) participant in the intervention group reported “Increased patience with busy life. Helped physically: more regular digestive elimination, decreased blood pressure, and my T cells were 480 with a measurable viral load when I started. Last week, T cells were 828, viral load undetectable. Probably not coincidence.” Another intervention-group participant reported “I am more relaxed, less likely to lose my temper. I have more patience and when I start to feel stressed, I think about the tapes.” Positive changes were also reported by the participants in the control group, although not as many and as strongly as those reported by the intervention group. Some of the reported changes were: “It just gave me a calmer feeling. I think the music is good” and “The questionnaire brought some things to my attention which

I wish to examine about myself and allowed me to assert a different approach to dealing with some problems I found.”

Overall comments about the study

Twenty-nine (29) of the 36 intervention-group participants wrote comments in the open-ended question. Half (15 of 29) of the responses included positive comments related to benefits from the study, praise for the study, and expressing gratitude to the study. One (1) patient commented “I can’t say enough of how honored I feel to have been part of this study and how it worked for me. I will continue from the memory of what I have learned.” Another wrote “It has really opened me to meditation and to next try yoga. Being in recovery, I really have brought a lot of this into my life.” Some participants particularly mentioned their intention to continue using the tapes after study. One (1) patient wrote “I will make attempts to use the home tapes in the future. I do feel that they were a great benefit during acupuncture. Thank you for the opportunity.” Negative comments were also reported by 3 patients and were all related to tapes. One (1) wrote “Combining the moxa treatments with the relaxation treatment was difficult for me. They worked best when I was resting with the needles.” Another patient wrote “Found the ‘pause’ in verbal instructions annoying. Often after the instruction, I would become peaceful only to become ‘alerted’ when it continued.” Four (4) patients made suggestions about improving the study intervention. One (1) patient wrote “I feel that listening to the tapes should have been shorter; add time gradually to find out how much time a person needs to relax and feel more peaceful. Everyone is different.” Five (5) patients provided no comments.

Thirty-two (32) of the 44 participants in the control group had written comments. Ten (10) of the 32 comments were positive comments which were usually brief. Four of the 10 positive comments simply stated “thank you.” The other five positive comments related to enjoying listening to the music tapes and comments on the staff and recruiter. One (1) patient wrote “All the staff are great, the facility is comfortable, and it’s always a pleasant experience.” Three (3) patients expressed the desire to keep the tapes after the study. One (1) wrote “I think individual tapes should be available to all clients who prefer to use them. I would use them every time.” Eight (8) patients had negative comments mostly related to the music tapes and the acupuncture with listening to tapes using earphones. One (1) patient wrote “I enjoy the acupuncture treatment with soft music in the background without earphones, or silence.” Another wrote “I like listening to music during acupuncture but I like to choose the type of music. Some of the music wasn’t relaxing enough and made me energized instead of relaxed.” Seven (7) wrote “No comment” or “None.”

DISCUSSION

We have demonstrated the feasibility of applying the gold standard for research “a randomized, controlled trial” to investigate CAM practices without compromising their integrity. In our trial, which added a self-care intervention (RR) to usual acupuncture practice, we showed that blinding to the RR intervention can be done by wearing earphones while receiving acupuncture. Most of the participants indicated no discomfort wearing earphones during the acupuncture treatment. Feasibility of the trial was further supported by the positive feedback from study participants, who reported that the study met their expectations and that they would recommend the study to others. The feasibility of studying the RR and acupuncture alone on various patient populations, including HIV patients, has been reported in the literature.^{8–14} Our study is the first to show the feasibility of combining these two CAM interventions with a study design that can successfully blind the study subjects to the intervention.

Although we observed disproportionate dropout rates in terms of education and income levels, the two study groups were similar in terms of these two characteristics, as well as other patient characteristics, such as age, gender, and race, and HIV status and CD4 count. Other studies

also reported similar dropout patterns that higher education predicted with the completion of a behavioral medicine intervention, which included the RR practice.¹⁵ These findings highlight the need to pay special attention to lower educated and lower income patients to ensure that they can benefit from these types of interventions.

Data collected from study evaluation forms indicated that the intervention group reported more positive experiences than the control group and were more likely to report positive emotional/physical/spiritual changes and relaxed/peaceful/calm feelings from study participation, giving positive overall comments about the study. These positive effects from the RR intervention mirror the results we reported in another paper, in which we used standardized quality-of-life scales as the study outcomes to measure treatment effect.⁶

Our study suggests a feasible, sound approach to designing control group in CAM clinical trials. Rather than assigning the control group to no intervention (such as a wait-list), which does not control for possible placebo effect, we were able to conduct a study that accommodated a control and intervention group simultaneously. The positive experiences and feedback of the majority of study participants regardless of group assignment indicates that this approach was well received.

Some of our findings may be useful in designing home-based RR interventions. First, we found variation in the preference of the techniques used to elicit the RR. Although one technique can be a favorite of some study participants, it can be disliked by other participants. This finding highlights the importance of providing a variety of techniques for eliciting the RR in research and clinical settings. Second, difficulties with home practice were reported. It is, therefore, important to address these issues. For example, the difficulty of falling asleep while listening to the tapes can be addressed by changing the practice time to the first activity of the morning or by advising patients to keep their eyes open while listening to the tapes.

Important clinical implications of our study findings are that participants reported an interest in self-care. Study participants expressed an interest in getting access to the tapes and in having the ability to choose their tapes. Further, RR, a low-cost self-care practice, can be easily integrated into usual acupuncture practice, as demonstrated in this trial.

CONCLUSIONS

We conclude that it is feasible to conduct a blinded trial that integrates a self-care component (RR) with a CAM practice (acupuncture) to evaluate the added, combined effects of both. The blinding of tape contents can be done by having participants wear earphones. More positive changes and comments were reported by the participants who received the RR intervention. The lessons we learned from this pilot trial can be useful in planning future randomized, clinical trials using CAM modalities.

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Table 1**Patient Characteristics by Study Completion Status**

Variable	Completed study (n = 80)	Dropped out (n = 39)
	Mean (SD)/N(%)	Mean (SD)/N(%)
Demographic characteristics		
Age (year)	45.3 (7.7)	45.9 (7.2)
Gender		
Male (%)	69 (86%)	32 (82%)
Race		
White/Caucasian	53 (66%)	22 (56%)
African American	16 (20%)	9 (23%)
Hispanic/Latino	8 (10%)	3 (8%)
Other	3 (4%)	5 (13%)
Education *		
College and above	66 (83%)	18 (46%)
Income **		
Less than \$10,000	28 (37%)	21 (60%)
\$10,000–\$19,999	30 (40%)	11 (31%)
\$20,000 or more	17 (23%)	3 (9%)
HIV status		
HIV+ (not AIDS)	49 (61%)	17 (43%)
HIV+ (AIDS status unknown)	5 (6%)	3 (8%)
AIDS	26 (33%)	19 (49%)
Last CD4 count		
LOG (last CD4 count)	6.1 (0.6)	5.9 (0.7)

* $p < 0.0001$;

** $p \leq 0.05$ comparing patients who completed the study with patients who dropped out.

SD, standard deviation; HIV, human immunodeficiency virus; AIDS, autoimmune deficiency syndrome.

Table 2

Patient Characteristics by Study Group

Variable	Intervention group (n = 36)	Control group (n = 44)
	Mean (SD)/N(%)	Mean (SD)/N(%)
Demographic characteristics		
Age (year)	45.4 (7.2)	45.2 (8.2)
Gender		
Male (%)	31 (86%)	38 (86%)
Race		
White/Caucasian	26 (72%)	27 (61%)
African American	6 (17%)	10 (23%)
Hispanic/Latino	4 (11%)	4 (9%)
Other	0 (0%)	3 (7%)
Education		
College and above	30 (83%)	36 (82%)
Income		
Less than \$10,000	13 (39%)	15 (36%)
\$10,000–\$19,999	15 (45%)	15 (36%)
\$20,000 or more	5 (15%)	12 (29%)
HIV status		
HIV+ (not AIDS)	20 (56%)	29 (66%)
HIV+ (AIDS status unknown)	2 (6%)	3 (7%)
AIDS	14 (39%)	12 (27%)
Last CD4 count		
LOG (last CD4 count)	6.1 (0.7)	6.0 (0.7)

SD, standard deviation; HIV, human immunodeficiency virus; AIDS, autoimmunodeficiency syndrome.