

## The Combined Effect of Relaxation Response and Acupuncture on Quality of Life in Patients with HIV: A Pilot Study

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### ABSTRACT

**Objectives:** Treatment advances have transformed human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) into a chronic manageable disease; quality of life (QoL) has become an important health outcome. Some studies have shown the individual effects of acupuncture and the relaxation response (RR) in improving QoL of patients with HIV/AIDS. In light of the presumed shared features of acupuncture and the RR, we conducted a pilot study to examine the effects of adding the RR to usual acupuncture treatment on improving the QoL of HIV/AIDS patients.

**Design:** Two-arm double-blind randomized controlled trial.

**Settings/location and subjects:** We enrolled 119 patients with HIV/AIDS (mean age 46 years, 85% male) who had at least 1 of the highly prevalent HIV-related symptoms and who were receiving acupuncture treatment in an acupuncture clinic in Boston, MA.

**Intervention:** We randomized patients into intervention (N = 58) and control (N = 61) groups. All participants received individualized acupuncture treatments prescribed by their acupuncturists. While receiving acupuncture treatment, the intervention group wore earphones to listen to tapes with instructions to elicit the RR followed by soft music that was routinely played in the clinic; the control group listened only to soft music.

**Outcome measures:** Three (3) QoL scales: the Medical Outcomes Study HIV health survey, the Functional Assessment of HIV Infection, and the Functional Assessment of Chronic Illness Therapy–Spiritual Well-Being, measured at baseline, 4-week, 8-week, and 12-week follow-ups.

**Results:** At the 12-week follow-up, the intervention group showed significant improvements in emotional ( $p = 0.0002$ ), spiritual/peace ( $p = 0.02$ ), physical ( $p = 0.003$ ) and mental health ( $p = 0.0003$ ) QoL from baseline. Results of mixed effects regression models indicated linear trends of improvement over time in these dimensions of QoL for the intervention group ( $p < 0.02$ ). In the control group, the only significant improvement was observed in the emotional QoL ( $p < 0.01$ ). The intervention group showed trends of greater improvements than the control group ( $p = 0.07$  for 12-week physical health QoL).

**Conclusions:** Data from this pilot trial suggested that adding the RR to acupuncture may enhance improvement in QoL of patients with HIV/AIDS. Further investigation on this putative synergistic effect is warranted.

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## INTRODUCTION

While remaining a serious illness associated with potentially significant morbidity, human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) has become a chronic manageable infection.<sup>1,2</sup> As in other chronic illnesses, quality of life (QoL) is recognized as an important health outcome in people living with HIV/AIDS.<sup>3,4</sup> Patients living with HIV/AIDS experience a wide range of symptoms associated with clinical manifestations of the disease, related opportunistic conditions, and side-effects from medications. Studies indicate that these symptoms are strongly associated with QoL. Many patients use complementary and alternative medicine (CAM) to help alleviate HIV-related symptoms and to improve their QoL<sup>5,6</sup>; acupuncture and the relaxation response (RR) are commonly used treatments.<sup>7-10</sup>

The RR is a state in which individuals evoke a bodily calm that has the opposite effect of the fight-or-flight response, with concomitant favorable physiologic changes<sup>11</sup> that are shown to be associated with improved immune functioning.<sup>12-14</sup> Numerous mind-body approaches can elicit the RR including meditation, repetitive prayer, autogenic training, deep breathing exercises, progressive muscle relaxation, biofeedback, and guided imagery.<sup>15,16</sup> Acupuncture and the RR are thought to share common features in that both induce calm and deep relaxation in mind and body.<sup>17</sup> The shared features of these 2 therapies can complement each other because acupuncture facilitates the effect of RR, while on the other hand, the RR prepares the body to be more responsive to acupuncture. Although the ways in which acupuncture and RR exert their effects are not well understood and remain areas of scientific inquiry, studies have found similar physiologic and neurologic responses produced by these two therapies.<sup>18</sup> For example, studies show that acupuncture accelerates the release of endogenous opioid peptides (e.g., endorphin, enkephalin) in the central nervous system.<sup>19,20</sup> Similarly, the release of neurotransmitter opioids and nitric oxide has also been hypothesized and demonstrated in studies explaining the health effects of the RR.<sup>15,21</sup>

Clinical effects of each of these two therapies alone have been widely studied. The effects of acupuncture on alleviating symptoms and improving QoL are supported in some studies<sup>22-25</sup>; however, negative results have also been reported in the literature.<sup>26,27</sup> Studies that included RR as part of the study intervention reported beneficial effects of the intervention on enhancing immune function, reducing psychologic distress, and improving QoL among patients with HIV/AIDS.<sup>28-30</sup> Given the shared and complementary features of the RR to acupuncture, we posit that adding RR to acupuncture is likely to have enhanced beneficial effects in patients with HIV/AIDS. We conducted a pilot study to collect preliminary data for examining the effects of adding the RR to usual acupuncture treatment on improving the QoL

of patients with HIV/AIDS. Since the RR is a method of low-cost self-care that can be easily integrated into usual acupuncture practice, the findings from this study can potentially provide valuable information in acupuncture practice.

## METHODS

### *Study design*

This pilot study is a 2-arm, double-blind, randomized trial. Patients were told that the purpose of the study was to investigate the effect of relaxation combined with acupuncture treatments on managing HIV/AIDS symptoms and improving QoL. The study intervention involved listening to audiotapes while receiving acupuncture treatment. Two types of tapes were used during the acupuncture treatment; one contained instructions to elicit the RR followed by soft music and the other contained soft music only. The study intervention was administered weekly for 12 weeks. For the purpose of blinding, the content of the tapes was revealed neither to the patients nor to the acupuncturists, with patients listening to tapes by wearing earphones. In addition, acupuncturists and patients were instructed not to discuss the content of the tapes. The institutional review boards at the Boston University Medical Campus and the Veterans Hospitals at Bedford and Boston, Massachusetts approved this study. Patients signed an informed consent form before the study enrollment.

### *Study population/patient eligibility*

The study subjects were mainly recruited from the clients in the clinic site of the study, the acupuncture clinic at Pathways to Wellness/AIDS Care Project (ACP) in Boston, Massachusetts. Recruitment methods also included posting flyers in various AIDS clinics and organizations in the Boston area. Inclusion criteria for HIV/AIDS patients stipulated that potential study participants report having at least one of the following highly prevalent HIV-related symptoms: sinus problem, headache, dental pain/sore or bleeding gums, nausea, diarrhea, vomiting, muscle aches, joint pain, neuropathy, weakness, depression, anxiety, or insomnia. Patients were ineligible if they reported acute opportunistic infection, current practice of RR, current enrollment in another intervention study, or if they demonstrated cognitive impairment (Mini Mental Status Examination <24 points), or lack of English proficiency.

### *Patient recruitment and randomization*

Between July 2003 and September 2004, 160 HIV-positive patients were approached for study participation; 15 of these individuals refused to participate while 145 agreed to be screened. Among the 145 patients, 16 were found to be

ineligible mainly due to current practice of some kind of relaxation technique (70%); 10 eligible patients did not complete the baseline assessments (Fig. 1). One hundred and nineteen (119) patients completed the baseline measures and were randomly assigned to either the intervention group (N = 58) or the control group (N = 61) based on a block randomization with a block size of 4, stratified by gender.

The random numbers were generated in advance by the project statistician using a computer program, and were placed in sealed envelopes. The study research assistant opened 1 envelope to assign a patient to a study group once he/she finished the baseline questionnaire. We exceeded the original goal of recruiting 50 patients in each groups. The sample size was determined by the practical considerations of

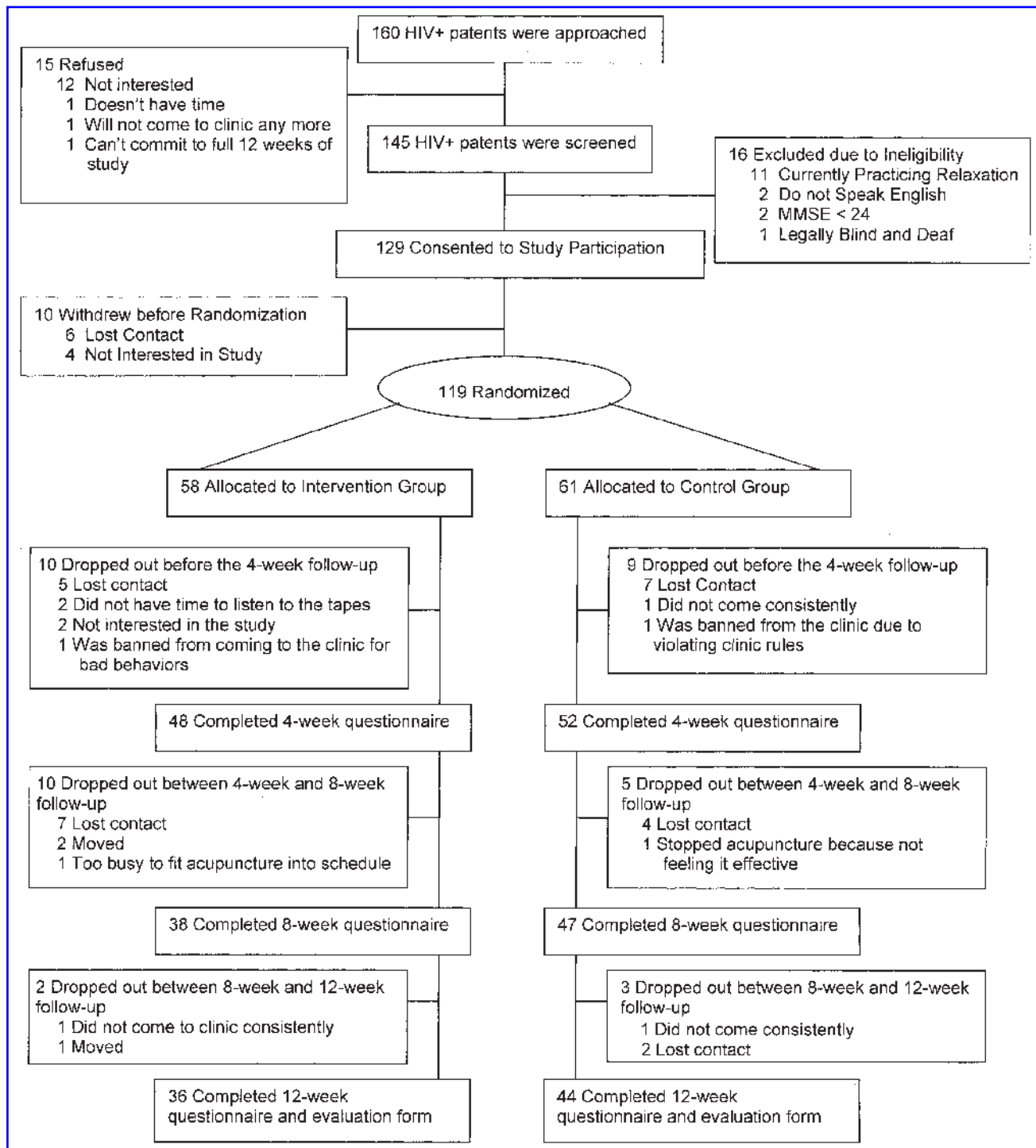


FIG. 1. Recruitment and Intervention flow chart. MMSE, Mini Mental Status Examination.

the time and budget limitations of the grant we received for conducting this exploratory study.

### *Acupuncture treatment*

Since the purpose of the study was to examine the effect of adding the RR to usual acupuncture treatment, the study did not interfere with the usual acupuncture practices at the study clinic ACP. A primary focus of the acupuncture treatment for all clients at the ACP is to provide support for the immune system. Secondly, symptom management is addressed. All treatment was provided according to the clinical judgment of the acupuncturist; each treatment consisted of points determined to be optimal according to standard of care. This individualized treatment is practiced by most acupuncturists and is considered the norm for acupuncture treatment.<sup>31–33</sup> All acupuncturists at ACP are licensed by the Massachusetts Board of Registration in Medicine and have completed ACP's internship program for HIV/AIDS specific treatment. The treatment plan in the ACP acupuncture clinic usually recommends weekly treatments of 45–60 minutes; however, in some cases more than 1 treatment per week may occur. To standardize the amount of study intervention patients receive, patients only listened to the RR and/or soft music tape during 1 treatment per week.

### *Study intervention*

Patients in the intervention group listened to tapes that contained instructions for the following RR techniques: (1) breathing awareness; (2) mental repetition of a word, sound, phrase, or prayer; (3) autogenics (self-hypnosis); (4) guided body scan; (5) self-healing visualization; and (6) guided imagery. These 6 techniques are commonly used for eliciting the relaxation response and have been used in our previous study on patients with chronic heart failure.<sup>34</sup> A tape for each of these techniques was prepared, and each tape was used in 2 weekly acupuncture treatments during the 12-week study period. The instruction for each of these RR techniques lasted for 20 minutes. Since the duration of an acupuncture session was 45–60 minutes, soft music was added after the RR instructions in the rest of the tapes, which were used during the acupuncture treatment for patients in the intervention group. The intervention group was also asked to practice RR at home twice daily by listening to tapes with instructions to elicit the RR. During their acupuncture treatments, patients in the control group listened to tapes with soft music only, such as sounds of nature or classical music that was routinely played in the clinic during treatment. The control group was not required to listen to tapes at home.

### *Study outcomes*

Health-related QoL measure is the study outcome. Health-related QoL refers to a person's level of functioning and to his or her perceptions of well-being in various do-

main of life. In this study, 3 scales were used to measure multiple dimensions of QoL: the Medical Outcomes Study HIV health survey (MOS-HIV), the Functional Assessment of HIV Infection (FAHI), and the Functional Assessment of Chronic Illness Therapy–Spiritual Well-Being (FACIT-Sp). All 3 of these scales have scoring systems in which higher scores indicate better QoL. The MOS-HIV is a brief, comprehensive measure of health-related QoL consisting of 35 items.<sup>35,36</sup> It measures 10 specific dimensions: health perceptions; pain; physical, role, social, and cognitive functioning; mental health; health distress; QoL; and energy. Based on factor analysis, physical health (PHS) and mental health (MHS) summary scores are derived from these 10 subscales (mean score of the first 5 listed subscales plus energy for physical health and mean score of the next 4 subscales plus energy for mental health).<sup>37</sup> The MOS-HIV has been shown to be internally consistent, with Cronbach's  $\alpha$  coefficients for all subscales exceeding 0.75.<sup>36</sup>

The FAHI comprises 5 subscales: physical, emotional (EWB), social (SWB), function global well-being (FGWB), and cognitive functioning (CF).<sup>3</sup> This self-administered 44-item assessment tool has reliable psychometric properties with an overall Cronbach's  $\alpha$  of 0.91.<sup>3</sup> The 2 QoL measures, FAHI and MOS-HIV, are different in that the former includes items that are specifically in reference to HIV/AIDS disease and symptoms, while the latter covers items not specifically related to HIV/AIDS.

The FACIT-Sp was developed to assess the spiritual dimension of QoL of patients with chronic illness such as cancer and HIV.<sup>38</sup> This 12-item scale measures important aspects of spirituality. Two subscales are derived based on factor analysis: Meaning/Peace (PEACE) and Faith/Strength (STRENGTH).<sup>39</sup> High levels of internal consistency have been reported on the overall scale and the 2 subscales (Cronbach  $\alpha = 0.87, 0.81, \text{ and } 0.88$ , respectively).<sup>38</sup>

To evaluate the progression of QoL during the 12-week study period, we measured these 3 scales at baseline and at 4-week intervals thereafter. For participants who skipped a scheduled acupuncture session, we waited until the subjects completed 4 weekly treatments to administer the outcome assessment. This design ensured that each study participant received the same number of acupuncture treatments and study interventions. We took the difference in the time period between outcome assessments into account in the analysis by modeling the time trend of changes in the outcome measures.

### *Statistical analysis*

We first calculated the descriptive statistics of the outcome measures at each time point using all available data. A paired *t* test was used to test the within-group difference between each of the follow-up outcome measures and the baseline measures. We then conducted longitudinal analysis by employing a mixed effects model to estimate the in-

tervention effect; this method is considered to be more robust and immune to potential bias from missing data.<sup>40–42</sup>

In the mixed effects model, we included a random intercept and a random slope to capture the linear time trend of each subject. The group indicator (intervention versus control group), time (days from baseline measure), and the interaction of group and time were included as fixed effects in the model. The average intercept and slope of each study group as well as the difference in intercept and slope between study groups were estimated from this mixed effects model. The slope indicates the change rate over time (in days) in the outcome measures. We also employed the com-

monly used Last Observation Carried Forward method (i.e., replacing the missing follow-up outcome measures by the previous observed value), and reran the mixed effects model.

## RESULTS

### *Study participant characteristics*

The study sample was predominately male (85%), white (63%), with a mean age of 46 years, high education (70% had at least college education), low income (82% had an-

TABLE 1. GROUP COMPARISON ON PATIENT BASELINE CHARACTERISTICS AND BASELINE SCORES

Variable	<i>Intervention group</i> (n = 58) <i>Mean (SD)/N(%)</i>	<i>Control group</i> (n = 61) <i>Mean (SD)/N(%)</i>
Demographic characteristics		
Age (year)	45.5 (7.3)	45.5 (7.8)
Gender		
Male	49 (84%)	52 (85%)
Race		
White/Caucasian	40 (69%)	35 (57%)
African American	9 (16%)	16 (26%)
Hispanic/Latino	7 (12%)	4 (7%)
Other	2 (3%)	6 (10%)
Education		
College and above	39 (67%)	45 (74%)
Income		
Less than \$10,000	24 (45%)	25 (44%)
\$10,000–\$19,999	21 (40%)	20 (35%)
\$20,000 or more	8 (15%)	12 (21%)
HIV status		
HIV+ (not AIDS)	29 (50%)	37 (61%)
HIV+ (AIDS status unknown)	4 (7%)	4 (7%)
AIDS	25 (43%)	20 (33%)
Last CD4 count		
LOG (last CD4 count)	6.1 (0.7)	6.0 (0.7)
Total number of HIV symptoms reported <sup>a</sup>	6.1 (2.5)	5.3 (2.5)
Baseline quality of life measures		
FAHI <sup>b</sup>		
Physical well-being (0–40) <sup>c</sup>	26.4 (8.7)	28.1 (9.4)
Emotional well-being (0–40)	23.6 (7.9)	25.5 (8.8)
Function and global well-being (0–52)	28.5 (10.2)	31.9 (10.5)
Social well-being (0–32)	18.3 (7.7)	19.2 (8.0)
Cognitive functioning <sup>**</sup> (0–12)	6.7 (2.5)	8.3 (3.0)
MOS-HIV <sup>d</sup>		
Physical health summary score (0–100)	57.5 (21.1)	62.0 (21.4)
Mental health summary score <sup>*</sup> (0–100)	57.5 (17.0)	64.1 (17.9)
FACIT-Sp <sup>e</sup>		
Peace (8–40)	26.4 (6.7)	28.0 (7.0)
Strength (4–20)	12.6 (4.7)	12.6 (4.9)
Prior acupuncture experience	47 (81%)	47 (77%)

SD, standard deviation.

<sup>a</sup>Symptoms in the inclusion criteria.

<sup>b</sup>FAHI: revised Functional Assessment of Human Immunodeficiency Virus Infection.

<sup>c</sup>Possible range of the score.

<sup>d</sup>MOS-HIV: Medical Outcomes Study HIV Health Survey.

<sup>e</sup>FACIT-Sp: Functional Assessment of Chronic Illness Therapy—Spiritual Well-Being.

Statistical significance: \* $p < 0.05$ , \*\* $p < 0.01$ .

nual income less than \$20,000), a high number of symptoms listed in the inclusion criteria (mean 5.7 symptoms), and a majority had previous acupuncture experience (79%). The 2 study groups were similar in demographic characteristics, HIV status and CD4 count at baseline, number of symptoms listed in the inclusion criteria, and prior acupuncture treatment experience (Table 1). The intervention group, however, had lower scores in two baseline QoL measures, CF and MHS ( $p < 0.01$  and  $p < 0.05$ , respectively).

### The QoL measures at each time point

The completion rates at the 3 follow-up times were 83%, 66%, and 62% for the intervention group and 85%, 77%, and 72% for the control group (Fig. 1). All available data were included in calculating the descriptive statistics of the QoL measures (Table 2). For the intervention group, the mean scores of all but 2 subscales of the three QoL measures increased continuously over the 4 time points. Particularly, the mean for EWB increased 5.7 points from 23.6 at baseline to 29.3 at the 12-week follow-up. An increase of 3.4 points was considered to be clinically significant because

it corresponded to improvement over 4 months in performance status, as measured by the Karnofsky Performance Index, in patients with HIV.<sup>3</sup> A clinically significant improvement was also observed in MHS. The MHS increased 10.6 points from baseline to 12-week follow-up. A 7-point difference in the energy subscale, which is 1 component of MHS, was considered to be clinically significant as it distinguished between asymptomatic and symptomatic patients with HIV.<sup>35,36</sup> Statistically significant increases were observed in EWB (4.0 points, paired  $t$  test  $p = 0.0002$ ), MHS (38.0 points,  $p = 0.0003$ ), PHS (33.0 points,  $p = 0.003$ ) and PEACE (1.7 points,  $p = 0.02$ ) from baseline to 12-week follow-up when we included only patients with data at both time points (Fig. 2).

For the control group, the mean for EWB had a clinically significant increase of 3.8 points from baseline to the 12-week follow-up (Table 2). When complete data were used, the increase was 3.3 points ( $p = 0.001$ ), slightly below the clinically significant increase of 3.4 points. None of the other subscales had statistically and/or clinically significant increases for the control group. There was a trend toward greater increases at 12 weeks in all subscale scores in the intervention

TABLE 2. QUALITY OF LIFE (QoL) MEASURES AT BASELINE AND THE FOLLOW-UP ASSESSMENTS

QoL measures <sup>a</sup>	Intervention group				Control group			
	Baseline (n = 58)	4 week (n = 48)	8 week (n = 38)	12 week (n = 36)	Baseline (n = 61)	4 week (n = 52)	8 week (n = 47)	12 week (n = 44)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
<b>FAHI<sup>b</sup></b>								
Physical well-being (0–40) <sup>c</sup>	26.4 (8.7)	26.9 (9.1)	28.0 (8.1)	28.9 (7.7)	28.1 (9.4)	30.1 (7.8)	29.9 (9.5)	30.0 (9.3)
Emotional well-being (0–40)	23.6 (7.9)	25.3 (8.8)	27.9** (6.6)	29.3*** (7.4)	25.5 (8.8)	27.9* (7.0)	27.6 (8.0)	29.4** (7.9)
Function and global well-being (0–52)	28.5 (10.2)	30.1 (10.3)	31.5 (10.5)	32.7 (10.5)	31.9 (10.5)	34.0 (8.9)	34.6 (10.3)	35.5 (9.4)
Social well-being (0–32)	18.3 (7.7)	18.5 (7.3)	18.9 (7.2)	19.6 (7.6)	19.2 (8.0)	19.6 (8.0)	19.1 (8.1)	19.6 (7.6)
Cognitive functioning (0–12)	6.7 (2.5)	7.2 (2.5)	7.0 (2.1)	7.5 (2.5)	8.3 (3.0)	9.1 (2.4)	8.5 (3.1)	9.2 (2.4)
<b>MOS-HIV<sup>d</sup></b>								
Physical health summary score (0–100)	57.5 (21.1)	61.3 (20.1)	62.7 (21.1)	65.6** (19.2)	62.0 (21.4)	66.7 (18.3)	66.4 (21.0)	65.7 (22.6)
Mental health summary score (0–100)	57.5 (17.0)	62.9* (18.2)	62.8 (14.9)	68.1*** (15.4)	64.1 (17.9)	71.0** (12.8)	69.5 (18.1)	70.7 (17.1)
<b>FACIT-Sp<sup>e</sup></b>								
Peace (8–40)	26.4 (6.7)	26.6 (6.8)	27.8 (6.7)	28.8* (5.8)	28.0 (7.0)	28.2 (6.3)	29.9 (6.4)	30.0 (6.8)
Strength (4–20)	12.6 (4.7)	12.9 (4.6)	13.1 (4.5)	13.4 (4.3)	12.6 (4.9)	12.8 (4.4)	12.0 (4.5)	13.0 (4.9)

SD, standard deviation.

<sup>a</sup>Higher scores indicate better quality of life.

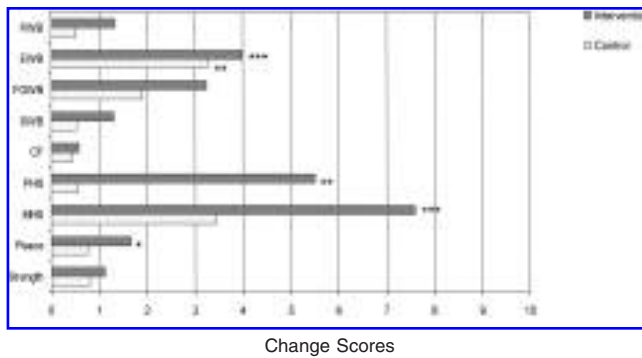
<sup>b</sup>FAHI, revised Functional Assessment of Human Immunodeficiency Virus Infection.

<sup>c</sup>Possible range of the score.

<sup>d</sup>MOS-HIV, Medical outcomes study HIV health survey.

<sup>e</sup>FACIT-Sp, Functional assessment of chronic illness therapy–spiritual well-being.

Significance level of paired  $t$  tests for change scores from baseline to each follow-up using complete data at the 2 time points: \* $p < 0.05$ , \*\* $p < 0.01$ , \*\*\* $p < 0.001$ .



Paired *t*-test within group comparison: \*  $p < .05$ , \*\*  $p < .01$ , \*\*\*  $p < .001$ .  
 PWB: Physical well-being, EWB: Emotional well-being, FGWB: Function and Global well-being  
 SWB: Social well-being, CF: Cognitive functioning  
 PHS: Physical Health Summary Score, MHS: Mental Health Summary Score  
 Peace: Peace subscale of Spiritual Well-Being Scale, Strength: Strength subscale of Spiritual Well-Being Scale

**FIG. 2.** Quality-of-life change scores from baseline to 12-week follow-up.

group compared to the control group; however, marginal significant difference was observed only in PHS ( $p = 0.07$ ).

*Time trends of the QoL measures*

We used a mixed effects regression model to estimate the time trend of the QoL measures that took into account the variation in the time of outcome measures. The results of the mixed effects regression model are listed in Table 3. For the intervention group, significant positive slopes, indicating improvement over time, were observed in EWB (slope = 0.037, SE = 0.0090,  $p = 0.00007$ ), FGWB (slope = 0.028, SE = 0.012,  $p = 0.018$ ), MHS (slope = 0.053, SE = 0.019,  $p = 0.006$ ), and PEACE (slope = 0.016, SE = 0.0068,  $p =$

0.018). SWB, PHS, and STRENGTH had positive slopes at the significance level of 0.1 (i.e.,  $p < 0.1$ ). For the control group, although the slopes of all the scales were positive, EWB was the only subscale with significant slope (slope = 0.021, SE = 0.0077,  $p = 0.007$ ). The intervention group had larger slopes, indicating greater improvement over time, in all of the QoL measures. However, the group differences were not statistically significant;  $p$  values of  $\leq 0.20$  were observed for EWB, SWB, MHS, and PHS.

After we replaced the missing data with the last observed QoL score and refit the mixed effects model, the significant results in EWB ( $p = 0.001$ ), FGWB ( $p = 0.03$ ), MHS ( $p = 0.03$ ), and PEACE ( $p = 0.04$ ) subscales remained for the intervention group. Slopes of SWB, PHS, and STRENGTH, however, became nonsignificant ( $p > 0.1$ ). For the control group, the slope of EWB remained significant ( $p = 0.003$ ).

**DISCUSSION**

The data from this pilot trial indicated that both intervention and control groups showed trends toward improvement in the QoL measures. The data also show trends of greater improvements in the intervention group than the control group. Clinically and statistically significant improvements were evident mainly in the intervention group, particularly in emotional, functional global well-being, mental, and peace/spiritual dimensions of QoL. For the control group, the only significant improvement was observed in the emotional dimension of QoL. These results suggest that adding RR to acupuncture treatment might enhance the improvement on QoL of patients with HIV. Future studies are needed to validate this finding.

TABLE 3. RESULTS OF THE MIXED EFFECTS REGRESSION MODELS FOR QUALITY OF LIFE (QoL) MEASURES

QoL measures <sup>a</sup>	Intervention group			Control group		
	Slope <sup>e</sup>	SE <sup>e</sup>	p value	Slope	SE	p value
FAHI <sup>b</sup>						
Physical well-being	0.0095	0.0086	0.26	0.0032	0.0071	0.65
Emotional well-being	0.037	0.0090	<0.001***	0.021	0.0077	0.0071**
Function and global well-being	0.028	0.012	0.018*	0.017	0.010	0.11
Social well-being	0.011	0.0061	0.06 <sup>†</sup>	0.00082	0.0049	0.87
Cognitive functioning	0.0042	0.0029	0.14	0.0016	0.0022	0.49
MOS-HIV <sup>c</sup>						
Physical health summary score	0.034	0.019	0.08 <sup>†</sup>	0.0024	0.016	0.88
Mental health summary score	0.053	0.019	0.0062**	0.020	0.016	0.21
FACIT-Sp <sup>d</sup>						
Peace	0.016	0.0068	0.018*	0.0073	0.0055	0.19
Strength	0.0071	0.0043	0.10 <sup>†</sup>	0.0028	0.0034	0.42

SE, standard error.

<sup>a</sup>Higher scores indicate better quality of life.

<sup>b</sup>FAHI, revised functional assessment of human immunodeficiency virus infection.

<sup>c</sup>MOS-HIV, medical outcomes study HIV health survey.

<sup>d</sup>FACIT-Sp, functional assessment of chronic illness therapy–spiritual well-being.

<sup>e</sup>Regression coefficient and its standard error from the mixed effects regression model.

Statistical significance: <sup>†</sup> $p < 0.10$ ; \* $p < 0.05$ ; \*\* $p < 0.01$ ; \*\*\* $p < 0.001$ .

This study has a number of strengths. This is the first study to examine the effect of combining 2 commonly used CAM approaches with potential synergistic effects due to their similar physiologic and neurologic effects: the RR and acupuncture. Second, the acupuncture protocol in this study was individualized, with each individual patient receiving what the acupuncturist determined to be the optimal treatment based on accepted standards of care. This form of individualized acupuncture treatment follows the principles of Traditional Chinese Medicine practice that are practiced in the real world. Third, placebo effects due to expectation of improvement from receiving interventions were likely to be similar between the two study groups because both groups were told the same about the purpose of the study, and also because of the blinding design of the study. The placebo effects were therefore not likely to explain the enhanced effects of the RR.

There are some limitations to this study. First, the study was conducted in a single acupuncture clinic that mainly served low-income HIV-positive patients. Thus, generalizability of the study results to other HIV populations may be limited. Second, a moderate number of study participants did not follow the study protocol of weekly acupuncture treatment and/or completion of the 3 follow-up outcome measures. Patient retention is a challenge for longitudinal clinical studies, especially for trials on patients with chronic medical conditions. This limitation is therefore not unique to our study. To overcome this limitation, we employed statistical techniques that used all available data to fit a mixed effects model and took into account the variation in the time of outcome measures. In addition, a commonly used imputation method of last observation carried forward was also used in the analysis. Third, due to the small sample size, our study had limited statistical power in detecting group differences. Fourth, since only the intervention group was required to do home practice, the dosage of the intervention is therefore different between the 2 study groups. Despite these limitations, this pilot trial provides valuable information that may inspire future larger studies to further demonstrate the synergistic effects of the RR and acupuncture.

## CONCLUSIONS

The data from this pilot trial suggest that adding the RR to usual acupuncture treatment may enhance improvement in QoL of HIV patients. If the synergistic effects of these two commonly used CAM therapies can be confirmed in larger trials, there may be important implications in acupuncture practice.

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