Can Laypersons be Trained to Effectively Deliver Osteopathic Manual Therapy to Patients With HIV? A Pilot Study

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Context: Osteopathic manipulative treatment (OMT) may provide added benefits to standard human immunodeficiency virus (HIV) and AIDS treatments. However, lack of access to trained OMT providers is a potential barrier to the widespread use of OMT in the management of HIV and AIDS.

Objectives: To determine the best time to measure the short-term impact of a brief OMT protocol on white blood cell counts in individuals with HIV and AIDS. Also, to explore recruiting and training laypersons to administer select osteopathic manual techniques.

Methods: Participants were HIV-positive men aged between 18 and 65 years who had not undergone antiretroviral therapy in the past 12 months, had CD4+ lymphocyte counts of 200 to 1800 copies/mL, and had viral load levels of less than 100,000 copies/mL. Participants were randomly assigned to an OMT group or a control group; those in the OMT group recruited a layperson for training in osteopathic manual therapy. Participants in the OMT group received a 15-minute OMT protocol consisting of myofascial release of the thoracic inlet, pectoral traction, rib raising, thoracic pump, and abdominal pump. Participants in the control group engaged in conversation with the researcher for 15 minutes. Between-group differences for each white blood cell type were examined at varying time intervals after the protocols. Laypersons were trained to administer thoracic and abdominal pump techniques. They were tested by multiple choice examinations and by an independent rater for fidelity of administration.

Results: Twenty-one participants met the eligibility criteria. Of those, 18 returned for their study visit (OMT group, n=9; control group, n=9). An optimal time interval for measurement of white blood cell changes across the 5 cell types was not determined. However, P values for the 30-minute interval were consistently below 0.18 for neutrophils, eosinophils, and monocytes. Nine laypersons were trained in osteopathic manual therapy, 5 of whom scored 100% on initial completion of the multiple-choice examination; the remaining 4 laypersons scored 80% on the first try and 100% on the second try. All laypersons appropriately administered the manual therapy protocol.

Conclusion: It is feasible to recruit and train laypersons to administer selected osteopathic manual therapy techniques with fidelity. Longitudinal studies on this concept are needed to examine patient outcomes and to evaluate the retention and fidelity of laypersons over time. (ClinicalTrials.gov number NCT00703248)

Preserving an intact lymphatic system is critical to human survival. If a person’s lymphatic system stopped functioning, that person would die within 24 hours of cessation of lymph flow. The lymphatic system not only plays a role in the return of proteins and fluids to central circulation, it serves as the main place where the adaptive component of the immune system becomes exposed to antigens. Osteopathic manipulative treatment (OMT) of the lymphatic system is one of the central components of osteopathic medicine and may have clinical implications for the treatment of individuals with impaired immune function, including persons living with human immunodeficiency virus (HIV) or AIDS.

Among the health benefits of OMT is the prevention of lymph stasis, which is involved in several pathophysiologic processes. The published literature provides some evidence that OMT may augment lymph flow, alter lymph and blood composition, and improve immune function. For instance, some studies reported post-OMT increases in lymph flow or lymph contraction frequency. Increases in serum antibody titers have also been reported. Other studies reported increases in absolute leukocyte counts in lymph, absolute leukocyte counts in peripheral blood, or leukocyte differential shifts. Opsonic and phagocytic indices...
and humoral immune response to antigens were also reported to increase after OMT.1,2,5,10

Case reports and anecdotal evidence have linked lymphatic OMT to improved clinical outcomes among HIV-positive patients.12 An OMT protocol that could stimulate immune function, specifically T-cell lymphocytes, could be beneficial for persons living with HIV or AIDS. If such a protocol is developed and found to be effective, it could become part of the treatment regimens used to manage HIV and associated infections.

Lack of access to trained osteopathic physicians and continuity of care are potential barriers to the widespread use of OMT in the management and care of individuals with HIV or AIDS. A number of OMT techniques (eg, high-velocity, low-amplitude) should only be administered by trained osteopathic physicians. However, some techniques that can stimulate immune function (eg, thoracic pump) are less complicated and may be administered by laypersons with proper training and supervision, thereby removing some of the barriers to OMT care. Although paraprofessionals and laypersons have been trained to successfully and efficaciously deliver a variety of different therapies (eg, cardiopulmonary resuscitation), to our knowledge, use of laypersons to administer simple OMT procedures has not yet been explored.16

In preparation for a future study regarding efficacy of OMT in improving clinical care for individuals with HIV and AIDS, we conducted the present pilot study to determine the optimal time to measure white blood cell count to assess the short-term impact of a brief OMT protocol on persons with HIV or AIDS. In addition, we aimed to explore the feasibility of recruiting and training a layperson to administer an osteopathic manual therapy protocol with fidelity.

Methods

The study was approved by the Nova Southeastern University Institutional Review Board on October 11, 2007, and was registered with ClinicalTrials.gov (number NCT00703248). The study was conducted during a 6-month period of a 1-year student research fellowship that was internally funded by the Nova Southeastern University College of Osteopathic Medicine.

Participants

From January 2008 to May 2008, physicians at the Nova Southeastern University College of Osteopathic Medicine’s medical clinic and an HIV specialty care private practice in Fort Lauderdale, Florida, referred 36 potential participants to be considered for the study. We explained the study to the referred patients and obtained written informed consent prior to conducting the eligibility assessment. Included in the study were HIV-positive men aged between 18 and 65 years who had not undergone antiretroviral therapy (ART) for the past 12 months. Participants had CD4+ lymphocyte counts between 200 and 700 cells/mm³, and a viral load level of less than 100,000 copies/mL. Participants had to be willing to recruit a person for training in osteopathic manual therapy (ie, “layperson provider”). Exclusion criteria for participants included medical conditions that would limit a participant’s ability to participate in this study as defined by his physician and verified by physical examination, recreational drug use, and prescription of systemic steroids. Women were excluded from this study to control for the variable effects of a fluctuating hormonal cycle on the immune system.17

Inclusion criteria for layperson providers included recruitment by a study participant, willingness to administer osteopathic manual therapy to the participant, knowledge of the study participant’s HIV status prior to engaging in the study, and willingness to sign consent to participate in the study.

Participants were randomly assigned to either an OMT group or a control group and scheduled for their study visit. Those assigned to the OMT group were asked to bring their layperson to be trained in an osteopathic manual therapy protocol to their study visit. Informed consent was obtained from the layperson provider prior to initiating the study visit. Participants were compensated 20 dollars for the study visit. Layperson providers were not compensated.

Patient Procedures

All study procedures were completed in 1 visit. When participants arrived at their study visit, their blood was drawn for baseline comparison, and they completed a brief structured interview designed to assess the following domains:

- **Demographic**: age, ethnicity, partner status (including length of time in that relationship), past medical history, current medical history, and medication history
- **Stress**: stressful life events (measured with the 34-item adaptation of Rosser and Ross [1989] Gay Affect and Life Events Scale18)
- **Lifestyle**: regularity of exercise and use of recreational drugs, alcohol, and tobacco
- **Biological Data**: complete blood cell counts with differential and CD4+ and CD8+ lymphocyte absolute counts and percentages

In the first part of the study visit, study participants underwent either an OMT protocol or a control protocol according to their assigned study group.

OMT Protocol—In the OMT group, an OMT provider (M. A.N.) administered an OMT protocol that consisted of the following techniques: myofascial release to open the thoracic inlet until the tissues relaxed (1 minute or less in all participants), pectoral traction for 1 minute, rib raising for 2 minutes on each side of the thoracic spine for a total of 4 minutes, thoracic pump at a rate of 60 times per minute for a total of 5 minutes, and abdominal pump at a rate of 30 times per minute.
for a total of 5 minutes. The same OMT provider performed the techniques in consecutive order without pausing on all OMT group participants.

**Control Protocol**—Participants in the control group remained in a seated position and engaged in conversation with the research staff for 15 minutes—equal in length to the time required for the OMT treatment in the OMT group. No physical interactions between research staff and participants occurred during that time.

Blood was drawn at 2, 5, 10, 15, 30, and 45 minute intervals after completion of the respective protocols.

**Layperson Provider Procedures**

The second part of the study visit occurred while patients’ blood samples were being collected. It consisted of training the laypersons to administer thoracic pump and abdominal pump techniques. Abdominal pump consisted of applying a wave-like force from palms to fingertips to the abdominal area below the ribcage. The OMT provider who administered the OMT protocol led the training, which lasted 15 to 20 minutes and consisted of the following 3 phases:

- **Phase 1:** First, the OMT provider gave the layperson provider illustrated descriptions of the techniques used in the osteopathic manual therapy protocol (Figure 1). Then, the OMT provider demonstrated the protocol on the patient in the OMT group and verbally described thoracic and abdominal pump techniques, highlighting any special points.
- **Phase 2:** During the second phase, the layperson provider practiced applying each of the 2 techniques on his or her protocol partner. The OMT provider placed the layperson provider’s hands in the correct position and watched his or her technique, providing coaching and feedback.
- **Phase 3:** In the final phase, an independent researcher evaluated the layperson provider on knowledge of techniques and physical application. To assess knowledge, the researcher asked the layperson provider to take a 5-question multiple-choice test (Figure 2); a score of 5/5 was considered passing. If the layperson provider did not pass after the first attempt, the physician spent an additional 5 minutes redescribing the techniques and the test was re-administered. After the layperson passed the test, the layperson provider performed thoracic pump at a rate of 60 times per minute for a total of 5 minutes and abdominal pump at a rate of 30 times per minute for a total of 5 minutes on the partner. The independent researcher used the Physical Assessment Scale (Figure 3) to evaluate the layperson provider’s physical application of each technique. A score of 6/6 on the Physical Assessment Scale was considered passing.

Layperson providers were given handouts with descriptions of the techniques for home use.

**Analyses**

We conducted descriptive analyses to examine the comparability of participants across both study arms and examined the distribution of the data. The normal distribution of the data was sufficient to justify the use of parametric analyses. To determine the short-term impact of the 15-minute standardized OMT protocol on complete white blood cell counts and differential white blood cell counts, we calculated the paired differences in baseline and interval measures. We calculated the overall change at each time point and compared the OMT group with the control group using paired Student t tests.
1. What is the rate of thoracic pump?
   a) 2 times every 1 second
   b) 1 time every 1 second*
   c) 1 time every 2 seconds
   d) 1 time every 5 seconds

2. What is the correct hand placement for the thoracic pump technique?
   a) Both palms on top of the chest muscles spread apart so the thumbs are almost touching.
   b) Both palms on top of the collar bone spread apart so the thumbs are almost touching.
   c) Both palms just below the collar bone and above the chest muscles spread apart so the thumbs are almost touching.*
   d) Both palms just below the collar bone and above the chest muscles spread apart so the thumbs are touching.

3. What is the rate of the abdominal pump technique?
   a) 2 times every 1 second
   b) 1 time every 1 second
   c) 1 time every 2 seconds*
   d) 2 times every 5 seconds

4. What is the correct hand placement for abdominal pump technique?
   a) Both palms on top of the stomach with fingertips on top of the ribs and fingers on each hand spread apart.
   b) Both palms on top of the stomach with fingertips just below the ribs and fingers on each hand spread apart.
   c) Both palms on top of the stomach with fingertips on top of the ribs and fingers on each hand kept together.
   d) Both palms on top of the stomach with fingertips just below the ribs and fingers on each hand kept together.*

5. What is the correct amount of time that the thoracic pump technique and abdominal pump technique should be done?
   a) 5 minutes each for a total of 10 minutes*
   b) 10 minutes each for a total of 20 minutes
   c) 4 minutes each for a total of 8 minutes
   d) 2 minutes each for a total of 4 minutes

**Figure 2. Knowledge examination administered to laypersons trained to perform osteopathic manual therapy. Correct answers are marked with an asterisk (*).**

**Results**

Twenty-one participants met the eligibility criteria. Eleven were randomly assigned to the OMT group, and 10 were assigned to the control group. Of those, 18 returned for their study visit (OMT group, n=9; control group, n=9); 2 from the OMT group and 1 from the control group did not return.

Participants ranged in age from 23 to 49 years. The 9 layperson providers consisted of adult men and women who were either friends or partners of participants. Participants in both the OMT group and the control group had comparable demographic characteristics, initial CD4+ lymphocyte counts, viral loads, and history of ART (Table 1). Information collected on patients’ stress and lifestyle was used as a control variable to determine the comparability of the groups but did not undergo analysis.

Results of the differential white blood cell counts did not reveal an optimal time interval to sample blood for the identification of changes across the 5 cell types (ie, neutrophils, lymphocytes, monocytes, eosinophils, and basophils). However, Student t test P values for the 30-minute time interval were consistently below 0.18 for neutrophils, eosinophils, and monocytes (Table 2, Table 3, and Table 4). Given the number of statistical comparisons we made and the consistency of these values, it is conceivable that these values would reach statistical significance with a larger sample size.

On the initial administration of the multiple-choice examination (Figure 2), 5 of 9 layperson providers scored 100%; the remaining 4 layperson providers scored 80%. No layperson provider required more than 2 administrations of the examination to receive a score of 100%. In addition, all 9 layperson providers appropriately administered the osteopathic manual therapy protocol on the first try according to the Physical Assessment Scale (Figure 3).

**Comment**

The present pilot study supports the feasibility of recruiting and training laypersons to administer certain osteopathic manual therapy techniques with fidelity. Thoughtful and careful use of trained laypersons to supplement OMT provided by a licensed osteopathic physician may have beneficial outcomes for the patient as well as osteopathic medicine. By ameliorating one of the barriers to OMT care, our findings—if supported in larger, longitudinal trials—may help promote widespread use of OMT in the management and care of indi-
while we could not identify any limitations related to training laypersons, the data presented in this paper is preliminary. Longitudinal studies to more fully examine recruitment and retention as well as fidelity of training are necessary before this approach can become widely adopted.

why we could not determine the most propitious time after OMT intervention to collect blood samples that capture fluctuations in white blood cell counts. We found some evidence that the 30-minute interval may be optimal for measuring white blood cell count changes. This finding suggests that limiting white blood cell assessment to the period immediately after intervention may not be appropriate—immune fluctuation may be found up to 30 minutes postintervention. Future studies with larger sample sizes are necessary to fully examine this concept.

Conclusion
By demonstrating the feasibility of recruiting and training laypersons to administer select osteopathic manual therapy techniques with fidelity, this study can be viewed as an important first step in the scientific examination of trained laypersons as adjuncts to physician-administered OMT. The next step in this line of inquiry is to conduct a longitudinal study to examine patient outcomes and to evaluate the retention and fidelity of laypersons over time.

Acknowledgments
This work was conducted as part of the Nova Southeastern University College of Osteopathic Medicine’s Research Fellowship Program. We are grateful to Anthony J. Silvagni, DO, PharmD, for this fellowship program and to the private practice physicians and patients who gave their time and effort. We also acknowledge David R. Boesler, DO; Robert T. Hasty, DO; and William Thomas Crow, DO, for the generous knowledge and expertise they contributed to the study and its publication.

References
5. Lane MA. On increasing the antibody content of the serum by manipulation of the spleen. J Osteopath (Kirkville). 1920;27:361-364.

Table 1. Demographic Characteristics of Men With HIV and AIDS, N=18

<table>
<thead>
<tr>
<th>Screening and Demographic Variables</th>
<th>Control Group (n=9)</th>
<th>Treatment Group (n=9)</th>
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<tbody>
<tr>
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<tr>
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<tr>
<td>African American</td>
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<tr>
<td>Asian/Pacific islander</td>
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<td>0</td>
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<tr>
<td>Age, y</td>
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<tr>
<td>Range</td>
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<td>23.49</td>
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<tr>
<td>Mean (SD)</td>
<td>38.4 (8.69)</td>
<td>35.2 (11.32)</td>
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<tr>
<td>Pre-enrollment Test Results, Mean (SD)</td>
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<tr>
<td>CD4+ lymphocytes, cells/mL</td>
<td>512 (134.08)</td>
<td>505.67 (118.04)</td>
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<td>Viral load, copies/mL</td>
<td>28,459 (24,902)</td>
<td>23,743 (30,939)</td>
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<td>History of Antiretroviral Therapy</td>
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</tr>
<tr>
<td>Y</td>
<td>1</td>
<td>3</td>
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<tr>
<td>N</td>
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Abbreviations: OMT, osteopathic manipulative treatment; HIV, human immunodeficiency virus; SD, standard deviation.

Table 2. Neutrophil Count Changes in Men With HIV and AIDS After OMT

<table>
<thead>
<tr>
<th>Sample Time Collected From Baseline, min</th>
<th>Mean Difference From Baseline by Group</th>
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<tr>
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<td>Control (n=9)</td>
<td>Treatment (n=9)</td>
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<tr>
<td>15</td>
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<tr>
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<tr>
<td>45</td>
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<td>1.8000</td>
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* In the control group, n=8 at 10 minutes from baseline and n=7 at 15 minutes from baseline.

Abbreviations: HIV, human immunodeficiency virus; OMT, osteopathic manipulative treatment.

individuals with HIV or AIDS. While we could not identify any limitations related to training laypersons, the data presented in this paper is preliminary. Longitudinal studies to more fully examine recruitment and retention as well as fidelity of training are necessary before this approach can become widely adopted. The limited size of our sample may have been a factor in why we could not determine the most propitious time after OMT intervention to collect blood samples that capture fluctuations in white blood cell counts. We found some evidence that the 30-minute interval may be optimal for measuring white blood cell count changes. This finding suggests that limiting white blood cell assessment to the period immediately after intervention may not be appropriate—immune fluctuation may be found up to 30 minutes postintervention. Future studies with larger sample sizes are necessary to fully examine this concept.

Conclusion
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References
5. Lane MA. On increasing the antibody content of the serum by manipulation of the spleen. J Osteopath (Kirkville). 1920;27:361-364.

(continued)
Table 3. Eosinophil Count Changes in Men With HIV and AIDS After OMT

<table>
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<th>Sample Time Collected From Baseline, min</th>
<th>Mean Difference From Baseline by Group</th>
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<th>Treatment (n=9)</th>
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* In the control group, n=8 at 10 minutes from baseline and n=7 at 15 minutes from baseline.

Abbreviations: HIV, human immunodeficiency virus; OMT, osteopathic manipulative treatment.

Table 4. Monocyte Count Changes in Men With HIV and AIDS After OMT

<table>
<thead>
<tr>
<th>Sample Time Collected From Baseline, min</th>
<th>Mean Difference From Baseline by Group</th>
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<th>Treatment (n=9)</th>
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</table>

* In the control group, n=8 at 10 minutes from baseline and n=7 at 15 minutes from baseline.

Abbreviations: HIV, human immunodeficiency virus; OMT, osteopathic manipulative treatment.


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